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Overview of Robotics in Neurosurgery

Chris Wagner, PhD; Michael Raber, MD; Venita Simpson, MD; Omaditya Khanna, MD; Shweta B. Gupta, MME, MBA; Chengyuan Wu, MD, MSBmE

Introduction

The promise of robotics for surgery is large - they have the potential to increase the dexterity of the surgeon, provide minimally-invasive access without loss of surgical ability, feature motion-scaling so surgeons can easily manipulate small delicate structures, integrate with image guidance so the robot can avoid critical anatomy, and increase the accuracy and precision of changing that anatomy. Robots for surgery are also becoming more popular and widespread. Laparoscopy, gynecology, neurosurgery, vascular surgery, cardiothoracic surgery, and recently pulmonary interventions all have had robotic systems on the market, with many more clinical specialties in the process of adopting this technology into their practice (Leal Ghezzi, 2016).

While there are a range of surgical robots for various surgical disciplines, the way the robots provide a benefit can be broken down into three broad categories. The first category is *tele-surgical systems* where the surgeon directly controls every motion of the machine; an example of which is the da Vinci Surgical System (Intuitive Surgical, Inc.). The key benefit of these systems is that they enable minimally-invasive access without a significant training burden - allowing the surgeon to carry out complex manipulations on tissue such as suturing through a small incision. The second type of robots are *supervisory controlled systems* in which the machine is preprogrammed with actions which are autonomously performed by the robot itself under close supervision of the surgeon. These systems are interlinked with image-guidance - the use of preoperative or intraoperative imaging to allow the robot to understand its location relative to anatomy. And lastly, the third type of surgical robots available are *shared-control models*, in which both the surgeon and the robot concurrently control motions. These systems also will typically rely on imaging information to understand the robot position relative to patient anatomy (Fiani, 2017).

Despite the activity and possible benefit, the use of robotics in surgery is still at an early stage. Robotics are not the standard of care in most fields. This is due to a number of factors - cost/benefit trade-offs, familiarity, and ease of integration being several primary ones. This is to be expected when adopting new tools, especially ones of a deeply technical nature like robotics. At this stage of adoption, the early users of the technology are asked to take on more of a burden - in terms of cost, usability, training, and reliability - to gain the potential benefits that this technology allows.

In this paper, we give a brief overview of current neurosurgical robotic systems - robotic surgical systems that aid both cranial and spinal surgery - as well as **establish the main questions clinicians should ask of these systems** to understand their trade-offs. Answers to these questions should allow clinicians a systematic way to understand how the robotic systems achieve accuracy and efficiency, and what trade-offs the system is asking the user to make to achieve these benefits. For example, the series of questions should lead to understanding of simple workflow trade-offs (e.g., if a step is compromised, how does it affect the final execution?) and equipment dependencies (e.g., what imaging is needed to plan the operation?). These questions are structured around the basic workflow shared by both cranial and spine systems; and then augmented by concerns specific to each. Ideally, these sets of questions highlight the important decision points clinicians have on adopting and using current and future systems.

Workflow of a robotic neurosurgery operation

Neurosurgery procedures heavily rely on imaging to aid the surgeon. Surgeons examine a number of preoperative x-ray, CT, and/or MRI images to formulate a surgical plan and approach. Then intraoperative imaging (such as fluoroscopy and direct viewing) and intraoperative monitoring (such as neuromonitoring or patient interaction) are employed to further guide clinical decisions and ensure the surgery was carried out in the correct location in the anatomy. One limitation is the inability to directly observe detail intraoperatively that only exists on preoperative imaging (such as anatomy or pathology on an MRI that is deep in the brain). Another limitation of this approach is the significant exposure of ionizing radiation to both the patient and clinical staff. Navigated and robotically-assisted neurosurgery procedures are an attempt to deliver the accuracy and confidence of procedures that use direct intraoperative imaging, but with less radiation exposure and improved workflow.

Robotically assisted spine and cranial surgery systems achieve these benefits using a pre-operative image-guided procedure workflow, similar to a stereotactic or “navigated” procedure workflow. A 3-D image is acquired before the procedure, a geometric plan (such as stereotactic trajectory or screw trajectory) is determined based on that image, then the image (and thus the plan) are aligned to the actual anatomy in the operating room. Because the robot system now understands the plan location relative to the actual anatomy, it can hold a tool or drill guide in that location, allowing the surgeon to accurately achieve the plan. The key to achieving overall accuracy - placing the drill or implant in the exact planned position relative to the anatomy - is thus to ensure all steps of this procedure maintain accuracy.

