Technology Review – The clinical utility of surgical navigation systems in spinal fusions

Freehand navigation – slow learning curve

During a spinal fusion, metal screws are inserted into both sides of two or three adjacent spine vertebrate (Morrison & Vieweg, 2012). A short metal rod is anchored to the screw heads to minimize movement of vertebrate and stabilize the spine. A similar procedure was first described in the 1900s to treat deformities associated with tuberculosis infections (Lipson, 2004). Later in the century, technological advancement in imaging and metal instrumentations enabled better diagnosis and shorter recovery time, enhancing the clinical success of spine fusions (Lipson, 2004). Spine fusion gained wide acceptance in trauma and severe spondylolisthesis (vertebrate displacement) in the 1980s (Roy-Camille, Saillant, & Mazel, 1986). During the 1990s, as discussed above, the popularity of the procedure exploded, and spinal-fusion in adults is indicated today as a spine stabilizing treatment for diverse conditions ranging from traumatic injury to disc degeneration (James N. Weinstein et al., 2006).

Subsequent to exposing the posterior face (back facing) of the patient's spine, the surgeon uses a sharp tool to penetrate the hard cortical bone of the vertebrate. To avoid harming the nerves in the spinal canal the surgeon aim to prepare a guiding hole for the screw in the pedicle bone, the narrow part of the vertebrate surrounding the nerve canal. Hard cortical bone surface protects a softer, spongy bone termed cancellous bone or trabecular bone. To prepare the route for the screw in the pedicle, the surgeon uses either a curved probe or a straight probe, similar in appearance to a screw driver, to manually dig a hole through the bone tissue (Morrison & Vieweg, 2012; Roy-Camille et al., 1986). During the entire procedure, only the most posterior facet of the vertebrate is exposed, while the pedicle portion is not visible. The surgeon must rely exclusively on tactile information received from the probe through the softer spongy bone or the harder cortical bone to guide the probe into the pedicle. Once the guiding hole is complete, the surgeon inserts the metal screw into the spine. With post-operative X-ray computed tomography (CT scans), free-hand placement of pedicle screws can be assessed. A study of thoracic screws placement in complicated spine deformities can demonstrate the challenge facing spine surgeons. A total of 856 thoracic screws placed by spine surgeons with varying experience level were examined (Samdani et al., 2010). In this study, 2 mm medial or lateral misplacement were considered a breach of the bone, a reasonable assumption due to the young age of the scoliosis patients and the narrow diameter of thoracic pedicles. The authors calculated a 12% rate of pedicle breaches. When the breach rates were stratified by surgeon experience, there was a trend toward decreased rate of breach with surgeon's experience. However, only surgeons with more than five years' experience gained a statistically significant advantage in lowering medial breaches from 8% to 3.5% (Samdani et al., 2010). Similarly, Wang et al (2010) used CT scans of 268 thoracic screws to examine freehand accuracy by surgical residents, reporting 85% accuracy overall (V. Y. Wang, Chin, Lu, Smith, & Chou, 2010). In this study experienced surgeons had a lower rate of accuracy, likely because they operated more complicated cases.

Gaining the tactile knowledge and dexterity for accurate screw placement takes years of practice. The long process of improvements in freehand guidance starts with cadaver training. Unexperienced orthopedic surgeons misplace (>2mm breach) as many as 29% of the cadaveric screws, out of which there were 74% non-critical violations and 26% were considered critical violations (Bergeson et al., 2008). The serious violation rate among inexperienced surgeons is thus 7.5%. As expected, there are many variations among surgeons in training. In a study of freehand placement of lumbar and thoracic screws by one Korean resident with two years' experience, a much lower rate of 3.9% perforation was observed (Lee et al., 2014). At the institutional level, the prestigious Johns Hopkins Hospital reported a 9% rate of bone perforation out of 964 patients operated with freehand guidance between 2002and 2009 (Parker et al., 2011). In conclusion, critical pedicle bone perforation by freehand insertion of spinal screws can range from as low as 3.5% in the most experienced and gifted surgeons to as high as 29% in the most inexperienced surgical interns. An 85%-90% rate of accuracy can be observed as standard of care without navigation devices (**Table 3**). Freehand navigation appears more challenging in the narrow thoracic pedicles than in lumbar pedicles. The utility of surgical navigation devices to increase accuracy, decrease complications and improve clinical outcomes will be reviewed in the next section.

