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Risk of Postoperative Complications and Revision Surgery Following Robot-assisted Posterior Lumbar Spinal Fusion

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Study Design. Retrospective Study.

Objective. This investigation examined matched cohorts of lumbar spinal fusion (LSF) patients undergoing robot-assisted and conventional LSF to compare risk of revision, 30-day readmission, 30-day complications, and postoperative opioid utilization.

Summary of Background Data. Patient outcomes and complication rates associated with robot-assisted LSF compared to conventional fusion techniques are incompletely understood.

Methods. The PearlDiver Research Program (www.pearldiver-inc.com) was used to identify patients undergoing primary LSF between 2011 and 2017. Patients receiving robot-assisted or conventional LSF were matched using key demographic and comorbidity variables. Indication for revision was also studied. Risk of revision, 30-day readmission, 30-day complications, and postoperative opioid utilization at 1 and 6 months was compared between the cohorts using multivariable logistic regression additionally controlling for age, sex, and Charlson Comorbidity Index.

Results. The percent of LSFs that were robot-assisted rose by 169% from 2011 to 2017, increasing linearly each year ($p = 0.0007$). Matching resulted in 2528 patients in each cohort for analysis. Robot-assisted LSF patients experienced higher risk of revision (adjusted odds ratio [aOR] = 2.35, $P \leq 0.0001$), 30-day readmission (aOR = 1.39, $P = 0.0002$), and total 30-day complications (aOR = 1.50, $P < 0.0001$), specifically respiratory (aOR = 1.56, $P = 0.0006$), surgical site infection (aOR = 1.56, $P = 0.0061$), and implant-related complications (aOR = 1.74, $P = 0.0038$). The risk of revision due to infection after robot-assisted LSF was an estimated 4.5-fold higher (aOR = 4.46, 95% confidence interval [CI] 1.95–12.04, $P = 0.0011$). Furthermore, robot-assisted LSF had increased risk of revision due to instrument failure (aOR = 1.64, 95% CI 1.05–2.58, $P = 0.0300$), and pseudarthrosis (aOR = 2.24, 95%CI = 1.32–3.95, $P = 0.0037$). A higher percentage of revisions were due to infection in robot-assisted LSF (19.0%) than in conventional LSF (9.2%) ($P = 0.0408$).

Conclusion. Robotic-assisted posterior LSF is independently associated with increased risk of revision surgery, infection, instrumentation complications, and postoperative opioid utilization compared to conventional fusion techniques. Further research is needed to investigate long-term postoperative outcomes following robot-assisted LSF. Spine surgeons should be cautious when considering immediate adoption of this emerging surgical technology.

Key words: robot, lumbar spine fusion, post-operative outcomes, revision, opioid, pedicle screw.

Level of Evidence: 3

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Adoption of robotic technology in spine surgery has steadily increased.[1] Surgeons utilizing robotic-assistance in other disciplines such as gynecology, urology, and general surgery have purported benefits in 3D visualization, coordination, decreased radiation exposure, lower risk of infections, postoperative pain, and decreased length of hospital stay.[2] For lumbar spine fusion (LSF), the most common current application of robot-assistance is for a hypothetical increase in accuracy of screw placement.[3] Although some studies report lower rates of pedicle screw repositioning associated with robotic-assisted LSF, the evidence of this finding is inconsistent.[4,5]

Schroder *et al*[6] performed a literature review of fusion procedures and reported a higher incidence of revision surgery for screw malposition in studies of freehand procedures compared to studies of robot-assisted procedures. However, a randomized controlled study of 60 patients

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found that 93% of pedicle screws placed had good positions in freehand conventional technique, compared to 85% in robot-assisted LSF.[4] Furthermore, surgical time was significantly shorter using the conventional technique compared to robot-assisted LSF. Other studies have also not found pedicle screw accuracy in robot-assisted LSF to be superior.[5,7–9] These studies have not addressed the impact of robotic assistance on postoperative outcomes such as 30-day readmission and 30-day medical complications nor have they been performed on a national level. Given high costs associated with robotic-assistance, this gap in knowledge and mixed evidence for increased screw placement accuracy encourage further investigation of robot-assistance in LSF.[3]

The purpose of this study was to utilize a robust cohort-matched analysis to examine the impact of robot-assisted LSF on the risk of revision, 30-day readmission, 30-day complications, and postoperative opioid utilization compared to conventional LSF at the national level. We hypothesized that rate of 30-day complications and readmission would not be decreased in robot-assisted LSF.

