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Original article

Short-segment posterior instrumentation combined with calcium sulfate cement vertebroplasty for thoracolumbar compression fractures: Radiographic outcomes including nonunion and other complications



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ABSTRACT

Objective: To evaluate the radiographic outcomes of short-segment posterior instrumentation plus vertebroplasty using injectable calcium sulfate cement (CSC) for thoracolumbar compression fractures.

Materials and methods: Twenty-eight patients with a single-level thoracolumbar compression fracture, who underwent short-segment pedicle screw fixation and CSC vertebroplasty, were included in the study. The anterior vertebral body height ratio, local kyphosis angle, and the height of the intervertebral disc adjacent to the fractured vertebra were used to evaluate the radiographic results. Complications including bone nonunion, instrument failure, cement leakage, and disc vacuum formation were also assessed.

Results: The patients were followed up for an average of 24.20 ± 5.40 months. The relative preoperative anterior body height was $55.71 \pm 15.29\%$, which improved to $94.93 \pm 5.39\%$ immediately after surgery ($P < 0.001$), and at final follow-up showed a $6.50 \pm 3.89\%$ loss of height correction ($P < 0.001$). The mean preoperative local kyphosis angle was $22.23 \pm 5.65^\circ$, which corrected to $2.67 \pm 4.43^\circ$ immediately after surgery ($P < 0.001$), but reverted to $6.71 \pm 4.95^\circ$ at final follow-up, showing a $4.04 \pm 1.91^\circ$ loss of correction ($P < 0.001$). The mean height of the intervertebral disc proximal to the fractured vertebra was 9.87 ± 0.91 mm before surgery, 12.53 ± 0.98 mm after operation ($P < 0.001$), and the loss of correction at final follow-up was 2.35 ± 1.15 mm with a significant difference compared to immediate postoperative values ($P < 0.001$). Bone nonunion occurred in 7 patients, 2 patients had hardware failure, 9 patients had cement leakage, and 10 patients had disc vacuum phenomenon adjacent to the fractured vertebra.

Conclusions: The patients who underwent this procedure had a loss of correction of vertebral height and local kyphosis. Complications such as bone nonunion, instrument failure, cement leakage, and disc vacuum may occur. Rapid CSC resorption accounts for these radiographic outcomes and complications.

Level of evidence: Level IV, retrospective study.

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1. Introduction

Thoracolumbar compression fracture caused by trauma is a common spinal injury [1]. Surgical treatment is necessary if stability or neurological function is impaired. Compared with anterior

surgical procedures, posterior short-segment pedicle screw fixation, which results in indirect reduction of the collapsed vertebra, preservation of segment motion, lower blood loss, and a decrease in postoperative morbidity, remains an ideal technique to treat thoracolumbar compression fractures [2,3]. However, higher implant failure and loss of reduction are usually seen in patients with only posterior pedicle screw fixation due to insufficient anterior column support [4]. Therefore, anterior column augmentation via a posterior procedure is essential.

Augmentation of the fractured vertebral body is usually performed by injection of bone cement such as polymethylmethacrylate (PMMA), which provides good strength and fixation of the vertebral fractures, and excellent clinical results have been

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reported [5]. Unfortunately, PMMA has several disadvantages, including toxic monomers, thermal necrosis, non-bioabsorbability, and biomechanical mismatch between treated and untreated vertebral levels [6,7]. Therefore, injectable bone cements such as CSC (calcium sulfate cement) with bioabsorbability has been developed, and used for augmenting the fractured vertebral body by vertebroplasty [2]. A biomechanical study in a cadaverous vertebral compression fracture model showed that CSC can provide vertebral stiffness and strength immediately after surgery comparable to PMMA [8]. And two clinical studies have demonstrated that posterior short-segment instrumentation and vertebroplasty with injectable CSC is an effective procedure for thoracolumbar compression fractures [2,9].

From 2007 to 2009, 28 patients with thoracolumbar compression fracture accepted posterior short-segment instrumentation plus injectable CSC (MIIG X3; Wright Medical Inc., Arlington, TN) vertebroplasty. In this group, the patients showed satisfactory short-time clinical results as reported in the literature [2,9]. However, some complications associated with this procedure were also found according to imaging findings. Therefore, the purpose of this study was to evaluate the imaging outcomes of CSC vertebroplasty, importantly, to evaluate its complications.

