A Prospective, Multi-Institutional Comparative Effectiveness Study of Lumbar Spine Surgery in Morbidly Obese Patients: Does Minimally Invasive Transforaminal Lumbar Interbody Fusion Result in Superior Outcomes?

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Key words
BMI 
Fusion 
MIS-TLIF 
Morbid obesity 
Obese 
TLIF

Abbreviations and Acronyms
BMI: Body mass index
BP-VAS: Back Pain-Visual Analog Scale
DDD: Degenerative disc disease
LP-VAS: Leg Pain-Visual Analog Scale
MCS: Mental component score
MIS-TLIF: Minimally invasive transforaminal lumbar interbody fusion
ODI: Oswestry Disability Index
PCS: Physical component score
SF-36: Medical Outcomes Study Short-Form 36
TLIF: Transforaminal lumbar interbody fusion
VAS: Visual Analog Scale

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INTRODUCTION
The prevalence of obesity in the United States is high, exceeding 30% in most age and sex groups (17). Numerous studies have demonstrated a strong association between obesity and medical resource use for low back pain and chronic low back pain (10, 11, 14, 15, 31, 34, 35). Although many obese patients with spinal stenosis are effectively treated nonoperatively (33), many patients do not respond to conservative treatments; furthermore, there is growing evidence that long-term outcomes may be inferior to nonoperative treatment modalities (27). Obese (body mass index [BMI] >30) and morbidly obese (BMI >35) patients undergoing lumbar spinal fusion surgery present a unique challenge to the spine surgeon because of poor operative corridors and difficult access to necessary anatomical landmarks. Collectively, these may contribute to increased risk of intraoperative complications (e.g., malpositioned pedicle screw, incidental durotomy, wrong-level surgery) (18, 21).

TRANSFORAMINAL LUMBAR INTERBODY FUSION (TLIF) remains the gold standard for

BACKGROUND: Obese and morbidly obese patients undergoing lumbar spinal fusion surgery are a challenge to the operating surgeon. Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) and open-TLIF have been performed for many years with good results; however, functional outcomes after lumbar spine surgery in this subgroup of patients remain poorly understood. Furthermore, whether index MIS-TLIF or open-TLIF for the treatment of degenerative disc disease or spondylolisthesis in morbidly obese results in superior postoperative functional outcomes remains unknown.

METHODS: A total of 148 (MIS-TLIF: n = 40, open-TLIF: n = 108) obese and morbidly obese patients undergoing index lumbar arthrodesis for low back pain and/or radiculopathy between January 2003 and December 2010 were selected from a multi-institutional prospective data registry. We collected and analyzed data on patient demographics, postoperative complications, back pain, leg pain, and functional disability over 2 years. Patients completed the Oswestry Disability Index (ODI), Medical Outcomes Study Short Form 36 (SF-36), and back and leg pain numerical rating scores before surgery and then at 12 and 24 months after surgery. Clinical outcomes and complication rates were compared between both patient cohorts.

RESULTS: Compared with preoperative status, Visual Analog Scale (VAS) back and leg pain, ODI, and SF-36 physical component score/mental component score were improved in both groups. Both MIS-TLIF and open-TLIF patients showed similar 2-year improvement in VAS for back pain (MIS-TLIF: 2.42 ± 3.81 vs. open-TLIF: 2.33 ± 3.67, P = 0.89), VAS for leg pain (MIS-TLIF: 3.77 ± 4.53 vs. open-TLIF: 2.67 ± 4.10, P = 0.18), ODI (MIS-TLIF: 11.61 ± 25.52 vs. open-TLIF: 14.88 ± 22.07, P = 0.47), and SF-36 physical component score (MIS-TLIF: 8.61 ± 17.72 vs. open-TLIF: 7.61 ± 15.55, P = 0.93), and SF-36 mental component score (MIS-TLIF: 4.35 ± 22.71 vs. open-TLIF: 5.96 ± 21.09, P = 0.69). Postoperative complications rates between both cohorts were also not significantly divergent between (12.50% vs. 11.11%, P = 0.51).

