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Treatment Efficacy of CT-Guided Percutaneous Kyphoplasty Combined with Three-Dimensional Coordinate Guidance System on Osteoporotic Vertebral Compression Fracture

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Abstract: *Purpose:* To investigate the clinical effect of percutaneous kyphoplasty (PKP) guided by computed tomography (CT) combined with the three-dimensional coordinate guidance system on the treatment of osteoporotic vertebral compression fracture (OVCF). *Methods:* 32 cases of OVCF in the elderly admitted to our hospital from October 2019 to March 2021 underwent CT-guided PKP combined with the three-dimensional coordinate guidance system, and 36 vertebrae were treated. The patients' VAS pain scores (visual analog scale) and ODI (Oswestry disability index) were observed after surgery, and the paired *t*-test was used to compare these indexes. *Results:* The 36 vertebrae that were treated with CT-guided PKP combined with the three-dimensional coordinate guidance system underwent unilateral pedicle puncture according to the path planned by CT images. With the ideal position of the puncture needle and a high success rate of puncture, the puncture time was 1.2–2.6 minutes, with an average of about 1.5 minutes; the injected bone cement ranged from 3 to 5.5 mL, with an average of 4.2 mL, and there were no spinal nerve injuries or leakage of the cement in the canal. VAS score decreased from 7.65 ± 0.60 before the operation to 2.59 ± 0.28 one day after the operation ($P < 0.01$); ODI decreased from 62.3 ± 2.18 before the operation to 27.91 ± 1.32 after the operation ($P < 0.01$). *Conclusion:* The application of CT-guided PKP combined with the three-dimensional coordinate guidance system has the advantages of accurate puncture, short operation time, less intraoperative bleeding, and low complications. This treatment is safe, reliable, and satisfactory for patients, and is worthy of clinical promotion.

Keywords: Computed tomography; Three-dimensional coordinate guidance system; Percutaneous kyphoplasty

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1. Introduction

With the aging of society, the prevalence of osteoporosis is rapidly increasing. Osteoporotic vertebral compression fracture (OVCF) is the most common fracture, and it has become one of the major diseases that seriously threaten the health of the elderly. As an emerging minimally invasive technique for the treatment of OVCF in recent years, percutaneous kyphoplasty (PKP) has been gradually popularized and applied for its advantages of rapid pain relief, improvement of kyphotic deformity, and relatively less cement leakage [1,2]. As PKP surgery requires several adjustments of the angle of the C-arm X-ray in the prone position for surgical positioning [3], elderly patients often have spinal deformities, severe spinal degeneration, and other pathological changes, which make it difficult for them to tolerate being in the prone position for a long period. Therefore, completing the surgical operation as soon as possible, reducing surgical complications, and minimizing intraoperative accidents are the keys to treating elderly OVCF. Conventional PKP surgery involves vertebral puncture and cement injection under C-arm X-ray monitoring, which is complex and requires a physician with surgical experience. Therefore, the risk of vertebral body puncture and intraoperative complications such as cement leakage are still important factors affecting the surgical results at present. Operators are exposed to ionizing radiation and surgeons have a long learning curve. In order to improve the accuracy of targeted puncture and puncture efficiency in vertebroplasty, PKP surgery was guided by computed tomography (CT) with the help of the three-dimensional coordinate guidance system, which can achieve fast and precise puncture and better observation of cement dispersion during cement injection, greatly reducing the risks of spinal cord and nerve injury and cement leakage, and shortening the operation time.

2. Structure and working principle of three-dimensional coordinate guidance system

The guiding instrument is composed of body frame, head frame, and guiding system, which is a "three-dimensional coordinate body," utilizing precise micro-angular displacement sensors to realize the digital display of any three-dimensional angle of the X-axis, Y-axis, and Z-axis. In the process of specific puncture diagnosis and treatment, with the help of CT scanning, the puncture path from the body surface to the deep target point is planned in advance on the CT image, and the data of the two-dimensional or three-dimensional angle of the puncture path is measured by the CT measurement software. The above data is presented in three dimensions through the guiding instrument, so it can be accurately guided in accordance with the pre-designed puncture path and facilitate the puncture operation, so that it can be completed in a simple, easy-to-grasp, safe, and error-free manner.

