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What Is the Comparison in Robot Time per Screw, Radiation Exposure, Robot Abandonment, Screw Accuracy, and Clinical Outcomes Between Percutaneous and Open Robot-Assisted Short Lumbar Fusion?

A Multicenter, Propensity-Matched Analysis of 310 Patients

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Study Design. Multicenter cohort.

Objective. To compare the robot time/screw, radiation exposure, robot abandonment, screw accuracy, and 90-day outcomes between robot-assisted percutaneous and robot-assisted open approach for short lumbar fusion (1- and 2-level).

Summary of Background Data. There is conflicting literature on the superiority of robot-assisted minimally invasive spine surgery to open techniques. A large, multicenter study is needed to further elucidate the outcomes and complications between these two approaches.

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The device(s)/drug (s) is/are FDA-approved or approved by corresponding national agency for this indication.

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Methods. We included adult patients (\geq 18 yrs old) who underwent robot-assisted short lumbar fusion surgery from 2015 to 2019 at four independent institutions. A propensity score matching algorithm was employed to control for the potential selection bias between percutaneous and open surgery. The minimum follow-up was 90 days after the index surgery.

Results. After propensity score matching, 310 patients remained. The mean (standard deviation) Charlson comorbidity index was 1.6 (1.5) and 53% of patients were female. The most common diagnoses included high-grade spondylolisthesis (grade >2) (48%), degenerative disc disease (22%), and spinal stenosis (25%), and the mean number of instrumented levels was 1.5(0.5). The operative time was longer in the open (198 min) versus the percutaneous group (167 min, P value = 0.007). However, the robot time/screw was similar between cohorts (P value > 0.05). The fluoroscopy time/ screw for percutaneous (14.4s) was longer than the open group (10.1 s, P value = 0.021). The rates for screw exchange and robot abandonment were similar between groups (P value > 0.05). The estimated blood loss (open: 146 mL vs. percutaneous: 61.3 mL, P value < 0.001) and transfusion rate (open: 3.9% vs. percutaneous: 0%, P value = 0.013) were greater for the open group. The 90-day complication rate and mean length of stay were not different between cohorts (P value > 0.05). Conclusion. Percutaneous robot-assisted spine surgery may increase radiation exposure, but can achieve a shorter operative time and lower risk for intraoperative blood loss for short-lumbar fusion. Percutaneous approaches do not appear to have an advantage for other short-term postoperative outcomes. Future multicenter studies on longer fusion surgeries and the inclusion

Key words: lumbar spine surgery, minimally invasive spine surgery, multicenter, percutaneous spine surgery, posterior

of patient-reported outcomes are needed.

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lumbar fusion, radiation exposure, robot abandonment, robot time per screw, robot-assisted spine surgery, short-term complications.

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ercutaneous spinal instrumentation was first introduced by Magerl¹ in 1977 for the treatment of thoracic and lumbar spinal fractures. Since then, numerous clinical studies have compared this technique to the conventional open approach for various lumbar pathologies and demonstrate numerous benefits including decreased postoperative pain, lower intraoperative blood loss, shorter operative time, and reduced length of hospital stay.²⁻⁵ With the emergence of computed tomography (CT)based navigated systems, minimally invasive surgery demonstrated even greater precision, safety, and accuracy for pedicle screw instrumentation.^{6,7} Over the last two decades, robot-assisted spine surgery has taken center-stage because of the potential for greater reliability and safety in pedicle instrumentation, especially for those with complex and variable anatomy, as well as decreased radiation exposure for the patient and operative team.^{8,9}

A plethora of literature exists comparing the outcomes between robot-assisted minimally invasive techniques and conventional open approaches; however, the comparison between robot-assisted percutaneous and robot-assisted open surgeries remains largely unknown.¹⁰ Determining the clinical differences between these cohorts can better inform surgeons and patients during their preoperative planning phase of care. Current literature on this topic only comments on this comparison in their subanalysis, and are limited by singlesurgeon or single-center series, small sample sizes, inpatient complications, and early generation robot systems.^{11–13}

This is the first multicenter study of four geographically diverse institutions on robot-assisted spine surgery to directly compare the outcomes and complications between percutaneously placed pedicle screws and open approach surgeries. With 310 patients and over 1000 robotically placed screws, we compare the robot time per screw, radiation exposure, robot abandonment rate, screw accuracy, and 90-day postoperative complications between these two cohorts for short lumbar fusion (1- and 2-levels). We hypothesize that there will be statistically significant advantages to minimally invasive robot-assisted spine surgery.

