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ORIGINAL ARTICLE

Preoperative planning of compact zone trajectory is necessary in treating osteoporotic vertebral compression fracture with endplate involvement: A prospective randomized controlled study

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Abstract

Background: This prospective randomized controlled study compares the clinical and radiological outcomes between reduction methods with or without compact trabecular bone during percutaneous kyphoplasty in osteoporotic vertebral fractures.

Methods: The cohort of 100 patients who underwent percutaneous kyphoplasty was randomly divided into group A (guide pin and balloon introduced directly into fracture site) and group B (guide pin and balloon inserted away fracture site). The surgery duration, clinical and radiological outcomes postoperatively and at follow-up, and complications of cement leakage and adjacent fracture were recorded. Patients were followed up for an average of 20.18 months. The clinical outcomes were assessed using the Oswestry Disability Index and visual analog scale.

Results: The two groups had similar patient demographics, surgery times, and volume of cement injected. The method using elevation of the collapsed endplate indirectly had no significant influence on radiological outcomes but significantly decreased the occurrence of intradiscal cement leakage and improved 1- and 12-month postoperative functional outcomes.

Conclusion: Elevating and reinforcing the collapsed endplate rather than just filling the defect during percutaneous kyphoplasty is safe and effective. This technique decreased pain and improved function with lower rates of further collapse of the osteoporotic vertebrae compared to defect-filling alone.

Keywords: Endplate fracture; Kyphoplasty; Osteoporotic vertebral compression fracture; Percutaneous vertebroplasty

1. INTRODUCTION

Osteoporotic vertebral fracture (OVF) is one of the most common sequelae of osteoporosis.[1] The prevalence of OVF increases as the proportion of aging people in a population grows.[2] OVF often leads to lower back pain and spinal deformity, which seriously affect the patients' quality of life.[3] Percutaneous kyphoplasty (PKP) offers significant pain relief for patients who respond poorly to conservative treatment.[4] However, PKP mainly addresses the fractured vertebral body itself and does not include treatment of the adjacent injured endplate-disc complex (EDC).[5] The EDC plays important roles in maintaining the stability and integrity of the spine, protecting the spinal nerves, absorbing shocks, and dispersing axial load.[6] When trauma acts on the vertebral body, it often causes simultaneous injury to the adjacent EDC.[7] A previous study reports that the incidence rate of EDC injury was 67.0% among OVF patients.[8] Injury to EDCs, the human body's largest blood-free tissue, often accelerates disc degeneration, leading to chronic spinal instability and even secondary kyphosis.[9] Thus, addressing endplate integrity is critical in treating vertebral compression fractures.[10]

Treatment strategies for OVF with endplate damage have changed with improvements in bone cement and implant designs. In addition, growing knowledge of fracture mechanisms and biomechanical properties of the vertebral body and endplate has informed modifications in treatment strategies, resulting in better patient outcomes and fewer complications.[11] Several studies further support the importance of EDC treatment during OVF repair. One such study confirms the involvement of endplate fracture in postoperative vertebral height loss and the aggravation of kyphosis. Endplate fracture also contributes to a higher rate of cement extravasation into the disc, increasing the incidence of adjacent fracture and poor outcomes.[12–14] Another study emphasizes the importance of the cement distribution pattern between the upper and lower endplates in these patients.[15] Cement leakage through a broken endplate was found to contribute to subsequent disc degeneration in dog and rabbit models.[16] The degree of intervertebral disc degeneration correlates with the time after surgery and the doses of bone cement.[17] In a human model, the quantity of cement leaking into the disc

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space significantly influences the rate of progression of disc degeneration.[18]

Despite the demonstrated importance of endplate integrity in OVF treatment, few studies have focused on endplate fracture treatment strategies. The present study compares the techniques of direct and indirect (through trabecular bone) reduction of the endplate using balloon kyphoplasty (BKP) to treat vertebral compression fracture with endplate deficit.

2. METHODS

From January 2018 to August 2020, 100 patients with single-level painful OVF and concomitant endplate fracture for whom conservative treatment failed were enrolled prospectively. The study was approved by the institutional review board of Taipei City Hospital. Patients were excluded for the presence of pathological facture, multiple-level fracture, endplate fracture with too little trabecular bone to create the compact zone via balloon in the vertebral body, and fracture that occurred more than 12 weeks earlier. The fracture pattern and morphology were carefully investigated from preoperative computed tomography (CT) or magnetic resonance imaging (MRI) scans. The fracture clefts were clearly identified. If the location of the fracture clefts or compact zone left was uncertain, the patient was excluded.

