Technological Advances in Spine Surgery

Navigation, Robotics, and Augmented Reality

Tarek Yamout, MD[a], Lindsay D. Orosz, MS, PA-C[b], Christopher R. Good, MD[a], Ehsan Jazini, MD[a], Brandon Allen, BA[b], Jeffrey L. Gum, MD[c,*]

KEYWORDS

• Spine • Surgery • Navigation • Robotics • Computer-assisted navigation • Augmented reality • Pedicle screw

KEY POINTS

- Accurate screw placement is critical to avoid vascular or neurologic complications during spine surgery, resulting in the development and transformation of screw guidance or assist technologies within the past 3 decades.
- Computer-assisted navigation, robotic-guided spine surgery, and augmented reality surgical navigation are currently available technologies that have seen greater incorporation in the operating room.
- Each of these technologies has its advantages and disadvantages, and implementation must be carefully executed with appropriate understanding of how the technology functions and its limitations.

INTRODUCTION

Accurate screw placement is critical to avoid vascular or neurologic complications during spine surgery and to maximize fixation for fusion and deformity correction. As such, screw guidance or assist technologies have undergone significant evolution within the past 3 decades to enhance accuracy, precision, and reliability during instrumentation. In the traditional open screw insertion technique, trajectories were determined by exposing both the screw entry point and anatomic landmarks. Several drawbacks are associated with an open approach, including the utilization of large incisions coupled with tissue trauma and the disruption of adjacent structures.[1] To overcome these challenges, image-based navigation techniques were developed to offer a more minimally invasive approach. Minimally invasive surgery (MIS) is associated with a reduction in blood loss, length of hospital stay, and narcotic use in the postoperative period.[2,3] The consequence of an MIS approach is that direct visualization of relevant anatomic structures is forfeited or reduced.[4] However, as technology has advanced, indirect visualization has improved via assist technology.

The first step in the evolution was 2-dimensional imaging (fluoroscopic guidance), which was used for percutaneous instrumentation and continues to be a popular technique. Landmarks that would have been visualized directly in an open approach can be indirectly visualized

[a] Virginia Spine Institute, 11800 Sunrise Valley Drive, Suite 800, Reston, VA 20191, USA; [b] National Spine Health Foundation, 11800 Sunrise Valley Drive, Suite 330, Reston, VA 20191, USA; [c] Norton Leatherman Spine Center, 210 East Gray Street Suite 900, Louisville, KY 40202, USA
* Corresponding author.
E-mail address: Jlgum001@gmail.com

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during fluoroscopy in the anterior-posterior and lateral planes. Advantages with this technology include its versatility across a variety of different procedures, low operating cost, and fast learning curve.[1] However, the main limitations with fluoroscopic guidance are a lack of 3-dimensional (3D) understanding and the significant radiation exposure to the patient and operating room (OR) staff, with exposure being reported in one study as double when compared with freehand screw placement.[5]

The development of faster computer processors and advanced imaging technology allowed for successful integration of real-time information with 3D anatomy, called computer-assisted navigation (CAN), which has become increasingly popular.[6] CAN has been shown to improve workflow in the OR and increase both safety and accuracy in minimally invasive instrumentation when compared with freehand or fluoroscopic-guided screw placement.[6–9] In addition, a significant benefit for using CAN is the reduction in radiation exposure for both the OR staff and patient.[10,11]

Robotic guidance (RG) expands upon CAN by incorporating a robotic arm that provides a trajectory for pedicle screw instrumentation. RG can be further divided into 2 groups: robotic arms controlled by navigation (RAN) and automated anatomy recognition-based RG, of which the latter does not depend on optical navigation. RG exhibits several potential advantages when compared with fluoroscopic guidance including an increased ability for surgical planning and decreased risk of surgical complication, revision surgery, and significantly less radiation exposure.[4,12] Fluoroscopic guidance was also found to be less accurate with pedicle screw placement when compared with automated anatomy recognition-based RG.[13]

Augmented reality (AR) surgical navigation is a relatively novel screw guidance technology that operates by superimposing relevant anatomic structures, possible screw trajectories, as well as ideal screw locations onto the surgical field. Images identifying important structures can be obtained from both preoperative and intraoperative scans. This image projection onto the surgical field enables the surgeon to maintain a line of sight with the patient while operating, allowing proper orientation in the limited field of view that is a known accompaniment to MIS.[1,14]

The purpose of this review is to provide an overview of the current technologies available within CAN, RG, and AR, including details about the different operating systems available, their effects on efficiency and safety, radiation exposure, OR workflow, overall cost, learning curve, and future trends in spine surgery assistive technology.

