

## Original Article

# A novel technique of unilateral percutaneous kyphoplasty achieves effective biomechanical strength and reduces radiation exposure

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**Abstract:** Purpose: To develop a novel technique of percutaneous kyphoplasty (PKP) with effective biomechanical strength and lower radiation exposure. Methods: Thirty fresh lumbar vertebrae isolated from six hogs were decalcified and compressed to induce osteoporotic vertebral compression fractures. Kyphoplasty was performed using three different techniques (ten for each group): conventional unilateral approach (group A), conventional bilateral approach (group B) and novel unilateral approach (group C). Biomechanical indexes including Yield load and stiffness were tested before and after kyphoplasty. The anterior height of each vertebral body (AHVB) was measured before compression, after compression and after kyphoplasty. Frequency of C-arm use and volume of bone cement were also recorded in the process. Results: Compared with group A, our novel technique in group C can significantly improve the recovery of AHVB after compression fractures. However, there was no statistical difference between group B and group C. Values of Yield load in both group B and group C were statistically higher than that in group A, however, no significant difference was found between group B and C. Statistical results of stiffness were similar to Yield load. Regarding volume of bone cement and radiation exposure, the novel technique in group C needed more bone cement and fluoroscopy use than in group A but less than in group B. Conclusions: This novel device makes unilateral kyphoplasty feasible, safe and effective. In the premise of guaranteed biomechanical strength, the new technique significantly reduces risk of radiation exposure in kyphoplasty.

**Keywords:** Compression fracture, unilateral percutaneous kyphoplasty, biomechanics, radiation exposure, bone cement leakage

