Chapter 14
Image and Robotic Guidance in Spine Surgery

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Introduction

The advent of spinal instrumentation allowed spine surgeons to treat complex spinal pathologies while maintaining or correcting alignment and maintaining or restoring spinal stability. Pedicle screws became an integral part of these complex procedures [1]. As spinal procedures progressed and became more complex, misplacement of pedicle screws, with the attendant risk of injury to the spinal cord, nerve roots, great vessels, or visceral tissue, or loss of mechanical stability, became a factor influencing surgical outcome.

Risk factors related to screw misplacement include the surgeon's experience, anatomic variables (level in the spine, i.e., cervical, thoracic, lumbar, or sacral, and size of the pedicle), congenital anomalies or variances, deformity, and revision surgery (notably posterolateral bone fusion mass) [2–16]. In the literature detailing free hand or fluoroscopy-assisted pedicle screw instrumentation, misplacement rates of 7.4–65.5 % have been reported in the cervical spine [17, 18], 5–41 % in the lumbar spine, and 3–55 % in the thoracic spine [2–16, 19–27]. Implant-related nerve damage has been reported in 0–8 % of cases, while the reported incidence of dural laceration caused by screws is 0–16 % [2–16, 28]. Screw-related injuries to viscera and blood vessels have also been reported sporadically [29, 30]. However, these complications may be underreported, and they represent the experience in large centers with high patient volumes, which are assumed to have lower complication rates compared with centers with smaller patient volumes [28].

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Over the last 20 years, surgeons' efforts to consistently achieve perfect screw placement have been paralleled by technological advances leading to the introduction of new tools aimed at reducing the rate of screw misplacement, reducing complication rates, and improving clinical outcomes. Screw placement was once verified with intraoperative X-ray, but this technique has clear drawbacks–it is retrospective and does not allow real time verification. It is also time consuming and increases the risk of infection. Later, real-time two-dimensional (2D) fluoroscopy was introduced to guide and verify screw placement. The drawbacks to 2D fluoroscopy include lower accuracy compared with techniques offering three-dimensional (3D) visualization and guidance [31], increased risk of infection due to repeated fluoroscopy machine movement between AP and lateral trajectories [32], and exposure of the patient, operating room staff, and surgeon to ionizing radiation.

Radiation exposure has become an important issue in the recent years. Both patients [33] and surgeons [34, 35] are at risk for radiation-induced malignancies. The risk for cancer among orthopedic surgeons has been estimated to be 5.37 times greater than risk in the general population [35], and the risk for breast cancer in female orthopedic surgeons is 2.88 times higher [34]. One study estimated that up to 29,000 future cancers could be related to CT scans performed in the US in 2007 [36]. The risk of developing a radiation-related cancer may be higher in the young, especially young females, and in cases where radiation exposure focuses on areas rich in viscera [33]. Radiation exposure has also been linked to other health problems, such as cataracts in the young and dermatological conditions. For all of these reasons, the US Food and Drug Administration (FDA) launched an initiative to reduce unnecessary radiation exposure from medical imaging in February 2010 [37].

Radiation exposure during fluoroscopy-guided spine surgery is estimated at 3.4–66 s per screw [38–42], depending on fluoroscopy technique (check fluoroscopy versus real-time continuous fluoroscopy) and whether the surgeon uses open freehand or percutaneous fluoroscopy-guided implantation. Surgeons performing vertebral body augmentation and minimally invasive spine surgery (MISS) under fluoroscopy guidance are exposed to higher doses of ionizing radiation [43–45].

Well-placed pedicle screws have a biomechanical advantage over misplaced screws. One cadaver study demonstrated that pedicle breaching reduces pullout strength by 11 % [46]. Another cadaver study found that medially misplaced screws had slightly greater mean pullout strength compared with well-placed pedicle screws, and that laterally misplaced screws had less mean pullout. "Airball" screws had only 66 % of the mean pullout strength of well-placed screws [47].

For all these reasons, navigation and robotic systems were developed, with the goals of reducing patient and staff exposure to radiation, as well as achieving greater accuracy and enhanced stability, and thus reducing surgical complications and the need for revision surgeries. The aim of this chapter is to discuss the different navigation and robotic systems, and to summarize the data regarding their accuracy and the radiation associated with their use. We will also raise questions that may need to be addressed in future studies.

Systems and Registration Processes for Image-Guided Spine Surgery (IGSS)

Two-Dimensional (2D) Fluoroscopy-Based Image Guidance (Virtual Fluoroscopy)

A calibration grid is attached to the C-arm. A series of fluoroscopy images in AP, lateral, and sometimes the pedicle oblique view are acquired with a reference frame attached to a stable anatomical landmark, often a spinous process in the vicinity of the vertebrae that will be operated. These images are transferred to the navigation workstation and this data set is used to navigate implants on the virtual anatomy viewed on the screen. An infrared camera aimed at the reference arc and navigation tools allows continuous recognition of the navigation tools in relation to the relevant anatomy. A continuous "line of sight" must be kept between the infrared camera, the reference arc, and the navigation tools. The accuracy of the system will be maintained as long as the stability of the reference arc is maintained, motion segments do not change their position compared to acquired images, and the navigation tools are kept in line with the desired trajectory.

Two-dimensional-fluoroscopy guidance has the advantage of a simple registration process. In addition, patients are spared the requirement of obtaining preoperative CT examinations, reducing their radiation exposure. However, it does not provide 3D visualization of the spinal anatomy during navigation; thus, the risk of navigation errors is increased and abnormal axial anatomy is more likely to remain unrecognized. Errors may also be greater in cases of poor bone quality, excess intra-abdominal gas, morbid obesity, spinal deformity, prior surgery, and congenital anomalies [48]. Furthermore, image resolution is typically best in the center of the field and any structures around the periphery may appear distorted secondary to parallax, so to maintain the accuracy of navigation across several spinal segments the process of data acquisition and anatomic registration may need to be repeated several times [49].

CT-Based Image Guidance

Navigation systems based on CT guidance use preoperative thin-slice scans and one of several registration processes to create a data set, which forms the basis for intraoperative navigation. Preoperative CT scans are obtained with the patient in a supine position, while patients are in the prone position during surgery, usually on a Jackson frame, allowing a free abdomen. The resulting vertebral shift and realignment creates a risk for navigation errors; thus, each vertebra must be registered separately to accurately plan and perform the surgery.

Registration for Preoperative CT-Based Navigation

Point-Matching Technique

Chosen anatomical points on reconstructed views of the preoperative CT scan are registered intraoperatively to the patients' carefully dissected anatomy and viewed on the navigation screen. This procedure is time consuming, requires careful dissection of the relevant anatomy to the bony landmarks and matching of 4–8 points to allow adequate registration [50, 51]. Previous laminectomy that has left little posterior bony anatomy may leave a patient with an inadequate set of anatomical points for registration [52]. The registration process must be repeated for each vertebra separately to compensate for motion between the preoperative CT (supine) and the intraoperative anatomy (prone) [53–55].

Surface-Matching Technique

Multiple randomly chosen anatomical points on the patients' surface anatomy are touched to increase the number of data points. Selection of multiple points reduces the chance of error in the -point matching technique but adds to procedure time [51].

