

Appendix A

Patent and Literature Search

AccuSpine

An Explanation

In the course of our patent search, we used several means to expose as much of the landscape as possible. Firstly, inventors and assignees were comprehensively investigated to trace the lineage of the patent and locate any immediately related patents. Oftentimes, this provided insight as to probe-related patent litigation and common impediments such as rationale for rejection. Secondly, particular attention was paid to patent citations both for and of the patents we found, including those listed previously. Numerous citations were analyzed in each of the four pathways previously listed. The majority were independent implementations of technology. The most relevant examples follow:

Ultrasound: 6299580, 6579244, 6592520; Imaging: 7235076, 8050769, 8277461; Optical: 6179611, 6579244, 6934576

We note an absence of patents pertaining to mechanical and electric solutions for the pedicle probe. There were no patents whatsoever for an electromechanical system such as that described for our device. Numerous patents exist for bone drills, though we found it difficult to locate applicable technology for use in a probe.

It became clear that, across the board, there is a great deal of patent potential in integrating otherwise external solutions into the pedicle probe.

Patent Search

Leading up to 1990, patents relevant to pedicle probes are extremely sparse. The extent of this is so as to provoke the question of semantics—what alternate names are there to “pedicle probe” and was there some paradigm shift of terminology in the field of spinal fixation? Patent 5102412 dating from 1990 seems to indicate at the very least that “pedicle probe” is the proper terminology, but references seem to cease prior to this point. Searches using alternating keywords such as “gauge”, “finder”, “seeker”, “tool”, and “depth” also fall short of producing other references, as does use of these terms in conjunction with “bone”. This may merit closer examination of the history of the device itself.

Assuming this constitutes an accurate representation of the patent landscape, this should be construed as an overall negative. The bulk of patents relative to pedicle probes falls within a legally potent timeframe, and though there are not necessarily a multitude of threatening patents, none of them can be disregarded either.

This being said, there are still a number of patents which should be noted for their relevancy to other pedicle probe solutions. Namely, a slew of nerve location/stimulation devices appear around 1970-1990, and constitute foundation work and citations for systems such as Medtronic’s

Nim-Spine. Examples are 4962766 (Nerve locator and stimulator, 1990), 3830226 (Variable output nerve locator, 1974). Many of these are heavily referenced but also very specific in the scope of their claims.

An interesting note is that the definitive patent for the pedicle screw, 4946458, was published in 1990. Its priority date of 1986 suggests that the idea likely did not predate 1980. For reasons passing understanding, 1993 seems to be the boom year for spinal fixation. Two method patents: 5196015 (Procedure for spinal pedicle screw insertion, 3/1993) and 5181917 (System and method for instrumentation of the spine in the treatment of spinal deformities, 1/1993), were published detailing screw placement and spinal fixation respectively. Their scope is limited by technical specifics, yet present the fairly rare instance of patenting any surgical procedure. In particular, 5196015 specifies the use of intraoperative screw stimulation, an early application of checking for proper placement.

A fascinating case study presents itself with 5242443 (Percutaneous fixation of vertebrae, 9/1993). This is a very well-written patent that encompasses a broad range of surgical techniques related to pedicle screw placement. This is the first patent that specifically mentions procedures for properly inserting and guiding the pedicle probe, namely fluoroscopy. Ordinarily, it would still be in effect (just barely, and it would not impact work on a pedicle probe specifically), but this patent lapsed by reason of non-payment of fees when its holder went bankrupt.

The first patent that might be defined as a pedicle probe is 5242448 (Bone probe, 9/1993). Though mentions of a pedicle probe predate this device, it seems that a pedicle probe, so far as a rod mounted on a grip is concerned, might have been too self-evident to necessitate or allow for patent publication. The only notable claim of this patent is to a “super-elastic” shaft, meaning some flexible alloy as nitinol. Poorly conceptualized and poorly written, this patent is more of a historical footnote than anything else.

