CLINICAL ARTICLE

Pedicle screw instrumentation plus augmentation vertebroplasty using calcium sulfate for thoracolumbar burst fractures without neurologic deficits

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Objective: To evaluate the efficacy of posterior instrumentation plus vertebroplasty and posterolateral fusion using calcium sulfate for thoracolumbar burst fractures without neurologic deficits.

Methods: Between July 2005 and January 2008, a total of 45 patients who had been diagnosed as having thoracolumbar burst fractures without neurologic deficits were treated with pedicle screw instrumentation plus vertebroplasty using calcium sulfate in our unit. The Cobb angles and loss rates of anterior-middle columns height at different time intervals were measured on lateral radiographs, and the preoperative and postoperative functional outcomes were evaluated using the Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI).

Results: The Cobb angles and loss rates of anterior-middle columns height postoperatively period were restored significantly compared with those noted preoperatively. The angles and heights were well maintained for at least two years using this technique. The mean postoperative VAS (back pain) score was 2.1 ± 0.8 , which was significantly better ($P < 0.001$) than the mean preoperative VAS score 7.9 ± 1.1 . The average preoperative ODI was $66.6 \pm 8.1\%$ and this had improved significantly to $15.5 \pm 4.5\%$ by the latest follow-up ($P < 0.001$). No instrumentation failure was detected in this study. The calcium sulfate had been absorbed completely by 3–6 months postoperatively.

Conclusion: Pedicle screw instrumentation plus augmentation vertebroplasty with calcium sulfate is an economic, efficient and reliable technique for treating unstable thoracolumbar fractures without neurologic deficits.

Key words: Calcium sulfate; Pedicle screw instrumentation; Thoracolumbar spine fractures; Vertebroplasty

Introduction

Thoracolumbar burst fracture is a serious traumatic injury, which can impact on the quality of life and even threaten the survival of patients. Thoracolumbar burst fractures are usually classified as of unstable type, because burst injuries of vertebral bodies always involved the middle column. According to the Denis' three-column theory, the middle column is very important in stabilizing the spine¹. Despite the fact that some patients with thoracolumbar burst fracture have no neurologic deficits, it is

essential to undertake active surgical treatment to reduce and fix the unstable spinal column².

Over the past few decades, posterior pedicle screw fixation has been one of the most highly regarded techniques for treating unstable thoracolumbar fractures. However, recent researchers have reported that many complications, such as delayed kyphosis, instrument failure and secondary nerve injury, have emerged after performing pedicle screw instrumentation alone³. The main reason may be related to disequilibrium in load-sharing by the three spinal columns. Although pedicle screw instrumentation can temporarily reduce a fractured vertebral body, it cannot support the height of the anterior-middle vertebral columns in the long term⁴. Because of this, some researchers have attempted to fill the fractured vertebral body with various grafts or substitutes as part of the surgical management of unstable thoracolumbar fractures^{5,6}.

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At present, injectable biomaterials which have been used in reconstruction of bone structure include polymethyl methacrylate (PMMA), calcium phosphate cement, calcium sulfate and hydroxyapatite stick^{7,8}. Although PMMA and calcium phosphate have sufficient rigidity and strength to support a fractured vertebral body, in their clinical application they have many disadvantages, such as slow biodegradation, strong inflammatory reaction, low osteogenic capacity and thermal injury. In contrast, calcium sulfate not only has ideal biomechanical properties which are close to those of vertebral bone, but also has the potential to enhance bone formation and fusion⁸. In the past few years, various investigations have been conducted on thoracolumbar burst fractures to determine the feasibility and efficacy of reconstruction of the anterior-middle columns with PMMA or calcium phosphate plus pedicle screw instrumentation. However, it has rarely been reported that calcium sulfate has been used to reconstruct fractured vertebral bodies.

In view of this, the present study was designed to investigate the feasibility and efficacy of pedicle screw instrumentation reduction plus transpedicular vertebroplasty using calcium sulfate for thoracolumbar burst fractures without neurologic deficits.

Materials and Methods

Between July 2005 and January 2008, a total of 45 patients who were diagnosed as having thoracolumbar burst fracture without neurologic deficit were selected into our retrospective study. All had been treated in the same unit. The inclusion criteria were single fresh burst fractures (Arbeitsgemeinschaft für Osteosynthesefragen [AO]/type A3) or thoracolumbar burst fractures combined with posterior ligament injury (AO/type B1.2). The exclusion criteria were as follows: (a) osteoporotic fracture; (b) associated neurologic deficits; (c) multi-segmental spinal injuries and associated injuries which were directly connected with the thoracolumbar fracture; (d) severe compression or displacement injuries of the posterior wall; (e) comminution of the vertebral body scoring less than five on the Load-Sharing Classification of spinal fractures⁹.

