Accuracy of Robot-Assisted Placement of Lumbar and Sacral Pedicle Screws

A Prospective Randomized Comparison to Conventional Freehand Screw Implantation

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Study Design. Single-center prospective randomized controlled study.

Objective. To evaluate the accuracy of robot-assisted (RO) implantation of lumbar/sacral pedicle screws in comparison with the freehand (FH) conventional technique.

Summary of Background Data. SpineAssist is a miniature robot for the implantation of thoracic, lumbar, and sacral pedicle screws. The system, studied in cadaver and cohort studies, revealed a high accuracy, so far. A direct comparison of the robot assistance with the FH technique is missing.

Methods. Patients requiring mono- or bisegmental lumbar or lumbosacral stabilization were randomized in a 1:1 ratio to FH or RO pedicle screw implantation. Instrumentation was performed using fluoroscopic guidance (FH) or robot assistance. The primary end point screw position was assessed by a postoperative computed tomography, and screw position was classified (A: no cortical violation; B: cortical breach <2 mm; C: ≥2 mm to <4 mm; D: ≥4 mm to <6 mm; E: ≥6 mm). Secondary end points as radiation exposure, duration of surgery/planning, and hospital stay were assessed.

Results. A total of 298 pedicle screws were implanted in 60 patients (FH, 152; RO, 146). Ninety-three percent had good positions (A or B) in FH, and 85% in RO. Preparation time in the operating room (OR), overall OR time, and intraoperative radiation time were not different for both groups. Surgical time for screw placement was significantly shorter for FH (84 minutes) than for RO (95 minutes).

Ten RO screws required an intraoperative conversion to the FH. One FH screw needed a secondary revision.

Conclusion. In this study, the accuracy of the conventional FH technique was superior to the RO technique. Most malpositioned screws of the RO group showed a lateral deviation. Attachment of the robot to the spine seems a vulnerable aspect potentially leading to screw malposition as well as slipping of the implantation cannula at the screw entrance point.

Key words: lumbar/lumbosacral spinal instrumentation, pedicle screws, robotics, image guidance, computer-assisted surgery. Spine 2012;37:E496–E501

During recent years, image guidance is increasingly used in spinal surgery.1–5 Main advantages are (1) an increased accuracy of implant position1,4 and (2) a reduction of radiation exposure during surgery for the patient and—which is even more important concerning the cumulative exposure—the surgeon.4–7 The advantage of image-guided techniques in the placement of pedicle screws with respect to screw position has been shown for the cervical, thoracic, and lumbosacral spines by several publications.1,3,4 However, while screw position is improved, a clinical benefit for the patient deducted from the higher accuracy has not been confirmed, so far.

SpineAssist (Mazor Surgical Technologies [HQ] Ltd., Caesarea, Israel), a miniature robot mounted on the spine, has to be considered as a refinement of spinal navigation or image guidance which has the purpose to increase accuracy of screw position and reduce intraoperative radiation exposure.4–15 Although conventional image guidance requires an alignment of surgical instruments to preplanned trajectories by hand and, therefore, complex hand-eye coordination, SpineAssist robotically guides the surgeon to preplanned trajectories. The semiactive hexapod robotic system guides the surgeon whereas the active drilling is not performed by the robot but by the surgeon.

Currently, SpineAssist is mostly used for the implantation of lumbar pedicle screws, revealing a high accuracy in cadaver studies10,12–15 as well as in vivo as assessed by observational cohort studies.5,11,16 A prospective study evaluating 100 lumbar and sacral pedicle screws in 19 patients revealed good screw positions in 97% of screws; the median deviation of the

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Acknowledgment date: August 12, 2010. Acceptance date: September 13, 2011.

The device(s)/drug(s) is/are FDA approved or approved by corresponding national agency for this indication.

No funds were received to support this work.

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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DOI: 10.1097/BRS.0b013e31824b7767

E496 www.spinejournal.com

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screws from the plan was 0.34 mm and the angular deviation was 2.7°. 17

However, so far, controlled data comparing the robot-assisted (RO) approach with the conventional freehand (FH) technique are missing but would be mandatory to prove the potential advantages of robot assistance compared with conventional FH surgery.

Therefore, we designed a prospective randomized controlled trial performed at a single center to compare the accuracy of screw position with the SpineAssist miniature robot with the conventional FH fluoroscopy-guided technique.

MATERIALS AND METHODS

Study Population
All patients recruited for this study had to fulfill the following inclusion criteria: (1) age older than 18 years, (2) indication for mono- or bisegmental lumbosacral stabilization using a dynamic pedicle screw–based internal fixator, and (3) informed consent to participate in the study. Patients were randomized to conventional fluoroscopy-assisted FH pedicle screw placement or RO pedicle screw placement in a 1:1 ratio.

