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COMMENTARY

New spinal robotic technologies

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Abstract **Robotic systems in surgery have developed rapidly. Installations of the da Vinci Surgical System® (Intuitive Surgical, Sunnyvale, CA, USA), widely used in urological and gynecological procedures, have nearly doubled in the United States from 2010 to 2017. Robotics systems in spine surgery have been adopted more slowly; however, users are enthusiastic about their applications in this subspecialty. Spinal surgery often requires fine manipulation of vital structures that must be accessed via limited surgical corridors and can require repetitive tasks over lengthy periods of time — issues for which robotic assistance is well-positioned to complement human ability. To date, the United States Food and Drug Administration (FDA) has approved 7 robotic systems across 4 companies for use in spinal surgery. The available clinical data evaluating their efficacy have generally demonstrated these systems to be accurate and safe. A critical next step in the broader adoption of surgical robotics in spine surgery is the design and implementation of rigorous comparative studies to interrogate the utility of robotic assistance. Here we discuss current applications of robotics in spine surgery, review robotic systems FDA-approved for use in spine surgery, summarize randomized controlled trials involving robotics in spine surgery, and comment on prospects of robotic-assisted spine surgery.**

Keywords robotics; spine surgery; Mazor; ExcelsiusGPS; ROSA; pedicle screw

Introduction

The development and adoption of robotic systems in surgery have progressed rapidly. Recently, Childers *et al*. reported that installations of the da Vinci Surgical System® (Intuitive Surgical, Sunnyvale, CA, USA), which is widely used in urological and gynecological procedures, have nearly doubled in the United States from 2010 to 2017, with the estimated annual procedure volume increasing from 136 000 to 877 000 over the same period [1]. Although the development of robotics systems in spine surgery has proceeded more slowly [2], there is nevertheless evolving enthusiasm for robotics in this subspecialty [3,4]. Spinal surgery procedures often require fine manipulation of vital structures that must be accessed via limited surgical corridors and can require repetitive tasks over lengthy periods of time — issues for which robotic assistance is well-positioned to complement human ability [4]. A critical next step in the adoption of surgical robotics in spine surgery is the design and implementation of comparative studies to interrogate the utility of robotic assistance. In this commentary, we discuss current application areas for robotics in spine surgery, review the robotic systems that have received United States Food and Drug Administration (FDA) approval for use in spine surgery, overview randomized controlled trials involving robotics in spine surgery, and comment on future prospects of robotic assistance in spine surgery.

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Application areas

The most studied area of robotics in spine surgery remains robotic-assisted spinal instrumentation — specifically, open and percutaneous thoracic and lumbar pedicle screw placement. Briefly, pedicle screws and rods are used to obtain internal spinal fixation during spinal fusion procedures. Historically, pedicle screws have been placed by surgeons using only anatomic landmarks ("freehand") without the assistance of image-guided technologies, though fluoroscopy-assisted and real-time navigated technologies (e.g., "CT navigation") have gained popularity due to the improved accuracy these methods offer [5–7]. Pedicle screw placement is an optimal application of

robotic technologies, as robotic assistance can reduce the risks associated with inaccurate screw trajectory, including nerve and vascular injuries, and can minimize radiation exposure to the surgical team [8–10]. As robotics systems advance, it is likely that more complex instrumentation applications (e.g., C1-C2 posterior fusion, S2-alar-iliac screw placement) will become commonplace with robotic assistance.

FDA-approved robotic systems in spinal surgery

The United States FDA has approved 7 robotic systems across 4 companies for use in spinal surgery: (1) Mazor SpineAssist® (Mazor Robotics; Caesareas, Israel), (2) Mazor Renaissance® (Mazor Robotics; Caesareas, Israel), (3) Mazor X™ (Mazor Robotics; Caesareas, Israel), (4) Mazor X™ Stealth Edition (Medtronic; Dublin, Ireland [acquired Mazor Robotics in 2018]), (5) ROSA® Spine (Zimmer Biomet; Warsaw, IN, USA), (6) ROSA® ONE Spine (Zimmer Biomet; Warsaw, IN, USA), and (7) ExcelsiusGPS™ (Globus Medical; Audubon, PA, USA; Figs. 1 and 2). Of note, the ROSA® Spine system was originally created by Medtech (Montpellier, France), which was later acquired by Zimmer Biomet in 2016. The Mazor X™ Stealth Edition, ROSA® ONE Spine, and ExcelsiusGPS™ systems, which offer the latest technologies from each of the respective companies, are all currently commercially available. Key features of these systems are noted in Table 1. An additional system, the TiRobot® (Tinavi Medical Technologies; Beijing, China) has undergone clinical trials (NCT02890043) but has yet to receive FDA approval. Further, the iSYS1 robot (Medizintechnik GmhH, Kitzbühel, Austria), which is a user-controlled electromechanical arm with a needle guide, has been used in cadaveric studies to guide Kirschner wire placement in the spine [11]. The da Vinci Surgical System, which costs approximately $2 000 000 per unit, has also been used in spine surgery (e.g., anterior lumbar interbody fusions [12,13]), though it is not FDA-approved for use in spinal instrumentation. This robotic system is different from the 7 FDA-approved systems noted above, operating as a "telesurgical system" and not serving to guide instrumentation.

