Guided pedicle screw insertion: techniques and training

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Abstract

BACKGROUND CONTEXT: In spinal fusion surgery, the accuracy with which screws are inserted in the pedicle has a direct effect on the surgical outcome. Accurate placement generally involves considerable judgmental skills that have been developed through a lengthy training process. Because the impact of misaligning one or more pedicle screws can directly affect patient safety, a number of navigational and trajectory verification approaches have been described and evaluated in the literature to provide some degree of guidance to the surgeon.

PURPOSE: To provide a concise review to justify the need and explore the current state of developing navigational or trajectory verification techniques for ensuring proper pedicle screw insertion along with simulation methods for better educating the surgical trainees.

STUDY DESIGN: Recent literature review.

METHODS: To justify the need to develop new methods for optimizing pedicle screw paths, we first reviewed some of the recent publications relating to the statistical outcomes for different types of navigation along with the conventional freehand (unassisted) screw insertion. Second, because of the importance of providing improved training in the skill of accurate screw insertion, the training aspects of relevant techniques are considered. The third part is devoted to the description of specific navigational assist methods or trajectory verification techniques and these include computer-assisted navigation, three-dimensional simulations, and also electric impedance and optical and ultrasonic image-guided methods.

CONCLUSIONS: This article presents an overview of the need and the current status of the guidance methods available for improving the surgical outcomes in spinal fusion procedures. It also describes educational aids that have the potential for reducing the training process. © 2014 Elsevier Inc. All rights reserved.

Keywords: Spinal fusion surgery; Pedicle screw insertion; Image-guided surgery; Surgical navigation; Resident training

Introduction

Spinal fusion is a surgical technique implemented to fuse two or more vertebrae in the spine. It is typically performed for the treatment of a number of conditions such as trauma, spinal deformity (e.g., scoliosis or kyphosis), degenerative disease, and infectious or neoplastic disease [1].

Screw insertion in spinal fusion procedure

The method of pedicle screw fixation gained widespread acceptance after the pioneering work and presentations of Roy-Camille et al. [2] and Kabins and Weinstein [3]. The procedure for pedicle screw placement is complex and technically demanding with a steep learning curve. There is limited visibility of spinal anatomical landmarks during surgery; so, it is important to gain a conceptualization of anatomy of spinal structures that are hidden from direct view. Moreover, the close proximity of many vital neural and vascular structures and variability in pedicle morphology both contribute to the difficulties of accurate placement. Of major concern is the fact that in the case of perforation of the vertebral wall, improperly placed screws could place the neural and vascular structures at serious risk of damage. Such a perforation can lead to potential problems such as dysesthesia,
neurological injury, and hemorrhage. Misplaced screws can also lead to early structural construct failure or pseudoarthrosis formation.

A screw hole is generally prepared by using a cannulation probe (pedicle finder) although sometimes a drill is used. The cannulation probe is a blunt-tipped, awl-like boring tool that is advanced through the vertebral cancellous bone in the pedicle. To avoid improper placement of the screws, the surgeon relies on tactile feedback and experience-based judgment to differentiate between lesser resistive cancellous bone and the tougher cortical bone encapsulating the pedicle. If probe advancement becomes difficult, this may indicate that the probe is in contact with cortical bone. On the other hand, if it feels too effortless, then the probe could have perforated outside the confines of the cortical bone, providing an indication to the surgeon that a correction in direction is required. As a result, occasional errors are inevitable for such a procedure with only manual feedback as the guide. With these challenges, it would seem that a fruitful approach would be to harness the developments of modern technology through the use of some guidance methods. Probably, the first attempt to do this was the work published in 1995 by Nolte et al. [4], part of which is illustrated in Fig. 1.

Screw misplacement: error rates and clinical significance

Many studies are available in the literature in which the error rate and the clinical significance associated with the misplacement of pedicle screws have been reported. In this article, our focus will be on a few recent (2007–2011) reports, one of which has summarized the results from most of the earlier studies.

Samdani et al. [5] reported an investigation as to whether a surgeon’s experience affects the accuracy with which pedicle screws can be inserted without using any navigational aids. In this study, the surgeons were grouped into three categories based on the years of experience: less than 2 years, 2 to 5 years, and more than 5 years. The results for the overall breach rate are summarized in Table 1.

