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Effect of Serious Adverse Events on Health-Related Quality of Life Measures Following Surgery for Adult Symptomatic Lumbar Scoliosis

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Abstract

Study Design: Secondary analysis of prospective multicenter cohort

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Objective: To assess effect of serious adverse events (SAEs) on 2- and 4-year patient-reported outcomes measures (PROMs) in patients surgically treated for adult symptomatic lumbar scoliosis (ASLS)

Summary of Background Data: Operative treatment for ASLS can improve health-related quality of life (HRQL), but has high rates of SAEs. How these SAEs effect HRQL remains unclear.

Methods: The ASLS study assessed operative versus nonoperative ASLS treatment, with randomized and observational arms. Patients were 40- to 80-years-old with ASLS, defined as lumbar coronal Cobb ≥30° and Oswestry Disability Index (ODI) ≥20 or Scoliosis Research Society-22 (SRS-22) ≤4.0 in pain, function and/or self-image domains. SRS-22 subscore and ODI were compared between operative patients with and without a related SAE and nonoperative patients using an as-treated analysis combining randomized and observational cohorts.

Results: 286 patients were enrolled, and 2- and 4-year follow-up rates were 90% and 81%, respectively, although at the time of data extraction not all patients were eligible for 4-year follow-up. A total of 97 SAEs were reported among 173 operatively treated patients. The most common were implant failure/pseudarthrosis (n=25), proximal junctional kyphosis/failure (n=10), and minor motor deficit (n=8). At 2 years patients with an SAE improved less than those without an SAE based on SRS-22 (0.52 vs 0.79, p=0.004) and ODI (−11.59 vs −17.34, p=0.021). These differences were maintained at 4-years for both SRS-22 (0.51 vs 0.86, p=0.001) and ODI (−10.73 vs −16.69, p=0.012). Despite this effect, patients sustaining an operative SAE had greater PROM improvement than nonoperative patients (p<0.001).

Conclusions: Patients affected by SAEs following surgery for ASLS had significantly less improvement of PROMs at 2- and 4-year follow-up versus those without an SAE. Regardless of SAE occurrence, operatively treated patients had significantly greater improvement in PROMs than those treated nonoperatively.

Keywords

adult; adverse events; complications; nonoperative; outcomes; scoliosis; spine deformity; surgery

Introduction

Operative treatment for symptomatic adult spinal deformity (ASD) can significantly improve health-related quality of life (HRQL), but complication rates remain high.[1–9] Complication severity ranges from minor, requiring minimal or no treatment, to potentially major, with permanent morbidity or need for reoperation.[7,10] Many complications cluster around the perioperative time period, but delayed complications may occur months or years following surgery.[10,11] It is generally accepted that complications can negatively impact recovery[12] and increase cost,[13,14] but whether they affect ultimate clinical outcomes remains unclear.

Several reports suggest that complications associated with ASD surgery have no significant effect on clinical outcomes.[7,15–19] For example, Daubs and colleagues reported on 46 patients who underwent fusion for ASD.[15] Overall, 37% of patients experienced complications, but complications had no apparent effect on patient-reported outcomes

measures (PROMs) at 4-year follow-up. Other reports suggest measureable effects on outcomes,[20–24] including one from Glassman and colleagues,[21] in which they reported deterioration of the SF-12 at one year following ASD surgery for patients who experienced a major complication, but whether this effect remained with further follow-up was not reported.

Our objective was to assess the effect of complications, with a focus on serious adverse events (SAEs), on 2- and 4-year PROMs in a prospective multicenter series of patients surgically treated for adult symptomatic lumbar scoliosis (ASLS). We hypothesized that SAEs associated with ASLS surgery will have negative effect on PROMs at 2- and 4-year follow-up. As a secondary assessment, we compared the change in PROMs between non-operatively treated patients and those treated operatively either with or without an SAE.

