

MIS TLIF, EndoTLIF, and the Ability of Navigation/Robotics to Enable Spinal Surgery in an Ambulatory Care Setting

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Abstract

Study Design: Technical Report.

Objective: Performing surgeries in the ambulatory surgery center affords improved efficiencies in terms of cost and speed. However, ambulatory surgery is only successful if complications, re-admissions, and re-operations are avoided. This report describes the San Diego Outpatient Lumbar Fusion Program, a culmination of cumulative incremental improvements in patient selection and patient education, meticulous peri-operative management, minimally invasive techniques together with navigation/robotics.

Methods: Retrospective review of prospectively collected data on 1–2 level minimally invasive transforaminal lumbar interbody fusions (MIS TLIF).

Results: Healthy patients (age 72 years old or less, BMI less than 50, ASA I or 2) with good social support and reasonable pre-operative function (ODI 50 or less) treated with the MIS TLIF technique can be discharged home in less than 1 midnight with good clinical results.

Conclusions: Relatively young, healthy patients can safely and effectively undergo 1–2 level lumbar fusion surgery in the ASC setting when using contemporary minimally invasive techniques and computer-assisted navigation/robotics.

Keywords

lumbar, lumbar interbody fusion, sagittal alignment, pedicle screw, stenosis, spondylolisthesis, low back pain, sagittal balance

Introduction

Lumbar interbody fusion surgery remains the mainstay of treatment for many spinal disorders. Currently, the vast majority of such surgeries are performed in the acute care hospital inpatient setting.¹ Posterior lumbar fusion surgery has evolved to become less invasive, with less pain, decreased morbidity, and shorter recovery.² This evolution has occurred through cumulative incremental improvements in patient selection, patient education, meticulous peri-operative management, and the application of cutting-edge technologies including advanced minimally invasive techniques and intraoperative navigation/robotics, along with ongoing process improvement efforts.³ We are now at a place similar to orthopaedic sports surgeons, where we can

transition much of our spinal procedures to the ambulatory surgery center (ASC) setting, including posterior lumbar interbody fusions.

The ambulatory surgery setting has numerous potential advantages. First and foremost, it promises to improve the efficiency of care, by decreasing costs and increasing speed.¹ But numerous other advantages are evident. Mundane issues such as accessibility, parking, and customer service, often

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neglected by large hospital systems, may not be trivial for patients with pain and disability. In addition, ASCs tend to have smaller teams, allowing for more consistency in staffing. Finally, the issue of physician burnout may be addressed by creating an environment where the surgeon feels engaged as a key member of the enterprise. This is especially relevant in the hospital setting where surgeons are greatly outnumbered by the explosive growth of hospital administrators who may try to unduly influence surgical decision-making.⁴

Beyond the added convenience, improved working environment, and improved efficiencies of the ASC, outpatient posterior lumbar interbody fusions must be safe and clinically effective. Ultimately, it must provide an added benefit to the patient, as well as, to the healthcare system as a whole. This study describes our experience with minimally invasive posterior lumbar interbody fusion procedures (MIS TLIF and EndoTLIF) using navigation/robotics. Combined with processes for careful patient selection, contemporary patient education, and meticulous peri-operative management, the

