Chapter 2
Background Review

Many studies have demonstrated the need for accuracy in spinal fusion procedures as well as for improvements in education and training of residents. This chapter provides a review of current approaches for the training in orthopedic screw insertions for spinal fusion surgery together with a detailed review of the various approaches that can be used to provide the surgeon with navigational guidance for screw insertion as a means of improving the surgical outcome.

2.1 Educational Tools for Teaching Screw Insertion

Most current teaching techniques for orthopedic screw insertions involve "learning by doing" in the operating room. One possible manner to minimize the misplacement of pedicle screws in the long term is by 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 "Pedicle Screw Simulator" software packages, animations, and *iPhone* apps.

One of the first studies dates back to 2002 (Eftekhar et al. 2002) 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 (Rush et al. 2008) described the development and implementation of a simulator for minimally invasive screw insertion using accurate three-dimensional patient-specific computed tomography-based visualization of the pelvic and upper sacral anatomy.

This chapter is in part based on Manbachi et al. (2014).

A. Manbachi, *Towards Ultrasound-guided Spinal Fusion Surgery*,
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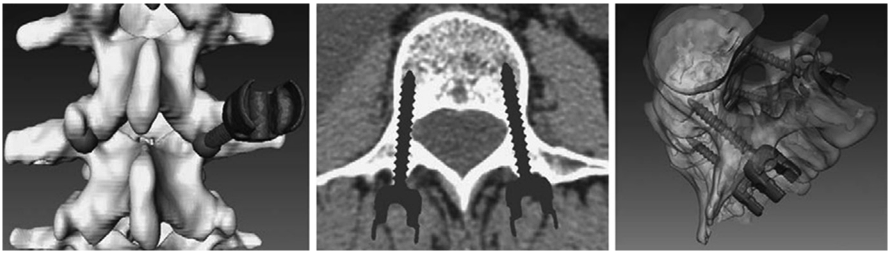


Fig. 2.1 (*Left*) Insertion of screw into an entry point on a 3-D patient-specific spine model, (*middle*) 2-D axial image of placed screws, and (*right*) 3-D translucent image of placed screws. Reproduced with permission from Podolsky et al. (2010)

More recently, aiming to familiarize the residents with the concept of the three-dimensional anatomy of the spine and to practice placement of virtual screws, a software simulator program was developed by Klein et al. (2009). In this program, the geometry of cadaver spines (based on 3-D models 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. It also enabled them to practice placement and insertion. The computer program was designed to assess the trainee's performance by analyzing the grip of the inserted screw. This was done by computing the bony purchase[1] 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 the trajectory of that screw by rotating and visualizing the insertion trajectories and inspecting the extent/direction of possible perforations (e.g., medial, lateral). Figure 2.1 shows some snapshots from the computer screen to illustrate various stages in the simulation process whose flowchart is shown in Fig. 2.2.

In a pilot study to investigate whether the above simulator would affect the training time, Podolsky et al. divided the residents into two groups (Podolsky et al. 2010): one of which made use of the above simulator of the pedicles prior to insertion, and a control group. Unfortunately, the data failed to show an improvement in successful pedicle screw placement with the addition of simulator training, perhaps due to the following reason: "*The 2 spines randomly assigned to the patient group were severely pathologic. In contrast*, *the 2 control group spines had relatively normal morphology and bone quality. As pedicle screw insertion is much more difficult in pathologic vertebrae*, *the low number of cadavers* ($N=4$) *and their bias very likely confounded the results*." However, in a survey of those using it and the faculty who supervised the stu-

[1] Purchase here means "grip," referring to the areas in which the screw is in contact with the cancellous bone.

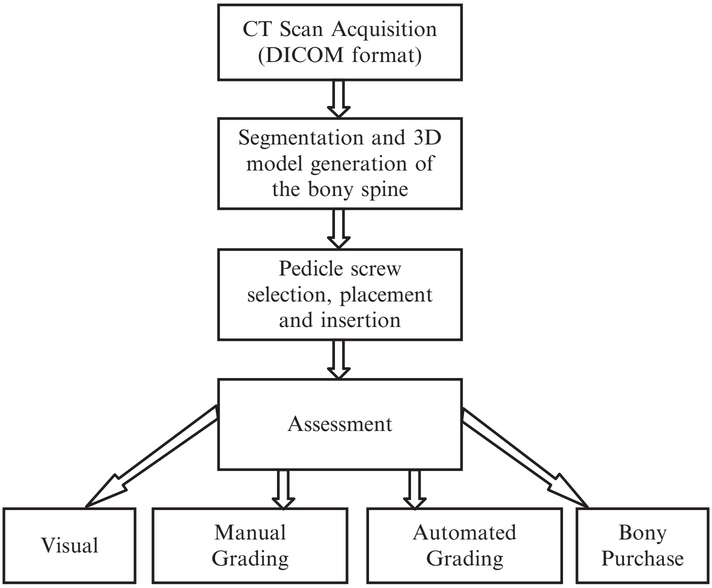


Fig. 2.2 Flowchart describing the process used in the simulator described in Klein et al. (2009): from computed tomography acquisition to outcome assessment. Reproduced with permission from Klein et al. (2009)

dents involved, it was unanimously concluded that practice on the simulator was very helpful in teaching the trainees about the complex, three-dimensional anatomy of the patient-specific spine vertebras 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. The user wears special glasses to see real-time 3-D images of a real patient's body taken from either a CT scan or MRI. Recently, the use of this as a training tool for placement of thoracic pedicle screws has been evaluated (Luciano et al. 2011). A visual example of such simulations can be found in Neurosurgery CNS (2011). 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 (GPS) 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 they could also be utilized in an educational 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 OR setting or when practicing on 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 utilized as educational toolkits.

2.2 Navigation Techniques for Guided Screw Insertion

While 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. Because of this, a number of guidance techniques have been employed in spinal fusion surgery to assist the surgeon in real time, and there is 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 in the following section.

