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RESEARCH ARTICLE

Evolution of Navigation and Robotics in Spine Surgery

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ABSTRACT

Techniques and technology for spinal surgery have evolved together throughout the past few decades. There has been a growing popularity of image-guided surgery that has now progressed to robotic-assisted surgery with many FDA approved image-guided surgical robot systems now widely available such as Medtronic's Mazor X Stealth™ Edition robotic guidance system or Globus Medical's ExcelsiusGPS® Robotic Navigation Platform. As this trend continues, it is important to understand the basis for these technologies and examine the benefits and trajectories to improve safety and effectiveness going forward. In this review we examine the history, currently available technology, and the multiple benefits that have been studied regarding image-guided navigation and robotics in spine surgery.

History of Image-Guidance and Robotics in Spine Surgery

Spinal surgery with placement of instrumentation has been evolving rapidly with improvement in multiple aspects. These surgeries are unique in that instrumentation is placed within a narrow space where full visualization is not possible, yet there is potential for inaccuracy and a risk of clinical complications[1,2]. The use of imaging techniques has expanded rapidly from the first X-ray that was obtained to the development of fluoroscopy for intraoperative rapid imaging, intraoperative computed tomography, image-guided navigation, and now robotics that harness the power of image-guidance to assist surgeons[3].

Spinal applications of stereotaxy have evolved from cranial frame based stereotactic techniques along with the evolution of imaging technology[4]. As with most experimental techniques, in vitro studies were performed[5] showing good accuracy and later expanded to initial patient cohorts[6]. This technique was further pushed towards screw placement at the C1-2 level with transarticular screws showing that in 17 cadavers 16 were feasibly instrumented with image guidance whereas only 13/17 were feasible with the standard fluoroscopy-assisted approach.

As with many new technologies there were initial limitations that prevented rapid early adoption of emerging technologies: difficulties in registration process, lack of trackable instruments, applications only for screw placement, increased OR time, and cost were all factors to consider. To combat some of these limitations, other applications were being found for navigation technology such as for mapping out approach and decompression for calcified thoracic disc surgery[7], novel screw placements such as C1 laminar screws[8], sacroiliac screw placement[9], surgical planning for osteotomies in scoliosis surgery[10], and even assistance in spinal tumor resection[11]. Development of imaging systems such as the O-Arm (Medtronic Inc., Dublin, Ireland) which allow for cone-beam computed tomography images obtained directly within the operating room further improved the quality of images. The partnership of image-guidance technology with minimally invasive techniques further improved both the application and the workflow of image-guidance within spine surgeons' practice.

The next stage of development within this field was integration of robotic technology with image-guidance. The first spine robotic system approved by the FDA was Spine Assist (Mazor Robotics Ltd., Caesarea, Israel) released in 2004. Multiple robotic systems have now been released within the spine surgery marketplace: Mazor X Stealth (Medtronic, Dublin, Ireland), Rosa One Spine (Zimmer Biomet, Warsaw, IN, USA), Exelcius GPS (Globus Medical, Audubon, Pennsylvania, USA), Cirq (Brainlab, Munich, Germany), TiRobot (Tinavi, China), and Cuvis spine (Curexo, Seoul, Korea). The current robotic technology for spine harnesses the image-guided technology within its framework and use preplanned coordination to create a rigid working channel that assists in approach and gives real time feedback on instrument placement, skiving forces (force vectors against the rigid working channel), and reference array movement.

There are multiple potential benefits when considering intraoperative navigation with or without robotic assistance for spinal instrumentation: greater accuracy of placement[12], surgeon comfort/ergonomics, and decreased radiation exposure to surgeon and staff[13].

