

## Comparison of best versus worst clinical outcomes for adult spinal deformity surgery: a retrospective review of a prospectively collected, multicenter database with 2-year follow-up

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**OBJECT** Although recent studies suggest that average clinical outcomes are improved following surgery for selected adult spinal deformity (ASD) patients, these outcomes span a broad range. Few studies have specifically addressed fac-

**ABBREVIATIONS** ASA = American Society of Anesthesiology; ASD = adult spinal deformity; BMI = body mass index; CCI = Charlson Comorbidity Index; EBL = estimated blood loss; HRQOL = health-related quality of life; ISSG = International Spine Study Group; LL = lumbar lordosis; ODI = Oswestry Disability Index; PI = pelvic incidence; PT = pelvic tilt; SDGS = Spinal Deformity Study Group; SF-36 = 36-Item Short Form Health Survey; SRS-22 = Scoliosis Research Society–22 Patient Questionnaire; SVA = sagittal vertical axis.

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tors that may predict favorable clinical outcomes. The objective of this study was to compare patients with ASD with best versus worst clinical outcomes following surgical treatment to identify distinguishing factors that may prove useful for patient counseling and optimization of clinical outcomes.

**METHODS** This is a retrospective review of a prospectively collected, multicenter, database of consecutively enrolled patients with ASD who were treated operatively. Inclusion criteria were age > 18 years and ASD. For patients with a minimum of 2-year follow-up, those with best versus worst outcomes were compared separately based on Scoliosis Research Society–22 (SRS-22) and Oswestry Disability Index (ODI) scores. Only patients with a baseline SRS-22  $\leq 3.5$  or ODI  $\geq 30$  were included to minimize ceiling/floor effects. Best and worst outcomes were defined for SRS-22 ( $\geq 4.5$  and  $\leq 2.5$ , respectively) and ODI ( $\leq 15$  and  $\geq 50$ , respectively).

**RESULTS** Of 257 patients who met the inclusion criteria, 227 (88%) had complete baseline and 2-year follow-up SRS-22 and ODI outcomes scores and radiographic imaging and were analyzed in the present study. Of these 227 patients, 187 had baseline SRS-22 scores  $\leq 3.5$ , and 162 had baseline ODI scores  $\geq 30$ . For the SRS-22, best and worst outcomes criteria were met at follow-up for 25 and 27 patients, respectively. For the ODI, best and worst outcomes criteria were met at follow-up for 43 and 51 patients, respectively. With respect to the SRS-22, compared with best outcome patients, those with worst outcomes had higher baseline SRS-22 scores ( $p < 0.0001$ ), higher prevalence of baseline depression ( $p < 0.001$ ), more comorbidities ( $p = 0.012$ ), greater prevalence of prior surgery ( $p = 0.007$ ), a higher complication rate ( $p = 0.012$ ), and worse baseline deformity (sagittal vertical axis [SVA],  $p = 0.045$ ; pelvic incidence [PI] and lumbar lordosis [LL] mismatch,  $p = 0.034$ ). The best-fit multivariate model for SRS-22 included baseline SRS-22 ( $p = 0.033$ ), baseline depression ( $p = 0.012$ ), and complications ( $p = 0.030$ ). With respect to the ODI, compared with best outcome patients, those with worst outcomes had greater baseline ODI scores ( $p < 0.001$ ), greater baseline body mass index (BMI;  $p = 0.002$ ), higher prevalence of baseline depression ( $p < 0.028$ ), greater baseline SVA ( $p = 0.016$ ), a higher complication rate ( $p = 0.02$ ), and greater 2-year SVA ( $p < 0.001$ ) and PI-LL mismatch ( $p = 0.042$ ). The best-fit multivariate model for ODI included baseline ODI score ( $p < 0.001$ ), 2-year SVA ( $p = 0.014$ ) and baseline BMI ( $p = 0.037$ ). Age did not distinguish best versus worst outcomes for SRS-22 or ODI ( $p > 0.1$ ).

**CONCLUSIONS** Few studies have specifically addressed factors that distinguish between the best versus worst clinical outcomes for ASD surgery. In this study, baseline and perioperative factors distinguishing between the best and worst outcomes for ASD surgery included several patient factors (baseline depression, BMI, comorbidities, and disability), as well as residual deformity (SVA), and occurrence of complications. These findings suggest factors that may warrant greater awareness among clinicians to achieve optimal surgical outcomes for patients with ASD.

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**KEY WORDS** adult spinal deformity; complications; depression; sagittal alignment; pelvic parameters; surgery; outcomes

**A**DULTS with spinal deformity characteristically present with pain and disability.<sup>6,8,10,18,19,22,37,42–44,46,47,49,51,52</sup> In the absence of significant or progressive neurological deficit, first-line treatments for symptomatic adult spinal deformity (ASD) are typically nonoperative and may include physical therapy, steroid injections, nonsteroidal antiinflammatory drugs, and, potentially, narcotics.<sup>2,48</sup> For patients who do not achieve a satisfactory response with nonoperative approaches, surgical treatment may become an option.

Recent studies have suggested that operative treatment for selected patients with ASD has the potential to provide significant relief of pain and disability, especially when compared with nonoperative treatments.<sup>8,10,23,43,49</sup> However, the complication rates associated with these procedures are not insignificant, with reported rates ranging from 10% to more than 80%.<sup>10,43,49</sup> Both the surgeon and the patient must carefully weigh the risks of surgical treatment versus the potential benefits in deciding whether surgical treatment is appropriate and worthwhile to pursue. An important part of this risk-benefit analysis and of patient counseling is the discussion regarding reasonable expectations.