The designation of “bone probe” continues in **5361766** (Quick release bone probe and x-ray marker, 11/1994). A pedicle probe in all but name, this design claim is relegated to use in the pedicle. In theory, it is designed so that once the probe is positioned, the surgeon engages a spring-fired release mechanism so that the handle disengages from the shaft of the probe. Fluoroscopy is then used, and the disengaged shaft thus helps visualize the placement. This eliminates the need for inserting a marker into the probed hole. In practice, this seems to fill a need that either never existed or at the very least, no longer exists. However, like any design patent, utility is a specified quantity. In this case, the claim for a quick release system is described as:

“a handle having a gripping means and further including fastening means for selectively engaging the proximal end of the probe, said fastening means including spring means which allows for quick release of the probe”

This is a fairly broad claim, and the other sub-components of the first claim are all very typical to pedicle probes. In short, this patent, though otherwise unordinary, is about the closest to patenting a pedicle probe that makes sense. If not for the quick-release mechanism, most modern pedicle probes would infringe on this patent in some way. This is one to watch if we present

some mechanical disengagement solution. From the perspective of the inventors, this must have seemed like a home run.

Another important yet generally irrelevant patent is 5360431 (Transpedicular screw system and method of use, 11/1994). It is arguably a defining patent in the spinal fusion landscape, and broadly encompasses hardware installed in the course of spinal fixation.

The first patent for a pedicle probe is 5928243 (Pedicle probe and depth gauge, 1999). Incidentally, its claims are for a “bony probe” and do not specify use within the pedicle. The device encompasses a means of determining the depth of the probe penetration by having the probe tip mounted to a sliding shaft with depth markers along the shaft. The operation is described somewhat like a hypodermic needle, whereby the surgeon pushes down the sliding component into position, and reads the depth gauge. Nonetheless, the claims are simply for a sliding shaft that can be extended and retracted, which may also prove troublesome to an automatic retraction mechanism. An addendum is that the patent is written such that this internal sliding shaft is removable. **This patent requires further analysis and reading.** Fortunately, the patent lapsed by reason of non-payment of fees in 2011, even though it is held by Zimmer Spine which is still active (though it appears they may have restructured).

The next patent for a pedicle probe is 6855105 (Endoscopic pedicle probe, 2/2005). The claims are for a fairly archetypal pedicle probe with the exception of a distally-mounted camera wired through a hollow pedicle shaft. There are numerous additional claims for a number of alternatives so far as the camera placement and installation, but on the whole, the “endoscopic” nature of the probe is the defining difference. Given knowledge of the pedicle anatomy, particularly during a procedure, the idea seems almost numbingly incompetent. Nonetheless, it presents no anticipated challenge.

A number of systems for guiding and determining pedicle probe position emerge in the 2000s. Though these are external to the actin of the probe, they nonetheless represent solutions to malposition and breaching.

One highly relevant early manifestation is **6579244** (Intraosteal ultrasound during surgical implantation, 07/2003). This method patent claims guidance and placement of an implant within a region characterized by differences in acoustic impedance within a transducer/receiver system. It is broadly written and among other things, essentially encompasses any ultrasound-based technique that can differentiate between cortical bone and cancellous bone. Without a doubt, this patent is an effective roadblock in any efforts involving acoustic-based differentiation of bone types or densities. That said, its assignee, Cutting Edge Surgical Inc, appears to be defunct, but the maintenance fee continues to be paid, suggesting that this has either been licensed or is being used as a sleeper patent. Its inventor, Mark R. Goodwin, continues to be active in patenting, particularly such pedicle probing systems.

A fairly vague tracking system is described in 6741883 (Audible feedback from positional guidance systems, 3/2004). The claims are for a surgical instrument tracking system whereby the position of the surgical instrument relative to a predetermined marker is relayed by means of audible feedback. There is little of concern about this poorly-conceived patent.

The modern system of computer-assisted surgery using intra-operative fluoroscopy seems to be established in 6697664 (Computer assisted targeting device for use in orthopaedic surgery, 02/2004). This patent claims the entirety of the system that enables the imaging-based approach: superposition of images of surgical instruments and the body. With 44 claims, this is an exceptionally well-written and powerful patent, not surprisingly issued to GE Medical Systems. Any approach to solving pedicle breaching that involves improving or modifying current imaging paradigms will need to go through this patent first. This patent does not cover any surgical instruments or devices beyond the calibration/tracking hardware which would be added to such instruments and devices.

It is important to note that GE owns numerous other powerful patents in the instrument-tracking landscape.

There is a fairly unorthodox system of little note described in 6342056 (Surgical drill guide and method for using the same, 1/2002). Though its claims do not specifically reference the pedicle, the invention is offered as an alternative to current pedicle probe techniques. It claims a drill guide mounted in some maneuvering element, with the guide approaching the pedicle in a different plane than the drill.

