introduction

The pedicle screw is a structure with strong internal fixation and three-column support. Its structural peculiarities provide the basis for the surgical treatment of spinal disorders and therefore is now widely used in the treatment of various spinal disorders[1]. The insertion of pedicle screws can restore spinal stability, prevent further neurological damage, and enable the early return of patient activity. Currently, pedicle screw fixation is the surgical procedure of choice for various spinal disorders, such as unstable spinal fractures, degenerative spinal disease, spinal deformities, and tumors[2]. Surgeons usually place pedicle screws using either a freehand or fluoroscopy-assisted technique[3]. The most basic freehand technique of screw placement tends to penetrate the medial wall of the pedicle, and the incidence of screw misplacement ranges from 8.3% to 50.6% in published articles[4]. Screw misplacement can lead to severe clinical consequences such as nerve, vascular, and vital organ injuries. To reduce the incidence of screw misplacement and to avoid as much as possible the severe clinical consequences due to screw misplacement, robot-assisted techniques are beginning to be used in surgery.
Robotic-assisted technology has gained popularity in many surgical procedures, and as technology advances, orthopedic surgical robots are becoming more widely used in the field of spine surgery. A growing number of studies have demonstrated the advantages of robot-assisted techniques in the surgical treatment of spinal trauma and degenerative diseases. This technique can significantly improve the surgical safety and accuracy of screw placement, thereby effectively reducing damage to adjacent vessels, nerve roots, and the spinal cord, as well as reducing the impact on adjacent small synovial joints. The current literature on spinal robots focuses on older devices, including Renaissance®, SpineAssist®, and ROSA®. The latest Mazor X robot has been released and is already used abroad.

Given the advantages of robot-assisted surgery and intending to update existing domestic reports on robotic technology, we conducted a case series study to determine the accuracy of robotic use for surgical pedicle screw placement in lumbar spine disorders. We studied the accuracy of screw placement, preparation time, and screw placement time with the Mazor X robotics in 12 patients who underwent pedicle screw placement.

Although the feasibility, safety, and learning curve of the Mazor X robot have been reported in overseas studies, to our knowledge, we are the first in China to use the Mazor X robot to assist in pedicle screw placement for lumbar spine disease surgery and to report its associated characteristics.

**MATERIAL AND METHODS**

**Patient selection and inclusion criteria**

At a single institution (Xuanwu Hospital), consecutive patients undergoing minimally invasive pedicle screw placement using the Mazor X between July 2022 to September 2022 were retrospectively enrolled. All cases were performed by a neurosurgeon with resident assistance.

**Workflow**

The Mazor X robot can produce a preoperative plan based on existing CT images through a computerized program that precisely positions surgical tools or spinal implants along a developed trajectory. We obtained high-resolution 3D CT sweeps preoperatively and used the Mazor X software to plan the screw trajectory, including identifying and optimizing the axial and sagittal trajectories of the screws, and the preoperative planning for one of the patients is shown in Fig. 1.

![Figure 1. Mazor X Software's Preoperative Screw Trajectory Planning Diagram.](image-url)
surgical procedures, surgical sites, and operator preferences. The intraoperative robotic arm takes images above the patient, stitching the images together for 3D modeling and 3D scanning of the operative area, which defines a safe distance between the arm and the patient during the operation. Any joint of the robotic arm never enters the established surgical area, ensuring the safety of the patient. With safety guaranteed, the robotic arm takes the most efficient trajectory during operation, improving surgical efficiency.

We used 6.5-mm diameter pedicle screws with the patient in a prone or lateral position during the operation. After merging the CT plan images with the preoperative radiographs and the surgeon in charge confirms the screw trajectory, the surgical tool is placed into the robotic arm introducer, the robotic arm is aligned with the potential screw hole for drilling and the corresponding pedicle screw is placed.

