

Robotic Spine Surgery in Rhode Island

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ABSTRACT

Surgical robots were first proposed in the 1960s with subsequent development and clinical implementation in the 1980s and 1990s. Recent advances in technology have led to widespread utilization of robots in many surgical subspecialties. In spine surgery, robots are primarily utilized for pedicle screw placement, with several studies highlighting the potential benefits of improved accuracy and reduction in radiation exposure. Once streamlined, robotic spine surgery (RSS) can provide financial remuneration through potential cost savings and marketing benefits, and in the future will likely aid in more complex surgeries. In Rhode Island, this technology has been implemented and has the potential to deliver optimized outcomes for patients. Robotic spine surgery is not a substitute for a skilled spine surgeon however, and careful diagnosis, care planning, and surgical execution are still mandatory to deliver the best possible patient outcomes. In this review, we chronicle the history of RSS, outline currently available RSS platforms, describe the efficacy, risks, and complications of RSS procedures, and explain the current and future utilization of RSS in Rhode Island.

KEYWORDS: robotic surgery; spine surgery; Rhode Island

BACKGROUND AND HISTORY OF ROBOTIC SURGERY AND ROBOTIC SPINE SURGERY

Advances in robotic technology have led to increased implementation of robotic spine surgery (RSS) platforms. This technology is rapidly improving and is becoming more common across the country. This technology has recently been implemented in Rhode Island, and thus education regarding this new technology will be important for patients and their care team can make informed decisions regarding robotic spine surgery.

Initial investment in robotic surgery began in the 1980s as NASA attempted to resolve the issue of providing surgery to astronauts in space.¹ In terrestrial operating rooms, the first documented robotic surgery was in 1985, when a brain biopsy was performed using a Programmable Universal Machine Assembly (PUMA) to place and stabilize a biopsy cannula.² Subsequent to these early trials, the private

sector amassed substantial investment, allowing surgeons to explore these novel techniques, and the first Food and Drug Administration (FDA)-approved surgical robot was the Automated Endoscope System for Optional Positioning (AESOP) in 1989.² This set the stage for further advancement, and in the 1999, Intuitive Surgical launched the DaVinci Standard, a platform still widely used today.³ Since then, the field of surgical robotics has rapidly evolved and become mainstream – now surgical robots are used in many surgical specialties including gynecology, urology, pediatric surgery, general surgery, neurosurgery, cardiothoracic surgery, otolaryngology, and orthopedics.³⁻¹⁰

RSS was first attempted in the 1990s. The German Aerospace Center developed the “Miro System,” and the Center for Intelligent Surgery Systems in China developed the “Spine Bot”.^{11,12} Lack of flexibility with the robotic arm, software malfunctions, confusing user interfaces, and failure to effectively synchronize pre and peri-operative imaging limited the success of these preliminary systems.^{13,14} However, these platforms set the foundation for technological advancement in the early 2000s that culminated in the RSS platforms that are widely used today.¹⁵

ROBOTIC SPINE SURGERY ROBOT TECHNOLOGY

Today, a wide variety of RSS platforms exist. These platforms are all known as shared control systems, meaning they are controlled by both the robot and the surgeon in real time.¹⁶ RSS platforms utilize an intraoperative navigation system as well as a robotic arm for pedicle screw placement. Intraoperative navigation systems can exist on their own or in concert with a surgical robot.¹⁷ These navigation systems allow surgeons to precisely track the position of surgical instruments and project this position onto preoperative or intraoperative imaging data. Within RSS platforms, the options for intraoperative navigation are preoperative or intraoperative CT, or intraoperative fluoroscopy.¹⁸ RSS platforms map spinal anatomy in a “frame based” manner. A spinous process clamp, pelvic pin, or other fixed standard point of reference is recognized by the robot’s navigation system, allowing direct image to robot registration. This stability allows RSS systems to be faster, more precise, and more accurate than frameless systems which do not utilize a physical landmark to navigate.^{19,20}