Computer assisted navigation system for spinal fusions –pioneer study

To improve the accuracy of pedicle screw placement, optical systems were first developed in the 1990s. A landmark first study of spinal fusion patients randomized 91 patients into a conventional group and computer assisted group, measuring the post-operative placement of pedicle screws by CT (Laine, Lund, Ylikoski, Lohikoski, & Schlenzka, 2000). The guidance system used optical cues placed on the patient and the surgical tool to increase the correct placement of pedicle screws from 88% to 95% (Laine et al., 2000). The rate of severe misplacement (4 to 6 mm perforation) was reduced from 1.6% to 0% (Laine et al., 2000). Five major case complications were noted by Laine et al. in the unguided group, and only one major complication was noted in the experimental guided group. The complication in the guided group was an infection, a serious risk in the medical device industry. One problem with the study was that causative link of medical complications and misplacement of pedicle screws remained elusive. It appears that concerns over prolonging the length of the surgery and the learning curve for surgeons with the new technique prevented the acceptance of the early navigation device. These concerns also sparked a wave of innovative improvements, and will be discussed below.

Guided pedicle screw insertion – critical review

Over the years many navigation systems were developed, by academic groups and corporations (reviewed by Manbachi et al, 2014). For almost all navigation systems, high resolution CT or MRI scans are pre-recorded before the surgery (perioperative imaging). A 3D map is synthesized from the 2D scans, and the map is referenced to the patient and the surgical probe, to allow navigation during the surgery. In X-ray fluoroscopy systems, real-time navigation under 2D X-ray vision is possible. Real-time imaging with intraoperative CT or MRI systems, is becoming more common, but the drawback of these techniques is the high price and exposure of patients and staff to ionizing radiation. Meta-analysis studies surveying hundreds of patients and thousands of pedicle screws indicate the utility of surgical navigation systems in enhancing accuracy of pedicle screws insertion.

Combining data from 130 studies over forty years and 37,337 total pedicle screws, 95% of screws were accurately inserted when a guiding system was used, versus 90% accuracy in the absence of a guiding system (Kosmopoulos & Schizas, 2007). Loosely defined binary states of accuracy (yes or no) in this meta-analysis study may have resulted from lack of consistency in the literature regarding the criteria for accuracy pedicle screw insertion and the clinical implication of screw misplacements, illustrating an ongoing challenge in the field. In general, the golden standard in clinical trials is the so-called 'double blind' study, designed to limit compounding factors of human bias. Naturally, surgeons could not be blinded in navigation studies, creating an inherent flaw in many surgical studies, since surgeons could unintentionally influence the results of the study by their desire to contribute the success (or failure) of the navigation system. Partial remedies for this challenge can come by randomizing the patients into treatment groups, avoiding potential selection bias if hard to treat or complicated cases are allocated to one group over the other. In addition, since post-operative screw accuracy is measured by CT scans, it is important to ensure that the radiologist interpreting the scans is blinded regarding the group label.

Some of the concerns discussed above were partially addressed in the next round of studies. Twenty studies, two of which randomized patients, published between 2000 to 2011 included 3,725 non-navigated pedicle screws and 4,814 navigated screws, mostly using CT scans (Shin, James, Njoku, & Hartl, 2012). The authors calculated a pedicle bone perforation rate of 15% for non-navigated screws, and this rate was reduced to 5% when a navigation device was used (Shin et al., 2012). The authors note that there were no differences in total operative time or in estimated blood loss between the two modalities.   Assembling data from 54 studies, Tian and Xu (2009) set to compare CT and X-ray Fluoroscopy navigation systems (Tian & Xu, 2009). For the CT subgroup, 3,554 screws were assessed, ranging in placement accuracy from 72% to 98%, with a median accuracy of 90%. In the 2D Fluoroscopy subgroup, a total of 1,219 pedicle screws were assessed ranging from 72% to 96% accuracy, with a median of 85%. CT navigation systems appear more accurate than 2D navigation systems. This could be due to the challenge of transposing 3D reality into a 2D map, or due to a lack of surgeon experience with this technique. Notably, the level CT navigation accuracy reported in this meta-study appears lower in comparison to accuracy levels reported in other studies (90% versus 95%, respectively).

