Clinical outcomes following spinal fusion using an intraoperative computed tomographic 3D imaging system

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OBJECTIVE Improvements in imaging technology have steadily advanced surgical approaches. Within the field of spine surgery, assistance from the O-arm Multidimensional Surgical Imaging System has been established to yield superior accuracy of pedicle screw insertion compared with freehand and fluoroscopic approaches. Despite this evidence, no studies have investigated the clinical relevance associated with increased accuracy. Accordingly, the objective of this study was to investigate the clinical outcomes following thoracolumbar spinal fusion associated with O-arm–assisted navigation. The authors hypothesized that increased accuracy achieved with O-arm–assisted navigation decreases the rate of reoperation secondary to reduced hardware failure and screw misplacement.

METHODS A consecutive retrospective review of all patients who underwent open thoracolumbar spinal fusion at a single tertiary-care institution between December 2012 and December 2014 was conducted. Outcomes assessed included operative time, length of hospital stay, and rates of readmission and reoperation. Mixed-effects Cox proportional hazards modeling, with surgeon as a random effect, was used to investigate the association between O-arm–assisted navigation and postoperative outcomes.

RESULTS Among 1208 procedures, 614 were performed with O-arm–assisted navigation, 356 using freehand techniques, and 238 using fluoroscopic guidance. The most common indication for surgery was spondylolisthesis (56.2%), and most patients underwent a posterolateral fusion only (59.4%). Although O-arm procedures involved more vertebral levels compared with the combined freehand/fluoroscopy cohort (4.79 vs 4.26 vertebral levels; $p < 0.01$), no significant differences in operative time were observed (4.40 vs 4.30 hours; $p = 0.38$). Patients who underwent an O-arm procedure experienced shorter hospital stays (4.72 vs 5.43 days; $p < 0.01$). O-arm–assisted navigation trended toward predicting decreased risk of spine-related readmission (0.8% vs 2.2%, risk ratio [RR] 0.37; $p = 0.05$) and overall readmissions (4.9% vs 7.4%, RR 0.66; $p = 0.07$). The O-arm was significantly associated with decreased risk of reoperation for hardware failure (2.9% vs 5.9%, RR 0.50; $p = 0.01$), screw misplacement (1.6% vs 4.2%, RR 0.39; $p < 0.01$), and all-cause reoperation (5.2% vs 10.9%, RR 0.48; $p < 0.01$). Mixed-effects Cox proportional hazards modeling revealed that O-arm–assisted navigation was a significant predictor of decreased risk of reoperation (HR 0.49; $p < 0.01$). The protective effect of O-arm–assisted navigation against reoperation was durable in subset analysis of procedures involving < 5 vertebral levels (HR 0.44; $p = 0.01$) and ≥ 5 levels (HR 0.48; $p = 0.03$). Further subset analysis demonstrated that O-arm–assisted navigation predicted decreased risk of reoperation among patients undergoing posterolateral fusion only (HR 0.39; $p < 0.01$) and anterior lumbar interbody fusion (HR 0.22; $p = 0.03$), but not posterior/transforaminal lumbar interbody fusion.

CONCLUSIONS To the authors' knowledge, the present study is the first to investigate clinical outcomes associated with O-arm–assisted navigation following thoracolumbar spinal fusion. O-arm–assisted navigation decreased the risk of reoperation to less than half the risk associated with freehand and fluoroscopic approaches. Future randomized controlled trials to corroborate the findings of the present study are warranted.

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KEY WORDS O-arm; navigation; pedicle screw; spinal fusion; reoperation; multivariable regression; surgical technique

ABBREVIATIONS ALIF = anterior lumbar interbody fusion; BMI = body mass index; CCI = Charlson Comorbidity Index; ED = emergency department; PLIF = posterior lumbar interbody fusion; RR = risk ratio; SSI = surgical-site infection; TLIF = transforaminal lumbar interbody fusion.

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INTRAOPERATIVE techniques have steadily evolved to incorporate and leverage advances in imaging technology. Within the field of spine surgery, the O-arm Surgical Imaging System, a mobile, intraoperative CT 3D modality, has increasingly been used to assist with the insertion of pedicle screws. Recently, several studies have compared the accuracy associated with O-arm use to freehand techniques and fluoroscopic guidance.^{9–11} CT navigation modalities, such as the O-arm, achieve pedicle screw accuracy ranging from 89% to 100%.³ In contrast, freehand pedicle screw insertion (69%–94%) and fluoroscopic guidance insertion (28%–85%) were reported to be significantly less accurate, with several studies corroborating this observation.^{2,4–7,8,12–17}

Despite evidence suggesting greater accuracy associated with intraoperative CT navigation, no studies have investigated the clinical ramifications of greater accuracy. Identifying the long-term benefits of O-arm–assisted navigation is critical to determine the role of navigation in improving patient care. Accordingly, we sought to compare clinical outcomes between patients undergoing thoracolumbar spinal fusion with and without the use of O-arm–assisted navigation. We hypothesized that, compared with the freehand technique and fluoroscopic guidance, increased accuracy achieved with the O-arm decreases the rate of reoperation secondary to reduced hardware failure and screw misplacement.

