

# Percutaneous kyphoplasty treatment evaluation for patients with Kümmell disease based on a two-year follow-up

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**Abstract.** Percutaneous kyphoplasty (PKP) has been used in Kümmell disease treatment for years. The objective of the current study was to evaluate the efficacy and safety of PKP in the treatment of patients with Kümmell disease and to explore the association between cement injection volume and pain relief. A total of 50 patients were enrolled in the present study and follow-up was 2 years. Efficacy was evaluated using the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI) and the kyphotic angle (Cobb's angle). VAS and ODI were determined at the initial evaluation (prior to surgery), at 3 days, 3 months, and 1 and 2 years post surgery. Cobb's angle was measured prior to and 3 months, 1 year and 2 years following surgery. PKP safety was assessed by evaluating complications, including cement leakage and spinal cord compression. In the follow-ups, VAS significantly decreased from  $7.00 \pm 0.78$  pre-PKP to  $3.14 \pm 0.67$  at 2 years post-PKP ( $P < 0.05$ ). ODI significantly decreased from  $73.88 \pm 8.60$  prior to surgery to  $22.84 \pm 8.85$  at 1 year following surgery ( $P < 0.05$ ) and did not significantly change at the following 2-year measurement ( $26.44 \pm 8.63$ ). The Cobb's angle, measured at  $17.73 \pm 2.43^\circ$  preoperatively, significantly decreased to  $8.32 \pm 2.21^\circ$  at 3 months following surgery ( $P < 0.05$ ). On subsequent follow-ups at 1 and 2 years, the Cobb's angle increased to  $9.55 \pm 2.82$  and  $10.27 \pm 3.22^\circ$ , respectively. A total of 8 patients exhibited signs of cement leakage during the PKP procedure. No patients experienced severe neurological deficits or complications. Spearman analysis demonstrated a positive correlation between cement

injection volume and pain relief. The current study indicated that PKP was a safe and effective treatment for patients with Kümmell disease and that there was a positive correlation between cement injection volume and pain relief. The current study may be used as a reference in cement dosing for the treatment of PKP.

## Introduction

Kümmell disease is a delayed complication of osteoporotic vertebral compression fractures (VCF) and was first described by Hermann Kümmell in 1895 (1,2). It is routinely encountered in patients suffering from long-term osteoporosis or following spinal injury (3). It may lead to back pain, spinal canal stenosis or neurological deficits that negatively impact quality of life and increase the risk of disability, morbidity and mortality (4-6). The intravertebral cleft, formed through osteonecrosis absorption, is an important radiographic feature in diagnosing Kümmell disease (3). The rapid development of advanced imaging technology has allowed for an improved diagnosis of Kümmell disease (7).

Traditional surgical interventions may be the first treatment choice for a majority of patients, as conservative treatments, including analgesics and bed rest, exhibit little benefit in pain relief (8). However, shortcomings of open surgery, including major trauma and long recovery times are concerns for patients (9). Minimally invasive treatment approaches have become widely accepted by patients. Percutaneous kyphoplasty (PKP) serves an important role in pain relief and vertebrae strengthening in benign and malignant spinal lesions (10-12). Compared with traditional open surgery, PKP results in decreased wounds and allows for earlier mobilization, which is conducive to faster recovery (10). PKP has been used in the treatment of Kümmell disease since 2005 and substantial work has been performed to evaluate its efficacy and safety (13,14). However, to the best of the present authors' knowledge, there are few studies evaluating long-term follow-up (>2 years), including a study by Zhang *et al* (15) with a follow-up time of 19.3 months. The association between cement injection volume and the degree of pain relief in patients with Kümmell disease remains unclear.

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In the current study 50 patients with Kümmell disease that were treated with PKP were enrolled and a 2-year follow-up analysis was conducted. The aim of the present study was to assess the efficacy and safety of PKP as treatment and to explore the potential correlation between cement volume and pain relief levels. The present study may be regarded as a reference for facilitating pain relieve in the treatment of patients with Kümmell disease.

