

A Retrospective Analysis of Pedicle Screw Placement Accuracy Using the ExcelsiusGPS Robotic Guidance System: Case Series

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BACKGROUND: Robotic guidance has become widespread in spine surgery. Although the intent is improved screw placement, further system-specific data are required to substantiate this intention for pedicle screws in spinal stabilization constructs.

OBJECTIVE: To determine the accuracy of pedicle screws placed with the aid of a robot in a cohort of patients immediately after the adoption of the robot-assisted surgery technique.

METHODS: A retrospective, Institutional Review Board–approved study was performed on the first 100 patients at a single facility, who had undergone spinal surgeries with the use of robotic techniques. Pedicle screw accuracy was graded using the Gertzbein–Robbins Scale based on pedicle wall breach, with grade A representing 0 mm breach and successive grades increasing breach thresholds by 2 mm increments. Preoperative and postoperative computed tomography scans were also used to assess offsets between the objective plan and true screw placements.

RESULTS: A total of 326 screws were analyzed among 72 patients with sufficient imaging data. Ages ranged from 21 to 84 years. The total accuracy rate based on the Gertzbein–Robbins Scale was 97.5%, and the rate for each grade is as follows: A, 82%; B, 15.5%; C, 1.5%; D, 1%; and E, 0. The average tip offset was 1.9 mm, the average tail offset was 2.0 mm, and the average angular offset was 2.6°.

CONCLUSION: Robotic-assisted surgery allowed for accurate implantation of pedicle screws on immediate adoption of this technique. There were no complications attributable to the robotic technique, and no hardware revisions were required.

KEY WORDS: Robot-assisted surgery, Pedicle screws, Gertzbein–Robbins grading system, Case series

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Pedicle screws provide a rigid, 3-column fixation for spinal surgeries. For a long time, the freehand technique has been the standard method for pedicle screw insertion. However, there have been multiple reports of screw misplacement when inserted using a freehand technique (especially in the thoracic spine).^{1–3} A misplaced screw weakens construct strength and stability, can worsen adjacent segment disease, and has the potential to injure the surrounding anatomic structures such as the spinal cord, blood vessels, or exiting and traversing nerve roots.⁴ Thus, the accurate placement of pedicle screws and their orientation are of great importance. Fluoroscopy and intraoperative

computed tomography (CT) navigation can be used to guide the surgeon in placing the screws more accurately, but they also increase potential radiation exposure to the patient, surgeon, and operating room staff.

Robot-assisted surgery was introduced as an alternative way to insert pedicle screws in 2004.⁵ There are numerous potential advantages with this technique such as reduced radiation exposure, faster screw insertion, and more accurate screw placement. ExcelsiusGPS (Globus Medical, Inc), in addition, boasts a real-time navigation system, uses a rigid robot arm to guide screw placement, and monitors for patient movement. ExcelsiusGPS was cleared by the U.S. Food and Drug Administration in 2017. Since then, there have been a number of clinical reports of application-specific accuracy with this

ABBREVIATION: GRS, Gertzbein–Robbins scale.

robot.⁶⁻²³ The purpose of this study is to retrospectively examine the accuracy of pedicle screw placement assisted by the ExcelsiusGPS robotic system in an early cohort of patients immediately after adoption of this robotic technique.

METHODS

An Institutional Review Board–approved retrospective case series study was conducted to analyze the pedicle screw placement accuracy of the first 100 consecutive patients who had surgery with the ExcelsiusGPS robot at a single surgical facility. The Waiver of Authorization Approval allowed the researchers to conduct the research without obtaining informed consents from patients because this study was a retrospective analysis of deidentified data. All patients had pedicle screws placed in the thoracic (2 screws), lumbar (282 screws), and/or sacral spine (42 screws) using the robotic technique. Data were collected retrospectively from patient records without any identifying information. Of the first 100 patients, 28 patients had to be excluded because of loss of their preoperative imaging studies and plans when a hard drive failure occurred. The 72 remaining study patients were included in the analysis. The screws of 16 patients (70 screws, 21.5%) were inserted percutaneously, and the rest of screws were placed through an open approach (256 screws, 78.5%).

