Evaluation of the clinical efficacy of the bilateral pedicle cement anchoring technique in percutaneous vertebroplasty for Kümmell disease

DEXIN ZOU, HUIMIN WANG, YONG ZHAO, XURI SUN and WEI DU

Department of Spine Surgery, Yantaishan Hospital, Binzhou Medical University, Yantai, Shandong 264003, P.R. China

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Abstract. The present study aimed to evaluate the clinical efficacy of the bilateral pedicle cement anchoring technique combined with the postural reduction in percutaneous vertebroplasty (PVP) for Kümmell disease. For this purpose, a retrospective study was performed on 18 patients with Kümmell disease who between January 2018 and June 2021 underwent bilateral pedicle cement anchoring combined with postural reduction in PVP. Pre- and post-operative bone mineral density, injected cement volume, visual analogue scale (VAS) values, Oswestry disability index (ODI) scores, Cobb angle measurements and anterior vertebral height (AVH) were recorded and assessed. The mean follow-up duration was 8.4±1.2 months. The average VAS score decreased from 8.17±0.71 pre-operatively to 1.56±0.62 post-operatively and remained at 2.00±0.91 at the final follow-up visit (P<0.05). The average ODI improved from 86.44±5.5 pre-operatively to 24.33±7.82 post-operatively. Until the last follow-up, the ODI remained at 27.11±8.76 (P<0.05). Similarly, the changes in the Cobb angle and AVH before and after surgery were also statistically significant in the radiological evaluation (P<0.05). During the follow-up, two patients experienced adjacent vertebral fractures. The loosening of cement was not found. Overall, the present study demonstrated that during the treatment of Kümmell disease with PVP, the bilateral pedicle cement anchoring technique combined with postural reduction can achieve good clinical outcomes.

Correspondence to: Professor Wei Du, Department of Spine Surgery, Yantaishan Hospital, Binzhou Medical University, 10087 Science and Technology Avenue, Yantai, Shandong 264003, P.R. China
E-mail: spineduwei@163.com

Abbreviations: PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty; IVC, intravertebral vacuum cleft; OVCF, osteoporotic vertebral compression fracture; CT, computed tomography; MRI, magnetic resonance imaging; PMMA, polymethyl methacrylate; VAS, visual analogue scale; ODI, Oswestry disability index; AVH, anterior vertebral height; BMD, bone mineral density; DXA, dual energy X-ray absorptiometry

Key words: Kümmell disease, percutaneous vertebroplasty, osteoporosis, cement anchoring, postural reduction

Introduction

In 1895, the German surgeon, Hermann Kümmell, described six patients with delayed compression fractures for the first time (1). All of these patients had a history of slight spinal trauma. After an asymptomatic period lasting a few weeks or months, they experienced progressive back pain, accompanied by a gradually worsening kyphosis, and even neurological deficits. At first, Kümmell disease was considered to be very rare; however, with the rapid development of imaging technologies, particularly CT and MRI, the detection rate of Kümmell disease increased significantly (2). The intravertebral vacuum cleft (IVC) is a typical imaging manifestation (3). The exact pathogenesis of Kümmell disease remains controversial and the majority of researchers consider that it is caused by the ischemic necrosis of vertebral bodies (4-8).

According to the clinical symptoms and the degree of damage in the fractured vertebral body on a radiograph and MRI, Li *et al* (9) divided Kümmell disease into three stages as follows: Stage I, in which the loss of vertebral body height is <20%, there is no degeneration of adjacent intervertebral discs, no low back pain symptoms or mild symptoms; stage II, in which the loss of vertebral body height is <20%, the fractured vertebral body has dynamic instability and there is adjacent intervertebral disc degeneration; stage III, in which the posterior cortex breakage is accompanied by dynamic instability and kyphosis of the vertebral body leads to spinal canal stenosis with or without neurological deficits. According to relevant literature reports (2,4,5,10,11), percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have achieved good clinical outcomes in the treatment of stage I and II Kümmell disease, and even stage III Kümmell disease without neurological deficits can also be treated by PKP. Although both Kümmell disease and common osteoporotic vertebral compression fracture (OVCF) can be treated with PKP or PVP, there are still significant differences in post-operative radiographs between them. Polymethyl methacrylate (PMMA) in common OVCF surgery is evenly distributed in the fractured vertebra and PMMA and bone trabeculae are interlocked with each other. However, PMMA in Kümmell disease is mainly concentrated in the IVC of the

fractured vertebra to form a bone cement mass, which has a clear boundary with the surrounding bone. In this case, PMMA is very easy to loosen at the bone-cement interface, which will lead to the recurrence of vertebral instability, and the patient's low back pain will once again worsen, even with neurological deficits (3,8,12-14). Therefore, for patients with Kümmell disease, identifying a method to firmly fix the PMMA in the IVC to prevent loosening is the key to achieving good clinical outcomes.

