

## Outcomes of Anterior Lumbar Interbody Fusion Surgery Based on Indication: A Prospective Study

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**BACKGROUND:** There is limited information on clinical outcomes after anterior lumbar interbody fusion (ALIF) based on the indications for surgery.

**OBJECTIVE:** To compare the clinical and radiological outcomes of ALIF for each surgical indication.

**METHODS:** This prospective clinical study included 125 patients who underwent ALIF over a 2-year period. The patients were evaluated preoperatively and postoperatively. Outcome measures included the Short Form-12, Oswestry Disability Index, Visual Analog Scale, and Patient Satisfaction Index.

**RESULTS:** After a mean follow-up of 20 months, the clinical condition of the patients was significantly better than their preoperative status across all indications. A total of 108 patients had a Patient Satisfaction Index score of 1 or 2, indicating a successful clinical outcome in 86%. Patients with degenerative disk disease (with and without radiculopathy), spondylolisthesis, and scoliosis had the best clinical response to ALIF, with statistically significant improvement in the Short Form-12, Oswestry Disability Index, and Visual Analog Scale. Failed posterior fusion and adjacent segment disease showed statistically significant improvement in all of these clinical outcome scores, although the mean changes in the Short Form-12 Mental Component Summary, Oswestry Disability Index, and Visual Analog Scale (back pain) were lower. The overall radiological fusion rate was 94.4%. Superior radiological outcomes (fusion >90%) were observed in patients with degenerative disk disease (with and without radiculopathy), spondylolisthesis, and failed posterior fusion, whereas in adjacent segment disease, it was 80%.

**CONCLUSION:** ALIF is an effective treatment for degenerative disk disease (with and without radiculopathy) and spondylolisthesis. Although results were promising for scoliosis, failed posterior fusion, and adjacent segment disease, further studies are necessary to establish the effectiveness of ALIF in these conditions.

**KEY WORDS:** Anterior lumbar interbody fusion, Degenerative disk disease, Indications, Scoliosis, Spinal fusion, Spondylolisthesis

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**A**nterior lumbar interbody fusion (ALIF) has become a widely accepted surgical technique for various degenerative pathologies of the lumbar spine. After the introduction of ALIF in the 1930s, little progress was made with the technique until the 1980s. Several advancements were then made to reduce mor-

idity, including bone grafting substitutes, metallic hardware instrumentation, improved surgical technique, and improved lighting and retraction technologies.<sup>1–5</sup> Despite being an established treatment option for a variety of lumbar pathologies, the current indications for ALIF have yet to be clearly defined in the literature,<sup>6</sup> and the question of which surgical approach is the preferred treatment for various pathologies of the lumbar spine still exists.<sup>7–12</sup> The purpose of this study was to examine the effectiveness of ALIF, based on clinical and radiological outcomes for 6 different indications.

**ABBREVIATIONS:** ALIF, anterior lumbar interbody fusion; ASD, adjacent segment disease; BMI, body mass index; DDD, degenerative disk disease; ODI, Oswestry Disability Index; PSI, Patient Satisfaction Index; SF-12, Short Form-12; VAS, Visual Analog Scale

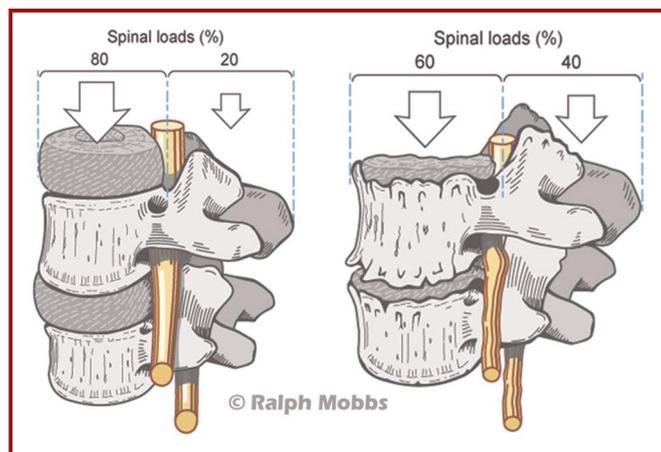
## RATIONALE FOR ALIF

The primary rationale for ALIF is that it potentially results in superior biomechanical and perioperative outcomes compared with other approaches. In a normal lumbar spine in the upright standing position, the anterior and middle weight-bearing columns of the spine support approximately 80% of the spinal load, and the posterior column supports approximately 20%.<sup>13-16</sup> However, with aging and the consequences of the degenerative cascade, including dehydration of the nucleus and repetitive annular injuries reducing the height of the disk, the weight-bearing distribution shifts so that the posterior column supports a greater percentage of the axial load (Figure 1). With ALIF, an interbody fusion device is used to redistribute the weight-bearing distribution to the original ratio. Furthermore, according to the Woolf law, the fusion potential increases if grafts are placed under the direct compression that supports the placement of the graft in the anterior column. Additionally, the anterior and middle columns provide 90% of the more vascular osseous surface area, and this wide cancellous bed for graft contact enhances the fusion potential<sup>5,15</sup> over the posterolateral space.

Compared with posterior approaches, the retroperitoneal approach in ALIF spares iatrogenic trauma to the paraspinal musculature, posterior spinal nerves, and posterior bony elements.<sup>15,17-19</sup> Another advantage over the posterior approach is that nerve root retraction and entrance into the spinal canal are unnecessary, thereby eliminating epidural scarring and perineural fibrosis.<sup>3,20-22</sup> Moreover, there is decreased morbidity from pulmonary complications with regard to other approaches.<sup>18</sup>

## METHODS

This study represents data from a single surgical team series (R.J.M.) as part of a prospective study performed at the Prince of Wales Hospital. Clearance for the trial was obtained through the Human Research Ethics Committee of



**FIGURE 1.** *Left*, distribution of spinal loads on the anterior and posterior weight-bearing columns in a normal lumbar spine. *Right*, shifting of spinal loads to the posterior column after degenerative pathology to the lumbar spine. This figure is presented in full color online.

New South Wales Health (reference No. 11/183). One hundred twenty-five patients were studied prospectively between July 2009 and June 2011.

The surgical pathology was verified by magnetic resonance imaging, computed tomography, bone mineral density study, bone scan, and dynamic x-rays. All patients required a period of conservative treatment involving physical therapy and pain management for an appropriate period before being considered for ALIF.

The patients were divided according to the following indications for surgery: degenerative disk disease (DDD) with radiculopathy, DDD without radiculopathy, spondylolisthesis, scoliosis, failed posterior fusion, and adjacent segment disease (ASD) above or below a previous lumbar fusion.

The criteria for classification of indications (as per the senior author [R.J.M.]) were based on imaging data of the clinical findings and are described as follows:

1. DDD without radiculopathy. Inclusion: a patient presenting with diskogenic back pain with no radicular symptoms and with disk degeneration signs on imaging (black disk, Modic changes, or high uptake on nuclear magnetic scan). Exclusion: spondylolisthesis >15%, ASD, major degree of scoliosis requiring correction, or pseudoarthrosis.
2. DDD with radiculopathy. Inclusion: a patient presenting with diskogenic back pain with radicular symptoms and with signs of disk degeneration on imaging (black disk, Modic changes, or high uptake on nuclear magnetic scan). Exclusion: spondylolisthesis >15%, ASD, major degree of scoliosis requiring correction, or pseudoarthrosis.
3. Spondylolisthesis. Inclusion: a patient presenting with back pain with or without radicular symptoms and with >15% spondylolisthesis (degenerative or isthmic). Exclusion: ASD, major degree of scoliosis requiring correction, or pseudoarthrosis.
4. Failed posterior fusion. Inclusion: a patient presenting with back pain related to nonfusion at the index level without new pathology demonstrated on imaging as the source of the patient's problem. Exclusion: patients requiring fusion at other levels in addition to the index level or patients requiring correction of scoliosis.
5. ASD. Inclusion: a patient presenting with back pain related to a degenerative process at a level adjacent to a previous fusion without significant scoliosis contributing to the patient's symptoms. Exclusion: major degree scoliosis requiring correction or spondylolisthesis >15%.
6. Scoliosis. Inclusion: major degree of scoliosis requiring correction. Exclusion: minor degree not requiring correction.

The following patients were excluded: pregnant or nursing women; patients with osteoporosis, significant cardiac disease, infection, fever (>38.5°C), or metal allergy; patients who were mentally incompetent; patients with a history of alcohol or drug abuse; and patients with a high risk of vascular or bowel complications related to the anterior approach.

## Clinical Outcome Measurement

Clinical outcome was measured preoperatively and postoperatively using 4 questionnaires, the Short Form-12 (SF-12), the Oswestry Disability Index (ODI), the Visual Analog Scale (VAS) pain score (back pain), and the Patient Satisfaction Index (PSI), and the clinical success rate (proportion of patients with a PSI score of 1 or 2). Radiographs were reviewed and graded by 2 independent radiologists, and the primary fusion end point was assessed by use of axial and coronal fine-cut reconstructed computed tomography scans. In addition, demographic information, operative procedure details, blood loss, and adverse events were prospectively recorded. Questionnaire data were compiled in a custom-designed database. Baseline (preoperative) patient characteristics were examined with analysis of variance. Presurgical and postsurgical study outcomes were examined with repeated-measures

general linear models adjusted for age and sex. Analyses were based on 2-sided tests with values of  $P < .05$  considered significant with Bonferroni correction when appropriate.