There were 33 men and 12 women in this study, with an average age of 42.2 years (range, 25–60 years). All eligible patients had unstable burst fractures; the AO classifications were 41 type A3 and 4 type B1.2¹⁰. The fractured segments were in T11 ($n = 2$), T12 ($n = 10$), L1 ($n = 20$), L2 ($n = 9$), and L3 ($n = 4$). The causes of these injuries included 14 traffic accidents and 31 falls from a height.

All eligible patients signed an informed consent after admission, and were then operated on as soon as possible,

always within 72 hours. Under general anesthesia with endotracheal intubation, the patients were placed in a prone position on a fracture-reduction table. With the help of C-arm radiography, repositioning of the thoracolumbar fractures was monitored initially in real-time. The fractured segment and adjacent spinal accessories were widely exposed through a midline posterior incision. Four pedicle screws were inserted into the affected vertebra cephalad and caudad to the fractured segment in the usual transpedicular fashion. The structure of the anterior column and posterior wall was restored by means of lordotization and moderate distraction of the pedicle screws, which locked onto the rods. Anatomic segmental alignment was then temporarily achieved by ligamentotaxis. If the reduction of the vertebral column was insufficient, the collapsed endplates of the upper and lower vertebrae were prised apart using a crook introduced through the transpedicular pathway of the fractured segment. Subsequently, vertebroplasty using calcium sulfate to fill the defects in the reduced vertebral body was performed.

After assembly of the screw-rod instrumentation (TSRH or Tenor, Medtronic Sofamor Danek, Memphis, TN, USA/Moss-Miami, DePuy Spine, Raynham, MA, USA), vertebroplasty with calcium sulfate was performed as follows: cannulas were inserted unilaterally or bilaterally into the central region of the fractured vertebral body by the transpedicular technique. Meanwhile, sequential fluoroscopic guidance was employed to regulate the position of the cannulas. Thereafter, minimally invasive injectable calcium sulfate cement (Wright Medical Technology, Arlington, TX, USA) was prepared according to the manufacturer's instructions, and then injected into the cavity in the vertebral body within one minute. The volume of injected cement was approximate 3.0 to 5.5 mL (mean, 4.0 mL). Throughout the procedure of calcium sulfate perfusion, dynamic fluoroscopic monitoring was used to avoid cement leakage. In all of these cases, neither laminectomy nor laminotomy was implemented to decompress vertebral canal because there were no neurologic deficits and <50% canal compromise.

At the end of the operation, the excess calcium sulfate cement and bone fragments were used for posterolateral fusion after intertransverse decortication of the articular facets and laminae. Postoperatively, the patients were required to remain supine in bed for 3 days; then were mobilized wearing a waist brace for 8–10 weeks. In the third postoperative month, the patients were allowed to resume normal activity.

Anteroposterior and lateral plain radiographs of the spine were taken preoperatively, on the third postoperative day, at 3, 6, and 12 months and at the latest follow-up (all patients in this study had a minimum of two years

Table 1 The loss rates of vertebral body heights and Cobb angles preoperatively, postoperatively and at the latest follow-up (measured as mean $\pm$ SD)

Item	Preoperative	Postoperative	At latest follow-up
Loss of anterior column height (%)	44.9 $\pm$ 6.9	11.4 $\pm$ 3.5*	12.7 $\pm$ 3.4*†
Loss of middle column height (%)	31.5 $\pm$ 5.6	10.1 $\pm$ 2.9*	10.8 $\pm$ 2.9*†
Loss of posterior column height (%)	4.5 $\pm$ 3.1	3.8 $\pm$ 2.2†	4.1 $\pm$ 1.9†‡
Cobb angle (°)	19.1 $\pm$ 5.0	5.2 $\pm$ 2.7*	5.7 $\pm$ 2.5*‡

*, $P < 0.005$, versus the preoperative group; †, $P > 0.05$, versus the preoperative group; ‡, $P > 0.05$, latest follow-up versus the postoperative group.

follow-up). In addition, where possible, CT and/or MRI were obtained for accurate assessment before and after surgery. Based on the preoperative, postoperative and latest follow-up lateral X-ray films, the Cobb angle of segmental kyphosis and the loss rates of vertebral body height were calculated in order to comprehensively estimate the efficacy of this technique. The Cobb angle is the angulation between the superior end plate of the vertebra cephalad to the fractured segment and the inferior end plate of the vertebra caudad to the fractured segment. The loss rates of vertebral body height (anterior-middle-posterior) were measured by dividing the height of the injured vertebral body (anterior-middle-posterior) by the average height of the superior and inferior vertebral body (anterior-middle-posterior) and then subtracting these numbers from 100%. Absorption and fusion of calcium sulfate were also judged via X-ray films or/and CT at different time intervals by two radiologists. The clinical outcomes were determined based on the Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI)¹¹, both of which were assessed preoperatively and at the latest follow-up.

