Assessment of Pedicle Screw Placement Accuracy, Procedure Time, and Radiation Exposure Using a Miniature Robotic Guidance System

Isador H. Lieberman, MD, Mitchell A. Hardenbrook, MD,† Jeffrey C. Wang, MD,‡ and Richard D. Guyer, MD**

Study Design: Controlled, cadaveric implantation trial.

Objective: To evaluate the effect of a robotic guidance system on screw placement accuracy, amount of radiation exposure, and length of procedure time during percutaneous pedicle screw implantation.

Summary of Background Data: Pedicle screws are associated with low complication rates, and several computer-assisted image guidance systems exist that facilitate accurate screw placement. However, these systems may represent substantial radiation exposure risk to patients and surgeons.

Methods: We implanted 234 pedicle screws in 12 cadavers (study group: 15 surgeons, 197 screws, and 10 specimens; control group: 2 surgeons, 37 screws, and 2 specimens). We measured procedure time, fluoroscopy time, and radiation exposure and evaluated screw placement accuracy with computed tomography scans. To evaluate the learning curve, we compared measurements with those of an experienced robotic guidance user through the 2-sample (heteroscedastic), 1-tail t test ($P < 0.05$).

Results: Relative to control, the study group had fewer screw placement deviations (average, 2.6 ± 0.7 mm vs. 1.1 ± 0.4 mm; $P < 0.0001$), fewer pedicle wall breaches of 4 mm or greater (average, 5.4% vs. 1.5%), lower surgeon radiation exposure (average, 136 mrem vs. 4.2 mrem), lower fluoroscopy time per screw (average, 33.0 s vs. 0.9 s), and shorter procedure time (average, 1.98 h vs. 1.23 h). Use of robotic guidance increased the accuracy of percutaneous pedicle screw placement by 58%, thereby reducing the risk of neurologic injury (as measured by breaches > 4 mm), new-user radiation exposure (by 98.2%), and procedure time (by 36%).

Conclusions: The advantages associated with a robotic guidance system may make the surgeon more at ease about offering minimally invasive or percutaneous surgical options to patients and more comfortable about implementing pedicle-based fixation in general. This advanced technology may also allow inclusion of patients with complicated anatomic deformities, who are often excluded from pedicle screw-based surgery options.

Key Words: pedicle screws, computer guidance, robotic surgery, radiation exposure, pedicle screw accuracy

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Pedicle screws are typically used to achieve mechanical stabilization during bony fusion. Pedicle fixation has proven to be beneficial and is now commonly used in the surgical treatment of debilitating lower back pain, scoliosis,[1,2] spondylolisthesis,[3–5] spinal fractures,[6–12] and tumor reconstructions,[4,13] and in facilitating multilevel arthrodeses.[1,2,4,7,10–20]

Although pedicle screw techniques are associated with low complication rates, even in the hands of less-experienced surgeons,[21,22] substantial disadvantages still exist. Conventional open spinal instrumentation procedures are associated with pain, tissue scarring, paraspinal muscle injury, and extended recovery times.[23] Contemporary, less-invasive methods of screw implantation are reported to ameliorate these disadvantages.[24–26] However, despite the anticipated increased use of minimally invasive surgery (MIS) or percutaneous surgical methods for pedicle screw implantation, only a small portion of all spinal surgeries are conducted in this manner; most surgeons still rely on traditional open methods. This sluggish evolution to more contemporary surgical techniques stems largely from the higher incidence of screw malpositioning,[27,28] higher overall procedure time, and greater exposure to ionizing radiation that are associated with these MIS techniques.

There are several computer-assisted image guidance systems that facilitate the accurate placement of spinal instrumentation.[29,30] Such systems typically improve the accuracy of screw placement while reducing the need for extensive fluoroscopic imaging. One miniature robotic guidance system (SpineAssist, MAZOR Surgical Technologies, Caesarea, Israel)[31] has been shown to provide

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From the *Texas Back Institute, Plano, TX; †The Boston Spine Group, Newton, MA; and ‡The University of California Los Angeles Comprehensive Spine Center, Los Angeles, CA.
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Reprints: Isador H. Lieberman, MD, c/o Elaine P. Henze, BJ, ELS, Medical Editor and Director, Editorial Services, Department of Orthopaedic Surgery, Johns Hopkins Bayview Medical Center, 4940 Eastern Avenue, #A665, Baltimore, MD 21224-2780 (e-mail: ehenze1@jhmi.edu).