## RESULTS

### Demographic Data

The demographic profiles of the patients in this study are summarized in Table 1. There were 56 male (45%) and 69 female (55%) patients, and the spread over the different indications is shown in Figure 2. The patient age ranged from 25 to 86 years and averaged 57 years. Tobacco use was reported in 22 patients (18%), and 12 patients (10%) were diabetic. Workers' compensation was claimed by 25 patients (20%).

The average body mass index (BMI) category of patients in this study was category 2, which is within the recognized normal range (18.5-25 kg/m<sup>2</sup>; Figure 3).

### Hospital Data

Surgery details and hospital discharge data are summarized in Table 2. The average operative time for single-level surgery was 89 compared with 151 minutes for multilevel surgery. Similarly, blood loss was significantly higher in the multilevel surgeries, with a mean value of 127 cm<sup>3</sup>, whereas single-level surgeries averaged 102 cm<sup>3</sup>. Blood transfusions were administered 3 days postoperatively in 2 patients after retroperitoneal hemorrhage. None of the patients required blood transfusions intraoperatively or on the same day of surgery. The length of hospital stay was similar between the 2 groups, with single-level averaging 4 days and multilevel averaging 6 days. There was no significant difference in complication rate for single-level and multilevel surgeries.

### Baseline Clinical Outcome Scores

Some questionnaires were incomplete because some of the patients were unwilling to participate (Table 3). There were interesting findings for the examination of baseline clinical outcome scores and demography data. Stratification by age revealed that patients >60 years of age had significantly worse physical health on the Physical Component Summary of the SF-12 ( $P = .03$ ), whereas younger patients had worse mental health (SF-12 Mental Component Summary; approaching significance,

$P = .07$ ). Mental health in patients claiming workers' compensation was also poorer compared with patients not claiming compensation ( $P = .05$ ). ODI scores were lower in women compared with men ( $P = .01$ ). Diabetics had lower scores regarding mental state on the Mental Component Summary of the SF-12 ( $P = .04$ ) and the ODI ( $P = .02$ ) compared with nondiabetics. There were no significant differences in baseline outcome scores when tobacco use, BMI, and indications were considered.

### Postoperative Clinical Outcome

The follow-up rate was 94% in all the outcome measurement tests. Clinical outcomes were measured preoperatively and on average 20 months postoperatively (range, 18-48 months; Table 4).

All clinical outcome indicators showed significant gains after ALIF surgery (Figures 4-6) compared with presurgical levels.

### Indication

There was no statistically significant effect of the indication group on postoperative changes in clinical outcomes (Figures 7-10). Calculated mean changes in SF-12 Mental Component Summary were lower in failed posterior fusion and ASD than in other groups. The mean change in ODI was lower in scoliosis, failed posterior fusion, and ASD than in other groups, and the mean change in VAS was lower in failed posterior fusion and ASD than other groups.

PSI values were similar across indications, as was clinical success rate, apart from the failed posterior fusion and ASD groups, which had slightly lower scores. These differences, although nonsignificant, may reflect effects that are not captured by this analysis owing to insufficient statistical power.

### Tobacco Use

No significant differences in improvement on clinical outcome scores were observed between smokers and nonsmokers (Table 4 and Figures 11-14).

### Diabetes Mellitus

Diabetic patients showed significantly greater improvements after surgery in the mental health component than nondiabetics (Figures 11-14). Closer inspection of the data suggests that this effect may reflect the lower baseline scores for these outcomes. Before surgery, ODI scores were worse in diabetic patients, but there was no significant difference between groups regarding postsurgical changes.

### Workers' Compensation

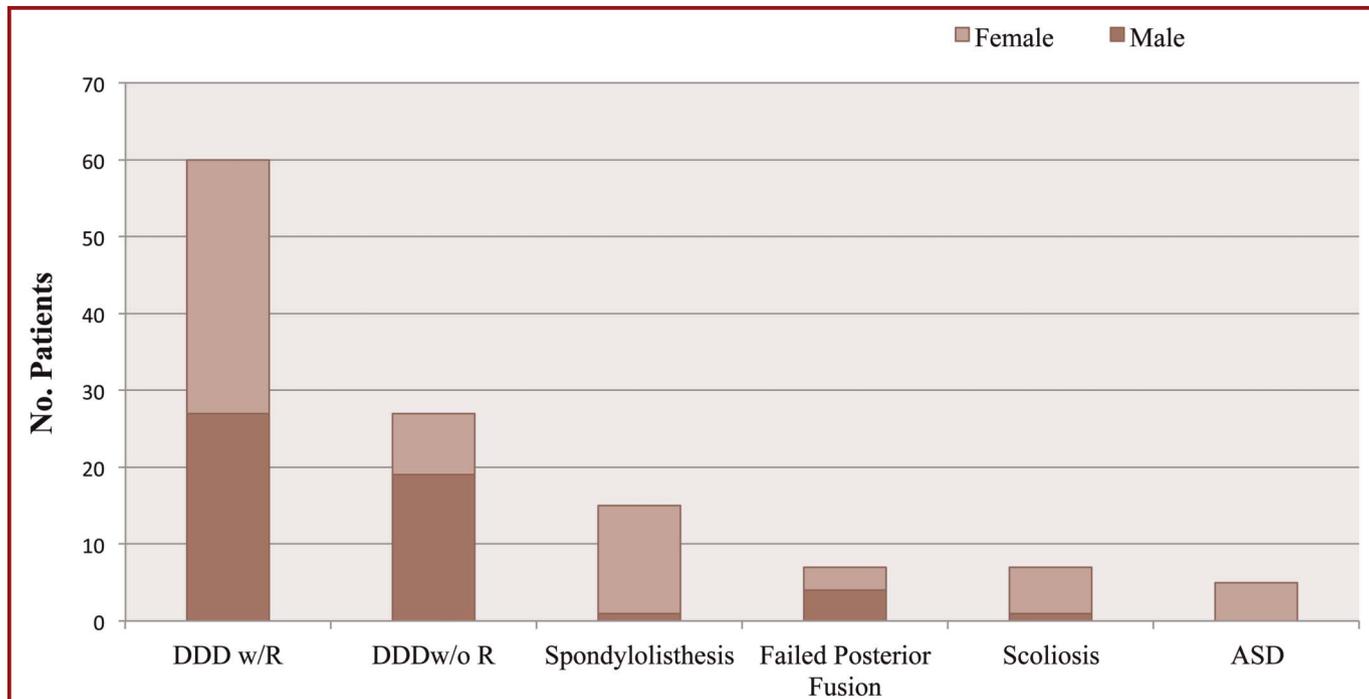
Patients claiming workers' compensation improved significantly in all outcome scores except VAS back pain ( $P < .001$ ) and PSI ( $P < .001$ ; Figures 11-15) compared with patients not claiming workers' compensation.

### BMI

There were no statistically significant differences in clinical outcomes based on BMI characteristics.

**TABLE 1. Demographic Profile of the Patients in This Study**

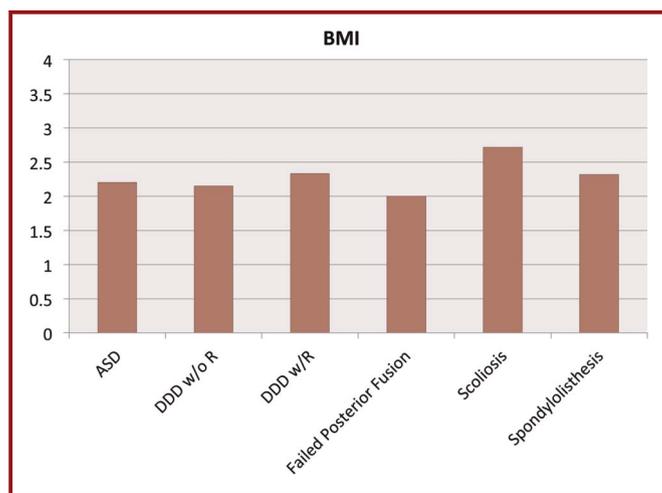
Patients, n	125
Mean (range) age, y	57 (25-86)
Levels, n	161
Male/female, n	56/69
Tobacco use, Y/N	22/103
Diabetic, Y/N	12/113
Workers' compensation, Y/N	25/100
Mean (range) follow-up, mo	20 (12-42)



**FIGURE 2.** Number of patients for each indication. ASD, adjacent segment disease; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy. This figure is presented in full color online.

**Radiological Fusion Outcomes**

The bone graft substitutes used were iFactor (Cerapedics, Westminster, Colorado) for 109 patients, INFUSE (Medtronic, Memphis, Tennessee) for 9 patients, autologous iliac crest bone grafts harvested for 6 patients, and allograft used for 1 patient



**FIGURE 3.** The body mass index (BMI) classification average for the different indications. ASD, adjacent segment disease; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy. This figure is presented in full color online.

(Table 5). A solid fusion rate was 86% in smokers and 96.1% in nonsmokers. Diabetics had a poorer fusion rate (67%) than nondiabetics, but this was not statistically significant. There was no difference in fusion rate between patients claiming workers’ compensation and patients not claiming workers’ compensation (92% and 95%, respectively).

Eventual fusion rates were 98% for single-level and 81.5% for 2-level fusions. All triple- and quadruple-level patients fused at all levels.

On the basis of indications, DDD (with and without radiculopathy), spondylolisthesis, scoliosis, and failed posterior fusion had the best solid fusion rates. However, ASD still had good rates.

