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Comparison of Accuracy of Pedicle Screw Insertion Among 4 Guided Technologies in Spine Surgery

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Background: As an available new tool for spinal surgery, robotic technology holds great potential and has been demonstrated to have better clinical outcomes compared with traditional techniques. However, it has not been compared with other assisted tools for the treatment of lumbar degenerative disease. This article focused on studying such variances.





Material/Methods: A total of 176 pedicle screws were inserted in 39 patients using a spine robot (group 1), 134 screws were implanted in 28 patients using navigational template (group 2), 234 screws were implanted in 51 patients by O-arm-based navigation (group 3), and 346 screws were implanted in 72 patients by fluoroscopy-guided assistance (group 4). The screw position was evaluated using postoperative scans according to Rampersaud A to D classification, and other secondary data were also collected.

Results: "Perfect" pedicle screw insertion (Grade A) was 90.34%, 91.79%, 84.19%, and 65.03% of groups 1–4, respectively. "Clinically acceptable" screw implantation (Grade A+B) was 94.32%, 95.52, 90.60%, and 78.03% in groups 1–4, respectively. Deviation sagittal (°) respectively was 3 ± 9 , 2 ± 10 , 4 ± 7 , and $10\pm 8^\circ$ in groups 1–4, respectively. Deviation transversal (°) screw insertion was 3 ± 8 , 3 ± 7 , 4 ± 9 , and $8\pm 13^\circ$ in groups 1–4, respectively. Statistical analysis showed group 1 had no significant difference in the accuracy of "Perfect and Clinical acceptable" as well as deviation sagittal or transversal, respectively, compared with groups 2 and 3 but not group 4.

Conclusions: Robotic-assistance technology no clear advantage in terms of accuracy compared to the navigation template or O-arm systems for screw implantation, but it significantly reduced adverse events, fluoroscopy time per screw, postoperative stay, and blood loss.

MeSH Keywords: **Bone Screws • Fluoroscopy • Robotics • Surgery, Computer-Assisted • Templates, Genetic**

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Background

Digital orthopedics technology applied in the field of spinal surgery has developed rapidly in recent years. The introduction of robotics SpineAssist™, a spinous process-mounted miniature robot, holds great potential. Although robotic-assisted surgery is an emerging field [1], the advantages of minimal invasiveness and high accuracy of screw implantation are critical reasons why some “pioneering” surgeons are focusing on this new field. Now it has routinely been advocated to apply for lumbar fracture and degenerative disease, enabling surgeons to visualize and guide complex spine anatomic structures during preoperative and intraoperative stages. Because of the anatomical proximity of the vertebral pedicles to associated neurovascular structures, there is added risk of serious morbidity from neurovascular damage, dural tearing or visceral injury from misplaced pedicle screws [2].

Other guiding methods, such as clinical patient-specific templates and computer-assisted navigation systems, have also been used to enhance insertion accuracy and lower the incidence of neurological complications. A series of low- to high-level studies [3–6] have shown better accuracy of the SpineAssist™ compared with the conventional fluoroscopy-guided method, which has advantages compared with the pragmatic navigational template or image-guided navigation systems. Therefore, we retrospectively collected data on differences among these various methods. Comparisons were made regardless of accuracy or surgical time, adverse events, intraoperative revision of screws, fluoroscopy time, postoperative stay, and blood loss.

Material and Methods

Subjects and study design

Between 2013 and 2017, 890 pedicle screws were placed in 190 adult patients to reconstruct 3-column stability for the treatment of spine degenerative disease. Underlying lumbar degenerative diagnoses included lumbar spinal stenosis (67), lumbar disc herniation (84), and lumbar spondylolisthesis (39). Medical records containing demographic, clinical, and diagnostic data, as well as intraoperative measurement and imaging, were retrospectively reviewed. Thirty-nine patients underwent minimally invasive robotic-assisted surgery, 28 patients underwent navigational template-assisted surgery, 51 patients underwent O-arm-based navigation system-assisted spinal fixation, and 72 patients underwent conventional open spinal instrumentation. All included patients underwent decompression or TLIF surgery with 1–2 fusion segments (Table 1). Hospital Review Board approval was granted for all aspects of this study. The patients with degenerated pathology that showed obvious clinical symptoms or neurologic deficit were identified as possessing an indication

for operative treatment for spinal instrumentation and decompression. Patient exclusion criteria were: (1) Degenerative scoliosis, infection of spine, tumor, discitis, or vertebral tuberculosis; (2) Patients who underwent decompression surgery without fusion; (3) Relevant data incomplete.