CT-to-Fluoroscopy Merging Systems

Intraoperative AP and lateral fluoroscopy images are taken with a grid connected to a C-arm and a reference arc attached to the patients' anatomy. These images are merged to the preoperative CT scan, allowing registration of more than one vertebra [56–58].

Electromagnetic Registration Systems

Electromagnetic (EM) systems have been developed as another method for tracking the location of instruments during surgical navigation to address the disadvantages of optical devices, mainly. cables and the requirement to maintain a "line of sight" between the infrared camera, the reference arc, and the surgical instruments. Three orthogonal electromagnetic fields are generated by a transmitter attached to a fixed anatomic reference point. The positional data of these instruments are collected by a receiver and integrated to facilitate navigation. Since a line of sight is not required, the surgeon and nursing staff are able to work freely within the operative field. However, EM image guidance may be compromised by metal artifacts, including surgical implants, as well as by any electromagnetic fields originating from other equipment in the operating room such as monopolar electrocautery, electrocardiogram monitoring, and cell phones. Given the limited area of these EM fields, the transmitter may also need to be repeatedly transferred to additional anatomic structures to obtain sufficient tracking information for multilevel procedures [40, 41, 59, 60].

Another EM investigational system combined a needle with an EM tip and a robotic arm-based flat panel CT to guide interventional pain clinic procedures, such as facet injections and selective nerve root blocks [61].

Intraoperative Cone Beam CT-Based Systems

The advent of cone-beam CT (cbCT) registration systems is considered a breakthrough compared with navigation systems based on preoperative CT studies (Fig. 14.1). During the scan, multiple (usually 50–100) fluoroscopy images are taken as the cbCT automatically rotates around the patient for 190–360°, covering a variable range of motion segments. These properties vary from one system to another. The scan is performed after the patient is positioned for surgery to prevent positional changes in anatomy. A reference arc is attached close to the surgical target to allow automatic registration and transfer of the data set to the navigation system. Two-dimensional images are reconstructed in the axial, coronal, and sagittal planes, similar to a CT scan. These reconstructions allow intraoperative planning of implant trajectory, size, and length, as well as intraoperative navigation. A second intraoperative scan may be performed to confirm implant position and may lead to immediate intraoperative correction of misplaced implants, thereby avoiding early revision surgery.

Intraoperative CT

The use of standard CT equipment within the operating theater provides higher image quality compared with cbCT. Patient radiation exposure is significant; however, the surgeon and OR staff are not exposed [62]. The capital expense is greater,

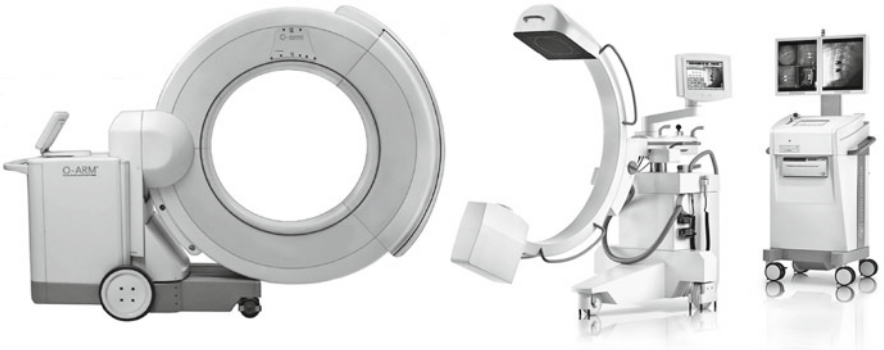

Fig. 14.1 Cone beam CT (cbCT) used for spine surgery. The Ziehm Vision Vario 3D (Ziehm Imaging, Nuremberg, Germany) and O-Arm (Medtronics, Minneapolis, MN, USA) are representative of a range of cbCT products that are currently available

the process of scanning and registration is longer, and intraoperative CT (iCT) does not allow the use of a Jackson frame. The system cannot be mobilized between different operating rooms [62–65].

Robotic Guidance in Spine Surgery

In recent years, a variety of robots for different surgical applications have been introduced [66, 67]. Surgical robots can be divided into three broad categories: (1) Supervisory-controlled systems enable the surgeon to plan the operation offline, specifying motions that the robot must follow to perform the operation. The robot then performs the procedure autonomously with the surgeon supervising closely. (2) Telesurgical systems allow the surgeon to directly control surgical instruments held by the robot via a joystick or hand controls, with either passive or active task execution. (3) Shared-control systems allow both the surgeon and the robot simultaneous direct control of surgical instruments [68]. To date, the majority of robotic-assisted spine operations have involved a shared-control system.

A recent review [69] discussed 18 robotic systems, of which five are clinically available. One is dedicated to spine surgery, one aimed at needle interventions, two are focused on radiosurgery, and one was tested for spine surgery but is used primarily in other surgical specialties. The authors concluded that the field of spine surgical robots "is still at an early stage of development but with great potential for improvement."

A Robotic System in Clinical Use

To the authors' best knowledge, only one robotic system dedicated to spine surgery is clinically used [70–76]. The system consists of a grid attached to a C-arm, a workstation containing a miniature robot, a computer running dedicated software that allows preoperative planning and intraoperative execution, and a screen (Fig. 14.2a). The bone-mounted miniature robot is a semi-active system offering surgical tool guidance while leaving performance of the actual surgical operation, such as drilling, in the surgeon's hands (Fig. 14.2b). The concept was first published in 2003 and 2004 [77, 78], followed by lab testing [79, 80], and a clinical developmental phase [81, 82].

The robotic procedure consists of five steps:

1. Preoperative planning–DICOM images of a dedicated protocol CT scan are imported by the robotic workstation software. This software can be installed on a standard laptop or desktop computer and allows for preoperative planning. The software creates 2D reconstruction images of each vertebra in the region of interest with planning for virtual implant placement in the optimal position. This is a crucial step that allows for detection of abnormal anatomy, absent pedicles, and deformity, as well as determination of implant diameters and lengths (Fig. 14.3).