Demographic and surgical variables collected were patient age, weight, height, operative time, blood loss, length of hospital stay, vertebral levels instrumented, and intraoperative and 90-day postoperative complications.

Navigated Robot-Assisted Pedicle Screw Positioning System

The robotic positioning system uses real-time surgical navigation and robotic guidance in conjunction with an integrated cohesive camera to guide pedicle screw placement. A dynamic reference base is affixed directly to the patient’s spine. The rigid robotic arm is mounted on a base station separated from the patient and surgical table, allowing consistent, uninterrupted movement of the arm. All the navigated instruments are registered to the robotic system before being used for surgery.

The robotic system allows for 3 different streamlined workflows based on the surgeon’s preference (preoperative CT, intraoperative CT, or intraoperative fluoroscopy). The workflow used in this study was based on preoperative CT images, in which the surgeon creates a preoperative plan for the screw placement based on the CT images obtained before the surgery.

Accuracy and Screw Offset

Preoperative CT scans were obtained for all patients within 30 days of their date of surgery, and postoperative CT scans were obtained during their initial postoperative hospitalization stay.

The Gertzbein–Robbins scale (GRS) was used to assess screw placement within the pedicle. The GRS is a scale that assigns a grade to each pedicle screw placement based on pedicle screw breach. Screws are considered grade A if they are completely within the pedicle; B, if there is a breach of <2 mm; C, if there is a breach of 2 to 4 mm; D, if there is a breach 4 to 6 mm; and E, if there is a breach >6 mm (Table 1). Screws graded as A or B are considered accurate; therefore, accuracy was calculated as the number of screws graded as A or B divided by the total number of screws placed.²⁴

TABLE 1. Gertzbein–Robbins Classification System of Pedicle Screw Accuracy

Grade	Breach size (mm)
A	0
B	<2
C	2-4
D	4-6
E	>6

The radiographic evaluation was completed by using a quantitative 3-dimensional (3D) overlay analysis that compared the preoperatively planned CT images with postoperative CT scans to assess offsets of the screw tip (mm), tail (mm), and angle (°). Offsets represent deviations between virtual screw plans and actual screw placements when normalized by vertebral anatomy. Patients’ pre- and postoperative CT scan images were overlaid, and offset values were calculated using the software. Tip deviation was measured between plan and placement at the end of the screw (screw exit point), whereas tail deviation was at the head of the screw (screw entry point). Both these measurements were based on the axial and sagittal planes, using the two-dimensional distance formula to report a translational deviation in mm. Angular deviation is the 3D angle between the tip–tail vector of the planned trajectory and the final placement, measured in degrees.

Statistical Analyses

Data were analyzed using SPSS v20.0.0 software for Windows (IBM Corp). Patient demographic data such as age, weight, and body mass index (BMI) were reported as mean and standard deviation, whereas sex was reported as frequencies. Intraoperative data such as operative time, blood loss, and length of stay were reported as averages, whereas levels treated and the number of levels treated were reported as frequencies. GRS grades were reported as frequencies. Offset values were reported as mean and SD.

This case series has been reported in line with the Preferred Reporting of CasE Series in Surgery (PROCESS) Guideline.²⁵

RESULTS

All surgeries occurred between December 2017 and December 2018 at a single facility. Of the 72 patients, the mean patient age was 63.5 years (range 21-84 years) and 52% (38/72) were female. The mean BMI was 31.5 kg/m², and the mean weight was 88.5 kg. The mean number of screws per case was 4.9, with a total of 326 screws. The mean number of instrumented vertebrae per case was 2.3 (Table 2).

Most screws were implanted at L4 (118/326 screws), followed by L5 (116/326 screws). Most of the patients (75%) had screws implanted at 2 vertebral levels. The average surgical time was 174 ± 36.9 minutes, the average fluoroscopic time was 13.4 ± 5.9 seconds, and the average blood loss was 136.0 ± 90.5 mL. The average postoperative hospital length of stay was 2.5 days, but ranged from 1 to 9 days (Table 3). Of the 72 surgeries, 16 (22.2%) were performed using a Wiltse paraspinally minimally invasive

TABLE 2. Patient Demographics

Parameter	Overall
No. of patients	72
Sex	
Female, <i>n</i> (%)	38 (52%)
Male, <i>n</i> (%)	34 (48%)
Mean age (SD, range)	63.5 (11.2) (21-84)
Mean weight in kg, (SD)	88.5 (22.3)
Mean BMI (SD)	31.5 (6.5)
Mean No. of screws per case (SD)	4.5 (1)
Mean No. of vertebrae per case (SD)	2.3 (0.5)

BMI, body mass index.

approach. The remaining 56 surgeries were performed using a midline open technique.

