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Original Article

# Safety of robotic-assisted screw placement for spine surgery: Experience from the initial 125 cases

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ABSTRACT

*Background:* The present study aimed to evaluate the safety of robot-assisted screw placement in 125 cases after introducing a spinal robotics system and to identify the situations where deviation was likely to occur.

*Methods:* The subjects were 125 consecutive patients who underwent robotic-assisted screw placement using a spinal robotics system (Mazor X Stealth Edition, Medtronic) from April 2021 to January 2023. The 1048 screws placed with robotic assistance were evaluated. We investigated intraoperative adverse events of the robotics system and complications occurring within 30 days after surgery. We evaluated screw accuracy and deviation and compared them for vertebral levels, screw insertion methods (open traditional pedicle screw [Open-PS], cortical bone trajectory screw [CBT], percutaneous pedicle screw [PPS], and S2 alar iliac screw [S2AIS]), diagnosis, and phases of surgical cases.

*Results:* The deviation rate of robotic-assisted screw placement for spine surgery was 2.2%. Complications were reoperation due to implant-related neurological deficit in 0.8% and surgical site infection in 0.8%. There was significant difference in the deviation rate between vertebral levels. The deviation rate of the T1–T4 level was high at 10.0%. There was significant difference in the deviation rate between Open-PS, CBT, PPS, and S2AIS. The PPSs had a high deviation rate of 10.3%. The deviation rates were not significantly different between patients with and without deformity. The deviation rate did not change depending on the experience of surgical cases, and the deviation rate was favorable from the onset.

*Conclusion:* Although the robotic-assisted screw placement was safe, we should be extra vigilant when placing screws in the upper thoracic region (deviation rate 10.0%) and when using PPSs (deviation rate 10.3%).

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## 1. Introduction

Numerous articles have been published regarding the accuracy of robotic-assisted screw placement for spine surgery. Some articles describe the Gertzbein and Robbins grade [1], with Grades A and B (breach of less than 2 mm) being sufficiently accurate to calculate accuracy and deviation rates. A systematic review indicated that the accuracy of spinal robotic systems before 2017 was between 85% and 100% [2]. A meta-analysis reported in 2022 found that pedicle screw placement accuracy rates for old and new-generation robotics platforms were 97% and 99%, respectively, with the new-generation robotics being more accurate than the older-generation robotics [3].

Compared with the conventional method, a meta-analysis of 19 articles found that the probability of accurate screw placement was 1.68 times higher using robotics than a freehand technique [4]. Compared with preoperative CT-based navigation, the accuracy of robotic-assisted screw placement is also significantly higher [5,6]. Compared with O-arm navigation, its accuracy tended to be higher [7].

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Previous reports on robotic-assisted spine surgery have focused on the accuracy compared to conventional freehand or navigation methods, as well as the learning curve, surgical time, and radiation exposure. However, there are few reports that have analyzed in detail situations where robotic-assisted screw placement deviates. Understanding the situations where screws deviate will lead to preventing such deviations. The present study aimed to evaluate the safety of robot-assisted screw placement in 125 cases after introducing a spinal robotics system and to identify the situations where deviation was likely to occur.

## 2. Materials and methods

### 2.1. Study subjects

This study was approved by our Institutional Review Board. No funding was provided for this research. The subjects were 125 consecutive patients who underwent robotic-assisted screw placement using a spinal robotics system (Mazor X Stealth Edition, Medtronic Inc., Dublin, Ireland) from April 2021 to January 2023. There were 50 male and 75 female patients, with an average age of 61.1 (range, 12–88) years. Their diagnoses were lumbar spinal stenosis in 66 patients, adolescent idiopathic scoliosis in 19, vertebral fracture in 12, adult spinal deformity in 8, lumbar disc herniation in 7, lumbar spondylolysis in 5, thoracic myelopathy in 3, metastatic spinal tumor in 2, syndromic scoliosis in 2, and neuromuscular scoliosis in 1.

