<u>Manuscripts</u>

# Preoperative Back Pain Severity Influences Postoperative Clinical Outcomes and Trajectory in Patients Undergoing Lateral Lumbar Interbody Fusion

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### Background

The Visual Analog Scale (VAS) is a frequently used and validated instrument for assessing a patient's self-perceived lower back and leg pain and is often employed to assess the efficacy of lumbar surgical intervention. Our study seeks to assess how preoperative severity of presenting lumbar back pain may influence postoperative clinical trajectory and patient-reported outcome measures (PROMs) following lateral lumbar interbody fusion (LLIF)

### Objective

To compare perioperative and postoperative mean patient-reported outcome measures and minimum clinical important difference (MCID) achievement following LLIF in patients stratified by preoperative back pain.

### Methods

A prospectively maintained surgical database was retrospectively reviewed for lumbar operations between June 2005 and December 2021. Inclusion criteria was set as primary, elective, single or multi-level LLIF procedures for degenerative lumbar spinal pathology. Patients undergoing a revision procedure, or surgery indicated for infectious, malignant, or traumatic etiologies were excluded. Additionally, patients who did not fill out a preoperative VAS back survey were excluded as well. Patient demographics, perioperative characteristics, and PROMs were collected. PROMs were administered at preoperative and 6-week, 12-week, 6-month, 1-year, and 2-year postoperative time-points and included Patient-Reported Outcomes Measurement Information System- Physical Function (PROMIS-PF), Visual Analogue Scale (VAS) for back and leg pain, Oswestry Disability Index (ODI), and 12-Item Short Form Physical Composite Score (SF-12 PCS).

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a [Conflicts of Interest Statement for Dr. Jacob](#)

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Postoperative complications were collected for each group as well. Patients were grouped into two cohorts, depending on whether a patient had a preoperative VAS back score of < (mild to moderate back pain cohort or VAS back score ≥ 7 (Severe back pain cohort). Demographic and perioperative characteristics were compared among groups using chi-square and Student's t-test for categorical and continuous variables, respectively. Mean PROM scores were compared between cohorts at each time point utilizing a unpaired Student's t-test. Postoperative improvement from preoperative baseline within each cohort was assessed with paired samples t-test. Achievement of Minimum Clinical Important Difference (MCID) was determined by comparing ΔPROM scores to previously established threshold values. MCID achievement rates were compared between groups with chi-squared analysis.

## Results

Patient cohort consisted of 199 patients – 84 patients in VAS back preoperative <7 and 115 patients in the VAS back Preoperative ≥ 7 cohort (Table 1). Significant demographic differences between cohorts were noted for hypertensive status with VAS back Preoperative< 7 cohort having significantly higher rates of hypertension (p<0.029) (Table 1). The majority of patient cohort were male (51.8%), Caucasian (80.8%), non-smokers (81.6%), non-diabetic (85.9%) and utilizing private insurance(62.8%). Majority of patients in both cohorts had presenting spinal pathology of Degenerative Spondylolisthesis (50.8%) with concomitant central stenosis(86.9%) (Table 2). A significantly greater proportion of patients in VAS back preoperative < 7 cohort reported central and foraminal stenosis. No significant differences were noted between cohorts for operative duration, estimated blood loss, or postoperative day of discharge. Patients in the severe back pain cohort demonstrated significantly greater mean postoperative length of stay (53.9 hrs vs 40.6 hrs), greater postoperative VAS pain scores on POD0 and 1, and greater postoperative narcotic consumption on POD1 (p<0.049, all) (Table 2).

Rate of postoperative complications did not differ between cohorts. Preoperative mean PROM scores were significantly different for all PROMs collected (Table 4). Cohorts demonstrated significant mean postoperative differences for the following PROMs at the following postoperative time points: VAS back at 6-weeks, 12-weeks, 6-months, and 2-years, VAS leg at 6-months, ODI at 6-weeks, 12-weeks. 6-months, and 2-years, SF-12 PCS at 6-months, and PROMIS-PF at 12-weeks, 6-months, and 1-year(p<0.049, all) (Table 4). Preop VAS back <7 patient cohort demonstrated improvement from preoperative baseline to the 2-year time point for all PROMs collected at all individual postoperative timepoints with the exception of VAS leg at 1-year, ODI at 6-weeks, SF-12 PCS at 6-weeks, and PROMIS-PF at 6-weeks. (Table 4). Preop VAS back ≥ 7 patient cohort demonstrated improvement from preoperative baseline to 2-year time point for all PROMs collected at all individual postoperative timepoints (Table 4). Patients in the VAS back ≥ 7 patient cohort demonstrated greater proportion achieving MCID for VAS back at 6-weeks, 12-weeks, 1-year, and overall as well as for VAS leg at 6-weeks (p <0.043, all) (Table 5).

