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The Effect of TiRobot Assisted Percutaneous Kyphoplasty in the Osteoporotic Vertebral Compression Fractures

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Abstract: *To explore the clinic application of two operative methods between orthopaedic robot systems (TiRobot) assisted and convention freehand pedicle puncture surgical procedures in percutaneous kyphoplasty (PKP). Twenty-one patients with osteoporotic vertebral compression fractures(OVCF)who underwent PKP by TiRobot-assisted in 2021 are compared to the ones by freehand in 2020.The operative intraoperative fluoroscopy frequency,pedicle puncture frequency, time, hospital length of stay and expense,postoperative recovery of the two group were recorded and compared between the two groups. The number of intraoperative fluoroscopy in the TiRobot group (RG) and the freehand group (HG) were 7.8±1.2 (RG) Vs 14.4±0.8 (HG),the number of pedicle puncture were 2.2±0.6(RG)Vs 9.4±1.1(HG),the operative time was (96.6±16.7)min (RG) Vs (69.2±12.7)min (HG), thel expenses were ¥30577.68±3542.18 (RG) Vs ¥25933.38±2735.24 (HG).These differences between the two groups were statistically significant (P<0.001).The hospital stay time was (5.7±2.3)d (RG) Vs (5.0±2.4)d (HG), the VAS score at 3 days after operation were 0.2±0.5 (RG) Vs 0.2±0.4 (HG) and the ODI index (%) at last follow-up were 4.15±4.0 (RG) VS 6.33±8.13 (HG).The above data shows no statistical difference between the two groups (P>0.05). The orthopaedic robot systems (TiRobot) has a great of potential. Although it can prolong the operation time and increase the hospitalization cost to a certain extent, it can reduce the number of intraoperative fluoroscopy, improve the accuracy of pedicle puncture, and significantly relieve the back pain and improve quality of life in a long time of patients just like the traditional freehand surgery.*

Keywords: *Osteoporotic vertebral compression fracture, Robotics, Percutaneous balloon kyphoplasty (PKP)*

1. Introduction

With the rise of people's average life span, population aging has become a worldwide phenomenon, which also makes osteoporosis a common senile disease[1]. Osteoporosis is the main cause of fractures in the elderly. The most common is vertebral compression fracture (OVCF)[2], which is also the main factor for osteoporosis patients admitted to hospital, and has brought huge economic burden to society and families. Some scholars even predict that by 2040, there will be 241.7 million female osteoporotic fracture patients in China, and the cost of treating the disease will reach US $997billion[3]. In the treatment of OVCF disease, percutaneous vertebroplasty (PVP) or percutaneous balloon kyphoplasty (PKP) is considered as a classic surgical method, which has the advantages of short operation time, less intraoperative blood loss and fast postoperative recovery[4-6]. The most critical and important operation in PVP or PKP surgery is actually the transpedicular puncture technique[7]. According to the survey of relevant people, the average width of the pedicle in Asian people is only about 8mm[8], which leads to the possibility of multiple fluoroscopy or even continuous fluoroscopy to determine the location of the puncture needle in the process of pedicle puncture[9]. But even so, there will still be some corresponding complications in clinic, such as damage to the surrounding tissues, nerves, blood vessels, etc; And the location of the puncture point will also affect the distribution of bone cement in the vertebral body, thus affecting the degree of improvement and recovery of postoperative pain. In recent years, orthopedic surgical robots have been widely used in clinic, effectively helping spine surgeons to complete surgical operations more conveniently and accurately, reducing manual errors and postoperative complications. Since 2021, our hospital has adopted the latest generation of orthopedic robots independently developed in China to assist pedicle puncture and achieved satisfactory surgical results. The situation is reported as follows.

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2. The Data and the Methods

2.1. The General Information

2.1.1. The Clinical Data

This group was a clinical randomized controlled study, including 21 patients admitted to the spine surgery group of the second Department of orthopedics, Jingdezhen first people's Hospital from January 2021 to December 2021 for PKP surgery due to OVCF, and compared with 23 patients who underwent PKP surgery with traditional fluoroscopy guided bare hands from January 2020 to December 2020. All patients gave written informed consent.