2. Subjects and methods

2.1. Subjects

Twenty-eight patients between March 2007 and May 2009 were enrolled in this retrospective study on the basis of the following criteria. Inclusion criteria were: a single-level fracture at T12–L3 without neurological symptoms; posterior short-segment pedicle screws fixation plus CSC vertebroplasty; type A3.1 or severely type A1.2 and 1.3 fracture according to Magerl classification [10]; local kyphotic angle $>20^\circ$, or anterior body height collapse $>30\%$; less than 60 years old and at least 12-month follow-up with imaging data. Exclusion criteria were: patients with spinal deformity; previous vertebral fracture in the adjacent vertebra; severe degenerative spinal disease; and previous spinal operation. Patients comprised of 16 men and 12 women with mean age of 41.64 ± 11.73 years (range: 19–60). Injury was caused by a fall in 22 patients, vehicle accident in 6 patients. The fracture level was T12 in 6 patients, L1 in 11 patients, L2 in 9 patients, L3 in 2 patients. Type A1.2.1 in 15 patients, type A1.2.2 in 1 patient, type A1.3 in 3 patients, and type A3.1.1 in 9 patients [10]. The mean time from injury to operation was 3.21 ± 1.75 days (range: 1–10). This study design was approved by the hospital's ethics committee. All patients provided informed consent for the procedure. Patients' clinical data are presented in Table 1.

2.2. Surgical procedures

Surgical procedures were performed under general anesthesia. The patients were placed in the prone position with the abdomen suspended. Closed reduction was performed by compression of the most prominent site in the thoracolumbar kyphosis with the hands. After restoring the shape of the fractured vertebra under C-arm fluoroscopy, a standard posterior midline approach was made to expose the lamina and facet joints with the posterior vertebral column intact. Pedicle screws were inserted into the vertebral body one level above and below the injured vertebra. After connecting the rods and pedicle screws, distraction force was applied using spreader forceps to further restore the height of the anterior column. After completing the fixation, a trocar in a cannula was inserted unilaterally into the fractured vertebra until it reached the optimal position. After removing the trocar, CSC was slowly

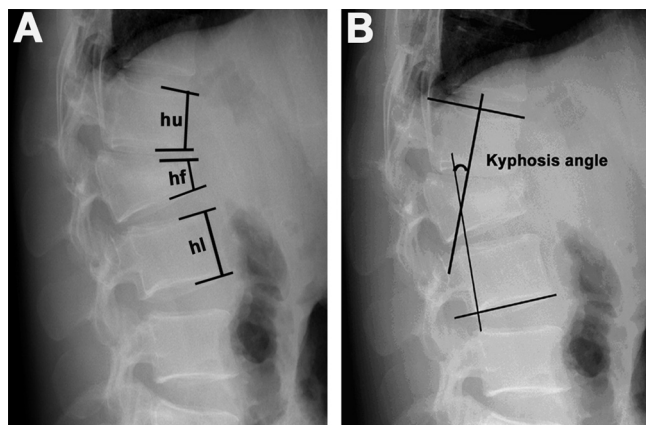


Fig. 1. Radiograph of the fractured vertebra height and the regional kyphotic angle. A. hf represents the anterior height of the fractured vertebra, hu and hl represent the anterior height of the vertebra above and below the fractured vertebra. B. The regional kyphotic angle.

injected into the defect in the fractured body through the cannula. Before closing the incision, a negative-pressure catheter drain was fitted. The surgical procedure was performed under continuous fluoroscopic monitoring. In this study, the fracture was Magerl type A3.1.1, type A1.2.1 and type A1.3, posterior column is not seriously damaged. Therefore, we did not perform posterior or posterolateral fusion.

After surgery, the patients were immobilized in bed in a supine position for 24 h. Drains were removed 48 hours postoperatively. During the postoperative period, the patients were encouraged to resume their daily routine but required to wear a brace for 12 weeks. Vigorous activities were restricted for six months after surgery. All patients were assessed using X-ray radiographs and CT scans before surgery and during follow-up.