## Conclusion

Patients in both preoperative back pain severity cohorts demonstrated significant long term clinical improvement from their respective preoperative baselines at 2-years postoperatively for back pain, leg pain, physical function, and general disability. Patients with severe preoperative back pain (VAS >7), however, demonstrated significantly inferior short (6weeks-6months) and long term (2-year) mean outcome scores for back pain and general disability. 2-year mean outcome scores for leg pain and physical function were similar between cohorts. Results from our study may be used by surgeons to understand differing postoperative trajectories of patients undergoing LLIF stratified by back pain severity.

INTRODUCTION

Low back pain (LBP) is a major contributor of disability and disease burden worldwide, requiring significant resources in the diagnosis and treatment of patients (Hoy et al. 2014).

LBP may be present in all age groups, but prevalence is higher in aging populations and those with comorbid diseases (Wong, Karppinen, and Samartzis 2017). Pathologies affecting the lower back have variable symptomatic presentations, including radiculopathy, myelopathy, point tender-

ness, and disability. While conservative treatment should be started early in patients with mild to moderate symptoms, more severe or treatment resistant pathologies may require surgery to alleviate the underlying anatomical deformity responsible for symptoms (Mobbs et al. 2015). Of the various surgical options, the lateral lumbar interbody fusion (LLIF) technique may be indicated for all degenerative pathologies of the lumbar spine (Mobbs et al. 2015). First described by Ozgur et al. in 2006, the disc space is accessed via a lateral retroperitoneal transpsoas corridor. The LLIF involves a minimally invasive (MIS) muscle-splitting approach, allowing for rapid postoperative mobilization. Furthermore, the MIS approach has demonstrated reduced operative time, decreased blood loss, and shorter hospital stays than comparable open procedures (Patel, Zfass-Mendez, Lebwohl, et al. 2015). Due to the lateral approach, the method is particularly effective at sagittal and coronal deformity correction in lumbar degenerative scoliosis with laterolisthesis (Arnold, Anderson, and McGuire 2012). The LLIF technique is suitable to access the T12/L1 to L4/L5 disc spaces, however more caudal segments may be obstructed by the iliac crest and are at higher risk for lumbar plexus, iliac vessel, and bowel injury.

Measures of success in spine surgery have recently shifted to evaluate patient reported outcome measures (PROMs), as they demonstrate the patient's perspective of their health-related status. While subjective in nature, these patient-centered metrics often act as an adjunct to clinical and radiographic findings, allowing for the development of a holistic assessment of surgical outcomes in the treatment of spinal pathologies (Finkelstein and Schwartz 2019). While past ideas of operative success consisted of objective clinical measures, current satisfaction assessment includes preoperative factors, the patient's interpersonal relationships with the treatment team, and PROMs (Menendez et al. 2019). Outcome assessment using PROMs has demonstrated quality of care and cost effectiveness, and has established the patient perspective as playing a leading role in the treatment plan (Finkelstein and Schwartz 2019). Furthermore, utilizing PROM scores, the minimum clinically important difference (MCID) achievement may be determined to quantify improvements that may yield significant benefit to functional, pain, or mental status metrics. Commonly used PROMs in the assessment of lumbar surgical outcomes include the Visual Analog Scale (VAS) for pain in the back and leg, Oswestry Disability Index (ODI), 12-Item Short-Form for Physical Composite Score, (SF-12 PCS), and Patient-Reported Outcomes Measurement Information System for Physical Function (PROMIS-PF) (McCormick, Werner, and Shimer 2013; Bernstein et al. 2019).

While prior literature has established that preexisting comorbid conditions may have a negative effect on lumbar spine surgery outcomes, the effect of preoperative PROM values on postoperative success and patient satisfaction has not been thoroughly investigated. By stratifying patients undergoing LLIF by preoperative back pain severity to determine differences in PROM scores and MCID, surgeons can be informed of determinants that may alter expected postoperative outcomes. These findings may be used in the development of realistic postoperative expectations for individuals at risk for poor surgical improvement, thus allowing patients to make appropriately informed decisions regarding their treatment. Therefore, the aim of the current study is to provide an evaluation of the predictive capacity of preoperative back pain severity on postoperative PROM and MCID achievement following LLIF. Utilizing the findings from this study, we hope surgeons will garner a better understanding of factors predicting postoperative success, thereby leading to more favorable future outcomes following LLIF for lumbar pathologies.

## METHODS

### PATIENT POPULATION

Institutional Review Board (ORA #14051301) approval and informed patient consent were obtained prior to onset of the study. Surgical procedures were performed between June 2005 and December 2021 at a single academic institution by one surgeon. These operations were retrospectively identified in a prospectively maintained database cataloging surgical outcomes. Patients were included in this study if they received primary, elective, single or multi-level LLIF procedures for degenerative lumbar spinal pathologies. Patients were excluded if they received surgery for traumatic, malignant, or infectious etiologies. Additionally, patients who did not fill out a preoperative VAS back survey were excluded as well.