MATERIALS AND METHODS

Patient Selection

We included adult patients (\geq 18 yrs old) who underwent robot-assisted short lumbar fusion (1- and 2-level) surgery from 2015 to 2019 at four independent institutions and among seven spine attending surgeons. The minimum follow-up was 90 days after the index admission. Three robot systems were used during this study's timeframe: Mazor Renaissance, Mazor X, and Mazor Stealth Edition. Cases with missing data were excluded. This study was approved by the institutional review board.

Data Collection

Patient factors included sex, body mass index, Charlson comorbidity index, and indication for surgery. Operative factors included prior spine surgery, number of instrumented levels per patient, pelvic fixation, interbody fusion, robot system, and number of planned robot screws per patient.

The primary outcomes of interest included robot time/ screw (minutes/screw), radiation exposure, robot abandonment, screw exchange for breach, and 90-day postdischarge outcomes. Total operative time, robot time, and fluoroscopy time were recorded by dedicated research coordinators at each hospital site. Robot time was measured as the time from when the robot was brought into the operating field to when the robot was removed. Robot time per screw was calculated by dividing the robot time by the number of screws placed by the robot. Radiation exposure was measured as the fluoroscopy time spent per screw (seconds/ screw). Robot abandonment was defined as discontinuing robot use for a preoperatively planned robot screw, and instead using freehand technique and/or fluoroscopy. The 90-day postdischarge outcomes included any readmission and reoperations.

Other non-robot-related outcomes and complications were recorded as well. These included length of hospital stay, dural tear, loss of intraoperative motor/sensory signals, perioperative blood transfusion, estimated blood loss (mL), and return to the operating room during the same inpatient stay.

Propensity Score Matching

A propensity score matching algorithm was employed to control for the potential selection bias between percutaneous and open surgery. The designation of open versus percutaneous was made based on whether screws (e.g., pedicle or iliac/S2AI screws) were placed through percutaneous incisions or conventional open, larger incisions. Both patient and operative factors were included in this algorithm (Table 1). Bivariate analyses were performed for perioperative factors and outcomes/complications between percutaneous and open surgery. The Chi-square or Fisher exact test (where appropriate) and t tests/ANOVA were used for categorical and continuous variables, respectively. Statistical significance was defined as a *P* value < 0.05. Propensity score matching was performed in R version 3.0.2 (Vienna, Austria, http://www.R-project.org/) using the Matchlt (Ho, Imai, King, and Stuart, 2011) package. SAS Studio Version 3.4 (SAS Institute Inc, Cary, NC).

Robotic Systems

Three Mazor robot systems were used and controlled for in the propensity score matching algorithm of this study. First, the Renaissance was used which replaced Mazor's 1st generation robot system (SpineAssist). The Renaissance relies on several mounting platforms and a portable computer-controlled, hexapod device to spatially position and Spine Surgery

matching		_					
	All		Percutaneous		Open		
	N	%	N	%	Ν	%	P Value
Total # of patients	310	100%	155	48.4%	155	50%	
Female	163	53%	82	52.9%	81	52.3%	0.909
Obese $(BMI > 30 kg/m^2)$	122	39%	63	40.6%	59	38.1%	0.642
CCI, mean (standard deviation, SD)	1.6	(1.5)	1.5	5 (1.4)	1.7	(1.7)	0.241
Preoperative diagnosis							
High grade spondylolisthesis	150	48%	83	53.5%	67	43.2%	0.398
Degenerative disc disease	68	22%	33	21.3%	35	22.6%	
Spinal stenosis	76	25%	32	20.6%	44	28.4%	
Pseudarthrosis, implant failure	10	3%	4	2.6%	6	3.9%	
Other	6	2%	3	1.9%	3	1.9%	
Operative				•		-	
Prior spine surgery	9	3%	4	2.6%	5	3.2%	0.735
Instrumented levels per patient, mean (SD)	1.5	(0.5)	1.5	5 (0.5)	1.4	(0.5)	0.141
Pelvic fixation	5	2%	2	1.3%	3	1.9%	0.652
Interbody fusion	124	40%	54	34.8%	70	45.2%	0.064
Planned robot screws per patient, mean (SD)	3.6 (1.2)		3.7 (1.3)		3.4 (1.2)		0.155
Robot system							
Renaissance	41	13%	22	14.2%	19	12.3%	0.297
Х	231	75%	110	71.0%	121	78.1%	
Stealth	38	12%	23	14.8%	15	9.7%	

