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Complications and Revision Rates in Minimally Invasive Robotic-Guided *Versus* Fluoroscopic-Guided Spinal Fusions

The MIS ReFRESH Prospective Comparative Study

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Study Design. Prospective, multicenter, partially randomized.
Objective. Assess rates of complications, revision surgery, and radiation between Mazor robotic-guidance (RG) and fluoro-guidance (FG).
Summary of Background Data. Minimally invasive surgery MIS ReFRESH is the first study designed to compare RG and FG techniques in adult minimally invasive surgery (MIS) lumbar fusions.
Methods. Primary endpoints were analyzed at 1 year follow-up. Analysis of variables through Cox logistic regression and a Kaplan–Meier Survival Curve of surgical complications.
Results. Nine sites enrolled 485 patients: 374 (RG arm) and 111 (FG arm). 93.2% of patients had more than 1 year f/u. There were no differences for sex, Charlson Comorbidity Index, diabetes, or tumor. Mean age of RG patients was 59.0 versus 62.5 for FG ($P = 0.009$) and body mass index (BMI) was 31.2 versus 28.1 ($P < 0.001$). Percentage of smokers was almost double in the RG (15.2% *vs.* 7.2%, $P = 0.029$). Surgical time was similar (skin-to-skin time/no. of screws) at 24.9 minutes RG and 22.9 FG ($P = 0.550$). Fluoroscopy during surgery/no. of screws was 15.5 seconds RG *versus* 35.4 seconds FG, (15 seconds average reduction). Fluoroscopy time during instrumentation/no. of screws was 3.6 seconds RG *versus* 17.8 seconds FG showing an 80% average reduction of fluoro time/screw in RG ($P < 0.001$). Within 1 year follow-up, there were 39 (10.4%) surgical complications RG *versus* 39 (35.1%) FG, and 8 (2.1%) revisions RG *versus* 7 (6.3%) FG. Cox regression analysis including age, sex, BMI, CCI, and no. of screws, demonstrated that the hazard ratio (HR) for complication was 5.8 times higher FG *versus* RG (95% CI: 3.5–9.6, $P < 0.001$). HR for revision surgery was 11.0 times higher FG *versus* RG cases (95% CI 2.9–41.2, $P < 0.001$).
Conclusion. Mazor robotic-guidance was found to have a 5.8 times lower risk of a surgical complication and 11.0 times lower risk for revision surgery. Surgical time was similar between groups and robotic-guidance reduced fluoro time per screw by 80% (approximately 1 min/case).
Key words: complication rate, intraoperative radiation, lumbar fusion, minimally invasive, prospective, revision rate, robotic-guided spine surgery.
Level of Evidence: 2
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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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Precise implant placement during spinal surgery is crucial to avoid neurologic and vascular damage, while providing proper fixation and stability to support the formation of bone fusion. This procedure is particularly challenging in minimally invasive surgery (MIS) because surgeons must rely on indirect visualization of the anatomy by imaging systems. In recent years, guidance has been shown to be both reliable and accurate when instrumenting pedicles[1,2]; however, accuracy alone may not predict clinical outcome.[3–6]

Advances in technology have provided spine surgeons with several options of enhanced guidance abilities in the operating room. Currently available guidance systems can be generally divided into different categories: optical

navigation-based systems that track reference markers (NAV), NAV systems with robotic arms (RNAV), and automated anatomy recognition-based robotic guidance (Mazor). RNAV systems typically utilize a floor-mounted mechanical arm and rely on tracking reference markers attached to the patient, with registration to the patient usually performed by intraoperative 3-dimensional (3D) imaging. Mazor systems are patient- or bed-mounted systems that connect directly to the patient's bony anatomy and rely on preoperative planning using high-resolution 3D imaging. The automated anatomy recognition software recognizes individual vertebrae and uses two fluoroscopy images to merge the segmented spine to the 3D images with the patient's location relative to the robotic system, with each vertebra registered individually.

While some recent reports in the literature on robot-guidance have related to RNAV,[7] most reports have focused on Mazor, with accuracy rates ranging from 83.4% to 100%.[8–23] Prospectively collected data on complications and revisions following robot-guided spinal instrumentation are more limited.