**Complications**

There were clinically relevant adverse events with an overall complication rate of 10% for patients in this study (Table 6). The most serious and potentially fatal complication was postoperative retroperitoneal hematoma, which occurred in 3 patients. Two cases required surgical intervention. One case resulted in a post-traumatic stress disorder requiring referral to a psychiatrist. Retrograde ejaculation was observed in 4 patients, and erectile dysfunction also affected 1 of these patients. There were 2 cases of incisional hernia requiring repair and in 1 case bowel obstruction (with pre-existing diverticulitis) requiring a laparotomy. Minor complications are listed in Table 6.

**TABLE 2. Surgery Details and Hospital Discharge Data**

Perioperative Parameters	Single-Level Fusion	Multilevel Fusion
Mean blood loss, cm <sup>3</sup>	102 (20-700)	127 (20-400)
Operative time, min	89 (40-160)	151 (100-195)
Blood transfusion required, n (%)	1 (1)	1 (3)
Hospital stay, d	4 (1-13)	6 (3-19)
Complications, n (%)	10 (11)	3 (10)

**DISCUSSION**

The ALIF procedure is a popular technique used to treat various pathologies of the lumbar spine. Although there is ongoing debate as to whether the anterior approach is better than the posterior approach, Jiang et al reported in a systematic review that clinical outcomes and failed fusion rates were similar in both techniques.<sup>23</sup> Radiological outcomes, including height restoration and focal

and lumbar lordosis, were superior in ALIF, whereas cost, blood loss, and operative time were greater in ALIF compared with transforaminal lumbar interbody fusion.

Other authors have expressed that ALIF results in less blood loss and shorter operative times. Burke<sup>3</sup> reported an average blood loss of 200 to 300 mL. This study has supported this view, with single-level procedures averaging 102 cm<sup>3</sup> blood loss and multilevel averaging 127 cm<sup>3</sup>. However, there were some cases in which blood loss was very high. One patient lost 700 cm<sup>3</sup> because of a common iliac vein tear, which was repaired without the patient needing blood transfusions. The sole quadruple-level procedure had a blood loss of 400 cm<sup>3</sup>, which was consistent considering the length (195 minutes) and extent of the surgery.

Operative time for a single-level procedure averaged 90 minutes, which is similar to the times in other studies.<sup>2,13,17</sup> ALIF has previously been shown to have low perioperative morbidity, resulting in a short hospital stay and bed rest. Sparing of the paraspinal musculature allows most patients (97%) to be mobile on the first postoperative day.

**TABLE 3. Baseline Clinical Outcomes Scores by Patient Characteristics<sup>a</sup>**

Patient Characteristics	Categories	SF-12 Physical Component Summary	SF-12 Mental Component Summary	ODI	VAS Back Pain
Age	25-39 y	35.3 ± 7.3	28.5 ± 5.5	56.6 ± 14.7	7.1 ± 1.9
	40-59 y	32.3 ± 6.0	38.0 ± 12.4	59.1 ± 21.0	7.4 ± 1.3
	60+ y	30.3 ± 5.8	37.1 ± 13.1	61.5 ± 23.6	7.3 ± 1.7
		<i>P</i> = .03 <sup>b</sup>	<i>P</i> = .07	<i>P</i> = .8	<i>P</i> = .9
Sex	Male	32.0 ± 6.2	38.8 ± 13.7	54.3 ± 22.8	7.3 ± 1.5
	Female	31.3 ± 6.0	35.0 ± 11.4	64.5 ± 20.0	7.3 ± 1.5
		<i>P</i> = .5	<i>P</i> = .1	<i>P</i> = .01 <sup>b</sup>	<i>P</i> = .9
Tobacco use	No	31.6 ± 6.2	36.7 ± 12.3	59.6 ± 22.1	7.3 ± 1.6
	Yes	31.9 ± 6.3	36.0 ± 13.9	62.4 ± 20.3	7.4 ± 1.3
		<i>P</i> = .8	<i>P</i> = .8	<i>P</i> = .6	<i>P</i> = .8
Diabetes	No	31.2 ± 6.3	37.4 ± 12.2	58.5 ± 21.2	7.3 ± 1.5
	Yes	31.4 ± 5.1	29.4 ± 13.4	74.5 ± 22.4	8.0 ± 1.8
		<i>P</i> = .9	<i>P</i> = .04 <sup>b</sup>	<i>P</i> = .02 <sup>b</sup>	<i>P</i> = .2
Workers' compensation	No	31.8 ± 6.4	37.8 ± 13.2	58.6 ± 22.8	7.4 ± 1.6
	Yes	31.2 ± 5.0	32.0 ± 7.5	66.0 ± 15.8	7.2 ± 1.4
		<i>P</i> = .7	<i>P</i> = .05 <sup>b</sup>	<i>P</i> = .2	<i>P</i> = .7
Indication of surgery	DDD w/R	32.0 ± 6.0	37.0 ± 13.1	61.1 ± 23.5	7.4 ± 1.4
	DDD w/o R	32.5 ± 6.5	33.7 ± 10.0	60.0 ± 20.0	7.1 ± 1.6
	Spondylolisthesis	31.7 ± 5.9	38.5 ± 13.2	59.3 ± 21.7	7.3 ± 1.6
	Scoliosis	27.0 ± 4.7	33.6 ± 11.4	62.5 ± 16.6	8.7 ± 1.1
	Failed posterior fusion	31.9 ± 8.1	38.0 ± 17.4	58.8 ± 23.8	7.6 ± 1.8
	ASD	28.3 ± 5.6	40.9 ± 10.8	50.0 ± 20.2	6.1 ± 2.1
		<i>P</i> = .3	<i>P</i> = .8	<i>P</i> = .9	<i>P</i> = .1
BMI	Underweight	31.5 ± 8.2	34.8 ± 13.0	51.5 ± 22.4	7.4 ± 1.7
	Normal	32.0 ± 6.3	37.0 ± 13.0	58.3 ± 22.2	7.3 ± 1.6
	Overweight	30.5 ± 5.6	36.7 ± 11.1	62.6 ± 20.7	7.3 ± 1.4
	Obese	33.7 ± 6.5	30.6 ± 15.8	81.0 ± 10.2	7.8 ± 1.0
		<i>P</i> = .6	<i>P</i> = .8	<i>P</i> = .2	<i>P</i> = .96

<sup>a</sup>ASD, adjacent segment disease; BMI, body mass index; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy; ODI, Oswestry Disability Index; SF-12, Short Form-12; VAS, Visual Analog Scale. Values are given as mean ± SD. *P* values were calculated from 1-way analysis of variance *F* tests. <sup>b</sup>Significant.

**TABLE 4. Changes in Clinical Outcomes by Patient Characteristics<sup>a</sup>**

Patient Characteristics	Categories	SF-12 Physical Component Summary Δ (n = 112)	SF-12 Mental Component Summary Δ (n = 113)	ODI Δ (n = 110)	Back Pain Δ (n = 113)	PSI (n=125)	Clinical Success Rate, <sup>b</sup> %
Tobacco use	No	12.4 ± 1.1	12.2 ± 1.5	31.2 ± 2.5	4.7 ± 0.2	1.7 ± 0.1	86.7
	Yes	10.4 ± 2.6	14.5 ± 3.4	33.6 ± 5.4	4.4 ± 0.6	1.9 ± 0.2	85.0
		<i>P</i> = .5	<i>P</i> = .5	<i>P</i> = .7	<i>P</i> = .6	<i>P</i> = .29	<i>P</i> = .7
Diabetes	No	12.3 ± 1.1	11.6 ± 1.4	30.8 ± 2.3	4.6 ± 0.2	1.7 ± 0.1	85.8
	Yes	10.2 ± 3.2	21.9 ± 4.2	39.3 ± 7.0	5.0 ± 0.7	1.7 ± 0.2	91.7
		<i>P</i> = .6	<i>P</i> = .02 <sup>c</sup>	<i>P</i> = .3	<i>P</i> = .6	<i>P</i> = .92	<i>P</i> > .99
Workers' compensation	No	13.0 ± 1.2	12.3 ± 1.5	32.2 ± 2.5	5.1 ± 0.2	1.6 ± 0.1	91.0
	Yes	10.8 ± 2.5	11.0 ± 3.3	29.5 ± 5.3	2.9 ± 0.5	2.2 ± 0.1	68.0
		<i>P</i> = .6	<i>P</i> = .6	<i>P</i> = .7	<i>P</i> < .001 <sup>c</sup>	<i>P</i> < .001 <sup>c</sup>	<i>P</i> = .006 <sup>c</sup>
Indication of surgery	DDD w/R	12.4 ± 1.4	13.0 ± 1.9	34.9 ± 3.1	4.6 ± 0.3	1.7 ± 0.1	90.0
	DDD w/o R	12.4 ± 2.4	15.6 ± 3.2	33.6 ± 4.9	4.8 ± 0.5	1.7 ± 0.1	81.5
	Spondylolisthesis	10.4 ± 2.8	10.2 ± 3.7	30.8 ± 5.9	5.2 ± 0.6	1.7 ± 0.2	89.5
	Scoliosis	11.9 ± 4.6	13.7 ± 6.1	12.4 ± 9.7	5.8 ± 0.9	1.6 ± 0.3	85.7
	Failed	12.5 ± 4.4	7.1 ± 5.8	24.5 ± 9.3	3.7 ± 0.9	1.9 ± 0.3	71.4
	ASD	11.0 ± 5.1	6.0 ± 6.7	12.6 ± 11.9	2.4 ± 1.1	1.8 ± 0.3	80.0
		<i>P</i> = .99	<i>P</i> = .7	<i>P</i> = .2	<i>P</i> = .1	<i>P</i> = .97	<i>P</i> = .72
BMI	Underweight	12.8 ± 4.7	8.3 ± 6.4	28.6 ± 11.6	5.3 ± 1.0	1.64 ± 0.3	80.0
	Normal	11.9 ± 1.2	13.6 ± 1.7	33.5 ± 2.7	4.8 ± 0.3	1.64 ± 0.1	88.0
	Overweight	13.8 ± 1.9	10.9 ± 2.6	27.6 ± 4.2	4.1 ± 0.4	1.84 ± 0.1	81.8
	Obese	-0.4 ± 5.3	11.3 ± 7.3	31.4 ± 11.8	3.7 ± 1.2	2.04 ± 0.4	100
		<i>P</i> = .1	<i>P</i> = .7	<i>P</i> = .7	<i>P</i> = .4	<i>P</i> = .51	<i>P</i> = .67

<sup>a</sup>ASD, adjacent segment disease; BMI, body mass index; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy; ODI, Oswestry Disability Index; PSI, Patient Satisfaction Index; SF-12, Short Form-12; Visual Analog Scale; Δ, absolute change from preoperation to postoperation score. Values are estimated marginal mean ± SE. All analyses are adjusted for age and sex. *P* values were calculated from general linear models. The  $\chi^2$  was used as appropriate.