Aiming to examine the clinical benefits of surgical navigation systems for spinal fusions, a meta-analysis study of 23 publications including 1,288 patients in total was conducted (Verma, Krishan, Haendlmayer, & Mohsen, 2010). From 5,992 pedicle screws examined, Verma et al. confirmed the advantage of navigation systems in placement of pedicle screws, increasing accuracy in navigated cases compared to non-navigated cases, from 85% in to 94%, consistent with other studies reported above. Only 14 studies had control groups, with two studies conducted as randomized control studies and twelve conducted as non-randomized control studies. Verma et al. calculated from these studies a statistically significant advantage ($p<0.00001$) for navigation systems in surgical accuracy. Misplaced screws can cause three types of complications: neurological, vascular and mechanical. Vascular complications (excessive bleeding) are very rare in spine fusions, as there are no major blood vessels in the back. Severe neurological complications (extreme pain to disability) could result from lateral misplacement of the screw into the nerve canal. In the cohort of studies examined by Verma et al. (2010) thirteen cases of neurological complications were reported among 569 non-navigation cases (2.2%). In contrast, no cases of neurological complications were noted among navigated patients. Taking complications into consideration, Verma et al. barley favoured navigation systems for spinal fusions, due to the low statistical significance ($p=0.07$, (Verma et al., 2010). Assessing the clinical implications of pedicle screw misplacement is limited by a reporting bias. Pain relief and general health outcomes such as disability, are rarely reported in navigation studies. Moreover, neurological complications are relatively rare, and hence larger (and more expensive) studies are needed to monitor the rate of complications. Importantly, out of the fourteen studies reporting neurological complications analyzed by Verma et al., only four studies actually observed the presence of complications. Not surprisingly, three of these four studies were also the largest with: 100 patients (Amiot, Lang, Putzier, Zippel, & Labelle, 2000), 180 patients (Kotani, Abumi, Ito, & Minami, 2003) and 41 patients (Laine et al., 2000). Even in these studies, the navigated group was half the size of the non-navigated group (except (Laine et al., 2000)). The majority of the studies reviewed by Verma. et al. were under 100 patients. More rigorous experimental design would include larger groups of patients in both experimental groups, to increase the likelihood of capturing neurological complications. Better design would include also self-reported pain measurements and intake of pain-relief medication post-surgery in both groups. Lastly, misplacement of pedicle screws could lead to more severe complications when the targeted bones are narrower, leaving less room for misplaced screws. Pediatric scoliosis patients, cervical patients and lumbar patients could all have different profiles of neurological complications. Combining these studies into one meta-analysis could mask important clinical differences.

Table 3. Utility of surgical navigation in spinal fusions						
	Accuracy		**Complications**		**n=**	
Meta-analysis studies	**+ nav**	**-nav**	**+nav**	**-nav**	**Screws**	
Kosmopoulos & Schizas, 2007	95%	90%			37,337	
Shin, et al., 2012	95%	85%			8,539	Mostly CT
Tian & Xu, 2009	90%				3,554	3D CT
Tian & Xu, 2009	85%				1,219	2D X-ray Fluoroscopy
Verma, et al., 2010	94%	85%			5,992	
			0%	3.80%		
Individual studies reporting neurological complications					**Cases**	**Average age, anatomy**
Laine, et al. 2000	96%	83%	0/50	2/41	91	54 yrs, Thoraco-lumbar
Amiot, et al., 2000	93%	84%	0/50	7/100	150	48 yrs, Thoraco-lumbar
Kotani 2003	98%	93%	0/17	3/180	197	42 yrs, Cervical
Kotani 2007	98%	88%	0/20	1/25	45	14 yrs, Thoraco-lumbar

Table 3: Meta-analysis studies describe surgical navigation (nav) as enhancing accuracy (top). Studies examining the clinical utility of surgical navigation in preventing neural complication (bottom).

Ultrasound navigation system for pedicle screws

The bone challenge in medical ultrasound systems

Sound waves oscillating at frequencies above the upper limit of human hearing are termed ultrasound. Medical ultrasound devices typically generate sound waves from 20 KHz (20,000 per second) to several gigahertzes (billions per second). Ultrasound technology revolutionized medicine by allowing physicians to noninvasively view inner organs of patients. In a nutshell, ultrasound imaging requires two elements, a transducer and a receiver. The transducer transmits high frequency sound waves through the body tissues, and the reflected sound waves are detected by the receiver. Sophisticated signal processing is required to interpret the reflected waves and depict the form of the organ imaged. The physical properties of soft tissues (any tissue other than bone) can be approximated by water, the main component of our bodies. Water medium enables most of the sound energy to pass through, leaving but a small portion of waves to be reflected and allow imaging. In contrast, in bone tissue, the hard structures have sound properties much different than water. Sound waves are easily reflected from bones, preventing sound penetration into the bones. In addition, high decay of sound waves in the dense bone nearly prevents ultrasound imaging of the interior of bones.