### 2.2. Surgical workflow

We conducted all surgeries using the "CT to Fluoro" workflow. Preoperative CT images were obtained and used to plan screw placements. A spinal robotics system was used to place the screws with the patient in a prone position. The robotic arm unit was attached to the operating table on the caudal side. The spinal robotics system was programmed with the planning data. A C-arm (STX-1000A, Toshiba Medical Systems, Ohtawara, Japan or Zenition 70, Philips, Amsterdam, Netherlands) was used to acquire frontal and oblique X-ray images during the surgery. Preoperative CT images and intraoperative X-ray images were matched by CT-to-Fluoro registration. Without Kirschner-wire guidance, drilling, tapping, and screw insertion were performed using the robotic arm guide.

### 2.3. Evaluation

Of the 1085 screws placed in total, we excluded 33 pedicle screws, 2 S2 alar iliac screws, and 2 iliac screws placed using a freehand technique or other imaging guidance. Ultimately, 1048 screws placed with robotic assistance were evaluated. The screw insertion methods used were traditional trajectory pedicle screws with an open procedure (Open-PS) for 589 screws, cortical bone trajectory (CBT) screws with an open procedure for 346 screws, 97 percutaneous pedicle screws (PPS), and 16 S2 alar iliac screws with an open procedure (S2AIS). On postoperative CT within one week after the surgery, deviation was evaluated according to the Gertzbein–Robbins grade: Grade A, no breach of the cortical layer; Grade B, breaches <2 mm; Grade C, breaches of ≥2 mm but <4 mm; Grade D, breaches of ≥4 mm but <6 mm; and Grade E, breaches of ≥6 mm [1]. Pedicle screw placement was assessed by one author (J.U.) who was blinded to the clinical symptoms. The rate of Grade A was calculated as the perfect accuracy rate. A penetration rate of ≥2 mm (Grades C, D, and E) was calculated as the deviation rate because Grades A and B were considered acceptable.

We investigated intraoperative adverse events of the robotics system and complications occurring within 30 days after surgery.

We evaluated accuracy and deviation and compared them for the following items.

### 2.4. Comparison by vertebral levels

We classified the vertebral levels into the following 4 regions: 1st to 4th thoracic vertebra, T1––T4; 5th to 8th thoracic vertebra, T5–T8; 9th to 12th thoracic vertebra, T9–T12; 1st lumbar to 1st sacrum vertebra, L1–S1; and 2nd sacrum vertebra to iliac, S2.

### 2.5. Comparison between Open-PS, CBT, PPS, and S2AIS (screw insertion methods)

We classified the screw insertion methods into the following 4 categories: Open-PS in 589 screws, CBT in 346, PPS in 97, and S2AIS in 16.

### 2.6. Comparison between patients with and without spinal deformity

According to their condition, we classified the patients into a group with deformity and a group without deformity. The group with deformity included 30 patients with adolescent idiopathic scoliosis, adult spinal deformity, syndromic scoliosis, or neuromuscular scoliosis. The group without deformity included 95 patients with lumbar spinal stenosis (without scoliosis), vertebral fracture (including pure kyphosis without scoliosis), lumbar disc herniation, spondylolysis, metastatic spinal tumor, or thoracic myelopathy. The group with deformity had 446 screws placed, and the group without had 602 screws placed.

### 2.7. Comparison by phases of surgical cases

We classified the surgical cases into 5 stages of 25 cases to assess the learning curve. The first 25 cases were in phase 1, the 26th to 50th cases were in phase 2, the 51st to 75th cases were in phase 3, the 76th to 100th cases were in phase 4, and the 101th to 125th cases were in phase 5.

### 2.8. Statistical analysis

A Fisher exact test was used to compare the deviation rate between the groups. Differences with $p < 0.05$ were considered significant.

**Table 1**
Overall perfect accuracy rate and deviation rate.

| | Overall |
|---|---|
| Number of screws | 1048 |
| Gertzbein-Robbins grade | |
| A | 961 |
| B | 64 |
| C | 21 |
| D | 1 |
| E | 1 |
| Perfect accuracy | 91.7% |
| Deviation rate | 2.2% |



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## 3. Results

### 3.1. Overall

The Gertzbein–Robbins grades were Grade A for 961, Grade B for 64, Grade C for 21, Grade D for 1, and Grade E for 1. The perfect accuracy rate was 91.7% and the deviation rate was 2.2% (Table 1). Regarding the direction of the 23 deviated screws (Grade C, D, and E), 13 medial, 9 lateral, and 1 cranial breach were observed. In Open-PS, 3 medial and 6 lateral breaches were observed. In PPS, 7 medial and 3 lateral breaches were observed. In CBT, 3 medial and 1 cranial breach were observed.