A summary of observed frequency of breach grades per level and corresponding percentages in general is presented in Table 4 and Figure, respectively. Based on the GRS grading, 97.5% (318/326) were graded A or B, 1.5% (5/326) were graded C, and 1% (3/326) was graded D. No levels received a GRS score of E. When stratified by level, 98% (45/46) of L2 and L3 screws were graded A or B. Of the L4 screws, 97.5% (115/118) were graded A or B and 2.5% (3/118) were graded C. Of the L5 screws, 98% (114/116) were graded A or B, whereas 2% were graded C. All S1 screws received a grade of A or B. Levels T12, L1, and L2 each had 1 screw graded D. The average offset from the preoperative plan to the final placement was 1.9 + 1.6 mm for the tip, 2.0 + 1.3 mm for the tail, and 2.6° + 2.3° for screw angulation.

TABLE 3. Procedure Characteristics

Parameter	Overall
Vertebral levels treated, <i>n</i> (%)	
L1	2 (0.60)
L2	10 (3.03)
L3	36 (10.91)
L4	118 (35.76)
L5	116 (35.15)
S1	40 (12.73)
S2	2 (1.21)
T12	2 (0.61)
No. of levels treated, <i>n</i> (%)	
2	54 (75)
3	15 (21)
4	3 (4)
Mean surgery time in min (SD)	174.5 (36.6)
Mean fluoroscopic time in s (SD)	13.4 (5.9)
Mean estimated blood loss in mL (SD)	136 (89.9)
Mean postoperative hospital stay in d (range)	2.5 (1-9)

TABLE 4. Frequency of Gertzbein–Robbins Grades per Level

Level treated	Grade A	Grade B	Grade C	Grade D	Grade E
T12	1	0	0	1	
L1	1	0	0	1	
L2	5	4	0	1	0
L3	32	4	0	0	0
L4	82	33	3	0	0
L5	106	8	2	0	0
S1	39	1	0	0	0
S2	2	0	0	0	0
Total	268	50	5	3	0

