Received: 19 July 2019 | Revised: 18 September 2019 | Accepted: 24 October 2019
DOI: 10.1002/rcs.2054

ORIGINAL ARTICLE

The International Journal of Medical Robotics and Computer Assisted Surgery
WILEY

Navigated robotic assistance improves pedicle screw accuracy in minimally invasive surgery of the lumbosacral spine: 600 pedicle screws in a single institution

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Abstract

Background: In the emerging field of robot-assisted spine surgery, radiographic evaluation of pedicle screw accuracy in the surgical setting is of high interest. Advances in medical imaging have improved the accuracy of pedicle screw placement, from fluoroscopy-guided to computer-aided navigation.

Methods: A retrospective, institutional review board–exempt review of the first 106 navigated robot-assisted spine surgery cases was performed. Radiographic evaluation of preoperative and postoperative computerized tomography (CT) scans were collected.

Results: In the first 106 cases, 630 lumbosacral pedicle screws were placed. Thirty screws were placed in five patients without the robot because of surgeon discretion. Of the 600 pedicle screws inserted by navigated robotic guidance, only 1.5% (9/600) were repositioned intraoperatively.

Conclusion: This study demonstrated a high level of accuracy (98.2%) in terms of grade A or B pedicle screw breach scores in the clinical use of navigated, robot-assisted surgery in its first 101 cases.

KEYWORDS
minimally invasive, pedicle screw placement, robot-navigated, spine surgery

1 | INTRODUCTION

The risks of conventional open and minimally invasive surgery (MIS) pedicle screw placement (freehand pedicle screw placement) include a high risk of radiation exposure to patients, surgeons, and operating room (OR) staff, as well as an increased risk of screw misplacement, even with the addition of two-dimensional (2D) fluoroscopy.[1] The risk of neurovascular injury and the need for lower radiation dosage and improved pedicle screw accuracy have influenced the development of navigated robot-assisted spine surgery.

A major positive step in the field of neurosurgery was taken when a robot was first used for needle placement in a computerized tomography (CT)–guided brain biopsy almost 35 years ago.[2] Robots used in surgery provide a rigid guide to a planned trajectory and integration with modern imaging technology, as well as many additional benefits inherent to individual surgical specialties.[3]

Because of this recent advancement, evaluation of pedicle screw accuracy in the surgical setting is necessary to determine the efficacy of navigated robotic guidance in spine surgery. The objective of this study is to determine the accuracy of pedicle screw placement using navigation with robotic guidance for the first 600 pedicle screws (101 patients) in a private practice clinical setting.

2 | MATERIALS AND METHODS

A retrospective, institutional review board–exempt review of the first 106 navigated robot-assisted spine surgery cases was performed. Radiographic evaluation of preoperative and postoperative CT scans was collected, along with complication rates.

2.1 | Navigated robot-assisted pedicle screw positioning system

The robotic positioning system (ExcelsiusGPS; Globus Medical, Inc, Audubon, PA, USA) that was studied uses patient radiographs (preoperative CT, intraoperative CT, or fluoroscopy), along with a dynamic reference base (DRB) that is visualized by the infrared motion capture camera to guide pedicle screw placement in real time (Figure 1). The robot allows verification of operative planning and real-time navigation feedback, including active navigation, force sensing technology, navigated integrated instruments, and preoperative and intraoperative planning. The robot combines a rigid robotic arm and full navigation capabilities to aid in precise trajectory alignment in spine surgery. It allows for real-time intraoperative imaging, registration, and direct screw insertion through a rigid external arm without the need for interspinous clamps or K-wires.[4]

