Three-Dimensional Fluoroscopic System to Assess Robotically Placed Pedicle Screws

Should We Confirm Robotic Pedicle Screw Placement With Advanced Imaging?

Jordan Lebovic, MD, MBA, Maxwell Trudeau, BS,† Lefko T. Charalambous, MD, MBA,* Nitya Venkat, BA,‡ Jason Gallina, MD,* and Jeffrey A. Goldstein, MD**

Study Design: Retrospective cohort study.

Objective: The purpose of this study is to determine the utility of advanced imaging to confirm the placement of robotic pedicle screws.

Summary of Background Data: With increasing robotic adoption, certain institutions and surgeons have developed protocols for obtaining 3D intraoperative imaging after robotic pedicle screw placement to ensure proper hardware placement. No studies have assessed the utility of these protocols relative to the potential risks of increased radiation exposure and operative time. The purpose of this study is to determine if we should be obtaining advanced imaging to confirm the placement of robotic pedicle screws.

Methods: This is a single institution retrospective cohort study of patients from May 2022 to July 2023 who underwent lumbar spinal fusion by a high-volume orthopedic spine surgeon at a level 1 metropolitan hospital. All cases used combined robotics and navigation systems for pedicle screw placement and intraoperative 3D imaging for evaluation of screw position. Pedicle screw accuracy was assessed using the Gertzbein and Robbins system (GRS). Acceptable pedicle screw position was defined as GRS A or B.

Results: Seventy patients with 354 robotically placed pedicle screws were assessed with intraoperative 3D fluoroscopy. All pedicle screws were placed in either a GRS type A or type B position. Three hundred fifty-one were placed in a GRS A classification (99.2%, 351/354), and 3 were placed in a GRS B classification (0.08% 3/354). No patients had screw-related complications. The average radiation dosage of 3D imaging was 289.7 ± 164.6 mGy.

Conclusion: The robotic system places pedicle screws accurately without 3D intraoperative imaging. Given the increased radiation and operative time associated with 3D imaging protocols 3D imaging scans should only be obtained in cases with heightened clinical concern.

Level of Evidence: Level IV.

Key Words: robotic spine surgery, intraoperative spine imaging, utility analysis, 3D spine imaging

(*Clin Spine Surg* 2025;38:E295–E299)

Fusion for degenerative lumbar spine disorders remains among the most commonly performed procedures in the United States.[1] With advancements in navigation and robotic technology, the prevalence and accuracy of robotic-assisted pedicle screw placement has continued to increase.[2] The traditional method of placing freehand pedicle screws has a misplacement rate of approximately 5%.[3] Pedicle screw misplacement carries the potential for catastrophic complications, such as neurological injury and biomechanical compromise,[3] and preventative measures should be taken to avoid these complications.

Given the concerns of misplacement with freehand techniques, CT-based navigation was introduced in the early 2000s to guide pedicle screw placement. To potentially further improve accuracy, robotic-assisted navigation was developed and first became a part of clinical practice in 2004 with the Food and Drug Administration approval of the Mazor SpineAssist.[4] Currently, TiRobot (TINAVI Technologies, Beijing, China), ExcelsiusGPS (Globus Medical, Audubon, PA), and ROSA (Zimmer Biomet, Warsaw, IN) are robotic systems that allow intraoperative navigation and pedicle screw placement through robotic arms.[5] While there exist many studies debating the accuracy of pedicle screw placement through different modalities, more recent and larger scale meta-analyses have demonstrated increased accuracy with robotic pedicle screw placement.[2]

There has been significant debate as to the level of trust we should place in these new technologies.[6] With