Although there was a trend toward a lower overall breach rate in the experienced group, it did not attain statistical significance. For medial breaches, which would indicate higher possibility of neurological damages and hence possessing greater clinical significance, the statistical significance of the trend was considerably higher (p = .58). For the conventional freehand placement of screws, these results suggested that the chance of having a medial breach was significantly lower for the most experienced surgeons. However, even for experienced surgeons, 1 in 30 will produce medial breaches. This is in accord with a previous report, which showed that a single surgeon’s medial breach rate decreased over an 8-year time period [6]. However, it should be noted that these data would not capture screw breaches that were recognized and corrected intraoperatively; hence, these results are likely to underestimate the breach rate. Aside from the previously mentioned errors and the associated clinical significance, there is an educational aspect to the problem of pedicle screw misplacement. Residents need to obtain practical experience in pedicle screw insertion, and this is normally done under the supervision of a senior surgeon. However, without a means for the senior surgeon to check and control the fixation procedure by the resident, additional stress could be caused in the supervision process. Also, trying to correct a breach often leads to a weak, less than ideal pedicle screw. To further investigate the matter, we have cited a few recent studies that have aimed to investigate the rate of error among the surgical residents. Wang et al. [7] used postoperative computed tomography (CT) scan analysis to investigate how successful neurosurgery residents are when inserting pedicle screws in human cadavers. They report an overall error rate of around 15% and that the accuracy is not a simple or linear function of the surgeon’s experience. Surprisingly, their results as summarized in Fig. 2 demonstrate greater error for some more senior resident categories, perhaps because of the fact that in training programs the senior
residents might receive the more complicated cases. In addition to neurosurgery residents, Bergeson et al. [8] focused in a separate thoracic cadaver study on orthopedic residents who were given the task of instrumentation of 297 pedicles in 149 intact vertebral body specimens. It was shown that 29% of the screws were not fully within the pedicle, out of which 74% were noncritical violations and 26% were critical.

As pointed out earlier, the previously mentioned studies were reviewed to demonstrate the need for accuracy in spinal fusion procedures and for improvements in education and training of residents. In the following two sections, current and possible approaches to both aspects are described.

Table 1
Results of an investigation on whether surgeon experience would make a difference on the accuracy of the freehand placement of pedicle screws [5]

<table>
<thead>
<tr>
<th>Surgical group</th>
<th>Less than 2 y of practice</th>
<th>2 to 5 y of practice</th>
<th>Greater than 5 y of practice</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall breaches*</td>
<td>12.7%</td>
<td>12.9%</td>
<td>10.8%</td>
<td>12.1%</td>
</tr>
<tr>
<td>Medial breaches†</td>
<td>7.4%</td>
<td>8.4%</td>
<td>3.5%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Sample size, (no. of screws)</td>
<td>283</td>
<td>286</td>
<td>287</td>
<td>856</td>
</tr>
</tbody>
</table>

* p=.58
† p<.01

Educational tools

Most current teaching techniques for orthopedic screw insertion involve “learning by doing” in the operating room. One possible manner to minimize the misplacement of pedicle screws in the long term is seeking ways to train surgical residents or fellows with accessible technologies or new technological advancements. A number of approaches have been described in the literature and World Wide Web as endeavors to develop three-dimensional (3D) “Pedicle Screw Simulator” software packages, animations, and “iPhone” apps.

One of the first studies dates back to 2002 [9] and reports the development of a small, stand-alone computer program that simulated insertion of pedicle screws in...
different spinal vertebrae (T10–L5). Subsequently in 2008, another study [10] described the development and implementation of a simulator for minimally invasive screw insertion using accurate, 3D, patient-specific, CT-based visualization of the pelvic and upper sacral anatomy.

More recently, aiming to familiarize the residents with the concept of the 3D anatomy of the spine and to practice placement of virtual screws, Klein et al. [11] developed a software simulator program. In this program, the geometry of cadaver spines (based on a 3D model of CT scans of the spine) could be loaded into the simulator that allowed trainees to pick various virtual pedicle screws that popped up onto the screen and enabled them to practice the placement and insertion. The screws used in this simulator were 3D renderings of actual pedicle screws of various sizes. The computer program was designed to assess the trainee’s performance by analyzing how good the grip of the inserted screw might be expected to be in practice, and this was done by computing the bony purchase at the screw-bone interface. The program would then grade the screw placement performance by assessing the number of cortical perforations. The program also allowed the user to make the spine translucent and study on their own, the trajectory of that screw, by rotating and visualizing the insertion trajectories and inspecting the extent/direction of possible perforations (eg, medial, lateral). Fig. 3 shows some snapshots from the computer screen to illustrate various stages in the simulation process whose flowchart is shown in Fig. 4.

In a pilot study to investigate whether the previously mentioned simulator would affect the training time, Podolsky et al. [12] divided the residents into two groups: one of which made use of the previously mentioned simulator to play around with the simulation model of the pedicles before insertion and the other a control group. But the results were not statistically significant; perhaps because of their choice of methodology, the studies were done on human cadavers with metastatic cancer and severe osteoporosis, which would facilitate easy accidental penetration of cortical bone. This said, in a survey of those using it and the faculty who supervised the students involved, it was unanimously concluded that practice on the simulator was very helpful in teaching the trainees about the complex, 3D anatomy of the patient-specific spine vertebrae and that there was likely to be an educational advantage to such an approach.