Materials and Methods

Study Design

The present study was based on ASLS patients prospectively enrolled in a multicenter study from 2010 to 2014 with the aim of assessing the effectiveness of operative versus nonoperative treatment for ASLS.[3] Patients were enrolled through nine centers across the United States and Canada. At enrollment, patients chose between randomized and observational study arms. Patients who consented to randomization were randomly assigned 1:1 to either operative or nonoperative treatment, while those who preferred to select their treatment approach were enrolled into the observational arm. For the present study, patients in both the observational and randomized arms were included as a single cohort.

Each site monitored patients for SAEs, which were defined based on the definition from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS),[25] the primary study sponsor, as any death, life-threatening event, event that caused significant or permanent disability, or an event that resulted in prolonged or new hospitalization. SAEs were collected by each site at the time of follow-up clinic visits at 3, 12, 24, 36 and 48 months. In addition to follow-up visits, patients completed PROMs at 6, 9, 15, 18, 21, 30 and 42 months. Patients were contacted directly to determine if an adverse event had occurred if their PROMs worsened [drop in Scoliosis Research Society-22 (SRS-22) domain scores of ≥0.5 points or increase in Oswestry Disability Index (ODI) of ≥10 points]. All participating centers received Institutional Review Board approval for study participation.

Patient Population and Interventions

Inclusion criteria for primary study enrollment were age of 40–80 years and ASLS. ASLS was defined as either idiopathic or *de novo* lumbar scoliosis with a Cobb angle ≥30°, and symptomatic was defined as an SRS-22 score ≤4.0 in the domains of Pain, Function, and/or Self-Image and/or an ODI score ≥20. Exclusion criteria included excessive medical comorbidities, pregnancy, osteoporosis (femoral neck dual-energy X-ray absorptiometry t-score <−3.0), previous thoracolumbar fusion, multilevel thoracolumbar decompression, high-grade spondylolisthesis, congenital spine anomalies, neuromuscular scoliosis, and a high risk of operative failure or morbidity.

Operative treatment included instrumented spinal fusions and decompression as indicated. Non-operative treatments were chosen by patients in consultation with the surgeon and/or physiatrist and included physical therapy, injections, pain medications, and complimentary/alternative therapies.

Outcomes

For the present study, primary outcome measures were the SRS-22 subscore and ODI at 2-year and 4-year follow-up. Other collected PROMs were used for baseline adjustments for comparisons between treatment groups. Only SAEs deemed to be potentially related to the spine pathology or treatment were analyzed.

Analysis

Baseline characteristics were compared between patients who underwent surgery and patients who only had nonoperative treatment. Among patients who underwent surgery, characteristics were also compared between those who did and did not experience an SAE. SAE incidence density rates were calculated for the 2- and 4-year follow-up time points. Chi-squared tests were used to compare frequencies between groups for categorical variables. T-tests were used to compare means between groups for continuous variables.

For the present study, patients were analyzed in their respective as-treated group regardless of whether they enrolled as part of the randomized or observational arms. For example, a patient who was initially managed with nonoperative treatment would contribute their follow-up time and PROMs to the nonoperative group, but if that patient later chose to pursue operative treatment, then follow-up time and PROMs occurring after surgery were contributed to the operative group.

Outcomes were compared between operative patients with and without an SAE. In addition, outcomes were compared between operative and nonoperative patients with stratification of the operative patients based on SAE occurrence. For comparisons of outcomes, estimates for the SRS-22 subscore and ODI score were derived from generalized linear mixed effects models accounting for the correlation among repeated measures using a heterogeneous autoregression covariance matrix. All models were adjusted for the following baseline characteristics: age, body mass index, depression/anxiety/psychiatric disorder, lumbar coronal Cobb angle, lumbar lordosis, stenosis levels, education, osteoporosis, SRS-22 subscore, ODI, numerical rating scale score for back pain, and SF-12 Physical Component Score (PCS).

All statistical analyses were performed using SAS software (version 9.4; SAS Institute, Cary, NC). All statistical tests were two-sided and statistical significance was determined based on an alpha of 0.05.