<u>Stages of Robotic Procedures</u>

1. **3-D Imaging.** The basis of image-guided procedures is to acquire a high-resolution 3-D image of the anatomy. This can be a preoperative CT scan, preoperative MRI, or intraoperative O-arm scan. Note that the accuracy of the final robotic guidance begins with accuracy in this step - if the slice reconstruction of the data is too coarse, or if there are significant imaging artifacts (such as patient movement mid-MRI scan, or metal artifact in a CT scan over relevant anatomy), this will limit the achievable accuracy.

2. **Planning.** Based on the 3-D anatomical image, the surgeon determines a desired trajectory. This can include entry position, trajectory through the tissue avoiding critical structures, and final implant or tool placement. This plan is the "ideal" - what the surgeon would like to achieve if the achievable accuracy is perfect.

3. **Registration.** This is the key step that aligns the 3-D imaging frame of reference (which contains the image of the anatomy as well as the plan) with the actual patient position in the OR. There are a number of different ways of achieving this registration, each with workflow and accuracy trade-offs. Options include mechanical based surface registration or bone fiducial registration (where a surgeon uses a probe to specify the location of anatomy, which also exists in the preoperative image) or intraoperative 2-D imaging (where a series of x-rays are taken in the OR and the x-ray images and the position of the C-arm are aligned with the preoperative image).

4. **Delivery.** Once the plan has been registered to the intraoperative patient position and anatomy, an image-guided robot can position a guide to help achieve the plan. This can be positioning a drill guide for pedicle screws or lead guide for electrode placement. Again, accuracy of the overall operation also relies on accuracy in this step - ensuring the robot is holding the guide in the proper position relative to the plan, and ensuring that the system understands any shift in patient position after the registration step has occurred.

5. **Postoperative Verification**. After completion of the surgical procedure, it is important to verify the accuracy of the delivered plan - not only to evaluate the appropriateness of the surgery itself, but also to quantify any errors with the intent to correct for them in future procedures.

Navigated and robotic systems achieve accuracy and workflow benefits using a series of accurate alignments between pre-operative images, intra-operative tracking tools, and the patient's anatomy (Figure 1). All of these alignments need to be correct for the final system to be accurate; however, the relationship between what the user is doing at each step, and the accuracy implications can be subtle. Also, a number of safety checks exist in the systems so that user errors do not manifest as final accuracy errors; however, these checks only protect against some errors, and understanding what type of errors are not caught can also be subtle. Hence, this paper provides a series of relevant questions to help a user or prospective user understand accuracy and workflow implications at each step of the operation.

3-D Imaging	- What equipment is needed to enable 3-D imaging? - Can an existing diagnostic MRI or CT image be used as a guidance image? - Can an OR based 3-D image be used, such as with cone beam CT, or an O-arm? - What additional steps are required for the patient, clinician, and

	clinical staff to take during imaging, as compared to a non-robotic operation? - How sensitive is the final outcome to these additional steps? - Does the system allow a double-check to make sure all steps were carried out correctly?
Planning	- When can the planning step be carried out (e.g., before the surgery in the surgeon's office, or in the OR)? - How long does planning take? - Can the plan be updated before and/or during the operation? - Can I share the plan with others? - Can I use a plan from one system, but review and deliver from another? - How sensitive is the final outcome to errors in this step (e.g., incorrect screw size choice)?
Registration	- What equipment is needed to enable registration? Additional imaging equipment? Additional sterilized tool trays? - Are there multiple ways of registering with the same system? - If so, what are the accuracy trade-offs? - What additional steps are required for the patient, clinician, and clinical staff to take during registration, as compared to a non-robotic operation? - Are there workflow changes required, as compared to a non-robotic operation? - What assumptions does the system make about the anatomy (e.g., rigid bones, thin soft tissue layer) to guarantee accuracy? - Are there double-checks to make sure the registration is accurate? - Do these double-checks result in a visible sign of accuracy, or does the user have to trust the double check has been carried out? - Do the double-checks check all sources of inaccuracy? - If the double-check fails, what steps need to be repeated to use the system? How long does this take? Can this be overridden?
Delivery	- The navigation screen will always show an estimate of the current tracked tool position relative to the anatomy - how accurate is this estimate? - How does the system account for significant forces during guidance of the tool or implant? - Does the system provide any confirmation of the accuracy of the delivery against plan?
Postoperative Verification	- What image types are necessary to perform this postoperative verification? - Can routine postoperative imaging be incorporated into this workflow for assessment? - Is the system capable of automatically calculating the degree and type of error that has resulted?