CONCLUSION: MIS-TLIF is a safe and viable option for lumbar fusion in morbidly obese patients and, compared with open-TLIF, resulted in similar improvement in pain and functional disability. Postoperative complications rates between both cohorts were also not significantly divergent.
surgical decompression and fusion in patients with medically refractory lumbar stenosis and has been shown to have good long-term effectiveness (1, 20, 29). In nonobese patients, both minimally invasive transforminal lumbar interbody fusion (MIS-TLIF) and open-TLIF have been shown to have good long-term clinical outcomes with equivocal results (28). Whether MIS-TLIF or open-TLIF procedures for treatment of degenerative disc disease (DDD) or spondylolisthesis result in superior postoperative functional outcomes in this subset of patients remains unknown.

The primary aim of this study is to assess and compare the long-term patient-reported outcomes after MIS-TLIF and open-TLIF procedures for treatment of symptomatic DDD or spondylolisthesis in obese and morbidly obese patients.

METHODS

Study Design
From January 2003 to December 2010, we queried a prospectively maintained data registry that included consecutive patients who underwent lumbar spine surgery by one of a cohort of 106 neurosurgeons or orthopedic surgeons from 41 different institutions in the United States and Canada. Institutional review board approval was obtained from all 41 institutions.

Patient Selection
We included patients ages 18–70 years old with 1) low back pain and/or radiculopathy; 2) evidence on magnetic resonance imaging of DDD or Grade I spondylolysis with central or foraminal stenosis; 3) who after failed at least 6 weeks of nonsurgical treatment; 4) who underwent lumbar spinal fusion (e.g., pedicle screw fixation, TLIF, or extreme lateral interbody fusion, anterior lumbar interbody fusion); 5) BMI >30 kg/m²; and 6) had available patient-reported outcomes data at baseline and also at 1- and 2-year time points after surgery. The exclusion criteria included: 1) previous back surgery; 2) an extra spinal cause of back pain or sciatica; 3) an active medical or workman’s compensation lawsuit; 4) any pre-existing spinal pathology; or 5) unwillingness or inability to participate with follow-up procedures. Patients with notable associated abnormalities, such as inflammatory arthritis, or metabolic bone disease, also were excluded.

To minimize the variability and selection bias inherent to the use of a large, multi-institutional database registry, we excluded institutions that contributed <60% of their overall institutional spinal surgical cases to the database. Patients were also excluded if they had 1) previous back surgery; 2) severe coexistent pathology that could confound the assessment of operative outcome (e.g., rheumatoid arthritis, osteoarthritis, metabolic bone disease); and 3) an active medical or workman’s compensation lawsuit.

Surgeon Selection
We included board-certified neurosurgeons and orthopedic surgeons from both private and academic institutions. Patient selection and intraoperative and postoperative rehabilitation were performed according to each surgeon’s clinical judgment.

Surgical Technique
MIS-TLIF. Fluoroscopy was used to determine the operative level. The TLIF procedure was performed on the side of radicular symptoms. If both the legs were symptomatic, the approach was from the side of more severe pathology and contralateral lamina and foramina decompressed by a unilateral exposure. An incision was made 3–4 cm off midline. Sequential soft-tissue dilators were inserted through the incision down to the facet complex until the desired working diameter was achieved. A facetectomy was then performed with a high-speed drill from lateral to medial side to expose the posterolateral aspect of the disc.

Intrasdiskal distraction and disc space preparation were performed with the use of standard interbody fusion instruments. Cartilaginous material was removed from the endplates with an endplate scraper. An interbody graft was then placed in a direction anterior and contralateral to the annulotomy within the interbody space. Autograft was not used in any cases. Fluoroscopy was used to ensure satisfactory placement of the graft. When necessary, the contralateral ligamentum flavum was resected to expose the contralateral exiting and traversing nerve roots. If needed, the tubular retractor was angled contralaterally so that a more extensive bony decompression could be performed.

The tubular retractor was then removed and 4 percutaneous pedical screws placed immediately above and below the interbody segment to be fused. Under fluoroscopic guidance, a Jamshidi needle was inserted into the pedicles. A K-wire was then passed through the Jamshidi trocar into the pedicles. With the use of cannulated instruments, a bone tap followed by cannulated screw was advanced over the K-wire. The rod was then placed percutaneously to connect the screws. Compression was applied to the construct before final tightening, providing compression of the bone graft and maximizing lordosis. All wounds were copiously irrigated, and the wounds were closed in layers.

