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SURGERY

Clinical Pedicle Screw Accuracy and Deviation From Planning in Robot-Guided Spine Surgery

Robot-Guided Pedicle Screw Accuracy

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Study Design. A retrospective chart review was performed for 112 consecutive minimally invasive spinal surgery patients who underwent pedicular screw fixation in a community hospital setting.

Objective. To assess the clinical accuracy and deviation in screw positions in robot-assisted pedicle screw placement.

Summary of Background Data. Accuracy of pedicle screw placement in *in vivo* studies varies widely, especially when minimally invasive techniques are used. Robotic guidance was recently introduced to increase screw placement accuracy but still reported accuracies vary.

Methods. Reproducibility of the surgeon's plan using robotic guidance was assessed by fusing individual vertebras from the preoperative computed tomography (CT) containing the planning with a postoperative CT. Deviation in entry point and difference in angle of insertion was measured on axial and sagittal planes. Grading of pedicle screw placement was performed on postoperative CTs using the Gertzbein-Robbins classification.

Results. CT-to-CT fusion succeeded for 178 screws, but these appeared to be random, with no apparent selection bias. Mean deviation in entry point was 2.0 ± 1.2 mm. Mean difference in angle of insertion was 2.2° ± 1.7° on the axial plane and 2.9° ± 2.4° on the sagittal plane. Assessment of pedicle screw accuracy showed that 477 of 487 screws (97.9%) were safely placed (<2 mm, category A+B), 8 screws in category C and 1 in category D. None of the screws necessitated resurgery for revised placement.

Conclusion. Preoperative planning of robotic guidance is reproduced intraoperatively within acceptable deviations. We conclude that robotic guidance allows for highly accurate execution of the preoperative plan, leading to accurate screw placement.

Key words: lumbar fusion, laminectomy, screw accuracy, robot-guided spinal surgery, pedicle screws, minimally invasive surgical procedures.

Level of Evidence: 3

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Pedicle screw fixation has become the standard of care in patients with spinal instability or deformity to stabilize the thoracic or lumbar spine.[1,2] Accurate screw placement is essential to avoid injury to adjacent neural structures and blood vessels. In patients with severe spinal deformity, osteoporosis, or prior surgeries this can even be more challenging.[1,2] Yet, the accuracy of pedicle screw placement in *in vivo* studies varies widely, ranging from 28% up to 100%.[3,4]

Introduction of cannulated percutaneous techniques, such as navigated spine surgery, has led to a significant increase in screw placement accuracy, ranging from 72% up to 100% accuracy.[2–7] Such navigation systems for spinal surgery have been commercially available during the last several years. Recently, a bone-mounted robotic guidance device was introduced, which seems to offer some advantages over earlier image-guidance systems by providing mechanical guidance to a desired trajectory. Guidance to the surgeon is based on a preoperatively planned trajectory that is reproduced in the operating room by the robotic device. This device is mounted to the patient's spine for drilling holes in preparation for placement of pedicle screws. The bone mounting feature allows patient breathing and motion without altering the position of the robotic unit relative to the spine, which maintains the system's accuracy.[5] The reported clinical results are encouraging: high accuracy and reduced intraoperative exposure to radiation, reduced blood loss and shorter postoperative hospitalization and surgery time.[5–8] However, pedicle screw accuracies reported in literature vary between 85% and 99%.[1,2,5–7,9,10] Moreover, there is paucity of data on the reproducibility of screw position between the preoperative planning and postoperative positions.

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The purpose of this study was to assess the clinical accuracy and the deviation in screw positions for pedicle screw placement using robot-guided surgery.

MATERIALS AND METHODS

Study Design and Population

In this retrospective study 112 patients were included consecutively. They all underwent clinically indicated robotic-guided percutaneous posterior lumbar interbody fusion using the SpineAssist™ (Mazor Robotics, Caesarea, Israel), with posterior bilateral or unilateral decompression when clinically indicated. All operations were planned and performed by 2 specialized and trained neurosurgeons. Cases where robotic guidance was aborted during the operation were excluded from this study.