### Patients and methods

**Patients.** Between September 2012 and December 2014, 50 patients (female, 38; male, 12) diagnosed with Kümmell disease underwent PKP treatment at the First Hospital of China Medical University (Shenyang, China). Patients with neurological deficits, history of spinal surgery, infection or tumor were excluded. All patients provided written informed consent prior to surgery and the current study was approved by the Institutional Review Board of the First Hospital of China Medical University (Shenyang, China). A total of 62 vertebral lesions were treated, including thoracic (T)8 (n=1), T9 (n=4), T10 (n=9), T11 (n=4), T12 (n=11), lumbar (L)1 (n=12), L2 (n=13), L3 (n=6) and L4 (n=2). A total of 41 patients exhibited single lesions, 6 patients exhibited two lesions and 3 lesions were observed in 3 patients. Patients were aged between 56-85 years, with  $69.00 \pm 7.17$  years mean age. All patients suffered from varying degrees of back pain and leg weakness for 1-12 months; the mean duration of pain was  $5.1 \pm 1.2$  months. Patient demographics are presented in Table I. A total of 35 patients had a history of trauma, whereas 15 patients had no obvious inciting event. In all patients pain increased during activity and eased at rest according to their pain reception. Some patients (90%; 45/50) were treated conservatively with bed rest or medical therapies with transient pain relief, but progressive pain developed following an asymptomatic period (5-7 days). All patients were diagnosed by X-ray, computed tomography (CT) and magnetic resonance imaging (Fig. 1).

**PKP procedure.** The PKP procedure was performed as previously described (10). Under local anesthesia, puncture needles were inserted bilaterally through the pedicle of the vertebral arch under fluoroscopic guidance. Needles penetrated into the vertebral body and at 1/3 of the distance from the posterior wall, a 3-dimensional CT was recorded to monitor the efficacy and safety of the puncture. Puncture needles further continued to infix to the anterior. Subsequently, a balloon was inserted into the vertebra to restore vertebral body height and to create a cavity in the vertebra for the injection of cement. Next, polymethyl methacrylate (PMMA; Heraeus Medical GmbH, Wehrheim, Germany) and non-ionic contrast medium (Heraeus Medical GmbH) were prepared at 26 g/10 ml and injected into the vertebra using a bone cement injector under fluoroscopic monitoring (Fig. 2). Upon hardening of PMMA, the injector was removed. Following the procedure, patients remained in bed for  $\geq 6$  h and vital signs, neurological status, urine output and sensory and motor function were monitored. Patients were administered 250 ml mannitol (20%; Zhejiang Huakang Pharmaceutical Co., Ltd., Huabu, China) and 80 mg solumedrol (Pfizer, Inc., New

Table I. Clinical characteristics of patients with Kümmell disease (n=50).

Characteristics	Patients, n (%)
Age, years	
55-65	14 (28)
66-75	24 (48)
76-85	12 (24)
Gender	
Male	12 (24)
Female	38 (76)
Vertebral lesions treated, n	
1	41 (82)
2	6 (12)
3	3 (6)

York, NY, USA) once daily for 3 days following surgery to prevent and treat spinal cord edema. Representative images are presented in Fig. 3.

**Efficacy and safety evaluation.** To evaluate the efficacy of PKP treatment in patients with Kümmell disease, the Visual Analog Scale (VAS; 0, no pain; 10, worst pain) (10), Oswestry Disability Index (ODI) (16), kyphotic angle (Cobb's angle), anterior and posterior vertebral height and injected cement volume were analyzed. VAS and ODI analyses were performed preoperatively and 3 days, 3 months and 1 and 2 years following surgery via outpatient review or telephone interview. Cobb's angle and anterior and posterior vertebral height data were collected radiographically preoperatively and at 3 months and 1 and 2 years following surgery. PKP safety was assessed by evaluating for pre- and postoperative complications, including cement leakage, spinal cord compression and inflammation. Inflammation assessment was based on serum white blood cells and inflammatory factors, including C-reactive protein.