The present study attempted to solve the problem of PMMA loosening by using a modified PVP technique. The present study aimed to evaluate the clinical efficacy of the bilateral pedicle cement anchoring technique combined with the postural reduction in PVP for Kümmell disease.

Patients and methods

Patients. Written informed consent was obtained from each patient and the use of any relevant clinical images was authorized by the patient for scientific research and online open-access publication. The present study was approved by the Ethics Committee of Yantaishan Hospital (Yantai, China; approval no. 20211005028). The study protocol strictly adhered to the ethical guidelines of The Declaration of Helsinki 1975 (15).

Based on the sample size calculation formula $N=2[1+(K+1)\rho][(\sigma^2(Z_{1-\alpha}+Z_{1-\beta})^2/K\delta^2)]$, the hospital statistician suggested that the minimum sample size (N) should be ≥16 cases to obtain meaningful statistical results based on the incidence of Kümmell disease, based on confidence intervals (α and β), the critical value of the normal distribution (Z), the number of repeated measurements (K), smallest meaningful difference to be detected (δ), measurement standard deviation (σ) and internal correlation coefficient (ρ).

Between January 2018 and June 2021, a total of 26 patients diagnosed with Kümmell disease based on medical history, radiograph (Multix Fusion; Siemens Healthineers), 128-detector multislice CT scanner (Somatom Definition Flash; Siemens Healthineers) and 1.5-T MRI (Magnetom Aera; Siemens Healthineers) were visited at Yantaishan Hospital (Yantai, China; approval no. 20211005028) and retrospectively included in the present study. However, the patients with ≥2 spinal vertebral fractures, tumors, infections, pedicle fractures and neurological deficits were excluded from the present study. All patients were initially screened according to the exclusion criteria and a total of eight patients were excluded from the study, including three with multilevel involvements, one with pedicle fracture, and three with neurological deficits. Finally, 18 patients were included in this study (Fig 1A-D). All patients were treated with PVP with the bilateral pedicle cement anchoring technique and postural reduction. The surgeries were performed by the same experienced surgeon at the Department of Spine Surgery, Yantaishan Hospital. In terms of sex distribution, the study involved five male and 13 female patients. The age of the patients ranged from 69-82 years, with an average age of 76.5±3.8 years. In total, 15 of the 18 patients had senile diseases, including six cases of hypertension, three cases of diabetes, three cases of coronary heart disease and three cases of diabetes with coronary heart disease, which were well controlled during the peri-operative period. The other demographic and clinical data, such as bone mineral density (BMD), fractured level, injected cement volume, etc., are presented in Table I. BMD was measured using dual-energy X-ray absorptiometry and osteoporosis was defined by a T-score ≤-2.5 standard deviations (SD).

Surgical procedure. All surgeries were performed under local anesthesia. The patient was placed in a prone position on a Jackson operating table, the chest and iliac region were elevated and the abdomen was suspended, so that the fractured vertebra was opened and repositioned as much as possible under the hyperextension position. The bilateral transpedicular approach was performed under biplanar fluoroscopic guidance. Unlike traditional PVP surgery, the puncture point was located in the outer upper quadrant of the pedicle, and the needle angle was more vertical to avoid injury to the inner and lower walls of the pedicle as much as possible. First, under the guidance of fluoroscopy, the trocar and cannula systems are placed into the vertebral body through one side of the pedicle. The ideal position was that the needle tip was located in the IVC. Second, the drill was advanced to create a tunnel and then it was removed and Polymethylmethacrylate (PMMA, Tecres, Spa.) was injected into the vertebra. PMMA was divided into several 1-ml syringes in advance; thus, it was easy to evaluate the injected cement volume by counting the number of syringes used. Generally, the early injected PMMA cement was located in the IVC. After the IVC was filled, it was necessary to slowly inject PMMA cement while retreating the working cannula. In particular, when the working cannula was located in the pedicle, the injection speed of PMMA cement needed to be slower. At the same time, it was necessary to observe whether there was PMMA cement leakage under fluoroscopy and to ask the patient whether there was nerve irritation. Similarly, the same operation was performed on the opposite side to finally complete the surgical procedure.

