Observational Study

Full-Endoscopic Lumbar Fusion Outcomes in Patients with Minimal Deformities: A Retrospective Study of Data Collected Between 2011 and 2015

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Background: Open transforaminal lumbar interbody fusion (TLIF) is the gold standard treatment for back pain due to degenerative disc disease and lumbar instability. Traditional open TLIF has been associated with extensive tissue dissection, excessive blood loss, and slow recovery time. Full-endoscopic transforaminal lumbar interbody fusion (FE-TLIF) is an evolving treatment.

Objectives: This study aims to review outcomes of FE-TLIF performed in an ambulatory surgery center (ASC) on patients with advanced disc disease with minimal spinal deformity.

Study Design: This study employed a retrospective cohort design.

Methods: This Western Institutional Review Board-approved study (#1-925640-1) assessed blood loss, operative time (OR time), post anesthesia care unit time (PACU time), and Visual Analog Scale (VAS) of 85 patients who underwent FE-TLIF between 2011 and 2015 and were followed up for 12 months. Relationships between risk factors (demographics, clinical presentation) and outcomes were analyzed.

Results: No intraoperative complications were observed. There were 2 cases of postoperative sympathetically mediated pain and 3 reoperations. The number of decompression/fusion levels was crucial to OR time but had a smaller impact on PACU time. OR time for patients with 2-level fusion was 110 minutes longer than for those with one level operation. BMI and age had no significant effect on OR time. BMI had a modest effect on PACU time. Gender and age did not affect PACU time. A significant decrease in VAS was observed.

Limitations: This study has several limitations, including the lack of a control group and reliance on patient-reported outcomes (VAS). In addition, fusion rate and global sagittal alignment were not measured. Although not statistically significant, the use of facet screws, unilateral, or bilateral pedicle screws presented variation in techniques within the group. Early recovery also diminished the incentive for long-term follow-up.

Conclusion: FE-TLIF is a feasible technique for lumbar stabilization surgery in an ASC in select patients. This level-II study demonstrates safety in a variety of clinical presentations, including obesity, extremes of age, and anatomical access challenge. Larger clinical series are necessary to validate this technique, particularly for the treatment of patients with advanced spinal deformities.

Key words: Full-endoscopic, minimally invasive spine surgery, postoperative complications, TLIF, lumbar fusion, low back pain

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Minimally invasive surgery (MIS) for spinal instrumented fusion has gradually become well-accepted for treatment of lumbar degenerative disease. Reduced destruction of the soft tissue has been reported to achieve reduced postoperative pain and narcotic use as well as diminished length of hospital stay (1-9).

Transforaminal lumbar interbody fusion (TLIF) aims

to decompress nerve impingement, remove damaged disc material, enlarge the neuroforamina through disc height restoration, re-establish segmental stability, and restore sagittal alignment in appropriate anterior loading (10). TLIF has a proven track record for corrective treatment of spondylolisthesis, intractable symptomatic degenerative disc disease, and any form of lumbar instability (10-13). Traditional open TLIF has been challenged by reports of extensive tissue dissection with associated detachment of critical paraspinal support musculature, muscle necrosis, destruction of kinesthetic function of the lumbodorsal fascia, and loss of multifidi muscular support for posterior spine stabilization (14-20).

Tissue-sparing approaches commonly described as minimally invasive surgery are becoming the standard in many areas for treatment of intractable low back pain and radiculopathy; these approaches are preferred over traditional open lumbar surgery in both hospital and ambulatory same-day surgery facilities. Full-endoscopic or arthroscopic techniques with rigid rod lens are becoming the standard tissue-sparing approaches for treatment of central and lateral recess stenosis, intervertebral disc herniation, or any situation that otherwise requires extensive open decompression laminectomy.

Traditional open lumbar fusion intraoperative complication rates vary from 1.4% to 12.8%, and postoperative complication rates vary from 2.8% to 29.8% (1,3,21-24).

MIS fusion is a mini-open procedure that aims to reduce morbidity and complications associated with traditional open fusion as discussed above. MIS fusion can be performed utilizing various approaches, including mini-open, tube cannula, endoscopic, and percutaneous. Microscope or full-endoscope (rigid rod lens) can be used for surgical magnification (25-34).

The primary purpose of this study was to review the surgical outcomes for full-endoscopic MIS lumbar fusion surgical techniques performed in an outpatient facility, with respect to patient demographic, pathologic, and anatomic characteristics as predictors of operating time (OR time), postoperative recovery unit time (PACU time), estimated blood loss (EBL), and postoperative Visual Analog Scale (VAS) pain scores over 12 months.

Method

Literature Review

A computerized search of peer-reviewed original studies, literature reviews, and case reports published before February 2016 was performed (PubMed). Keywords used for the search included "lumbar," "surgery," and "complication." We restricted the language to English. A total of 233 articles were identified and 29 unique complications were reported (1-3,10,12,13,19-24,35-60). These complications were classified into 2 groups: major and minor (Table 1).