Methods

Patient Selection

A consecutive retrospective review of all patients undergoing open thoracolumbar spinal fusion at a single tertiary-care institution between December 2012 and December 2014 was conducted. The cohort of patients who underwent spinal fusion with O-arm–assisted navigation was compared with 2 control cohorts of patients who underwent spinal fusion with either the freehand approach without intraoperative imaging (as first described by Roy-Camille et al.^{9–11}) or fluoroscopic guidance. Patients younger than the age of 18 years or undergoing cervical fusion were excluded. IRB approval was obtained prior to initiation of the study.

Data Collection

Demographic, medical history, operative, and outcome data were retrospectively collected from electronic medical records. Preoperative data included patient age, sex, race, marital status, smoking status, body mass index (BMI), Charlson Comorbidity Index (CCI) score, surgical history, and indications for surgery. Operative data included type of procedure, number of vertebral levels, length of surgery (defined as time from incision to completion of closure), and use of allograft or autograft. Postoperative data included length of hospital stay, discharge disposition, surgical-site infection (SSI), emergency department (ED) visit within 30 or 90 days of surgery date, readmission within 30 or 90 days of surgery date, and reoperation. Postoperative SSI data were prospectively collected by the institutional Infection Prevention Program and characterized as superficial or deep. Reasons for postopera-

tive ED visits and readmissions were classified as spine related (that is, back pain), wound complications, or other. Reoperation was defined as any spine surgery involving a vertebral level that was previously operated on. Reasons for reoperation were classified as hardware failure (screw fracture or dislodgement) secondary to screw misplacement or pseudarthrosis, wound and hardware debridement, or other (extension of prior fusion).

Statistical Analysis

All collected data were analyzed using R version 3.3.1 (R Foundation for Statistical Computing). Descriptive statistics were presented as mean values with standard deviations or as counts with percentages. Continuous variables were compared using either Student t-tests or Wilcoxon rank-sum tests. Categorical variables were compared with chi-square tests, and corresponding risk ratios (RRs) were calculated to compare the O-arm cohort with the combined freehand and fluoroscopy cohort. Kaplan-Meier analysis was used to determine the freedom from reoperation for the O-arm and control cohorts. Log-rank tests were used to compare the corresponding survival distributions.

Mixed-effects Cox proportional hazards modeling was used to identify significant independent predictors of reoperation. The decision to use O-arm–assisted navigation, a freehand approach, or fluoroscopic guidance was specific to the patient and surgeon; thus, to account for the potential confounding effect of different practice patterns among 21 surgeons, surgeon was included in these models as a random effect. The following covariates were adjusted for: age, sex, race, marital status, current smoking status, BMI, CCI, operative indications, operative procedures, thoracic involvement, and number of vertebral levels, including all 2-way interactions. Backward stepwise regression was used to arrive at the final model, with $p < 0.20$ set as the stopping criterion. Hazard ratios (HRs) were reported for the Cox proportional hazards regression. All values of $p < 0.05$ were considered statistically significant. Additional mixed-effects Cox proportional hazards models were established for subsets of patients grouped by number of vertebral levels (< 5 or ≥ 5 levels) or type of operation (posterolateral fusion only, anterior lumbar interbody fusion [ALIF], and posterior/transforaminal lumbar interbody fusion [PLIF/TLIF]).

Results

Patient and Operative Characteristics

A total of 1208 patients underwent open thoracolumbar spinal fusion during the study period and were eligible for inclusion. Among these patients, 614 procedures were performed using O-arm–assisted navigation, 356 using freehand techniques, and 238 using fluoroscopic guidance (Table 1). Patients who underwent an O-arm procedure were on average older (63.3 vs 60.2 years; $p < 0.01$) and less often male (41.7% vs 48.5%; $p = 0.02$) compared with the combined freehand and fluoroscopy cohort. Race, marital status, current smoking status, and BMI were similar across cohorts. Patients in the O-arm cohort suffered a slightly smaller comorbidity burden, with a lower average