Received for publication January 4, 2024; accepted September 23, 2024.
From the *Department of Orthopedic Surgery, NYU Langone Orthopedic Hospital, New York, NY; †Department of Orthopedics, University of Connecticut, Storrs, CT; and ‡Department of Orthopedics, Thomas Jefferson University, Philadelphia, PA.
The author JAG receives royalties from Globus Medical Inc.
The authors declare no conflict of interest.
Reprints: Jordan Lebovic, MD, MBA, NYU Langone Medical Center's Hospital for Joint Diseases: NYU Langone Orthopedic Hospital, 301 E 17th St, New York, NY 10003 (e-mail: jordan.lebovic@nyulangone.org)

DOI: 10.1097/BSD.0000000000001724

increasing adoption and awareness, surgical centers have introduced new protocols through which we can ensure the safety of integrating these technologies into patient care. One such protocol includes the decision to obtain a 3D imaging scan after placing robotic guided pedicle screws. While these 3D fluoroscopic scans can provide reassurance and possibly improve the safety of pedicle screw placement, they also increase radiation exposure as well as intraoperative time and cost.

The purpose of this study is to review the utility of obtaining intraoperative 3D imaging scans after pedicle screw placement using the newest robotic-assisted software. This advanced imaging can serve as an additional safety measure because it may discover misplaced hardware that could then be corrected before leaving the operating room and thereby potentially avoid a potentially serious complication. Conversely, this additional imaging adds operative time and therefore time under anesthesia as well as adds a significant amount of radiation exposure to the patient. This study analyzes the frequency that this imaging detects correctable misplaced hardware and balances it with an analyzes of radiation exposure. This nonindustry-funded study describes a single surgeon and institution's experience with 3D fluoroscopic confirmation of a robotic navigated system in placing thoracolumbar and pelvic fixation, using screw placement and radiation exposure as the primary outcome measures.

METHODS

This is a single-institution retrospective cohort study of patients undergoing spinal fusion from May 2022 to July 2023. Patients were included if they underwent a spinal fusion with lumbar pedicle screw placement through any approach and positioning. All cases were performed by a single board-certified high-volume orthopedic spine surgeon at a metropolitan hospital who has performed over 100 prior robotic-assisted cases. All cases leveraged combined robotics and navigation system ExcelsiusGPS and Excelsius 3D (Globus, Audubon, PA) to assist pedicle screw placement as well as intraoperative CT for evaluation of screw position. Figure 1 includes representative images of the robot with intraoperative screw positioning guidance.

Patient demographics, operative details, and screw position evaluation were undertaken by independent reviewers through a retrospective chart review. The following operative details were documented: procedure type, patient positioning, spinal fusion levels, and intraoperative radiation exposure. Each pedicle screw placed was evaluated using the Gertzbein and Robbins System (GRS) classification.

The GRS classification was used to evaluate the accuracy of screw placement within the midline of the pedicle, with grade A screws positioned at the midline within the pedicle. Grade B screws breached the pedicle by <2 mm, grade C screws breached the pedicle by 2–4 mm and 4 mm of the pedicle, grade D screws breached the pedicle by 4–6 mm, and grade E screws breached the pedicle by >6 mm. Type A and B screws were defined as in acceptable positions.[7] All 3D fluoroscopic-based screw position evaluations were performed by a senior orthopedics resident with a second evaluation completed by trained independent reviewers.

Operative Details

Included patients underwent a spinal fusion with lumbar pedicle screw placement while undergoing either posterior lumbar fusion (PLF), transforaminal lumbar interbody fusion (TLIF), lateral lumbar interbody fusion (LLIF), or anterior lumbar interbody fusion (ALIF). PLF and TLIF patients were positioned prone, and LLIF patients were positioned in lateral decubitus for interbody placement and thereafter positioned prone for screw placement. ALIF patients were positioned supine for interbody placement and thereafter positioned prone for screw placement.

