Justin S. Smith, MD, PhD*
Virginie Lafage, PhD‡
Christopher I. Shaffrey, MD*
Frank Schwab, MD‡
Renaud Lafage, MS‡
Richard Hostin, MD§
Michael O'Brien, MD§
Oheneba Boachie-Adjei, MD¶
Behrooz A. Akbarnia, MD‖
Gregory M. Mundis, MD‖
Thomas Errico, MD‡
Han Jo Kim, MD¶
Themistocles S. Protopsaltis, MD‡
D. Kojo Hamilton, MD#
Justin K. Scheer, BS**
Daniel Sciubba, MD‡‡
Tamir Ailon, MD*
Kai-Ming G. Fu, MD, PhD§§
Michael P. Kelly, MD¶¶
Lukas Zebala, MD¶¶
Breton Line, BSME‖‖
Eric Klineberg, MD##
Munish Gupta, MD##
Vedat Deviren, MD***
Robert Hart, MD‡‡‡
Doug Burton, MD§§§
Shay Bess, MD‖‖
Christopher P. Ames, MD¶¶¶
on behalf of the International Spine Study Group

*Department of Neurosurgery, University of Virginia Medical Center, Charlottesville, Virginia; ‡Department of Orthopedic Surgery, NYU Hospital for Joint Diseases, New York, New York; §Department of Orthopedic Surgery, Baylor Scoliosis Center, Plano, Texas; ¶Department of Orthopedic Surgery, Hospital for Special Surgery, New York, New York; ‖San Diego Center for Spinal Disorders, La Jolla, California; #Department of Neurosurgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; **Department of Neurosurgery, Northwestern University Medical Center, Chicago, Illinois; ‡‡Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, Maryland; §§Department of Neurosurgery, Weill Cornell Medical College, New York City, New York; ¶¶Department of Orthopedic Surgery, Washington University, St. Louis, Missouri; ‖‖Department of Orthopedic Surgery, Rocky Mountain Hospital for Children, Denver, Colorado; ##Department of Orthopedic Surgery, University of California Davis, Sacramento, California; ***Department of Orthopedic Surgery, University of California San Francisco, San Francisco, California; ‡‡‡Department of Orthopedic Surgery, Oregon Health Sciences University, Portland, Oregon; §§§Department of Orthopedic Surgery, University of Kansas Medical Center, Kansas City, Kansas; ¶¶¶Department of Neurosurgery, University of California San Francisco, San Francisco, California

Correspondence:
Justin S. Smith, MD, PhD,
Department of Neurosurgery, University of Virginia Health Sciences Center, PO Box 800212, Charlottesville, VA 22908.
E-mail: jss7f@virginia.edu

Received, June 1, 2015.
Accepted, September 20, 2015.
Published Online, November 16, 2015.

Outcomes of Operative and Nonoperative Treatment for Adult Spinal Deformity: A Prospective, Multicenter, Propensity-Matched Cohort Assessment With Minimum 2-Year Follow-up

BACKGROUND: High-quality studies that compare operative and nonoperative treatment for adult spinal deformity (ASD) are needed.
OBJECTIVE: To compare outcomes of operative and nonoperative treatment for ASD.
METHODS: This is a multicenter, prospective analysis of consecutive ASD patients opting for operative or nonoperative care. Inclusion criteria were age >18 years and ASD. Operative and nonoperative patients were propensity matched with the baseline Oswestry Disability Index, Scoliosis Research Society-22r, thoracolumbar/lumbar Cobb angle, pelvic incidence–to–lumbar lordosis mismatch (PI-LL), and leg pain score. Analyses were confined to patients with a minimum of 2 years of follow-up.
RESULTS: Two hundred eighty-six operative and 403 nonoperative patients met the criteria, with mean ages of 53 and 55 years, 2-year follow-up rates of 86% and 55%, and mean follow-up of 24.7 and 24.8 months, respectively. At baseline, operative patients had significantly worse health-related quality of life (HRQOL) based on all measures assessed ($P < .001$) and had worse deformity based on pelvic tilt, pelvic incidence–to–lumbar lordosis mismatch, and sagittal vertical axis ($P \leq .002$). At the minimum 2-year follow-up, all HRQOL measures assessed significantly improved for operative patients ($P < .001$), but none improved significantly for nonoperative patients except for modest improvements in the Scoliosis Research Society-22r pain ($P = .04$) and satisfaction ($P < .001$) domains. On the basis of matched operative-nonoperative cohorts (97 in each group), operative patients had significantly better HRQOL at follow-up for all measures assessed ($P < .001$), except Short Form-36 mental component score ($P = .06$). At the minimum 2-year follow-up, 71.5% of operative patients had ≥1 complications.
CONCLUSION: Operative treatment for ASD can provide significant improvement of HRQOL at a minimum 2-year follow-up. In contrast, nonoperative treatment on average maintains presenting levels of pain and disability.