accurate planning and target placement of pedicle screws during open, MIS, and percutaneous approaches[32] for patients experiencing various types and degrees of spinal disorders.[32–36] Furthermore, a detailed preoperative planning step ensures minimal intraoperative fluoroscopic imaging, reducing the radiation exposure to patients, surgeons, and operating room staff during intraoperative fluoroscopic imaging.[37,38]

The goal of this study was to evaluate the effect of a robotic guidance system on screw placement accuracy, amount of radiation exposure, and length of procedure time during percutaneous pedicle screw implantation. We hypothesized that the use of a robotic system would increase the accuracy and reduce the required radiation exposure and procedure time.

MATERIALS AND METHODS

Study Design

In this controlled cadaveric implantation trial, 17 surgeons implanted 234 pedicle screws in the thoracic, lumbar, and sacral regions (T9-S1) of 12 cadavers.

Study and Control Groups

The surgeons were divided into 2 groups. The study group consisted of 15 spine surgeons (12 orthopedic surgeons and 3 neurosurgeons), who used the robotic guidance system to aid in the preoperative planning and intraoperative positioning of pedicle screws. This group implanted 197 screws in 10 specimens, all using a fully percutaneous approach. Of the surgeons in the group, 14 were first-time SpineAssist users, and 1 surgeon was an experienced user of that system. Data collected from the experienced surgeon were used to evaluate the learning curve and possible differences in performance between new and experienced users of robotic guidance technology. The control group comprised 2 spine surgeons (1 orthopedic surgeon and 1 neurosurgeon) performing screw insertions through conventional free-hand techniques (no robotic guidance). This group implanted 37 screws in 2 specimens: 27 screws were implanted percutaneously under fluoroscopic imaging in 2 specimens, and 10 were open placements in the thoracic area of 1 of these specimens without fluoroscopy.

Robotic Technology

The robotic guidance system used for this study is a fully integrated, bone-mounted, miniature robotic system that was designed to provide simple and accurate guidance for tools and implants in a wide range of spinal procedures.[30,31] In summary, the system is comprised of 5 main components (Fig. 1):

1. The robotic device, a miniature (2.5-inch diameter, 6-inch tall, 250 g) semiactive, parallel, 6 degrees-of-freedom manipulator;
2. The workstation, which contains all software and hardware for preoperative computerized tomography

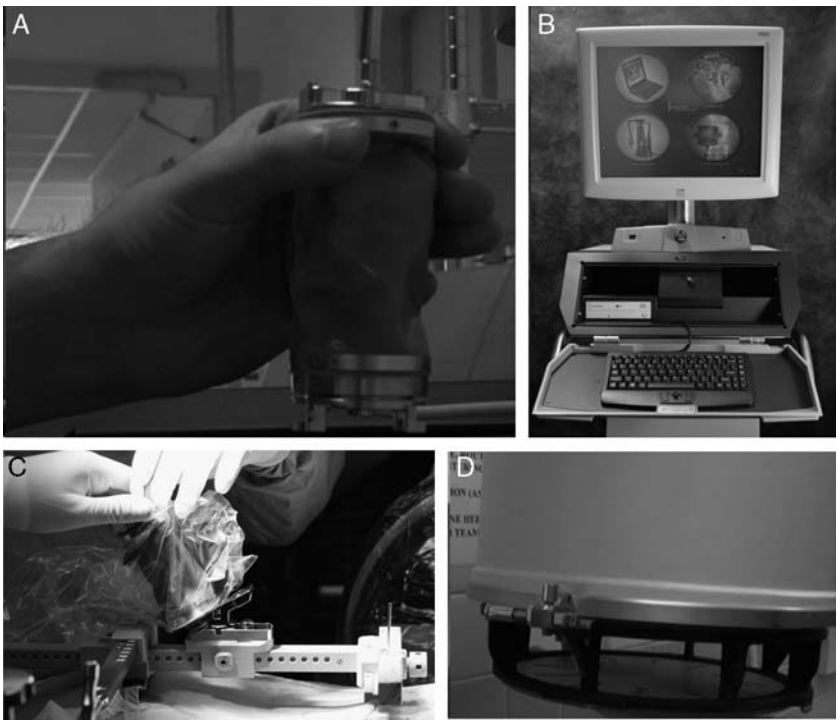

FIGURE 1. System components. A, Robotic device with side arm attachment. B, Work station. C, Robot attached to the hover T frame. D, C-arm reference grid.

