Robotic-assisted pedicle screw placement: lessons learned from the first 102 patients

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Abstract

Introduction Surgeons' interest in image and/or robotic guidance for spinal implant placement is increasing. This technology is continually improving and may be particularly useful in patients with challenging anatomy. Only through careful clinical evaluation can its successful applications, limitations, and areas for improvement be defined. This study evaluates the outcomes of robotic-assisted screw placement in a consecutive series of 102 patients.

Methods Data were recorded from technical notes and operative records created immediately following each surgery case, in which the robotic system was used to guide pedicle screw placement. All cases were performed at the same hospital by a single surgeon. The majority of patients had spinal deformity and/or previous spine surgery. Each planned screw placement was classified as: (1) successful/accurately placed screw using robotic guidance; (2) screw malpositioned using robot; (3) use of robot aborted and screw placed manually; (4) planned screw not placed as screw deemed non essential for construct stability. Data from each case were reviewed by two independent researchers to identify the diagnosis, number of attempted robotic guided screw placements and the outcome of the attempted placement as well as complications or reasons for non-placement.

Results Robotic-guided screw placement was successfully used in 95 out of 102 patients. In those 95 patients,

949 screws (87.5 % of 1,085 planned screws) were successfully implanted. Eleven screws (1.0 %) placed using the robotic system were misplaced (all presumably due to “skiving” of the drill bit or trocar off the side of the facet). Robotic guidance was aborted and 110 screws (10.1 %) were manually placed, generally due to poor registration and/or technical trajectory issues. Fifteen screws (1.4 %) were not placed after intraoperative determination that the screw was not essential for construct stability. The robot was not used as planned in seven patients, one due to severe deformity, one due to very high body mass index, one due to extremely poor bone quality, one due to registration difficulty caused by previously placed loosened hardware, one due to difficulty with platform mounting and two due to device technical issues.

Conclusion Of the 960 screws that were implanted using the robot, 949 (98.9 %) were successfully and accurately implanted and 11 (1.1 %) were malpositioned, despite the fact that the majority of patients had significant spinal deformities and/or previous spine surgeries. “Tool skiving” was thought to be the inciting issue with the misplaced screws. Intraoperative anteroposterior and oblique fluoroscopic imaging for registration is critical and was the limiting issue in four of the seven aborted cases.

Keywords Pedicle screws · Robotic-assisted · Minimally invasive · Spinal surgery

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Introduction

Use of pedicle screw systems for deformity correction and spinal stabilization has been widely accepted in spine surgery. However, screw implantation can be challenging especially in patients with severe spinal deformity (such as

scoliosis), osteoporosis, or tumor [1]. Screw misplacement may cause neurologic and vascular complications. Pedicle screw-related complications have been reported to range from 1 % up to 54 % [1–6].

The need for improved accuracy and consistency in pedicle screw placement has led to the development of various new techniques, such as computer navigated and robotic-assisted spine surgery [7–11]. There are now reports showing that these newer techniques have improved the accuracy of pedicle screw placement [5, 12, 13]. Computer-assisted robotic devices are now available in the form of a bone mounted positioning tool that guides the surgeon in the placement of pedicle screws according to a preoperatively planned trajectory (Renaissance, Mazor Robotics Ltd., Israel) [7, 10]. This new technology is continually improving and may be particularly useful in patients with challenging anatomy.

The purpose of this study was to review one clinic's experience and the lessons learned in a series of consecutive cases involving this technology during pedicle screw placement.

Materials and methods

Patient selection

We conducted a retrospective review of prospectively collected data of 102 consecutive patients who were scheduled for surgery using the bone-mounted robotic system to place pedicle screws over the dates of June 2010 and December 2011. Patient's age, sex, body mass index

(BMI), and etiology of spine instability were documented. Operative levels, intraoperative fluoroscopy images, accuracy of screw placement and intraoperative complications were obtained from technical notes and operative records created immediately following each surgery. All cases were performed at the same hospital by a single surgeon.

