

Long-term efficacy and safety of bone cement-augmented pedicle screw fixation for stage III Kümmell disease

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Research article

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Abstract

Purpose This study aimed to evaluate the efficacy and safety of bone cement-augmented pedicle screw fixation for stage III Kümmell disease.

Methods Twenty-five patients with stage III Kümmell disease who received bone cement-augmented pedicle screw fixation at the First Affiliated Hospital of Guangzhou University of Chinese Medicine between June 2009 and December 2015 were enrolled. All patients were females with a history of osteoporosis. The vertebral Cobb angle (V-Cobb angle), the fixed segment Cobb Angle (S-Cobb angle), pelvic parameters, visual Analogue Scale (VAS) score, and Oswestry Disability Index (ODI) were assessed preoperatively, postoperatively and at the final follow-up. Complications, loosening rate, operation time, and intraoperative bleeding were recorded.

Results The average lumbar vertebral density T-value was -3.68 ± 0.71 SD, and the average age was 71.84 ± 5.39 . The V-Cobb angle, S-Cobb angle, and Sagittal Vertical Axis (SVA) were significantly smaller postoperatively compared to the preoperative values. The VAS and ODI at 1 month after surgery were 3.60 ± 1.00 and $36.04 \pm 6.12\%$, respectively, which were both significantly lower than before surgery (VAS: 8.56 ± 1.04 , ODI: $77.80 \pm 6.57\%$).

Conclusion Bone cement-augmented pedicle screw fixation is a safe and effective treatment for stage III Kümmell disease. It can effectively correct kyphosis, restore and maintain sagittal balance, and maintain spinal stability.

Introduction

The frequency of Kümmell disease, a complication of osteoporotic vertebral fracture (OVF), is increasing globally[1]. Since the condition was first described by Herman Kümmell in 1891, the literature has referred to Kümmell disease as being characterized by delayed osteonecrosis after trauma[2], nonunion of compression fracture[3], delayed collapse of OVF[4], intravertebral pseudarthrosis[5], and vertebral vacuum sign[6]. A history of minor trauma was also present in some patients. However, patients without a history of trauma, gradually develop activity-related back pain or lower extremity nerve symptoms after a few weeks or months of an asymptomatic period.

The development of Kümmell disease involves the following 3 stages: Stage I, spinal vertebral bodies are slightly injured due to minor trauma or in the absence of trauma; Stage II, vertebral bodies experience dynamic instability in the cleft area, followed by fracture and bone collapse; and Stage III, the compressed fractured vertebral body compresses the posterior spinal cord, leading to continuous back pain and other neurological symptoms[7].

The current treatment strategies for Kümmell disease remain controversial because there are no specific treatment criteria. Various surgical strategies have been developed, including percutaneous kyphoplasty (PKP) or vertebroplasty (PVP), anterior-only, posterior-only, and combined anterior and posterior

procedures[8–10]. For stages I and II Kümmell disease, adequate pain relief, vertebral body height restoration, and kyphosis correction are achieved with PKP and PVP[11–12]. However, stage III Kümmell disease patients with spinal canal stenosis, particularly with nerve damage, PKP or PVP are less effective, with a higher risk of cement leakage, and potential severe neurological damage. The final aim of treatment for patients with mild spinal canal stenosis is to relieve back pain, prevent further collapse of the affected vertebrae, and delay neurological deficits[13]. The long-term efficacy of treatment for stage III Kümmell disease is rarely reported in clinical literature. We aimed to address this gap by retrospectively analyzing groups of patients in our hospital to investigate the efficacy of bone cement-augmented pedicle screw fixation for stage III Kümmell disease.

Materials And Methods

The study was approved by the local ethical committee and performed in accordance with the ethical standards of the Declaration of Helsinki. From June 2009 to December 2015, patients with stage III Kümmell disease who visited in our hospital for bone cement-augmented pedicle screws were recruited. The inclusion criteria were: (1) diagnosis with the stage III Kümmell disease by symptoms, signs, and imaging examinations; (2) lumbar vertebral bone mineral density (BMD) of $T \leq -2.5$ SD measured by dual energy X-ray absorptiometry; (3) with or without neurological symptoms. Exclusion criteria included: (1) pathological vertebral fractures such as tumors or infections, and (2) serious medical diseases or intolerance to operation. There were 34 stage III Kümmell disease patients treated with bone cement-augmented pedicle screw fixation. A total of 25 patients were enrolled in this study. Four patients died of other diseases, and 9 were lost to follow-up. All patients were females with a mean patient age of 71.84 ± 5.39 years and T scores of -3.68 ± 0.71 SD. Patients were treated with short-segment fixation ($n = 11$) or long-segment fixation ($n = 14$) combined with posterolateral fusion.

