Surgical Testing Comparison of Single-Position Robot-Assisted Surgery Utilizing ExcelsiusGPS® or Conventional MIS Screw Trajectory During LLIF Procedure

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Abstract

Supplemental posterior fixation, following lateral lumbar interbody fusion (LLIF) utilizing conventional minimally invasive surgery (CMIS), requires the patient to be repositioned prone to provide bilateral access to the pedicles. Conversely, robot-assisted navigation (RAN) utilizing the ExcelsiusGPS® system allows for insertion of pedicle screws from a single position without repositioning the patient. RAN is theorized to reduce patient surgical time and radiation, and increase pedicle screw accuracy due to positioning and workflow effects.

Investigators used a cadaveric model to perform a two-level lateral lumbar interbody fusion (LLIF) followed by posterior bilateral pedicle screw fixation, which was inserted using CMIS or single-position RAN. Screw planning was performed using preoperative CT scans, which were merged with intraoperative fluoroscopy. Surgical time and radiation exposure were measured. Patient repositioning times from published historical data were used for comparison. RAN resulted in significantly lower surgical time and time per screw insertion compared to CMIS ($P<0.05$). Surgical times for preoperative RAN and CMIS were 64.7 ± 4.1 and 123.0 ± 13.7 minutes, respectively. Insertion time per screw for preoperative RAN and CMIS was 2.7 ± 0.6 and 4.3 ± 1.3 minutes, respectively. RAN and CMIS radiation dosages during posterior fixation were 0.4 ± 0.2 and 2.7 ± 1.6 rads, respectively ($P<0.05$). In conclusion, single-position RAN resulted in shorter surgical times, less radiation exposure, and fewer pedicle breaches than CMIS, which requires patient repositioning. Consideration should be given to single-position LLIF procedures that utilize RAN to instrument the spine with bilateral pedicle screws.

Introduction

The prevalence of lower back pain is estimated to be 18% in the United States; moreover, 80% of the general population will have lower back pain during their lifetime [1]. Lateral lumbar interbody fusion (LLIF) is routinely used for treating a variety of spinal pathologies, with benefits including stabilization and restoration of vertebral height and alignment, avoidance of paraspinal muscle dissection, and minimization of possible vascular or neural complications associated with other approaches [1-4]. The lateral approach allows for removal of considerable amounts of disc material, placement of large stable interbody implants, and a large fusion area [2, 4-6]. LLIF is supplemented by posterior fixation, typically bilateral pedicle screw (BPS) fixation, which requires patient repositioning to obtain access to both pedicles and results in longer surgical times compared to single-position surgery [2, 4, 6].

While some studies have advocated for unilateral pedicle screw (UPS) fixation, which can be accomplished without patient repositioning, BPS may offer several advantages. Both methods of posterior fixation have been shown to decrease range of motion (ROM) and increase the stiffness of the spine during the fusion process, but several studies have noted a difference in the degree of effectiveness between these two fixation methods [7-10]. UPS fixation has been associated with increased segmental ROM, increased subsidence, less stiffness, and increased off-axis movement when compared to BPS; however, UPS is clinically associated with shorter surgical times, less blood loss, faster pain relief, and faster functional recovery [7-10]. Consequently, patient repositioning during LLIF is required for BPS, which leads to longer surgery times and increased blood loss. However, the authors theorize that the use of robot-assisted surgery may mitigate the increased operative time of BPS fixation (compared to UPS) while retaining optimum biomechanics.

The purpose of this study was to compare surgical times, radiation exposure, and breach rates of single-position robot-assisted navigation of bilateral pedicle screws to those of conventional MIS methods that require patient repositioning. Testing parameters were evaluated in an *in vitro* testing environment that simulated LLIF and bilateral posterior fixation surgical procedures.