Robotic guidance system and surgical techniques

The robotic guidance system consists of a cylindrical 250 g device that can move in six degrees of freedom and a workstation that runs an interface software which facilitates preoperative planning, intraoperative image acquisition and registration, kinematic calculations, and real-time robot motion control. Details of the device and related surgical techniques have been described previously [7, 10, 12, 14]. A CT scan using 1 mm cuts was obtained preoperatively in all patients for the surgery planning using the proprietary robotic software (Fig. 1).

Assessment of screw placement accuracy

Assessment of screw placement accuracy was based on intraoperative biplanar fluoroscopy, postoperative radiographs and surgeon's clinical judgment as most patients do not have postoperative CT scans. Similar methods have been used to evaluate the position of pedicle screws by other researchers [15]. Each attempted screw placement was classified as: (1) successful/accurately placed screw using robotic guidance; (2) screw malpositioned using robot; (3) use of robot aborted and screw placed manually; (4) planned screw not placed as screw deemed non

Fig. 1 A virtual 3D planning of pedicle screw placement based on preoperative CT scans

Table 1 Characteristics of the 95 patients who successfully underwent robotic-assisted pedicle screw placement

Age (years)	
Mean	50.7
Range	12–79
Gender	
Male	25 (26.3 %)
Female	70 (73.7 %)
Etiology	
Deformity and/or previous spine surgery	85 (89.5 %)
Other	10 (10.5 %)
Surgery route	
Open	71 (74.7 %)
Percutaneous or MIS	16 (16.8 %)
Percutaneous and open	8 (8.4 %)

essential for construct stability. Data from each case were reviewed by two independent researchers to identify the diagnosis, number of attempted robotic-guided screw placements and the outcome of the attempted placement as well as complications or reasons for non-placement.

Results

The robotic guidance system was successfully used in 95 out of 102 consecutive patients between June 2010 and December 2011 (Table 1). The mean age of the patients was 50.7 years (range 12–79). Seventy (73.7 %) of which were female and 46 (48.4 %) patients were overweight or obese ($BMI \geq 25$). Eighty-five patients (89.5 %) had spinal deformity (scoliosis and/or kyphosis) and/or previous spine surgery. Other diagnoses included spondylolisthesis, stenosis, spondylolysis, ankylosing spondylitis, fracture, neurofibromatosis, neuromuscular scoliosis, osteomyelitis, Scheuermann's kyphosis, and spinal tumor.

Among these 95 patients, 71 (74.7 %) had open surgery; 16 (16.8 %) had percutaneous or MIS surgery (Fig. 2); 8 (8.4 %) had open and percutaneous surgery (Table 1). On average, there were six instrumented levels per patient. One thousand and eighty-five screws were planned to be placed and 960 of them were implanted with the robotic guidance. Of the 960 screws, 949 (98.9 %) were successfully and accurately implanted and 11 (1.1 %) were malpositioned. These 11 malpositioned screws were presumed to have been implanted in an aberrant trajectory due to “skiving” of the drill bit or trocar off the side of the facet or transverse process. Ten of the 11 malpositioned screws were immediately recognized and repositioned manually at the time of surgery. One patient developed a L3 radiculopathy recognized in the immediate postoperative period. A CT scan verified that the right L4 pedicle screw was

Fig. 2 Robot guided pedicle drilling during a minimally invasive spinal fusion using the Hover-T frame **Fig. 3** Postoperative CT scan shows the misplaced right L4 pedicle screw

misplaced (Fig. 3) and the screw was removed 3 days after the surgery. Details of the 11 misplaced screws are presented in Table 2.

In 110 planned screws (10.1 %), robotic guidance was aborted and the screws were placed manually, generally due to poor registration and/or trajectory issues. 61.8 % of the screws that were converted to manual placement were at thoracic spine, followed by lumbar spine (30.0 %), sacral level (6.4 %) and iliac level (1.8 %) (Table 3). The remaining 15 screws (1.4 %) were not placed after intraoperative determination that they were not essential for construct stability.