The purpose of the MIS ReFRESH study was to prospectively evaluate surgical outcomes by comparing the complication and revision rates between Mazor and fluoroscopy-guided (FG) surgery in MIS instrumentation of degenerative lumbar or lumbosacral spine disease. In addition, the exposure to intraoperative radiation was analyzed.

MATERIALS AND METHODS

Study Design and Patients

MIS ReFRESH is a prospective, multicenter, controlled, partially randomized study approved by a centralized institutional review board (Western IRB 20131864). The study is registered on Clinicaltrials.gov as NCT02057744. All participants signed an informed consent form prior to entering the study. Adult patients (21 years and older) scheduled to undergo primary short (four or fewer consecutive vertebrae) lumbar or lumbosacral percutaneous/MIS spinal fusion surgery were included in the study. Patients were excluded if they were pregnant, undergoing revision surgery following prior instrumentation of pedicles at the index level/s, if they had extension of a prior fusion due to adjacent level disease, an infection or malignancy, primary abnormalities of bones, primary muscle diseases (*e.g.*, muscular dystrophy), neurologic diseases, spinal cord abnormalities with neurologic symptoms or signs, spinal cord lesions requiring neurosurgical interventions (*e.g.*, hydromyelia), or paraplegia.

Ten surgeons participated in the study at nine sites. Eight surgeons enrolled patients to the Mazor arm, one surgeon served as a control site and a single surgeon randomized patients to both treatment arms. Each of the nine surgeons enrolling in the Mazor arm were required to have performed at least 30 cases using the Mazor Renaissance Surgical Guidance Robot prior to the study start date. Together, the experience in number of cases prior to the start date ranged from 50 to 400 cases, with an average of 152 cases. The single site that randomized into both treatment arms first obtained patient consent to randomization, then using an electronic data capture system, a randomization report was generated to notify the site of the assignment.

Surgical Techniques

Mazor Surgical Procedure

A para-spinal, percutaneous, or transmuscular approach was used to place the pedicle screws, with pilot holes drilled using Mazor Core^{TM} technology (Renaissance Surgical Guidance Robot, Mazor Robotics Ltd., Caesarea, Israel). Prior to surgery, a computed tomography (CT) scan of the spinal region of interest was uploaded to proprietary software and used for planning optimal screw dimensions and positioning relative to the patient's anatomy in 3D views. In the operating room, the surgeon secured a bone-mounted platform to the patient's spine. Once the platform was firmly attached, a fiducial array was placed on it and a coronal plane image and an image 60° oblique to the sagittal plane were captured by a 2-dimensional C-arm. The fluoroscopy images were then automatically merged with the preoperative CT by the software, registering the actual location of the mounting platform relative to the patient's anatomy, and the surgical plan. The robotic manipulator was placed on the bone-mounted platform and aligned itself with the planned trajectories consecutively, according to the surgeon's commands. A scalpel was inserted through the robot's arm and advanced percutaneously through the soft tissues until the pedicle entry point was reached. A drill guide was then inserted through the robot's arm and securely docked to prevent its movement while drilling the pilot hole. Drilling was performed manually utilizing a 30×3-mm drill bit through the drill guide, and a K-wire was placed inside each pilot hole. Standard technique was utilized to manually insert pedicle screws over the guidewires. The robotic set up time was included in the skin-to- skin time to account for any potential length of time this may have added to the surgery.

Fluoroscopic-guided Surgical Procedure

In the control arm, pedicle screws were inserted in a minimally invasive approach, using trocars, K-wires, and single or double fluoroscopic imaging for guidance and verification.

In both study arms, placement of interbody devices, and decompression when needed, were performed through the paramedian screw incisions or through a mini-open, midline incision, using retractors and tubes. Intraoperative radiography was performed using C-arm fluoroscopy to assess screw locations. In the robotic arm, 250 (66.8%) patients underwent decompression *versus* 43 (38.7%) patients in the control arm, $P < 0.001$. Interbody fusion was inconsistently documented throughout the study and therefore no statistical analysis of this factor can be performed. Decompression and interbody fusion times were included in the measurement of skin-to-skin time but specific times for this portion of the procedure were not separately documented or analyzed.

TABLE 1.

