Clinical Acceptance and Accuracy Assessment of Spinal Implants Guided with SpineAssist Surgical Robot: Retrospective Study

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Abstract and Introduction

Abstract

Study Design. Retrospective, multicenter study of robotically-guided spinal implant insertions. Clinical acceptance of the implants was assessed by intraoperative radiograph, and when available, postoperative computed tomography (CT) scans were used to determine placement accuracy.

Objective. To verify the clinical acceptance and accuracy of robotically-guided spinal implants and compare to those of unguided free-hand procedures.

Summary of Background Data. SpineAssist surgical robot has been used to guide implants and guide-wires to predefined locations in the spine. SpineAssist which, to the best of the authors' knowledge, is currently the sole robot providing surgical assistance in positioning tools in the spine, guided over 840 cases in 14 hospitals, between June 2005 and June 2009.

Methods. Clinical acceptance of 3271 pedicle screws and guide-wires inserted in 635 reported cases was assessed by intraoperative fluoroscopy, where placement accuracy of 646 pedicle screws inserted in 139 patients was measured using postoperative CT scans.

Results. Screw placements were found to be clinically acceptable in 98% of the cases when intraoperatively assessed by fluoroscopic images. Measurements derived from postoperative CT scans demonstrated that 98.3% of the screws fell within the safe zone, where 89.3% were completely within the pedicle and 9% breached the pedicle by up to 2 mm. The remaining 1.4% of the screws breached between 2 and 4 mm, while only 2 screws (0.3%) deviated by more than 4 mm from the pedicle wall. Neurologic deficits were observed in 4 cases yet, following revisions, no permanent nerve damage was encountered, in contrast to the 0.6% to 5% of neurologic damage reported in the literature.

Conclusion. SpineAssist offers enhanced performance in spinal surgery when compared to free-hand surgeries, by increasing placement accuracy and reducing neurologic risks. In addition, 49% of the cases reported herein used a percutaneous approach, highlighting the contribution of SpineAssist in procedures without anatomic landmarks.

Introduction

This article summarizes the activity of the SpineAssist surgical robot which, to the best of the authors' knowledge, is currently the only robot in use to assist spine surgeries.

The development of SpineAssist started some 7 years ago and went through several developmental phases that have been previously reported.\textsuperscript{1,2} Since reaching specific developmental and regulatory milestones, SpineAssist has been applied in operating rooms in the United States, Germany, and Israel. Reports of SpineAssist performance\textsuperscript{3–8} have been published, where each surgeon individually recounted his own experiences. The current article reports on the clinical experience obtained with this surgical robot and summarizes its activities, between June 2005 and June 2009.

Performing spine surgery is a delicate and hazardous procedure due to its proximity to both the central nervous system and main blood vessels. The unsatisfactory rate of misplaced screws in spinal fusion procedures inspired the emergence of a proposal to robotically guide pedicle screw insertion. To effectively achieve this goal, a number of issues had to be addressed, including screw trajectory planning, typically performed on preoperative computed tomography (CT) images, registration of the preoperative plan with the intraoperative
fluroscopy images, and development of an appropriate robotic system, a clamping fixation device, and robot control software.

The aim of the present article is to provide a comprehensive review of all clinical cases in which SpineAssist was applied and data were reported and to determine the clinical acceptance and placement accuracy of 3271 pedicle screw and guide-wire insertions under SpineAssist guidance. A short description of the robot structure and workflow, followed by a comprehensive report of all SpineAssist-guided cases are presented. Clinical acceptance of robot-assisted implant placements was assessed by intraoperative fluoroscopy images, while actual placement accuracy was measured wherever postoperative CT images were available. This was accomplished by comparing the CT images employed for preoperative planning to the actual implant location as captured by a postoperative CT scan. Overall, the robot was found to be advantageous in enhancing degree of positioning accuracy especially in complicated cases, minimizing invasiveness, and reducing radiation exposure.

Materials and Methods

System Description and Surgical Technique

SpineAssist (Mazor Surgical Technologies, Caesarea, Israel), is a bone-mounted miniature robot designed to guide surgeons toward accurate placement of implants, e.g., pedicle screws, or positioning of surgical tools during spine surgery (Figure 1). The bone-mounting feature was designed to improve procedure accuracy by ensuring that patient breathing or motion does not alter the relative position of the robot with respect to the vertebra.

Figure 1. SpineAssist surgical robot.