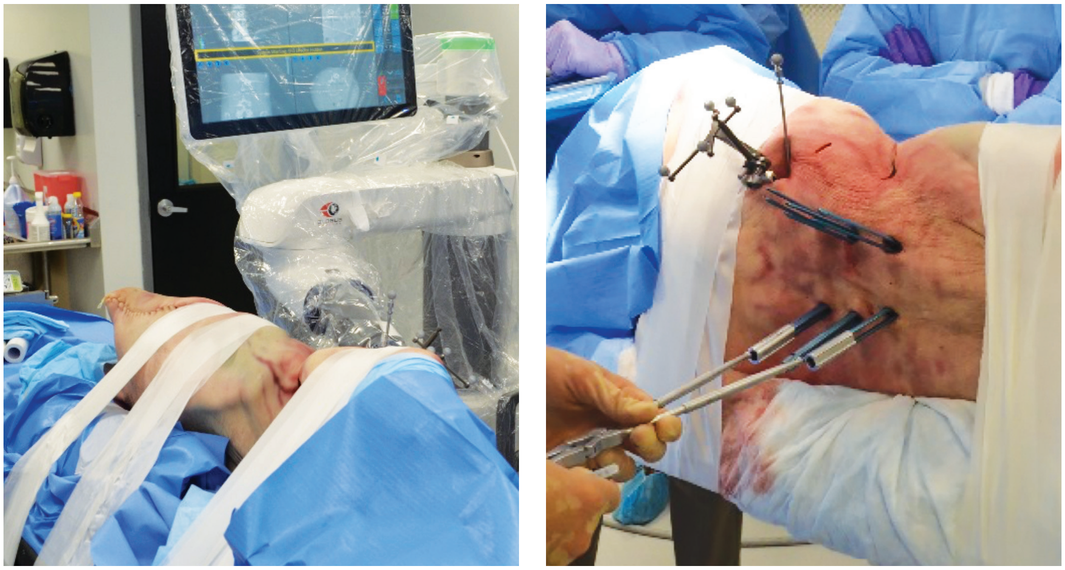

Figure 1: ExcelsiusGPS® robot-assisted navigation system used for the placement of bilateral pedicle screw fixation from the lateral decubitis position.

Materials and Methods

Specimen Preparation

Twelve unembalmed human torsos were used for this investigation (L2-L4). All specimens were selected based on lateral and anteroposterior radiography, and the absence of gross pathology. Dual-energy X-ray absorptiometry scans were obtained with a Lunar Prodigy Scanner 8743 (GE Medical Systems, Madison, WI) to evaluate bone mineral density (BMD). All specimens were double-wrapped in plastic bags and stored at -20°C until testing.

Surgical Construct

Each specimen was separated into one of two treatment groups. All specimens in each group had a two-level LLIF followed by posterior fixation via MIS insertion using conventional methods (CMIS) or a robotic guidance and navigation system (ExcelsiusGPS®, Globus Medical, Inc., Audubon, PA) that utilized a CT scan. The CT scan was merged with intraoperative fluoroscopy to facilitate screw planning. The operative construct was an LLIF using PEEK static LLIF spacers (TransContinental®, Globus Medical, Inc.) from L2-L4 followed by posterior fixation utilizing titanium alloy (TAV) pedicle screws (CREO MIS® Stabilization System, Globus Medical, Inc.) and 5.5mm-diameter TAV rods. Screw sizes were selected based on pedicle dimension. Following implant placement, postoperative data collection was performed with a CT scanner (O-Arm® Intraoperative 2D/3D Imagine System, Medtronic, Inc., Minneapolis, MN).

Experimental Procedure

Time and radiation were recorded for each procedural step using a calibrated stopwatch and C-arm software, respectively. The LLIF procedure was performed as follows: the specimen was placed on a surgical table in a straight 90° right lateral decubitus position and secured to the table, while surgical chucks were placed underneath to improve disc space access. The operative area was carefully cleaned and an incision locator was used to identify the center of the disc space to be treated. Incision marks were traced on the specimen’s skin to indicate the position and insertion site for the retractor.

Following access, disc preparation began with an annulotomy using a bayoneted knife to create a window centered in the anterior half of the annulus. A Cobb elevator was passed along both endplates through the disc space, far enough to provide release of the contralateral annulus. Leaving the posterior annulus intact, the intervertebral disc and osteophytes were removed as needed. The intervertebral space was trialed using the static trials to determine implant length and size. After trialing, the appropriately sized spacer was inserted manually into the intervertebral space using the holder and insertion instruments. Implant position was confirmed utilizing tantalum beads internal to the spacer.