Parameter	Robot-Guided	Fluoroscopic-Guided	*P*-Value
n	374	111	
% females	56.1%	62.2%	0.260
Age, yrs	59.0 ± 12.6	62.5 ± 12.8	0.009
BMI	31.2 ± 6.8	28.1 ± 5.2	<0.001
% Charleson >0	33.2	24.3	0.078
% Smokers	15.2	7.2	0.029
Patients >12-month	343 (91.7%)	109 (98.2%)	<0.001
Follow-up, mo	25.2 ± 10.5	35.5 ± 9.9	<0.001

% Charlson > 0 indicates percent of sample that had a Charlson Comorbidity Index (CCI) greater than 0; % females, percent of sample that were female; % smokers, percent smokers; BMI, body mass index; n, sample size; Patients > 12- month, patients that are greater than 12months after surgery.

Endpoints

The primary endpoints of the study are the incidence of surgical/wound complications and of revision surgeries, as well as the intraoperative exposure to x-ray radiation during surgery.

Secondary endpoints include patient reported outcome measures (PROM) and technical execution parameters, such as instrumentation time per screw and total surgery time. The PROM collected are numerical rating scales for back and leg pain, Oswestry Disability Index (ODI), and EQ5D, recorded preoperatively, and at 6, 12, 24, 60, and 120 months, however patient completion was inconsistent, not allowing for statistical analysis. The current analysis was done for endpoints collected during the first year after surgery.

Statistical Analysis

Statistical analysis was performed using SPSS Statistics for Windows (IBM, Armonk, NY) version 25.0. Results were summarized and presented in tabular format. Continuous variables were expressed as mean (SD), median [IQR], and [min-max]. Categorical variables were expressed as number and percentage (%). Comparisons between groups of continuous variables with normal distribution were performed with independent *t* test, for variables with nonnormal distribution were performed with Mann - Whitney *U* test. Fisher exact test, or x^2 test was used to compare categorical variables. The Cox Proportional Hazard Model (Cox), with backward elimination method, was used to evaluate the risk of developing complications or requiring a revision surgery, with a 95% confidence interval (CI) adjusting for confounders: age, BMI, skin- to-skin time, number of executed screws, total pack years, gender, Charlson more than 0. The Kaplan - Meier model (KM) analyzed the proportion of patients who were complication-free at 90-days and 1 year postsurgery. All statistical comparisons were two-sided and significance was defined as $P < 0.05$.

RESULTS

Between October 2014 and September 2018, 485 patients were enrolled in the study, with 374 Mazor patients (56.1% females), and 111 FG (62.2% females, $P = 0.260$) (Table 1). One Mazor patient was excluded from the analysis due to developing ALS in the early postoperative setting.

On average, Mazor patients were statistically significantly younger but with a higher BMI. Both study arms had similar Charlson Comorbidity Index (CCI) and indications for surgery.

A total of 1813 screws were executed with Mazor (4.8 ± 1.3 per patient) and 484 with FG (4.4 ± 0.9 per patient, $P < 0.001$). The mean skin-to-skin time per screw was similar in both arms: 24.9 ± 14.1 minutes with Mazor compared with 22.9 ± 7.6 minutes with FG (P = 0.550). Fluoroscopy time per screw during instrumentation was 3.6 ± 3.9 seconds with Mazor compared with 17.8 ± 9.0 seconds with FG, indicating an 80% reduction in intraoperative exposure time to radiation per screw ($P < 0.001$). The total average intraoperative exposure to radiation per case in Mazor was less than half that of FG (74.8 ± 57.3 seconds of fluoro *vs.* 151.9 ± 53.1 seconds of fluoro, $P < 0.001$) (Table 2).

TABLE 2.

Parameter	Robot-Guided	Fluoroscopic-Guided	% Reduction	*P*-Value
Skin-to-skin time, min	118 ± 67	99 ± 36	−19%	0.124
Screws per case	4.8 ± 1.3	4.4 ± 0.9	−9%	<0.001
Skin-to-skin, minutes per screw	24.9 ± 14.1	22.9 ± 7.6	−9%	0.550
Total case fluoroscopy, s	74.8 ± 57.3	151.9 ± 53.1	51%	<0.001
Total case fluoroscopy, s, per screw	15.5 ± 11.2	35.4 ± 12.0	56%	<0.001
Instrumentation fluoroscopy, s, per screw	3.6 ± 3.9	17.8 ± 9.0	80%	<0.001

% Reduction indicates percent reduction.