2.2.1 Image-Guided Pedicle Screw Insertion

2.2.1.1 Intraoperative Fluoroscopy

Fluoroscopic images provide a two-dimensional X-ray projection, usually a lateral projection, of the spine (see Fig. 2.3). When taken during cannulation of the pedicle or placement of the pedicle screw, fluoroscopic images can provide the surgeon with important two-dimensional information regarding the accuracy of the approach in either the lateral or anteroposterior projection. However, this is 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. In 2008, Fu et al. reported a correct pedicle screw insertion rate of 93.2 % using fluoroscopy (Fu et al. 2008); whereas in the same year, Kotil et al. reported an incorrect pedicle screw insertion rate of only 5.6 % without using any fluoroscopic guidance (Kotil and Bilge 2008).

Since limited information is available through two-dimensional images, and in order to better assess the accuracy of pedicle screw placement, three-dimensional fluoroscopy was employed for spine surgery that utilizes several consecutive fluoroscopy images, taken from different angles, in order to reconstruct 2-D images in

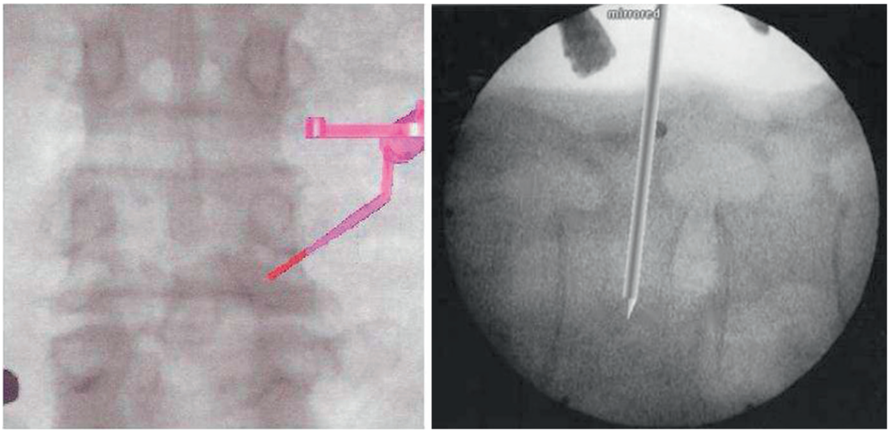


Fig. 2.3 Intraoperative fluoroscopy. (*Left*) Posterior projection of spine, providing a cross-sectional image of the pedicles. (*Right*) lateral projection, providing a lateral view of the pedicles. Both images reproduced, respectively, with permission from Fu et al. (2008) and Kim et al. (2008)

any plane. This is at the cost of even greater doses of ionizing radiation than standard fluoroscopy. Using this technique, Ito et al. (2008) reported a success rate of 97.2 % for cervical screw insertion and that none of the cortical bone perforations (2.8 %) were clinically significant.

2.2.1.2 Computer--Assisted Surgery

CAS, 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 (Schep et al. 2003).

In describing CAS methods, sometimes the analogy with GPS 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 roadmap, the surgeon sees a roadmap consisting of the pre- or intraoperatively obtained MR or CT image. Superimposed on this image is the position of the instrument as obtained from tracking sensors or transmitters attached to the instruments (see Cleary and Peters 2008; Peters and Cleary 2008). A number of different electromagnetic, acoustic (ultrasonic), and optical tracking sensors are commercially available. Figure 2.4 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 while

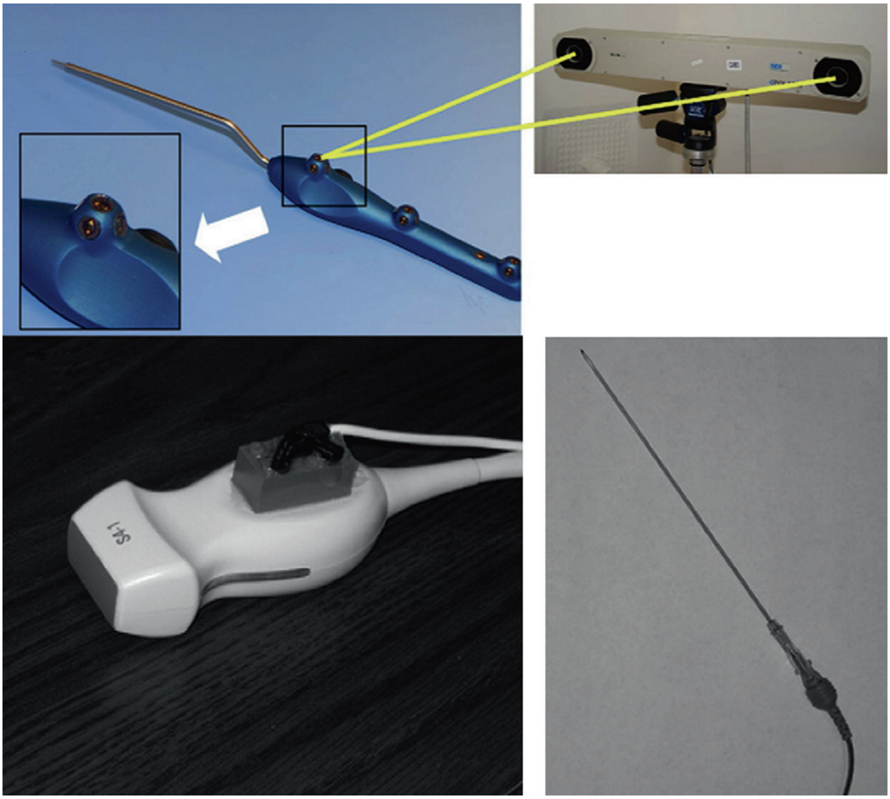


Fig. 2.4 Examples of (*top*) optical and (*bottom*, *left,* and *right*) electromagnetic tracking systems. (*Top*) Both lenses of the camera (Polaris; Northern Digital) must view at least three infrared light-emitting diodes on the probe handle (area shown within *black box*) to determine the location of the probe tip. Reproduced with permission from Glossop (2009). (*Bottom*, *left* and *right*) Electromagnetic marker attached to (*bottom left*) an ultrasound imaging transducer, and to (*bottom right*) a stylet-sheath combination. Reproduced with permission from Krücker et al. (2007)

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 (2009).

