



CLINICAL ARTICLE

Application of Spinal Robotic Navigation Technology to Minimally Invasive Percutaneous Treatment of Spinal Fractures: A Clinical, Non-Randomized, Controlled Study

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Objective: To introduce a new robotic navigation system that assists pedicle screw implantation and verify the accuracy and stability of the system.

Methods: Pedicle screw placements were performed on the thoracic vertebrae (T)9–Lumbar vertebrae (L)5 thoracolumbar vertebrae of cadavers using robotic guidance. The operative duration, puncture success, correction, and correction time were assessed. Additionally, a total of 30 thoracolumbar fractures from September 2017 until June 2019 were included in a clinical study. Two groups were evaluated: the robotic guidance group and freehand group. Both sexes were evaluated. Mean ages were 47.0 and 49.1 years, respectively, in the robotic and freehand groups. Inclusion criteria was age >18 years and a thoracolumbar fracture. Intervention was the operative treatment of thoracolumbar fractures. Outcome parameters were the operation time, intraoperative bleeding, and fluoroscopic data. The accuracy of the pedicle screw placement and screw penetration rate of the two groups were compared using intraoperative fluoroscopic axial images.

Results: The success rate for 108 one-time nail placements in cadavers was 88% and two-time nail placement was 100%. Vertebral punctures at L5 took the longest to perform and achieve correction. Clinically, there were no significant differences in patients' sex, body mass index, age distribution, or intraoperative bleeding between the groups. The average X-ray exposure time for patients and operators were 37.69 ± 9.24 s and 0 s in the robotic group (significantly lower than in the freehand group: 81.24 ± 6.97 s vs 56.29 ± 7.93 s, respectively). Success rates for one-time screw placements were 98.64 and 88.46% in the robotic and freehand groups, respectively, which is significant. Screw penetration rates (1.36% vs 11.54%, robotic vs freehand), were significantly different.

Conclusions: The robotic system improved the accuracy and safety of pedicle screw internal fixation and reduced patients' and operators' intraoperative radiation exposure.

Key words: Fluoroscopy guidance; Minimally invasive; Pedicle screw implantation; Robot-assisted surgery; Spinal fracture

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Introduction

Thoracolumbar fractures account for approximately 50% of all spine fractures. With increased road traffic and fall injuries, the incidence of spine fractures has gradually increased in recent years and posterior pedicle screw internal fixation (open or minimally invasive) is currently used to repair thoracolumbar fractures.

In 1982, Magerl first described percutaneous pedicle screw fixation based on the traditional open pedicle screw fixation¹. Today, percutaneous pedicle puncture technology is the basic means for achieving minimally invasive spine surgery^{2,3}, with advantages of requiring only a small incision, causing little bleeding, minimally interfering with nerves and muscles, and a low infection rate. Complications associated with this surgery, such as injuries to nerves and blood vessels, visceral injuries, and decreased vertebral body stability, only occur when penetrating the pedicle cortex or by poor positioning^{4,5}. However, there are limitations. The medical staff and patients suffer more radiation exposure because of the requirements for screw implantation and large doses during X-ray fluoroscopy.

In recent years, various navigation technologies have emerged with the development of imaging equipment and computer-aided technology. With the maturation of artificial intelligence applied to pedicle screw implantation technology⁶⁻⁹, screw implantation has become more accurate and safer. Moreover, the radiation exposure of doctors and patients were significantly reduced during operation.

Compared with general navigation technologies, robot-assisted systems can overcome the limitations of human physiological fatigue that interferes with a high operative accuracy, good operative repeatability, and strong operation stability. Thus, it is possible to apply robot-assisted technology to pedicle screw internal fixation, thereby improving its accuracy.

Nowadays, the surgical robots^{7,10-15} used in spine surgery include SpineAssist/Renaissance, Rosa, SPINEBOT, BITEBOT II, and Tianji robot systems. Moreover, the SpineAssist/Renaissance system developed by Mazor medical technology company is relatively mature. This system can obtain the entry point, angle, and implantation path of the screw according to three-dimensional (3D) reconstruction of preoperative computed tomography (CT) image. In the operation process, the robot was installed on the spine bony mark by the Hover-T fixed frame. Meanwhile, the image registration was conducted after the patient's anteroposterior fluoroscopy. Finally, the SpineAssist/Renaissance workstation and the computer navigation system were used to complete the manual screw implantation under the guidance of guide pin.