2.1.2. The Brief Introduction of Orthopedic Surgery Robot System

TiRobot, which was commercialized by Beijing Tianzhihang Medical Science and Technology Co., Ltd., is an orthopedic surgical robot product independently researched and developed in China and registered as a Class III medical device product[10]. It includes three functions: spatial mapping, path planning and path positioning. It is a robot positioning system for spatial mapping and path planning of surgery based on intraoperative 3D images (Figure 1). The system is mainly composed of surgical planning and control software system, robot and optical tracking system. The optical tracking system provides real-time tracking data of the position of the patient and the robot, and the surgical planning and control software system calculates the relative position of the surgical tool and the planned surgical path in real time according to these data, and controls the robot movement accordingly to realize the positioning compensation of the surgical tool position (Figure 2).

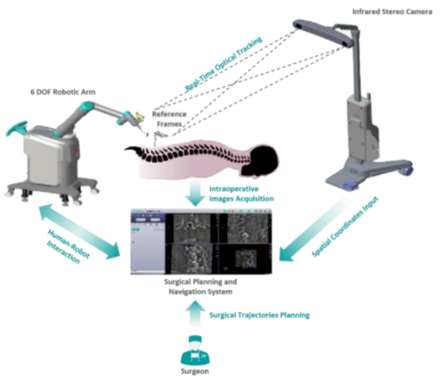

Figure 1: TiRobot (the 3rd generation orthopedic surgical robot product) (Left)

Figure 2: Schematic diagram of the operating system of TiRobot (Right)

2.2. The Inclusion and Exclusion Criteria of Robot-assisted Surgery Cases

2.2.1. The Inclusion Criteria

One is a single-segment thoracolumbar fracture. Second, the T value of bone mineral density measured by dual-energy X-ray absorptiometry (DEXA) is less than-2.5. Third, it meets the indications of PKP surgery. Fourth, it is agreed to use orthopedic surgery robot to assist puncture and locate patients during operation.

2.2.2. The Exclusion criteria

One is a multi-level thoracolumbar fracture. Second, the bone mineral density T measured by dual-energy X-ray absorptiometry (DEXA) is >-2.5, and patients who need pedicle screw fixation need to be selected. The third is the old fracture. The fourth is the combination of other serious basic diseases. Fifth, patients who cannot maintain prone position for a long time. Finally, it refused to use orthopedic surgery robot to assist puncture and locate patients.

2.3. The Surgical Methods

2.3.1. The Robot Assisted Group

All operations are operated by the same chief physician. All patients were given local anesthesia,

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lying prone on the all-carbon operating table, and using conventional disinfection towels. At the same time, the connected robot system is placed, the optical tracking camera is placed at the head end of the patient, facing the operating area, and the robotic arm is placed on the side of the operating table to ensure that the operating area can be covered with a sterile protective sleeve. In the past surgery, the "human tracer" needs to be fixed on the patient's spinous process through the "spinous process clip", while PKP surgery is usually a local anesthesia operation, and it is difficult for patients to tolerate the "spinous process clip". We improved the fixing method of the "human tracer": put the "human tracer" at the upper 3-4 segments of the surgical segment, and fix it from many directions with a strip-shaped surgical film, and can't block the sapphire on the "human tracer". Adjust the optical tracking camera so that the "mechanical arm tracker" and "human body tracker" can be recognized at the same time (Figure 3 and Figure 4). Use the 3D-C arm system to shoot the frontal radiograph to determine the position of the surgical segment and the "ruler" of the mechanical arm, use the 3D scanning mode to see through and obtain the image, and then transmit the digital image to the surgical planning operation platform of the surgical robot to reconstruct the 3D image of the patient's surgical site, and plan the pedicle puncture entry point, direction and depth according to the 3D image(Figure 5). Replace the "ruler" on the base of the manipulator with the corresponding "guide" to simulate the operation of the manipulator and start the operation of the robot system. The robot system automatically runs to the preset position according to the planned path, and sends out a puncture catheter tip after confirming that the pedicle screw placement accuracy is less than 1 mm. (Figure 6).

Figure 3: Position relationship between "human tracer" and "optical tracking camera"