Operative methods

Through the posterior median approach to the spine, the intersection of the midpoint of the transverse process of the vertebral body and the vertical line of the outer margin of the superior articular process was exposed. Cannulated pedicle screws were inserted into the vertebrae under the monitoring of a C-arm X-ray machine, and then 1.5–2.5 ml of bone cement was injected into each screw channel.

Data collection and radiographic assessment

Evaluation of clinical efficacy

The VAS and ODI scores were recorded by ward clinicians during outpatient visits or telephone follow-up. The operation time and blood loss were obtained from medical records. The incidence of complications, such as nerve injury, dural tearing, and bone cement leakage were also recorded.

Imaging evaluation

The V-Cobb angle and S-Cobb angle of the injured vertebrae were measured by lateral X-ray and compared at the preoperative, postoperative and final follow-up appointments. Loosening of the pedicle screw was observed on CT or X-ray film during the final follow-up. All spinopelvic parameters were measured twice on total spine photography by two orthopedists, independently, and the mean values were used for analysis. The degree of lumbar lordosis (LL) was assessed from the inferior endplate of T12 to the superior endplate of S1[14]. Pelvic title (PT) was defined as the angle subtended by a line drawn from the midpoint of the sacral endplate to the center of the bicoxofemoral axis and a vertical plumb line extending from the bicoxofemoral axis[15]. Sacral slope (SS) was defined as the angle between the end plate of S1 and the horizontal line[15]. Pelvic incidence (PI) was defined as the angle between the line perpendicular to the sacral endplate at its midpoint and the line connecting this point to the midpoint of femoral heads axis[15].

Statistical analysis

IBM SPSS 19.0 Software was used to analyze the data. All data are expressed as mean \pm SD. One-way ANOVA followed by the Student–Newman–Keuls post hoc test was used, and $p < 0.05$ was statistically significant.

Results

All patients underwent spinal surgery successfully. Two patients underwent a second surgery on day 6 and 7 after the first surgery because of poor efficacy, and were then discharged successfully. The surgical wound of three patients did not heal well, but they were discharged successfully after extended antibiotic treatment. During the operation, none of the patients experienced nerve injury or dural sac tearing. A total of 178 pedicle screws were used, and all were reinforced with bone cement. Among them, 45 screws showed bone cement leakage beside the vertebra or along the vertebral body vein, with a leakage rate of 25.28%. No patients had serious complications such as nerve compression or pulmonary embolism due to bone cement leakage. During the follow-up, we found 7 fixed segments with adjacent vertebral fractures, however, these were relieved with vertebroplasty. No pedicle screw loosening was found during follow-up. Before surgery, most patients showed signs of nerve compression, but symptoms were significantly recovered after surgery (Table 2). Postoperative and follow-up ODI and VAS scores were significantly lower than preoperative scores (Fig. 4).

Table 1
Baseline patient data

Cases	25
Sex (male/female)	0/25
Age (years)	71.84 ± 5.39
Bone mineral density	-3.68 ± 0.71
Follow-up (months)	43.08 ± 26.51
Operation time(min)	261.44 ± 54.27
Blood loss(ml)	376.40 ± 227.54

Table 2
Frankel classification

	A	B	C	D	E
Preoperative	0	1	3	17	4
Postoperative	0	0	1	1	23

No significant differences were observed in PI, PT, LL, and SS (Table 3). The V-Cobb angle, S-Cobb angle, and SVA of patients at the post-operative and the final follow-up appointments were significantly lower than the pre-operative appointment, no significant difference was observed between the post-operative and final follow-up appointments (Table 4).

Table 3
Radiographic results

	n	Preop	Postop	Final follow-up	F	P-value
V-Cobb angle	25	25.60 ± 10.71	10.81 ± 6.41	15.65 ± 20.99	7.686	0.001
S-Cobb angle	25	25.77 ± 10.71	13.26 ± 10.67	15.57 ± 9.76	10.271	0.000
PI	25	48.62 ± 12.41	50.60 ± 13.47	49.41 ± 9.76	0.145	0.865
PT	25	18.76 ± 8.25	22.00 ± 12.63	19.73 ± 8.53	0.579	0.563
LL	25	32.08 ± 14.46	33.92 ± 10.54	34.06 ± 12.56	0.166	0.848
SS	25	31.38 ± 10.64	28.75 ± 4.04	29.38 ± 5.93	0.720	0.491
SVA(cm)	25	5.76 ± 2.14	3.40 ± 0.93	3.45 ± 1.67	13.863	0.000