### DATA COLLECTION

Patients were separated into two cohorts by their preoperative VAS back pain score. The first cohort (moderate back pain) reported preoperative VAS back scores ≤ 7, while the second (severe back pain) reported scores >7. VAS back scores of 7 were chosen as the cutoff point to indicate severe back pain, as Boonstra et al. defined VAS >6.5 as severe with regard to impact on functioning, and VAS >7.5 as severe on the verbal rating scale. To account for the impact

of pain on both verbal and functional scales, this study utilized a point of division at VAS back scores of 7.0.

Patient demographic information was collected, including age, body mass index (BMI), smoking status, the presence of diabetic and hypertensive comorbidities, American Society of Anesthesiologists (ASA) score to determine operative risk, Charlson Comorbidity Index (CCI) to assess for comorbid disease burden and insurance type. Perioperative characteristics were collected as well, detailing spinal pathology, number of operative levels, operative duration, estimated intraoperative blood loss (EBL), length of stay (LOS), and postoperative day of discharge. Other data regarding immediate postoperative pain scores, narcotic consumption, and 1-year arthrodesis rates were collected. Postoperative complications were analyzed among both cohorts.

PROMs were collected at baseline (preoperatively) and postoperatively at 6-weeks, 12-weeks, 6-months, 1-year, and 2-years for all metrics. The assessed PROMs included VAS back, VAS leg, ODI, 12-Item Short-Form for Physical Composite Score, SF-12 PCS, and PROMIS-PF. Minimum clinically important differences (MCID) were also determined for each PROM among cohorts at all postoperative timepoints.

STATISTICAL ANALYSIS

Stata 16.0 (StataCorp LP, College Station, TX) was used for data analysis. Descriptive characteristics including mean and standard deviation values were calculated for all demographic factors, perioperative characteristics, and PROM scores at each timepoint. Categorical data differences in demographic and perioperative data between cohorts were analyzed using Chi-square tests to determine significance, or with Student's t-tests for continuous variables. Mean PROM scores were compared between cohorts at each time interval with an unpaired Student's t-test. Postoperative improvement from baseline PROM scores within each cohort were assessed using a paired samples t-test. Achievement of MCID was determined by comparing the change in PROM values from baseline to previously established threshold values. MCID achievement rates were compared between groups with chi-squared analysis.

RESULTS

DESCRIPTIVE ANALYSIS

A total of 199 patients were included in this study, with 84 in the moderate VAS back cohort and 115 in the severe cohort. Demographically, both cohorts demonstrated similarities in average age (59.6 years), gender (48.2% female and 51.8% male), average BMI (30.3 kg/m$^2$), and ethnicity. Patients in each cohort had a similar prevalence of diabetes (85.9% non-diabetic) and smoking status (81.6% non-smokers). Furthermore, no significant differences were observed regarding ASA classification, CCI, and insurance type between groups. Hypertensive status among cohorts varied significantly with 37.4% reporting hypertension in the moderate back pain cohort, compared to 53.0% in the severe back pain cohort (p=0.029) (**Table 1**). A significantly greater proportion of patients in the moderate back pain cohort experienced pathologies of central stenosis and foraminal stenosis than the severe back pain cohort (p=0.034 and p=0.041, respectively), but rates of herniated nucleus pulposus, degenerative spondylolisthesis, degenerative scoliosis, and isthmic spondylolisthesis were similar. As both single- and multi-level LLIF were included, both cohorts demonstrated a similar number of operative levels, which was most often a single level (73.1%). Intraoperative parameters, including operative duration (163.3 minutes) and estimated blood loss (96.8 mL), were similar among cohorts as well. Patients in both cohorts also experienced a similar postoperative day of discharge, which was most commonly day 1 in both groups (36.6%). However, the total LOS varied significantly among cohorts (40.6 hours in the moderate back pain cohort versus 53.9 hours in the severe back pain cohort, p=0.011). Furthermore, postoperative VAS pain scores on days 0 and 1 were significantly greater in the severe back pain cohort (p=.008 and p=.013, respectively), and day 1 narcotic consumption was significantly higher in the severe back pain cohort (p=0.049). One-year arthrodesis rates were 99.1% among both cohorts (**Table 2**). Postoperative complications among each cohort were similar, and were most commonly fever of unknown origin (10.6%), nausea/vomiting (7.5%), and urinary reten-

