Highlights from the First Annual Spinal Navigation, Emerging Technologies and Systems Integration Meeting

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Abstract: This paper provides a detailed report of the "First Annual Spinal Navigation, Emerging Technologies and Systems Integration" meeting held December 3, 2016 at the Seattle Science Foundation.

Keywords: Spinal navigation; emerging technologies; robotics; trauma; spine; workflow; system integration

Submitted Nov 21, 2017. Accepted for publication Mar 15, 2018.
doi: 10.21037/atm.2018.03.22
View this article at: http://dx.doi.org/10.21037/atm.2018.03.22

Introduction

This paper provides a detailed report of the "First Annual Spinal Navigation, Emerging Technologies and Systems Integration" meeting held December 3, 2016 at the Seattle Science Foundation. The convention highlighted emergent and future navigation, robotics assistance for use in spinal surgeries, and technologies that focus on enhancing surgical precision, decreasing the invasiveness of surgical procedures and decreasing radiation exposure. Our event brought together a diverse group of professionals interested in adapting emergent technologies in the operating room. We worked to address the barriers associated with incorporating new methods of operating, focusing on roadblocks including hospital bureaucracy and pricing. The main goal of this event was to raise awareness of the potential benefits to patients and to surgeons of using spinal navigation, emerging technologies and systems integration in health care facilities. Past instances show that the diffusion of medical technology usually occurs first from major academic medical centers down to university-affiliated hospitals and finally, to community hospitals and outpatient centers. Robotics is a unique case, as community hospitals are working to adapt new technologies on their own.

Navigation and robotics: what's in the literature?

Pedicle screw placement, a crucial step in spinal instrumentation procedures, is prone to complications caused by screw misplacement. Misplacement can result in injury to neural structures or vessels, as well as to insufficient screw purchase with possible postoperative construct failure (1).

Screw placement is the predominant part of a fusion procedure where the patient and OR staff are exposed to radiation (2). Rampersaud *et al.* measured a 10–12 times increase in radiation exposure during fluoroscopically assisted thoracolumbar pedicle screw placement compared to non-spinal musculoskeletal procedures that involve the use of a fluoroscope (2).

Various navigation and robotic systems have recently been introduced which enhance screw placement accuracy and decrease intraoperative radiation exposure. The benefits of these systems have been extensively studied in cadavers and clinical trials. Accuracy has been assessed on post-operative CT imaging according to established grading systems based on the width of screw breeching in mm (3,4).

The use of intraoperative navigation has demonstrated to be of higher accuracy compared to free hand screw placement in multiple studies (5-7). Higher accuracy also demonstrated to significantly reduce revision rates for misplaced screws according to a meta-analysis by Fichtner *et al.* (8). This was confirmed in a recently published study using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database. This study demonstrated fewer adverse events in patients undergoing spinal fusion when computer assisted surgery was used (9). The benefit of navigation systems is specifically pronounced in the thoracic spine (95.5% *vs.* 79.0% acceptable screw placement) and in scoliotic deformities (10). The least benefit might be expected in single level lumbar fusions (6,11). Boon Tow *et al.* demonstrated no improvement in accuracy in single level degenerative listhesis procedures (11).

Regarding the preference for intraoperative imaging when using navigation systems, a meta-analysis found higher accuracy when intraoperative CT imaging or 3D fluoroscopy was used compared to 2D fluoroscopy based systems (10). To our knowledge, intraoperative CT imaging (O-arm) has not been compared to 3D fluoroscopy based systems yet.

The use of navigation results in significantly less radiation exposure to the surgeon and OR staff (12). However, when intraoperative CT is used, there is an increased radiation exposure for the patient (12) when compared to the use of fluoroscopic imaging.

Recently, Joseph *et al.* published a review paper on robotics which confirmed the aforementioned results on the use of navigation systems (13). Robotic systems evenly allow for higher accuracy and reduced radiation exposure when compared to free hand pedicle screw placement. Compared to navigation systems, a benefit of robotic systems is their potential of being more time efficient, as the ideal trajectory is set by the robot and not manually (14). To our knowledge as of now, no study compared the use of navigation systems to robotic systems in terms of screw accuracy and patient safety.