(CT)-based planning, CT-to-fluoroscopy image registration, and control of the robotic device;
3. A set of surgical accessories, including the bone-mounted frame;
4. A set of disposable components (not shown in Fig. 1), including sterile drapes for the robotic device and a specially designed target bearing a pattern of metallic beads to assist in the CT-to-fluoroscopic image registration process; and
5. An image adapter, assembled onto the image intensifier of the C-arm for automatic calibration of fluoroscopic images and correction of inherent distortions.

Use of the robotic system consists of preoperative planning and intraoperative execution. The preoperative planning is based on a CT scan of the spinal region of interest loaded into the proprietary software (on the surgeon's computer or on the workstation) for determination of optimal implant size and position (Fig. 2). The intraoperative procedure involves percutaneous mounting of the robot's frame to the patient's bony anatomy using 2 Schanz pins into the posterosuperior iliac spine and 1 Kirschner wire into a spinous process. Two fluoroscopic images are then obtained, 1 anteroposterior (AP) and 1 oblique. The system then performs automatic CT-to-fluoroscopic image registration and determines kinematic solutions for the robotic device to access all the preplanned trajectories. The robotic device is then mounted onto the frame and the system aligns itself, 1 by 1, with the planned trajectories. For each planned trajectory, a set of arms and cannulated tools can be attached to the robotic device through which the surgeon can access the desired anatomy and, in the case of pedicle screws, drill, prepare, and instrument the pedicle.

The fluoroscopic acquisition and registration process is performed only once. The system then guides trajectories to as many spinal levels as appears in the fluoroscopic image.

Operative Technique

Study Group

Preoperative CT scans were taken and then used by the study group surgeons, in conjunction with the system's preoperative planning software, to determine optimal screw sizes and positions. Hypoplastic pedicles that were incapable of supporting screws because of their small diameter were also identified.

A frame was percutaneously attached to the bony anatomy as described above. AP and oblique fluoroscopic images were taken and registered to the preoperative CT data and plan. After the surgeon's visual verification of the image matching, the targeting device was removed and the robotic device was attached to the frame. The robotic device then positioned itself at the desired entry point and trajectory for the first screw and locked itself in place. Next, the surgeon made a stab incision at the skin entry point, and a path down to the bone was created through the soft tissue with a blunt dilator and a cannulated guide tool. A second cannulated tool with a pronged tip was inserted through the first tool with a small mallet to achieve bone purchase. The pedicle was then cannulated through the same channel, a guide wire was introduced, and a cannulated tap was used for pedicle preparation. All of the above steps were performed through the robot's guiding arm. The arm and cannulated tools were then removed, and a screw was introduced over the guide wire and into

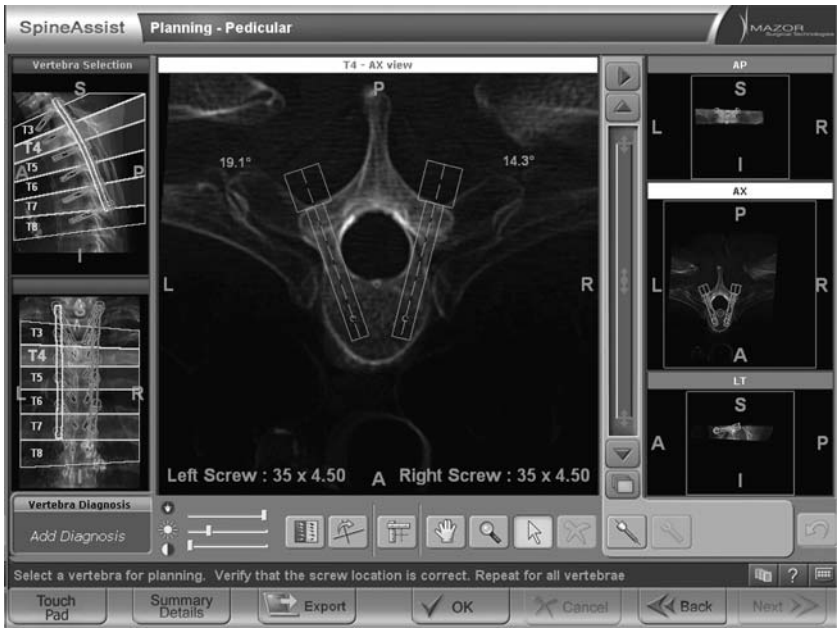

FIGURE 2. Screen capture from the preoperative planning step showing the proposed diameter, length, and orientation of the pedicle screws for a thoracic posterior spinal arthrodesis. AP indicates anteroposterior; AX, axial; LT, lateral.

the pedicle. Finally, fluoroscopic images were obtained to confirm the positioning of the screws.