Clinical and radiological assessment. Clinical and radiological assessments were performed pre-operatively, 1 day after the surgery and at the final follow-up. The visual analogue scale (VAS) was used to assess the degree of lower back pain and the Oswestry disability index (ODI) was used to assess the degree of dysfunction (16,17). Radiological data were obtained and measured through the hospital's image archiving and communication systems (PACS) under authorization. The change in the anterior vertebral height (AVH) was obtained by measuring lateral radiographs or sagittal CT images. A straight line was drawn from the superior endplate one level above the fractured vertebral body and a straight line was then drawn from the inferior endplate of the one level below the fractured vertebral body. The intersection of the two lines was defined as the Cobb angle (Fig. 1A). The last follow-up time and postoperative complications were also recorded and analyzed (Table I). The criteria for judging the post-operative loosening of PMMA cement were as follows: i) VAS or ODI scores of the patient were significantly worse than those on the first day after surgery; ii) instability of PMMA cement could be observed on a lateral radiograph film of the flexion and extension position; iii) on T2-weighted sagittal images of an MRI, there was an obvious annular edema enhancement zone between the PMMA cement and the surrounding bone (Fig. 1E-H).

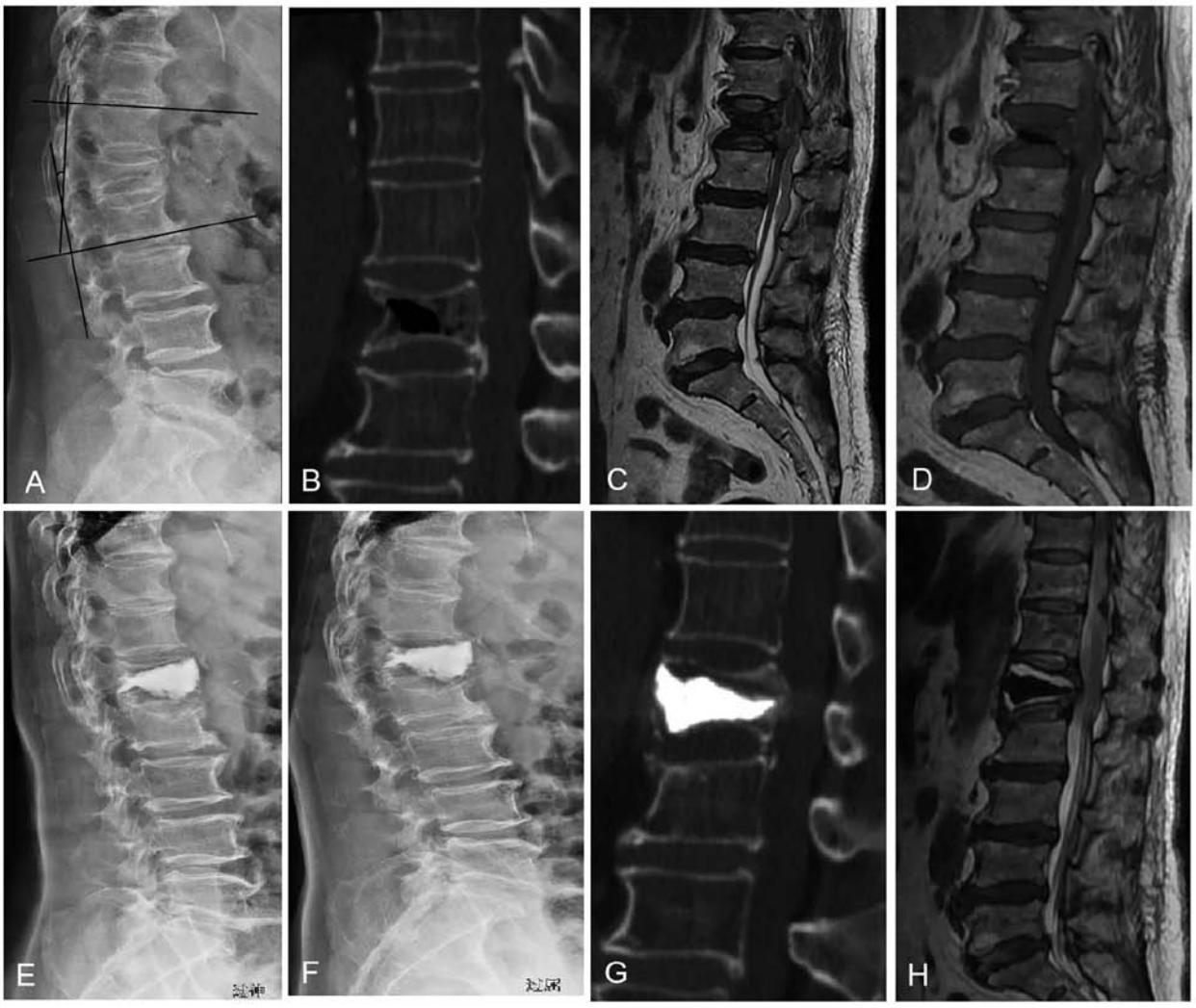

Figure 1. A 76-year-old male patient with Kümmell disease at L1. (A) Lateral radiograph illustrating the measurement method of the Cobb angle. (B) CT and (C and D) MRI illustrating the intravertebral vacuum cleft of Kümmell disease (stage II). Post-operative (E) Flexion and (F) Extension radiographs illustrating the instability of PMMA cement in the vertebral body. (G) Post-operative CT scan illustrating the low-density area between the PMMA cement and vertebral body. (H) Post-operative T2-weighted sagittal images of MRI showing annular edema enhancement zone between the PMMA cement and surrounding bone. PMMA, polymethyl methacrylate.

Treatment of osteoporosis. Regular anti-osteoporosis treatment was performed throughout the course of the treatment and during follow-up. Patients were advised to take daily calcium and vitamin D supplements, as well as bisphosphonates. Teriparatide is currently recommended for patients as a first-line anti-osteoporosis treatment option as well.

Statistical analysis. All statistical analyses were performed using SPSS 19.0 software (IBM Corp.). Each variable is presented as the mean ± SD. Data were analyzed using repeated measures ANOVA and the Bonferroni post hoc test. $P<0.05$ was considered to indicate a statistically significant difference.

Results