Finally, it should be noted that the program called Sensimmer (http://www.immersivetouch.com/), initially developed by professors at the University of Illinois and which has been on the market for 3 years, uses both visual and tactile interactions. Specifically, the user wears special glasses to see real-time, 3D images of a real patient’s body taken from either a CT scan or a magnetic resonance imaging. Recently, the use of this as a training tool for placement of thoracic pedicle screws has been evaluated [13]. A visual example of such simulations could be found at http://www.youtube.com/watch?v=ZtIRIL_uMRU. There can be little doubt that such systems could be of benefit to surgical trainees in improving the trajectory of pedicle screw insertion.

In the next section, some of the computer-assisted surgical navigation techniques will be introduced with an analogy to global positioning systems devices. These systems can help the surgeons in real-time tracking of the pedicle screws inside the patient’s body. It is important to note that these devices could not only be of direct assistance in surgical environments but also be used in an educational setting.
context, which is the main focus of this section. By way of example, if such a device is given to surgical resident trainees, whether in an operating room (OR) setting or when practicing in human cadavers, both the trainee and the senior surgeon could have the opportunity to track the process in real time and make necessary corrections to the trajectory of the screw insertion. Therefore, most image-guidance techniques and navigation devices could also be used as educational toolkits.

Navigation techniques for guided screw insertion

Although remaining a dominant basis of the procedure, tactile feedback is limited by the fact that the resistance of the bone to cannulation can vary considerably depending on the patient’s age and bone density. Osteoporosis can also result in a very low level of bone resistance to cannulation, reducing the effectiveness of tactile feedback in differentiating between cortical and cancellous bone. In this regard, the incorporation of haptics into the training for surgical residents can help to provide a qualitative sense of tactile feedback. Nonetheless, a number of guidance techniques have been employed in spinal fusion surgery to assist the surgeon in real time, and there are ongoing research activities aimed to seek various alternatives for avoiding improper pedicle screw placement. Some examples of currently available guided screw insertion include, but are not limited to intraoperative fluoroscopy, both fluoroscopic and CT-guided computer-assisted surgery (CAS), electrophysiological monitoring techniques, and ultrasonic image-guided pedicle screw insertion. The current status of these techniques along with their advantages and disadvantages will be discussed next.

Image-guided pedicle screw insertion

Intraoperative fluoroscopy

Fluoroscopic images provide a 2D X-ray projection, usually a lateral projection, of the spine (see Fig. 5). When taken during cannulation of the pedicle or placement of the pedicle screw, fluoroscopic images can provide the surgeon with important 2D information regarding the accuracy of the approach in either the lateral or the anteroposterior projection, however, at the cost of exposing the patient and staff to ionizing radiation.

The total radiation exposure varies depending on the number of images acquired during a given procedure. Fu et al. [14] reported a correct pedicle screw insertion rate of 93.2% using fluoroscopy, whereas in the same year, Kotil and Bilge [15] reported an incorrect pedicle screw insertion rate of only 5.6% without using any fluoroscopic guidance. Because limited information is available through 2D images, and to better assess the accuracy of pedicle screw placement, 3D fluoroscopy has been employed for spine surgery using several consecutive fluoroscopy images, taken from different angles, to reconstruct 2D images in any plane, of course, at the cost of even greater doses of ionizing radiation than standard fluoroscopy. Using this technique, Ito et al. [16] reported a success rate of 97.2% for cervical screw insertion and that none of the cortical bone perforations (2.8%) were clinically problematic.

Computer-assisted surgery

Computer-assisted surgery, also known as surgical navigation, is a technique based on the use of markers and appropriate software that allows surgeons to track and monitor surgical instruments relative to a patient’s anatomy in real time for a variety of procedures. It aims to improve pre-surgical planning, reduce errors, and thus enhance patient outcomes. It also has the potential to allow a surgeon to remotely monitor the progress of residents [17].

