Retrospective Review

Full-Endoscopic Assisted Lumbar Decompressive Surgery Performed in an Outpatient, Ambulatory Facility: Report of 5 Years of Complications and Risk Factors

Solomon Kamson, MD, PhD[1], Andrea Trescot, MD[2], Paul D. Sampson, PhD[3], and Yiyi Zhang, BS[1]

From: [1]Spine Institute Northwest, Bothell, Washington; [2]Pain and Headache Center, Wasilla, Alaska; [3]Department of Statistics, University of Washington, Seattle, Washington

Address Correspondence: Solomon Kamson, MD Spine Institute Northwest 1629 220th St SE Bothell, Washington E-mail: research@spineinstitutenw.com

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Background: Minimally invasive surgery (MIS) technique is becoming the standard tissue sparing approach for decompression of lumbar central and lateral recess stenosis, intervertebral disc herniation, or any situation that would have required extensive open decompression laminectomy. Full-endoscopic or arthroscopic assisted surgery is arguably the "ultra-MIS" approach to lumbar spinal pathology. Age and body mass index (BMI) are significant risk factors to be considered in full-endoscopic assisted ultra-MIS. With limited medical literature published on complication rates for MIS, reports on the ultra-MIS approach are even scarcer for free-standing, outpatient ambulatory settings.

Objectives: The primary goal of this study is to compare outcomes for full-endoscopic assisted ultra-MIS lumbar decompression surgical techniques, performed in a free-standing, outpatient ambulatory facility, with other spine surgery techniques.

Study Design: This is a Western Institutional Review Board (WIRB)-approved retrospective review of prospectively collected patient demographic and outcomes data for full-endoscopic assisted interlaminar and transforaminal lumbar decompressive surgery.

Setting: Free-standing, outpatient ambulatory surgery facility.

Methods: A population of 178 patients, whose age ranged between 16 and 90 years old (mean 45.5 years), with a variety of clinical presentation of symptoms underwent lumbar decompressive surgery using an interlaminar or transforaminal full-endoscopic assisted approach between January 2011 and December 2015. Operative (OR) time, complication rates, estimated blood loss, preoperative and postoperative leg and back VAS, and patient satisfaction ratings at 6, 9, and 12 months post operation are reported.

Results: Age is a significant predictor of OR time; older patients generally have longer surgeries. BMI does not have statistically significant effect on OR time; heavier patients have similar OR time as other cohorts. There were no reportable intra-operative complications in this series of 178 patients. There were 3 major (1.69%) and three 3 (1.69%) postoperative complications. The 3 major complications were all incidences of early postoperative reherniation that resulted in re-operation. The minor complications included 2 cases of sympathetically mediated pain syndrome and one case of postanesthetic transient urinary retention. About 95% of patients had less than 5 mL of blood loss. No patients lost more than 35 mL of blood during surgery. Visual analog scale (VAS) score dropped from 7 to 3, on a scale of 0 to 10 with 10 being the worst pain imaginable, within 2 months postoperative. On average, 70% to 80% of patients were satisfied or greatly satisfied with the surgery, and 85% to 92% of patients would recommend this type of surgery.

Limitations: Retrospective study.

Conclusions: Full-endoscopic assisted ultra-MIS technique is a viable option for lumbar decompressive surgery in a free-standing, outpatient ambulatory facility. The patient population in this study demonstrates its safety, efficacy, and effectiveness for treatment of various lumbar pathologies. It is particularly relevant that age and obesity are not contra-indications.

Key words: Full-endoscopic, minimally invasive spine surgery, postoperative complications, lumbar discectomy, lumbar decompression, lumbar disc herniation, spinal stenosis, endoscopic discectomy, ultra-MIS, arthroscopic

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Lumbar spinal stenosis is a very common degenerative condition in aging adults' spines worldwide (1). The prevalence ranges from 5.7% to 10.8% (2-5). Symptoms present with varying degree of back and leg pain associated with claudication related to intermittent compression and ischemia or nerve root or cauda equina. It may occur centrally or laterally in the neural canal and can be caused by disc protrusions, ligamentum flavum hypertrophy, osteophytes, or space-occupying lesions (such as synovia cyst). The frequency of lumbar stenosis has steadily increased in all population groups due to improved longevity and inevitable degenerative changes of the elderly spine. A conservative algorithm of care is recommended for early symptomatology, which upon failure or rapid progress of symptoms or in cases of severe neurological deficits might result in surgical treatment. In such cases of moderate to severe lumbar degenerative condition with spinal stenosis, the traditional approach has been laminectomy for surgical decompression (6-13). There has been an increase in the number of lumbar spine surgeries performed in western countries over the last decades. The frequency of surgery differs with regard to the country (14).

