Prospective Study

Efficacy and Safety of Establishing an Optimal Path Through Unilateral Pedicle Under the Assistance of Surgical Robot in Percutaneous Kyphoplasty

Jun Qian, PhD, Chao Fang, MD, Peng Ge, MD, Ren-Jie Zhang, PhD, Pei-wen Song, PhD, Peng Xu, PhD, Yong Zhang, PhD, and Cai-Liang Shen, PhD

From: Department of Orthopedics & Spine Surgery, The First Affiliated Hospital of Anhui Medical University, Anhui Province, China

Jun Qian and Chao Fang contributed equally to this study.

Address Correspondence: Cai-Liang Shen, PhD Department of Orthopedics & Spine Surgery, The First Affiliated Hospital of Anhui Medical University, No.218 Jixi Road, Shushan District of Hefei, Anhui Province, China. E-mail: shencailiang@ahmu.edu.cn

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Background: Despite percutaneous kyphoplasty (PKP) being widely used to treat osteoporotic vertebral compression fractures (OVCFs), the details of puncture are still controversial. With the development of surgical robots in spine surgery, robotic-assisted PKP surgery will become a promising treatment strategy.

Objectives: To evaluate the efficacy and safety of establishing an optimal working path through a unilateral pedicle approach to improve bone cement distribution under the assistance of a surgical robot in percutaneous kyphoplasty.

Study Design: Experimental and prospective study.

Methods: PKP surgery under the assistance of the TINAVI robot was performed on 78 patients with osteoporotic vertebral compression fractures (OVCFs) from May 2018 to January 2020 in a single spine center. During the operation, the optimal path of the working channel made through unilateral pedicle puncture was designed according to the details of the fractured vertebral body under the guidance of the TINAVI surgical robot. Visual analog scale (VAS) scores of back pain, intraoperative blood loss, surgical time, and complications were recorded and evaluated. Postoperative fluoroscopy and 3D-CT were used to evaluate the distribution of bone cement.

Results: We have successfully performed 78 PKP surgeries under the assistance of the TINAVI robot. The mean procedure time was 13.9 ± 2.6 minutes from the beginning of C-arm scan to finish the injection of bone cement, and the intraoperative blood loss was 5.4 ± 2.8 mL. Pain of all cases was relieved immediately and significantly after PKP surgery; the VAS score was 7.5 ± 2.3 before surgery and 1.4 ± 0.8 post-surgery. The mean volume of bone cement was 4.7 ± 1.9 mL, and bone cement leakage occurred at the anterior edge of the fractured vertebral body in 2 patients, with no neurological and vascular injury in any of the cases. Postoperative fluoroscopy and 3D-CT showed that a good bone cement distribution evenly through unilateral pedicle puncture in the fractured vertebral body in all cases except the bone cement leakage in 2 patients.

Limitations: More cases are needed to evaluate the efficacy and stability of robot-assisted PKP surgery. A control group of PKP performed freehand should be included in this study.

Conclusions: Robotic-assisted PKP surgery through the unilateral approach to establishing an optimal working channel is a safe and available procedure for treating OVCFs in terms of better distribution of bone cement, high accuracy, good repeatability, and less surgical trauma.

Key words: Surgical robot, percutaneous kyphoplasty, unilateral pedicle approach, osteoporotic vertebral compression fractures, TINAVI, optimal path, spinal surgery, treatment strategy

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Percutaneous kyphoplasty (PKP) is a minimally invasive technique to inject bone cement into the diseased vertebrae under image guidance for reinforcement of vertebral structure and relief of back pain (1,2). In recent years, PKP has become a widely used procedure for treating painful osteoporotic vertebral compression fractures (OVCFs) (3,4). To a certain extent, a successful PKP procedure depends on a good puncture path, whether from a unilateral or bilateral approach, because an inaccurate puncture path could result in a bad bone cement distribution, bone cement leakage, or even serious complications such as nerve and blood vessel injury (5). Compared with the bilateral approach, puncture from a unilateral approach has the advantages of less surgical trauma and x-ray irradiation (6). However, some studies have reported that the complications including nerve and vascular injury, secondary vertebral fractures, dissatisfied bone cement distribution in the diseased vertebral body, and trauma associated with puncture, are closely related to the puncture technique and approach (7,8).