Results

Patient Population

A total of 286 patients were enrolled in the ASLS study, including 63 in the randomized cohort and 223 in the observational cohort.[3] By four years, in the combined study cohort, 6

patients had crossed over from planned operative to nonoperative treatment, and 40 patients had crossed over from nonoperative to operative treatment.[3] Overall loss to follow-up/withdrawals were 12/286 (4.2%) at 2 years and 28/286 (9.8%) at 4 years.

At the time of data extraction, 256 (90%) patients had completed minimum 2-year follow-up and 207 (81%) had completed 4-year follow-up in the combined overall cohort, although not all patients were yet eligible for 4-year follow-up. Importantly, since the mixed model approach used for analyses incorporates information from outcomes at all time points, patients contribute to the outcomes estimates even if they did not attend the precise 2- or 4-year visit.

Patient Characteristics and SAEs

Baseline characteristics of the 173 operatively treated patients and 113 patients who only received nonoperative treatment are summarized in Table 1. Comparisons between these as-treated groups demonstrated that operative and nonoperative patients had similar demographics and comorbidities. Operatively treated patients had modestly but significantly greater severity of spinal disease (Table 1). In addition, operative patients had significantly worse mean baseline health status and disability than nonoperative patients based on all assessed PROMs except the SF-12 Mental Component Score (MCS).

Serious adverse events for the 173 patients in the as-treated operative group are summarized in Table 2. At 2-years, 75 SAEs had been reported that affected 51 patients, and at 4-years, 97 SAEs had been reported that affected 67 patients. During the first 2 years post-surgery the incidence density rate was 22 SAEs per 100 person-years, and by 4 years post-surgery the incidence density rate was 15 SAEs per 100 person-years. The most common SAEs were operative/implant related, including implant failure/pseudarthrosis (n=25), proximal junctional kyphosis (PJK)/proximal junctional failure (PJF) (n=10), implant failure (n=4), and wound issues including infection (n=4). Seventeen new neurological deficits were reported (Table 2); 4 were major (American Spinal Injury Association [ASIA] C) and the remaining were minor. One patient with a major deficit died, and 2 others improved to ASIA D. The most common medical SAEs were cardiovascular (n=5), respiratory failure (n=4), and gastrointestinal (n=4) (Table 2). A total of 54 revision surgeries were performed in 45 patients. The most common indications for revision were pseudarthrosis and PJK/PJF.

Table 3 provides a summary comparison between the baseline characteristics and surgical parameters for the 173 patients in the as-treated operative group with stratification based on whether an SAE occurred. Demographics were not different between the patients with and without an SAE. At baseline, patients with an SAE more frequently had autoimmune disorders, diabetes, and gastrointestinal comorbidities and had worse baseline PROMs (Table 3). SAE and no SAE patients had no differences in surgical treatments nor mean operative times, but patients with an SAE had greater EBL (Table 3).

Effect of SAEs on Outcomes

The effect of SAEs on the SRS-22 subscore and ODI at 2- and 4-year follow-up are summarized in Table 4. Although both outcomes measures demonstrated favorable improvements at 2- and 4-year follow-up regardless of whether patients experienced an

SAE, the mean improvements were significantly less among patients who had an SAE. At 2-year follow-up the mean differences in improvement for the SRS-22 subscore and ODI were −0.27 (p=0.004) and 5.76 (p=0.021), respectively. Significant differences in improvement were maintained at 4-year follow-up, with mean differences in improvement for the SRS-22 subscore and ODI of −0.36 (p=0.001) and 5.97 (p=0.012), respectively (Table 4).

Comparison of changes in outcomes measures at 2- and 4-year follow-up for operative patients with and without an SAE to nonoperatively treated patients is summarized in Table 5. At both 2- and 4-year follow-up, operatively treated patients, regardless of whether an SAE occurred, had significantly greater mean improvements in SRS-22 subscore and ODI compared with nonoperatively treated patients (p<0.001).