3. General information and methods

3.1. General information

From October 2019 to March 2021, 32 cases of osteoporotic vertebral compression fracture in the elderly admitted to our hospital were selected. Among them, 8 cases were male and 24 cases were female; their age ranged from 56–91 years old, with an average age of 74 years old; there were 29 cases of single-segment fracture, 2 cases of two-segment fracture, and 1 case of three-segment fracture, involving 23 lumbar vertebrae, 13 thoracic vertebrae.

Inclusion criteria included patients who agreed to the operation and signed the consent form for surgery; osteoporotic vertebral compression fracture confirmed by CT and magnetic resonance imaging (MRI); MRI showed that the fractured vertebral body had low signal in T1-weighted image and high signal in T2-weighted image and fat suppression; simple vertebral compression fracture, CT confirmed that there was no breakage of the posterior wall of vertebral body; normal laboratory results for blood routine, coagulation, and biochemistry.

Exclusion criteria were pathologic compression fracture of the vertebral body caused by primary tumor, hemangioma, tuberculosis, metastasis, etc.; accompanied by symptoms and signs of damage to the spinal cord and nerve roots; accompanied by severe cardiovascular disease and other basic diseases that cannot tolerate surgery;

coagulation dysfunction; skin infection at the surgical site; inability to tolerate a longer period of prone position.

3.2. Instruments and equipment

The instruments used included the three-dimensional coordinate guidance system, Germany Siemens Dual Source CT (Somatom Spirit), C-arm X-ray machine; percutaneous vertebral kyphoplasty instrumentation (provided by Shanghai Kelite Medical Technology Co., Ltd.); and MENDEC bone cement (provided by Tecres S.p.A., Italy).

3.3. Surgical method

The CT room was air sterilized before surgery, the patient was placed prone on the CT bed with the abdomen suspended in the air, and a metal positioning fence was placed in the roughly superficial area of the diseased vertebral body. A thin-layer CT scan of the diseased vertebrae was performed (1-mm tomography), which was positioned in the plane of the vertebral arch root. The transforaminal puncture path was planned on the CT tomographic images (middle and upper thoracic vertebrae via the extraforaminal route), which needed to cross the vertebral midline. Using the point where the CT infrared aperture intersected the metal fence, the projection point of the puncture path on the body surface was determined and a marking line was drawn. The medial inclination angle of the puncture path, the sagittal caudal inclination angle, and the distance from the skin puncture point to the target (pedicle base) were measured on the CT image, and the values were recorded.

A three-dimensional coordinate guidance system was installed in the patient's surgical area, and the above data were entered into the console to lock the puncture trajectory. The surgical area was routinely sterilized and toweled, and a disposable sterile protective sleeve was used to cover the guiding device. The laser light of the guiding system was turned on, the laser spot (0.5 mm in diameter) was made corresponding to the puncture point and then fixed, the puncture needle sleeve was installed (the inner diameter of which was the same as the outer diameter of the puncture needle). 1% lidocaine hydrochloride injection for local anesthesia was administered, an incision of about 0.6 cm was made on the skin, and the vertebroplasty-specific puncture needle was inserted into the puncture needle sleeve determined by the guiding instrument using a hammering method, and attention was paid to observing the scaling of the needle, reaching the pre-measured depth and the hammering method. A CT scan was performed to confirm that the needle was located in the pedicle and that the extension of the puncture path crossed the midline of the vertebral body. The core of the needle was removed, the guidewire was inserted, and the working sheath was replaced. The distal end of the working sheath was located in the middle and posterior third of the vertebral body on C-arm fluoroscopy. A bone drill was inserted and slowly advanced about 2.0 cm to the anterior middle third of the vertebral body. After the bone drill was removed, the uninflated balloon was inserted to the anterior middle third of the vertebral body. The balloon was inflated by injecting contrast medium (iohexol) until the height of the vertebral body was restored to a satisfactory level under the supervision of the C-arm, the contrast medium was withdrawn and the balloon was pushed out under the supervision of the C-arm; the cement was inserted under the supervision of the C-arm and the cement was distributed to a satisfactory level. Subsequently, a CT scan was performed to confirm that there was no leakage of the bone cement in the vertebral canal, and that the cement distribution was across the vertebral body midline to the contralateral side, and the working sheath was withdrawn. The sheath tube was removed and the incision was bandaged. The patient's blood pressure, heart rate, respiration, and oxygen saturation were monitored throughout the operation, and intravenous fluid access was established.

3.4. Evaluation of pain and mobility

The patients were evaluated before and after surgery using visual analog scale (VAS) and Oswestry disability index (ODI). The paired *t*-test was used to compare the above indexes, and there was a statistically significant difference if $P < 0.01$.