All patients were treated with BKP (Kyphon; Medtronic, Sunnyvale, CA), followed by the injection of high-viscosity polymethyl methacrylate bone cement (Cohesion, Vexim Sa, Balma, France).

Patients were assigned randomly to group A or group B using computer-generated random numbers. For patients in group A, the guide pin and balloon were introduced into the fracture site directly under fluoroscopy. For patients in group B, the guide pin and balloon were inserted away from the fracture site, leaving more distance between the balloon and the fractured endplate to prevent direct contact. The volume of injected cement depended on the bone defect and the individual patient's condition as determined under fluoroscopy. Patient demographic features, including age, sex, body mass index (BMI), bone mineral density, fracture pattern, and fracture level, are shown in Table 1.

2.1. Surgical techniques

CT or MRI scans were used for preoperative templating. The endplate fracture location was determined. If the endplate fracture occurred unilaterally or centrally, a unilateral transpedicular approach was used. A bilateral transpedicular approach was used for bilateral endplate fractures. We located the fracture cleft and then chose the guide pin trajectory based on sagittal views in CT or MRI scans. For fractures that involved the upper endplate, the guide pin was aimed downward and toward the anterior lower endplate. The final location of the needle tip was confirmed by simultaneous intraoperative anteroposterior (AP) and lateral images and by the feedback of resistance during guide pin advancing.

For patients in group B, the guide pin was aimed below and away from the fracture cleft (Fig. 1). Because the desired target plane was away from the fracture plane, the compact trabecular zone was detectable via sensing resistance while introducing the guide pin. The guide pin trajectory was adjusted if an empty space without resistance was reached, signaling entry into the fracture plane.

During the procedure, we adjusted the guide pin under fluoroscopy until the optimal guide pin trajectory and position were achieved as per preoperative templating in both AP and lateral views. The cannula was placed over the guide pin, and the guide pin was removed. A bone drill was used to create a space in the vertebral body to facilitate balloon insertion. An inflatable bone tamp (IBT) was inserted to an adequate depth as determined by templating. The IBT was inflated progressively in 0.25-mL increments, and the inflation progress was verified in the lateral and AP views.

The inflation progression was terminated for patients in group B if the collapsed endplate realigned or there was compact bone zone between the inflated balloon and the endplate (Fig. 1C). Patients lacking a compact bone zone between the balloon and the endplate due to osteoporosis were excluded.

For patients in group A, the guide pin was aimed toward the fracture plane. An empty space without resistance was identified while introducing the guide pin (Fig. 2).

Bone filler was inserted into the anterior portion of the balloon cavity, and cement was delivered until the cavity created by the balloon was filled. The filling was stopped immediately if we observed any cement extravasation, cement leaking into the intervertebral disc, or cement reaching the posterior portion of the vertebral body.

2.2. Outcome analysis

Patients were followed at postoperative months 1, 3, 6, and 12. Radiological clinical outcomes, including visual analog scale (VAS) scores for pain and Oswestry Disability Index (ODI)

Table 1

Patient demographics

Variables	Group A (n = 51)	Group B (n = 49)	p
Age, y (± SD)	80.18 ± 6.74	79.76 ± 7.50	0.768
Sex (M:F)	13:38	12:37	0.908
BMI, kg/m^2	23.67 ± 4.51	23.06 ± 3.73	0.460
BMD (DEXA)	−2.45 ± 0.67	−2.55 ± 0.86	0.507
Vertebra fractured, %			0.376
T5-T10	6 (11.8)	5 (10.6)	
T12-L1	19 (37.3)	25 (51.0)	
L2-L5	26 (51.0)	19 (38.8)	
Fracture type, %			0.926
Wedge	38 (74.5)	35 (71.5)	
Biconcave	13 (25.5)	14 (28.6)	
Pre-op VAS (± SD)	8.1 ± 0.70	8.2 ± 0.77	0.392
Pre-op ODI (± SD)	62.59 ± 12.28	60.33 ± 9.15	0.205

BMD = bone mineral density; BMI = body mass index; DEXA = dual-energy x-ray absorptiometry; Pre-op ODI = preoperative Oswestry Disability Index; Pre-op VAS = preoperative visual analog scale.