### 3.2. Complications and intraoperative adverse events

Complications were reoperation due to implant-related neurological deficit in 1 case (0.8%) and surgical site infection in 1 case (0.8%). There was no mortality. Intraoperative adverse events related to the robotics system were the failure of the robotics system during surgery in 1 case (0.8%) and the intrusion of the robotic arm into the wound in 2 cases (1.6%). When the robotics system stopped during surgery, we abandoned the robotic-assisted screw placement and continued using a freehand technique. In the 2 instances where the robotic arm intruded into the wound, the surgeon immediately stopped the movement by activating the emergency stop button on the robotic arm unit, with no adverse event resulting for the patients.

### 3.3. Comparison by vertebral level

There were significant differences in the perfect accuracy rate and the deviation rate between vertebral levels. The perfect accuracy rate was the lowest at 66.7% for T1–T4 and the highest at 100% for S2. Similarly, the deviation rate was highest in T1–T4 at 10.0% and lowest in S2 at 0% (Table 2).

### 3.4. Comparison between Open-PS, CBT, PPS, and S2AIS (screw insertion methods)

There were significant differences in the perfect accuracy rate and the deviation rate between Open-PS, CBT, PPS, and S2AIS. The deviation rate of PPSs was 10.3%, significantly higher than those of Open-PS, CBT, and S2AIS (Table 3).

### 3.5. Comparison between patients with and without deformity

The perfect accuracy rate for the group with deformity was significantly lower than for the group without deformity. However, there was no significant difference in the deviation rate between the groups (Table 4).

**Table 2**
Comparison by vertebral levels.

| | T1–T4 | T5–T8 | T9–T12 | L1–S1 | S2 | p |
|---|---|---|---|---|---|---|
| Number of screws | 30 | 81 | 224 | 697 | 16 | |
| Gertzbein-Robbins grade | | | | | | |
| A | 20 | 64 | 203 | 658 | 16 | |
| B | 7 | 13 | 17 | 27 | 0 | |
| C | 3 | 4 | 4 | 10 | 0 | |
| D | 0 | 0 | 0 | 1 | 0 | |
| E | 0 | 0 | 0 | 1 | 0 | |
| Perfect accuracy rate | 66.7% | 79.0% | 90.6% | 94.4% | 100% | <0.001 |
| Deviation rate | 10.0% | 4.9% | 1.8% | 1.7% | 0% | 0.002 |

T1–T4; 1st to 4th thoracic vertebra, T5–T8; 5th to 8th thoracic vertebra, T9–T12; 9th to 12th thoracic vertebra, L1–S1; 1st lumbar to 1st sacrum vertebra, S2; 2nd sacrum vertebra to iliac.

**Table 3**
Comparison between Open-PS, CBT, PPS, and S2AIS (Screw trajectory and insertion methods).

| | Open-PS | CBT | PPS | S2AIS | p |
|---|---|---|---|---|---|
| Number of screws | 589 | 346 | 97 | 16 | |
| Gertzbein-Robbins grade | | | | | |
| A | 523 | 338 | 84 | 16 | |
| B | 57 | 4 | 3 | 0 | |
| C | 9 | 4 | 8 | 0 | |
| D | 0 | 0 | 1 | 0 | |
| E | 0 | 0 | 1 | 0 | |
| Perfect accuracy rate | 88.8% | 97.7% | 86.6% | 100% | <0.001 |
| Deviation rate | 1.5% | 1.2% | 10.3% | 0% | <0.001 |

Open-PS; traditional trajectory pedicle screw with open procedure, CBT; cortical bone trajectory screw, PPS; percutaneous pedicle screw, S2AIS; S2 alar iliac screw.