3.5. Statistical analysis

All statistical data were analyzed using SPSS21.0 statistical software, and the quantitative data were expressed as mean ± standard deviation (SD) and *t*-test was performed. All count data were analyzed using χ^2 test, and $P < 0.05$ was considered statistically significant.

4. Results

All 32 OVCF patients with a total of 36 vertebrae were successfully treated with CT-guided PKP combined with the three-dimensional coordinate guidance system, and all of them underwent unilateral pedicle puncture according to the preoperative planning path (middle and upper thoracic vertebrae via the external pedicle route). The immediate intraoperative CT scanning confirmed that the bone cement was well distributed and crossed the vertebral body midline without any complications such as leakage of the cement into the vertebral canal or nerve injury. In two of the cases, due to changes in body position, the puncture path deviated from the preoperative plan. The angle of deviation was measured according to the CT images and adjusted accordingly in the three-dimensional coordinate guidance system to correct the direction of the puncture, and the operation was completed successfully without nerve injury. The puncture time for each vertebral body was about 1–2.6 minutes, with an average of 1.5 minutes. The amount of cement injected was 3.5–4.5 mL for lumbar vertebrae and 2.0–3.5 mL for thoracic vertebrae, and the statistical results of the preoperative and postoperative VAS and ODI scores are shown in **Table 1**. The preoperative, intraoperative, and postoperative pictures are displayed in **Figures 1** to **3**, showing the image data of L1 osteoporotic vertebral compression fracture undergoing PKP treatment with the 3D coordinate guidance system in a 72-year-old female.

Table 1. Preoperative and postoperative VAS scores and ODI index (mean ± SD)

Time	n	VAS score	ODI index (%)
Preoperative	32	7.65 ± 0.60	62.30 ± 2.18
1 day postoperative	32	2.59 ± 0.28*	27.91 ± 1.32*

*$P < 0.01$ compared with preoperative

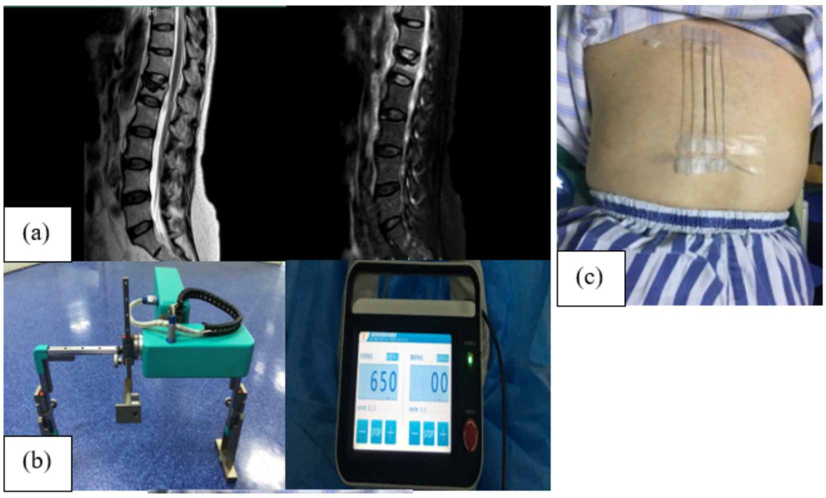

Figure 1. Preoperative pictures (a) Preoperative lumbar MRI (b) 3D coordinate guidance system and control console (c) Metal fencing placed on the body