After establishing a relationship between the patient's anatomy and the preoperative or intraoperative images, the positions of the surgical instruments and the implants are displayed on a computer screen in relation to the patient's anatomy (Nolte et al. 1995a). For this purpose, an interactive computer system matches the coordinates of the preoperative images and the patient's anatomy (see DiGioia 1998; Vannier and Haller 1999). An example is shown in Fig. 2.5 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 surgery. As noted earlier, in 1995, Nolte et al. (1995a, b)

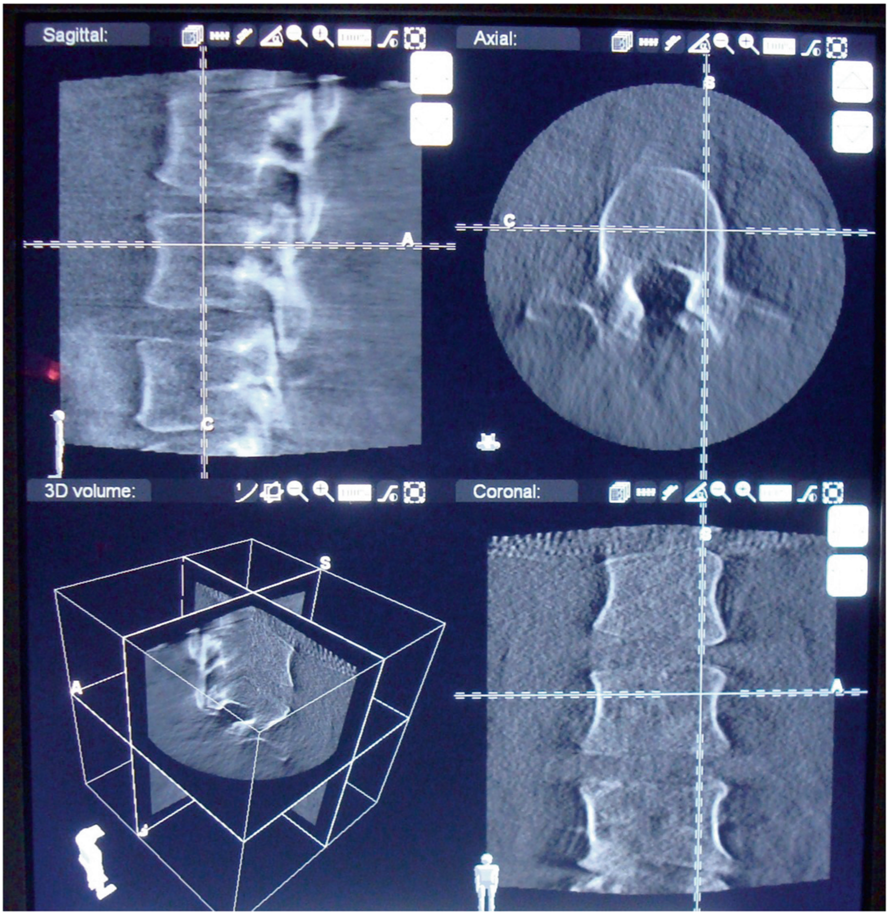


Fig. 2.5 A sample display from the CAS navigation systems as seen by the surgeon. (*Top left*) Sagittal; (*top right*) axial; (*lower right*) coronal; (*lower left*) three-dimensional image of the spine

described an in vitro 3-D scheme in which they demonstrated accurate drilling of pedicle holes in the lumbar vertebrae. The rationale for using an alternative technology was the need to improve the 10–40 % 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. (1998). Their technique combined CT imaging with intraoperative CAS navigation. Following its introduction into spine surgery, CAS was applied in hip, knee, and skeletal trauma surgery.

So far, more than a few hundred CAS systems have been developed by various universities and research institutes, often in collaboration with industry, though some of the features still remain in the experimental stage. Currently, some of the most widely used commercially available systems approved for

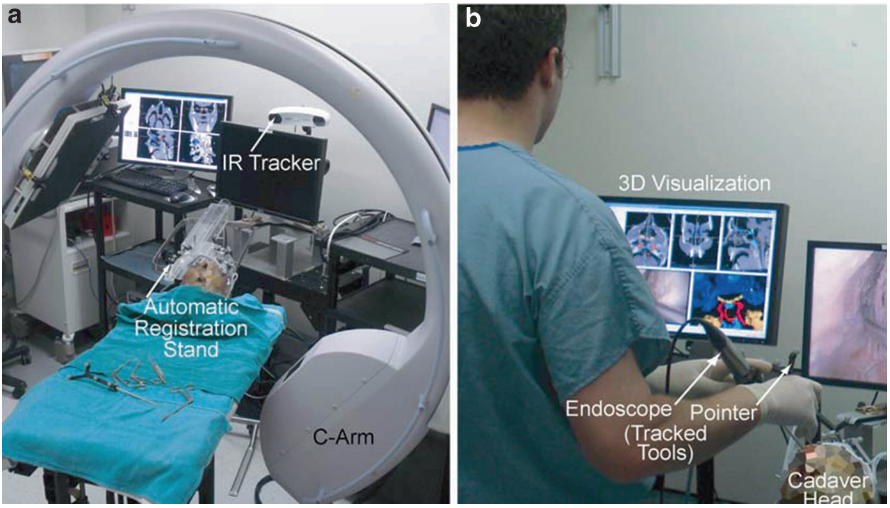


Fig. 2.6 (**a**) Example of a CAS system incorporating a C-arm CT system, optical tool tracking and automatic image-to-world registration during a cadaveric surgical procedure. (**b**) Real-time tracking of surgical pointer and rigid endoscope within intraoperative setting of a minimally invasive approach on a surgical cadaveric model. Reproduced with permission from Daly et al. (2010)

clinical use are: *ARCADIS® Orbic 3-D* (SIEMENS, Germany), *Ziehm Imaging* mobile C-arm technology (Ziehm Imaging, Germany), *StealthStation* O-Arm (Medtronic, USA), *eNLight* and *NavSuite* (Stryker Corporation, USA), and *VectorVision* (Brainlab, Germany). Figure 2.6 shows a sample 3-D C-arm technology system.