Discussion

The present study provides an assessment of the effect of SAEs on PROMs following surgical treatment for ASLS at 2- and 4-year follow-up. Data were drawn from a prospective multicenter study on ASLS operative and nonoperative treatment that employed rigorous efforts to achieve patient follow-up and to document SAEs. Incidence of SAEs was high, with an incidence rate of 22 SAEs per 100 person-years during the first two years post-surgery (equivalent to approximately 2 SAEs occurring for every 5 people followed for that time period). The present study demonstrates that SAEs do have significant effect on mean PROMs at 2- and 4-years following surgery for ASLS. However, regardless of SAE occurrence, operatively treated patients still experienced significantly greater improvement in PROMs than nonoperatively treated patients. Collectively, these data may prove useful for patient counseling and provide support for efforts to reduce complications, both early and delayed, as a means of maximizing the benefits of these often complex procedures.

The question of whether complications have significant effect on the ultimate patient outcome following ASD surgery has had conflicting answers. The lack of clarity likely results in part from marked heterogeneity in study populations, non-consecutive enrollment, varying definitions of complications, differences in outcome measures, limited follow-up, and a range of study designs that were often retrospective and without a rigorous focus on collection of adverse events. The present study utilized a multicenter, prospectively collected homogenous study population with meticulous collection of adverse events and high rates of follow-up. Although what constitutes a complication and how the severity of complications should be determined remains controversial, we chose to apply the objective definition of an SAE as provided by NIAMS.[25]

Multiple study groups have used observational registries to assess the effect of complications on outcomes following ASD surgery, including the International Spine Study Group (ISSG), European Spine Study Group (ESSG), and the Spinal Deformity Study Group (SDSG). In separate ISSG studies, Soroceanu and colleagues focused on two subsets of complications, radiographic/implant-related complications and medical complications, and reported that the former but not the latter resulted in a negative effect on PROMs at 2-year follow-up.[19,20] Based on the ISSG registry, Passias and colleagues found that revision surgical procedures (excluding wound complications) for ASD did not negatively affect PROMs or patient

satisfaction at 2-year follow-up.[18] Ailon and colleagues through the ISSG reported that radiographic fusion grade in the absence of rod fracture did not affect HRQL at up to 3-year follow-up.[17] Smith and ISSG colleagues noted that the occurrence of complications was one of the key factors that distinguished between patients with the best and worst outcomes 2 years following ASD surgery.[26] Haddad and ESSG colleagues reported that deep surgical site infection following ASD surgery negatively affected PROMs at 1-year, but there was no significant effect by 2-year follow-up.[16] In a single-center study, Faloon and colleagues reviewed 71 ASD patients and reported that unplanned reoperation had significant negative effect on ODI and SRS-22 subscore at 5-year follow-up.[22]

Three previous reports have assessed effect of adverse events on outcomes based on the primary study used for the present analysis. Glassman and colleagues identified a significant negative deterioration in the Charlson Comorbidity Index in patients that had a major complication at 1 and 2 years following surgery for ASLS.[23] Kang and colleagues reported that although most neurologic deficits that occurred following ASLS surgery improved by 1 year, there was significant negative effect on PROMs, including increased leg pain.[24] Pugely and colleagues assessed the effect of SAEs on PROMs for ASLS patients treated nonoperatively.[27] Although they noted significant negative effect, the majority of SAEs were associated with interventions not related to spinal deformity.