For the accuracy of puncture from a unilateral pedicle approach, a navigation system has been used in PKP procedures (9,10). Nowadays, with the development of surgical robot technology, it is gradually applied in spine surgery to increase the accuracy of pedicle puncture and reduce potential puncture complications. In the present study, an optimal working channel through pedicle puncture from a unilateral approach (Fig. 1) according to the details of the fractured vertebrae with OVCFs is established under the assistance of a new surgical robot. The new surgical robot system, namely the TINAVI robot assistant system, has been researched and made in China (developed by TINAVI Medical Technologies Co., Ltd.). Through the computer navigation system for 3-dimensional (3D) image data registration, operators can accurately design the puncture path to establish an optimal working channel to inject bone cement into the vertebral body from a unilateral approach (11). The purpose of this study was to introduce a new puncture technique from the unilateral approach in PKP surgery guided by the TINAVI robotic-assisted system and also to evaluate the efficacy and safety of establishing an optimal path through the unilateral pedicle to improve bone cement distribution under the assistance of a surgical robot in percutaneous kyphoplasty.

Methods

Patients

In the present study, 78 patients with OVCFs who underwent PKP surgery via unilateral pedicle approach assisted by TINAVI surgical robot in the First Affiliated Hospital of Anhui Medical University from May 2018 to January 2020 were analyzed prospectively. All patients were evaluated using bone mineral density measurement and imaging examination for the diagnosis of OVCF. There were 68 women and 10 men with an average age of 72.3 years (range, 62-92). The inclusion criteria were as follows: (1) Low back pain, aggravated when sitting up or turning over in bed, (2) Fresh osteoporosis compression thoracolumbar fractures or Kummell's disease, and (3) Poor efficacy of conservative treatment. The exclusion criteria were as follows: (1) Old osteoporosis compression thoracolumbar fractures, (2) Unidentified thoracolumbar fractures with suspi-

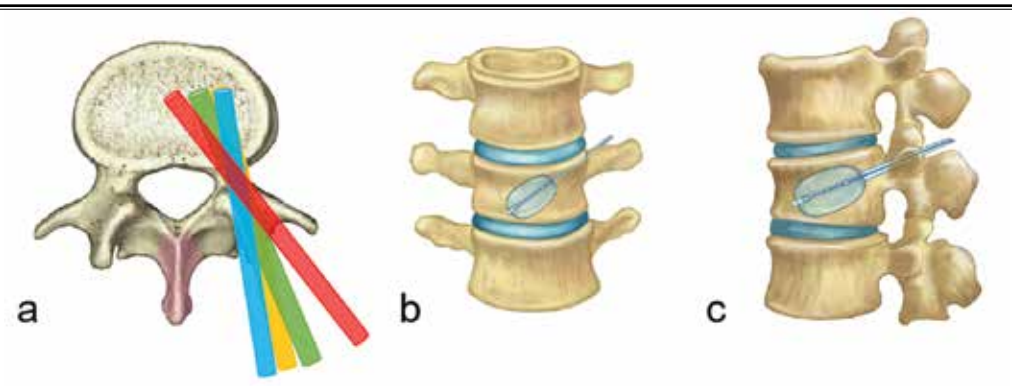

Fig. 1. *Diagram of the optimal puncture path. (a) Transverse section diagram of puncture path in vertebra body, the red one represents the optimal path. (b, c) Pedicle puncture through the unilateral approach.*

cious tumor, (3) spinal metastases or tumor in combination with OVCF, and (4) Contraindications to general anesthesia or coagulation dysfunction. All procedures in this study were approved by the Ethics Committee of the First Affiliated Hospital of Anhui Medical University.

TINAVI Surgical Robot

The TINAVI robot assistant system is composed of an infrared navigation system, host control system, and manipulator system (Fig. 2). During operation, the spine parameters of patients are automatically transmitted to the robot host control system after scanning by a 3D C-arm (Siemens, Erlangen, Germany). Through measuring the implantation depth of the guide pin and simulating the optimal working path according to the details of the fractured vertebral body, the actual operation instructions are conveyed to the mechanical arm by the host system. According to the operation instructions, the mechanical arm will automatically aim the puncture guide rod to the optimal target position.