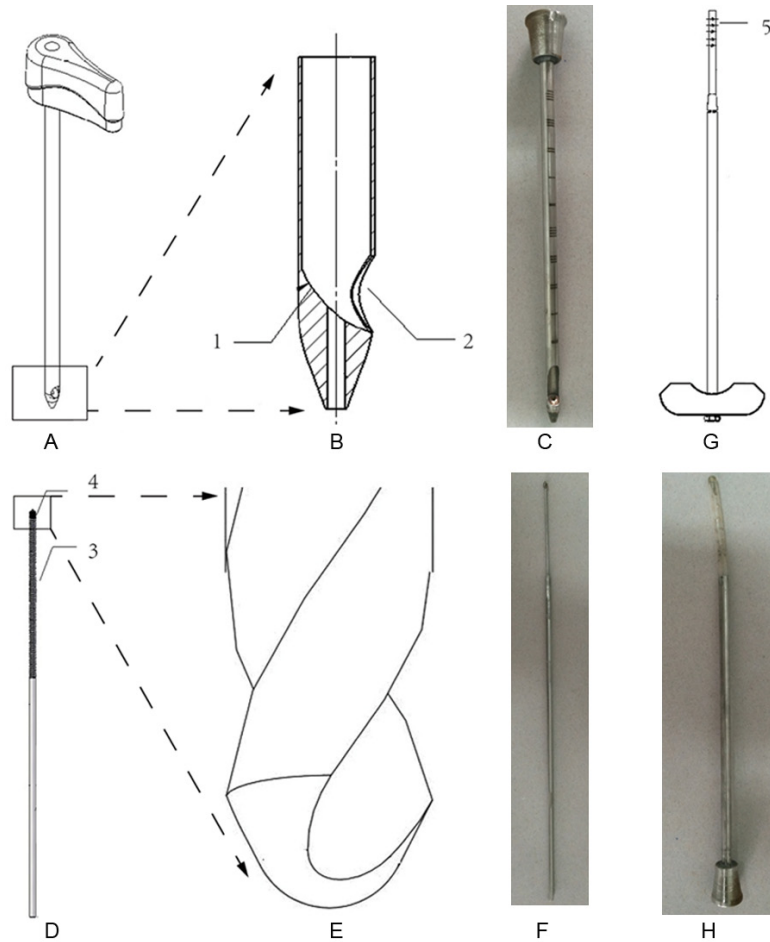
## Introduction

Percutaneous kyphoplasty (PKP) is a therapeutic intervention for osteoporotic vertebral compression fractures [1-5] which can be performed via unilateral or bilateral approach [6, 7]. For now, bilateral pedicular approach aided by C-arm was still more frequently used. A bipedicular approach improves the cement distribution symmetrically [7] but offers the disadvantages of increasing the risk of pedicle fracture, medial violation of the pedicle and/or transgression into the spinal canal, nerve injury, cement leakage, spinal epidural hematoma, and more fluoroscopic radiation exposure to operators and patients [8-11]. In recent years,

unilateral PKP has become more and more attractive for spinal surgeons [12, 13].

However, asymmetric distribution of bone cement in the vertebral body using unipedicular technique has been reported in many researches, thus leading to spinal instability [14, 15]. Given this, with the purpose of achieving the combination of advantages of unipedicular and bipedicular technique, we tried to design a novel device which can be safely, easily and effectively used in unilateral PKP and compared this novel technique with conventional techniques from different aspects including biomechanics, recovery of anterior height of vertebral body (AHVB), bone cement use and radiation exposure.

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**Figure 1.** Schematic and physical diagrams of the novel device for unilateral PKP. A. Schematic diagram of Part 1; B. A larger version of the tip of Part 1 (1: slope surface; 2: side hole), this design guides the puncture to the center of the vertebral body; C. Physical map of Part 1; D. Schematic diagram of Part 2 (3: springs; 4: bone drill); E. A larger version of the bone drill; F. Physical map of Part 2; G. Schematic diagram of Part 3 (5: Several injection holes were made on the distal side of the injection cannula for cement delivery); H. Physical map of Part 3.

### Materials and methods

#### *Design of the novel device for vertebroplasty via unilateral approach*

With the aim of reducing radiation exposure and lessening surgical trauma, we invented a novel device for the application of unilateral PKP. The invention consists of three main parts: guide sleeve (**Figure 1A-C**), bone drill (**Figure 1D-F**) and channel for bone cement injection (**Figure 1G, 1H**). Detailed information of each part was shown in the figure caption.

In summary, this novel technique of unilateral PKP using our designed device is easy to master. The design makes the bone cement injec-

tion closer to the center of the vertebral body and far away from the edge of the vertebra, thus not only achieving biomechanical balance but also reducing the risk of leakage of bone cement.

Additionally, due to unilateral puncture, this novel technique reduces risk of misleading into the vertebral canal and risk of radiation exposure, shortens operation time, and lessens surgical trauma.

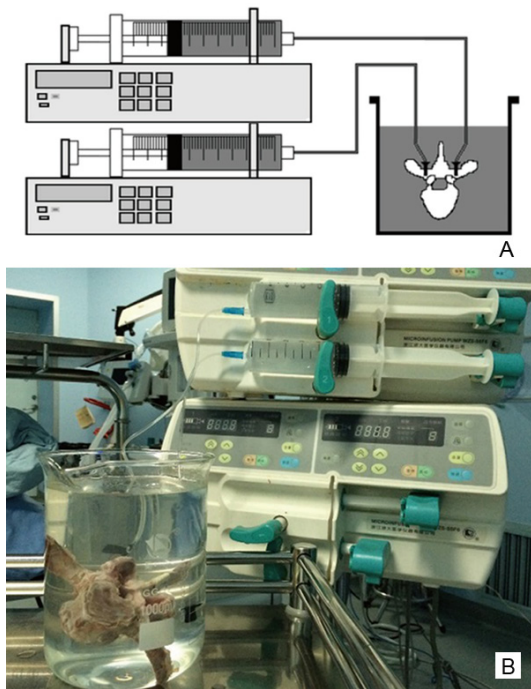
#### *Establishment of osteoporotic models of vertebrae*

