Retrospective Study

Efficacy and Safety of a 3D-printed Guide Device During Percutaneous Kyphoplasty for the Treatment of Osteoporotic Vertebral Compression Fractures

Hongwei Wang, PhD, Hongwen Gu, MD, Bin Zheng, MD, Yuanhang Zhao, MD, Hong Yuan, BSN, Hailong Yu, PhD, and Liangbi Xiang, MD

From: Department of Orthopedics, General Hospital of Northern Theater Command of Chinese PLA, Shenyang, Liaoning, China

Address Correspondence: Hailong Yu, PhD Department of Orthopedics, General Hospital of Northern Theater Command of Chinese PLA, Shenyang, 110016, Liaoning, China E-mail: yuhailong118@aliyun.com

Disclaimer: Hongwei Wang, Hongwen Gu, and Bin Zheng contributed equally to this work. This work was supported by the Shenyang Science and Technology Project (21-173-9-70, 22-321-33-35) and Applied Basic Research Project of Liaoning Province (2022JH2/101300024).

Conflict of interest: All listed authors have made substantial contributions to the manuscript and do not have any conflicts of interest. Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 05-04-2022
Revised manuscript received: 11-20-2022
Accepted for publication: 01-04-2023

Free full manuscript: www.painphysicianjournal.com

Background: During percutaneous kyphoplasty (PKP) for the treatment of osteoporotic vertebral compression fractures (OVCFs), repeated fluoroscopic images to adjust the puncture needle and inject the polymethylmethacrylate (PMMA) are critical steps. A method to further reduce the radiation dose would be of great value.

Objectives: To assess the efficacy and safety of a 3D-printed guide device (3D-GD) for PKP in the treatment of OVCFs and compare the clinical efficacy and imaging outcomes of traditional bilateral PKP, bilateral PKP with 3D-GD and unilateral PKP with 3D-GD.

Study Design: Retrospective study.

Setting: General Hospital of Northern Theater Command of Chinese PLA.

Methods: From September 2018 through March 2021, 113 patients diagnosed with monosegmental OVCFs underwent PKP. The patients were divided into 3 groups: traditional bilateral PKP (B-PKP group, 54 patients), bilateral PKP with 3D-GD (B-PKP-3D group, 28 patients) and unilateral PKP with 3D-GD (U-PKP-3D group, 31 patients). Their epidemiologic data, surgical indices, and recovery outcomes were collected during the follow-up period.

Results: The operation time was significantly shorter in the B-PKP-3D group (52.5 ± 13.7 minutes) than in the B-PKP group (58.5 ± 9.5 minutes) (P = 0.044, t = 2.082). The operation time was significantly shorter in the U-PKP-3D group (43.6 ± 6.7 minutes) than in the B-PKP-3D group (52.5 ± 13.7 minutes) (P = 0.004, t = 3.109). The number of intraoperative fluoroscopy applications was significantly lower in the B-PKP-3D group (36.8 ± 6.1) than in the B-PKP group (44.8 ± 7.9) (P = 0.000, t = 4.621). The number of intraoperative fluoroscopy times was significantly lower in the U-PKP-3D group (23.2 ± 4.5) than in the B-PKP-3D group (36.8 ± 6.1) (P = 0.000, t = 9.778). The volume of injected PMMA was significantly lower in the U-PKP-3D group (3.7 ± 0.8 mL) than in the B-PKP-3D group (6.7 ± 1.7 mL) (P = 0.000, t = 8.766). The Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores were significantly decreased one day after surgery in each group. However, there were no differences in postoperative VAS and ODI scores, anterior height or local kyphotic angle of the fractured vertebrae, PMMA leakage, or refracture of the vertebral body.

Limitations: Relatively small sample size and short-term follow-up period.

Conclusion: This new innovative 3D technique makes PKP safe and effective. The bilateral PKP with 3D-GD technique, even unilateral PKP with 3D-GD, has the advantages of accurate positioning, a short operation time, and reduced intraoperative fluoroscopy times to the patient and surgeon.

Key words: Percutaneous kyphoplasty, osteoporotic vertebral compression fracture, 3D printing, guide device, bilateral, unilateral, operation time, radiation exposure

Ethics Approval: All procedures performed in this study involving human paients were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Pain Physician 2023: 26:E143-E153

Osteoporotic vertebral compression fracture (OVCF) is a threat to the elderly and causes a diminished quality of life due to pain and deformity (1-5). Percutaneous kyphoplasty (PKP) has become one of the most commonly used techniques in the treatment of OVCFs. Not only can PKP promote pain relief and stabilization, but it can also significantly reduce the length of hospital stay, blood loss, and time to return to daily life (6-11). However, unlike the traditional open method, the small incision and limited sensory feedback make this procedure very technically demanding. The surgeons are heavily dependent on image-guided navigation, especially when the surgeon is inexperienced. Repeated fluoroscopic images are required to locate the best insertion site. This step is inevitable and makes the surgery time-consuming and causes high-dose radiation exposure.

