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Quality-of-Life Outcomes With Minimally Invasive Transforaminal Lumbar Interbody Fusion Based on Long-Term Analysis of 304 Consecutive Patients

Mick J. Perez-Cruet, MD, MS, Namath S. Hussain, MD, G. Zachary White, BS, Evan M. Begun, BS, Robert A. Collins, DO, Daniel K. Fahim, MD, Girish K. Hiremath, MD, Fadumo M. Adbi, BS, and Sammy A. Yacob, BS

Study Design. This was a prospective clinical study that took place in an outpatient spine clinic.

Objective. To demonstrate the short-/long-term outcomes from a large cohort of patients undergoing minimally invasive transforaminal lumbar interbody fusion (MITLIF).

Summary of Background Data. Long-term prospective outcomes in patients undergoing minimally invasive spinal fusion for debilitating back pain has not been well studied.

Methods. Presenting diagnosis was determined from clinical findings and radiographical (radiograph, magnetic resonance image, computed tomographic scan) evaluations preoperatively. Patients were assessed with outcome measures preoperatively, and postoperatively at 2 weeks, 3 months, 6 months, 12 months, 24 months, and annually 2 to 7 years (mean follow-up: 47 mo) final follow-up. The rate of postoperative complications and reoperations at the initial level of MITLIF and adjacent level(s) were followed. Fusion rates were assessed blinded and independently by radiograph.

Results. Visual analogue scale scores decreased significantly from 7.0 preoperatively to 3.5 at mean 47-month follow-up. Oswestry Disability Index scores declined from 43.1 preoperatively to 28.2 at mean 47-month follow-up. Short-Form 36 mental component scores increased from 43.8 preoperatively to 49.7 at 47-month follow-up. Short-Form 36 physical component scores increased from 30.6 preoperatively to 39.6 at 47-month follow-up ($P < 0.05$).

Conclusion. This prospectively collected outcomes study shows long-term statistically significant clinical outcomes improvement after MITLIF in patients with clinically symptomatic spondylolisthesis and degenerative disc disease with or without stenosis. MITLIF resulted in a high rate of spinal fusion and very low rate of interbody fusion failure and/or adjacent segment disease requiring reoperation while reducing postoperative complications.

Key words: lumbar fusion, minimally invasive spine surgery, minimally invasive transforaminal, lumbar interbody fusion, percutaneous pedicle screws, patient outcomes.

Level of Evidence: 3

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Lumbar fusion serves to eliminate abnormal motion and instability while maintaining load-bearing capacity and proper alignment to provide symptomatic treatment for spinal instability, stenosis, spondylolisthesis, and symptomatic degenerative disc disease.[1] During the past few decades there has been a dramatic increase in the rates of lumbar fusion procedures in the United States.[1,2]

For many surgical procedures, the method of choice is shifting from traditional open surgery to minimally invasive techniques. Postoperative histological and imaging studies have demonstrated that conventional open techniques are associated with increased scar tissue formation, significant muscle stripping, and muscle retraction which adversely affect outcomes, and increase reoperation rates.[3–6] Minimally invasive techniques are performed via a muscle-dilating approach that helps to preserve paraspinal muscular anatomy and bone architecture, and have been shown to diminish iatrogenic soft-tissue injury significantly.[6–8] Reasons for widespread transition to minimally invasive spine (MIS) techniques include decreased postoperative pain, decreased intraoperative blood loss, shorter postoperative hospital stay, faster return to normal activity, and reduced reoperation rates.[9,10]

From the Department of Neurosurgery, Oakland University William Beaumont School of Medicine, Royal Oak, MI.

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Address correspondence and reprint requests to Mick J. Perez-Cruet, MD, MS, Department of Neurosurgery, Oakland University William Beaumont School of Medicine, 3577 W. 13 Mile Rd, Ste 206, Royal Oak, MI 48073-4490; E-mail: perezcruet@yahoo.com

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Use of minimally invasive fusion techniques in lieu of traditional open fusion techniques remains a crucible of debate as long-term prospective outcomes in patients undergoing minimally invasive spinal fusion for debilitating back pain has not been well studied. We hope to contribute evidence to this debate by reporting long-term, prospectively collected outcomes on 1 of the largest currently available series of minimally invasive transforaminal lumbar interbody fusion (MITLIF) with a minimum follow-up of 24 months, and to determine if adjacent level pathology (ALP) is reduced by preservation of the normal anatomical integrity of the spine.

PATIENTS AND METHODS

This prospective clinical trial was conducted under the auspices of our institutional review board. Patient outcomes were collected independently from patients with informed consent, and analyzed blindly so as not to influence outcome scores.