<sup>b</sup>Clinical success rate shows percentages of success (scores of 1 or 2 on the PSI). *P* values were calculated with either the Fisher exact test or Pearson test.

<sup>c</sup>Significant.

There are numerous pathologies of the spine that are indications for ALIF. The primary objective of this study was to determine the relationship between indications for ALIF and their clinical and radiological outcomes.

**DDD (With or Without Radiculopathy)**

In DDD with mechanical low back pain, removing the intervertebral disk is essential for pain reduction, and implantation of an interbody device restores segmental stabilization and corrects abnormal loading.<sup>5</sup> Although mechanical pain is present in DDD with foraminal stenosis, the overriding issue is radiculopathy secondary to nerve root compression.<sup>16,24,25</sup> Generally, segmental stenosis and radiculopathy is caused by disk herniation, posterior osteophyte formation, facet overriding, and hypertrophy and in-folding of the ligamentum flavum combining to reduce neuroforaminal volume.<sup>26</sup>

Although DDD with radiculopathy and DDD without radiculopathy are rarely differentiated in the literature, in the present study, we analyzed them as 2 separate indications, but our study results demonstrated similar clinical outcomes and similar complication rates.

Burkus et al published a large prospective study with 279 ALIF cases and showed a clinical success rate of 81% and a complication rate of only 9%.<sup>21</sup> Several other studies have produced similar

results, indicating high clinical success rates ranging from 71% to 100% (Table 7).<sup>13,21,27-36</sup>

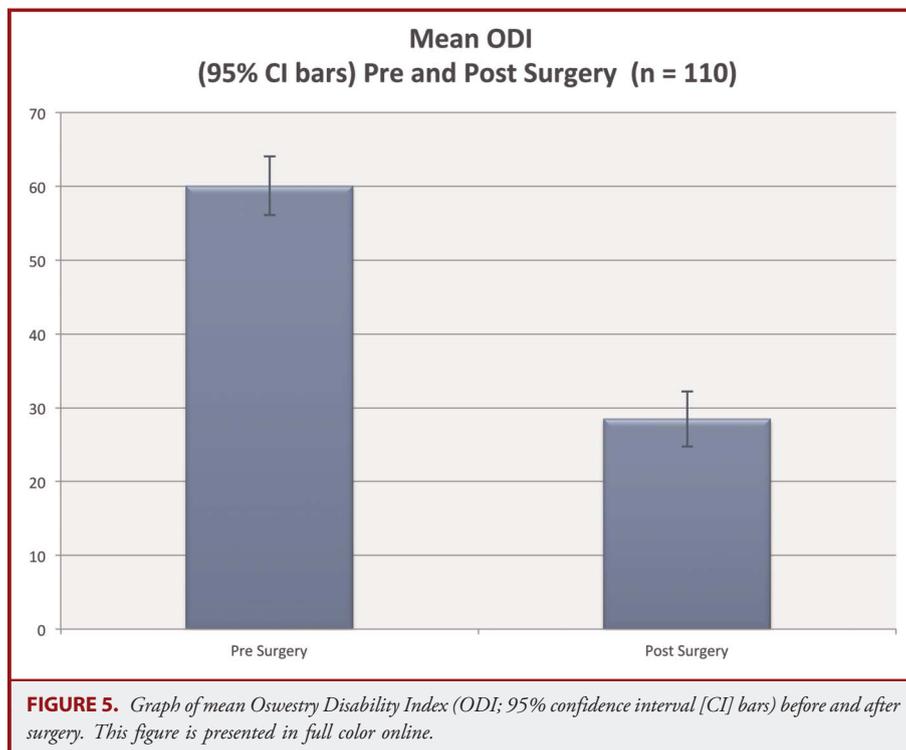
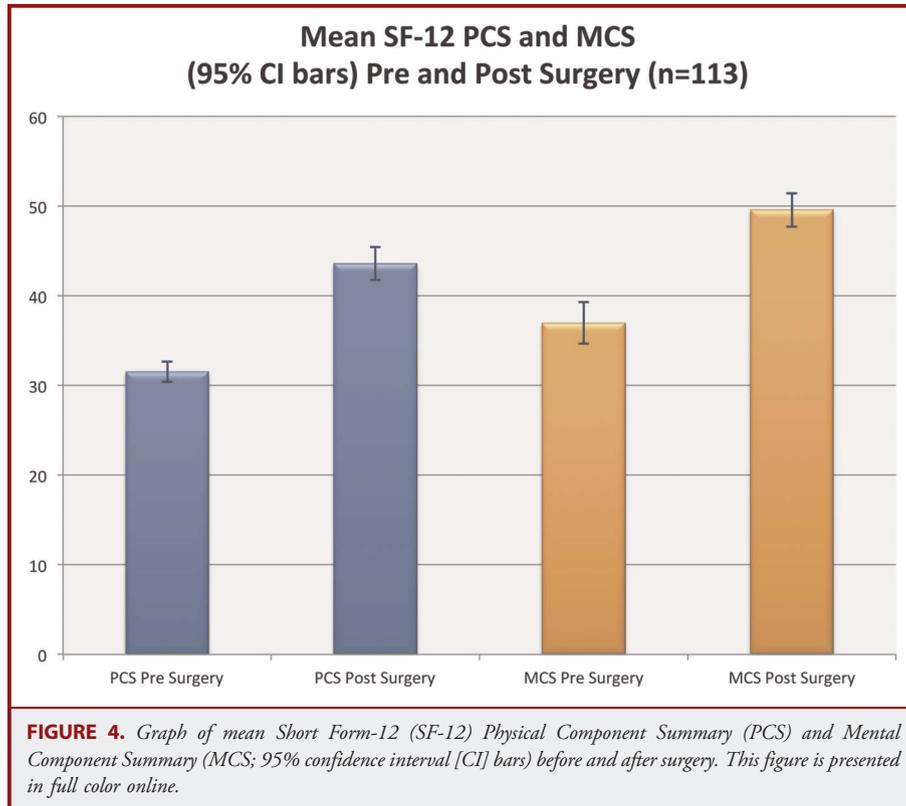
In short, ALIF is an appropriate treatment option for symptomatic DDD (with or without radiculopathy).