The robot was designed as a semiactive system offering surgical tool guidance while leaving performance of the actual surgical operation, such as the drilling, in the surgeon's hands. Unlike free-hand navigation techniques, the SpineAssist platform serves as a computerized mechanical positioning system that guides the surgeon along the planned trajectory. The system consists of 2 units: a miniature 50 × 80 mm, cylindrically shaped robot weighing 250 g that can move its end-effector in 6 degrees-of-freedom, and a workstation that
runs graphic user interface software responsible for the preoperative planning, image acquisition and registration, kinematic calculations and real-time robot motion control.

The surgical workflow consists of 5 steps:

1. Preoperative planning—preoperative CT scan-based planning of optimal positioning and dimensions of the implants (or tools).
2. Attachment to bony anatomy—attachment of a mounting frame to the bony anatomy of the patient spine to which targets for image registration are connected.
3. Image acquisition and registration—capture of 2 fluoroscopic shots which are automatically registered to the preoperative CT images.
4. Robot assembly and motion—attachment of the robot to the mounting frame. The robot then moves and locks into position so that a guiding tube at the distal end of its arm is aligned with the planned screw/tool trajectory.
5. Pedicle preparation and screw insertion—drilling through the guiding tube into the pedicle either percutaneously or via an open approach. Robot motion and screw insertion are then consecutively repeated for all planned implants.

SpineAssist assembly for less invasive pedicle screw insertion is shown in Figure 2.

**Figure 2.** SpineAssist assembly in a less invasive pedicle screws insertion. A guiding tube attached to the robot arm guides the surgical tool along a predefined trajectory.
SpineAssist-guided Surgical Cases

A total of 842 cases with SpineAssist guidance were conducted between June 2005 and June 2009. While the objective of this analysis was to summarize as much data as possible which, in some cases, demonstrated variances in degree of detail in the collected reports, all available data were included and categorized as per analyzed parameter (summarized in Table 1).

Table 1. Summary of SpineAssist-Guided Cases Included in This Report

<table>
<thead>
<tr>
<th></th>
<th>Execution Rate</th>
<th>Cases With Defined Treatment Objective</th>
<th>Pedicle Screw Cases</th>
<th>Open/Percutaneous Rate</th>
<th>Clinically Accepted Implants (Intraoperative Fluoroscopy)</th>
<th>Accuracy (Postoperative CT)</th>
<th>Time per Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. cases</td>
<td>682</td>
<td>673</td>
<td>593</td>
<td>607</td>
<td>635</td>
<td>139</td>
<td>376</td>
</tr>
<tr>
<td>No. screws/guide wires (S/GW)</td>
<td>3912</td>
<td>3236</td>
<td>3131</td>
<td>3054</td>
<td>3271</td>
<td>646</td>
<td>2161</td>
</tr>
<tr>
<td>Statistics</td>
<td>Robotically-guided S/GW 3271/391 2 From January 2008: 1555/171 4</td>
<td>Cases per treatment: spinal fusion, 593; vertebroplasty, 69; osteoid osteoma and biopsy, 11</td>
<td>Open: 307 Percutaneous: 300</td>
<td>Clinically accepted: 3204 screws</td>
<td>Within pedicle: 577 Deviation: &lt;2 mm, 58; 2–4 mm, 9; &lt;4 mm, 2</td>
<td>Minutes/screw levels: single, 13.5; multiple, down to 4 From January 2008: single, 10.6; multiple, down to 2</td>
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The vast majority of SpineAssist-guided procedures for which treatment type was reported (673 cases in total), involved pedicle screw insertions (593 cases, 88%), while others included needle placement in vertebral body augmentation (69 cases, 10%) or excision of osteoid osteoma and biopsy (11 cases, 2%). The success rates of all of the mentioned procedures lies in accuracy of reaching a predefined vertebral location—a task in which robots excel, the performance of which is the subject of this analysis.

As most patients do not undergo postoperative CT scans, accuracy verification is often solely based on intraoperative fluoroscopy, where axial views are lacking and hence, offer only details of clinical acceptability rather than measures of accuracy. In cases where only intraoperative fluoroscopies were available, the present analysis relied on the surgeon's experienced judgment of clinically accepted placement. When postoperative CT scans were available, the Gertzbein and Robbins criterion were adopted for quantitative assessments defined in 2-mm increments, as outlined below:

Screws were categorized as perfectly within the pedicle (group A); breaching less than 2 mm (group B); breaching between 2 and 4 mm (group C); breaching between 4 and 6 mm (group D); or breaching more than 6 mm (group E).