Free-hand/Control Group

Both control group surgeons used the robotic system's preoperative planning software to plan ideal screw placements. For the lumbar region (L1-S1 screws), the standard percutaneous technique requiring a Jamshidi needle with fluoroscopic guidance was used for percutaneous introduction of the guide wire into the pedicle. Then, a cannulated tap was used for pedicle preparation, followed by the introduction of a cannulated screw over the guide wire. One control group surgeon used a 2-C-arm setup (1 in the AP and 1 in the oblique positions), whereas the second surgeon used a single C-arm, rotating between the 2 positions as necessary. In the thoracic region, 1 control group surgeon used the same technique as described above for the lumbar area, and the second surgeon used an open approach by exposing the spine through a posterior midline incision and muscle dissection and introducing an awl, a tap, and a screw into the pedicle through visual and tactile landmarks without fluoroscopic imaging. Fluoroscopic images to evaluate screw placement were taken at the end of each procedure.

Outcome Measures

Pedicle Screw Position Evaluation

Postoperative CT scans of the specimens were obtained immediately after the surgical procedures. Examiners blinded to the type of technique compared actual screw placements with preoperatively planned trajectories and measured the distance between planned and executed paths by measuring the entry point to the pedicle and the position of the tip of the screw. Each screw was analyzed on AP, lateral, and axial planes, allowing for the calculation of individual 3-dimensional deviation vectors. As an additional assessment of accuracy, postoperative CT scans were then blindly examined by 3 independent spine surgeons in a similar triplanar manner to determine screw positioning in relation to pedicle boundaries. Screws were classified into 1 of 4 categories based on their clinical positions: category A, fully contained within the pedicle; category B, a breach less than 2 mm; category C, a breach of 2 to 4 mm; and category D, a breach greater than 4 mm. When breaches were detected, a note was made regarding the direction of the deviation.

We excluded 23 screws (9.8%), leaving 211 screws for analysis, for the following reasons: study materials limitation [the implanted screws had larger diameters than the pedicle; therefore, a breach was observed even though the centerline of the screw was perfectly aligned with that of the pedicle, (9 screws)]; hypoplastic pedicles forced the surgeon to plan an in-out-in trajectory, thus intentionally and by definition breaching the pedicle cortex (8 screws); and too lateral preoperative planning, leading to a breach as the screw followed the planned trajectory (6 screws) (Fig. 3). Accuracy of placements was compared between study and control groups. Consistency of accuracy within each group (measured by the SD) was also measured, as was the possible effect of surgeons' specialty (orthopedic surgery vs. neurosurgery).

Radiation Levels

Radiation exposure levels were detected by the chest badge (over a lead apron) and dosimeter ring (on the index or middle finger of the dominant hand) worn by each surgeon. Readings from both measuring devices were added to calculate overall exposure per surgeon, and