### 3.6. Comparison by phases of surgical cases

There were no significant differences in the perfect accuracy rate or the deviation rate between the surgical phases (Table 5).

## 4. Discussion

In the present study, the deviation rate of robotic-assisted screw placement for spine surgery was 2.2%. Complications were reoperation due to implant-related neurological deficit in 0.8% and surgical site infection in 0.8%. The deviation rate of the T1–T4 level was high at 10.0%. The PPSs had a high deviation rate of 10.3%. The deviation rates were not significantly different between patients with and without deformity. The deviation rate did not change depending on the experience of surgical cases, and the deviation rate was favorable from the onset. While previous studies have mostly focused on comparing the accuracy compared to conventional freehand or navigation methods, as well as analyzing factors such as the learning curve, surgical time, and radiation exposure, there are few reports that have extensively investigated situations where there are deviations in robotic-assisted screw placement. Our study demonstrated that although the robotic-assisted screw placement in 125 cases after the introduction of robotics was safe, the screws placed in the upper thoracic region and PPSs were likely to deviate from their intended.

The deviation rate of the pedicle screw placement may differ depending on the vertebral level. Higher deviation rates have been reported at the thoracic than the lumbar level. Guzey et al. reported that the rates of misplacements were 27.4% for screws inserted from T2 to T5 and 14.5% for screws inserted from T6 to T8 in patients without scoliosis [8]. However, in those with scoliosis, most screws with a deviated trajectory were inserted from T7 to T9, the apex of the main thoracic curve, and screws also deviated when inserted from T3 to T4 of the upper thoracic curve [9]. In the present study, screws inserted at T1–T4 had higher deviation rates than those inserted at T5–T8, T9–T12, and L1–S1. Moreover, the deviation rate was lower more caudally. Perhaps this was because the robotics unit is placed caudally in all cases. For upper thoracic screw placement, the robot extended its robotic arm (Fig. 1). The robotic arm extension would result in a large error in arm position because the distance between the base of the arm on the surgical table and the tip of the arm for inserting the screw would increase. We speculated that the error would become larger as the physical distance increased. If the robotic arm is extended, the error in the arm position may increase resulting in a high deviation rate.



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**Table 4**
Comparison between patients with and without deformity.

| | Group with deformity | Group without deformity | p |
|---|---|---|---|
| Number of screws | 446 | 602 | |
| Gertzbein-Robbins grade | | | |
| A | 392 | 569 | |
| B | 43 | 21 | |
| C | 11 | 10 | |
| D | 0 | 1 | |
| E | 0 | 1 | |
| Perfect accuracy rate | 87.9% | 94.5% | <0.001 |
| Deviation rate | 2.5% | 2.0% | 0.378 |

However, since we have no experience with the robotics unit positioned on the cranial side, this point remains unclear.

According to Urakov et al., the deviation rate for robotic-assisted PPSs was significantly lower than that of robotic-assisted open pedicle screws [10]. The deviation rate for robotic-assisted PPSs was reported to be 15.4%, consistent with that for fluoroscopic-assisted PPS insertion [11]. Because the entry point of PPS was not directly visible, it was difficult to notice even if drill skiving occurred. If the drill hits the slope of the bone when drilling the pilot hole, the lateral skiving force could cause the trajectory to deviate. A high-speed drill with a square bit can reduce drill skiving [12]. We considered that there were many deviations of PPSs in phase 1 using a traditional drill with a speed of from 120 to 180 rpm (Fig. 2A) and the deviation rates in phases 4 and 5 were improved due to the system upgrade and use of a high-speed drill of 60,000 rpm with a square bit (Fig. 2B). However, because of the small number of cases, we could not compare the PPS deviation rates between traditional and high-speed drills. The effect of using a high-speed drill on the deviation rate of PPS needs to be verified.