Advantages and disadvantages of CAS: Since 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.

Advantages: Several potential advantages can be identified.

1. *Surgical Changes*: The potential exists for easier pre-surgical planning, possible improved patient outcomes, less invasive operations, and more accurate placement of pedicle screws.
2. *Cost-Effectiveness*: In a study with 100 patients (total of 446 pedicle screws), it was reported (Watkins et al. 2010) that with image-guided pedicle screw insertion the surgical time was reduced and the rate of revision surgery was reduced. Using a CAS system costing just under $500,000, they achieved cost savings just over $70,000 for 100 cases (based on $93/min), and a decreased revision rate. A busy institution could perform 500–1000 spinal fusion operations with a single navigation system per year.
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.

Disadvantages: Several potential disadvantages of 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 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 3-D.
2. *Marker Positions*: If, by mistake, any of the markers are hit during the surgical procedure, the whole process of registration needs to be redone, making the procedure lengthier and hence more expensive.
3. *Radiation*: Ionizing radiation still remains a concern for surgical 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 the operating area.
5. *Tracking Precision*: Optical systems have a precision of around 0.3 mm (Nafis et al. 2006) and the electromagnetic systems possess precisions (RMS error) in the range of 0.5–0.9 mm (Wiles et al. 2004; Linte et al. 2010). Such errors are comparable to 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 of these systems are given in Frantz et al. (2004) and Chap. 2 of Peters and Cleary (2008). 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 (Watkins et al. 2010). Consequently, in addition to the time needed by the technicians to operate the systems, the money saved in reduced surgery times may be offset by the depreciation and maintenance costs (Watkins et al. 2010).

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

Table 2.1 Comparison of screw classification and intraoperative removal rate

Placement	O-arm navigated (%)	Non-navigated (%)	*P*-value
Optimal	74	42	<0.001
Acceptable	23	49	<0.001
Potentially unsafe	3	9	<0.001
Removed[a]	0.6	4.9	<0.003

Reproduced with permission from Rajasekaran et al. (2007)

[a]These screws were removed intraoperatively due to unsafe position

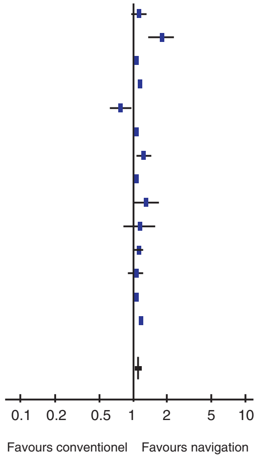
the accuracy with which pedicle screws are placed for a wide variety of conditions. For example, Rajasekaran et al. conducted a study to determine the effectiveness of CAS navigation in cases of thoracic deformity (Rajasekaran et al. 2007). Based on these results, they concluded that the use of CAS navigation techniques provided significant advantages in reducing the occurrence and severity of pedicle breaches. In another recent study (Ughwanogho et al. 2011), the outcome of pedicle screw placements with adolescent idiopathic scoliosis (AIS) 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 2.1. They concluded from these results that when navigation was used, significantly fewer potentially unsafe screws were placed as compared to 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. This type of improvement has been hypothesized to lead to higher fusion rates and lower hardware failure rates (Verma et al. 2010).

Verma et al. have reported a review of 23 separate prior studies from 1997 to 2007, including nearly 6000 pedicle screws (Verma et al. 2010). Table 2.2 illustrates some of the details of their analysis. As seen on the fourth column (RR: relative risk), 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 high statistical significance ($p<0.00001$), suggesting that CAS navigation can definitely help improve the placement of pedicle screws. 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 (i.e., strength of statistical association) suggested that CAS navigation was favored, however, the results were not statistically significant ($p=0.07$). Some of the studies included in their analysis had no neurological injuries in either group. This raised the question as to whether such injuries had been studied before, and as a result there appeared to be insufficient data in the literature to infer a conclusion in terms of fusion rate, pain relief, and health outcome scores. Thus, although many papers suggest that CAS navigation can improve the quality of pedicle screw placement, the evidence is still incomplete in terms of overall patient outcomes.

Table 2.2 Results presented in Verma et al. (2010) indicate that CAS navigation helps in more accurate placement of pedicle screws

Review: Spine.meta
Comparison: 02 Accuracy
Outcome: 01 Screw within pedicle

Study or sub-category	Navigation n/N	Non-navigation n/N	RR (random) 95% CI
Laine 1997	133/139	30/35	
Merloz 1998	57/64	32/64	
Amiot 2000	228/244	461/544	
Laine 2000	267/277	182/219	
Arand 2001	45/72	70/86	
Kotani 2003	77/78	624/669	
Schnake 2004	177/211	77/113	
Richter 2005	162/167	85/93	
Seller 2005	33/36	17/24	
Ito 2007	20/25	19/27	
Kotani 2007	56/57	72/81	
Lee 2007	69/86	83/108	
Merloz 2007	133/140	120/138	
Rajsekaran 2007	231/242	192/236	
Total (95% CI)	1838	2437	



Total events: 1688 (Navigation), 2064 (Non-navigation)
Test for heterogeneity: Chi^2 = 47.75, df = 13 (P <0.00001), I^2 = 72.8%
Test for overall effect: Z = 4.55 (P < 0.00001)

The forest plot appeared toward the right of the diagram, shows the relative risk (RR) quantifying the accuracy associated with the placement of pedicle screws in comparative trials. The term "n/N" embodies the ratio of the successful placements whether done by navigation or by non-navigation means. Reproduced with permission from Verma et al. (2010)

2.2.1.3 Ultrasonic-Guided Pedicle Screw Insertion

A potential alternative method for ensuring proper pedicle screw placement is by ultrasound image guidance using a miniature ultrasound probe that could be inserted within the pedicle's guide hole, similar to that used for intravascular imaging. But in this case the 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 (Sproul 2003; Goodwin 2005). However, experimental evidence as to their practicality is currently limited to a few recent publications by academic research groups in Canada (Aly et al. 2011; Mujagić et al. 2008; Lou et al. 2010), as well as in the US (Raphael et al. 2010; Chang et al. 2011) and Germany (Kantelhardt et al. 2009a, b, 2010). A brief description and discussion of these reports is presented in this section.