Currently Available Image-Guidance and Robotic Technologies

Image-guided navigation in spine surgery include 2D images, in which a fluoroscope or plain radiography is used, and 3D navigation, making use of cone-beam CT or CT scans. The main goal is to accurately track surgical instruments over the patient's anatomy and surgical field. This is accomplished by triangulation, in which two stationary points and one dynamic point are tracked by a computer, much like a GPS satellite tracks cars. Tracking is most commonly done with the use of cameras that project and detect reflected infrared light from either reflecting spheres or light-emitting diodes that are stationary and act as a reference point. Various methods have been employed over the years to "register" the stationary reference points to the patient's anatomical imaging scans. Some methods utilize a patient's pre-operative CT scans and others use intra-operative CT or fluoroscopy imaging. Pre-operative CT-based navigation was historically first employed by using either point-matching or surface-matching techniques to register the patient's anatomy to the pre-operative image. There were numerous disadvantages of this method, including extensive bony exposure for adequate registration, difficulty of identifying exact landmarks, and shifting of vertebral columns between the preoperative CT and positioning in the OR. Particularly in complex deformities and multi-level surgeries, re-registration was required and ultimately proved to be time consuming and tedious[14].

Intra-operative imaging via 2D fluoroscopic C-arm or 3D cone-beam CT after the patient has already been positioned in the OR, naturally supplemented pre-operative imaging over the years. In 2D fluoroscopy-based navigation, the computer recognizes a calibration target on the C-arm fluoroscope and registers AP and lateral fluoroscopic images from a dynamic reference base (DRB) attached to the patient. This dynamic reference base must be attached to a fixed anatomic location on a patient. The navigation system then outputs the presence of instruments by superimposing the images of the instruments onto the fluoroscopic images of the patient anatomy[15]. 3D cone-beam CT offers even more advantages than 2D methods due to superior anatomic representations of patient anatomy by including axial reconstructions. Furthermore, cone beam CTs offer superior image quality in obese and osteopenic patients compared to two-dimensional C-arm fluoroscopy[16]. The most widely used cone-beam CT-based system is the O-Arm (Medtronic) but other similar systems include the Arcadis Orbic 3D isocentric C-arm (Siemens AG), the Ziehm Vision FD Vario 3D (Ziehm), Airo (BrainLAB) and BodyTom (NeuroLogica Corp.).

As image-guidance technologies started maturing, the marriage of robotics and computer-assisted navigation was a natural next step. In 2004, the FDA approved the first robotic assistance device for thoracolumbar screw fixation: the SpineAssist (Mazor Robotics Ltd). This system consisted of a robotic arm, a mounting system, and guide-sleeves for pedicle screw placement. In the subsequent years, almost six other competitor systems have been introduced in the market as of this writing. The original Mazor spine robotics system was acquired by Medtronic in 2018; shortly thereafter in 2019, the company launched Mazor X Stealth Edition which allows surgeons to create personalized surgical plans prior to surgery and holds surgical instrumentation in place with a robotic arm during spine procedures. Globus Medical acquired Excelsius in 2014 and the ExcelsiusGPS system was approved by the FDA in August 2017. Zimmer Biomet acquired Medtech SA in 2016; Medtech developed the Rosa Brain and Rosa Spine robotic-assisted surgery systems and the Rosa One Spine System received FDA approval in March 2019. Brainlab received FDA approval for two surgical robots in 2021: the Cirq spine system and the Loop X Mobile Imaging Robot. According to Brainlab, the Loop-X is the first fully robotic intra-operative imaging device on the market. Other less known companies include Curexo, a South Korean device maker, which received FDA licensing for its spine robot in May 2021 as well as Accleus, which was previously known as Fusion Robotics, which also received FDA 501(k) clearance in early 2021[17].

Advantages

Pedicle Screw Accuracy

Image-guidance and robotics allow for increased accuracy of spinal instrumentation, planning minimally invasive trajectories to spine pathology, and decrease the radiation exposure to the surgeon. Although spinal instrumentation has been quite varied historically, pedicle-screw fixation is now the most utilized technique in thoracolumbar spine fusion. Accurately placed screws without medial or inferior breaches of the pedicle are paramount in avoiding injury to neural elements. However, difficult patient anatomy can often make freehand insertion using bony landmarks quite challenging and often the learning curve remains quite steep[18]. The rate of thoracolumbar pedicle screw misplacement using freehand techniques varies in literature from 2% - 50%[19,20,21]. Newer literature, particularly by those surgeons utilizing 2-D fluoroscopy techniques quote a lower misplacement rate between 2% to 22%[22]. It is important to note that there were inconsistencies in the studies as to the definition of a mispositioned screw; furthermore, pedicle screws that breach laterally or even medially or inferiorly by just 1-2mm may be clinically insignificant.