RESULTS
The study included 12 patients with lumbar spine disease requiring pedicle screw placement with a total of 60 screws placed. Eight patients were female, the mean age of all patients was 56.25 years, the mean weight was 67.36 kg, and the mean age of all patients was 56.25 years, the mean weight was 67.36 kg, and the mean BMI was 25.41 kg/m^2. The basic information characteristics of the patients are summarized in Table 1.

<table>
<thead>
<tr>
<th>Parameter</th>
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<td>Number of patients</td>
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<td>Gender</td>
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<tr>
<td>Female, n(%)</td>
<td>8, 66.7%</td>
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<tr>
<td>Mean age (years)</td>
<td>56.25</td>
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<tr>
<td>Mean mass (kg)</td>
<td>67.36</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>25.41</td>
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</table>

Table 1. Patient demographics.

We recorded the total screw placement time for seven surgeries from Aug 11 to Aug 25, 2022 (Fig. 2). The total screw placement time was not recorded for the Aug 23 surgery because the fixed screw in the posterior superior iliac spine was found to be positioned inward during fluoroscopic registration, so it was re-stapled and registered. Our data indicated that total screw placement time showed a decreasing trend as the dates of the case proceeded.

To assess their accuracy, we measured the degree of cortical invasion of the 60 screws we placed according to the Gertzbein Robbinson classification. Accuracy of pedicle screw placement is classified into 5 grades, which are as follows: grade A, the screw is completely within the pedicle; grade B, the screw breaches the pedicle’s cortex by <2mm; grade C, pedicle cortical breach <4mm; grade D, pedicle cortical breach <6mm; grade E, pedicle cortical breach of ≥6mm. The total number of screws in the “safe zone”[8], i.e., the total number of screws rated A, B, and C, was 59, accounting for 98.3% of all screws (Fig. 3). It is not difficult to see that robot-assisted pedicle screw placement has high accuracy in each vertebral segment, and most of the pedicle screws can be classified as Grade A, which indirectly proved the accuracy of robot-assisted pedicle screw placement.

The fluoroscopic exposure time of the surgery from Aug 11 to Aug 23 was also recorded (Fig. 4). We plotted fluoroscopy time recorded from Aug 11 to Aug 23 as well. Our data showed that fluoroscopy time also presented a decreasing trend with increasing surgeon experience.

We evaluated the difference between the preset screw track and the actual screw track by measuring the angle between the screws on both sides of the cone and the midline of the cone, which is plotted in Figs 5-6. We can see that the discrepancy
between the pre-set screw track and the actual screw track does not decrease significantly as the surgery date progresses. However, all angular differences remain within 10°, which proves to some extent that our Mazor X robot has a high degree of accuracy. With an average angle of 3.805°, the right side shows a higher accuracy than that of the left side with an average angle of 4.225°.

Before surgeries, most patients experienced weeks or months of lower back pain and numbness, tingling and other sensory abnormalities in the lower limbs. After surgeries, all patients’ incisions healed well with smooth recoveries, and patients were discharged within three to seven days.

**Figure 3.** Gertzbein-Robbins screw classification based on the vertebral body level.

**Figure 4.** Time of fluoroscopy.

**Figure 5.** Left side average angle deviation.

**Figure 6.** Right side average angle deviation.
DISCUSSION

Whereas in past years, pedicle screw placement was often performed with freehand or 3D fluoroscopic assistance, in recent years, there have been tremendous advances in robotic-assisted technology and science in spine surgery. Freehand screw placement has a high rate of screw malposition, and while navigation has improved accuracy, it requires repeated trajectory adjustments, resulting in a very inconvenient procedure. Robot-assisted surgery can make this process easier and has been shown to improve safety and accuracy.\(^9\)

The surgical technique requires a learning curve to reduce case completion time and improve surgical accuracy. However, due to the small number of cases we included, we could only observe the trend of total screw placement time, and fluoroscopy time. However, we could not obtain a more accurate learning curve. In our case series, the total screw placement time increased from 27 to 143 minutes but decreased to 7 minutes in a recent case, with an overall decreasing trend. Fluoroscopy time was also reduced from the initial 45 minutes required to 15 minutes.