Results

Patient Statistics and SpineAssist Execution Rate

SpineAssist has been applied for tool guidance in 842 cases over the reported 4-year period in 14 hospital centers. As several cases provided only partial reports, the size of the database of the parameters of interest varies, as summarized in Table 1. Patient gender distribution was 58% female and 42% male, with a mean age of 52 years. The age range was relatively wide, extending between 7 (scoliosis) and 94 years of age (vertebroplasty), where the youngest age group (7–18 years) included a significant number, 66/74, of scoliosis
cases. Most of the operations for which treatment type was defined (593/673), were spinal fusion, while 80 cases were either vertebroplasty, excision of osteoid osteoma or biopsy in which the SpineAssist robot directed needles or guide-wires to a given vertebral location. Of the cases reported, herein, 49% employed percutaneous or minimally invasive approaches (Table 2), in contrast to the approximate 5% of minimally invasive fusion procedures reported for unassisted thoracolumbar fixations in Europe (4960 minimally invasive procedures of total 101,044 Thoracolumbar Fixations, iData Research Inc, Europe Statistics, 2009).

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Of the 682 cases in which 3912 Screw/Guide-Wire (S/GW) insertions were planned and for which execution rates were reported, 83.6% (3271 S/GW) were fully implanted under robotic guidance, while the remainder were initiated under robotics guidance and manually continued by the surgeon. In the latter cases, both system-dependent and patient/user dependent factors influenced the choice to manually continue the operation. Reasons for manually continue the operation were: registration issues 9.2% (361 S/GW), robot reachability (physical limitations of robot arm extensibility) 1.1% (43 S/GW), device failure 1.8% (69 S/GW), mechanical movement 0.1% (3 S/GW), and surgeon aborted 4.2% (162 S/GW), see Figure 3A. However, when only considering cases from January 2008 (276 cases; 1714 S/GW), execution rates reached 90.8% (1555 S/GW), reflecting the contribution of accumulated experience with and system maturity of the robotic guidance system (Figure 3B).

Table 2. Number of Cases Categorized as per Diagnosis and Surgical Approach

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Open</th>
<th>Percutaneous</th>
</tr>
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<tbody>
<tr>
<td>Deformities</td>
<td>78</td>
<td>9</td>
</tr>
<tr>
<td>Disc disease</td>
<td>56</td>
<td>55</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>52</td>
<td>76</td>
</tr>
<tr>
<td>Stenosis</td>
<td>45</td>
<td>37</td>
</tr>
<tr>
<td>Instability</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Fracture</td>
<td>17</td>
<td>67</td>
</tr>
<tr>
<td>Tumor</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Other</td>
<td>45</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>307</td>
<td>300</td>
</tr>
</tbody>
</table>
Figure 3. Execution rate of Screw/Guide-Wire (S/GW) insertions. Ratios of executed SpineAssist-guided S/GW insertions to planned position as calculated from the 682 cases involving S/GWs. Reasons for partial executions are presented along with their respective ratios for the entire reported period June 2005 to June 2009 (A) and for cases since January 2008 (B).

When calculating the time for instrumentation of pedicle screws under robotic guidance, from mounting frame assembly through registration, robot mounting, drilling, screw insertion and frame disassembly, the average time required per screw (376 cases, 2161 screws) ranged from 13.5 minutes for 1 level down to approximately 4 minutes for multiple levels (Figure 4). However, for pedicle screw cases reported since January 2008 (176 cases, 1139 screws), time per screw ranged between 10.6 minutes for 1 level down to 2 minutes for multiple levels (Figure 4), again highlighting the contribution of accumulated experience and improved surgical workflow on system performance.

Figure 4. Average time per screw. Average time per screw measured from mounting frame assembly through registration, robot mounting, drilling, screw insertion, and frame disassembly. Values are presented as averages of cases with identical numbers of screw insertions for the entire series (solid columns) and for cases performed after January 2008 (striped columns).
Pedicle Screw Placement—Clinical Acceptance and Implant Accuracy