In addition, the correlation between injected volume of cement and variation in VAS was evaluated. The variation of VAS over the 2-year follow-up was defined as:  $\delta\text{VAS} = (\text{VAS at 2-years follow-up}) - (\text{VAS prior to surgery})$ . Correlation between cement injection volume and variation of VAS was assessed using Spearman analysis (GraphPad Prism 5; GraphPad Software, Inc., La Jolla, CA, USA).

**Statistical analysis.** All data are expressed as the mean  $\pm$  standard deviation. All statistical analyses were performed using GraphPad Prism 5 (GraphPad Software, Inc.). A comparison of preoperative and postoperative continuous variables was performed using one-way analysis of variance followed by Tukey's multiple comparison test.  $P < 0.05$  was considered to indicate a statistically significant difference.

### Results

**Follow-up times for patients who underwent PKP treatment.** All PKP treatment procedures were successful. Clinical

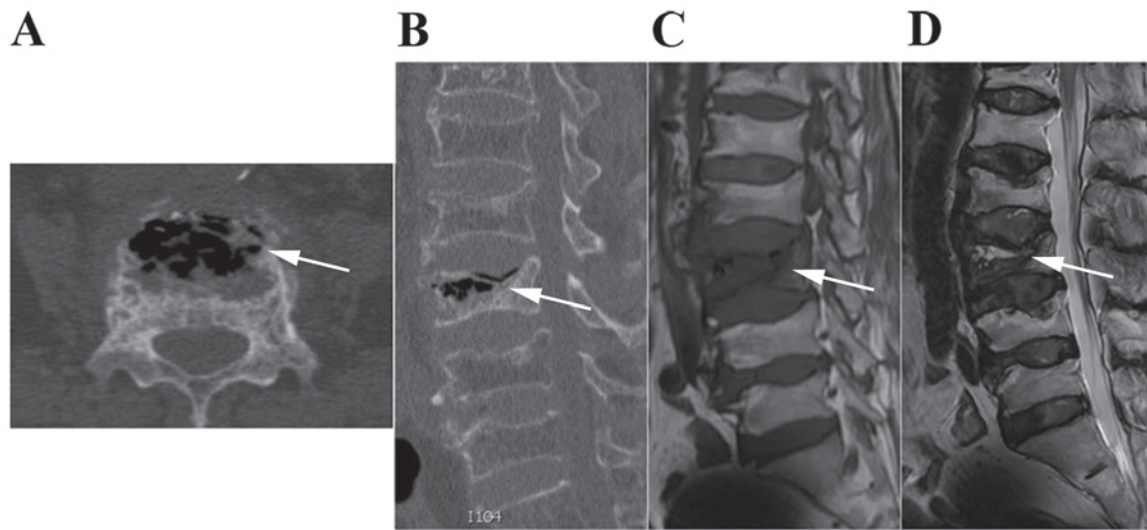


Figure 1. Gas signal as an important characteristic in patients with Kümmell disease. The lumbar-3 vertebra is destroyed and gas is visualized entering into the vertebra (arrow) on computed tomography in (A) the transverse section and (B) the lateral position. (C) Magnetic resonance imaging revealing that the gas turned out lower density on CT image, (C) low signal on the T1-weighted image and (D) high signal on the T2-weighted image.