**Table 5**
Comparison by phases of surgical cases.

| | Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 | p |
|---|---|---|---|---|---|---|
| Number of screws | 226 | 227 | 191 | 198 | 206 | |
| Gertzbein-Robbins grade | | | | | | |
| A | 208 | 201 | 177 | 182 | 193 | |
| B | 12 | 17 | 12 | 14 | 9 | |
| C | 5 | 9 | 2 | 1 | 4 | |
| D | 1 | 0 | 0 | 0 | 0 | |
| E | 0 | 0 | 0 | 1 | 0 | |
| Perfect accuracy rate | 92.0% | 88.5% | 92.7% | 91.9% | 93.7% | 0.399 |
| Deviation rate | 2.7% | 4.0% | 1.0% | 1.0% | 1.9% | 0.232 |

Phase 1; the 1st to 25th cases, Phase 2; the 26th to 50th cases, Phase 3; the 51st to 75th cases, Phase 4; the 76th to 100th cases, Phase 5; the 101th to 125th cases.

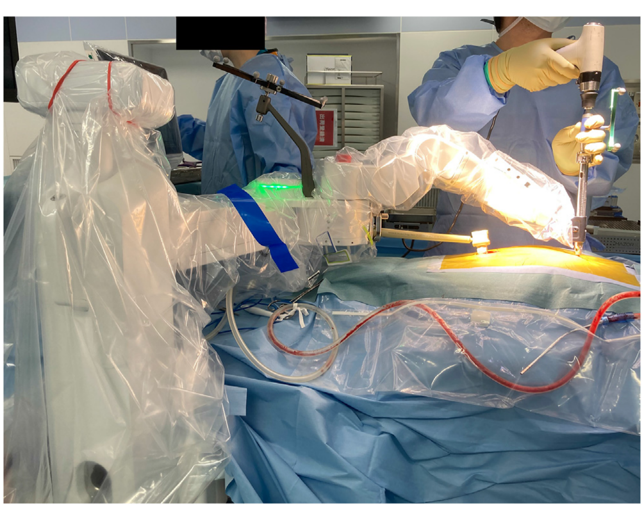

**Fig. 1.** The robotic arm unit was attached to the operating table on the caudal side. For upper thoracic screw placement, the robot extended its robotic arm. If the robotic arm is extended, the error in the arm position may increase resulting in a high deviation rate.

Segmental pedicle screw fixation is frequently used in surgery to correct spinal deformity, but a freehand technique tends to cause screw deviation. A statistically higher lumbar cortical perforation by pedicle screws was found in patients with scoliosis than in those with trauma [13]. Furthermore, a meta-analysis found higher deviation rates using the freehand technique than with navigation [14]. The deviation rate in patients with scoliosis was from 1.5% to 11.4% for navigation [9,15–18] and from 1.3% to 7.2% for robotics [6,19–21]. In our robotic-assisted screw placement, the deviation rate in spinal deformity cases was 2.5%, consistent with the deviation rate in patients without spinal deformity.

Various articles on the learning curve for robotic-assisted spine surgery reported from no learning curve to 30 required cases [22–28]. In these studies, the indices that define the learning curve also vary, including total surgical time, screw insertion time, and screw accuracy. A learning curve for screw insertion time has been reported to be 23 cases [27]. Based on previous reports, it is believed that the learning curve is between 20 and 30 cases. As 125 has factors of 1, 5, and 25, we defined one phase as 25 cases. In our study, the deviation rate was low from the onset, and we can consider the learning curve to have a very steep gradient curve in terms of screw accuracy.

A meta-analysis reported fewer complications (odds ratio: 0.31) for robotic-assisted pedicle screw placement compared with the conventional freehand technique [4]. Patients undergoing robotic-assisted lumbar fusion for degenerative disease did not have an increased 90-day complication rate compared with patients undergoing lumbar fusion with the freehand technique [29]. Kantelhardt et al. reported that complication rates for robotic-assisted pedicle screw placement were 1.0% for reoperation because inappropriate screws were inserted and 2.7% for wound infection [30]. In our present study, the complication rates were 0.8% for reoperation because of an implant-related neurological deficit and 0.8% for surgical site infection.