**Table 1. Patient Demographics**

| | Total (n=199) | VAS- Back <7 (n=84) | VAS- Back>=7 (n=115) | *p-value |
|---|---|---|---|---|
| Age (mean±SD) | 59.6 ± 11.6 | 60.5 ± 11.2 | 58.9 ± 11.9 | 0.323 |
| Gender | | | | |
| Female | 48.2% (96) | 42.9% (36) | 52.2% (60) | 0.194 |
| Male | 51.8% (103) | 57.1% (48) | 47.8% (55) | |
| Body Mass Index (Mean ± SD) | | | | 0.069 |
| | 30.3 ± 6.1 | 29.4 ± 5.7 | 30.9 ± 6.2 | |
| Ethnicity | | | | |
| Caucasian | 80.8% (160) | 83.1% (69) | 79.1% (91) | |
| African-American | 6.6% (13) | 6.0% (5) | 6.9% (8) | |
| Hispanic | 7.1% (14) | 4.8% (4) | 8.7% (10) | |
| Asian | 2.0% (4) | 2.4% (2) | 1.7% (2) | 0.862 |
| Other | 3.5% (7) | 3.6% (3) | 3.5% (4) | |
| Smoking Status | | | | |
| Non-Smoker | 81.6% (111) | 79.1% (34) | 82.8% (77) | 0.602 |
| Smoker | 18.4% (25) | 20.9% (9) | 18.2% (16) | |
| Diabetes | | | | |
| Non-Diabetic | 85.9% (171) | 86.9% (73) | 85.2% (98) | 0.735 |
| Diabetic | 14.1% (28) | 13.1% (11) | 14.8% (17) | |
| Smoking Status | | | | |
| Non-Smoker | 85.3% (168) | 82.9% (68) | 86.9% (100) | 0.431 |
| Smoker | 14.7% (29) | 17.1% (14) | 13.0% (15) | |
| Hypertensive Status | | | | |
| Non-Hypertensive | 53.5% (106) | 62.7% (52) | 46.9% (54) | **0.029** |
| Hypertensive | 46.5% (92) | 37.4% (31) | 53.0% (61) | |
| ASA Classification | | | | |
| <3 | 70.1% (138) | 68.7% (57) | 71.1% (81) | 0.719 |
| >= 3 | 29.9% (59) | 31.3% (26) | 28.9% (33) | |
| CCI Score (Mean ± SD) | 3.1 ± 2.2 | 3.3 ± 2.4 | 2.9 ± 2.1 | 0.224 |
| Insurance | | | | |
| Medicare/Medicaid | 21.1% (42) | 15.5% (13) | 25.2% (29) | |
| Workers' Compensation | 16.1% (32) | 11.9% (10) | 19.1% (22) | 0.050 |
| Private | 62.8% (125) | 72.6% (61) | 55.7% (64) | |

ASA = American Society of Anesthesiologists

CCI = Charlson Comorbidity Index

tion (6.0%). No major postoperative complications were reported in either cohort (**Table 3**).

PRIMARY OUTCOME MEASURES

PROMs at nearly all postoperative time points were improved among each metric compared to baseline. The moderate back pain cohort experienced significant improvements at all timepoints for VAS back pain, significant benefits in VAS leg pain at all but 1-year follow-up, and ODI, SF-12 PCS, and PROMIS-PF at all but 6-weeks postoperatively (p<0.038, all). The severe back pain cohort noted significant benefits from preoperative baseline PROM scores in all metrics at every time point (p<0.039, all). Comparing PROM values among cohorts, the results were more variable. Significant improvement was noted in the moderate back pain cohort over the severe back pain group for VAS back, ODI (all points except 1-year), and PROMIS-PF (12-weeks, 6-months, and 1-year) at most postoperative follow-ups. VAS leg and SF-12 PCS only noted significant benefit in the moderate pain cohort at 6-months (p<0.041, both). Furthermore, all baseline preoperative PROM values significantly favored the moderate back pain cohort for each measure (p<0.003, all) (**Table 4**). MCID achievement rates were similar between cohorts for PROMIS-PF, SF-12 PCS, and ODI at all intervals. VAS leg demonstrated significant differences in MCID achievement at 6-weeks postoperatively, and VAS back had differences at 6 weeks, 12 weeks, 1 year, and overall (p<0.043, all). In the severe back pain