The Mazor systems are the most extensively studied robotic spinal systems [14–16], reflecting the fact that the Mazor SpineAssist® robot, the first iteration in the Mazor line, was the first robotic system to receive FDA approval for use in spine surgery (in 2004). This system evolved into the Renaissance® system, which received FDA approval in 2011, with a similar operational workflow and notable software changes relative to its predecessor. Operation of the Mazor Renaissance® system follows 4 steps: (1) *preoperative planning*, in which a preoperative CT is uploaded to the Mazor software and the optimal implant size and trajectory are planned; (2) *mounting*, in which the robot, a small frameless platform, is mounted to the

Fig. 1 Globus ExcelsiusGPS® robot with intraoperative navigation station. (Copyright permission obtained from Globus Medical.)

Fig. 2 Overhead schematic showing positioning and workflow with the Globus ExcelsiusGPS® robot. (Copyright permission obtained from Globus Medical.)

Table 1 Comparison of robotic systems that have been approved by the FDA for spine surgery.

Feature	Mazor			
	SpineAssist®	Renaissance®	X™	X™ Stealth
Manufacturer	Mazor Robotics; Caesareas, Israel			Medtronic; Dublin, Ireland
FDA Approval (year)	2004	2011	2016	2018
Preoperative CT required	Yes	Yes	No	No
Mount	Bone	Bone	Bone	Bone
Instrument tracking	No	No	Yes	Yes
Guide wires required	Yes	Yes	Yes	Yes
Additional features	Small frameless platform	Small frameless platform	Mazor X™Align application	Medtronic's Stealth navigation

Feature	ROSA		ExcelsiusGPS™
	Spine	ONE Spine	
Manufacturer	Zimmer Biomet; Warsaw, IN		Globus Medical; Audubon, PA
FDA Approval (year)	2016	2019	2017
Preoperative CT required	No	No	No
Mount	Floor	Floor	Floor
Instrument tracking	Yes	Yes	Yes
Guide wires required	Yes	Yes	No
Additional features	Real-time dynamic guidance	Platform can also treat brain and knee pathologies	Surveillance of navigation integrity and skiving

Abbreviations: FDA, Food and Drug Administration; CT, computed tomography.

patient's spine; (3) *3D syncing*, in which the intraoperative anatomy is matched with the preoperative CT via intraoperative fluoroscopic images (anteroposterior and oblique); and (4) *operating*, in which the robotic guidance arm is sent to the preplanned trajectory to guide instrumentation. The Mazor X™, which received FDA approval for spine surgery in 2016, integrates 3 processes: (1) *preoperative analytics*, in which a preoperative or intraoperative CT is uploaded to the Mazor software and screw planning is performed; (2) *intraoperative guidance*, in which the robot is attached to the operating table and then mounted rigidly to the patient's spine, a 3D image of the surgical field is obtained, and the intraoperative anatomy is matched with the CT scan via two fluoroscopic images (anteroposterior and oblique); and (3) *intraoperative verification*, in which the robotic guidance arm is sent

to the preplanned trajectory and real-time instrument tracking is afforded by the integrated 3D camera (Mazor X–Eye). Unique to this system are its preoperative analytical features, including the *Mazor X™ Align* application, which can simulate the impact of a correction on the alignment of a patient's entire spine. Lastly, the Mazor X™ Stealth Edition is the latest robotic system offered in the Mazor/Medtronic line, receiving FDA approval in 2018. This system integrates Medtronic's Stealth surgical navigation software into the Mazor X™ surgical platform. RCTs have been conducted to assess the performance of the Mazor systems; these are discussed in the following section.