Surgery Procedures

All surgical procedures were performed in the standard operating room. Patients with general anesthesia were positioned prone. Then, the position of the target vertebra pedicle and spinous process was marked after x-ray. After routine disinfection, the infrared tracker was fixed on the skin of the superior segment of the

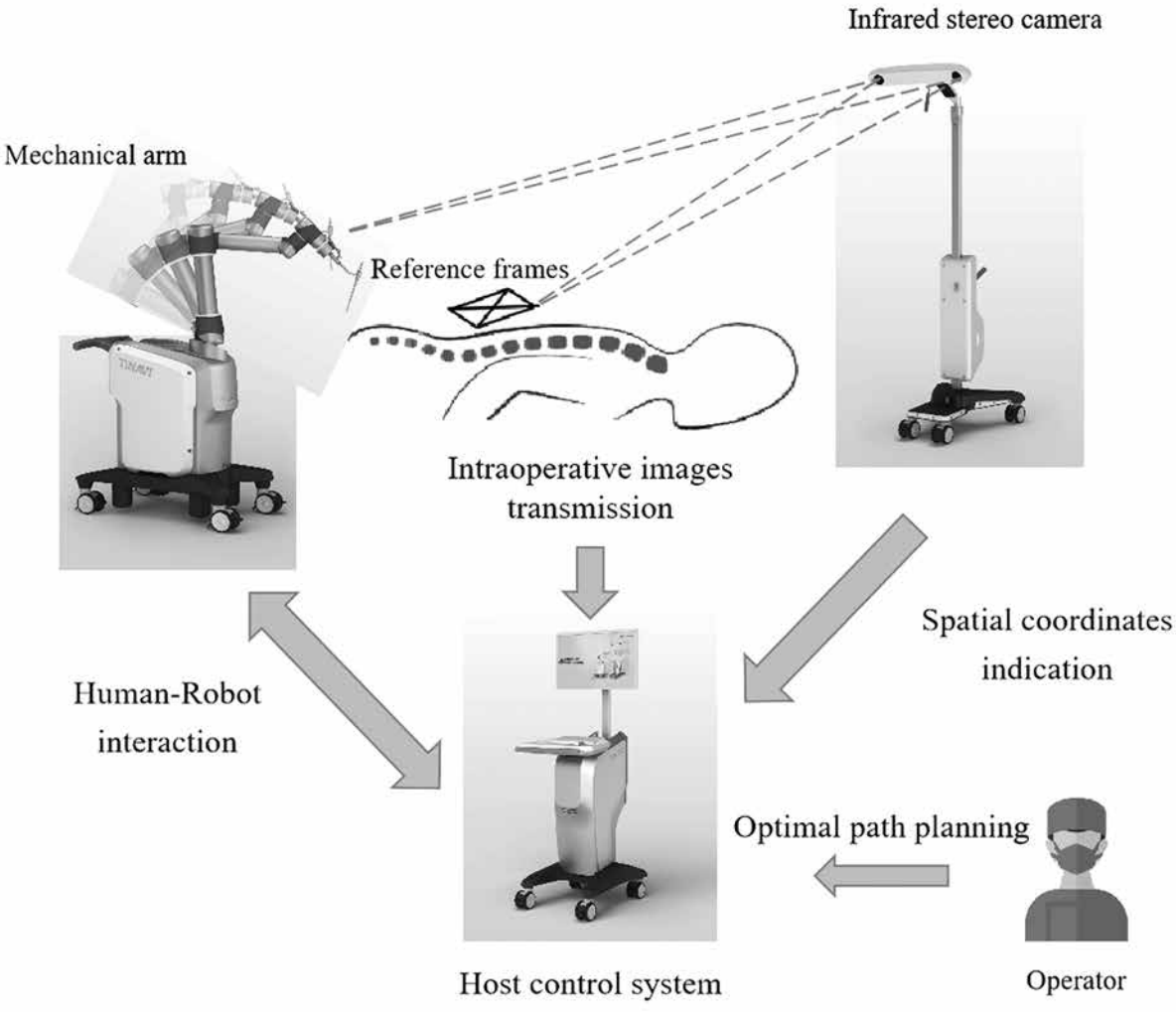

Fig. 2. *Working diagram of the TINAVI robot assistant system.*

fractured segment, and the positioning indicator was placed parallel to the skin of the target area (a distance of about 5mm was kept to eliminate the interference of respiratory movement) (Fig. 3a). All marked points on the infrared tracker (sagittal, coronal, and transversal surface) were in view of the 3D C-arm (Fig. 3b,c). The 3D C-arm would automatically scan the target segment and transmit the 3D images to the host control system of the TINAVI robot for registration, and then the optimal puncture path was designed, including the puncture position, direction, and depth of guide pin (Fig. 4b,c). According to the operation instructions of the host control system, the mechanical arm would automatically align the guide rod to the puncture site and then drill the guide pin into the fractured vertebral body through a unilateral pedicle approach (Fig. 4a). C-arm fluoroscopy was used to confirm whether the position of the guide pin was in accord with the optimal working channel designed before surgery (Fig. 4d,e). Then, the working channel was inserted along the guide pin, and the fractured vertebral body was propped up with a balloon (Fig. 4f,g), and then bone cement was injected into the target vertebral body under fluoroscopy. The injection amount of bone cement was determined by the segment of the fractured vertebra and the distribution of bone cement observed during operation. All cases underwent routine pathological examination after surgery. The workflow of the robotic-assisted PKP surgery is shown in Figs. 3 and 4.