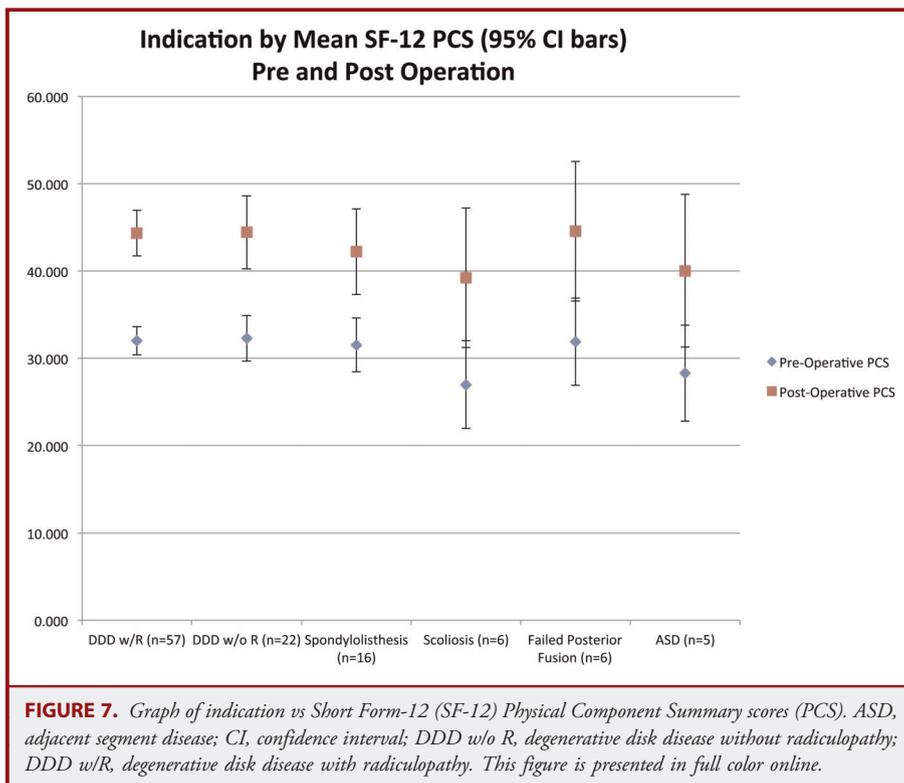
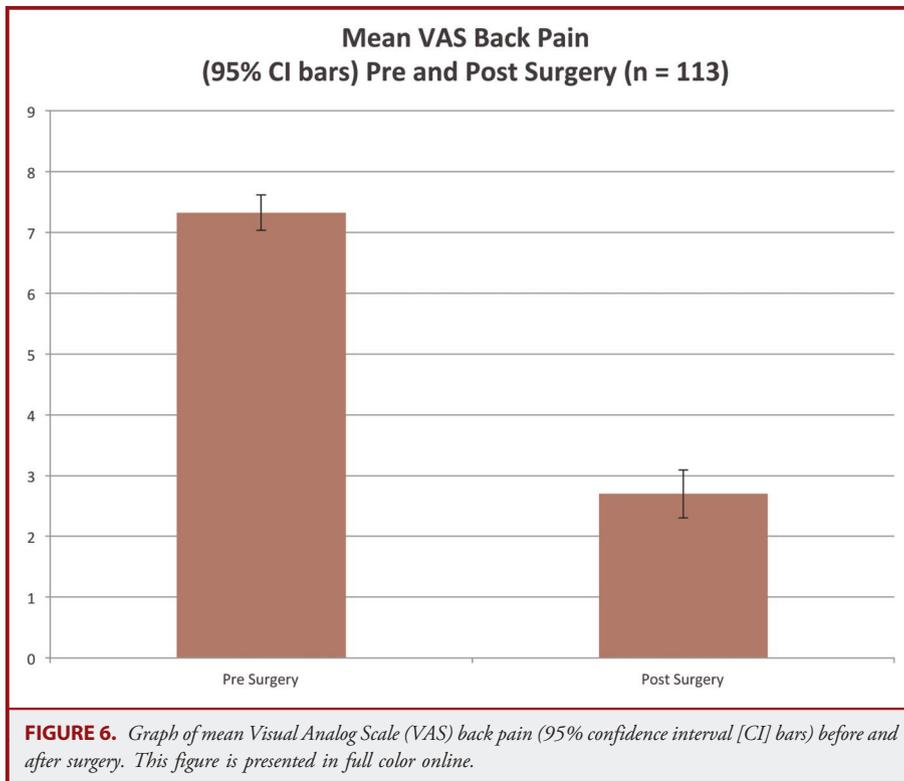
**Spondylolisthesis**

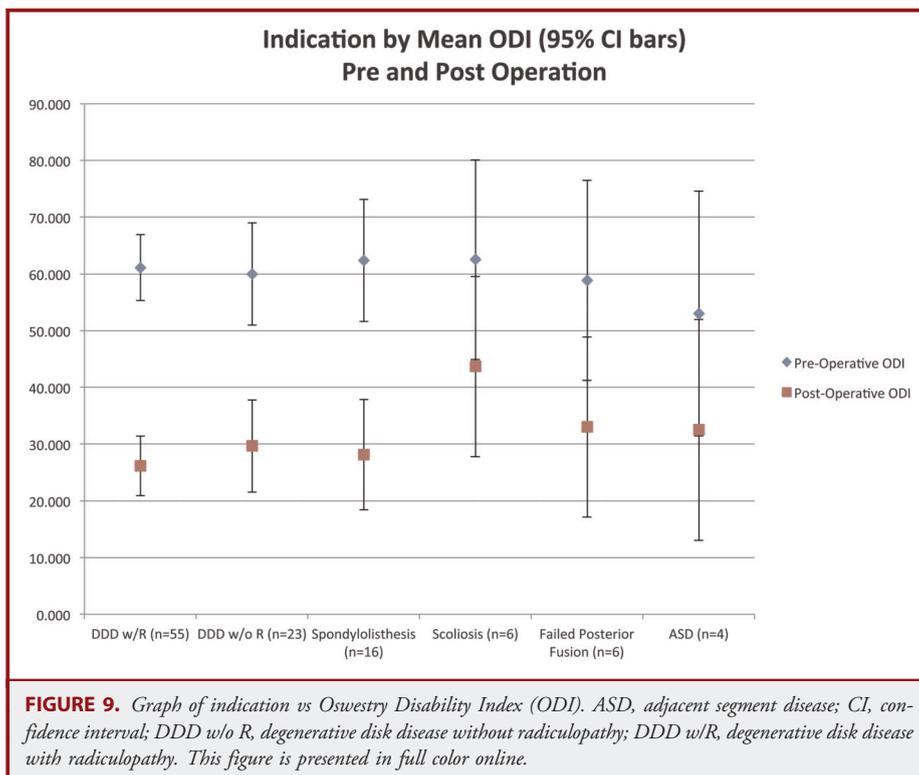
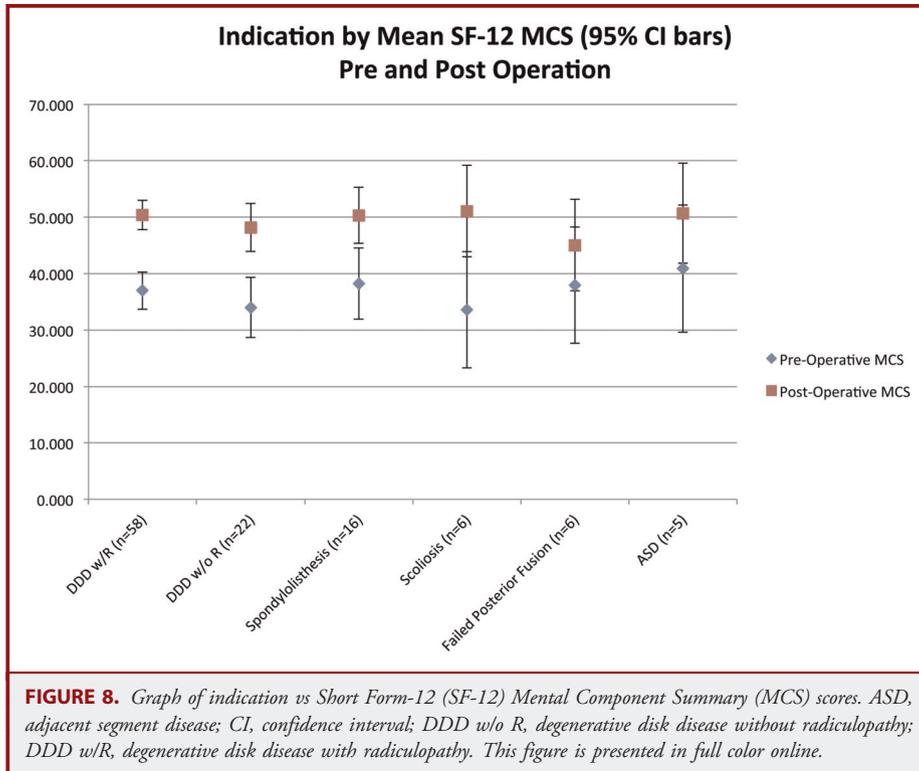
The patients suffering from spondylolisthesis (isthmic and degenerative) in this study generally had successful outcomes, with an 89% clinical success rate and 95% radiological fusion with a serious complication rate of 5%. Similar studies have reported fusion rates ranging from 47% to 100% (Table 8),<sup>19,29,37-45</sup> as well as similarly low complication rates; this cohort is consistent with the literature in establishing ALIF as an effective treatment option for spondylolisthesis.

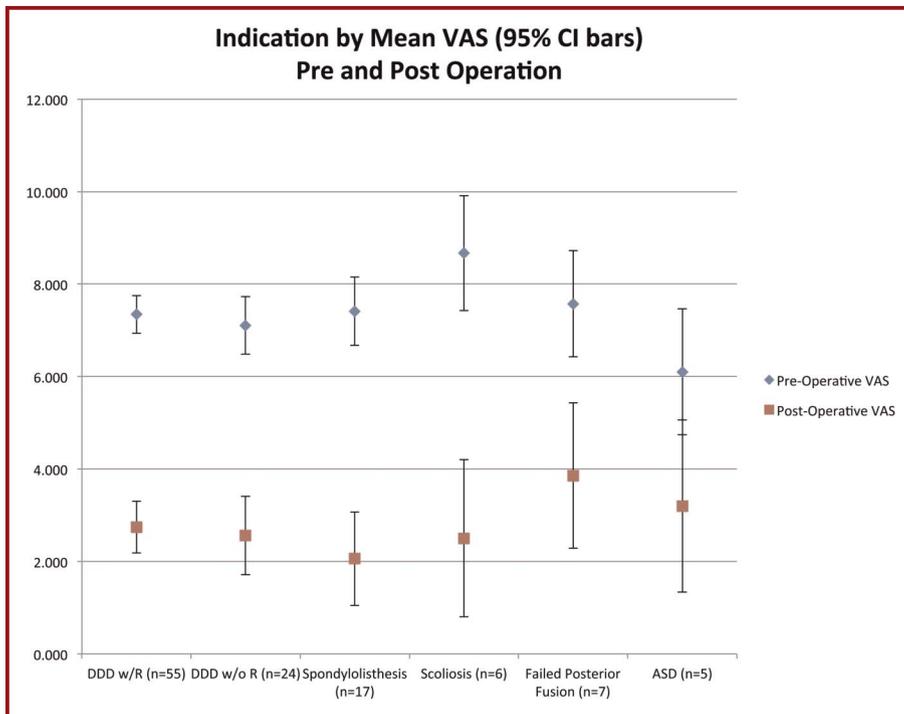
**Scoliosis**

ALIF for degenerative scoliosis is considered a reliable option because it allows thorough release of contracted tissues and osteophytes, complete discectomy, distraction of the intervertebral space, and placement of a larger interbody fusion device.<sup>46</sup> All these factors contribute to strong anterior structural support.

