The Effect of Obesity on the Improvement in Health State Outcomes following Minimally Invasive Transforaminal Interbody Fusion

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Abstract Keywords	 Study Design Observational study. Objective Studies have shown a correlation between obesity and lumbar spine pathology, but also that obese patients have higher rates of complication following lumbar spine surgery. It is unknown if obese patients have clinical gains following lumbar spine surgery comparable to the gain of normal-weight patients. This study investigated the correlation of obesity and the delta change in outcomes in a single surgeon's cohort of normal-weight and obese patients undergoing minimally invasive (MIS) transforaminal lumbar interbody fusion (TLIF). Methods A retrospective review was performed of a single surgeon's patients at an academic medical center who underwent MIS TLIF between July 2011 and December 2013. Statistical analyses included independent sample t test for continuous variables, Fisher exact test for categorical data, and repeated measures two-way analysis of variance to assess the interaction between obesity status and the change in Short-Form Health Survey 12 (SF-12) results.
 obesity back pain lumbar spine degenerative disk disease transforaminal lumbar interbody fusion (TLIF) minimally invasive patient-reported outcomes 	Results Thirty-eight patients from a single institution were reviewed, and 19 had a body mass index greater than 30. The nonobese and obese postoperative SF-12 mental composite scores (MCS; 52.70 ± 2.50 versus 52.16 ± 1.91 ; $p = 0.87$) and physical composite scores (PCS; 45.56 ± 2.72 versus 41.03 ± 2.65 ; $p = 0.24$) did not show any significant differences. There was no significant interaction between obesity and change in SF-12 MCS (F [1, 36] = 0.96, $p = 0.33$) or SF-12 PCS (F [1, 36] = 0.74, $p = 0.40$) between the pre- and postoperative scores. There was a significant effect of obesity on SF-12 PCS scores (F [1, 36] = 7.15, $p = 0.01$). Conclusions Patients undergoing MIS TLIF sustain meaningful and significant gains in SF-12 MCS and PCS that is not impacted by their obesity status.

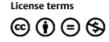
Introduction

The obese patient presents a challenge for the spine surgeon. More than one-third of Americans have a body mass index (BMI) greater than 30, and current and future surgeons will

received September 7, 2015 accepted after revision January 15, 2016 published online March 2, 2016 DOI http://dx.doi.org/ 10.1055/s-0036-1579747. ISSN 2192-5682. patients who undergo spine surgery have higher rates of perioperative and postoperative complications, such as urinary and pulmonary complications, extended length of stay, and more wound complications.^{2–4} However, the obese

be forced to address the issue.¹ Studies have shown that obese

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population has nevertheless reported improvements in pain and functional outcomes on par with nonobese patients.^{5–8} The incidence of lumbar back pain, degenerative disk disease, and radiculopathy strongly correlate to obesity, and the prevalence of obesity is increasing, even at younger ages.^{9,10} Thus, the crux of the issue is to determine the true benefit of surgical intervention in the obese patient.

Transforaminal lumbar interbody fusion (TLIF) was developed to decompress the spine and achieve fusion. Historically, open TLIF has been an effective surgical technique with excellent clinical outcomes and fusion rates.^{5–8} More recently, a variation, minimally invasive (MIS) TLIF, has been shown to have comparable outcomes scores and fusion rates as open TLIF.^{11–13} MIS TLIF, with its percutaneous incisions and significantly reduced muscle dissection, is an appealing alternative for the obese patient to potentially lessen the preoperative and postoperative complication risk.

Obese patients have been shown to do equally as well following MIS TLIF as after open TLIF. Data has shown that open and MIS TLIF have comparable improvements in patient-reported and functional scores, such as the visual analog scale (VAS), Oswestry Disability Index (ODI), Short-Form Health Survey 36 (SF-36), and similar time to return to work.^{14–17} Complication rates in some studies were reduced in the MIS group compared with the open group.¹⁸ However, it is not yet clear whether the obese patient experiences clinical benefits comparable to the nonobese patient.

There is limited data addressing the comparison of patient-reported outcomes following only MIS TLIF in obese patients compared with nonobese patients.¹⁹ The purpose of this study is to investigate the correlation of obesity and the change in outcomes in a single surgeon's cohort of normal-weight and obese patients undergoing MIS TLIF.