**Table 2. Perioperative Characteristics**

| | Total (n=199) | VAS- Back <7 (n=84) | VAS- Back>=7 (n=115) | *p-value |
|---|---|---|---|---|
| Spinal Pathology | | | | |
| Central Stenosis | 86.9% (173) | 92.9% (78) | 82.6% (95) | **0.034** |
| Foraminal Stenosis | 38.2% (76) | 46.4% (39) | 32.2% (37) | **0.041** |
| Herniated Nucleus Pulposus | 7.5% (15) | 4.8% (4) | 9.6% (11) | 0.205 |
| Degenerative Spondylolisthesis | 50.8% (101) | 47.6% (40) | 53.0% (61) | 0.450 |
| Degenerative Scoliosis | 32.2% (64) | 36.9% (31) | 28.7% (33) | 0.221 |
| Isthmic Spondylisthesis | 10.1% (20) | 15.5% (13) | 6.1% (7) | 0.080 |
| Number of Operative Levels | | | | 0.242 |
| Single Level | 73.1% (144) | 77.4% (65) | 69.9% (79) | |
| Multiple Levels | 26.9% (53) | 22.6% (19) | 30.1% (34) | |
| Operative Time (Mean±SD; min) | 163.3 ± 90.5 | 156.8 ± 87.0 | 167.9± 93.0 | 0.395 |
| Estimated Blood Loss (Mean±SD; mL) | 96.8 ± 176.4 | 103.1 ± 250.8 | 92.0 ± 84.8 | 0.673 |
| 1-year arthrodesis | 99.1% (112) | 97.2% (36) | 100.0% (75) | - |
| Length of Stay (Mean±SD; hours) | 48.3 ± 35.1 | 40.6 ± 31.8 | 53.9 ± 36.3 | **0.011** |
| Postoperative Day of Discharge (POD) | | | | |
| POD0 | 11.3% (21) | 14.1% (11) | 9.3% (10) | 0.129 |
| POD1 | 36.6% (68) | 42.3% (33) | 32.4% (35) | |
| POD2 | 23.1% (43) | 26.9% (21) | 20.4% (22) | |
| POD3 | 14.5% (27) | 7.7% (6) | 19.4% (21) | |
| POD4 | 8.6% (16) | 6.4% (5) | 10.2% (11) | |
| Postoperative VAS Pain Score | | | | |
| POD0 | 5.4 ± 1.9 | 4.8 ± 1.9 | 5.7 ± 1.9 | **0.008** |
| POD1 | 4.8 ± 1.8 | 4.2 ± 1.3 | 5.1 ± 1.9 | **0.013** |
| Postoperative Narcotic Consumption (OME) | | | | |
| POD0 | 61.2 ± 41.1 | 54.5 ± 32.5 | 66.0 ± 45.9 | 0.051 |
| POD1 | 47.5 ± 47.6 | 39.7 ± 32.2 | 53.2 ± 55.7 | **0.049** |

OME = Oral Morphine Equivalents

POD = Postoperative Day

Re-hospitalization = Defined as returning to hospital within 6-weeks of surgery with a surgical related complaint.

cohort, MCID was most likely to be reached in VAS back and SF-12 PCS (83.3%), followed by VAS leg (77.2%) and PROMIS-PF (74.3%). The moderate back pain cohort was most likely to achieve MCID in SF-12 PCS (72.0%), followed by PROMIS-PF (67.4, however stark differences were noted among cohorts in MCID achievement for VAS back (**Table 5**).

## DISCUSSION

### INTRODUCTION

This study evaluated the predictive capacity of stratifying a patient cohort undergoing LLIF into moderate or severe preoperative back pain using the VAS to determine postoperative pain, disability, and functional status as measured through patient-reported outcome measures and achievement of MCID. Overall, the PROM data demonstrated significant postoperative improvements in VAS Back and Leg Pain, ODI, SF-12 PCS, and PROMI-PF scores in both cohorts compared to their respective baselines. When the two co-

horts were compared, the moderate preoperative back pain cohort demonstrated significantly better short- and long-term VAS Back and ODI measures compared to the severe preoperative back pain cohort. This study also showed that patients with severe preoperative baseline back pain (VAS back score ≥7) had significantly longer LOS, greater VAS pain and narcotic consumption on day 0 and day 1 postoperatively, and higher MCID achievement for overall VAS back pain compared to patients with moderate preoperative back pain (VAS back score <7).

### PERIOPERATIVE OUTCOMES

It is interesting to note that though back pain severity differed between groups, the surgical characteristics such as the number of operative levels, operative time, and EBL were similar. The average operative time (163min) and EBL (96.8ml) noted in both groups of this study were shorter and smaller respectively compared to a retrospective case series of 84 LLIF patients by Youssef et al (2010) which reported an average OR time of 199min and EBL of 155ml.

**Table 3. Postoperative Complications**

| Complication | Total (n=199) | VAS-Back <7 (n=84) | VAS- Back>=7 (n=115) | *p-value |
|---|---|---|---|---|
| Reintubation | 0.0% (0) | 0.0% (0) | 0.0% (0) | - |
| Urinary Retention | 6.0% (12) | 9.5% (8) | 3.5% (4) | 0.077 |
| Urinary Tract Infection | 0.0% (0) | 0.0% (0) | 0.0% (0) | - |
| Acute Renal Failure | 0.0% (0) | 0.0% (0) | 0.0% (0) | - |
| Altered Mental Status | 2.0% (4) | 0.0% (0) | 3.5% (4) | 0.084 |
| VTE | 0.0% (0) | 0.0% (0) | 0.0% (0) | - |
| Pulmonary Embolism | 0.5% (1) | 0.6% (1) | 0.0% (0) | 0.672 |
| Pneumothorax | 0.5% (1) | 0.0% (0) | 0.9% (1) | 0.392 |
| Pneumonia | 0.5% (1) | 0.0% (0) | 0.9% (1) | 0.392 |
| Atelectasis | 1.5% (3) | 0.0% (0) | 2.6% (3) | 0.136 |
| Pleural Effusion | 0.5% (1) | 0.0% (0) | 0.9% (1) | 0.392 |
| Arrhythmia | 0.5% (1) | 1.2% (1) | 0.0% (0) | 0.241 |
| Ileus | 2.5% (5) | 0.0% (0) | 4.4% (5) | 0.053 |
| Nausea / Vomiting | 7.5% (15) | 4.8% (4) | 9.6% (11) | 0.205 |
| Fever of Unknown Origin | 10.6% (21) | 7.1% (6) | 13.0% (15) | 0.392 |