With the IVUS (IntraVascular UltraSound) being the standard of care in cardiovascular diagnostic imaging, there is a major difference between IVUS and that of bone sonography. The major challenge of ultrasound imaging within bone concerns high signal attenuation, which increases sharply with higher transmit frequencies (Cobbold 2007). This implies that while IVUS imaging is based on successful signal transmission through soft tissue at relatively high frequencies (>20 MHz), ultrasound imaging of trabecular bone has a far higher attenuation over the same frequency range (Laugier and Haïat 2011), causing the returned signal to be lost in the background noise. Consequently, much lower frequencies (a few MHz) must be used leading to considerable loss in resolution.

Despite these difficulties, some progress has been reported. For example, Kantelhardt et al. (2009a, b, 2010) demonstrated intra-pedicular imaging using a 20 MHz intravascular ultrasound probe catheter. The catheter was placed into the guide hole and used to obtain cross-sectional images from within the pedicle. Due to the high frequency, the attenuation of the ultrasound beam within the first few millimeters of traveling inside the trabecular bone was near total. This prevented the ultrasound beam from penetrating any significant distance into the trabecular bone so that the cortical wall could not be imaged.

Other fundamental studies (Mujagić et al. 2007, 2008) have investigated the speed of propagation and attenuation of ultrasound in cancellous bone—key factors in designing a suitable transducer. It appears that one of these papers (Mujagic et al. 2007) was the first to describe the transducer specifically designed for imaging from within a pedicle bore hole. This transducer, shown in Fig. 2.7, was subsequently used by Aly et al. (2011) for producing B-mode images from human pedicles in vitro. Similar work has also been reported by Raphael et al. (2010) and Chang et al. (2011), though without the images. Although a number of necessary improvements were suggested, these studies have provided good evidence that with further development, the use of ultrasound could become a viable trajectory verification

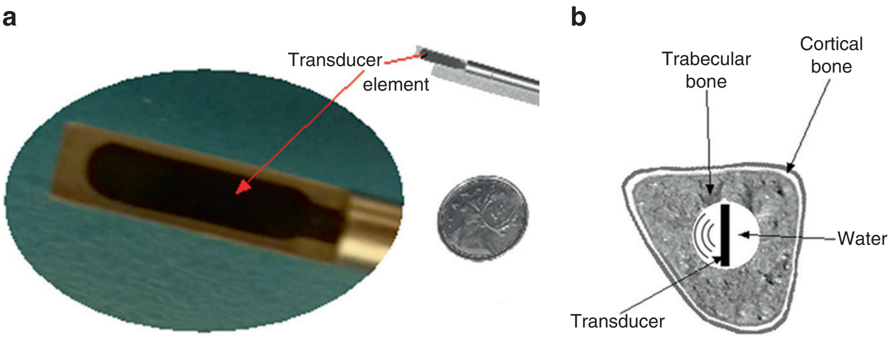


Fig. 2.7 (**a**) Ultrasonic probe prototype with a transducer at its tip. (**b**) Cross-sectional sketch showing the rotatable transducer inserted in a pedicle borehole for obtaining a B-mode image. Reproduced with permission from Aly et al. (2011)

method. Aly et al. (2011) demonstrated that frequencies in the range of 1–3 MHz were the best compromise between spatial resolution and adequate depth of penetration, and that the resultant acoustic echoes provided distinguishable features sufficient for identification of boundaries of the cortical bone encapsulating the porous cancellous bone. As illustrated in Fig. 2.7, the transducer consisted of a single rectangular element that was mounted on a probe designed to be inserted within a pedicle borehole. By rotating the probe and recording the reflected signal for each angle, B-mode images could be created that could show the dependence of the cortical-trabecular edge boundary on the probe angle. Sample results are illustrated in Fig. 2.8 as reported in Aly et al. (2011).

In order for the idea of ultrasonic guidance of pedicle screw insertion to transfer from the scientific research lab bench to the clinic, an area of potential need is to develop rotational and three-dimensional scanners that could provide real-time circumferential feedback to the surgeon at each given cross section of the pedicle bone. Due to the nature of pedicle anatomy, an appropriate ultrasonic transducer might need to include not only side-viewing capacity but also a forward-viewing feature (Lee and Benkeser 1991; Wang et al. 2001).

Further investigations are required to determine whether and how ultrasound guidance will benefit pedicle screw insertion in spinal fusion surgery. Aside from providing an inexpensive, portable, non-ionizing, and real-time imaging alternative, 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 would provide the surgeon with the option of using it only in the cases where necessary, and the inexpensive nature of the device facilitates its use in less-privileged countries. Finally, since the device could be integrated with the toolkit that drills the first pilot hole, it offers the advantage of not changing the surgical workflow, i.e., the procedure remains the same and hence easier for a surgeon to employ such devices.

2.2.1.4 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 (2011) reported a photothermal approach for bone diagnostics, with a shallow penetration of the order of ~1 mm. Moreover, optical approaches, such as Optical Coherence Tomography (OCT), are currently under academic investigations and commercial developments for guided pedicle screw placement (e.g., http://www.7dsurgical.com). Figure 2.9 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.