Clinical Outcome Measures

To evaluate the efficacy and safety of establishing an optimal working path through a unilateral pedicle approach under the assistance of the TINAVI surgical robot in PKP procedure, intraoperative blood loss, surgical time, the volume and leakage of bone cement, and complications were all recorded. A 3D-CT of the target spine segment post-PKP surgery was used to identify the bone cement distribution. A VAS score from 0 (no pain) to 10 (maximal pain) was also used to assess the back pain before and after surgery.

Statistical Analysis

All data were analyzed by SPSS 17.0 software (SPSS Inc., Chicago, IL, USA). The measurement data were expressed as mean ± standard deviation, and t-test was used for comparison between preoperative and postoperative, with $P < 0.05$ indicating statistical significance.

Results

PKP procedures, including establishing an optimal working channel through the unilateral pedicle approach according to the details of the fractured vertebral body under the guidance of the TINAVI surgical robot, were successfully performed on 78 patients. All patients were able to move autonomously, including sit, stand, and walk on the first day after PKP surgery, and no nerve and vascular injury showed in any patient. The mean procedure time was 13.9 ± 2.6 (range, 12-19) minutes from the beginning of the C-arm scan to the insertion of the guide pin. The incision was less than 6 mm, and the mean intraoperative blood loss was 5.4 ± 2.8 mL. There was no additional muscle and organ damage except for blunt dissection of lumbar muscles to insert the working channel. In addition, low back pain was relieved immediately and significantly after PKP surgery. The mean VAS score in all cases was 7.5 ±

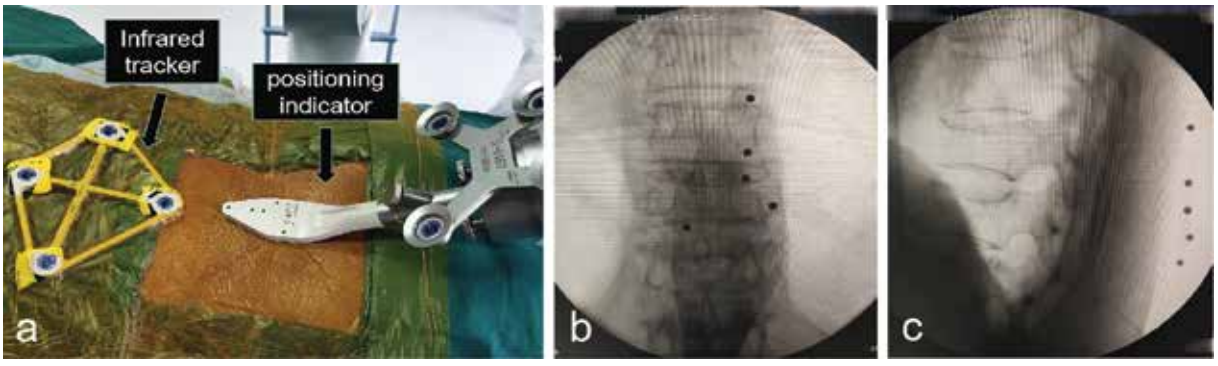

Fig. 3. *Diagram of positioning indicator of TINAVI robot in the body surface. (a) Locate target vertebra by infrared navigation system; (b, c) A-P and lateral view were investigated.*