DISCUSSION

3D Image-Based Computer-Assisted Navigation

Platforms

Successful use of CAN with 3D imaging for placement of open lumbar pedicle screws was first described in the literature in 1995.[6] Since then, there has been a concurrent development of CAN from a multitude of companies for use in both open and MIS spine surgery. In general, CAN systems use an optic sensor to coordinate relevant spinal anatomy with surgical instruments, using reference markers from a fixed frame attached either to bony anatomy (spine/pelvis) or to the skin.[15]

The Airo Mobile Intraoperative computed tomography (CT)-based CAN platform (Brainlab, Feldkirchen, Germany) is one of the earlier navigation platforms used in spine surgery, gaining US Food and Drug Administration (FDA) approval in 2013. Workflow for this system is as follows: (1) once the patient is positioned, prepped, and draped, three reference points attached to instruments used in this system are calibrated with the camera before intraoperative scanning; (2) a 360° CT scanner is deployed; (3) the reference points are then coupled with an anatomic reference clamp that is attached to an exposed spinous process or to the iliac crest via pins in percutaneous cases; and (4) an image is generated that is automatically registered to the platform's software thereby resulting in a real-time 3D image. Of note, the reference clamps or pins cannot be moved after registration with the system's camera due to shift in the registration, which would then necessitate a repeat scan.[6]

The StealthStation S8 with O-arm (Medtronic, Minneapolis, MN, USA) and the ZiehmVision FD Vario 3-D with NaviPort integration (Ziehm Imaging, Orlando, FL, USA) are similar CAN operating systems, which were FDA approved in 2017 and 2020, respectively. Medtronic had released its first O-arm system in 2006, having undergone a series of evolutions since then. The former uses an O-arm with 360° of rotation that opens at 90° to better mobilize around the patient. The latter uses a C-arm that obtains images via 190° rotation around the patient before reformatting those images into a 3D anatomic map. Both technologies have a reference registration system similar to the Airo Mobile

platform, and as a result face a similar limitation that any movement of reference clamps can lead to inaccurate registration; this would necessitate repeat scanning, which increases the length of surgery and radiation exposure.[6]

The NAV3i platform with SpineMask Tracker and SpineMap Software (Stryker, Kalamazoo, MI, USA) was FDA approved in 2014 and differs from the aforementioned technologies because the SpineMask Tracker operates with a noninvasive form of referencing. This rectangular adhesive tracker is affixed to the patient's skin surrounding the area of interest, which avoids obstruction of the system's camera due to hand positioning or movement of reference points after calibration. Once the tracker is in place, registration occurs automatically using the SpineMap software algorithm to match the imaging to the patient's anatomy. The size of the operative field is limited by the predefined size parameters of the reference points, and excessive skin tension or deep retraction can result in inaccurate mapping, thereby constraining use of this device to MIS. If a surgeon elects to use this device for a large, open surgery then reference points must be placed at an area distal from the surgical wound that would be unaffected by retraction.[6] Stryker's Q Guidance system, FDA approved in June 2022, is its latest CAN release; however, there is no published literature about its clinical efficacy at this time. This system features a high-performance camera and redesigned software, and is the first navigation software to receive FDA clearance with pediatric patients as young as 13 years.

The 7D Surgical System (SeaSpine, Carlsbad, CA, USA) was FDA approved in 2021 and uses a relatively novel technology called machine vision navigation. Machine vision combines video cameras with computer systems to create an image. Workflow for this system is as follows: (1) once the patient is positioned, prepped, and draped, the device is placed next to the operating table with its head consisting of a surgical lamp, cameras, and light projector positioned above the surgical field; (2) the light projector is coupled with the 2 stereoscopic cameras to create a 3D image of exposed anatomy; and (3) the image is coregistered with a preoperatively or intraoperatively obtained CT or fluoroscopic image in seconds. If the reference array is moved, reregistration can be repeated without the need for repeat CT or fluoroscopic imaging, which allows for less radiation exposure when compared with other CAN devices. A limitation of this device is that the system head requires visualization of spinal surface anatomy for registration, which negates the ability to perform percutaneous instrumentation.[16]