A side note is made for 6638281 (Gravity dependent pedicle screw tap hole guide, 10/2003). This design patent claims a drill guide replacing the pedicle probe which can be attached to a drill and provides indication of axial changes in the direction of the guide. This is of little concern.

Before proceeding any further, it is important to make note of two particular probe-based solutions which have been treadmilling through the patent cycle for some time. These patent applications have no legal ground, but should still be kept in mind. It should also be noted that most applications' claims are often misleading in their breadth. The first is WO 2006132946 (Pedicle impedance measuring probe, 06/2006). The first visible disclosure of an electrical-impedance system, this would likely have conflicted with Spineguard's Pediguard. The claim is effectively for a pedicle probe with any impedance wires. It appears that this patent is no longer being pursued, as no action has been taken regarding it since 2007. A more disconcerting patent application is EP 2442731 (Spinal probe with tactile force feedback and pedicle breach prediction, 4/2012). This is the third iteration of a nearly-identical series of patents claiming a pedicle probe with a force transducer. The claims encompass any algorithmic or computational approach to predicting or interpreting the output of said force transducer. Each iteration seems to be slightly more sane and likely than the last, and at this pace, this patent should likely be issued by the end of the century. Fortunately, no claim was ever made to any mechanical alterations to the pedicle probe.

A number of alternative placement and positioning systems are also proposed. Depuy Spine's 6929606 (Retractor and method for spinal pedicle screw placement, 08/2005) is a design patent for a tool with guide channels that facilitates alignment of instruments and hardware. It has very little to do with the actual pedicle probe, but demonstrates a potential solution to placement issues.

Yet another system is disclosed in 7522953 (System and methods for performing surgical procedures and assessments, 04/2009). This patent from Nuvasive details an EMG-based system for determining pedicle integrity and proximity to nerves. Using pre-determined threshold values, the system is supposedly able to determine whether a screw is properly placed and identify breaches, cracks, or stresses to the local anatomy. Its claims are fairly specific, but should be kept in mind. Nuvasive also holds several follow-up patents, one being 8050769 (Systems and methods for determining nerve proximity, direction, and pathology during surgery, 11/2011), which details a system for stimulating and monitoring nerves and EMG responses, though is oddly more specific than its predecessor.

Arguably the most familiar system is 7235076 (Method of improving pedicle screw placement in spinal surgery, 06/2007). This method patent essentially details a software solution to imaging data. It is intended to allow the surgeon to calculate a pedicle screw size and trajectory; effectively a means of automating what is currently done. A follow-up patent 8277461 (Methods for determining pedicle base circumference, pedicle isthmus and center of the pedicle isthmus for pedicle screw or instrument placement in spinal surgery, 10/2012) details a different software solution. The claims are slightly broader, but both patents are still fairly specific in the execution of the method. The latter patent also takes claim to an ungainly long name.

A peripheral design is disclosed in 8449555 (Pedicle probe, 05/2013). The claims encompass a bone probe with a broad tip, designed such that this tip acts in a jackhammer-like fashion, vibrating to make its way through the pedicle. The inclusion of the highly unorthodox broad tip likely eliminate this patent from concern.

The contemporary ultrasound device to note is disclosed in **8206306** (Ultrasound systems and methods for orthopedic applications, 06/2012). This design patent claims a diagnostic instrument, though it is clearly intended as a pedicle probe. The claims are fairly orthodox, specifying the physical parameters of the instrument with the additional of an ultrasound transducer and certain modifications to accommodate this component. Given these limitations, the claims are still fairly broad and appear to encompass a wide array of ultrasound-based designs. A follow-up patent 8343056 (1/2013) broadens the claims even further, eliminating some specifics on the design. That being said, it does not appear to cover any mechanical approach. This patent belongs to Hitachi.