TABLE 1. Patient demographic data and operative characteristics

Variable	O-Arm	Freehand	Fluoroscopy	Combined	p Value*
No. of procedures	614	356	238	594	
Patient characteristic					
Age, yrs	63.3 ± 11.6	62.0 ± 14.1	57.5 ± 16.4	60.2 ± 15.2	<0.01†
Male	256 (41.7)	181 (50.8)	107 (45.0)	288 (48.5)	0.02†
White	575 (93.6)	322 (90.4)	222 (93.3)	544 (91.6)	0.17
Married	404 (65.8)	225 (63.2)	146 (61.3)	371 (62.5)	0.23
Current smoker	68 (11.1)	26 (7.3)	32 (13.4)	58 (9.8)	0.46
BMI, kg/m ²	30.1 ± 5.87	29.7 ± 6.47	29.6 ± 5.97	29.7 ± 6.17	0.20
CCI score	0.88 ± 1.37	1.12 ± 1.82	1.09 ± 1.82	1.11 ± 1.82	0.01†
≥2	119 (19.4)	85 (23.9)	59 (24.8)	144 (24.2)	0.04†
Op indication					
Spondylolisthesis	356 (58.0)	206 (57.9)	117 (49.2)	323 (54.4)	0.21
Spinal stenosis	325 (52.9)	176 (49.4)	100 (42.0)	276 (46.5)	0.02†
Scoliosis	105 (17.1)	53 (14.9)	50 (21.0)	103 (17.3)	0.91
Degenerative disc disease	104 (16.9)	59 (16.6)	50 (21.0)	109 (18.4)	0.52
Spondylosis	95 (15.5)	75 (21.1)	36 (15.1)	111 (18.7)	0.14
Disc herniation	78 (12.7)	38 (10.7)	24 (10.1)	62 (10.4)	0.22
Prior spine op	65 (10.6)	37 (10.4)	21 (8.8)	58 (9.8)	0.64
Kyphosis	36 (5.8)	30 (8.4)	17 (7.1)	47 (7.9)	0.16
Op procedure					
Posterolateral fusion only	358 (58.3)	208 (58.4)	152 (63.9)	360 (60.6)	0.42
PLIF/TLIF	211 (34.4)	116 (32.6)	38 (16.0)	154 (25.9)	<0.01†
ALIF	58 (9.4)	36 (10.1)	50 (21.0)	86 (14.5)	<0.01†
Apply interbody cage	198 (32.2)	122 (34.3)	77 (32.4)	199 (33.5)	0.64
Allograft	100 (16.3)	49 (13.8)	36 (15.1)	85 (14.3)	0.34
Autograft	8 (1.3)	9 (2.5)	14 (5.9)	23 (3.9)	<0.01†
Remove hardware	56 (9.1)	11 (3.1)	8 (3.4)	19 (3.2)	<0.01†
Osteotomy	36 (5.9)	30 (8.4)	19 (8.0)	49 (8.3)	0.11
Thoracic involvement	134 (21.8)	63 (17.7)	56 (23.5)	119 (20.0)	0.44
No. of vertebral levels	4.79 ± 2.65	4.06 ± 2.53	4.56 ± 2.96	4.26 ± 2.72	<0.01†

Values are presented as the mean ± SD or number (%) of procedures. Subtotals may exceed 100% if patient had multiple preoperative symptoms, operative indications, and so on.

* Analyses used t-tests for continuous variables and chi-square tests for categorical variables to compare the O-arm cohort to the combined freehand and fluoroscopy cohort.

† Statistically significant: $p \leq 0.05$.

CCI (0.88 vs 1.11; $p = 0.01$) and fewer patients categorized as CCI ≥ 2 (19.4% vs 24.2%; $p = 0.04$). The most common indication for surgery was spondylolisthesis (56.2%), and spinal stenosis was more common among patients in the O-arm cohort (52.9% vs 46.5%; $p = 0.02$). All other operative indications were similar across cohorts. The most common operative procedures were posterolateral fusion only (59.4%), PLIF/TLIF (30.2%), and ALIF (11.9%). Patients in the O-arm group more often underwent PLIF/TLIF (34.4% vs 25.9%; $p < 0.01$) and less often underwent ALIF (9.4% vs 14.5%; $p < 0.01$). Patients in the O-arm group received fewer autografts (1.3% vs 3.9%; $p < 0.01$) and more often required hardware removal (9.1% vs 3.2%; $p < 0.01$). Thoracic involvement was similar across cohorts, although O-arm procedures involved more vertebral levels (4.79 vs 4.26; $p < 0.01$).

Clinical Outcomes

Patients were followed for an average of 18.8 months. Patients in the O-arm–assisted navigation cohort were followed longer than the combined freehand and fluoroscopy cohort (19.5 vs 18.1 months; $p = 0.01$; Table 2). No significant differences in mean operative time were observed between the O-arm cohort and the combined freehand and fluoroscopy cohort (4.40 vs 4.30 hours; $p = 0.38$). Length of hospital stay was shorter among patients in the O-arm group compared with the combined freehand and fluoroscopy cohort (4.72 days vs 5.43 days; $p < 0.01$). The majority of patients (67.4%) were discharged to home following surgery, with no significant differences between cohorts ($p = 0.67$). Patients in the O-arm cohort experienced more superficial SSIs compared with the combined freehand