All patients underwent either preoperative CT or intraoperative 3D fluoroscopy for robotic-assisted screw trajectory planning and additional 3D fluoroscopic imaging after screw placement for assessment of screw positioning. All procedures were guided by ExcelsiusGPS, which includes a fiducial marker and a surveillance marker placed percutaneously in the patient's posterior superior iliac spine. Preoperatively, CT of the lumbar spine was obtained and uploaded to the ExcelsiusGPS system to assist with screw trajectory mapping. Intraoperatively, fluoroscopic images of the levels to be instrumented are obtained to complete a merge between the fluoroscopic images and the preoperative CT scan. The surgeon utilizes the robot in a sterile manner, drills, taps, and places the screw along the trajectory provided by the robot along the planned trajectory.

RESULTS

One hundred five patients were included in the initial study cohort for having undergone robot-assisted pedicle screw placement of these patients, 31 patients were excluded as the intraoperative images did not completely transfer into the electronic medical system. An additional 4 patients were excluded as they did not contain intraoperative CT radiation dose information. There were 70 patients included in the study. The average age was 62.2 ± 13.3 years (59.4% were female). The average body mass index (BMI) was 28.4 ± 5.4 kg/m^2.

In the 70 cases, 354 pedicle screws were placed. All 354 screws were placed under ExcelsiusGPS robotic guidance. Four of seventy cases were PLFs, 16/70 cases were TLIFs, 12/70 cases were LLIFs, and 38/70 cases were ALIFs. As such, the most common positioning was supine followed by prone (52.2%). Fifty patients underwent placement of interbody cages before pedicle screw placement (12 LLIFs, 38 ALIFs). L4–L5 (28.5%) was the most common level fused, followed by L5–S1 (24.2%) (Table 1).

In evaluating screw position, all pedicle screws were placed in either a GRS classification type A or type B position. 0.8% or 3 of 354 screws were placed in the type B position of the type B screws, 2 screws were found to be