Bilateral posterior fixation for the robot-assisted navigation group was performed using the preoperative CT workflow. First, screw planning was performed on ExcelsiusGPS® proprietary software. Each pedicle screw was virtually planned to the desired trajectory and size, and confirmed by the surgeon. While the screw planning phase can be carried out before or during the case, the recorded procedural time was considered to have occurred prior to surgery. Next, C-arm images were gathered to register the preoperative plan to the current intraoperative patient positioning. This procedure, referred to as registration or merging, was conducted following placement of interbody spacers to account for any displacement due to spacer insertion. Segmental registration was performed using lateral and anteroposterior C-arm images, with vertebral body identification performed using the robotic software. Once registration was complete, screws were inserted through the robotic arm end effector, by positioning the rigid robotic arm to the planned trajectory. During screw insertion, the navigation software tracked the screw and instruments. Screws were inserted according to the steps outlined in Figure 2.

Bilateral fixation for the conventional MIS group involved repositioning the patient prone. Screw insertion for conventional MIS involved identification of the pedicles. Jamshidi and K-wire insertion was then performed for all screws in succession. Following K-wire insertion, each pedicle was tapped and pedicle screw inserted.

After surgery, all spines were excised and stored at -20°C until future testing.

<table>
<tr><th colspan="3">Procedural Workflow</th></tr>
<tr><th colspan="2">LLIF</th><th>Steps</th></tr>
<tr><td colspan="2">Setup</td><td>• Identification of spinous process
• Identification of ALL/PLL</td></tr>
<tr><td colspan="2">LLIF Workflow</td><td>• Incision
• Dissect through muscle layer
• K-wire placement in disc
• Verify placement
• Dilators, cannula, and retractor insertion</td></tr>
<tr><th colspan="2">Conventional MIS</th><th>Steps</th></tr>
<tr><td colspan="2">Setup</td><td>• Demarcation of pedicles with marker
• Identification of vertebrae</td></tr>
<tr><td colspan="2">Posterior Fixation Workflow</td><td>• Incision
• Jamshidi needle insertion
• K-wire placement
• Tapping of pedicle
• Screw placement
• Rod insertion</td></tr>
<tr><th colspan="2">Robotic Navigation</th><th>Steps</th></tr>
<tr><td colspan="2">Preoperative Setup</td><td>• Software setup
• Pedicle screw planning
• Instrument verification</td></tr>
<tr><td rowspan="2">Posterior Fixation Workflow</td><td>Registration</td><td>• Dynamic reference array insertion/attachment
• Anatomic landmark check
• Intraoperative registration/merge with preoperative CT scan</td></tr>
<tr><td>Pedicle Screw Insertion</td><td>• Incision
• Preparatory drilling
• Tapping of pedicle
• Screw placement
• Rod insertion</td></tr>
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Figure 2: Procedural workflow.