TABLE 1. Patient Demographics, Comorbidities, and Perioperative Factors After Propensity Score Matching

orient surgical tools according to the surgeon's preoperative plan. Second, the Mazor X system was used which had a number of considerable advantages in comparison with prior platforms. These included a more sophisticated three-dimensional software to improve preoperative planning. The Align application combined standing spine x-rays with CT-scan to model the impact of corrective changes, such as osteotomies, on a patient's global alignment (e.g., sagittal and coronal planes). The X robot introduced a robotic arm, which was designed to be serial, rather than parallel, to increase the range of motion of the robotic device and an integrated three-dimensional camera with spatial tracking to better self-detect its location and reduce collision error with the operative landscape. Finally, Mazor X Stealth Edition was used which is Mazor's most recent iteration of robot systems. It combines Medtronic's Stealth navigation technology with the Mazor X platform to allow surgeons to have real-time three-dimensional feedback as they drill and place their implants down preoperatively planned trajectories.

RESULTS

After propensity score matching, a total of 310 patients were included in this study. The mean (standard deviation) Charlson comorbidity index was 1.6 (1.5), 53% (N=163) of patients were female, and 39% (N=122) of patients were obese. (Table 1). The most common diagnoses included high-grade spondylolisthesis (grade >2) (48%, N=150), spinal stenosis (25%, N=76), and degenerative disc disease (22%, N=68). Prior spine surgery was observed in 3%

(N=9) of patients and the mean number of instrumented levels was 1.5 (0.5). Pelvic fixation rate was 2% (N=5), interbody fusion rate was (40%, N=124), and the mean number of planned robot screws per patient was 3.6 (1.2). Most cases were performed by the Mazor X (Renaissance: 13%, N=41; X: 75%, N=231, Stealth: 12%, N=38). No statistically significant differences were observed among these patient and operative factors between percutaneous and open surgery after propensity score matching (*P* value > 0.05) (Table 1).

The mean operative time was significantly longer in the open group (198 min) *versus* the percutaneous group (167 min, P value = 0.007) (Table 2). However, the overall robot time and mean robot time per screw was similar between cohorts (P value > 0.05). The mean fluoroscopy time per screw for percutaneous surgery (14.4 s) was significantly longer than the open group (10.1 s, P value = 0.021).

The exchange rate of robot screws was low and similar between cohorts (Percutaneous: 0.8%, N=4; Open: 1.3%, N=7, P value=0.348) (Table 3). Similarly, the robot abandonment rate was low and similar between groups (Percutaneous: 0.6%, N=1; Open: 2.6%, N=4, P value=0.176). In regards to non-robot related complications, the incidence of dural tear was similar between cohorts (Percutaneous: 1.3%, N=2; Open: 3.2%, N=5, P value=0.251). No cases were recorded to have an intraoperative motor/sensory loss and no cases required a return to the operating room during the same inpatient stay. The estimated blood loss (Percutaneous: 61.3 mL; Open:

TABLE 2. Operative Efficiency and Radiation for Open Versus Percutaneous Surgery								
Mean (SD)	All	Percutaneous	Open	P Value				
Operative time (minutes)	182 (92)	167 (106)	198 (73)	0.007				
Robot time (minutes)	24.5 (12.0)	24.0 (11.9)	25.6 (12.5)	0.562				
Robot time per screw (minutes/screw)	7.8 (6.3)	7.5 (4.2)	8.5 (9.3)	0.553				
Total fluoroscopy time (seconds)	39.1 (33.0)	41.7 (30.8)	33.6 (37.1)	0.095				
Fluoroscopy time per screw (seconds/screw)	13.0 (13.6)	14.4 (14.4)	10.1 (11.4)	0.021				