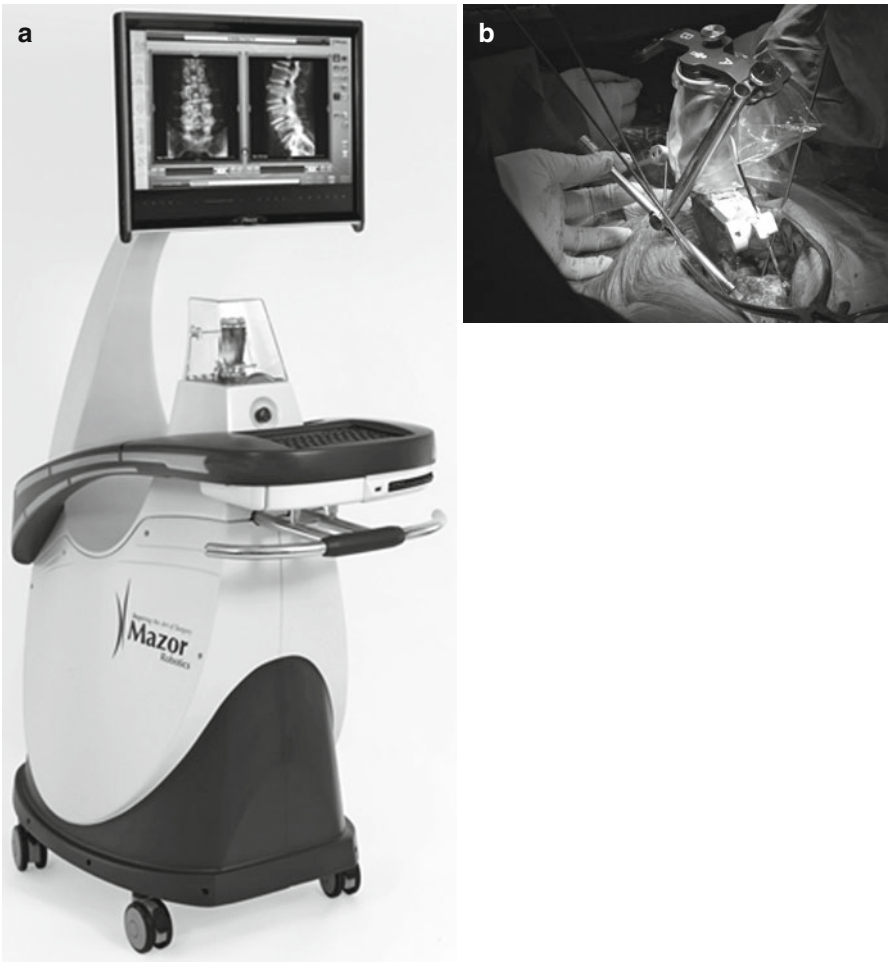

Fig. 14.2 (**a**) A robotic workstation (Renaissance, Mazor Robotics, Caesarea, Israel). The computer runs software allowing preplanning, image acquisition, registration, and control of robot execution; a touch screen and a 250 g 6 DF miniature robot. (**b**) The robot is mounted on a clamp, which is connected to a posterior fusion mass in a revision surgery (Photo courtesy Dr. I.H. Lieberman, Texas Back Institute, Plano TX, USA)

2. Platform attachment–One of three platforms is used. The unilateral bed mount device or the bilateral multidirectional bed mount device are attached to the surgical frame caudally and to the patients' anatomy through a K-wire or a miniclamp cranially. The Hover-T Bridge is attached to Steinmann pins drilled into the posterior iliac crests and to a K-wire drilled into a spinous process. Both platforms are designed for minimally invasive surgery. A clamp may be connected to a spinous process in open procedures after subperiosteal dissection is completed (Fig. 14.4).

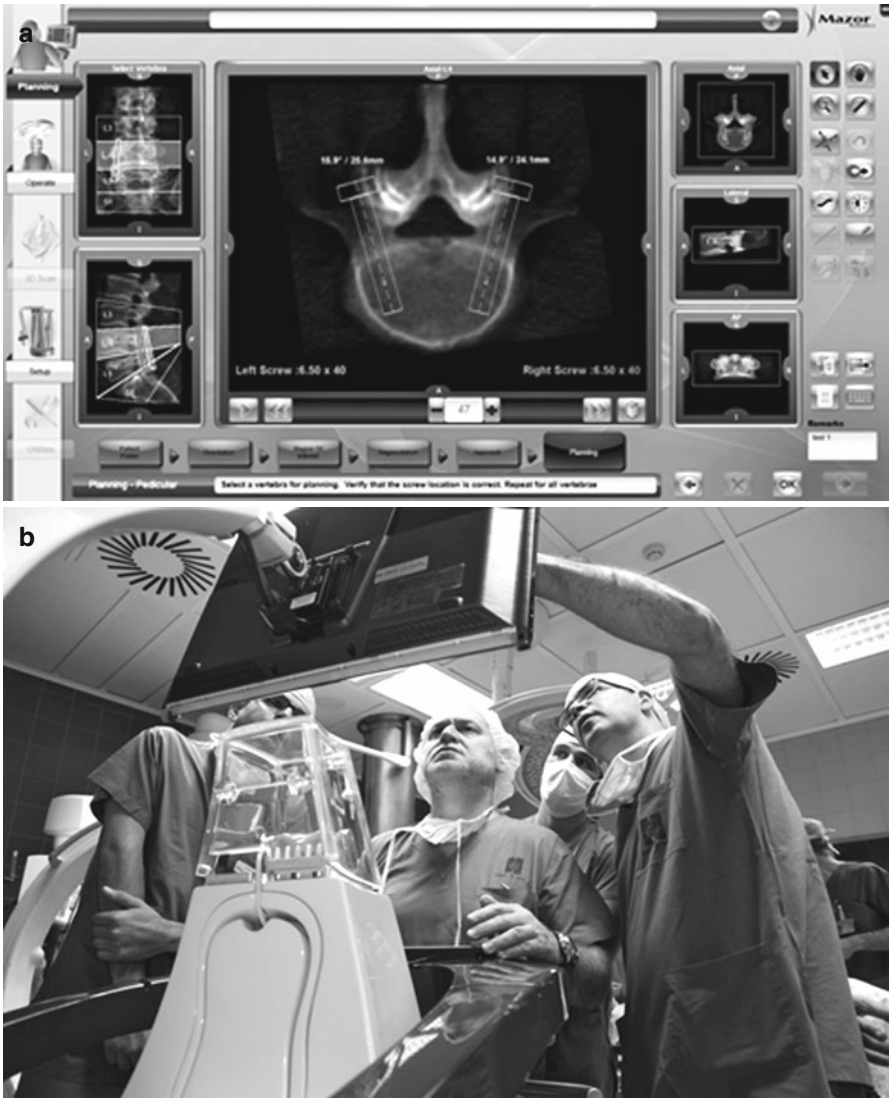

Fig. 14.3 Preoperative planning allows recognition of patients' unique anatomy, and allows preoperative measurement of implant length and size. (**a**) The summary window allows preoperative assessment of implant alignment and the estimated rod length. (**b**) Surgical team at the workstation during preoperative planning

3. Image acquisition and registration–Targets for image acquisition are connected to the robotic platform, and AP and 60° oblique fluoroscopic images are semi-automatically registered to the preoperative CT images. The surgeon must visually verify the accuracy of the registration process before going forward.