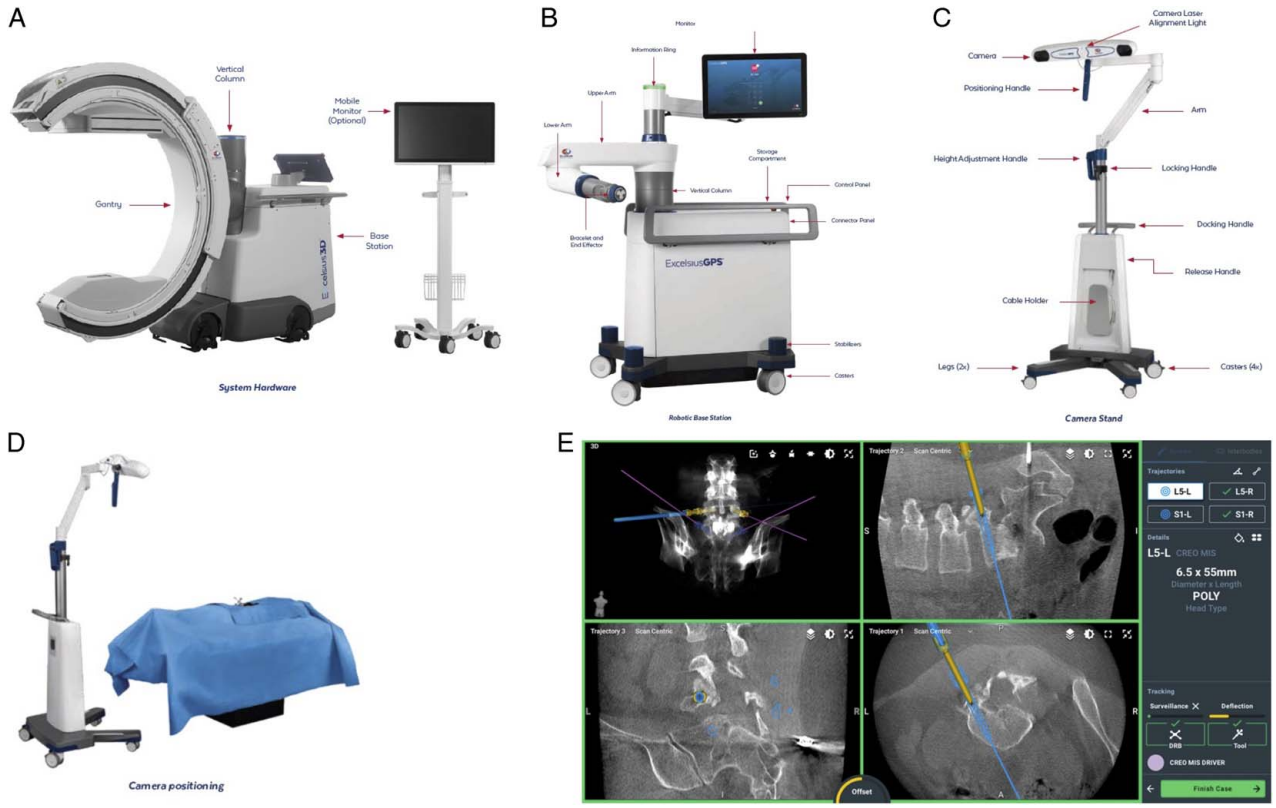

FIGURE 1. Excelsius Robot components and representative intraoperative images. The representative components of the Excelsius navigation system can be utilized for intraoperative 3D imaging and guidance. A, Excelsius 3D gantry system, including the C arm capable of intraoperative fluoroscopy and 3D imaging which can be combined with the ExcelsiusGPS system. B, ExcelsiusGPS base station which includes the End Effector robotic arm for targeted screw trajectory. C, Camera stand which is positioned viewing the surgical field (as in D) to register optical markers for the robotic arm to navigate relative to (E) example of the intraoperative monitor demonstrating the multiplanar trajectory planning for screws.

lateral to the pedicle cortex, while 1 was found to be medial to the pedicle. Two of the 3 type B screws were part of an L4–L5 TLIF. The third type B screw was during an L4–5 ALIF. No pedicle screws were found to be in an unacceptable position (Table 2). There were no significant relationships between type B screw placement and patient age, gender, BMI, procedure type, positioning, spinal fusion level, and mean screw count for the case.

No patients had pedicle screw-related functional or neurological complications, and none returned to the OR for revision screw placement. All screws were deemed to be in an acceptable position for optimal patient outcome.

The average radiation duration of intraoperative 3D fluoroscopy to assess screw position was 29.9 ± 10.6 seconds. The average Air Kerma (kinetic energy transferred per unit mass) per patient was 289.7 ± 164.6 mGy. The average dose area product (DAP, marker of x-ray energy delivered to patient) per patient was 79.3 ± 36.1 (Table 3), converted to millisieverts is 17.4 ± 7.9.

DISCUSSION

Misplaced instrumentation can potentially require revision, increasing cost and morbidity to the patient.[8] While misplaced hardware occurs more often in less experienced surgeons, this still regularly occurs in more experienced surgeons, especially in complex deformity cases.[9,10] Robotic-assisted pedicle screw placement offers an important opportunity to improve accuracy and reliability, and technology for this has improved significantly in the 20 years since its inception, along with surgeons becoming more advanced and plateauing with these systems' learning curves.[2,11,12] This study reviews the utility of routine utilization of an intraoperative 3D fluoroscopic protocol after pedicle screw placement to ensure proper pedicle screw positioning.

In this study, 100% of pedicle screws (n = 354) that were placed robotically were in an acceptable position, as confirmed by a review of 3D intraoperative fluoroscopic scans. Three hundred fifty-one pedicle screws were found to be GRS grade A (99%) and 3 pedicle screws were found to be grade B (1%). No screws were found to have breached the pedicle cortices > 2 mm (Table 2). There were no screw-related complications. No patients required repositioning of the screws intraoperatively and no patients required return to the operating room for screw revision.