Traditional open spine surgery has been associated with extensive tissue cutting, excessive blood loss, epidural space scaring, prolonged hospital stay, and long recovery time (15-17). Tissue sparing approaches commonly described as minimally invasive or minimal access surgery (MIS) are becoming the standard in many areas for treatment of intractable low back pain and radiculopathy in favor of traditional open lumbar surgery in both hospital and ambulatory same-day surgery facilities. Among the various forms of MIS, full-endoscopic or arthroscopic assisted technique, which is considered the ultra-MIS, is gradually gaining its popularity among patients.

The aim in this study is to compare the outcomes for full-endoscopic ultra-MIS lumbar decompressive surgery performed in a free-standing, outpatient facility with that for various surgical approaches.

Methods

Patient Characteristics

Upon approval of Western Institutional Review Board, we retrospectively reviewed the medical records of 178 consecutive patients who underwent full-endoscopic assisted minimally invasive lumbar discectomy between January 2011 and December 2015.

These patients all presented with intractable back and leg pain with clinically significant symptomatic lumbar radiculopathy.

Table 1 presents demographic characteristics of the patient population. The patients were primarily 30 – 60 years old, ranging from 16 to 90 years with a mean of 46 years. This population's body mass index (BMI) ranged from 18.34 to 47.95 kg/m^2, with an average of 29.36 kg/m^2. They were predominately males. Slightly over half of the population was Caucasian (55.6%) and 28.1% were Hispanic or Latino. About 20% of patients had prior lumbar surgery.

Lumber degenerative disc disease was a presenting diagnosis in 97% of patients. Other common clinical presentations include facet arthropathy (82%), foraminal stenosis (72%), and central canal stenosis (57%). Table 2 summaries the clinical presentation of pathologies.

All of the patients failed conservative treatment for at least 6 months and their nerve compressions were confirmed by magnetic resonance imaging (MRI) or computed tomography (CT) imaging.

Patients presented with a variety of symptoms at different parts of the body. A summary of the symptoms is shown in Table 3.

One hundred sixteen patients (65.2%) had one-level decompression. Sixty patients (33.7%) had 2-level decompression, and 2 patients (1.1%) had 3-level decompression. Figure 1 shows the specific level(s) where patients had lumbar decompressive surgery.

Surgical Setting

This study was performed in a free-standing, outpatient ambulatory facility as opposed to a traditional hospital setting.

Anesthetic Technique

Monitored anesthesia care (MAC) was administered for all of the patients. None of the patients had general endotracheal anesthesia. All patients were placed in a prone position on a Kambin frame with careful monitoring by an anesthesiologist. Supplemental oxygen was given by nasal prongs or face mask. Intra-spinal narcotic medication was given via a regional anesthetic technique with light intravenous supplementation. Wake-up test was performed in every case for neurophysiological monitoring with documentation of extremity movement on verbal command. This technique offers direct and immediate feedback in the event of contact with a neural structure as the patients