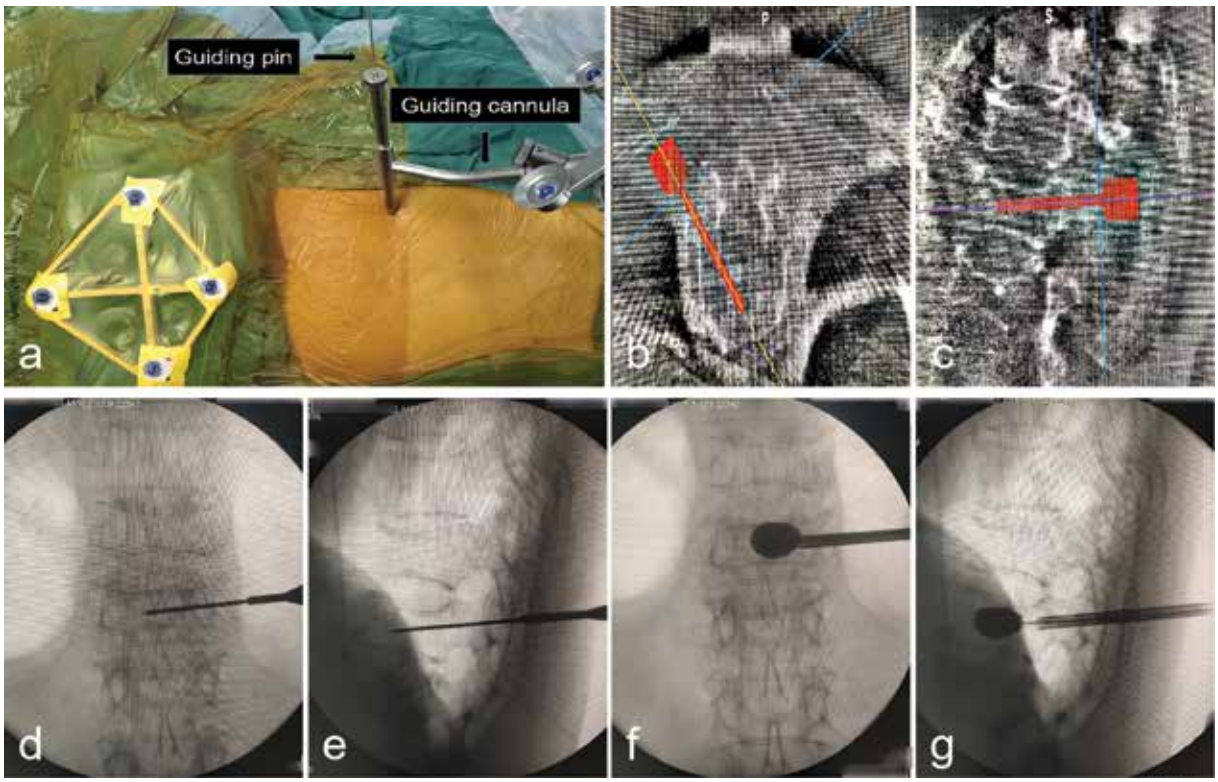

Fig. 4. *Workflow of robotic-assisted PKP surgery. (a) Implant the guiding pin along the direction of the guiding cannula; (b,c) Design the optimal puncture path on a 3D image; (d,e) Confirm the position of the guiding pin by intraoperative 3D C-arm fluoroscopy; (f,g) Intraoperative 3D C-arm fluoroscopy to confirm the position of the balloon.*

2.3 before surgery and dropped to 1.7 ± 0.9 on the first day postoperative; a statistical difference in the mean VAS score was shown before and after PKP surgery ($P < 0.05$).

The mean injection volume of bone cement was 4.7 ± 1.9 (range, 3-7.5) mL. Two cases showed bone cement leakage at the anterior and lateral edge of the fractured vertebral body, but no peripheral tissue and nerve injury or bone cement distant migration was found in these 2 cases. Postoperative x-ray and 3D-CT of each patient showed that the bone cement filled in the fractured vertebral body and located on both sides of the midline in the vertebral body evenly from the coronal CT scan (Fig. 5). No secondary vertebral body fractures occurred postoperatively in any of the cases through the last follow-up.

Discussion

Since PKP was first introduced by Mark Reiley in 1999, PKP has been widely used to treat OVCFs and spinal tumors successfully. However, up until now, there has been no clinical guideline about PKP procedures, and there are still some debates about the puncture details related to the practical application of PKP, such as puncturing from unilateral pedicle approach and bilateral approach (12). Chung et al (13) considered that a bilateral approach had advantages in reducing the vertebral fracture and avoiding loss of vertebral height. It also demonstrated that injection of bone cement from a unilateral approach could achieve the same clinical and imaging results as from a bilateral approach (14). Therefore, there is no clinical consensus on whether to puncture through a unilateral or bilateral pedicle approach in PKP surgery.