The contemporary optical device to note is disclosed in **8249696** (Smart pedicle tool, 08/2012). Though this is not at all a probe, it promises to be an all-in-one pedicle screw solution. The claims encompass a bone screw with navigational abilities facilitated by an optics approach determining the optic characteristics of surrounding tissue. That being said, the claims are very broad, even if they do not extend beyond the pedicle screw. This patent belongs to Depuy Spine. The contemporary impedance device to note is disclosed in **8419746** (Exploration device to monitor the penetration of an instrument in an anatomical structure, 04/2013). This is SpineGuard's patent for PediGuard. **This patent requires further analysis and evaluation.** The claims are broad, encompassing any anatomical exploration device with a two-electrode impedance functionality, and an angular detection capability. The preceding patent to this one is 7580743 (Device for monitoring penetration into anatomical members, 08/2009), which holds

substantially narrower claims. Spineguard also holds a patent for a smart pedicle implant (namely a screw) that also uses impedance technology, 8486119 (Implant comprising one or more electrodes and corresponding insertion instrument). This patent is fairly specific but does encompass the use of the Pediguard with a smart pedicle screw system.

The closest contemporary mechanical device to note is the previously-discussed **EP 2442731** (Spinal probe with tactile force feedback and pedicle breach prediction). As explained earlier, it is highly unlikely that any patent has or will be issued encompassing the design of the typical pedicle probe, which is generally described as a handle and a shaft coupled to the handle.

Literature Search:

An extensive literature search was also performed, with some key papers outlined below. This proved critical for establishing and refining our understanding of spinal fusion surgeries and the problem of screw misplacement, as well as the role of the pedicle probe.

Boos, N. "The impact of economic evaluation on quality management in spine surgery." *Eur Spine J* (2009). 18:Suppl 3, S338-S347.

- Economic evaluations of health care through (1) the human-capital approach (HCA), (2) cost-effectiveness analysis (CEA), (3) cost-utility analysis (CUA) and (4) cost-benefit analysis (CBA)
- Statistics with reference to healthcare cost of back problems
- Different schools of thought regarding the valuation of improved life based on income with reference to surgery
- Values for the Quality of Life measurement

Stauff MP, Freedman BA, et al. "The effect of pedicle screw redirection after lateral wall breach—a biomechanical study using human lumbar vertebrae." *The Spine Journal* (2013). Article in Press.

- Study of the biomechanical strength of a screw placed perfectly vs. a screw that is adjusted after lateral breach
- Compared with a CC lumbar pedicle screw, an RD lumbar pedicle screw placed after a lateral wall breach is significantly weaker in terms of maximal insertional torque, seating torque, screw loosening force, and axial pullout strength
- Methods for screw placement – freehand, fluoroscopy, electromyography, image guidance, ultrasound
- Report 1.7% to 29% malposition rate for free hand screw placement
- Kosmopoulos and Schizas found an inaccuracy rate of 4.8% for screws placed using navigation versus 9.7% for screws placed without navigation
- Many other statistics reported in the introduction
- Insertional and seating torque and pullout forces
- We do not know the actual rate of breaches because they may be corrected by RD during surgery. The conclusion is that RD screws are much less biomechanically stable.

Hicks JM, Singla A, et al. "Complications of Pedicle Screw Fixation in Scoliosis Surgery." *Spine* (2010). 35:11, E465-E470.

- Reported 15.7% malposition rate when postoperative CT scan was taken

- Other complications reported include loss of curve correction, intraoperative pedicle fracture or loosening, dural laceration, deep infection, pseudarthrosis, and transient neurologic injury
- Posterior spinal instrumented fusion is the current gold standard in the treatment of progressive idiopathic scoliosis
- 1-5% of patients had reoperation because of malpositioned screws
- Complications: intraoperative pedicle fracture (0.5%), pulmonary complications, dural lesions (0.35%), infection (1.9%), neurologic and vascular (0.07%) complications, pseudoarthritis, loosening or pullout (0.54-0.67%)
- Most studies are conducted with experienced surgeons so results may not reflect less experienced surgeons or those going through learning curve
- The true incidence of pedicle and vertebral body breaches is likely closest to 15%, represented by the studies where CT scans were universally obtained
- 85% accuracy in placing screws – will be much less when needing many screws
- 2 mm breach may be acceptable but more than that is up to debate
- 16 yr old girl who had screws placed with 4mm breaches - epigastric pain, right foot resting tremor, and dysesthesias of her legs
- We have tried ourselves to check screw placement with intraoperative axial reconstruction fluoroscopy, but we found this not to be accurate enough because of the metal scatter notwithstanding the limited visualization field, the time required, and the amount of radiation delivered by such technique
- Clinical judgment should be used to decide the removal of asymptomatic implant to avoid late vascular or neurologic complication

Grauer JN, Vaccaro AR, et al. “Evaluation of a Novel Pedicle Probe for the Placement of Thoracic and Lumbosacral Pedicle Screws.” *Journal of Spinal Disorders & Techniques* (2004). 17:6, 492-497.