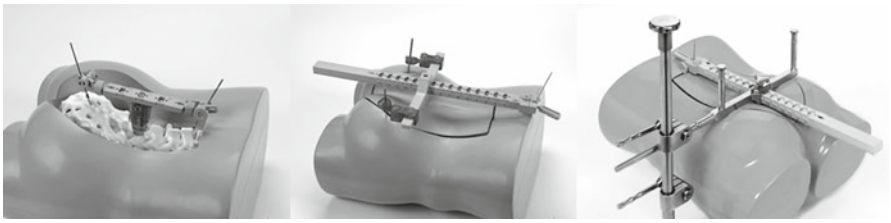

Fig. 14.4 Three platforms allow robotic guidance: a clamp (*left*), the Hover T frame (*center*), and a bed-mount device (*right*). The latter two are for use in minimally invasive spine surgery, while the clamp is used in open procedures

4. Robot assembly and motion–The miniature robot is attached to the mounting frame and one of three arms is connected to it, according to the software guidance. It is then instructed to move and lock into position, so that a guiding tube at the distal end of its arm is aligned with the planned screw/tool trajectory. The guiding tube, with trocar inserted, is then advanced percutaneously or through the open wound until contact with the pedicle entry point is felt. The trocar is withdrawn and replaced with a working channel. The toothed end of the working channel is gently tapped into the bony surface anatomy of the spine.
5. Trajectory execution–Drilling through the working channel along the planned trajectory is performed. Following drilling, a fiducial may be tapped into the pedicle in open procedures. In percutaneous procedures, a hollow reduction tube is placed through the working channel and advanced into the pedicle and through the posterior vertebral wall. A K-wire is then placed into the vertebral body and the reduction tube is withdrawn. This procedure is repeated until trajectories are drilled and fiducials or K-wires (KW) are placed at all levels to be treated. Instrumentation may then be placed. At this point robotic guidance is complete. In minimally invasive procedures, the mounting system may be left attached to allow repeat robot guidance in case one of the trajectories is lost.

Robotic Systems Under Development

In 2010, a Korean group published a cadaver study on an investigational system combining a bi-planar fluoroscopy machine, a computerized workstation, and an assistive robot for percutaneous KW and pedicle screw insertion [83]. The system does not use a target device or a reference frame, and therefore does not need a secondary procedure to attach these structures to the patient's anatomy. Two registration processes are required. The first registration matches the coordinates of the robot manipulator and the bi-planar images based on point matching; the second registration is between preoperative CT or MRI and intraoperative bi-planar fluoroscopy. The researcher reported a distance of error of 1.38 ± 0.21 mm, $2.45° \pm 2.56°$ deviation in the axial plane, and $0.71° \pm 1.21°$ deviation in the sagittal plane when comparing post-op CT to planning. The system has not reached clinical usage.

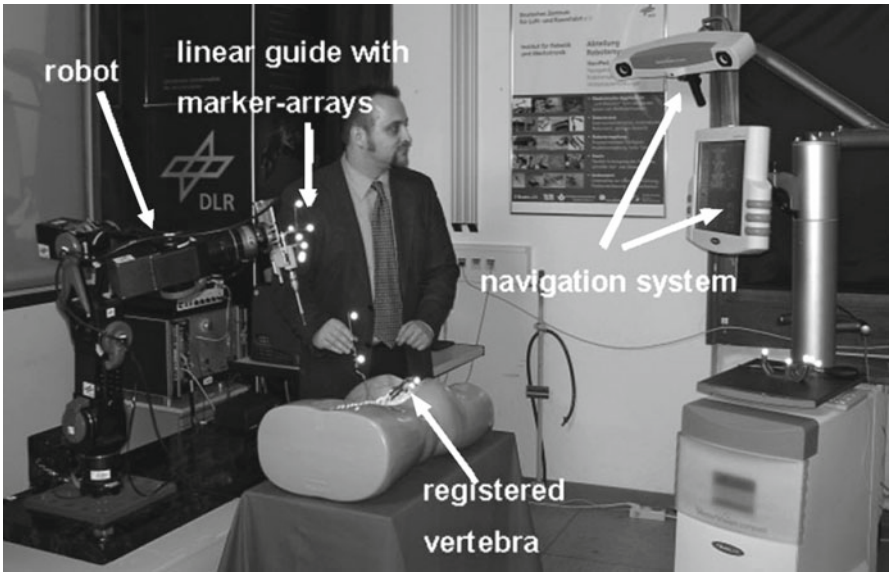

Fig. 14.5 Experimental setup for the placement of pedicle screw with robotic assistance in a prototype robotic system (German Aerospace Centre [DLR e.V.] Institute of Robotics and Mechatronics, Wessling, Germany), shown here with a VectorVision navigation system (BrainLab, Feldkirchen, Germany) (Used with permission from John Wiley and Sons. Ortmaier et al. [85])

In 2012, a Swiss group published their results on an investigational robotic navigated system developed for cervical applications [84]. The system consists of a compact robot with four degrees of freedom, suspended over the operative field by a passive supporting structure. Additional components include an optical tracking system, a surgical input device, and a workstation with software for planning and navigation. The data set is generated by point-to-point and surface matching of each vertebra registered to a preoperative thin-slice CT. The robot is positioned by the surgeon over the operative field. After locking the passive supporting structure, the robot guides the surgeon to the planned trajectory using guiding tools, and KW is drilled and is replaced by a screw.

In 2006, a team in a German aerospace center published a trial on a navigation system and an impedance-controlled light-weight robot holding a surgical instrument [85]. The navigation system was used to position pedicle screws in artificial bone and bovine spine and to compensate for pose errors during machining. The robot "floats" over the spine, and occupies a significant space (Fig. 14.5). The authors concluded that milling was more accurate than drilling, that the robot should withstand higher milling forces (30 N) than the tested design (15 N), and that the accuracy of the tracking system is a critical parameter, as it is used to close the position control loop. In the set-up used, tracking accuracy seemed to be a limiting factor. Additionally, the latency of the tracking system would have been minimized. This project did not reach clinical usage in spine surgery. The robot under current development by this group is planned for other fields of surgery.

In 2009, South Korean scientists published an investigational system for fusion procedures [86]. The system consisted of a human-guided robot for the spinal fusion surgery with a dexterous end-effector that is capable of high-speed drilling, and is position-controlled by a five degrees-of-freedom robot body that has a kinematically closed structure to withstand strong reaction forces. The robot allows the surgeon to control the position and orientation of the end-effector. Incorporated for improved safety is a "drill-by-wire" mechanism wherein a screw is tele-drilled by the surgeon in a mechanically decoupled master/slave system. The system has haptic properties, imitating the sensation during screw insertion. A tracking system has not been yet developed for the system.

A Clinically Available Tele-Surgical Robotic System

A tele-surgical system (Fig. 14.6) has been in clinical use for urological, gynecological, and surgical procedures for over the last decade [87–94] with an impressive penetration into the market in these specialties. This system has been tested for spinal applications on a healthy pig. In preliminary studies, laminotomy, laminectomy, excision of disc material, and repair of a dural tear were performed [91]. The authors concluded that with proper robotic tools, the system can be used for posterior spinal procedures. The same system has also been tested in a swine model for laparoscopic anterior lumbar interbody fusion (ALIF) using a retroperitoneal approach [88]. The authors reported little retraction of the great vessels and a very clear view of the operative field, allowing successful ALIF. In humans, only case