In the present study, decalcification was conducted to establish osteoporotic models of vertebrae. Thirty fresh-frozen lumbar vertebrae (L1-L5) were disarticulated from six hogs, weighing 95-105 kg, male or female. Each vertebra was radiographed (OPTI 150/30/50 HC, SIEMENS, Wuxi, China) to rule out spinal fractures, tumor, metabolic bone disease or deformity. For each vertebra, muscle, ligament, and tendon tissue were removed, whereas the normal osseous structure was preserved. The

specimens were then sealed in plastic bags, and stored frozen at  $-20^{\circ}\text{C}$  and allowed to thaw slowly at room temperature for 24 hours before testing. Care was taken to keep the specimens moist throughout the experiment. The bone mineral density (BMD) of the specimens was assessed using a dual energy x-ray absorptiometry scan (Hologic Discovery; Hologic, Inc. BEDFORD, MA, USA), and the anterior heights of vertebral body (AHVB) were measured using digital verniercalipers (Shanghai Measuring and Cutting Tools Limited Company, Shanghai, China; accurate to  $\pm 0.03$  mm).

Specimens were subject to demineralization procedure. The details are described below: for each vertebra, one hole was prepared at the

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**Figure 2.** Schematic and physical diagrams of decalcification of the hogs' vertebrae. A. Schematic diagram of decalcification; B. Physical photo of decalcification.

junction of midlines of transverse process and lateral border of superior articular process bilaterally using transfusion needles ( $0.8 \times 21$  TW, KDLCHINA Corp. Shanghai, China) which were stayed in the vertebrae and then connected to the syringes on infusion pump (WZS-50F6, Medical Instrument Limited Company of Zhejiang University, Zhejiang, China) with plastic tubing and a plastic cone type connector. Each vertebra was placed into a glass filled with 1000 ml 3% hydrochloric acid decalcifier solution (Guangzhou Chemical Reagent Factory, Guangzhou, China). The decalcifier solution in syringes was then introduced through the holes into the pedicles with the help of infusion pump at the speed of 50 ml/h, keeping and irrigating for 12 hours (**Figure 2**). Specimens were washed under running tap water. Saline was given through pedicular holes until the decalcifier solution was completely removed. The specimens were DEXA-scanned for BMD after decalcification.

### *Establishment of models of osteoporotic vertebral compression fractures*

A quasi static axial compression was applied to each decalcified vertebra to establish the

model of compression fracture (setting 25% compression of the original height) using Electromechanical Universal Testing Machine (Model CMT7504, MTS SYSTEMS CHINA Co. LTD., China).

### *Surgical procedures of kyphoplasty*

Specimens were randomly divided into three groups of equal size: kyphoplasty using conventional device via unipedicular approach (group A,  $n = 10$ ), kyphoplasty using conventional device via bipedicular approach (group B,  $n = 10$ ), kyphoplasty using novel device via unipedicular approach (group C,  $n = 10$ ).

#### *Group A*

For group A, a needle 3.0 mm in diameter was advanced through unilateral pedicle into vertebral body utilizing intermittent fluoroscopy. The needle was exchanged for a working cannula over a K-wire 1.5 mm in diameter through which a drill trocar was advanced creating a channel for the balloon. The drill trocar was removed and the inflatable balloon tamp was advanced into the anterior one-third of the vertebral body under fluoroscopy. The balloon was inflated under fluoroscopy no more than 200 psi. The balloon was deflated and removed. Polymethylmethacrylate (Tianjin Synthetic Material Industrial Research Institute Co., Ltd, Tianjin, China) was prepared with barium sulfate and when satisfactory consistency was achieved, was injected under fluoroscopy into the cavity in the vertebral body. The volume of cement and times of fluoroscopy during the procedure were recorded. All instrumentation was removed at the end of the procedure (**Figure 3A, 3B**).