Patient Characteristics

We reviewed the medical records of 85 consecutive patients who underwent full-endoscopic minimally invasive lumbar fusion between January 2011 and December 2015.

These patients presented with intractable back pain and clinically significant symptomatic lumbar radiculopathy. All patients had severe disc height loss, and 64% of patients had a grade 1 antero-spondylolisthesis. There were no scoliotic or other advanced deformities.

Table 2 presents demographic characteristics of the patients. Patients' ages ranged from 22 to 89 years, with a mean of 52 years. Patients' body mass index (BMI) ranged from 21.53 to 48.77 kg/m^2, with an average of 31.40 kg/m^2. Seventy-eight percent of patients were Caucasian, with men and women equally represented. Seventy-nine percent of the patients had chronic pain, defined as the constant presence of pain for over 2 years, and 24% had had prior lumbar surgery.

Ninety-two percent of the patient population for this study presented lumbar disc herniation, protrusion, or extrusion. Other clinical presentations included severe facet arthropathy (80%), advanced degenerative disc (73%), and spondylolisthesis (64%). Table 3 summarizes the clinical presentation of pathologies.

All of the patients had failed conservative treatment for at least 6 months and nerve compressions were confirmed by magnetic resonance imaging (MRI) or CT. Summary of various presenting symptoms is shown in Table 4.

Men typically have a narrower pelvic opening and higher iliac crest, which increase challenges to access by posterior lateral/transforaminal entry.

Fusion levels were nearly evenly distributed across the patient population of this study (Fig. 1). Table 4 details the levels of fusion and decompression surgeries performed. The statistical analysis described in Tables 6 and 7 points to the levels of decompression and the number of levels of fusion most relevant for predicting outcomes. For decompression, the 3-category factor identifying L5/S1 only, L5/S1 plus other levels, or levels

Table 1. *Intraoperative and postoperative complications.*

Type of Complication	No. Incidents	% Occurrence
Minor Complications	**2**	**2.35**
Donor site pain	0	0
Ileus	0	0
Muscle spasm	0	0
Superficial wound infection	0	0
SMP[1]	2	2.35
Transient urinary retention	0	0
Major Complications	**3**	**3.53**
Arachnoiditis	0	0
Bowel perforation	0	0
Cardiac arrest	0	0
Complication from epidural block	0	0
Deep venous thrombosis	0	0
Deep wound infection	0	0
Dural tear	0	0
ER visit[2]	0	0
Fracture of interior articular process	0	0
Hospitalization	0	0
New neurological deficit	0	0
Nonfusion	0	0
Optical blindness	0	0
Pulmonary embolism	0	0
Re-operation	3	3.53
Retrograde ejaculation	0	0
Stroke	0	0
Systemic infection	0	0
Transfusion	0	0
Uncontrolled bleeding	0	0
Ureteral avulsion	0	0
Vascular damage	0	0
Wrong level exposure	0	0
Overall Complications	**5**	**5.88**

[1] SMP= sympathetically mediated pain
2 ER= emergency room

Table 2. *Clinical demographic data.*

Demographic Information	No. Patients	%
Age		
20-29	3	3.53
30-39	7	8.24
40-49	28	32.94
50-59	24	28.24
60-89	23	27.06
Gender		
Women	41	48.24
Men	44	51.76
Ethnicity		
African American	4	4.71
American Indian/Alaska Native	3	3.53
Asian	1	1.18
Caucasian	66	77.65
Hispanic/Latino	7	8.24
Multi-ethnic	4	4.71
Native Hawaiian/Pacific Islander	0	0
BMI (kg/m^2)[1]		
<18.5	0	0
18.5-24.99	9	10.59
25.00-29.99	33	38.82
30.00-34.99	21	24.71
35.00-39.99	14	16.47
> 40.00	8	9.41
Smoking History		
Non-smoker	37	43.53
Quitter	15	17.65
Smoker	33	38.82
Time Between Date of Injury and Date of Surgery		
< 1 yr	15	17.65
1-2 yrs	3	3.53
> 2 yrs	20	23.53
> 5 yrs	47	55.29
Injury Type		
Chronic	67	78.82
MVA/PI[2]	15	17.65
Work-related	3	3.53
Prior Lumbar Surgery		
Yes	20	23.53
No	65	76.47

[1] BMI = body mass index
[2] MVA/PI = motor vehicle accident/personal injury

other than L5/S1 is used. For fusion, the number of spinal levels performed is relevant for predicting outcomes.

Surgical Setting

This study was performed in a free-standing ambulatory facility.