Materials and Methods

A retrospective review was performed for patients of a single surgeon at an academic medical center who underwent MIS TLIF between July 2011 and December 2013. The electronic medical record and paper office charts were reviewed to retrieve data consistent with the study's inclusion criteria. This study was approved by the Institutional Review Board.

All patients included in the study underwent an appropriate trial of nonoperative treatment including activity modification, physical therapy, anti-inflammatory medications, opioid analgesics, or transforaminal epidural steroid injections for at least 3 months. The operative indications included degenerative spondylosis or spondylolisthesis resulting in central or foraminal stenosis, radiculopathy, or neurogenic claudication, as well as failure of nonoperative management.

A standard MIS TLIF was performed in all cases. The patients were placed prone on a Jackson table with a chest roll was used to increase lumbar lordosis. Using fluoroscopic localization, the pedicles above and below the level of pathology were identified. A 2- to 3-cm incision was made lateral the pedicle on the side of the pathology. Jamshidi needles were then placed in the pedicles at the appropriate level. Guide wires were then advanced under fluoroscopic imaging. Following sequential dilation, a 21-mm

tubular retractor was placed and docked on the pars interarticularis at the disk space. A laminectomy was performed on the ipsilateral side with removal of the medial edge of the pars, lamina, and the medial facet joint. To decompress the contralateral side, the tubular retractor was medicalized to allow undercutting of the spinous process. The facet joint was removed until the medial wall of the pedicle could be palpated. The ligamentum flavum was removed, the epidural veins overlying the disk space were coagulated, and the traversing nerve root was retracted medially. The disk space was then entered and prepared with the use of rongeurs, curettes, and disk space shavers. Trial interbody cages were inserted until appropriate tension was achieved. A combination of recombinant human bone morphogenetic protein-2 and local bone was placed anterior within the disk space followed by impaction of the final PEEK interbody cage. Percutaneous medical screws were then placed over the placed guide wires following appropriate tapping. Once all pedicle screws were placed, a rod was placed percutaneously and secured with end caps.

Epidemiologic variables were recorded, including age, sex, BMI, medical comorbidities, and smoking status. Prospectively recorded outcomes data included the 12-item Short-Form Health Survey-12 (SF-12). The mental composite score (MCS) and physical composite score (PCS) were calculated for both pre- and postoperative data.

GraphPad Prism v6.5 (La Jolla, California, United States) was utilized for statistical analysis with independent sample *t* test for continuous variables and Fisher exact test for categorical data. A repeated measures two-way analysis of variance (ANOVA) was used to assess the interaction between patient obesity status and the change in SF-12 outcomes scores from the preoperative to the postoperative state. A *p* value < 0.05 was considered statistically significant.

Results

Patient Characteristics and Demographics

The records of 38 patients from a single institution were reviewed. Patient characteristics can be found in -Table 1. Obesity in the study was defined as a BMI > 30. Nineteen patients had a BMI < 30. Conversely, 19 patients had a BMI > 30. Of those with a BMI > 30, 11 patients were categorized as morbidly obese with a BMI > 35. The average age in the nonobese group was 60.00 \pm 3.26 compared with 60.26 \pm 1.64 in the obese group (p = 0.94). BMI averaged 24.42 \pm 0.82 in the nonobese group and 36.66 ± 1.31 in the obese group (p < 0.0001). There was no difference in the two groups with respect to hypertension, diabetes, smoking history, or number of vertebral levels involved. The operative time was significantly longer in the obese group (202.80 versus 156.47 minutes, p = 0.009). The average clinical follow-up was 25.29 ± 1.28 months in the nonobese group and 23.83 ± 1.45 months in the obese group (p = 0.48). There were no perioperative complications encountered in either group.