In describing CAS methods, sometimes the analogy with global positioning systems for automobile navigation is used. With CAS, the surgical instrument replaces the car; so that instead of the driver seeing the virtual position of the car on a digital road map, the surgeon sees a road map consisting of the pre- or intraoperatively obtained magnetic resonance and/or CT image. Superimposed on this image is the position of the instrument as obtained from tracking sensors or transmitters attached to the

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Fig. 5. Intraoperative fluoroscopy. (Left) Posterior projection of spine, providing a cross-sectional image of the pedicles. (Right) Lateral projection, providing a lateral view of the pedicles. Images reproduced, with permission from Spine [58] and Fu TS. Pedicle screw insertion: computed tomography versus fluoroscopic image guidance. Int Orthop 2007;32:517–21 [14].
instruments [18,19]. A number of different electromagnetic, acoustic (ultrasonic), and optical tracking sensors are commercially available. Fig. 6 illustrates the use of optical and electromagnetic methods in which markers are attached to the instrument to be tracked. In the optical case, these can be small, passive reflectors or active, light sources, whereas for electromagnetic sensors, they can consist of small coils. It is the positions of these markers that are sensed by the “base” station, and the information is relayed to the computer/display system. A comparison of these two types has been presented by Glossop [20].

After establishing a relationship between the patient’s anatomy and the preoperative or intraoperative images, the position of the surgical instruments and the implants are displayed on a computer screen in relation to the patient’s anatomy [21]. For this purpose, an interactive computer system matches the coordinates of the preoperative images and the patient’s anatomy [22,23]. An example is shown in Fig. 7 where an image of a vertebra is shown in various views and in real time under CAS guidance.

In fact, insertion of the pedicle screws was likely the initial application of CAS in orthopedic and trauma surgeries. As noted earlier, Nolte et al. [4] described an in vitro, 3D scheme in which they demonstrated accurate drilling of pedicles in the lumbar vertebrae. The rationale for using an alternative technology was the need to improve the 10% to 40% error rate associated with incorrect placement of the screws under fluoroscopy guidance, as reported in 1990s. One of the first clinical evaluations of CAS in spinal surgery was that reported by Merloz et al. [24]. Their technique combined CT imaging with intraoperative CAS navigation. After its introduction into spine surgery, CAS was applied in hip, knee, and skeletal trauma surgeries.

So far, more than a few hundred CAS systems have been developed by various universities and research institutes, often in collaboration with industry, although some of the features still remain in the experimental stage. Currently, some of the most widely used, commercially available systems approved for clinical use are ARCADIS Orbic 3D (Siemens, Munich, Germany), Ziehm Imaging mobile C-arm technology (Ziehm Imaging, Nuremberg, Germany), StealthStation O-Arm (Medtronic, Minneapolis, MN, USA), eNLight and NavSuite (Stryker Corporation, Freiburg, Germany), and VectorVision (Brainlab, Feldkirchen, Germany). Fig. 8 shows a sample 3D C-arm technology system.

Advantages and disadvantages of CAS. Because CAS is the most commonly used guidance technique in spine surgery with many international manufacturers, it is worthwhile to examine some of the advantages and disadvantages.

Some of the potential advantages are as follows:
1. Surgical changes: The potential exists for easier visualization of the patient-specific anatomy and so more effective presurgical planning, possible improved patient outcomes, less invasive operations, and more accurate placement of pedicle screws.

2. Cost effectiveness: In a study with 100 patients, it was reported [25] that with image-guided pedicle screw insertion, the rate of revision surgery was reduced, compared with freehand approach. Using a CAS system costing just under $500,000, they reported a cost saving of just over $70,000 for 100 cases (based on $93/minute) and a decreased revision rate. A busy institution could perform 500 to 1,000 spinal fusion operations with a single navigation system per year. However, it should be noted that navigation systems are known to involve lengthy setup procedures and these, together with complex display features, further contribute to a stressful environment. As an example, Abe et al. [26] describe this issue with the aim of introducing a novel computer-assisted technique that is relatively inexpensive and suitable for teaching. Consequently, there is an evidence to support the view that the use of commonly used navigation devices increases the time for a single surgery, regardless of a possibility of requiring a revision. However, in expert hands with sufficient experience, the setup and execution time becomes negligible. Also, when using intraoperative, 3D fluoroscopy image acquisition, no registration is required. For example, the Ziehm FD Vario 3D (Ziehm Imaging, Nurenburg, Germany) typically requires 58 seconds to acquire an intraoperative, 3D image, covering 4 to 5 vertebrae, and no registration is required for immediate navigation.

3. Training: As noted earlier, intraoperative CAS navigation could also be valuable for a surgeon to perform real-time monitoring of residents in training and, if necessary, to correct the trajectory of the pedicle screw inserted.

Several potential disadvantages of current CAS systems can be identified:

1. Geometry changes: A significant problem for systems that depend on preoperative images becomes apparent when the anatomy changes during surgery. Such a situation can occur, for example, when the patient’s
position during surgery is different from that during the preoperative CT scan or there has been a reduction of a fracture or spondylolisthesis. The guidance system may still verify the best pedicle screw placement based on the preoperative images; however, the changes to the anatomy of the spine during surgery are not reflected in these images. To some extent, this problem can be obviated by the use of intraoperative images from systems like the Medtronic O-arm, Siemens Arcadis, or Ziehm FD Vario 3D.