Anesthetic Technique

Epidural analgesia was administered to all of the patients. None of the patients had general endotracheal anesthesia. All patients were placed in the prone position with monitoring by an anesthesiologist. Supplemental oxygen was given by nasal prongs or face mask. Epidural narcotic medication was administered. The epidural procedure was performed by a surgeon using bi-planar fluoroscopic verification of needle placement with radiographic contrast agent. Most patients had light intravenous supplementation with fentanyl and/or midazolam. No patient had loss of consciousness. All patients were able to move legs and feet to command throughout the procedure using a low concentration local anesthetic for the epidural, typically 0.25% bupivacaine further diluted with continuous fluid irrigation intrinsic to the endoscopic visualization technique. The wake-up test was performed in every case for neurophysiological monitoring with documentation of lower extremity movement on command. This awake-state anesthetic technique offered unique direct and immediate feedback in the event of contact with a neural structure, as patients were instructed to verbalize immediately in response to a painful event. No patient was converted to general anesthetic technique.

Table 3. *Clinical presentation of pathology.*

Clinical Presentation of Pathology	No. Patients	Prevalence (%)
Disc herniation/disc protrusion/extrusion	78	91.76
Facet arthropathy/hypertrophy	68	80.00
Degenerative disc	62	72.94
Spondylolisthesis	54	63.53
Foraminal stenosis	36	42.35
Lateral recess stenosis	28	32.94
Central canal stenosis	17	20.00
Annular tear	13	15.29
Ligamentum flavum stenosis	8	9.41
Osteophyte/bone spur	4	4.71

Table 4. *Pre-operative symptoms.*

	No. Patients	Prevalence (%)
Back Pain Present		
Yes	**71**	**83.53**
No	**4**	**4.71**
Leg Pain Present		
Yes	**72**	**84.71**
No	**13**	**15.29**
Leg Numbness Present		
Yes	**51**	**60.00**
No	**34**	**40.00**
Leg Weakness Present		
Yes	**53**	**62.35**
No	**32**	**37.65**
Leg vs Back, Which Is Worse		
Leg	**12**	**14.12**
Back	**37**	**43.53**
Same	**36**	**42.35**
Distribution of Pain		
Bilateral	**51**	**60.00**
Bilateral, left is worse	**9**	**10.59**
Bilateral, right is worse	**12**	**14.12**
Left	**6**	**7.06**
Right	**7**	**8.24**

Surgical Technique

Full-endoscopic transforaminal technique provided access for the lumbar spine surgery. This is a minimally invasive surgical technique for spinal decompression, a validated and standard procedure (25-30).

The procedure was performed with the patient in a prone position with biplanar radiological imaging. Newer surgical access rigid optics, trephines, ronguers, kerrisons, and burrs were utilized to provide sufficient bone resection under direct, continuous visualization with control. Transforaminal approaches were performed by entering through Kambin's triangle and trephining into the lateral recesses bilaterally for both the direct and indirect decompression techniques; these approaches were completed under direct visual control with a high-speed side-cutting articulating bur and constant cold fluid irrigation. This bilateral approach releases epidural and adnexal tissue as well as hypertrophied facets, rim osteophytes, and undersurfaces of both lamina as well as hypertrophied ligamental flavum. The trephining action via posterior-lateral approach easily addresses both the anterior and posterior osteophytes equally upon entry into the spinal canal, resulting in reduced operating time. Following posterolateral surgical resection extended medially to the ligamentum flavum, the underlying exiting and traversing neural structures can be exposed and visualized. With the joystick technique, there was complete cranial and caudal mobility as well as medial and lateral access

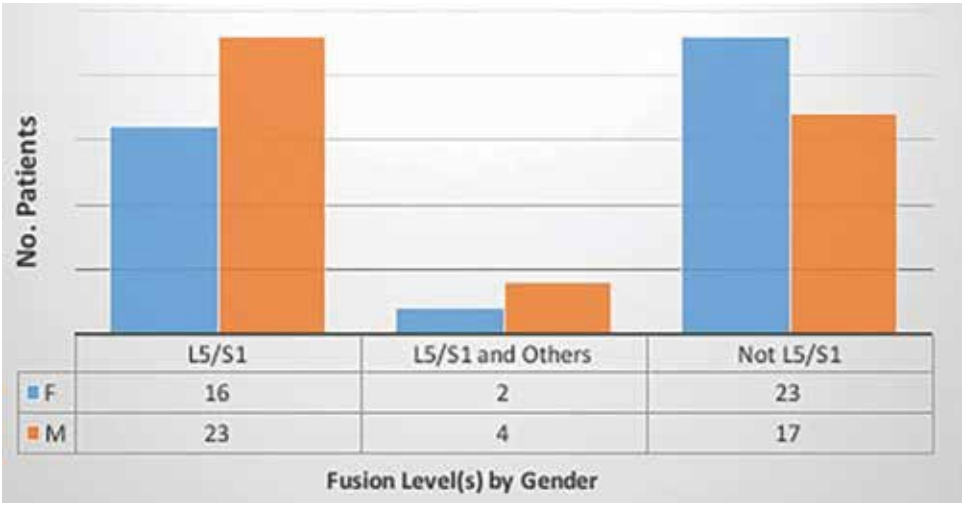

Fig. 1. *Fusion level(s) by gender.*

within the foraminal, lateral recess, and central canal of the epidural space.