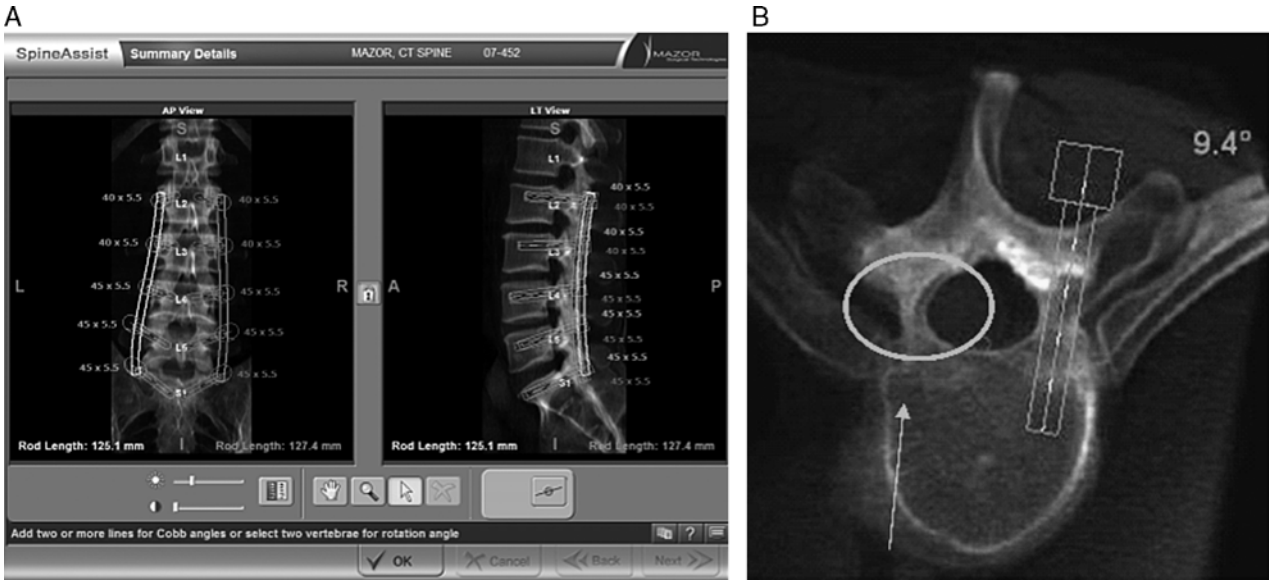

FIGURE 3. A, Typical preoperative planning. B, Hypoplastic pedicle where preoperative plan designates in-out-in projectory.

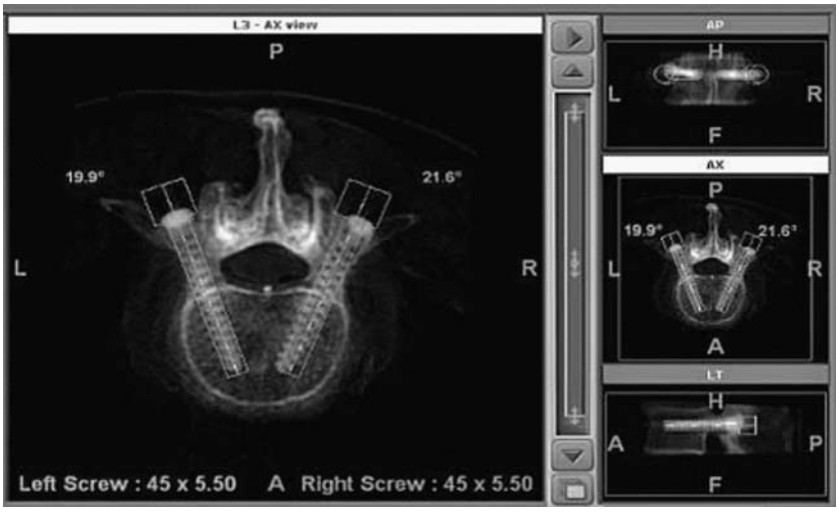

FIGURE 4. Example of postprocedural computerized tomography analysis of accuracy. The robotically assisted screw placements are perfectly aligned with preplanned optimal trajectories. AP indicates anteroposterior; AX, axial; LT, lateral.

the combined values were compared between the control and study groups.

Fluoroscopy Time

Read-outs from the C-arm display were recorded to account for fluoroscopy use throughout the procedure. We computed all fluoroscopy time, including that used for "orientation" imaging before the first incision, AP and oblique registration images for robotic guidance, instrumentation, and final verification images.

Procedure Time

Procedure time was measured with stopwatches from first skin incision to the completion of implantation of the last screw and then recorded. Measurement of procedure time did not include the setup of the frame or mounting of the robot. Procedure time (overall and per screw) was compared between study and control groups. Consistency of procedure length within each group (measured by the SD) was also measured and compared.

Statistical Analysis

Mean values and SDs for all variable parameters were calculated for each group. To test for the significance of the findings, statistical probability (P value) for each comparison between the groups was calculated through the 2-sample (heteroscedastic), 1-tail t test method. Within the study group, outcome measures were also compared between first-time users of robotic guidance and the 1 experienced user. The significance level was set at P value less than 0.05.