The surgical team is recommended to wear shielding devices since their effectiveness has been reported by previous studies (12-14). However, these shielding devices are usually very heavy, and the surgeons can easily become exhausted. To be able to adjust the guide wires immediately according to the radiograph, the senior surgeon usually has to stand close to the patient and hold the guide wires during each fluoroscopy session. This could reduce the time of radiation exposure during each session, but the cumulative dose to the surgeons over time is quite remarkable. During PKP, repeated fluoroscopic images to adjust the puncture needle and inject the polymethylmethacrylate (PMMA) are critical steps.

Recent studies have pointed out that unilateral PKP would be an attractive alternative to traditional bilateral PKP owing to a lower radiation dose and shorter operation time, a higher degree of deformity correction, and fewer complications (9-11). A method to further reduce the radiation dose while maintaining accurate puncture needle insertion and safe cement injection would be of great value for unilateral puncture. Previous researchers have pointed out that the insertion time and radiation exposure can be significantly reduced during percutaneous pedicle screw placement by using preoperative localization methods and an intradermal locator of their own invention (15-17). However, this intradermal locator cannot help determine the inner inclination angle of the trajectory; meanwhile, the diameter of the locator is too large to be applied in PKP, so we designed a new invention and made it using 3D printing technology.

The main purpose of this retrospective study was to assess whether radiation exposure and operation time is reduced with an innovative 3D-printed guide device (3D-GD) and unilateral puncture technique applied during PKP.

Methods

Patients

All procedures performed in this study involving human paients were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study protocol was approved by the ethics committee of the General Hospital of the Northern Theater Command of the Chinese PLA, and informed consent was obtained from all patients.

From September 2018 through March 2021, 113 patients diagnosed with monosegmental OVCFs underwent PKP. The patients were divided into 3 groups: traditional bilateral PKP (B-PKP group, 54 patients), bilateral PKP with 3D-GD (B-PKP-3D group, 28 patients) and unilateral PKP with 3D-GD (U-PKP-3D group, 31 patients). Their epidemiologic data, surgical indices, and recovery outcomes were collected during the follow-up period.

The inclusion criteria were as follows: 1) severe back pain related to a single-level OVCF refractory to analgesic medication for at least one week; 2) pain more than 5, measured on the Visual Analog Scale (VAS), and tapping pain at the spinal process of the fractured vertebral body during the previous 3 months; 3) a new fracture without any previous fractures of the vertebrae; 4) osteoporosis (diagnosed by bone mineral density [BMD], calculated as a T score ≤ -2.5); and 5) an intact vertebral posterior wall.

The exclusion criteria were as follows: 1) a patient history of previous percutaneous vertebroplasty or PKP; 2) clinical or imaging evidence of a metastatic bone tumour or multiple myeloma; and 3) comorbidities involving the endocrine system (such as thyroid dysfunction).

Patients were treated by the same senior surgeon (H.W.), who used the same surgical techniques at the same institution during the study period. The senior surgeon had performed more than 200 kyphoplasty procedures before the study. Preoperative, one-day postoperative and 12-month postoperative VAS scores and ODI (Oswestry Disability Index) indices were made by an orthopedic resident. X-ray, or computed tomography or magnetic resonance imaging images were taken preoperatively, one day postoperatively, and 12

months postoperatively by a radiologist. The orthopedic resident and radiologist were blinded to our grouping of patients.

Device Composition

The guide device includes Kirschner wires, an intradermal locator, and an angle measuring device (Fig. 1A). The intradermal locator, which is 10 cm in length and 0.8 cm in diameter, is a bullet-shaped device with 4 channels of approximately 0.2 cm each. The diameter of each channel is slightly larger than that of a Kirschner wire. The angle-measuring device includes a semicircle mold with an angular scale and a bone cement ball with silk thread (Fig. 1B). We deflect the guide device while observing the deflecting angle through the angle measuring device (Fig. 1 A). The intradermal locator and angle-measuring device were created by reverse engineering and rapid prototyping techniques (Fig. 1C). The 3D-GD can be used repeatedly after sterilization with ethylene oxide.

Surgical Procedures

Traditional PKP

The patient was placed prone. X-ray fluoroscopy was used throughout the procedure. A preoperative grid locator was used to localize the incision for the PKP. After local anesthesia, the pedicle of the vertebral arch was punctured bilaterally, and then the guide needle, dilated cannula, and working cannula were inserted to establish the working passage. Lateral fluoroscopy showed that the tip of the puncture needle was located at the junction of the pedicle and vertebral body. This ensured that the puncture needle passed through the pedicle and reached the first third of the vertebral body. After removing the puncture needle, the height of the vertebral body reached a satisfactory level through balloon dilation, and PMMA was injected into the injured vertebral body during the later stage of Kirschner wire removal. After the PMMA hardened, we removed the needle, disinfected the wound, and dressed it with a sterile dressing.