CURRENTLY AVAILABLE FDA-APPROVED SPINE ROBOTS

One of the most ubiquitous RSS platforms is Mazor (Medtronic Navigation, Louisville, CO, USA). From 2004–2011, the SpineAssist was the only FDA-approved RSS robot. It planned pedicle screw trajectories by pairing preoperative CT with intraoperative fluoroscopy.^{21,22} However, this robot was restricted by the number of vertebral bodies that it could image, drill skive against the lamina and transverse processes, the number of rail mounts and arm attachments, and soft tissue pressure on the arm. These factors contributed considerably to malpositioned screws after it was first approved.²³ In 2011, the FDA approved the Mazor Renaissance which improved artifact rejection, allowed auto-segmentation of vertebral bodies, and provided faster image processing. These upgrades improved pedicle screw placement accuracy.^{23,24} The Mazor X launched in 2016 and included a fully automatous robotic arm that no longer required attachment to the patient (attaches to operating table instead), software upgrades allowing independent registration of each vertebral body augmenting surgical planning, and an optic camera that allows the robot to self-detect its location and avoid intraoperative collisions.² In 2019 Medtronic acquired Mazor robotics and integrated their Stealth navigation platform into Mazor X, providing fully independent navigation capability and real-time instrumentation position feedback.²¹ This fourth generation is known as the Mazor X Stealth addition. All Mazor Robotic arms have six degrees of freedom.²⁵

The Excelcius GPS (Globus Medical, Inc., Audubon, PA, USA), launched in 2017 and includes a fully integrated navigation platform that allows real-time instrument tracking and pedicle screw placement without guidewires.²⁶ This navigation platform is compatible with multiple imaging modalities (both two and three dimensional), can merge preoperative CT scans with intraoperative fluoroscopic imaging, and can localize manufacturer specific instrumentation.²¹ The arm is anchored to a floor mounted base station, as opposed to the patient or operating table, as in some versions of the Mazor robots. This rigid, modular arm has six degrees of freedom, allows the attachment of additional surgical instruments and can withstand extreme deflection forces of up to 200N.²⁷

The ROSA (Zimmer Biomet, Warsaw, IN, USA) received FDA clearance in 2016 and can be used for instrumentation in cranial surgeries and knee arthroplasties, as well as in spine surgery. It uses preoperative and intraoperative CT images to plan screw trajectories that are placed over guidewires using a fully automated robotic arm with six degrees of freedom.²⁸ The ROSA ONE received FDA clearance in 2019 and added a fully integrated navigation system that is compatible with manufacturer specific instrumentation.²¹

Other new types of RSS platforms include the Cirq Robot (Brainlab, Munich, Germany) which received FDA clearance for spine procedures in September 2019, the TiRobot (TINAVI Medical Technologies, China) which is not yet

FDA-approved but is widely used in China, and the Remi Robotic Navigation system (Accelus, Palm Beach Gardens, FL), recently FDA-approved in 2021.

EFFICACY, SAFETY AND OTHER POTENTIAL BENEFITS

RSS has been shown to increase accuracy in pedicle screw placement and prevent associated complications, as demonstrated by multiple meta-analyses.^{29,30} Fatima et al conducted a meta-analysis of 19 studies that included a total of 1,525 patients (7,379 pedicles screws). Patients in the RSS group had significantly higher “perfect” and “clinically acceptable” pedicle screw placement accuracy, a 92% lower rate of cranial facet joint violation, 69% lower rate of overall complications, and significantly lower radiation exposure, but longer overall intraoperative time compared to the traditional fluoroscopy-assisted screw placement group.²⁹ Kosmopoulos et al analyzed 130 studies on robotic versus conventional pedicle screw implantation (37,337 total implanted pedicle screws). In the RSS group, pedicle screw placement accuracy was 99.2% in the cervical spine, 85.1% in the thoracic spine, and 92.1% in the lumbar spine compared to 91.3% in the cervical spine, 56.0% in the thoracic spine, and 87.3% in the lumbar spine in non-navigated surgeries.³⁰ Finally, studies have also shown that despite an increased operative time, total radiation exposure to both the patient and surgical team are dramatically reduced when using robots, and that as experience with the robot increases, surgeons become more efficient and operative time decreases.^{31,32}