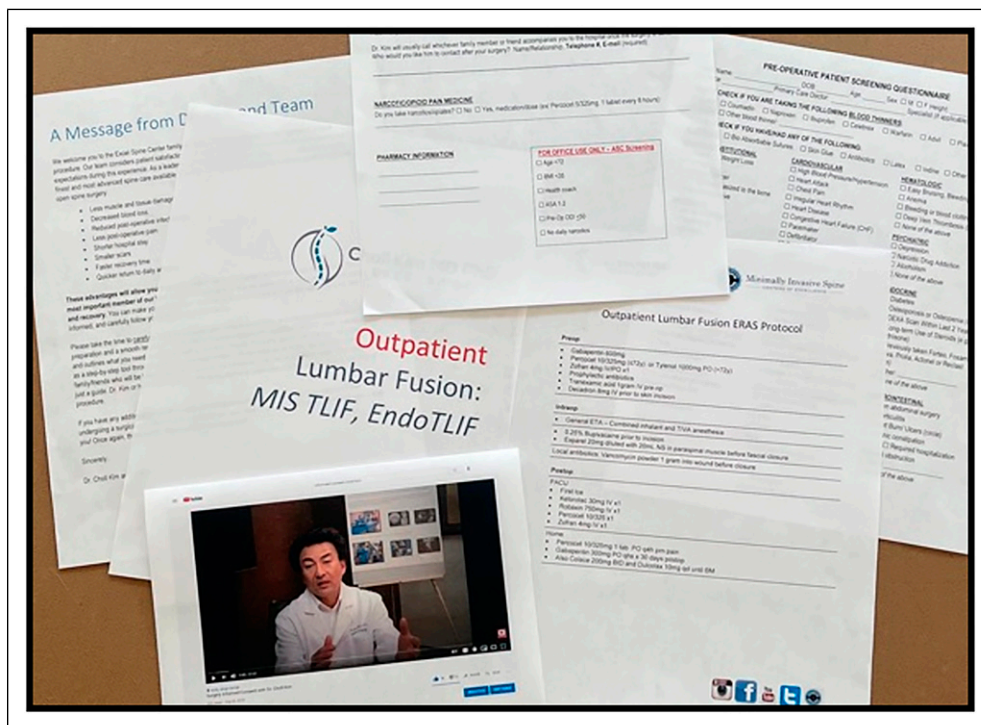


Figure 1. Patient selection and education are vital to a successful outpatient spine fusion program. Screening questionnaires combined with informational handouts and videos assist with proper patient selection, manage expectations, and allows the team to monitor results and make incremental improvements over time.

Table 1. Summary of outpatient MIS TLIF and EndoTLIF surgery.

	All MIS TLIF, EndoTLIF	Outpatient Group	Facility with Nav	Facility without Nav
Total patients	104	43	38	5
Male	56	24	23	1
Female	46	19	15	4
Age (range)	65.5 (31–88)	60y (31–71)	60y (35–71)	61.2 (58–66)
BMI	27.6 (19.5–46.0)	26.6 (20.0–33.9)	26.8 (20.2–33.9)	25.2 (20.3–32.3)
Preop ODI	43.7 (16–100)	37.2 (18–50)	36.8 (16–50)	40.8 (32–44)
LOS (midnights)	1.2 (1–4)	0.8 (0–2)	0.8 (0–2)	1.2 (1–2)
Postop ODI	23.3 (0–86)	17.6 (0–54)	17.5 (0–54)	18.8 (10–34)
PGI-I	1.9 (1–6)	1.8 (1–6)	1.8 (0–6)	1.8 (1–3)
Complications	3/104	1/43	1/38	0/5
30-Day Readmissions	0/104	0/43	0/38	0/5
90-Day Reoperations	1/104	0/43	0/38	0/5

San Diego Outpatient Lumbar Fusion Program describes the parameters that allow for safe and effective treatment of spine fusion patients in the ASC setting. It also serves as a starting point by which to pursue additional improvements in the future.

Materials and Methods

This is a retrospective review of prospectively collected data, along with a description of the processes used in our outpatient lumbar fusion program, which is a combination of patient selection, patient education and customer service, meticulous peri-operative management, the application of minimally invasive techniques and navigation/robotics, and ongoing process improvement. Informed consent was obtained from all patients (Aspire IRB #520130239).

Patient Selection

Patients who have elected to proceed with a 1–2 level posterior lumbar interbody fusion surgery, a pre-operative questionnaire is used to assess for outpatient surgery eligibility. Patients are screened for key psychosocial, medical, and disability parameters. Patients with poor social support, poor communication skills, and poor coping skills are considered poor candidates for outpatient lumbar fusion surgery. In addition, factors such as age, medical comorbidities (including obesity), narcotic dependence, and level of pre-operative disability are used to screen patients for suitability (Figure 1).⁵