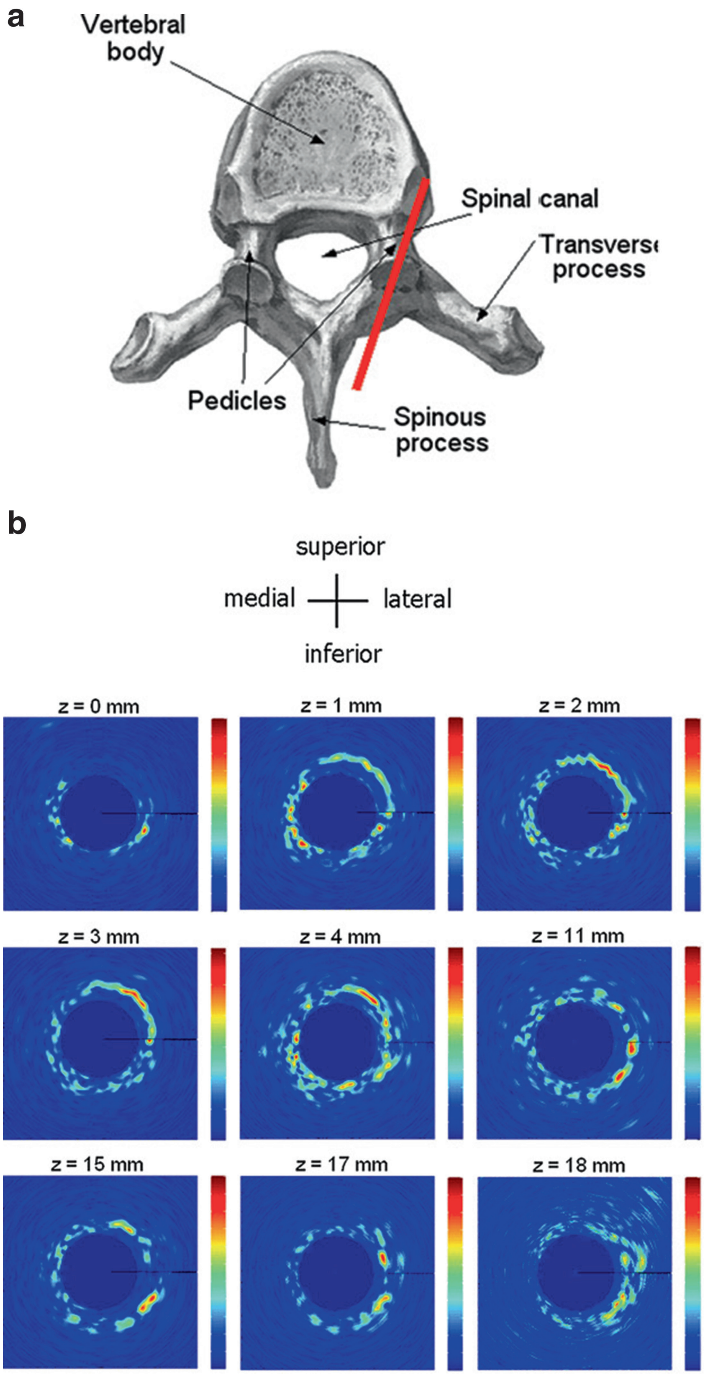


Fig. 2.8 Successive cross-sectional ultrasonic images from the right pedicle of T12 vertebra, as previously reported in Aly et al. (2011). (**a**) Bore hole (*red line*) was deliberately created so that a breach of the lateral cortical wall nearly occurred. (**b**) Selection of 9 B-mode images: The ultrasound probe was first placed just outside the pedicle at position $z=0$ mm, and then advanced through the pedicle in 1 mm increments. Reproduced with permission from Aly et al. (2011)

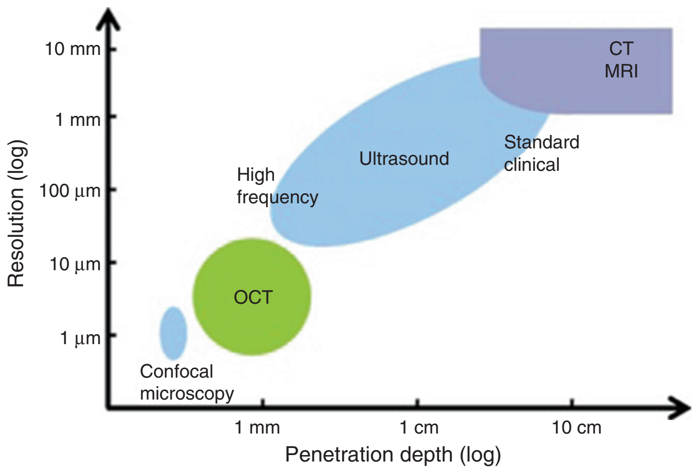


Fig. 2.9 Penetration depth and resolution of various imaging approaches (Medizinische Universitat Wien 2015)

2.2.2 Non-imaging Techniques

Many non-imaging techniques such as electromyography (EMG), somatosensory-evoked potentials (SSEPs), and spinal cord monitoring have been utilized as a means for avoiding potential complications. However, the use of EMG, SSEP, and spinal cord monitoring requires 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 injury. Finally, even with an optimal screw insertion, changes to EMGs or SSEPs could still arise from changes in spatial 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, since the pilot hole is often filled with blood, its presence can cause misleading measurements, and hence potential false detection of the region. In order to make use of the concept of electrical characteristics of the tissue, while avoiding the above-mentioned challenge, a freehand drilling instrument (PediGuard™, Spineguard, 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. (2007). Similar to the ultrasonic-guided

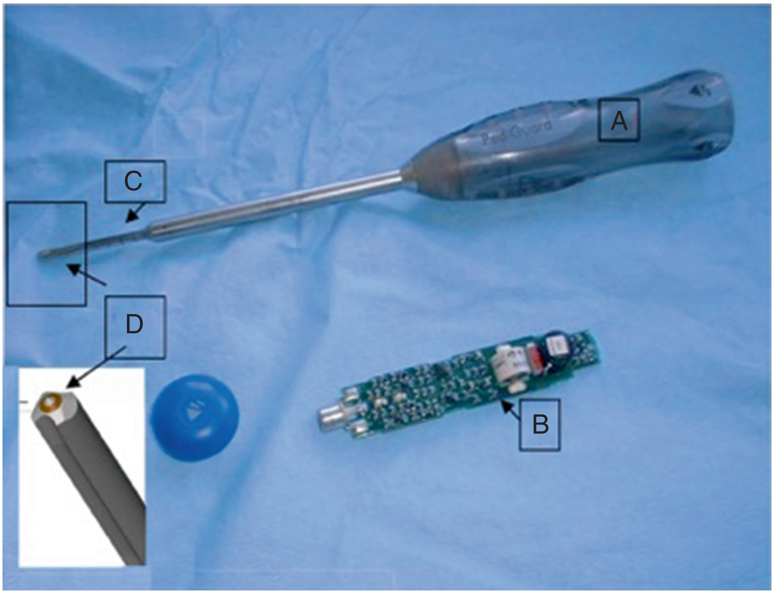


Fig. 2.10 Example of an electrical impedance probe. (**a**) Assembled probe. (**b**) Disposable circuit board is inserted into the handle. (**c**) Lower extremity of the probe containing the electromagnetic sensor (**d**) electrodes at the tip. Reproduced with permission from Bolger et al. (2007)