Benefits and limitations

Several studies have investigated radiation exposure in spine surgery with CAN compared with fluoroscopic guidance.[11,17–21] With fluoroscopic guidance, there is significant radiation exposure for the surgeon and OR staff. Spine surgeons are susceptible to radiation exposure, facing 50 times the amount of radiation over the course of their career compared with other orthopedic surgeons.[22] Use of CAN in spine surgery has been demonstrated to reduce radiation exposure to OR staff and surgeons by at least a factor of 10.[20,21] Gebhard and colleagues,[19] in their 2006 study, reported that surgeons who used CAN for thoracolumbar instrumentation were exposed to a median radiation dose of 432 mSv as opposed to a dose of 1091 mSv using fluoroscopy with an average time of 40 seconds. A study by Kim and colleagues[10] demonstrated that CAN reduces fluoroscopy time by up to 90 seconds per case, significantly reducing exposure for the surgeon, who in some cases can leave the room while a scan is being conducted, thereby avoiding radiation. It is important to note that there is a variation in the amount of fluoroscopy used among spine surgeons, and radiation doses in some cases may be comparable to that for a singular intraoperative CT.[21,23]

There have been several studies conducted to evaluate the accuracy of CAN.[24–41] In a study by Amiot and colleagues,[39] the error rate with pedicle screw placement was compared between CAN and freehand techniques. Screws placed from T5 to S1 with freehand technique had a malposition rate of 15.3% for 544 screws as opposed to 5.4% for 294 screws inserted via CAN.[39] Yu and colleagues[32] similarly demonstrated that screws placed with CAN breached pedicles by more than 2 mm 4.6% of the time as opposed to a 16% malposition rate when using freehand technique. Luther and colleagues[37] compared pedicle breach between CAN (12%) and lateral fluoroscopy (18%). Towner and colleagues[40] compared 271 cases using CAN with 419 cases using fluoroscopy or freehand technique. The investigators found that only 1.1% of CAN cases required revision due to improperly positioned hardware as opposed to 2.4% of fluoroscopy or freehand cases, although these differences were not statistically significant.[40] In a study by Baky and colleagues,[41] they comparably found that 1% of screws placed using CAN had a 4-mm breach as opposed to 3.3%

of those placed via fluoroscopy (P = .27). In addition, 3.6% of fluoroscopy cases required a return to the OR, whereas 0% of cases using CAN returned to the OR (P = .02).[41] These studies demonstrate that computer-assisted navigated screw placement is associated with increased accuracy, and less complications, when compared with more traditional methods.

Despite its reported advantages regarding accuracy, safety, and radiation exposure, CAN also has some limitations. One potential drawback is the steep learning curve. Sclafani and colleagues[42] reported that novice surgeons learning how to perform percutaneous screw insertion using CAN with an O-arm had slower insertion times without loss of accuracy compared with those using traditional fluoroscopy who had faster insertion times but experienced reduced accuracy. Of note, accuracy did not suffer because operational speed improved throughout the training process with CAN.[42]

CAN has high upfront equipment costs, with platforms costing anywhere from $175,000 to $700,000 USD, with implementation costs and contracting contributing to variability in pricing.[43] Despite this high upfront financial investment, studies have demonstrated that there is a reduced rate of revision surgery when CAN is used, which in turn results in significant cost savings.[44–46] Drazin and colleagues[46] reported that the cost of a revision spine surgery ranges from $17,650 to $39,643 USD following a systematic cost analysis. This finding illustrates that the high upfront investment can be mitigated by avoiding revision spine surgery, which can result in significant savings. Similarly, Zausinger and colleagues[45] reported an average savings of $27,813.18 USD when revision surgeries are avoided in a 2-year retrospective analysis.