Previous reports suggest that surgery for selected patients with ASD can provide approximately 60% relief of back and leg pain and approximately 40% improvement in disability at 2-year follow-up compared with baseline lev-

els.<sup>46,47</sup> Although these results offer simple objective measures that may be useful for patient counseling, it is important to recognize that they are based on averages of large groups of patients with wide ranges of spinal deformities, symptoms, and health states. Certainly not all patients will achieve the average improvements in pain and disability, and at the opposing extremes of the spectrum of clinical outcomes are those who are fortunate to be left with very limited or even no residual symptoms and those with the misfortune of having no improvement of symptoms or potentially even worsened symptoms and disability.<sup>50</sup> Assessing and comparing the patients at these opposing ends of the outcomes scales may provide insight into important factors for optimization of patient outcomes.

Our objectives in the present study were to define the ranges of outcomes for ASD surgery based on standardized health-related quality of life (HRQOL) measures and to assess for factors that may distinguish between those patients with the best and worst clinical outcomes.

## Methods

### Patient Population

This is a retrospective review of a prospectively collected, multicenter database of consecutively enrolled patients with ASD collected through the International Spine

Study Group (ISSG), which is composed of 11 sites across the United States. Patients were enrolled at each site after institutional review board approval. Inclusion criteria for the ISSG database are age > 18 years and presence of at least 1 of the following measures of spinal deformity: scoliosis Cobb angle  $\geq 20^\circ$ , sagittal vertical axis (SVA)  $\geq 5$  cm, pelvic tilt (PT)  $\geq 25^\circ$ , and thoracic kyphosis  $\geq 60^\circ$ . Only patients treated surgically were included in the present study. In addition, only patients with available baseline and 2-year follow-up outcomes measures and radiographic data were included in the analyses.

### Data Collection and Radiographic Assessment

Data collection at baseline and at 2 years following surgical treatment included standardized HRQOL questionnaires as well as clinical, demographic, and radiographic information. Standardized HRQOL questionnaires included the Oswestry Disability Index (ODI),<sup>16</sup> the Scoliosis Research Society–22 Patient Questionnaire (SRS-22),<sup>9</sup> and the 36-Item Short Form Health Survey (SF-36).<sup>53</sup> Basic demographic and clinical data included patient age, sex, body mass index (BMI), Charlson Comorbidity Index (CCI),<sup>13</sup> American Society of Anesthesiology (ASA) grade, history of prior spine surgery, smoking status at baseline, and diagnosis of depression at baseline. In addition, a numeric rating scale score ranging from 0 to 10 for back and leg pain was collected, with 0 representing no pain and 10 reflecting the most unbearable pain. Surgical data were extracted from standardized data collection sheets and included surgical approach, number of posterior levels operated on, operating room time, and estimated blood loss (EBL). Information regarding complications, including those occurring intraoperatively and through the time of last follow-up, was collected and classified as minor or major, as recommended by Carreon et al.<sup>11</sup>

Full-length, free-standing anteroposterior and lateral spine radiographs (36-inch cassette) obtained at baseline and at follow-up were analyzed using validated software<sup>12,34</sup> (Spineview; ENSAM Laboratory of Biomechanics). All radiographic measurements were performed at a central location (NYU Hospital for Joint Disease), based on standard techniques,<sup>3,33</sup> and included coronal Cobb angle, global coronal alignment (based on the offset of the C-7 plumb line relative to the central sacral vertical line), lumbar lordosis (LL; Cobb angle between superior endplate of L-1 and superior endplate of S-1), SVA (C-7 plumb line relative to S-1), PT, pelvic incidence (PI), and mismatch between PI and LL (PI-LL mismatch). For patients with a coronal Cobb angle of at least  $10^\circ$ , curve type (upper thoracic, thoracic, or thoracolumbar/lumbar) was categorized based on the curve with the maximum Cobb angle.

### Data and Statistical Analysis

Patients with the best and worst clinical outcomes were identified separately based on the ODI and SRS-22 outcomes measures. The cut-offs for the best and worst outcomes for the ODI and SRS-22 scores were based on assessment of distribution plots for each outcome measure, with specific focus on the tails at the extremes (best and

worst) and previously reported score correlates to health states.<sup>5,16,17</sup> For each outcomes measure, patients with the best and worst outcomes were compared based on demographic, clinical, radiographic, and surgical parameters. To minimize floor effects of the ODI, comparisons of best versus worst clinical outcomes were based on patients with a baseline ODI of at least 30. Similarly, to minimize the ceiling effects of the SRS-22, comparisons of best versus worst clinical outcomes were based on patients with a baseline SRS-22  $\leq 3.5$ . These baseline cutoffs of ODI and SRS-22 were selected to reflect values corresponding to thresholds of moderate disability based on previous reports.<sup>5,16,17</sup>

Frequency distributions and summary statistics were calculated for all demographic, clinical, operative, and radiographic variables. For categorical variables, cross-tabulations were generated and Fisher's exact or Pearson chi-square tests were used to compare distributions. For continuous variables, unpaired t-tests were used to assess differences in the distributions between subsets of patients classified by categorical data, and paired t-tests were used to assess differences in means for the same cohort between baseline and 2-year follow-up time points. Binary logistic regression analysis was used to adjust for the effects of multiple covariates predictive of best versus worst outcomes. Forward stepwise regression analyses used variables with  $p < 0.1$  for statistical assessment for capacity to distinguish between patients with best versus worst outcomes on univariate assessments. Statistical analyses were 2-sided, and  $p < 0.05$  was considered statistically significant.