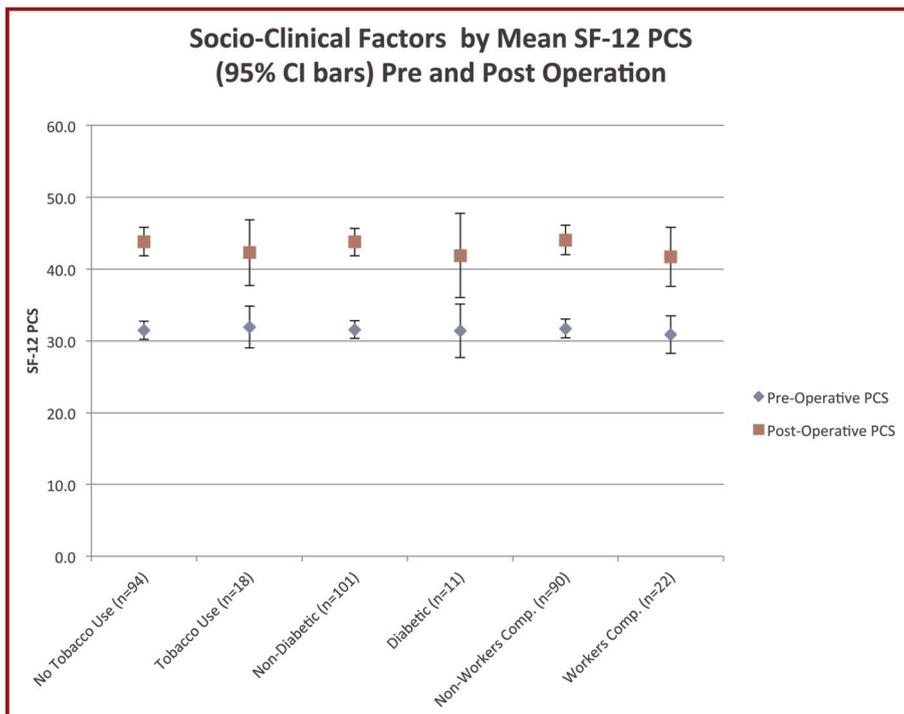




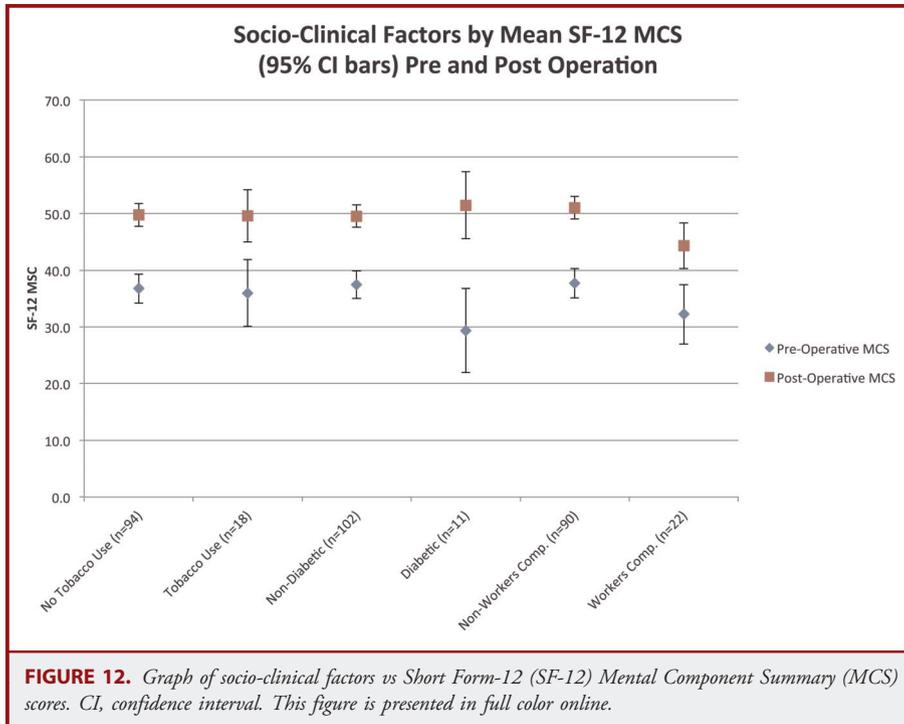




**FIGURE 10.** Graph of indication vs Visual Analog Scale (VAS). ASD, adjacent segment disease; CI, confidence interval; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy. This figure is presented in full color online.

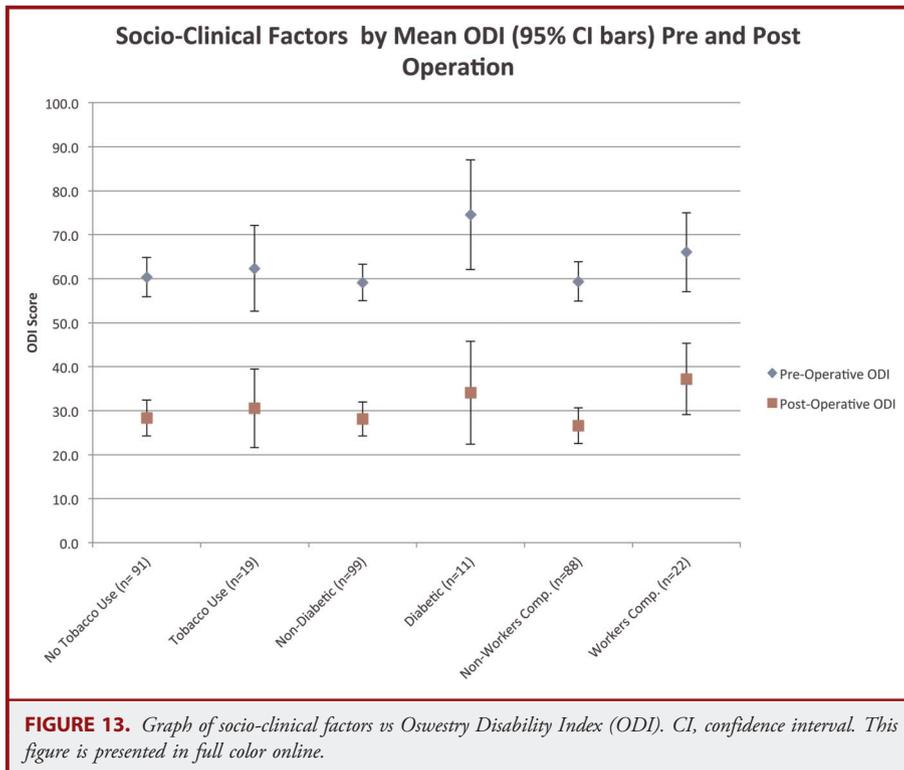


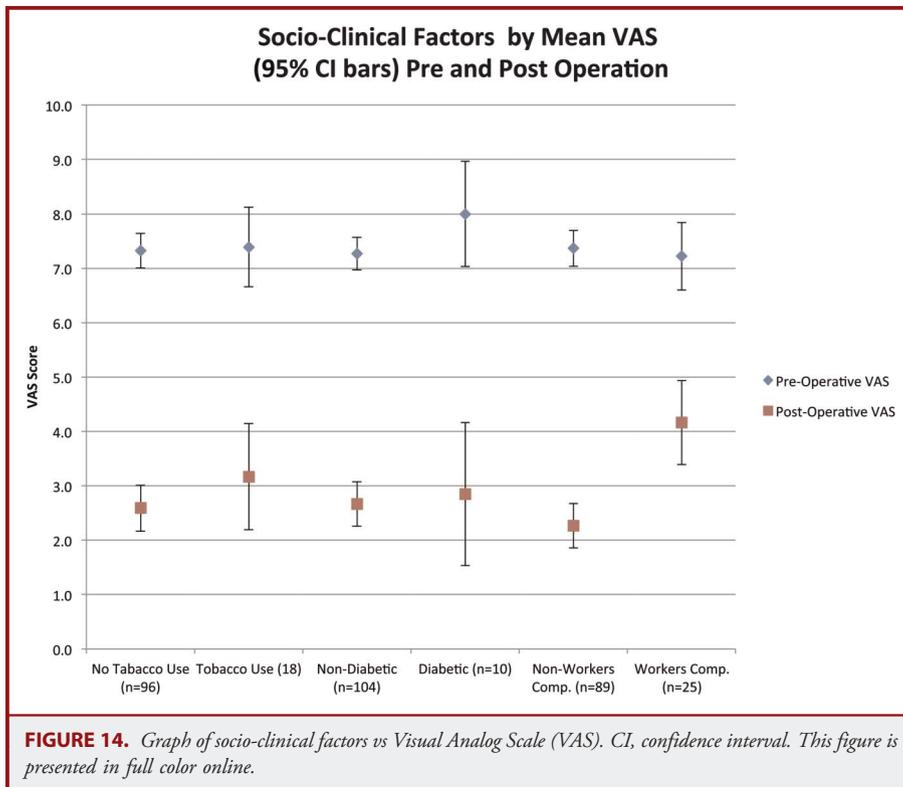
**FIGURE 11.** Graph of socio-clinical factors vs Short Form-12 (SF-12) Physical Component Summary (PCS) scores. CI, confidence interval. This figure is presented in full color online.