TABLE 3.

AE Type	Robotic-Guided	RG %	Fluoroscopic-Guided	FG%	Total	Total%
Surgical	39	10.4%	39	35.1%	78	16.1%
Wound	5	1.3%	13	11.7%	18	3.7%
Total	**44**	**11.8%**	**52**	**46.8%**	**96**	**19.8%**

FG% indicates fluoroscopic-guided percent; RG%, Robotic-guided percent; Total%, total percent.

Complications and Revisions

The mean postoperative follow-up period was 25.2 ± 10.5 months in Mazor and 35.5 ± 9.9 months in FG ($P < 0.001$) (Table 1). Complications were classified into surgical and wound related (including infections) (Table 3). One surgical complication described as new onset right lower extremity radiculopathy that fully resolved after 8 days of conservative treatment, occurred in the control group, was considered minor, and not counted in the analysis.

Of 485 patients analyzed, 78 (16.1%) suffered a surgical complication (10.4% Mazor vs. 35.1% FG) and 15 (3.1%) patients had a total of 18 (3.7%) wound complications (1.3% Mazor vs. 11.7% FG) (Table 3). Of those 15 patients, 13 (1.3% Mazor vs. 7.2% FG) were treated non-surgically and 2 (0% Mazor vs. 1.8% FG) were treated surgically with IV antibiotics. The Cox model, adjusted for age, BMI, sex, skin-to-skin time, CCI, smoking, and number of screws per case, showed that the risk for an unresolved complication in Mazor was significantly lower compared with FG with a hazard ratio (HR) of 5.8 (95% CI, 3.5–9.6; $P < 0.001$) (Table 4). Therefore the use of robotic guidance led to a 5.8 times lower risk of complication compared with fluoroscopic guidance. Kaplan-Meier model showed a significant difference in the complication-free "survival" curves. At 90 days postsurgery, 97% of Mazor patients were free of complications compared with 73% of FG patients ($P < 0.001$). At 1 year postsurgery, 90% of Mazor patients were complication-free compared with 65% of FG patients ($P < 0.001$) (Figure 1).

In the first year of follow up there were eight revision surgeries in Mazor (2.1%) and seven (6.3%) in FG. Cox analysis showed that the risk for revision surgery in Mazor was significantly lower compared with FG with a HR of 11.0 (95% CI: 2.9–41.2; $P < 0.001$) (Table 4). Indications for revisions in both groups include pseudoarthrosis, infection, instrumentation causing low back pain requiring instrumentation removal, radiculopathy requiring decompression, and radiculopathy requiring screw removal (eight [2.1%] RG and seven [6.3%] FG) (Table 5).

Analysis of Single-Level Cases

Most procedures were single-level fusions, performed in 231 Mazor patients (61.8%) and 88 FG patients (79.3%) ($P < 0.001$, Figure 2). A Cox analysis showed the risk for complications in single-level cases using Mazor was significantly lower compared with FG with a HR of 7.1 (95% CI: 3.8–13.2; $P < 0.001$). For eight revision surgeries in single-level cases a HR of 6.6 (95% CI: 1.1 - 38.0) was measured but it only trended toward statistical significance ($P = 0.036$) (Table 4).

DISCUSSION

There is no standard definition of what constitutes a complication in spine surgery, with different studies using independent definitions/classifications or leaving the subject vague. As the purpose of the current study was to assess the impact of the use of automated anatomy recognition based robotic-guidance on patient outcomes, complications of a medical nature (*e.g.*, cardiac, urinary, pulmonary symptoms) or of traumatic etiology (falls and motor vehicle accidents) were removed from the analysis. We also opted to distinguish between complications based on whether they have fully resolved or not within 90 days postsurgery. Surgical revision cases were counted separately.

The overall event rates of complications and revisions reported in our study are consistent with previous reports on Mazor Core technology[8–10,15,24–28] as well as on FG surgeries.[29–31] The 5.8-fold reduction in complication rates and 11.0-fold reduction in revision rates during the first year after surgery are significant both statistically and clinically. The reduced complication and revision rates with Mazor have led the investigator who initially randomized patients to discontinue randomization and continue to enroll.

