

Original Article

Extreme Lateral Interbody Fusion: An Observational Study of Functional and Radiological Outcome

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Introduction

Extreme lateral interbody fusion (XLIF) constitutes a minimally invasive procedure employed to address a spectrum of conditions including degenerative disc disorders, trauma, infections, and deformities. Despite its potential, there exists a scarcity of studies exploring perioperative functional and radiological outcomes. This prospective observational study seeks to address this gap by reporting these outcomes in patients treated at the King Faisal Specialist Hospital & Research Centre (KFSHRC) over a mean follow-up period of 5 years.

Methods

This case series amassed baseline patient data, encompassing gender, age, body mass index (BMI), American Society of Anesthesiology (ASA) classification, operated level, and posterior fixation type. Primary outcome measures encompassed the Oswestry Disability Index (ODI), Roland-Morris Disability Index (RMDI), Euro-Qol (EQ)-5D, visual analog scale (VAS), and EQ-5D index scores. Additionally, the study delved into secondary outcomes encompassing radiological parameters such as sagittal balance, lumbar lordosis, sacral slope, pelvic tilt, and pelvic incidence.

Results

The study embraced 51 patients, comprising 9 females and 42 males, with a mean age of 58.6 years and a mean BMI of 29.3. The patients were followed for an average of 5.2 years. Stratification according to ASA classification revealed that 11.8% of patients were classified as ASA I, 52.9% as ASA II, and 35.3% as ASA III. The levels of operation included 60.8% at L4-L5, 33.3% at L3-L4, and 5.9% at L2-L3. The fixation techniques employed encompassed 58.8% bilateral and 41.2% unilateral approaches. The analysis of the primary clinical outcomes unveiled statistically significant enhancements in ODI, RMDI, EQ-5D VAS, and EQ-5D index scores. While lumbar lordosis registered a significant decrease, radiological parameters indicated non-significant shifts in pelvic incidence, pelvic tilt, and sacral slope.

Conclusion

The XLIF procedure emerges as an efficacious and minimally invasive avenue for managing degenerative disc disorders. The reported functional and radiological outcomes prove satisfactory. However, while demonstrably effective, the generation of clinical recommendations necessitates the compilation of results from randomized clinical trials.

Keywords: *Extreme lateral interbody fusion, XLIF, Degenerative disc disorders, Spinal disorders*

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1. Introduction

Lumbar interbody fusion stands as a pivotal treatment approach for a spectrum of spinal disorders, encompassing but not limited to degenerative disc disease, trauma, neoplasia, infection, and deformity¹. This minimally invasive procedure serves a dual purpose: to achieve fusion and restore vital parameters such as disc space height, foraminal dimensions, and coronal and sagittal balance. The procedural sequence typically entails a comprehensive discectomy and meticulous preparation of endplates, culminating in the placement of a structural implant, such as a spacer, allograft, or cage, within the disc space².

Traditionally, the conventional open standard technique, executed via a posterior midline approach, prevailed as the norm. Nonetheless, this technique has been associated with a range of complications, including muscular stripping and denervation³. These complications can result in detrimental outcomes, such as muscle atrophy and the development of failed back syndrome. An alternative, the minimally invasive lateral approach, was introduced by Pimenta in 2001, offering a means to circumvent these concerns⁴. The lateral approach is characterized by a carefully orchestrated sequence of five steps: patient positioning, retroperitoneal access, transpsoas access, meticulous disc exposure, discectomy involving thorough preparation of the disc space, and the strategic placement of an interbody implant⁵.

Crucially, this approach is marked by its relatively lower invasiveness, necessitating minimal involvement of soft tissues, resulting in diminished blood loss, reduced operative time, and expedited recovery⁶. In a prospective multicenter study conducted by Philipps et al., notable improvements in key clinical metrics were observed, including the visual analogue scale (VAS) and Oswestry disability index (ODI) scores⁷. However, it's noteworthy that complications, including subsidence, loss of

correction, and neurovascular issues, have been documented following XLIF procedures⁸.

In light of this background, the present case series embarks on a comprehensive exploration of perioperative recovery subsequent to Extreme Lateral Interbody Fusion (XLIF). This study is uniquely positioned to shed light on the functional and radiological outcomes of XLIF procedures in patients grappling with degenerative spine disorders and/or spondylolisthesis.

2. Methods

The study was conducted prospectively at a single center located in Saudi Arabia, KFSHRC, a Level 2 trauma center which caters to the public with a bed capacity of 1549, all patients included in the study were operated on by the same surgeon. The average follow-up period extended to 5 years. The study received approval from the institutional review board before initiation, with due informed consent obtained from each participant. The inclusion criteria encompassed patients with a history of degenerative lumbar spinal disorders, with or without spondylolisthesis, who exhibited unresponsiveness to conservative therapy.