Arthrodesis of the targeted intervertebral lumbar segment was accomplished by using a working tube. An intervertebral spacer device (PEEK, bone mesh, expandable or non-expandable cage) was subsequently applied.

Fusion bed preparation was endoscopically verified for cortical bone bleeding surface without endplate destruction. The fusion extender allograft used were OsteoAmp granules (Advanced Biologics, Carlsbad, CA), Vivex -DBM (University of Miami Tissue Bank, Miami, FL), Biomet Spine DBM (Biomet, Parsippany, NJ), or Kinexplus putty (Globus Medical, Philadelphia, PA). None of the cases involved the use of recombinant human bone morphogenic protein-2 (rhBMP-2, Infuse, Medtronic Sofamor Danek, Minneapolis, MN). Allograft bone and harvested iliac crest bone marrow were packed into the cage device.

Posterior fixation used either facet or pedicle screws under bi-planar fluoroscopic guidance. The screws were passed subfascially using dilating tubes to avoid tissue dissection. Facet screws were used for posterior fixation in cases without spondylolisthesis. Five cases used interspinous fusion implants (no screws). Pedicle screws and rods were used in 5 patients with high grade listhesis.

Table 8 summarizes the types of implants and screws used during surgery.

Radiologic qualitative evaluation of fusion stability and hardware alignment was performed at 2 weeks, 2, 4, 6, 9, and 12 months by plain x-rays. This study did not focus on quantitative fusion rate measurement.

Table 5. *Level(s) of surgery performed.*

Fusion Levels	No. Patients
L3/4 only	5
L3/4 and L4/5	5
L4/5 only	31
L4/5 and L5/S1	4
L4/S1	1
L5/6 and L6/S1	1
L5/S1 only	38
Decompression Levels	**No. Patients**
T12/L1 and L5/S1	1
L1/2 and L5/S1	1
L2/3 and L5/S1	1
L2/3, L3/4 and L4/5	1
L3/4 only	3
L3/4 and L4/5	10
L3/4 and L4/S1	1
L3/4 and L5/S1	1
L3/4, L4/5 and L5/S1	2
L4/5 only	21
L4/5 and L5/S1	18
L5/S1 only	24
L5/6	1

Table 6. *Summary of multiple regression of OR time on selected risk factors.*

	Estimate	Std. Error	t value	Pr(>|t|)	
(Intercept)	71.73	31.52	2.28	0.03	*
Age	-66.50	73.08	-0.91	0.04	
Age^2 (squared)	-100.02	71.16	-1.41	0.16	
BMI	-41.21	71.00	-0.58	0.56	
BMI^2 (squared)	94.12	75.50	1.25	0.22	
Male	36.29	16.08	2.26	0.03	*
Osteophyte	-86.45	37.02	-2.34	0.02	*
LegWeakness	41.72	16.75	2.49	0.02	*
Decomp.L5S1plus[1]	38.37	17.09	2.25	0.03	*
Fusion2[2]	109.95	24.26	4.53	2.2E-05	***

Significant codes: "***": $P < 0.0001$, "**": $P < 0.001$, "*": $P < 0.01$
Residual standard error: 69.51 on 75 df
Multiple R^2: 0.39, Adjusted R^2: 0.32
F statistic: 5.29 on 9 and 75 df, P value: 1.416e-05
Average OR time: 247 minutes
Standard deviation: 84 minutes
1 Decomp.L5S1plus = L5/S1 plus other levels of Decompression; [2]Fusion2 = 2-level fusion; Regression coefficient estimates for the analysis of ORTime represent differences in ORTime in minutes relative to the reference category.

Table 7. *Summary of multiple regression of PACU time on selected risk factors.*

	Estimate	Std. Error	t value	Pr(>|t|)	
(Intercept)	5.00	0.19	25.94	< 2e-16	***
Age	0.66	0.57	1.16	0.25	
Age^2 (squared)	0.18	0.54	0.33	0.75	
BMI	1.54	0.55	2.79	0.01	**
BMI^2 (squared)	-0.12	0.56	-0.21	0.83	
Male	-0.03	0.12	-0.27	0.79	
Fstenosis[1]	-0.32	0.13	-2.53	0.01	*
PainSideBilateral	-0.35	0.12	-2.80	< 0.01	**
Fusion2[2]	0.29	0.11	2.61	0.01	*
Decomp.L5S1plus[3]	0.59	0.23	2.50	0.01	*

Residual standard error: 0.5307 on 75 df
Multiple R^2: 0.3363, Adjusted R^2: 0.2567
F statistic: 4.223 on 9 and 75 df, P value: .0001901 Average
PACU time: 201 minutes
Standard deviation: 150 minutes

Outcomes Assessment

Patients completed the VAS for both back and leg pain prior to surgery.