Obesity and Clinical Outcomes

The patients were divided into dichotomous groups (nonobese and obese), and average pre- and postoperative SF-12

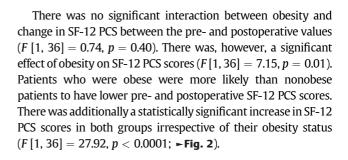
Characteristics	Nonobese	Obese	p Value
n	19	19	
Age (y)	60.00 ± 3.26	60.26 ± 1.64	0.94
Men;women	10;9	7;12	0.33
Body mass index	24.42 ± 0.82	36.66 ± 1.31	<0.0001
Hypertension	10 (52.6%)	13 (68.4%)	0.32
Diabetes	3 (15.8%)	5 (26.3%)	0.42
Smoking history	3 (15.8%)	5 (26.3%)	0.42
No. of vertebral levels involved	1.21 ± 0.12	1.21 ± 0.10	>0.99
1	16	15	
2	2	4	
3	1	0	
OR time (min)	156.47	202.8	0.009
Preoperative SF-12 PCS	29.53 ± 2.10	25.72 ± 1.60	0.16
Preoperative SF-12 MCS	45.08 ± 2.43	36.93 ± 3.16	0.04
Postoperative SF-12 PCS	45.56 ± 2.72	41.03 ± 2.65	0.24
Postoperative SF-12 MCS	52.70 ± 2.50	52.16 ± 1.91	0.87

Table 1 Patient characteristics and demographics

Abbreviations: MCS, mental composite score; OR, operating room; PCS, physical composite score; SF-12, Short-Form Health Survey 12.

MCS and PCS scores were calculated. The average preoperative SF-12 MCS score was 45.08 ± 2.43 in the nonobese group and 36.93 ± 3.16 (p = 0.04) in the obese group. Similarly, the average preoperative SF-12 PCS score was 29.53 ± 2.10 in the nonobese group and 25.72 ± 1.60 in the obese group (p = 0.16). Comparing the nonobese and obese postoperative SF-12 MCS (52.70 ± 2.50 versus 52.16 ± 1.91 ; p = 0.87) and PCS (45.56 ± 2.72 versus 41.03 ± 2.65 ; p = 0.24) scores did not show any significant differences between the two groups.

There was no significant interaction between obesity and change in SF-12 MCS between the pre- and postoperative values (F [1, 36] = 0.96, p = 0.33). There was no significant effect of obesity on overall SF-12 MCS scores. Patients who were obese were no more likely to have lower postoperative SF-12 MCS scores than nonobese patients. There was, however, a significant increase from the pre- to postoperative SF-12 MCS state for both the nonobese and obese groups (F [1, 36] = 20.01, p < 0.0001; **– Fig. 1**).



Discussion

Obesity remains a clinically relevant concern as the prevalence of obese and morbidly obese patients continues to rise. Current estimates identify roughly one-third of the U.S. population as obese.²⁰ These patients represent a significant challenge for the treating physician as a growing body of evidence supports a higher risk for perioperative

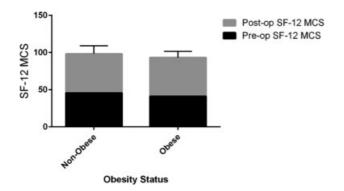


Fig. 1 Two-way analysis of variance of Short-Form Health Survey 12 (SF-12) mental composite score (MCS) and obesity.

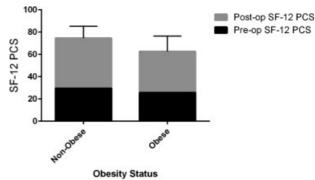


Fig. 2 Two-way analysis of variance of Short-Form Health Survey 12 (SF-12) physical composite score (PCS) and obesity.

complications including wound infections, airway-related events, deep vein thromboses, and even pulmonary embolus.^{4,5,21–26} Foley et al were the first to describe the MIS TLIF using tubular retractors via a muscle-splitting approach to decrease the amount of soft tissue injury.²⁷ The subsequent data has shown MIS TLIF to be safe and efficacious with clinical and radiographic results comparable to the open TLIF approach.

The current study is one of the first to directly compare the change in outcomes between the preoperative and postoperative states of nonobese and obese patients undergoing MIS TLIF. To date, several studies have demonstrated the efficacy of MIS TLIF when compared with the open TLIF procedure in obese patients. Furthermore, evidence supports clinically significant gains in VAS, ODI, and SF-36 among obese patients undergoing MIS TLIF. However, there is limited published literature looking at the change in outcomes from the pre- to postoperative state between a nonobese and obese population that both underwent an MIS TLIF.