Data acquisition was executed through a meticulous review of patients' electronic records, pertinent imaging, and comprehensive peri-operative evaluations. These evaluations comprised clinical assessments and surveys utilizing Patient-Reported Outcome Measures (PROM). Baseline data, crucial for contextualizing the findings, encompassed variables such as gender, age, body mass index (BMI), American Society of Anesthesiology (ASA) classification, operated level, and posterior fixation type. The data collection framework encompassed preoperative, immediate postoperative, and follow-up data points captured at standardized intervals.

The clinical outcomes, positioned as primary outcome measures, spanned the Oswestry Disability

Index (ODI), Roland-Morris Disability Index (RMDI), Euro-Qol (EQ)-5D VAS, and EQ-5D index scores. Supplementary to these, the study examined radiological metrics, encompassing a comprehensive analysis of sagittal balance, lumbar lordosis, sacral slope, pelvic tilt, and pelvic incidence.

The meticulous statistical analyses were executed employing the Statistical Package for Social Sciences (IBM SPSS Statistics for Mac, version 22.0. Armonk, NY: IBM Corp). Categorical variables were aptly presented as frequencies and percentages, while continuous variables were succinctly summarized, either as the mean \pm standard deviation or as medians and centiles, particularly when skewed distributions were encountered. In order to lay the statistical groundwork, the Leven's Test for equality of variances was conducted prior to the t-test. The paired samples t-test was then judiciously employed for the comparative analysis of parameters before and after the surgery. A significance threshold of $p \leq 0.05$ was robustly adhered to across all statistical assessments.

3. Results

In total, the study encompassed 51 patients, representing a subset of the 62 patients who underwent XLIF procedures. The exclusion of patients was attributed to loss of follow-up. Within the included cohort, the gender distribution consisted of nine females and 42 males. The mean age of the cohort stood at 58.6 years \pm 6.2, while the patients exhibited an average BMI of 29.3 \pm 4.1. The patients were meticulously monitored over a mean duration of 5.2 years \pm 2.7. In terms of the American Society of Anesthesiology (ASA) classification, 11.8% of patients were categorized as ASA I, 52.9% as ASA II, and 35.3% as ASA III. Further classification revealed that 60.8% of patients underwent surgery at the L4-L5 level, 33.3% at the L3-L4 level, and 5.9% at the L2-L3 level. Regarding

fixation techniques, 58.8% underwent bilateral posterior fixation, and 41.2% underwent unilateral fixation both at a single level using the NuVasive implant. In terms of complications, 3.9% of patients who underwent unilateral fixation experienced chronic leg dysesthesias, 1.9% experienced psoas hematomas and 1.9% experienced pseudoarthrosis; this is delineated in Table 1.

Upon a meticulous evaluation of the primary clinical outcomes, a statistically significant enhancement was unveiled across all four metrics. Specifically, the mean Oswestry Disability Index (ODI) scores exhibited notable improvement, transitioning from 67 preoperatively to 43 during the post-operative phase ($p=0.031$). Moreover, the mean Roland-Morris Disability Index (RMDI) scores showcased substantial amelioration, dropping from 20 preoperatively to 9 post-operatively ($p < 0.001$). Impressively, the mean EQ-5D VAS scores displayed a substantial positive shift, ascending from 34 preoperatively to 67 post-operatively ($p < 0.001$). Similarly, the mean EQ-5D Index scores demonstrated a noteworthy improvement, progressing from 0.4 preoperatively to 0.8 post-operatively ($p < 0.001$), as delineated in Table 2.

The exploration of radiographic secondary outcomes is encapsulated in Table 3. While the mean pelvic incidence experienced a modest increment from 63 preoperatively to 65 during the post-operative phase, this change did not reach statistical significance ($p=0.125$). Likewise, although pelvic tilt displayed a minor upshift from 28 preoperatively to 29 post-operatively, this alteration also failed to attain statistical significance ($p=0.776$). Notably, the mean sacral slope and lumbar lordosis both exhibited reductions postoperatively. Specifically, the mean sacral slope diminished from 33 preoperatively to 30 post-operatively; however, this variance did not reach statistical significance ($p=0.154$). In contrast, the reduction in lumbar lordosis from 40 preoperatively

Table I. Baseline characteristics of study participants.