Estimated blood loss, operative complications, OR time, and PACU time were recorded. Patients were assessed during clinical visits or by telephone 1 day, 2 weeks, 2 months, 4 months, 6 months, 9 months, and 1 year post operation to fill out postoperative questionnaires containing VAS for back and leg pain and a satisfaction survey for surgery and quality of life.

Statistical Analysis

Complications were tabulated for comparison with reports in the literature of open microsurgical procedures performed on patients with lumbar spinal stenosis and for comparison with reports of endoscopic surgeries performed in traditional hospital settings. Due to low rates of complications in this study of 85 patients, no formal statistical analyses are reported.

We reported descriptive statistics for relationships between surgical outcomes and a range of possible risk factors. Risk factors included demographic characteristics, pathology, preoperative symptoms, and anatomic targets of the surgery (levels of decompression and fusion). These were summarized in Tables 2-5. *P* values determined from chi-square tests are presented for EBL and patient satisfaction. Changes in VAS pain scores were presented graphically. Continuous outcomes (OR time and PACU time) were assessed using multiple regression analysis models resulting from examination of results of all subsets regression methods with 3 key demographic factors – age, BMI, and gender – forced into all models. Age and BMI were coded as 5-level ordered categorical variables as shown in Table 2, but the original numerical values were used in the regression analyses to permit nonlinear effects represented by quadratic functions of age and BMI (the quadratics were actually represented by orthogonal polynomial terms). Due to the highly skewed distribution of postoperative recovery times, this outcome was analyzed on a log scale, with regression coefficients representing percent differences in PACU time. All subsets regression methods identify sets of risk

Table 8. *Implants summary.*

Types of Implants	No. Patients
Expandable cage - Titanium	7
Expandable cage - Optimesh	7
Non-expandable - PEEK cage	69
Non-expandable - Titanium	2
Types of Screws	No. Patients
Facet screws only	74
Pedicle screws only	5
Facet and pedicle screws	1
No screws (interspinous implants)	5

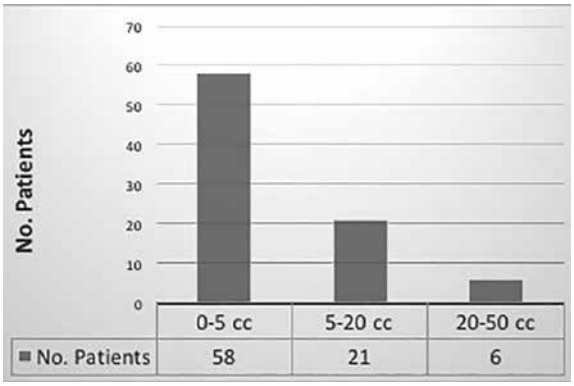

Fig. 2. *Intra-operative estimated blood loss.*

factors that best predict outcomes, using 2 fit criteria to select best-fitting models: adjusted multiple correlation (R^2) and Bayes information criterion. In these analyses, different sets of risk factors can predict nearly equally well. We report single regression models, but comment on other contending risk factors. All analyses were carried out using the R system (61).

Results

Estimated Blood Loss

Results for EBL are reported in Fig. 2.

As shown in Table 9, the probability of EBL higher than 5 mL is greater in cases of lateral recess stenosis. There is a negative correlation between annular tear and EBL when annular tear is a significant factor for fusion surgery.

Table 9. *EBL analysis*

1 Positive correlation between lateral recess stenosis and estimated blood loss

Estimated Blood Loss	LR Stenosis No	LR Stenosis Yes
0-5 mL	45	13
5-20 mL	9	12
20-50 mL	3	3

P value = .008097

2 Negative correlation between annular tear and estimated blood loss

Estimated Blood Loss	Annular Tear No	Annular Tear Yes
0-5 mL	45	13
5-20 mL	21	0
20-50 mL	6	0

P value = .0167

Factors Affecting OR Time & PACU Time

OR Time

The average OR time was 247 minutes (standard deviation 84 minutes).

Nonlinear regression of OR time on age, gender, BMI, decompression and fusion levels, indicators of osteophyte/bone spur (osteophyte), and leg weakness results in a model explaining 32% of the variation in OR time (R^2 = 0.32). As indicated in Table 6, the coefficients of gender and weakness suggest that each of these factors may lead to increases in OR time of over 30 minutes, on average, while cases scoring positive for osteophyte are, on average, over 1 hour faster. These multiple regression coefficients represent adjustments for the other factors in the model. Increasing numbers of decompression/fusion levels are the most clearly significant factors for OR time, most notably among the 10 patients with 2-level fusion resulting in an estimated OR time 110 minutes longer than those with 1-level decompression and fusion, again adjusting for the other factors in the model.

PACU Time

The average PACU time was 201 minutes with a standard deviation of 150 minutes.