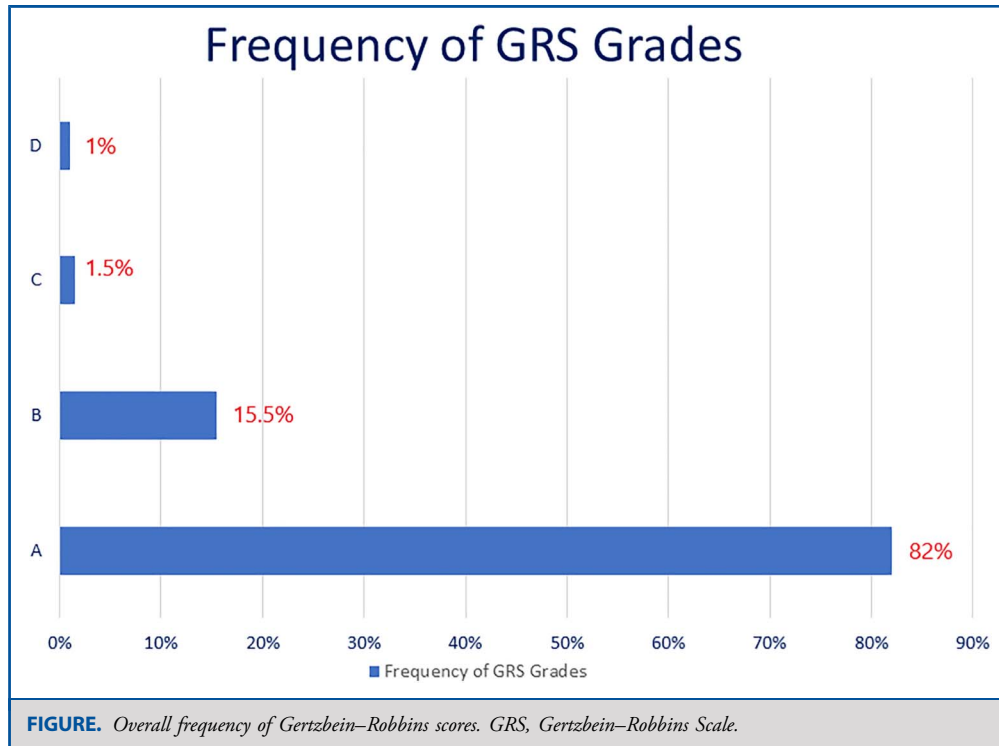
Complications

No complications occurred that would be attributable to the robotic technique. There were no neurologic deficits related to robotic screw insertion. One lumbar fusion patient had an acute radial nerve palsy that was completely resolved by 2 months after surgery. There were no implant failures, and no revision or removal of the implants occurred during the study period. Of the 72 surgeries performed, 3 (4.2%) required some nonrobotic screw insertion where the navigation aspect of the system was still used. Two of these 3 surgeries were due to a malfunction in the end effector on the robotic arm.

DISCUSSION

The use of both freehand and fluoroscopy-assisted pedicle screw placement techniques is often associated with complications and injuries along with decreased pedicle screw placement accuracy.^{9,26} As a consequence, other surgical approaches to reduce complications while improving pedicle screw accuracy, such as robot-guided pedicle screw placement, have been introduced.^{5,27-29} Various systematic reviews have shown that robotic technology increases pedicle screw placement accuracy. For example, Kosmopoulos and Schizas³⁰ reviewed 130 studies and reported that pedicle screws placed with the use of robotic technology had a median placement accuracy of 95.2%, whereas those without robotic technology had an accuracy of 90.3%. Similarly, in a meta-analysis of 9 studies, Fatima et al³¹ concluded that the accuracy of robotic-guided pedicle screw placement is superior to that of freehand. Many other studies also corroborate the notion that robotic technology allows for enhanced pedicle screw placement accuracy.^{4,6,27,32,33} However, few studies focus on platform-specific contributions to this knowledge. This study evaluated the accuracy of pedicle screw placement using ExcelsiusGPS.

This study demonstrated a high level of pedicle screw placement accuracy. Per the GRS grading scale, 96.4% of screws were graded A or B, which was consistent with what was observed in reviews reporting 85% to 100% of screws receiving an A or B grade when using robotic technology.^{30,34,35} Ringel et al³⁴ and Kosmopoulos and Schizas³⁰ reported 84.4% and 85% of screws



to be graded A or B, respectively. Both these studies used different robotic technologies, further suggesting that the type of robotics system used might affect pedicle screw placement accuracy.

At present, limited studies have presented the offset value from the planned screw trajectory to actual placement. Benech et al⁷ reported a 1.9 + 1.6 mm tip offset, 2.3 + 1.6 tail offset, and 2.8° + 2.3° angular offset with pedicle screws placed with the ExcelsiusGPS robotics system. The tip offset, tail offset, and angular offset data from this study are consistent with these findings. It should be noted that these offsets did not cause any clinically significant concern because there were no neurologic or vascular injuries, no implant-related cerebrospinal fluid leaks, and no implants that required revision or removal. It is also possible that some deviations were due to technical issues with screw plans. For example, an offset can occur if the planned screw is too deep in the bone and the screw head will not permit this placement depth to be obtained.

The surgical time of 177 minutes was comparable with other robot-assisted surgery times, which range from 151 to 336 minutes^{34,36,37} The 2.5-day length of hospital stay was slightly shorter than other studies using Mazor Robotics systems such as those published by Hyun et al³⁸ and Kantelhardt et al,³⁹ which reported 6.8 and 10.6 days, respectively. However, the average length of hospital stay of 2.9 days using the ExcelsiusGPS robotic system was recently reported by Huntsman et al⁶ Even immediately after implementation of the ExcelsiusGPS robotic system, this study shows that it was successfully used in 69 of the 72 patients. The navigation aspect of the system was still used in the remaining 3 cases, and the reasons for the 3 deviations are no longer applicable

to the current commercial robotic system because of improvements that have changed the end effectors and system software. Because this study was performed on the initial patients right after implementation of robotic surgery, it is likely that these outcome measures could further improve with additional surgical experience.