2. Marker movements and reregistration: If, by mistake, any of the markers are hit during the surgical procedure or if for any reason (eg, large skin deformations) the markers are moved, the whole process of registration needs to be redone, making the procedure lengthier and hence more expensive. Registration accuracy and anatomical or random marker movement errors are main topics of research within the research and development departments of navigation companies, and depending on their products, this issue might be less or more problematic from a clinical perspective.

3. Radiation: Ionizing radiation still remains a concern for operating room staff when fluoroscopy is used to confirm the accuracy of navigation, although the associated dosage should be much less than that when more extensive intraoperative fluoroscopy is used for screw guidance.

4. Field of view: This is limited because at most a surgeon can accurately register from three to five vertebrae at a time. In the case of spinal deformities where longer segments are typically exposed, multiple registrations are needed to obtain a full and accurate view of the operating area.

5. Registration and tracking accuracy: Because of registration inaccuracies, optical systems have an accuracy of around 0.3 mm [27] and the electromagnetic systems have accuracies (root mean square error) in the range of 0.5 to 0.9 mm [28,29]. Such errors are comparable with the pedicle sizes in the cervical spine, and as a result, improvements would be needed if they were to be used in this application. Further details concerning the accuracy are given in Frantz et al. [30] and Chapter 2 of Peters and Cleary [19]. Patient respiration can also cause the tracking device to move relative to the rest of the spine during the operation and hence can also interfere with tracking accuracy.

6. Tracking features: Optical systems require a direct line of sight between the satellite camera and the tools. On the other hand, this is unnecessary for electromagnetic tracking, but they are susceptible to distortion caused by metal parts such as instruments and other sources of radiofrequency noise that are normally part of the OR environment.

7. Cost-effectiveness: A concern arises from a cost-benefit analysis of CAS systems especially when it is realized that the capital cost of such systems can be around a half-million dollars and would likely require expert maintenance [25]. Consequently, the money saved from the reduced rate of revision surgery relative to the freehand technique may be offset by the depreciation and maintenance costs [25].

Effectiveness of CAS in pedicle screw insertion. There have been a considerable number of studies that have examined the effectiveness of CAS in terms of improving the accuracy with
which pedicle screws are placed for a wide variety of conditions. For example, Rajasekaran et al. [31] conducted a study to determine the effectiveness of CAS navigation in cases of thoracic deformity. Based on these results, they concluded that the use of CAS navigation techniques provided significant advantages in reducing the occurrence and severity of pedicle breaches. In another recent study [32], the outcome of pedicle screw placements with adolescent idiopathic scoliosis was evaluated. They assessed 547 thoracic screws in 42 consecutive patients undergoing posterior fusion over a 1-year period. A comparison was made between the results for a CT-assisted navigation insertion group using a Medtronic O-arm and a freehand group. They used CT images of the screw positions obtained after insertion to assess the accuracy of placement, and their results are summarized in Table 2. They concluded from these results that when navigation was used, significantly fewer potentially unsafe screws were placed compared with the freehand technique. It should be noted from this table that many navigated screws fall into the optimal category instead of acceptable, which by itself is an indication of improvement in screw insertion. It has been suggested that this could lead to higher fusion rates and lower hardware failure rates [33].

Verma et al. [33] reported a review of 23 separate prior studies from 1997 to 2007, including nearly 6,000 pedicle screws. Table 3 illustrates some of the details of their analysis. As seen on the fourth column (RR), the table compares CAS navigation versus conventional freehand technique in terms of screw placement errors. It can be seen that CAS navigation was favored with a very high statistically significant probability (p < .00001), suggesting that CAS navigation can help improve the accuracy of pedicle screw placement. The authors also addressed the question as to whether improvements in pedicle screw placement necessarily imply enhanced patient outcome. In addressing this question, they aimed to look at the patient neurological outcomes. The odds ratio (ie, strength of statistical association) suggested that CAS navigation was favored, in a trend with little statistical significance (p = .07). The authors were, therefore, unable to make conclusions regarding the fusion rates after the use of CAS because of the lack of enough information in the studies included in their meta-analysis. They stated “None of the studies reported any vascular complications and none of them used patient-based outcome measures like Oswestry disability index, SF-36, or SF-12 scores.” Thus, although many articles suggest that CAS navigation can improve the quality of pedicle screw placement, it seems that the evidence is still incomplete in terms of ultimate patient outcomes [34,35].