In the following sections, we explore more details of these questions in the context of cranial and spine robotically assisted systems.

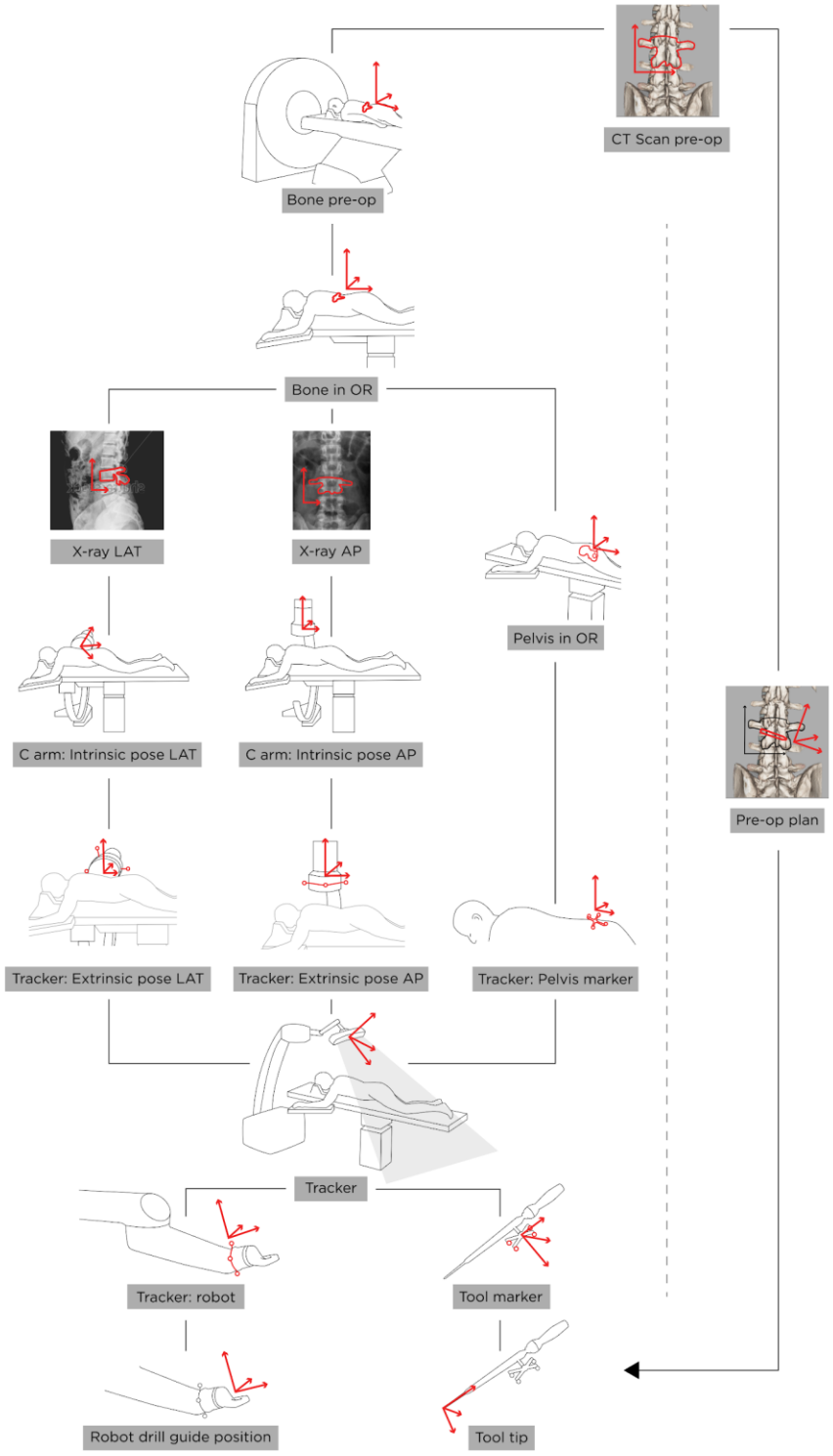

Figure 1 - Relationships between frames of reference used in a sample robotic spine operation. Each line represents a change of reference frame, where errors can accumulate. Understanding