The accuracy of robot-assisted pedicle screws has been demonstrated in numerous published articles. Li et al.\(^{10}\) pointed out in their study that the TINAVI robot-assisted technique was more accurate in screw positions, whereas the Renaissance robot-assisted technique showed the same accuracy as the freehand technique in screw positions. Matur et al.\(^{11}\) proved that robotic and navigated pedicle screw placement techniques were associated with higher odds of screw accuracy. Han et al.\(^{12}\) discovered that in the robot-assisted group, 95.3% of the screws were perfectly positioned (grade A). In the freehand group, 86.1% screws were perfectly positioned. Zhou et al.\(^{13}\) pointed out in his article that, the robot-assisted techniques showed more accurate pedicle screw placement and lower intraoperative radiation dose. Tarawneh et al.\(^{14}\) reached a conclusion that robot-assisted technology is superior to the conventional freehand technique in terms of grade A and grade A+B screw accuracies and in the reduction of intraoperative radiation time and dosage. Fu et al.\(^{15}\) found out the extent of the improvement with robot-assisted techniques in screw position grade A in Gertzbein-Robbins classification of the screw placement accuracy, postoperative stay, intraoperative blood loss, intraoperative radiation dose, and proximal facet violations was significantly better than conventional freehand techniques.

We report an accuracy rate of 98.3% for 59 of 60 screws inserted within the safety zone, demonstrating the high accuracy of the screw placement procedure using Mazor X robotic assistance.

Our case series indicate that the primary surgeon required less screw placement time and fluoroscopy time as the time of the case progressed while the screw placement accuracy remained at a relatively high level. This proves that Mazor X robot-assisted screw placement surgery has superior results.

To evaluate the angular difference between the actual screw placement track and the pre-set screw placement track, we collected data and found that the angle between the extension of the screws placed on both sides of the pedicle and the midline of the pedicle ranged from 4° to 27° in the pre-set Mazor X system, while the actual angle ranged from 4° to 23°, and the difference between the pre-set and actual values was within 10°and showed a tendency to repeat back and forth. Therefore, we believe that the difference between the actual placement track and the pre-set track when using the Mazor X robot for screw placement proves that the accuracy of the screw placement track of the new generation Mazor X robot system still needs to be improved.

The Mazor X system shares many core technologies with its predecessors. However, compared to previous robotic systems, the Mazor X system introduces a newly designed robotic arm that avoids the need for additional platforms or assistive tools. The Mazor X 3D camera is designed to reduce collision errors between the patient and the surgical environment, and the Mazor X Eye camera is used to verify proper arm position and trajectory at each instrumented level, helping to reduce the robot abandonment rate and improve screw accuracy. Our findings also suggest that using the Mazor X robot to assist in pedicle screw placement effectively improves screw placement accuracy and reduces intraoperative screw placement and fluoroscopy time. Therefore, we consider the Mazor X robot a reliable surgical assistant technology.

There are known limitations in this study. Only 12 cases were included in our case series, and we believe the number of cases is too small to obtain an accurate learning curve for the Mazor X robot. We need to include more cases to study the learning curve of the robot and to determine if the Mazor X robot has more advantages over its predecessors.
CONCLUSIONS

We present the first Mazor X robotic-assisted technique in China to our knowledge. Our screw placement accuracy was 98.3%, with a decreasing trend in total screw placement time as well as fluoroscopy time during the procedure over case time. We believe the Mazor X robotic technique offers high accuracy and efficiency.

Conflict of Interests

The authors declare that there are no conflicts of interest.

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List of Abbreviations

CT: Computed Tomography
3D: three-dimensional

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Mazor X Robot-Assisted Pedicle Screw...


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