### Ultrasonic-guided pedicle screw insertion

An alternative, potential guidance method for determining the best screw trajectory is to use real-time ultrasound imaging similar to that used for intravascular imaging. There are at least two possible circumstances under which ultrasound could be used, depending on the available technology. If a B-mode imaging transducer can be incorporated into the tip region of the cannulation probe (pedicle finder), then checking for the best trajectory could be done in a quasi-continuous manner. Alternatively, if just a separate imaging probe is available, this could be used to repeatedly check the trajectory of an initial guide hole already generated relative to its surrounding boundaries. This is clearly a trajectory verification technique whose primary objective is to identify and judge the distance of the hole from the trabecular/cortical bone interface and from this to determine whether the proposed insertion trajectory is satisfactory. Patents have been granted for this idea [36,37] using single-element transducers. However, experimental evidence as to their practicality is currently only under growing scientific attention especially after investigational publications in recent years by academic research groups in Canada [38–40] and also in the USA [41], Korea [42], and Germany [43–45]. A brief description and discussion of these reports are presented in this section.

As an example, Kantelhardt et al. [43,45] demonstrated intrapedicular imaging using a 20-MHz intravascular ultrasound (IVUS) probe catheter. The catheter was placed into the guide hole and used to obtain cross-sectional images from within the pedicle. Unfortunately, the boundary between the guide hole wall and the trabecular bone surrounding it caused near-total reflection of the ultrasound beam. This prevented the ultrasound beam from penetrating any significant distance into the trabecular bone, thereby preventing the cortical wall surrounding the pedicle from being imaged. Thus, although the authors were among the first to implement the idea of using ultrasound imaging, they were unable to achieve the primary objective of a trajectory verification technique.

The reason for the high reflection could be attributed to the high acoustic impedance of the bone relative to the vasculature and soft tissues. In other words, although the IVUS is a common technique in cardiovascular diagnostic imaging, there is a major difference between IVUS and that of the bone sonography. The major challenge of ultrasound imaging within bone concerns the high attenuation (decay) of the signal sent through the bone. It is important to note that this decay increases with higher transmit frequencies [46]. This implies that, whereas IVUS imaging is based on successful signal transmission through soft tissue at relatively high frequencies (>20 MHz), using the same

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**Table 2**

<table>
<thead>
<tr>
<th>Placement</th>
<th>O-arm navigated (%)</th>
<th>Non-navigated (%)</th>
<th>p Value</th>
</tr>
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<tr>
<td>Optimal</td>
<td>74</td>
<td>42</td>
<td>&lt;.001</td>
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<tr>
<td>Acceptable</td>
<td>23</td>
<td>49</td>
<td>&lt;.001</td>
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<tr>
<td>Potentially unsafe</td>
<td>3</td>
<td>9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Removed*</td>
<td>0.6</td>
<td>4.9</td>
<td>&lt;.003</td>
</tr>
</tbody>
</table>

* These screws were removed intraoperatively because of unsafe position.
ultrasound transducer over the same frequency range [47] will not lead to success in imaging bone. This is also due to the very high attenuation, causing the returned signal to be lost in the background noise. Consequently, much lower frequencies (few MHz) must be used leading to considerable loss in resolution.

Other studies [38,48] have investigated some of the fundamental aspects of ultrasound propagation in cancellous bone, such as the attenuation and speed of propagation and determined a frequency range over which adequate penetration and resolution could be achieved. Based on their results, they designed a low-frequency transducer specifically for imaging from within a pedicle guide hole. This transducer, which is shown in Fig. 9, operates in the frequency range of 1 to 3 MHz. By rotating the transducer through $360^\circ$ and recording the reflected signal for each angle, B-mode images were subsequently obtained from human pedicles in vitro, as shown in Fig. 10. Therefore, for the idea of ultrasonic guidance of pedicle screw insertion to transfer from the scientific research laboratory bench to the clinic, an area of potential need is to develop rotational and 3D scanners that could provide real-time circumferential feedback to the surgeon at each given cross-section of the pedicle bone. Because of the nature of pedicle anatomy, an appropriate ultrasonic transducer might need to include not only a side-viewing capacity but also a forward-viewing feature [49,50].

The current status of the ultrasound pedicle imaging is indicative of the potential for providing confirmation of the proper trajectory through checking the guide hole placement. However, it does have the potential of being mounted on the cannulation probe so as to provide the location information in real time, as the surgeon is creating the insertion trajectory, or when watching a resident trainee doing so. This said, the technology still requires significant anatomic expertise by the operator and may not help reduce the steep learning curve associated with pedicle screw insertion.