TABLE 2. Spinal fusion outcomes

Characteristic	O-Arm	Freehand	Fluoroscopy	Combined	RR (95% CI)*	p Value†
No. of procedures	614	356	238	594		
Follow-up duration, mos	19.5 ± 9.3	18.6 ± 10.4	17.2 ± 10.2	18.1 ± 10.3		0.01‡
Length of op, hrs	4.40 ± 2.03	4.11 ± 1.82	4.59 ± 1.86	4.30 ± 1.85		0.38
Length of stay, days	4.72 ± 3.02	5.18 ± 4.31	5.81 ± 5.31	5.43 ± 4.74		<0.01‡
Discharge disposition					0.98 (0.91–1.06)	0.67
Home	411 (66.9)	236 (66.3)	167 (70.2)	403 (67.8)		
Rehabilitation center	201 (32.7)	118 (33.1)	69 (29.0)	187 (31.5)		
SSI						
Superficial	14 (2.3)	0 (0)	2 (0.8)	2 (0.3)	6.77 (1.55–29.7)	<0.01‡
Deep	5 (0.8)	12 (3.4)	5 (2.1)	17 (2.9)	0.28 (0.11–0.77)	<0.01‡
Total	19 (3.1)	12 (3.4)	7 (2.9)	19 (3.2)	0.97 (0.52–1.81)	0.92
ED visit w/in 30 days						
Spine	26 (4.2)	13 (3.7)	8 (3.4)	21 (3.5)	1.20 (0.68–2.11)	0.53
Wound	8 (1.3)	8 (2.2)	3 (1.3)	11 (1.9)	0.70 (0.28–1.74)	0.44
Total	58 (9.4)	30 (8.4)	20 (8.4)	50 (8.4)	1.12 (0.78–1.61)	0.53
ED visit w/in 90 days						
Spine	35 (5.7)	23 (6.5)	9 (3.8)	32 (5.4)	1.06 (0.66–1.69)	0.81
Wound	10 (1.6)	10 (2.8)	3 (1.3)	13 (2.2)	0.74 (0.33–1.68)	0.48
Total	92 (15.0)	58 (16.3)	29 (12.2)	87 (14.6)	1.02 (0.78–1.34)	0.87
Readmission w/in 30 days						
Spine	2 (0.3)	2 (0.6)	6 (2.5)	8 (1.3)	0.24 (0.05–1.13)	0.05
Wound	6 (1.0)	7 (2.0)	4 (1.7)	11 (1.9)	0.53 (0.20–1.42)	0.20
Total	19 (3.1)	12 (3.4)	13 (5.5)	25 (4.2)	0.74 (0.41–1.32)	0.30
Readmission w/in 90 days						
Spine	5 (0.8)	3 (0.8)	10 (4.2)	13 (2.2)	0.37 (0.13–1.04)	0.05
Wound	7 (1.1)	9 (2.5)	4 (1.7)	13 (2.2)	0.52 (0.21–1.30)	0.15
Total	30 (4.9)	23 (6.5)	21 (8.8)	44 (7.4)	0.66 (0.42–1.03)	0.07
Reop						
Hardware failure	18 (2.9)	20 (5.6)	15 (6.3)	35 (5.9)	0.50 (0.28–0.87)	0.01‡
Screw misplacement	10 (1.6)	15 (4.2)	10 (4.2)	25 (4.2)	0.39 (0.19–0.80)	<0.01‡
Pseudarthrosis	10 (1.6)	6 (1.7)	5 (2.1)	11 (1.9)	0.88 (0.38–2.06)	0.77
Debridement	12 (2.0)	14 (3.9)	6 (2.5)	20 (3.4)	0.58 (0.29–1.18)	0.13
Total	32 (5.2)	37 (10.4)	28 (11.8)	65 (10.9)	0.48 (0.32–0.72)	<0.01‡

Values are presented as the mean ± SD or number (%) of procedures. Reported totals include ED visit, readmission, and reoperation for any reason (illness, stroke, extension of fusion).

* Risk in O-arm cohort compared to combined freehand and fluoroscopy cohort.

† Analyses used t-tests for continuous variables and chi-square tests for categorical variables to compare the O-arm cohort versus the combined freehand and fluoroscopy cohort.

‡ Statistically significant: $p \leq 0.05$.

and fluoroscopy cohort (2.3% vs 0.3%, RR 6.77, 95% CI 1.55–29.7; $p < 0.01$), but fewer deep SSIs (0.8% vs 2.9%, RR 0.28, 95% CI 0.11–0.77; $p < 0.01$). Ultimately, the overall incidence of SSIs was similar between cohorts (3.1% vs 3.2%, RR 0.97, 95% CI 0.52–1.81; $p = 0.92$).

The 30- and 90-day incidence rates of spine-related, wound-related, and total ED visits were similar between cohorts. However, the incidence of readmission was lower among patients in the O-arm group compared with control subjects, with fewer spine-related (0.8% vs 2.2%, RR 0.37, 95% CI 0.13–1.04; $p = 0.05$) and total (4.9% vs 7.4%, RR 0.66, 95% CI 0.42–1.03; $p = 0.07$) readmissions in the 90-day period. Furthermore, the O-arm was sig-

nificantly associated with fewer reoperations for hardware failure (2.9% vs 5.9%, RR 0.50, 95% CI 0.28–0.87; $p = 0.01$), screw misplacement (1.6% vs 4.2%, RR 0.39, 95% CI 0.19–0.80; $p < 0.01$), and any cause (5.2% vs 10.9%, RR 0.48, 95% CI 0.32–0.72; $p < 0.01$) compared with the combined freehand and fluoroscopy cohort. However, no differences in reoperation rates for pseudarthrosis were observed between the O-arm group and the combined freehand and fluoroscopy group (1.6% vs 1.9%, RR 0.88, 95% CI 0.38–2.06; $p = 0.77$). The O-arm cohort trended toward requiring fewer reoperations for debridement (2.0% vs 3.4%, RR 0.58, 95% CI 0.29–1.18; $p = 0.13$).