A nonlinear regression of log PACU time on age, gender, BMI, bivariate decompression/fusion levels, indicators of foraminal stenosis (Fstenosis), and an indicator of bilateral pain resulted in a model with a

squared multiple correlation of $R^2 = 0.26$. Table 7 shows the results of the statistical analysis of various factors associated with PACU time.

We see a highly significant linear effect of BMI, with heavier patients having longer PACU times, on average, after adjusting for levels of decompression/fusion and pathology. In contrast to the result for OR time, it is the number of levels of decompression together with the indicator for the 6 patients with fusion involving L5/S1 plus other levels that is selected in this "best" model.

Foraminal stenosis (Fstenosis) appears to have a significant negative effect (32% shorter) on PACU time. The bilateral pain effect indicates a shorter PACU stay, on average, for the 51 patients with bilateral pain, in contrast to the 34 patients with dominant left- or right-side pain.

Visual Analog Scale Assessment

Boxplots of pre- and postoperative VAS scores for back and leg pain are shown in Fig. 3. There is a significant drop of VAS at 2 months post operation.

Intra-operative Imaging

X-ray images of 1-level lumbar fusion using facet and pedicle screws are shown in Fig. 4.

Complications

There were no reportable intra-operative complications in this series of 85 subjects. Three major incidents that occurred postoperatively involved reoperation due to hardware migration (2 incidents) and negative re-exploration (1 incident). We were concerned about the persistence of pain and the patient insisted on re-exploration. The 2 minor incidents were both persistent sympathetically mediated postoperative pain syndrome (SMP). SMP is a form of complex regional pain syndrome from unmitigated inflammatory responses to tissue injury (38,39).

Figure 5 shows the incidence of complications.

Table 1 shows the details of major and minor complications reported in the medical literature and the incidence of each complication in this study.

6, 9, and 12-month Satisfaction Report

Satisfaction with surgery was recorded at 6, 9, and 12 months postoperation (Table 10).

Eighty to 85 percent of patients were satisfied or greatly satisfied with the outcomes of their surgery and would elect to do this type of surgery again, and 85-95% would recommend this type of surgery to others.

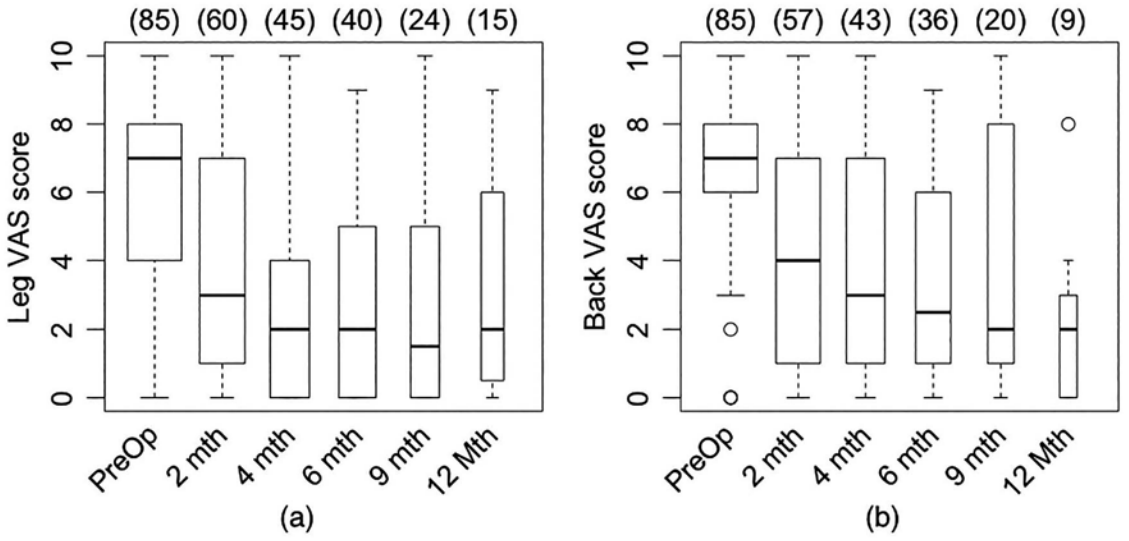

Fig. 3. *VAS scores for leg and back pain. A) reports the VAS scores for preoperative leg pain and at 2, 4, 6, 9, and 12 months post operation. B) reports the VAS scores for preoperative back pain and at 2, 4, 6, 9, and 12 months post operation. The numbers of patients who responded to the questionnaires are reported on the top of the boxplots.*