The commonly used robot artificial intelligence system had some defects. SpineAssist system^{7,11} was a spine surgery navigation-assisting robot based on the parallel structure, which adopted "Hover-T" technology and was directly fixed on the patient's spine. The disadvantage of SpineAssist was that its reconstruction was based on the invasive operation, which increased the negative damage,

and the operation procedure is complex. Moreover, the positioning of Renaissance guidance system was conducted by the navigation principle, which would produce "drift" phenomenon and error. Also, the accuracy deviation of Tianji robot system^{16,17} mainly came from the process of 3D image data reconstruction and image automatic registration. In the imaging process, ARCADIS Orbic 3D system acquired images had some degree of distortion due to the deflection of electromagnetic field, which was determined by the imaging principle. In the automatic registration process of the 3D image and the guidance process of the robot arm system by the navigation system, the system error of surgical robot would also be increased due to the error of optical reflection between infrared stereo camera and tracer.

In view of the tedious process of establishing and calibrating MARK, binocular vision imaging system, and registration system for commonly used robot systems, our team introduces a new robot-assisted pedicle screw embedded system. This spine navigation robot system, which was jointly developed by our group and Beijing University of Aeronautics and Astronautics, allows direct navigation of the pedicle according to pinhole imaging as well as the three points and one-line principle¹⁸. Based on the pinhole imaging principle of the end device, the monitoring was improved and the error caused by binocular vision of the tracking mark was avoided. In order to verify the accuracy and stability of the robot-assisted system, we design the cadaver experiment *in vitro* and clinical trial. Firstly, we report the accuracy and stability of robot-assisted pedicle puncture technology in a cadaver experiment. Then, we also compare the differences between the freehand puncture and robot-assisted puncture in a clinical experiment.