## Results

### Patient Population

Of 257 patients who met inclusion criteria, 227 (88%) had complete baseline and 2-year follow-up SRS-22 and ODI outcomes scores and radiographic imaging and were included in the present study. Of these 227 patients, 187 had baseline SRS-22 scores  $\leq 3.5$ , and 162 had baseline ODI scores  $\geq 30$ . Demographic, clinical, and operative parameters for these 227 patients are summarized in Table 1. Their mean age was 55 years, and 84% of the patients were women. The mean BMI was 27 ("overweight") and ranged from 17 ("moderate thinness") to 54 ("Class III obesity").<sup>54</sup> Mean CCI and ASA grade were 1.4 and 2.2, respectively, and at baseline, 25% of the patients had a diagnosis of depression and 10% were active smokers. Curve types, based on maximum Cobb angle, were relatively evenly distributed across upper thoracic (34%), thoracic (27%), and thoracolumbar/lumbar (39%) regions. Nearly all patients (97%) underwent a posterior surgical procedure, and the mean number of levels operated on was 10. Anterior and lateral interbody procedures were performed in 28% and 7% of patients, respectively. The overall minor and major complication rates were 53% and 40%, respectively.

The mean preoperative and 2-year follow-up HRQOL scores and radiographic measures for the entire study cohort of 227 patients are summarized in Table 2. Compared with baseline, all measures of HRQOL improved at 2-year follow-up, including ODI, SRS-22, and back and leg pain scores. Similarly, the cohort demonstrated significant improvement in measures of coronal and sagittal deformity,



**TABLE 1. Demographic, clinical, and operative parameters for 227 surgically treated adults with spinal deformity**

Parameter	Value
F/M	191:36
Mean age, yrs (SD, range)	55 (15, 19–84)
Mean BMI (SD, range)	27 (6, 17–54)
Mean CCI (SD, range)	1.4 (1.5, 0–8)
Mean ASA grade (SD, range)	2.2 (0.7, 1–4)
Depression/anxiety (%)	25
Smoker (%)	10
Curve type (%)*	
Upper thoracic	34
Thoracic	27
Thoracolumbar/lumbar	39
No. of posterior procedures (%)	221 (97)
Mean no. of levels (SD, range)	10 (4, 2–17)
No. of anterior interbody procedures (%)	64 (28)
No. of lateral interbody procedures (%)	16 (7)
Mean operating room time, hrs (SD, range)	7.4 (2.9, 2.3–18.9)
Mean estimated blood loss, L (SD, range)	2.0 (1.7, 0.2–12.2)
No. of minor complications (%)	121 (53)
No. of major complications (%)	91 (40)

\* Percentages based on the number of patients with a coronal Cobb angle of at least 10° (n = 219).

including maximum coronal Cobb angle, global coronal alignment, SVA, PT, and PI-LL.

### Best and Worst Outcomes Based on ODI

Of the 227 patients in the study cohort, 162 (71%) had a baseline ODI score  $\geq 30$ . For these 162 patients, the mean baseline ODI score was 51 (SD 13, range 31–86) and the mean 2-year ODI score was 31 (SD 20, range 0–82) (Fig. 1 left). Based on the ODI, the best outcome group (ODI score  $\leq 15$ ) consisted of 43 (27%) patients and the worst outcome group (ODI score  $\geq 50$ ) consisted of 51 (31%) patients (Fig. 1 left). The worst outcome group had a mean baseline ODI score of 59 (SD 14) and a mean 2-year follow-up ODI score of 55 (SD 9) (Fig. 2 left). In contrast, the best outcome group had a mean baseline ODI score of 43 (SD 9) that improved to a mean of 7 (SD 5) at 2-year follow-up (Fig. 2 left).

Univariate comparisons between the patients with best versus worst outcomes based on the ODI are summarized in Table 3. Compared with best outcome patients, at baseline those with worst outcomes had worse ODI ( $p < 0.001$ ), SRS-22 ( $p < 0.001$ ), SRS-22 mental ( $p < 0.001$ ), and SF-36 mental component ( $p < 0.001$ ) scores and had more back pain ( $p = 0.003$ ), greater BMI ( $p = 0.002$ ), higher prevalence of depression ( $p = 0.028$ ), higher prevalence of positive sagittal malalignment ( $p = 0.009$ ), and a trend toward worse PI-LL mismatch ( $p = 0.063$ ). Notably, best versus worst outcome groups did not differ significantly based on mean age (57 years vs 60 years, respectively,  $p = 0.138$ ), CCI ( $p = 0.082$ ), or smoking status ( $p = 0.247$ ). Mean operative time and EBL did not differ significantly between

**TABLE 2. Radiographic and clinical outcomes at baseline and at 2-year follow-up for 227 operatively treated adults with spinal deformity**

Parameters	Preoperative	2-Yr Follow-Up	p Value*
Mean ODI score (SD)	41 (19)	25 (20)	<b>&lt;0.001</b>
Mean SRS-22 score (SD)	2.9 (0.7)	3.7 (0.8)	<b>&lt;0.001</b>
Mean back pain score (SD)	7.0 (2.3)	3.4 (3.1)	<b>&lt;0.001</b>
Mean leg pain score (SD)	4.2 (3.4)	2.4 (2.9)	<b>&lt;0.001</b>
Mean maximum Cobb angle, ° (SD)	45 (21)	26 (20)	<b>&lt;0.001</b>
Mean coronal alignment, mm (SD)	33 (32)	25 (23)	<b>0.001</b>
Global positive sagittal malalignment†	45	28	<b>&lt;0.001</b>
Mean PT, ° (SD)	23 (11)	21 (10)	<b>&lt;0.001</b>
Mean PI-LL mismatch, ° (SD)	13 (21)	3 (14)	<b>&lt;0.001</b>

\* p values are from paired t-tests; significant p values are in bold.