Open-TLIF. A midline skin incision was used. The fascia was incised, and the paravertebral muscles were dissected from the spine. Radiographs were used to check the appropriate level. Bilateral pedicle screw rod constructs were inserted, and laminecetomy and unilateral facetectomy was then performed at that level. This was followed by unilateral anulotomy, discectomy, and placement of the interbody graft. Similar to the MIS approach, cartilaginous material was removed from the endplates with an endplate scraper. Interbody graft was then placed anteriorly and contralateral to the anulotomy within the interbody space. For posterior-lateral arthodesis, local autogenous bone with or without bone extenders was used for bone grafting. The wound was copiously irrigated and closed in layers.

Immediate Postoperative Complications
We assessed postoperative complications for each patient included in the study. Complications were divided into those likely or possibly associated with MIS-TLIF versus open-TLIF (e.g., durotomy, nerve root injury, surgical-site drainage or infection, and need for reoperation) and other complications known to be associated with lumbar spinal fusion surgery (e.g., pulmonary embolism/deep vein thrombosis), hardware failure, nonunion, and adjacent segment disease.

Patient-Reported Outcomes
Back pain was assessed using the Back Pain-Visual Analog Scale (BP-VAS), whereas leg pain was assessed using the Leg Pain-Visual Analog Scale (LP-VAS) (7, 9). Functional status was assessed using the...
were compared with the patients whose data came from institutions and type of fusion performed. Clinical outcome variables included severity of back and leg pain at baseline, functional status at baseline, and the change in functional status at the 1- and 2-year time points. Parametric data were expressed as the means ± SD and compared via the Student t test. Nonparametric data were expressed as median [interquartile range] and compared via the Mann-Whitney U test. Nominal data were compared with the χ² test. All tests were 2-sided and statistical significance was determined by P < 0.05. We used the software SAS 9.3 (SAS Institute, Inc., Cary, North Carolina, USA) for data preparation and data analysis.

RESULTS
From January 2003 to December 2010, a large, multicenter spine registry was queried, and on the basis of our inclusion and exclusion criteria, 148 obese and morbidly obese patients were enrolled in the study. We included patients between 18 and 70 years of age who had both clinical and radiographic indications for lumbar spinal fusion with available 1- and 2-year follow-up data. We excluded patients whose data came from institutions that contributed <60% of their spine surgeries to the database, had previous back surgery, severe pathologies that can confound the assessment of potentially operative back pain, or an active medical or workman’s compensation lawsuit.

In total, 148 obese patients undergoing TLIF for degenerative disc disease or spondylolisthesis were involved: MIS-TLIF: (n = 40) and open-TLIF (n = 108). The overall mean ± SD age was 56.25 ± 10.92 years (MIS-TLIF: 56.62 ± 11.99 years vs. open-TLIF: 56.12 ± 10.88 years, P = 0.82), of which 67 were men and 81 were women, Table 1. All patients presented with back and leg pain with associated radiculopathy and radiographic evidence attributed to magnetic resonated—documented DDD or Grade I spondylolisthesis. The duration of preoperative symptoms was not available for this study. Overall mean (±SD) BMI was 35.32 ± 4.66 kg/m² (MIS-TLIF: 34.48 ± 4.39 kg/m² vs. open-TLIF: 35.63 ± 4.74 kg/m², P = 0.16). L4–L5 and L5–S1 were the most common vertebral levels involved, 72.00% and 56.00%, respectively, Table 1.

### Baseline (Preoperative) Patient-Reported Outcome
At baseline, there was no significant difference in baseline functional status between both groups. At presentation, the mean ± SD BP-VAS score for patients undergoing MIS-TLIF and open-TLIFs were 6.97 ± 2.49 and 7.00 ± 2.44 (P = 0.93), respectively. Mean ± SD LP-VAS score for the MIS-TLIF and open-TLIF cohorts were 7.07 ± 3.00 and 6.38 ± 2.98 (P = 0.38), respectively, Table 1.