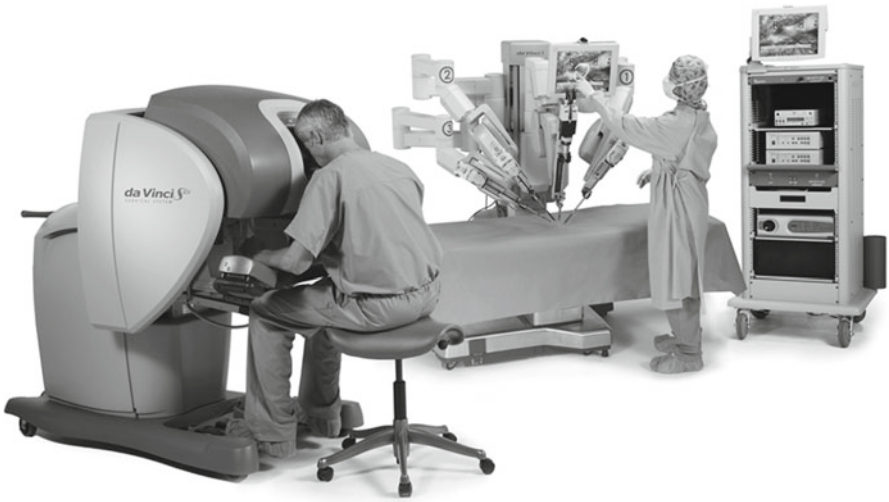

Fig. 14.6 Tele-surgical robotic system (da Vinci, Intuitive Surgical, Sunnyvale CA, USA). The system has been tested for spine surgery in an animal model and used in cases of soft tissue tumor removal in different areas of the spine (Copyright Intuitive Surgical, used with permission)

reports were published, including robot-assisted transoral odontoidectomy for decompression of the craniocervical junction [87], resection of paraspinal schwannoma [93], and resection of a thoracolumbar neurofibroma [90].

Review of the Literature Regarding Image and Robotic Guidance in Spine Surgery

Image guidance has been used in spine surgery for about three decades, while robotic-guided spine surgery emerged only in the past decade. In addition, several companies have developed fluoroscopy-based 2D and 3D systems, and preoperative or intraoperative cbCT based image-guided systems, leading to competition and continuous improvement in these products, but only one company has developed a commercially available robotic system for spine surgery. Other robotic systems are still in the developmental phases or were abandoned. For these reasons, the published data regarding IGSS [2, 11, 17, 19, 21, 40, 41, 52, 95–127] are far more extensive than the body of literature regarding robotic-guided spine surgery [69, 75, 87–94].

In our review of the literature, we have chosen to focus on specific questions related to the effect of image or robotic guidance on spine surgery:

1. Is there a learning curve? How long is it?
2. Do these systems improve the accuracy of implant placement?
3. Do these systems reduce the frequency of nerve damage or damage to other important organs?
4. Do these systems reduce radiation exposure to the patient, operating room staff, and surgeon?
5. Do these systems lead to superior mechanical properties through improved accuracy; if so, does this affect the need for revision surgery?

Image-Guided Spine Surgery

Learning Curve

A learning curve in image-guided spinal surgery has been documented [128–131]. In virtual fluoroscopy, one study suggested that the learning curve extends for approximately 6 months, after which guidance resulted in fewer breaches of the pedicles and shorter operating time [128]. Another study documented a decrease in the rate of thoracic pedicle cortex perforation from 37.5 % to 4.2 % in new users as they gained experience on cadavers practicing 3D point-matching techniques based on preoperative CT images [129].

It is thought that, during the learning curve period, surgeons adopt a new work flow. They must achieve acceptable registration of the patients' anatomy to the

imaging studies while positioning the infrared camera where it enables consistent recognition of the reference arc and navigation tools. The surgeon must become accustomed to looking at a computer screen instead of the operative field. In addition, operative instruments must be held in line with the planned trajectory, without tilting them, once the bone trajectory has been set; tilting the tools would create a "false-accurate trajectory" on screen and end in deviation [52].

Accuracy

How does IGSS compare to non-navigated pedicle screw instrumentation? In the growing mass of published data [2, 11, 17, 19, 21, 40, 41, 52, 95–127], most studies point to higher accuracy when using image guidance; only two studies concluded that image guidance is not superior to non-navigated instrumentation in spine surgery [95, 109].

The first meta-analysis comparing image-guided pedicle screw placement with non-navigated placement was published in 2007 [132]. The median accuracy of screw placement with assistance from navigation was 95.2 % versus a 90.3 % median accuracy for screws placed without navigation assistance. In 2010, another meta-analysis reported 93.3 % accuracy for the placement of pedicle screws with navigation, compared to 84.7 % without. In 2009, another meta-analysis reported 85.48 % accuracy for screw placement with 2D navigation and 90.76 % accuracy using 3D navigation [31]. The same authors published a newer meta-analysis in 2011 comparing accuracy using conventional methods of pedicle screw placement to accuracy using three types of image guidance (3D point matching, virtual fluoroscopy, and cbCT) [21]. They concluded that image guidance resulted in higher accuracy across the board. In comparisons between the three image guidance systems, no system was found to be more accurate for in vivo (clinical) studies; however, CT-based systems were more accurate in cadaver studies.

Two meta-analyses were published in 2012 [19, 133]. Gelalis et al. included only prospective clinical studies and omitted cadaver studies. The authors were in agreement with the conclusion of previous meta-analyses, and found greater accuracy with CT-based navigation compared to virtual fluoroscopy [19]. The authors also noted that screws inserted freehand tend to breach the pedicle medially, while CT-navigated screws tend to breach laterally. According to this meta-analysis, neurological complications were similar in image-guided and non-navigated procedures. The second meta-analysis reported the pooled breach rate to be 6 % in image-guided procedures versus 15 % using non-navigated techniques [133].

Five randomized controlled studies compared image-guided spine surgeries and conventional techniques. Four of these studies reported higher accuracy with IGSS [11, 117, 134, 135]. One study comparing 3D cbCT image guidance to conventional technique for the placement of thoracic pedicle screws for deformity correction reported much higher breach rates with the conventional technique (23 %) when compared to 3D cbCT IGSS (2 %) [117]. A second comparative study reported

95.3 % accuracy in procedures performed under 3D cbCT guidance versus 84.1 % in those performed freehand [135]. A third study evaluating 3D cbCT reported accurate placement in 95.65 % of the cases operated under guidance with breaches under 2 mm in 4.35 % and no breaches over 2 mm. With fluoroscopy control, accuracy fell to 83.33 % overall, with breaches under 2 mm in 13.1 % and over 2 mm in 3.57 % [134]. In a study comparing point-matching CT IGSS to non-navigated technique, the breach rate was 13.4 % using the conventional technique versus 4.6 % with CT guidance [11].

One randomized controlled trial reported no benefit using a preoperative CT-based navigation system compared to a conventional technique [136].

Radiation Exposure

Using fluoroscopy control for pedicle screw instrumentation in open procedures, radiation exposure time ranges from 3.4–66 s per screw [38–42, 137]. Exposure during pedicle screw insertion is 10–12-fold higher than in non-spinal procedures [137].

During fluoroscopy-controlled vertebral body augmentation procedures, the average fluoroscopy exposure time per level ranges between 2.9 min ± 23 s [138] and 10.1 min ± 22 s [33].

In a study measuring radiation exposure to the surgeon performing percutaneous one- and two-level transforaminal lumbar interbody fusion (TLIF) under fluoroscopy control [43], the mean exposure time per case was 1.69 min, with 76 mrem exposure to the surgeon's dominant hand. At this rate, the maximal annual occupational exposure allowance would be reached after 194 procedures. Since pulsed fluoroscopy was used in the study, TLIF cages were inserted without fluoroscopy control and running electromyography (EMG) was also used; thus, one can assume that in other set-ups the radiation exposure may be higher.