- SafePath device works better in lumbosacral spine than thoracic spine – statistics on the number of violations between gearshift probe, curette, and SafePath
- The risk of iatrogenic injury must be minimized as vital anatomic structures surround the pedicle: the dural sac medially, the nerve roots superiorly and inferiorly, and the vascular structures anterolaterally
- Pedicle screw instrumentation may be guided by anatomic landmarks, preoperative imaging, and intraoperative imaging tools such as plain radiography, fluoroscopy, and, more recently, image-guided technology
- 10-29% rate for lateral and medial breaches
- Screws were not inserted so possible screw violations were not recorded

Moran JM, Berg WS, et al. “Transpedicular Screw Fixation.” *Journal of Orthopedic Research* (1989). 7, 107-114.

- Studied drill vs probe for pilot hole – probe resulted in higher pullout strengths
 - One possible explanation for this phenomenon is that drilling actually removes material whereas probing merely compacts it. The screw threads might achieve better interlock with this compacted material. Second, and most importantly, the control, improved screw alignment, and margin of safety against perforation of the anterior cortex of the vertebra provided by probing are obvious advantages
- Geometric measurements for the various dimensions of pedicles

- Different vertebrae have different angles to the axis

Gautschi OP, Schatlo B, et al. “Clinically relevant complications related to pedicle screw placement in thoracolumbar surgery and their management: a literature review of 35,630 pedicle screws.” *Neurosurgical Focus* (2011). 31:4, 1-9.

- Some neurological complications such as dural lesions and nerve irritations
- Mentions PediGuard
- Displacement greater than 4 mm is associated with a high risk of injury to vital structures depending on the instrumented level
- The overall incidence of nerve root or spinal cord injury is rare, ranging between 0.6% and 11%
- Although no vascular complications were reported in the reviewed studies, it is evident that several vascular structures are in danger during pedicle screw insertion: the azygos vein, intercostal artery, inferior vena cava, and aorta for the thoracic spine and mainly the aorta and common iliac vessels for the lumbar spine

Gertzbein SD, Robbins SE. “Accuracy of Pedicular Screw Placement *In Vivo*.” *Spine* (1990). 15:1, 11-15.

- Study of 167 screw insertions – 9% breached 2-4mm into spinal canal and 6% breached 4.1-8mm
- Of 8 patients, 2 developed neurological symptoms – headaches and parasthesias
- Used AO Fixateur Interne for screw placement

Ma J, Fan S, et al. “Intraoperative malposition of pedicle probe or screws: A potential cause of the acceleration of degeneration in superior adjacent intervertebral disc.” *Medical Hypotheses* (2011). 77, 1102-1104.

- Pedicle probe or screw malposition may cause adjacent segment degeneration (ASD)

Samdani AF, Ranade A, et al. “Accuracy of free-hand placement of thoracic pedicle screws in adolescent idiopathic scoliosis: how much of a difference does surgeon experience make?” *European Spine Journal* (2010). 19, 91-95.

- Breach of >2mm was in 12.1% of screws studied, including all ranges of experience
- No significant difference in breach rate between ranges of experience, but more experienced surgeons had fewer medial breaches
- Has good pictures of screw breach CT scans
- At our institution, we have deemed EMG to be of limited use in the thoracic spine

Jutte PC, Castelein RM. “Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations.” *European Spine Journal* (2002). 11, 594-598.

- 54% patients had some sort of complication (malposition, dural lesion, screw break...)
- Pedicle screw placement is a technically demanding procedure with a high complication rate

Manbachi A, Cobbald RS, et al. “Guided Pedicle Screw Insertion: Techniques and Training.” *The Spine Journal* (2013). Article in Press.

- Spinal fusion is a technically demanding procedure with limited visibility of spinal landmarks. The surgeon needs to learn or gain a conceptualization of hidden structures.
- The pedicle has very close proximity to vital neural and vascular structures, which contribute to difficulty in screw placement.
- Misplaced screws may cause: dyesthesia, neurological injury, or hemorrhage.