The statistical data were expressed as mean $\pm$ SD. The differences were evaluated by Student's paired *t*-test and Fisher exact tests. A *P*-value < 0.05 was considered statistically significant.

Results

In this series, all operations were completed successfully. The operative time averaged 65 minutes (range, 55–80 minutes). The mean total blood loss was 305 mL (range, 100–650 mL). The average hospital stay was 10.8 days (range, 5–18 days). All patients underwent complete follow-up for an average of 28.7 months (range, 24–48 months), and nineteen (42.2%) of them underwent a second surgical procedure for removal of internal fixation instrumentation at least 18 months postoperatively.

The Cobb angles and loss rates of vertebral body height preoperatively, postoperatively and at the latest follow-up period are shown in Table 1. The angles and heights were well maintained for at least two years using this technique (Fig. 1A–E). No instrumentation failure was detected in

Figure 1 (A) Lateral radiograph of a 39-year-old man showing a burst fracture of T12; (B) Lateral roentgenogram 3 days postoperatively showing excellent reduction by means of posterior instrumentation and vertebroplasty plus posterolateral fusion using calcium sulfate; (C) Lateral radiograph 3 months after surgery showing that the calcium sulfate has almost been absorbed and is keeping pace with bone formation; (D) Lateral radiograph 28 months after surgery showing the vertebral body height and Cobb angle are well maintained; (E) CT on the third postoperative day showing vertebroplasty with calcium sulfate.

Figure 2 A 49 year-old man with a burst fracture of L1. CT on the third postoperative day showing slight leakage of calcium sulfate cement into the spinal canal, this was not accompanied by the appearance of clinical symptoms.

this study. In addition, no absorption of calcium sulfate cement was observed at 3–6 months postoperatively.

The mean postoperative VAS (back pain) score was 2.1 ± 0.8 at the latest follow-up period, which was a significant improvement ($P < 0.001$) over the mean preoperative VAS score of 7.9 ± 1.1 . The average postoperative ODI was $(15.5 \pm 4.5) \%$ at the latest follow-up; this had also improved significantly ($P < 0.001$) compared with the preoperative ODI ($66.6 \pm 8.1 \%$).

No iatrogenic neurologic deficits occurred in these patients. However, three patients had treatment-related complications such as calcium sulfate cement leakage ($n = 2$) and superficial wound infection ($n = 1$). Cement leakage was not accompanied by any clinical symptoms because the degree of leakage was slight (Fig. 2). Any wound infections healed with antibiotics and continuous changing of dressings within 20–25 days postoperatively.

Discussion

The commonest surgical technique for unstable thoracolumbar fractures is posterior short-segment pedicle screw fixation, which is a convenient and low-risk method for reduction of collapsed vertebral bodies. However, long-term follow-up has demonstrated that this procedure has considerable complications, such as a loss of height, instrumentation failure and secondary nerve injury. This is because there are massive cavitations and defects in the reduced vertebral body after posterior instrumentation and ligamentotaxis. Because of changes

in vertebral structure and instrumental stress, the center point of load-sharing is transferred from the anterior-middle columns to the posterior column, which increases the load on posterior instrumentation and makes this means of internal fixation ineffective¹². Hence, delayed loss of body height will inevitably occur if there is no augmentation of the anterior-middle spinal columns¹³. As shown by our results, the loss of height/ reduced Cobb angles and failure of instrumentation can be effectively inhibited by vertebroplasty using calcium sulfate. In addition, the low incidence of delayed kyphosis, instrument failure and secondary nerve injury also leads to significant improvement in function according to the VAS and ODI scales.

With the advent of vertebroplasty, the posterior transpedicular approach for injecting osseous substitutes or allografts has been widely utilized for reconstructing the anterior-middle columns¹⁴. Importantly, compared with the anterior approach for vertebral column reconstruction, this approach has advantages in regard to surgical procedures, blood loss, and prognosis and so on. Based on the above features, augmentation vertebroplasty plus pedicle screw fixation might be an efficient and reliable treatment for thoracolumbar burst fractures. Cho *et al.* reported the efficacy of short-segment pedicle screw fixation reinforced with PMMA vertebroplasty in 20 patients with thoracolumbar fractures, and concluded that this method decreases the instrumentation failure rate and controls postoperative pain more effectively¹⁵. Other researchers have reported preliminary results for balloon kyphoplasty with calcium phosphate and posterior short-segment instrumentation for thoracolumbar burst fractures *in vitro* and *in vivo*^{16,17}, and have verified that transpedicular balloon vertebroplasty is feasible for reduction of ruptured end plates, and that calcium phosphate cement is a desirable material for a bone substitute in the spinal column. Korovessis *et al.* also utilized balloon vertebroplasty with calcium phosphate for direct initial reduction of burst fractures, then stabilized and fixed them with pedicle screws by a minimally invasive pathway¹⁸. Subsequently, another research group reported a series of clinical outcomes for 28 patients with unstable thoracolumbar fractures, 18 of whom had neurologic deficits, who were treated by pedicle screw fixation supplemented with augmentation vertebroplasty with calcium phosphate and laminectomy¹⁹. In the above studies, loss of reduction height and failure of instrumentation decreased or did not occur at all, which proves that reconstruction of the vertebral body is necessary for treatment of thoracolumbar burst fractures. Our clinical data also verify that pedicle screw instrumentation plus vertebroplasty with calcium sulfate for thoracolumbar fractures achieves