RESULTS

The mean deviation from the preoperative plan was 2.6 ± 0.7 mm in the control group and 1.1 ± 0.4 mm in the study group ($P < 0.0001$). Pedicle screw placement accuracy in the study group was consistent, independent of surgeon specialty (neurosurgery or orthopedic surgery), and surgeon experience with robotic guidance. In summary, compared with the free-hand method (control group), use of the robotic guidance system resulted in a

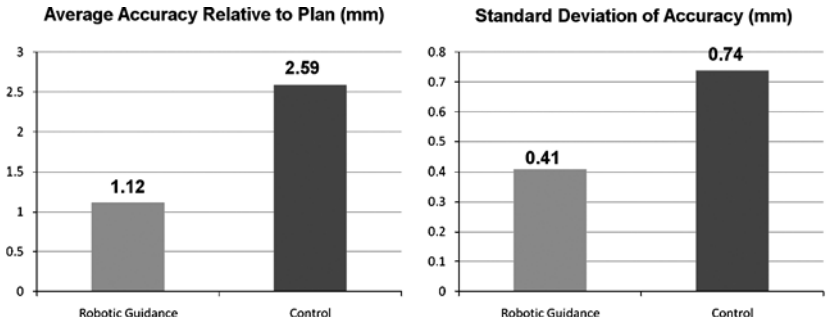

FIGURE 5. Average placement accuracy (left) and SD (right) relative to plan (in mm). The study group (grey) displays better accuracy (smaller average deviation from plan) and better consistency (smaller spread of results or smaller SD) than the control group (black).

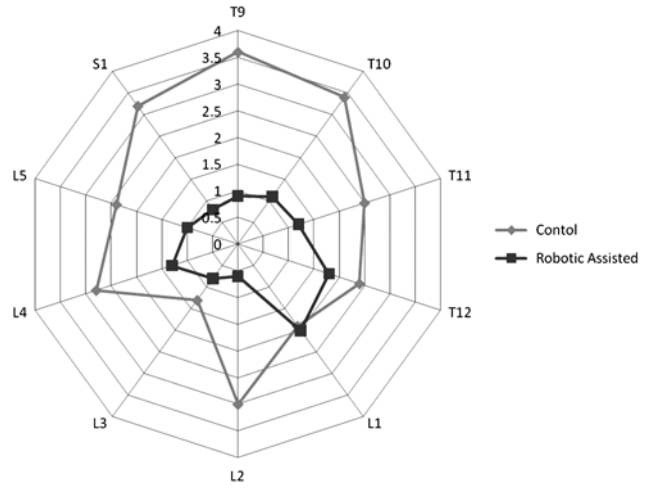

FIGURE 6. Average accuracy per level (in mm) relative to plan. The study group (black) displays better accuracy than the control group (grey).

58% higher pedicle screw placement accuracy and a 43% higher interuser consistency (Figs. 4–6). Improvement in accuracy when robotic guidance is used was calculated by taking the difference between the mean deviation of the 2 groups and dividing it by the mean deviation in the control group [(2.6–1.1)/2.6 = 58%]. Improvement in interuser consistency was calculated similarly, only with SD values instead of mean values [(0.7–0.4)/0.4 = 43%]. Reduced variability is interpreted as improved consistency.

The blinded clinical evaluations of screw placement indicated that the control group had 5.4% of screws in category D (a cortical breach of > 4 mm) and 94.6% of screws in categories A, B, and C combined (54.1%, 32.4%, and 8.1%, respectively) and that the study group had only 1.5% of screws in category D and 98.5% in categories A, B, and C combined (66.2%, 26.2%, and 6.1%, respectively) (Table 1). These data are not statistically significant but they do represent a strong trend ($P = 0.082$) and show that the study group has 72.2% fewer screws in category D, which is the category that is considered to represent the highest risk of neural injury.

The location of the breaches varied. In the control group, 35.3% of breaches were lateral, 11.8% were caudal, 11.8% were medial, 5.9% were cranial, 17.6% were caudal-lateral, 5.9% were caudal-medial, 5.9% were cranial-lateral, and 5.9% were cranial-medial breaches; all screws in category D in the control group had purely lateral breaches. In the study group, 22.8% of breaches were lateral, 22.8% were medial, 13.6% were caudal, 13.6% were cranial, 13.6% were caudal-medial, and 13.6% were caudal-lateral.