KEY WORDS: Adult spinal deformity, Complications, Nonoperative treatment, Outcomes, Scoliosis, Surgery

Neurosurgery 78:851–861, 2016 DOI: 10.1227/NEU.0000000000001116 www.neurosurgery-online.com

Adults with spinal deformity characteristically present with pain and disability.[1-15] Initial treatment for symptomatic adult spinal deformity (ASD) is commonly nonoperative, including physical therapy, steroid injections, and medications.[16,17] Surgical treatment may be discussed if patients have unsatisfactory improvement with nonoperative measures.

ABBREVIATIONS: ASD, adult spinal deformity; **HRQOL,** health-related quality of life; **LL,** lumbar lordosis; **MCID,** minimal clinically important difference; **NRS,** numeric rating scale; **ODI,** Oswestry Disability Index; **PI,** pelvic incidence; **SF-36,** Short Form-36; **SRS-22r,** Scoliosis Research Society-22r; **SVA,** sagittal vertical axis

Recent studies suggest that operative treatment for selected patients with ASD may provide relief of pain and disability.[2,3,9,13,18] However, reported complication rates associated with ASD surgery are high, ranging from 10% to >80%.[3,9,13] When the risk-benefit analysis for ASD surgery is considered, discussions regarding anticipated postsurgical pain relief may be helpful for ASD

patients. Previous reports indicate that surgery for selected ASD patients can provide approximately 60% relief of back and leg pain and approximately 40% improvement in disability at the 2-year follow-up.[11,12] Although growing literature supports the benefits of operative treatment for selected ASD patients, additional high-quality studies comparing operative and nonoperative treatment are needed.

Our primary objective in the present study was to compare minimum 2-year outcomes for operative and nonoperative treatment for ASD using a prospective, multicenter patient population with propensity-matched operative and nonoperative cohorts.

METHODS

Patient Population

This is a multicenter, prospective assessment of ASD patients. Patients were prospectively enrolled in a multicenter database through an Institutional Review Board–approved protocol at 11 sites across the United States. Database inclusion criteria were age >18 years and at least 1 of the following measures: scoliosis ≥20°, sagittal vertical axis (SVA) ≥5 cm, pelvic tilt ≥25°, and thoracic kyphosis ≥60°.

At the time of study enrollment, patients chose either operative or nonoperative treatment. This is a prospective, observational study, not a randomized study, so the decision of whether to pursue operative or nonoperative treatment for each patient was determined by the consent process between the patient and the surgeon and was ultimately guided by patient choice. No attempt was made to randomize any patient in this study. Additionally, the choice of the type of operative or nonoperative treatment was based on the consent process between the patient and the corresponding surgeon. No attempt was made to randomize the type of treatment for any patient in this study. Operative planning was at the discretion of the surgeon. Standardized nonoperative treatment protocols were not used; instead, nonoperative care was tailored to those opting for this approach. Nonoperative treatments included, but were not limited to, physical therapy, epidural steroid injections, pharmacological treatments, and orthotic treatments. A flow diagram for patient selection is shown in Figure 1.

Data Collection and Radiographic Assessment

Baseline and minimum 2-year follow-up data collected included demographic, radiographic, operative, and health-related quality of life (HRQOL) outcome values. HRQOL data collected included the modified Oswestry Disability Index (ODI) as described by Fritz and Irrgang[19] and Fairbank et al,[20] Scoliosis Research Society-22r (SRS-22r),[21,22] the Short Form-36 version 2 (SF-36),[23] and the numeric rating scale (NRS) for back and leg pain. Complications were assessed for the operative patients and were classified as minor or major. Standardized data collection forms, on-site study coordinators, and regular central auditing helped to ensure the completeness of complication collection. A complication was classified as major if it substantially prolonged hospitalization, involved an invasive intervention, had prolonged or permanent morbidity, or resulted in death. Thus, any complication associated with the need for reoperation was considered major. Complications were further classified as perioperative (within 6 weeks of surgery) or delayed (beyond 6 weeks from surgery). Complications resulting from nonoperative treatments were not consistently collected and are not reported in the present study.