Overall, the mean preoperative ODI score was 49.60 ± 15.59 (MIS-TLIF: 50.18 ± 16.74 vs. open-TLIF: 49.15 ± 15.21, P = 0.59), Table 1. Baseline Medical Outcomes Study Short-Form 36 (SF-36) physical component score (PCS) and mental component score (MCS) were similar between both cohorts. The mean ± SD baseline SF-36-PCS and SF-36 MCS were 24.53 ± 10.11 (MIS-TLIF: 24.06 ± 11.25 vs. open-TLIF: 24.72 ± 9.70, P = 0.74) and 39.88 ± 17.67 (MIS-TLIF: 41.92 ± 16.69 vs. TLIF: 39.11 ± 18.04, P = 0.38), respectively, Table 1.

| Table 1. Baseline Characteristics and Patients Undergoing Index MIS- vs. open-TLIF Surgery |
|------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Combined Cohort, n = 148 | MIS-TLIF, n = 40 | Open-TLIF, n = 108 | P Value |
| Patient age, years | 56.25 ± 10.91 | 56.62 ± 11.99 | 56.12 ± 10.88 | 0.821 |
| BMI, kg/m² | 35.32 ± 4.66 | 34.48 ± 4.39 | 35.63 ± 4.74 | 0.167 |
| Male, % | 45.27 | 50 | 47 | 0.489 |
| Indication for surgery, % | | | | | |
| Degenerative disc disease | 104 (70.27) | 27 (67.50) | 81 (75.00) | 0.982 |
| Spondylolisthesis | 107 (72.29) | 29 (72.50) | 78 (72.22) | 0.973 |
| Surgical levels, n (%) | | | | | |
| L1—L2 | 35 (23.64) | 1.0 (2.5) | 34 (31.48) | 8.61E-08 |
| L2—L3 | 45 (30.40) | 7.0 (17.50) | 38 (35.18) | 0.022 |
| L3—L4 | 48 (32.43) | 7.0 (17.50) | 41 (37.96) | 0.009 |
| L4—L5 | 107 (72.29) | 24 (60.00) | 83 (76.85) | 0.061 |
| L5—L1 | 83 (56.08) | 21 (52.50) | 62 (57.40) | 0.600 |
| Preoperative patient-reported outcomes | | | | | |
| BP-VAS | 7.00 ± 2.44 | 6.97 ± 2.49 | 7.00 ± 2.44 | 0.939 |
| LP-VAS | 6.71 ± 2.98 | 7.07 ± 3.00 | 6.58 ± 2.98 | 0.386 |
| SF-36 MCS | 39.88 ± 17.67 | 41.92 ± 16.69 | 39.11 ± 18.04 | 0.383 |
| SF-36 PCS | 24.53 ± 10.11 | 24.06 ± 11.25 | 24.72 ± 9.70 | 0.740 |
| ODI | 49.60 ± 15.59 | 50.18 ± 16.74 | 49.15 ± 15.21 | 0.594 |

Both cohorts were matched at baseline. Values given as mean ± SD. AUIF, anterior lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion; MIS-TLIF, minimally invasive transforaminal lumbar interbody fusion; BMI, body mass index; BP-VAS, Back Pain-Visual Analog Scale; LP-VAS, Leg Pain-Visual Analog Scale; SF-36, Medical Outcomes Study Short-Form 36; MCS, mental component score; PCS, physical component score; ODI, Oswestry Disability Index.
Postoperative Complications Profile Between Both Cohorts
There was no difference in reoperation rate or surgical-site infection between the 2 groups (P > 0.26, Table 2). There were no differences in the rate of nerve root injury between the 2 groups (P = 0.81). Statistically more incidental durotomies occurred in the open-TLIF cohort (P = 0.02, Table 2). Hardware failure occurred in 1 (0.67%) patient (MIS-TLIF: 1 [2.50%] patient vs. open-TLIF: 0 [0.00%] patients; P = 0.32), adjacent segment degeneration occurred in 1 (0.67%) patient (MIS-TLIF: 0 [0.00%] patients vs. open-TLIF: 1 [0.92%] patient; P = 0.31), Table 2.