2.3. Radiographic evaluations

Imaging was performed before and after surgery using anteroposterior and lateral radiograph and CT scans. The anterior height of the fractured vertebra was defined as the height of the fractured vertebra. The mean value of the anterior height of the vertebrae above and below the fractured vertebra was defined as the normal height of the fractured vertebra. The relative height of the fractured vertebra was defined as the height of the fractured vertebra divided by the normal height of the fractured vertebra, and was expressed as a percentage (Fig. 1A) [11]. The regional kyphotic angle of the affected segments was defined as the measured angle between the superior endplate of the upper vertebra and the inferior endplate of the lower vertebra (Fig. 1B) [11]. The height of the intervertebral disc above and below the fractured vertebra were also measured. The radiological data were measured using DICOM VIWERE software.

Patients were also monitored for radiographic complications including the development of nonunion which express no bone tissue growing into the defect of the vertebra at the final follow-up time; cement leakage into the paravertebral soft tissues, spinal canal, paravertebral vein and intervertebral disc; instrument failure which express implant breakage; and disc vacuum phenomenon adjacent to fractured vertebra.

2.4. Statistical analysis

Data are presented as mean \pm standard deviation. A paired Student's *t*-test and the Wilcoxon nonparametric test were used to evaluate data changes before and after surgery. Statistical

Table 1
Clinical demographic data of the patients.

Case	Gender	Age (years)	Cause	Level	Classification (Magerl/AO)	Injury-surgery interval (days)	Blood loss (ml)	CSC volume (ml)	Operation time (min)	CSC absorption time (days)	Follow-up (months)
1	F	19	Fall	L1	A1.2	2	210	4	80	29	24
2	F	45	Fall	L1	A1.2	3	260	3.8	70	55	26
3	F	30	Fall	L1	A1.2	1	250	4	80	60	38
4	F	23	Fall	L2	A3.1	4	220	4.3	80	45	23
5	M	38	MVA	L1	A1.3	6	300	4.2	86	36	24
6	F	60	Fall	L1	A1.2	4	220	5	78	38	24
7	M	35	MVA	L1	A1.2	3	190	4.5	85	43	32
8	M	41	Fall	L1	A3.1	2	250	4	68	50	19
9	F	37	Fall	L1	A1.2	3	189	3.8	70	35	32
10	M	56	Fall	L2	A1.3	3	267	4.6	89	45	22
11	F	43	MVA	L2	A1.2	10	250	4.8	90	40	18
12	M	56	Fall	L1	A3.1	2	190	5	70	50	26
13	M	28	Fall	T12	A1.2	4	200	3.6	68	45	32
14	M	41	Fall	T12	A3.1	3	210	3.7	80	52	25
15	M	38	Fall	T12	A1.2	2	260	4.8	80	35	30
16	F	56	Fall	L3	A3.1	3	185	5	75	50	18
17	F	58	Fall	T12	A1.2	3	200	4.5	76	45	24
18	M	52	Fall	L1	A3.1	3	210	4	75	40	24
19	M	33	Fall	L2	A1.3	3	198	3.9	75	36	14
20	F	51	Fall	L2	A1.2	3	210	5.5	80	38	26
21	M	37	MVA	T12	A3.1	3	260	5	86	45	14
22	M	24	Fall	L3	A1.2	2	220	4	66	50	22
23	M	30	Fall	L2	A1.2	3	250	4.5	74	45	23
24	M	43	Fall	L2	A1.2	3	200	4.7	64	39	24
25	F	60	MVA	L1	A1.2	6	250	5	78	39	25
26	F	51	MVA	L2	A3.1	1	200	4	68	40	22
27	M	36	Fall	L2	A1.2	2	210	4.5	75	45	28
28	M	45	Fall	T12	A3.1	3	198	4.3	78	38	19
Mean ± SD		41.64 ± 11.73				3.21 ± 1.75	223.5 ± 30.20	4.39 ± 0.49	76.57 ± 6.93	43.14 ± 6.92	24.2 ± 5.4

M: male; F: female; MVA: motor vehicle accident.

analyses were performed using SPSS 15.0. The results were considered significant at a level of $P < 0.05$.

3. Results

3.1. Clinical data

The mean operation time was 76.57 ± 6.93 min (range: 64–90), volume of CSC injected into the vertebral body was 4.39 ± 0.50 ml (range: 3.6–5), blood loss was 223.5 ± 30.20 ml (range: 185–300). The average follow-up time was 24.2 ± 5.4 months (range: 14–38). The absorptive time of the CSC was 43.14 ± 6.92 days (range: 29–60; Table 1). No neurologic deficit was noted.

