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Can Robotic Spine Surgery Become the Standard of Care?

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ABSTRACT

Concerns regarding traditional techniques led to the development of robotic systems to facilitate the safe and accurate placement of pedicle screws. The Mazor Spine Assist was the first robotic spine surgery (RSS) platform to receive US Food and Drug Administration approval in 2004. Since then, there has been a steady increase in the application of RSS with several additional iterations of the Mazor platform and other competing systems receiving approval. As the indications, potential benefits, and utilization of RSS continue to expand, the question naturally arises as to whether RSS will eventually become the standard of care for spine surgery. In this article, we review the available evidence and experience with RSS and discuss the potential for RSS to become the medical standard of care.

Special Issue

Keywords: robotic spine surgery, standard of care, minimally invasive spine surgery

INTRODUCTION

In 2004, the Mazor Spine Assist (Medtronic, Minneapolis, MN) became the first robotic spine surgery (RSS) platform to receive Food and Drug Administration (FDA) approval.[1–3] Since that time, there has been a steady increase in the application of RSS with several additional iterations of the Mazor platform and other competing systems receiving FDA approval. Presently, there are 3 RSS systems available in the United States that have received FDA approval. The Mazor X Stealth Edition gained approval in 2018 and incorporates real-time intraoperative navigation and represents the fourth generation of the Mazor RSS platform. The other available systems are the ExcelsiusGPS (Globus Medical, Audubon, PA) and ROSA (Zimmer Biomet, Warsaw, IN). The ExcelsiusGPS gained FDA approval in 2017 and has real-time intraoperative navigation capabilities.[1] While these systems have different features, they are all based on a shared control model—whereby surgeon and robot concurrently control motions, and the surgeon performs the pedicle drilling and screw placement.[4–6]

Pedicle screws allow for rigid 3-column spinal fixation. The accurate placement of pedicle screws is a critical component of instrumented spinal fusion surgeries. Malpositioned pedicle screws can cause catastrophic damage to adjacent neurologic and vascular structures. Furthermore, inaccurate placement can compromise the mechanical stability of a hardware construct. Freehand placement relies solely on described anatomic landmarks and level-specific average medial-lateral trajectories for accurate pedicle screw placement. The subsequent introduction of computer-assisted navigation led to improvements in precision and safety over freehand placement,[7–10] but they are not without patient safety concerns and include increased radiation exposure to the patient and staff.[1] Additionally, both techniques are subject to surgeon fatigue and diminished precision.[11] Concerns with the aforementioned techniques led to the development of robotic systems to facilitate the safe and accurate placement of pedicle screws.

As the indications, potential benefits, and utilization[12] of RSS continue to expand, the question naturally arises as to whether RSS will eventually become the standard of care (SOC) for spine surgery.

DEFINING SOC

While the term SOC is often referenced and discussed, it is not a concept taught in medical education or defined in routine clinical practice. Rather, it is primarily a legal concept used by attorneys in cases of medical negligence. Others believe that SOC cannot be universally defined and should be interpreted in both legal and clinical contexts.[13] While evidence and data play a role, the concept of medical SOC is more abstract.

Legal SOC is typically defined as the level and type of care that a reasonably competent and skilled health care professional, with a similar background and in the same medical community, would have provided under the circumstances that led to the alleged breach of care. The legal community has established 4 pillars in their effort to define the SOC—knowledge, skill, diligence, and care. These 4 pillars today act as the foundation for determining liability in most instructions to the jury when deliberating medical malpractice cases. Regardless of how SOC is defined, it is subject to change over time as a given specialty evolves and improves.[14] To that end, the SOC is in a constant state of flux and evolution. However, as pointed out by Greenberg,[15] simply recognizing that medical practice changes over time does not provide insight on to how those changes occur. Rather than being a seamless transition, the introduction and subsequent adoption of new technology occur by "fits and starts" and at first represent a departure from what most physicians are doing.

When defining medical SOC for disc replacement, Gornet et al considered both evidence and experience.[13] In doing so, they acknowledged that when evaluating the best treatment in individual situations, one must also consider surgeon comfort and experience rather than simply the one that has the best data. There is no standard definition of medical SOC, but the idea that evidence and experience define medical SOC will serve as a guide for our discussion of RSS.