The modified PVP surgery used herein was successfully performed in all patients (Figs. 2 and 3). The mean follow-up duration was 8.4±1.2 months (range, 6-11 months). The fractured vertebrae were mainly located in the thoracolumbar region (T10-L2): One in T10; three in T11; five in T12; six in L1; two in L2 and one in L3. The mean T-score of BMD in the present study was -3.2±0.4 SD (range, -2.6--4.2 SD). The mean injected cement volume was 8.5±1.0 ml (range, 7-10.5 ml).

The back pain of the patients improved significantly after the surgery, and their self-care ability and quality of life also significantly improved (Table II). The average pre-operative VAS score was 8.17±0.71 (range, 7-9) and the VAS score on the first day after surgery decreased to 1.56±0.62 (range, 1-3). The difference was statistically significant between the two groups before and after surgery ($P<0.05$). The pain relief continued to be maintained. Until the final follow-up, the VAS score remained at 2.00±0.91 (range, 1-4), with only a slight change compared with that on the first day after surgery. The average pre-operative ODI was 86.44±5.5 (range,76-94) and the ODI on the first day after surgery decreased to 24.33±7.82 (range, 14-40). Until the final follow-up, the ODI remained at 27.11±8.76 (range, 16-44).

The mean Cobb angles and anterior vertebral heights were significantly improved compared with those before surgery. The Cobb angles decreased from 18.77±3.55° (range, 12-24°)

Table I. Demographic and clinical data.

Case no.	Sex/age, years	Level	Bone mineral density	Injected cement volume, ml	Visual analogue scale score			Oswestry disability index, %			Cobb angle, deg			Anterior vertebral height, mm			FFU, months	Complication	Comorbidity
					Pre	Post	FFU	Pre	Post	FFU	Pre	Post	FFU	Pre	Post	FFU			
1	F/75	L2	-3.1	9.5	8	2	2	90	24	26	18	7	8	12	19	18	9	-	HTN
2	F/78	L1	-3.5	8	8	2	3	86	30	30	12	8	8	13	15	15	6	-	DM
3	M/80	T12	-4.2	8.5	9	3	4	92	36	42	22	12	16	10	15	13	8	ACL, AVF	DM, CHD
4	F/76	L1	-2.8	9	8	1	1	86	24	26	20	9	10	13	17	17	10	-	DM
5	M/75	L1	-3.6	8	7	1	2	82	20	20	16	8	9	14	18	17	8	-	-
6	F/82	T12	-3.2	9.5	9	2	3	92	28	30	24	10	12	10	18	17	7	-	HTN
7	F/73	T10	-2.8	8.5	9	1	1	88	16	20	15	7	7	11	16	16	10	ACL	CHD
8	F/76	T12	-3	7	8	2	2	86	20	24	24	10	12	11	22	19	8	-	HTN
9	M/82	L1	-3.4	10.5	9	2	3	94	40	44	22	12	17	13	20	16	7	AVF	HTN
10	F/75	L1	-2.7	8	8	1	2	80	18	20	15	9	9	14	21	20	11	-	DM, CHD
11	F/78	L2	-3	9.5	8	1	1	78	16	16	17	10	10	15	19	19	8	ACL	HTN
12	M/69	T12	-2.8	7.5	9	1	1	90	20	22	20	14	15	14	20	19	10	-	-
13	F/81	L3	-3.5	9	8	2	2	92	36	40	13	10	10	16	18	18	7	-	DM, CHD
14	M/77	L1	-2.9	7	8	1	1	76	14	18	18	10	11	16	22	21	10	-	-
15	F/74	T12	-3.5	7.5	7	1	2	86	22	24	20	12	16	13	19	18	6	ACL	CHD
16	F/70	L1	-2.6	8	7	1	1	78	16	18	19	8	8	16	21	19	10	-	HTN
17	M/81	T12	-3.8	9.5	9	2	3	92	32	38	22	10	13	14	20	16	9	-	CHD
18	F/75	L1	-3.2	8.5	8	2	2	88	26	30	21	13	15	13	19	18	8	ACL	DM