Planning and Surgery

Patients were instructed to discontinue use of antiplatelet medication for 5 days or more. Prior to surgery, a 0.5 to 2 mm 64 slice spiral computed tomography (CT) scan (Aquilion, Toshiba Medical Systems, Tokyo, Japan) was performed in all patients in supine position. Consecutively, the pedicle screw positions were planned on the CT scans using the SpineAssist™ planning software. Planning included optimization of pedicle screw length, diameter, position, and trajectory.

All patients were operated in prone position. The robotic platform was attached to the posterior superior iliac crest and a spinous process using the Hover-T frame (Mazor Robotics, Caesarea, Israel) as described in detail by Lieberman *et al.*[8] Yet, when bilateral or unilateral decompression was clinically indicated, the robotic platform was attached to a spinous process with a specialized clamp attachment after performing a three-centimeter midline incision, as illustrated in Figure 1A, B. A reference fiducial array was attached to the robotic platform for registration with the preoperative CT (containing the planning) using 2 intraoperative fluoroscopy images: 1 in the coronal plane and 1 60° oblique to the coronal plane (Ziehm Solo, Ziehm Imaging, Nuremberg, Germany). The planning, containing the planned screw entry points and trajectories for all vertebrae, was registered intraoperatively for each individual vertebra, transforming the virtual planning made on the preoperative CT to the operative locations of the vertebrae. After registration, the reference array was removed and the robot was attached to the platform. Separate 1.5 cm paramedian incisions were made as entry points for each screw. After drilling the pedicle through the robot's arm, K-wires were inserted in the pedicle for screw guidance, as described in detail by Pechlivanis *et al*, Lieberman *et al*, and Togawa *et al*.[7,8,11] Intraoperative lateral fluoroscopy was conducted to inspect the accuracy of the k-wire position when considered necessary. A cannulated screw was guided into the pedicle using the K-wires. Percutaneous pedicle screw-rod fixation was performed using the Serengeti system (K2M, Leesburg, VA). Decompression of the spinal canal by laminectomy or hemilaminectomy was performed when clinically indicated using a surgical 3D microscope (OPMI PENTERO 900 Carl Zeiss Meditec, Jena, Germany). Fusion was achieved by fixing the longitudinal rods supported by implanting a posterior lumbar interbody fusion-cage augmented by autologous bone grafts, when clinically indicated.

A postoperative CT scan with 0.5 to 2 mm slice thickness was performed in all cases for clinical purposes 1 day after surgery to assess vertebra, screw, and implant positions.

Screw Placement Accuracy

Pedicle screw accuracy was measured in millimeters on postoperative CT scans using all 3 planes to seek possible cortical breaches of the pedicle borders by the screws in the lateral, medial, caudal, and cranial directions, as illustrated in Figure 2A–D. Screw accuracy was categorized using the 2-mm increment Gertzbein and Robbins classification.[12] Screws within the pedicle were classified as category A, encroachment of the pedicle wall by less than 2 mm was

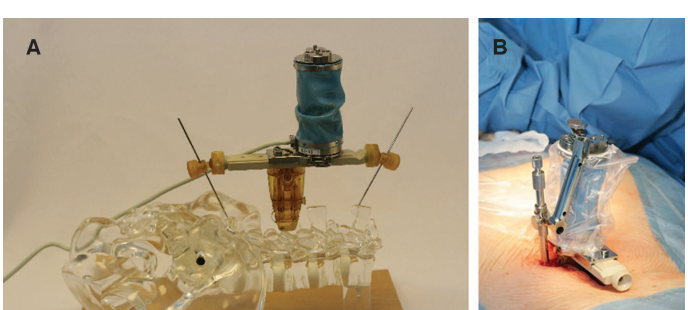

Figure 1. Example of the robotic platform attached to a spinous process of **(A)** a phantom spine and **(B)** a patient using the specialized clamp attachment with the robot mounted to the platform.