EVIDENCE

Screw Accuracy

Numerous studies, including randomized controlled trials (RCTs), have been conducted to assess the accuracy of pedicle screws placed using RSS systems. Mazor robotics pioneered RSS and, as a result, their systems have been the most extensively studied to date.[5,16–28] Cadaveric studies have confirmed accuracy of the Mazor system within 1 mm of preoperative templates.[29,30] A retrospective case series published by Hu et al reported 98.9% accuracy of 960 screws placed in 95 patients.[31]

In 2012, Ringel et al published the first RCT comparing pedicle screws placed via the Mazor Spine Assist, the first iteration of the Mazor platform, with freehand technique.[32] In total, 298 pedicle screws were placed in 60 patients. Surprisingly, a lower percentage of the robotic-placed screws were deemed acceptable (Gertzbein-Robbins score grade A or B) than the freehand group; 85% vs 93%. Lateral pedicle breaches were attributed to insufficient fixation of the robot to the patient, leading to deviation of the implantation cannula at the entry point. Subsequent models of the Mazor robot (Renaissance, Mazor X, and Mazor X Stealth Edition) have greatly enhanced fixation mechanisms. To date, this remains the only study that has demonstrated inferiority of robotic assistance.[16]

In a 2016 RCT comparing screw accuracy of the Mazor Renaissance robot with freehand technique, Kim et al found no differences in screw accuracy using the Gertzbein-Robbins classification.[20] However, there was a significant reduction in proximal facet violation with robotic assistance. A subsequent RCT completed by Hyun et al also evaluated the accuracy of screws placed by the Mazor Renaissance model and compared them with fluoroscopically placed pedicle screws.[33] In total, 270 pedicle screws were placed in 60 patients. Screws placed with the robot were more accurate (100% vs 98.6%) and reduced the number of proximal facet violations.[19]

Additional RCTs and meta-analyses have found comparable or improved placement of pedicle screws using the Mazor robotic system when compared with more traditional techniques.[20,34–37]

To date, there are no prospective RCTs evaluating the ExcelsiusGPS, but lower-level studies have shown high accuracy and safety profile similar to the Mazor platform.[38–46] Additional non-RCTs have demonstrated increased pedicle screw accuracy with different robotic assistance systems compared with traditional techniques.[19,47]

Radiation Exposure

While preoperative and/or intraoperative computed tomography is utilized, a theorized benefit of RSS is the reduction or elimination of radiation exposure to the surgeon and operating room staff. Numerous studies have evaluated radiation exposure during RSS with varying results based on robotic platform, surgeon experience, and technique.[1,2] Fan et al reported a 50% reduction in average fluoroscopy time for screw placement with robotic assistance compared with freehand technique.[48] When combining the results of 2 RCTs, Gao et al found that robotic assistance significantly reduced intraoperative radiation time and dosage.[35]

Perhaps the greatest potential for reducing radiation exposure is in minimally invasive spine surgery, specifically percutaneous pedicle screw placement. Open procedures require exposure of the relevant anatomy for proper placement of pedicle screws and are associated with increased estimated blood loss, more postoperative pain, and greater length of stay.[49–51] Conversely, minimally invasive percutaneous pedicle screws are placed via small, muscle-sparing paramedian incisions. However, traditional percutaneous techniques require frequent biplanar fluoroscopy for safe screw placement. Robotic assistance can provide similar minimally invasive benefits while significantly reducing radiation exposure. To that end, in a cadaveric study comparing the ExcelsiusGPS to conventional minimally invasive techniques, Vaccaro et al demonstrated improved pedicle screw accuracy and reduced surgical time while eliminating radiation exposure to the surgeon and operating room staff with robotic assistance.[52] In an RCT evaluating percutaneous pedicle screw placement, Hyun et al found that RSS significantly reduced per-screw radiation exposure to the surgeon compared with a fluoroscopy-guided open approach.[33]

Cost

High initial acquisition cost (>$1 million) and expensive annual service contracts ($100,000) remain key barriers to widespread adoption of RSS.[5,16] Concern regarding these costs is amplified by a lack of long-term cost-effectiveness data. However, several factors related to RSS, such as reduced operative time,[52] reduced blood loss,[48] less revision surgeries,[19,53] fewer postoperative infections,[19] and shorter length of stay[20,33,48] may ultimately offset these costs and indirectly produce long-term financial savings.

To that end, Menger and colleagues[54] retrospectively reviewed 557 patients and evaluated the financial impact of minimally invasive spine surgery made possible by RSS. Their analysis found RSS to be cost-effective through reduced length of stay, fewer revision surgeries, lower infection rates, and shorter operative time.

Additional high-level studies are needed to better understand the financial implications of RSS and to set benchmarks for cost savings such as number of cases needed to recuperate initial cost.

EXPERIENCE

The current state of RSS and surgeon experience can be analyzed from multiple perspectives. First, one must consider, as with any new technology, the associated learning curve and how it impacts clinical practice. It is certainly understandable that established, efficient, high-volume surgeons would be hesitant to introduce robotics into their practice. Initial accounts analyzing the learning curve associated with RSS efficiency,[55] successful screw placement,[31] and screw accuracy[56] seemed to reinforce this belief. However, a more recent account of user experience with a modern robotic platform (Mazor X) demonstrated minimal learning curve with high reliability and accuracy.[57] As the performance and user experience of newer robotic platforms improve, the learning curve and the associated resistance to adoption will continue to decrease.