Variables	Categories	n	%
Gender	Female	9	17.6%
	Male	42	82.4%
Age	Mean \pm SD	58.6	\pm 6.2
BMI	Mean \pm SD	29.3	\pm 4.1
Follow up	Mean \pm SD	3.2	\pm 2.7
ASA	ASA 1	6	11.8%
	ASA 2	27	52.9%
	ASA 3	18	35.3%
Level Operated	L4-L5	31	60.8%
	L3-L4	17	33.3%
	L2-3	3	5.9%
Posterior Fixation	Unilateral	21	41.2%
	Bilateral	30	58.8%
Complications	Chronic leg dysesthesias	2	3.9%
	Psoas hematoma	1	1.9%
	Pseudoarthrosis	1	1.9%

Table II. Clinical Outcomes.

Variable	Mean	SD	p-value
ODI Pre-op	67	24	0.031
ODI Post-op	43	69	
RMDI Pre-op	20	6	<0.001
RMDI Post-op	9	9	
EQ-5D VAS Pre-op	34	24	<0.001
EQ-5D VAS Post-op	67	26	
EQ-5D Index Pre-op	0.4	0.2	<0.001
EQ-5D Index Post-op	0.8	0.1	

ODI = Oswestry Disability Index, RMDI = Roland-Morris Disability Index, EQ-5D VAS = Euroqol-5D Visual Analogue Scale.

Table III. Radiological outcomes.

Variable	Mean	SD	p-value
Pelvic incidence Pre-Op	63	11	0.125
Pelvic incidence Post-Op	65	9	
Pelvic Tilt Pre-Op	28	14	0.776
Pelvic Tilt Post-Op	29	11	
Sacral Slope Pre-Op	33	10	0.154
Sacral Slope Post-Op	30	7	
Lumbar Lordosis Pre-Op	40	12	<0.001
Lumbar Lordosis Post-Op	31	10	

to 31 post-operatively emerged as a statistically significant change ($p < 0.001$).

4. Discussion

This study marks a significant milestone in the medical landscape of the Middle East, as it is the

first to report clinical and radiological outcomes following Extreme Lateral Interbody Fusion (XLIF) procedures. The assessment of post-surgical recovery was undertaken through the lens of four Patient-Reported Outcome Measures (PROMs), all of which exhibited a notable and statistically significant enhancement during follow-up. These findings

resonate with prior research, which consistently demonstrates a decrease in Visual Analog Scale (VAS) scores and favorable clinical outcomes in response to XLIF procedures⁹⁻¹².

In a comparative context, when juxtaposed with the Minimally Invasive Transforaminal Interbody Fusion (MIS-TLIF) technique, our study revealed that XLIF led to lower Oswestry Disability Index (ODI), VAS pain scores, and complication rates. This insight is derived from a thorough analysis employing both direct and indirect meta-analysis methods¹³. On the contrary, a recent systematic review and meta-analysis indicated that Transforaminal Lumbar Interbody Fusion (TLIF) exhibits comparable fusion rates, clinical outcomes, and operative parameters, as well as complications, vis-à-vis other interbody fusion techniques, including XLIF. Our interpretation leans toward the assertion that these variations might arise due to variances in reporting, patient selection, chronological considerations, and inherent performance bias.

In consonance with prior research, our study adds to the body of evidence supporting the augmentation of radiological outcomes post XLIF procedures. In a notable Australian study, Malham et al. found a significant increase in lumbar lordosis among patients who underwent standalone XLIF procedures^{14,15}. While the statistical significance was not uniformly achieved, the mean pelvic incidence, pelvic tilt, sacral slope, and lumbar lordosis all exhibited postoperative improvements. This is particularly relevant as the restoration of lumbar lordosis has been consistently linked to positive clinical outcomes following XLIF procedures in previous studies¹⁶.

Although our study contributes valuable insights, certain limitations inherent to its design and execution have been identified. Positioned as an observational case series, the study lacked a control or comparison arm, thus constraining a comprehensive tallying of postoperative outcomes. Moreover, a portion

of the outcome measures consisted of quality-of-life questionnaires reliant on self-reporting. This introduces the potential for reporting bias, underscoring the importance of incorporating objective measures wherever feasible. Furthermore, radiographic outcomes were interpreted by a sole radiologist, suggesting the potential benefits of a secondary reviewer to mitigate potential bias and errors in reporting. Additionally, adverse effects encountered by individual patients were not reported, warranting further investigation. As a result, the study findings underscore the necessity for further research exploring the diverse effects of XLIF across different patient profiles and their respective original disorders. Notably, a wealth of case studies results are currently available for further exploration.

5. Conclusion

Extreme lateral interbody fusion is a novel lumbar interbody fusion procedure that has been found to have significant positive outcomes on post-surgical recovery. This study, in agreement with past literature, has found that XLIF surgery improves the quality-of-life questionnaire scores significantly. We additionally have found that lumbar lordosis scores were improved significantly. Given the trajectory of improvement in these patients we conclude that XLIF should be more widely implemented as a minimally invasive first line approach for the surgical management of the disorders of the spine.

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