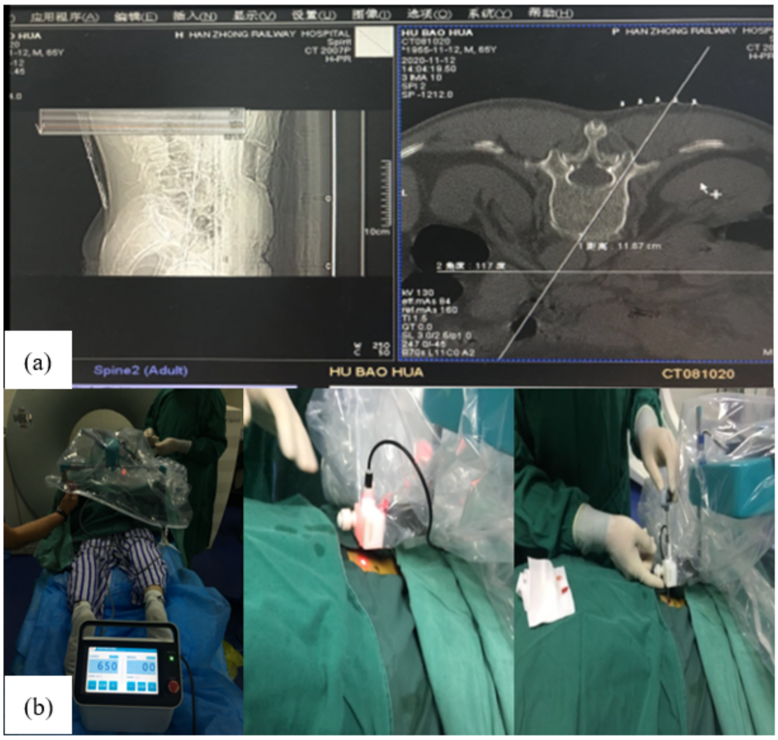

Figure 2. Intraoperative pictures (a) Intraoperative CT images for planning and designing the puncture route (b) 3D coordinate guidance system input data to determine the direction of puncture

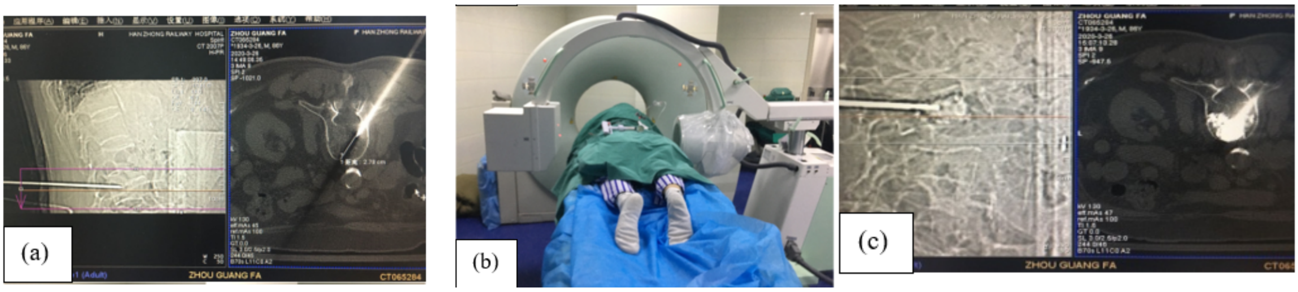

Figure 3. Intraoperative and postoperative pictures (a) Intraoperative CT scanning to verify the puncture route (b) Cement injection under C-arm monitoring (c) Satisfactory cement distribution observed on postoperative CT scanning

5. Discussion

Percutaneous vertebroplasty (PVP) has the advantages of low trauma and rapid pain relief, and is the primary means of treatment for OVCF [4-8]. Percutaneous kyphoplasty (PKP) is a modified technique developed on the basis of PVP, in which the vertebral body is inflated by a balloon, which can better restore the height of the injured vertebrae; at the same time, a cavity is formed in the vertebral body after the balloon is inflated, which can reduce the chances of cement leakage. Both PVP and PKP require the injection of polymethylmethacrylate (PMMA) bone filler into the diseased vertebrae through percutaneous puncture. This technique involves entering the vertebral body through the pedicles, which are lined with important spinal nerves and can lead to serious nerve damage if deflected, or nerve compression or nerve burns from leakage of the cement through the pedicles, as high temperatures can be generated by the polymerization of PMMA. Therefore, the surgery may be associated with a series of complications related to cement injection [9]. Hadjipavlou *et al.* [10] statistically analyzed the cement leakage rate of 2,729 vertebral bodies undergoing PVP and 1,279 vertebral bodies undergoing PKP. The overall leakage rate was 29% for PVP and only 8.4% for PKP. Chen *et al.* [11] concluded that the overall leakage rate of unilateral and bilateral PKP surgery was 14.63%. Zheng *et al.* [12] suggested that the complexity of the PKP procedure increases the incidence of surgical complications. Bone cement leakage seems to be an insurmountable problem for both PVP and PKP and has been reported in almost every relevant literature. Numerous clinical studies have confirmed that there is no direct linear relationship between the amount of bone cement injected or the degree of filling and clinical pain relief. However, most clinicians still strive to fill the vertebral body as much as possible without causing leakage, which correspondingly increases the risk of cement leakage.