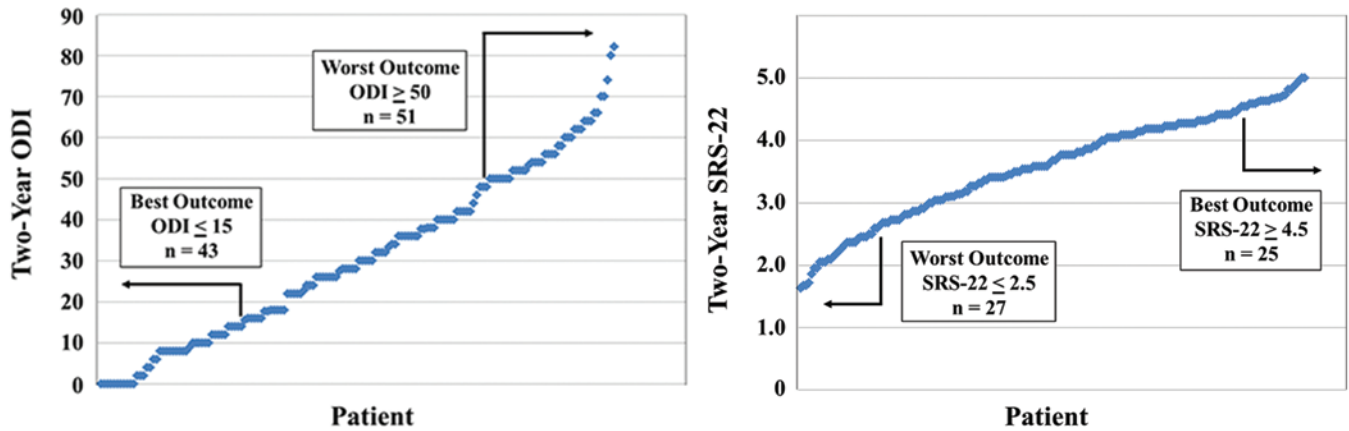
† Percent with SVA > 5 cm.

the best and worst outcome groups (Table 3). Patients in the worst outcome group had a higher rate of major complications compared with patients in the best outcome group (65% vs 30%,  $p = 0.001$ ), but the 2 groups had similar minor complication rates (55% vs 49%, respectively,  $p = 0.020$ ). Compared with best outcome patients, at follow-up, those with the worst outcomes had greater leg and back pain ( $p < 0.001$ ), worse ODI and SRS-22 scores ( $p < 0.001$ ), modestly greater PI-LL mismatch (9° vs 3°,  $p = 0.042$ ), and trended toward a higher prevalence of positive sagittal malalignment ( $p = 0.062$ ) (Table 3). Notably, the 2 groups did not differ significantly with regard to PT, global coronal alignment, or maximum coronal Cobb angle. The magnitude of change in deformity from baseline to follow-up was also compared between the best and worst outcome groups, and no significant differences were identified with regard to SVA, PT, PI-LL mismatch, or global coronal alignment (Table 3). The best outcome group had a slightly, but significantly greater correction of coronal Cobb angle ( $-23^\circ$  vs  $-17^\circ$ ,  $p = 0.037$ ).

Based on logistic regression analysis, only 3 parameters were incorporated into the final best-fit model, including baseline BMI ( $p = 0.037$ ), follow-up SVA ( $p = 0.014$ ), and baseline ODI ( $p < 0.001$ ) (Table 4).

### Best and Worst Outcomes Based on SRS-22

Of the 227 patients in the study cohort, 187 (82%) had a baseline SRS-22 score  $\leq 3.5$ . For these 187 patients, the mean baseline SRS-22 score was 2.9 (SD 0.7, range 1.3–3.3) and the mean 2-year SRS-22 score was 3.7 (SD 0.8, range 1.6–5.0) (Fig. 1 right). Based on the SRS-22, the best outcome group (SRS-22 score  $\geq 4.5$ ) consisted of 25 patients (13%) and the worst outcome group (SRS-22 score  $\leq 2.5$ ) consisted of 27 patients (14%) (Fig. 1 right). The worst outcome group had a mean baseline SRS-22 score of 2.2 (SD 0.7) and a mean 2-year follow-up SRS-22 score of 2.2 (SD 0.3) (Fig. 2 right). In contrast, the best outcome group



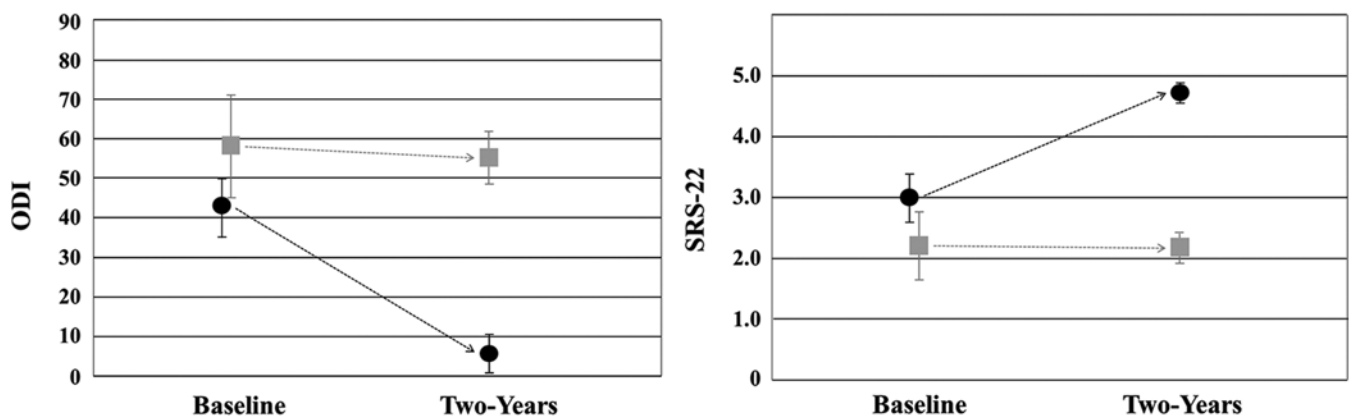
**FIG. 1.** Lowest to highest ODI and SRS-22 scores at 2 years following surgical treatment for spinal deformity, with cut-offs for best and worst outcomes indicated. **Left:** ODI scores for 162 adults; each patient had an ODI  $\geq 30$  at baseline. **Right:** SRS-22 scores for 187 adults; each patient had an SRS-22  $\geq 3.5$  at baseline. Figure is available in color online only.

had a mean baseline SRS-22 of 3.0 (SD 0.4) that improved to a mean of 4.7 (SD 0.1) at 2-year follow-up (Fig. 2 right).