3.2. Radiographic outcomes

The relative mean preoperative anterior body height was $55.71 \pm 15.29\%$ (range: 30–75%), which improved to $94.93 \pm 5.39\%$ (range: 78–99%) immediately after surgery ($P < 0.001$). There was a mean correction of $39.21 \pm 14.84\%$ (range: 23–74%). However, the height had collapsed significantly to $88.43 \pm 7.32\%$ (range: 68–97%) at final follow-up ($P < 0.001$). The average loss of height correction was $6.50 \pm 3.89\%$ (range: 2–15%). From injury to final follow-up, however, there was still a statistically significant $32.71 \pm 16.29\%$ (range: 15–65%) correction ($P < 0.001$; Table 2).

The mean preoperative local kyphosis angle was $22.23 \pm 5.65^\circ$ (range: 5–30°), which was corrected to $2.67 \pm 4.43^\circ$ (range: –3–15°) immediately after surgery ($P < 0.001$). The mean angle became $6.71 \pm 4.95^\circ$ (range: 2–22°) at final visit with a significant difference compared with the immediate postoperative values ($P < 0.001$). Loss of kyphosis correction was $4.04 \pm 1.91^\circ$ (range: 2–10°). However, the mean angle at final follow-up still showed a $16.52 \pm 5.97^\circ$ (range: 2–25°) correction from injury to final visit with a statistically significant difference ($P < 0.001$; Table 2).

Table 2
Radiographic data of the patients (mean ± standard deviation).

Variable	Anterior body height (%)	Local kyphosis degree (°)
Preoperative	55.71 ± 15.29	22.23 ± 5.65
Postoperative	94.93 ± 5.39	2.67 ± 4.43
Final follow-up	88.43 ± 7.32	6.71 ± 4.95
Correction by surgery	39.21 ± 14.84^a	20.55 ± 5.22^a
Loss of correction at final	6.50 ± 3.89^b	4.04 ± 1.91^b

^a Denotes a significant difference between the preoperative and postoperative results ($P < 0.001$).

^b Denotes a significant difference between the postoperative and final results ($P < 0.001$).

The mean height of the intervertebral disc proximal to the fractured vertebra was 9.87 ± 0.91 mm (range: 9–11.5) before surgery, 12.53 ± 0.98 mm (range: 11–14) at immediate postoperative time, and 10.18 ± 1.21 mm (range: 8–13) at final visit. There was a 2.65 ± 0.95 mm (range: 2–5) height correction with a significant difference between preoperative and immediate postoperative values ($P < 0.001$). The loss of correction at final follow-up was 2.35 ± 1.15 mm (range: 0–4) with a significant difference compared to immediate postoperative values ($P < 0.001$; Fig. 2A). There was no significant difference between the mean height of the intervertebral disc distal to the fractured vertebra before and after surgery (Fig. 2B).

3.3. Radiographic complications

Bone nonunion occurred in 7 patients. According to CT scans, the shape of the fractured vertebrae was restored immediately after surgery, and the CSC was well filled into the body void. After a mean of 43.14 days, the CSC was entirely absorbed. At an average of 15 months after surgery, no obvious bone tissue was observed growing into the defect. Mean 8 months after implant removal, the bone defect was still present (Fig. 3).