VTE = venous thromboembolism

Another study by Ahmadian et al (2013) examining 84 patients with LLIF for L4-5 spondylolisthesis found a mean EBL of 94ml - similar to the present study. The similar intra-operative parameters likely contributed to the similar rates of all postoperative complications between the groups. These findings suggest that subjective measures of pain severity may not necessarily correlate with the severity of spinal pathology anatomically in patients undergoing LLIF, though a future study examining this relationship would be necessary to provide clarity. Separately, though this study found significantly longer average LOS for patients with severe preoperative back pain based on number of hours (53.9hrs vs. 40.6hrs, p=.011), this finding did not necessarily translate into a significant shift in postoperative day of discharge (p=0.129). One possible explanation for the discrepancy in length of stay between groups is the increased time required to monitor and treat the significantly higher postoperative pain observed on postoperative day (POD) 0 and 1 in the VAS ≥7 back pain cohort, though increased pain alone may not have significantly influenced the planned day of discharge.

CLINICAL OUTCOMES

As described previously, patients in both preoperative back pain cohorts saw statistically significant short- and long-term improvements in measures of pain, disability, and physical function post-operatively – findings consistent with existing literature of patients undergoing LLIF (Youssef et al. 2010; Ahmadian et al. 2013; Rodgers, Gerber, and Patterson 2011; Phillips et al. 2013; Salzmann, Shue, and Hughes 2017; Kotwal et al. 2015). In the retrospective study of 84 patients undergoing LLIF by Youssef et al, VAS improved by 77% and ODI improved by 56% from baseline at 1-year follow-up (2010). Similarly, in a prospective analysis of 600 patients undergoing XLIF, Rodgers et al found an immediate 65% improvement (8.82 to 3.12) in VAS pain score (2011). Further, Ahmadian et al (2013) analyzed 31 patients with L4-5-level stenosis and spondylolisthesis treated with LLIF without laminectomy and reported a 38.6% improvement in ODI and 44.6% improvement in VAS Back from pre-operation to last follow-up. In our study, we found a 25.5% and 36.2% improvement in VAS Back score in the moderate preoperative back pain group and 57% and 30.1% improvement in the severe back pain group at 1-year and 2-year follow-ups, respectively. Regarding ODI,