Bilateral pedicle puncture approach is the classic surgical approach for PKP, but bilateral puncture, which increases the operation time, the number of intraoperative fluoroscopy, and the surgical trauma, invariably increases the surgical risk. As the concept of minimally invasive surgery continues to deepen, the advantages of unilateral approach for the treatment of OVCF continue to be highlighted. It has been reported that as long as the puncture angle is well mastered, a satisfactory therapeutic effect can be achieved by a unilateral pedicle puncture approach [13,14]. More and more spine surgeons are attempting to choose the unilateral approach for the treatment of OVCF [15]. Papadopoulos *et al.* [16] reported the use of unilateral approach for the treatment of OVCF at an early stage, and demonstrated that the unilateral approach was as effective as the bilateral approach in relieving pain and restoring the height of the vertebral body. Song *et al.* [17] concluded in a retrospective study that there was no significant difference between unilateral and bilateral approaches in the recovery of vertebral height and lordosis, but the unilateral approach was superior to the bilateral approach in the relief of pain. It has been shown that if the puncture needle crosses the midline of the vertebral body and reaches the anterior third of the vertebral body at the distal end during the unilateral approach to PKP, the bone cement can be evenly distributed in the vertebral body to achieve a mechanical balance, so that the vertebral body can be uniformly strengthened [18,19]. Unilateral approach not only can achieve similar efficacy as bilateral puncture, but also offers the advantages of shorter operation time, less trauma, and fewer X-ray fluoroscopies, etc., and there are many clinical applications and studies conducted in this area. A meta-analysis by Cheng *et al.* [20] showed that the unilateral approach group was better than the bilateral approach group in terms of operation time, trauma to the patient, and radiographic exposure, etc.

OVCF is more common in the elderly, who often have heart disease, hypertension, diabetes mellitus, pulmonary disease, renal disease, and other multi-system diseases, and cannot tolerate being in a prone position for a long period. Thus, the longer the duration of the operation, the higher the risk it brings to the patient. Conventional PKP/PVP surgery is performed under the supervision of a C-arm X-ray machine, which requires repeated fluoroscopy to observe the puncture angle from the front and side, and to gradually guide the needle to the correct position, resulting in a long surgical learning curve. The arch root of the upper and middle thoracic spine is narrow and obscured by the heart, lungs, and other mediastinal tissues, coupled with severe osteoporosis, obesity, and other patient factors, the fluoroscopic image is often fuzzy, poorly layered, and unable to clearly display the anatomical structure of the spine. This issue seriously affects the accuracy of the angle and depth of the puncture needle, resulting in a decrease in the quality of the surgery, an increase in the medical staff's radiation exposure, and a higher risk of nerve damage and other complications. It is also difficult to detect the real leakage of bone cement from the lateral image alone during cement injection. Bone cement leakage should be prevented, and high-quality and clear imaging equipment is indispensable to minimize the occurrence of bone cement leakage.

In recent years, along with the rapid development of science and technology, the high-tech combination of computer-aided surgery navigation system (CASNS) came into being. Orthopedic navigation system, on the other hand, can accurately provide the patient's preoperative or intraoperative image data and the patient's anatomical structure during surgery, track the surgical instruments during surgery, and display the position of the surgical instruments in real time on the image in the form of virtual probes, so that the surgeon can have a clear understanding of the positional relationship between the surgical instruments and the patient's anatomical structure, which can make the surgery more accurate, safer, and faster. Sun and Xu [21] reported that the use of navigation systems to guide vertebroplasty can significantly improve surgical accuracy and safety, and can shorten the operation time and reduce the number of fluoroscopy. However, the development of computer-aided navigation systems is relatively slow, and the following shortcomings exist: (1) the equipment is expensive with high costs of use and maintenance, which increases the medical burden of patients; hospitals below the tertiary level do not have sufficient purchasing power; (2) intraoperative acquisition of three-dimensional image data is required, and the transmission of the image data to the navigation system workstation for image registration is a relatively cumbersome and time-consuming operation; (3) intraoperative fixation of the dynamic reference base to the root of the spinous process requires an additional surgical incision, which increases the damage. (4) image drift, i.e., the error between the navigation system image and the real position caused by the displacement of tissue structures during surgery, is the biggest defect of the navigation system, and its incidence has been reported to be as high as 66% in foreign countries [22]; (5) as current navigation images can contain up to four vertebrae, a second image acquisition may be required in noncontiguous multi-segmental osteoporotic compression fracture cases, and even the position of the reference frame may need to be adjusted, which increases additional operation time.