what types of errors can accumulate, and what system features let a user double check those relationships, is important to delivering a high quality surgery.

Robotics for Cranial Surgery

Robotics for cranial surgery is the latest technology that builds on the historical trend of increasing accuracy for neurosurgery. Early forays into stereotaxy, dating back to the late 1800s, were severely constrained by the wide variability between bony landmarks and intracranial targets. Frame-based stereotaxy was first introduced by Spiegel and Wycis in 1947, who paired pneumoencephalograms with intracranial reference landmarks such as the foramen of Monro and the pineal gland (Gildenberg, 2001). Later combination of frames with 3-D imaging enabled principled access of anatomic locations based on locations identified on the image. Stereotaxy has continued to develop over the past several decades, leading to improvements such as frameless methods of stereotaxy.

Robotics for cranial surgery uses the coordinate frame established by a stereotactic headframe, in combination with CT imaging, to deliver a tool or an implant to a precise location. First demonstrated in 1985, with the Programmable Universal Machine for Assembly (PUMA) robotic device (Kwoh, 1988) aiding navigation to an intracranial lesion, there are now several robotic systems that have gained FDA approval, each with its own relative strengths and limitations.

Current systems

Renaissance Guidance System, Mazor Robotics

The system from Mazor was initially designed for use in spinal surgery, to assist with pedicle screw placement, gaining FDA approval for this application in 2004, before it was expanded to allow for intracranial stereotactic applications in 2012. For cranial procedures, a target, entry point, and trajectory are identified on a preoperative MRI. A low profile reference platform is attached to the skull, and an associated marker attachment is secured to it. A CT scan is obtained and co-registered with the MRI; this data is fed into a software that is able to interpret the planned trajectories by synchronizing it with the reference platform. In a retrospective case series of 20 DBS implants in a single center, the mean radial error was found to be 0.7 +/- 0.36 mm (VanSickle, 2014).

ROSA, Zimmer Biomet

The ROSA robot (Zimmer Biomet) also affords the surgeon with six degrees of freedom and exists as a free-standing system. It gained FDA approval for intracranial applications in 2012. Coregistration of a patient can be performed with a noninvasive laser registration system that automatically captures 5,000-8,000 individual points along the face and forehead as long as the patient is positioned supine. After registration has occurred, the robot is locked in this position throughout the duration of the stereotactic procedure to preserve the registration and maintain

accuracy. ROSA has been used extensively for stereoelectroencephalography (sEEG) electrode implantation with a high degree of accuracy; entry point error has been shown to be less than 2 mm in more than 90% of cases, and targeting error is less than 2 mm in 83% of cases (Gonzalez-Martinez J, 2016).

A key feature of this system is the haptic feedback that its robotic arm provides. Specifically, once providing the appropriate command, the surgeon can move the arm simply by directly manipulating the arm in the desired direction. Such movement can occur either along the designated trajectory of interest or freely without restriction; when the movement has been completed, the arm locks into this new position.

Neuromate Robot, Renishaw

The Neuromate robot (Renishaw) provides surgeons with five degrees of freedom for use in stereotactic applications. It gained FDA approval for intracranial procedures in 2014 (it is currently not approved for use in spine surgery). Before surgery, the surgeon plans the intended trajectories on preoperative images, which usually consists of a gadolinium-enhanced MRI and may also include other forms of vascular imaging or functional imaging. Registration can then be performed with either frame-based or frameless methods.