Robot-assisted surgical instrumentation

Thirty-nine patients underwent robot-assisted percutaneous spinal instrumentation. Prior to surgery, 1-mm slice computed tomographic (CT) scans for 3D reconstructions and CT data were transferred to a PC and imported to the SpineAssist planning software to design the screw trajectories, with the plan transferred to the SpineAssist workstation in the operating room. The preoperative CT scan was matched with intraoperative fluoroscopy images (anteroposterior and oblique directions) acquired from patient's anatomy for registration of the robot. Basic steps in the SpineAssist™ operation were: 1. Preoperative planning; 2. Attachment to bony anatomy; 3. Image acquisition and registration; 4. Robot assembly and motion; 5. Soft tissue perforate; 6. Drilling and placing tubing system; 7. Cannula introduction and K-wire placement; and 8. Soft tissue protection and screw insertion. Surgical workflow of the robotic system assistance is shown in Figure 1, with a minimal access with a 1–2 cm incision for decompression or reset under microendoscopy, or an open access for other operations.

Conventional free-hand fluoroscopy-guided approach

For conventional FH pedicle screw implantation, AP and lateral fluoroscopy was used during the procedure. A midline skin incision and approach to the spine were established, identifying anatomical landmarks by lateral and AP fluoroscopy, then the pedicle screws were implanted and connected to rods according to the manufacturer's instructions. If necessary, a subsequent decompression of the spinal canal or fusion procedure was performed.

Patient-specific template-guided surgical procedure

The major procedures for assisting screw implantation were: 1) CT scanning with thin slice for target spine vertebral body; 2) Three-dimensional reconstruction by captured data, then identifying optimal entry hole and calculating width, height and length of target pedicle on the special software; 3) Designing a digital template contrary to anatomic structure of target level; 4) Printing digital patient-specific template except pre-reserved column using a 3D printer; 5) Preoperative sterilization of solid template and intraoperative clear of soft tissue behind the intended vertebral plate and spinous process; and 6) Attach template on the rest of the bone structure, then insert the screw through the pre-designed trajectory. If necessary, a subsequent decompression or fusion procedure was performed.

Table 1. Baseline characteristics.

| | Value | | | |
|--------------------------|----------|-----------|----------|----------|
| | RA | NT | ON | FG |
| Parameter | | | | |
| No. of patients | 39 | 28 | 51 | 72 |
| Females, n (%) | 20 (51) | 15 (54) | 31 (61) | 39 (54) |
| Age (years) | 60.6±7.9 | 63.9±10.3 | 65.1±8.0 | 62.4±8.9 |
| Mean BMI | 22.9±4.7 | 24.4±2.8 | 24.8±3.5 | 25.0±7.3 |
| No. of screws | 176 | 134 | 234 | 346 |
| Screw diameter (n) | | | | |
| 6.5 mm | 129 | 99 | 179 | 302 |
| 5.5 mm | 47 | 35 | 55 | 44 |
| Diagnosis (n) | | | | |
| LSS | 14 | 8 | 18 | 27 |
| LDH | 18 | 13 | 23 | 30 |
| Lumbar spondylolisthesis | 7 | 7 | 10 | 15 |
| Level (n) | | | | |
| L2–L3 | 3 | 2 | 7 | 9 |
| L3–L4 | 10 | 7 | 12 | 16 |
| L4–L5 | 19 | 13 | 23 | 31 |
| L5–S1 | 20 | 14 | 26 | 39 |
| Fusion extent | | | | |
| One segment | 26 | 19 | 34 | 48 |
| Two segments | 13 | 8 | 17 | 23 |

RA – robot-assisted; NT– navigation template; ON – O-arm navigation system; FG – fluoroscopy guided; All baseline parameters did not significantly differ among the 4 groups.