Intraoperative fluoroscopy-based positioning evaluations of 3271 SpineAssist-guided S/GW in 635 cases yielded 3204 (98%) clinically accepted placements. However, since intraoperative fluoroscopic images define clinical acceptability rather than accuracy, a more quantitative verification of screw placement accuracy was conducted on the 646 screws, inserted over 139 cases, for which postoperative CT scans were available. Planned versus actual placements as defined by preoperative versus postoperative CT images (Figure 5A), were compared at 6 locations per screw. These locations defined the entry point to and exit from the pedicle and the pedicle length as measured in both sagittal and axial views resulting in a 3-dimensional positional and orientational accuracy assessment of the screw (Figure 5B). This comparison showed that for these 646 screws, the actual placement matched the planned one with a mean deviation of 1.2 ± 1.49 mm on the axial plane and 1.1 ± 1.15 mm on the sagittal plane. However, as pedicle violation is of utmost clinical importance, the Gertzbein and Robbins criterion was used to further define screw placement accuracy, and yielded 89.3% (577) of screws within class A and 9% (58) in class B (Figure 6). Thus, as, grade B screws are considered clinically safe,[10,11] 98.3% (635) of the analyzed screws fell within the safe zone. The remaining 1.4% (9) of the screws were categorized as group C, while only 2 screws deviated by more than 4 mm from the pedicle wall.

Figure 5. Screw positioning accuracy measurements as determined on postoperative CT scans. A, Planned (screw-shaped sketch) merged over actual placement (white signal). B, Points of measurement along the inserted pedicle and equation for defining the positional error in comparison to the planned position.
Figure 6. Accuracy of implanted screws as defined by the Gertzbein and Robbins criterion. Postoperative CTs were used to determine placement accuracy of 646 S/GW inserted under Spine Assist guidance and to categorize screw as within the pedicle (A) or with a breach of <2 mm (B), 2 to 4 mm (C) or >4 mm (D).

Discussion

Despite the widely accepted usage of pedicle screws for spine stabilization, various estimates of the rate of misplaced pedicle screws can be found in the literature ranging from a few percent to 40%. This vast discrepancy in reports raises questions with regard to the definition of a misplaced screw. In a meta-analysis performed by Kosmopoulos and Schizas where 37,337 inserted pedicle screws were evaluated in 130 studies, it was concluded that a unified accuracy measure should be adopted, as 35 different pedicle screw placement assessment methods were identified. The same was concluded in an additional study analyzing screw placement accuracy. Clearly, without standard measurements and acknowledged criteria, reports of accuracy are of little value and do not allow for cross-comparison between research groups.

The mentioned meta-analysis assessed a total of 16,717 pedicle screw placements according to detailed evaluation guidelines, of which 42.3% were based on postoperative CT scans. The overall weighted average of accurate lumbar and thoracic placements for the evaluated screws was 81.9%. Since the 2 most popular assessment methods reported in this meta-analysis defined pedicle screw violations as present versus absent or as per the Gertzbein and Robbins criterion, a comparison of grade A screws of the present investigation to accurate screw placements reported by Kosmopoulos and Schizas is valid for both assessment methods. Moreover, it can be assumed that a screw described as completely within the pedicle will be considered accurate by all assessment methods. As such, the 89.3% of SpineAssist-guided procedures resulting in grade A screw insertions yielded a 7.4% lead ($P < 0.01$) over free-hand inserted implants in placement accuracy. More specifically, when separately considering grade A screws of thoracic and lumbar spine segments inserted under SpineAssist guidance, 30/38 (79%) thoracic and 547/608 (90%) lumbar screws fell into this category, compared to 56% and 87.3%, respectively, using the free-hand insertion.

In a work describing the accuracy of pedicle screws inserted through a percutaneous approach, deviations were assessed by postoperative CT scans as defined by the Wiesner assessment criterion. In the coronal view, 30% of the screws breached the cortical pedicle wall with 21.7% encroachment, 5% minor breaching of less than 3 mm, and 3.3% severe breaching of more than 6 mm, whereas in the axial view the reported rates were 23.3%, 20%, 0%, and 3.3%, respectively. The authors conclude that the resulting accuracy rate is considered satisfactory as it largely falls within the limits of misplacement rates measured for open procedures.
When considering the robotically-guided percutaneously inserted screws for which postoperative CT scans were available (48%, 67/139 cases), 7 (2.4%) of the 292 analyzed screws breached beyond 2 mm, in comparison with the 8.3% of the screws that breached beyond 3 mm in the above report of free-hand percutaneous screw insertions.\[^{19}\]

Analysis of the number of open versus less or minimally invasive cases performed under SpineAssist guidance highlighted the platform's advantage in assisting percutaneous and minimally invasive approaches. As SpineAssist guides the surgeon to predefined locations without requiring anatomic visibility, the 49% rate of less or minimally invasive procedures reported in the present investigation, was much higher than the 5% reported in published literature (iData Research Inc, Europe Statistics, 2009). In open cases, where the anatomy is clearly visible, SpineAssist was less appealing to surgeons. In addition, in cases of severe deformity, e.g., scoliosis, where visualization of surface anatomy alone may not be sufficient, the robotic guidance proved to be advantageous. Such guidance can be especially relevant to the concave vertebral scoliotic pedicles along the apex of a large curve, where pedicles are often deformed, sometimes with a very narrow "waist" (only a few millimeters wide), and even fully deficient, for which an in-out-in trajectory is planned.