Table 1. *Clinical demographic data.*

Demographic Information	No. Patients	%
Age		
0-19	1	0.56
20-29	18	10.11
30-39	38	21.35
40-49	52	29.21
50-59	45	25.28
60-90	24	13.48
Gender		
Female	67	37.64
Male	111	62.36
Ethnicity		
African American	5	2.81
American Indian/Alaska Native	2	1.12
Asian	11	6.18
Caucasian	99	55.62
Hispanic/Latino	50	28.09
Multi-ethnic	10	5.62
Native Hawaiian/Pacific Islander	0	0
No answer	1	0.56
BMI1 (kg/m^2)		
<18.5	1	0.56
18.5 – 24.99	34	19.10
25.00 – 29.99	77	43.26
30.00 – 34.99	36	20.22
35.00 – 39.99	18	10.11
≤ 40.00	12	6.74
Smoking History		
Non-smoker	91	51.12
Quitter	25	14.04
Smoker	62	34.83
Time Between Date of Surgery and Date of Injury		
< 1 year	61	34.27
1-2 years	17	9.55
> 2 years	58	32.58
> 5 years	42	23.60
Injury Type		
Chronic	103	57.87
MVA/PI2	39	21.91
Work-related	36	20.22
Prior Lumbar Surgery		
Yes	34	19.10
No	144	80.90

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

Table 2. *Clinical presentation of pathology.*

Clinical Presentation of Pathology	No. Patients	Prevalence (%)
Degenerative disc	173	97.19
Facet arthropathy/ hypertrophy	146	82.02
Foraminal stenosis	128	71.91
Central canal stenosis	101	56.74
Lateral recess stenosis	44	24.72
Spondylolisthesis	15	8.43
Disc herniation/ disc protrusion/ extrusion	11	6.18
Annular tear	4	2.25
Ligamentum flavum stenosis	4	2.25
Osteophyte/ bone spur	1	0.56

Table 3. *Pre-operative symptoms.*

	No. Patients	Prevalence (%)
Back Pain Present		
Yes	171	96.07
No	7	3.93
Leg Pain Present		
Yes	161	90.45
No	17	9.55
Leg Numbness Present		
Yes	118	66.29
No	60	33.71
Leg Weakness Present		
Yes	110	61.80
No	68	38.20
Leg vs Back, Which Is Worse		
Leg	33	18.54
Back	58	32.58
Same	87	48.88
Distribution of Pain		
Bilateral	59	33.15
Bilateral, left is worse	28	15.73
Bilateral, right is worse	37	20.79
Left	32	17.98
Right	22	12.36

were instructed to verbalize immediately to a painful event. No patient was converted to general anesthetic technique. No patient had complete motor deficit from local anesthetic.

Surgical Technique

Full-endoscopic transforaminal and interlaminar

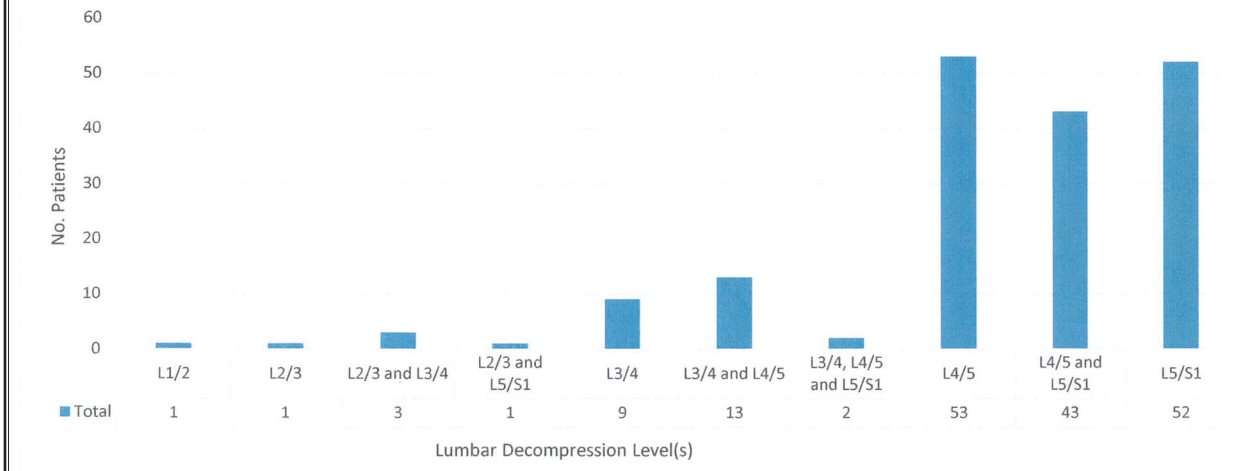

Fig. 1. *Lumbar decompression level(s) performed.*

techniques provided access for our lumbar spine surgeries. This is a minimally invasive surgical technique for spinal decompression, which has been a validated and is a standard procedure (15,18-20). New surgical access and optics with a 4 mm intra endoscopic working tube with specially designed trephines, ronguer, kerrison, and power burs were utilized to provide sufficient bone resection under direct continuous visualization with control.