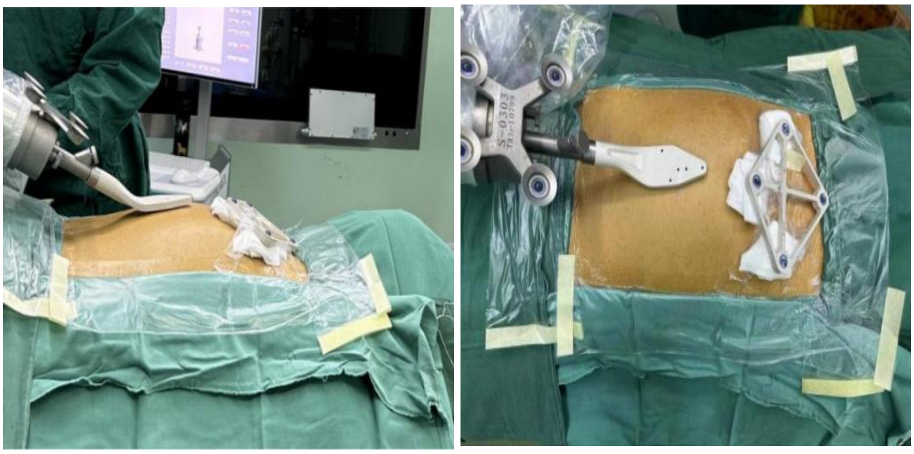

Figure 4: Fixing the "Human Tracer" with a surgical patch

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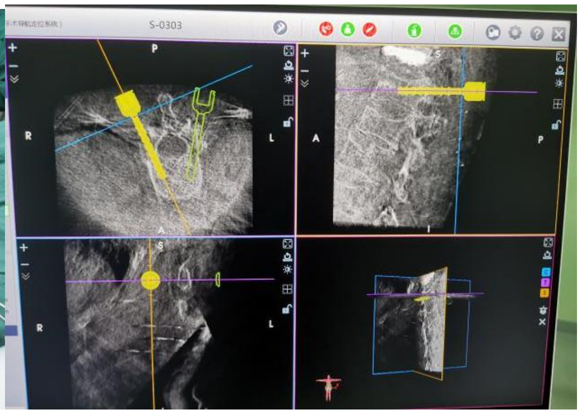

Figure 5: Reconstructs the three-dimensional image of the patient's surgical site, and plans the pedicle puncture point, direction and depth according to the three-dimensional image. (Left)

Figure 6: The insertion of guide pin. (Right)

2.3.2. The Traditional Perspective Group

The patient took a prone position, confirmed the surgical segment under the fluoroscopic positioning of the C-arm machine, marked the position of bilateral pedicles on the body surface, selected an appropriate needle entry point, routinely disinfected the skin in the operation area, and 1% lidocaine injection locally infiltrated, made skin incisions with a length of about 0.5cm at each positioning point about 1 to 1.5cm outside the projection of the body surface of the bilateral pedicles, opened the pedicle bone surface under the guidance of the C-arm, and replaced the inner core of the puncture needle for pedicle puncture. The anteroposterior fluoroscopy showed that the inner core of the puncture needle was located in the pedicle and the position, depth and angle of the inner core were satisfactory and appropriate. The vertebroplasty puncture needle, working sleeve and bone cement filler were replaced along the guide needle direction respectively, and then the operation was completed according to the conventional PKP operation method (Figure 7).

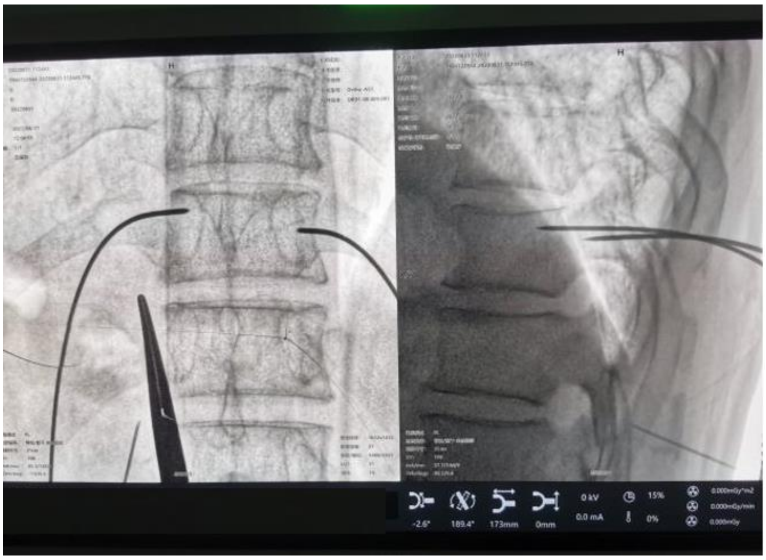

Figure 7: The position of the guide needle during fluoroscopy.

2.3.3. The Postoperative Treatment

All patients were sent back to the ward after their vital signs were stable. Patients were required to lie on their back for at least 6 hours after operation, and they were able to exercise properly with their waistlines on. All patients were given regular anti-osteoporosis treatment after operation. The anteroposterior radiographs of spine were reviewed after operation and before discharge to evaluate the dispersion of bone cement. The VAS score and ODI index were recorded 3 days after operation and 6 months after operation. At the same time, complications such as bone cement leakage, nerve root injury during or after operation, cerebrospinal fluid leakage, pulmonary embolism, anaphylactic shock and postoperative infection were recorded.