The most common SAEs in the present study were related to pseudarthrosis and implant failures, PJK/PJF, and wound issues including infection. Although the patient series for this study was collected recently, even since the time of enrollment initiation there have been significant advances that have helped to reduce the incidence of these SAEs.[8] The occurrence of implant failure with pseudarthrosis has been reduced or at least delayed through recognition of risk factors and use of novel multi-rod configurations.[28,29] Considerable progress has been made in defining optimal radiographic alignment to help reduce the risk of PJK/PJF,[30–33] and proximal junctional tether techniques have been devised as a means of providing junctional support with preliminary data suggesting possible clinical benefit.[34–37] In addition, multiple recent publications have advanced the use of intrawound vancomycin powder to reduce wound infections.[38,39]

The health impact of symptomatic ASD is substantial and rivals or exceeds that of many other chronic diseases,[40,41] and operative treatment in selected patients offers the potential for significant improvement of pain and disability.[1–7] Nevertheless, it is important to recognize that these procedures have high complication rates.[2,7,10] In addition to the effect on long-term patient outcomes demonstrated in the present study, it should be acknowledged that complications can have multiple other consequences, including increasing length of hospital stay, need for invasive procedures and reoperations, increased cost, and negatively impacting patient recovery.[12–14]

This study is not without limitations. The small numbers of each type of SAE limit the ability to assess the effect of specific types of complications on outcomes. It is possible that there may be some SAEs with relatively limited or no effect, while other types and severities of SAEs may result in even greater effect than is suggested by the present study. Patient treatments were predominantly performed at high-volume universities which introduces

potential for expertise bias. When using an as-treated approach, treatment comparisons may be biased if some differences in patient characteristics between treatment groups were not captured. Although SAEs were actively collected at each follow-up visit, it is possible that the strategy to contact patients to inquire about SAE occurrence based on declines of PROM scores may have led to a more accurate collection of SAEs in this patient subset. In addition, patients were not stratified by frailty or surgical invasiveness.[42,43] Finally, while statistical differences in PRO change existed between those sustaining SAE and those without SAE, these differences are smaller than the minimum detectable measurement difference and the clinical relevance of this difference is unknown.[44]

Conclusions

Operative treatment for ASLS can improve HRQL but has a high rate of SAEs. Surgically treated patients affected by an SAE had significantly less improvement in PROMs at 2- and 4-year follow-up compared with those not affected by an SAE. Regardless of SAEs, operatively treated patients had significantly greater improvement in PROMs than those treated nonoperatively. These data may prove useful for patient counseling and support efforts to reduce complications as a means of maximizing the benefits of these complex procedures.

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Table 1.

Comparison of baseline characteristics of 173 patients who ever received operative treatment and 113 patients who only received nonoperative treatment for adult symptomatic lumbar scoliosis.*

Patient Parameter	Operative Treatment (n=173)	Nonoperative Treatment (n=113)	p^2
Age, yrs, mean (SD)	59.8 (8.8)	61.2 (10.1)	0.213
BMI, mean (SD)	27.1 (5.1)	26.3 (6.2)	0.257
Male gender	20 (11.6%)	8 (7.1%)	0.213
Race			0.134
White	166 (96.0%)	102 (90.3%)	
Black	5 (2.9%)	9 (8.0%)	
Other	2 (1.2%)	2 (1.8%)	
Currently working/employed[3]	98 (56.7%)	73 (64.6%)	0.180
Baseline comorbidities			
Autoimmune	17 (9.8%)	5 (4.4%)	0.094
Cancer	30 (17.3%)	27 (23.9%)	0.175
Cardiac disease	10 (5.8%)	8 (7.1%)	0.658
Circulatory disorders, arterial	5 (2.9%)	1 (0.9%)	0.247
Circulatory disorders, venous	5 (2.9%)	3 (2.7%)	0.906
Diabetes mellitus	10 (5.8%)	4 (3.5%)	0.391
Gastrointestinal (ulcer, stomach)	18 (10.4%)	13 (11.5%)	0.770
Hypertension	74 (42.8%)	41 (36.3%)	0.274
Infection history	6 (3.5%)	4 (3.5%)	0.974
Lung disease/Asthma	17 (9.8%)	16 (14.2%)	0.262
Nervous system disorder	2 (1.2%)	0 (0%)	0.251
History of depression/anxiety/psychiatric disorder	61 (35.3%)	27 (23.9%)	0.042
Renal disease	3 (1.7%)	1 (0.9%)	0.550
Substance use			
Current or former tobacco/nicotine use	66 (38.2%)	38 (33.6%)	0.437
Current or former alcohol/drug use	7 (4.1%)	1 (0.9%)	0.113
Coronal plane, mean (SD)			
Lumbar Cobb, °	54.9 (15.2)	50.1 (12.2)	0.003
Fractional Cobb, °	23.0 (10.4)	21.7 (8.8)	0.271
Coronal balance (absolute value), mm	26.0 (24.9)	20.1 (16.5)	0.018
Thoracic curve >30 °, %	97 (56.1%)	58 (51.8%)	0.478
Sagittal plane, mean (SD)			
Global sagittal alignment, mm	36.38 (45.9)	23.9 (42.6)	0.020
Pelvic incidence, °	55.5 (11.0)	56.5 (13.6)	0.503
Pelvic tilt, °	24.1 (9.1)	23.5 (10.2)	0.592
PI-LL mismatch	19.5 (18.3)	13.8 (18.5)	0.013