Two-year freedom from any reoperation was signifi-

FIG. 1. Kaplan-Meier analyses of reoperations. Reported *p* values for comparisons were obtained by log-rank tests. **A:** Freedom from total reoperations ($p < 0.001$). **B:** Freedom from reoperations for hardware failure ($p = 0.02$). **C:** Freedom from reoperations for screw misplacement ($p = 0.02$). **D:** Freedom from reoperations for pseudarthrosis ($p = 0.75$).

cantly greater in the O-arm cohort (94.5%) compared with the freehand (87.7%) and fluoroscopy (85.1%) cohorts ($p < 0.001$; Fig. 1A). Similarly, 2-year freedom from reoperation for hardware failure (96.7% vs 92.3% vs 90.1%, respectively; $p = 0.02$; Fig. 1B) and screw misplacement (98.2% vs 94.4% vs 94.2%, respectively; $p = 0.02$; Fig. 1C) was greater in the O-arm cohort compared with the freehand and fluoroscopy groups. Two-year freedom from

reoperation for pseudarthrosis was similar between the O-arm cohort (98.1%) and the freehand (97.6%) and fluoroscopy (95.9%) groups ($p = 0.75$; Fig. 1D).

Multivariable Regression Analysis

Following simple mixed-effects Cox proportional hazards regression with surgeon as a random effect, several variables were associated ($p < 0.20$) with freedom from

all-cause reoperation, including O-arm use, CCI, spondylosis, kyphosis, osteotomy, thoracic involvement, and number of vertebral levels (Table 3). After inclusion into a multivariable mixed-effects Cox proportional hazards model with surgeon as a random effect, O-arm use remained significantly and independently protective against reoperation (HR 0.49, 95% CI 0.32–0.76; $p < 0.01$). In addition, spondylosis (HR 2.02, 95% CI 1.30–3.14; $p < 0.01$), kyphosis (HR 3.13, 95% CI 1.80–5.45; $p < 0.0001$), and increased length of stay (HR 1.04, 95% CI 1.02–1.07; $p < 0.001$) all predicted reoperation.

To ascertain the observed protective effects of O-arm–assisted navigation, additional mixed-effects Cox proportional hazards models were established for specific subsets of patients grouped by number of vertebral levels (Table 4). For procedures involving < 5 vertebral levels, O-arm–assisted navigation predicted decreased risk of reoperation (HR 0.44, 95% CI 0.23–0.84; $p = 0.01$), whereas increased length of stay predicted increased risk of reoperation (HR 1.10, 95% CI 1.03–1.17; $p < 0.01$). Similarly, for procedures involving ≥ 5 vertebral levels, O-arm–assisted navigation again predicted decreased risk of reoperation (HR 0.48, 95% CI 0.25–0.91; $p = 0.03$), as did posterolateral fusion only (HR 0.50, 95% CI 0.26–0.95; $p = 0.03$). In addition to subsets by vertebral levels, patient cohorts were also grouped by the type of procedure performed (Table 5). Within these subsets, O-arm–assisted navigation was found to predict decreased risk of reoperation for posterolateral fusion only (HR 0.39, 95% CI 0.21–0.72; $p < 0.01$) and ALIF (HR 0.22, 95% CI 0.06–0.83; $p = 0.03$). However, O-arm–assisted navigation was not associated with risk of reoperation for PLIF/TLIF procedures. Increased length of surgery (HR 1.23, 95% CI 1.06–1.44; $p < 0.01$) and increased length of stay (HR 1.05, 95% CI 1.02–1.08; $p < 0.01$) predicted increased risk of reoperation solely within the posterolateral fusion only cohort.

Discussion

The accuracy of pedicle screw insertion using O-arm–assisted navigation has been well described in the literature. However, it is unknown whether this greater accuracy is clinically meaningful, given the cost and complexity of these systems. Identifying differences in clinical outcomes is critical to establishing the true value of O-arm–assisted navigation in spine surgery. Thus, in an effort to ascertain the clinical benefit of O-arm–assisted navigation, we compared length of hospital stay and freedom from spinal reoperation between patients undergoing spinal fusion using O-arm–assisted navigation and freehand or fluoroscopic guidance. We hypothesized that the greater accuracy provided by O-arm–assisted navigation would translate to significant clinical benefits by reducing the risk of reoperation for hardware failure or screw misplacement. Indeed, we observed that O-arm–assisted navigation reduced the risk of reoperation $> 50\%$ compared with both freehand and fluoroscopic approaches. This effect remained durable when looking at procedures involving both < 5 vertebral levels and ≥ 5 levels, as well as when looking at posterolateral fusion only or ALIF procedures.