Thus far, two randomized control trials have compared pedicle screw placement rates between image-guided techniques and freehand techniques. Laine et al compared 100 patients randomized to either conventional pedicle screw placement or computer-assisted screw application using an optoelectronic navigation system. They found pedicle perforation rate was 13.4% in the conventional group and 4.6% in the computer-assisted group[23]. Rajasekaran et al studied 31 patients with spinal deformity (27 patients with scoliosis and 6 patients with kyphosis) and randomized 17 patients to image-guidance navigation and 16 patients to 2-D fluoroscopy and found 54 (23%) pedicle breaches in the non-navigation group as compared to only 5 (2%) in the navigation group[24]. Meta-analysis and systematic reviews have also shown superior pedicle screw fixation when surgeons utilize image-guidance. Mason et al reported in their meta-analysis of 30 studies in which a total of 1973 patients in whom 9310 pedicle screws were inserted, only 68.1% of screws were inserted accurately with conventional fluoroscopy; however, 84.3% of screws were inserted accurately with 2D fluoroscopic navigation and a remarkable 95.5% of screws were inserted accurately with 3D fluoroscopic navigation[25]. Gelalis et al, in their systematic review of 26 studies, reported pedicle screw accuracy rates of 69% to 94% using freehand techniques, 28% to

85% when utilizing 2-D fluoroscopy, and 89% to 100% when utilizing image-guidance[26].

The accuracy conferred by spinal robotic systems also show a trend towards increased accuracy. Kim et al randomized 40 patients into two equal groups with one group undergoing robot-assisted minimally invasive posterior lumbar interbody fusion (using the Mazor ™ spine robot) and another group undergoing conventional open posterior PLIF using freehand technique. They found no significant difference in screw placement accuracy, but the robot-assisted arm did have significantly less proximal facet joint violations[27]. Ringel et al randomized 60 patients into robotic-assisted and freehand-technique pedicle screw placement groups and found that 85% of patients had acceptable screw placement via robotic assistance compared to 93% using the free-hand technique[28]. The authors commented that skiving of the cannula on enlarged degenerative facets at the screw entry point was a potential factor that led to misplacement. Hyun et al randomized 30 patients to a robot-assisted arm and 30 patients to a fluoroscopic-guided arm and found 100% accuracy using robotic assistance compared with 98% using the free-hand fluoroscopic technique[29]. A meta-analysis by Gao et al looking at five randomized controlled studies have shown that robotic assistance is equivalent to free-hand technique, with fewer proximal facet joint violations[30].

Radiation Exposure and Operative Time

Minimizing radiation exposure to the staff and patient are essential components to consider when using image-guidance or spine robotic systems. Since the surgeon and other ancillary operative room staff perform many spine procedures in their lifetimes, radiation exposure to the operating personnel ought to be as low as possible. Spinal instrumentation utilizing active fluoroscopy can be burdensome due to the constant maneuvering of the fluoroscope and the need to use heavy lead protection. Furthermore, in cases with complex deformities and re-operations on the spine, radiation exposure can increase many-fold[31].

The advent of low-dose intra-operative helical computed tomography (e.g., O-Arm Navigation) has resulted in a 20-fold decrease in total radiation dose compared with standard CT[32]. Another study by Nottmeier et al showed that if the surgeon and staff stood more than ten feet away from a conebeam CT-guided imaging system, there was little to no radiation exposure to the OR personnel[33]. Keric et al, in their retrospective cohort study of robotic percutaneous instrumentation versus free-hand techniques, found that radiation time per screw in the robotic procedure (0.4 min / screw) was significantly less than the free-hand cohort (0.94 min /screw)[34]. Gao et al in 2018 performed a meta-analysis of six randomized control trials involving 158 patients with 688 pedicle screws and noted that robotic assistance reduced operative radiation time by an average of 12.38 seconds[30]. Interestingly the same study also found increased total operative time in robot-assisted cohort.