Patient Parameter	Operative Treatment (n=173)	Nonoperative Treatment (n=113)	*P*[2]
Baseline PROs			
SRS-22 subscore	3.1 (0.6)	3.4 (0.5)	<0.001
Oswestry Disability Index	38.2 (15.2)	30.0 (13.8)	<0.001
NRS back pain	6.3 (2.2)	5.5 (2.2)	0.004
NRS leg pain	3.9 (3.0)	3.1 (3.0)	0.016
SF-12 Mental Component Score	50.0 (11.3)	50.8 (10.5)	0.503
SF-12 Physical Component Score	33.2 (9.3)	38.3 (10.2)	<0.001

[*] SD = standard deviation; BMI = body mass index; global sagittal alignment was assessed based on the C7–S1 sagittal vertical axis; PI = pelvic incidence; LL = lumbar lordosis; PRO = patient report outcome measure; SRS = Scoliosis Research Society; NRS = numeric rating scale score

[2] P-values from chi-squared tests for categorical variables and t-tests for continuous variables Missing values included the following: 1 missing value for thoracic curve >30degrees among those who only received nonoperative (nonop) treatment; coronal balance missing for 1 operative (op) and 1 nonop patient; fractional Cobb missing for 4 op and 5 nonop patients; lumbar Cobb missing for 1 nonop patient; PI-LLmismatch missing for 8 op and 9 nonop patients; pelvic tilt missing for 8 op and 10 nonop patients; pelvic incidence missing for 8 op and 9 nonop patients; sagittal balance missing for 1 op and 1 nonop patient.

[3] Includes part-time and full-time homemaker

Table 2.

Summary of related serious adverse events among patients treated operatively for adult symptomatic lumbar scoliosis.*

Serious Adverse Event	Number during First 2 Years Post-Surgery	Number during First 4 Years Post-Surgery
Operative/Implant		
Implant failure/pseudarthrosis (reoperation)	9	25
PJK/PJF (reoperation)	7	10
Implant failure (reoperation)	4	4
Wound issues including infection (reoperation)	3	4
Implant other (reoperation)	2	2
Malpositioned screw (reoperation)	2	2
Durotomy/CSF leak (reoperation)	1	1
Durotomy/CSF leak (prolonged LOS)	1	1
New Neurological Deficit		
Minor motor postoperative deficit	8	8
Major motor postoperative deficit	2	2
Minor sensory postoperative deficit	2	2
Minor nerve root/cauda equina deficit	2	2
Major motor intraoperative deficit	1	1
Major neuro/new myelopathy	1	1
Minor motor and sensory postoperative deficit	1	1
Medical and Miscellaneous		
Cardiovascular	5	5
Respiratory failure	4	4
Gastrointestinal	3	4
Pleural effusion	1	2
Pulmonary embolism	2	2
Deep venous thrombosis	2	2
Altered mental status	2	2
Genitourinary	2	2
Stroke	1	1
Renal failure	1	1
Miscellaneous	6	6
Total SAEs	75	97
Total Affected Patients (1 or more SAEs)	51	67
Person-time	336 person-years	645 person-years
Total Incidence Rate	22 SAEs per 100 person-years	15 SAEs per 100 person-years

* PJK = proximal junctional kyphosis; PJF = proximal junctional failure; CSF = cerebral spinal fluid; LOS = length of stay; SAE = serious adverse event

Table 3.