Rosen et al were the first to look at the role of obesity and patient-reported outcomes after MIS TLIF.¹⁶ The authors looked at 110 patients, of whom 32% were defined as obese with a BMI > 30. Linear regression analysis did not identify a correlation between weight or BMI and pre- and postsurgery changes in any of the outcome measures. Wang et al compared ODI and VAS scores in obese patients undergoing open or MIS TLIF.¹⁷ The authors found that the MIS TLIF group had significantly less operating time, less blood loss, and less postoperative back pain. The radiation time was significantly longer in the MIS TLIF group. The clinical outcomes were not significantly different between the two groups. Similarly, Terman et al compared the outcomes of open and MIS TLIF in obese patients, concluding that obese patients experienced clinically and statistically significant improvement in both pain and function after undergoing either open or MIS TLIF.¹⁴

Lau et al recently published the only study in the literature that directly compared the relative preoperative to postoperative improvement in nonobese and obese patients following MIS TLIF.¹⁸ Estimated blood loss, operative time, complication rate, and length of hospital stay were compared. The outcomes variables of interest were ODI and VAS. Both groups had significant improvements in VAS (obese, p = 0.003; normal, p = 0.016) and ODI (obese, p = 0.020; normal, p = 0.034) scores. There were no statistically significant differences between the nonobese and obese groups in postoperative VAS (p = 0.728) and ODI (p = 0.886) scores. Patients with significant obesity experienced clinical improvement similar to that of normal-weight patients, suggesting that obesity does not impact MIS TLIF outcomes. This study is limited in the conclusions that can be drawn due to a low number of patients included in both groups (seven nonobese, nine obese).

In the current study, the baseline SF-12 MCS and PCS were lower in the obese patient population, though the difference was only significant for the MCS. As the SF-12 is a general health survey, the lower preoperative score in the obese group is not surprising. In a study by Wee et al, obese patients when compared with normal-weight controls scored 8.8 points lower on the PCS-12 and 5.7 points lower on the PCS-36 after adjustment for age, sex, and race.²⁸ In the postoperative period, there were no significant differences between the nonobese and obese groups with respect to either SF-12 MCS or PCS. The net change from baseline for MCS was \sim 7 points in the nonobese group and 15 points in the obese group. This change between pre- and postoperative scores was not significantly different between the two groups when analyzed with the two-way ANOVA model (p = 0.33). In the model, however, both groups demonstrated a statistically significant gain in MCS after surgery. Similarly, there was no significant difference between the average pre- and postoperative SF-12 PCS scores between the two groups. Although the obese group started at a lower baseline PCS state, each group improved by \sim 15 points postoperatively. This change between pre- and postoperative scores was not significantly different between the two groups when analyzed with the two-way ANOVA (p = 0.40). However, each group demonstrated a statistically significant improvement from their baseline state (p < 0.001).

The major limitations of this study are the retrospective nature and relatively small number of patients in each cohort. This study did not have a matched cohort; instead, it was a retrospective review of a single surgeon's consecutive series of patients. The outcomes data used in this study was prospectively collected by the treating surgeon as part of the normal scope of practice, which likely eliminates any bias in terms of data collection, as the data was systematically collected according to the surgeon's established postoperative protocol. Given the small number of patients in each arm of the study, it is possible that the study is underpowered to detect a true statistically significant difference in outcomes between the two groups. However, when compared with similar studies published in the literature, this study represents the largest cohort comparison of outcomes in nonobese and obese patients undergoing MIS TLIF.

Another potential limitation of this study is the use of only a single outcome metric for comparison between the two groups. It is possible that another validated outcome measure such as the Euroqol-5 Dimension, ODI, or VAS would have yielded a different result.

Conclusions

This study is one of the first and largest to look at the correlation of obesity and the change in outcomes between the preoperative and postoperative state in patients undergoing MIS TLIF. Patients undergoing MIS TLIF achieved meaningful and significant gains in SF-12 MCS and PCS that was not impacted by their obesity status.

Disclosures Steven J. McAnany: none Diana C. Patterson: none Samuel Overley: none Daniel Alicea: none Javier Guzman: none Sheeraz A. Qureshi: Committee board member (AAOS, Cervical Spine Research Society, Musculoskeletal Transplant Foundation, NASS); Editorial board member (*Clinical Orthopaedics and Related Research, Contemporary Spine Surgery, Global Spine Journal, Spine, The Spine Journal*); Speakers' bureau (Globus Medical, Medtronic Sofamar Danek, Stryker); Consultant (Medtronic, Orthofix, Inc., Stryker, Zimmer); Royalties (Zimmer).

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