MATERIALS AND METHODS

Data

The PearlDiver Patient Records Database (http://www.pearldiverinc.com) was utilized for this study. PearlDiver is a national database containing deidentified Humana Inc. and Medicare medical records capturing around 25 million records.

Patient Cohort and Matching

Patients who underwent LSF between 2011 and first quarter of 2017 were identified with first instance Current Procedure Terminology (CPT) codes (Appendix A, http://links.lww.com/BRS/B632). These patients were divided into two cohorts: LSF with robotic assistance (CPT-0054T, CPT-0055T, CPT-20985, CPT-61783 coded the same day as surgery) and LSF without robotic assistance.

Matching was performed through the PearlDiver database software to match patients receiving robot-assisted LSF in a 1:1 ratio with patients receiving LSF without robotic assistance, using a similar protocol as a previous study investigating LSF in the same database.[10,11] The following key demographic and comorbidity variables were used: age, sex, year of procedure, asthma, chronic obstructive pulmonary disease, chronic kidney disease, congestive heart failure, depression, diabetes, hypertension, obesity, tobacco use, peripheral vascular disease, pneumonia, and urinary tract infection.

Matched cohorts were also stratified by number of fusion levels with single level (CPT-22633, CPT-22558, CPT-22612, CPT-22630, CPT-22840, CPT-22845 only) and multilevel fusions (one or more instances of CPT-22534, CPT-22585, CPT-22614, CPT-22632, CPT-22842, CPT-22846).

Outcome Measures

ICD-9-CM and *ICD-10-CM* codes were used to identify postoperative complications within 30 days of surgery, including surgical site, implant-related, durotomy, deep vein thrombosis, neurologic, respiratory, cardiac, myocardial, cardiac arrest, coagulation, sepsis, pneumonia, spinal cord, plexus, visual, iatrogenic, reintubation, and hyperthermia-related complications, as well as an aggregate total of all complications and 30-day readmission (Appendix B, http://links.lww.com/BRS/B633). Preoperative opioid utilization was determined based on records of a filled opioid prescription within 3 months of index surgery.[12] Postoperative opioid utilization was assessed at 1 and 6 month time points, which is considered to be prolonged.[13–15]

Revision LSF was specified by CPT code as well (Appendix A, http://links.lww.com/BRS/B632). The indication for revision LSF was queried as one of five possible diagnoses coded on the same day as the revision surgery (Appendix C, http://links.lww.com/BRS/B634). These five diagnoses were pseudarthrosis, instrument failure, thoracolumbar fracture, spine infection, or neurological deficit, as identified by a previous study.[16]

Statistical Analysis

Descriptive statistics were generated for each patient cohort. Odds of each complications were computed directly as the number of events occurring within 30 days of LSF. Odds of opioid use in a specific month following surgery were also evaluated. Risk of revisions and total 30-day complications were compared between robot-assisted and conventional LSF for stratified single and multilevel fusion. Risk for each reason for revision was also compared, and proportion of revisions due to a specific reason was compared using χ^2 analysis. Multivariable logistic regression was used to calculate odds ratios, controlling for age, sex, and Charlson Comorbidity Index (CCI). Logistic regression of opioid utilization also controlled for preoperative opioid use. Statistical analysis was performed using the PearlDiver software, built on R, Version 1.1.442 (RStudio Inc., Boston MA). An α value of 0.05 was set as the level of significance.

SOURCE OF FUNDING

This investigation had no sources of funding.

RESULTS

Between 2011 and the first quarter of 2017, the percent of all LSFs that were robot-assisted was 2.7 times higher in 2016 than 2011, increasing linearly each year ($P = 0.0007$) (Figure 1). Matching between cohorts of robot-assisted LSF and conventional LSF yielded 2528 patients in each matched cohort (Table 1). The most common comorbidities included hypertension (92.5%), diabetes (56.2%), urinary tract infection (42.7%), and obesity (42.3%).