Many literature reported that in CT-guided PKP surgery, the three-dimensional image of CT is used to reconstruct and localize the diseased vertebrae from multiple planes, which can more accurately determine the position and angle of the puncture needle, guide the puncture needle to reach the target position precisely, and monitor and observe the dispersion of the bone cement in real time from multiple perspectives, so as to reduce the rate of bone cement leakage [23-25]. Compared with conventional PKP surgery under C-arm, CT-guided surgery can significantly improve the precision of surgical operation, reduce complications such as nerve injury and cement leakage, and effectively improve the patient's pain and mobility, which is a safe and effective treatment method. According to Rauschmann *et al.* [26], the positioning and puncture under the guidance of a CT machine is accurate and easy to operate, and through multiple tomography scans, it is possible to grasp whether the tip of the needle enters the correct position and whether the depth is appropriate during the puncture process, and it can be adjusted according to the specific situation at that time until it is satisfactory. However, the CT-guided PKP operation is too cumbersome and repetitive, for each step, it is necessary to exit the CT examination bed, and then scan and adjust again after the operation, resulting in a time-consuming operation, which cannot provide real-time impact information and cannot guarantee the success of a puncture.

Three-dimensional coordinate guidance system is a completely mechanized, semi-automated new type of guiding system, the head frame part of which is a miniature angular displacement sensor with extremely high sensitivity. Through the control panel input data, it can realize the X-axis, Y-axis, Z-axis of any three-dimensional angle, and it can accurately present three-dimensional data such as the direction of the puncture, angle, etc., and provide intuitive guidance for the targeted puncture. The vertebroplasty performed under the joint guidance of CT and the three-dimensional coordinate guidance system offers the advantages of both approaches. By combining the advantages of the two, it overcomes the disadvantages of repeated fluoroscopy and poor image effect under the C-arm, as well as multiple step-by-step punctures under CT guidance alone, so as to complete the localization of the puncture quickly and avoid the damage caused by blind puncture and multiple adjustments of the puncture needle position. With the help of CT measurement software, the distance from the skin puncture point to the target point of the pedicle root can be accurately measured, and under the guidance of the guiding instrument, it is generally possible to perform the puncture in place at one time. In addition, the guidance system is simple, low-cost, and easy to use, is not as cumbersome as the navigation system, and does not require an additional non-penetrating part of the incision. After the successful puncture, we still rely on C-arm fluoroscopy when injecting the bone cement, which can synchronize the dynamic monitoring of bone cement dispersion, avoiding the time loss caused by moving for CT scans. When there is a tendency of leakage of bone cement injection, real-time CT thin-layer scanning can provide information on the distribution of bone cement in time, and can better recognize the safety illusion under C-arm fluoroscopy, so as to determine the time window for the termination of bone cement injection and the effective injection dose. Surgical safety is effectively ensured and blindness in puncture and bone cement injection is reduced.

CT-guided PKP combined with three-dimensional coordinate guidance system offers the following advantages: (1) abstract data such as internal inclination and sagittal inclination measured by the patient's CT three-dimensional image are presented more intuitively, making the puncture easier, faster, safer, and more accurate; (2) the maximal internal inclination angle of the path is planned according to the CT image to obtain the optimal unilateral pedicle puncture path, which prevents the additional damage caused by bilateral puncture, and significantly shortens the operation time; (3) for adjacent multi-segment vertebrae (non-continuous vertebrae) surgery, the puncture can be completed quickly in the same time period under the guidance of the guiding system, eliminating the need for multiple scanning and image acquisition, and saving fluoroscopy time to the greatest extent possible; (4) the indications for the surgery are expanded, due to the precise positioning of the puncture, the ideal position of the puncture can also be obtained in patients with vertebral compression of more than 75%; (5) the equipment is easy to operate and master, which shortens the learning curve of PKP surgery; (6) the cost of the equipment is cheaper than that of the computerized navigation system, and the maintenance cost is low, which makes the medical burden borne by the patients light and acceptable.

6. Conclusion

In summary, CT-guided PKP combined with the three-dimensional coordinate guidance system is simple, fast, and highly accurate in puncture, which improves the safety of patients without increasing medical expenses, and reduces radiation exposure to medical staff. Thus, the clinical effect is satisfactory and worthy of popularization in clinical application.

Disclosure statement

The authors declare no conflict of interest.

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