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2.4. Observation Index and Evaluation Method

The times of fluoroscopy, operation time, hospitalization days and expenses, Visual analogue scale (VAS) of patients with low back pain at discharge, and Oswestry disability index (ODI) at the last follow-up were recorded.

2.5. The Statistical Treatment

SPSS 27.0 statistical software was used for data analysis, normal distribution measurement data were expressed as (±s), paired sample t test was used for comparison between groups, count data were expressed as the number of cases and percentage, and x2 test was used for comparison between the two groups. P < 0.05 was considered statistically significant (Figure 8).

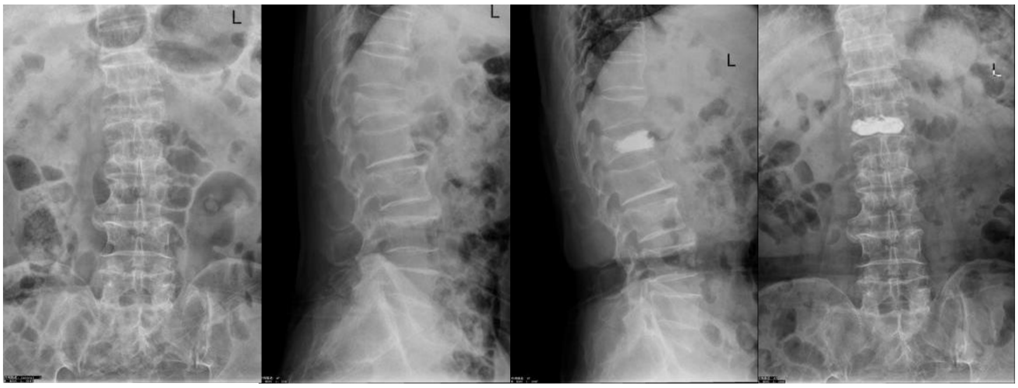

Figure 8: Anterior and postoperative radiographs of lumbar spine and distribution of bone cement in robot group.

3. The Contrast Result

A total of 44 patients were included in this study, aged (69.3±9.2) years. There were 8 males and 36 females. Robot assisted group 21 cases (4 cases were male, female 17), age (68.6 + 10.2), the traditional perspective of 23 cases (4 cases were male, female 19), age (67.0-8.4). Two groups of gender, age, there was no significant difference (P = 0.847). The operation was successful in all patients, and the symptoms were significantly relieved. There were no serious surgical complications such as adverse reactions related to the occurrence of bone cement, nerve injury, infection, cerebrospinal fluid leakage, pulmonary embolism, and anaphylactic shock in both groups after operation.

3.1. The Surgical Situation

The average fluoroscopy times and pedicle puncture times in robot-assisted group were significantly less than those in traditional fluoroscopy-guided group, and the difference was statistically significant (P < 0.001). The average length of hospital stay in the robot-assisted group was slightly longer than that in the traditional fluoroscopic guidance group, but there was no significant difference between the two groups (P > 0.05). The operation time of robot-assisted group and the total expenses needed by patients during hospitalization were significantly higher than those of traditional fluoroscopic guidance group, with statistical significance (P < 0.001) (Table 1).

Table 1: Comparison of surgical conditions between two groups of OVCF patients

Comparison of surgical conditions between two groups of OVCF patients						
Group	Cases Number	Perspective times	Pedicle puncture times	Operation time (min)	Average length of stay (days)	Hospitalization expenses (Yuan)
Robot assisted group	21	7.8±1.2	2.2±0.6	96.6±16.7	5.7±2.3	30577.68±3542.18
Traditional perspective group	23	14.4±0.8	9.4±1.1	69.2±12.7	5.0±2.4	25933.38±2735.24
P values		<0.001	<0.001	<0.001	0.298	<0.001

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3.2. The Comparative Effectiveness

Compared with the traditional fluoroscopy group, there was no significant difference in the VAS score 3 days after operation and the ODI index 6 months after operation (P > 0.05) (Table 2).