TABLE 4.

Case	Parameter	*P*	HR	95% Confidence Interval	
				Lower Bound	Upper Bound
All cases	Complications within 1 year	<0.001	5.8	3.5	9.6
	Revisions within 1 year	<0.001	11.0	2.9	41.2
Single-level	Complications within 1 year	<0.001	7.1	3.8	13.2
	Revisions within 1 year	0.036	6.6	1.1	38.0

HR indicates hazard ratio.

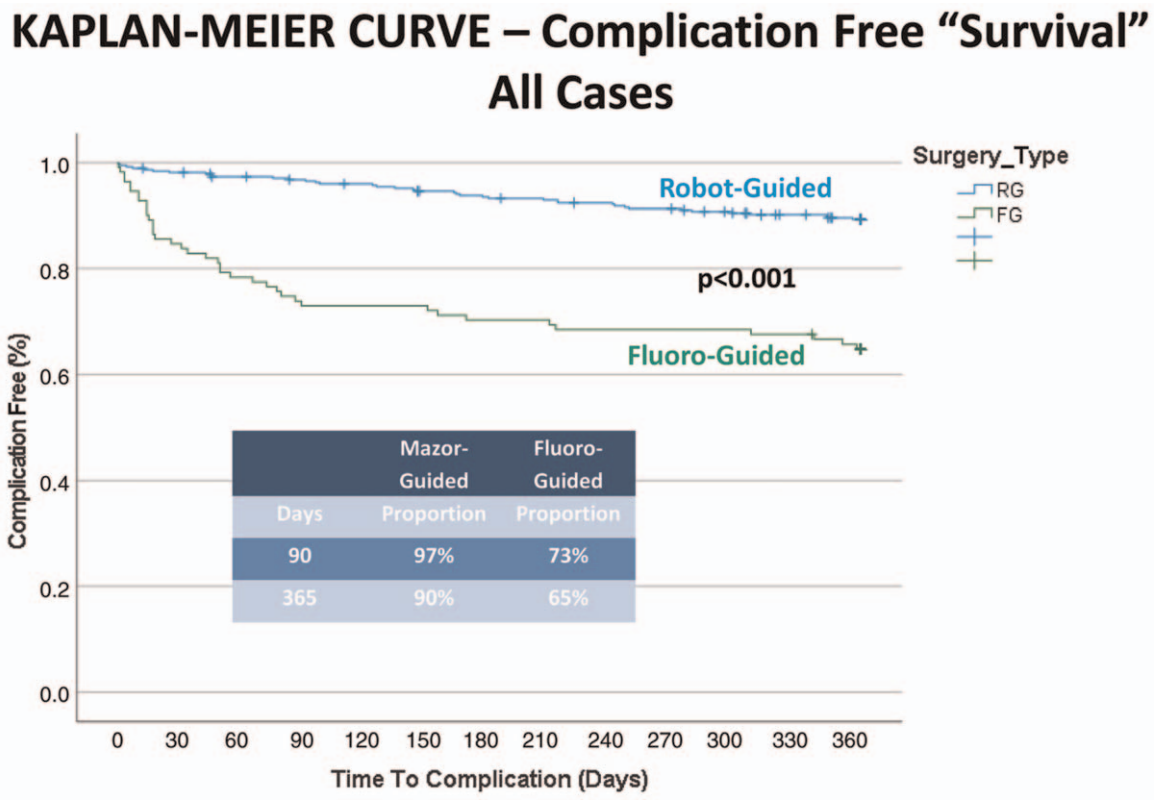

Figure 1. All cases of Kaplan-Meier curve.

patients only with Mazor. Our findings on the reduction in complications and revisions are consistent with several previous reports. Fan *et al*[32] noted a significantly lower complication rate with Mazor (5.1%) as compared with navigation template (17.9%), 3D-navigation (13.7%), and FG (19.4%), although only the Mazor arm utilized a percutaneous screw insertion technique.