a satisfactory prognosis, and has a comparable follow-up result to previously reported techniques using other bone substitutes.

In last few years, PMMA and calcium phosphate have been widely used as bone substitutes clinically. However, with widespread and continuous research, the long-term side effects of PMMA and calcium phosphate are becoming more and more evident^{20,21}. Therefore, ascertaining which of these bone substitutes is optimal has become the focus of research scholars in recent years. In a recent article, Perry *et al.* found that the strength and rigidity of calcium sulfate were closer to that of vertebral bone tissue. They therefore concluded that calcium sulfate may be an ideal alternative bone cement for treatment of vertebral fractures⁸. This research has laid a theoretical basis for reconstruction of spinal columns using calcium sulfate cement. The latest research also indicates that calcium sulfate might play an even more important role in the field of bone substitutes because of its osteoconductive, non-toxic and absorbable properties. Calcium sulfate can isolate thermal conduction and is absorbed completely within a few months, which may prevent secondary neurovascular compression and thermal injury. Moreover, in parallel with the absorption of calcium sulfate, vascular tissue and osteogenic cells grow in to fill the osseous defects and cavitation, reconstructing the osseous structure²². Currently, calcium sulfate has been reported to have been utilized in a variety of clinical applications, such as tibial metaphyseal fractures and benign bone lesions^{23–25}. In the current study, we also noted that calcium sulfate as a bone substitute has sufficient capacity to support maintenance of the height of the fractured vertebral body and accelerate bony fusion. Moreover, its ability to induce osteogenesis and its isothermic properties also make calcium sulfate more appropriate for filling vertebral body defects and promoting synostosis. In addition, defects in the damaged body might also provide a microenvironment which allows calcium sulfate to play its role to maximum extent²².

We also noted that balloon-assisted instruments were applied in most of the reported cases. Balloon-assisted instruments can promote vertebral body shaping and surgical safety. However, previous studies and our investigation have both demonstrated that the repositioning of posture associated with instrumentation reduction has enough potential to restore body heights and correct sagittal alignments²⁶. Moreover, we also found that direct vertebroplasty can maintain body shape and support the collapsed body after instrumental reduction. For the above reasons, we decided to firstly restore the vertebral body shape by means of posterior pedicle screw instrumentation, and then maintain the height of the vertebral

body by vertebroplasty without balloon-assisted instruments. The absence of balloon-assistance means that our method not only reduces medical costs considerably, but is also convenient for surgeons. Nevertheless, in order to ensure the safety of vertebroplasty, we advocate monitoring the perfusion of calcium sulfate using dynamic fluoroscopy and remodeling the vertebral upper/lower endplate and posterior wall using a crook introduced via the transpedicular pathway intraoperatively. Our results confirm that the success of vertebroplasty without balloon-assisted instruments can be guaranteed to a higher degree by the above means. In this trial, both of the cases of cement leakage occurred in the early period due to lack of experience. In one case the cause was excessive injection of cement and in the other improper position of the injection catheter.

Nevertheless, our study does have some shortcomings. Because patients with neurologic deficits were not included in this series, the current study could not assess whether this surgical technique is effective in producing neurologic improvement in fractures with neurologic deficits. In addition, some authors have reported that composites of calcium sulfate and other materials might have superior bioactivity to calcium sulfate alone. Further study is required to find the optimal one amongst the various substitute materials for bone.

Conclusion

The present study has demonstrated that pedicle screw instrumentation plus augmentation vertebroplasty with calcium sulfate is an economic, efficient and practical technique for treatment of thoracolumbar burst fractures without neurologic deficits. Direct vertebroplasty using calcium sulfate effectively maintains vertebral body shape and avoids instrumentation failure.

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Disclosure

This manuscript does not contain information about medical device(s)/drug(s). No benefits in any form have been, or will be, received from a commercial party related directly or indirectly to the subject of this manuscript.

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