O-arm-based navigation system-guided surgical instrumentation

Use of the O-arm-based navigation system for surgery included 4 steps. 1) A reference clamp was applied to the spinous process of the vertebra; 2) Obtained CT data were automatically registered by 3D fluoroscopy; 3) Entry point and screw trajectory were identified using a navigation probe; and 4) Insert a curved pedicle probe, and then insert pedicle screws. If necessary, a subsequent decompression or fusion procedure was performed.

Primary outcomes

The primary measure was screw accuracy, which was assessed according to Rampersaud A to D classification using axial,

coronal, and sagittal reconstruction views of the CT scans (Figure 2) [7]. Grade A: screw is completely within the pedicle; Grade B, screw breaches the pedicle's cortex by <2 mm; Grade C, pedicle cortical breach <4 mm; Grade D, pedicle cortical breach ≥4 mm. Deviation sagittal and transversal were also evaluated for pedicle screw placement accuracy. Two spine surgeons independently evaluated all CT scans in the 4 groups. Screws graded A are perfect, those graded A+B are clinically acceptable, and those graded C+D classification have a significant deviation from the intended trajectory.

Secondary parameters

We recorded the time of surgery, intraoperative revision of misplaced screws, and adverse events. Postoperative neurological evaluation was performed in all cases. We collected data on

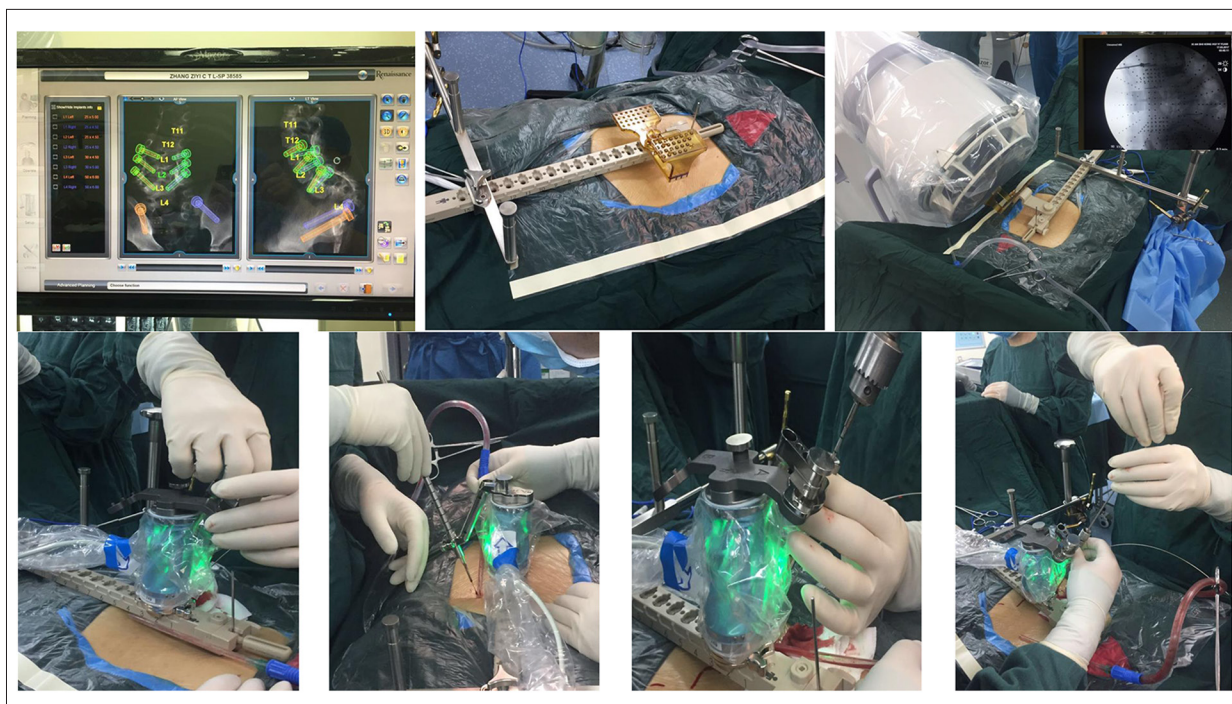


Figure 1. Surgical workflow of the robotic system assistance.

intraoperative blood loss and postoperative stay. We also collected intraoperative fluoroscopy time per screw.