LEARNING CURVE, TRAINING CONSIDERATIONS, RISKS AND POTENTIAL COMPLICATIONS

Studies suggest a surgeon and their OR team need to carry out 20-30 cases to achieve proficiency and efficiency in pedicle screw placement using RSS.³³⁻³⁷ Additionally, blood loss, radiation exposure, and operative time all decrease after surgeons and their OR teams have performed more cases.^{24,38,39}

The most concerning complication unique to RSS is frameshift. This occurs when a robotic navigation system does not have the patient’s anatomy mapped correctly, which can occur due to a shift in the tracking arm or patient anatomy, subsequently resulting in inaccurate 3D referencing. This may lead to malpositioned screws, inaccurate instrument navigation, and catastrophic neurological or vascular complications. Another potential disadvantage of RSS is that surgeons do not experience the same degree of tactile feedback as with traditionally open techniques. This accentuates the critical importance of accurate surgical referencing when using robots, and checking instrumentation with fluoroscopy or 3D imaging prior to leaving the operating room. Additionally, RSS has high up-front financial and time expenditures, and comprehensive training programs are mandatory for the entire surgical team prior to RSS implementation.⁴⁰

UTILIZATION AND EPIDEMIOLOGY

The number of patients undergoing spine surgery is increasing. Each year, approximately 4.83 million spinal operations are performed, with 1.34 million of those occurring in the United States.²² New RSS systems have improved to meet demand and improve surgeon performance. Robots are principally used to place pedicle screws, but latest research has demonstrated utility in more complex surgeries such as spinal tumor resections and ablations, vertebroplasties, interbody fusions, and osteotomies for deformity correction.^{22,26,41}

HISTORY OF RSS IN RI

In Rhode Island, robot-assisted surgery has become an integral part of patient care across numerous surgical specialties. In 2014, 38% (5/13) of RI hospitals performed a total of 1312 robot-assisted surgeries, all of which utilized the DaVinci (Intuitive). The majority of cases were hysterectomies and unicompartmental knee arthroplasties.⁴² In spine surgery, the utilization of surgical robots has grown nationwide since their implementation in the early 2000s. However, Rhode Island has only recently adopted RSS. The first RSS case in Rhode Island was a lumbar decompression and spinal fusion with the ExcelsiusGPS performed in January 2019 at South County Hospital. At the time, South County Hospital was the only hospital in the state of Rhode Island that offered RSS.⁴³ In January 2021, a surgeon at Ortho Rhode Island reported to *The Independent* that they implement robots in half of their spine cases.⁴⁴ In May 2021, University Orthopedics surgeons using the ExcelsiusGPS became the first orthopaedic surgeons to perform RSS in Northern Rhode Island at Our Lady of Fatima Hospital.⁴⁵ In June of 2022, Orthopedic surgeons at The Miriam Hospital performed the first Mazor-X assisted spinal surgery in Rhode Island. Neurosurgeons at Rhode Island Hospital also launched the brain and spine robotic surgical platforms using the ExcelsiusGPS in June 2022.⁴⁶

CURRENT ESTABLISHED CLINICAL USES IN RI AND CASE EXAMPLES

Posterior lumbar fusions and thoracolumbar fusions can be performed using robotic surgical devices, and these procedures are being successfully implemented in RI. Robotic spine surgery is also utilized for combined single-position lateral and posterior spinal fusion, and to assist in increasingly complex minimally invasive surgical operations. The recent addition of the Mazor X robotic system to the Miriam Hospital has had a positive impact upon patient care. The case presented illustrates the intraoperative and post-operative radiographs for a patient with spondylolisthesis and degenerative scoliosis undergoing a two staged surgery with interbody fusion and posterior spinal fusion. Intraoperative

navigation of the minimally invasive pedicle screw placement was performed using fluoroscopy and a tracking marker (Figure 1). The Mazor X robot was utilized for pedicle screw insertion from L4-S1 with a percutaneous approach (Figure 2). There were no complications intraoperatively and the patient was discharged two days later. At follow-up, the patient reported improved pain and imaging demonstrates intact instrumentation and no cage subsidence and accurate screw placement (Figure 3).