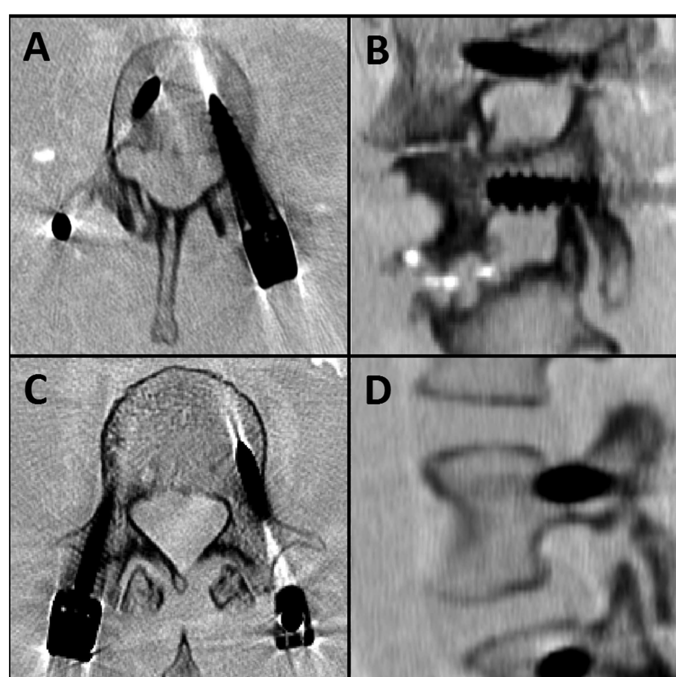

Figure 2. Four examples of the pedicle screw assessment in the postoperative CT scans within **(A)** a left medial encroachment of 2 mm, **(B)** caudal encroachment of 2 mm, **(C)** right and left lateral encroachment of 2 mm, and **(D)** cranial encroachment of 2 mm.

classified as category B, breaching the pedicle wall by 2 to 4 mm was classified as C, 4 to 6 mm category D, and 6 mm or more category E. Screws categorized as category A or B were determined to be safe and well placed, as previously demonstrated.[5,12,13]

Screw Entry Points

In addition to the assessment of accuracy, the deviation in screw entry point and angle of insertion was assessed, because deviation in entry point or angle of insertion will result in a different trajectory that leads to a misplaced screw. Deviations were assessed by comparing the planned screw positions with the actual screw positions using the preoperative and postoperative CT scans. Assessment was performed using dedicated SpineAssist software (SpineAssist SW, Mazor Robotics, Caesarea, Israel) by fusing individual vertebras of both CT scans to exclude the influence of vertebra repositioning. Overlay accuracy of the fused images was manually verified in all 3 planes. Deviation was defined as the distance between the planned and postoperative screw entry point position. It was measured in the axial and sagittal planes by determining the perpendicular distance of the midline of the planned screw *versus* the midline of the actual screw position. This latter line was drawn manually in the software as a best estimate on the slice with the widest screw diameter. Calculating the squared root of the summed squared deviation in both planes $\left(\sqrt{\text{axial deviation}^2 + \text{saggital deviation}}\right)$ resulted in the deviation (mm) per screw. The difference in angle was determined by comparing the angles of both midlines relative to the center line of the assessed vertebras in both the axial and lateral planes, as shown in Figure 3.

A pilot measurement was performed, including 30 vertebras, to optimize the measurement technique and to prevent learning effects in the determination of the deviation. The pilot measurements were excluded from the analysis. In addition, the intra-user variability in determining the deviation was tested in 20% (36) of the screws, which were selected randomly.

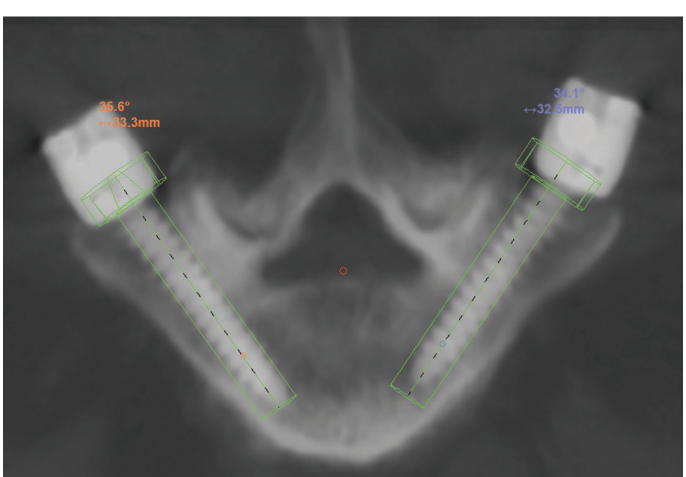

Figure 3. Fusion of the preoperative CT scans containing the planning with the postoperative CT scan. The deviation was measured using a digital ruler and angle measurement tool.