Application of robotic guidance in percutaneous cases offers 2 additional advantages. First, the robotic platform allows the surgeon to locate the optimal point of entry at the skin level, thereby reducing the required incision size. Second, SpineAssist-guided procedures require significantly shorter imaging sessions, exposing the patient and staff to approximately 50-fold less radiation when compared to non-navigated control groups, as previously reported for the mini-open technique of 217 pedicle screws inserted in 11 human cadavers by 16 surgeons.\[^{20}\]

The rate of neurologic deficits bears significant weight when considering spinal fusion complications. These have been reported to range between 2% and 5%.\[^{9,21–23}\] A lower rate of 1.1% was reported by Davne and Myers,\[^{14}\] where 0.6% were related to posterior lumbar interbody fusion and 0.6% to instrumentation. Similarly, Faraj and Webb\[^{24}\] report on a 1.09% rate of neurologic complications caused by pedicle screws, and significant nerve injury in 0.15% of the 648 analyzed cases. In contrast, Amiot\[^{25}\] et al reported higher rates, with reoperations in 7 of 100 patients due to postoperative neurologic deficits. No such deficits were reported in the parallel computer-assisted navigated group analyzed in the same study. In an investigation by Lonstein\[^{26}\] et al, 3 of 9 patients with nerve root irritation demonstrated permanent neurologic weakness despite removal of the screws. Of note, a further consideration put forth by Burch:\[^{27}\] "Neural complications may be underreported in large series, because rates seem higher in prospective trials with close follow-up...."

Unlike the 2% to 5% rates of permanent neurologic deficits reported in the literature, and even for the 0.6% reported in another, SpineAssist-guided pedicle screw insertions showed reversible neurologic deficits in 0.7% (4 of 593) of the cases, none of which led to permanent neurologic deficit once revision was performed. Moreover, this modest rate of required revisions is even more striking when considering the 49% performed less or minimally invasively.

**Conclusion**

Owing to its status as the first robot to clinically assist spine surgery in a substantial number of cases, the SpineAssist robotic guidance platform faced many issues unique to introduction of novel devices and workflow into the operating room arena. As a new tool in the surgeon's armament, the objective of this report was to summarize all available data collected from the initial phases of SpineAssist application.

The accumulated intraoperative fluoroscopy-based statistics presented here demonstrate a 98% clinically accepted robotically-guided S/GW placements. Postoperative CT accuracy assessments concluded with a 89.3% rate of robotically-guided S/GW completely within the pedicle. Assuming up to 2-mm pedicle breach as one which can be considered clinically safe, then 98.3% of the CT-analyzed S/GW fell within the safe zone.

Surgeon tendency favored SpineAssist guidance for less invasive cases, where anatomy was less visible and where heightened guidance was naturally needed. Such a conclusion can be deduced from the high rate, 49%,...
of percutaneous cases in the present investigation as compared to about the approximately 5% reported in Europe.

Despite the infancy stages in which robotics surgery currently stands, we believe that the few surgical robots, currently in use in various surgical applications worldwide, have proven their potential in improving surgical outcomes, especially where accuracy and minimal invasiveness are required.

Sidebar

Key Points

- Robotic guidance of pedicle S/GW in spinal surgery yielded increased accuracy and reduced neurologic risks.
- Intraoperative fluoroscopy and in some cases postoperative CT scans, verified implants’ clinical acceptance and positional accuracy and demonstrated higher rates than free-hand procedures.
- No permanent neurologic deficit was noted among the 635 cases analyzed with intraoperative fluoroscopy, half of which were performed percutaneously, in which a total of 3271 robotically-guided implants were inserted.

References

12. Deleted in proof.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication. No funds were received in support of this work. One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: e.g., honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position. Boris Silberstein and Alon Friedlander received consultation fee. Moshe Shoham has stocks and decision making position.

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