Statistics

We used the *t* test for statistical analysis of count data by comparing group 1 with groups 2–4. Mean values are presented as mean \pm SD. For quantitative data, the chi-square test was used. Significance level was set $\alpha=0.05$.

Results

Mean patient age was 63.0 years (range: 39–84), gender ratio (m/f) was 190/105. Average BMI was 24.3. All baseline parameters (\pm SD) did not significantly differ among the 4 groups (Table 1). Screw diameters varied from 5.5 to 6.5 mm.

Accuracy of pedicle screw placement

“Perfect” pedicle screw insertion (Grade A) in groups 1–4 were 90.34%, 91.79%, 84.19%, and 65.03%, respectively. “Clinical acceptable” screw implantation (Grade A+B) in groups 1–4 had accuracy of 94.32%, 95.52, 90.60%, and 78.03%, respectively. Prevalence of possible breach (Grade C+D) was 5.68%, 4.48%, 2.99%, and 21.97%, respectively. Deviation sagittal (°) was 3 ± 9 , 2 ± 10 , 4 ± 7 , and 10 ± 8 , respectively. Deviation transversal (°) was 3 ± 8 , 3 ± 7 , 4 ± 9 , and 8 ± 13 , respectively. Statistical analysis showed group 1 had no significant difference in the

accuracy of “Perfect and Clinically acceptable” placement, as well as deviation sagittal or transversal, respectively, compared with groups 2 and 3, but not with group 4 (Table 2).

Secondary results

The total time for surgery, as shown in Table 3, was 201 ± 42 min in group 1, 180 ± 30 min in group 2, 194 ± 38 min in group 3, and 178 ± 55 min in group 4. Clearly, group 1 has longer surgical times than group 2 and group 4, but group 1 was not significantly different from group 3. Group 1 had lower prevalence of total adverse events (2 [5.13%]) than in group 2 (5 [17.86%]), group 3 (7 [13.73%]), and group 4 (14 [19.44%]). The prevalence of dural tears in groups 1–4 was 1 [2.56%], 0 [0%], 2 [3.92%], and 4 [5.55%], respectively; the prevalence of surgical wound revision was 0 [0%], 4 [14.28%], 5 [9.80%], and 5 [6.94%], respectively; the prevalence of wound infections was 1 [2.56%], 0 [0%], 2 [3.92%], and 3 [4.17%], respectively; the prevalence of seroma was 0 [0%], 1 [3.57%], 2 [3.92%], and 1 [1.41%], respectively; and the prevalence of screw-related neurological complications was 0 [0%] in groups 1–3 and 1 [1.41%] in group 4. Intraoperative revision of screws, because the screw did not show sufficient bone grip or lateral fluoroscopy showed that the entry point was not pointing directly on the craniocaudal center of the pedicle, a new trajectory was re-identified based on fluoroscopy-guided. Therefore, every revised screw was considered as an inaccuracy (Grade C or Grade D) that was clinically unacceptable. The rate in the robot-assisted group was lower than in the fluoroscopy-guided group,