Of the total of 57 patients having the best outcome based on either the ODI or SRS-22, 11 were defined by both the ODI and SRS-22, 14 were defined based only on the SRS-22, and 32 were defined by the ODI only. Of the total of 57 patients having the worst outcome based on either the ODI or SRS-22, 21 were defined by both the ODI and SRS-22, 6 were defined based only on the SRS-22, and 30 were defined by the ODI only.

Univariate comparisons between the patients with best versus worst outcomes based on the SRS-22 are summarized in Table 5. Compared with patients with the best outcomes, at baseline, those with worst outcomes had worse SRS-22 ( $p < 0.001$ ), ODI ( $p < 0.001$ ), SRS-22 mental ( $p < 0.001$ ), and SF-36 mental component ( $p < 0.001$ ) scores and had more back pain ( $p = 0.006$ ), greater comorbidities

based on CCI ( $p = 0.012$ ) and ASA ( $p = 0.004$ ), higher prevalence of depression ( $p = 0.028$ ), higher prevalence of previous spine surgery ( $p = 0.007$ ), worse PI-LL mismatch ( $p = 0.034$ ), and a trend toward greater BMI ( $p = 0.066$ ). Best versus worst outcome groups did not differ significantly based on mean age (56 years vs 58 years, respectively,  $p = 0.684$ ) or smoking status ( $p = 0.340$ ). Mean operative time and EBL did not differ significantly between the best and worst outcome groups (Table 5). Patients in the worst outcome group had a higher overall rate of combined minor and major complications compared with patients in the best outcome group (89% vs 56%,  $p = 0.012$ ). Compared with the patients with best outcomes, at follow-up, those with worst outcomes had greater leg and back pain ( $p < 0.001$ ) and worse ODI and SRS-22 scores ( $p < 0.001$ ) (Table 5). The 2 groups did not differ significantly with regard to prevalence of positive global sagittal malalign-



**FIG. 2.** Comparisons of the mean ODI and SRS-22 scores at baseline and 2 years following surgical treatment for ASD between the best clinical outcome and worst clinical outcome subgroups. **Left:** Comparison of mean ODI scores between the 2 groups of patients are shown, with *black circles* representing the subgroup with the best clinical outcome based on the ODI (defined as ODI score at 2 years  $\leq 15$ ;  $n = 43$ ) and *gray squares* representing the subgroup with the worst clinical outcome based on the ODI (defined as ODI score at 2 years  $\geq 50$ ;  $n = 51$ ); each patient had an ODI score  $\geq 30$  at baseline. *Error bars* represent SDs. **Right:** Comparison of mean SRS-22 scores between 2 groups of patients are shown, with *black circles* representing the subgroup with the best clinical outcome based on the SRS-22 (defined as SRS-22 score at 2 years  $\geq 4.5$ ;  $n = 25$ ) and *gray squares* representing the subgroup with the worst clinical outcome based on the SRS-22 (defined as SRS-22 score at 2 years  $\leq 2.5$ ;  $n = 27$ ); each patient had an SRS-22  $\leq 3.5$  at baseline. *Error bars* represent SDs.

**TABLE 3. Univariate analysis of baseline, operative, and follow-up parameters between patients with the best versus the worst outcomes based on the ODI following surgery for adult spinal deformity**

Parameters	Worst (n = 51)	Best (n = 43)	p Value*
<b>Baseline</b>			
M/F	10:41	6:37	0.583
Mean age, yrs (SD)	60 (10)	57 (13)	0.138
Mean BMI (SD)	30 (6)	26 (5)	<b>0.002</b>
Smoker (%)	4	12	0.247
Depression (%)	43	21	<b>0.028</b>
Mean CCI (SD)	1.7 (1.6)	1.2 (1.1)	0.082
Mean ASA grade (SD)	2.6 (0.6)	2.6 (0.5)	0.895
Prior spine surgery (%)	61	40	0.059
Mean leg pain score (SD)	5.1 (3.0)	5.1 (3.6)	0.984
Mean back pain score (SD)	8.3 (1.6)	7.2 (1.9)	<b>0.003</b>
ODI (SD)	59 (14)	43 (9)	<b>&lt;0.001</b>
SRS-22 (SD)	2.2 (0.5)	2.9 (0.5)	<b>&lt;0.001</b>
SRS-22 mental subscore (SD)	2.9 (0.9)	3.6 (0.8)	<b>&lt;0.001</b>
SF-36 mental component score (SD)	37.9 (12.2)	47.6 (12.7)	<b>&lt;0.001</b>
Global positive sagittal malalignment†	69	37	<b>0.009</b>
Mean PT, ° (SD)	27 (10)	24 (9)	0.154
Mean PI-LL mismatch, ° (SD)	23 (22)	15 (20)	0.063
Mean coronal alignment, mm (SD)	36 (29)	32 (29)	0.507
Max coronal Cobb angle, ° (SD)	39 (23)	44 (17)	0.242
<b>Operative</b>			
Operative time, hrs (SD)	8.3 (2.8)	7.4 (2.6)	0.109
Estimated blood loss, L (SD)	2.3 (2.0)	1.9 (1.8)	0.224
Major complications (%)	65	30	<b>0.001</b>
Minor complications (%)	55	49	0.679
Minor or major complications (%)	84	63	<b>0.020</b>
<b>Follow-up</b>			
Mean leg pain score (SD)	4.8 (3.1)	1.2 (2.2)	<b>&lt;0.001</b>
Mean back pain score (SD)	6.2 (2.9)	1.5 (1.7)	<b>&lt;0.001</b>
ODI score (SD)	55 (9)	7 (5)	<b>&lt;0.001</b>
SRS-22 score (SD)	2.6 (0.5)	4.4 (0.3)	<b>&lt;0.001</b>
SRS-22 mental subscore (SD)	3.1 (1.0)	4.3 (0.5)	<b>&lt;0.001</b>
SF-36 mental component score (SD)	38.5 (13.6)	56.7 (5.6)	<b>&lt;0.001</b>
Global positive sagittal malalignment†	61	37	0.062
Mean PT, ° (SD)	24 (10)	22 (9)	0.405
Mean PI-LL mismatch, ° (SD)	9 (14)	3 (15)	<b>0.042</b>
Mean coronal alignment, mm (SD)	26 (18)	27 (21)	0.768
Max coronal Cobb angle, ° (SD)	23 (19)	21 (13)	0.481
<b>Change from baseline to 2 yrs</b>			
SVA, mm	-35 (73)	-31 (63)	0.764
Mean PT, ° (SD)	-4 (10)	-2 (7)	0.377
Mean PI-LL mismatch, ° (SD)	-15 (20)	-12 (16)	0.428
Mean coronal alignment, mm (SD)	-6 (47)	-10 (39)	0.715
Max coronal Cobb angle, ° (SD)	-17 (15)	-23 (15)	<b>0.037</b>