In a recent meta-analysis of comparative studies, Staartjes *et al*[33] pooled three randomized controlled trials and three retrospective studies of Mazor (242 patients) *versus* freehand (233 patients) surgeries. They found a combined odds ratio (OR) of 0.31 (95% CI: 0.11–0.93, $P = 0.04$) for a revision surgery for screw malposition in the Mazor arm compared with freehand surgery, which translates to a 3.2-fold reduction in the odds for a revision surgery compared with freehand surgery. However, when their analysis included trials that reported zero revisions in both arms, the statistical significance was lost. Keric *et al*[19] reported that implant revision due to misplacement was necessary in 5.0% of cases in the free-hand group compared with 0.6% of cases in the Mazor group ($P = 0.024$).

Conversely, Lieber *et al*[34] analyzed historic data from the national inpatient sample and the nationwide inpatient sample of 257 patients operated with robotic-guidance (type unspecified) which they have matched with freehand controls. No significant difference in the rates of major complications between the robotic-guided and conventional cohorts were observed, including with multivariate analysis; however, while the patient characteristics were well- matched, 31% of the diagnoses were marked as "other" in both arms, which introduced variability to the analysis.

A multivariate regression analysis of 627 patients operated in a MIS approach, 403 Mazor and 224 FG controls,

TABLE 5.

Revision Indication	No. in RG	No. in FG	Total
Pseudoarthrosis	1	1	2
Infection	0	2	2
Instrumentation causing low back pain requiring removal	2	1	3
Radiculopathy requiring decompression	4	3	7
Radiculopathy requiring screw removal	1	0	1
Total:	8 (2.1%)	7 (6.3%)	15 (3.1%)

No. In RG indicates number in Robotic-Guidance; No. in FG, number in Fluoro-Guidance.

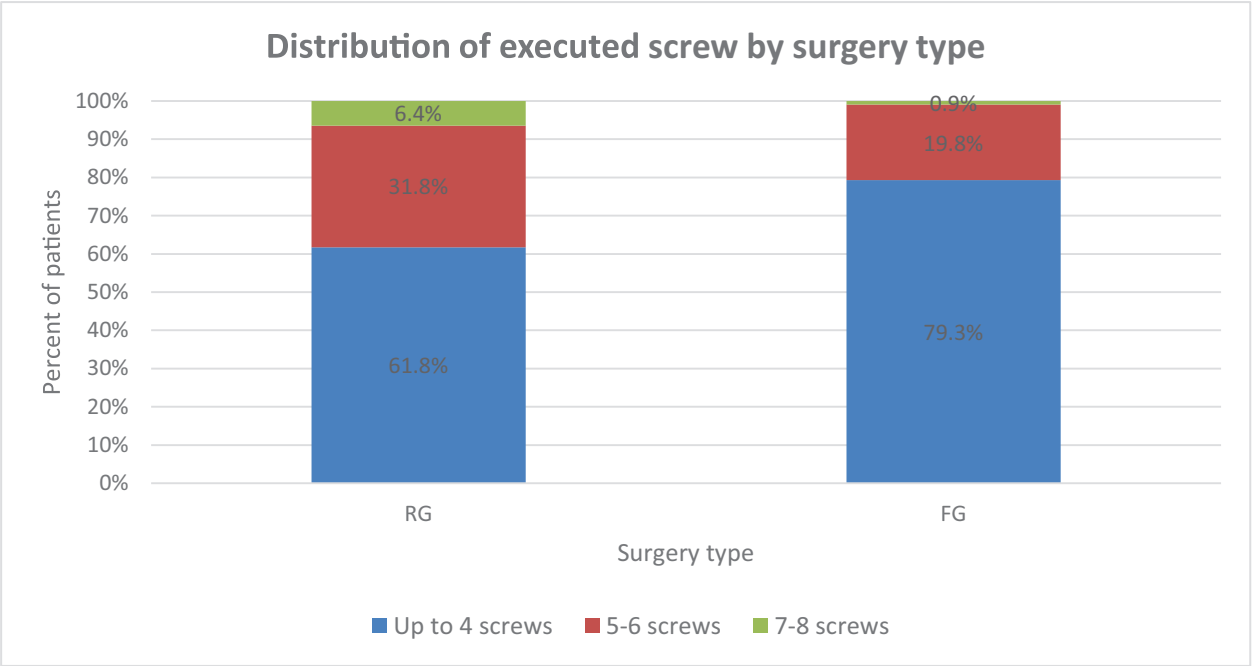

Figure 2. Executed screw distribution.