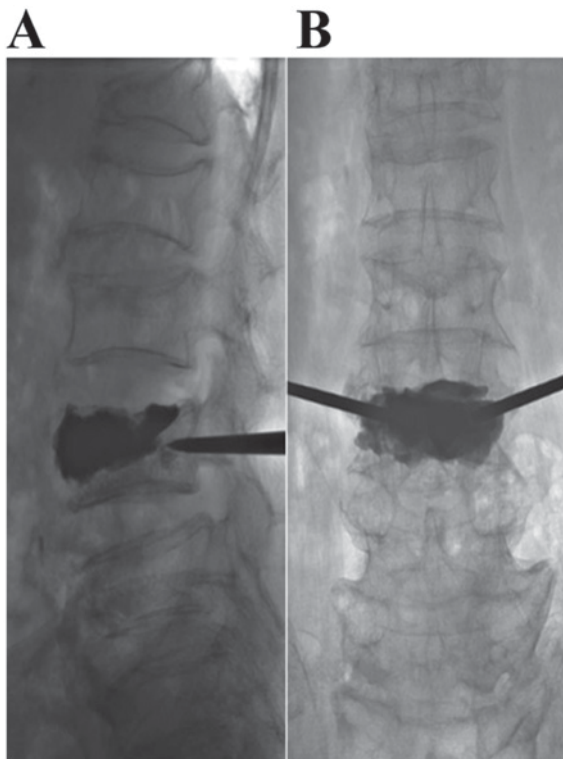


Figure 2. Bone cement injected into the vertebral lesions. Following bilateral puncturing and creating a cavity using a balloon, cement is injected into the vertebral lesion as viewed in (A) the lateral and (B) the posterior-anterior positions digital subtraction angiography images during surgery.

assessments, including pain problem, physical ability index and imaging, were conducted preoperatively and 3 days, 3 months, 1 year and 2 years following surgery via outpatient review or telephone interview. All 50 patients were available for follow-up during the 2-year period.

*PKP improves VAS scores in patients with Kümmell disease.* VAS was used to quantify the severity of pain. All patients

reported pain relief preoperatively and 3 days, 3 months, 1 year and 2 years following PKP. The preoperative VAS score was  $7.00 \pm 0.78$ , which decreased significantly to  $3.10 \pm 0.93$  at 3 days following surgery ( $P < 0.05$ ; Fig. 4). Following this initial decrease, VAS scores remained at a stable level with  $2.98 \pm 0.84$ ,  $2.98 \pm 0.77$  and  $3.14 \pm 0.67$  at 3 months, 1 and 2 years following surgery, respectively (Fig. 4).

*PKP improves ODI scores in patients with Kümmell disease.* General disability status was assessed by ODI. Over the 2-year follow-up period, marked improvements in ODI were observed following PKP treatment. ODI significantly decreased from  $73.88 \pm 8.60$  preoperatively to  $29.2 \pm 8.98$  at 3 days following surgery ( $P < 0.05$ ) and remained at a similar level of  $25.48 \pm 8.48$ ,  $22.84 \pm 8.85$  and  $26.44 \pm 8.63$  at 3 months and 1 and 2 years following surgery, respectively ( $P < 0.05$  vs. preoperative; Fig. 5).

*PKP positively affects the Cobb's angle and vertebral heights in patients with Kümmell disease.* The kyphotic angle has been defined as Cobb's angle (10,17). In the current study, the preoperative Cobb's angle in vertebral lesions significantly improved from  $17.73 \pm 2.43$  to  $8.32 \pm 2.21^\circ$  recorded at 3 months following surgery based on lateral X-ray images ( $P < 0.05$ ; Fig. 6). Follow-up revealed that the Cobb's angle still remained improved at the 1-year and 2-years checks with  $9.55 \pm 2.82$  and  $10.27 \pm 3.22^\circ$ , respectively ( $P < 0.05$  vs. preoperative).

The anterior vertebral height exhibited a marked increase following PKP. The anterior vertebral height was  $14.25 \pm 2.64$  mm prior to treatment and significantly increased to  $18.03 \pm 2.77$ ,  $17.29 \pm 2.66$  and  $17.11 \pm 3.23$  mm following PKP at 3 months, 1 and 2 years, respectively (all  $P < 0.05$ ). Unlike the marked increase observed for the anterior vertebral height, the posterior vertebral height exhibited no variations over the 2-year follow-up period, with  $20.23 \pm 1.89$  mm preoperative and  $21.04 \pm 1.55$ ,  $20.98 \pm 2.87$  and  $20.60 \pm 2.23$  mm at 3 months, and 1 and 2 years following surgery, respectively.