Three experienced spine surgeons familiar with both techniques, that is, conventional FH pedicle screw implantation and the RO implantation, performed the surgical procedures in equal proportions.

Conventional FH Pedicle Screw Implantation
For conventional FH pedicle screw implantation, anteroposterior and lateral fluoroscopy (Siremobil Compact L; Siemens, Erlangen, Germany) was used during the procedure. A midline or modified Wiltse approach to the spine was established according to the surgeon’s preference. By identification of anatomical landmarks and the use of lateral and anteroposterior fluoroscopy, pedicle screws were implanted and connected to rods (Cosmic; Ulrich Medizintechnik, Ulm, Germany). If necessary, a subsequent decompression of the spinal canal or fusion procedure was performed.

Robot-Assisted Lumbosacral Pedicle Screw Implantation
For RO lumbosacral pedicle screw implantation, the Food and Drug Administration–approved and European Conformity–certified miniature robot SpineAssist was used. Prior to surgery, patients obtained a helical computed tomographic (CT) scan (collimation $64 \times 0.625$ mm, matrix $512 \times 512$, reconstruction in 1 mm slices, no gap between slices). CT data were transferred to a standard PC and imported to the SpineAssist planning software. In multiplanar reconstructions of the CT data, pedicle screws of the respective levels were planned. The plan was transferred to the SpineAssist workstation in the OR.

At the beginning of the surgical procedure, a platform for the robot was attached to the spinous process superior to the levels, requiring instrumentation using a K-wire and the lower end of the base was attached to the OR table using a “bedmount.” A reference array was attached to the platform, and fluoroscopic images in anteroposterior and oblique directions were acquired (Siremobil Compact L, Siemens, Erlangen, Germany) for CT-fluoro matching of the patient’s anatomy with the preoperative CT data set. The surgeon controlled matching accuracy by comparing the CT-fluoro fusion at anatomical landmarks; a calculated accuracy is given by the system. Following the registration procedure, the reference array was removed and the robot was mounted on the platform over the patient’s spine. Pertinent preplanned trajectories for screw implantation were given by the robot. Using Wiltse approaches, a drill guide was inserted through the robot’s arm to the screw entrance point and the pedicles were opened by a 2.3-mm drill. K-wires were inserted in the pedicles, and after opening of all pedicles and insertion of K-wires, pedicle screws (CosmicMIA; Ulrich Medizintechnik, Ulm, Germany) were implanted over the K-wires. Finally, the instrumentation was concluded by the implantation and fixation of rods without the assistance of the robot. During the RO pedicle screw implantation, the surgeon was allowed to control drill, K-wire, or screw position by fluoroscopy, as he felt necessary. After instrumentation, a decompression or fusion was performed where necessary.

Study Parameters
Primary end point of the study was position of the pedicle screws as assessed by a postoperative thin-cut CT scan. An independent neuroradiologist blinded for the implantation technique assessed the screw position. Any cortical breaches of the pedicular borders by the screw were measured in millimeter in medial, lateral, cranial, or caudal direction. According to Gertzbein and Robbins, 14 screw position was classified within the pedicle (group A), cortical breach of less than 2 mm (group B), cortical breach of 2 mm or more but less than 4 mm (group C), cortical breach of 4 mm or more but less than 6 mm (group D), and cortical breach of 6 mm or more (group E). Any anterior perforations of the vertebral bodies were measured.

As secondary end points, the duration of trajectory planning, the duration of the preparation in the OR, the duration of surgery with and without decompression, the radiation exposure, and the screw revision rate were assessed.

Furthermore, patients’ sex, age, and body mass index, levels of instrumentation, number of instrumented levels, the calculated accuracy of the CT-fluoro matching, the days of postoperative hospitalization, number of screw revisions, and conversions to an FH approach in the RO group were acquired.

Statistical Analysis
Before initiation of the study, a statistical power analysis was performed. For the primary end point screw position, a positioning failure, that is, malposition of 1% was assumed for RO screws in comparison with an assumed 10% malposition rate of conventionally placed screws. To detect this difference with a power of 80% at an error probability of 5% when using 2-sided testing, the implantation of 106 screws per group was necessary. Therefore, the study aimed for randomization of 30 patients per group with at least 4 screws.
per patient, resulting in a minimum of 120 implanted screws per group.

For further statistical analysis, the $\chi^2$ test was used for comparison of proportions and the signed rank sum test was used for comparison of ordinal data of both groups. A significant difference was accepted at an error probability of 0.05. The local ethics committee approved the study.

RESULTS

Within 13 months, 60 patients were included in the study and randomized in a 1:1 ratio to conventional FH or RO pedicle screw implantation. Patient data are summarized in Table 1. In brief, there were no significant differences of median patient age, male/female ratio, median body mass index, or the proportion of mono- and bisegmental instrumentations between both groups. The median duration of preoperative planning of the screw trajectories using the SpineAssist software was 24 minutes for RO, whereas no planning time was necessary for FH.