Of the 7 procedures for scoliosis, 6 were multilevel, which in other indications predisposes the patient to poorer outcomes. However, solid fusion was achieved in 100% of

the patients, and successful clinical outcomes were achieved in 86%. Considering the small numbers of patients in this group, it is difficult to comment on the future of ALIF for

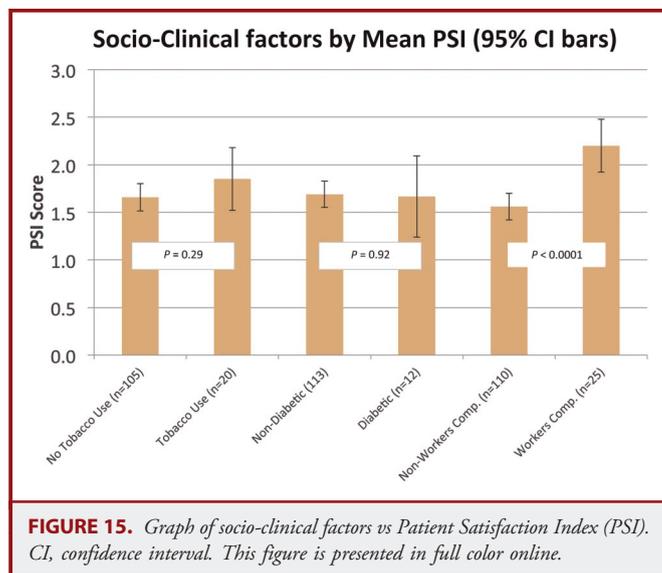




scoliosis or whether posterior fixation is necessary with these procedures.

Similar fusion rates, as well as complication rates that are much higher than those observed in this study, have been reported in the literature (Table 9).<sup>46,47</sup> The largest study thus far on ALIF for

scoliosis (Paterer et al<sup>47</sup>) involved retrospective analysis of a series of 75 patients who underwent ALIF surgery with pedicle screw fixation for scoliosis. As a result of the anterior thoracoabdominal approach with manipulation of major vessels and additional posterior approach, the complication rate was 24% with same-day operation and 45% in anterior-posterior staged surgery. The correction of deformity was high, and the clinical outcomes correlated with the fusion rate, which was 88%.<sup>36</sup> A retrospective study by Crandall and Revella of 20 cases of scoliosis patients found similar results.<sup>46</sup>



### Failed Posterior Fusion

This study included many patients who presented with previously unsuccessful posterior fusions. Although pseudoarthrosis from a posterior fusion is not usually an indication for an additional lumbar fusion procedure, surgical intervention has been considered a necessity in some patients with relentless back and leg pain<sup>48-51</sup> related to their nonunion. The pain is attributed in part to the sclerotic bone adjacent to the fibrous soft tissue accompanied by microfractures of cancellous bone and the ongoing motion of the segment.<sup>52</sup> As a salvage procedure, ALIF can be beneficial, and provided that additional graft material is used via a different approach, the biological environment for fusion is enhanced and stable biomechanics of the spine are provided.<sup>48,49</sup>

This study had promising radiological outcomes with solid fusion in all 7 cases. However, only 71% of the patients experienced clinical

**TABLE 5. Radiological Outcomes by the Various Groups<sup>a</sup>**

	Solid Fusion, n (%)
Total (n = 125)	118 (94.4)
Tobacco use (n = 22)	19 (86)
No tobacco use (n = 103)	99 (96.1)
Diabetic (n = 12)	8 (67)
Nondiabetic (n = 113)	108 (97.3)
Workers' compensation (n = 25)	23 (92)
Non-workers' compensation	95 (95)
<b>BMI classification</b>	
1 (n = 5)	4 (80)
2 (n = 83)	80 (96.3)
3 (n = 33)	32 (97)
4 (n = 4)	2 (50)
Single level (n = 94)	92 (98)
Double level (n = 27)	22 (81.5)
Triple level (n = 3)	3 (100)
Quadruple level (n = 1)	1 (100)
L2-L3 (n = 4)	4 (100)
L3-L4 (n = 17)	14 (82.4)
L4-L5 (n = 62)	56 (90.3)
L5-S1 (n = 78)	78 (100)
DDD w/R (n = 60)	57 (95)
DDD w/o R (n = 27)	25 (93)
Spondylolisthesis (n = 19)	18 (95)
Scoliosis (n = 7)	7 (100)
Failed posterior fusion (n = 7)	7 (100)
ASD (n = 5)	4 (80)

<sup>a</sup>ASD, adjacent segment disease; BMI, body mass index; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy.

success, and there were 2 complications resulting in poor outcomes compared with the other indications. To determine whether ALIF is a suitable salvage procedure for a failed posterior fusion, a study with a larger patient sample is necessary.

**Adjacent Segment Disease**

ASD has been cited as a long-term complication of spinal arthrodesis when degeneration occurs at the vertebral disk directly above or below a fused spinal segment.<sup>53,54</sup> Surgery is not generally a treatment option because performing another fusion procedure places further stress on the other unfused segments, and the chances of recurrent ASD are high.<sup>55</sup> In this study, ASD was indicated when medical treatment was not sufficient for management of back and radicular leg pain. Of the 5 patients who participated in this study, radiological fusion was observed in 4 patients, and the average PSI score was 1.8.

Although there was no significant difference in clinical outcomes based on indication, there was a lower mean change in several outcome measures (SF-12 Mental Component Summary, ODI, and VAS) in both failed posterior fusion and ASD, which reflected the findings of the National Neurosurgery Quality and

**TABLE 6. Complications by Indication<sup>a</sup>**

Complications	Major	Minor
DDD w/R (n = 7, 12%)	Retrograde ejaculation and erectile dysfunction, retroperitoneal hematoma	Vague abdominal pain
		Donor site pain
		Postop ileus
		Sympathectomy
		Posttraumatic stress disorder
DDD w/o R (n = 2, 7%)	Incisional hernia	INFUSE radiculitis
Spondylolisthesis (n = 1, 5%)	...	Sympathectomy
Scoliosis (n = 2, 29%)	Retroperitoneal hematoma, incisional hernia	...
Failed posterior fusion (n = 2, 29%)	Retrograde ejaculation	Deep venous thrombosis
ASD (n = 0, 0%)	...	...

<sup>a</sup>ASD, adjacent segment disease; DDD w/o R, degenerative disk disease without radiculopathy; DDD w/R, degenerative disk disease with radiculopathy.

Outcomes Database data that indicated that repeat surgery was an independent predictor for a satisfactory patient outcome.<sup>56</sup> The sample size in the present study remains too small to reach a definitive conclusion on ALIF as a surgical option for ASD, echoing the lack of clinical studies in the literature that focus solely on ASD and ALIF as a result of low patient numbers.<sup>53,54</sup>

**Demographic Parameters**

The secondary objectives of this study were to investigate the roles of BMI, tobacco use, diabetes mellitus, workers' compensation, single vs multilevel, and the specific level performed with the ALIF surgical technique. BMI categorization showed similar outcomes in all groups. Smokers had results similar to those of nonsmokers. The literature suggests that smoking negatively affects spinal fusion because it diminishes revascularization of cancellous bone and several other mechanisms that reduce solid fusion and clinical success rates.<sup>57</sup> This was not strongly reflected in the results of this study, but the reason may be that the 2 groups were not of equivalent size.

There was no significant difference in fusion rate between diabetics and nondiabetics. However, the overall clinical outcomes were similar between these groups, although diabetics had statistically better mental outcomes after surgery than nondiabetics. Although diabetes mellitus is a known inhibitor of bone fusion, it is well documented that solid bony fusion does not always correlate with successful clinical outcome.<sup>58</sup>

**TABLE 7. Summary of Clinical Studies With Degenerative Disk Disease as the Indication for Anterior Lumbar Interbody Fusion<sup>a,13,21,26-34</sup>**

Author	Study Type	Surgery	Patients, n	Fusion Rate, %	Clinical Success Rate, %	Serious Complication Rate, %
Newman and Grinstead <sup>26</sup>	Prospective study	ALIF	36	89	86	11
Blumenthal et al <sup>27</sup>	Prospective study	ALIF	34	73	74	3
Christensen et al <sup>28</sup>	Retrospective study	ALIF	63	58	76	7
Boden et al <sup>29</sup>	Prospective, randomized, controlled trial	ALIF	14	93	86	N/A
Burkus et al <sup>31</sup>	Prospective, non-blinded study	ALIF	46	83	73	11
Burkus et al <sup>21</sup>	Prospective, randomized, nonblinded	ALIF	279	92	81	9
Kleeman et al <sup>31</sup>	Prospective, controlled, nonrandomized	ALIF	22	100	100	0
Sasso et al <sup>32</sup>	Prospective, randomized, controlled clinical trial	ALIF	140	77	100	0
Strube et al <sup>33</sup>	Prospective cohort study	ALIF	40	71	91	6
Moore et al <sup>34</sup>	Retrospective study	ALIF + PLF	58	95	86	5
Matge and Leclercq <sup>13</sup>	Retrospective study	ALIF	222	96	80	10
Pavlov et al <sup>36</sup>	Prospective study	ALIF	58	99	98	10
Rao et al, 2014	Prospective study	ALIF	87	94	90	6

<sup>a</sup>ALIF, anterior lumbar interbody fusion.

Patients claiming workers' compensation had outcomes similar to those of patients not claiming workers' compensation in most of the clinical outcome scores except VAS back pain and PSI score postoperatively, which were statistically significantly worse in patients claiming workers' compensation, replicating previous findings.<sup>21,31,33,59,60</sup>

Bony fusion was achieved in a higher percentage of patients with single-level procedures compared with those with double-level procedures. Levels L4-L5 and L5-S1 had the highest solid fusion rates.