Comparison of baseline characteristics and surgical parameters of 173 patients treated operatively for adult symptomatic lumbar scoliosis with and without a serious adverse event.[*]

Patient Parameter	Serious Adverse Event		*P*[2]
	No (n=107)	Yes (n=66)	
Age, yrs, mean (SD)	59.1 (9.1)	60.8 (8.2)	0.189
BMI, mean (SD)	26.7 (4.7)	27.9 (5.5)	0.140
Male gender	10 (9.4%)	10 (15.2%)	0.246
Race			0.556
White	104 (97.2%)	62 (93.9%)	
Black	2 (1.9%)	3 (4.6%)	
Other	1 (0.9%)	1 (1.5%)	
Currently working/employed[3]	64 (59.8%)	34 (51.5%)	0.285
Baseline comorbidities			
Autoimmune	5 (4.7%)	12 (18.2%)	0.004
Cancer	15 (14.0%)	15 (22.7%)	0.142
Cardiac disease	5 (4.7%)	5 (7.6%)	0.427
Circulatory disorders, arterial	3 (2.8%)	2 (3.0%)	0.931
Circulatory disorders, venous	1 (0.9%)	4 (6.1%)	0.051
History of depression/anxiety/psychiatric disorder	37 (34.6%)	24 (36.4%)	0.811
Diabetes mellitus	3 (2.8%)	7 (10.6%)	0.033
Gastrointestinal (ulcer, stomach)	6 (5.6%)	12 (18.2%)	0.009
Hypertension	46 (43.0%)	28 (42.4%)	0.942
Infection history	6 (5.6%)	0 (0%)	0.050
Lung disease/Asthma	9 (8.4%)	8 (12.1%)	0.426
Nervous system disorder	2 (1.9%)	0 (0%)	0.264
Renal disease	2 (1.9%)	1 (1.5%)	0.862
Substance use			
Current or former tobacco/nicotine use	36 (33.6%)	30 (45.5%)	0.120
Current or former alcohol/drug use	5 (4.7%)	2 (3.0%)	0.594
Coronal plane, mean (SD)			
Lumbar Cobb, °	53.6 (14.5)	57.2 (16.2)	0.140
Fractional Cobb, °	22.5 (10.4)	23.8 (10.5)	0.443
Coronal balance (absolute value), mm	24.6 (20.3)	28.2 (30.9)	0.403
Thoracic curve >30 °, %	59 (55.1%)	38 (57.6%)	0.754
Sagittal plane, mean (SD)			
Global sagittal alignment, mm	34.3 (42.7)	39.8 (50.9)	0.465
Pelvic incidence, °	55.5 (11.6)	55.4 (10.1)	0.952
Pelvic tilt, °	23.8 (9.1)	24.7 (9.1)	0.582

Patient Parameter	Serious Adverse Event		P[2]
	No (n=107)	Yes (n=66)	
PI-LL mismatch	18.9 (17.4)	20.6 (20.0)	0.587
Baseline PROs			
SRS-22 subscore	3.1 (0.5)	2.9 (0.6)	0.019
Oswestry Disability Index	35.1 (13.9)	43.3 (16.0)	<0.001
NRS back pain	6.2 (2.3)	6.4 (2.1)	0.491
NRS leg pain	3.4 (3.0)	4.8 (2.8)	0.004
SF-12 Mental Component Score	51.6 (10.8)	47.4 (11.6)	0.020
SF-12 Physical Component Score	34.5 (9.4)	31.0 (8.9)	0.016
Surgical procedure			
Staged procedure	8 (7.5%)	6 (9.1%)	0.705
Number vertebra instrumented, mean (SD)	11 (4)	12 (4)	0.287
3-column osteotomy	5 (7.6%)	5 (4.7%)	0.427
Combined anterior-posterior	10 (9.4%)	8 (12.1%)	0.561
EBL, mL, mean (SD)	1909 (1595)	2704 (1750)	0.003
Operative time, min, mean (SD)	406 (140)	439 (126)	0.114