Most lumbar spine surgeries utilize the transforaminal approach. We use the interlaminar approach in cases where the pathological entities are technically inoperable with the transforaminal technique (21). Surgery was performed with bi-planar radiological imaging. Transforaminal and interlaminar approaches were performed under direct visual control and constant irrigation following midline or lateral incisions into the ligamentum flavum with exposure of neural structures in preservation of epidural lubricating fat tissue. The beveled opening of the operating tube can be rotated and used as a secondary instrument to navigate around and preserve the nerve. There is completely controlled optics, with cranial and caudal mobility as well as medial and lateral access within the lateral recess, foraminal, and central canals of the epidural space.

Measuring Instrument

Patients were asked to assess their back and leg pain using a visual analog scale (VAS) scoring system prior to surgery. Estimated blood loss, perioperative complications, and operating and postoperative recovery time were recorded by physicians and nurses. Patients were assessed during clinical visits or contacted by phone at one day as well as 2 weeks, 2 months, 4 months, 6 months, 9 months, and one year post operation. During each of the time points, patients were asked to fill out postoperative questionnaires which include VAS for back and leg pain and a satisfaction survey for surgery and quality of life.

Literature Review

A computerized search of peer-reviewed original studies, literature reviews, and case reports published before February 2016 was performed in PubMed and through the University of Washington library literature search engine (University of Washington, Seattle, WA). The following key words were used for the search: "lumbar," "surgery," and "complication." We restricted the language to English. A total of 233 articles were identified and 28 unique complications for lumbar decompressive surgery were reported (Table 6) (6,7,10,11,17,22-47). These complications were classified into 2 groups: major and minor.

Statistical Analysis

Major and minor complications were tabulated for comparison with reports in the literature for various surgical approaches (Open, MED, and other forms of MIS) performed on patients with lumbar spinal stenosis. Due to the low rates of complications in this study of 178 patients, no formal statistical analyses are reported.

We report descriptive statistics on relationships of

surgical outcomes with a range of possible risk factors. Risk factors include demographic characteristics, pathology, and preoperative symptoms. These are summarized in Tables 1 – 3 and Fig. 2. The changes in VAS pain scores are presented graphically (Fig. 3). The quantitative outcomes, operative time (ORTime), and post-operative recovery time (PACUTime) are 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 are coded as 6-level ordered categorical variables in Table 1, but the original numerical values were used in the regression analyses that permitted nonlinear effects by using quadratic functions of age and BMI in the modeling. Because of the highly skewed distribution of post-operative recovery times, this outcome was analyzed on a log scale, with regression coefficients, therefore representing percent differences in PACUTime. All subsets regression methods identify sets of risk factors that best predict outcomes. We focused on 2 fit criteria: adjusted multiple correlation (R2) and the Bayes information criterion (bic) to select best-fitting models. All analyses were carried out using the R system (48).