Despite the evidence supporting RSS and increased use, a major question remains regarding the adoption of RSS: Will there ever be a procedure or technique that is solely done through RSS? Surely, if this was the case, one could consider RSS the SOC. While this is not currently the case, examples outside of spine surgery can provide insight into the factors associated with this potential transition.

The da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA) is a telerobotic platform that gained FDA approval in 2000. Since then, it has become increasingly popular in general surgery, gynecology, and urology.[58] For example, in 2003, less than 1% of surgeons in the United States performed robotic-assisted radical prostatectomies (RARP). By 2014, RARP accounted for 90% of radical prostatectomies performed in the United States. While less invasive than traditional techniques, some have criticized the platform's high cost with similar long-term outcomes.[59] However, RARP is less invasive (reduced blood loss, less pain, and shorter recovery) than traditional techniques and has distinct advantages for the surgeon. Use of the platform increases visualization and allows the surgeon to sit for the 2- to 4-hour procedure. While the surgeon does not currently sit during RSS, some authors have pointed to the obvious ergonomic advantages of RSS over traditional techniques.[11] Given the aforementioned advantages (evidence) and widespread utilization (experience), RARP would be considered the SOC as defined by Gornet and colleagues.

Additional insight into the adoption of new orthopedic technology and techniques can be gained by examining the transition from open to arthroscopic shoulder surgery at the end of the 20th century and beginning of the 21st century. In a 2003 American Academy of Orthopedic Surgeons Instructional Course Lecture, Yamaguchi and colleagues[60] discuss the growing enthusiasm for complete arthroscopic rotator cuff repair, which was first introduced in 1980. As surgeons became more comfortable with arthroscopic shoulder surgery, both the use and acceptable indications increased. While outcomes were similar to older techniques, the arthroscopic technique was associated with less morbidity, less pain, and quicker recovery. Regardless, the authors encouraged surgeons to not compromise basic surgical principles and to employ the technique that is most reproducible in their hands.

These concepts can be applied to new technology in any surgical field. With a proper transition strategy, surgeons can gradually and safely become more skilled and comfortable utilizing new surgical techniques. As the benefits of new technology become more apparent, more surgeons transition to new technology, and trainees pursue programs to gain early exposure and specialized training. In some instances, such as arthroscopic rotator cuff repair, the new and technically challenging procedure becomes the clinical SOC.

When discussing experience in this context, we would be remiss to not discuss the potential negative unintended consequences of widespread RSS adoption. The large capital costs associated with RSS have the potential to increase inequality gaps between hospitals and even countries. There are also concerns regarding surgeon training and experience. Currently, all surgeons have at least some proficiency with freehand pedicle screw techniques. While the available robotic systems are highly accurate and safe, the surgeon still must know the general landmarks and trajectories for screw placement. What will happen if the robot malfunctions or fails midcase and the surgeon only knows how to perform RSS? Will the surgeon fail to see the seemingly obvious screw trajectory or be unable to continue the case without the robot? Perhaps, even as RSS becomes more popular, freehand techniques should remain part of surgical training to avoid these exact scenarios. However, what proportion of today's graduating orthopedic residents are familiar with an open rotator cuff repair or knee meniscectomy?

CONCLUSIONS

While a universally accepted definition of clinical SOC does not exist, prior authors have utilized both experience and evidence to define clinical SOC in spine surgery. Despite growing support regarding the benefits of RSS over traditional techniques (evidence), more time is needed to see if there is widespread adoption (experience) of RSS. Nevertheless, the potential for greater adoption of RSS certainly exists. As such, we believe that RSS will eventually become the clinical SOC for spine surgery. Barriers to adoption include high capital costs, the perceived learning curve, and competition from emerging technologies such as augmented reality. Examples from outside of spine surgery can provide insight into the modern adoption of new technology that was fraught with similar concerns yet managed to become the SOC in their respective fields—RARP and arthroscopic shoulder surgery. Additional untapped potential for RSS lies in minimally invasive spine surgery. Perhaps endoscopic spine surgery, a rapidly advancing field within minimally invasive spine surgery, will one day be incorporated into a robotic platform. Further advances and the incorporation of navigation will facilitate minimally invasive decompressions, tumor resections, facet decortication, and interbody placement using robotic assistance.[61] This will allow RSS to be more comprehensive and further reduce perioperative morbidity, length of stay, and, ultimately, costs associated with spine surgery.

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