Patients and Selection Process

A total of 318 MITLIF procedures were performed using a paramedian, muscle-sparing approach on 304 consecutive patients, spanning 7 years from 2003 to 2010. The study population included 120 men and 184 women with a mean age of 62.4 years (range, 19–93 yr) at the time of surgery. All participants were recruited from an outpatient neurosurgical spine clinic, and all 318 MITLIF procedures were performed by the senior author. Diagnosis was established through thorough clinical history, physical examination, and radiographical evaluations of the lumbar spine including plain dynamic radiograph films, computed tomography, myelography, and magnetic resonance imaging. Spondylolisthesis and retrolisthesis were graded using the Meyerding classification (I–IV).[11] All patients were evaluated in an outpatient setting.

Patient comorbidities are summarized in Table 1. Clinical diagnosis at presentation included spondylolisthesis (66%), central spinal stenosis (47%), foraminal stenosis (34%), degenerative disc disease (23%), retrolisthesis (1%), and other diagnosis (10%). Refractory chronic debilitating low back pain, neurogenic claudication, and signs of radiculopathy were the predominant clinical findings. The average length of symptoms prior to surgery was 68.6 months. Prior lumbar surgical procedures were performed in 70 patients (23%). The distribution of MITLIF procedures performed at each spinal level is detailed in Table 2.

Patients with a concordance of findings on clinical examination and imaging, and symptoms lasting greater than 6 months unresponsive to nonoperative treatment were deemed candidates for MITLIF. A total of 210 patients underwent conservative, nonoperative treatment, which is detailed in Table 3. Surgical treatment was initiated earlier than 6 months if a neurological deficit was worsening, or if the patient presented with severe, incapacitating pain with good correlation between clinical and radiographical findings. Surgical treatment was indicated as a last resort to failed nonoperative therapy. Patients were excluded if they were medically unfit to undergo a surgical procedure, had a history of ongoing or recent bleeding diathesis, ongoing infection, or had incongruent clinical and radiographical findings.

TABLE 1. Common Comorbidities

Comorbidity	Incidence, No. (%)
Hypertension	111 (37)
Diabetes	36 (12)
High cholesterol	23 (8)
Cardiovascular disease	22 (6)
Smoking	18 (6)
Urinary incontinence	11 (4)
Arthritis	10 (3)
Osteoporosis	8 (3)
History of stroke	6 (2)

The values are given as the number of patients affected with the percentage in parenthesis.

Outcome Measures

The following patient-reported outcome measures were evaluated: visual analogue scale (VAS) for low back pain, Oswestry Disability Index (ODI) for back-related functional disability, and Short-Form 36 (SF-36) for physical and mental quality of life.

Patients were asked to complete these validated questionnaires preoperatively at the time of enrollment, and at various points postoperatively. Preoperative baseline scores, all follow-up scores, and change scores (calculated as the difference between respective mean follow-up and baseline scores) were used for analysis.

Secondary outcomes included fusion rate, reoperation rate, intraoperative blood loss, and length of postoperative hospital stay. Fusion was assessed independently and blindly by radiologists during the postoperative period using lumbar anterior-posterior and lateral flexion/extension view radiograph films. Criteria for successful fusion included a lack of significant motion/angulation at the fused level, lack of lucency around implants, absence of hardware loosening or

TABLE 2. Spinal Levels Undergoing MITLIF

Spine Level	Patients, No. (%)
L1–L2	4 (1)
L2–L3	15 (5)
L3–L4	33 (11)
L4–L5	152 (50)
L5–S1	88 (29)
2 level	12 (4)

MITLIF indicates minimally invasive transforaminal lumbar interbody fusion.

TABLE 3. Conservative Treatments

Conservative Treatment	Patients, No. (%)
Total number of patients	210 (69)
Physical therapy	171 (56)
Epidural steroid injections	111 (37)
Transcutaneous electrical nerve stimulation	26 (9)
Chiropractic manipulation	11 (4)
Bracing	8 (3)
Dorsal root rhizotomy	5 (2)
Acupuncture	4 (1)
Nerve block	3 (1)

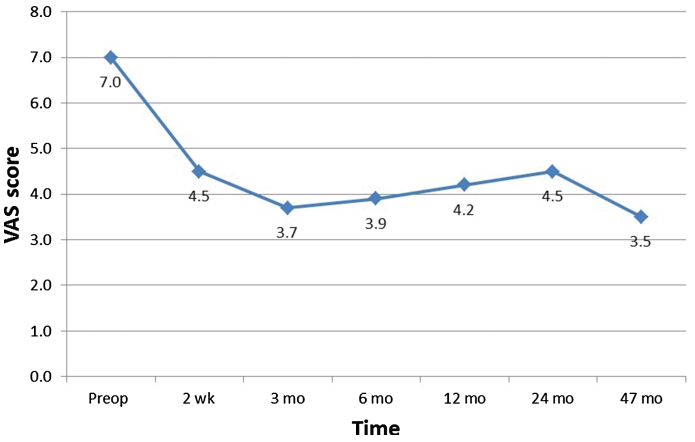

Figure 1. Line graph demonstrating mean VAS scores over time ($P < 0.001$ for 2-week to 24-month follow-up scores). *Lower VAS scores show improvement. VAS indicates visual analogue scale.

breakage on flexion/extension dynamic radiographical views, and presence of bridging bone formation indicative of fusion.