We examined all patients undergoing 1–2 level MIS TLIF and EndoTLIF procedures between January 1, 2019 and December 31, 2020 via a retrospective review of prospectively collected data (Aspire IRB approved #520130239). A total of 104 patients underwent 1–2 level MIS TLIF or EndoTLIF performed by a single surgeon during this time period. The selection criteria for the San Diego Outpatient Lumbar Fusion Program are as follows: patients age 72 years or younger, body mass index (BMI) less than 35, does not live alone, and is not dependent on daily opiate use. Furthermore, patients are selected for outpatient lumbar fusion surgery using medical and functional parameters. All patients are ASA 1 or 2 and have a pre-operative ODI score of 50 or less (Table 1).⁵ Of the 104 patients undergoing 1–2 level lumbar fusion surgery, 43 patients were suitable for outpatient surgery,

Patient Education

Patient education is an important part of a successful outpatient lumbar fusion practice. We utilize a combination of verbal education, printed materials, electronic media and videos (Figure 1). The information is given in multiple phases through the pre-operative, peri-operative, and post-operative period, again in multiple formats including verbal, electronic, and video communication. Both the patient and the assigned family member are asked to participate in all phases of the process.

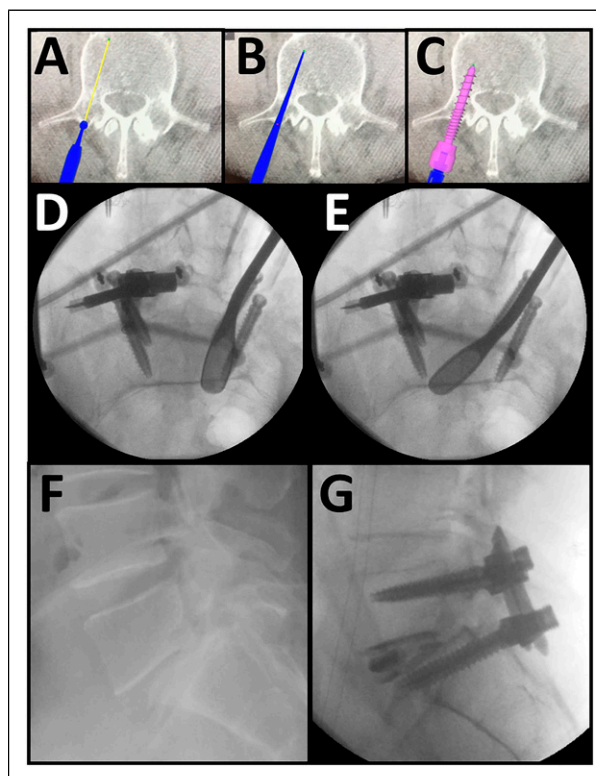


Figure 2. Computer navigation assisted minimally invasive lumbar interbody fusion. Computer navigation is used to identify and create optimal trajectories for pedicle screw insertion. (A) Axial view of vertebral body is used to create the optimal entry point into the pedicle using a navigated 5 mm round cutting burr, similar to that used in traditional open surgery. (B) Once the entry point is created, the navigation gearshift probe is used to sound the pedicle and create a path for the screw within the vertebral body. The optimal screw fills the pedicle and touches the inner wall of the bony cortex and is positioned in-line with the axis of the pedicle, parallel to the upper endplate.¹⁰ (C) Pedicle of the appropriate size (usually 7.5 mm diameter and 45 mm length at L4, L5, and S1) is inserted with navigation along the track created by the gearshift probe. The anterior longitudinal ligament (ALL) and anterior annulus can be released from a posterior approach with great care. Using a navigated rotating shaver, the anterior annulus and ALL are released at the midline. Curved rotating shavers can be used with intra-operative C-arm imaging in the pelvic inlet view to release the anterior structures more laterally as needed (D and E). Careful review of pre-operative imaging is needed to avoid injury to the blood vessels anterior to the spine. The lateral x-ray images before (F) and after (G) surgery shows a typical realignment of the interbody space.