- Several methods to prevent screw misplacements: (1) Intraoperative Fluoroscopy, (2) Computer-assisted Surgery, (3) Ultrasonic-guided pedicle screw insertion, (4) EMG, Somatosensory-evoked Potentials (SSEPs) or spinal cord monitoring, (5) Electrical Impedance.
- Current market for spinal implants and devices is \$2 billion per year
- 1998-2008: 2.4-fold increase in spinal fusion discharges (174,233 to 413,171).
- Average cost of fusion procedure: \$34,000
- Current Standard of Care (SOC): tactile feedback and experience-based judgment.

Witham TF, Gokaslan ZL, et al. "Accuracy of Free-Hand Pedicle Screws in the Thoracic and Lumbar Spine: Analysis of 6816 Consecutive Screws." *Neurosurgery* (2011). 68:1, 170-178.

- Retrospective study in which the authors reviewed records of all patients undergoing free-hand pedicle screw placement without fluoroscopy in the thoracic or lumbar spine between June 2002 and June 2009.
- Using CT scans postoperatively, 87 of the 964 (9%) total patients were identified as having breaches – 25 % of the screw residing outside the pedicle or vertebral body cortex.
- Breaches occurred more frequently in the thoracic (2.5%) than the lumbar spine (.9%). Most breaches were lateral (61.3%) than medial (32.8%) or superior (2.5 %).
- Only eight patients underwent revision surgery to correct malpositioned screws.
- Breaches were measured from the lateral and medial pedicle cortex.
- No cases of lateral breach resulted in postoperative symptoms. This finding is consistent with the notion of a 4-mm "safe zone" surrounding the lateral borders of the pedicles and vertebral bodies first postulated by Gertzbein and Robbins.
- Free-hand technique is a viable option for experienced surgeons operating at high volume. For surgeons that are not comfortable with free hand technique or operate in low volume, the authors recommend navigational aids.

Zdichavsky M, Blauth M, et al. "Accuracy of Pedicle Screw Placement in Thoracic Spine Fractures." *European Journal of Trauma* (2004). 30:4, 241-247.

- Retrospective study of 278 thoracic pedicle screws of 43 patients were assessed using a scoring system and postoperative CT scans.
- Studied were transpedicular reduction and fixation. All patients (29 men, 14 women) had traumatic thoracic spine fractures (T1-T10).
- This study may not have used a pedicle probe. Pedicles were bored using Leur's forceps. Once pedicles were opened, a 3-mm Kirschner wire was inserted into the center of the pedicle, at which point the screw was inserted after the pedicle canal was explored for bony contact. Position of the pedicles and screws were determined intraoperatively by fluoroscopic images in two planes.
- Pedicle screw insertions were scored on Grade I – III.
- 14 of the 278 (5%) of the pedicle screws needed to be revised.
- In the study most vertebral fractures were located at T7 followed by T6, T5, and T8.
- There were no neurovascular complications in this study.
- This study cited a huge range of pedicle wall perforation between 28.1% and 43%.
- In the study flourscopy-guided placement of pedicle screws reached a transpedicular accuracy rate of 81.6% (total Grade IA).

Gelalis ID, Paschos NK, et al. "Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques." *Eur Spine J* (2012) 21:2, 247- 255.

- Comprehensive, prospective study of 1,105 patients in which 6,617 screws were inserted.
- Screws fully contained in pedicle:
 - Free-hand: 69-94%
 - Fluoroscopy: 28-85%
 - CT navigation: 89-100%
 - Fluoroscopy based navigation: 81-92%.
- Screws positioned free-hand tended to perforate cortex medially, whereas screws placed with CT navigation perforated more often laterally.
- 24 patients presented with neurological complications.

Rajasekaran S, Vidyadhara S, et al. "Randomized Clinical Study to Compare the Accuracy of Navigated and Non-Navigated Thoracic Pedicle Screws in Deformity Correction Surgeries." *Spine* (2007) 32:2, E56 – E64.

- Study of the SIREMOBIL Iso-C^{3D} C-arm (Siemens, Medical Solutions, Erlangen, Germany) compared with computer navigation by VectorVision (BrainLAB, Germany).