PI, pelvic incidence; LL, lumbar lordosis; PT, pelvic title; SS, sacral slope; Preop: preoperative; postop: postoperative; SVA, sagittal vertical axis

Table 4
Comparison of radiographic results at different time points

	Preop vs Post-op		Preop vs Final follow-up		Postop vs Final follow-up	
	T value	P value	T value	P value	T value	P value
V-Cobb angle	3.867	0.000	2.495	0.015	1.372	0.174
S-Cobb angle	4.259	0.000	3.472	0.001	0.787	0.434
PI	0.536	0.594	0.215	0.831	0.321	0.749
PT	1.048	0.299	0.313	0.755	0.735	0.465
LL	0.480	0.633	0.516	0.608	0.036	0.972
SS	1.148	0.255	0.876	0.385	0.273	0.786
SVA	4.613	0.000	4.505	0.000	0.108	0.914

PI, pelvic incidence; LL, lumbar lordosis; PT, pelvic title; SS, sacral slope; Preop: preoperative; postop: postoperative; SVA:sagittal vertical axis

Discussion

Kümmell disease was first described in 1891 as an uncommon complication of osteoporotic vertebral fracture, more frequently encountered in patients with severe osteoporosis that have taken long-term courses of corticosteroids or sustained a spinal injury[16]. Kümmell disease is different from fresh vertebral fracture, and intra-bone clefting is the most important characteristic used to diagnose Kümmell disease. Kümmell disease mostly occurs in women[13]. The thoracolumbar junction, particularly the T12 vertebra, is the most commonly affected vertebral segment[17]. In our study, 76% of injured vertebra were in the thoracolumbar segment.

Different stages of Kümmell disease have unique pathological features. The early stages include avascular necrosis characterized by an accumulation of fluid and inflammatory exudate components[17]. During stage I, the compressed, fractured vertebral body compresses the posterior spinal cord, leading to continuous back pain and other neurological symptoms. Stage III Kümmell disease is characterized by the collapse of the posterior vertebral body wall, the formation of spinal canal stenosis, and dural sac compression[17]. Most stage I patients, including 84% of the patients in our study, have preoperative neurological symptoms.

The treatment of the Kümmell disease remains controversial. Most spinal surgeons suggest that Kümmell disease should be treated by operative interventions because conservative treatments are less effective and are associated with a high risk of complications and delayed neurological deficits[18]. For early stages patients without neurological symptoms, the aim of treatment is to preserve movement in the diseased vertebrae, and maintain the sagittal balance of the spine. PKP and PVP restore the height of

the vertebral body and correct any deformities, which can help achieve satisfactory pain relief[21]. However, PVP and PKP are less suitable for stage III patients because the surrounding vertebral cortex has already been compromised, as well as a higher risk of severe nerve damage caused by bone cement leakage[13]. In our study, the bone cement leakage rate was 25.28%, but there were no serious complications, suggesting that short-term leakage is not damaging. Delayed cement displacement and further collapse have been reported in cases of Kümmell disease treated by cement augmentation alone, with poor bone incorporation of cement noted after a long-term follow-up[22, 23]. Therefore, displacement of bone cement and further vertebral collapse may occur after PKP or PVP[24].

There are alternative treatment strategies for stage III Kümmell disease, but consensus regarding which is most feasible and effective is lacking. For stage III patients with severe stenosis of the spinal canal and neurological symptoms, the objective of surgery is to relieve cord compression, eliminate spinal instability, and restore the sagittal balance of the spine[12, 19]. Many studies have suggested that the main factor contributing to delayed neurological deficits following vertebral collapse in the osteoporotic spine is instability at the fracture site, rather than mechanical compression of the spinal cord by bone fragments[25, 26]. Therefore, maintaining spinal stability is important for treating stage III patients. Other studies suggested that modified posterior vertebral column resection surgery was an effective and safe surgical method to treat stage III Kümmell disease, especially for patients with kyphosis and obvious symptoms of nerve compression; however, the long-term clinical effects require additional evaluation⁸. Anterior reconstruction and posterior osteotomy have also been proposed for the management of stage III Kümmell disease with neurological deficits[27]. Anterior reconstruction permits direct resection of bony fragments and provides anterior column support. Posterior osteotomy is a common treatment; the advantages include dissection of the posterior cortex by posterior spinal shortening osteotomy and correction of kyphosis[28, 29]. Moreover, these major surgical interventions can be challenging in patients of advanced age, and confer numerous morbid complications and frequent instrumentation failure secondary to severe osteoporosis[1]. Traditional posterior long-segment fixation was not appropriate for stage III Kümmell disease because the procedure was associated with significant trauma and multiple complications, which are worrisome in elderly patients with comorbidities[30].