This study of the first consecutive 100 ExcelsiusGPS robotic surgeries confirms that a robotic technique can be used with safe and highly accurate results on immediate adoption of this technique. These results were obtained in a nonselected patient population with a large age variation and high average BMI. Because GRS scoring discounts screw placement even if the deviation from ideal placement had been purposely planned because of patient anatomy, offset measurements provide a method to determine if the planned screw placement was achieved.

Limitations

This study does present with some limitations including its retrospective nature, limited long-term patient outcome measures, and generalizability because it is a single-surgeon, single-site case series. The loss of accuracy data of 28 patients in this case series may be considered as one of the shortcomings. However, the loss of data occurred randomly because of a computer glitch. Future studies reporting offset values are needed to investigate pedicle screw placement accuracy using robotic guidance incorporating data from multiple sites and multiple surgeons.

CONCLUSION

In conclusion, the use of robotic-assisted technology allowed for navigated and guided implantation of pedicle screws at a high accuracy rate similar to or better than the published literature. There were no complications from the robotic technique, and no hardware revisions were required. Robotic surgery was safe and effective in this study and should be considered for widespread adoption.

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Disclosures

Dr Kanaly, Dr Toossi, and Dr Bucklen have financial relationships with Globus Medical Inc. Dr Backes has no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENTS

We read this case series with great interest as the adoption of robotic techniques has the potential to dramatically change our field. However, the question of which placement technique is superior remains unsolved and likely will remain so until experience with this technology matures. Although multiple studies have demonstrated the exceptional accuracy of pedicle screw accuracy with robotic assistance, this field remains in the early phase of adoption.

Previous analyses of robotic screw placements have provided grouped analyses to increase both the number of screws and patients.^{1a-3a} This methodology may increase study power at the cost of diluting the specificity of the study. For instance, in 1 large comparative cohort study, 321/406 (79%) of the screws were placed in the lumbar or lumbosacral area with most cases consisting of single-level fusions (261/406 or 64%). Furthermore, 193/406 (48%) were indicated due to degenerative pathologies.^{2a} The data are not clear, however, for larger constructs or thoracic or pelvic instrumentation. Furthermore, more work is needed to compare the accuracy of minimally invasive with open screw fixation. For example, the ExcelsiusGPS (Globus Medical Inc) relies on separate reference guides: 1 on the spinous process (in open surgery) and 1 in the posterior superior iliac spine (open or MIS). As distance grows from the posterior superior iliac spine with thoracic fixation, there are questions of how this distance could alter robotic accuracy.

The authors present an exceptional work to provide specificity to the level of pedicle screw accuracy with the Globus ExcelsiusGPS. Robotic spine surgery is a promising technology that likely will continue to evolve with time. Nevertheless, studies need to be performed to demonstrate the power of these systems in under-represented areas of the spine and under-represented indications.

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In a December 1987 meeting with the Soviet Union's General Secretary Mikhail Gorbachev, President Ronald Reagan quoted an old Russian adage, "Doveryai, no proveryai," which translates to "Trust, but verify." President Reagan used this saying in reference to the planned safeguards that would go into effect as he negotiated nuclear treaties.

The authors of this article have taken this sage advice and are to be commended on their efforts to document their early experience using a robotic platform in spinal surgery. They undertook this self-assessment without blindly relying on previously published descriptions of accuracy. Acknowledging the learning curve associated with any enabling technology and taking the time to critically analyze their results, the authors detailed their experience with the first 100 patients who were treated with this robotic platform at a single facility.

They demonstrate an accuracy of 97.5% (grade A or B on the Gertzbein–Robbins scale) utilizing both pre- and postoperative computed tomography. Their findings are certainly in line with other referenced publications, and the accuracy that they report is better than reports of freehand accuracy rates of 90.3% from similar studies and meta-analyses.^{1b} As our field increasingly turns to technology to help increase our accuracy and improve outcomes, we must continue to be diligent and critical in assessing outcomes, as these adjuncts come with a cost.

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