Although it can significantly reduce pain and correct kyphosis post PKP from a unilateral or bilateral pedicle approach, the unilateral approach was favored by many operators because of its shorter operation time, less radiation intake, and trauma compared with the bilateral approach (15). However, the abduction angle of the puncture pin would inevitably increase if puncturing just from a unilateral approach, which will

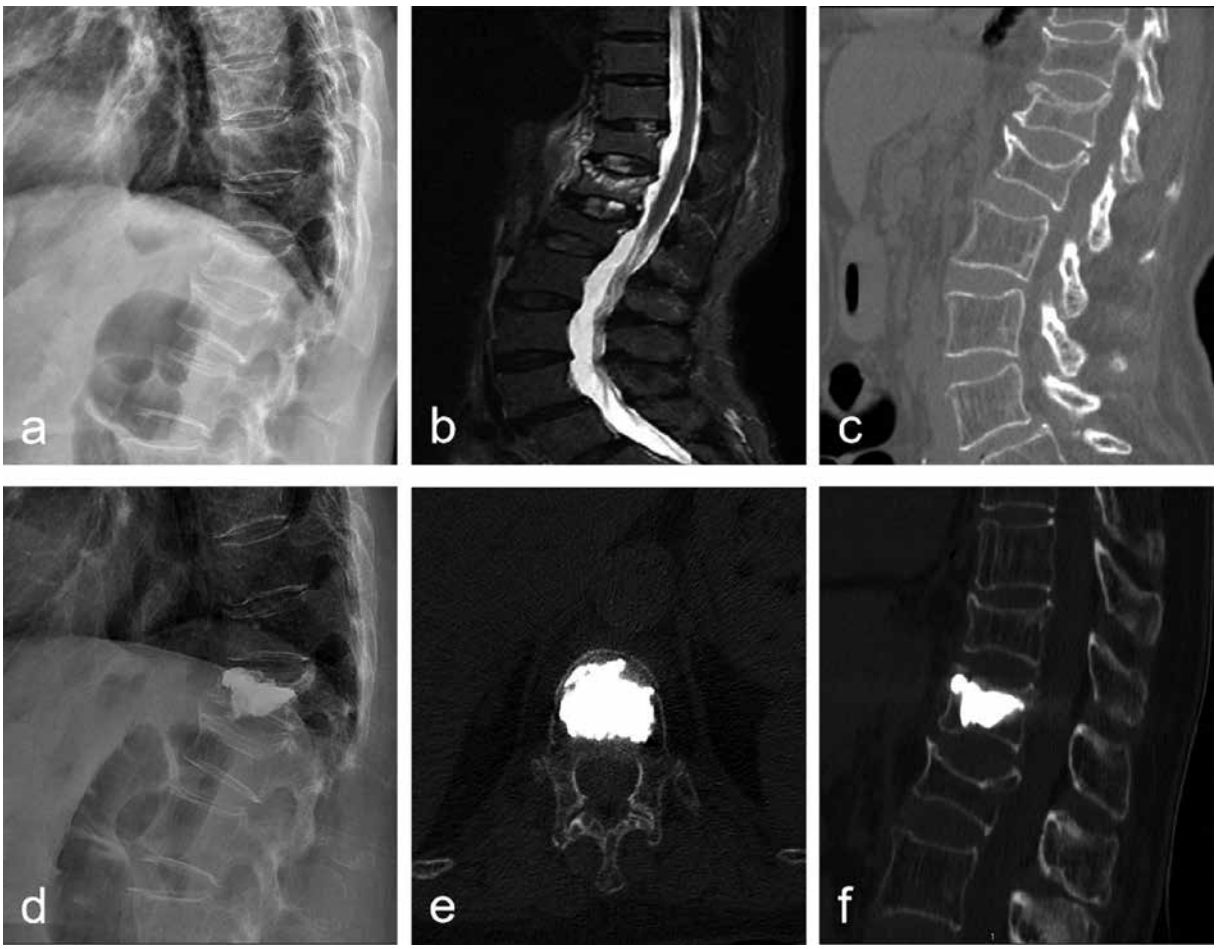

Fig. 5. *Preoperative and postoperative images in a case with osteoporotic compression fracture treated by PKP surgery under the assistance of a TINAVI surgical robot. (a) Lateral view of lumbar spine before surgery, compression fracture was shown at T11,12 and L1; (b) The fracture at T12 was new in MRI of lumbar spine before surgery; (c) Preoperative coronal CT of lumbar spine; (d) Lateral view of the lumbar spine after surgery; (e,f) Postoperative horizontal and coronal CT of the lumbar spine showed an even distribution of bone cement at T12 vertebral body.*