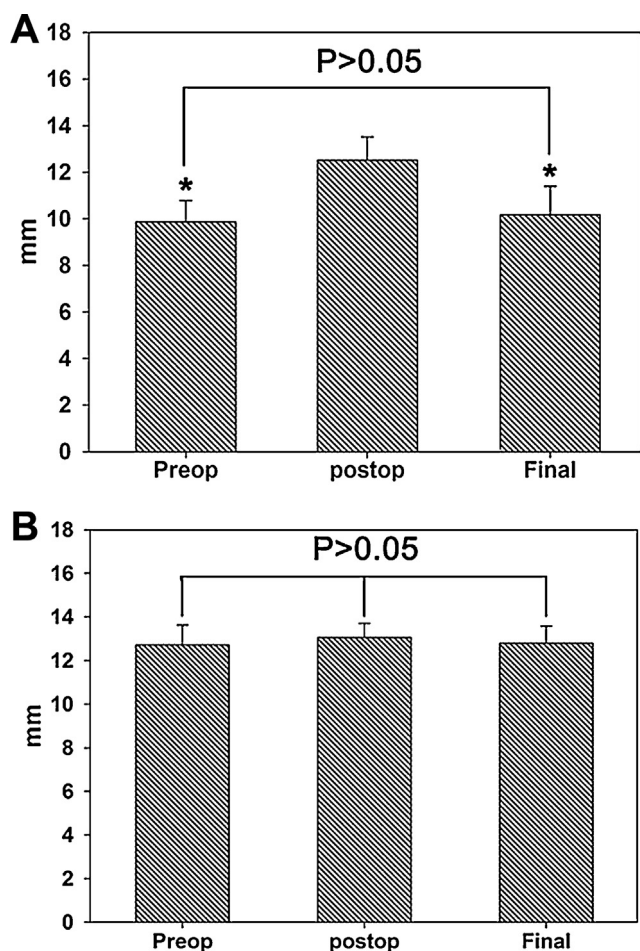


Fig. 2. Height of the intervertebral disc proximal (A) and distal (B) to the fractured vertebra. The asterisk (*) indicates a statistically significant difference ($P < 0.001$) compared with the value at immediate postoperative time.

Two patients suffered hardware failure with screw breakage. We initially discovered that the screw was broken on one side at the 12-month follow-up. The implant was left in situ owing to the lack of any clinical symptoms, and was removed 18 months after surgery (Fig. 4).

Nine patients suffered cement leakage. In detail, leakage into adjacent superior disc in 1 patient, paravertebral soft tissues in 5 patients, paravertebral veins in 2 patients, and spinal canal in 1 patient (Fig. 5).

Ten patients had disc vacuum phenomenon (Fig. 6). Intervertebral disc in 8 patients, both proximal and distal intervertebral disc in 2 patients. The vacuum phenomenon emerged after CSC absorption and disappeared at final follow-up.

4. Discussion

Injectable CSC is currently used to augment anterior column of fractured vertebra [2,9]. In this study, although local kyphosis and anterior vertebral body height demonstrated immediate improvement after surgery, loss of correction at the final follow-up visit was $4.04 \pm 1.91^\circ$ for local kyphosis, and $6.50 \pm 3.89\%$ for anterior vertebral body height. The radiographic results were in agreement with the data reported by others [2,9]. However, in these studies, the authors did not explain the reasons for the correction loss. As we know, transpedicular screw fixation plus grafting in fractured vertebrae can restore vertebral body height. However, maintaining body height requires a balance between bone healing and graft reabsorption. If graft absorption occurs faster than new bone formation, bone height will gradually collapse. Injectable CSC with its biocompatible, biodegradable, and easily moldable properties, is widely used as a filler for bone defects. However, one of the disadvantages of using it in vivo is that its resorption rate is faster than the rate of new bone formation, which leads to the development of immature bone in the bone defect [12,13]. According to the results of our present research, CSC was completely resorbed within 43.14 days, which was in accordance with the literature [14], while no obvious bone tissue had formed in the body void on CT. Furthermore, the rapid resorption of CSC significantly influenced the quantity of newly formed bone due to occupation of the bone defect by avascular fibrous tissue [15], thus decreasing the mechanical properties of the fractured vertebral body, and ultimately promoting the loss of correction of local kyphosis and vertebral body height.

When analysing the height of the adjacent vertebral disc, the restoration of proximal disc height was not maintained at the final evaluation. In our study, fractures were mainly type A3.1.1 and type A1.2.1, characterized by proximal terminal vertebral plate injury and the introjection of the adjacent disc into the vertebral body [16]. Although the height of the vertebral body and adjacent vertebral disc were nearly restored, the CSC was rapidly resorbed and the bone tissue did not form in the vertebral void, leading to reinstruction of the proximal intervertebral disc into the vertebral defect and the loss of correction of the intervertebral disc. The latter is further a main factor related to the loss of local kyphosis.

Complications associated with this technique were the specific focus in this study. Two patients suffered hardware failure.