PKP With 3D-GD

The entry point and trajectory were planned through preoperative 3D computed tomography scans; the entry point and inner inclination angle of the trajectory were recorded (18,19). The patient was placed prone. We then ensured that the spinous process was located in the middle of the line between both projections of the pedicles (Fig. 2A). After disinfection, dressing, and local anesthesia, the Kirschner wires were percutaneously inserted to dock at the approximate position of the lateral margin of the facet joint (Figs. 2B, 2C), and then the intradermal locator was placed along the Kirschner wire (Fig. 2D). Then, we inserted other Kirschner wires through the channels of the 3D-GD (Fig. 2 E). The Kirschner wire with the best location was chosen and left after anteroposterior and lateral fluoroscopy (Figs. 2F, 2G).

Because our guide device has a certain length, the traditional puncture needle is not long enough to reach the bone surface through the guide device, so we chose Kirschner wires which are long enough. The Kirschner wire in the PKP with 3D-GD technique is similar to the puncture needle used in traditional PKP surgery. We determined the safe position of the Kirschner wire through fluoroscopic imaging. Then, we deflected the guide device, and inserted the Kirschner wire into the body according to the preoperative inner inclination angle which can be observed on the angle measuring device intraoperatively (Fig. 2H). A dilated cannula and a working cannula were then inserted to establish a working passage. The rest of the procedure was the same as for traditional PKP surgery.

Outcome Measures

Data were collected from medical records for pa-

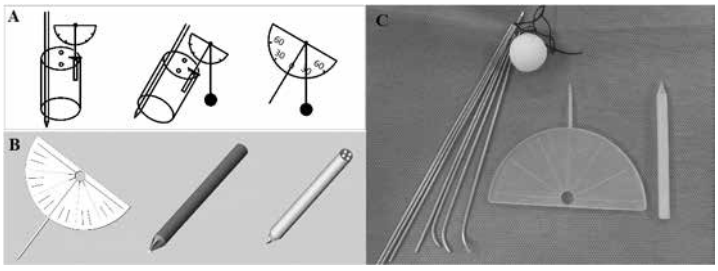

Fig. 1. *3D-printed guide device. (A) Design diagrams of the guide device. (B) Computer graphic design of the guide device, including the intradermal locator and the angle measuring device. (C) The guide device produced by 3D printing technology.*

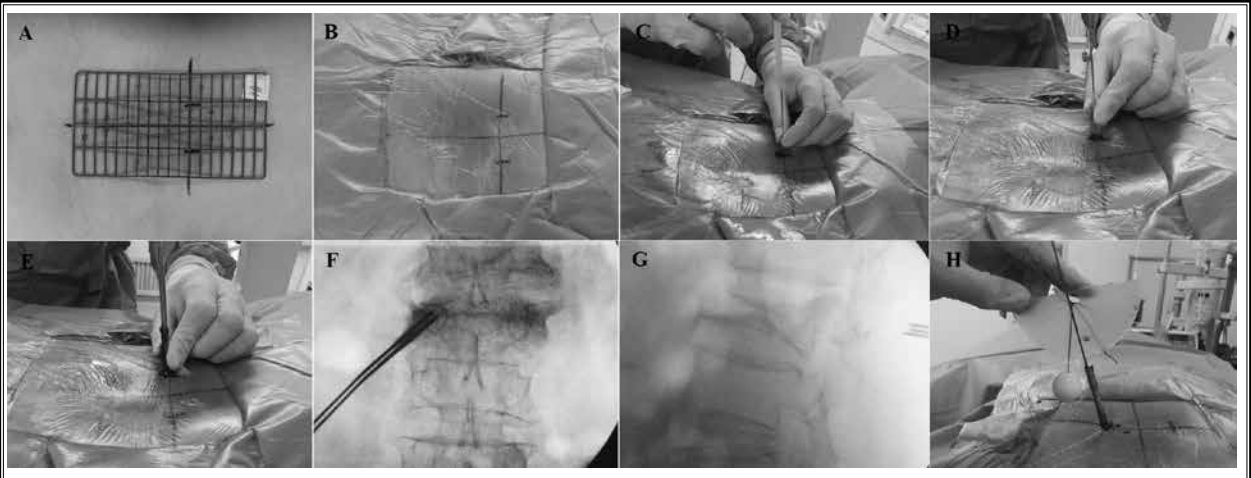

Fig. 2. *Intraoperative imaging data showing the performance of PKP using a 3D printed guide device. (A, B) The preoperative grid locator was used to locate the skin incision. (C-G) After disinfection and dressing, the best located Kirschner wire was chosen using the intradermal locator. (H) The Kirschner wire was inserted into the body according to the preoperative planned inner inclination angle of the trajectory measured intraoperatively by the angle measuring device.*

tient age, gender, body mass index, bone mass density (T score), the volume of injected PMMA, fracture level, and perioperative parameters, including the operation time, intraoperative bleeding, intraoperative fluoroscopy times, hospital stay and hospitalization cost. The VAS scores for back pain and the ODI scores were routinely administered and recorded to all patients. Clinical outcomes were compared between groups. Meanwhile, preoperative, one day postoperative, one month postoperative and 12 month postoperative VAS and ODI scores were compared. X-rays or computed tomography were taken preoperatively, one day postoperatively, and 12 months postoperatively. They were reviewed for PMMA leakage, the fractured vertebrae anterior height (AVH), and the local kyphotic angle (LKA) of the fractured vertebrae as well as the extent of reduction and correction. Illustrated cases are shown in Figs. 3,4.