Table 2: Comparison of surgical situations between the two groups of OVCF patients

Two groups of OVCF patients postoperative VAS and ODI index to compare			
	Robot assisted group	Traditional perspective group	P values
VAS score 3 days after surgery	0.2±0.5	0.2±0.4	0.715
ODI index (%) at 6 months follow-up	4.15±4.06	6.33±8.13	0.433

4. Conclusions

PKP has a good relief effect on the pain in the low back caused by OVCF. In PKP surgery, pedicle puncture is a key step in the operation and unsatisfactory puncture or dislocation can lead to catastrophic nerve injury. In order to solve this potential neurological and vascular complication, there are many new methods to improve the accuracy of pedicle puncture, and orthopedic surgery robot is one of them. Robot-assisted pedicle screw implantation is a relatively new technology. Through reasonable surgical planning and accurate 3D imaging positioning, it can significantly improve the accuracy of pedicle screw implantation, improve the safety of surgery, reduce the time of intraoperative radiation exposure, and thus reduce the incidence of postoperative complications [11-14]. Molliqaj et al[15] retrospectively analyzed the medical records of 169 patients and found that robot-assisted spinal surgery is safer and more accurate than traditional spinal surgery. Macke et al[16] reached a similar conclusion by using orthopedic robot-assisted technology to treat adolescent idiopathic scoliosis. A large number of clinical case analysis and this study show that robot-assisted pedicle puncture is a safe and effective treatment method, which reduces the occurrence of related neurovascular injury complications caused by improper pedicle puncture.

Nevertheless, Computer Assisted Orthopaedic Surgery (CAOS)[17] still has its limitations and strong expansibility. The connection and placement of orthopedic surgery robot system and C-arm machine in the operating room will affect the spatial layout of the operating room. If the operating room is short of space, it is bound to conflict with the patient's posture, infusion pipeline and anesthesia monitoring, which will affect the operator's operating space and aggravate the occlusion of the optical tracking camera system. Digital operating room will gradually replace the current conventional operating room, and optical tracking equipment will be hoisted on the roof of the operating room, which is more convenient to receive tracer signals. Various data transmission interfaces will be all over the wall, and the transmission data lines will be hidden in the wall to become "hidden lines", thus avoiding loosening or damage caused by robot pushing or unintentional stepping[18-19]. In surgery, especially under local anesthesia, patients need to have good compliance and cooperation, so as to avoid unnecessary body movement after placing "tracer" and "ruler", which will lead to positioning deviation and prolong the operation time; The prolonged operation time will affect the medical experience of patients under local anesthesia, and further increase the probability of unnecessary body movement, which mainly depends on the pre-operation education of medical staff, the reasonable planning before and during operation, the mastery of CAOS, and the operator's mastery of relevant theoretical knowledge, surgical technology and operation process. On the other hand, in the operation, three-dimensional scanning and positioning of the spine requires C-arm machine to take 256 photos from different angles. Although the radiation dose of medical staff has decreased, the radiation received by patients has increased. In 2001, new york, 7000km away, controlled Zeus robot of Strasbourg University Hospital through network, and completed a trans-Atlantic remote cholecystectomy, which was called "Operation Lindbergh" [20]. "Lindbergh Operation" has preliminarily proved the technical and clinical feasibility of tele-surgery and is considered as an important milestone in the development of tele-surgery technology. Even if there are problems such as communication interruption and packet loss during the operation, they have been solved in time. Subsequently, in March 2006, after the "Lin Bai Operation", beijing jishuitan hospital cooperated with Beihang University to complete the first domestic case of intramedullary nail fixation teleoperation between Beijing and Yan 'an [21]. With the rapid development of information technology, remote surgery will become as simple as "online shopping", and CAOS has become an important means to realize minimally invasive, digital and intelligent surgery[22-24]. Through the introduction of remote orthopedic surgery robot to carry out orthopedic surgery, the combination of surgical robot and remote consultation and control technology has been realized, which can not only solve the orthopedic trauma treatment ability in the poor old revolutionary areas, but also improve the local technical level, which is of great help and has important social and practical significance in reducing the economic burden of patients' transfer to hospitals and benefiting patients[18,25-26].

Although the CAOS share some difficulties, in clinic, we became the orthopaedic surgeon's assistant, but also puts forward higher requirements on our orthopaedic surgeons. Under the era of unprecedented development of artificial intelligence, we need to constantly learning new knowledge in science and technology, flexible use and master the surgical robot, avoid the blind use of CAOS equipment, cause the surgery time is too long, complicated operation, the results of such often backfire and may even cause serious complications[27].

With the full cooperation of orthopedic surgeons and engineers, with the rapid development of artificial intelligence, computer-assisted navigation orthopedic surgery and medical robot technology will gradually be popularized and become routine treatment methods in orthopedics. They will greatly improve the level of medical treatment in orthopedics and benefit more orthopedic patients.

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