M, male; F, female; anterior vertebral height; FFU, final follow-up; AVF, adjacent vertebral fracture; ACL, asymptomatic cement leakage; HTN, hypertension; DM, diabetes mellitus; CHD, coronary heart disease.

Table II. Comparisons of preoperative, postoperative and final follow-up clinical parameters.

Parameters	Preoperative	Postoperative	Final follow-up	F[a]
Visual analogue scale	8.17±0.71	1.56±0.62[b]	2.00±0.91[b,c]	920.98
Oswestry disability index, %	86.44±5.5	24.33±7.82[b]	27.11±8.76[b,c]	2,464.97
Cobb angle, deg	18.77±3.55	9.94±2.01[b]	11.83±3.96[b,c]	122.45
Anterior vertebral height, mm	13.22±1.90	18.83±2.12[b]	17.56±1.91[b,c]	101.87

Data were analyzed using repeated measures ANOVA followed by Bonferroni's correction. [a]Geisser-Greenhouse adjusted F-value. [b]P<0.05 vs. preoperative values; [c]P<0.05 vs. postoperative values after Bonferroni's correction.

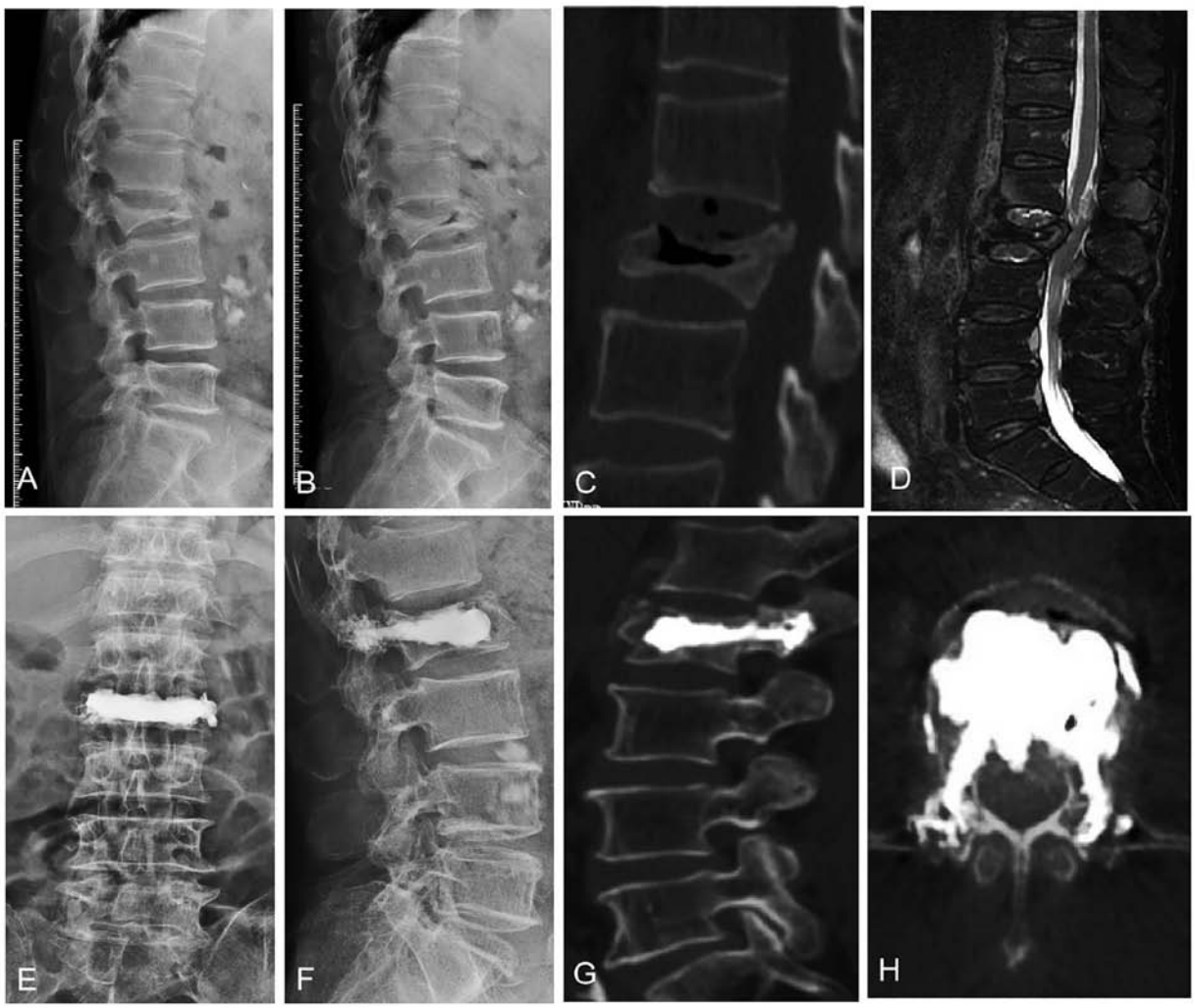

Figure 2. A 78-year-old female patient with Kümmell disease at L2. Pre-operative (A) Flexion and (B) Extension radiographs illustrating the instability of the L2 vertebral body. (C) CT and (D) MRI illustrating the intravertebral vacuum cleft of Kümmell disease (stage III). (E and F) Post-operative radiographs and (G and H) CT scans illustrate that the intravertebral vacuum cleft was filled with PMMA cement and the PMMA cement was firmly fixed to the vertebral body through bilateral pedicle anchoring technology. PMMA, polymethyl methacrylate.

pre-operatively to 9.94±0.21˚ (range, 7-14˚) on the first day after surgery. At the final follow-up, the Cobb angles remained at 11.83±3.96˚ (range, 7-20˚). The anterior vertebral heights increased from 13.22±1.90 mm (range, 10-16 mm) pre-operatively to 18.83±2.12 mm (range, 15-22 mm) on the first day after surgery. At the final follow-up, the anterior vertebral heights remained at 17.56±1.91 mm (raange, 13-21 mm). Statistically significant differences were found in kyphosis correction and vertebral height recovery between the pre-operative and post-operative time points (P<0.05).

During the surgery and follow-up, no serious complications were encountered, such as pulmonary embolism, neurological deficits, cardiac arrest, etc. Similar to the traditional PVP procedure, PMMA cement leakage continues to be the most common complication. In the present study, five patients exhibited an asymptomatic