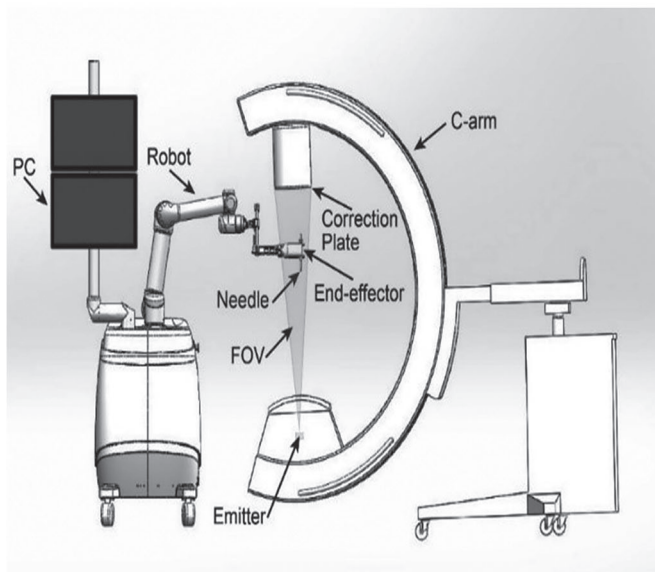
Materials and Methods

Apparatus

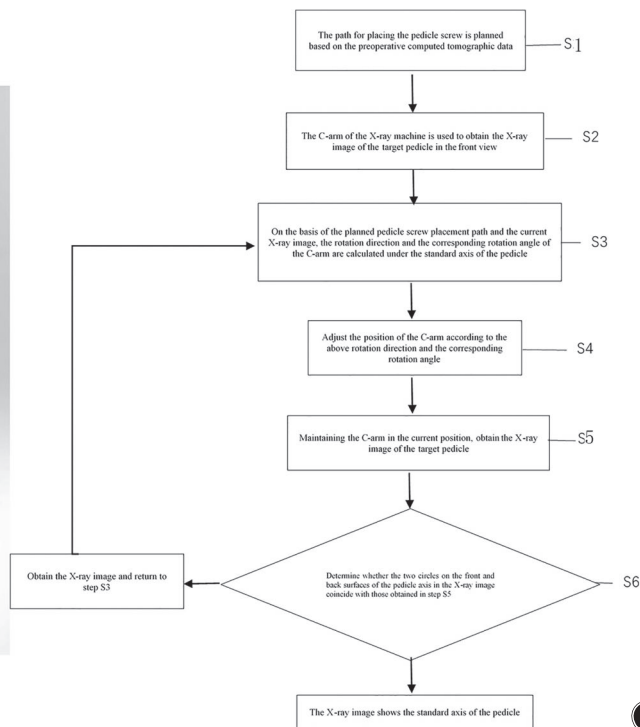
The minimally invasive surgery robotic system (Zhuzheng, Suzhou, China) for the spine (Fig. 1A) consists of a robot with six-degrees-of-freedom, a digital C-type arm, a terminal effector, an image corrector, and a computer for robot control and image processing. The key technical process of pedicle axial mapping is performed under guidance of a robotic system (Fig. 1B).

Cadaver Experiment

In the cadaver experimental process, three fresh-frozen cadavers were selected that included the ninth thoracic vertebra to the fifth lumbar vertebra, with 36 pedicles. Each pedicle was tested three times and 108 pedicle screws were placed. We recorded the operation time for each pedicle, the success or failure of each puncture, the need for correction of the screw implantation, and the number of corrections (Table 1).



A



B

Fig 1 (A) Comprises of robot system; (B) The key technical process of achieving the pedicle axial map.

Clinical Experiment

Grouping

For the clinical study, 30 patients with thoracolumbar fractures were selected from September 2017 to June 2019, including 13 patients who underwent minimally invasive percutaneous pedicle puncture with robotic assistance (robotic group). Additionally, 17 patients with thoracolumbar fractures underwent pedicle puncture using a freehand technology (freehand group).

Inclusion and Exclusion Criteria

Inclusion criteria included: (i) age ≥ 18 years; (ii) compliance with the pedicle screw fixation; and (iii) patient's informed consent. Exclusion criteria were: (i) severe osteoporosis; (ii) old thoracolumbar fractures; (iii) thoracolumbar fracture with neurological symptoms that required spinal decompression; (iv) serious systemic disease; (v) coagulation dysfunction; and (vi) clinical unsuitability.

Operation

Robotic Group

Preoperatively, patients underwent surgical planning using CT scans of the spine and data collection. The researchers then planned the angle and position of the pedicle screw based on the operative plan.

After general anesthesia, the patient was placed in a prone position. The robotic equipment was installed along with the C-type arm fluoroscopy apparatus. The robotic equipment was placed at the patient's head and the C-type arm was used to perform fluoroscopic scanning. The robot automatically adjusted the operating arm to the planned pedicle screw implantation site according to the fluoroscopy that confirmed the accurate implantation position.

The skin was incised ~ 1 cm through a sleeve. Fluoroscopy confirmed that the inner sleeve core was concentric and projected onto the pedicle. A Kirschner wire was then placed along the inner sleeve core to the bone of the vertebral body.

Freehand Group

The anesthesia and position was the same as the robotic group. The operator located the vertebral pedicle under X-ray fluoroscopic guidance. The skin was incised ~ 1 cm at the mark. The puncture needle penetrated the cortical bone vertebral pedicle under fluoroscopic guidance. During internal puncture of the pedicle, multiple fluoroscopic images were used to ensure that the puncture needle was in the pedicle. The puncture was continued until the tip of the puncture needle was finally in the front one-third of the vertebral body.