TABLE 3. Mixed-effects Cox proportional hazards model for reoperation

Covariate	Univariable (p value)	Multivariable		
		HR	95% CI	p Value
O-arm	$<0.01^*$	0.49	0.32–0.76	$<0.01^*$
Patient characteristic				
Age	0.21	—	—	—
Male	0.42	—	—	—
White	0.90	—	—	—
Married	0.96	—	—	—
Current smoker	0.95	—	—	—
BMI	0.40	—	—	—
CCI score ≥ 2	0.01*	—	—	—
Op indication				
Spondylolisthesis	0.78	—	—	—
Spinal stenosis	0.21	—	—	—
Scoliosis	0.29	—	—	—
Degenerative disc disease	0.38	—	—	—
Spondylosis	$<0.01^*$	2.02	1.30–3.14	$<0.01^*$
Disc herniation	0.64	—	—	—
Prior spine op	0.62	—	—	—
Kyphosis	$<0.0001^*$	3.13	1.80–5.45	$<0.0001^*$
Op procedure				
Posterolateral fusion only	0.70	—	—	—
PLIF/TLIF	0.56	—	—	—
ALIF	0.31	—	—	—
Apply interbody cage	0.28	—	—	—
Allograft	0.53	—	—	—
Autograft	0.25	—	—	—
Remove hardware	0.70	—	—	—
Osteotomy	$<0.001^*$	1.78	0.99–3.20	0.06
Thoracic involvement†	0.03*	—	—	—
No. of vertebral levels	0.15	—	—	—
Length of op	$<0.01^*$	—	—	—
Length of stay	$<0.00001^*$	1.04	1.02–1.07	$<0.001^*$

* Statistically significant: $p \leq 0.05$.

† Relative to lumbosacral.

Pedicle Screw Accuracy With O-Arm–Assisted Navigation

Several studies have compared the accuracy of screw insertion using O-arm–assisted navigation with freehand and fluoroscopic approaches. Gelalis et al. conducted a systematic review comparing CT-based navigation with freehand and fluoroscopic guidance.³ They reported that CT navigation achieved pedicle screw placement accuracy ranging from 89% to 100%; in contrast, freehand accuracy ranged from 69% to 94%, and fluoroscopic guidance ranged from 28% to 85%.³ A separate systematic review and meta-analysis by Shin et al. reported that the relative risk of pedicle screw perforation with O-arm–assisted navigation was 0.39 ($p < 0.001$), with a 6% overall perforation rate with the O-arm and a 15% perforation rate

TABLE 4. Subset mixed-effects Cox proportional hazards model for reoperation by number of vertebral levels

Covariate	<5 Vertebral Levels				≥5 Vertebral Levels			
	Univariable (p value)	Multivariable			Univariable (p value)	Multivariable		
		HR	95% CI	p Value		HR	95% CI	p Value
O-arm	<0.01*	0.44	0.23–0.84	0.01*	0.02*	0.48	0.25–0.91	0.03*
Patient characteristic								
Age	0.10	0.98	0.95–1.00	0.03*	0.80	—	—	—
Male	0.96	—	—	—	0.16	1.87	1.02–3.43	0.04
White	0.84	—	—	—	0.81	—	—	—
Married	0.41	—	—	—	0.33	—	—	—
Current smoker	0.88	—	—	—	0.79	—	—	—
BMI	0.40	—	—	—	0.72	—	—	—
CCI score ≥2	0.36	—	—	—	0.01*	2.25	1.19–4.25	0.01*
Op indication								
Spondylolisthesis	0.18	2.57	1.26–5.21	<0.01*	0.06	—	—	—
Spinal stenosis	0.43	—	—	—	0.31	—	—	—
Scoliosis	0.60	—	—	—	0.57	—	—	—
Degenerative disc disease	0.17	—	—	—	0.79	—	—	—
Spondylosis	0.02*	1.91	1.05–3.48	0.03*	0.10	1.96	0.98–3.92	0.06
Disc herniation	0.91	—	—	—	0.40	—	—	—
Prior spine op	0.38	—	—	—	0.88	—	—	—
Kyphosis	<0.001*	3.28	1.06–10.2	0.04*	<0.00001*	3.21	1.67–6.20	<0.001*
Op procedure								
Posterolateral fusion only	0.91	—	—	—	0.33	0.50	0.26–0.95	0.03*
PLIF/TLIF	0.48	—	—	—	0.96	—	—	—
ALIF	0.38	—	—	—	0.35	—	—	—
Apply interbody cage	0.82	—	—	—	0.11	—	—	—
Allograft	0.75	—	—	—	0.62	—	—	—
Autograft	0.16	—	—	—	0.84	—	—	—
Remove hardware	0.76	—	—	—	0.69	—	—	—
Osteotomy	0.73	—	—	—	<0.001*	2.41	1.24–4.66	<0.01*
Thoracic involvement†	0.22	—	—	—	0.10	—	—	—
Length of op	0.31	—	—	—	<0.01*	—	—	—
Length of stay	<0.00001*	1.10	1.03–1.17	<0.01*	<0.01*	1.03	0.99–1.07	0.16

* Statistically significant $p \leq 0.05$.