The ROSA® system comprises 2 mobile bases, one equipped with a robotic guidance arm and the other equipped with an optical tracking camera. Trajectory planning can be performed using either intraoperative fluoroscopy or an intraoperative CT, and the system provides real-time instrument tracking. The ROSA® ONE Spine system, which received FDA approval in 2019, is an evolution of the ROSA® Spine system and is uniquely built on the same surgical platform as the ROSA® ONE Brain and ROSA® Knee systems. Consequently, this system is the only robotic hardware platform on the market to treat spinal, brain, and knee pathologies, potentially increasing its cost-effectiveness by expanding upon its applications. The ROSA® system is not as well studied relative to the Mazor systems. However, preliminary studies have described initial operative experiences with the robot [17–19], including a prospective, non-randomized case-matched analysis comparing ROSA® to freehand pedicle screw placement [19]. This comparative study examined 20 patients operated on by a single surgeon, and found a higher accuracy rate after robotic screw placement (97.3%) compared to freehand placement (92%) [19].

The ExcelsiusGPS™ (Globus Medical, Audubon, PA, USA) is a floor-mounted, highly rigid robotic arm system fully integrated with real-time image guidance. The robot is not attached to the patient for functionality (Figs. 1 and 2). Planning of screw trajectory can be performed using either intraoperative cone beam CT, preoperative CT, or simple anteroposterior and lateral radiographs. Screws are deployed via the rigid tubular robotic arm, eliminating reliance upon patient-mounted frames and surgical guide (e.g., Kirschner) wires. In addition, this system incorporates several features to ensure navigation integrity, including a shock-absorbing dynamic reference base (which can deflect forces and spring back to its original position), a separate surveillance marker with Quattro™ spike (which anchors securely into the iliac crest via four small spikes), and associated surveillance software (which can alert the surgeon of a loss of navigation integrity) [20]. The ExcelsiusGPS™ system also integrates hardware and software to alert the surgeon of possible instrument deflection (i.e., skiving) during instrumentation placement [20]. No prospective, randomized studies of the ExcelsiusGPS™ have been reported as of yet, though initial case reports and cohort series suggest high accuracy, efficacy, and safety [21–24]. Huntsman *et al.* and Godzik *et al*. have reported accuracy rates (based on Gertzbein–Robbins assessment) ranging from 96.6% to 99% [25,26]. Jiang *et al.* has also reported minimal screw deviation compared to a pre-planned trajectory in a small lumbar fusion case series [21]. Representative cases of our experience with the ExcelsiusGPS™ robot are illustrated in Figs. 3–5.

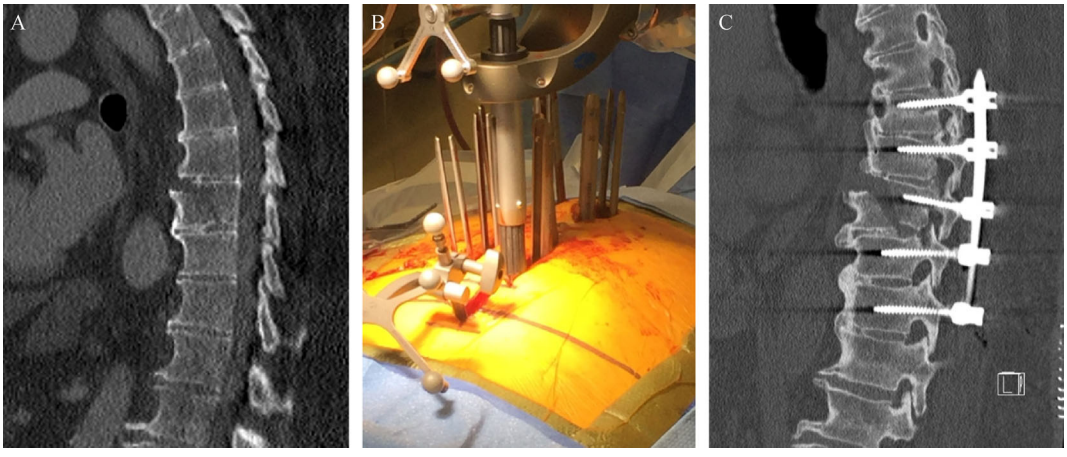

Fig. 3 (A) Preoperative computed tomogram (CT), (B) intraoperative clinical photograph, and (C) immediate postoperative CT of a septuagenarian male patient presenting with an unstable traumatic T8 burst fracture in the setting of ankylosing spondylitis. This patient was treated with a T6-T10 instrumented spinal fusion with robotic assistance using the ExcelsiusGPS™ robotic system.