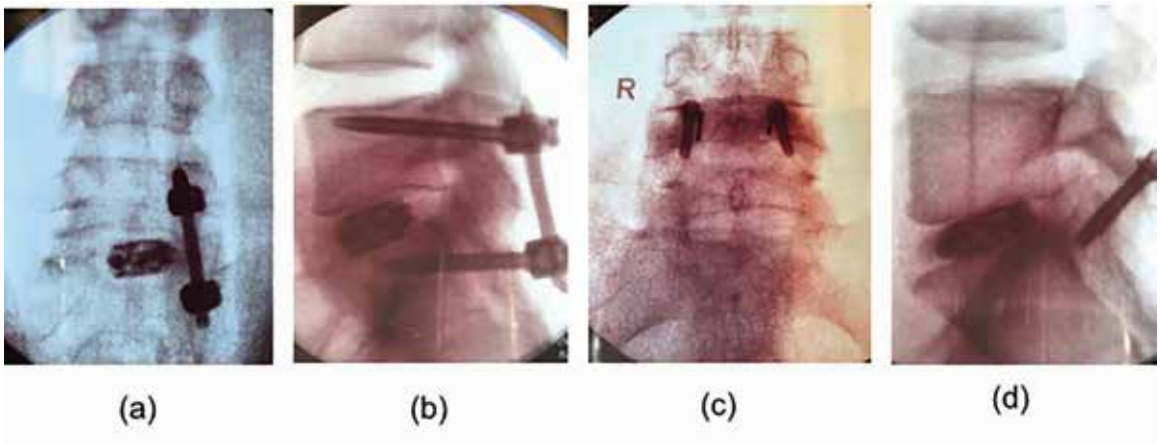

Fig. 4. *Intra-operative x-ray images of full-endoscopic-assisted surgery.n A) and B) show AP and lateral views of pedicle screw fixation, respectively. C) and D) show AP and lateral views of facet screw fixation, respectively.*

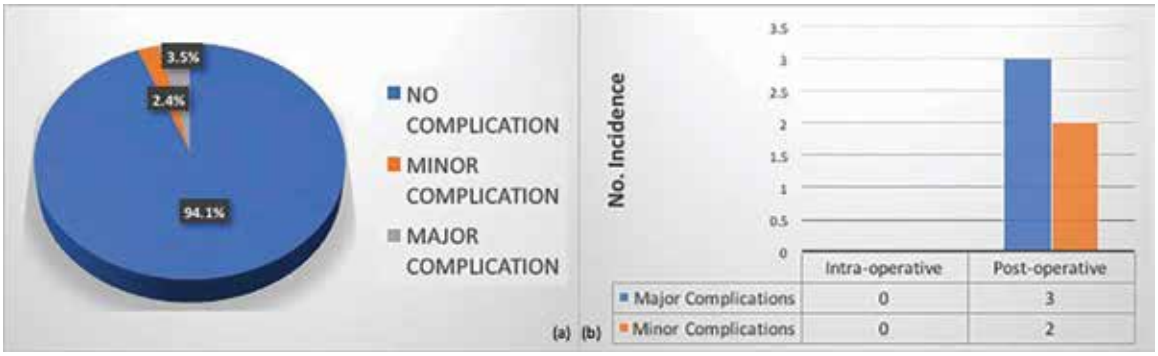

Fig. 5. *Complication rates. A) and B) report total complication rate; no intra-operative complications were observed. The 3 major postoperative incidents were re-operation due to hardware migration (2) and negative re-exploration (1). The 2 minor incidents were both persistent sympathetically mediated post-operative pain syndrome (SMP).*

Discussion

Patient Selection Criteria

This study demonstrates a viable treatment for older highly functional patients whose activities are only limited by back and leg pain, as in the case of the 89-year-old candidate. Avoidance of general anesthesia and tissue sparing are contributory factors.

Outpatient Setting

This study represents valuable information with respect to outpatient surgery setting and risk evaluation of OR time, PACU time, bleeding risk, use of regional anesthesia, and awake patient electrophysiologic self-monitoring utilizing FE-TLIF.

Bleeding Risk

Blood loss (0-5, 5-20, 20-50 mL) was minimal, and blood loss of less than 50 mL is generally considered as a minimal adverse consequence. The amount of intra-operative bleeding in this series re-affirmed the advantages associated with minimal dissection in fusion surgery using the MIS technique. The full-endoscopic transforaminal approach to MIS fusion could potentially eliminate the need for blood transfusions and other risks of uncontrolled bleeding or excessive blood loss.

Table 10. *Satisfaction report at 6, 9, and 12 months.*

	6 months	6 Months %	9 months	9 months %	12 Months	12 Months %
Satisfied with surgery						
great deal	28	68.29	13	56.52	9	69.23
satisfied	7	17.07	5	21.74	2	15.38
little satisfied	4	9.76	3	13.04	1	7.69
unsatisfied	2	4.88	2	8.70	1	7.69
Satisfied with life						
great deal	22	56.41	7	31.82	6	46.15
satisfied	8	20.51	7	31.82	2	15.38
little satisfied	6	15.38	4	18.18	2	15.38
unsatisfied	3	7.69	4	18.18	3	23.08
Surgery Improve Life Satisfaction						
Yes	37	90.24	13	59.09	10	71.43
No	4	9.76	9	40.91	4	28.57
Do This Type of Surgery Again						
Yes	36	87.80	15	75.00	12	85.71
No	5	87.80	5	25.00	2	14.29
Recommend This Type of Surgery						
Yes	38	95.00	17	85.00	12	85.71
No	2	5.00	3	15.00	2	14.29

OR Time & PACU Time

Prolonged OR time and PACU time can be significantly improved with surgeons' experience and is a significant factor that has been looked at (62-64). Notwithstanding physician experience, this study demonstrates certain factors of significance. For instance, the increasing number of decompression and fusion level is highly significantly associated with the length of OR time. In addition, male gender and presence of leg weakness are also factors that may lead to an increase in OR time. There is a negative correlation with presenting symptoms of osteophyte.