**Table 4. Patient Reported Outcome Measures**

| | VAS-Back <7 Mean±SD | VAS-Back <7 Postoperative PROM Improvement | VAS-Back >=7 Mean±SD | VAS-Back >=7 Postoperative PROM Improvement | *p-value |
|---|---|---|---|---|---|
| **VAS Back** | | | | | |
| Preoperative | 4.7 ± 1.7 | - | 8.3 ± 0.9 | - | **<0.001** |
| 6-weeks | 3.3 ± 1.9 | **<0.001** | 4.2 ± 2.5 | **<0.001** | **0.012** |
| 12-weeks | 2.6 ± 2.2 | **<0.001** | 3.6 ± 2.7 | **<0.001** | **0.017** |
| 6-months | 2.0 ± 2.3 | **<0.001** | 3.5 ± 2.7 | **<0.001** | **0.003** |
| 1-year | 3.5 ± 3.0 | **0.038** | 3.6 ± 2.9 | **<0.001** | 0.841 |
| 2-year | 3.0 ± 2.6 | **<0.001** | 5.8 ± 3.4 | **0.006** | **0.049** |
| **VAS Leg** | | | | | |
| Preoperative | 4.8 ± 2.5 | - | 6.9 ± 2.2 | - | **<0.001** |
| 6-weeks | 2.9 ± 2.7 | **<0.001** | 3.8 ± 2.5 | **<0.001** | 0.117 |
| 12-weeks | 1.9 ± 2.2 | **<0.001** | 3.1 ± 2.8 | **<0.001** | 0.064 |
| 6-months | 1.9 ± 2.6 | **<0.001** | 3.5 ± 2.7 | **0.002** | **0.026** |
| 1-year | 3.1 ± 3.5 | 0.060 | 3.6 ± 2.9 | **<0.001** | 0.593 |
| 2-year | 2.7 ± 2.7 | **0.018** | 4.9 ± 3.5 | **0.002** | 0.122 |
| **ODI** | | | | | |
| Preoperative | 32.9 ± 13.0 | - | 49.0 ± 15.0 | - | **<0.001** |
| 6-weeks | 32.6 ± 16.7 | 0.981 | 39.1 ± 16.4 | **<0.001** | **0.045** |
| 12-weeks | 21.1 ± 16.6 | **<0.001** | 35.4 ± 20.9 | **<0.001** | **0.001** |
| 6-months | 19.1 ± 14.9 | **<0.001** | 29.6 ± 18.7 | **<0.001** | **0.010** |
| 1-year | 24.8 ± 21.3 | **0.019** | 36.4 ± 25.6 | **0.013** | 0.091 |
| 2-year | 19.6 ± 18.8 | **0.028** | 39.0 ± 22.5 | **0.017** | **0.043** |
| **SF-12 PCS** | | | | | |
| Preoperative | 31.9 ± 8.4 | - | 27.3 ± 6.8 | - | **0.003** |
| 6-weeks | 32.6 ± 8.8 | 0.738 | 31.7 ± 9.5 | **0.012** | 0.651 |
| 12-weeks | 37.8 ± 10.4 | **0.007** | 37.2 ± 11.1 | **<0.001** | 0.808 |
| 6-months | 41.3 ± 11.4 | **0.004** | 35.1 ± 12.0 | **<0.001** | **0.041** |
| 1-year | 41.7 ± 11.6 | **0.003** | 36.2 ± 13.4 | **0.003** | 0.122 |
| 2-year | 43.6 ± 10.3 | **0.026** | 41.9 ± 12.4 | **0.004** | 0.691 |
| **PROMIS PF** | | | | | |
| Preoperative | 37.7 ± 5.5 | - | 31.7 ± 5.8 | - | **<0.001** |
| 6-weeks | 37.9 ± 5.9 | 0.959 | 35.3 ± 6.1 | **0.039** | 0.075 |
| 12-weeks | 42.0 ± 6.7 | **0.015** | 38.5 ± 6.9 | **<0.001** | **0.043** |
| 6-months | 46.3 ± 8.4 | **<0.001** | 39.9 ± 7.2 | **<0.001** | **0.005** |
| 1-year | 46.3 ± 6.9 | **<0.001** | 40.2 ± 9.2 | **0.001** | **0.014** |
| 2-year | 44.2 ± 5.8 | **0.014** | 41.8 ± 7.4 | **0.026** | 0.414 |

*p-values calculated using paired samples t-test to determine postoperative improvement

our study found a 24.6% and 40.4% improvement in the moderate back pain group and 26.7% and 20.4% improvement in the severe back pain group at 1-year and 2-year follow-ups, respectively. Campbell et al's (2018) retrospective evaluation of 18 consecutive patients with Grade 1 or 2 spondylolisthesis found an average ODI and SF-12 PCS score improvement of 26 and 5.4 points respectively at the 6-month follow up. In our study, the moderate back pain

**Table 5. MCID Achievement**

| PROM | VAS-Back <7 | VAS-Back>=7 | *p-value |
|---|---|---|---|
| VAS Back | | | |
| 6-weeks | 34.9% | 72.7% | **<0.001** |
| 12-weeks | 44.5% | 72.3% | **0.002** |
| 6-months | 56.5% | 72.9% | 0.068 |
| 1-year | 33.3% | 75.0% | **0.005** |
| 2-year | 55.6% | 50.0% | 0.795 |
| Overall | 57.1% (44) | 83.3% (90) | **<0.001** |
| VAS Leg | | | |
| 6-weeks | 40.8% | 61.2% | **0.043** |
| 12-weeks | 50.0% | 63.9% | 0.223 |
| 6-months | 56.3% | 56.3% | 1.000 |
| 1-year | 52.4% | 66.7% | 0.329 |
| 2-year | 44.4% | 77.8% | 0.147 |
| Overall | 61.0% (36) | 77.2% (44) | 0.060 |
| ODI | | | |
| 6-weeks | 16.0% | 28.6% | 0.133 |
| 12-weeks | 34.2% | 44.7% | 0.335 |
| 6-months | 50.0% | 52.8% | 0.819 |
| 1-year | 33.3% | 33.3% | 1.000 |
| 2-year | 55.6% | 55.6% | 1.000 |
| Overall | 46.7% (28) | 60.0% (36) | 0.143 |
| SF-12 PCS | | | |
| 6-weeks | 34.1% | 53.6% | 0.102 |
| 12-weeks | 58.3% | 82.6% | 0.052 |
| 6-months | 71.4% | 77.3% | 0.640 |
| 1-year | 73.9% | 75.0% | 0.935 |
| 2-year | 75.0% | 81.8% | 0.675 |
| Overall | 72.0% (36) | 83.3% (30) | 0.220 |
| PROMIS PF | | | |
| 6-weeks | 23.8% | 41.7% | 0.135 |
| 12-weeks | 46.7% | 64.0% | 0.199 |
| 6-months | 68.0% | 66.7% | 0.921 |
| 1-year | 76.2% | 70.0% | 0.655 |
| 2-year | 55.6% | 50.0% | 0.809 |
| Overall | 67.4% (29) | 74.3% (26) | 0.510 |