146 mL, *P* value < 0.001) and perioperative blood transfusion rate (Percutaneous: 0%, N=0; Open: 3.9%, N=6, *P* value = 0.013) were significantly greater for the Open group *versus* the Percutaneous group (Table 3). The 90-day readmission (Percutaneous: 5.8%, N=9; Open: 5.8%, N=9, *P* value = 1) and reoperation rates (Percutaneous: 2.6%, N=4; Open: 4.5%, N=7, *P* value = 0.357) were similar between groups. Similarly, the reasons for reoperation (*e.g.*, wound complication, implant failure) were not different between cohorts (Table 4). The mean length of stay (Percutaneous: 3.0 days; Open: 3.1days, *P* value = 0.579) were not significantly different.

DISCUSSION

The advent of new imaging and surgical technologies continues to evolve the landscape of spine surgery. In recent decades, the concept of minimally invasive spine surgery (MIS) has gained increasing popularity.^{10,14} Furthermore, the introduction of robot-assisted platforms nearly 20 years ago has brought another paradigm shift within spine surgery. A plethora of literature exists on the comparison between MIS and conventional open pedicle screw insertion. There is ample evidence to suggest that percutaneous pedicle screws can achieve less blood loss, decreased iatro-genic disruption to muscle and soft tissues, less postoperative pain, and shorter length of stay.^{15–23} However, nonrobot MIS techniques have been associated with increased radiation exposure to patients and operating staff.^{24–27} The use of robot-assisted techniques is thought to potentially overcome this shortcoming of fluoroscopy-guided MIS by improving the mechanical control of instruments and implant insertion in a precise, preplanned manner without the need for excessive fluoroscopy.²⁸ Although extensive research on the utility of robotic technology in spine surgery is underway,^{29–31} the comparison between robot-assisted percutaneous instrumentation and robot-assisted open techniques remains limited in current literature.

A few studies have commented on the use of percutaneous pedicle screw insertion using robot platforms. In 2009, Pechlivanis et al³² described the first clinical assessment of percutaneous posterior lumbar interbody fusion with the SpineAssist. In 31 consecutive patients and 133 pedicle screws, a deviation of <2 mm from the preoperative plan was observed in more than 91% of screws. Hyun et al^{28} performed a prospective randomized clinical trial of 60 patients undergoing 1- or 2-level spinal fusions between robot-guided percutaneous instrumentation (Mazor Renaissance) and fluoroscopic-guided open surgery. They demonstrated a mean reduction of 62.5% in intraoperative radiation exposure for the robot-assisted percutaneous cohort as well as a significant reduction in length of stay (Percutaneous: 6.8 days; Open: 9.4 days, P value = 0.020). It is important to note that the robot's dependence on preoperative CT scan for planning purposes is a potential source

Surgery		0					
	All		Percutaneous		Open		
	Ν	%	N	%	N	%	P Value
Total # of executed robot screws	1051	100%	530	50.4%	521	49.6%	
Exchange of malpositioned robot screw (per executed screws)	11	1.0%	4	0.8%	7	1.3%	0.348
Robot abandonment	5	1.6%	1	0.6%	4	2.6%	0.176
Registration issue	3	1.0%	0	0.0%	3	1.9%	0.082
Unreachable anatomy	2	0.6%	1	0.6%	1	0.6%	1
Other surgical complications		•				•	
Dural tear	7	2.3%	2	1.3%	5	3.2%	0.251
Loss of motor/sensory function	0	0.0%	0	0.0%	0	0.0%	
Perioperative blood transfusion	6	1.9%	0	0.0%	6	3.9%	0.013
Estimated blood loss (mL), mean (SD)	104	4 (155)	61.3	(98.4)	140	5 (187)	< 0.001
Return to operating room during same inpatient stay	0	0.0%	0	0.0%	0	0.0%	

 TABLE 3. Robot Technical Errors and Other Surgical Complications for Open Versus Percutaneous