Secondary Endpoints

The correlation between screw deviation and screw accuracy was calculated to determine whether lower screw accuracies were due to imprecise robotic guidance or incorrect planning. Operated spinal level (thoracic, lumbar, or sacral) and the use of different surgical extension arms on the accuracy and the deviation of screw placement were tested. In addition, the learning curve of both operators regarding the deviation and accuracy of the screw was determined.

Statistical Analysis

All patient and surgery characteristics, as well as the deviation and accuracy, were presented as mean±standard deviation. The correlation between screw accuracy and deviation was determined using the Pearson correlation coefficient. The intraobserver variability in measuring the screw deviation was tested using the intraclass correlation coefficient.

The influence of the operated spinal level and the use of different surgical extension arms were tested using the Mann-Whitney-Wilcoxon or Kruskal Wallis test. To test for a learning effect, the accuracy of the first 100 screws was compared for each operator with the accuracy related to the rest of the screws using the Mann-Whitney-Wilcoxon test. The same test was used to compare the deviation of the first 30 placed screws to the rest of the placed screws for each operator.

The level of statistical significance was set to 0.05 for all statistical analysis.

RESULTS

The baseline characteristics including surgery parameters are shown in Table 1.

TABLE 1. Baseline Patient and Surgery Characteristics of All 112 Patients Who Underwent Spinal Fusion Surgery Using Robot-Guided Screw Placement

Characteristic	Mean/Percentage	SD
Age (yr)	56.8	12.5
Male sex (%)	59.8	
Screws inserted (#)	4.4	1.5
Location pedicle screws		
Thoracic (%)	83	
Lumbar (%)	7	
Sacral (%)	10	
Length planned screw sizes (mm)	41.2	2.8
Width planned screw sizes (mm)	6.2	0.7
Time per K-wire (min)	11.2	2.3
Blood loss during OR (mL)	216	259
Surgery duration (min)	154	60
Length of stay (d)	4.9	2.4

Data are presented as percentages or mean ± standard deviation.

In total, 494 screws were placed in the 112 included patients and robotic guidance was aborted in 7 screws due to unknown reasons. These screws were excluded from analysis. Of all assessed screws, 97.9% (477) were categorized as placed in the safe zone (category A or B) using the Gertzbein and Robbins criteria,[12] as illustrated in Figure 4. There were 191 screws breaching the internal pedicular cortex. Of these, 68% breached lateral, 35% medial (only category B), 3% cranial, and 7% caudal or a combination of 2 breaching directions, as illustrated in Figure 4. No vertebral cortex perforations were observed.

The preoperative CT, including the planning, and postoperative CT fusion were performed successfully on 178 screws in 63 patients. In this subset of screws, the mean entry point deviation was 2.0 ± 1.2 mm, with an axial angular deviation of 2.2±1.7º and a lateral angular deviation of 2.9º ± 2.4º. The intraclass correlation coefficients for measuring the mean deviation and axial and lateral angular deviations were 0.99, 0.95, and 0.99, respectively.

Secondary Endpoints

A significant correlation between screw accuracy and screw deviation was observed, as illustrated in Figure 5 ($P < 0.01$).

Screw accuracy and deviation differed per surgery location. Of all thoracic screws, 92% (33) were classified as category A or B in contrast to 97.9% (394) and 100% (50) for lumbar and sacral screws, respectively. The thoracic screw accuracy was found to be significantly lower than the lumbar and sacral screw accuracy ($P < 0.01$). However, these influences were not observed comparing the mean thoracic, lumbar, and sacral deviation of 2.2, 2.0, and 2.2 mm, respectively ($P > 0.10$).