There were no differences of the instrumented lumbosacral levels between both groups, which were from L2 to S1 ($P = 0.712$) (Table 2). The median time for preparation in the OR (positioning of the patient, setup of the SpineAssist, disinfection, and draping) was not significantly different, with 23 minutes for FH and 25 minutes for RO. Although the overall OR time, from skin to skin, was not significantly different between both groups (132 minutes for FH and 151 minutes for RO), the surgical time for the instrumentations, that is, overall time without the time for decompression, was significantly shorter for FH than for RO, 84 minutes versus 95 minutes ($P = 0.04$), respectively.

RO required an additional planning of computed tomography, with a dose length product of 411 mGy cm, which was not necessary for FH. Surprisingly, the time of intraoperative radiation was not different for both groups, with a median time of 1.9 minutes.

The duration of postoperative hospitalization after FH or RO was 6 and 7 days, respectively.

Screw positions, according to the Gertzbein Robbins classification, are summarized in Table 3. Of 298 implanted screws, 152 were implanted in FH and 146 were implanted in RO. Ninety-three percent of the screws in FH were group A and B, that is, good screw positions, whereas significantly less good screw positions were achieved in RO (85%) ($P = 0.019$). Inversely, the proportion of suboptimal screw positions (groups C + D + E) was significantly larger in RO compared with FH, 15% and 7%, respectively. Furthermore, 10 screws of RO in 7 patients required a conversion to a FH approach after the robot-guided drill hole was in the soft tissue lateral to the vertebral body and pedicle without sufficient bone contact. One misplaced group E screw of FH was revised in a second procedure because the patient had radicular pain from the misplaced screw.

TABLE 1. Study Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Free Hand (n = 152)</th>
<th>Robotics (n = 146)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (yr)</td>
<td>67</td>
<td>68</td>
<td>0.599</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>12/18</td>
<td>14/16</td>
<td>0.794</td>
</tr>
<tr>
<td>Median body mass index</td>
<td>28</td>
<td>26</td>
<td>0.666</td>
</tr>
<tr>
<td>Mono/bisegmental</td>
<td>14/16</td>
<td>17/13</td>
<td>0.605</td>
</tr>
<tr>
<td>Median planning (min)</td>
<td>NA</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>OR time wt deco (min)</td>
<td>132</td>
<td>151</td>
<td>0.087</td>
</tr>
<tr>
<td>OR time w/o deco (min)</td>
<td>84</td>
<td>95</td>
<td>0.040</td>
</tr>
<tr>
<td>Radiation exp. planning (mGy cm)</td>
<td>NA</td>
<td>411.6</td>
<td></td>
</tr>
<tr>
<td>Intraoperative radiation exposure (min)</td>
<td>1.9</td>
<td>1.9</td>
<td>0.433</td>
</tr>
<tr>
<td>Postoperative stay (d)</td>
<td>6</td>
<td>7</td>
<td>0.285</td>
</tr>
</tbody>
</table>

OR time indicates surgical time; wt deco, with decompression; w/o deco, without decompression; NA, not applicable.

TABLE 2. Number of Screws Per Level and Group

<table>
<thead>
<tr>
<th>Instrumented VB</th>
<th>Free Hand (n = 152)</th>
<th>Robotics (n = 146)</th>
<th>Total (n = 298)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L2</td>
<td>8</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>L3</td>
<td>30</td>
<td>24</td>
<td>54</td>
</tr>
<tr>
<td>L4</td>
<td>52</td>
<td>50</td>
<td>102</td>
</tr>
<tr>
<td>L5</td>
<td>52</td>
<td>48</td>
<td>100</td>
</tr>
<tr>
<td>S1</td>
<td>10</td>
<td>16</td>
<td>26</td>
</tr>
</tbody>
</table>

VB indicates vertebral body.

TABLE 3. Screw Position According to the Gertzbein Robbins Classification in Percentage of Implanted Screws

<table>
<thead>
<tr>
<th>Screw Position</th>
<th>Free Hand (n = 152)</th>
<th>Robotics (n = 146)</th>
<th>Total (n = 298)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>68</td>
<td>56</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>25</td>
<td>29</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>A + B</td>
<td>93</td>
<td>85</td>
<td>89</td>
<td>0.019</td>
</tr>
<tr>
<td>C</td>
<td>3</td>
<td>11</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>C + D + E</td>
<td>7</td>
<td>15</td>
<td>11</td>
<td>0.019</td>
</tr>
<tr>
<td>Conversion/ immediate revision</td>
<td>0</td>
<td>10</td>
<td>10</td>
<td>0.003</td>
</tr>
<tr>
<td>Secondary revision</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.984</td>
</tr>
</tbody>
</table>
that the accuracy of the conventional FH technique was superior to the robot-assisted technique. More screw malpositions occurred with robot assistance; however, this did not translate in an increased revision rate. Most malpositioned screws of the RO group showed a lateral deviation from the ideal trajectory. Furthermore, intraoperative radiation exposure was not reduced by robot assistance while an additional preoperative planning CT with the respective radiation dose for the patient is necessary. Surgical time for spinal instrumentation with robot assistance increased significantly by 11 minutes; however, this amount of time is acceptable for a new technique. In addition to the increased surgical time, an additional median planning time for the screw trajectories of 24 minutes was necessary in the RO group.