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	All		Percutaneous		Open		
	N	%	N	%	N	%	<i>P</i> Value
Any readmission within 90 days after surgery	18	5.8%	9	5.8%	9	5.8%	1
Any reoperation within 90 days after surgery	11	3.5%	4	2.6%	7	4.5%	0.357
Wound complication	9	2.9%	4	2.6%	5	3.2%	0.735
Implant failure	1	0.3%	0	0.0%	1	0.6%	0.317
New neurologic deficit	0	0.0%	0	0.0%	0	0.0%	
Dura fistula	0	0.0%	0	0.0%	0	0.0%	
Screw malposition	0	0.0%	0	0.0%	0	0.0%	
Other	1	0.3%	0	0.0%	1	0.6%	0.317
Length of hospital stay, mean (SD)	3.0	0 (2.3)	3.0) (1.9)	3.1	1 (2.6)	0.579

for increased radiation exposure to the patient. However, it is not uncommon to routinely preform preoperative CT scans for both robot and non-robot cases. No differences in patient-reported outcomes (i.e., Visual Analog Scale and Oswestry Disability Index), operative time, and screw accuracy were observed; however, the mean facet to screw distance was significantly smaller in the open, freehand cohort, and no proximal facet violations occurred in the robot group.

Similarly, in a prospective cohort study, Zhang et al³³ compared the screw accuracy between robot-assisted percutaneous pedicle screw placement (TiRobot, TINAVI Medical Technologies) and open fluoroscopic-guided surgery for transforaminal lumbar interbody fusion in 100 patients. They found that the robot-assisted MIS cohort was associated with a lower intraoperative blood loss, fewer proximal facet joint violations, larger facet to screw distance, and improved pedicle screw accuracy. Iatrogenic injury to the facet could potentially accelerate adjacent level facet degeneration and thus adjacent segment disease. Furthermore, the MIS cohort experienced a greater total radiation exposure (Percutaneous: $65.3 \,\mu$ Sv; Open: $30.3 \,\mu$ Sv, P value < 0.001) and longer operative time (Percutaneous: 184.7 min; Open: 117.8, *P* value < 0.001). These authors attributed the increased radiation exposure to the need for additional intraoperative fluoroscopy for robot registration and intraoperative planning. The extended operative time was noted to be largely related to the additional time needed for robot setup.

A dearth of literature exists comparing robot-assisted MIS and robot-assisted open approach spine surgery. In a single-center, retrospective study, Kantelhardt et al¹¹ compared the perioperative outcomes and screw accuracy in robot-assisted open (SpineAssist), robot-assisted percutaneous, and conventional open approach spine surgery in 112 patients with a mean follow-up of 90 days. In their series, pre- and post-CT scans were routinely preformed for all cases. These authors observed a decrease in intraoperative fluoroscopic radiation for robot-assisted percutaneous cases compared with robot-assisted open procedures, but this was not statistically significant. Furthermore, Kantelhardt et al observed lower opioid analgesic requirements (P < 0.05)

and shorter length of stay (-1.5 d, P < 0.05). No differences between robot cohorts were observed for operative time per screw, screw accuracy, short-term adverse events, and revision surgery.

In 2014, Schatlo *et al*¹² performed a single surgeon study on 95 patients to examine the screw accuracy and inpatient complications between robot-assisted percutaneous/open and conventional open lumbar fusion. No significant differences were observed for screw accuracy or inpatient complications, except for a significantly lower blood loss for robot cases. These authors attribute this to the fact that the majority of robot cases were performed percutaneously (69%, N=38). Unfortunately, no direct comparative analvsis was performed between robot-assisted percutaneous and robot-assisted open surgeries.

Most recently, Vaccaro et al¹³ performed a cadaveric investigation (N = 10) on screw accuracy and fluoroscopy radiation for MIS (fluoroscopic-guided and robot-assisted [ExcelsiusGPS, Globus Medical]) and open approach (fluoroscopic-guided and robot-assisted). Of note, the operative time per screw was 3.1 minutes for conventional open, 3.3 minutes for robot-assisted open, 7.6 minutes for fluoroscopic MIS, and 3.6 minutes for robot-assisted percutaneous groups. Furthermore, robot assisted groups, regardless of technique, reduced the number of pedicle breaches, and the fluoroscopic radiation compared with conventional MIS and conventional open techniques. Although this study illustrated the advantages of robot-assisted procedures, no direct comparison was made between robot-assisted percutaneous and robot-assisted open groups.