Utilizing ultrasound in bone imaging

To provide spine surgeons with an ultrasound navigation device the two problems of bone surface reflection and sound decay need to be addressed. Reflection from the hard cortical surface of the bone is bypassed in the pedicle probe designed by SpineSonics. During the surgical procedure for spine fusion, the cortical bone is penetrated with a bore hole created by the surgeon before the insertion of the surgical probe into the bone (Morrison & Vieweg, 2012). This maneuver creates an opportunity to insert a ultrasound transducer and receiver into the bone tissue, imaging the bone from within to mitigate the strong reflection from the bone surface (Aly, Ginsberg, & Cobbold, 2011). The problem of sound decay through the bone can be mitigated by lowering the frequencies of sound wave to 2.5 MHz to allow for maximal transmission of signal and minimizes 'noise' in the narrow confinement of the pedicle bone (Aly et al., 2011). To visualize the pedicle bone cortex, a single probe was rotated 360 degrees inside the pedicle (Aly et al., 2011). Clearly, 360 degree rotations are not practical in a clinical setting. To eliminate the need for probe rotation, an innovative radial array of 32 ultrasound transducers fitted into a surgical probe was built and tested (Manbachi, Cobbold, & Ginsberg, 2014). The circular array can detect various features in a circle surrounding the array when tested in an in-vitro test. The array concept is modular and the number of element in an array and the number of arrays in a probe can be varied potential with product development needs.

Intellectual property portfolio

Three patents applications were submitted by Dr. Amir Manbachi and Prof. Cobbold to protect the array approach for ultrasound imaging in bones. These patents cover the design and concept of the probe (patent #1), the signal processing of the signal (patent #2), and the overall design of the device (patents #3). These patents are expected to be approved by November 2015.

1. A. Manbachi and R.S.C. Cobbold, "Ultrasonic Array for Bone Sonography," Patent Pending, May, 24, 2013.
2. A. Manbachi and R.S.C. Cobbold, "Ultrasonic Signal Processing for Bone Sonography," Patent Pending, May, 24, 2013.
3. A. Manbachi and R.S.C. Cobbold, "Ultrasound Transducer Probe," Design Patent application Feb, 20, 2014.

Database search for patents describing the use of ultrasound imaging in bones reveal a number of existing patents. To the best of my knowledge the array approach of Manbachi and Cobbold for ultrasound imaging in bone is unique and original. The pending patent portfolio is adequate.

Conclusions from the medical literature research

Freehand guidance of pedicle screw insertion is only 85% accurate, and accuracy can be improved to 95% with the aid of computed tomography (CT) X-ray scans. Surgical navigation systems that augment freehand guidance require high-resolution pre-operative CT or MRI scans to portray a 3D map for surgical navigation. A large body of literature supports the claim that surgical precision can be enhanced with 3D intra-operative imaging systems that provide real-time mapping of the probe and surgical construct within the spine. Can increased precision in pedicle screw insertion lead to better clinical outcomes? Can readmission rate (6.8%) or surgical revision rate (10%) be lowered with surgical navigation? Careful analysis of the medical literature reveals a discrepancy between the reported effect of surgical navigation systems in enhancing accuracy and a disappointedly low impact on clinical outcome (**Table 3**). The rate of reported neurological complications resulting from misplacement of pedicle screws is actually much lower than the reported rate of readmission and revision. The calculated rate of neurological complications from four controlled studies of large experimental groups followed for extended periods reveal a neurological complication rate of 3.8% (**Table 3**). Calculating the rate of complication among 30 day readmissions following a lumbar fusion in the US reveals a low rate of approximately 1% (**Table 2**, 6.8% X 15%). Even though, it is not known how many of these 24,000 surgeries were actually performed with guided navigation and how many were freehand navigated. The cost-saving achieved by implementing a CT based navigational system is likely minor. Interestingly, an Italian study calculated cost savings of only 288 Euro per case achieved by implementing an intraoperative O-arm system (Costa et al., 2014). The low economic benefit from high cost CT spinal navigation systems generate the commercial potential for a low-cost ultrasound navigation system for spinal fusions.