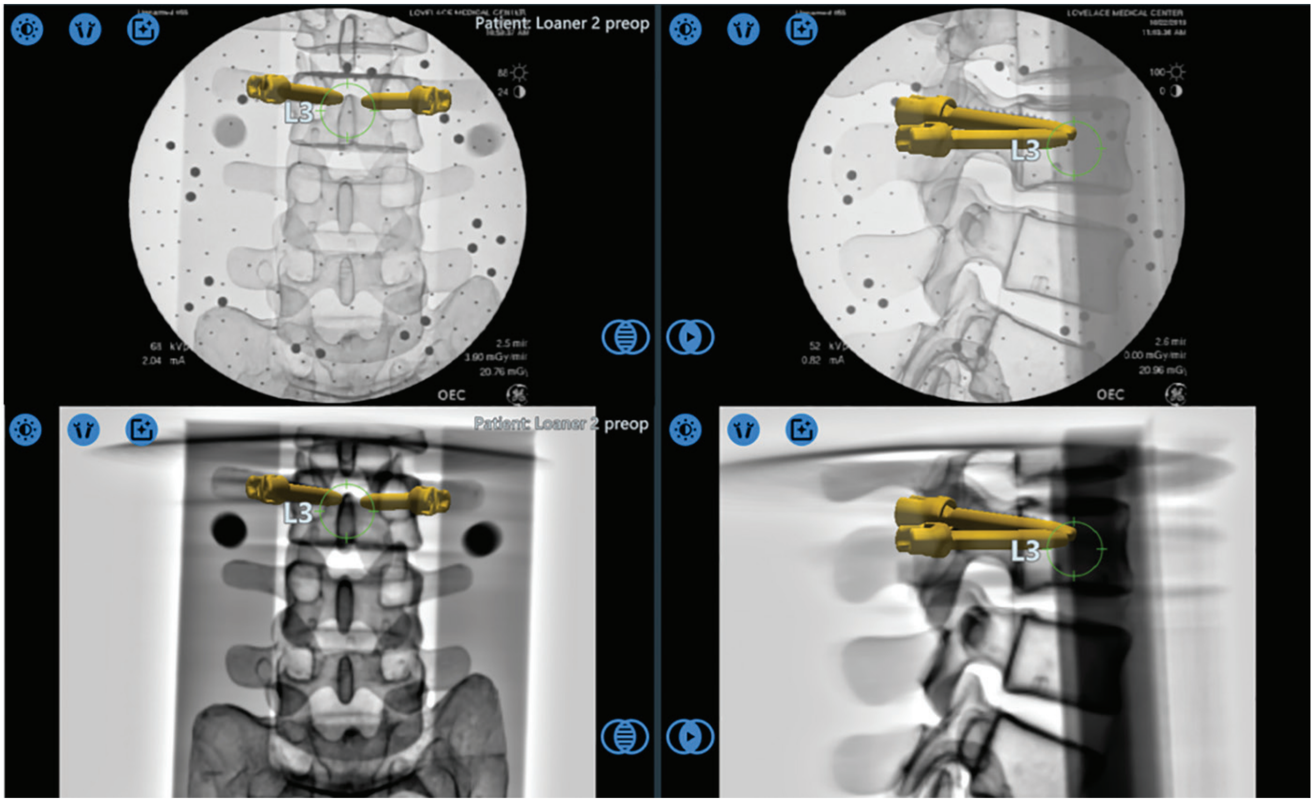

Figure 3: Intraoperative merge and preoperative plan comparison.

Breach Score

Operative levels were disarticulated for physical inspection of potential breaches. Radiographic images (O-arm scan and axial fluoroscopic images) were reviewed by a researcher and grades were assigned according to a breach classification system. The grading scale for the extent of screw malposition at each tested level was as follows (distance was measured from lateral pedicle wall to the most lateral surface of the pedicle screw): (1) In the pedicle, (2) 0≤2.0mm, (3) 2.0≤4.0mm, (4) 4.0≤6.0mm, and (5) <6.0mm [11]. The accuracy of the robot-assisted screw placement was compared to the traditional MIS method.

Radiation

During both the LLIF and posterior fixation procedures, C-Arm fluoroscopy was used for intraoperative imaging for the insertion of spacer or pedicle screws. During these procedures radiation exposure was reported by C-arm software, following each use, as rads. Radiation exposure was separated into either LLIF or posterior fixation. Posterior fixation was determined by group, K-wire/Jamshidi insertion (CMIS group), and intraoperative registration (RAN group).

Statistical Analysis

Statistical analysis was performed using IBM SPSS® Statistics software (SPSS® v22, IBM Corp., Armonk, NY). Comparisons were made between operative techniques in terms of (1) total operative time and (2) surgeon radiation exposure. An independent samples t-test was performed to assess differences in surgical time and radiation. Statistical significance was indicated at $P<0.05$.

Results

Significant differences in surgical time and radiation dosages were found between the two groups. Surgical times for preoperative RAN and CMIS were 64.7±4.1 and 123.0±13.7 min, respectively, as shown in Table 1. Insertion times per screw for single-position RAN and multi-positional CMIS workflows were 2.7±0.6 and 4.3±1.3 min, respectively. RAN resulted in significantly less surgical time and time per screw insertion compared to CMIS ($P<0.05$). RAN and CMIS radiation dosages during posterior fixation were 0.4±0.2 and 2.7±1.6 rad, respectively ($P<0.05$). Screw accuracy, in the form of breach grading, was as follows: CMIS resulted in four total breaches, averaging a breach grade of 1.28, with two grade-2 breaches and two grade-5 breaches (11% of total insertions) while RAN resulted in a single grade-2 breach (3% of total insertion) resulting in an average breach grade of 1.03.