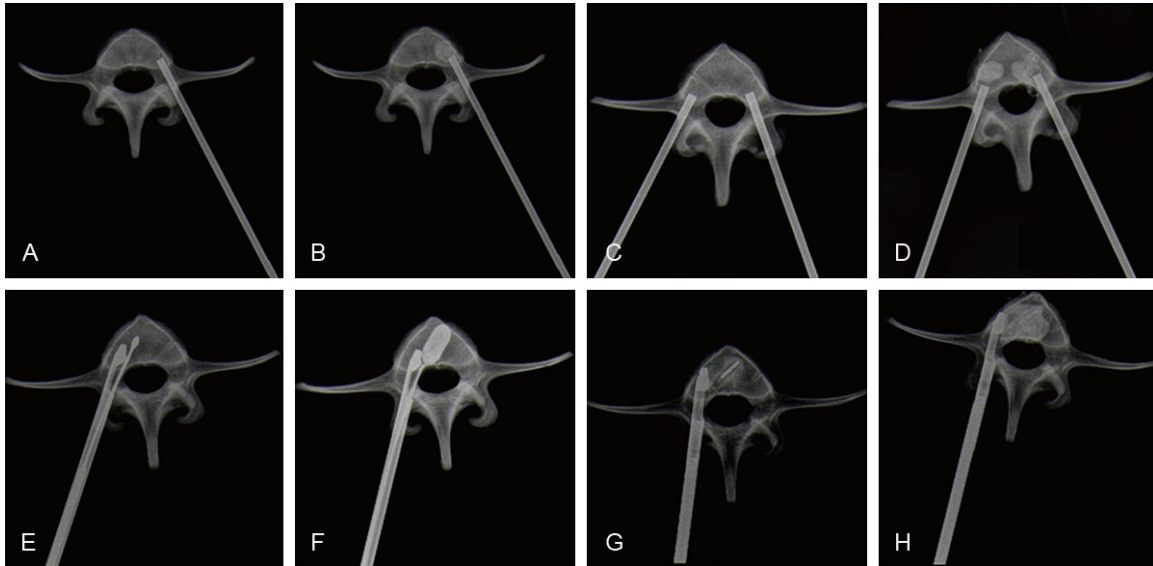
#### *Group B*

For group B, the procedure was almost the same as group A but cement was administered through bilateral pedicle. The volume of cement and times of fluoroscopy during the procedure were also recorded (**Figure 3C, 3D**).