Statistical Analysis

All data were analyzed using IBM SPSS Statistics 24.0 (IBM Corp.). The χ^2 test or Fisher's exact test was used for frequency data. The Shapiro-Wilk method was used for the normality test of measurement data. Analysis of variance (ANOVA) was used for comparing measurement data that had a normal distribution, and Fisher's least significant difference method was used for post hoc analysis. The Kruskal–Wallis H test was used for the comparing groups of measurement data that had a partial distribution. The Bonferroni method was used for comparisons between groups. The characteristics of each of the 2 groups were compared by the independent sample t test. The AVH, LKA, VAS score, and ODI within groups were compared using the paired t test. $P < 0.05$ was considered statistically significant.

Results

General Information

A total of 23 men and 90 women with 62 lumbar vertebrae and 51 thoracic vertebral compression fractures underwent PKP in our hospital. The mean age of all patients was 70.0 ± 8.7 years (51 - 90 years). Body mass index and BMD were 23.3 ± 3.0 kg/m2 and -3.1 ± 0.4, respectively. There were no statistically significant differences in age, gender, BMI, BMD, fractured vertebrae, preoperative VAS, ODI, AVH, or LKA among the 3 groups. The mean follow-up duration was not significantly different among the 3 groups (Table 1).

Surgery Outcomes Comparison

Surgery was successful in all patients; none experienced lower-limb deep venous thrombosis, pulmonary embolism, or spinal nerve injury. The operation time was significantly shorter in the B-PKP-3D group (52.5 ± 13.7 minutes) than in the B-PKP group (58.5 ± 9.5 minutes) ($P = 0.044$, $t = 2.082$). The operation time was significantly shorter in the U-PKP-3D group (43.6