\* Significant p values are in bold.

† Percent with SVA &gt; 5 cm.

ment, PT, global coronal alignment, or maximum coronal Cobb angle. The magnitude of change in deformity from baseline to follow-up was also compared between the best and worst outcome groups, and no significant differences were identified with regard to SVA, PT, PI-LL mismatch, or global coronal alignment (Table 5). The best outcome group had a modestly, but significantly greater correction of coronal Cobb angle ( $-25^\circ$  vs  $-16^\circ$ ,  $p = 0.015$ ).

Based on logistic regression analysis, only 3 parameters were incorporated into the final best-fit model, including baseline depression ( $p = 0.018$ ), follow-up SVA ( $p = 0.035$ ), and baseline ODI score ( $p = 0.010$ ) (Table 6).

## Discussion

This study provides an assessment of the ranges of outcomes of surgery for adults with spinal deformity and provides comparisons between patients with the best and worst clinical outcomes at 2 years following surgery. Although the overall clinical outcomes measures at 2 years following surgery clearly demonstrated significant improvements in pain and disability based on multiple measures, the ranges of outcomes are remarkably broad. For example, ODI scores 2 years after surgery ranged from 0 (corresponding to essentially no disability) to 82 (corresponding to crippling back pain or being bed-bound). A similarly broad range was also identified for the SRS-22 scores. Comparing the patient groups with the best and worst outcomes based on the ODI and SRS-22 demonstrated several distinguishing features that included patient-related factors such as obesity and depression, surgical parameters such as complication rates, and deformity-related measures, including baseline and residual sagittal spinopelvic malalignment. Collectively, these data emphasize the range of clinical outcomes following ASD surgery and suggest that parameters distinguishing patients with the best versus worst outcomes are complex and multifactorial.

Two different standardized HRQOL instruments were used in the present study to determine best versus worst outcomes. The ODI is an index that was developed to measure the degree of disability in a patient with low-back pain.<sup>16</sup> The questions are focused on function and concern intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. In contrast, the SRS-22 was developed through the Scoliosis Research Society as a disease-specific measure of HRQOL for spinal deformity patients.<sup>9</sup> The SRS-22 focuses on 5 primary domains, including function, pain, self-image, mental health, and satisfaction. Despite the differing emphasis of the ODI and SRS-22, it is notable that there was substantial overlap in the factors that distinguished between the best and worst outcome patients defined by each questionnaire.

Smith and colleagues previously reported on comparisons of best versus worst outcomes following ASD surgery based on the Spinal Deformity Study Group (SDSG) database.<sup>50</sup> None of the patients in the present study, which drew patients from the ISSG database, overlap with this previous report, and there is only limited overlap between the contributing surgeons. In the previous report, baseline and perioperative factors that distinguished between the

**TABLE 4. Multivariate analysis of factors distinguishing between the best and worst outcomes based on the ODI following surgery for adult spinal deformity\***

Parameter	OR	95% CI	p Value
Baseline BMI	0.893†	0.803–0.993	0.037
Follow-up SVA	0.987‡	0.976–0.997	0.014
Baseline ODI	0.914§	0.872–0.959	<0.001

\* Stepwise binary logistic regression. See text for discussion of factors included in the analysis; results of best-fit model presented.

† OR for BMI is per BMI unit.

‡ OR for SVA is per millimeter.

§ OR for ODI is per ODI unit.

best and worst outcomes were also assessed based on the ODI and SRS-22 questionnaires and were predominantly patient-related factors, including BMI, depression/anxiety, smoking, and pain severity at baseline (Table 7).<sup>50</sup> Factors that did not distinguish between these groups included comorbidities, severity of deformity, operative parameters (EBL and operative time), and occurrence of complications. Importantly, the SDSG study, in contrast to the present study, did not include assessment of pelvic parameters, including PT and PI-LL mismatch. In the SDSG analysis, there were sufficient numbers of younger patients (18–45 years) to enable separate assessments of outcomes based on age groups (18–45 and 46–85 years). Although there were significant differences in deformity patterns, operative parameters, and complication rates between the younger and older patient groups, there was substantial overlap in the factors that distinguished the best and worst outcome patients between the age groups.