The robot was not used as planned in seven patients, one due to severe deformity, one due to very high BMI (49.9), one due to extremely poor bone quality and one due to previously implanted loosened hardware. In these four instances, the underlying pathology precluded adequate

Table 2 Details of the 11 misplaced screws

Case number	Diagnosis	Position of misplaced screw	Surgery route
16	Degenerative spondylolisthesis	Right L5	Percutaneous
18	Degenerative scoliosis; previous spine surgery	Right L5	Percutaneous
23	Degenerative scoliosis	Right L4	Percutaneous
43	Scoliosis, revision surgery	Left L4	Percutaneous
44	Degenerative and idiopathic scoliosis	Right L3	Open
65	Idiopathic scoliosis	Right L4 and left T8	Open
76	Kyphosis, revision surgery	Left T12 and right T12	Open
87	Degenerative spondylolisthesis	Left S1	Open
94	Spondylolisthesis, revision surgery	Right L3	Percutaneous

Table 3 Location and number of screws that were converted to manual placement

Location	Number of screws	Percentage
Thoracic	68	61.8
Lumbar	33	30.0
Sacral	7	6.4
Iliac	2	1.8
Total	110	100

intraoperative anteroposterior and oblique fluoroscopic images used for registration. In the fifth instance, the robot was not used due to difficulty with drill seating and platform mounting. In the sixth and seventh instance, the robot was not used due to device technical issues. No other intraoperative neurologic or vascular complications were encountered.

Discussion

The use of pedicle screws has become the foundation of spine surgery as pedicle screw fixation can afford multi-dimensional control and generate greater rigidity to facilitate fusion. These advantages has led to the wide use of pedicle screws in different spinal diseases, such as degenerative, traumatic, and developmental spinal conditions [16].

The accuracy of pedicle screw placement depends largely on the patient's anatomic landmarks, and the surgeon's experience. Screw malposition may lead to serious vascular and neurologic complications especially when the patient's anatomy is altered [17]. In a retrospective study, Carbone et al. [18] reported that 12.7 % of thoracic screws penetrated the pedicle cortex and 5.6 % penetrated the vertebral body. Merloz et al. [8] reported a 13 % pedicle cortex penetration for the conventional surgical procedure group. In a systematic review of the complication of

pedicle screw fixation in pediatric patients, Hicks et al. [17] found that 4.2 % (518 of 12,248 screws) screws were malpositioned. In the studies that took postoperative CT scans, the malposition rate was 15.7 % (346 of 2,202 screws).

In recent years, various new technologies such as intraoperative CT scan imaging coupled with infrared guidance technology systems have been introduced and have been reported to significantly increase the surgeon's ability to accurately perform surgical procedures in various surgical conditions [5, 12, 19–21]. The robotic guidance system used in this review likewise has been successfully applied in spine surgeries and its advantages have been reported in previous studies. Sukovich et al. [22] reported their early clinical experience with the system in 14 patients and found that it performed successfully in 93 % of the cases and 96 % of the screws placed were within 1 mm of the planned trajectory. Pechlivanis et al. evaluated the accuracy of percutaneous pedicle screw placement in the lumbar spine using this robotic system. As analyzed by postoperative CT scans, out of 133 total pedicle screws placed, in the axial plane, 91.7 % screws were placed exactly within the pedicle and 6.8 % screws deviated <2 mm. In the longitudinal plane, 81.2 % screws were placed exactly within the pedicle and 9.8 % screws deviated <2 mm [14]. More recently, through a retrospective multicenter study, Devito et al. reported that in 682 cases in which 3,912 screw placement were planned, 83.6 % (3,271 screws) were fully implanted under robot guidance, while the remaining screws were initiated under robotic guidance and manually continued by the surgeon. The main reasons for the manually placement were registration issues, the robot not being able to reach the appropriate trajectory, device technical issues, mechanical movement, and surgeon decision to abort [12].