Once in the operating room, the patient's head is directly fixed to the robot base, which ensures that the robotic arm is at a standard and consistent distance from the patient's head. The head may be fixed within a Leksell or CRW frame for frame-based registration, or the Neuromate head holder for frameless registration. Rather than laser registration of facial anatomy, the frameless registration of the Neuromate robot relies on ultrasound registration of the patient's head via a base plate fixed to the skull. Fidelity has been demonstrated in multiple studies: registration error averages 0.44-0.86 mm for frame-based and 1.6-1.95 mm for frameless setup; both have an average error of less than 2 mm, but the frame-based method is significantly more accurate than frameless (Varma, 2006). Entry point error for frame-based application is 2 mm or less in 91-96% of patients (Cardinale, 2013). Target point error for frame-based averages has been cited as 0.86 mm in one study, with two other studies reporting median targeting error of 1.7 mm; average targeting error for frameless application has been cited at 1.7 mm (Li, 2002).

Workflow summary and key questions

The use of robots in the cranial operating room comes with it inherent benefits and limitations, which must be taken into account in order to ensure seamless integration into the surgical workflow. The operating room itself has to be spacious enough to house the robot system, in addition to any accessory equipment such as C-arm or O-arm, and to accommodate the surgeons, anesthesiologists, nurses, techs, and company representatives involved in the case. The presence of a large robotic system that needs to remain in a fixed position near the patient's head limits the space available around the surgical field. For intracranial procedures such as DBS and sEEG electrode placement, the surgeons and the support staff must be familiar with the nuances of incorporating the robot into the surgical procedure, which includes sterile draping of the robot, understanding when and where the robotic arm should and should

not move, and how to preserve efficient instrument passing between the operator and assistant(s) within the constraints of the limited workspace around the patient and robot position.

In order to benefit from the increased potential for surgical precision offered by robotic systems, the surgeon must spend time planning the operation (e.g., devising sEEG trajectories and targets), and become familiar with the computing software. Then, adequate time must be appropriated to set up the robot system and ensure its proper functioning. The use of robots inherently carries with it the risk of technical failure and systems malfunction, and requires a greater degree of user knowledge compared to traditional image-guidance systems. Thus, although robots confer greater surgical precision, this must be weighed against the inherent risk of mechanical failure that comes with utilizing machine-based systems.

The use of robotic systems carry a steep financial cost, in regards to both the up-front capital cost of purchasing the machine system and the long-term cost of regular maintenance, servicing, and calibration. The financial costs incurred from the purchase and maintenance must be weighed against the incremental benefits obtained from cost-saving achieved during procedures performed using robotic systems. Automation of repetitive movements using a robotic system has the additional benefit of decreasing operative time in cases where multiple trajectories are used, such as with sEEG implants. The value of decreased operating room time cannot be overstated; one study cited an average decrease in OR time of 222 min when compared with traditional stereotactic frames. If OR time is valued at $100 per minute, the savings for a single robot case may exceed $22,000 (Gonzalez-Martinez, 2016; Macario, 2010). At our institution's series, the marginal cost savings from total OR time using a robot becomes appreciable after the implantation of 4 sEEG electrodes, compared to traditional frame-based stereotaxy. Furthermore, these factors also help to reduce surgeon fatigue and ultimately to minimize the risk for associated adverse events.

The following questions can help further identify the main decision points when considering the introduction of robotics for cranial surgery:

3-D Imaging	- What image file types can the system accept? - By what means can data be imported into the robot? - Can the software automatically highlight structures of interest?
Planning	- Can the system co-register multiple image modalities (e.g., CT with MRI) to aid planning? How many images can be co-registered? - Is the planning software intuitive and easy to use? - Does the system provide any assistance for planning?
Registration	- What are all the possible methods of registration? - How is the accuracy of registration verified? - What contingency protocols exist if registration were to fail?
Delivery	- How easily can the robotic system be incorporated into your workflow? - What personnel is needed to operate the robot during the surgical

	procedure? - How versatile is the system with regards to potential applications? - Are there any features that help improve accuracy of delivery?

Robotics in Spine Surgery

Robotic-assisted systems in spinal surgery have become available relatively recently, as compared to cranial systems. The evolution of robotics in spinal surgery parallels the evolution of image guidance for cranial cases, where robotic spine surgery expands on the technology of computer assisted navigation (CAN) while attempting to address drawbacks around workflow and accuracy during delivery.