	Procedural Step	Single-Position Robot-Assisted Navigation (Preoperative)	Multi-Positional Conventional Minimally Invasive Surgery	*P* Value
Time (min) Average ± SD	LLIF Insertion	26.5 ± 4.1	32.3 ± 9.2	0.187
	Patient Repositioning	N/A	59.8	N/A
	Posterior Fixation	29.2 ± 4.9	30.8± 7.1	0.833
	Per Screw Time	2.7 ± 0.6	4.3 ± 1.3	0.024
	Total	64.7 ± 4.1	123.0 ± 13.7	**<0.001**
Radiation (rad) Average ± SD	Posterior Fixation	0.4 ± 0.2	2.7 ± 1.6	0.005
	Total	1.7 ± 0.4	4.4 ± 2.1	**0.01**

Table 1: Surgical time and radiation dosage comparison between RAN and CMIS.

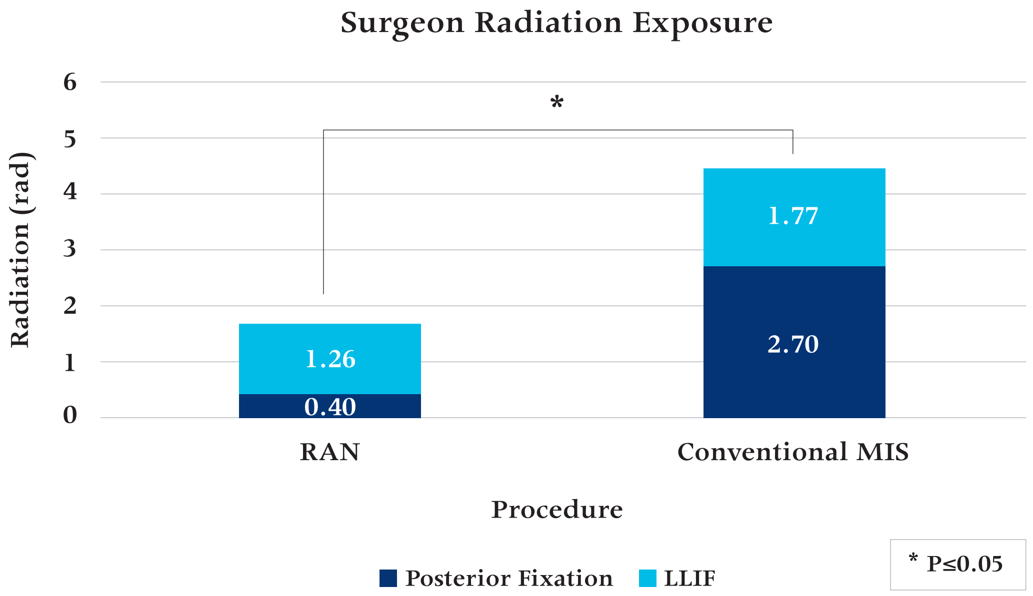

Figure 4: Surgeon radiation exposure comparison between RAN and CMIS. Radiation for posterior fixation includes exposure during image registration, screw placement, and rod placement, when applicable per procedure.