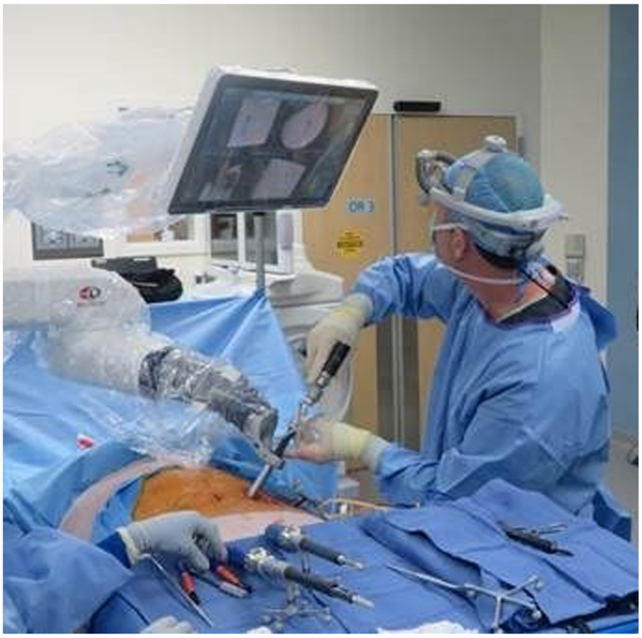

FIGURE 1 Screw insertion with the robotic positioning system

2.2 | Surgical technique: Minimally invasive navigated, robot-assisted surgery

In this study, the robotic system operated on one functional modality, intraoperative CT. In this mode, the image coordinate system was obtained from a portable intraoperative CT (eg, O-arm; Medtronic SNT, Louisville, CO, USA) or a standard CT scan taken at the time of surgery with the patient already in surgical position (prone). After a CT scan was taken and the spinal levels were identified, pedicle screw trajectories were planned and saved. Reference frames were installed and fixated to the pelvis, and instruments and arrays with reflective markers were registered. A surgeon-controlled foot pedal activated and positioned the robot arm to the planned pedicle trajectory. Stab incisions were made on the skin using a scalpel. Fluoroscopic control was not used while inserting pedicle screws. Pedicle screws were inserted percutaneously using navigated instruments guided by the robotic arm. This sequence was repeated until all pedicle screws were placed. Rods were then placed, and locking caps were set once the rods were in the proper position. Intraoperative CT images were taken to verify screw and rod position. These images allowed the surgeon to assess for pedicle screw accuracy. Interbody devices (when used) were inserted manually. Surgical incisions were cleaned and closed in the standard fashion.

2.3 | Outcome measures

A CT-based Gertzbein-Robbins system (GRS) was used to classify pedicle screw placement, in which screws were graded as A (screw is completely within the pedicle), B (pedicle cortical breach < 2 mm), C (pedicle cortical breach < 4 mm), D (pedicle cortical breach < 6 mm), or E (pedicle cortical breach > 6 mm).[5] The evaluator was blinded to the study purpose. Screws assigned an A or B grade were deemed as accurate, while screws with a C, D, or E grade were considered inaccurate, as previously demonstrated.[5-8] The number of accurate screws divided by the number of total screws placed with robotic navigation resulted in percentage accuracy. Additionally, quantitative three-dimensional screw tip, screw tail, and screw angulation offsets were determined using CT scans and an image overlay analysis to compare preoperative planned trajectories with actual postoperative screw placement. This was performed using a proprietary semiautomatic 3D image overlay software application that digitally measures offsets between planned and actual pedicle screw placement (Figure 2 and 3). Pedicle screw malposition, reposition, and return to OR rates were collected.

2.4 | Statistical analysis

A statistical analysis was performed using SPSS Statistics Version 25 software (IBM Corp, Armonk, NY, USA). Data were presented as mean ± standard deviation. The level of statistical significance was set to $P < .05$ for all statistical analyses.

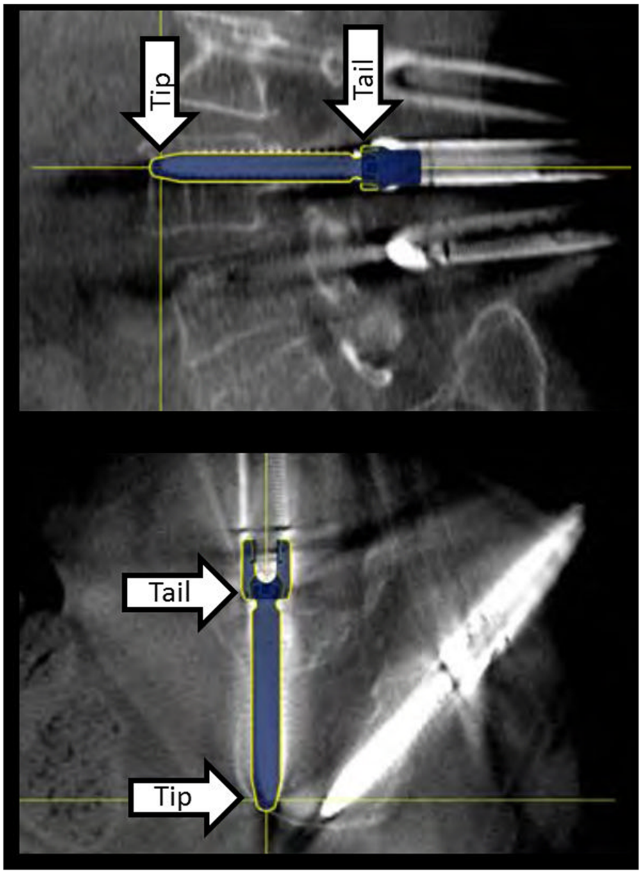

FIGURE 2 Description of the translational (tip and tail) offset

3 | RESULTS

3.1 | Patient demographics

The average patient age was 64.8 ± 11.5 years, and 55.4% (56/101) were female. The average body mass index was 30.6 ± 5.7 kg/m^2. The majority of surgery diagnoses were degenerative disc disease (78.2%; 79/101) or adjacent segment disease (18.8%; 19/101) (Table 1).