The accuracy of computer-assisted navigation depends on several variables, including a direct line of sight from the tracking system camera to the instrumentation tools, relative angles between the camera and registered instruments, camera quality, surgeon skill and expertise in acquiring and registering images, and environmental conditions such as heat, humidity, and light. In an attempt to mitigate some of these shortcomings, and as distinct from cranial robotic systems, miniature robotic systems that attach directly to bony landmarks were conceptualized in the early 2000s (Overley, 2017). These robotic assistants utilize the same CAN platforms, and add the indefatigability and reproducibility inherent to robotic systems, while attempting to minimize the drawbacks of surgeon interference with the tracking system.

The application of CT-based 3-D navigation in spine surgery has been well studied with over twenty clinical trials utilizing various manufacturers' platforms. Primary end points in the majority of studies have evaluated the accuracy and safety of pedicle screw placement utilizing this technology. Schwarzenbach et al first published on the accuracy of pedicle screw placement utilizing a novel CT-based navigation system. They found a rate of 2.7% pedicle breach in 162 lumbar pedicle screws placed *in vivo*. The authors also commented on the learning curve of the computer assisted navigation, noting more breaches in the earlier utilizations of the technology (Schwarzenbach, 1997). In the largest single *in vivo* study to date, Yu et al evaluated the accuracy of 2,062 thoracic and lumbar pedicle screws utilizing intraoperative 3-D imaging and found only 4.6% to be breached greater than 2 mm compared to 16% in 276 free-hand screws ($P < .001$). The authors additionally found a significantly decreased rate of operative time in the navigation cohort and concluded that 3-D navigation-assisted screw instrumentation was more accurate and less time consuming than conventional free-hand techniques (Yu, 2008).

In addition to computer assisted navigation, robotic spine surgery also addresses excess radiation exposure to the surgeon and patient during fluoroscopy-guided free hand techniques by reducing the reliance on fluoroscopy. This reduction is critically important for spine surgery, as the hazardous ionizing radiation exposure incurred by the surgeon, patient, and OR staff has been shown to be exponentially increased over other subspecialties in orthopedics and neurosurgery. When comparing radiation exposure experienced by a spine surgeon to other orthopedic subspecialties, a spine surgeon sees fifty times the lifetime radiation dose compared

to that of a hip surgeon (Overley, 2017). To further this alarming statistic, the increasing popularity of MIS, which relies even more on fluoroscopic imaging for percutaneous instrumentation, subjects all parties involved to even more radiation that has been linked to the development of cataracts, skin erythema, leukemia, thyroid carcinoma, and other neoplasms (Mountford, 1992; Mroz, 2011).

Current Systems

The applications for intraoperative navigation and image-guided robotics have expanded to surgical resection of spinal column and intradural tumors, revision procedures on arthrodesed spines, and deformity cases with distorted anatomy.

Renaissance, Mazor Robotics Ltd.

The SpineAssist, along with the Renaissance (second generation) (Mazor Robotics Ltd., Casesarea, Israel), is a miniature bone-mounted robot that has six degrees of freedom, and has been extensively studied. A preoperative CT is used to plan trajectories, and intraoperative fluoroscopy is used to register the images. The robot then guides the surgeon to the appropriate trajectory (Joseph, 2017). Previous studies of the SpineAssist by Mazor demonstrated an average error of less than 2 mm in 98.3% of pedicle screws inserted (N=646) (Devito, 2010). In a study comparing freehand fluoroscopy-guided screws to robotic assisted thoracolumbar pedicle screws, SpineAssist had a significantly greater proportion of non-misplaced screws in comparison to freehand (Gertzbein-Robbins Grades A and B;P=0.005). SpineAssist's successor, the Renaissance Guidance System (Mazor Robotics Ltd.), demonstrated 94.5% accuracy versus 91.4% accuracy with conventionally placed screws (Molligaj, 2017).

ROSA (Zimmer Biomet)

The ROSA robot (formerly Medtech now Zimmer Biomet) is another system with similar abilities approved for use in Europe. It uses an intraoperative O-arm (Medtronic Inc) to scan the patient and integrate information to its system with markers in place. They function in a semi-active mode, aligning instruments for pedicle screw placement. This is connected to the central processing unit, which is essentially a computer that integrates the preoperative CT scan to the intraoperative radiographic image (Madhavan, 2017). ROSA does not always require a pre-operative CT and allows 3-D planning for robot-assisted instrumentation by relying on intraoperative fluoroscopy or CT scan. Furthermore, the ROSA takes advantage of a navigation camera and image-guided reference which allows for instrument tracking in real-time (Ghasem, 2018). The ROSA robot includes a mobile floor-fixed base attached to a robotic arm with six degrees of freedom. A second mobile base has a navigation camera mounted to it. The ROSA is an image-guided device and uses an iliac pin for a reference point.