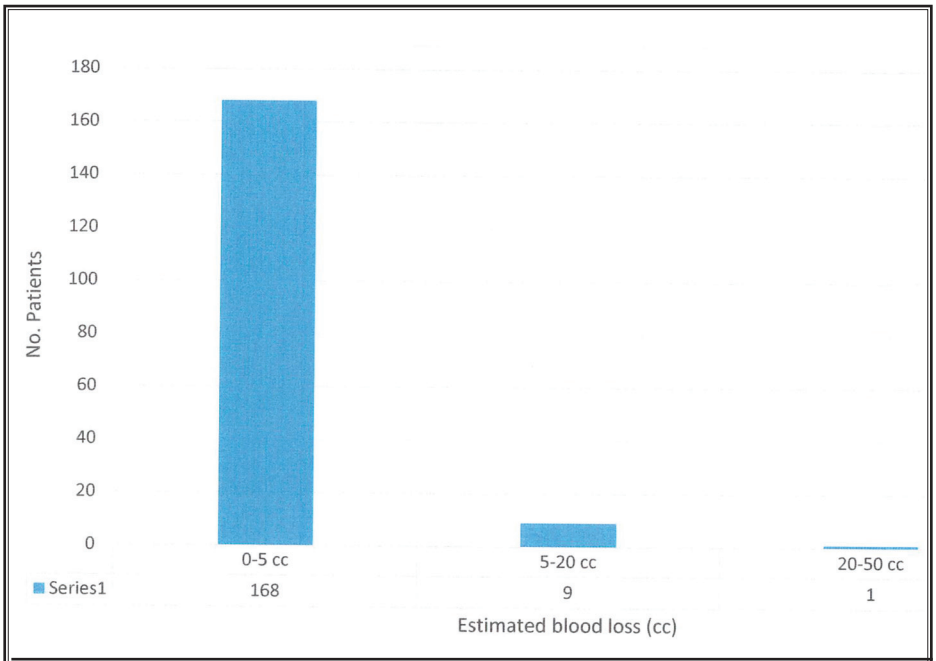

Fig. 2. *Intra-operative estimated blood loss.*

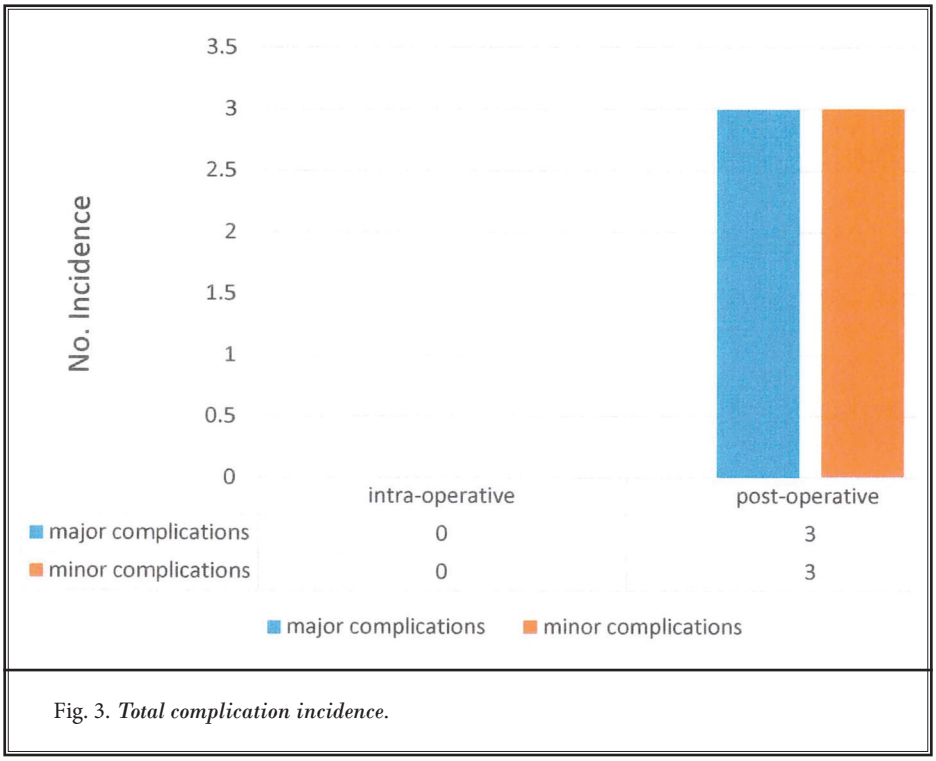

Fig. 3. *Total complication incidence.*

Results

Estimated Blood Loss (EBL)

Estimated blood loss is reported in Fig. 2. About 95% of patients had less than 5 mL of blood loss. No patients lost more than 35 mL of blood during surgery.

Factors Affecting OR Time and PACU Time

OR Time

A non-linear regression of operating time on age, gender, BMI, and indicators of degenerative disc and central canal stenosis results in a model explaining 33% of the variation of OR time ($R^2 = 0.33$).

Age is a significant predictor of OR time; older patients generally had longer surgeries.

BMI does not have a statistically significant effect on OR time.