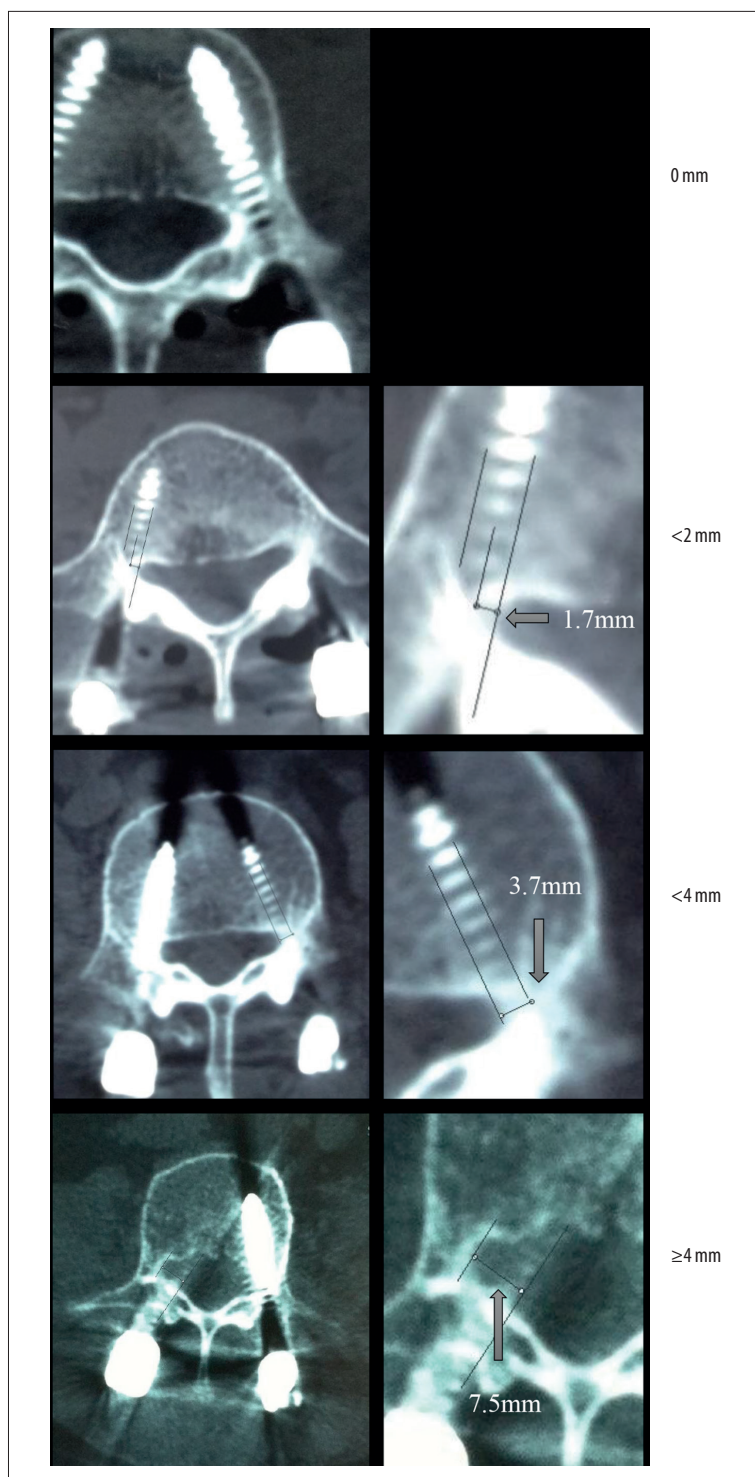


Figure 2. Rampersaud classification according to CT scans shows the deviation of the screw from the optimal trajectory. The systems are: Grade A, screw is completely within the pedicle; Grade B, screw breaches the pedicle's cortex by < 2 mm; Grade C, pedicle cortical breach < 4 mm; Grade D, pedicle cortical breach ≥ 4 mm.

but there was no statistically significant difference between group 1 and group 2 or 3. Fluoroscopy times per screw were 4.02 ± 1.6 s, 1.29 ± 0.6 s, 6.36 ± 1.7 s, and 8.89 ± 3.1 s, respectively, and the navigation template group had shorter times than in the other groups. Blood loss was 362 ± 120 ml, 554 ± 272 ml, 528 ± 250 ml, and 557 ± 261 ml, respectively. Postoperative stay

was 6.3 ± 1.2 d, 8.5 ± 1.4 d, 7.9 ± 1.1 d, and 8.9 ± 1.8 d, respectively, and group 1 had the least blood loss and shortest length of stay. All secondary results of count data are shown in the 4-column graph in Figure 3.