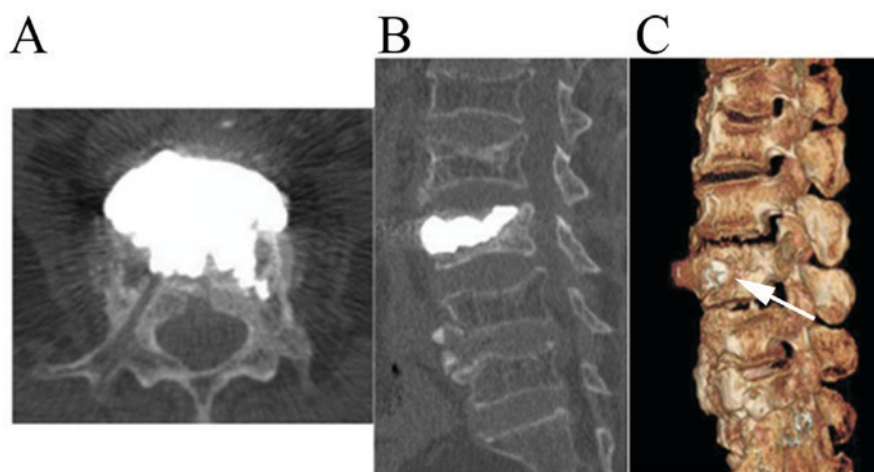


Figure 3. Cement filling of the L3 vertebra recorded 2 years following percutaneous kyphoplasty. Computed tomography image highlighting cement (high density) evenly filling the L3 vertebra in (A) the transverse section and (B) the lateral position. (C) 3D-computed tomography highlighting the cement spread in the vertebral lesion (arrow). L, lumbar.

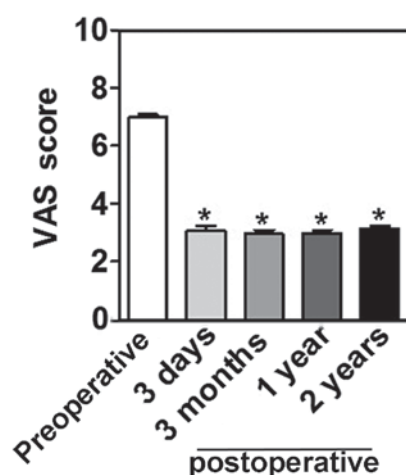


Figure 4. Evaluation of the degree of pain relief using VAS. Mean VAS scores for patients with Kümmell disease (n=50) determined prior to and 3 days, 3 months, 1 and 2 years following percutaneous kyphoplasty. No pain, 0; worst pain, 10. \*P<0.05 vs. preoperative. VAS, visual analog scale.

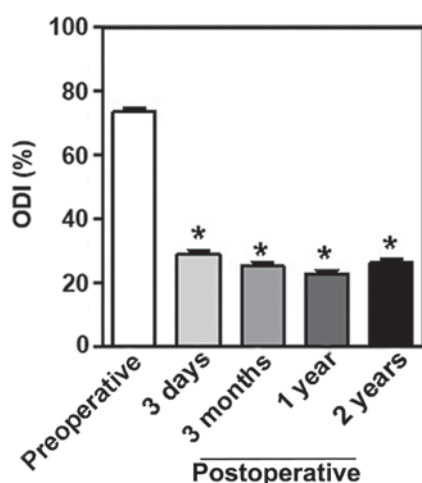


Figure 5. Assessment of disability status. Mean ODI scores for patients with Kümmell disease (n=50) determined prior to and 3 days, 3 months, 1 and 2 years following percutaneous kyphoplasty. \*P<0.05 vs. preoperative. ODI, Oswestry disability index.