Figure 1. Intraoperative fluoroscopy images of tracking marker navigation for minimally invasive pedicle screw insertion.

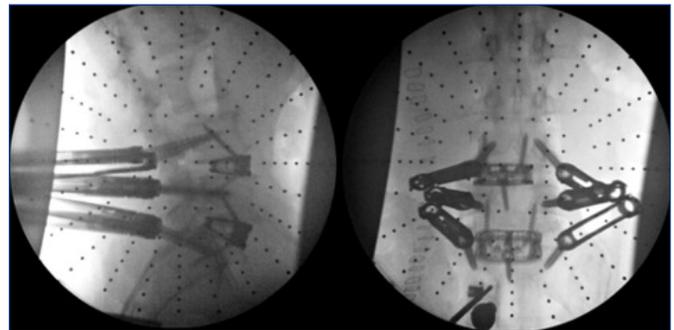
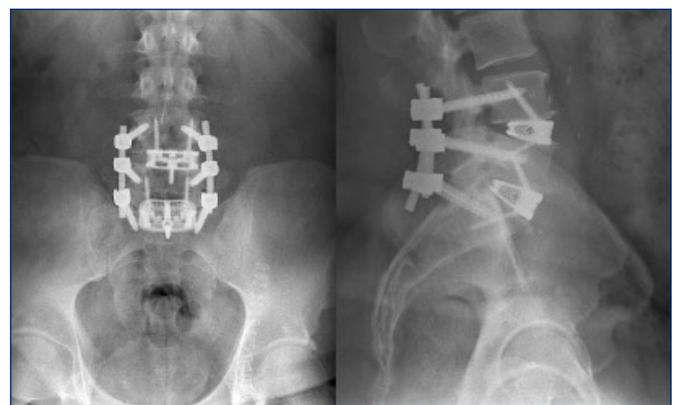


Figure 2. Incision site for the minimally invasive percutaneous screw placement.



Figure 3. AP and lateral radiographs demonstrating a posterior L4-S1 interbody fusion with L4-L5 and L5-S1 ALIF.



FUTURE DIRECTIONS IN RI

The utilization of RSS is gradually increasing on an annual basis across the country, including the state of Rhode Island. At this point, there are 4 RSS programs at 4 hospitals in Rhode Island (Rhode Island Hospital, The Miriam Hospital, South County Hospital, and Our Lady of Fatima Hospital), providing patients from all corners of the state with access to RSS. In addition, many of these programs will also be supplemented with technologies such as intraoperative 3D navigation, which will further improve safety and accuracy of spinal instrumentation even when RSS platforms are not available. While these enabling technologies have the potential to improve patient care, they cannot become a substitute for traditional open surgical techniques. Ultimately, all spine surgeons should understand and maintain proficiency with freehand techniques, as there will be times where these technologies are either unavailable or malfunctioning.

CONCLUSION

A common adage in spine surgery is that enabling technologies, such as RSS and intraoperative navigation, are tools that don't make a bad surgeon good but a good surgeon better. With the development of several robotic spine surgery programs in various locations throughout the state, patients will have improved access to these technologies, which have the potential to improve the delivery of spine care to patients in Rhode Island. However, surgeons should be careful that they do not become completely reliant on these technologies, and they should never be a substitute for a good diagnostician, a thoughtful surgical plan, and a skilled spine surgeon.

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