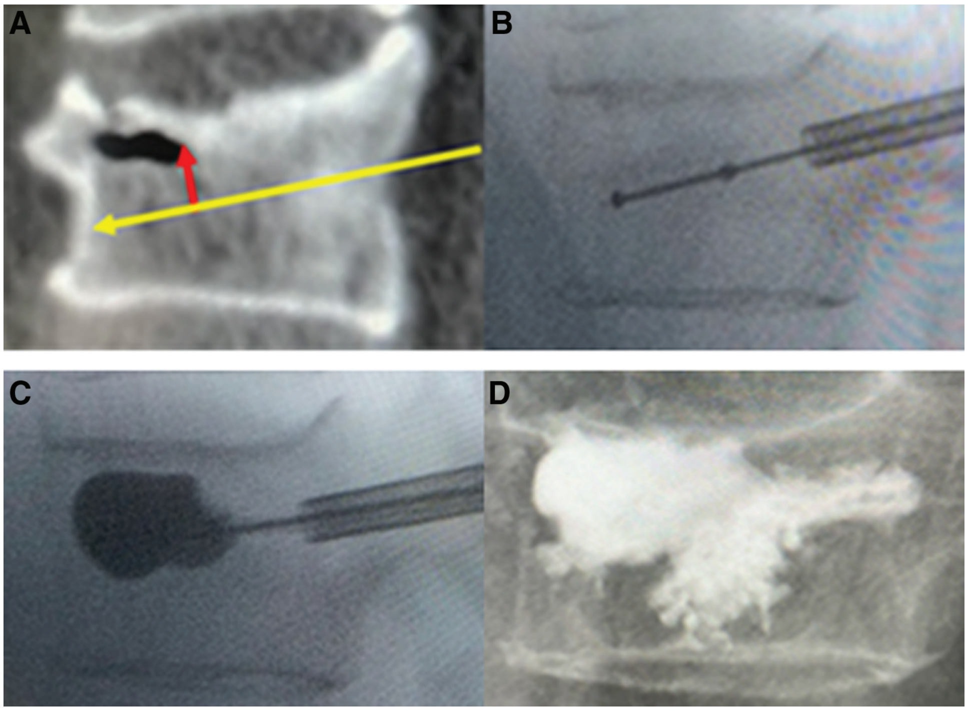

Fig. 1 A 93-year-old man with an L3 compression fracture and upper endplate fracture. The guide pin and balloon were inserted away from the fracture site. A, Preoperative planning of the guide pin trajectory (yellow line), which is away from the fracture site (red line) on the CT scan. B, Intraoperative fluoroscopy of the guide pin position. C, Intraoperative fluoroscopy of balloon inflation and endplate reduction. D, Postoperative 1-mo plain x-ray. CT = computed tomography.

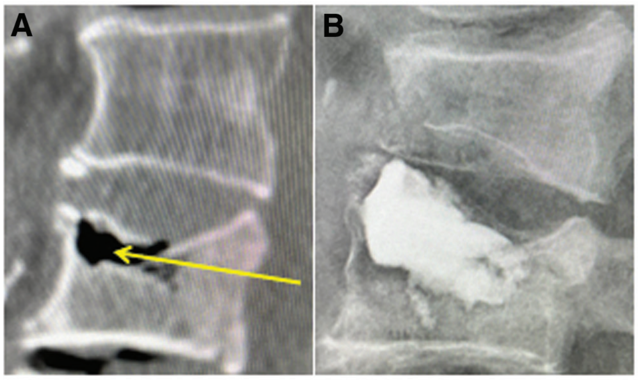

Fig. 2 An 86-year-old woman with an L2 compression fracture and upper endplate fracture. The guide pin and balloon were introduced into fracture site directly. A, Preoperative planning of the guide pin trajectory directly into the fracture site (yellow line). B, Postoperative 1-mo plain x-ray with adjacent vertebral fracture.

for function, were recorded preoperatively and at postoperative months 1 and 12 if no new symptoms had occurred during follow-up.