Economical standpoint

In today's day and age, it is impossible to overview the technological progress in medicine. Specifically in spine surgery, there is continuous development of new implantation devices, visualization systems and more recently, navigation and robotic systems.

At our annual meeting, Dr. David Simon cautioned surgeons to carefully choose what new technology to invest in. "Clinical value alone does not suffice; the device must have economic value as well."

This brings up the question: is investing in spinal navigation worth it?

The measure of effectiveness is hard to define from an economic standpoint, given the difficulty associated with assigning qualitative measurements. Currently, the primary measurement of efficiency is the number of reoperations for a misplaced screw done within one year, and the secondary measure includes the adverse event rate, surgical time, and length of stay. Dr. Charles Fisher reported on his study (15) which analyzed cost-effectiveness of intraoperative CT based navigation systems. The authors concluded that this technology is economically justified, predominantly due to the reduction of reoperation rates due to higher screw placement accuracy (15). They calculated a cost-effectiveness ratio of $15,962 USD ($12,618 CAD) per reoperation that was prevented in patients undergoing fusion procedures. However, according to their calculation, spinal navigation is only cost-effective if more than 254 spinal instrumentation procedures are performed at a health care facility per year. Thus, this technology is financially most beneficial in high volume centers.

In addition to more accurate pedicle screw placement which will potentially lower the reoperation rate, there are other possible economic advantages of computer assisted surgery. Less surgical time and the elimination of intraoperative monitoring and post-operative imaging also need to be considered.

It is noteworthy that the cost-effectiveness of robotics and navigation systems is not universally applicable to each institution. An individual hospital can perform its own cost-effectiveness calculation as applies to factors at their own institution like patient volume, accuracy related complication rates and surgical experience. Based on their individualized cost-effectiveness ratio, a hospital can then make a more educated decision about whether an investment in spinal navigation will provide an economic benefit to them.

In this regard, Dr. J. Patrick Johnson mentioned an important factor regarding the motivation of surgeons in a facility to adapt new technologies, despite the learning curve associated with it. Expensive surgical tools might need to be used by a majority of surgical staff to become cost-effective.

Learning curve

Dr. Meyer spoke about the learning curve associated with spinal navigation. His group published their experience after introducing navigation into their clinical practice. They demonstrated significant learning effects with a reduction of 3D scan time and pedicle screw insertion time as well as an improved screw placement accuracy in an 18-month period (16). According to Dr. Meyer's opinion, easy controllable cases should be performed at the beginning before moving on to more high-performance concepts and operations. He also noted that anatomy comprehension is crucial; image guidance should be utilized in areas where visualization would enhance surgical outcome. For instance, in cases where you only have one good chance to perform a successful operation- i.e., complex revisions, pelvic fixations with long fusions, osteotomies, wound infections or high-risk cases including: operations lacking identifiable posterior anatomy, involving small pedicles, concerning distorted spinal curvature, or dealing with poor bone quality. Image guidance allows for custom trajectories, but it is notable that there are limitations to the universality of navigation. Image guidance cannot be used in every operation but it is beneficial in cases involving: far lateral discs, craniovertebral junction, C1–2 lateral mass and pedicle screws, anterior cervical, transoral, cervical thoracic junction, posterior thoracic, open transthoracic, thoracic endoscopic, thoracolumbar junction, lumbar pedicle screws, lumbosacral junction, sacrum and pelvis.

Pearls and pitfalls

David Polly analyzed the pearls and pitfalls of robotics in minimally invasive surgery (MIS). Navigation tends to be favored in the thoracic and lumbar spine, as it decreases perforation risk and blood loss without any apparent change in operable time or complication rate. Use of navigation requires a capital investment, but when used for pedicle screw placement, it permits better biomechanical control and spinal deformity correction leading to lower rates of reoperation. Polly contrasted navigation and free-hand, finding the malpositioning of screws when placed freehand (without navigational aids) to be most often medial; he believes medial deviations to be more problematic than lateral deviations associated with malpositioning of screws with navigation. Specially, David Polly stated that surgeons who used navigation removed or repositioned their screws 0.6% of the time, while surgeons who did not use navigation removed or repositioned their screws 4.9% of the time.