† Relative to lumbosacral.

with fluoroscopy.¹³ No differences in total operative time or estimated blood loss were identified between cohorts.

Several individual studies have reached similar conclusions. Oertel et al. investigated the placement of 278 pedicle screws using O-arm–assisted navigation and found a 3.2% perforation rate.⁶ Similarly, Ling et al. studied the placement of 467 pedicle screws using O-arm–assisted navigation and found that 95.3% were accurately placed with no breaches.⁵ Moreover, when comparing operative times between the O-arm cohort and a matched fluoroscopy cohort, the authors found that O-arm procedures trended toward requiring longer operative time. Finally, Silbermann et al. compared pedicle screw placement during PLIF and TLIF procedures and found that the O-arm achieved 98.9% accuracy compared with 94.1% accuracy for the freehand approach.¹⁴

Fewer studies have investigated the role of pedicle size

on the accuracy of screw placement in thoracic pedicles. Jeswani et al. investigated the role of O-arm–assisted navigation in inserting pedicle screws into the thoracic spine, with a special emphasis on the accuracy of screws placed into smaller pedicles.⁴ O-arm–assisted navigation achieved 100% accuracy for large pedicles (≥ 3 mm narrowest diameter) and 96.6% accuracy for small pedicles (≤ 2 mm), which led the authors to conclude that O-arm–assisted navigation allows for safe, effective, and accurate instrumentation of small thoracic pedicles. Furthermore, Rivkin and Yocom studied the accuracy rates of thoracolumbar pedicle screw placement in 270 patients and reported an overall breach rate of 5.3%.⁸ The authors found that thoracic pedicles were more frequently breached compared with lumbar pedicles (6.6% vs 5.1%). Finally, it is important to note that O-arm navigation is accompanied by radiation exposure; however, the overall radiation expo-

TABLE 5. Subset mixed-effects Cox proportional hazards model for reoperation by type of operation

Covariate	Posterolateral Fusion Only				PLIF/TLIF				ALIF			
	Univariable (p value)	Multivariable			Univariable (p value)	Multivariable			Univariable (p value)	Multivariable		
		HR	95% CI	p Value		HR	95% CI	p Value		HR	95% CI	p Value
O-arm	<0.001*	0.39	0.21–0.72	<0.01*	0.61	—	—	—	0.11	0.22	0.06–0.83	0.03*
Patient characteristic												
Age	0.39	—	—	—	0.99	—	—	—	0.17	—	—	—
Male	0.48	—	—	—	0.30	—	—	—	0.35	—	—	—
White	0.28	—	—	—	0.37	—	—	—	1.00	—	—	—
Married	0.80	—	—	—	0.78	—	—	—	0.68	—	—	—
Current smoker	0.42	—	—	—	1.00	—	—	—	0.30	—	—	—
BMI	0.51	—	—	—	0.52	—	—	—	0.63	—	—	—
CCI score ≥2	0.11	—	—	—	<0.01*	2.63	1.22–5.69	0.01*	0.64	—	—	—
Op indication												
Spondylolisthesis	0.67	2.65	1.32–5.32	<0.01*	0.25	—	—	—	0.81	—	—	—
Spinal stenosis	0.45	—	—	—	0.22	—	—	—	0.96	—	—	—
Scoliosis	0.50	—	—	—	0.23	—	—	—	0.93	—	—	—
DDD	0.50	—	—	—	1.00	—	—	—	0.84	—	—	—
Spondylosis	0.09	1.67	0.90–3.09	0.10	0.02*	2.54	1.17–5.49	0.02*	0.65	—	—	—
Disc herniation	0.82	—	—	—	0.79	—	—	—	1.00	—	—	—
Prior spine op	0.48	—	—	—	0.81	—	—	—	0.81	—	—	—
Kyphosis	<0.0001*	3.51	1.62–7.62	<0.01*	<0.0001*	4.22	1.75–10.2	<0.01*	0.03*	3.61	1.22–10.7	<0.01*
Op procedure												
Apply interbody cage	0.45	—	—	—	0.38	—	—	—	0.40	—	—	—
Allograft	0.31	—	—	—	0.79	—	—	—	0.17	—	—	—
Autograft	1.00	—	—	—	0.02*	—	—	—	0.43	—	—	—
Remove hardware	<0.01*	—	—	—	0.21	—	—	—	0.16	—	—	—
Osteotomy	0.27	—	—	—	0.01*	2.97	0.87–10.1	0.08	0.05*	—	—	—
Thoracic involvement†	0.08	—	—	—	0.08	—	—	—	0.62	—	—	—
No. of vertebral levels	0.19	—	—	—	0.30	—	—	—	0.53	—	—	—
Length of op	<0.0001*	1.23	1.06–1.44	<0.01*	0.46	—	—	—	0.70	—	—	—
Length of stay	<0.001*	1.05	1.02–1.08	<0.01*	<0.01*	—	—	—	0.24	—	—	—

* Statistically significant: $p \leq 0.05$.