Revisions, Readmission, Complications, and Prolonged Opioid Use in Robot-assisted LSF

The rate of 30 day complications was 17.1% in robot-assisted LSF and only 12.2% in conventional LSF patients (adjusted odds ratio [aOR] = 1.50, 95% confidence interval [CI] 1.27–1.76, $P < 0.0001$) (Table 2). Specifically, robot-assisted

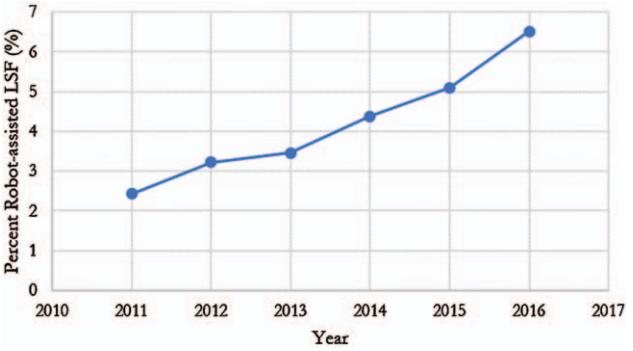

Figure 1. Percent of LSF that are robot-assisted across years of investigation.

LSF patients had higher risk of respiratory (aOR = 1.56, 95% CI 1.21–1.90, $P = 0.0006$), surgical site (aOR = 1.56, 95% CI 1.14–2.16, $P = 0.0061$), and implant-related complications (aOR = 1.74, 95% CI 1.20–2.54, $P = 0.0038$).

Correspondingly, robot-assisted LSF patients experienced a 2.4 times higher risk of revision compared to conventional LSF patients (7.4% *vs.* 3.3%, aOR = 2.35, 95% CI 1.81–3.07, $P < 0.0001$) (Table 2). Risk of 30-day readmission was higher with robotics (13.7% *vs.* 10.3%, aOR = 1.39, 95% CI 1.17–1.65, $P = 0.0002$), and patients were more likely to fill opioid prescriptions at 1 month (aOR = 2.62, 95% CI 2.16–3.19, $P < 0.0001$) and 6 months (aOR = 3.18, 95% CI 2.53–4.03, $P < 0.0001$), even after adjusting for preoperative opioid use.

Reasons for Revision Following Robot-assisted LSF

Multivariable analysis showed that robot-assisted LSF surgery is associated with increased risk of revision secondary to instrument failure, infection, and pseudarthrosis (Table 3). The risk of revision due to infection after robot-assisted LSF was an estimated 4.5-fold higher (aOR = 4.46, 95% CI 1.95–12.04, $P = 0.0011$). Risk of risk of revision due to instrument failure was 1.6 times higher (aOR = 1.64, 95% CI 1.05–2.58, $P = 0.0300$) and risk of revision due to pseudarthrosis 2.2 times higher (aOR = 2.24, 95% CI = 1.32–3.95, $P = 0.0037$).

In conventional LSF, 49.2% of revisions were due to instrument failure, 29.2% to pseudarthrosis, 12.3% to thoracolumbar fracture, 9.2% to infection, and 0% to neurological deficit, whereas in robot-assisted LSF 36.1% of revisions were due to instrument failure, 29.3% to pseudarthrosis, 19.0% to infection, 10.9% to thoracolumbar fracture, and 4.8% to neurologic deficit. A higher percentage of revisions were due to infection in robot-assisted LSF (19.0%) than in conventional LSF (9.2%) ($P = 0.0408$).

DISCUSSION

Overall, robot-assisted LSF is associated with increased risk of revision surgery, 30-day readmission, and prolonged post-operative opioid use compared to conventional LSF surgery, even after matching for demographics and medical comorbidities and controlling for CCI. Furthermore, robot-assisted LSF increases the risk of total 30-day complications including surgical site infection and implant-related complications.