Two-Year Outcomes After MIS-TLIF Versus Open-TLIF
Both cohorts (MIS-TLIF and open-TLIF) demonstrated a similar improvement in BP-VAS, LP-VAS, and functional status Table 3, Figure 1. One year after index spine surgery, the mean ± SD improvement in BP-VAS and LP-VAS scores was 3.27 ± 3.74 (MIS-TLIF: 2.62 ± 3.82 vs. open-TLIF: 3.50 ± 3.70, P = 0.21), and 3.12 ± 4.44 (MIS-TLIF: 3.35 ± 4.77 vs. TLIF: 3.03 ± 4.34, P = 0.71), respectively. Overall, the mean ± SD change from baseline in SF-36 PCS and SF-36 MCS was 18.43 ± 22.41 (MIS-TLIF: 17.97 ± 21.69 vs. TP-LIF: 17.43 ± 22.41, P = 0.77), Table 3. Overall, the mean ± SD change from baseline in SF-36 PCS and SF-36 MCS was 4.75 ± 17.97 (MIS-TLIF: 4.61 ± 21.69 vs. open-TLIF: 4.80 ± 16.50, P = 0.96) and 1.48 ± 25.23 (MIS-TLIF: 1.00 ± 26.82 vs. open-TLIF: 2.31 ± 24.70, P = 0.53).

Similarly, 2 years after index spine surgery, the mean ± SD improvement in BP-VAS and LP-VAS scores was 2.35 ± 3.69 (MIS-TLIF: 2.42 ± 3.81 vs. open-TLIF: 2.33 ± 3.67, P = 0.89), and 2.97 ± 4.23 (MIS-TLIF: 3.77 ± 4.53 vs. open-TLIF: 2.67 ± 4.10, P = 0.18), respectively. Overall, the mean ± SD improvement in functional status (ODI) was 14.00 ± 23.01 (MIS-TLIF: 11.01 ± 25.52 vs. open-TLIF: 14.88 ± 22.07, P = 0.47), Table 3. Overall, the mean ± SD change from baseline in SF-36 PCS and SF-36 MCS was 7.88 ± 16.11 (MIS-TLIF: 8.61 ± 17.72 vs. open-TLIF: 7.61 ± 15.55, P = 0.75) and 5.52 ± 21.47 (MIS-TLIF: 4.35 ± 22.71 vs. open-TLIF: 5.96 ± 21.09, P = 0.69), respectively, Table 3.

DISCUSSION
In this multi-institutional study assessing long-term functional outcomes after MIS-TLIF versus open-TLIF procedures in obese and morbidly obese patients, we observed no difference in patient-reported outcomes of back pain, leg pain, or functional status, 1 and 2 years after index lumbar arthrodesis. Furthermore, there was no statistically significant difference in the incidence of postoperative complications between both groups. These findings should be helpful to surgeons when counseling obese patients who are considering lumbar arthrodesis for treatment of symptomaticDDD or low-grade spondylolisthesis.

MIS-TLIF and open-TLIF procedures have been demonstrated to have equivocal long-term improvement in pain and functional disability in nonobese patients (29). The theoretical advantages of MIS-TLIF include decreased tissue damage, fewer intraoperative and postoperative complications, as well as decreased duration of hospital stay (1, 20). Whether these theoretical advantages of the minimally invasive approach hold true in obese and morbidly obese patients remain unknown. Obesity often has been correlated with worse outcomes in spinal surgery (8). Lumbar surgery in the obese and morbidly obese patients requires a significantly longer setup and operative time (32), which may lead to greater rates of complication (4, 36). In addition to difficult operative corridors (19), the obese patient may have a statistically greater likelihood of developing pulmonary embolisms, deep-vein thrombosis, and other complications related to surgery that adversely affecting long-term functional outcomes (11). A recent study of 2653 patients from the Swedish spinal registry demonstrated that obese patients had both inferior postoperative functional outcomes and quality of life after spinal surgery. The aforementioned study used ODI and EQ-5D, 2 previously validated outcomes questionnaires (12). In contrast, Lau et al. (23) in a retrospective, single institutional series observed no difference in functional outcomes between obese and nonobese patients after MIS-TLIF procedures. In a recent prospective analysis of open-TLIF versus MIS-TLIF in obese patients, Wang et al. demonstrated equivocal long-term clinical outcomes in both patient cohorts (2, 3, 11, 16). Analogous to the findings of Lau et al., we observed no difference in pain and functional status in obese patients undergoing MIS-TLIF versus open-TLIF 2 years after index lumbar arthrodesis.

For our study, the incidence of nerve injury, reoperation, pulmonary emboli, hardware failure, and adjacent segment disease were not statistically different between both groups. Nine durotomies were noted in the open-TLIF cohort compared with one in the MIS-TLIF cohort, which was the only complication noted to be significant.