In contrast to prior literature, our study used a multicenter database of seven independent spine surgeons to directly compare percutaneous and open approaches with robotassisted platforms. This study is the first and largest multicenter comparison between these cohorts. Total operative time was significantly longer for the robot-assisted open group (+30 min, P = 0.007). This is likely due to the increased time needed for exposure and closure of the spinal wound for open approaches. However, the mean robot time per screw was not significantly different between cohorts. Of note, prior literature measured operative time divided by number of screws, as opposed to the robot time divided by

number of screws. The latter is a more accurate representation of the time needed for robot screw placement. The mean fluoroscopy time per screw was longer for the percutaneous cohort. This is in contrast to the Kantelhardt et al study, which found no difference between groups.¹¹ This discrepancy may be explained by the learning curve and the increasing confidence in robot-assisted technology of a single platform. In comparison, our study involved multiple centers and utilized newer robotic technology over the study's timeframe. Furthermore, the longer radiation time for percutaneous approach may be due to surgeons repeatedly checking the entry point and final screw placements. Interestingly, the screw accuracies for both cohorts were excellent and similar (Percutaneous: 99.2%, N=526, Open: 98.7%, N = 514, P = 0.348). In addition, the robot abandonment rate for either registration issues or unreachable anatomy was not statistically different between groups. Due to the high accuracy of robot-assisted platforms, it may not be necessary to take additional fluoroscopy shots and the intraoperative radiation exposure may decrease over time as surgeons become more confident in their use of the robot. Of note, the perioperative blood transfusion rates were significantly higher for the open approach cohort, which is consistent with prior literature.^{12,33} Although prior literature suggests that MIS techniques are associated with decreased hospital stays, this was not observed in our study. The mean length of stay for both cohorts was about 3 days, which is substantially lower than what has been cited in literature for robot-assisted MIS (Hyun et al: 6.8 d; Kantelhardt et al: 10.1 d).^{11,28} Finally, the 90 day postoperative outcomes were low and similar between groups.

There are a number of limitations to this study. First, the minimum follow-up was 90 days. Longer term follow-up is needed to determine the differences in other complications, such as pseudarthrosis, between open and percutaneous approaches. Second, there was one surgeon who performed only open procedures in our database. The use of a large multicenter database with propensity score matching may diminish potential surgeon-specific biases. Third, patientreported outcomes have previously been cited as a benefit of MIS techniques. Unfortunately, this data was not included in our database at the time of our study. Fourth, another variable that was not included was using either preoperative CT scan to intraoperative fluoroscopy versus intraoperative CT scan and plan method. It is possible that differences in radiation exposure may be found with these two robot approaches. However, intraoperative CT scan and plan method was not an option for the Renaissance robot platform.

CONCLUSION

For short lumbar fusion, percutaneous robot-assisted spine surgery can achieve a shorter operative time and lower risk for intraoperative blood loss requiring a blood transfusion. This must be weighed against the significantly increased radiation exposure observed for the percutaneous cohort. However, as surgeons become more confident with robotassisted platforms, it is possible that excessive intraoperative radiation exposure may decrease over time. Furthermore, percutaneous screw placement has comparable outcomes to robot-assisted open approach, including screw accuracy, robot reliability, 90-day reoperations, and length of hospital stay. Future multicenter studies with longer follow-up, greater fusion levels, and patient-reported outcomes are needed.

> Key Points

- □ This is the first and largest multicenter study to compare percutaneous and open approaches with robot-assisted platforms.
- □ For short lumbar fusion (1-, 2-levels), percutaneous robot-assisted spine surgery can achieve a shorter operative time and lower risk for intraoperative blood loss requiring blood transfusion.
- □ The percutaneous robot-assisted cohort experienced greater radiation exposure; however, as surgeons become more confident with robotassisted technology, it is possible that excessive intraoperative radiation exposure may decrease overtime.

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