Full-length free-standing anteroposterior and lateral spine radiographs were analyzed with validated software (Spineview, ENSAM Laboratory of

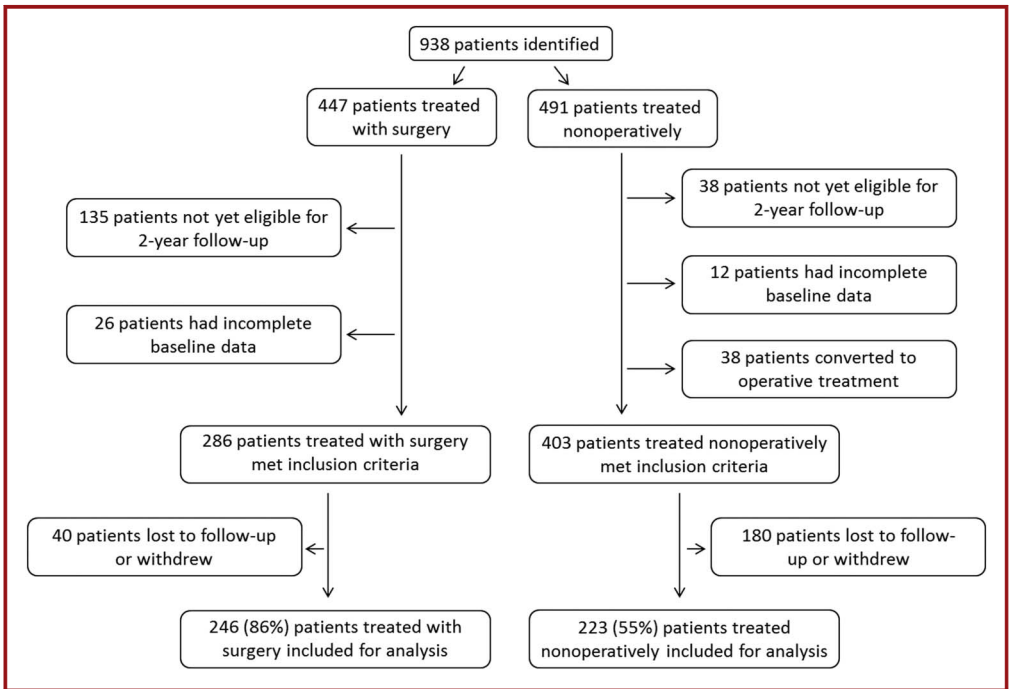

FIGURE 1. *Flow diagram for patient selection.*

Biomechanics, Paris, France).[24,25] All radiographic measures were performed at a central location and based on standard techniques,[26,27] including scoliosis, global coronal alignment (offset of C7 plumb line relative to the central sacral vertical line), thoracic kyphosis (Cobb angle between superior endplate of T4 and inferior endplate of T12), lumbar lordosis (LL; Cobb angle between superior endplate of L1 and superior endplate of S1), SVA, pelvic tilt, pelvic incidence (PI), and mismatch between PI and LL (PI-LL), as previously described.[27] Operative and nonoperative patients were classified on the basis of the SRS-Schwab adult thoracolumbar spinal deformity classification.[10,15,28]

Data and Statistical Analysis

Frequency distributions and summary statistics were calculated for all variables. For categorical variables, cross-tabulations were generated, and the Fisher exact or Pearson χ^2 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. Statistical analyses were 2 sided, and values of $P < .05$ were considered statistically significant.

Unmatched and propensity-matched analyses of the study cohort were performed. For unmatched analyses, all patients meeting study criteria were assessed. The propensity-matched analysis included generation of operative and nonoperative patient groups matched according to baseline ODI, SRS-22r, maximum thoracolumbar/lumbar Cobb angle, PI-LL, and leg pain NRS score.[29-31] Minimal clinically important difference (MCID) values used for the corresponding HRQOL measures included ODI (12.8), SF-36 physical component score (4.9), SRS pain (0.587), SRS appearance (0.8), SRS activity (0.375), SRS mental (0.42), back pain NRS score (1.2), and leg pain NRS score (1.6), as previously reported.[10,32-37]

RESULTS

Patient Population

A total of 689 patients met the inclusion criteria, including 286 in the operative group and 403 in the nonoperative group, with mean ages of 54 and 55 years, respectively. Before reaching the minimum 2-year follow-up, 38 nonoperative patients converted to operative treatment and were not analyzed in the present study. A minimum 2-year follow-up was achieved by 246 operative (86%) and 223 nonoperative patients (55%), and the mean follow-up for these groups was 24.7 and 24.8 months, respectively.