The first information packet is a general information and screening sheet given to the patient and family at the time surgery is considered. They are asked to review the information packet prior to making a final decision on surgery. Thereafter, highlighted information is subdivided into smaller packets appropriate for the phase of the pre-operative and post-operative events. For example, approximately 2 weeks prior to surgery, the patient and assigned family member

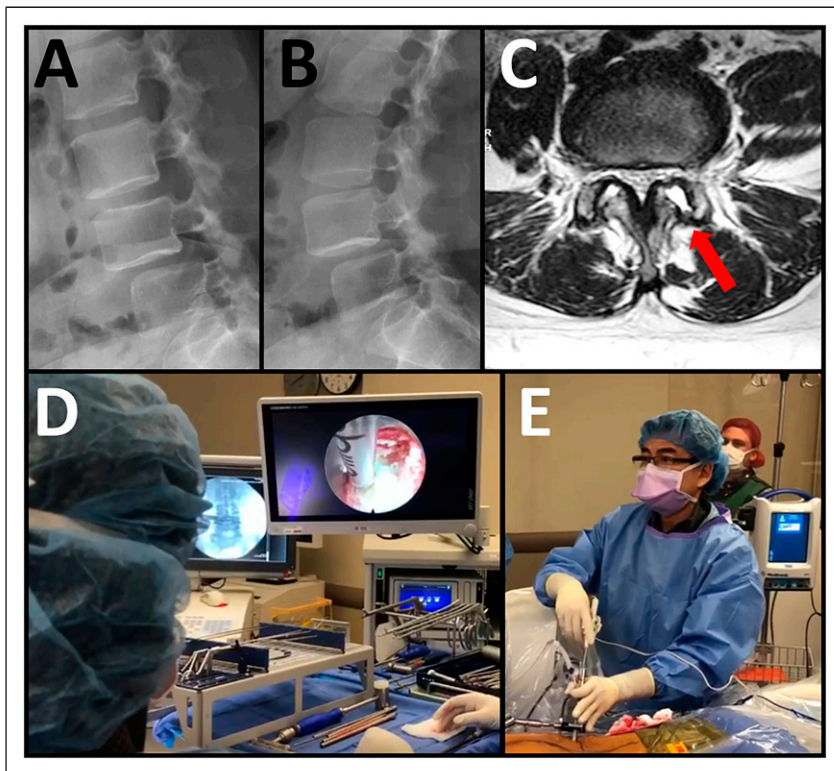


Figure 3. Endoscopically assisted minimally invasive transforaminal interbody fusion (EndoTLIF) is a modification of the MIS TLIF technique. Pedicle screws are inserted with navigation assistance as described. The interbody reconstruction is performed percutaneously and does not include hemilaminectomy to perform a direct decompression. Ideal patients have segmental instability and therefore rely on indirect decompression achieved through segmental realignment and stabilization (A, B). MR imaging may reveal secondary signs of instability such as gapping facet joints (red arrow, C). The interbody space and endplate preparation is performed through an 8 mm working channel and visualized using irrigating endoscope (D, E).

receives the “Preop Info Packet” containing information and checklist items most pertinent to this phase of treatment. We include a video specifically for the informed consent. Importantly, reliable means of communication is established to instill confidence that help is available even after leaving the hospital.

Meticulous Peri-Operative Management

Peri-operative management encompasses the formation of a consistent team that works together frequently in the operating room and the recovery room. This “Spine Team” includes anesthesiology, who follow an agreed-upon ERAS protocol for pre-operative, intra-operative, and post-operative care.⁶ The ERAS protocol is conspicuously available in printed and electronic formats to all spine team members, along with reminders and callouts (Figure 1). For example, patients, family members, and support staff are educated on how to use pain scales along with reminders that post-operative goals are to manage, not eliminate, pain.

Intra-operatively, incision sites are pre-injected with 0.25% bupivacaine. Meticulous hemostasis is achieved prior to wound closure using a combination of hemostatic agents and gentle tamponade for 2–3 minutes. No drains are used. Long-

acting, local anesthetic is injected into the paraspinal musculature prior to fascial closure such as Exparel 20 mL (Pacira Pharmaceuticals, Parsippany, NJ, USA). Dressings are applied so that it does not need to be changed until it is removed in 3 days (i.e., Telfa with small Tegaderm), and thereafter left open to air under a clean garment. Showering is allowed, and encouraged, but no soaking in water (such as bathing or swimming) for at least 4 weeks, or until the incision is healed.