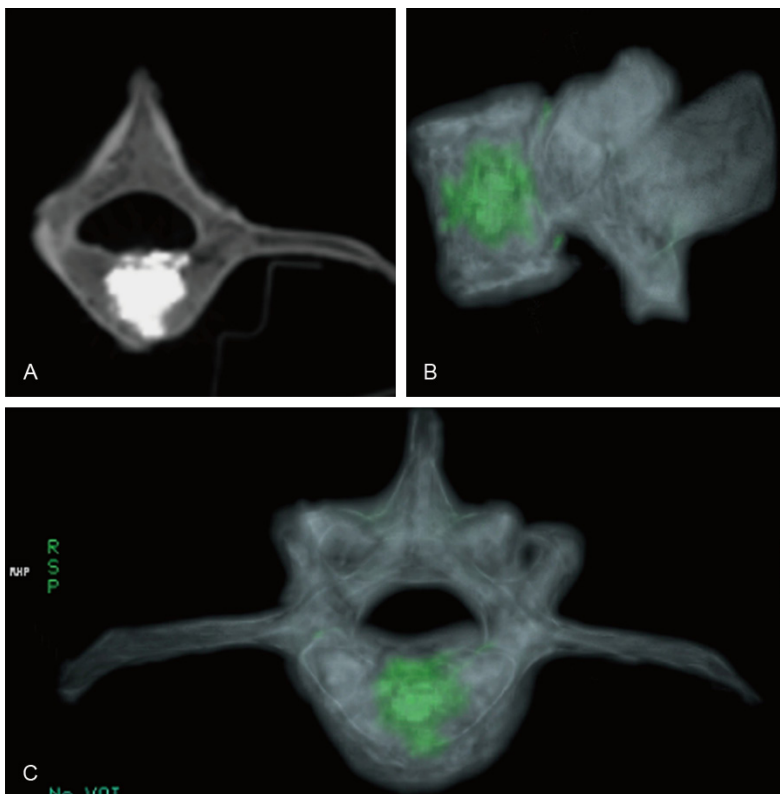
#### *Group C*

For group C, a needle 3.0 mm in diameter was advanced through unilateral pedicle into vertebral body utilizing intermittent fluoroscopy. The needle was exchanged for a working cannula over a K-wire 1.5 mm in diameter through which a drill trocar was advanced creating a channel

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**Figure 3.** Intraoperative real-time fluoroscopic images of three different techniques of PKP. A, B. Show images before and after bone cement injection in the process of conventional unilateral PKP; C, D. Show images before and after bone cement injection in the process of conventional bilateral PKP; E-H. Show the detailed processes of puncture, balloon dilation and cement injection in the novel technique.



**Figure 4.** Evaluation of the position of bone cement in the novel technique. A. Cross-sectional CT image shows the position of bone cement; B. Position of bone cement in 3D CT image (viewed from above); C. Position of bone cement in 3D CT image (viewed from the side).

for the new designed working cannula (**Figure 3E, 3F**). A drill which can be bended easily was advanced through the side hole of the new working cannula into the anterior one-third of the vertebral body under fluoroscopy then removed. The inflatable balloon tamp was advanced into the anterior of the vertebral body under fluoroscopy through the side span. The balloon was inflated under fluoroscopy no more than 200 psi (pounds per square inch). The balloon was deflated and removed. Polymethylmethacrylate was prepared with barium sulfate and injected under fluoroscopy into the cavity in the vertebral body through the side spans on the new injector when satisfactory consistency was achieved (**Figure 3G, 3H**). The volume of cement and times of fluoroscopy use

**Table 1.** BMD before and after decalcification in each group

	BMD (g/cm <sup>3</sup> )	
	Before decalcification	After decalcification
Group A	0.707 ± 0.062	0.482 ± 0.075
Group B	0.761 ± 0.054	0.543 ± 0.119
Group C	0.744 ± 0.061	0.553 ± 0.059

during the procedure were recorded. All instrumentation was removed at the end of the procedure. Positions of the injected bone cement were evaluated using CT and three-dimensional CT (Figure 4).

*Biomechanical tests*

Biomechanical indexes including the yield load values and the stiffness values were recorded. The yield load values were computed for each vertebra on the Electromechanical Universal Testing Machine and stiffness values were computed using linear models fitted to the linear portion of the force and moment load-displacement curves.

*Statistical analysis*

The data are presented as the mean ± standard deviation and were analyzed using the software SPSS 20.0. An ANOVA (Analysis of variance), in conjunction with the least significant difference (LSD) test, was used to examine the differences of the measurements including BMD, AVBH, yield load, stiffness and bone cement volume among the three groups. Due to the absence of homogeneity of variance, Kruskal-Wallis test was used to investigate the difference of times of fluoroscopy among groups instead. Paired t test was conducted to investigate the difference of AVBH between before and after PKP. The statistical analyses were 2-sided, and P < 0.05 was considered statistically significant.

**Results**

Thirty vertebrae were all successfully modeled as osteoporotic compression fractures using the above methods and were corrected by three different techniques of PKP. Among the 30 specimens, there were 8 cases of bone cement leakage (2 in group A, 4 in group B and 2 in group C). Detailed measurements were shown below.

*BMD*

BMD was 0.707 ± 0.062 g/cm<sup>2</sup> in group A, 0.761 ± 0.054 g/cm<sup>2</sup> in group B and 0.744 ± 0.061 g/cm<sup>2</sup> in group C, decreasing by 31.8%, 28.6% and 25.7% after demineralization, respectively (Table 1), representing a range consistent with that of osteopenic vertebrae. No significant difference was found among groups before (P = 0.1871) or after demineralization (P = 0.1694).