Table 2. Cohort-Specific Postoperative Complication Rates

<table>
<thead>
<tr>
<th>n (%)</th>
<th>Combined Cohort, n = 148</th>
<th>MIS-TLIF, n = 40</th>
<th>Open-TLIF, n = 108</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSI</td>
<td>3 (2.02)</td>
<td>2 (5.00)</td>
<td>1 (0.92)</td>
<td>0.285</td>
</tr>
<tr>
<td>Spinal cord/nerve root injury</td>
<td>3 (2.02)</td>
<td>1 (2.5)</td>
<td>1 (1.85)</td>
<td>0.818</td>
</tr>
<tr>
<td>Durotomy</td>
<td>10 (6.75)</td>
<td>1 (2.5)</td>
<td>9 (8.33)</td>
<td>0.021</td>
</tr>
<tr>
<td>Return to OR</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0.000</td>
</tr>
<tr>
<td>PE/DVT</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0.000</td>
</tr>
<tr>
<td>Hardware failure</td>
<td>1 (0.67)</td>
<td>1 (2.5)</td>
<td>0 (0.00)</td>
<td>0.327</td>
</tr>
<tr>
<td>Nonunion</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0.000</td>
</tr>
<tr>
<td>ASD</td>
<td>1 (0.67)</td>
<td>0 (0.00)</td>
<td>1 (0.92)</td>
<td>0.319</td>
</tr>
</tbody>
</table>

There was no significant difference in the incidence of postoperative complication rates 2 years after index MIS-TLIF and open-TLIF surgery. Values significant at the P < 0.05 level are in bold.

MIS-TLIF, minimally invasive transforminal lumbar interbody fusion; SSI, surgical-site infection; OR, operating room; PE, pulmonary emboli; DVT, deep-vein thrombosis; ASD, adjacent segment disease.
(P = 0.02). Senker et al. (30), in their analysis of perioperative complications, demonstrated similar results in obese patients after MIS approaches. For perioperative outcomes, the authors noted improvements in the operative length, less blood loss and radiation exposure, as well as shortened time to narcotic independence. Furthermore, in their series, there was a trend toward greater incidence of intraoperative durotomies in the open-TLIF cohort.

Our study design is unique in the literature as the current study is the first to include only primary fusion cases treated by multiple surgeons as difference institutions. In addition, our study is strengthened by the inclusion of one- and two year validated patient outcomes measures evaluating back pain, leg pain and functional status. In addition, the current study included a robust statistical analysis to adjust for baseline risk stratification.

Although the clinical management of individual patients was performed according to the judgment of individual board certified surgeons, patient selection adhered to published guidelines for lumbar fusion (22-26).

One surprising finding of the current study was that post-operative complications rates between both cohorts were also not significantly divergent (12.50% vs. 11.11%, P = 0.51). Despite this finding, it must be acknowledged that the overall rate of general complications (12.16%) was well within the range of previously reported complication rates. Our analysis

Table 3. Improvement in Reported Pain (VAS-BP, VAS-LP) and Disability (ODI, SF-36 PCS) after Index Spine Surgery

<table>
<thead>
<tr>
<th></th>
<th>Combined Cohort, n = 148</th>
<th>MIS TLIF, n = 40</th>
<th>Open-TLIF, n = 108</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year change from baseline in patient reported outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP-VAS</td>
<td>3.27 ± 3.74</td>
<td>2.62 ± 3.82</td>
<td>3.50 ± 3.70</td>
<td>0.211</td>
</tr>
<tr>
<td>LP-VAS</td>
<td>3.12 ± 4.44</td>
<td>3.35 ± 4.77</td>
<td>3.03 ± 4.34</td>
<td>0.718</td>
</tr>
<tr>
<td>SF-36 MCS</td>
<td>1.48 ± 25.23</td>
<td>1.00 ± 26.82</td>
<td>2.31 ± 24.70</td>
<td>0.532</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>4.75 ± 17.97</td>
<td>4.61 ± 21.69</td>
<td>4.80 ± 16.50</td>
<td>0.960</td>
</tr>
<tr>
<td>ODI</td>
<td>18.07 ± 23.57</td>
<td>17.09 ± 26.73</td>
<td>18.43 ± 22.41</td>
<td>0.778</td>
</tr>
<tr>
<td>2-year change from baseline in patient reported outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP-VAS</td>
<td>2.35 ± 3.69</td>
<td>2.42 ± 3.81</td>
<td>2.33 ± 3.67</td>
<td>0.896</td>
</tr>
<tr>
<td>LP-VAS</td>
<td>2.97 ± 4.23</td>
<td>3.77 ± 4.53</td>
<td>2.67 ± 4.10</td>
<td>0.184</td>
</tr>
<tr>
<td>SF-36 MCS</td>
<td>5.52 ± 21.47</td>
<td>4.35 ± 22.71</td>
<td>5.86 ± 21.09</td>
<td>0.697</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>7.88 ± 16.11</td>
<td>8.61 ± 17.72</td>
<td>7.61 ± 15.55</td>
<td>0.754</td>
</tr>
<tr>
<td>ODI</td>
<td>14.00 ± 23.01</td>
<td>11.61 ± 25.52</td>
<td>14.88 ± 22.07</td>
<td>0.475</td>
</tr>
</tbody>
</table>