Data Acquisition

The patient's age, sex, body mass index, classification of spine fracture, and other basic data were recorded for each

TABLE 1 The experiment data of corpse experiment

Vertebrae	Number	Number of screw implantation	Number of corrections	Mean time of screw implantation (min)
T9 left	1	3	0	5.00
T9 right	1	3	0	4.33
T10 left	1	3	1	4.67
T10 right	1	3	1	4.33
T11 left	1	3	0	7.33
T11 right	1	3	0	5.67
T12 left	1	3	1	5.33
T12 right	1	3	0	3.67
L1 left	3	9	0	5.44
L1 right	3	9	1	5.89
L2 left	3	9	1	5.33
L2 right	3	9	0	6.00
L3 left	3	9	1	7.22
L3 right	3	9	1	5.78
L4 left	3	9	1	7.00
L4 right	3	9	1	6.00
L5 left	2	6	2	11.67
L5 right	2	6	2	10.00

group. The total operation time of each patient was calculated according to the beginning and end of the operation, as recorded by the anesthesiologist. A retrospective search of the patient's surgical record was conducted to determine the amount of intraoperative bleeding.

Radiation Exposure Time

The total exposure time during the operation was recorded as the patient's radiation exposure. The exposure time of the operator, who wore protective clothing, was recorded as the radiation exposure (surgeons during the robotic operation are always protected by a lead wall, so their exposure time is zero).

Screw Position

The axial map of each pedicle was examined using intraoperative fluoroscopy to confirm that each screw penetrated the pedicle cortex. When screws were in the pedicle cortex, a score of 0 was recorded. When the screw penetrated tissue outside the pedicle cortex, a score of 1 was recorded.

Ethical Considerations

Our institutional ethics committee approved this study. Informed consent was obtained from each participant.

Statistical Analysis

Because the measurement data had a normal distribution, the mean \pm standard deviation was used for comparisons. An independent sample t test was used for group comparisons. The relative number was used to describe the count data and the χ^2 test was used for statistical inference. The

SPSS 25 software package (IBM, Armonk, NY, USA) was used to process the data. A value of $P < 0.05$ indicated statistical significance.

Results

Cadaver Experiment

One hundred and eight screw implantations were performed, 13 of which had to be artificially corrected. The successful screw implantation rate was 88%, and the successful second screw implantation rate was 100%.

The number of screw implantations and artificial corrections were recorded for each cone. The thoracic vertebrae (T)10, T12 and lumbar vertebrae (L)5 vertebral bodies were artificially corrected with screw placement. The reasons for correction were: (i) the position of the C-type arm was not ideal; and (ii) the fluoroscopy double rings were not concentric. The correction at L5 took a long time (Table 1).

The average time distribution for each vertebral body of nine cones is shown in Fig. 2. The average time for correcting T11 and L5 was longer than other vertebral bodies, especially the L5 vertebral body, which took the longest for screw implantation and required more time for artificial correction.

Clinical Experiment

The patients' average ages in the robotic and freehand groups were 47.0 and 49.1 years, respectively. The male/female ratio of the two groups was 17/13 and their average body mass indexes were 24.16 and 25.13 kg/m², respectively. Hence, there were no significant differences between these two groups ($P > 0.05$; Table 2).

The operation duration was calculated from the completion of anesthesia to completion of incision closure. The average operative time in the robotic group was 212.31 min and that of the freehand group was 148.29 min, which indicates a statistically significant difference ($P = 0.002$). The operation time for the robotic group was significantly longer

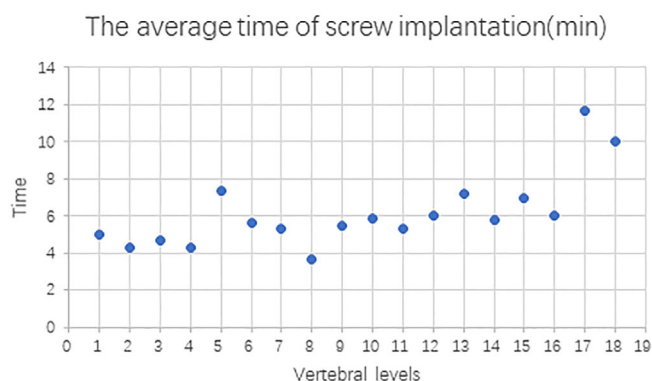


Fig 2 The average time distribution of screw implantation for each vertebral body (The left and right pedicles of T9-L5 vertebrae are represented by the Numbers 1–18).