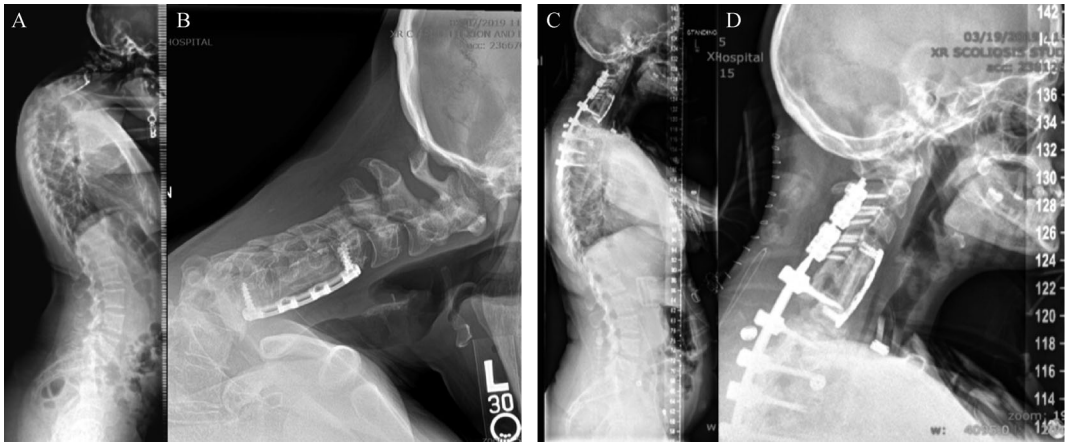

Fig. 4 (A & B) Preoperative and (C & D) postoperative computed tomograms of a tricenarian female patient presenting with a chin-on-chest deformity in the setting of a previous spinal epidural abscess treated with an anteroposterior C5-C7 corpectomy and reconstruction, which was complicated by an infection with subsequent removal of the posterior hardware. This patient was treated with a C2-T4 instrumented spinal fusion for deformity correction with robotic assistance using the ExcelsiusGPS^{TM} robotic system.

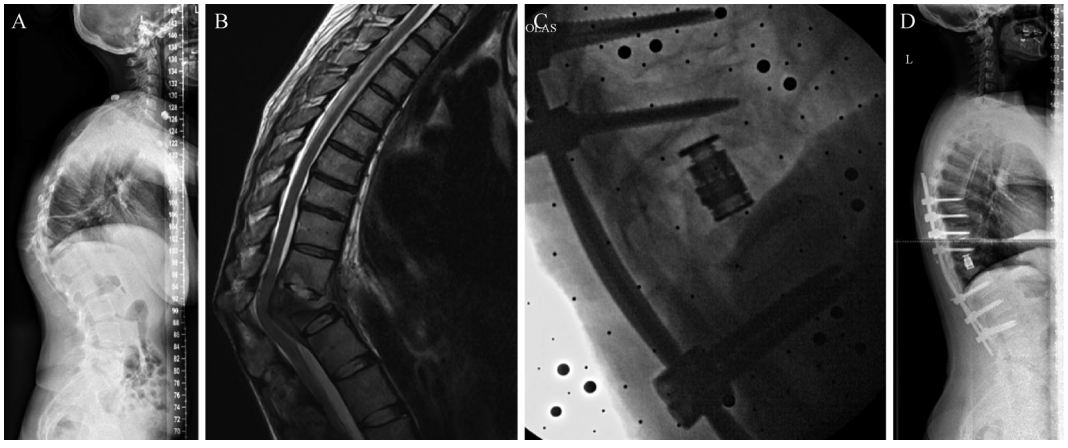

Fig. 5 (A) Preoperative radiograph, (B) preoperative magnetic resonance imaging, (C) intraoperative fluorograph, and (D) 7-month postoperative radiograph of a quadragenarian female patient presenting with a severe kyphotic deformity of approximately 90° in the setting of vertebral osteomyelitis and discitis causing virtually complete destruction of T11 and T12. This patient was treated with a T8-L3 instrumented spinal fusion with a T11-T12 corpectomy and expandable interbody cage with robotic assistance using the ExcelsiusGPS^{TM} robotic system.