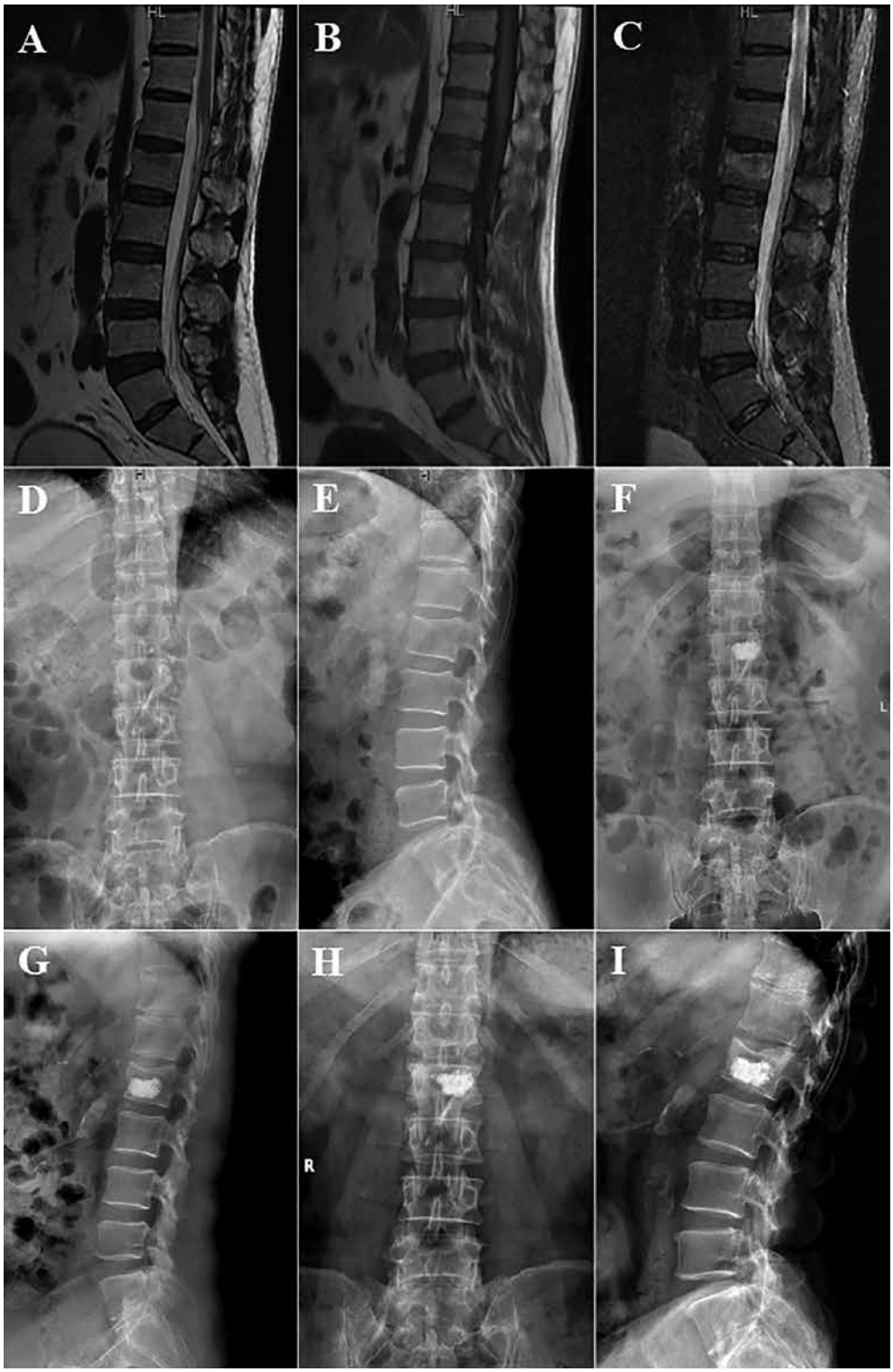

Fig. 3. *The imaging data of a 63-year-old man showed L1 vertebral compression fracture. (A-C) Preoperative MRI; (D, E) Preoperative lumbar radiograph; (F, G) One-day postoperative lumbar radiograph after unilateral PKP; (H, I) Twelve-month postoperative lumbar radiograph after unilateral PKP.*

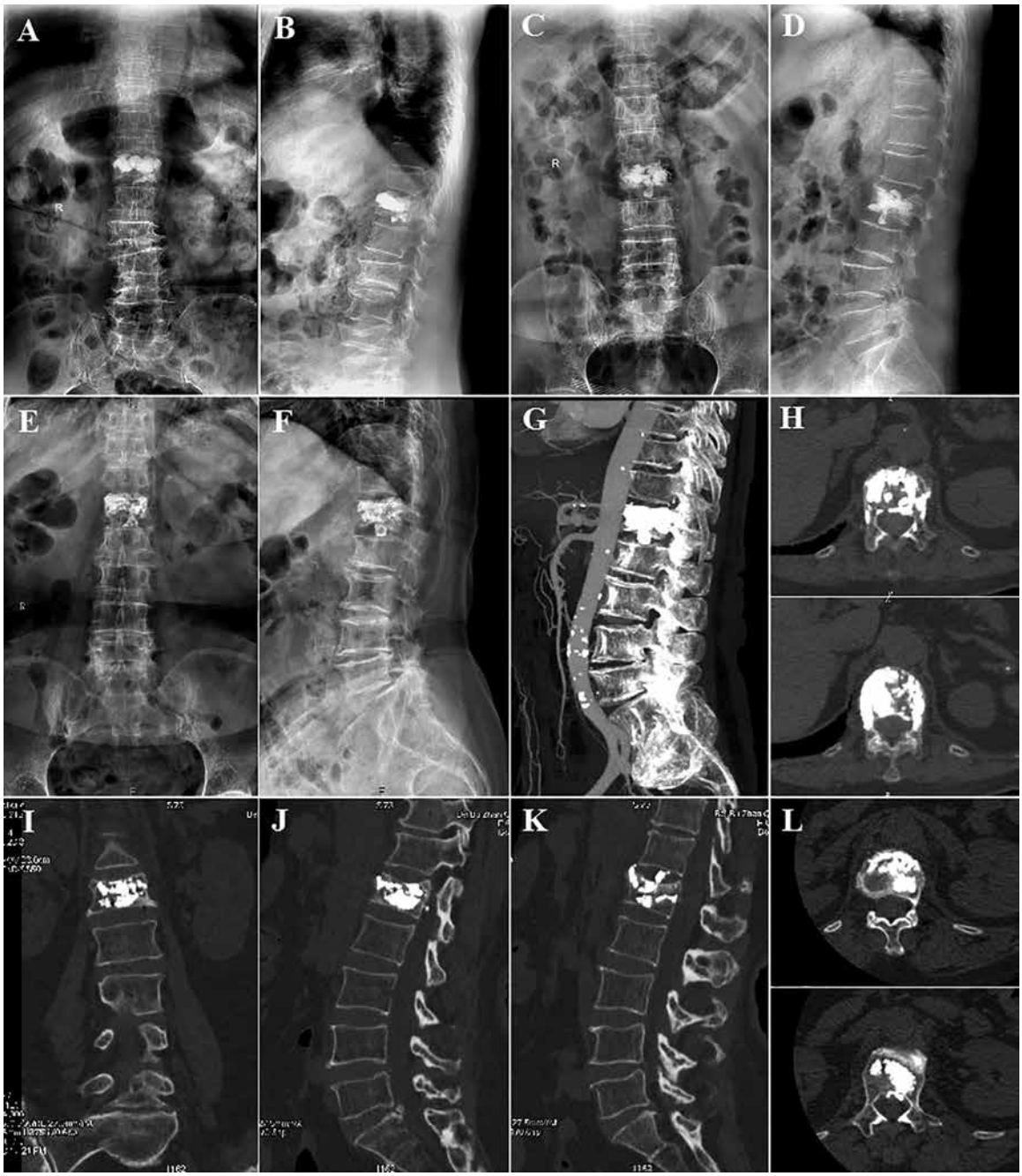

Fig. 4. *The imaging data of typical cases with bone cement leakage. (A, B) Intervertebral leakage in a patient with a T12 fracture treated with bilateral PKP. (C, D) Intervertebral leakage in a patient with an L2 fracture treated with bilateral PKP. (E-H) Intervertebral leakage in a patient with an L1 fracture treated with bilateral PKP. The bone cement was well filled in the vertebra and diffused to the posterior margin of the vertebral body on x-rays. The PMMA was found to fill both pedicles and the intervertebral discs on CT scans. (I-L) Intervertebral and intraspinal leakage in a patient with an L1 fracture treated with unilateral PKP. The bone cement is well filled in the vertebra and diffused to the intervertebral disc and spinal canal, as shown by CT scans.*