[*] SD = standard deviation; BMI = body mass index; global sagittal alignment was assessed based on the C7–S1 sagittal vertical axis; PI = pelvic incidence; LL = lumbar lordosis; PRO = patient report outcome measure; SRS = Scoliosis Research Society; NRS = numeric rating scale score; 3-column osteotomy includes pedicle subtraction osteotomy and vertebral column resection; EBL = estimated blood loss

[2] P-values from chi-squared tests for categorical variables and t-tests for continuous variables. Missing values included the following: coronal balance missing for 1 patient with no serious adverse event (SAE), fractional Cobb missing for 3 patients with no SAE and 1 patient with SAE; PI-LL mismatch missing for 2 patients with no SAE and 6 patients with SAE; pelvic tilt missing for 2 patients with no SAE and 6 patients with SAE; pelvic incidence missing 2 patients with no SAE and 6 patients with SAE; sagittal balance missing for 1 patient with no SAE

[3] Includes part-time and full-time homemaker

Table 4.

Effect of related serious adverse events on patient outcomes among 173 patients treated operatively for symptomatic lumbar scoliosis.*

	Average Change from Baseline (SE)		Mean Difference (95% CI)	P value
	SAE	No SAE		
2-Year Follow-up				
SRS-22 subscore	0.52 (0.08)	0.79 (0.06)	−0.27 (−0.45, −0.09)	0.004
ODI score	−11.59 (2.07)	−17.34 (1.35)	5.76 (0.87, 10.64)	0.021
4-Year Follow-up				
SRS-22 subscore	0.51 (0.09)	0.86 (0.07)	−0.36 (−0.57, −0.14)	0.001
ODI score	−10.73 (1.91)	−16.69 (1.39)	5.97 (1.30, 10.63)	0.012

*SE = standard error; SAE = serious adverse event; CI = confidence interval; SRS = Scoliosis Research Society; ODI = Oswestry Disability Index

Table 5.

Comparison of primary outcomes on operatively treated adult symptomatic lumbar scoliosis patients with and without a related serious adverse event to nonoperatively treated patients.*

	Average Change from Baseline (SE)	Mean Difference (95% CI)	P value
2-Year Follow-up			
SRS-22 subscore			
Non-operative	0.11 (0.05)	Referent	
Operative with an SAE	0.51 (0.07)	0.39 (0.22, 0.56)	<0.001
Operative with no SAE	0.75 (0.05)	0.64 (0.50, 0.77)	<0.001
ODI Score			
Non-operative	−1.57 (1.26)	Referent	
Operative with an SAE	−10.51 (1.91)	−8.94 (−13.34, −4.54)	<0.001
Operative with no SAE	−15.79 (1.29)	−14.22 (−17.59, −10.85)	<0.001
4-Year Follow-up			
SRS-22 subscore			
Non-operative	0.04 (0.06)	Referent	
Operative with an SAE	0.49 (0.09)	0.45 (0.24, 0.65)	<0.001
Operative with no SAE	0.83 (0.06)	0.79 (0.62, 0.96)	<0.001
ODI Score			
Non-operative	−1.10 (1.27)	Referent	
Operative with an SAE	−9.34 (1.81)	−8.24 (−12.47, −4.00)	<0.001
Operative with no SAE	−15.13 (1.37)	−14.03 (−17.52, −10.54)	<0.001

* SE = standard error; CI = confidence interval; SRS = Scoliosis Research Society; SAE = serious adverse event; ODI = Oswestry Disability Index