Important studies of robotic-assisted spine surgery

A 2017 systematic review of robot-assisted spinal instrumentation identified 22 studies assessing accuracy of spinal robotic systems, including 4 RCTs [15]. In general, robot-assisted instrumentation was found to be highly accurate and safe, with reported accuracy using the Gertzbein–Robbins System (Grades A or B) ranging from 85% to 100%. Most comparative studies investigating robot-guided pedicle screw placement versus freehand placement demonstrated an accuracy benefit with robotic assistance. Only one early RCT from 2012 found diminished accuracy of the SpineAssist® (Mazor Robotics, Caesareas, Israel) system compared to freehand placement (85% vs. 93%, respectively) [27]. Another systematic review and meta-analysis of pedicle screws placed into the spine reported overall pooled accuracy rates of 93.1% following the freehand technique alone, 91.5% with fluoroscopy assistance, and 90.5% with robotic assistance, though in this review only 7 studies involving robotic assistance were included [7]. A meta-analysis of 6 RCTs including 158 patients (3 Mazor SpineAssist® robots; 2 Mazor Renaissance® robots; and 1 TiRobot) found that robotic-assisted pedicle screw placement had equivalent accuracy compared to freehand placement (RR: 1.01; P =

0.029). Moreover, analyzing 2 RCTs, the authors found that radiation time (mean difference of −12.38; $P < 0.001$) and radiation dosage (standard mean difference of −0.64; $P < 0.001$) were significantly decreased [28]. Furthermore, Han *et al*. showed in a randomized controlled trial that the use of the TiRobot system in thoracolumbar surgeries resulted in a higher percentage of both radiographically and clinically acceptable outcomes in the robot-assisted cohort compared to a matched fluoroscopy-assisted cohort [29].

In 2018, an updated meta-analysis of 10 RCTs and cohort studies concluded statistically significant superiority in accuracy using robotic-assisted techniques compared to conventional methods [30]. Recently, with the advent of the first real-time image-guided spinal robotic system (ExcelsiusGPS™), accuracy rates (based on Gertzbein–Robbins assessment) have ranged from 96.6% to 99% [25,26]. Further, by reducing the need for intraoperative fluoroscopy, surgical robots may help reduce radiation exposure to the surgical team [10,31,32]. However, this finding has varied among studies and may be influenced by the type of robot and the imaging paradigm used [19,33].

Future directions

We envision several key future directions for robotic spine surgery. First, continued innovation in the development of robotic systems is necessary — critical areas of improvement include better-integrated software systems to facilitate operating room workflow and designs that minimize soft-tissue pressure. Second, the indications and use cases for robotic-assisted spine surgery will continue to expand. Evolving from open and percutaneous placement of thoracic and lumbar pedicle screws, future robots will likely be able to facilitate surgical decompression and aid in complex cases, including tumor resection, advanced osteotomies, and even revision and deformity surgeries. The evolution of robotics will coincide with the need for improved image guidance and new imaging paradigms. For instance, augmented reality headsets can directly project visual data to the operator's retina and be overlaid onto the surgical field, thereby removing the requirement to shift attention to a remote display. Future directions can include the integration of augmented reality headsets with a robotic machine to enhance the user experience with robotic-assisted spinal navigation [34]. New navigation systems such as 7D Surgical use machine-vision image guided surgery (MvIGS) technology to operate without radiation and in doing so, have the potential to offer both time and cost savings while reducing line-of-sight issues for instrument tracking. Next-generation spinal robotics may also include automatic pedicle screw planning, a concept that incorporates machine learning and has been validated in simulation clinical studies [35,36].

Finally, the evaluation of accuracy in robotic spine surgery will trend toward comparison between a preplanned trajectory and actual placement, with reliability and reproducibility defined by angular and tip/tail offsets. This change will likely result in a new paradigm for defining accuracy, one that may replace the Gertzbein-Robbins scale in the spinal robotics literature.

Conclusions

Current evidence suggests that robotic-assisted pedicle screw placement achieves equivalent or greater accuracy compared to freehand placement and offers decreased radiation exposure to the surgical team. Further comparison to image-guided placement is warranted and future studies should endeavor to incorporate patient-centered clinical endpoints. Though robotic-assisted spine surgery is still in its infancy, the potential for augmenting surgeon performance and improving patient outcomes is significant.

Compliance with ethics guidelines

The Excelsius GPS™ robot described in this presentation was invented by Drs. Theodore and Crawford and is manufactured by Globus Medical. They are both entitled to royalty payments on sales of the robot. Dr. Theodore is also a paid consultant to Globus Medical and owns Globus Medical stock. Dr. Crawford is an employee of Globus Medical.

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