† Relative to lumbosacral.

sure to the surgical team is minimal and probably substantially less than with fluoroscopic guidance.¹

Clinical Outcomes Associated With O-Arm–Assisted Navigation

In the present study, clinical outcomes among patients undergoing open thoracolumbar spinal fusion with O-arm–assisted navigation were compared with outcomes following use of freehand or fluoroscopic approaches. Although spinal fusions using O-arm–assisted navigation were on average half a vertebral level longer than controls, no differences in operative time were observed. Of note, the O-arm was associated with a mean length of hospital stay that was one-half of a day shorter than controls. It may be plausible that a shorter length of stay associated with O-arm use is driven by increased pedicle insertion accuracy, reduced soft tissue retraction time, reduced surgical trauma from screw reinsertion, and therefore reduced postopera-

tive pain. Nevertheless, this effect requires corroboration in a randomized setting to reduce undetected confounding.

O-arm assisted–navigation seems to reduce the risk of reoperation for hardware failure and screw misplacement compared with freehand and fluoroscopic methods. When comparing the O-arm cohort with the combined freehand and fluoroscopy cohort, the RRs of reoperation for hardware failure and screw misplacement were 0.50 ($p = 0.01$) and 0.39 ($p < 0.01$), respectively, whereas the RR for overall reoperation was 0.48 ($p < 0.01$). This significant difference seems to be a result of increased accuracy achieved using O-arm–assisted navigation, because no significant differences in reoperation rates for pseudarthrosis were observed between the O-arm cohort and the combined freehand and fluoroscopy cohort.

These observations were corroborated with Kaplan-Meier analyses, which demonstrated significantly greater freedom from all-cause reoperation ($p < 0.001$), reopera-

tion for hardware failure ($p = 0.02$), and reoperation for screw misplacement ($p = 0.02$) among patients in the O-arm cohort, although there were no differences in freedom from reoperation for pseudarthrosis ($p = 0.75$). After adjustment via mixed-effects Cox proportional hazards modeling with surgeon as a random effect, the risk of reoperation was less than half among patients with O-arm–assisted navigation (HR 0.49; $p < 0.01$). Furthermore, this effect remained durable within subsets of patients who had < 5 vertebral levels fused (HR 0.44; $p = 0.01$) and those who had ≥ 5 levels fused (HR 0.48; $p = 0.03$).

When subsets were analyzed by operation, patients who underwent posterolateral fusion only (HR 0.39; $p < 0.01$) or ALIF (HR 0.22; $p = 0.03$) experienced significantly decreased risk of reoperation. The long-term decreased risk of reoperation associated with O-arm–assisted navigation is a critical finding to establish the importance and benefit of intraoperative imaging. The present results suggest that O-arm use decreases the risk of reoperation by more than half compared with either the freehand or fluoroscopic method. Thus, increased use of O-arm–assisted navigation could yield significantly improved long-term patient outcomes and represent a cost-effective modality.

Limitations of the Study

The present study includes several limitations. Because it is a retrospective study, the collected clinician-reported data were not standardized, subjecting our results to measurement bias. Furthermore, our results are subject to selection bias, because surgeons may have used O-arm, freehand, or fluoroscopic guidance on the basis of patient characteristics, operative factors, or personal surgeon preference. Attempts to mitigate selection bias included controlling for a variety of patient, disease-related, and operative characteristics using multivariable modeling. Similarly, using mixed-effects modeling with surgeon as a random effect allowed for controlling of potential surgeon-specific effects on outcomes. It is important to note that although the present study suggests that O-arm–assisted navigation decreases the risk of postoperative reoperation, the clinical benefit of O-arm–assisted navigation can only be confirmed in a randomized controlled trial to eliminate potential biases that may have affected our conclusions. Furthermore, only a multicenter trial would be able to confirm that O-arm–assisted navigation truly decreases the risk of reoperation across clinical settings.

Conclusions

To our knowledge, the present study is the first to investigate clinical outcomes associated with O-arm–assisted navigation following thoracolumbar spinal fusion. Consistent with the increased accuracy of pedicle screw insertion achieved with this modality, the O-arm was a significant independent predictor of decreased length of hospital stay and decreased risk of reoperation for hardware failure and screw misplacement. Of note, the O-arm reduced the risk of reoperation to less than half the risk associated with freehand and fluoroscopic approaches. Future prospective randomized controlled trials to corroborate the findings of the present study are warranted.

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Disclosures

Dr. Mroz is a consultant for Stryker, Globus Medical, and RTI Surgical. He has ownership interest and distribution rights in PearlDiver Inc. Dr. Benzel is a consultant for Axiomed. He has ownership interest and distribution rights in Axiomed, DePuy, Orthomems, and Turning Point.

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