Further investigations are required to determine whether and how ultrasound guidance will benefit pedicle screw insertion in spinal fusion surgery. Aside for providing a cheap, portable, nonionizing, and real-time imaging alternative, the ultrasonic guidance is a method that could be employed either as a stand-alone alternative or in combination with other techniques, such as CAS navigational systems. This

<table>
<thead>
<tr>
<th>Study or subcategory</th>
<th>Navigation, n/N</th>
<th>Non-navigation, n/N</th>
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<tr>
<td>Total (95% CI)</td>
<td>1,838</td>
<td>2,437</td>
<td></td>
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CAS, computer-assisted surgery; RR, relative risk; CI, confidence interval.

The forest plot that appears toward the right of the diagram shows the RR quantifying the accuracy associated with the placement of pedicle screws in comparative trials. Review: spine.meta; comparison: 02 accuracy; outcome: 01 screw within pedicle. Total events: 1,688 (navigation) and 2,064 (non-navigation); test for heterogeneity: $\chi^2=47.75$, degree of freedom $=13$ ($p<.00001$), and $I^2=72.8%$; test for overall effect: $Z=4.55$ ($p<.00001$). Reprinted with permission from Verma R. Functional outcome of computer-assisted spinal pedicle screw placement: a systematic review and meta-analysis of 23 studies including 5,992 pedicle screws. Eur Spine J 2010;19:370–5 [33].
would provide the surgeon with the option of using it only in the cases where necessary. The inexpensive nature of the device facilitates its use in less-privileged countries and finally because the device could be integrated with the toolkit that drills the first pilot hole, it offers the advantage of not changing the surgical workflow, that is the procedure remains the same and hence easier for a surgeon to adapt for using such devices.

Other imaging approaches

Other applicable bone-imaging techniques could include optical, optical/acoustic, and photothermal methods. Although promising aspects of these concepts are known, there are serious fundamental limitations. For example, Kaiplavil and Mandelis [51] reported a photothermal approach for bone diagnostics, with a shallow penetration in order of ~1 mm. Moreover, optical approaches, such as optical coherence tomography, are currently under academic investigations for guided pedicle screw placement (eg, http://www.marsinnovation.com/asset/7d-surgical/). However, the high absorption of an optical beam, especially in trabecular bone, makes the optical coherence tomography approach far less promising than pure ultrasound methods.

Fig. 11 illustrates the fact that optical approaches possess much lower penetration depths. Nonetheless, for applications involving shallow bone imaging, perhaps such as those of dentistry, optical methods offer far higher spatial resolutions than those achievable with ultrasound techniques.

Nonimaging techniques

Many nonimaging techniques such as electromyography (EMG), somatosensory-evoked potentials (SSEPs), and spinal cord monitoring have been used as a means for avoiding potential complications. However, the use of EMG, SSEP, and spinal cord monitoring requires the employment of extra-trained personnel for the surgery, and although implemented in many hospitals in western countries, the cost associated with that is high. Also, they often indicate the presence of a problem such as a nerve or spinal cord injury after it has occurred and, as a result, would not help reduce the risk of neurological injury. Finally, even with an optimal screw insertion, changes to EMGs or SSEPs could still arise from changes in spinal position after reduction of injury, deformity, or osteotomy; so, changes in these values may or may not be directly the representative of the changes in the pedicle screw insertion trajectory or fixation.

The idea of using the electrical impedance as a means for distinguishing cortical bone from cancellous bone or soft tissue is based on the fact that the impedance exhibited by biological tissue depends on the tissue structure. However, because the pilot hole is often filled with blood, its presence can cause misleading measurements and hence false detection. To make use of the concept of electrical characteristics of the tissue, while avoiding the previously mentioned challenge, a freehand drilling instrument (PediGuard; SpineVision, France) was designed to measure the electrical conductivity at the tip and to detect the occurrence of a cortical breach. Details of its features and its practical application have been described by Bolger et al. [52]. Similar to the potential ultrasonic-guided alternative, this device has been integrated into the tool that drills the first pilot hole. Measurements of the changes in conductivity are translated into visible and audio signals. Relative to other available techniques, the PediGuard is cheap, easy to learn, and fits well into the surgical workflow. As shown in Fig. 12, the device consists of a standard awl instrument with a hollow handle that accepts a built-in electronic printed circuit board and the electromagnetic field sensor at the tip of the awl. Depending on surgeon’s preference, the awl is available as either a reusable or a disposable instrument.