TABLE 2 Characteristics of the patients between robotic and freehand groups

	Robotic group (n = 13)	Freehand group (n = 17)
Age		
Average	47	49.1
Min-max	23–70	25–69
Gender ratio		
m/f	8/5	9/8
BMI		
Average	24.16	25.13
Min-max	19.13–27.04	18.73–31.12

n represents the numbers of patient (no statistically significant differences concerning patient age, BMI, and gender ratio could be found between two groups).

than that of the artificial group (Table 3). However, there was no significant difference in intraoperative bleeding between these two groups ($P = 0.286$; Table 3).

The patients' average radiation exposure times were 37.69 s for the robotic group and 81.24 s for the freehand group. The average exposure time for the robotic group was significantly less than that for the freehand group ($P = 0.000$). The operators in the robotic group had no radiation exposure, whereas the operator in the freehand group had 56.29 s of exposure. The difference between these two groups was statistically significant ($P = 0.000$; Table 3).

Overall, 178 pedicle screws were implanted in 30 patients. In the robotic group, as observed by intraoperative fluoroscopy, 73 screws were completely in the pedicle cortex, and one pedicle screw on the left of L5 penetrated the pedicle cortex. The success rate of one-time screw implantation was 98.64%. In the freehand group, 12 pedicle screws penetrated the pedicle bone and 92 pedicle screws were completely in the pedicle cortex. The success rate of one-time screw implantation was 88.46% (Table 4). The screw penetration rate in the robot treatment groups was

TABLE 3 The exact number of each parameter of patients for two different groups

	Robotic group (n = 13)	Freehand group (n = 17)	P
X-ray exposure time (s patient)	37.69	81.24	0.000
X-ray exposure time (s doctor)	0	56.29	0.000
Operation time (min)	212.31	148.29	0.002
bleeding volume (mL)	115.38	99.41	0.286

n represents the numbers of patient, $P < 0.05$ means statistically significant differences.

TABLE 4 The relative frequency of the success rate of one-time screw implantation and the screw penetration rate between two groups

Grading	Robot group (n = 74)(%)	Freehand group (n = 104)(%)
0	98.64%	88.46%
1	1.36%	11.54%

n represents the numbers of pedicle screw. All of the screws which were in the pedicle cortex was recorded as 0. While the screw penetrated tissue outside the pedicle cortex, it was recorded as 1.

lower than that in the freehand groups ($P = 0.014$; Table A1). Satisfactory positioning for these two groups was achieved *via* two-time correction, the success rate of which was 100% (Fig. 3).

Discussion

Most spine navigation robots^{19–22} use the image registration method and then track the registered external marker points by binocular vision. There are two errors in the coordinate system established by this method: (i) the relative displacement between the cone mark and the cone; and (ii) the relative displacement between the end of the guide and the marked point on the mechanical arm. The latter displacement is especially difficult to avoid or identify.

The robotic system we developed is based on the principle of pinhole imaging and a three-point line, which can complete the axis positioning of pedicle screws and assist operators in the implementation of pedicle screw implantation. Moreover, the principle is characteristic of light propagation along a straight line in the same homogeneous medium (Fig. 4A) and has been adopted by the robot auxiliary positioning system. The ideal operative method for pedicle implantation is to use the standard axis positioning principle of the pedicle; that is, make the axis pedicle overlap the axis of the X-ray machine with a C-type arm¹⁸. The angle of the pedicle channel can be determined according to contour recognition and matching the characteristic image.

Using a specially designed terminal effector (Fig. 4B), it is possible to calculate the operation directly using two-ring data of the operation space on the information gained during the operative planning on characteristic images. Moreover, the relative position between the path and two rings can be adjusted using the ring plan. Using this method, only one X-ray image can be used to calibrate the imager, register the robot to the image space, and aim at the target. As two rings are concentric on the perspective image, the standard axial image of the pedicle can be obtained (Fig. 4C–E). Additionally, it is not necessary to build a mapping model between the operation space and image space, which can avoid image deviation caused by respiratory interference.