In a cadaver study testing radiation exposure to the surgeon during percutaneous screw placement [139], all screws were within the bone confines, with acceptable trajectory. Total fluoroscopy time for placement of ten percutaneous pedicle screws was 4 min 56 s (29 s per screw). The protected dosimeter recorded less than the reportable dose. The ring dosimeter recorded total radiation exposure of 103 mrem, or 10.3 mrem per screw placed. Exposure to the eyes was 2.35 mrem per screw. The authors concluded that a surgeon would exceed occupational exposure limit for the eyes and extremities with percutaneous placement of 4,854 and 6,396 screws, respectively.

In cadaver studies [38, 41, 140, 141], image-guided procedures were associated with less radiation exposure to the surgeon when compared with conventional use of fluoroscopy. With the use of navigation systems based on preoperative CT with point-matching registration, or iCT-based image guidance, the surgeon is exposed to no intraoperative radiation [64]. In image-guided procedures that require intraoperative acquisition of fluoroscopy images or an intraoperative 3D fluoroscopy study

as well as cbCT, the surgeon's radiation exposure depends on both the amount of radiation used and distance from the radiation source. In these procedures, the operating room staff can step back behind a leaded wall or stay out of the room during periods of active radiation.

From the patient's perspective, preoperative CT-based IGSS is associated with higher levels of radiation exposure compared with fluoroscopy [42, 142]. Intraoperative cbCT scan is equivalent to 40 s of fluoroscopy, or about half of a CT scan of the same region-of-interest (ROI) [143]. A patient undergoing two intraoperative cbCT scans, for example, prenavigation for registration and post instrumentation to validate screw position, is thus exposed to a radiation dose that is equivalent to a CT scan of the same ROI, or 80 s of fluoroscopy. This is a similar level of exposure to the reported radiation dose during percutaneous fluoroscopy-controlled one- and two level TLIF [43], and less than the dose associated with one-level fluoroscopy-controlled vertebral body augmentation [138].

Procedure Duration

Several studies investigated the effect of image guidance on operative time. Image guidance was associated with longer operative time in some studies [11, 53, 115, 136, 144, 145], while surgeries were shorter in others [117, 131, 134, 146].

Several investigators described a reduction in procedure duration as they moved down their learning curve, suggesting that the relationship between use of image guidance and operative time depends on how well navigation systems are assimilated in a specific hospital. How effective is the setup? Is the infrared camera positioned properly for undisturbed navigation? How far down the curve have the surgeons traveled? And how good is the coordination between X-ray technicians and the surgical team?

Robotic Guidance in Spine Surgery

Accuracy

In a cadaver study, 2 experienced spine surgeons inserted pedicle screws to the thoracolumbar spine of a cadaver with fluoroscopy control (control group), while 13 surgeons instrumented cadaver thoracolumbar spine with robotic guidance (study group). A total of 234 pedicle screws were implanted in 12 cadavers. Screw placement accuracy was measured according to the Gertzbein and Robbins classification [10]. Screw placement deviations in the group using the robotic guidance averaged 1.1 ± 0.4 mm versus 2.6 ± 0.7 mm in the control group. Pedicle wall breaches of 4 mm or more occurred in 1.5 % of the study group placements versus 5.4 % of control group placements [147].

In the early clinical phases, robotic guidance performed successfully in 93 % of the cases in which it was used, and 96 % of the screws were assessed as accurate [76].

In a case series of 31 patients undergoing robotic-guided percutaneous posterior lumbar interbody fusion (PLIF) with posterior fixation, 133 pedicle screws were placed [73]. According to the Gertzbein and Robbins scoring system [10], in the axial plane, 91.7 % of the screws were evaluated as group A and 6.8 % were evaluated as group B. In the sagittal plane, 81.2 % of the screws were evaluated as group A and 9.8 % were evaluated as group B. One screw was evaluated as group C in the axial plane, and one as group D in the longitudinal plane.

A retrospective multinational-multicenter study summarized placement of 3,271 pedicle screws and guide-wires inserted in 635 patients; 49 % were inserted percutaneously [70]. The series included diverse clinical entities, from simple degenerative cases to severe deformities. Accuracy was assessed in 646 pedicle screws inserted in 139 patients using postoperative CT scans, and in the remaining patients assessment was by intraoperative fluoroscopy. Clinically acceptable screw placement was recognized in 98 % of the cases. Postoperative CT scans demonstrated that 98.3 % of screws (635/646) fell within the safe zone; 89.3 % were completely within the pedicle, 9 % had a breach of <2 mm, 1.4 % breached 2–4 mm, and only two screws (0.3 %) deviated by more than 4 mm from the pedicle wall. Transient neurologic deficits were observed in four cases, but following revision, no permanent nerve damage was encountered.

In a retrospective analysis [72], patient records and CT scans were analyzed in a cohort of 57 conventional open screw placement performed in 2006, 20 open robotic-guided placements performed in 2007, and 35 percutaneous robotic-guided pedicle screw placements performed in 2008–2010. A total of 94.5 % of robot-assisted and 91.4 % of conventionally placed screws were within the pedicle or encroaching the cortical pedicle wall. Percutaneous robotic and open robotic-guided subgroups did not differ. The revision rate for misplaced screws was 1 % for robotic guided surgery and 12.2 % for conventional open surgery.

In a retrospective analysis of prospective data in a series of 102 consecutive patients undergoing robotic-guided spine surgery [71], robotic-guided screw placement was executed in 95 patients. The robot was not used as planned in seven patients for the following reasons: severe deformity (one patient), very high body mass index (one patient), extremely poor bone quality (one patient), registration difficulty caused by previously placed loosened hardware (one patient), difficulty with platform mounting (one patient), and technical issues with the device (two patients). In the 95 executed cases, 949 screws (87.5 % of 1,085 planned screws) were successfully implanted, and 98.9 % of executed screws were in clinically acceptable position. Eleven screws (1.0 %) were misplaced (all presumably due to “skiving” of the drill bit or trocar off the side of the facet). Ten misplacements were recognized intraoperatively and corrected manually; one diagnosed postoperatively resulted in a revision surgery for screw removal. In 110 screws (10.1 %), robotic guidance was aborted and screws were manually placed, generally due to poor registration and/or technical trajectory issues (the trajectory was out of the working volume of the robot).

Only one randomized controlled trial was conducted to compare freehand and robotic-guided lumbar and sacral pedicle screw insertion [74], including 60 patients who were randomly allocated into the two groups. A total of 298 screws were implanted; 93 % had good positions in the freehand group (Gertzbein and Robbins A or B), and 85 % in the robotic-guidance group. Ten robot-guided screw placements required intraoperative conversion to freehand. One misplaced screw that had been placed freehand needed surgical revision.

The authors felt the bed mount device, which was connected to the operative bed on the caudal side and to a spinous process via a KW on the cranial side, was unstable, leading to motion and incorrect trajectories, and that "cannula skidding" (skiving of the working channel on the side of the facet) led to lateral screw misplacement in some cases.