The main aim of image-guided techniques and RO techniques for spinal instrumentation is the increase of accuracy of implant position and a reduction of intraoperative radiation exposure which is especially important for the surgeon exposed regularly. For classical image-guided techniques, those goals were achieved, as proven, by prospective randomized studies, concerning pedicle screw implantation in the cervical, thoracic, and lumbar spines. In contrast, the current results do not support that these goals are accomplished by the use of spinal robotics while the accuracy achieved by conventional FH technique is well within the previously reported range. However, the RO results of this study are in contrast with previously published excellent results concerning screw positions from prospective observational studies that evaluated a cohort of patients with RO screws. The study by Pechliavanis et al. reported a rate of 98.5% Gertzbein Robbins group A+B screw position in their series of 31 patients, with 133 RO implanted screws. Several aspects may contribute to the inferior results of our present series.

DISCUSSION
This study evaluated the accuracy of lumbosacral pedicle screw implantation by an RO technique in comparison with the conventional FH fluoroscopy-assisted approach in a prospective randomized design. The central finding of the study is that the accuracy of the conventional FH technique was superior to the robot-assisted technique. More screw malpositions occurred with robot assistance; however, this did not translate in an increased revision rate. Most malpositioned screws of the RO group showed a lateral deviation from the ideal trajectory. Furthermore, intraoperative radiation exposure was not reduced by robot assistance while an additional preoperative planning CT with the respective radiation dose for the patient is necessary. Surgical time for spinal instrumentation with robot assistance increased significantly by 11 minutes; however, this amount of time is acceptable for a new technique. In addition to the increased surgical time, an additional median planning time for the screw trajectories of 24 minutes was necessary in the RO group.

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Robot Fixation to the Patient
There are different ways offered by the manufacturer to attach the robot to the patients’ spine: (1) a platform connected to a spinous process clamp which is additionally fixed by 2 K-wires to a cranial and caudal spinous process, (2) a hover T, which is a T-shaped platform fixed by 1 K-wire to a cranial spinous process and by 2 additional K-wires to the iliac crest bilaterally, and (3) a platform fixed to a cranial spinous process with a K-wire and caudally attached to the operating
table by a so-called “bed mount.” For this study, option 3 was chosen, as recommended by the manufacturer. However, this might be an insufficient method of fixation, because a relative movement of robot to patient can occur because the robot is directly attached to the patient by only a single K-wire. Such dislocations might explain the cases where no sufficient bone contact was achieved by single trajectory and a conversion to an open approach was necessary. Especially 1 case, in which the implantation of the left-sided screws was accurate and on the right side both screws were far too lateral, might be explained by such a dislocation of the robot in relation to the patient’s spine.

Skidding of the Cannula
The semiactive robot guides the surgeon to the preplanned trajectories and over the robotic arm, a cannula is inserted to the entrance point of the screw. The tip of the cannula is provided with some sharp teeth to anchor at the bony entrance point. However, most entrance points for pedicle screws are on the slope of the lateral aspect of the facet joint. Especially in cases of degenerative facet joint hypertrophy, the slope can get steep giving rise to a lateral skidding of the cannula at the entrance point because bony anchorage of the cannula is not consistently reliable. This skidding could explain the predominantly lateral deviation of the misplaced pedicle screws in the RO group.

Other Dislocations of the Cannula
For the present series of RO screws, the cannula was advanced to the entrance points after incision of the skin and the fascia. The muscle was bluntly perforated by the cannula. With this technique, any muscle bundles could lead to a deflection of the cannula from the planned trajectory. Furthermore, any soft tissue pressure can dislocate the cannula from the screw entrance point. A further problem arises at the S1 level. The iliac crest is not seen in the planning window for the screw trajectories. Therefore, at S1, converging screws coming from far lateral might get displaced by the iliac crest, resulting in a more medial trajectory. In one patient of this series, the S1 screws showed bilateral medial displacement, which might be attributable to this problem, which was not appreciated during surgery.

Surprisingly, the time of intraoperative radiation was not reduced for the RO implantation group in comparison with the FH group. The radiation times in the FH group are within the range previously reported. The equal duration of intraoperative radiation was not reduced by robot assistance.

References