First, as for the clinical experimental robotic group, the success rate of one-time screw implantation was 98.64% and the screw penetration rate was 1.36%. For the artificial group, the success rate of one-time screw implantation was 88.46% and the screw penetration rate was 11.54%. Satisfactory positioning in these two groups is obtained by two-time correction, with a success rate of 100%.

The failure rate of traditional artificial pedicle screw implantation is high^{20–23}, reaching 28.1%–39.9%. Kuo *et al.*²⁴ suggested that the success rate of pedicle screw implantation guided by the SpineAssist system was 98.74%, which is similar to this study, and it is not necessary for our robotic navigation to establish an additional stent fixed to the pelvis and spine.

Second, the robotic approach can reduce the screw implantation time and reduce the exposure to X-ray fluoroscopic radiation without increasing the amount of intraoperative bleeding. Moreover, the clinical experiment confirmed that patients' radiation exposure was significantly less in the robotic group than in the artificial group ($P = 0.000$). The operators' radiation exposure in the robotic group was 0 s, whereas that in the artificial group was 56.29 s. The difference between these two groups was significantly different ($P = 0.000$). Conversely, there was no significant difference in intraoperative bleeding between those two groups ($P = 0.286$). In a retrospective study, Kantelhardt *et al.*²⁵ reported that the average X-ray exposure time during screw implantation under a robotic system was 34 s, whereas