**Complications**

This study had a low serious complication rate (6%), with 7 patients experiencing major complications. The anterior approach requires mobilization of the great blood vessels and peritoneal contents and exposure of the superior hypogastric sympathetic plexus and places the patients at risk for iatrogenic injury.<sup>5</sup> There are a host of approach-related complications reported in the literature. However, the most commonly reported complications are retrograde ejaculation, vascular injury, superficial infection, urological injury, and abdominal muscle damage.<sup>61,62</sup>

Retrograde ejaculation and sterility have been reported in many studies resulting from injury of the superior hypogastric sympathetic nerve plexus, particularly when operating at the L4/L5 level.<sup>3,11,15,18,34,63-67</sup> In our study, the incidence of retrograde ejaculation was low (3%). One patient experienced erectile dysfunction and retrograde ejaculation after surgery, which resolved after 7 months.

Vascular injury is more common when operating at the L4/L5 levels and above because of the anatomy of the aorta, iliac vessels,

and iliolumbar vein.<sup>5,68</sup> This study included 3 cases of postoperative retroperitoneal hematoma and 1 serious iliac vein tear during the procedure.

Spine-specific complications include implant migration, graft collapse/expulsion, and pseudoarthrosis.<sup>3,11,13,15,18,34,63,64</sup> The spine-specific complications observed in this study included 7 cases of pseudoarthrosis and 1 case of INFUSE radiculitis. The graft material used for the majority of procedures (87%) was iFactor (Cerapecics). A small volume of migration of graft material from the original implantation site was observed in the majority of patients. However, no adverse clinical consequences of graft migration were experienced or reported. Migration was evident on postoperative computed tomographic scanning when the radiopaque i-Factor graft substitute was used but not with INFUSE.

**Limitations**

Because there were limited numbers of patients in some of the indication groups over the 2 years of recruiting for this study, the patient numbers were not equivalent between groups. The small sample sizes of patients in some of the subgroups resulted in limited statistical power to detect changes in clinical outcomes presurgically and postsurgically or differences between indication groups.

**CONCLUSION**

ALIF has re-emerged as a suitable option for various pathologies of the lumbar spine in the past few decades. This study has demonstrated that ALIF is an effective treatment measure both radiologically and clinically for DDD with and without

**TABLE 8. Summary of Clinical Studies With Spondylolisthesis as the Indication for Anterior Lumbar Interbody Fusion<sup>a,19,28,59-67</sup>**

Author	Study Type	Indication	Surgery	Patients, n	Fusion Rate, %	Clinical Success Rate, %	Serious Complication Rate, %
Takahashi et al <sup>60</sup>	Retrospective study	Degenerative spondylolisthesis	ALIF	39	90	76	3
Satomi et al <sup>61</sup>	Retrospective study	Degenerative spondylolisthesis	ALIF	27	96	93	4
Muschik et al <sup>62</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF	29	76	69	7
Muschik et al <sup>62</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF + posterior instrumentation	30	93	83	13
Kim and Lee <sup>63</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF	20	90	85	25
Ishihara et al <sup>64</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF	35	83	...	...
Johnson et al <sup>59</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF ± various instrumentation	44	96	96	11
Christensen et al <sup>28</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF	57	47	76	7
Lee et al <sup>65</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF + PSF	73	97	94	16
Shim et al <sup>67</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF + PSF/PLF	49	84	88	4
Kim et al <sup>19</sup>	Retrospective study	Isthmic spondylolisthesis	ALIF + PSF	63	100	89	...
Suk et al <sup>44</sup>	Retrospective study	Spondylolisthesis	ALIF + PSF	21	100	...	14
Min et al <sup>66</sup>	Retrospective study	Spondylolisthesis	ALIF	25	100	92	16
Rao et al, 2014	Prospective study	Spondylolisthesis	ALIF	19	95	89	5

<sup>a</sup>ALIF, anterior lumbar interbody fusion; PLF, posterolateral fusion; PSF, pedicle screw fixation.

radiculopathy and spondylolisthesis. The patient populations for scoliosis, failed posterior fusion, and ASD were small; however, outcomes were positive for these indications. The future of ALIF is promising in instances of instability, deformity, and degeneration of the lumbar spine.

**Disclosure**

The study was supported by funding from Cerapedics, which was used to conduct the study and for database maintenance. The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

**TABLE 9. Summary of Clinical Studies With Degenerative Scoliosis as the Indication for Anterior Lumbar Interbody Fusion<sup>a,35,36</sup>**

Author	Study Type	Surgery	Patients, n	Fusion Rate, %	Clinical Success Rate, %	Serious Complication Rate, %
Crandall and Revella <sup>35</sup>	Prospective, nonrandomized, consecutive single-surgeon series	ALIF + posterior instrumentation	20	80	Average ODI and VAS scores improved	40
Pateder et al <sup>36</sup>	Retrospective study	ALIF + posterior instrumentation	75	88	...	24-45
Rao et al, 2014	Prospective Study	ALIF	7	100	86	29

<sup>a</sup>ALIF, anterior lumbar interbody fusion; ODI, Oswestry Disability Index; VAS, Visual Analog Scale.

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## COMMENTS

In this article, the authors present the results of a prospective study of anterior lumbar interbody fusion in 125 consecutive patients for a variety of indications. All procedures were performed by a single surgical team at a single institution between 2009 and 2011. Mean follow-up was 20 months. Data collected included patient demographics, procedure details, blood loss, adverse events, and preoperative and postoperative Short Form-12, Oswestry Disability Index, Visual Analog Scale, and Patient Satisfaction Index. Patients were then divided into various groups and subgroups for analysis, including groups based

on diagnosis, smoking status, and diabetes status, including various combinations of each.

With regard to the primary end point of the study, comparison of outcomes of anterior lumbar interbody fusion for each surgical indication, this was a negative study. There were no significant differences in outcome by clinical indication.

Despite this lack of effect, the study provide some potentially useful information. For the whole group of patients, the results showed that there was a statistically significant improvement in all measures. Diabetic patients showed a significantly greater increase in mental health postoperatively than nondiabetics and patients claiming workers' compensation had a significantly lower improvement in Visual Analog Scale and Patient Satisfaction Index than patients not claiming workers' compensation. Surprisingly, neither body mass index nor tobacco use had a significant effect on clinical outcome.

This interesting and ambitious study is hampered primarily by small sample size. Its strengths include a prospective design, single-institution administration, appropriate follow-up length, and 94% follow-up rate. Although the results may be difficult to generalize to other patient populations, the authors are to be congratulated for their meticulous data collection and analysis. I hope that this will be continued and a follow-up report with a larger sample size will be able to resolve the primary question of this study.

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In this study, the authors prospectively examined 125 patients treated with anterior lumbar interbody fusion (ALIF) at a single European institution over a 2-year period. The primary aim of the study was to determine the clinical efficacy of this surgical procedure based on the pathology being treated. They subdivided their patients into those being treated primarily for degenerative disk disease (DDD) without radiculopathy, DDD with radiculopathy, spondylolisthesis, pseudarthrosis, spinal deformity, and adjacent segment disease. The authors used established outcome criteria, including the Visual Analog Scale, Oswestry Disability Index, Patient Satisfaction Index, and Short Form-12 scores to assess clinical efficacy. The follow-up ranged from 12 to 42 months (mean, 20 months).

The authors found that ALIF is a reliable technique that does in fact improve clinical outcomes over a broad spectrum of pathologies and through a host of indicators intended to measure a patient's pain level, function, and well-being. Of note, the authors identified a >30-point drop in the Oswestry Disability Index scores after ALIF surgery. These results are impressive given that the study included 20% workers' compensation patients. One of the drawbacks of the study is that given the division of 125 patients into 6 subsets, there is likely insufficient power to draw any definitive conclusions by pathological subset. Indeed, only 5 patients were treated for adjacent segment disease. This is why studies such as this would have benefitted from a preinvestigational power analysis. Perhaps the data from this publication can be used by future investigators to design a more definitive research plan. A second criticism is that 4 different osteobiological adjuvants were used, and this was not controlled. For example, the harvesting of autologous iliac crest or the use of rh-BMP-2 may have effects that were significant but not revealed during this study. A final criticism is that the division of patients into these

subsets is somewhat artificial. Is adjacent segment disease not a form of DDD? It would have been interesting if the investigators had weighted the relative contribution of each of the pathological processes within each patient to better determine their relative effects. ALIF is not a new technique, and this is one in a long series of publications studying its utility. However, this investigation was unique in that it set out with the goal of identifying differences in outcome based on the patient's presenting pathology. Whether these differences are intrinsic to the pathology or the technical procedure

remains unclear and can be elucidated only by a larger study investigating anterior, posterior, and combined approaches across different pathologies. As is typical, this article raises more questions than it answers. Nevertheless, I congratulate the authors on opening these questions to a large audience of surgeons through their well-conducted prospective study.

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### Alan Turing

Alan Turing was a British mathematician, logician, cryptanalyst, philosopher, pioneering computer scientist and mathematical biologist. He was highly influential in the development of computer science, providing a formalization of the concepts of “algorithm” and “computation” with the Turing machine, which can be considered a model of a general purpose computer. During World War II, Turing worked for the Government Code and Cypher School at Bletchley Park, Britain’s codebreaking center. For a time he led Hut 8, the section responsible for German naval cryptanalysis. He devised a number of techniques for breaking German ciphers, including improvements to the pre-war Polish bombe method, an electromechanical machine that could find settings for the Enigma machine.