Statistical Analysis

The Student *t* test was used to compare VAS, ODI, and SF-36 outcome scores at each time interval. Statistical significance was defined as $\alpha = 0.05$, and $P < 0.05$ were considered significant. Statistical analyses were performed with use of Microsoft Excel software (version 2010; Microsoft Corporation; Redmond, WA).

Source of Funding

There was no external source of funding for this study.

RESULTS

The average follow-up time was 47 months (range, 2–8 yr). Mean estimated blood loss and hospital stay was 128.4 mL and 4.4 days, respectively. Mean operative time for 1-level fusions was 185.4 minutes. Only 1 case had to be converted to an open-TLIF technique. Overall fusion rate was greater than 95% with an average fusion time of 6.8 months.

VAS scores averaged 7.0 points preoperatively, and decreased to 4.5 points ($P < 0.001$) at 2 weeks postoperatively (Figure 1), representing an immediate short-term improvement of 35.7%. 268 (88.2%) patients had preoperative VAS scores of 7 or greater, indicating significant pain. Thus, a large majority of our patients were in severe pain even after nonoperative therapy. VAS scores maintained improvement long-term, averaging 4.5 ($P < 0.001$) and 3.5 ($P < 0.05$) at 24 mo and 47 mo, respectively (Table 4).

ODI scores averaged 43.1 points preoperatively, and displayed significant short-term improvement averaging 31.6 points ($P < 0.001$) and 28.7 points ($P < 0.001$) at 3 months and 6 months, respectively (Figure 2). ODI outcomes maintained long-term improvement, averaging 30.2 points and 28.2 points ($P < 0.05$) at 24 months and 47 months, respectively (Table 4). By ODI criteria, patients who were "severely disabled" preoperatively, improved to "moderate disability" status by 3 months postoperatively, and remained improved at 47 months.

Short-Form physical component scores (SF-PCS) averaged 30.6 preoperatively, and improved above baseline scores by 3 months postoperatively (Figure 3), averaging 36.8 ($P < 0.001$). SF-PCS averaged 38.1 ($P < 0.001$) and 39.6 ($P < 0.05$) at 24 months and 47 months post-operatively, respectively (Table 4). Short-Form mental component scores averaged 43.8 preoperatively, and also improved by 3 months postoperatively (Figure 3), averaging 47.3 ($P < 0.001$). Short-Form mental component scores maintained long-term improvement, averaging 49.7 ($P < 0.001$) and 49.7 ($P < 0.05$) at 24 months and 47 months, respectively (Table 4).

Complications

Surgical complications included pedicle screw malposition requiring return to operating room for reposition in 1 patient, durotomy in 1 case requiring conversion to open TLIF, and interbody cage retropulsion requiring reoperation in 3 cases. One patient had intraoperative hemorrhage (>500 mL). Pedicle screw breakage was encountered in 1 patient 7 months postoperatively. Other complications included urinary retention in 17 patients, superficial wound infection in 11 patients, atelectasis in 8 patients, pneumonia in 3 patients, urinary tract infection in 2 patients, and deep vein thrombosis in 1 patient. No patient experienced a neurological complication.

Overall reoperation rate was 3.9% (n = 12). Reoperation at the original MITLIF level occurred in 6 (2%) patients. Adjacent level reoperation was performed in 6 (2%) patients.

DISCUSSION

The TLIF procedure reduces the need for significant retraction of the nerve root and thecal sac, avoids having to enter the abdominal cavity, preserves the anterior and posterior longitudinal ligaments, and allows the disc space to be accessed unilaterally, preserving the contralateral facet complex, without forfeiture of direct, bilateral decompression of the neural elements[11] (Figures 4, 5). The TLIF approach also creates greater fusion area, enhanced fusion blood supply, access for

TABLE 4. Long-Term Results

	Baseline	Follow-up Time		
		12 mo*	24 mo*	47 mo*
Back pain visual analogue scale	7.0 ± 2.4	4.2 ± 3.0 (2.8, 40%)	4.5 ± 3.0 (2.5, 35.7%)	3.5 ± 2.8 (3.5, 50%)
Oswestry Disability Index	43.1 ± 15.7	29.7 ± 18.8 (13.4, 31.1%)	30.2 ± 20.4 (12.9, 29.9%)	28.2 ± 21.7 (14.9, 34.6%)
SF-36 physical component score	30.6 ± 7.8	38.3 ± 11.3 (7.7, 25.2%)	38.1 ± 11.7 (7.5, 24.5%)	39.6 ± 11.7 (9, 29.4%)
SF-36 mental component score	43.8 ± 11.0	48.3 ± 13.0 (4.5, 10.3)	49.7 ± 12.9 (5.9, 13.5%)	49.7 ± 11.2 (5.9, 13.5%)
P		<0.001	<0.001	<0.05

The values are given as the mean and the standard deviation.
**Net change and percent improvement from baseline, respectively, are in parenthesis.*
SF-36 indicates Short-Form 36.

medial and lateral decompression, and optimal restoration of disc height while allowing for reduction of spondylolisthesis to improve sagittal alignment, foraminal height, and central canal diameter[12] (Figures 6, 7). The application of a MIS technique to the TLIF approach allows for the preservation of back musculature, reduction of soft-tissue injury, blood loss, and hospital stay compared with open technique. Despite these advantages, concerns regarding long-term clinical outcomes may influence the decision to use the MITLIF technique.