Excelsius GPS (Globus Medical)

The Excelsius GPS (Globus Medical, Inc.) was approved by the FDA in 2017. This robot allows for real-time intraoperative imaging, registration, and direct screw insertion through a rigid external arm—without the need for interspinous clamps or K-wires. The active end effector

communicates with the camera to dynamically adjust arm position and optimize kinematics. The end effector aligns the rigid robotic arm along the planned trajectory to enable precise implant placement with GPS systems. The robotic arm automatically moves along the planned trajectory. The rigidity of the robotic arm remains stable during implant insertion on steep trajectories. Excelsius GPS is compatible with preoperative CT, intraoperative CT, and fluoroscopic imaging systems allowing surgical workflow and planning, and navigation in 2-D or 3-D (Zygourakis, 2018).

Workflow summary and key questions

Robotics in spine surgery is a new technology that holds promise for future applications. Currently, placement of pedicle screws with robotics appears to be safe, and accuracy appears to be superior to freehand placement, although the data from recently published studies are inconclusive. Although the technology may be pricier upfront along with the annual expenditure on technical support and maintenance, the reduction in intraoperative fluoroscopy, faster procedures leading to decrease in OR time, and fewer surgeries for complications or revisions may result in long-term cost savings for the hospital or institution (Fiani, 2017). New studies looking into increased utilities of this technology, such as brain and spine tumor resection, deep brain stimulation procedures, and osteotomies in deformity surgery, might authenticate the cost of the equipment.

3-D Imaging	- Using 3-D models, is there an option to export plans into navigation systems used in the operating room?
Planning	- Can systems implement complex plans into surgical practice? For example, the simulation of osteotomy cuts, or placement of commercial or individualized implants (with different designs, adjustable sizes, and dimensions).
Registration	- What assumptions are the systems making about the anatomy to achieve accuracy (e.g., thin, constant tissue thickness, etc.)?
Delivery	- How does the system control for drilling forces that cause the bit to mis-align with the desired axis (i.e., skyve forces)? - Can the systems adapt in “real time” to acknowledge the anatomical changes made during a deformity correction surgery? - Can systems provide (currently, or in the future) ‘‘no-fly zones’’ around protected structures, such as the dura? Do these systems have to be robots, or can they be mechanically passive (e.g., a clever system of brakes)?

Trends and future directions

Integration of robots into the neurosurgical operating room offers many benefits, and inherent limitations, for both the patient and the surgeon. Indeed, the use of robots increases the commercial appeal of the hospital and the services offered. A recent study quantifing the effect of marketing robotic surgery as “innovative” or “state of the art” found that greater than 30% of patients would choose to undergo a novel procedure over a conventional alternative if it was framed in this manner (Dixon, 2015).

As we have seen with computer hardware in other industries, advancements in technology will allow for a number of improvements in the use of the technology. For example, miniaturization of components will lead to a decreased robotic footprint and increased portability and, in turn, minimize the concerns of operating room space. Such advancements will also improve the reliability and longevity of robotics, thereby reducing overall costs. Furthermore, improved user interfaces will make integrating robotics into neurosurgical practice more intuitive, with improved automation of perioperative tasks. As robotics gain more widespread use in practice, we predict increased software and hardware compatibility with other technologies. Finally, ongoing development may also push robots into a greater role in surgical education as robots with improved visual and haptic feedback can be used to create safe, but realistic, surgical stimulators.

To achieve this future, it is critical that the current generation of surgical robotics users are well informed as to their features, benefits, and limitations. We hope this work provides the important questions that current users can ask to guide understanding and expertise. Then, use of robots to aid in operating planning, whether it be DBS or sEEG leads, or pedicle screw trajectories for patients with difficult anatomy, will undoubtedly gain mainstream appeal and likely become an integral part of neurosurgical practice.

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