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 inexpensive, easy to learn, and fits well into the surgical workflow. As shown in Fig. 2.10, 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 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. (1986) have described six patients who demonstrated postoperative neurological deficits despite unchanged somatosensory-evoked potentials during intraoperative monitoring (see also Reidy et al. 2001).

2.3 Concluding Remarks

The development and marketing of new and improved pedicle screw guidance technology is highly dependent on the industrial willingness to make the necessary financial investment. 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 $2 billion per year with an annual growth rate of between 18 and 20 % (McWilliams 2011; Solomon 2010; Constance 2011; Devadason et al. 2013). Between 1998 and 2008, the annual number of spinal fusion discharges increased significantly by 2.4-fold (137 %) from 174,223 to 413,171 ($p < 0.001$) (Rajaee et al. 2011). Spinal fusion surgery is expensive with an average hospital bill of more than $34,000. Since improved outcome and reduced recovery time could decrease this, there is considerable incentive to develop, manufacture, and market improved technology.

The current standard of care for spinal fusion surgery relies on tactile feedback and experience-based judgment to differentiate between "soft" cancellous bone and the tougher 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 significantly impact the surgical outcome of the procedure. As such, there is a real opportunity for the development of novel technologies that help standardize the procedure, reduce the average time required for surgery, and improve the surgical outcomes. Technological advancements have made their way through spine surgery guidance (navigation) and education through three-dimensional simulators, Computer Assistance Surgery, Intraoperative Fluoroscopy, and electrical impedance techniques. Other techniques such as ultrasonic-guided pedicle screw insertion are currently at the level of scientific investigation and seem to be promising in terms of providing an inexpensive, portable, reliable and real-time, non-ionizing imaging. Optical imaging approaches are also being investigated. Perhaps, various combinations of some of these techniques would be the best solution, depending on the specific surgical situation (e.g., see Yan et al. 2011). It is important for all such image-guided toolkits to integrate easily within surgical workflows to gain acceptance from both surgeons and the regulatory authorities.

2.4 Preliminary Transducer Design Specifications

Among the many techniques described above, the primary focus of this thesis concerns the potential use of ultrasound guidance for pedicle screw insertion. As mentioned earlier, in order for such an idea to gain acceptance from the surgical community, an area of potential improvement is the development of radial arrays, eliminating the need for rotation of a single element transducer and hence preserving the surgical workflow. In this way, the surgical workflow could be preserved and real-time images could be obtained for guiding insertion. Figure 2.11 illustrates this concept. Although the overall idea of ultrasound use for pedicle screw navigation was patented a number of years ago (Goodwin 2005), the use of a radial imaging array for this purpose has not been fully explored. As a result, the main objective of this thesis is to fabricate and investigate the suitability of such an array for the above-described application. If successful, using this technology, the surgeon can make simultaneous corrections and adjustments to the insertion trajectory.

Presented below is a list of tentative design specifications that we believe to be important in the fabrication of the prototype array described in this book:

Low frequency ultrasound is necessary in order to overcome the high amount of attenuation in the trabecular bone and in order to increase the signal's penetration depth. However, such a low frequency also requires a trade-off, as it implies a poor resolution. Earlier studies (Aly et al. 2011; Mujagić et al. 2008) studied this trade-off. These suggested that the center frequency should be around 2 MHz with a bandwidth sufficient to include frequencies from 1 to 3 MHz. As a result, our aim was to fabricate an array with a centre frequency of 2 MHz having a 100 % bandwidth. This said, after careful consideration of the procedure and surveying a number of spine surgeons, in particular Dr. Ginsberg, it was found out that the device is not really expected to provide images with superb resolution. In fact, what is needed is a confirmation on whether the created guide hole is in the middle of the pedicle's cross section or whether it is close to one side.

Another constraint was the fact that the maximum diameter of the pedicle guide hole cannot be larger than 4 mm. As a result, the diameter of the array needs to be no larger than 4 mm.

Moreover, prior studies (e.g., Aly et al. 2011) have modeled a 5 mm thickness for the trabecular bone, from the inner wall of the guide hole to the cortical bone surrounding the pedicle. This in turn suggests that our array needs to be focused at approximately 7 mm from the center of the bore hole.

Finally, from a clinical perspective, the array needs to be sterilizable, possessing enough mechanical strength to withstand orthopedic procedures and the ultrasound array is intended to be incorporated with the surgical toolkit, in order to preserve the surgical workflow and to protect the array from scratches due to bone.

Further details of the specifications are presented in Table 2.3 and Fig. 2.12.