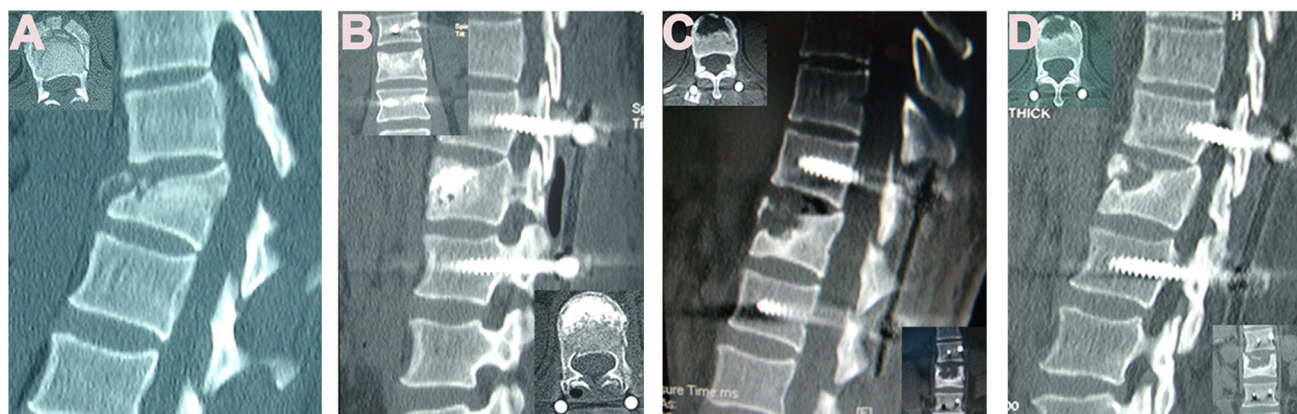


Fig. 3. CT scans of L1 compression fracture. A. Preoperative image showing type A1.2 fracture. B. The shape of the fractured vertebra was restored. C. CSC was absorbed after surgery. D. No bone tissue growing into the defect at final follow-up.

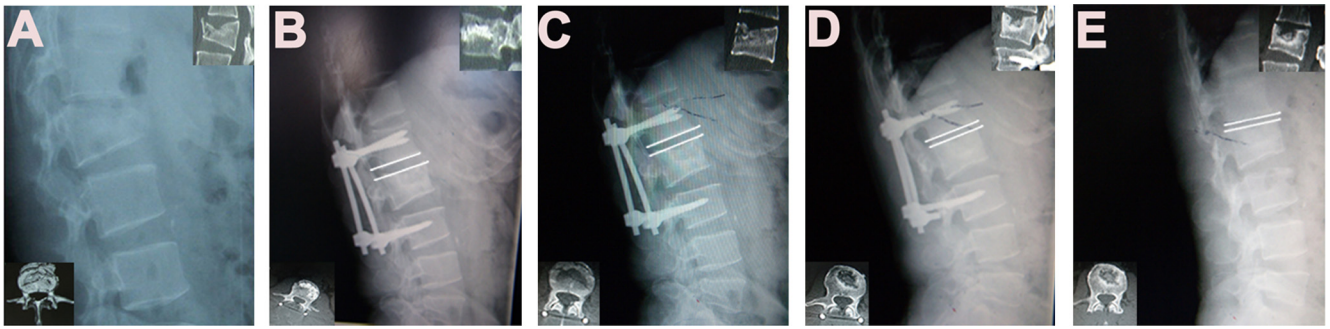


Fig. 4. Radiograph and CT scans of L2 compression fracture. A. Preoperative image showing type A3.1 fracture. B. CSC filled into the body defect. C. CSC was absorbed after surgery, and the superior endplate collapsed. D. The bone defect existed and screw breakage occurred. E. Eight months after implant removal, the bone defect was still present. The superior disc space gradually narrowed.

Radiographs obtained during follow-up showed that the superior disc space narrowed, and rapid resorption of the CSC without sufficient formation of new bone tissue led to recurrence of insufficient anterior column support. These factors increased the strength-loading of the instrument and finally caused its failure. Nonunion of the fractured vertebra occurred in 7 patients. In these patients, CSC was resorbed by 43 days postoperatively, and the disc could re-enter the fractured vertebra through the injured endplate and obliterate bone union [17]. In addition, the fibrous tissue occupying the bone defect also inhibits bone union [15].