Regarding revisions, risk of revision due to instrument failure, infection, and pseudarthrosis were increased in those undergoing robot-assisted LSF surgery. Instrument failure was the primary reason for revision for both robot-assisted and conventional LSF; however, infection was a more frequent indication for revision in robot-assisted compared to conventional LSF. Furthermore, the risk of revision due to infection was nearly 4.5-fold higher for patients receiving robot-assisted LSF compared to conventional LSF.

Previous studies have examined several parameters in comparing robot-assisted LSF and conventional LSF including accuracy of implantation, operative time, revisions, and functional outcomes.[3–5,7,17] Improved accuracy in screw placement has been cited as a primary advantage of robot-assisted LSF, likely contributing to the rise in its implementation.[2] Numerous studies, limited to single or multiple institution studies, have investigated screw placement accuracy, but evidence remains mixed. Kantelhardt *et al*[5] retrospectively studied 55 robot-assisted and 57 conventional pedicle screw placements, finding that 94.5% of robot-assisted and 91.4% of conventional screw placements were placed completely within the bone ($P = 0.00001$). However, in a randomized control trial of 60 patients, Ringel *et al*[4] found that 94% had no cortical violation or a cortical breach <2 mm in conventional screw placement compared to 85% for robot-assisted placements ($P = 0.019$).[4] Surgical time was significantly longer for robot-assisted screw placement compared to conventional screw placement. These findings are important as increased operative time is associated with increased risk for postoperative complications, and malpositioned pedicle screws may lead to persistent pain, dysfunction, morbidity.[5,18–20]

To our knowledge, only one previous study has compared robot-assisted fusion and conventional fusion on a national level. Lieber *et al*[3] used the National Inpatient Sample (NIS) to develop matched cohorts of 257 patients undergoing either robot-assisted or conventional fusions. The study found that 36.19% of robot-assisted fusion patients developed a complication, which included morbidities such as pneumonia, surgical site infection, and intraoperative hemorrhage, compared to 21.01% in the conventional group ($P < 0.001$). Inpatient costs associated with robotic assistance were >50% higher.

Our study adds to this emerging finding that associated risks may exist with robot-assisted LSF, especially when studying a nation-wide sample of patients instead of a single-site sample. We were able to study matched cohorts of 2528 patients at the national level, finding a 6.6% risk of respiratory complications, 4.0% risk of surgical site infection, and 3.1% risk of implant-related complications, all increased compared to conventional LSF. A possible mechanism of increased risk for surgical site infection may be increased operative time and increased length of stay that previous studies have shown to be associated with robot-assisted LSF. Ringel *et al*[4] found that an individual screw

TABLE 1. Demographics of Matched Lumbar Spinal Fusion Patient Cohorts

	Lumbar Spine Fusion			
	Robotic LSF		Conventional LSF	
	n	%	n	%
Variable				
All patients	2528		2528	
Age group				
<10	0	0	0	0
10–14	0	0	0	0
15–19	*	*	*	*
20–24	0	0	0	0
25–29	*	*	*	*
30–34	*	*	*	*
35–39	*	*	*	*
40–44	17	0.67	17	0.66
45–49	36	1.41	35	1.37
50–54	89	3.49	90	3.51
55–59	182	7.15	184	7.18
60–64	258	10.13	255	9.96
65–69	715	28.07	721	28.15
70–74	708	27.80	714	27.88
75–79	408	16.02	411	16.05
80–84	120	4.71	119	4.65
85–89	14	0.55	15	0.59
≤90	0	0	*	*
Sex				
Female	1499	59.3	1499	59.3
Male	1029	40.7	1029	40.7
Comorbidities				
Asthma	202	8.0	203	8.1
COPD	907	36.1	910	36.2
Chronic kidney disease	0	0.0	0	0.0
Congestive heart failure	316	12.7	318	12.6
Depression	989	39.4	989	39.3
Diabetes	1411	56.2	1414	56.2
Hypertension	2321	92.5	2324	92.4
Obesity	1062	42.3	1067	42.4
Tobacco	951	37.9	959	38.1
Peripheral vascular disease	792	31.6	792	31.5
Pneumonia	382	15.2	385	15.3
Urinary tract infection	1073	42.7	1076	42.8