Samdani AF, Ranade A, et al. "Accuracy of free-hand placement of thoracic pedicle screws in adolescent idiopathic scoliosis: how much of a difference does surgeon experience make?" *European Spine Journal* (2010) 19:1, 91-95.

- Of 856 screws studied, overall breach rate of 12.1% (> 2 mm).
- The most experienced surgeons demonstrated the lowest number of breaches, although it did not attain statistical significance.
- Variability in breach rates cited by different papers is most likely due to the radiographic method used to detect the breach. Plain x-rays underestimate the incidence, while CT based methods are more accurate.

Hicks JM, Singla A, et al. "Complications of pedicle screw fixation in scoliosis surgery: a systematic review." *Spine* (2010) 35:11, E465 – E470.

- 14 of the 21 articles reviewed were performed with a free-hand insertion technique.
- Out of 4452 pedicle screws in 1666 patients, 4.2% of screws were reported as malpositioned. However, not all studies used postoperative CT scans to examine screw position. Of the 2202 screws from this subset, 15.7% of screws were reported as malpositioned.
- The studies all came from centers with very experienced surgeons. Therefore, the review does not reflect what happens in less-experienced centers.
- Patients with malpositioned screws varied from 1.2% - 20% based on study, number of screws inserted, surveillance method (radiography, CT scans), and what is accepted as a pedicle screw breach.
- Screw breaches above 2mm are controversial: while some studies cite 2-4mm breaches as the "safe zone", others cite specific cases in which these breaches caused "epigastric pain, right foot resting tremor, and dyesthesias of [the] legs."

Bayraktar HH, Morgan EF, et al. "Comparison of the elastic and yield properties of human femoral trabecular and cortical bone tissue." *Journal of Biomechanics* (2004) 37:1, 27-35

- 12 human trabecular bone specimens from 11 cadavers were studied. All specimens were taken from the right, left, or both sides of the femoral neck.

- Due to the cumulative effects of small differences in elastic modulus, cortical bone is about 20-30% stronger than trabecular bone.

Tian NF, Huang QS et al. "Pedicule screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies." *European Spine Journal* (2011) 20:6, 846-859

- Review of 43 papers, including 28 clinical, 14 cadaveric, and 1 model study.
- Did not present information we did not know. Essentially, they proved that when compared to conventional methods, navigation provided a higher accuracy in the placement of pedicle screws.
- In order of decreasing accuracy: 3D FlouroNav, CT Nav (preoperative CT), 2D FlouroNav.
- CT navigation provided for lowest incidence of pedicle violation
- no strong in vivo evidence has detected significantly different pedicle screw placement accuracy among the three major navigation systems
- In 100 patient study, The pedicle perforation rate was significantly higher in the conventional group (13.4%) compared with 4.6% in the computer-assisted group (P = 0.006).
- For pedicle screw placement accuracy in posterior scoliosis surgery discovered 11% in the conventional group compared with only 1.8% in the navigated group
- CT-based navigation significantly enhanced the accuracy of pedicle screw insertion in adolescent scoliosis patients, violation rate was 28.0% in the control group (free-hand) and 11.4% in the navigation group
- In another study, a total of 54 (23%) pedicle breaches were found in the non-navigaion group as compared to only 5 (2%) in the navigation group

Rajae SS, Bae HW, et al. "Spinal Fusion in the United States – Analysis of Trends From 1998 to 2008." *Spine* (2012) 37:1, 67-76

- Data was obtained from the *Healthcare Cost and Utilization Project Nationwide Inpatient Sample*
 - Date comprises 20% random sample of community hospitals in the US.
- Between 1998 and 2008, spinal fusion discharges increased by 2.4-fold from 174,223 to 413,171.
- Primary thoracic fusion increased 1.8-fold from 13,205 to 24,003 discharges. This was significantly less of an increase than lumbar or cervical.
- Spinal fusion went from 37th most common procedure to 16th most common in 2008.
- 1.1% mortality rate for thoracic fusion (constant value from 1998 to 2008).
- Average hospital charges more than tripled from 1998 to 2008 (\$24,676 to \$81,960).
- Average length of stay decreased from 4.4 to 3.7 days.