*p-value calculated with chi-squared analysis

group showed an ODI and SF-12 PCS improvement of 13.8 and 9.4 points and the severe back pain group showed an improvement of 19.4 and 7.8 points respectively. Furthermore, in 107 patients with degenerative scoliosis treated by LLIF, Philips et al (2013) reported statistically significant mean improvements at 2-year follow-up in ODI scores and VAS scores for back and leg pain of 21.5, 3.4, and 3.5, respectively. Similarly, Kotwal et al (2015) analyzed 118 patients undergoing LLIF and found ODI, VAS score, and SF-12 PCS improvements of 12.9, 4.6, and 11.1 at 2-year follow up, respectively. In our study, the moderate preoperative back pain cohort showed a 2-year improvement of 13.3 for ODI, 1.7 for VAS Back, 2.1 for VAS Leg, and 11.7

for SF-12. The severe back pain group demonstrated improvements of 10, 2.5, 2.0, and 14.6 for respective measures. Overall, this study's PROM percentage and score differences reflect comparable improvements in VAS back pain and leg pain, inferior outcomes with regard to disability, and superior outcomes in physical function relative to other studies.

Examining the present study's data further, though the moderate preoperative back pain group reported significantly lower absolute VAS back pain and ODI scores and higher absolute overall physical function scores postoperatively, it must be noted that their mean baseline scores were significantly better than those in the severe VAS back

pain cohort. Interestingly, when minimum clinically significant difference achievements were calculated, we found that patients in the VAS Back ≥7 group demonstrated an overall clinically significant improvement in their back pain (83.3% vs. 57.1%, p<.001) and near-significant overall improvement in their leg pain (77.2% vs. 61.0%, p=.06) compared to the moderate back pain cohort. Thus, taking both sets of findings into consideration, it would be reasonable to recommend LLIF more strongly in patients with degenerative lumbar spinal pathologies who present with a VAS back pain score ≥ 7 as it more likely can result in a clinically significant improvement in back pain. Conversely stated, surgical intervention in patients with a VAS back pain score <7 may lead to improvements in patient-reported outcome measures as described above but is less likely to result in a clinically significant improvement compared to intervention in patients with more severe preoperative back pain.

### LIMITATIONS

This study has several limitations. First, as with any retrospective analysis of prospectively collected databases, data entry and manipulation errors are possible. Second, it is important to note that these data represent procedures performed by one spine surgeon at one quaternary level medical center in the United States. As such, the findings previously discussed were limited to a patient population that consisted of mostly healthy [non-diabetic (81.6%), non-smoking (85.3%), ASA <3 (70.1%)] Caucasians (80.8%) covered most often through private insurance (62.8%). Thus, the generalizability of this study's findings must be taken into consideration before being applied to a novel population. Third, LLIF specific complications - such as hip flexion dysesthesia/weakness, neurologic injury, vascular injury, visceral injury, and subsidence – that were examined in other comparable investigations (Marchi et al. 2013; Kim et al. 2013; Tormenti et al. 2010; Aichmair et al. 2015; Balsano et al. 2015; Tohmeh, Rodgers, and Peterson 2011; Lee et al. 2013) were not analyzed in this study.

### FUTURE DIRECTIONS

Future studies can consider examining differences in pain, disability, and functional status beyond two years. Also, as mentioned previously, future studies can also consider examining the relationship between preoperative severity of pain measured through the VAS and the severity of spinal pathology as determined through radiographic measurement. Furthermore, other investigations might consider performing a similar analysis by initially stratifying patients by VAS Leg, ODI, SF-12 PCS, PROMIS PF, or another validated PROM assessment tool to understand if any of these PROMs provide greater predictive potential for postoperative outcomes than the VAS Back.

### CONCLUSION

Patients in both preoperative back pain severity cohorts demonstrated significant long term clinical improvement from their respective preoperative baselines to 2-years postoperatively in back pain, leg pain, physical function, and general disability. Patients with severe preoperative back pain (VAS ≥ 7), however, demonstrated significantly inferior absolute short (6 weeks-6 months) and long-term (2-year) mean outcome scores for back pain and general disability when compared with their moderate preoperative back pain (VAS <7) peers. However, patients with severe preoperative back pain achieved an overall MCID in VAS back pain in a significantly higher percentage of patients compared to their moderate preoperative back pain peers. Thus, taking both PROM and MCID findings into consideration, it would be reasonable to recommend LLIF more strongly in patients with degenerative lumbar spinal pathologies who present with a VAS back pain score ≥ 7 as it is more likely to result in a clinically significant

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