We experienced the intrusion of the robotic arm into the wound in 2 cases (1.6%). We consider the intrusion of the robotic arm into the wound as an error in the robotic system. The occurrence of the intrusion of the robotic arm indicates a potential problem within the application, and it is speculated that partial unawareness during the 3D scanning of the surgical field volume may be the cause. Since the application has been upgraded, this issue has not reoccurred. The emergency stop button is installed on the robotic arm unit to stop the arm's movement in case of an unintended movement. Since this technology is not yet perfect, it is essential for the surgeon to continuously monitor the arm's movement during the surgery to prevent any adverse event to the patient.



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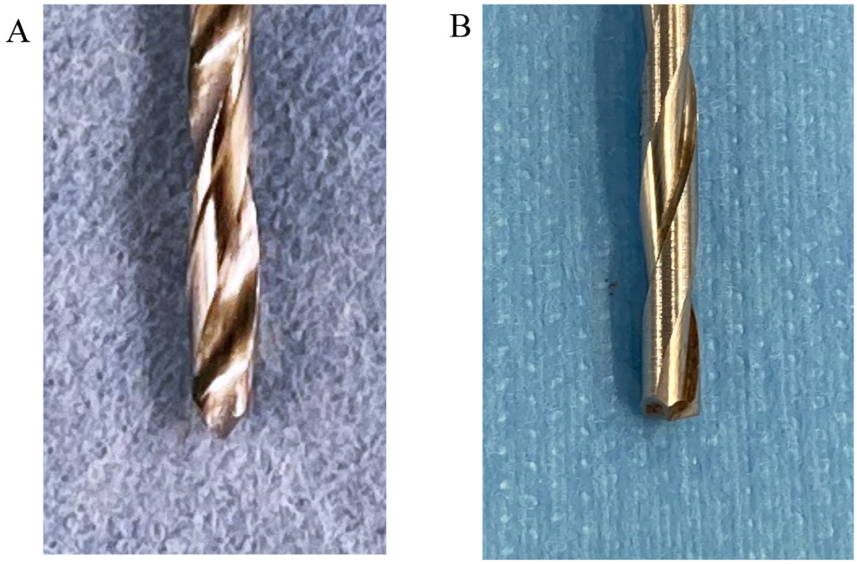


**Fig. 2.** Differences in the shape of the drill bit. (**A**) A traditional drill bit was tapered. (**B**) A new high-speed drill has a square bit. A high-speed drill with a square bit can reduce drill skiving.

The present study has several limitations. First, because it is not a randomized study, the numbers of cases or screws being compared were not equivalent. Second, we speculate that the deviation rate of the screws inserted at T1–T4 would be higher because of the position of the arm, but we could not verify this point because we had no experience in inserting screws with the robotics unit positioned cranially. We plan to place the robotics unit cranially to investigate whether the deviation rate in the upper thoracic region is improved. Third, we placed a relatively small number of screws, 30 in the upper thoracic spine and 97 in the PPS. During our experience with these cases, we had a poor impression of the deviation rate, which made us cautious about the indications for these robotic-assisted spine surgeries. However, through this study, we were able to clarify these issues and we will continue to address this challenge in the future. Forth, we believe that the perfect accuracy rate not only eliminates the possibility of nerve damage within an acceptable range of deviation but also signifies the successful insertion of screws according to the planning. By achieving planned screw insertion, we can potentially pave the way for the development of new insertion methods in the future. Finally, we have not verified the extent to which a high-speed drill improves the deviation rate. We plan to verify the effect of using a high-speed drill on the deviation rate in the future.

## 5. Conclusions

The deviation rate of robotic-assisted screw placement for spine surgery was 2.2%. Complications were reoperation due to implant-related neurological deficit in 0.8% and surgical site infection in 0.8%. Although the robotic-assisted screw placement was safe, we should be extra vigilant when placing screws in the upper thoracic region (deviation rate 10.3%) and when using PPSs (deviation rate 10.0%).

## Type of contribution of the authors

Tsutomu Akazawa wrote and prepared the manuscript. All authors participated in the study design. All authors have read, reviewed, and approved the article.

## Approval code

No. 5997, Institutional review board of St. Marianna University School of Medicine.

## Informed consent

The opt-out method was adopted to obtain informed consent for publication from the subjects.

## Declaration of competing interest

The authors declare the existence of a financial/non-financial competing interest from Medtronic and Globus Medical.

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