3.2 | Surgical data

In the first 106 cases, 630 lumbosacral pedicle screws were placed. Thirty screws were placed in five patients without the robot. In four of the cases, the images were not properly merged. In one case, the software malfunctioned. In all five cases, the robot could have been used after addressing the issues; however, the surgeon decided against using the robot to avoid delays and maintain workflow efficiency in the OR. This study includes data on the first 101 consecutive cases where 600 lumbosacral pedicle screws were inserted by aid of navigated robotic guidance. Of the 600 screws, only 1.5% (9/600) were repositioned intraoperatively with the aid of navigated robotic guidance. The screws were repositioned because of lateral skiving. The screws were still in acceptable position on the basis of the intraoperative CT scan assessment by the surgeon. However, the surgeon wanted to optimize screw placement and thus chose to reposition the screws. In these cases, the surgeon changed the starting point to a more lateral position and replanned and reinserted the

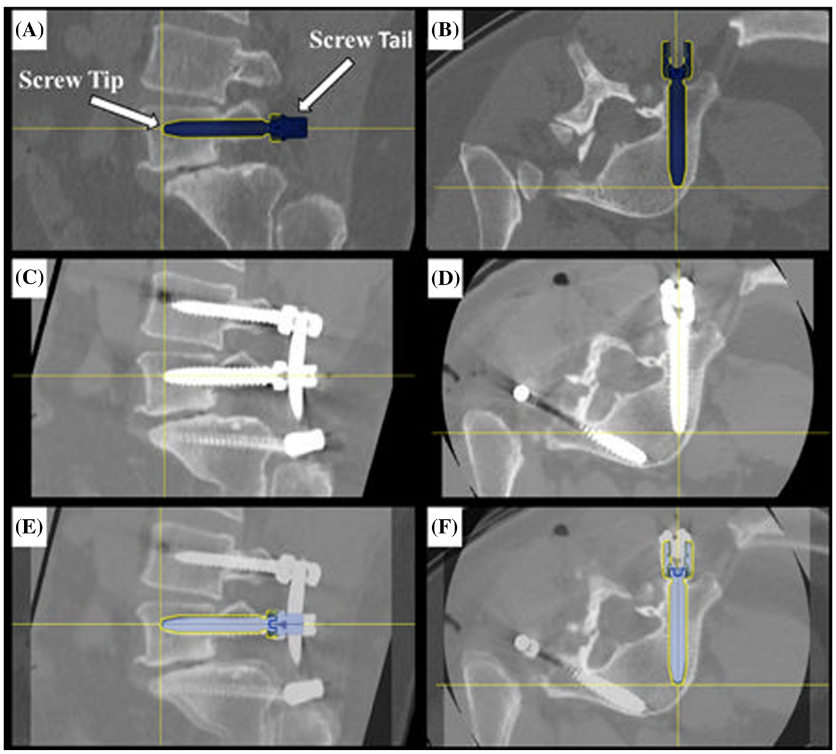

FIGURE 3 Screw tip, tail, and angle offset assessment. Right L5 screw planning: A, sagittal; B, axial planes. Image overlay analysis with preoperative planned trajectory and postoperative screw placement: C, sagittal planes; D, axial planes. Postoperative CT of L5 screw placement without a medial or lateral breach: E, sagittal plane; F, axial plane. The crosshairs indicate screw tip. CT, computerized tomography

TABLE 1 Baseline characteristics

Parameter	Overall
Number of patients	101
Gender	
Female, n (%)	56 (55.4%)
Male, n (%)	45 (44.6%)
Age, mean (SD, range)	64.8 (11.5) (31-87)
BMI, mean (SD, range)	30.6 (5.7) (19-44)
Diagnosis, n (%)	
Degenerative disc disease	79 (78.2%)
Adjacent segment disease	19 (18.8%)
Trauma	2 (2.0%)
Infection	1 (1.0%)

screws using the robot. CT scans were taken before and after screw reinsertion.

Of the 600 screws, 26.0% (156/600) were placed at L4 and 25.7% (154/600) were placed at L5. The most common screw size used was 7.5 × 50 mm (25.0%). The mean estimated blood loss was 165 ± 92.0 cm^3. The mean operative time was 142.3 ± 50.3 minutes. The mean length of hospital stay was 4.6 ± 1.9 days. The most common disposition was home (31.7%) or rehabilitation (30.7%) (Table 2).