Radiographs included AP and lateral thoracolumbar spine views. Radiological outcomes included adjacent fracture, kyphosis correction, and further collapse. The degree of vertebral body compression was calculated from plain films and included the kyphotic angle, anterior vertebral body height (AVH), middle vertebral body height, and posterior vertebral body height. The AVH at the level of treatment was measured at 1 and 12 months after treatment.

An additional CT scan was performed in cases of persistent, new-onset pain; suspected new fractures were assessed on plain films. Any adjacent-level fracture that occurred within 3 months after treatment was noted. Further collapse was defined as a loss of AVH of >50%.

Clinical and radiographic assessments were performed by an independent blinded observer not involved in patient care (primary health care). All patients were regularly followed up at our clinics. None of the patients dropped out of the study for unknown reasons.

2.3. Statistical analysis

The patients' age, BMI, preoperative VAS, preoperative ODI, and cement volume were analyzed using the independent sample *t* test. The clinical outcomes (VAS and ODI) after surgery for each group were analyzed using the paired *t* test. Differences in sex, medical history, and complications between groups were assessed using the χ^2 test or Fisher exact test. Statistical significance was set at a p value of <0.05. All statistical analyses were performed using SPSS, version 20 (IBM, Chicago, IL).

3. RESULTS

The mean age of the patients was 80.18 ± 6.74 years (range, 60-90 years) in group A and 79.76 ± 7.50 years (range, 63-91 years) in group B. Thirteen of 51 patients in group A were male, and 12 of 49 patients in group B were male. The mean BMI was 23.67 kg/m^2 in group A and 23.06 kg/m^2 in group B. The mean dual-energy x-ray absorptiometry T score was −2.45 in group A and −2.55 in group B.

The most common location of the vertebral fracture was the lumbar level in group A and the thoracolumbar junction in group B, but the difference was not statistically significant. Most fractures were wedge-shaped, and some were biconcave, with no significant difference in occurrence between groups (Table 1).

The preoperative VAS was 8.1 ± 0.70 in group A and 8.2 ± 0.77 in group B, and the preoperative ODI was 62.59 ± 12.28 in group

Table 2

Perioperative and clinical outcomes

Variables	Group A (n = 51)	Group B (n = 49)	*p*
Surgery time, min	36	35	>0.999
Cement volume, cc	3.85 ± 0.72	4.05 ± 0.63	0.144
Cement leakage, %			
Disc	39 (76.5)	1 (2.0)	<0.001
Other	10 (19.6)	6 (12.2)	0.315
VAS			
1-mo postoperative	3.65 ± 1.23	2.53 ± 1.02	<0.001
12-mo postoperative	2.27 ± 1.04	1.59 ± 0.84	<0.001
ODI			
1-mo postoperative	30.43 ± 12.82	22.45 ± 12.08	0.002
12-mo postoperative	24.16 ± 11.89	17.18 ± 10.02	0.002
Mean follow-up, mo	21.27 ± 4.36	19.10 ± 3.02	0.006
Revision surgery, %	5 (9.8)	5 (10.2)	>0.999

ODI = Oswestry Disability Index; VAS = visual analog scale.

A and 60.33 ± 9.15 in group B. No significant difference was observed in preoperative VAS (p = 0.392) or ODI (p = 0.205) between the groups (Table 1).

The mean surgical time was 36 minutes in group A and 35 minutes in group B. In both groups, intraoperative blood loss was of <30 mL. The volume of cement injected was 3.85 ± 0.72 mL in group A and 4.05 ± 0.63 mL in group B, with no significant difference between the groups. The rate of intradiscal leakage differed significantly between the groups, with only one case of intradiscal leakage in group B (2%) and 39 cases (76.5%) in group A (Table 2).

The VAS score 1 month after surgery was 3.65 ± 1.23 in group A and 2.53 ± 1.02 in group B; the VAS score 12 months after surgery was 2.27 ± 1.04 in group A and 1.59 ± 0.84 in group B (Table 2). The ODI score 1 month after surgery was 30.43 in group A and 22.45 in group B; the ODI score 12 months after surgery was 24.16 in group A and 17.18 in group B. Differences between the groups were statistically significant in the 1- and 12-month VAS and ODI scores (Fig. 3).

Radiological outcome measurements included anterior, middle, and posterior vertebral height and local kyphosis angle preoperatively and at postoperative months 1 and 12. No significant differences were observed between the groups (Table 3). However, the rate of further collapse was significantly lower in group B (8.2%) at an average postoperative 2.4 months than in group A (25.5%) at an average postoperative 1.7 months.