TABLE 1. Screw Placement Accuracy

	Percentage of Screws	
Screw Placement Category	**Study Group (n = 197)**	**Control Group (n = 37)**
A (fully contained)	66.2	54.1
B (breach < 2 mm)	26.2	32.4
C (breach of 2-4 mm)	6.1	8.1
Safe zone: combined A, B, and C	98.5	94.6
D (breach of > 4 mm): neurologic damage danger zone	1.5	5.4

Radiation Levels

Control group surgeons (traditional surgical approaches) were exposed to a mean of 136 mrem (range: 103 to 169 mrem) of x-ray radiation (Fig. 7). In contrast, 13 of the 15 (87%) robotic system users were exposed to an overall radiation dose that remained below measurable levels (< 1 mrem). For those surgeons, a worst-case assumption was made, and the exposure reading was assigned a value of 1 mrem and calculated into the group average, yielding a mean radiation exposure of 4.2 mrem for surgeons in the study group.

To allow for a more specific comparison between the groups, we calculated the average radiation per screw by dividing the overall radiation dose per surgeon by the number of screws inserted. The average exposure was 10.1 mrem per screw (range: 9.9 to 10.3 mrem/screw) in the control group and 0.2 mrem per screw (range: 0.04 to 1.67 mrem/screw) in the study group ($P < 0.001$). Thus, implementation of robotic guidance reduced the surgeons' exposure to ionizing radiation by 98.2%.

In terms of total fluoroscopy time, the average was 33.0 seconds (range: 26.6 to 39.5 s) per screw in the control group and 0.7 seconds (range: 0.19 to 1.14 s) in the study group ($P = 0.063$) (Fig. 8). Although this difference is not significant, it does indicate a strong trend (defined as $P < 0.1$, or a 10% significance level). Therefore, fluoroscopy usage was reduced by 97.8% with robotic guidance, a finding consistent with the 98.2% reduction in radiation exposure levels.

Procedure Time

The average time per procedure was 1.98 hours (range: 1.48 to 2.48 h; average of 19 screws per procedure) in the control group and 1.23 hours (range: 1.05 to 1.55 h; average of 20 screws per procedure) in the study group. The experienced user of robotic guidance completed a procedure (18 screws) in as little as 0.82 hours (49 min).

The average time per screw was 6.27 ± 3.05 minutes (range: 4.95 to 8.77 min) in the control group and 4.05 ± 1.08 minutes (range: 2.97 to 5.6 min) in the study group; that for the experienced user was 2.75 minutes (Fig. 9). These data indicate that new robotic system users had a 36% shorter time requirement than did free-hand surgeons, and an experienced user saw as much as a 56% time reduction over free-hand; however, these differences were not significant ($P = 0.192$). Furthermore, use of the robotic system decreased variability among surgeons, as evidenced by the relatively low degree of variance in procedure times among the surgeons. However, it

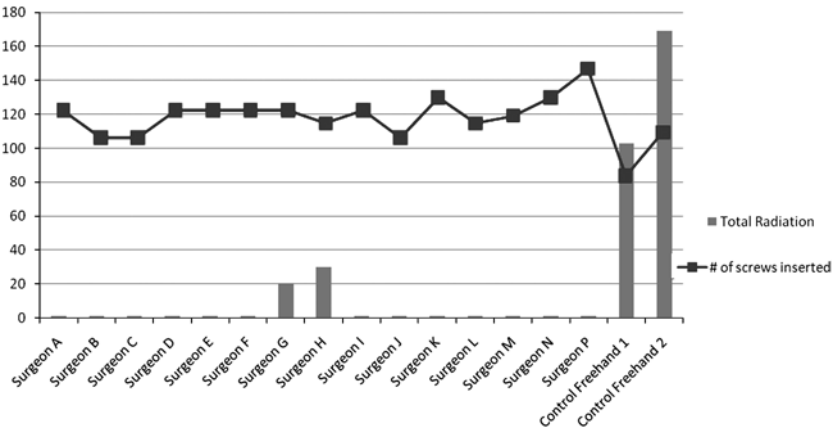

FIGURE 7. Total exposure to radiation and number of implanted screws per surgeon.

is important to note that this measurement relates only to the phase of screw implantation, not to the time for the complete spine surgery.