The authors of this chapter, who are experienced robotic-guided spine surgeons, feel that these misplacements are suggestive of surgeons who are still on a learning curve. Skiving (skidding) occurs for one of several reasons: (1) planning on a steep slope or on a ridge, leading to loss of entry point; (2) the entry point is not prepared or is insufficiently prepared (nibbling in open procedures or using a specific tool in percutaneous procedures), leading to slippage of the guiding tool; or (3) the guiding tool is inserted too forcefully or too deep, leading to skiving (Fig. 14.7). The authors have made all of these errors themselves, and teach others how to avoid them, but would not have initiated a randomized controlled trial while at a relatively early point on the learning curve.

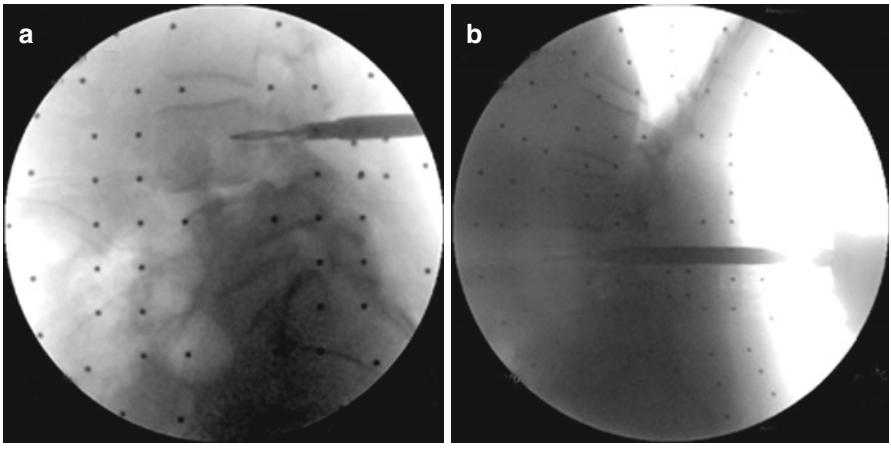

Fig. 14.7 There are three main reasons for pedicle screw misplacement in robotic-assisted spine surgery: planning errors, an unstable robotic platform, and skiving of the drill bit or trocar off the working channel. (**a**) Good surgical technique resulted in a well-placed fiducial and pedicle screw. (**b**) In this procedure, the trocar and the guiding tube were pushed too deep, resulting in slippage on the lateral border of the facet and lateral misplacement of the fiducial. This trajectory was corrected manually

Radiation Exposure

In a cadaver study comparing robotic-guided (study group) pedicle screws to fluoroscopy-controlled (control group) pedicle screw instrumentation, surgeons' radiation exposure in the study group averaged 4.2 mrem versus 136 mrem in the control group [147]. In a retrospective study comparing robotic-guided to fluoroscopy-controlled pedicle screws, the average fluoroscopy exposure per screw was 34 s in robotic-guided compared to 77 s in conventional cases [72]. In the only randomized controlled trial comparing fluoroscopy control to robotic guidance, intraoperative radiation did not differ between the two study groups (1.9 min), while preoperative CT in the robotic guided group added 411 mGy cm to patient exposure [74]. Radiation exposure in robotic-guided surgery reflects the confidence of the surgeon in the system. Exposure levels in the cadaver study [147] reflect the best scenario each surgeon should strive to reach.

Early in the learning curve, every step in robotic-guided procedures is monitored under fluoroscopy; however, as surgeons gain experience and adopt proper surgical technique, less radiation is needed. In the authors' institution, fluoroscopy images are taken for registration, after drilling is performed for all planned trajectories (with KW placed in minimally invasive procedures or metal fiducials placed in the drilled pedicles in open procedures), and at the end of the procedure, before closure. Fluoroscopy to assess placement during surgery is taken only if the guiding tube is felt to skive, before drilling is performed (unpublished data). These measures resulted in reduction in fluoroscopy time in vertebral body augmentation (manuscript under revision) and in spinal fusion surgery (unpublished data).

Procedure Time

In a cadaver study comparing fluoroscopy to robot guidance, 234 pedicle screws were implanted in 12 cadavers. Robot guidance resulted in an average procedure time of 1.23 h, compared with an average 1.98 h in the control group [147]. In a randomized controlled trial comparing robotic guidance with fluoroscopy [74], surgical time for screw placement was shorter with the freehand technique (84 min) compared with robotic guidance (95 min), however preparation time in the operating room and overall OR time were not different for the two groups.

The authors of this chapter agree that during the learning curve, screw-related procedure time is longer with robot guidance, as reported above in the discussion of the learning curve in image-guided procedures; however, in our experience, when the procedure is well assimilated in OR routines, the time required for robotic guidance will become comparable to fluoroscopy guidance in short-segment fixation and will be shorter for long-segment fixation. This notion is especially true for percutaneous pedicle screws.

Tele-Surgical Robotic Systems and Spine Surgery

Tele-surgical robotic systems allow the surgeon to directly control the surgical instruments held by the robot via a joystick or hand controls. Task execution can be

either passive or active. To date, only one tele-surgical robotic system is in clinical use. While the system has been used primarily in urology, it has also been used for ALIF procedures via the retroperitoneal approach in two porcine models [88, 94]. It was also tested on laminotomy, laminectomy, disc incision, and dural suturing procedures on the thoracolumbar spine of a porcine model [91]. The authors concluded that with the development of appropriate surgical tools, this system may be used clinically. A cadaveric study has shown the technical feasibility of trans-oral robotic surgery for decompression of the craniocervical junction as well as resection of both intra- and extradural tumors of this region [89].

In humans, case reports were published on robot-assisted transoral odontoidectomy for decompression of the craniocervical junction [87], on a retroperitoneal transdiaphragmatic robotic-assisted laparoscopic resection of a left thoracolumbar neurofibroma [90], thoracoscopical extirpation of paravertebral mediastinal neurogenic tumors such as schwannomas [92], and in the transperitoneal resection of paravertebral lumbosacral masses [93].

Practical Considerations When Using Image or Robotic Guidance

Image-guidance in spine surgery achieved "maturity" with systems based on cbCT that allowed intraoperative scanning in the "correct" position and registration of several motion segments simultaneously. These systems allow for a check scan before leaving the OR. They reduce occupational exposure for the surgeon and OR staff but result in significant radiation to the patient. An increasing number of surgeons are performing minimally invasive spine surgeries. They are exposed to significant radiation, and there are reports of early revision surgeries in up to 10 % of cases [148]. In response to these issues, the use of some form of guidance seems intuitive. In addition, image or robotic guidance can make a big difference in cases of revision surgery with a posterior fusion mass, abnormal anatomy, or spinal deformity. In all of these instances, the energy spent on lamino-foraminotomy or exposure of other relevant anatomical landmarks for successful screw placement can now be shifted to other important parts of revision surgery, such as osteotomy or decompression of the neural elements. One simple step, using the guidance system software for preplanning, upgrades the surgeon's readiness for the procedure, with preoperative exposure to abnormal bony and neural anatomy, enabling appropriate planning that avoids attempts at screw placement in locations where they cannot be introduced.