Long-Term Clinical Outcomes

Glassman *et al*[13] outlined VAS, ODI, and SF-36 outcome improvement thresholds for substantial clinical benefit from 357 patients at 12 months after lumbar spine fusion.[13] Three response parameters for each of the aforementioned clinical outcome measures were examined: net change (from baseline), percent change (from baseline), and final raw score. Substantial clinical benefit thresholds for the SF-PCS were a 6.2-point net improvement, a 19.4% improvement, or a final raw score of 35.1 or more points. Substantial clinical benefit thresholds for the ODI were an 18.8-point net improvement, a 36.8% improvement, or a final raw score of less than 31.3 points. Substantial clinical benefit thresholds for the VAS back pain numeric rating scale were a 2.5-point net improvement, a 41.4% improvement, or a final raw score of less than 3.5 points. The 12-month, 24-month, and 47-month VAS, ODI, and SF-PCS results in this study (Table 4) were statistically significant and all met 1 or more of Glassman criterion thresholds for substantial clinical benefit, therefore endorsing the long-term clinical efficacy of the MITLIF procedure.

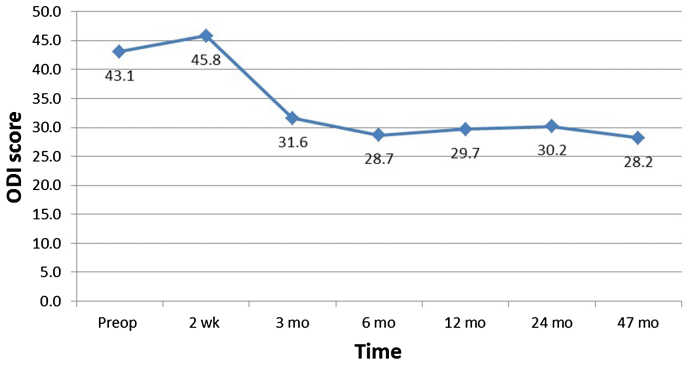

Figure 2. Line graph demonstrating mean ODI scores over time ($P < 0.001$ for 2-wk to 24-mo follow-up scores; $P < 0.05$ for 47-month follow-up score). *Lower ODI scores show improvement. ODI indicates Oswestry Disability Index.

In addition, Glassman *et al*[14] reported ODI improvements of 22.9% and 22.8% at 1-year and 2-year follow-up, respectively, from a group of 152 patients who underwent open TLIF and/or open PLIF,[14] which were significantly lower than the respective 12-month and 24-month ODI improvements (31.3% and 29.9%) from this study. This may support the superiority of the MITLIF approach compared with the open procedure, at least with regards to patient-reported improvements in ODI scores. Nevertheless, since the study by Glassman *et al*[14] is being used as a historical control for purposes of outcome comparison, no definitive conclusion regarding the long-term superiority of the MITLIF technique over the traditional, open technique, can be drawn. Multicenter long-term prospective randomized trials directly comparing the 2 approaches to lumbar fusion are needed to confirm this finding.

Reoperation and ALP

In this analysis, a total of 12 (3.9%) patients underwent reoperation. Six (2%) of those underwent surgery at the level where MITLIF was performed, either as a result of failed interbody device (either broken or retropulsion) or pedicle screw failure. No patients required re-exploration and arthrodesis of the MITLIF level for failed fusion. This study showed an extremely high fusion rate (>95%). We feel this high fusion rate was largely due to use of patient's own bone, preservation of the paraspinal muscular and bony anatomy, and instrumentation with bilateral percutaneous pedicle screws, making the final fusion construct extremely conducive to arthrodesis.

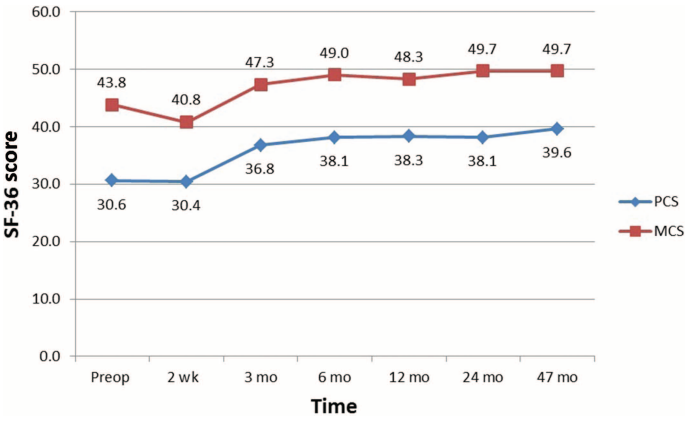

Figure 3. Line graph demonstrating mean SF-36 PCS and MCS over time ($P < 0.001$ for 2-wk to 24-mo follow-up scores; $P < 0.05$ for 47-month follow-up scores). *Higher SF-36 scores show improvement. PCS indicates physical component score; MCS, mental component scores; SF-36, Short-Form 36.