The use of a longer surgical navigation arm, to extend the reach of the robot, led to a significant higher accuracy ($P < 0.02$). When using the longest arm 66.8% (203) of the placed screws were categorized as class A. These were 52.4% (77) and 47.2% (17) when using the middle and shortest arms, respectively. Yet, this was not observed when assessing the deviation. A mean deviation of 2.3 mm was found for the shortest arm *versus* 2.5 mm and 1.7 mm for the middle and longest arm, respectively. Only the difference between the middle arm and the longest arm was found to be significant ($P < 0.01$).

No learning effects were observed in screw accuracy for both operators (336 and 151 screws, $P > 0.13$). Also no learning effects were observed when comparing the screw deviation for both operators (129 and 56 screws, $P > 0.15$).

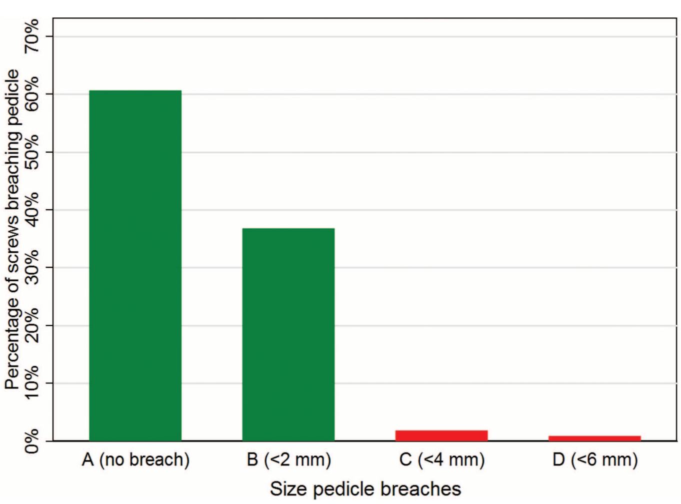

Figure 4. Column chart showing the percentage of screws breaching the pedicle wall according to the Gertzbein and Robbins criteria. Of all 487 robotic-guided placed screws, 98% (477) were safely placed (category A or B), whereas 2% (9) were breaching the intrapedicular trajectory with less than 4 mm and 1 with less than 6 mm (category C and 1 category D screw placements, respectively).

DISCUSSION

Of 487 pedicle screws placed percutaneously in patients using robotic guidance, 97.9% were within the safety zone, meaning completely within the pedicle or breaching it by less than 2 mm. This placement accuracy corresponded with the mean deviation of 2 mm between the planned and actual screw positions, as assessed in a subset of 37% of the screws where the fusion of the preoperative and postoperative CT scans succeeded. As the introduction of robot guidance in our department in 2011, no revisions were required.

Similar screw placement accuracies are reported in multiple recent studies using robotic guidance, all using postoperative CT scans to determine the screw placement accuracy.[2,5–7,9,10,14,15] All studies, except 2, reported 98 to 99% of their screws to be placed within a 2 mm pedicle breach margin, similar to the 97.9% found in our study. Although different methods were used to determine the screw deviation that might lead to different results, the observed results were very similar.[5,15] Ringel *et al* and Schatlo *et al* observed lower screw accuracies of 85% and 91.4% safely placed screws, respectively.[10,16] The lower accuracies encountered by Ringel *et al* might be due to the use of the bed-mounted frame, although it could also be caused by their surgical technique.