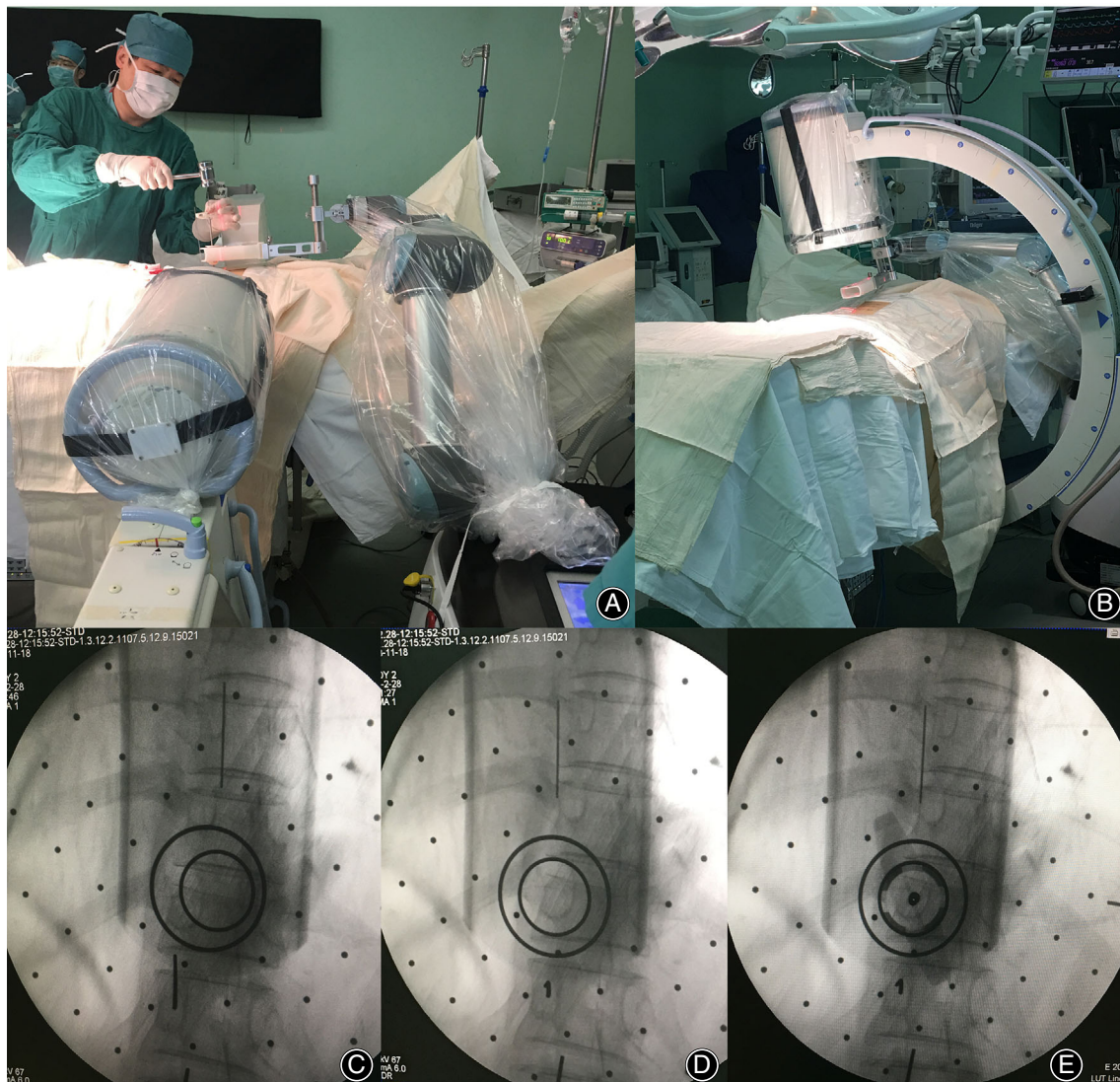


Fig 3 The operation process for the robot group patients. (A,B) C-type arm was used to perform fluoroscopic scanning; (C–E) image of X-ray fluoroscopic guidance during operation.