ALP was only seen in 6 (2%) patients during the study period. Four of these patients had symptomatic lumbar stenosis requiring minimally invasive laminectomy. Three of these patients required minimally invasive laminectomy alone. The remaining patient had a prior open laminectomy, which had removed the spinous processes and taken down the midline muscular anatomy, requiring adjacent level MITLIF with extension of percutaneous pedicle screw hardware. This low rate of ALP is thought to be due to preservation of the paraspinal muscular and bony anatomy afforded by the MITLIF approach. Open approaches strip these muscles off the midline bone and often remove the spinous process to visualize the thecal sac and its bony confines adequately to perform neural decompression. These anatomical structures are preserved in the MITLIF approach.[12] Additionally, postoperative magnetic resonance imaging performed on some of the patients in this series showed significantly less scar formation and normal anatomical distribution of nerve roots within the thecal sac in patients who underwent MITLIF when compared with patients who underwent open lumbar fusion.

Short-Term Benefits

There is a growing body of evidence supporting the short-term advantages of MITLIF compared with open TLIF. Lee *et al*[15] compared the outcomes of 144 patients who underwent MITLIF or an open TLIF (72 patients in each group). Mean operative time for the MIS group was 166.4 minutes, *versus* 181.8 minutes for the open group; mean blood loss was 50.6 mL, *versus* 447.4 mL for the open group; and mean hospital stay was 3.2 days, *versus* 6.8 days for the open group.[9] Peng *et al*[16] reported less blood loss with MITLIF (150 mL; open, 681 mL), a shorter hospital stay (MIS, 4 d; open, 6.7 d), less total morphine used (MIS, 17.4 mg; open, 35.7 mg), and similar fusion rates (MIS, 80%; open, 86%) between a 29-patient MIS TLIF group and 29-patient open TLIF group. Schizas *et al*[17] also reported less intraoperative blood loss with MITLIF (456 mL; open, 961 mL) and a shorter hospital stay (MIS, 6.1 d; open, 8.2 d) between an 18-patient MIS TLIF group and an 18-patient open TLIF group. Similar secondary outcomes were demonstrated in our present series as mean intraoperative blood loss was 128.4 mL, mean hospital stay was 4.4 days, and mean operative time was 185.4 minutes.

Cost-Effectiveness

The annual cost of treating spinal disorders has been estimated at more than $100 billion.[18] Although comparable long-term clinical outcomes between MITLIF and open TLIF have been demonstrated in small comparative studies,[16,17] the MITLIF commands cost-saving advantages compared with open TLIF secondary to decreased blood loss, shorter hospital stay, and lower infection rates.