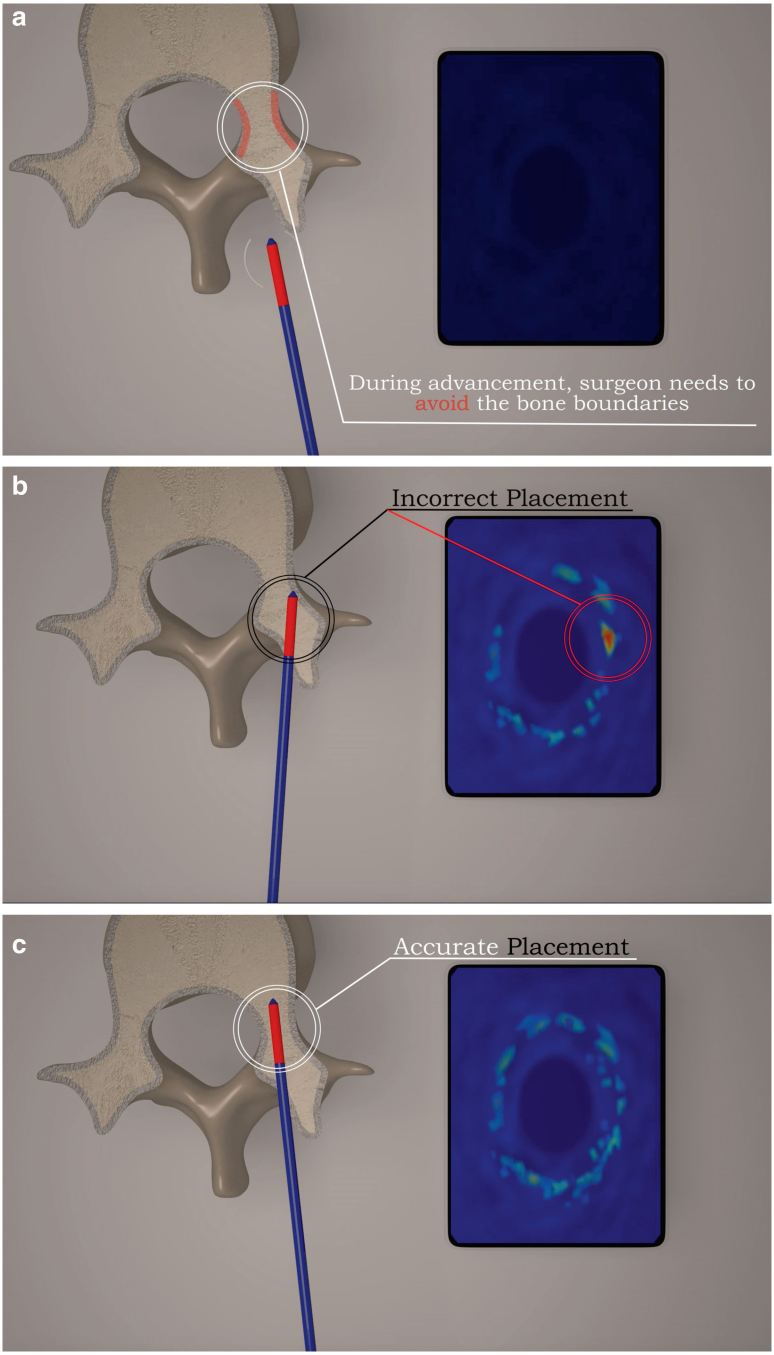


Fig. 2.11 An Illustration for the concept of radial ultrasound array, incorporated into the surgical toolkit, for the purposes of providing real-time images from within the pedicle bone. (**a**) Pedicle cortical boundaries and the ultrasound array close to the tip of the surgical toolkit, employed to create the guide hole; (**b**) sample incorrect trajectory and the corresponding envisioned ultrasound image; and (**c**) sample acceptable trajectory and the corresponding envisioned ultrasound image. These illustrations were generated by *MirroVisual Inc.* under contract to the University of Toronto

Table 2.3 Preliminary transducer design specifications

Parameter	Value	Notes or references
Centre frequency	2 MHz	Aly et al. (2011), Mujagić et al. (2007, 2008)
Bandwidth	Ideally 1–3 MHz	Aly et al. (2011), Mujagić et al. (2007, 2008)
Imaging mode	B-mode	
Excitation voltage	300 Vpp	Aly et al. (2011)
Device maximum diameter	4 mm	Pedicle's guide hole
Acceptable precision (axial resolution)	1 mm	Based on consulting spine surgeons
Depth of penetration within trabecular bone	10 mm (round-trip)	Aly et al. (2011), Mujagic et al. (2007)
Speed of sound in the trabecular bone	1540 m/s	Aly et al. (2011), Mujagić et al. (2007, 2008)
Attenuation in the trabecular bone	15–35 dB/cm at 2 MHz	Aly et al. (2011), Mujagić et al. (2007, 2008)
Estimated focal distance from the center of the radial array (based on lumbar spine)	7 mm	Aly et al. (2011), Mujagić et al. (2008)
Sterilizability	e.g., Autoclave Process (placed for 20 min at 121 °C under 100 kPa pressure)	
Strength of the probe	Sufficient for orthopedic applications	
Incorporation of the array with the device	Array to fit into the surgical toolkit	In order to prevent from scratches due to bone
Number of array elements	TBD	Needs modeling

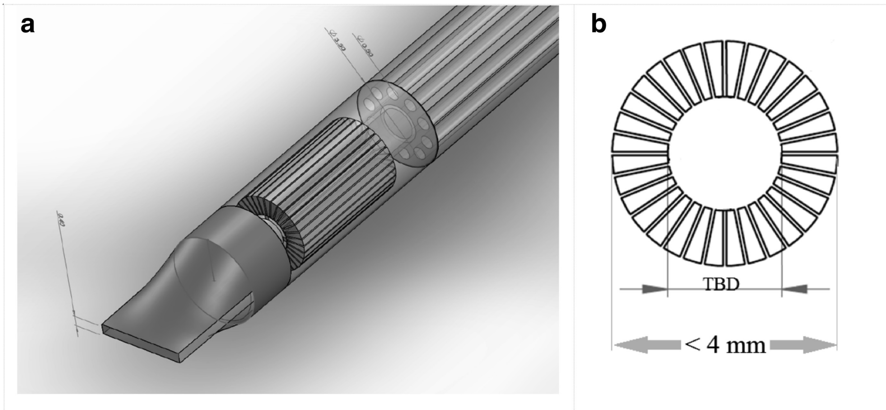


Fig. 2.12 The primary objective of this thesis is to fabricate the proposed device, in order to examine its suitability for providing real-time navigation in pedicle screw insertion. (**a**) Perspective view of the ultrasound transducer array probe incorporated into the surgical toolkit. (**b**) Cross section view of the array

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