Very few studies have prospectively analyzed operative times when utilizing intra-operative image-guidance. Khanna et al studied setup and procedural times with the use of O-arm-based navigation versus freehand techniques and found no significant differences between the groups in the setup times, but procedure time was significantly shorter in navigated cases (3 hours 39 minutes vs 4 hours 4 minutes; P = .0003). The authors did note a time-dependent decrease in operative time over a span of four years[35]. Data for robotic assistance is mixed but does show a trend towards longer operative times compared to free-hand techniques. Lonjon et al in their prospective study found a significantly longer average operating time using robotic assistance (336 min) compared with free-hand technique (226 min, $P<0.001$)[36]. Kantelhardt et al compared percutaneous and open robotic assistant pedicle screw to standard free-hand technique and found no significant differences among percutaneous (57 min/screw), open (65.2 min/screw), or free-hand technique (52.9 min/screw)[37]. Tian et al found no significant difference in total operating times but did find instrumentation time to be shorter with free-hand techniques[38].

Patient Outcomes and Complications

Image-guidance and robotics have often been tools in the armamentarium of minimally invasive spine surgery (MIS). The ultimate goal of MIS is to perform same surgery as a traditional open surgery with reduced soft tissue injury. This will naturally shorten length of stay, decrease complications, and improve patient outcomes. Indeed, Kantelhart et al have found robotic-assisted fusion resulted in an average decrease of 4 days of hospitalization compared with conventional techniques and Hyun et al found hospital length of stay to be approximately three days shorter using robotic assistance[29,37]. Tian et al showed that minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) using image-guidance resulted in less blood loss, fewer transfusions, and less postoperative drainage than open TLIF[39]. Xiao et al noted amongst 1208 procedures noted a 50% reduction in reoperation in the navigated group, especially with hardware failure and screw misplacement[40]. Jiang et al compared a cohort of robotic-assisted MIS versus freehand open technique in short segment lumbar fusions and found less intraoperative blood loss and shorter hospital stay in the robot group[41]. It is important to note, however, that the improved outcomes and post-operative complications noted in these studies may also be due to the differences between MIS and open techniques rather than primarily due to the use of image-guidance and robotics.

Economics of Image-Guidance and Spine Robotics

There are certainly cost limitations to implementing robotics in many hospitals and the learning curve may prove to be steep; but, in the right clinical setting, robotic-assisted spine systems can allow surgeons and hospitals to be efficient in getting through a large volume of complex cases. In fact, some reports anticipate a significant increase of healthcare accessibility to robotics in the near future[42].

In a systematic review on the topic of cost effectiveness and robotic spine surgery, Fiani et al. commented that no direct cost saving measures had been made to date, with studies only analyzing specific cost saving measures such as fluoroscopy time, revision rate, and operative time[43].

Menger et al. conducted one such study using estimated costs saved in a year by extrapolating available data on robotic surgery and applying length of stay, OR time, reduction of revisions, and reduction of infections on a one year cohort of patients[44]. Based on estimated savings from these parameters they found that in a cohort of 557 thoracolumbar instrumentation cases that a potential conservative savings estimate of $608,546 within a single year at their institution. Although these estimates were favorable, use of applied data to a potential patient cohort is inferior to conducting direct observations of cost saving outcomes in a cohort of treated patients.

Future Directions of Image-Guidance and Robotic Spine Systems

The newest evolving technology with regard to image guidance in spine surgery is augmented reality (AR) whereby an image overlay can give a surgeon real time vision of anatomy while looking directly at the patient/surgical field.

Within robotic assisted surgery the future lies in expanding the abilities and application. Currently the primary focus of the robot is in placement of pedicle screws[45] which limits its impact beyond that of a high end image-guidance system. Expansion of its abilities and applications within spine surgery will likely improve its effectiveness and improve the cost benefit analysis of interested health systems looking to integrate robotic systems.

Conclusions

Robotics and image-guided navigation have proven to be useful tools for spine surgeons in performing safe and effective surgeries. These systems have the potential to improve the accuracy of instrumentation, reduce operating room personnel radiation exposure, and ultimately lead to decreased length of stay and reduced complications. Based on the trajectory of image guidance in surgery, robotic spine surgery is here to stay and its footprint will further expand. Given the shift towards prioritizing patient reported outcomes, future studies should examine the role of image guidance and robotics to improve these outcomes as well as their application to the growing armamentarium of minimally invasive approaches.

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