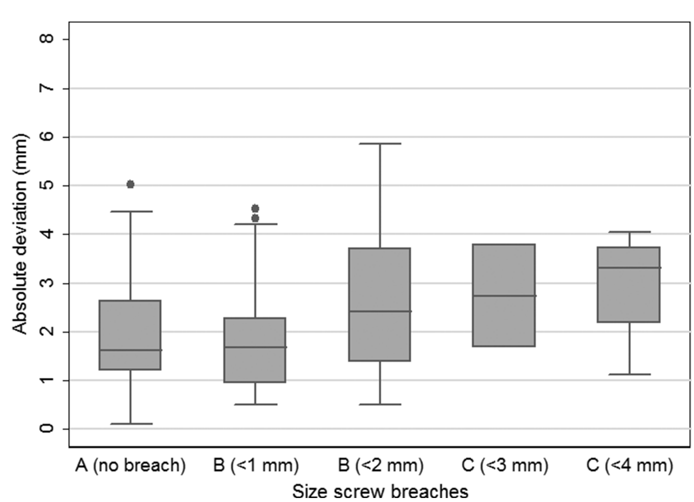

Figure 5. Boxplot showing the correlation between the screw accuracy using the Gertzbein and Robbins classification and screw deviation of the 178 screws in which image fusion succeeded ($P < 0.01$).

They reported screw deviations in multiple directions, whereas an error in the mounting should lead to deviations in a single direction. Furthermore, other studies that have used the bed mount did not have such inaccuracy.[9] The relatively low reported screw accuracy by Schatlo *et al* might be due to the inclusion of screws in which intraoperative alteration of the robotic-guided trajectory was applied. When excluding these screws, the accuracy increases to 93.7%. Difference in planning or surgical technique might explain the observed lower accuracy compared with other studies.

The deviations found in this study are also comparable with a previous study. Devito *et al*, who also assessed the screw deviation between the planning and postoperative CT scans, reported a mean axial deviation of 1.2 ± 1.5 mm and a mean sagittal deviation of 1.1 ± 1.2 mm. These measurements are quite similar to the 1.2±1.0 mm axial deviation and 1.4 ± 1.1 sagittal deviation we observed (data not shown). While Devito *et al* used a different methodology to assess screw deviation, namely, relying on the mean deviation of the screw entry point and exit point on the pedicle, instead of only assessing the deviation in entry point, the results seem comparable.

Besides the influence of robot guidance, there are several other factors contributing to the overall accuracy. First, the different anatomy of thoracic vertebras might have caused the lower screw accuracies, resulting in the lateral encroachment (category C) of 3 thoracic screws.[17,18] This is confirmed by the absence of a significant difference in deviation of the thoracic screws compared with the lumbar and sacral screws. Second, the use of the shorter arm led to lower accuracy and higher deviation compared with the use of the longer arm. However, this is counterintuitive, because the effect of mechanical tolerances is expected to be greater when using a longer arm. Yet, entering the pedicle with a relatively low angle (no flat drilling surface) might predispose the tools to skive off the side of the facet, causing the lower accuracy and higher deviation. This most likely resulted in the 7 lumbar screws (category C and D) breaching the cortex lateral or caudal. Furthermore, although some studies suggest the existence of a learning curve, linking performance improvement with experience, we did not observe any learning effects in screw accuracy or deviation as previously suggested by Kosmopoulos and Schizas, and Hu and Lieberman.[3,19]

The main limitation of this study was that it was only possible to compare the preoperative planning to the postoperative CT in about a third of the screws, though no particular pattern was observed in the cases of fusion failures. Moreover, the percentage of accurately placed screws category A and B in this subset was comparable with the total set of screws (96.7% and 97.9%, respectively). Furthermore, only medial and lateral deviations in the axial plane, and superior and inferior deviations in the sagittal plane were assessed. This is because the dorsal and ventral deviations depend on how deep the operator places the screw in the pedicle, a process that is independent of the robot. In addition, although intraoperative radiation exposure was not registered in our institution, the surgeons reported a decrease in the use of fluoroscopy using robotic-guided surgery, which is in line with previous studies.[6,9,14]

CONCLUSION

Use of robotic guidance for pedicle screw placement led to 97.9% safely placed screws. Preoperative planning of robotic guidance is reproduced intraoperatively within acceptable deviations (2.0 ± 1.2 mm). We conclude that robotic guidance allows for highly accurate execution of the preoperative plan, leading to accurate screw placement.

➢ Key Points

- ❑ In this retrospective study, accuracy and deviation of robot-guided pedicle screw placement was assessed.
- ❑ 97.9% of all placed screws were safely placed.
- ❑ Overall deviation of actual screw position from preoperative planning was 2.0 ± 1.2 mm.

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