Watkins IV, Gupta A, et al. "Cost-Effectiveness of Image-Guided Spine Surgery." *The Open Orthopaedics Journal* (2010) 4, 228-233

- Limitations on the use of image guidance include the cost of purchase of the systems, time required for usage in the operating room, and questionable accuracy of the systems.
- Compared 100 patients undergoing thoracolumbar fusion under image-guidance to 100 patients (retrospectively) prior to the use of image-guidance.
- Used Arcadis Orbic 3D (Siemens Medical, Munich, Germany) to acquire the image and the NaviVision (BrainLab AG, Feldkirchen, Germany) to allow real-time guidance.

- Placed 12 thoracic, 352 lumbar, and 82 sacral screws.
- Did not acquire postoperative CT scans to check accuracy of screws.
- 0% revision rate when using image guidance (3% without). However, a sample of 100 patients provides a p-value of 0.081, which is not statistically significant.

Kwon J, Jahng T, et al. "Endoscope-Assisted Pedicle Screw Fixation using the Pedicle Guidance System." *Korean J Spine* (2008) 5:3, 190-195

- Presented a minimally invasive system for pedicle screw fixation.
- Addressing need to limit "extensive tissue dissection in order to expose the entry points and provide the lateral-to-medial orientation required for optimal screw trajectory."
- This procedure requires entry wound of only 1-inch, and the procedure is performed under endoscopic visualization.
- Working in a minimal field proved time consuming, and the patient was subsequently exposure to increased radiation (compared with free-hand, but equal or less than fluoroscopic guidance).

Tian NF, Huang QS, et al. "Pedicle Screw Insertion Accuracy with Different Assisted Methods: a Systematic Review and Meta-Analysis of Comparative Studies." *European Spine Journal* (2011) 20, 856-859

- CT navigation provided for lowest incidence of pedicle violation
- no strong in vivo evidence has detected significantly different pedicle screw placement accuracy among the three major navigation systems
- In 100 patient study, The pedicle perforation rate was significantly higher in the conventional group (13.4%) compared with 4.6% in the computer-assisted group (P = 0.006).
- For pedicle screw placement accuracy in posterior scoliosis surgery discovered 11% in the conventional group compared with only 1.8% in the navigated group
- CT-based navigation significantly enhanced the accuracy of pedicle screw insertion in adolescent scoliosis patients, violation rate was 28.0% in the control group (free-hand) and 11.4% in the navigation group
- In another study, a total of 54 (23%) pedicle breaches were found in the non-navigaion group as compared to only 5 (2%) in the navigation group

Shin BJ, James AR, et al. "Pedicle Screw Navigation: A Systematic Review and Meta-Analysis of Perforation Risk for Computer-Navigated Versus Freehand Insertion." *J Neurosurg Spine*. (2012) 17, 113-122

- Meta-analysis of 20 papers, a total of 8539 screws (4814 navigated and 3725 nonnavigated/conventional)
- 6% pedicle screw perforation in navigated, 15% in conventional
- No neurological complications in navigated, 3 neuro complications in conventional
 - No information on severity of nuero damage and cost to hospital

Amato V, Giannachi L, et al. "Accuracy of pedicle screw placement in the lumbosacral spine using conventional technique: computed tomography postoperative assessement in 102 consecutive patients." *J Neurosurg Spine*. (2010) 12, 306-313

- Study of 102 patients (424 inserted pedicle screws).
- 17 patients (5%) had "frank" misplacements: pedicle screw was outside the pedicular boundaries.

- Nerve root injury was observed in 2 patients (2%) while 5 patients complained of radicular pain.
- 6 patients complained of lumbar pain.
- 9 patients underwent revision surgery, including 2 patients with pedicle fractures.
- 7 patients, even in follow-ups, still complained of some radicular pain.

Hodges SD, Eck JC, et al. "Analysis of CT-based Navigation System for Pedicle Screw Placement." *Orthopedics* 35:8, e1221 – 4

- In their study group of 386 patients, 4 (1%) required reoperation for a breeched pedicle screw.
- Based on this rate of 1% reoperation, the study concluded 2300 cases nationwide would require revision, with a cost of approximately \$40,595,000.

Rampersaud YR, Foley KT, et al. "Radiation Exposure to the Spine Surgeon During Fluoroscopically Assisted Pedicle Screw Insertion." *Spine* (2000) 25:20, 2637-2645

- Fluoroscopically assisted thoracolumbar procedures result in 10-12 times greater radiation exposure than other, nonspinal musculoskeletal procedures that use a fluoroscope.