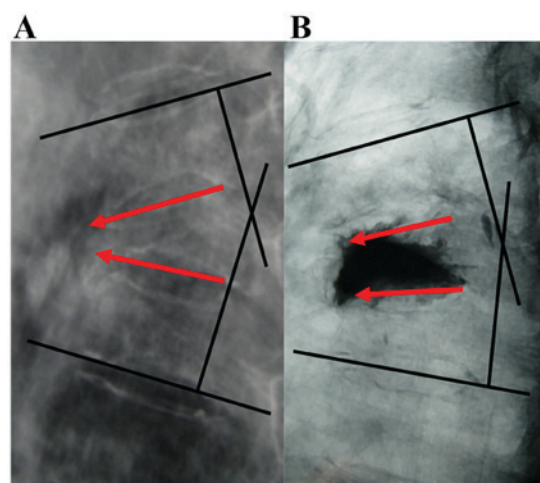


Figure 6. Percutaneous kyphoplasty restores vertebral height and improves the kyphotic angle. Spinal curvature (A) prior to surgery and (B) at 2-year follow-up on X-ray images. The outline of the vertebral lesion is marked with red arrows and the kyphotic angle is indicated with black lines.

*PKP is a safe treatment option for patients with Kümmell disease.* In 8 patients cement leakage was observed during PKP surgery, including 3 paravertebral, 3 intradiscal and 2 intracanal leakages. No neurological deficits were detected and no further complications, including spinal cord compression, inflammation or pulmonary embolism occurred following the 2-year follow-up.

*Cement injection volume is correlated with pain relief.* The mean injection volume of cement was  $7.59 \pm 1.22$  ml (range, 4.40-13.00 ml). VAS scores ranged from 2.00-6.00 preoperatively. Spearman analysis suggested that there was a correlation between the volume of injected cement and VAS scores. Correlation analysis revealed a correlation coefficient of  $R=0.67$  ( $P<0.05$ ; Fig. 7), indicating a positive correlation between the injected cement volume and pain relief effect. A larger amount of injected cement was correlated with a greater improvement in VAS.

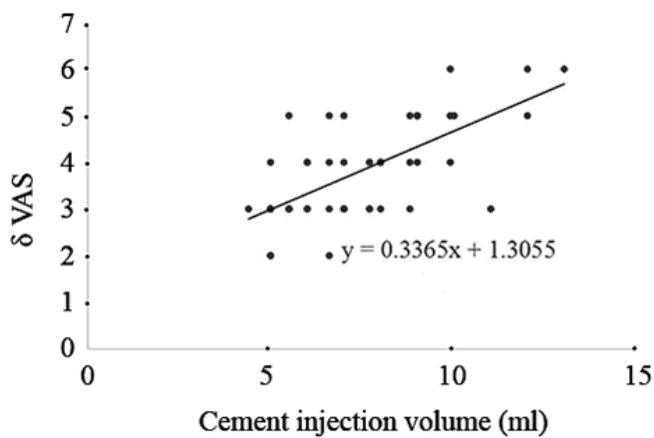


Figure 7. Correlation of cement injection volume with pain relief. Changes in VAS scores prior to surgery and at 2-year follow-up were calculated as follows:  $\delta\text{VAS} = (\text{VAS at 2-years follow-up}) - (\text{VAS prior to surgery})$ . Spearman correlation coefficient  $R=0.67$  at  $P<0.05$ . VAS, visual analog scale.

## Discussion

The current study demonstrated that PKP may be an effective treatment for patients with Kümmell disease. It resulted in rapid pain relief, improvement in quality of life based on VAS and ODI scores, correction of kyphosis and vertebral height restoration with complications in 16% patients (8/50). Postoperative follow-ups at 2 years revealed maintenance of pain relief and improvement of disability. Additionally, it was determined that bilateral puncture and injection of larger volumes of bone cement, which completely filled all cracks, resulted in improved pain relief.