There is high risk of pedicle screw loosening because of the osteoporotic vertebra in stage III Kümmell disease. Considering the unsatisfactory performance of traditional pedicle screws in damaged spines, bone cement-augmented pedicle screw fixation strengthens the anti-pullout capability by injecting cement carefully through the screws into the vertebral body. Moreover, it can effectively improve the sagittal balance and stability of the spine.

Bone cement-augmented pedicle screw fixation maintained the stability of the spine and pelvis of the stage III Kümmell disease patients. Posterior screw stress was markedly reduced because of the anterior support provided by the intravertebral cement, which can decrease the risk of internal fixation failure[13].

There are some limitations to our study. First, it was a retrospective study at a single center with a small sample size. Thus, further studies with larger samples are needed to confirm our findings. Secondly, we

observed long segmental fixation and short segmental fixation together; however, these two fixation methods may have different therapeutic effects.

Conclusion

Bone cement-augmented pedicle screw fixation is a safe and effective treatment for stage III Kümmell disease. It effectively corrects kyphosis, and safely maintains the stability of the spine and sagittal balance.

Abbreviations

V-Cobb angle

vertebral Cobb angle

S-Cobb angle

segment Cobb Angle

VAS

visual Analogue Scale

ODI

Oswestry Disability Index

SVA

Sagittal Vertical Axis

OVF

Osteoporotic vertebral fracture

PKP

percutaneous kyphoplasty

PVP

percutaneous vertebroplasty

BMD

bone mineral density

LL

lumbar lordosis

PT

Pelvic title

SS

Sacral slope

PI

Pelvic incidence

Declarations

Ethics approval and consent to participate

This study has been reviewed by the appropriate ethics committee of our hospital and have been performed in accordance with the ethical standards laid down in an appropriate version of the 1964 Declaration of Helsinki. All patients gave their informed consent prior to their inclusion in the study.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

GYM and TPZ conceived and designed the study. YXL, PJJ, and HZG collected and processed the data. GYM and DQG wrote the paper. DXL, YK, LM, YCT, and SCZ reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Figures



Figure 1

Case illustration of a patient. Female, 80 years , BMD(T score) was -3.4SD. A1-C1 Preoperative lateral X-ray and CT scan showed T12 vertebral fracture with , MRI showed low signal of the necrotic area on T2-weighted images. Follow-up standing X-ray at 2 year(D1-E1) and 5 year(F1-G1) post T10-L2 bone cement-augmented pedicle screw fixation.

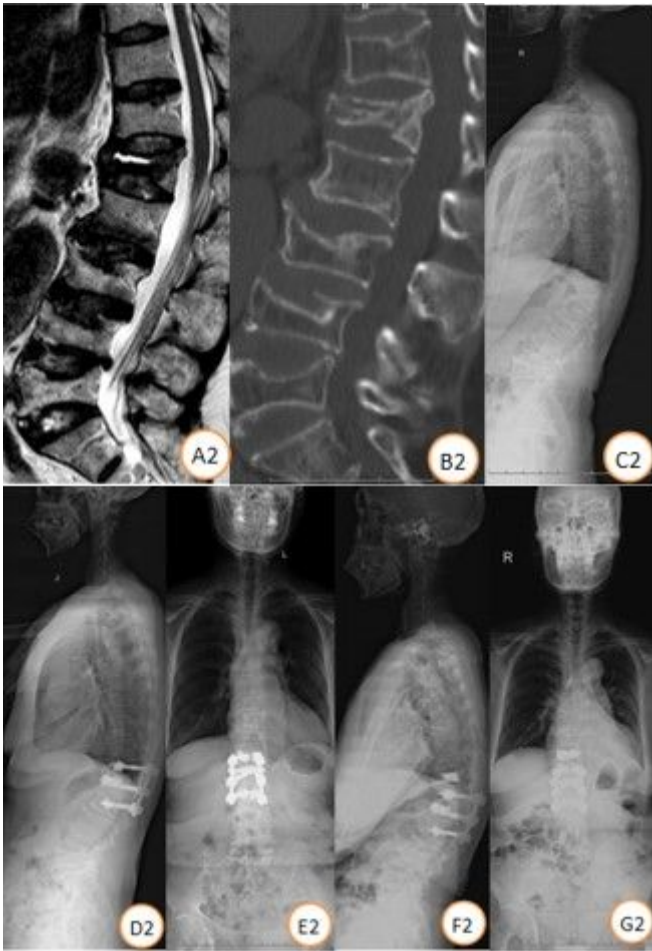


Figure 2

Case illustration of a patient. Female, 62 years , BMD(T score) was -3.8SD. A2-C2 Preoperative lateral X-ray and CT scan showed L1 vertebral fracture with , MRI showed low signal of the necrotic area on T2-weighted images. Follow-up standing X-ray at 3months (D2-E2) and 4 year(F2-G2) post T12-L2 bone cement-augmented pedicle screw fixation.