Conversely, the pitfalls linked to navigation included increased radiation exposure to the patient, frame bang/dislodgement, intersegmental motion, instrument deformation, system errors, ability to find the source of error causation. Polly also noted the learning curve, which he denoted to be trivial (or negligible) after placement of 80 pedicle screws in non-deformity cases. One meta-analysis suggested increased operation time, but this was found to be experience-based rather than a literature-based source of error with navigation.

Total navigation

Dr. Hartl mentioned the concept of "total navigation" which he incorporated into his daily practice since using intraoperative CT based navigation. It describes that all essential steps, starting with level localization and skin incision to screw/cage placement, tube insertion and lastly decompression/tumor removal, are done using image guidance. This allows maximal precision for each step and helps to avoid complication. Specifically for MIS procedures when anatomical orientation is limited, the concept of "total navigation" becomes very useful. According to Dr. Hartl, the advantages of total navigation are the elimination of radiation exposure to the OR staff, improved workflow, image quality and accuracy. Two further important advantages are the elimination of K-wires by using a navigated drill guide and the reduction of wrong level surgery, especially in the thoracic spine. The latter is attributed to the possibility to merge preoperative MR images with intraoperative CT scans.

The negatives Dr. Hartl linked to "total navigation" covered the associated learning curve, which can potentially increase time in the OR, interrupt surgical flow, and come with a time investment and commitment. Also mentioned were the upfront costs, lack of data supporting clinical benefit, line-of-sight limitations and the inability to use in lateral lumbar interbody fusion (XLIF) or oblique lumbar interbody fusion (OLIF) as the imaging would have to be updated for every cage placement.

Pros and cons of spinal navigation

By now, it should be clear that spinal navigation has pros and cons. Although it simultaneously increases accuracy and decreases radiation, these advantages do come at a cost. That cost is a steep learning curve. Because of this, some surgeons opt for using fluoro as opposed to computer-assisted surgery (CAS). Dr. Meyer and his colleagues are perfect examples of this. They prefer fluoro with thoracic and lumbar spinal procedures. However, they do use navigation when placing pedicle screws in the cervical spine or upper thoracic spine. In Dr. Meyer's opinion, the machinery interferes with line-of-sight in the OR, thus giving the wrong position and subsequently decreasing accuracy. But the line-of-sight is not the only limiting factor decreasing accuracy. The associated learning curve also plays a role. Dr. Meyer and his colleagues found that in one year's time, the learning curve for CAS equates to that of the free hand learning curve in regards to accuracy and time spent scanning and placing the screw. It is notable that in order for accuracy to increase, frequency of use must increase. One must work with the technology frequently and not just on select cases, as confidence and comfortability usually increase proportionally to that of use.

Studies have shown navigation to be associated with decreased pedicle screw insertion time and increased accuracy with respect to positioning. This is not to say that revisions never occur. Screw revisions still happen intraoperatively and postoperatively. But, Meyer attributes them to extenuating factors, including patient obesity which results in unclear imaging. Alternatively, the necessity of revision can be attributed to system malfunction. Overall, 3D showed a reduction in revision surgery with regard to acceptable screws.

The two ultimate goals of spinal navigation are (I) an increase in patient safety and (II) an improvement to the surgeon's vision, thus, improving accuracy and efficiency leading to better surgical outcomes.

Trauma

In spine trauma navigation, there are five specific considerations to do and not to do. The first and most important is table height and positioning. Spatial orientation cannot be altered after the intraoperative CT scans are taken. Second, make sure to leave the self-retaining retractors in during scanning since the metal scatter will not affect image capture. Third, reduce the respiratory volumes by 30% in order to reduce chest wall excursions. Fourth, make screw holes before performing the decompression because the lateral mass screws can interfere with central decompression. Finally, begin with the most distal screw because in trauma, accuracy tends to decrease with time and distance. This decline in accuracy is independent of what the surgeon is doing. The key consideration in doing all of these things before instrumentation is an effort to aide in overall accuracy.