Consistent with these previous reports, the current study by a single surgeon suggests that the robotic-assisted pedicle screw placement system significantly reduced the screw misplacement rate. In situations such as severe

deformity or revision surgeries when the normal spinal anatomic landmarks have been altered or obscured, the robotic-guided system was especially useful to improve the accuracy in pedicle screw placement. The patients with spine deformity and/or previous spine surgery suffered from various etiologies which include degenerative disease, congenital deformities and complex destructive spinal tumor. The diverse patient population demonstrated the broad utility of this robotic-assisted system in challenging spine surgeries. The robot system also demonstrated its advantages in percutaneous and minimally invasive surgeries which comprised 25.3 % of our patients. It has been shown that use of the robotic system in these percutaneous and minimally invasive surgeries not only gave the surgeon more confidence but also significantly decreased the intraoperative radiation exposure to the patient and surgical team [23, 24]. Despite the decreased intraoperative radiation exposure to the patient with this robotic system, the dose of radiation associated with the preoperative CT scan is still a concern. This however, has to be evaluated in the context of the surgeon's individual surgical technique, as most minimally invasive approaches and complex revision cases or deformity cases require substantial intraoperative radiation. In addition, many patients already have the CT scan available as part of their preoperative work up. This issue is the subject of further investigation where the CT dose will be compared to the typical intraoperative dose associated with image guided or fluoroscopic assisted screw placement.

Despite the overall success of the robotic-assisted pedicle screw placement in this series, we did encounter some difficulties during some surgeries. Eleven screws (1.0 %) were misplaced generally due to tool skiving. Ten percent of the screws were converted to manual placement generally due to difficulties with registration and/or trajectory. It is noted that 61.8 % of the manually placed screws were at the thoracic levels which is associated with the relatively small pedicle size and can be an area difficult to image.

The use of robot was aborted in seven cases due to various reasons. The first aborted case was a cerebral palsy patient with neuromuscular scoliosis. Thirty screws were planned to be placed by the robot system, however, only two screws were placed successfully and the remaining 28 screws were placed manually as the robot system failed to adequately register and reference due to the high-degree curvature. The second case was a patient with Scheuermann's kyphosis and a BMI of almost 50, where we were unable to obtain good fluoroscopic X-ray images for registration. The third case was a 75-year-old female patient with extremely poor bone quality where again we were unable to obtain adequate intraoperative fluoroscopic images. The robotic system was unable to pick up and recognize the vertebral anatomy with the very poor quality

fluoroscopic X-ray images. The fourth case was a revision surgery and the previously placed hardware had loosened. The movement of the loosed hardware caused difficulty during registration. The fifth case was a patient with L5–S1 spondylolysis, where the use of the robot was aborted due to difficulty with seating the drill bit on the mobile posterior elements of the lytic segment. The sixth and seventh cases were two degenerative scoliosis patients with acceptable anatomy, but the robot system failed due to technical issues. Overall, in light of the previously described cases, it is clear that the intraoperative fluoroscopic imaging for registration is critical and it was the limiting issue in four of the seven aborted cases.

In conclusion, this report summarized one clinic's experience of the first 102 consecutive surgeries using robotic-assisted pedicle screw placement. Of the 960 screws that were implanted using the robot, 98.9 % were successfully and accurately implanted and 1.1 % were malpositioned, despite the fact that the majority of patients had significant spinal deformities and/or previous spine surgery. "Tool skiving" was thought to be the inciting issue with the misplaced screws. Intraoperative anteroposterior and oblique fluoroscopic imaging for registration is critical and was the limiting issue in most of the aborted cases. Successful application of the robotic pedicle screw guidance system requires careful preoperative planning, an accurate study of the spinal anatomy and sound surgical experience. The robotic system is continuously evolving and we believe that with its continuous improvement, the robotic system will have even broader applications in future spinal surgeries.

Conflict of interest Xiaobang Hu received travel support for lecturing from Mazor Robotics. Donna D. Ohnmeiss is employed by a foundation that receives funding to conduct training labs from Mazor Robotics. Isador H. Lieberman receives royalty, intellectual property rights, consulting fee and ownership interest from Mazor Robotics.

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