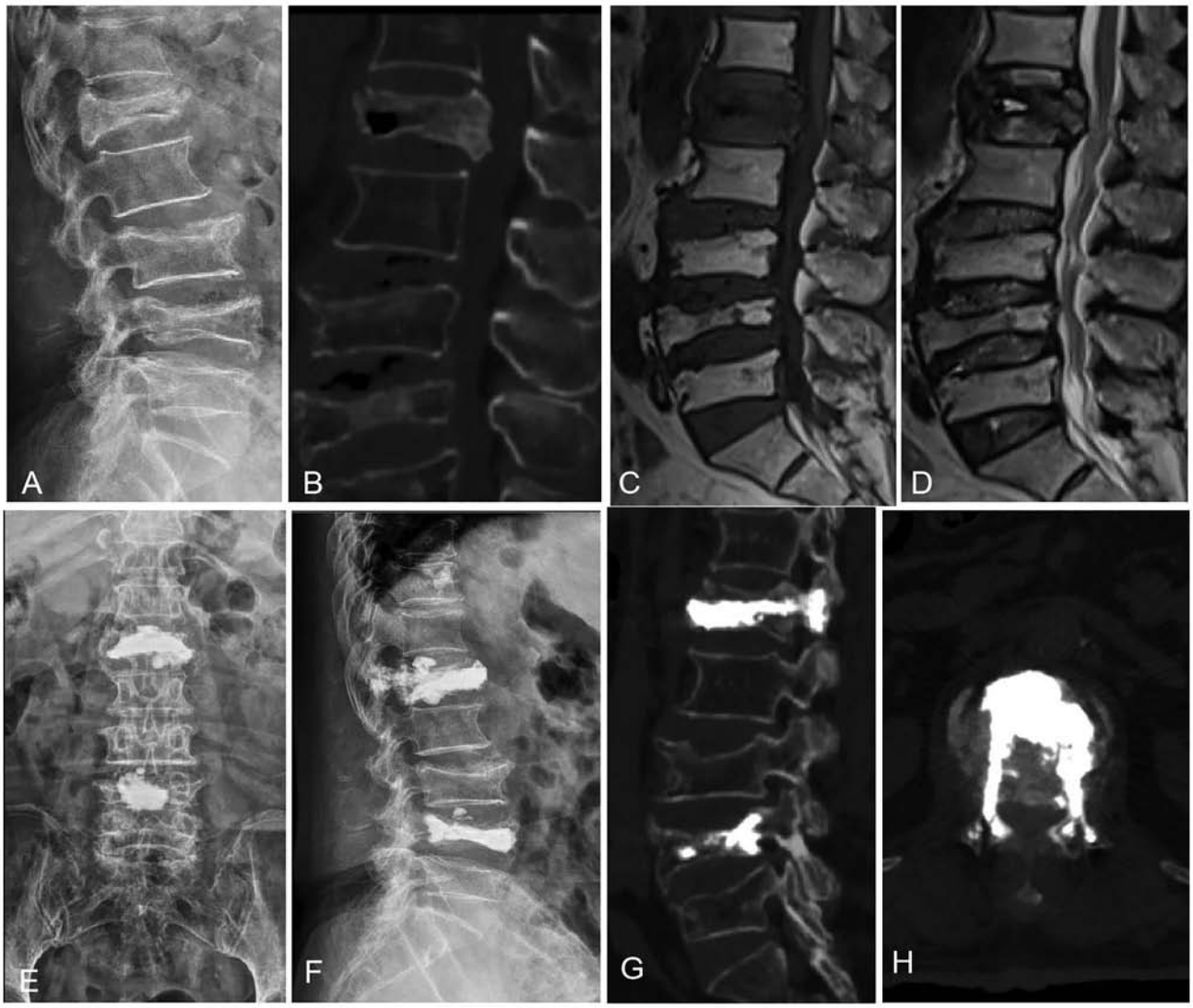

Figure 3. A 75-year-old male patient with Kümmell disease at L1. Pre-operative (A) Radiograph, (B) CT and (C and D) MRI scans illustrating the intravertebral vacuum cleft of Kümmell disease (stage III). Post-operative (E and F) Radiographs and (G and H) CT scans illustrate that the intravertebral vacuum cleft was filled with PMMA cement and the PMMA cement was firmly fixed to the vertebral body through bilateral pedicle anchoring technology. PMMA, polymethyl methacrylate.

leakage of PMMA cement and did not receive any specific treatment. In total, two patients with adjacent vertebral fractures were treated with PVP and the symptoms improved significantly. The loosening of cement was not observed in any of the patients.

Discussion

Although the mechanism of Kümmell disease remains controversial, delayed avascular osteonecrosis of the vertebral body is widely accepted (1,4-7). Kümmell disease can be regarded as a specific type of OVCF. The anterior 1/3 of the vertebral body is supplied by the terminal artery of the single segmental artery (6,14). For elderly patients with osteoporosis, the blood supply of the vertebral terminal artery is weakened due to arteriosclerosis. At this time, a minor vertebral fracture will cause the interruption of the blood supply, leading to avascular necrosis of the vertebral body and a nonunion fracture. With the increase in avascular osteonecrosis, IVC may occur and, eventually, the vertebral body collapses. At the same time, the patient's back pain becomes more severe, even with neurological deficits (8,18,19).

According to the patient's medical history, photograph, CT and MRI examinations, the diagnosis of Kümmell disease is not difficult at present (4). The appearance of IVC is a typical manifestation in an imaging examination. On MRI images, it can be observed that IVC is filled with gas or liquid which undergo a dynamic change according to the patient's position and bed rest time (20,21). On T2-weighted images, a double-line sign can be observed: The periphery of IVC is surrounded by a hyperintensity zone and the outer layer is surrounded by hypointense sclerotic bone (3). Hasegawa *et al* (22) through the IVC histological examination of five patients found that the hyperintensity zone consisted of fibrocartilage tissue. Therefore, due to these characteristics, traditional conservative treatments such as a brace, bed rest and analgesics may not be suitable for the treatment of Kümmell disease (8,23-25). At present, similar to the treatment of common OVCF, PVP