Many studies have been conducted comparing robotic guided screws with freehand technique. While most

TABLE 1. Operative Details for Globus Navigation-Assisted Cases

Procedure and positioning	N (%)
Procedure type	
PSF	4 (5.7)
TLIF	16 (22.8)
LLIF	12 (17.1)
ALIF	38 (54.2)
Patient positioning	
Prone	20 (28.5)
Prone+lateral	12 (17.1)
Prone+supine	38 (54.2)
Spinal levels fused	
L2–L3	2 (2.9)
L3–L4	5 (7.1)
L4–L5	20 (28.5)
L5–S1	17 (24.2)
L4–S1	5 (7.1)
L2–L5	3 (4.3)
L2–S1	1 (1.4)
L2–L4	1 (1.4)
L3–S1	1 (7.2)
L3–L5	10 (14.3)
T10–S1	1 (1.4)

N = 70.

have concluded increasing accuracy with robotic guidance, some, such as the randomized study of Ringel et al,[6] have concluded these technologies may be associated with a decreased accuracy of pedicle screw placement. Accordingly, several large systematic reviews have been conducted to explore this. Fan et al[13] performed meta-analyzes of 1255 freehand and 1682 robotic guided screws, demonstrating overall increased pedicle screw accuracy of robotic screws (OR: 1.69, $P < 0.01$). Fichtner et al[14] conducted another systematic review of 13,703 pedicle screws comparing navigation and freehand technique, demonstrating significantly lower rates of screw revisions in navigated screws compared with the freehand technique. A more recent meta-analyzes by Naik and colleagues analyzed 77,360 pedicle screws and demonstrated robotic-assisted pedicle screw accuracy of 98.4% when considering studies completed after 2016. As the software improves, the accuracy has continued to improve over time.

Given the pedicle screw accuracy in our study, as well as in recent meta-analyzes, the utility of intraoperative 3D fluoroscopic scanning for pedicle screw assessment comes to question.[2,15] 3D intraoperative fluoroscopy is not an entirely benign endeavor, as the patient is exposed to additional radiation, operative time is increased, and cost to the health care system increases substantially.

TABLE 2. Pedicle Screw Placement

Procedure and positioning	N (%)
Screw placement timing	
Before interbody	68 (20.4)
After interbody	264 (79.6)
GRS	
A	351 (99.2)
B	3 (0.8)
C	0
D	0
E	0

Total screw count = 354.

TABLE 3. Radiation Details

Procedure and positioning	Mean	STD
Radiation duration (s)	29.9	10.6
Air Kerma (mGy)	289.7	164.6
DAP (Gy×cm^2)	79.3	36.1
MilliSieverts (mSv)	17.4	7.9

N = 70.

In this study, we assessed average radiation using the intraoperative 3D fluoroscopy. Radiation duration refers to the amount of time a patient is exposed to ionizing radiation during an imaging procedure.[16] Air Kerma is a measure of the amount of energy transferred from ionizing radiation to air at a specific point in space, which can help quantify the amount of radiation affecting one area of a patient's body during an imaging study or procedure.[16] DAP is a measure of the total amount of radiation dose delivered over the imaged surface area during a procedure. DAP is commonly used in fluoroscopy to estimate the radiation exposure received by a patient's entire body.[17] DAP can be converted to Sieverts through a lumbar spine-specific conversion factor.[17] Before studies comparing radiation doses between computer-navigated versus fluoroscopic cases were often limited because they did not include all perioperative imaging. It was classically believed that CT navigation increases radiation exposure to the patient while reducing radiation exposure to the surgeon.[18] Interestingly, Wang et al[19] demonstrated that when the preoperative CT scans were included in total radiation, robotic cases still had less radiation exposure than fluoroscopically guided techniques. Few studies have summatively quantified the additional radiation exposure of a confirmatory 3D fluoroscopic image after pedicle screw placement. We quantified an average radiation dose of 289.7 mGy with a mean mSv of 17.4 ± 7.9 (Table 3). This is notably an additional radiation dose above the radiation from preoperative CT acquisition. For context, studies have found that new-generation 3D imaging units deliver approximately the same amount of radiation as a CT scan.[19,20] This was further confirmed by our study which demonstrated a mean mSv of 17.4 ± 7.9, which was within the SD of the average lumbar CT often cited at approximately 15 mSv.[21] It is crucial to understand that while some 3D fluoroscopy units are marketed with low-dose options, often to obtain clinically relevant images that can differentiate screws from the pedicle cortical wall, higher powered imaging is necessary. Proximity to the radiation source is the most significant factor when considering radiation exposure to the staff (1/distance^2). Similar to other authors, we advocate for the surgical teams to leave the operating room during scanning to ensure adequate protection from intraoperative scans.[20] Given the limit for occupaitonal radiation exposure is 20mSv per year aver-