Robotic-Guided Spine Surgery

Platforms

Pedicle screw instrumentation using RG arose in the late 1990s, with the first clinical reports in the mid-2000s, partially out of a concern about screw malposition rates and radiation exposure with other MIS instrumentation techniques.[15,47,48] All current FDA-approved and commonly used spine robotic-assist systems operate under the principle of shared control, meaning that the robot functions in tandem with the surgeon who is the primary controller in the procedure.[47,48] The theory behind shared control systems is that they are able to reduce human error via increased accuracy, decreased fatigue, motion scaling, and tremor suppression via mechanical aid.[49]

The Mazor family of robotic systems (SpineAssist [Mazor Robotics Ltd, Caesarea, Israel], Mazor Renaissance, Mazor X, and Mazor X Stealth Edition [MXSE; Medtronic Minneapolis, MN, USA]) all have evolved using a core technology that includes automated anatomy recognition-based RG in which the robotic system is rigidly attached to the patient using some type of "bony mount." The Mazor SpineAssist, FDA approved in 2004, was the first spine surgery robot approved in the United States, and the second-generation Mazor Renaissance was released in 2011. This device offered improvements over the prior iteration, including upgraded image recognition algorithms and prevention of skidding of the guiding cannula along sloped anatomy.[48] The third-generation Mazor X, FDA approved in 2016, offered significant advantages over prior models, most importantly increased arm reach and strength. The robotic arm includes a linear optic camera that enables the robot to make a real-time volumetric assessment of the surgical field to increase accuracy and avoid collision intraoperatively.[48] Another benefit offered by the Mazor X is its serial, as opposed to parallel, robotic arm, which allows for a greater range of motion as well as a reduction in the need for additional surgical tools.[4,15,47,48,50] The Mazor X Align application allows for better preoperative planning and can simulate the impact of corrective changes on alignment. The ROSA Spine Robot (Zimmer Biomet Wilson, IN, USA), FDA approved in 2016, operates similarly to the Mazor X with the exception that it consists of 2 separate stands for its robotic arm and navigation camera. The MXSE, FDA approved in 2018 and first used in January 2019, integrates the Mazor X robotic system with Medtronic's Stealth navigation. With the parallel integration of navigated instruments, real-time feedback on instrument position along with 3D visualization of preoperatively planned screw trajectories is now possible. In addition, the MXSE interfaces with the patient directly. The robot is mounted to both the patient and the bed independent of optical tracking arrays that would otherwise be susceptible to movement or camera blockage, thereby enabling the robot to adjust to changes in the patient's position while maintaining its target trajectory.[12,47,50]

With the concurrent benefits of CAN, modern spine RAN platforms are now integrated with CAN systems.[15,47,50] The Excelsius GPS (Globus Medical Inc, Audubon, PA, USA), FDA approved in 2017, was one of the first integrated platforms released in the United States that allowed for

real-time instrument tracking, intraoperative imaging, compensation for patient movement, and guidance of pedicle screw placement without the use of K-wires. The optical camera used for registration and tracking uses an intraoperative CT; however, the robot is capable of registration using a preoperative CT scan as well.[47,48] Similar to the MXSE, the ROSA platform acquired an FDA-approved upgrade in 2019 that includes a fully integrated CAN.[47]

Benefits and limitations

It is important to note that there are significant differences between robotic guidance systems in terms of hardware, but more importantly as it relates to the software, anatomy recognition, and registration. As such, research related to one type of robotic system cannot be applied or assumed to carry over to other systems.

eMany studies have reported a decrease in radiation exposure with RG.[4,47,48,51–54] In an RCT comparing fluoroscopic-guided pedicle screw placement and RAN, Roser and colleagues[54] demonstrated that the intraoperative radiation exposure was decreased by half in the RAN cohort. In systematic reviews by Peng and colleagues[52] and Fatima and colleagues,[51] intraoperative radiation exposure was significantly reduced in the RAN cohort compared with the freehand cohort by 12.4 and 3.7 seconds, respectively. In the MIS ReFRESH study by Good and colleagues,[4] RG with the Renaissance system reduced fluoroscopy time per screw by 80% (up to 1 minute per case) when compared with fluoroscopic guidance, and the total average intraoperative radiation exposure per RG case was less than half of the exposure per fluoroscopic case. In their multicenter cohort study, Lee and colleagues[50] compared navigated versus nonnavigated Mazor cohorts and found that the former had significantly shorter fluoroscopy time and mean fluoroscopy time per screw. All these findings demonstrate the potential RG has for reduced intraoperative radiation exposure compared with more conventional techniques.