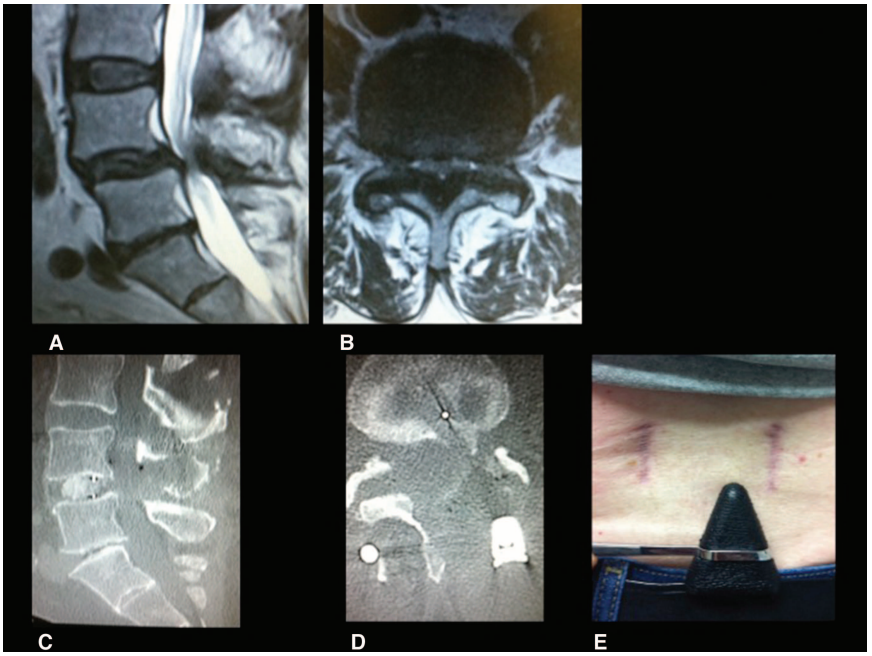

Figure 4. A 55-year-old female presents with severe refractory back pain and neurogenic claudication. Preoperative T2-weighted sagittal (**A**), and axial (**B**) MR images show L4–L5 grade 1 spondylolisthesis with associated spinal stenosis. Postoperative sagittal (**C**), and axial (**D**) CT images, and healed incision (**E**) after L4–L5 MIS laminectomy and MITLIF. Patient made an uneventful recovery with resolution of symptoms and return to work. MITLIF indicates minimally invasive transforaminal lumbar interbody fusion; MR, magnetic resonance; CT, computed tomography; MIS, minimally invasive spine.

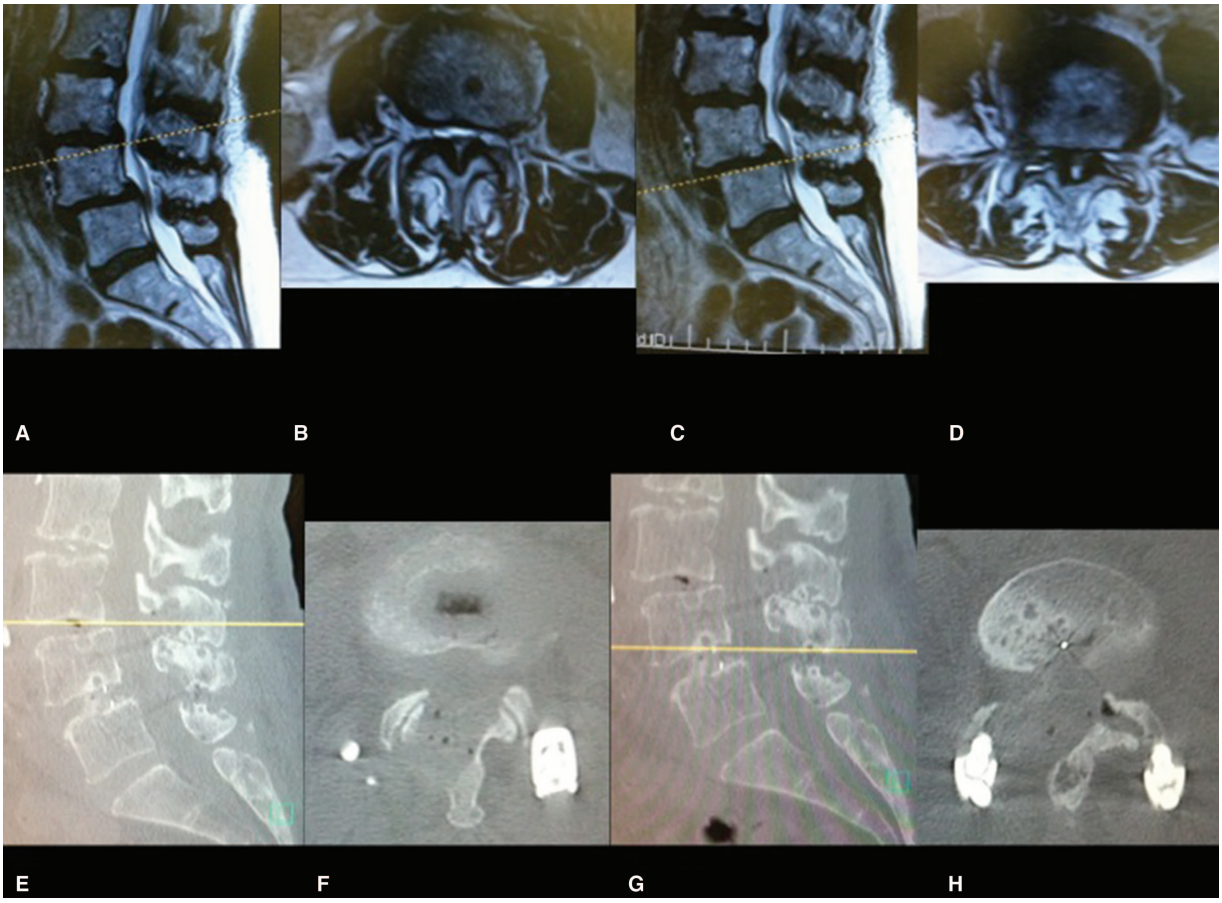

Figure 5. A 68 year-old female presenting with severe debilitating back pain and neurogenic claudication. Preoperative T2-weighted sagittal (**A**), and axial (**B**) MR images at the L3–L4 level showing stenosis, and L4–L5 MR image (**C**, **D**) showing stenosis and grade 1 spondylolisthesis. Postoperative corresponding sagittal and axial CT (**E**–**H**) showing MIS laminectomy at L3–L4 and L4–L5 levels with MITLIF at the L4–L5 level. Patient made an uneventful recovery with resolution of symptoms and return to activities of daily living. MITLIF indicates minimally invasive transforaminal lumbar interbody fusion; MR, magnetic resonance; CT, computed tomography; MIS, minimally invasive spine.