MIS TLIF, EndoTLIF, and Navigation/Robotics

It is the confluence of technological advancements that have made outpatient lumbar interbody fusion possible. Key to these advancements have the application of minimally invasive surgical techniques utilizing advanced intra-operative imaging. We use the minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) and the endoscopically assisted, percutaneous transforaminal lumbar interbody fusion (EndoTLIF) techniques for surgery and computer-assisted navigation/robotics for intra-operative imaging.

MIS TLIF and EndoTLIF. Minimally invasive lumbar fusion strategies are now well established.³ The MIS TLIF technique

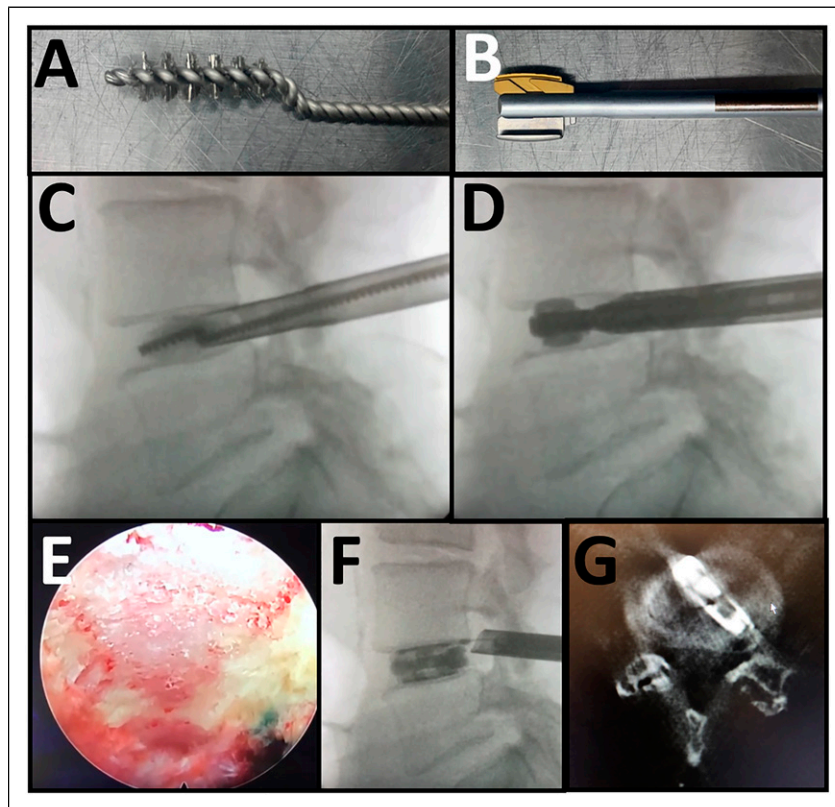


Figure 4. The EndoTLIF technique requires meticulous use of intraoperative imaging and specialized instruments to prepare the interbody space for reconstruction and fusion through an 8 mm working cannula. A combination of the spinning brushes (A, C) and expandable rotating shavers (B, D) are used to carefully remove the endplate cartilage (visualized with the endoscope, E). The interbody spacer is long and narrow and must fit through the 8 mm working cannula. Once inside the interbody space, it is expanded to fill the interbody space until bony opposition with the implant surface (F). The longest implant is used by placing the implant in an oblique position, taking care to avoid cage overhang, especially at the insertion window where the exiting nerve passes nearby (G).

in particular is well described, and well utilized in multiple different practice settings with reliable, consistent results.^{7,8} Contemporary advancements include the use of navigation to place pedicle screws safely and accurately, along with advanced interbody preparation techniques such as posterior release of the anterior annulus and anterior longitudinal ligament to optimize interbody realignment (Figure 2).