COPD indicates chronic obstructive pulmonary disease; LSF, lumbar spinal fusion.

placement was 11 minutes longer and that planning time for screw trajectories was 24 minutes longer in robot-assisted surgery compared to fluoroscopically guided surgery. Another study found that average length of stay in the robot-assisted group was 4.29 days, higher than average length of stay of 3.89 days in the conventional fusion group.[3] These differences are likely clinically significant as a meta-analysis of lumbar spinal surgery found that patients with surgical site infection had a weighted mean difference in operative time of 24.96 minutes and length of stay of 2.07 days.[21]

Overall, we found that the major indications for revisions following robot-assisted LSF included instrument failure, pseudarthrosis, and notably infection at 19.0% of total revision cases compared to 9.2% of total revision cases following conventional index fusion. Similarly, Keric *et al*[7] found that infection was a substantial indication for revision following robotic-assisted fusion, as 4.9% of the studied patients required revision due to infection, the most frequent indication compared to 1.7% due to loosening and 1.5% due to dislocation. Neurological deficit at 0.49% was also found to be the least frequent indication. We found that

TABLE 2. Outcomes Following Robotic LSF Surgery *Versus* Conventional LSF Surgery

	Conventional LSF		Robotic LSF		aOR	95% CI		*P*
	n	%	n	%				
Revision	83	3.3	186	7.4	2.35	1.81	3.07	**<0.0001**
Median time to revision	161 days		134 days					
30-day Readmission	259	10.3	345	13.7	1.39	1.17	1.65	**0.0002**
Complications								
30-day complications	307	12.2	430	17.1	1.50	1.27	1.76	**<0.0001**
Respiratory	109	4.3	166	6.6	1.56	1.21	1.90	**0.0006**
Surgical Site	65	2.6	100	4.0	1.56	1.14	2.16	**0.0061**
DVT	69	2.7	21	1.7	1.19	0.86	1.66	0.2865
Implant	45	1.8	77	3.1	1.74	1.20	2.54	**0.0038**
Sepsis	35	1.4	52	2.1	1.48	0.96	2.30	0.0763
Neurologic	9	0.4	11	0.4	0.31	0.05	1.04	0.6500
Spinal Cord	8	0.3	15	0.6	1.88	0.82	4.69	0.1500
Durotomy	4	0.2	9	0.4	2.26	0.73	8.34	0.1770
Myocardial	21	0.8	27	1.1	1.25	0.70	2.25	0.4526
Opioid utilization								
1 mo Preoperatively	723	28.8	801	31.9	—	—	—	—
Postoperatively								
1 mo	160	6.4	380	15.1	2.62	2.16	3.19	**<0.0001**
6 mo	104	4.1	303	12.1	3.18	2.53	4.03	**<0.0001**

Multivariable regression adjusted for age, sex, and CCI. Models for opioid utilization also included preoperative opioid as a covariate.

Bold represents P < 0.05 considered statistically significant. aOR indicates adjusted odds ratio; CI, confidence interval; DVT, deep vein thrombosis; LSF, lumbar spinal fusion.

risk of revision due to infection was 4.5-fold higher in patients receiving robot-assisted LSF compared to conventional LSF. This is significant as deep implant infection is associated with radiologic loosening of screws, demanding implant removal, as well as ongoing pain following surgery.[22] Long operating time may again contribute to higher rates of infection following robot-assisted LSF. In the study by Keric *et al*,[7] mean operating time was reported to be longer than what the surgeons from the two centers usually experience. This may reflect the general learning curve surgeons face in adopting new technology. The finding of increased instrument malposition/migration, infection, and pseudarthrosis complications leading to revision is paralleled in studies of the initial learning curve surgeons experience with minimally invasive LSF techniques.[23] Regarding robot-assistance, Myers *et al*[24] reported a single surgeon's experience using robotic-assisted pedicle screw placement for the first time. The study noted the high rate of postoperative complications—55% of the 67 patients experienced surgical or medical complication—and intraoperatively the surgeon aborted 5.4% of screw placements from using robotic assistance.[24]