Parker *et al*[19] examined the cost savings associated with open TLIF *versus* MITLIF among 30 patients (15 patients in each group). Total mean 2-year cost to treat the open-TLIF patient group after surgery was $44,727 compared with $35,996 to treat the MIS TLIF patient group, representing a total cost difference of $8731 between the 2 groups. In addition, duration of narcotic use for the MIS group was 2.6 weeks (*vs.* 6.5 wk, open) and return to work was 8.3 weeks

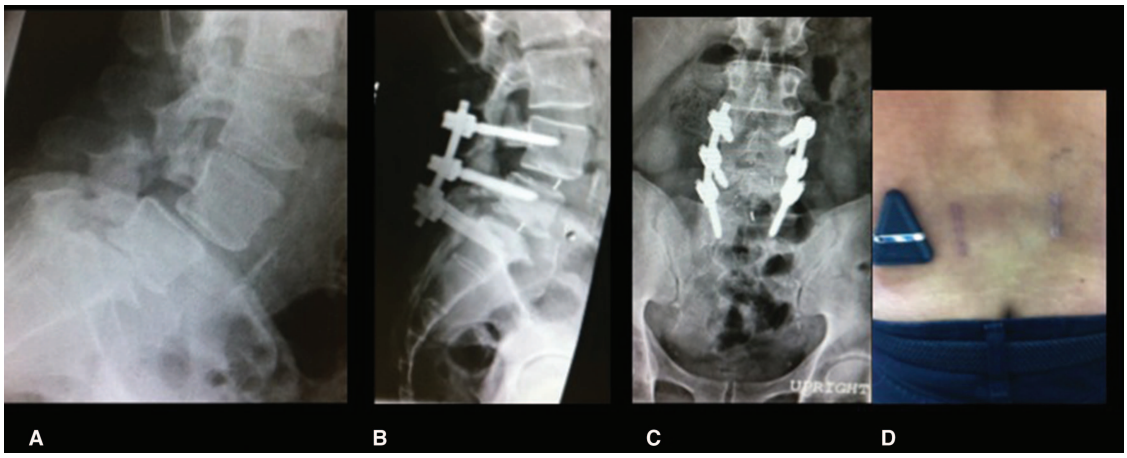

Figure 6. A 46-year-old male presenting with severe debilitating back pain from L4–L5 and L5–S1 grade 1 spondylolisthesis. Preoperative plain radiographs (**A**), and postoperative lateral (**B**) and anteroposterior (**C**) view after 2 level L4–L5 and L5–S1 MITLIF. Postoperative healed incision (**D**). Patient made an uneventful recovery with resolution of symptoms and return to work. MITLIF indicates minimally invasive transforaminal lumbar interbody fusion.