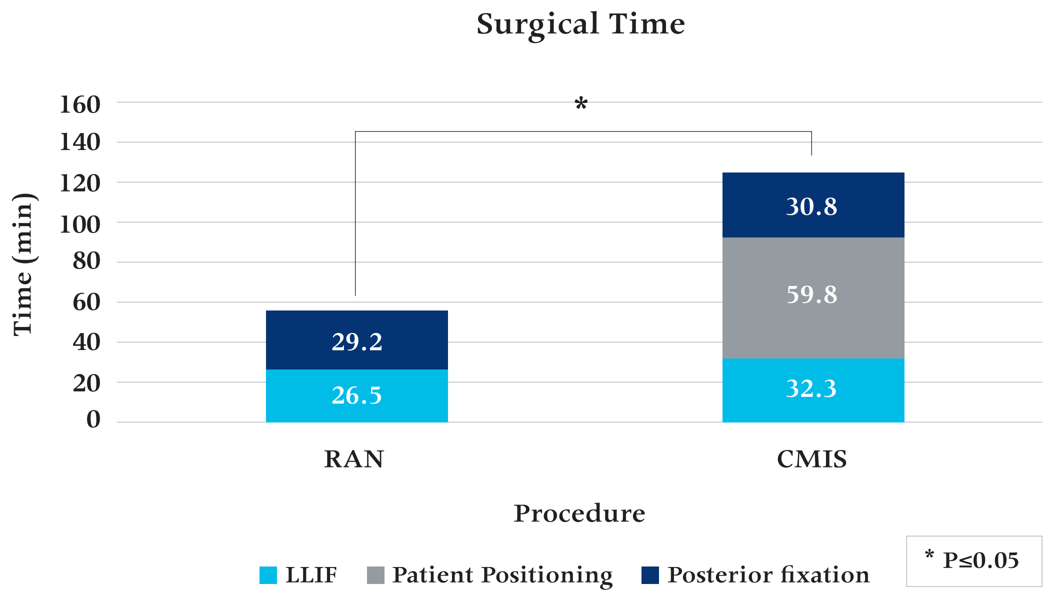

Figure 5: Surgical time breakdown comparison between RAN and CMIS.

Discussion

Following an LLIF procedure, posterior fixation is often required and has historically involved repositioning the patient prone to gain access to both pedicles [6]. This repositioning adds significant time to both the surgery and duration of the patient's anesthesia. The need for patient repositioning is a significant concern due to the time, resources, and hospital staff required for redraping and repositioning the patient from the lateral decubitus position to prone [6]. Previous studies have demonstrated the efficacy of the single-position technique, for both LLIF and posterior fixation in the reduction of operative time by eliminating the need for patient repositioning [6, 12]. The present study investigated ExcelsiusGPS®, a platform that incorporates navigation and robotics for screw planning, and the placement of bilateral pedicle screws following LLIF without the need for patient repositioning using the preoperative CT/registration merge workflow. Studies have shown that the single-position technique reduces surgical time, while other studies have shown that utilizing RAN reduces surgeon radiation dosage [8, 12-14].

The purpose of this study was to quantify and compare conventional MIS versus RAN techniques, in terms of radiation exposure, surgical time, and screw accuracy in an *in vitro* setting. In this model, there was a significant difference in total procedural time, time per screw insertion, and radiation exposure between conventional MIS and the ExcelsiusGPS® platform ($P<0.05$). There were more breaches and higher grade breaches for conventional MIS (11%) than for RAN (3%). The reduced number of breaches for RAN versus conventional MIS methods was also found by Gelalis et al., who performed a review of *in vivo* studies that compared freehand fluoroscopy guidance to navigation techniques [15].

The current study found that despite the additional setup time required for ExcelsiusGPS®, including mounting and registering a dynamic reference array, the total operative time is significantly shorter compared to conventional minimally invasive techniques that require patient repositioning (total operative time: 123.0±13.7 vs. 64.7±4.1). The total time of posterior fixation, however, was similar between treatments. Reduction of total operative time, including the insertion of bilateral posterior fixation without the need for patient repositioning, correlates with studies performed by Ziino et al. and Drazin et al. that reported that the single-position procedure resulted in significantly shorter operative times while not compromising lumbar lordosis, complication rates, or perioperative outcomes [8, 12].

The benefits of the single-position lateral procedure have been established in both cadaveric and clinical settings. The ExcelsiusGPS® system allows for the retention of those time benefits while also reducing surgeon radiation exposure and increasing pedicle screw accuracy. Villard et al. performed a radiation dosage comparison for physicians' eyes, chest, and forearms during posterior fixation following a transforaminal lumbar interbody fusion using conventional MIS or navigated techniques. They found that the use of navigation reduced the amount of surgeon radiation exposure in all categories while also reducing cumulative patient dosages, based on intraoperative CT imaging [13]. The present study's results corroborate this finding by demonstrating significant reduction of radiation exposure during bilateral pedicle screw and rod fixation when using the ExcelsiusGPS® system in comparison to conventional MIS techniques.