Table 2. Accuracy of pedicle screw placement among four guided technologies.

| Screw position* | RA (n=176) (%) | NT (n=134) (%) | ON (n=234) (%) | FG (n=346) (%) | P value | | |
|---|-------------------|-------------------|-------------------|-------------------|-----------|-----------|-----------|
| | | | | | RA vs. NT | RA vs. ON | RA vs. FG |
| A | 159 (90.34) | 123 (91.79) | 197 (84.19) | 225 (65.03) | 0.637 | 0.075 | 0.000 |
| B | 7 (3.98) | 5 (3.73) | 15 (6.41) | 45 (13.01) | 0.911 | 0.279 | 0.001 |
| A+B | 166 (94.32) | 128 (95.52) | 212 (90.60) | 270 (78.03) | 0.635 | 0.165 | 0.000 |
| C | 8 (4.55) | 5 (3.73) | 22 (9.40) | 58 (16.76) | 0.723 | 0.062 | 0.000 |
| D | 2 (1.14) | 1 (0.75) | 0 (0) | 18 (5.20) | 0.728 | 0.102 | 0.022 |
| C+D | 10 (5.68) | 6 (4.48) | 22 (9.40) | 76 (21.97) | 0.635 | 0.165 | 0.000 |
| Deviation sagittal (°), mean (SD) | 3±9 | 2±10 | 4±7 | 10±8 | 0.356 | 0.223 | 0 |
| Deviation transversal (°), mean (SD) | 3±8 | 3±7 | 4±9 | 8±13 | 1.081 | 0.244 | 0 |

* Screw position identified according to Rampersaud scale A to D classification; RA – robot-assisted; NT– navigation template; ON – O-arm navigation system; FG – fluoroscopy guided.

Table 3. Secondary parameters.

| | RA | NT | ON | FG | P value | | |
|--|-----------|------------|------------|-------------|-----------|-----------|-----------|
| | | | | | RS vs. NT | RA vs. ON | RA vs. FG |
| Time for surgery (min) | 201±42 | 180±30 | 194±38 | 178±55 | 0.027 | 0.347 | 0.025 |
| Adverse events (n) | | | | | | | |
| Dural tears | 1 | 0 | 1 | 4 | | | |
| Surgical wound revision | 0 | 4 | 3 | 6 | | | |
| Wound Infections | 1 | 0 | 1 | 1 | | | |
| Seroma | 0 | 1 | 2 | 2 | | | |
| Neurological complications | 0 | 0 | 0 | 1 | | | |
| Total | 2 (5.13%) | 5 (17.86%) | 7 (13.73%) | 14 (19.44%) | 0.006 | 0.002 | 0.003 |
| Intraoperative revision of screws (%) | 3 (1.70%) | 4 (2.99%) | 8 (3.42%) | 24 (6.94%) | 0.452 | 0.288 | 0.011 |
| Fluoroscopy time per screw (s) | 4.02±1.6 | 1.29±0.6 | 6.36±1.7 | 8.89±3.1 | 0.000 | 0.000 | 0.000 |
| Blood loss (ml) | 362±120 | 554±272 | 528±250 | 557±261 | 0.001 | 0.000 | 0.000 |
| Postoperative stay (d) | 6.3±1.2 | 8.5±1.4 | 7.9±1.1 | 8.9±1.8 | 0.000 | 0.000 | 0.000 |

RA – robot-assisted; NT– navigation template; ON – O-arm navigation system; FG – fluoroscopy guided.

Discussion

Patient safety must be the first priority of surgeons using advanced tools. The SpineAssist system-based accurate auxiliary measures were designed to improve pedicle screw accuracy and safety. Actually, its safety and accuracy is always doubted by experienced Chinese doctors who are good at free-hand screw insertion, have great confidence in their ability to

perform this technique, or just dislike complicated procedures. However, some high-level clinical studies [8–10] have reported that previous tools all have adequate safety and accuracy for spine surgery, such as conductivity measurement devices that detect cortical defects in the screw trajectory, and been improved [11,12].