± 6.7 minutes) than in the B-PKP-3D group (52.5 ± 13.7 minutes) (P = 0.004, t = 3.109). The number of intraoperative fluoroscopy applications was significantly lower in the B-PKP-3D group (36.8 ± 6.1) than in the B-PKP group (44.8 ± 7.9) (P = 0.000, t = 4.621). The number of intraoperative fluoroscopy times was significantly lower in the U-PKP-3D group (23.2 ± 4.5) than in the B-PKP-3D group (36.8 ± 6.1) (P = 0.000, t = 9.778). The volume of injected PMMA was significantly lower in the U-PKP-3D group (3.7 ± 0.8 mL) than in the B-PKP-3D group (6.7 ± 1.7 mL) (P = 0.000, t = 8.766). There were no significant differences in terms of intraoperative bleeding, hospital stay or hospitalization cost (Table 2).

Clinical Assessment Comparison

The VAS and ODI scores were decreased significantly at one day postsurgery in each group; there were no significant differences for the preoperative, one day postoperative, or 12 month postoperative VAS and ODI scores. The postoperative one day, one month, and 12 month VAS and ODI scores in the U-PKP-3D group were lower than those in the B-PKP and B-PKP-3D groups, but there were no significant differences (Table 3).

Radiographic Outcomes Comparison

The AVH and LKA improved significantly at one

Table 1. *Comparison of the characteristics of the patients in the 3 treatment groups at baseline.*

Characteristic	B-PKP (n = 54)	B-PKP-3D (n = 28)	U-PKP-3D (n = 31)	F/Z/χ^2 Value	*P* Value
Men/Women	12/42	7/21	4/27	1.551	0.461
Mean age (years)	67.0 ± 8.7	70.8 ± 8.3	70.0 ± 9.2	0.111	0.895
BMI (kg/m^2)	23.0 ± 3.1	23.4 ± 3.2	23.8 ± 2.8	0.809	0.448
BMD	-3.1 ± 0.5	-3.1 ± 0.4	-3.0 ± 0.3	1.251	0.535
Preoperative VAS	7.4 ± 0.8	7.4 ± 0.6	7.4 ± 0.8	0.091	0.955
Preoperative ODI	75.1 ± 9.0	75.9 ± 6.3	74.9 ± 8.7	0.186	0.911
Preoperative AVH (mm)	22.6 ± 6.7	21.5 ± 5.5	21.1 ± 6.6	2.179	0.336
Preoperative LKA (°)	10.3 ± 5.9	10.7 ± 5.0	10.9 ± 5.5	0.061	0.970
Fractured vertebrae					
T4-T8	3	4	7	-	0.216*
T11	5	4	1		
T12	13	9	5		
L1	17	8	10		
L2	9	1	4		
L3	3	1	4		
L4	4	1	0		
Mean follow-up duration (mo)	22.4 ± 9.2	22.8 ± 9.1	20.6 ± 9.5	1.361	0.506

*: Fisher's exact test; BMI: body mass index; BMD: bone mass density; VAS: visual analog scale; ODI: oswestry disability index; AVH: anterior height of the fractured vertebrae; LKA: local kyphotic angle

Table 2. *Comparison of the perioperative parameters of the patients in the 3 treatment groups.*

Characteristic	B-PKP (54)	B-PKP-3D (28)	U-PKP-3D (n = 31)	B-PKP vs B-PKP-3D		B-PKP-3D vs U-PKP-3D	
				P	t	P	t
Operation time (min)	58.5 ± 9.5	52.5 ± 13.7	43.6 ± 6.7	0.044	2.082	0.004	3.109
Intraoperative bleeding (mL)	10.9 ± 7.5	10.6 ± 5.9	10.3 ± 5.3	0.872	0.161	0.829	0.218
Intraoperative fluoroscopy times	44.8 ± 7.9	36.8 ± 6.1	23.2 ± 4.5	0.000	4.621	0.000	9.778
The volume of injected PMMA)	6.9 ± 1.5	6.7 ± 1.7	3.7 ± 0.8	0.537	0.620	0.000	8.766
Postoperative hospital stay (d)	1.5 ± 1.4	1.4 ± 1.0	1.5 ± 1.4	0.710	0.374	0.784	-0.276
Postoperative hospital stay (d)	1.5 ± 1.4	1.4 ± 1.0	1.5 ± 1.4	0.710	0.374	0.784	-0.276
Total hospitalization cost (CNY)	35596.2 ± 3599.4	36103.1 ± 3296.9	34903.9 ± 2964.1	-0.622	0.536	0.147	1.471