or PKP remains the first choice for Kümmell disease without neurological deficits. However, for patients with common OVCF, bone cement and trabecular bone are fully interdigitated in the vertebral body, while for patients with Kümmell disease, bone cement is mainly concentrated in IVC, which has a clear boundary with the surrounding vertebral body and there is no sufficient mechanical interlock between them (14). In this case, the bone cement mass in IVC gradually loosens, the scope of ischemic osteonecrosis is further expanded under repeated stress and, finally, kyphosis is aggravated due to the re-collapse of the vertebral body. Heo *et al* (14) reported that among 21 patients with Kümmell disease treated with PVP, six patients had vertebral body re-collapse during follow-up and the incidence of re-collapse was 28.57%. Their study suggested that PVP may be a relative contraindication of Kümmell disease (14). Kim and Kim (3) also reported that the corrected kyphotic angles may be reaggravated over time after PKP, suggesting that PKP is not suitable for Kümmell disease. On the contrary, through a prospective cohort study, Chang *et al* (5) found that PVP and PKP could achieve good clinical outcomes in the treatment of Kümmell disease and there was no significant difference between the two surgical methods during long-term follow-up.

In the present study, the PMMA cement mass was firmly fixed in the IVC in the vertebral body through the bilateral pedicle cement anchoring technology under postural reduction. The bilateral pedicle and the PMMA cement mass formed a three-dimensional stable structure, which prevented as much as possible the loosening of PMMA cement in the IVC. The VAS and ODI scores of the patients after surgery were significantly improved compared with those before surgery. Pain and quality of life improved and were maintained well during follow-up. The Cobb angles of the patients after surgery also significantly improved. Although a slight correction loss occurred during follow-up, the difference was not statistically significant. In the present study, PVP was selected as the surgical method for Kümmell disease rather than PKP. It was considered that PKP has no obvious advantage over PVP in the treatment of Kümmell disease (5). Due to the existence of IVC, the natural opening of the vertebral body can be achieved through postural reduction under the prone position, and kyphosis can be corrected to a certain extent. Although PKP balloon dilation can achieve a greater kyphosis correction, relevant research has shown that excessive kyphosis correction cannot achieve good clinical outcomes. Kim and Kim (3) indicated that excessive kyphosis correction could cause instability of the fractured vertebra, leading to the injury of paravertebral soft tissues and ligaments. PKP appears to be unnecessary for Kümmell disease.

As with the traditional PVP procedure, PMMA cement leakage remains the most common complication. In the present study, the leakage rate of bone cement was 27.8%. Chang *et al* (5) reported that the bone leakage rates for Kümmell disease were 17.9 and 10.7% in the PVP and PKP groups, respectively. As bone cement is mainly concentrated in the IVC and is surrounded by sclerotic bone, the leakage rate of bone cement may be lower than PVP for common OVCF (26). Another common complication is an adjacent vertebral fracture and the incidence rate (11.1%) of the present study was similar to that in a previous study (27).

However, the present study still had the following limitations. First of all, the present study was a retrospective study with small sample size. Although good clinical outcomes were achieved, a prospective, randomized controlled study with a larger sample size is required to further verify its clinical efficacy. Secondly, the follow-up time in the present study did not exceed 12 months. Whether vertebral re-collapse will occur, causing further aggravation remains unclear. Thus, the present authors aim to continue the long-term follow-up. In the future, the present authors aim to conduct a multicenter, prospective, randomized controlled study to compare the differences between the bilateral pedicle cement anchoring technique and traditional PVP technology in the treatment of Kümmell disease. The research protocol has been submitted to the hospital ethics committee for approval.

In conclusion, as demonstrated in the present study, during the treatment of Kümmell disease with PVP, the bilateral pedicle cement anchoring technique combined with postural reduction can effectively be used to prevent the loosening of PMMA cement in IVC, the aggravation of vertebral re-collapse and kyphosis. As a modified PVP technology, it can achieve good clinical outcomes.

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Availability of data and materials

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

Authors' contributions

WD designed the research plan and wrote the manuscript. DZ performed the statistical analysis of the research data and assisted WD in the writing of the manuscript. HW, XS and YZ were responsible for data collection. All authors read and approved the final version of the manuscript. DZ and WD confirm the authenticity of all the raw data.

Ethics approval and consent to participate

Written informed consent was obtained from each patient and the present study was approved by the Ethics Committee of Yantaishan Hospital (approval no. 20211005028). The authors declare that the methods carried out in this study were following The Declaration of Helsinki.

Patient consent for publication

The use of any relevant clinical images was authorized by the patient for scientific research and online open-access publication.

Competing interests

The authors declare that they have no competing interests.

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