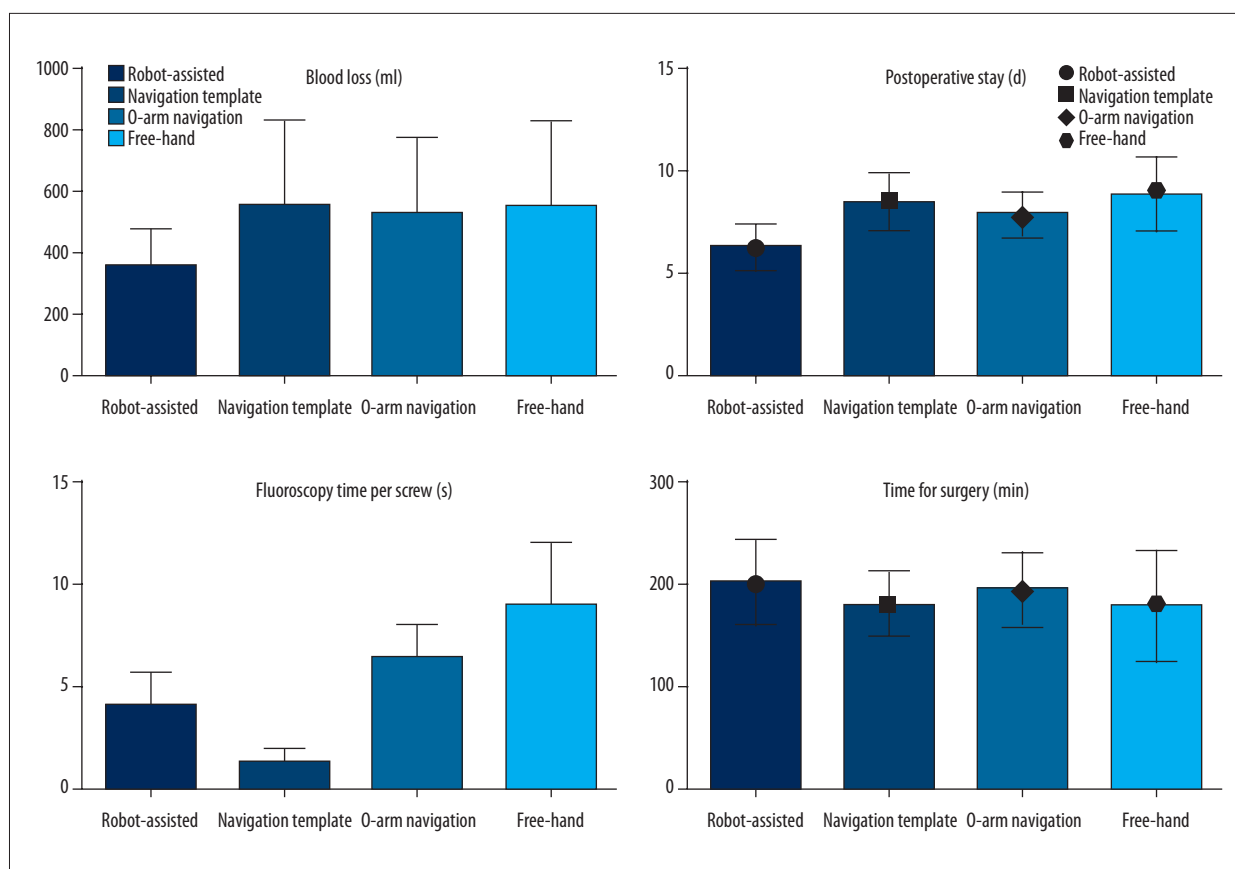


Figure 3. Column graph of comparison of adverse events, time for surgery, fluoroscopy time per screw, blood loss, and postoperative stay among the 4 guided technologies.

A retrospective series study by DeVito summarized the first experiences with the SpineAssist robot in 14 spine centers worldwide, showing a 98% rate of clinically acceptable screw insertion and no permanent nerve damage occurred [13]. Although 9% of screws showed a minor pedicle breach, they still had excellent biomechanical properties without the potential of clinically apparent neurological or vascular impairment, and with clinically acceptable safety regarding malposition.

Hyun [14] designed a prospective randomized clinical trial comparing a minimally invasive robotic and open fluoroscopic-guided spinal instrumented fusions, with pedicle screw positions classified using a modification of the Gertzbein-Robbins method: 97.7% of screws were located completely within the pedicle, and 2.3% of screws breached the pedicle cortex by <2 mm, and all screws were clinically acceptable without screw-related neurological damage.

Factors such as surgical time, fluoroscopy time, and adverse events must be comprehensively considered before the spine robot can gradually replace screw placement assistance methods.