aged over five years, one can imagine that if the surgical staff remains in the room for several cases they will quickly exceed the annual radiation exposure limit.

The average 3D fluoroscopic scanner costs ~$500,000.[22] While the scanner has demonstrated utility, given the high level of accuracy of the robotic pedicle screw placement, it is difficult to justify the routine utilization of the 3D scanner to check screw placement. These machines are useful in the context of patients without preoperative CT, who require intraoperative imaging for source imaging and registration. However, if these 3D fluoroscopic machines are primarily used for safety protocols instead of obtaining source imaging for registration, their cost-utility decreases. When considering the recommended registration method, Malham et al[22] created guidelines that note that 3D fluoroscopy is most useful in patients who have lower BMIs and in cases where the interbody cages are being placed before the pedicle screws. This thereby prevents any interference of interbody cage distraction on the registration process.

There are several limitations to this study. The primary limitation is that this study does not contain a control group. To be included in this study, the patients required advanced imaging to confirm pedicle screw placement, therefore all patient's required the 3D fluoroscopic scan. Many patients in this study underwent single-level fusions. Given the accuracy of these systems decreases with increasing levels, it is possible that worse accuracy could result in a population of larger fusion constructs. Furthermore, as this 3D fluoroscopic technology is new, our complete data set is from a single surgeon with a sample size of 70 patients and 354 screws. Importantly, this surgeon has significant experience with robotic pedicle screw placement. It is possible that robotic-assisted pedicle screw placement in lower-volume surgeons are not as accurate, but high-volume surgeons can approach 100% accuracy. Lastly, this study is retrospective, and therefore future prospective studies with larger sample sizes must be conducted to obtain more definitive evidence.

CONCLUSION

We found the accuracy of robotic pedicle screw placement for a high-volume surgeon to be 100%. In this situation, when considering the high accuracy of the robot in the context of the additional radiation exposure to the patient, increased cost, and increased operative time, the routine use of intraoperative 3D fluoroscopic imaging may not add value to the procedure for the patient or the health care system. Instead, we would recommend considering this additional imaging safety measure in cases in which there is either a clinical concern, such as neuromonitoring changes, or a registration concern in which there is evidence of poor fidelity between the source images and the patient's anatomy during the operation.