In the present study, 25% of the overall cohort had a diagnosis of depression at baseline. This high rate of depression likely relates to the impact of the spinal deformity on quality of life. These patients are, by inclusion criteria, those who have not sufficiently responded to nonoperative therapies and who have reached a point at which their spinal pathology has such significant impact that they are preparing for surgical treatment. The diagnosis of depression at baseline was a significant distinguishing factor between those with the best and worst 2-year clinical outcomes based on the ODI and on the SRS-22. The best and worst outcome groups based on the ODI and on the SRS-22 were also distinguished on univariate analysis by other measures of mental health status, including both the SF-36 mental component score and the SRS-22 mental subscore. For the SRS-22, depression remained a significant distinguishing factor after adjusting for the effects of baseline SRS-22 score and for the occurrence of complications. Notably, in the SDSG study, the rate of depression was very similar to that of the present study, with 26% of the younger (18–45 years) and 26% of the older (46–85 years) having this diagnosis at baseline.<sup>50</sup> For the SDSG patients, depression was a significant distinguishing factor between the best and worst outcomes on both univariate and multivariate analyses.<sup>50</sup> Poorer surgical outcomes have also been associated with depression for other spinal conditions, including lumbar stenosis,<sup>1</sup> adolescent idiopathic scoliosis,<sup>14</sup> and a broad range of lumbar pathologies.<sup>40</sup> Col-



**TABLE 5. Univariate analysis of baseline, operative, and follow-up parameters between patients with the best versus the worst outcomes based on the SRS-22 following surgery for ASD**

Parameters	Worst (n = 27)	Best (n = 25)	p Value*
<b>Baseline</b>			
M/F	7:20	4:21	0.503
Mean age, yrs (SD)	58 (11)	56 (15)	0.684
Mean BMI (SD)	29 (6)	26 (4)	0.066
Smoker (%)	4	13	0.340
Depression (%)	67	8	<b>&lt;0.001</b>
Mean CCI (SD)	1.9 (1.9)	0.8 (1.1)	<b>0.012</b>
Mean ASA grade (SD)	2.6 (0.6)	2.0 (0.8)	<b>0.004</b>
Prior spine surgery (%)	67	28	<b>0.007</b>
Mean leg pain score (SD)	5.0 (3.1)	3.8 (3.2)	0.172
Mean back pain score (SD)	8.2 (1.8)	6.7 (2.0)	<b>0.006</b>
ODI score (SD)	56 (20)	37 (13)	<b>&lt;0.001</b>
SRS-22 score (SD)	2.2 (0.6)	3.0 (0.4)	<b>&lt;0.001</b>
SRS-22 mental subscore (SD)	2.7 (0.9)	3.9 (0.8)	<b>&lt;0.001</b>
SF-36 mental component score (SD)	34.0 (13.5)	52.0 (13.8)	<b>&lt;0.001</b>
Global positive sagittal malalignment†	59	36	0.173
Mean PT, ° (SD)	26 (10)	24 (8)	0.376
Mean PI-LL mismatch, ° (SD)	23 (25)	9 (18)	<b>0.034</b>
Mean coronal alignment, mm (SD)	35 (33)	24 (25)	0.192
Max coronal Cobb angle, ° (SD)	38 (25)	49 (19)	0.076
<b>Operative</b>			
Operative time, hrs (SD)	7.8 (2.7)	7.3 (3.2)	0.496
Estimated blood loss, L (SD)	2.1 (1.6)	1.7 (1.1)	0.354
Major complication (%)	59	32	0.058
Minor complication (%)	52	36	0.278
Minor or major complication (%)	89	56	<b>0.012</b>
<b>Follow-up</b>			
Mean leg pain score (SD)	4.3 (3.5)	0.7 (1.5)	<b>&lt;0.001</b>
Mean back pain score (SD)	7.3 (2.8)	0.6 (1.3)	<b>&lt;0.001</b>
ODI score (SD)	56 (13)	6 (7)	<b>&lt;0.001</b>
SRS-22 score (SD)	2.2 (0.3)	4.7 (0.1)	<b>&lt;0.001</b>
SRS-22 mental subscore (SD)	2.4 (0.7)	4.7 (0.3)	<b>&lt;0.001</b>
SF-36 mental component score (SD)	30.0 (12.9)	60.1 (3.2)	<b>&lt;0.001</b>
Global positive sagittal malalignment†	44	24	0.158
Mean PT, ° (SD)	24 (9)	24 (9)	0.998
Mean PI-LL mismatch, ° (SD)	10 (14)	6 (13)	0.231
Mean coronal alignment, mm (SD)	24 (19)	33 (23)	0.113
Max coronal Cobb angle, ° (SD)	23 (18)	24 (18)	0.862
<b>Change from baseline to 2 yrs</b>			
SVA, mm	-35 (86)	-8 (54)	0.380
Mean PT, ° (SD)	-3 (8)	0 (6)	0.124
Mean PI-LL mismatch, ° (SD)	-14 (23)	-4 (22)	0.108
Mean coronal alignment, mm (SD)	-3 (54)	-9 (35)	0.679
Max coronal Cobb angle, ° (SD)	-16 (13)	-25 (14)	<b>0.015</b>

\* Significant p values are in bold.

† Percent with SVA &gt; 5 cm.



**TABLE 6. Multivariate analysis of factors distinguishing between the best and worst outcomes based on the SRS-22 score following surgery for ASD\***

Parameter	OR	95% CI	p Value
Baseline depression	0.081†	0.010–0.651	0.018
Complication (minor &/or major)	9.012‡	1.166–69.628	0.035
Baseline SRS-22 score	10.641§	1.760–64.335	0.010

\* Stepwise binary logistic regression. See text for discussion of factors included in the analysis; results of best-fit model presented.

† OR for BMI is per BMI unit.

‡ OR for SVA is per millimeter.

§ OR for ODI is per ODI unit.

lectively, these data strongly suggest that optimization of treatment for depression should be pursued for adults with spinal deformity, and that management of depression may have impact on the clinical success of surgical treatment.