As indicated in Table 4, the coefficients of degenerative disc disease and central canal stenosis suggest that the presence of a degenerative disc increases OR time by 38 minutes, whereas patients with central canal stenosis have a 16 minutes increase in their OR time.

PACU time

A non-linear regression of operating time on age, gender, and BMI results in a model that explains 9% of the variation of OR time ($R^2 = 0.09$).

Table 4. *Summary of multiple regression of OR time on selected risk factors.*

	Estimate	Std.Error	t value	Pr(>|t|)	
(Intercept)	149.94	20.40	7.06	4.42E-11	***
Age	62.57	49.85	1.26	0.21	
Age^2 (squared)	157.22	44.53	3.53	< 0.001	***
BMI	83.63	45.44	1.84	0.07	.
BMI^2 (squared)	19.75	45.71	0.43	0.67	
Male	14.63	7.31	2.00	0.05	*
DegenDiscY[1]	38.28	13.76	2.78	< 0.01	**
CCStenosisY[2]	15.94	6.75	2.36	0.02	*

Significance codes: 0 '***' ; 0.001 '**' ; 0.01 '*' ; 0.05 '.' Residual standard error: 43.63 on 166 degrees of freedom. Multiple R-squared: 0.3357; Adjusted R-squared: 0.2917 . F-statistic: 7.628 on 11 and 166 DF, p-value: 1.408e-10. [1]DegenDiscY = presence of degenerative disc disease. [2]CCStenosisY = presence of central canal stenosis

Table 5. *Summary of multiple regression of PACU time on selected risk factors.*

	Estimate	Std. Error	t value	Pr(>|t|)	
(Intercept)	4.81	0.07	71.46	< 2e-16	***
Age	0.94	0.49	1.92	0.06	.
Age^2 (squared)	0.45	0.48	0.94	0.35	
BMI	0.28	0.49	0.58	0.56	
BMI^2 (squared)	0.03	0.49	0.05	0.96	
Male	-0.02	0.08	-0.29	0.78	

Residual standard error: 0.4771 on 170 degrees of freedom . Multiple R-squared: 0.08937; adjusted R-squared: 0.05188 . F-statistic: 2.384 on 7 and 170 DF, p-value: 0.02381

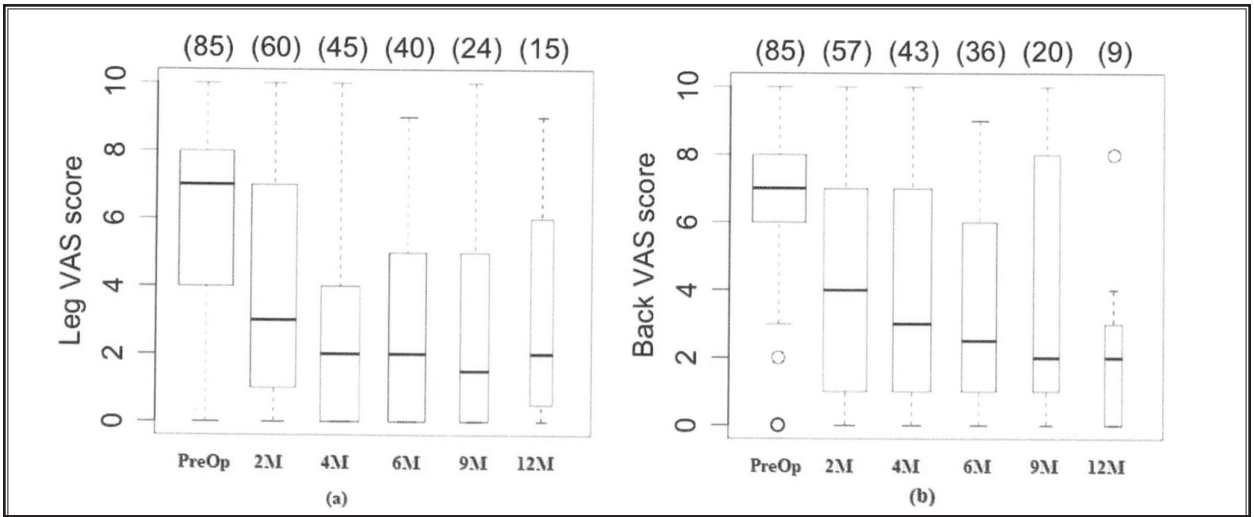

Fig. 4. *VAS scores for leg and back pain. (a) Reports the VAS scores for leg pain pre-operative and at 2. 4. 6. 9. and 12 months post-operative. (b) Reports the VAS scores for back pain pre-operative and at 2, 4, 6, 9, and 12 months post-operative. The numbers of patients who responded to the questionnaires are reported on the top of the boxplots.*