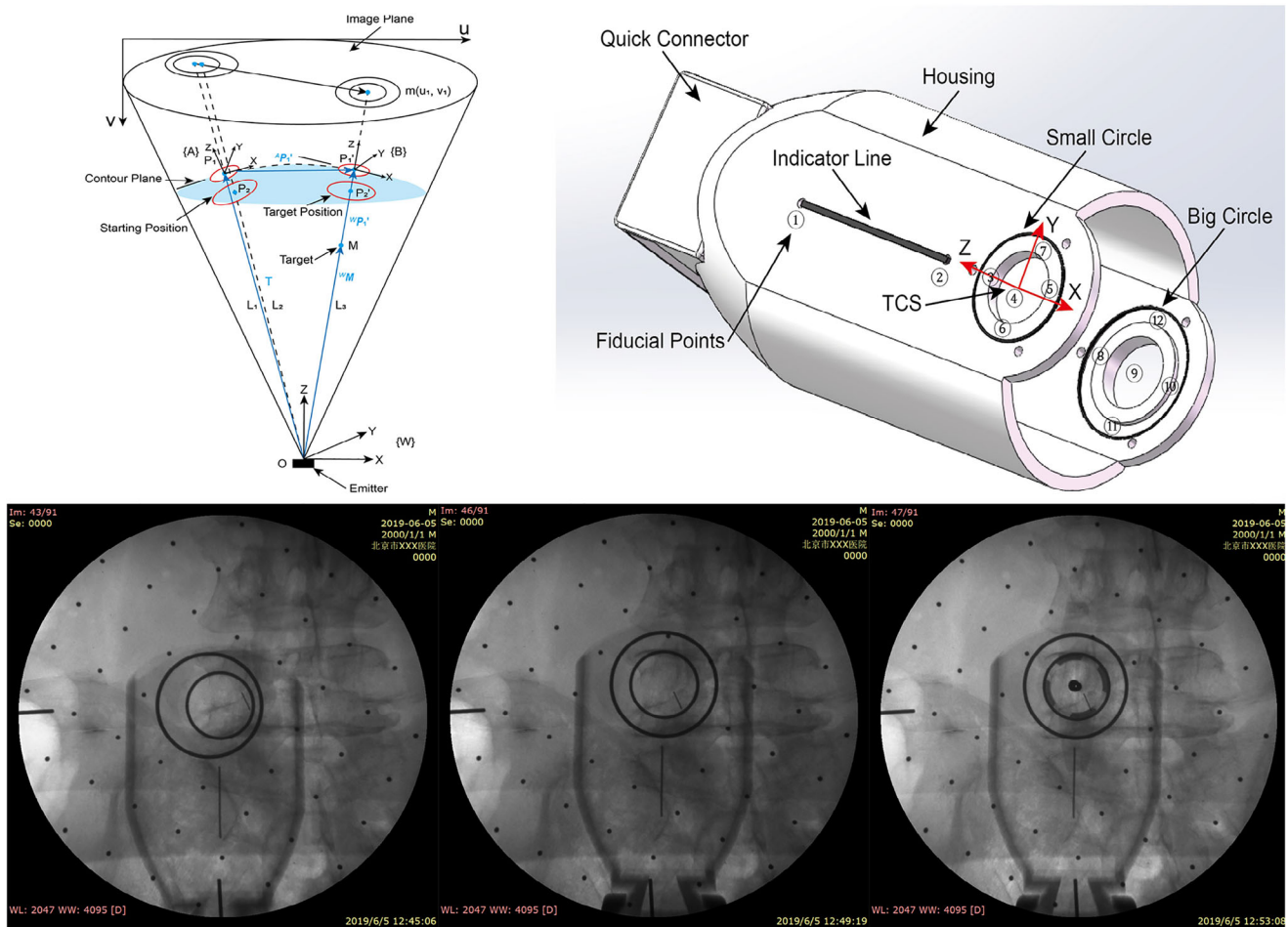


Fig 4 The robot auxiliary imaging. (A) the pinhole imaging and the principle of three points and one line; (B) a specially designed terminal effector; (C-E) the image of two concentric rings reflected the standard axial image of the pedicle in cadaver experiment.

the average time for a traditional artificial operation was 77 s, which was comparable to the time reported here.

X-ray exposure during traditional minimally invasive spine surgery is high and that of the immature technology is even greater²⁶. To ensure operational safety, the operator must wear heavy protective clothing, which makes operator fatigue more likely^{27,28}.

The navigation robot can cooperate with a variety of mobile X-ray diagnostic devices (C-type arm) to produce X-ray images without an additional special perspective device. There is no need for binocular vision, which is conducive to the use of a normal operating room design. Additionally, the cost is easy to control, which encourages promotion.

In the cadaver experiment, the L5 vertebral body requires the longest time for screw implantation and may need a second correction, as observed in the artificial group. Additionally, the only perforation and correction in the clinical experiment occurred at the L5 vertebral body. Compared

with other vertebral bodies, the L5 vertebral body is the most difficult to replace a screw, possibly because the pedicle shape of the L5 vertebral body is irregular, and the channel position of the L5 vertebral body is more difficult to register than that of other vertebral bodies.

The success rate in the cadaver experiment was lower than that in the clinical experiment, which might be attributed to completion of the cadaver experiment before the clinical experiment. Moreover, our team operational process is still in the exploratory stage.

Limitations

The experiment was performed by different doctors. Each doctor's learning curve for performing percutaneous minimally invasive screw implantation and robot-guided surgery¹⁹ has an effect on the experimental data. Additionally, the experiment was a retrospective and non-randomized

controlled study, and case selection bias could have interfered with the experimental data.

Conclusions

The cadaver experiment confirmed that the pedicle screw could be precisely placed under robotic guidance (success rate of 100%). In the clinical experiment, the one-time success rate of robot-guided pedicle screw placement (98.64%) was significantly greater than that guided by artificial fluoroscopy (88.64%). Moreover, the X-ray exposure time of the operators and patients in the robotic group was significantly shorter than that in the artificial group. Operators had no X-ray exposure during this surgery. Thus, robotic guidance can be used to achieve precise placement

of pedicle screws, which can greatly reduce patients' radiation exposure and provide zero radiation exposure for operators.

Acknowledgments

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APPENDIX

Table A1 Multivariate Logistic regression analysis of screw penetration rate between two groups

Groups	OR (95%CI)	P
Freehand group	1.000 (ref)	0.014
Robotic group	0.058 (0.006–0.557)	

Adjusted the factors of gender, age, BMI and classification of spine fracture, $P < 0.05$ means statistically significant differences