The decision by a spine surgeon to use image or robotic guidance is not an easy step. Several obstacles may have to be overcome:

1. The "I do not need it, I can do better than the machine" mindset must be changed. In fact, in most cases the machine will do better than the average surgeon in terms of accuracy with lower radiation exposure. Acknowledging these facts is the first step for a surgeon, before he or she can become interested in looking into guidance systems.

2. There is a learning curve, and it can take some time before a surgeon will benefit from image or robotic guidance. Two-dimensional fluoroscopy image-guidance systems are the most intuitive for spine surgeons. More sophisticated systems will require a longer learning curve; however, after achieving good understanding of the system and the surgical steps, the position of the implants will repeat itself case after case, with very few outliers. Many surgeons lose their patience during the learning curve and stop using the system. It takes motivation and discipline to stay focused on the long-term objective.
3. These systems are expensive and cannot be purchased by every spine surgeon around the world. In the future, their prices will fall as a result of mass production, competition, and device simplification. For now, it is important to work with hospital administration and convey the benefits of guidance for both patients and staff.
4. These systems are cumbersome, they require significant space in the OR, and require trained OR staff to operate them. With most navigation systems, cables run between the sterile area and the navigation system, and the surgeon and the OR staff must keep an open "line of sight" between the infrared camera, the reference arc, and the navigation tools. This requires an appropriate OR set-up. In the future, wireless systems may be available, a line of sight will not be needed, the system will be operated by the surgeon or will run automatically, and systems will become smaller, reducing their footprint in the OR.

Surgeon who choose to use image guidance must remember one simple fact: their eyes are centered on a screen showing virtual anatomy and virtual tools. Navigation errors may occur as a result of:

1. Scanning errors
2. Poor registration between the scan and the patient's anatomy
3. Motion of the relevant anatomy in relation to the reference arc following registration
4. Too great a distance between the reference arc and the relevant anatomy
5. Shift or instability in the reference arc
6. Suboptimal angle of view of the reference arc by the infrared camera
7. Tilted or misshapen tools that create a false trajectory on the screen

Current systems require some form of imaging that involves ionizing radiation. Future systems may be based on registration between preoperative MRI and intraoperative ultrasound, or on EM point-matching to preoperative MRI studies, which would save both the surgeon and the patient from the dangers of ionizing radiation; however, these ideals will not be achieved in the short term.

A surgeon who chooses to use robotic guidance must also remember several simple rules:

1. The platform must not move. No matter whether it is a clamp, Hover T, or a unilateral or bidirectional bed-mount device, the surgeon must make certain to create a stable platform before beginning the procedure.
2. AP and 60° oblique fluoroscopy images must be taken with the target seen clearly at the center of the field. The patient must be still during this step. If the

frame or bed may prevent the patient from remaining motionless, leading to motion during respiration, fluoroscopy images should be taken while respiration has been temporarily stopped by the anesthesiologist.
3. The semi-automatic registration should be visually verified by the surgeon. In case any shift is noted between preop CT and intraoperative fluoroscopy images, the surgeon should verify that the platform is stable and repeat the fluoroscopy study until registration is sufficient for robotic guidance.
4. Ensure that the robot is connected to the right station, and maintain constant and clear communication with the person operating the workstation. Connect the correct arm to the robot, again keeping clear communication with the trajectory plan on the workstation screen. Choose guiding tools and drill of the correct length.
5. Keep the skin incision in line with the point of the trocar. Keeping the trajectory line, cut the fascia. Push the trocar and guiding tube gently through muscle until reaching the pedicle entry point, but do not push the guiding tools too deep. Keep the outer tube floating over the anatomy, thus avoiding skiving (Fig. 14.7). Remove the trocar and tap the toothed working channel to the entry point. This step will have a learning curve, and skiving or slipping on sharp, bony ridges will be identified by the surgeon only after these occur several times. In open surgery, the surgeon must make sure no pressure is applied on the guiding tools by the paravertebral muscles since this may lead to skiving and screw misplacement.
6. Drill in and out, full speed ahead, holding the tip of the working channel to prevent dislodgement.
7. Leave a marker or a KW in each drilled trajectory and move on to the next trajectory. Make sure no force is applied on the robotic arm when disconnecting it, as this may lead to platform motion, especially if a unilateral bed-mount device is used.

Surgeons using robotic guidance should keep in mind an important difference from image guidance. During surgeries performed under image guidance, the surgeon has a sense of "where am I going" from following the virtual trajectory on the screen; however, with robotic guidance there is no control mechanism to alert the surgeon when an incorrect trajectory is drilled. The authors of this chapter consider this the weakest link of the currently available robotic guidance systems, and suggest that efforts should be made to develop a feedback mechanism that will identify any deviation from the planned entry point. With the current system, the entry point should be prepared by a designated tool using a percutaneous approach and by nibbling bone or burring it down in open surgery to create a comfortable "landing area" for the toothed working channel. Moreover, it is of great importance to understand the 3D anatomy of this landing area on the planning software, and to avoid areas with high risk for skiving and slipping. Surgeons in the beginning of their learning curve should be controlling their steps with check fluoroscopy. Later on, when the surgeon has developed the ability to sense skiving and slipping, less fluoroscopy will be required.

Robotic guidance is currently based on a preoperative CT scans. The protocol initially dictated by the company demands thin slices and high energy to allow

registration of the CT image to intraoperative fluoroscopy. The radiation dose to the patient from CT scans obtained with this protocol is high, and this has led to an ongoing dialogue between the authors of this chapter and the company. This led to two modifications in the recommended protocol of the preoperative CT. The modified protocol reduced the radiation dose to the patient down to 25 % of the original protocol, a level that is close to a normal CT scan of the relevant area of the spine.

Dedicated tele-surgical systems with haptics will be a big breakthrough, allowing spine surgeons to enjoy the proven benefits of this technology [91]. These benefits include better ergonomics and less fatigue, allowing more procedures per day; compensation for the challenges posed by hand tremor, loss of finger grip power, and visual deterioration in older surgeons; and excellent enlarged 3D visualization of the surgical field. Procedures performed with tele-surgical systems may frequently be less invasive, require less retraction of delicate anatomy, result in less blood loss, lead to less damage to soft tissue surrounding the spine, and a lower tendency to tear the dura while maintaining the feel of the surgical field.

Combining tele-surgical systems with image- and/or robotic guidance will allow the surgeon to perform robotic decompression and spinal instrumentation with guidance, and may assist in complicated tasks such as osteotomy and correction of alignment.

Conclusions

Image guidance systems for spine surgery have greatly advanced. They cover the cervical-to-sacral spine, front and back. They increase accuracy, and reduce radiation exposure for surgeons and operating room staff. Future systems are expected to improve visualization of outlying anatomy, decrease registration errors, and incorporate imaging techniques that are not dependent on ionizing radiation.

Robotic guidance for spine surgery is in its infancy, with many systems at different stages of development. The robotic system that is currently on the market has proven to be accurate and to reduce radiation exposure in the hands of trained surgeons who have advanced down a steep learning curve. This system lacks a mechanism to alert the surgeon and correct skiving and slipping from the correct entry point.

The future of tele-surgical systems used in combination with some form of guidance and haptic capabilities is exciting, and will take spine surgeons far beyond the current state-of-the-art.

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