Baseline demographic and clinical parameters for operative and nonoperative groups are summarized in Table 1. Compared with nonoperative patients, operative patients had significantly greater body mass index ($P = .003$), greater comorbidities ($P < .001$), and a higher prevalence of depression ($P = .009$), and a higher percentage of operative patients had previous spine surgery ($P < .001$). Sex, age, and smoking did not differ significantly between the groups.

The SRS-Schwab classifications for the operative and nonoperative groups are summarized in Figure 2. There were no significant differences in the distribution of coronal curve type between the groups ($P = .41$). Patients in the operative group had

TABLE 1. Baseline Demographic and Clinical Parameters for Adults With Spinal Deformity Stratified Based on Nonoperative vs Operative Treatment, Including Unmatched and Matched Cohorts[a]

	Treatment Group (Unmatched)		
Parameter	**Nonoperative (n = 223)**	**Operative (n = 246)**	***P* Value**
Female sex, %	87	84	.21
Mean age (SD, range), y	52.6 (16.1, 18-84)	55.4 (15.2, 19-84)	.06
Mean body mass index (SD, range), kg/m^2	25.5 (5.9, 15.0-48.3)	27.1 (5.9, 16.8-54.1)	.003[b]
Mean Charlson Comorbidity Index (SD, range)	0.9 (1.1, 0-5)	1.4 (1.6, 0-8)	<.001[b]
Depression, %	15.7	24.9	.009[b]
Smoker, %	11.9	9.3	.23
Previous spine surgery, %	18.6	42.6	<.001[b]

	Treatment Group (Matched)		
Parameter	**Nonoperative (n = 97)**	**Operative (n = 97)**	***P* Value**
Female sex, %	87.6	87.4	>.99
Mean age (SD, range), y	58.0 (13.5, 26-81)	51.4 (16.8, 19-80)	.003[b]
Mean body mass index (SD, range), kg/m^2	26.7 (5.8, 15.0-48.3)	25.4 (4.9, 18.0-42.5)	.09
Mean Charlson Comorbidity Index (SD, range)	1.2 (1.1, 0-5)	1.0 (1.3, 0-8)	.29
Depression, %	22.7	13.4	.14
Smoker, %	14.4	10.5	.51
Previous spine surgery, %	23.2	31.6	.15

[a]SVA, sagittal vertical axis.
[b]Significant.

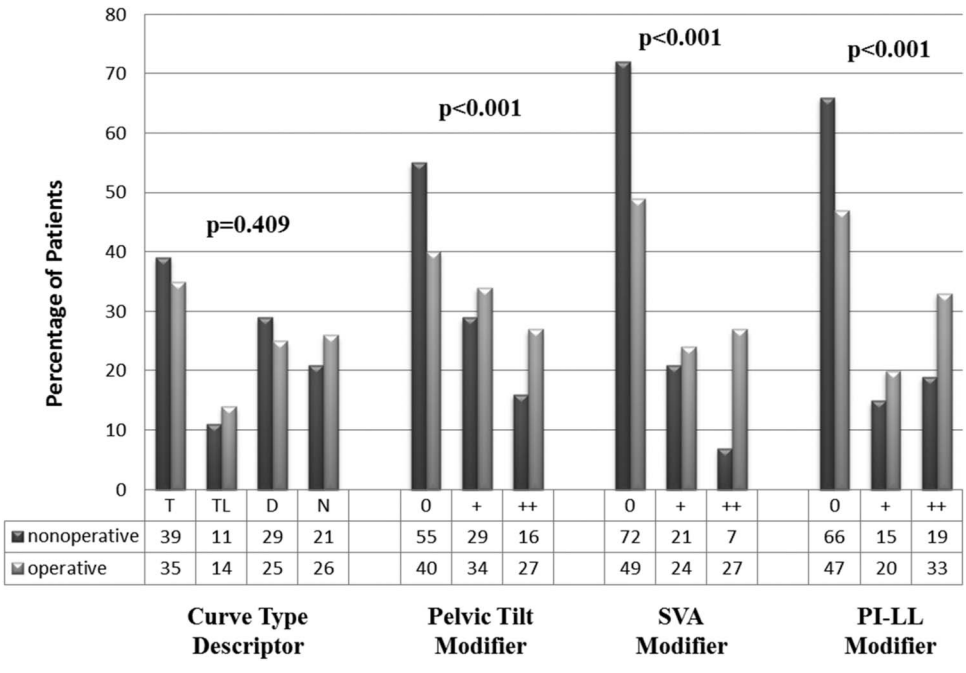

FIGURE 2. *Distribution of Scoliosis Research Society–Schwab thoracolumbar deformity classification for 469 adults with spinal deformity stratified based on nonoperative vs operative treatment. LL, lumbar lordosis; PI, pelvic incidence; SVA, sagittal vertical axis.*

significantly worse sagittal modifier grades, reflecting greater baseline spinal deformity ($P < .001$).