There is notably no increase in OR time on the basis of BMI or age; heavier people have similar OR time as other cohorts. PACU time results indicate a modest BMI effect; heavier people have longer PACU times. This suggests an immediate postoperative obesity effect. These findings are quite significant in view of the well-recognized higher risk associated with BMI in the open spine surgical scenario.

Regional Anesthesia and Patient Self-monitoring

A well-conducted anesthetic protocol is an essential part of spine fusion surgery. General anesthesia has been the "gold standard" and requires full neurophysiological, indirect monitoring with evoked potential technology that is unfortunately not without unmitigated risk of nerve damage. With adequate preparation, an awake patient can verbally provide direct self-monitoring of neural integrity during surgical dissection. This study successfully demonstrated application of awake self-neurophysiological monitoring using a regional anesthetic technique.

Complications

In our study of 85 patients, the intraoperative complication rate was zero and the total postoperative complication rate was 5.88%. Among those, 2 patients (2.35%) had hardware migration due to facet screws. There were no complications related to pedicle screw fixation for the 5 patients who had pedicle screw fixations. There were no cases of heterotopic bone formation, osteolysis, or pseudo-arthrosis. In a smaller-scaled study, Wang et al reported no intraoperative or postoperative complications in a cohort of 10 patients who underwent endoscopic minimally invasive transformational interbody fusion without general anesthesia. These results are comparable if not better than the

complication rates for traditional open lumbar fusion surgery, in which the intraoperative complication rate varies from 1.4% to 12.8% and the postoperative complication rate varies from 2.8% to 29.8% (1,3,21-24).

Limitations

This is a retrospective cohort study. Comparison with traditional open spine surgery was done by literature review. Further studies with multicenter participation are needed to evaluate other factors such as adjacent segment degeneration.

There is limited clinical application of the "ultra-MIS" procedure to patients with minimal deformity.

Another limitation is usage of patient-reported symptoms (Table 3). Quantified measurements of weakness and numbness by physical examination would provide more accurate clinical diagnoses. In addition, global sagittal alignment measurements were not performed, as study cohorts presented with minimal spinal deformities.

Three of the 85 patients (3.5 percent) required pedicle screw fixation due to the presence of a higher degree of listhesis. This number of patients represents variation in surgical technique. Notwithstanding known biomechanical differences between facet and pedicle fixations, there was no evidence of variation in fusion stability between the 2 techniques as measured by radiologic x-rays during the study period. This study did not perform a direct comparison between facet and pedicle fixation. Further studies might address this issue.

There were various fusion allograft products used over the course of 5 years; however, all products were established and acceptable without any off-label product usage.

Early recovery, as seen in this series of 85 patients, has the disadvantage of diminished incentive for follow-up beyond 3-month postoperative period. A larger study might need to consider appropriate incentives for patients to stay in the study long after they are symptom-free.

The statistical analysis of osteophyte as a contributing factor to OR time might be considered clinically insignificant given the small number of patients in this population.

Cost-savings

Reducing the direct and indirect costs of lumbar spine fusion in the US and western countries with their high prevalence of lumbar degenerative disease has been of great interest (7,8). Diminished risk of intraoperative complications, reduced blood loss, lack of need for extensive electrophysiological monitoring, shortened PACU time, outpatient surgery, and early recovery all present potential cost-savings that can be indirect benefits of the full-endoscopic MIS technique procedure for lumbar spine surgery.

Conclusion

Based on the results of this study, there appears to be a broader application of the full-endoscopic technique for lumbar discectomy and fusion by well-trained surgeons with expertise in transforaminal and interlaminar techniques. Full-endoscopic assisted fusion is a viable technique for treatment of all lumbar fusion surgery.

The specific technique of full-endoscopic assisted transforaminal lumbar fusion used in this study has been previously referred to an "ultra-MIS" approach and this study certainly supports such an assertion. 65

Full-endoscopic lumbar fusion technique used in this study demonstrated safety and efficacy across a variety of clinical presentations, including obesity, extremes of age, and the anatomic challenge of a high iliac crest such as those commonly seen in men.

A larger prospective study is necessary to validate these findings and to explore potential additional benefits of this "ultra-MIS" approach.

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