3.3 | Pedicle screw accuracy

Based on the GRS CT-based grading, 98.2% (589/600) of screws were graded A or B, 1.5% (9/600) screws were graded C, and 0.3% (2/600) screws were graded D (Figure 4).

3.4 | Translational and angular deviations

The average offset from preoperative plan to actual final placement was 1.7 ± 1.3 mm from the tip, 1.8 ± 1.2 mm from the tail, and 2.0 ± 1.6 degrees of angulation (Table 3).

3.5 | Complications

Two complications, interbody removal and wound vacuum–assisted closure, were reported as requiring a return to the OR, but these were not related to robotic guidance or pedicle screws. Based on postoperative CT scans, there was no evidence of superior facet joint violation.

4 | DISCUSSION

This study demonstrates a high level of accuracy of pedicle screw placement during percutaneous minimally invasive navigated robot-assisted spine surgery in the lumbosacral spine, in terms of pedicle breach rates. Pedicle screw placement using conventional freehand and 2D fluoroscopy is associated with clinically relevant complications including revision surgery because of pedicle screw misplacement, neurological deficit, and vascular and visceral injury.[1,9] This has led to the development of various approaches to reduce such complications and improve the accuracy of pedicle screw placement, with the most recent being robot-assisted navigated pedicle screw placement.

Robot-assisted navigated surgical systems are built to allow surgeons to place pedicle screws more accurately. Unlike standard navigation, these systems may include a skive meter, surveillance marker,

TABLE 2 Surgical data

Parameter	Overall
Levels treated, n (%)	
L1	16 (2.7%)
L2	48 (8.0%)
L3	128 (21.3%)
L4	156 (26.0%)
L5	154 (25.7%)
S1	98 (16.3%)
Screw size, n (%)	
5.5 × 45 mm	2 (0.3%)
5.5 × 50 mm	6 (1.0%)
5.5 × 55 mm	2 (0.3%)
6.5 × 45 mm	9 (1.5%)
6.5 × 50 mm	38 (6.3%)
6.5 × 55 mm	18 (3.0%)
6.5 × 60 mm	11 (1.8%)
7.5 × 35 mm	2 (0.3%)
7.5 × 40 mm	8 (1.3%)
7.5 × 45 mm	56 (9.3%)
7.5 × 50 mm	150 (25.0%)
7.5 × 55 mm	58 (9.7%)
7.5 × 60 mm	20 (3.3%)
7.5 × 65 mm	4 (0.7%)
8.5 × 40 mm	15 (2.5%)
8.5 × 45 mm	48 (8.0%)
8.5 × 50 mm	85 (14.2%)
8.5 × 55 mm	54 (9.0%)
8.5 × 60 mm	12 (2.0%)
8.5 × 65 mm	2 (0.3%)
Mean estimated blood loss (cm^3), n (SD)	165.4 (92.0)
Mean operative time (min)	142.3 (50.3)
Mean length of hospital stay (d)	4.6 ± 1.9
Disposition, n (%)	
Home	32 (31.7%)
Rehabilitation	31 (30.7%)
Home health	26 (25.7%)
Skilled nursing facility	11 (10.9%)

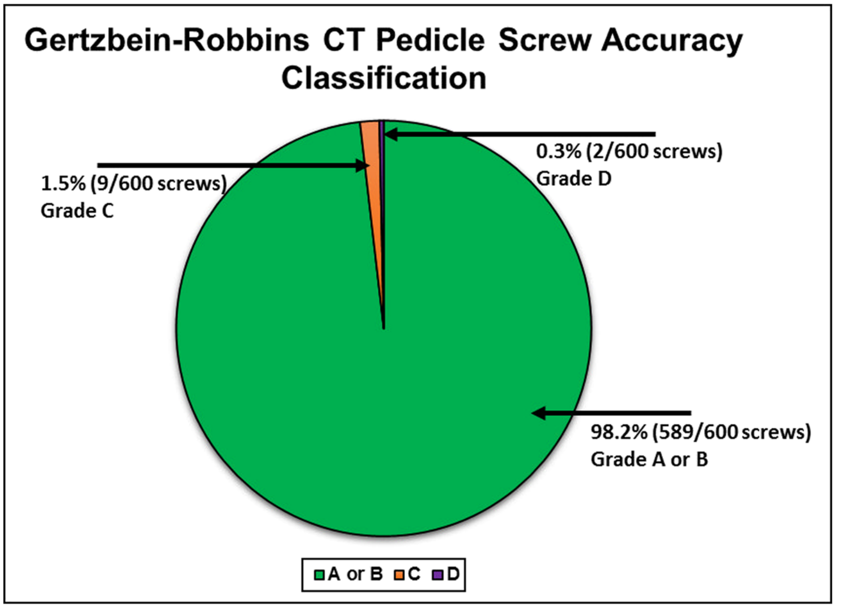

FIGURE 4 Gertzbein-Robbins CT pedicle screw accuracy classification. CT, computerized tomography