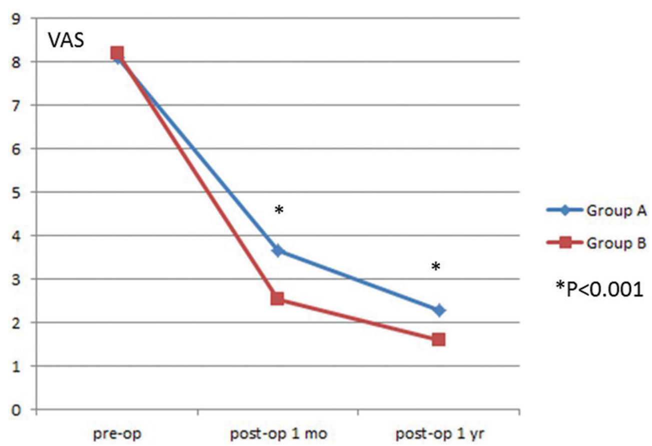

Fig. 3 Significant pain improvement when compact zone trajectory was used. VAS, visual analog scale.

4. DISCUSSION

We hypothesized that direct introduction of the guide pin into the fracture site and subsequent balloon expansion was responsible for cement leakage into the fractured endplate. In most cases, the fracture line inside the vertebral body remains very close to the endplate fracture site. The proximity of the fracture cleft allows endplate leakage to occur readily during cement distribution.[19]

We proposed a solution to this problem that involved creating a layer of cancellous bone beneath the injured endplate via balloon expansion to support the endplate defect and prevent cement leakage. Therefore, we inserted the guide pin away from the fracture site. As a result, the cancellous bone between the fracture site and guide pin provided support while the balloon expanded. The eggshell created this way is thicker and acts as a shield between the bone cement and fractured endplate. The fractured endplate could be partially reduced while the thicker cancellous layer was pushed upward by balloon expansion.[20]

We suggest that the principles underlying tibia plateau fracture treatment are applicable to treating vertebral endplate fracture. Sufficient subchondral bone grafting is critical for articular fracture reconstruction. The cancellous bone that is elevated while the balloon expands helps to support the fractured endplate, preventing cement leakage into the disc through the endplate defect (Fig. 4).

Different strategies have been proposed to decrease the risk of cement extravasation into the disc while treating vertebral compression fractures with a fractured endplate, including the trochar position (away from the broken endplate, and unnoticed perforation of endplate by needle tip). However, the efficacy and safety of kyphoplasty in treating endplate fracture have seldom been discussed.

A poor prognosis has been reported for patients with endplate fracture. One study showed that postoperative vertebral height loss and aggravation of kyphosis are associated with biomechanical changes in the vertebral body caused by endplate fracture.[5] Therefore, the optimal surgical treatment for Osteoporotic Vertebral Compression Fracture with endplate fracture should not only restore the compressed vertebral body height and correct kyphosis, but also correct the endplate deformity.

Table 3

Radiological outcomes

Variables	Group A (n = 51)	Group B (n = 49)	*p*
Preoperative, mm			
Anterior vertebral height	20.03 ± 5.38	19.53 ± 4.97	0.636
Middle vertebral height	19.81 ± 5.10	19.02 ± 5.82	0.471
Posterior vertebral height	26.01 ± 4.26	26.19 ± 4.83	0.844
1-mo follow-up, mm			
Anterior vertebral height	23.52 ± 5.34	24.32 ± 4.64	0.426
Middle vertebral height	23.65 ± 4.40	24.56 ± 4.80	0.322
Posterior vertebral height	28.43 ± 3.74	29.92 ± 4.54	0.076
12-mo follow-up, mm			
Anterior vertebral height	20.12 ± 5.27	21.55 ± 4.50	0.150
Middle vertebral height	20.75 ± 4.30	22.04 ± 4.78	0.158
Posterior vertebral height	26.59 ± 3.80	28.14 ± 4.57	0.068
Local kyphosis angle			
Preoperative	9.97 ± 6.06	11.45 ± 3.87	0.147
1-mo postoperative	7.98 ± 4.85	8.31 ± 4.57	0.724
12-mo postoperative	10.23 ± 5.03	10.76 ± 5.22	0.611
Further collapse, %	13 (25.5)	4 (8.2)	0.021
Adjacent fracture, %	7 (13.7)	7 (14.3)	0.936
Mean follow-up, mo	21.27 ± 4.36	19.10 ± 3.02	0.006