Percutaneous techniques for posterior lumbar interbody fusion promises to decrease the surgical morbidity of surgery even further.⁹ Butler, 2020 #8435} The EndoTLIF technique utilizes the spinal endoscope for direct visualization of the interbody space (Elliquence, New York, New York). While the MIS TLIF technique can be used for a wide variety of 1–2 level degenerative lumbar conditions, including those with severe bony stenosis, the EndoTLIF procedure is best used in patients who can be treated by realignment and indirect decompression (Figures 3 and 4).

Navigation/Robotics. The application of navigation and robotics in spine surgery is relatively new. Its promise to improve the efficiency and precision of inserting spinal instrumentation serves the needs of outpatient surgery well.¹⁰ Mal-positioned hardware can cause increased pain and, along

with the need for possible re-operation, can lead to extended stays. The Stealth Navigation System with O-arm image acquisition was used for most cases (Medtronic Spine, Minneapolis, MN, USA).

Ongoing Monitoring and Performance Improvement

The effectiveness of the program is monitored using a registry database system with ongoing monitoring of various outcome measures. Incremental improvements are introduced in a step-wise fashion according to the desired goals. Monthly, quarterly, and annual reports are generated to assist with program analysis and modification/improvement.

Results

Our experience with this program from January 1, 2019 through December 31, 2020 is summarized in Table 1. A total of 104 patients underwent 1–2 level MIS TLIF or EndoTLIF performed by a single surgeon. The average length of stay for the entire group, as measured in the number of midnights, was 1.2 (range 1–4). The average pre-operative ODI score

was 43.7 (range 16–100). Using the inclusion criteria for the San Diego Outpatient Lumbar Fusion Program, 43 of the 104 patients were suitable for outpatient surgery. The average age for the entire group was 65.5 years while the outpatient group was 60.0 years. There were slightly more males than females in both groups. The pre-operative BMI and ODI scores were slightly lower for the outpatient group. The average length of stay for the outpatient group was 0.8 midnights compared to 1.2 for the entire group. The post-operative ODI score of the outpatient group was 17.6 (range 0–54) compared to 37.2 (range 18–50) pre-operatively (Table 1). There were no 30-day re-admissions and no 90-day re-operations in the outpatient group. The pre-operative ODI score 37.2 improved to 17.6 post-operatively. Patient satisfaction was measured with the PGI-I, a validated 7-point Likert scale of the “patient’s global impression of improvement.”¹¹ Scores 1, 2, and 3 are very much improved, much improved, and somewhat improved, respectively. PGI-I score of 4 is no change. And PGI-I scores 5, 6, and 7 are somewhat worse, much worse, and very much worse, respectively. The average PGI-I score for the outpatient group was 1.8 (range 1–6).

We compared surgical outcomes including between facilities with and without navigation/robotics. In 1–2 level, MIS TLIF surgeries at our main facility where we use navigation routinely, the average LOS was 0.8 (range 0–2 midnights) compared to 1.2 midnights (range 1–2) at the facilities without navigation (Table 1).

Discussion

By utilizing state of the art MIS techniques, intra-operative navigation/robotics, together with strict patient selection and a consistent spine team pursuing meticulous peri-operative care, 1–2 level posterior lumbar interbody fusions can be safely and effectively performed in the ASC setting with good clinical results. As the indications for outpatient lumbar fusion surgery expands, ongoing monitoring and process improvement strategies must be in place and frequently reviewed. As practice profiles vary from region to region, this type of monitoring is important to customize the program according to specific needs and desired performance parameters of each surgeon. As stated by Lord Kelvin, “if you cannot measure it, you cannot improve it.”

Summary

Our ability to perform lumbar fusions in the ASC is a result of cumulative incremental improvements in multiple areas of patient care. Advanced technologies, careful patient selection, and contemporary patient education and customer service are keys to success. The ability to perform successful lumbar fusion in the ASC promises improved cost efficiencies, higher patient satisfaction, and a more engaging work environment for the surgeon. Efforts to move lumbar

fusions into the ASC is worthwhile and will likely contribute to improving overall healthcare delivery.

Declaration of Conflicting Interests

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