In our review, the robot's accuracy and safety have again been demonstrated compared with traditional fluoroscopy-guided technique; however, we failed to show a sufficient difference in terms of accuracy of "Perfect" and "clinically acceptable" pedicle screw insertion compared with the navigation template or O-arm-guided system, and in the sagittal and transverse deviation. We found that 94.32% of screws (Grade A+ Grade B) in this study were clinically acceptable, less than the 98% reported in a review by DeVito, because he identified pedicle cortical breach <4 mm without neurological complications as "Clinically acceptable" accuracy. Strictly speaking, a screw that breach the pedicle's cortex by ≥ 2 mm has risk of long-term screw-related neurological complications. In our experience, we only classify Grade A+B as appropriate criterion of clinically acceptable screw placement accuracy. Interestingly, the accuracy of "Acceptable" in the navigation template group (95.52%) was higher than in the robot-assisted group (94.32%), though the difference was not statistically significant. During the last decade, gradual advances in computer and additive manufacturing technology have result in a more practical and sophisticated application of individual templates in spine surgery, with promising outcomes [6].

As shown in Figure 3, intraoperatively, the robot-assisted method need more time for surgery due to the complicated procedures. However, the navigation template method only need 2 fluoroscopies, preoperative and postoperative, so it shows significant superiority over the robot in fluoroscopy time [15,16]. For adverse events, blood loss, and length of stay, the spine robot shows important advantages than other 2 tools, but there were no clear differences in rate of intraoperative revision of screws between the robot-assisted and navigation template, robot-assisted, and O-arm-guided system. Of all the assisted or guided tools, only the spine robot can be used for assisting percutaneous minimally invasive screw insertion, and the relatively lower rate of injury by technique itself may explain the reduced adverse events, blood loss, and length of stay.

The SpineAssist™ system consists of 2 units: a cylindrical miniature robot with an end-effector that can be moved in 6 degrees of freedom, and a connected workstation that runs graphic user interface software responsible for intraoperative real-time robot motion monitoring and control, preoperative planning, image acquisition, registration for matching, and calculations [13]. The miniature robot has characteristics of ergonomics, great dexterity that eliminates physiological tremor of surgeons, image-based semi-active guidance for screw insertion, ability to hold tools for long times and make repetitive motions, quick response to change in commands, excellent three-dimensional visualization, and reduction of intraoperative radiation exposure [17]. The SpineAssist™ platform uses a computerized mechanical positioning system that assists surgeons insert implants along the planned trajectory, with 2 advantages: 1) Registration does not require using bony landmarks and it can be applied even for difficult insertions and on deformed spines; and 2) The robot system works without relying on a camera tracking mechanism, thereby avoiding all the problems of reconnaissance between the camera and navigation instruments or targets [18].

We found certain weaknesses in the use of the robotic system. Robot-guided screws showed no grip and had to be revised openly. One patient with lumbar spinal stenosis with

degenerative scoliosis had a failed operation to match the pre-operative CT scan with intraoperative fluoroscopy images, which wasted some time and changed surgical planning as to open access. Other groups had screws revised due to no grip or failure to identify the optimal entry point, or the probe touched or penetrated the pedicle walls. All of this was considered as inaccuracy (Grade C of Grade D), included in the analysis as poor screw positioning that was clinically unacceptable. Although there was good registration, it still is possible that a cannula sliding off an angled bone surface results in most difficult-to-prevent lateral screw inaccuracy [19]. Normally, this occurs lateral to the facet joint, demanding care when using the robot.

One limitation of our study should be mentioned. The robot group underwent a percutaneous minimally invasive-type surgery, while the other groups underwent an open technique. The character of advanced technology itself may add some bias to current study, however, it is unlikely that the differences in screw placement approach would change the primary outcome and conclusion of this report.

Conclusions

Although the robot-assisted method failed to show significant differences for the accuracy of screw insertion, and it requires more surgical time compared with navigation template or O-arm guided system, it has superiorities that reduce adverse events, intraoperative revision of screws, fluoroscopy time, blood loss, and postoperative stay.

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Conflicts of interest

None.

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