CSC leakage into the soft tissue, adjacent disc and paravertebral veins was asymptomatic, which conformed to previous reports of PMMA leakage [18]. In this study, one patient suffered cement leakage into the spinal canal with no neurologic deterioration after surgery. Analysis of the cement leakage into the spinal canal showed that the compression was not serious and the cement was completely absorbed soon after surgery. Unlike PMMA with high polymerization temperature [6], CSC has a lower setting

temperature, which incurs no obvious damage to the soft tissue, although leakage into the spinal canal.

“Vacuum disc” is the accumulation of gas within the intervertebral disc. The gas, containing 90–92% nitrogen, along with oxygen, carbon dioxide, and traces of other gases, is usually a direct product of the liberation of gas from the surrounding tissue [19]. The vacuum phenomenon is usually seen in elderly patients because of degenerative disc disease or osteoporotic vertebral fracture [20]. One theory of the pathogenesis is cartilaginous endplate degeneration, which interferes with disc nutrition and aggravates intervertebral disc degeneration [21]. In our cohort of patients with a mean age of 41.64 years, we speculated that the vacuum phenomenon was a consequence of vertebral fracture, in which the intervertebral disc and the cartilaginous endplate were damaged. In addition, CSC was completely resorbed and thus the endplate collapsed and interfered with disc nutrition, promoting the disc degeneration and vacuum formation. As shown in Fig. 6C, the vacuum formation may also be closely associated with CSC

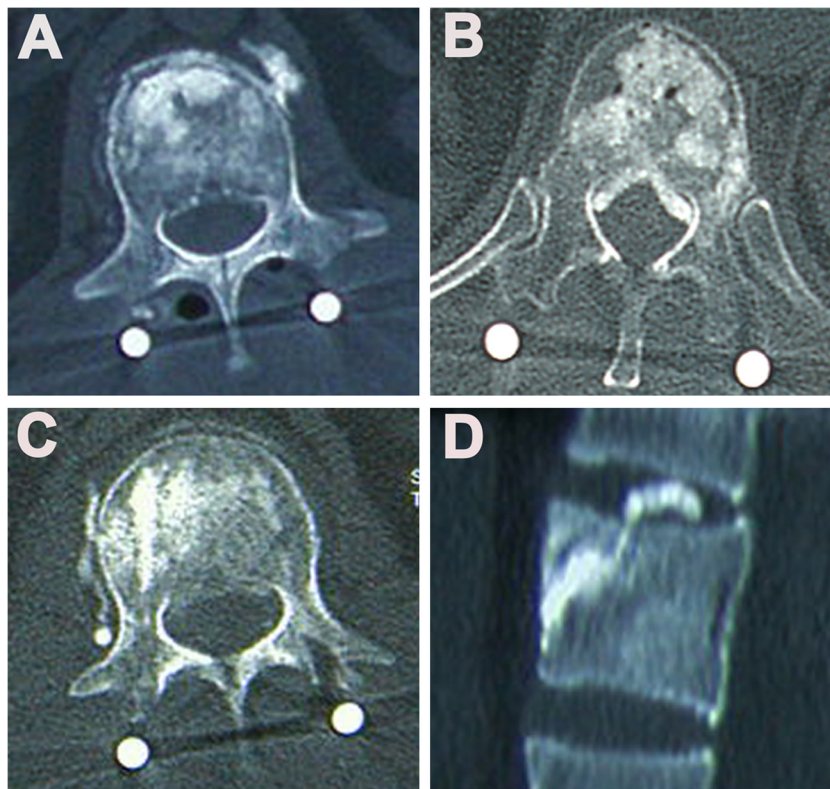


Fig. 5. CSC leakage. A. Paravertebral soft tissues. B. Spinal canal. C. Paravertebral vein. D. Intervertebral disc. The white arrows indicate cement leakage.