Table 5 shows the results of statistical analysis.

Based on this model, gender, age, and BMI do not appear to be statistically significant ($P > 0.05$) to PACU time.

Visual Analog Scale Scores Assessment

VAS dropped from 7 to 3, on a scale of 0 to 10 with 10 being the worst pain imaginable, within 2 months postoperative. Figure 4 shows the VAS for leg and back pain.

Complications

There were no reportable intra-operative complications in this series of 178 patients.

There were 3 major and 3 minor postoperative complications. The 3 major complications were all incidences of early postoperative reherniation that resulted in re-operation. The minor complications included 2 cases of sympathetically mediated pain syndrome and one case of transient urinary retention. Figure 4 reports the number of incidence for intra- and postoperative complications.

Table 6 presents a list of major and minor complications reported in the medical literature. The incidence and percentage occurrence of each complication for this study is reported.

6, 9, 12 Months Patient Satisfaction Report

Patients' satisfaction with surgery and their quality of life were recorded at 6, 9, and 12 months postoperative (Table 7). Among those who responded to the questionnaire, on average 70% – 80% of patients were satisfied or greatly satisfied with the surgery, and 85% – 92% of patients would recommend this type of surgery.

Table 6. *Intra-operative and post-operative complications.*

Type of Complication	No. Incidence	% Occurrence
Minor Complications	3	1.69
Donor site pain	0	0
Ileus	0	0
Muscle spasm	0	0
Superficial wound infection	0	0
SMP[1]	2	1.12
Transient urinary retention	1	0.56
Major Complications	3	1.69
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[2] visit	0	0
Fracture of interior articular process	0	0
Hospitalization	0	0
New neurological deficit	0	0
Optical blindness	0	0
Pulmonary embolism	0	0
Reoperation	3	1.69
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	6	3.37

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

Discussion

This study is a comprehensive report on a full-endoscopic assisted ultra-MIS technique for various manifestations of lumbar spine degenerative stenosis, inclusive of disco-osseous pathology and significant lateral recess stenosis.

Complication Rates

In the medical literature, the reported overall complication rates for traditional open lumbar disc surgery vary from 5.3% to 20.7% (7,16,17,33,39,49). The intra-operative complication rates for open spine lumbar discectomy range from 2% to 10.7% (50,51). The overall complication rates for microendoscopic discectomy (MED) vary between 4.0% and 41.5% (7,9,16,35,49). Ikuta et al (52) reported that the intra-operative complication rate for MED for lumbar spinal stenosis is 7.9% and the postoperative complication rate is 10.5 percent.

Few medical studies published data on complication rates for minimally invasive surgery. The reported overall complication rates vary between 5% and 15.4% (17,35,39,53). Even fewer studies are done on full-endoscopic assisted lumbar discectomy. Komp et al (54) reported an overall complication rate of 16.6%.

Choi et al (32) revealed a failure rate of 4.3% in

Table 7. *Post-operative satisfaction report.*

	6 Months	6 Months %	9 Months	9 Months %	12 Months	12 Months %
Satisfied with surgery						
great deal	31	45.59	18	34.62	15	45.45
satisfied	15	22.06	19	36.54	12	36.36
little satisfied	19	27.94	12	23.08	5	15.15
unsatisfied	3	4.41	3	5.77	1	3.03
Satisfied with life						
great deal	19	28.79	13	25.49	8	25.81
satisfied	23	34.85	18	35.29	11	35.48
little satisfied	13	19.70	10	19.61	6	19.35
unsatisfied	11	16.67	9	17.65	6	19.35
Surgery Improved Life Satisfaction						
Yes	51	73.91	26	74.29	23	67.65
No	18	26.09	9	25.71	11	32.35
Do This Type of Surgery Again						
Yes	55	83.33	24	68.57	27	79.41
No	11	16.67	11	31.43	7	20.59
Recommend This Type of Surgery						
Yes	61	91.04	28	84.85	31	91.18
No	6	8.96	5	15.15	3	8.82