*Anterior vertebral body heights*

Initial anterior vertebral body heights (AVBH) were 30.96 ± 1.96 mm in group A, 32.44 ± 2.94 mm in group B and 33.60 ± 2.53 mm in group C, which decreased to 24.32 ± 2.65 mm in group A, 26.03 ± 2.62 mm in group B and 25.62 ± 1.57 mm in group C post-compression and increased to 26.55 ± 1.91 mm in group A, 29.22 ± 1.78 mm in group B and 29.78 ± 2.28 mm in group C following Kyphoplasty. No significant difference was found among groups before (P = 0.1091) or after compression (P = 0.2461). Kyphoplasty significantly improved AVBH for each group (P < 0.05).

We also recorded the difference between AVBH before and after kyphoplasty, which represents the recovery of AVBH due to kyphoplasty. The results showed that statistical difference was only found between group C and A (group C vs. group A, P = 0.002). Compared with group B, AVBH was not significantly improved in group C (Table 2).

*Yield load and stiffness*

No significant difference was found among groups in yield load (P = 0.9028) and stiffness (P = 0.2341) initially. Kyphoplasty caused a significant increase in yield load of vertebral bodies in each group (by 65.69 ± 56.26%, P = 0.0033; 90.98 ± 34.21%, P < 0.001 and 101.26 ± 63.22%, P < 0.001 respectively) as similar results were found in stiffness (54.55 ± 24.87%, P = 0.0144; 92.45 ± 33.41%, P = 0.0001 and 79.38 ± 25.69%, P = 0.0032 respectively). Values of Yield load in both group B and group C were significantly higher than that in group A, however, no significant difference was found between group B and C (P = 1.000). Statistical analysis of stiffness has similar results to Yield load. Stiffness of verte-

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**Table 2.** Anterior vertebral body heights of each group before and after compression as well as after kyphoplasty

	Anterior vertebral body heights (mm)			
	Before compression	After compression	After kyphoplasty	D
Group A	30.96 ± 1.96	24.32 ± 2.65	26.55 ± 1.91	2.22 ± 0.94
Group B	32.44 ± 2.94	26.03 ± 2.62	29.22 ± 1.78	3.09 ± 1.57
Group C	33.60 ± 2.53	25.62 ± 1.57	29.78 ± 2.28	4.23 ± 0.9*

D = AVBH (After kyphoplasty) - AVBH (After compression), represents recovery of the anterior vertebral body heights after kyphoplasty. \*Compared with Group A, P < 0.05.

**Table 3.** Yield load and stiffness before and after kyphoplasty

	Before kyphoplasty		After kyphoplasty	
	Yield load (N)	Stiffness (N/mm)	Yield load (N)	Stiffness (N/mm)
Group A	2173.82 ± 841.26	864.72 ± 335.79	3282.04 ± 604.04	1278.10 ± 347.05
Group B	2269.19 ± 577.25	1006.42 ± 305.25	4190.36 ± 670.57	1873.96 ± 484.68
Group C	2316.60 ± 709.89	1148.29 ± 432.99	4311.22 ± 535.21	2005.51 ± 668.30

**Table 4.** Cement volume and fluoroscopic radiation exposure of each group during kyphoplasty

	Cement volume (ml)	Times of fluoroscopic radiation exposure
Group A	2.93 ± 0.27	6.2 ± 0.63
Group B	5.99 ± 0.27	15.1 ± 1.52
Group C	3.83 ± 0.39	8.7 ± 0.95

brae in group B and group C was superior to that in group A, but there was no significant difference between group B and C (P = 1.000) (Table 3).

### *Cement volume and fluoroscopic radiation exposure time*

Volume of bone cement used inkyphoplasty in group C was less than group B but more than group A. Mean times of C-arm use in the process of kyphoplasty for single vertebra were 6.2 ± 0.63, 15.1 ± 1.52 and 8.7 ± 0.95 respectively in group A, B and C.