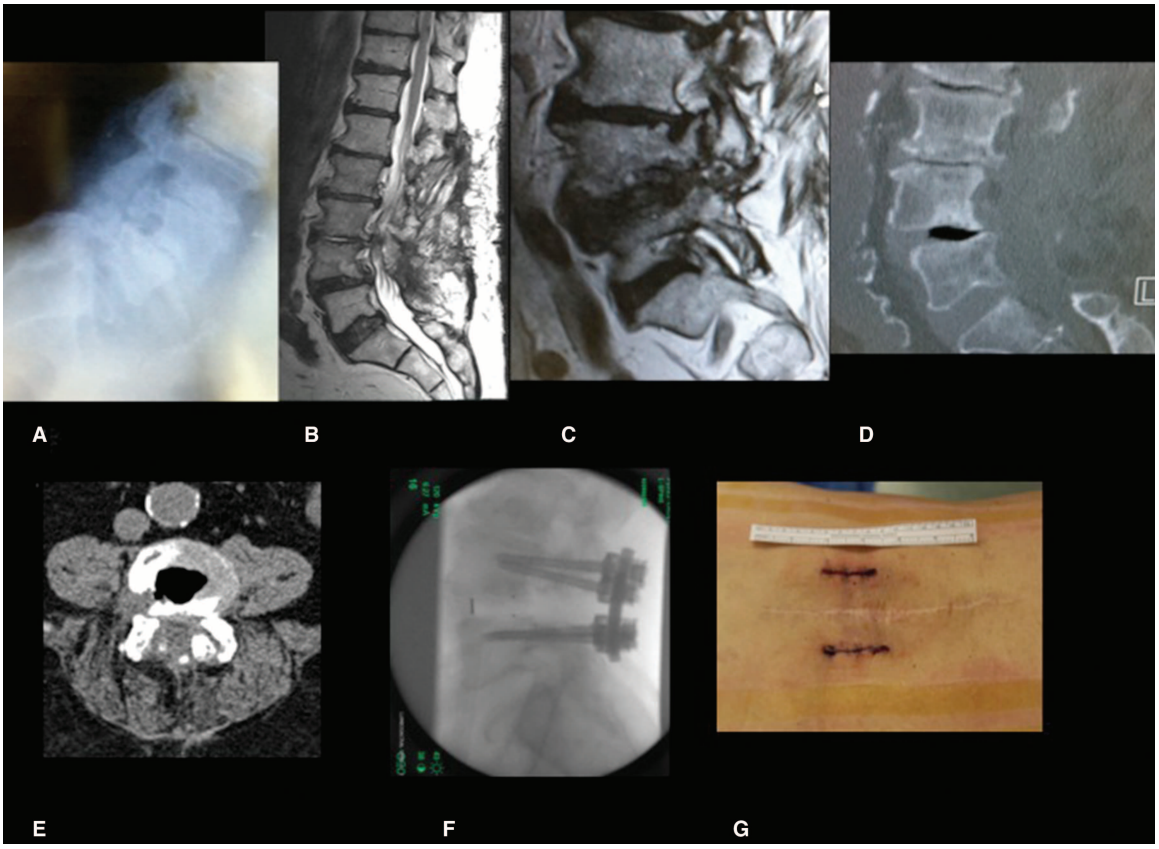

Figure 7. A 71 year-old male with severe debilitating back pain. Status post-traditional L2–L5 multilevel lumbar laminectomy. Preoperative (**A**) plain lateral radiograph, sagittal MR image (**B**, **C**), sagittal (**D**) and axial (**E**) CT showing L4–L5 grade 2 spondylolisthesis, severe bilateral foraminal stenosis, and air in the L4–L5 disc space. Postoperative (**F**) plain radiograph, and incision (**G**) after L4–L5 MITLIF. Patient made an uneventful recovery with resolution of symptoms. MITLIF indicates minimally invasive transforaminal lumbar interbody fusion; MR, magnetic resonance; CT, computed tomography.

(*vs.* 16.3 wk, open) ($P = 0.02$).[19] A large study by Wang *et al*[20] provides a powerful look at the cost savings associated with the minimally invasive surgical approach. This multicenter study examined 6106 patients who underwent either MITLIF (1667 patients) or open TLIF (4439 patients).[20] Although there was no significant cost-saving difference between 1-level open and MIS TLIF groups, total inflation-adjusted acute hospitalization cost averaged $2106 less ($P = 0.0023$) for patients who underwent 2-level MIS TLIF compared with those who underwent 2-level open TLIF.[20] Similarly, McGirt *et al*[21] conducted a meta-analysis of 5170 patients who underwent MIS—*versus* open—TLIF by examining the cost savings associated with lower surgical site infection (SSI) rates. The incidence of SSI was 65 (4.5%) for the MIS group *versus* 227 (6.1%) for the open group ($P = 0.037$), and the direct costs associated with the diagnosis and management of the SSIs identified in the study was $1,024,950 for MIS *versus* $3,593,862 for the open technique. In the current series an expected average direct cost per MITLIF case at our institution was $26,736. However, we observed an average direct cost of $16,505/case, based on acuity level, approach, operating room efficiency, techniques, instrumentation, and product use. This has resulted in significant cost savings.

Limitations to This Study and Future Directions

The findings in this study are limited to patients undergoing MITLIF because it was not controlled, randomized, or compared with patients undergoing open TLIF. Large, long-term, prospective, comparison studies need to be performed to solidify the short-term and long-term benefits and outcomes of MIS *versus* open spine surgery. Glassman *et al*[13] demonstrated that younger patients treated with open TLIF might have better clinical outcomes than older patients. Although MIS is thought to be better tolerated by older and obese patients, exploring this relationship was beyond the scope of this study and would be a useful area of future investigation.

CONCLUSION

The MITLIF approach seems to provide both short- and long-term statistically significant outcome improvements in patients experiencing debilitating low back pain. In addition, long-term benefits observed in this study include a reduced rate of adjacent segment disease requiring reoperation while providing high rates of fusion and a low rate of complications. From a clinical prospective these patients show an extremely high rate of satisfaction in the treatment of their chronic back pain disorders. In fact, the majority of these patients are

completely pain free and have returned to work or activities of daily living full time. The MITLIF procedure is a highly cost-effective approach for addressing a costly and debilitating medical condition.

➢ Key Points

- ❑ Long-term clinical outcomes after MITLIF are not well studied and this examines whether patients undergoing this surgery demonstrate appropriate spinal fusion over an average follow-up of 47 months.
- ❑ Patients with MITLIF demonstrate a high rate of spinal fusion and a very low rate of interbody fusion failure and/or adjacent segment disease requiring reoperation while reducing postoperative complications.
- ❑ This suggests MITLIF provides a cost-effective approach for addressing chronic lower back pain.

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