their 12-year retrospective study of 10,228 patients who had undergone percutaneous endoscopic lumbar discectomy. The common causes for failure were incomplete removal of herniated disc material (2.8%) and early recurrence (0.8%). Inappropriate positioning of the working channel, herniated disc type, migration characteristics of herniated disc, and technique also influence surgical outcomes (32). In addition, during the steep learning curve phase, longer operation times are required and the incidence of complications may be higher for less experienced surgeons (49,51,55-57).

According to a nationwide cohort study, there is no significant difference in the reoperation rate between open decompressive surgery (13.7%) and minimally invasive surgery (12.4%) (58).The authors have also reported that early reoperation rates (less than 3 months) were similar between the 2 groups (58).

With a reoperation rate of 1.69% (3 out of 178), the full-endoscopic assisted ultra-MIS technique, as performed in this original work, is an effective treatment.

Estimated Blood Loss

Measurement of intra-operative blood loss (EBL) is an important part of surgical outcomes that has been measured and reported in the medical literature. Khoo and Fessler (9) reported an average blood loss of 193 mL (range from 75 to 1000 mL) per operative level for open discectomy and an average of 68 mL (range 15 – 300 mL) per level for MED. Pao et al (10) reported an estimated blood loss of 104.5 +/- 126.2 mL for one level decompression using a microendoscopic technique. Yoshimoto et al (59) conducted a small-scaled study of 24 patients and reported EBL of 40 mL for MED procedures.

An important advantage of the full-endoscopic technique is the reduction of tissue dissection and blood loss. Among the few literature reports on surgical blood loss for full-endoscopic assisted lumbar decompressive surgery, using TESSYS technique, Pan et al (17) reported blood loss of 13.8+/- 3.6 mL.

Ruetten et al (18), in a prospective, randomized, controlled study, reported intra- and postoperative blood loss of 45 mL (range 5 – 235 mL) for patients who underwent microsurgical discectomy and no measurable blood loss for patients who had full-endoscopic assisted discectomy.

Our study confirms this advantage to the full-endoscopic approach. In the population of 178 patients, 95% had less than 5 mL of blood loss. This compares favorably with outcomes of similar studies in the medical literature.

OR Time

Operating time is a significant factor which can be influenced by surgeons' experience (57,60,61). Notwithstanding surgeons' expertise and experience, this study demonstrates that age is a factor which influences operating time. Older patients in this study had longer operating times. In contrast, gender and BMI had no significant effect on the length of the operating time. Heavier patients have similar operating times to others using the full-endoscopic assisted ultra-MIS technique.

Satisfaction

Wiese et al (51) reported that rate of unsatisfactory results after primary open spine surgery for disc herniation varies between 10% and 60%. The reason for failure might be incomplete tissue removal, post-surgical complication, inadequate rehabilitation, inaccurate working diagnoses, reherniation, chronic inflammation, fibrosis, infection, or segmental instability (62-70).

In our study of 178 patients, an unsatisfactory rate of 3% was reported at 12 months postoperative and 91% of patients would recommend full-endoscopic surgery to others.

Limitations of the Full-endoscopic Assisted Ultra-MIS Technique

Contrary to previous reports about limitations of the endoscopic technique, this study, which included various surgical indications, demonstrates that full-endoscopic assisted procedures, performed by experienced surgeons with expertise in transforaminal and interlaminar techniques, can be universally applied for lumbar decompression surgery.

Conclusions

Full-endoscopic assisted ultra-MIS technique is a viable option for lumbar decompressive surgery in a free-standing, outpatient ambulatory facility. The patient population in this study demonstrates its safety, efficacy, and effectiveness for treatment of various lumbar pathologies. It is particularly relevant that age and obesity are not contra-indications.

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