There has been extensive research on the overall safety profile of bone-mounted RG.[4,48,50,53,55–58] In a multicenter database assessment, Lee and colleagues[57] found that patients who underwent lumbar fusion with RG had a low (4.4%) 1-year reoperation rate. Robot-related factors such as robot time per screw, open or percutaneous approach, and the specific robotic system used were not found to be independent factors influencing the 1-year reoperation rate. However, robot-related complications such as intraoperative exchange of screw (0.9%), robot abandonment (2.5%), and return to the OR for screw exchange (1.3%) were found to increase the risk for greater blood loss and longer length of stay.[57] Good and colleagues[4] demonstrated that within a 1-year follow-up period the risk of complications was 5.8 times lower in the bone-mounted RG cohort compared with the fluoroscopic guidance cohort. The risk of a revision surgery was also 11.0 times lower for the RG cohort.[4] Yu and colleagues[58] demonstrated that patients undergoing a 1- to 3-level robotic-assisted posterior lumbar fusion did not have an increased 90-day complication rate compared with nonrobotic-assisted groups. Of note, there was an improvement in length of stay in the robotic-assisted group (2.5 vs 3.17 days, $P = .018$).[58] The literature supports the safety profile of RG.

Several studies have also determined screw placement accuracy with RG.[48,50,55,56] D'Souza and colleagues[48] noted that RG was more accurate and resulted in higher fusion rates than fluoroscopy-assisted procedures with a 95.3% and 86.9% fusion rate ($P = .038$), respectively. In a separate study evaluating S2AI screw placement via RG, Good and colleagues[55] found that RG is a reliable technique for accurate screw placement; 100% of screws graded for accuracy using postoperative CT scans were found to have 0 mm of breach. There was no significant difference in accuracy between RG integrated with CAN and nonnavigated RG cohorts when these were compared.[50] In their 5-year multicenter study on trends in RG, Lee and colleagues[56] found that screw accuracy, operative workflow, radiation exposure, rates of robot abandonment, and complication rates all improved at 4 institutions among 7 different surgeons between 2015 and 2019. Overall, the literature seems to support the accuracy of RG.

A potential limitation in the implementation of RG for institutions is the high upfront capital cost. Platforms may range in price anywhere from $550,000 to $1,100,000 USD. The price variability is attributed to the specific platform purchased as well as contracting. In addition, disposables and adjunct implants may contribute upward of $1500 USD in additional charges per case.[59] There is a paucity of multicenter cost-effectiveness studies; however, the MIS ReFRESH study did examine parameters that reflect cost savings such as radiation exposure, overall time in the operative room, and revision rates. RG was found to have a reduced risk for surgical complications and revision rates as well as significantly reduced fluoroscopy exposure.[4] In a single-center study, Gum and colleagues[60]

examined cost-saving parameters between patients undergoing traditional open thoracolumbar interbody fusion (tTLIF), midline interbody fusion (MIDLIF), and their newly developed robotic-assisted MIDLIF (RA-MIDLIF) technique and found that patients undergoing RA-MIDLIF had a shorter average length of stay (1.53 days) compared with MIDLIF (2.71 days) and tTLIF (3.58 days). Additionally, MIDLIF and RA-MIDLIF had lower estimated blood loss and less OR time when compared with tTLIF.[60] Another single-center study examining cost-effectiveness at an academic center demonstrated that utilization of RG saved $608,546 USD in 1 year.[61] Despite its high upfront cost, RG has the potential to be cost effective upon implementation based on the available literature.

Several studies have investigated the learning curve associated with implementing RG.[62–65] Procedural efficiency and accuracy were not found to be markedly different between experienced and novice RG users; however, performance improved as more experience was attained.[62,63,65] Siddiqui and colleagues[64] investigated the learning curve with a full navigation-enabled platform, the Excelsius GPS, and found that there was no noticeable difference in performance between experienced surgeons and trainees when using RAN with full navigation thereby suggesting that efficiency is easily transferable via observation. Further investigations into learning curve with RG are warranted, yet these early findings on the latest enabling technologies are promising.

Augmented Reality

Platforms

AR navigation in spine surgery is the most novel of the current approaches to the guidance of pedicle screw placement. Worldwide, there are 2 subtypes of AR technology that are used: AR-based head-mounted displays (AR-HMD) and AR surgical navigation systems with an image display on a computer, tablet PC, or video projector (ARSN).[66] At present, there are only 2 AR-HMD devices approved in the United States.