REFERENCES

1. Deyo RA, Gray DT, Kreuter W, et al. United States trends in lumbar fusion surgery for degenerative conditions. *Spine (Phila Pa 1976)*. 2005;30:1441–1445.
2. Naik A, MacInnis BR, Shaffer A, et al. Trends in technology for pedicle screw placement: a temporal meta-analysis. *Spine (Phila Pa 1976)*. 2023;48:791–799.
3. Amato V, Giannachi L, Irace C, et al. Accuracy of pedicle screw placement in the lumbosacral spine using conventional technique: computed tomography postoperative assessment in 102 consecutive patients. *J Neurosurg Spine*. 2010;12:306–313.
4. D'Souza M, Gendreau J, Feng A, et al. Robotic-assisted spine surgery: history, efficacy, cost, and future trends. *Robot Surg*. 2019;6:9–23.
5. Vo CD, Jiang B, Azad TD, et al. Robotic spine surgery: current state in minimally invasive surgery. *Global Spine J*. 2020;10(suppl):34S–40S.
6. Ringel F, Stuer C, Reinke A, et al. Accuracy of robot-assisted placement of lumbar and sacral pedicle screws: a prospective randomized comparison to conventional freehand screw implantation. *Spine (Phila Pa 1976)*. 2012;37:E496–E501.
7. Gertzbein SD, Robbins SE. Accuracy of pedicular screw placement in vivo. *Spine (Phila Pa 1976)*. 1990;15:11–14.
8. Shillingford JN, Laratta JL, Sarpong NO, et al. Instrumentation complication rates following spine surgery: a report from the Scoliosis Research Society (SRS) morbidity and mortality database. *J Spine Surg*. 2019;5:110–115.
9. Lehman RA Jr, Lenke LG, Keeler KA, et al. Computed tomography evaluation of pedicle screws placed in the pediatric deformed spine over 8 years. *Spine (Phila Pa 1976)*. 2007;32:2679–2684.
10. Gonzalvo A, Fitt G, Liew S, et al. The learning curve of pedicle screw placement: how many screws are enough? *Spine (Phila Pa 1976)*. 2009;34:E761–E765.
11. Vaccaro AR, Harris JA, Hussain MM, et al. Assessment of surgical procedural time, pedicle screw accuracy, and clinician radiation exposure of a novel robotic navigation system compared with conventional open and percutaneous freehand techniques: a cadaveric investigation. *Global Spine J*. 2020;10:814–825.
12. Jain D, Manning J, Lord E, et al. Initial Single-institution experience with a novel robotic-navigation system for thoracolumbar pedicle screw and pelvic screw placement with 643 screws. *Int J Spine Surg*. 2019;13:459–463.
13. Fan Y, Du JP, Liu JJ, et al. Accuracy of pedicle screw placement comparing robot-assisted technology and the free-hand with fluoroscopy-guided method in spine surgery: an updated meta-analysis. *Medicine (Baltimore)*. 2018;97:e10970.
14. Fichtner J, Hofmann N, Rienmuller A, et al. Revision rate of misplaced pedicle screws of the thoracolumbar spine-comparison of three-dimensional fluoroscopy navigation with freehand placement: a systematic analysis and review of the literature. *World Neurosurg*. 2018;109:e24–e32.
15. Cronin PK, Poelstra K, Protopsaltis TS. Role of robotics in adult spinal deformity. *Int J Spine Surg*. 2021;15(s2):S56–S64.
16. Sulieman A, Alzimami K, Habeeballa B, et al. Evaluation of occupational and patient radiation doses in orthopedic surgery. *Appl Radiat Isot*. 2015;100:65–69.
17. Crawley MT, Rogers AT. Dose-area product measurements in a range of common orthopaedic procedures and their possible use in establishing local diagnostic reference levels. *Br J Radiol*. 2000;73:740–744.
18. Mendelsohn D, Strelzow J, Dea N, et al. Patient and surgeon radiation exposure during spinal instrumentation using intraoperative computed tomography-based navigation. *Spine J*. 2016;16:343–354.
19. Wang E, Manning J, Varlotta CG, et al. Radiation exposure in posterior lumbar fusion: a comparison of ct image-guided navigation, robotic assistance, and intraoperative fluoroscopy. *Global Spine J*. 2021;11:450–457.
20. Navarro-Ramirez R, Lang G, Lian X, et al. Total navigation in spine surgery: a concise guide to eliminate fluoroscopy using a portable intraoperative computed tomography 3-dimensional navigation system. *World Neurosurg*. 2017;100:325–335.
21. Giordano BD, Grauer JN, Miller CP, et al. Radiation exposure issues in orthopaedics. *J Bone Joint Surg Am*. 2011;93:(e69)1. doi:10;10.2106/JBJS.J.01328
22. Malham GM, Wells-Quinn T. What should my hospital buy next?-guidelines for the acquisition and application of imaging, navigation, and robotics for spine surgery. *J Spine Surg*. 2019;5:155–165.