The use of robotic assistance in LSF is rapidly growing. We found that percentage of LSFs employing robotic assistance nearly tripled across 2011 to 2017. This fast adoption requires attention to the learning curve in using robotics. Some individual institutions and practices have inevitably experienced more difficulty than others in the implementation of the technology. For example, the initial iterations of the SpineAssist (Mazor Robotics Ltd., Caesarea, Israel) for lumbar fusion demonstrated improper registration of the preoperative CT scan with the intraoperative fluoroscopic

TABLE 3. Risk of Specific Reasons for Revision following Robotic LSF Surgery *Versus* Conventional LSF Surgery

	aOR	95% CI		*P*
Instrument failure	1.64	1.05	2.58	**0.0300**
Infection	4.46	1.95	12.04	**0.0011**
Pseudarthrosis	2.24	1.32	3.95	**0.0037**
Thoracolumbar fracture	1.99	0.87	4.93	0.1130
Neurologic deficit*	—	—	—	—

aOR indicates adjusted odds ratio; CI, confidence interval; LSF, lumbar spinal fusion.

**Insufficient numbers for analysis.*

images as well as software crashes and a 9 second per screw lengthy calculation time.[2] A 2017 investigation of the Renaissance miniature robot (Mazor Robotics Ltd., Caesarea, Israel) for spinal image guidance found that surgeons switched to conventional screw placement using a midline approach in 1.7% of the cases due to referencing problems.[7]

It is possible that as robotic systems continue to develop and surgeons progress through the learning curve, outcomes will improve and operative time will decrease.[2,25] A consecutive cohort of 174 patients undergoing pedicle screw placement by a senior surgeon showed accuracy rates that increased from 82% in the first 30 patients to 95% in the final group of 30 patients.[25] Although we were not able to directly study individual physician experience, subtle variability in surgical technique, or confidence in using the robotic technology, we found decreasing rates of revision and 30-day complications following robot-assisted LSF with each advancing year of the study, suggesting improved outcomes across time (Appendix D, http://links.lww.com/BRS/B635). Overall, the advantage of the present study is its use of a database based on insurance claims in efforts to ascertain generalizable findings with regards to robotic assistance in LSF across the United States.

This study has several potential limitations. First, although PearlDiver is commonly employed for orthopedic and neurosurgical research, for any retrospective database, study the data accuracy is contingent on accuracies within the system by administrators and physicians. We were not able to characterize baseline preoperative characteristics and intraoperative characteristics as well as relevant covariates such as operative time, which would enhance the analysis. Regarding possible correlation between levels involved in surgery and use of robot-assistance, the authors performed analyses stratifying by single level and fusion of multiple levels in the comparison of the two cohorts and found that results were conserved. Physician experience with robotic technologies and surgical technique was not captured. Coding in the dataset does not capture the symptomology of complications or severity of lumbar spinal pathologies, patient-reported outcomes, or functional outcomes. Lastly, the external validity of the findings of this study may not hold true for non-Humana patients or patients on public insurance.

Despite these limitations, the findings of this study are potentially valuable given this is the largest national study to date investigating the outcomes following robot-assisted *versus* conventional LSF.

CONCLUSION

Robot-assisted LSF may be associated with increased risk of revision, readmission, medical complications, and prolonged opioid use following surgery. Further research is needed to investigate long-term postoperative outcomes following robot-assisted LSF. Spine surgeons should be cautious when considering immediate adoption of this emerging surgical technology.

➢ Key Points

- ❑ From 2011 to 2017, the proportion of LSFs that were robot-assisted rose by 169%, increasing linearly.
- ❑ Patients receiving robot-assisted LSF experienced higher risk of revision compared to conventional fusion. For revisions due to infection, this was an estimated 4.5-fold higher increase in risk.
- ❑ Patients receiving robot-assisted LSF also experienced higher risk of 30-day readmission and total 30-day complications, specifically respiratory, surgical site infection, and implant-related complications.
- ❑ Further research is needed to investigate long-term postoperative outcomes following robot-assisted LSF. Spine surgeons should be cautious when considering immediate adoption of this emerging surgical technology.

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