TABLE 3 Translational and angular screw offset

Parameter	Overall
Tip	1.7 ± 1.3 mm
Tail	1.8 ± 1.2 mm
Angular	2.0 ± 1.6°

and rigid robotic guidance.[10] Specifically, the robot provides a stable platform to guide pedicle screw placement in the pre-planned trajectory. Contrary to the misconception that the robot has some degree of autonomy, the surgeon has full control of the robot at all times and places the pedicle screw according to the surgeon's plan.

In a simulated, comparative, cross-sectional study conducted by Xu et al,[11] a one-time accuracy rate between simulated freehand (SFH) and navigation simulated (NS) pedicle screw insertion was evaluated. In the SFH group, 257/370 (69.5%) of screws had a <2-mm breach rate, while in the NS group, 369/370 (99.7%) of screws had a <2-mm breach rate ($P < .05$). Freehand pedicle screw insertion resulted in a higher breach rate, predisposing this technique to a higher risk of injury and screw malposition.

In a recent comparable experimental prospective study, Wu et al[12] studied the safety and accuracy of robot-assisted percutaneous transfacet screw fixation combined with oblique lateral interbody fusion. According to these results, 95.8% of screws had a cortex perforation < 2 mm and 4.2% had a cortex perforation of >2 mm, which is comparable to our study at 98.2% and 1.8%, respectively. Their study also reported an angular deviation of 2.2 ± 0.4°, which is comparable to the present study at 2.0 ± 1.6°. These results demonstrate that robot-assisted techniques are reliable, and that percutaneous pedicle screw fixation is comparable to percutaneous transfacet screw fixation.

In a similar study, Yang et al[13] compared the accuracy of conventional percutaneous pedicle screw placement with robot-assisted percutaneous pedicle screw placement. Approximately 120/130 (92.3%) of screws in the conventional group had a breach of <2 mm compared with that of 128/130 (98.5%) of screws in the robot-assisted group. This compares to the current study in which 589/600 screws (98.2%) had a breach of <2 mm.

Regarding safety, postoperative complications of navigated robot-assisted pedicle screw placement were evaluated in the current study. Only two complications, interbody removal and wound vacuum–assisted closure, were reported as requiring a return to the OR but were not related to robotic guidance or pedicle screws. Results demonstrate that robot-assisted navigation is a safe technique in the cohort studied.

4.1 | Study limitations

Although this is a single-surgeon, single-site, retrospective study without comparison with a cohort, its results are consistent with findings from the literature. According to Obremskey et al,[14] a well-executed orthopedic study of this nature includes a patient population for which a standard treatment protocol is used, a standard that this study has met. This study forms the foundation for future studies with a higher level of evidence. Comparative studies with larger sample sizes and clinical follow-ups are needed to determine the effectiveness of robot-assisted navigated pedicle screw placement versus traditional treatment. There may be a learning curve associated with using navigated robot-assisted guidance; therefore, surgeons with substantial experience should be included in these studies.

5 | CONCLUSION

This study demonstrated a high level of accuracy (98.2%) on the basis of pedicle breach assessment in the clinical use of navigated, robot-assisted surgery in the first 101 robotic cases, with only two nonscrew-related complications requiring return to the OR. Navigated robotic guidance was shown to be a safe procedure in the cohort studied.

CONFLICT OF INTEREST

Authors N.R.C., J.R.R., S.L.G., and C.G.L. are salaried employees (with stock options) of Globus Medical, Inc. The Excelsius GPS robot described in this manuscript is manufactured by Globus Medical, Inc (GMI), where authors N.R.C., J.R.R., S.L.G., and C.G.L. are employees. A.B.V. is a paid consultant of GMI. Authors D.J.W. and G.A.B. declare that they have no conflicts of interest.

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How to cite this article: Wallace DJ, Vardiman AB, Booher GA, et al. Navigated robotic assistance improves pedicle screw accuracy in minimally invasive surgery of the lumbosacral spine: 600 pedicle screws in a single institution. *Int J Med Robotics Comput Assist Surg*. 2019;e2054. https://doi.org/10.1002/rcs.2054

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