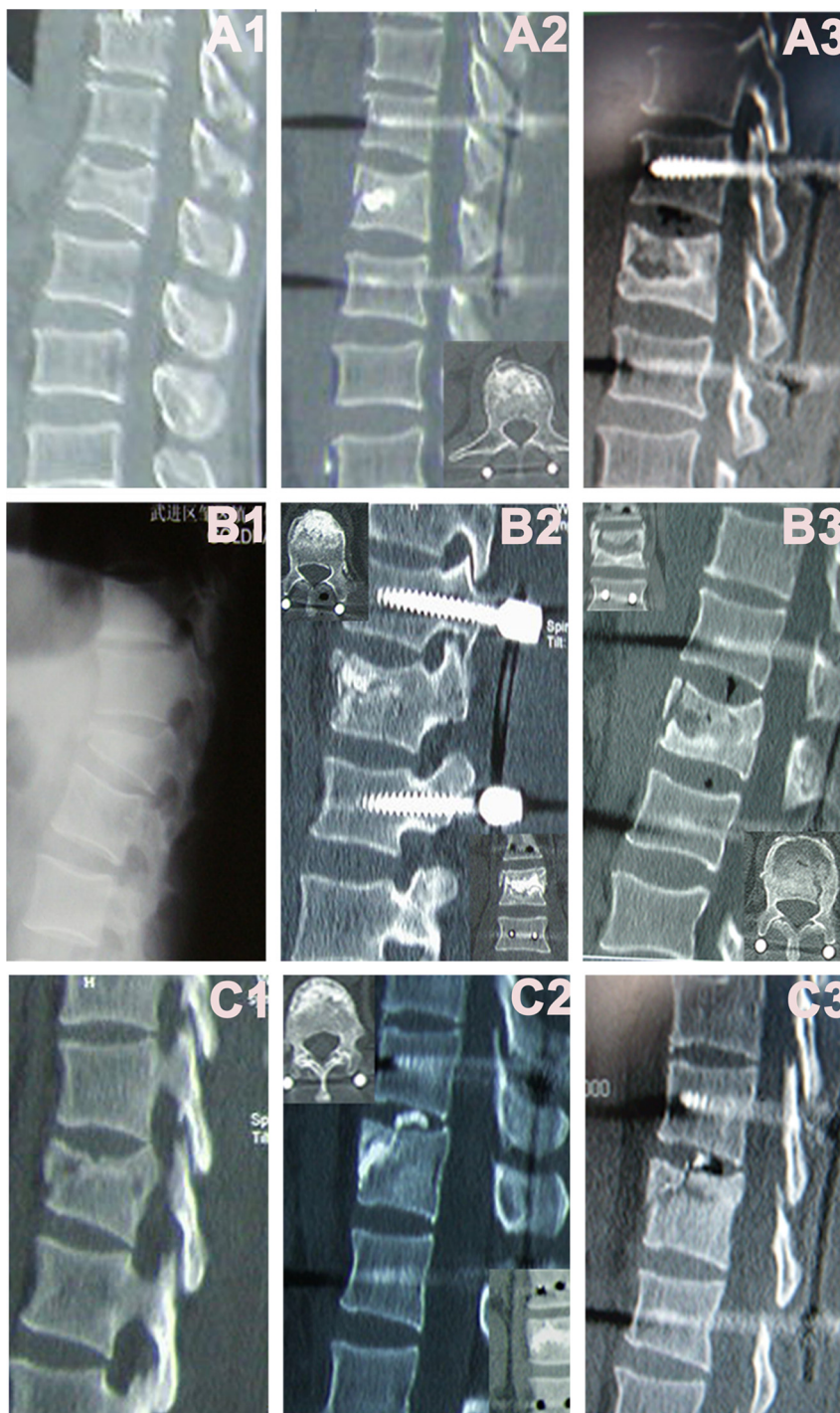


Fig. 6. The formation of the disc vacuum phenomenon. A. In proximal intervertebral disc. B. In proximal and distal intervertebral disc. C. Vacuum phenomenon formation accompanying with CSC absorption.

biodegradation, which also promotes disc degeneration and leads to loss of intervertebral height.

In summary, patients who underwent this technique had a loss of correction of vertebral height and local kyphosis angle. In addition, complications such as bone nonunion, instrument failure, cement leakage, and the disc vacuum phenomenon may occur. Rapid CSC resorption accounts for these radiographic outcomes and complications. Therefore, injectable CSC may not be the ideal augmentation material for thoracolumbar compression fractures. Limitations of this study included its small sample size and the lack of a control group; therefore, the results may be biased.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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