yielded an OR of 3.0 (95% CI: 1.2–7.1, $P = 0.014$) for complications in FG and an OR of 3.8 (95% CI: 1.5–10.0, $P = 0.006$) for revision surgery in FG.[35]

The reasons for the significantly lower rates of complications and revisions observed with Mazor, compared with FG, cannot be attributed solely to instrumentation accuracy. As each patient has specific anatomical features, Mazor robots require detailed 3D planning prior to the operation, which increases the surgeon's familiarity with the patient's anatomy, and reduces the chances of surprise findings during surgery.[36] Preoperative planning also allows optimization of implant size and trajectory to the patients' anatomy. The robotic system enables patientspecific simulation for the ideal screw trajectory according to patient-specific anatomical differences. The system then reproduces this simulation accurately and reliably in the operating room. In addition, screws placed with Mazor have found to be associated with fewer proximal facet joint violations and better convergence orientations.[20,37–39] Planned screw cadence may decrease tug on screws in the pedicles during rod insertion which might impact their bone purchase, and may decrease soft tissue tension and wound problems, especially in MIS fusion of two or more levels.

There is nascent evidence that use of Mazor also improves single-level construct biomechanics by alleviation of stress increments at proximal adjacent segments compared with pedicle screw insertion using freehand technique.[40] This might be explained by the implant-to-anatomy optimization and the "single-pass" drilling of the pilot hole, which may provide stronger bone purchase.

Exposure to intraoperative radiation is an occupational hazard to operating room teams. In this study there was an 80% reduction in intraoperative radiation exposure per screw during instrumentation with Mazor compared with FG. This is consistent with several previous reports.[10,13,32] Hyun *et al*[21] showed similar reduction in radiation per screw, while Solomiichuk *et al*[18] reported that radiation was higher with Mazor as compared with conventional surgery. Fluoroscopy time seems inversely correlated to the surgeons' experience in using Mazor.[8,39,41] It should be noted that while the robot-guided system allows reduced radiation within the operating room, the patients undergo a CT scan for the preoperative planning.

Our study shows no difference in surgery time between arms, even when normalizing the skin-to-skin time per screw or limiting the analysis to single-level cases. There is paucity of data in the literature on surgical efficiencies when utilizing robotic-guidance. Four randomized studies compared Mazor in MIS approach with freehand in an open approach; three found Mazor took about 2 minutes longer per screw[11,13,20] while the fourth found the operative time identical for both techniques.[21] Conversely, a report on RNAV noted patients spent approximately 2 hours longer in the operating room and 1 hour longer undergoing the surgical procedure.[7]

The advantages of the study include its prospective and comparative design, length of postoperative follow-up, and large cohort of patients undergoing robotic-guided spinal instrumentation by nine surgeons. The results are limited by the relatively smaller cohort of patients in the FG control arm and the fact that only two surgeons operated on these patients. In addition, 60% of the Mazor cases and 80% of FG were single-level, limiting the generalization of the results to more complex fusion. Finally, while the analyses of revision surgeries was statistically significant, the 95% confidence intervals are relatively wide due to the small

number of events, and significance was lost when limiting this analysis to single-level cases.

The authors recommend cautious interpretation of these results and to generally avoid extrapolation of our findings to materially different robotic or guidance systems (*i.e.*, RNAV or NAV) that do not rely on automated anatomy recognition software (*i.e.*, Mazor).

CONCLUSION

In this analysis of the prospective, controlled, MIS ReFRESH study, Mazor demonstrated a lower rate of complications and revisions compared with fluoroscopy-guided procedures, in a MIS approach, within a 1-year postoperative timeframe. Mazor also significantly reduced intraoperative radiation exposure per screw and total operative radiation as compared with fluoroscopy-guidance, helping offset the patients' exposure during the preoperative CT scan required for planning the robotic procedure. Operative time was equal in both arms.

➢ Key Points

- ❑ Use of robotic guidance led to a 5.8 times lower risk of surgical complication.
- ❑ Use of robotic guidance led to an 11.0 times lower risk of revision surgery.
- ❑ Mazor robotic guidance significantly reduced intraoperative radiation exposure per screw and total operative radiation as compared to fluoroscopy-guidance.

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