The xvision-Spine System (Augmedics, Ltd, Chicago, IL, USA), FDA approved in 2019, is the first AR-HMD approved in the United States. The device operates by superimposing relevant anatomic structures, possible screw trajectories, as well as ideal screw locations onto the surgical field.[14] The VisAR system (Novarad, Provo, UT, USA) is the second AR-HMD available for use in the United States since gaining FDA approval in 2022. This software works with Microsoft's HoloLens 2 (Microsoft Corporation, Redmond, WA, USA), transforming preoperative CT or fluoroscopic images into 3D virtual images, which are superimposed onto the patient. Of note, the device can respond to the surgeon's voice commands thereby allowing them to maintain focus on the procedure.[67]

Benefits and limitations

AR is advantageous with regard to reducing radiation exposure. Both currently available technologies only require a single preoperative or intraoperative CT scan for an entire procedure to be performed.[66] Carl and colleagues[68] implemented a low-dose protocol for intraoperative CT scanning, which they integrated with preoperative multimodal imaging for registration of the ARSN device. The investigators found that radiation exposure was reduced by about 70% when using this protocol.[68] This study was an attempt to establish a workflow for AR-assisted surgery with reduced radiation exposure. It is important to note that the literature on the implementation of AR in spine surgery and its effects on radiation exposure is limited, therefore more research needs to be conducted on the topic.

AR-assisted spine surgery has been demonstrated to be accurate and safe.[14,69,70] Elmi-Terander and colleagues[69] demonstrated that pedicle screw placement in minimally invasive thoracolumbar surgery using ARSN can be accurate without the use of intraoperative fluoroscopy or x-ray. The investigators had an 89% accuracy rate, with only 2 screws breaching 2 to 4 mm through the pedicle out of a total of 18.[69] In a follow-up matched-control study, they compared ARSN to traditional free-hand technique. The number of clinically accurate screws was higher in the ARSN cohort than the free-hand cohort, with a 93.9% and 89.6% rate, respectively ($P < .05$). In addition, only 36.6% of the ARSN cohort had a cortical breach compared with 69.4% for the free-hand cohort ($P < .001$).[70] Jazini and colleagues, in their prospective cohort study, examined accuracy and safety using AR-HMD. Screws were assessed for accuracy using the Gertzbein-Robbins (G-R) scale, and of the 208 screws, 97.1% were deemed to have a clinically accurate G-R grade of A or B (91.8% Grade A and 5.3% Grade B). Additionally, there were no early postoperative complications or revisions during the 2-week follow-up period.[14] Similarly, Liu and colleagues[71] found a screw accuracy rate of 98% based on grade A or B G-R scores following placement of 205 pedicle screws in their study using AR-HMD. Early safety and accuracy of AR-assisted spine surgery is promising; long-

term research is needed to further evaluate safety parameters with this technology.

Current, FDA approved, AR-HMD can range from $60,000 to $300,000 USD with variation attributed to the platform and contracting.[72] The capital required to purchase and implement these technologies may be prohibitive for some hospital systems but is notably less than other enabling technologies. Multicenter studies regarding cost-effectiveness upon implementation of AR in spine surgery should be conducted in the future.

SUMMARY

Spine surgery has experienced significant and rapid evolution over the past 3 decades with regard to assistive technology. With the advent of multiple generations of new technologies, surgeons now have a diverse array of choices when it comes to pedicle screw placement technologies. Each of the technologies mentioned in this article has its advantages and disadvantages, and implementation must be carefully executed with appropriate understanding of how the technology functions and its limitations. Considerations for patient safety and optimal outcomes must be paramount.

In a technology-driven world, future advancements within spine surgery are inevitable. We have already seen the CAN/RAN integration with an inevitable CAN/RAN/AR integration soon. Will the function of the robotic arms become more independent and go beyond trajectory guidance? Will software upgrades use artificial intelligence to determine ideal alignment, deformity correction, and implant size/shape and then perform 3D printing? This is indeed an exciting era with countless possibilities.

CLINICS CARE POINTS

- Accurate screw placement is critical to avoid vascular or neurologic complications during spine surgery, resulting in the development and transformation of screw guidance or assist technologies within the past 3 decades.
- Computer-assisted navigation, robotic-guided spine surgery, and AR surgical navigation are currently available technologies that have seen greater incorporation in the OR.
- Each of these technologies has its advantages and disadvantages, and implementation must be carefully executed with appropriate understanding of how the technology functions and its limitations.

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