PMMA: polymethyl methacrylate; CNY: China Yuan

Table 3. *Comparison of the changes in the VAS score and ODI for each group before and after surgery.*

Characteristic	B-PKP (n = 54)	B-PKP-3D (n = 28)	U-PKP-3D (n = 31)	B-PKP vs B-PKP-3D		B-PKP-3D vs U-PKP-3D	
				P	t	P	t
VAS score							
Preoperative	7.4 ± 0.8	7.4 ± 0.6	7.4 ± 0.8	0.809	-0.242	0.960	0.050
One day postoperative	3.6 ± 0.7	3.6 ± 0.6	3.4 ± 0.6	0.577	-0.561	0.132	1.526
One month postoperative	3.1 ± 0.8	3.0 ± 0.9	2.6 ± 0.7	0.920	0.100	0.072	1.833
12 months postoperative	1.9 ± 0.6	1.8 ± 0.6	1.7 ± 0.5	0.714	0.367	0.455	0.752
ODI							
Preoperative	75.1 ± 9.0	75.9 ± 6.3	74.9 ± 8.7	0.684	-0.409	0.631	0.483
One day postoperative	37.3 ± 6.3	37.9 ± 4.5	35.2 ± 7.9	0.639	-0.471	0.102	1.667
One month postoperative	28.3 ± 4.1	27.6 ± 3.2	26.6 ± 3.6	0.395	0.856	0.304	1.036
12 months postoperative	16.6 ± 4.5	16.8 ± 3.9	15.9 ± 3.1	0.878	-0.155	0.323	0.997

VAS: visual analog scale; ODI: oswestry disability index

day postsurgery in all groups. There were no significant differences among the 3 groups for the preoperative, one day postoperative, or 12 month postoperative AVH and LKA. In all groups, the AVH and LKA at one day postoperative and 12 months postoperative were significantly improved compared with those presurgery ($P < 0.05$). However, there were no significant differences in the AVH and LKA.

Thirty-three patients experienced PMMA leakage during the follow-up period, but none had clinical symptoms related to PMMA leakage. Seventeen (31.5%) patients had bone PMMA leakage in the B-PKP group, 8 patients (28.6%) in the B-PKP-3D group and 8 patients (25.8%) in the U-PKP-3D group. There was no significant difference.

A total of 6 patients experienced vertebral refracture during the follow-up period: two (3.7%) in the B-PKP group, one (3.6%) in the B-PKP-3D group and 3 (9.7%) in the U-PKP-3D group. There were no significant differences among the 3 groups. Only 3 patients (one patient in each group) had an adjacent vertebral fracture. The pain disappeared after reoperation. Typical cases from the B-PKP-3D and U-PKP-3D groups are shown in Fig. 3 and Fig. 4, respectively (Table 4).

Discussion

PKP can promote pain relief and vertebra stabilization and significantly reduce the length of hospital stay, blood loss, and time to return to normal life; it has become the most commonly used surgical technique for treating OVCFs (6-11). During PKP, performing repeated fluoroscopic images to adjust the puncture needle and inject the PMMA are critical steps. Thus, a method to reduce radiation exposure while maintaining accurate puncture needle insertion and safe PMMA injection would be of great value. The insertion time and radiation exposure can be significantly reduced during percutaneous pedicle screw placement using preoperative localization methods and an intradermal locator (15-17). However, the intradermal locator used in previous studies cannot help us to determine the inner inclination angle of the trajectory; meanwhile, the diameter of the intradermal locator is too large to be applied in PKP. The feasibility and practicability of an innovative 3D-printed guide device for PKP is described in the present study.

The 3D-printed guide device, including the intradermal locator and angle measuring device, was used for accurately determining the entry point and angle of trajectory. Furthermore, its use was able to significantly reduce the operation time and intraoperative fluoroscopy times compared with traditional bilateral PKP.

During PKP, the conventional methods used for a Jamshidi™ needle and the advancement of the guidewire into the pedicle require numerous radiographic images. With the help of our novel intradermal locator, the Kirschner wire with the best bony puncture point was easily detected through a small incision using anteroposterior and lateral fluoroscopy. After determining the bony puncture point, we could adjust the angle of the puncture trajectory using the angle measuring device and repeated fluoroscopy to determine the relationship between the needle and the pedicle is avoided. Then the PKP working cannula could be accurately placed along the Kirschner wire to achieve the best location.