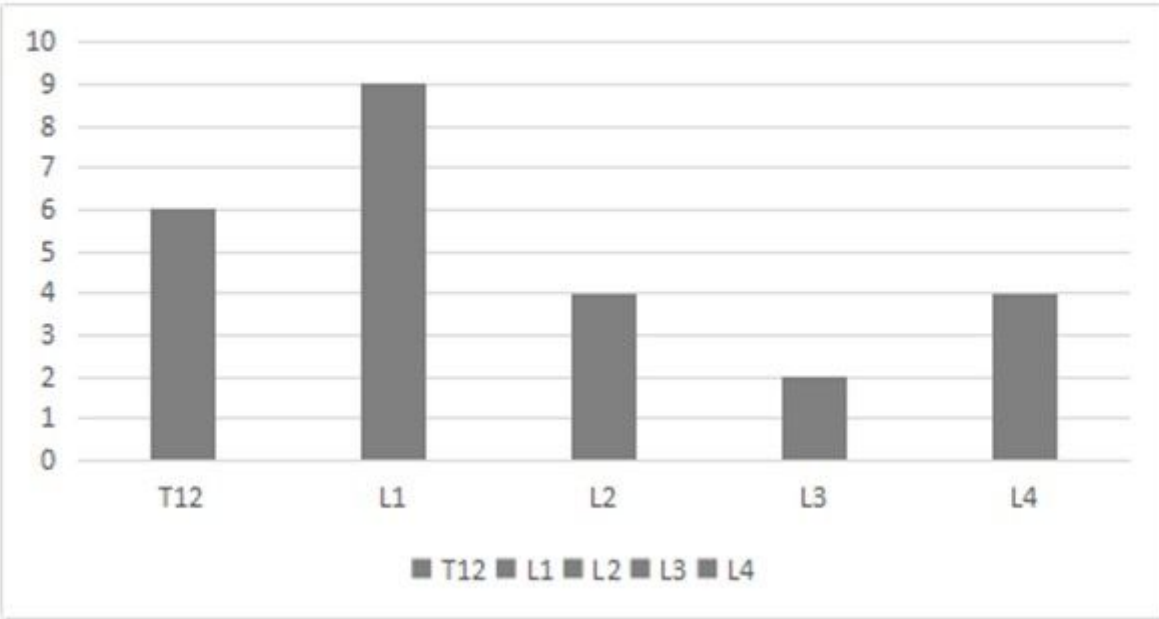


Figure 3

Distribution of the injured vertebrae

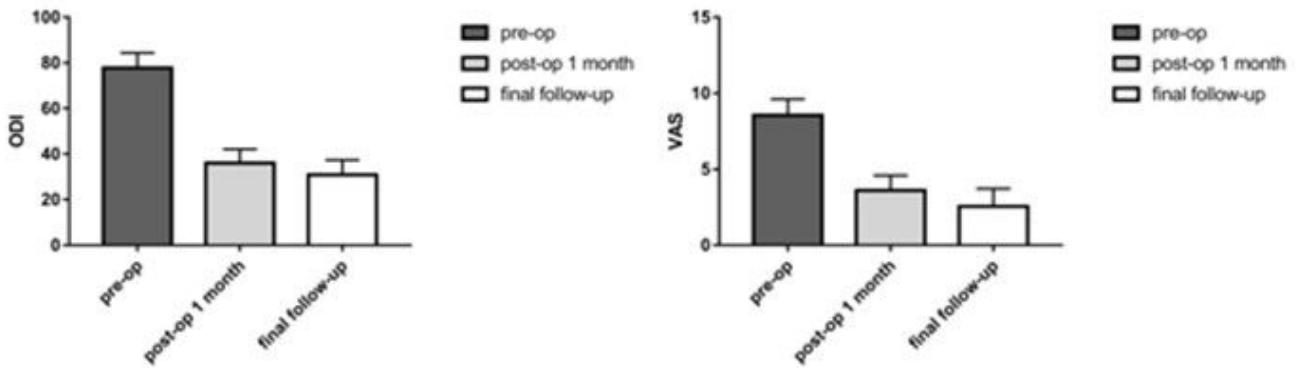


Figure 4

ODI and VAS scores ODI, Oswestry Disability Index; VAS, visual analogue scale