The mean BMI of the overall patient cohort in the present study was 27, which corresponds to the “overweight” category.<sup>54</sup> Although this may simply be reflective of the obesity issues facing many developed countries, it may also reflect the impact of pain and disability from spinal deformity on patient activity levels. In the present study, baseline BMI was a significant distinguishing factor between the patient groups with the best and worst clinical outcomes based on ODI and remained a significant distinguishing factor on multivariate analysis after adjusting for the effects of baseline ODI and follow-up SVA. In the SDSG study, baseline BMI was also a significant distinguishing factor between the best and worst outcome groups.<sup>50</sup> Although previous reports have suggested that obese patients treated surgically for degenerative lumbar disease do not necessarily have poorer outcomes than nonobese patients,<sup>4,15,20</sup> a recent report focused on spinal fusions involving 5 or more spinal levels has shown significant negative impact of obesity on clinical outcomes.<sup>32</sup> It is possible that obesity may have greater impact on recovery, rehabilitation, and long-term clinical outcomes for larger surgical procedures, such as those for spinal deformity, than for more limited procedures for degenerative conditions.

Previous reports have suggested that the occurrence of complications has only limited impact on clinical outcomes for ASD surgery, including the SDSG study that assessed best versus worst outcomes.<sup>24,49,50</sup> In a study by Bridwell and colleagues that focused on outcomes for ASD surgery, it was noted that patients who had a major complication still experienced significant improvement in clinical outcomes measures but that there was a trend toward a smaller incremental improvement at 2-year follow-up in this patient group compared with those patients who did not have a major complication.<sup>10</sup> In a subsequent report, the same authors documented the 3- to 5-year follow-up of this cohort and noted a significant impact of complications based on ODI and SRS scores at this longer-term follow-up.<sup>8</sup> In the present study, the occurrence of complications, especially major complications, was a significant distinguishing factor between patients with the best and worst outcomes. These data, in combination with those of

**TABLE 7. Summary of preoperative/operative and follow-up parameters that distinguished between the best and worst outcomes following surgery for ASD based on the present study from the ISSG database and a previous report from the SDSG database<sup>48</sup>**

ISSG	SDSG
Preoperative/Operative	Preoperative/Operative
Depression/anxiety	
Mean BMI	
Mean back pain score	
Mean leg pain score	
SVA > 5 cm	Age
Comorbidities	Smoking
Prior spine surgery	
Major complications	
Follow-Up	Follow-Up
Mean back pain score	
Mean leg pain score	
PI-LL mismatch	

Bridwell and colleagues, suggest that the impact of major complications on clinical outcomes may not be as benign as previously reported, especially when assessing differences between patient groups at the extremes (best and worst) of outcomes measures.

Since the time that patients were accrued into the SDSG database,<sup>50</sup> recognition of the importance of sagittal spinal alignment and pelvic parameters has greatly increased.<sup>3,7,21,22,25–31,35–39,41,44,45,48,51,52</sup> Although patient-related factors, including BMI, depression, and baseline levels of pain and disability, seemed to dominate the distinguishing factors between best and worst outcomes, sagittal spino-pelvic alignment parameters were also evident. Residual positive sagittal malalignment (SVA) was a significant distinguishing factor on multivariate analysis, which is consistent with previous reports that have documented negative impact of elevated SVA on HRQOL.<sup>22,27,37</sup> In addition, the PI-LL mismatch, a parameter with previously reported strong correlations to HRQOL measures,<sup>37</sup> was also a significant distinguishing factor between best and worst outcome patients on univariate analyses.

Although the present study suggests multiple factors associated with a greater likelihood of a patient with ASD having a poor outcome with surgery, these factors alone should not necessarily preclude such patients from being offered surgery. When contemplating surgical treatment, there are many other factors that should also be considered, including the overall severity of symptoms, impact of the symptoms on functionality and quality of life, health status of the patient, and the willingness of the patient to accept the risks of surgery.<sup>46,50</sup> The factors distinguishing between best and worst outcomes may provide opportunities for preoperative patient preparation. For example, optimization of treatment for depression and efforts to reduce excess weight preoperatively may mitigate the possible impact of these factors on outcomes. In addition, the distinguishing factors may also be helpful for preoperative

patient counseling, including discussions regarding realistic outcomes expectations.

Strengths of the present study include the use of a prospectively collected, multicenter database, standardized assessment of radiographic parameters at a single core institution, and inclusion of spinopelvic alignment measures. The primary limitation of the study is the retrospective design. In addition, although the overall number of patients in the study cohort was large, the numbers of patients compared between the best and worst outcome groups was relatively small, owing to the selection of the subsets of patients at the extremes of the outcome spectrum. These small patient groups limited the extent to which complex multivariate modeling could be performed.

## Conclusions

Few studies have specifically addressed factors that distinguish between the best versus worst clinical outcomes for ASD surgery. In this study, baseline and perioperative factors distinguishing between the best and worst outcomes for ASD surgery included several patient factors (baseline depression, BMI, comorbidities, and disability) as well as residual deformity (SVA) and occurrence of complications. These findings suggest factors that may warrant greater awareness and optimization to achieve optimal surgical outcomes for ASD patients.

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Conception and design: Smith, Shaffrey, Lafage, Scheer, Bess, Ames. Acquisition of data: Smith, Shaffrey, Lafage, Schwab, Protosaltis, Klineberg, Gupta, Hostin, Fu, Mundis, Kim, Deviren, Soroceanu, Hart, Burton, Bess, Ames. Analysis and interpretation of data: Smith, Lafage. Drafting the article: Smith. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Smith. Statistical analysis: Smith. Administrative/technical/material support: Shaffrey, Bess.

## Supplemental Information

### Previous Presentation

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