DISCUSSION

With the increased use of pedicle screw constructs in the surgical treatment of spinal disorders, improved accuracy and a lower radiation exposure are intuitively beneficial. Misplaced screws can lead to complications, including dural tear,[15,39] injury to the spinal cord or nerve roots,[15,39,40] neurologic deficit,[39,40] and skeletal perforation.[1,39] The rate of pedicle screw malpositioning ranges from 0% to 25%,[2–9] depending on the case's degree of complexity and the surgeon's level of experience. Although most misplaced screws are asymptomatic,[8,9,11] the prospect of neurologic and/or bone injury or unsatisfactory degrees of stabilization,[3,12,13] especially when manipulating the thoracic spine,[14–16] justify the development of guidance tools as an aid in the appropriate and safe screw orientation during insertion.

The use of surgical miniature robots has been proven to provide enhanced accuracy in various open, minimally invasive, and percutaneous spinal procedures.[31–34,36]

The technology offers the benefits of precise preoperative planning for the most suitable entry points, and the most appropriate trajectories and intraoperative execution plans. All of these parameters can be computed even in the presence of severe deformities and loss of anatomic landmarks.

Our study has shown that the use of robotic guidance improves the efficacy of percutaneous pedicle fixation while reducing operative time and significantly lowering clinical risk and occupational hazards. Robotic guidance resulted in a reduction in screw positioning deviation measurements of approximately 60% regardless of the spinal level being treated or of the surgeon's earlier experience. In terms of clinical categorization of screw placements, use of robotic guidance decreased the number of placements in the "danger zone"[17] (category D) by 72.2%, thus reducing the likelihood of injury to neurologic structures, the major risk related to screw misplacement. In addition, the surgeon's radiation exposure levels were lowered by 98.2% because of a dramatic decrease in the need for fluoroscopic imaging (97.8%) when using the robotic system. Overall procedure time for pedicular instrumentation was reduced by 36% for novice users, and an experienced user showed a 56% decrease in the duration of multilevel instrumentation compared with equivalent free-hand-based procedures.

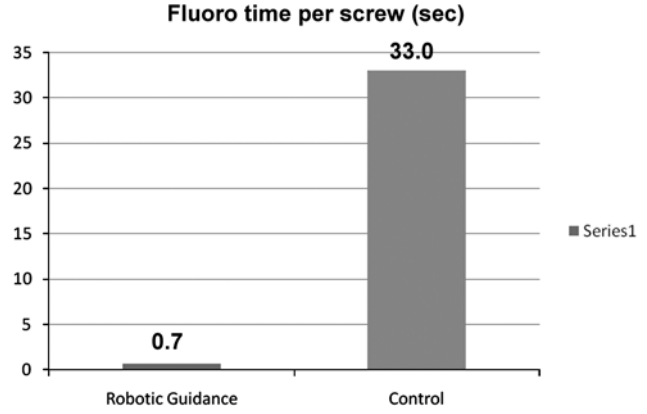

FIGURE 8. Average fluoroscopy use per screw.

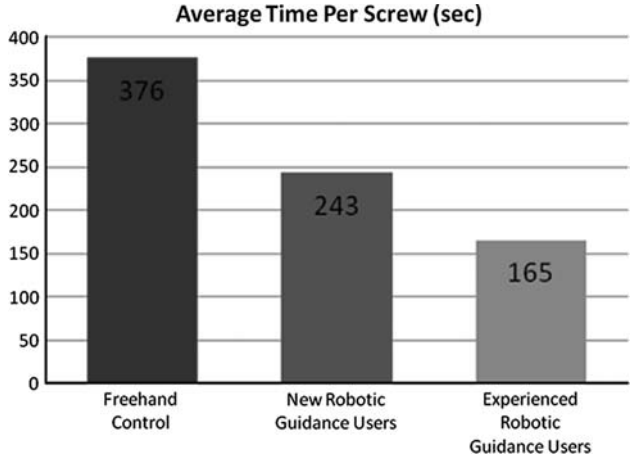

FIGURE 9. Average time per screw in each group.

In summary, the advantages associated with a robotic guidance system may make the surgeon more at ease about offering MIS or percutaneous surgical options to patients and more comfortable about implementing pedicle-based fixation in general. This advanced technology may also allow inclusion of patients with complicated anatomic deformities, who are often excluded from pedicle screw-based surgery options.

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