There was no statistically significant difference in pain relief or functional improvement between the

Table 4. *Comparison of the changes in the radiologic parameters for each group before and after surgery.*

Characteristic	B-PKP (n = 54)	B-PKP-3D (n = 28)	U-PKP-3D (n = 31)	B-PKP vs. B-PKP-3D		B-PKP-3D vs. U-PKP-3D	
				P	t/χ^2	*P*	t/χ^2
AVH (mm)							
Preoperative	22.6 ± 6.7	21.5 ± 5.5	21.1 ± 6.6	0.431	0.791	0.807	0.245
1 day postoperative	27.9 ± 5.2	26.5 ± 5.3	26.1 ± 6.9	0.250	1.158	0.833	0.212
12 months postoperative	26.8 ± 5.1	25.0 ± ±4.9	25.3 ± 7.3	1.130	1.532	0.874	-0.159
LKA (°)							
Preoperative	10.3 ± 5.9	10.7 ± 5.0	10.9 ± 5.5	0.743	-0.329	0.884	-0.147
1 day postoperative	6.5 ± 4.3	6.8 ± 4.2	7.4 ± 4.3	0.774	-0.288	0.539	-0.618
12 months postoperative	7.7 ± 4.5	7.8 ± 4.4	8.2 ± 4.6	0.933	-0.084	0.733	-0.343
Cement leakage (n)	17 (31.5%)	8 (28.6%)	8 (25.8%)	0.985	0.000	1.000	0.000
Lateral leakage	3 (5.6%)	0	1 (3.2%)				
Anterior leakage	2 (3.7%)	2 (7.1%)	1 (3.2%)				
Intravascular leakage	6 (11.1%)	4 (14.3%)	1 (3.2%)				
Intervertebral leakage	6 (11.1%)	1 (3.6%)	2 (6.5%)				
Intraspinal leakage	0	1 (3.6%)	3 (9.7%)				
Refracture (n)	2 (3.7%)	1 (3.6%)	3 (9.7%)	1.000	0.000	0.680	0.171
Adjacent vertebral fracture	1 (1.9%)	1 (3.6%)	1 (3.2%)				
Other vertebral fracture	1 (1.9%)	0	2 (6.5%)				

AVH: anterior height of the fractured vertebrae; LKA: local kyphotic angle.

B-PKP-3D group and the B-PKP group during the 12-month follow-up, but the operation time and intraoperative fluoroscopy times were significantly reduced in the B-PKP-3D group compared with the B-PKP group.

No apparent differences in the short- and long-term clinical outcomes or complications were observed between unilateral and bilateral PKP; unilateral PKP was associated with a shorter operation time and a lower x-ray exposure frequency and dosage of PMMA than bilateral PKP (20). In the current study, a significant improvement in the VAS, ODI, AVH, and LKA was observed after treatment.

PKP, using both unilateral and bilateral techniques, restored vertebral height and improved vertebral alignment. There was no statistically significant difference in pain relief or functional improvement between the B-PKP-3D group and the U-PKP-3D group during the 12-month follow-up. Regarding clinical outcomes, similar benefits were achieved with both treatment procedures. Unilateral PKP, therefore, seems to have advantages over bilateral PKP for the treatment of OVCFs due to a smaller injected PMMA volume, a lower radiation dose, and a shorter operation time.

A higher incidence of PMMA leakage was observed in patients with treated vertebrae exhibiting a single-dispersive or single-compact pattern (21). Greater PMMA distribution may indicate better vertebral restoration along with a higher bone cement extravasation (BE) risk (22). The integrity of the vertebral walls and the volume of injected PMMA significantly boosted the potential risk of PMMA leakage (23). Once any PMMA leaks are noted during the operation, PMMA injection should be terminated immediately (24). Therefore, we should pay more attention to the volume of PMMA injected, the distribution of the PMMA, the integrity of the vertebral walls, and the posterior margin of the vertebral body to avoid PMMA leakage.

In the current study, 31.5% of patients in the B-PKP group, 28.6% of patients in the B-PKP-3D group and 25.8% of patients in the U-PKP-3D group had PMMA leakage, but there were no significant differences among the 3 groups. A unilateral puncture did not show significantly less PMMA leakage, which may be related to the large volume of injected PMMA required to achieve a well-filled body. We should stop or slow down PMMA injection when the PMMA diffuses to the posterior margin of the vertebral body.

Diabetic status and alterations in the Cobb angle after PKP exhibited a statistically significant correlation with the incidence of new adjacent vertebral fractures (23). Patients with a lower preoperative BMD, a larger balloon volume, PMMA volume, recovery rate of ver-

tebral height, and intraoperative PMMA leakage have an increased risk of adjacent vertebral compression fracture after PKP (25). In the current study, 3.7% of patients in the B-PKP group, 3.6% of patients in the B-PKP-3D group and 9.7% of patients in the U-PKP-3D group experienced vertebral refracture in the follow-up period, and only one patient in each group had an adjacent vertebral fracture. All 3 patients had diabetes, and one patient in the U-PKP-3D group presented with intraspinal leakage. More thorough, meticulous research is necessary to investigate the risk factors for PMMA leakage and adjacent vertebral fractures in PKP.

Limitations

The main limitations of our study are the relatively small sample size and short-term follow-up period, which may affect the accuracy of the conclusions. However, we focused on its perioperative effects, such as radiation exposure and operation time. It is meaningful to describe the characteristics and advantages of the 3D-GD. Randomized controlled trials with a larger patient population and long-term follow-ups are warranted to generalize our results.

Conclusions

Our 3D-GD could help reduce radiation exposure and operation time in PKP while maintaining safety, especially when using unilateral puncture. It is a simple device and can be recycled after sterilization. Randomized controlled trials are necessary to validate its clinical application and broaden its usage in other spinal surgeries, such as pedicle screw placement.

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