In cervical spine trauma navigation, many prefer Jackson over Skytron tables that place the chest bolster where the clavicle is and where the chin is almost touching the chest pad. This stabilizes both the C-T junction, and the majority of the cervical spine. Additionally, reference frames matter, and spinous process clamps are widely used as a reference. However, in the mid-cervical spine, there tends to be no clear spinous process clamp. Thus, you can use pedicle-based reference arcs as in deformity since they not only rigidly hold the spine, but also provide a good reference frame. It is of note that in the cervical spine you do not have a C2 spinous process to clamp on so the Mayfield frame becomes extremely helpful.

Cancer therapy

The three pillars to cancer therapy make it a multi-disciplinary approach: systemic therapy, radiation therapy and surgery. Using navigation for accurate tumor resection margins has already been noted. There are five main goals associated with its use: local tumor control, preservation or resurrection of neurologic function, maintaining stability of the spine, pain control, and palliation (metastatic) *vs.* cure (primary). Palliation is not a cure considering it is only taking care of a local problem; thus, we can cure primary tumors if the operation is optimal and the entire tumor is removed. In all, spinal navigation takes on a prominent role and facilitates: tumor margin definition, the extent of decompression, stabilization, tumor ablation and radiation.

Systems integration

In addition, the course included a section on systems integration. New technology, such as spinal navigation, is a multi-systems and multi-team technology. Thus, it requires proficiency of all team members involved. The analogy is that of a pit stop model in race car driving. There needs to be a dedicated team that is proficient for it to succeed the right way, every time.

Operative work flow has become an important issue for spinal procedures especially for long segment fusions. Introducing navigation systems or robotics requires significant changes in established work flows, often adding steps such as multi-stage registration to the procedure. This might present a burden when introducing navigation systems or robotics into clinical practice.

Dr. Ken Catchpole is the chair of the section on systems integration. He introduced the concepts of human factors and system integrations in spinal surgery. He defined human factors as the scientific discipline that studies all aspects of the way humans relate to the world around them, with the aim of optimizing performance, safety, costs and adoption of new technology. Essentially, it is why humans do what they do and how they can get better at doing it. He discussed that poor designs can cause errors and automation can increase workload.

Dr. Doniel Drazin reviewed a human factors analysis which showed that surgeon expertise decreases flow disruptions. Questions, such as when do flow disruptions happen and what causes them, were answered. Dr. Drazin explained that flow disruptions occur mostly during screw placement. One single disruption in the workflow can result in a snowball effect, with cumulative disruptions leading to potential surgical mistakes and increased OR time. To adapt new technologies, particularly image-guided spinal surgeries, teams must acquire proficiency together to prevent mistakes and miscommunications. For example, some hospitals will send their scrub technicians to navigation courses to get training in how to use the technology.

The last speaker of this section was Dr. Rajiv Sethi. He has published on the role of the Toyota Production System to spine surgery. He posited that it would theoretically decrease waste of motion, transportation, overproduction, surgery times, and processing. Improving surgical outcomes requires three main things: carefully selecting patients, removing the fee for service incentives to better empower health care providers, and rewards for better care. Selecting which technologies to adapt is complicated and must be carefully considered; each one has a distinctive learning curve that must be overcome by each member of the team.

Conclusions

The "First Annual Spinal Navigation, Emerging Technologies and Systems Integration" brought together a panel of highly qualified speakers and a diverse group of professionals interested in learning about spinal navigation, robotics in spinal surgery, new technologies and systems integration in the operating room and in healthcare. The speakers and subsequent open discussions raised awareness that navigation and emerging technologies have the potential to benefit patients and surgeons by enhancing surgical accuracy, reducing the reoperation rates, and decreasing radiation exposure to the OR staff. High acquisition and maintenance costs can be offset by the equally high reoperation costs, and can provide dramatic cost-effectiveness, especially for high-volume centers. Everyone in attendance participated and helped make the conference a success for all attendees and speakers.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Drazin D, Grunert P, Hartl R, Polly D, Meyer B, Catchpole K, Laufer I, Sethi R, Perry T, Simon D, Wang M, Fisher C, Scribner M, White G, Tubbs RS, Oskouian RJ, Kim T, Johnson JP. Highlights from the First Annual Spinal Navigation, Emerging Technologies and Systems Integration Meeting. Ann Transl Med 2018;6(6):110. doi: 10.21037/atm.2018.03.22