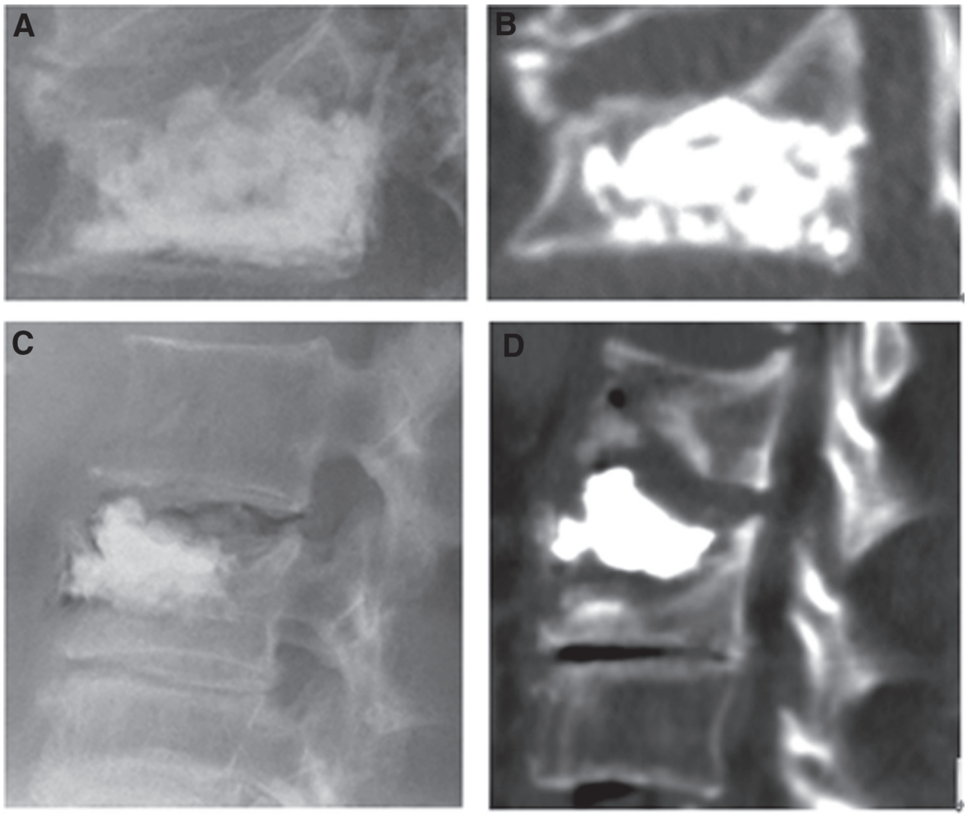

Fig. 4 An 83-year-old woman with an L2 compression fracture and upper endplate fracture, group B. A, Postoperative 2-mo x-ray shows no intradiscal leakage. B, Postoperative 2-mo CT shows no intradiscal leakage. An 82-year-old woman with an L3 fracture compression fracture and upper endplate fracture, group A. C, Postoperative 1-mo x-ray, patient complained of persistent back pain. D, Postoperative 2-mo CT with intradiscal cement leakage and adjacent fracture.

Our study has several limitations. First, the number of enrolled patients was too small to reach conclusions with adequate statistical power. We tried our best to contact all patients to complete the 1-year follow-up examination, but due to the COVID-19 pandemic, some patients had difficulty completing the second-year follow-up. Second, cement augmentation and leakage prevention were performed by an experienced surgeon under fluoroscopy to the greatest extent possible in all patients. Third, we did not routinely use postoperative CT to evaluate the radiological outcomes and cement leakage rates. Fourth, not every patient has a sufficient layer of compact bone in their vertebrae.

In conclusion, the indirect reduction method used in this study was used to reinforce the collapsed endplate rather than just fill the defect. Our findings suggest that this technique is a safe and more effective way to treat osteoporotic vertebral compression fractures with endplate fragmentation and showed better pain improvement with less intradiscal leakage and lower rates of further body height collapse.

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