In recent years, Kümmell disease has been diagnosed with increasing frequency due to disease progression and radiographic characteristics (1,2). The traditional disease course may include minor trauma, an asymptomatic period and the development of continuous activity-associated pain (18). A major factor causing pain in patients with Kümmell disease is micro-movement of vertebral fractures (19). The elimination of micro-fractures and stabilization of vertebral lesions results in the reduction of severe pain (20-22). An intra-vertebral cleft provoked by trauma is considered to be the most dominant feature in diagnosing Kümmell disease and the incidence rate is 79% (6,7,9,23). As a vertebral fracture occurs, gas enters the subchondral cleft and forms a specific gas phenomenon emitting a lower intravertebral signal visible in MR imaging (24). In quick succession, extensive fluid accumulates in the cleft as part of the process of avascular necrosis of the vertebral bodies (25,26). The cleft may lead to vertebral collapse and spinal canal stenosis, aggravating clinical symptoms (1).

A multitude of treatment options for patients with Kümmell disease exist, including conservative treatment (bed rest, narcotic analgesics), surgical intervention and less invasive interventional therapy, including nerve blockage. However, conservative treatments exhibit minimal impact on pain relief for symptoms attributed to intervertebral instability (27). Surgical intervention remains challenging owing to comorbidities secondary to osteoporosis (28).

PKP is increasingly accepted as an alternative treatment due to its minimally invasive nature and early postoperative mobilization (29). In the current study, PKP effectively stabilized collapsed vertebrae and strengthened intervertebral stability resulting in clinical improvement of affected patients with minimal complications.

Over the 2-year follow-up period, VAS scores had significantly decreased following surgery. Maximal pain relief is attributed to the stabilization of the spine, a key principle in PKP (30). Lower levels of pain improved the quality of life as evident from the significant decrease in ODI scores following surgery. Radiographic data further confirmed the effects of PKP on clinical outcomes. The kyphotic angle decreased following surgery and the anterior vertebral height improved over two years. Previous research indicated that the rate of cement leakage associated to PKP was 25% (31), while in the current study cement leakage occurred 16% patients. No severe neurological deterioration was observed in patients experiencing cement leakage. Other complications, including spinal cord compression, inflammation and pulmonary embolism were not observed.

To the best of the authors' knowledge, the current study, for the first time, identified a positive correlation between the volume of bone cement and pain relief measured by VAS. It is suggested that this was because a certain volume of bone cement was needed to successfully fill fracture cracks. Additionally, sufficient cement fused with vertebral lesions also contributes to bear balanced stress, but too much cement can increase the risk of leakage. Hence, the movement of cement during surgery was tightly monitored to prevent leakage.

Although PKP was effective in the treatment of patients with Kümmell disease, it also had exhibited limitations. Patients with severe spinal cord compression, neurological deficits or a history of spinal surgery were excluded from the current study, as the goal of PKP was primarily to strengthen vertebrae without aiming for neurological restoration. Additionally, the current study included a limited sample size of 50 patients.

In summary, the present study indicated that PKP is an effective treatment for patients with Kümmell disease by not only relieving pain but also by contributing to restoring the physiologic angle of the spine with only minor complications. Additionally, a positive correlation between volume of injected cement and the degree of pain relief was determined. The current study may be used as a reference for cement dosing and associated increased pain relieve in PKP treatment.

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## Availability of data and materials

All data generated or analyzed during the present study are included in this published article.

## Authors' contributions

KX and BF designed the experiments. BF, YX and LZ performed PKP treatments. GL and ZT conducted the follow-ups. FC analyzed data and performed the statistical analysis. All authors read and approved the final version of the manuscript.

## Ethics approval and consent to participate

The current study was approved by the Institutional Review Board in the First Hospital of China Medical University (Shenyang, China).

## Patient consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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