Although the presented work successfully quantified the effect of single-position surgery in a cadaveric setting, this study was not without its limitations. First, testing was performed in a cadaveric setting and does not take into account the difficulties and complications experienced in a clinical setting. Second, LLIF accuracy and disc preparation were not focuses of the study; however, these steps would not be expected to significantly impact the findings, due to the LLIF methods remaining constant for both groups.

Conclusion

The present *in vitro* study demonstrated that the ExcelsiusGPS® robotic navigation system significantly reduced surgical time and radiation exposure in comparison to conventional MIS procedures in a simulated *in vitro* surgical model. Robot-assisted navigation required setup time and fluoroscopic registration; however, the time required for setup and registration was offset by faster per screw insertion time for RAN and by the patient repositioning required in the conventional MIS group. The ExcelsiusGPS® system demonstrates the potential use of robot-assisted navigation for single-position LLIFs, which may result clinically in shorter surgical times and less radiation exposure than conventional methods. Future considerations should involve clinical investigations.

References

1. Tay, B.B. and S. Berven, Indications, techniques, and complications of lumbar interbody fusion. *Semin Neurol*, 2002. 22(2): p. 221-30.

2. Talia, A.J., et al., Comparison of the different surgical approaches for lumbar interbody fusion. *J Clin Neurosci*, 2015. 22(2): p. 243-51.

3. Teng, I., et al., A meta-analysis comparing ALIF, PLIF, TLIF and LLIF. *J Clin Neurosci*, 2017. 44: p. 11-7.

4. Winder, M.J. and S. Gambhir, Comparison of ALIF vs. XLIF for L4/5 interbody fusion: pros, cons, and literature review. *J Spine Surg*, 2016. 2(1): p. 2-8.

5. Cappuccino, A., et al., Biomechanical analysis and review of lateral lumbar fusion constructs. *Spine (Phila Pa 1976)*, 2010. 35(26 Suppl): p. S361-7.

6. Blizzard, D.J. and J.A. Thomas, MIS Single-position lateral and oblique lateral lumbar interbody fusion and bilateral pedicle screw fixation: feasibility and perioperative results. *Spine (Phila Pa 1976)*, 2018. 43(6): p. 440-6.

7. Chen, S.H., et al., Biomechanical comparison of unilateral and bilateral pedicle screws fixation for transforaminal lumbar interbody fusion after decompressive surgery--a finite element analysis. *BMC Musculoskelet Disord*, 2012. 13: p. 72.

8. Ziino, C., et al., Single position versus lateral-then-prone positioning for lateral interbody fusion and pedicle screw fixation. *J Spine Surg*, 2018. 4(4): p. 717-24.

9. Kasai, Y., et al., Biomechanical study of the lumbar spine using a unilateral pedicle screw fixation system. *J Clin Neurosci*, 2010. 17(3): p. 364-7.

10. Gertzbein, S.D. and S.E. Robbins, Accuracy of pedicular screw placement in vivo. *Spine (Phila Pa 1976)*, 1990. 15(1): p. 11-4.

11. Drazin, D., T.T. Kim, and J.P. Johnson, Simultaneous lateral interbody fusion and posterior percutaneous instrumentation: early experience and technical considerations. *Biomed Res Int*, 2015. 2015: p. 458284.

12. Villard, J., et al., Radiation exposure to the surgeon and the patient during posterior lumbar spinal instrumentation: a prospective randomized comparison of navigated versus non-navigated freehand techniques. *Spine (Phila Pa 1976)*, 2014. 39(13): p. 1004-9.

13. Hyun, S.J., et al., Minimally invasive robotic versus open fluoroscopic-guided spinal instrumented fusions: a randomized controlled trial. *Spine (Phila Pa 1976)*, 2017. 42(6): p. 353-8.

14. Gelalis, I.D., et al., Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. *Eur Spine J*, 2012. 21(2): p. 247-55.