Statistical results showed that operation in group C needed moreradiation exposure than in group A but less than in group B (Table 4).

### **Discussion**

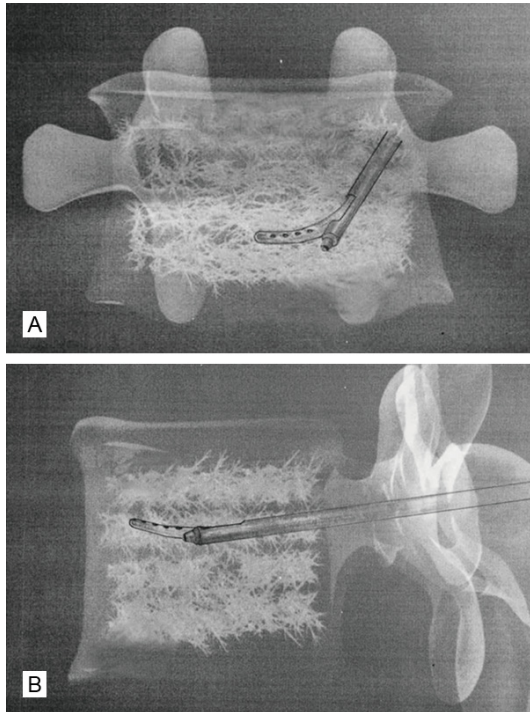
Effects of PKP in treating osteoporotic vertebral compression fractures have been demonstrated in many studies [1-5, 16, 17]. Due to disadvantages of longer operation time, more surgical trauma and higher doses of radiation

exposure [18], traditional bilateral PKP is gradually replaced by unilateral approach. However, problems such as asymmetric distribution of bone cement also existed in unilateral PKP, thus leading to biomechanical imbalance of the vertebra [6, 7, 15]. Given this, we designed this novel device to overcome the weaknesses of unilateral PKP.

Our design makes the injection cannula and balloon able to target the central of the vertebral body about 20° away from the working trocar through the side hole when the drill cleaned a pathway. The balloon which arrives appropriate destination can elevate endplate by tamping cancellous bone of the vertebral body to create a cavity large enough for bone cement filling in the optimum point (Figure 5). Therefore, the volume of filling cement was less in group C than in group B. Given that the inflation of the balloon was in the center of the vertebral body, the risk of pedicle fracture, cement leakage to anterior or posterior walls of vertebral body can be remarkably reduced. In addition, biomechanical analyses revealed that yield load and stiffness of the vertebrae in group C were superior to those in group A (conventional unilateral technique) and comparable to those in group B (conventional bilateral approach).

Besides, it's worth mentioning that our novel technique needed lower doses of radiation exposure compared with conventional bilateral PKP. In summary, our novel technique can achieve equal biomechanical strength with less

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**Figure 5.** Schematic drawings shows the injection cannula arriving center of the vertebral body. A. Viewed from the front; B. Viewed from the side.

bone cement and lower doses of radiation exposure. The present research still has some limitations. For instance, this study was conducted on animal models not humans, however, the vertebral anatomy of hogs and humans are not quite the same, thus maybe leading to inconsistent biomechanical results.

In the present study, the incidence rate of bone cement leakage was higher than that in clinical human studies which may be caused by the relatively smaller size of the hogs' vertebrae compared with humans. Additionally, despite randomization, our research was based on a relatively small sample size which may also lead to bias between the groups. Therefore, a study with a large sample size was needed to support the effects of our novel technique of PKP. In our further study, we planned to conduct cadaveric and clinical studies to provide sufficient evidence of this novel technique.

In conclusion, this novel designed device can be easily and safely used in unilateral PKP. Our research demonstrated that our novel technique of PKP can not only achieve effective biomechanical strength but also significantly

reduces risk of radiation exposure in the operation.

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### Disclosure of conflict of interest

None.

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