In general, electrophysiological monitoring techniques that are based on the conductivity experienced by electricity traveling from the pedicle screw through the bone and to the nearest nerve root face major limitations. First, the use of an anesthetic relaxant during the surgery limits neuromuscular reaction. Second, when a nerve is compressed, its stimulation threshold can be higher than normal, leading
to a false-negative finding. This is the case in most of the nerve decompression procedures. For example, Lesser et al. [53] described six patients who demonstrated postoperative neurological deficits despite unchanged SSEPs during intraoperative monitoring and [54] suggested that EMG monitoring does not significantly improve the reliability of screw placement. Because of the previously described reasons, these techniques might seem not as widely used these days as monitoring is more commonplace. However, the PediGuard device introduced here is a fairly recent toolkit from this category of technologies that has successfully found its way through operation rooms over the last few years.

Concluding remarks

The development and marketing of new and improved pedicle screw guidance technology are highly dependent on the industrial willingness to make the necessary financial investment. And this in turn depends both on the projected market and the cost savings that its use might offer. It is, therefore, appropriate to briefly consider both of these aspects. The current market for spinal implants and devices is estimated to be $2 billion per year with an annual growth rate of between 18% and 20% [25]. Between 1998 and 2008, the annual number of spinal fusion discharges in the United States increased significantly by 2.4-fold (137%) from 174,223 to 413,171 (p<.001) [55]. Spinal fusion surgery is expensive with an average hospital bill of more than $34,000. Because improved outcome and reduced recovery time could decrease this, there is considerable incentive to develop, manufacture, and market improved technology.

The current standard of pedicle screw placement for spinal fusion surgery relies on tactile feedback and hence experience-based judgment to differentiate between “soft” cancellous bone and the hard encapsulating cortical bone. If probe advancement becomes difficult (probe in contact with cortical bone) or too effortless (probe perforated cortical bone), the surgeon has to make a correction to an alternate direction. The very manual nature of this approach requires great surgical skill and can become quite time consuming (and variable), especially for complex surgery. The greatest risk is that improper drilling and placement of pedicle screws will place neural and vascular structures at risk and potentially negatively impact the surgical outcome of the procedure. As such, there may be an opportunity for the development of novel technologies that help make the procedure safer, reduce the average time required

Fig. 10. Successive cross-sectional ultrasonic images from the right pedicle of T12 vertebra. (Left) Borehole (red line) was purposefully created so that a breach of the lateral cortical wall nearly occurred. (Right) Selection of ten B-mode images: the ultrasound probe was first placed just outside the pedicle at position z=0 mm and then advanced through the pedicle in 1 mm increments. Reprinted with permission from Ultrasound Med Biol [39].
for surgery, and improve the surgical outcomes. Technological advancements have made their way through spine surgery guidance (navigation) and education through 3D simulators, haptic feedback systems, computer-assisted surgery, intraoperative fluoroscopy, and electrical impedance techniques. Other techniques, such as ultrasonic-guided pedicle screw insertion, are currently at the level of scientific investigation but have the promise for providing economical, portable, reliable, and real-time imaging without the hazard of ionizing radiation. Optical imaging approaches are also being investigated. Aside from the techniques listed or described in this review article, there are many other promising avenues of potential technologies.

These approaches include but are not limited to smart drills, injectable navigation sensors, stereolithography, and many other techniques.

The choice of method depends on several factors such as the type of surgical procedure, the patient’s history, and the surgeon’s experience and training. But because the technology is changing rapidly, there is no clear answer and best solution may turn out to be a combination of various techniques [26,56]. Listed subsequently are some of the issues that need to be considered:

1. It is important for all such surgical assistive toolkits to integrate easily within the surgical workflow to gain acceptance from both the surgeons and the regulatory authorities.
2. There needs to be a concrete evidence to support the claim of improvement in surgical outcomes. Unfortunately, there is an apparent lack of such investigations in the field of surgical bioengineering, and except in a few studies such as Podolsky et al. [12], Ughwanogho et al. [32], and Verma et al. [33], it appears that most companies and inventors have focused on producing assistive devices without supportive performance evaluation. Hence, before employing any such technique, it might be wise to investigate the performance of the device through marketing samples or by seeking advice from those with prior practical experience.
3. The difference between technologies that provide real-time navigation and guidance as opposed to techniques that confirm the appropriateness of already generated trajectories should be clearly understood. For example, the potential ultrasound-guided pedicle screw insertion requires the surgeon to create the guide hole in a conventional manner first and then to check from the cross-sectional ultrasound images as to whether the trajectory is appropriate. After that, using real-time, cross-sectional images, ultrasound can provide live guidance to the surgeon while perforating inside the pedicle. However, it still requires significant anatomical expertise to be able to create the initial starting hole without any assistive toolkits.
4. The CAS and fluoroscopy systems allow hole development under guidance and may be safer and more accurate (however more costly and radiating) than confirmatory navigation tools, but the incidence of adverse results may be too small in number or inaccurately reported in the studies to date to allow for an answer at present.

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