The mean 2-year improvement in VAS-BP score ranged from 2.33 to 2.42 and VAS-LP from 2.67 to 3.77. Mean 2-year improvement in ODI score ranged from 11.61 to 14.88, SF-36 PCS 7.61 to 8.61 and SF-36 MCS 4.35-5.96. Mental health status appeared to be more refractory to surgery in this cohort of patients. Values given as mean ± SD. BP-VAS, Back Pain-Visual Analog Scale; LP-VAS, Leg Pain-Visual Analog Scale; SF-36 MCS, SF-36 mental component score; SF-36 PCS, SF-36 physical component score; ODI, Oswestry Disability Index.
did not stratify patients on the basis of medical comorbidities, therefore we are unable to comment on whether there were factors predisposing the current finding. In addition, other factors such as the number of levels fused is not controlled for by the current study design. Additional research would be required to validate this finding.

An important finding of the current research was the absence of an increased rate of surgical-site infection, reoperation, or nerve root injury between both groups. Although this finding is not supported by some previous studies, our large sample size, uniform study selection criteria, and multicentered study design enhance the strength of this finding. In addition, the similar improvement in pain and functional status after both procedures (MIS-TLIF and open-TLIF), at 1- and 3-year follow-up should be reassuring to surgeons and patients alike.

Highlighting the limitations of our study is important to its interpretation. Although pre- and perioperative variables were recorded into a registry at the time of surgery, these variables were assessed retrospectively at the time of the study’s initiation. Although there was uniformity in the inclusion/exclusion criteria in this study, clinical indications for surgery (extent of pain, length of pain) were assessed independently and based on surgical gestalt. Bone morphogenic protein often is used adjunctively to facilitate arthrodesis. The intraoperative use of this compound was not a variable assessed, and as such we cannot correlate functional outcomes or fusion rates to its use.

Successful fusion can be assessed radiographically by translation of adjacent posterior elements with spinal flexion-extension or luency around the fusion construct. This is coupled with clinical findings suggestive of neural compression and is collectively indicative of pseudarthroses. We cannot assess the uniformity of diagnosis in this cohort; however, these pain symptoms would be assessed as a component of their follow-up (LP-VAS, BP-VAS). Second, postoperative computed tomography scans were not obtained routinely in this cohort, precluding a diagnosis in some cases. This prospective assessment was a 2-year comparative effectiveness study. Patients may have not responded to arthrodesis, with symptoms presenting greater than 2 years postoperatively. A more extensive longitudinal study would be required to capture these failures.

Finally, because this study included patients who were able to provide 1- and 2-year follow-up data, it is possible that some excluded patients had outcomes different that those included in this study. Despite these limitations, we believe that the current study provides a valuable addition to the literature by demonstrating in a large patient cohort that both MIS-TLIF and open-TLIF procedures were associated with significant improvement in all outcome measures. Back pain, leg pain, disability, and overall health states were improved markedly after both procedures through a 2-year follow-up period.

CONCLUSION

MIS-TLIF is a safe and viable option for lumbar fusion in morbidly obese patients, and compared with open-TLIF, resulted in similar improvement in pain and functional disability. Postoperative complications rates between both cohorts were also not significantly divergent.

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Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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