increase the risk of nerve injury under the condition of manual operation (16). Furthermore, in order to obtain better distribution of bone cement, the amount of bone cement injected from the unilateral approach will increase correspondingly, which is likely to result in more risk of bone cement leakage (17). Chen et al (18) demonstrated that a stress balance of both sides of the vertebral body could be obtained when the bone cement extends across the midline and fills the non-punctured side in unilateral PKP. This finding suggests that the injection point of bone cement should be as close to the midline of the fractured vertebrae as possible in the sagittal and coronal position in order to obtain good bone cement distribution in unilateral PKP. Therefore, a safe and accurate puncturing method just from the unilateral pedicle approach for a better bone cement distribution, less risk of nerve injury and trauma in PKP surgery will be more meaningful and important for the balance of biomechanics of the fractured vertebrae.

At present, various surgical robots are applied in spine surgery. Due to the accuracy of robotic-assisted system positioning, the complications of spine surgery decrease accordingly (19). In this study, we first applied the TINAVI robotic-assisted system in PKP surgery and successfully performed 78 PKP surgeries just from the unilateral pedicle approach. The TINAVI robotic-assisted system is an automatic robotic-assisted surgery instrument consisting of an infrared navigation system, a host control system, and a manipulator system. In or-

der to reduce the surgical trauma and improve bone cement distribution in PKP surgery via a unilateral pedicle approach, the optimal working path was designed and established under the guidance of the TINAVI robot. During operation, the optimal puncturing path was designed and made according to the 3D images. Through the optimal path, the bone cement was injected and distributed in the fractured vertebral body or in the target area in the diseased vertebrae body.

According to the specific conditions of the fractured vertebrae in this study, it is expected that the bone cement can be distributed in the whole vertebral body evenly. Because of the design of puncturing from a unilateral pedicle approach, the injection point of bone cement should be very accurate so that the bone cement can penetrate into the vertebral body evenly around the injection point. In order to achieve this, the puncture path in PKP with a unilateral approach is required to be very accurate and had been performed precisely under the guidance of a surgical robot.

In this study, the optimal puncture path was established successfully in 78 cases under the guidance of the TINAVI robotic-assisted system. Through the optimal puncture path, the injection point of bone cement was also in an ideal position expected before surgery. Furthermore, there was no case of nerve or blood vessel injury in any case. The average time from the beginning of the 3D scan to implantation of PKP guide pin was 13.9 ± 2.6 (range, 12-19) minutes, and the mean intraoperative blood loss was only 5.4 ± 2.8 mL. VAS scores also decreased obviously and immediately on all patients after PKP. Although it was punctured through a unilateral pedicle, the injected bone cement was distributed in the fractured vertebral body evenly with the guidance of the TINAVI robot. Furthermore, there was less surgical trauma via unilateral pedicle puncture and less risk of nerve injury caused by unilateral puncture with freehand.

Although surgical robotic-assisted PKP surgery has achieved good results in establishing the optimal working path to improve bone cement distribution, these new methods still need to be improved. For example, bone cement leakage was found in 2 patients, which reminds us to improve the accuracy of the optimal puncture path and pay more attention to the timing of bone cement injection during operation. For biomechanical balance, bone cement is injected into the fractured vertebral body and distributed evenly in the vertebral body through the optimal puncture path. Furthermore, more treated patients and longer follow-up times are required to evaluate the advantages of this new surgical technique. Unfortunately, we also did not include a control group of PKP surgery performed freehand to evaluate the efficacy and safety of establishing an optimal path through a unilateral pedicle.

Conclusion

This study showed that robot-assisted PKP surgery is a safe and available procedure for treating OVCFs with a unilateral approach. The superiorities of this procedure include high accuracy, good repeatability, and stability, minimizing damage to normal tissues, and optimizing bone cement distribution. Although there are still some defects to settle, it shows a good development prospect in PKP.

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