The majority of operative patients (99%) were treated with a posterior spinal fusion (mean, 9.7 [SD = 4.1] vertebral levels). Anterior lumbar interbody fusion and lateral interbody fusion procedures were performed for 27.3% and 7.3% of the operative patients, respectively. Pedicle subtraction osteotomy and vertebral column resection procedures were performed in 15.4% and 4.5% of patients, respectively. The mean operative time was 7.4 hours, and the mean estimated blood loss was 2.0 L. Complications by category for the operatively treated patients are summarized in Table 2. One or more perioperative complications occurred in 53.7% of patients, and ≥1 delayed complications occurred in 43.5% of patients. Overall, 71.5% of patients had experienced ≥1complications at a minimum 2-year follow-up.

Outcomes Assessment of Unmatched Operative and Nonoperative Cohorts

At baseline, operative patients had significantly worse spinal deformity compared with nonoperative patients, including worse global coronal alignment, greater proportion of patients with SVA >5 cm, greater pelvic tilt, and greater PI-LL ($P \leq .002$). The operative and nonoperative groups had similar mean baseline maximum coronal Cobb angles ($P > .99$). At the minimum 2-year follow-up, the spinal deformity for nonoperative patients did not significantly change (SVA, pelvic tilt, maximum coronal Cobb angle, and global coronal alignment; all $P \geq .19$), except for worsening of the mean PI-LL ($P < .001$). In contrast, at follow-up, operative patients had significant improvement in maximum coronal Cobb angle, global coronal alignment, proportion of patients with SVA >5 cm, pelvic tilt, and PI-LL ($P \leq .003$).

At baseline, compared with nonoperative patients, operative patients had significantly worse HRQOL based on all measures assessed (ODI, SF-36 physical and mental component scores, SRS-22r, and back and leg pain NRS scores; all $P < .001$). At the last follow-up, operative patients had significant improvement in all HRQOL measures ($P < .001$) compared with baseline values, and the improvement was at least 1 MCID for the corresponding HRQOL values. In contrast, the nonoperative patients demonstrated modest mean improvements for the SRS-22r pain domain (from 3.4 to 3.5; $P = .04$) and the SRS-22r satisfaction domain (from 3.3 to 3.6; $P < .001$), but no other significant improvements in outcomes measures were evident. The percentages of patients reaching at least 1 MCID improvement from baseline to follow-up with either nonoperative or operative treatment in the overall operative and nonoperative are summarized in Figure 3.

Outcomes Assessment of Matched Operative and Nonoperative Cohorts

A total of 97 operative and 97 nonoperative patients were propensity matched (Table 1). The groups were well matched on the baseline matching parameters: maximum thoracolumbar/

TABLE 2. Summary of Complications by Category for 246 Adult Spinal Deformity Patients Treated Surgically and With Minimum 2-Year Follow-up

	Perioperative (≤6 wk)			Delayed (>6 wk)			Total		
Complication Category	Minor/Major	Reoperation	%	Minor/Major	Reoperation	%	Minor/Major	Reoperation	%
Implant	2/6	3[a]	3.3	10/46	23[a]	22.8	12/52	26[a]	26.0
Radiographic	4/8	6[a]	4.9	24/34	27[a]	23.6	28/42	33[a]	28.5
Neurological	20/19	6[a]	15.9	15/15	9[a]	12.2	35/34	15[a]	28.0
Operative	37/27		26.0	0/0		0	37/27		26.0
Cardiopulmonary	30/19	1[a]	19.9	1/3		1.6	31/22	1[a]	21.5
Infection	8/18	7[a]	10.6	4/7	5[a]	4.5	12/25	12[a]	15.0
Gastrointestinal	22/1		9.3	0/0		0	22/1		9.3
Wound (excluding infection)	3/6	4[a]	3.7	0/5	4[a]	2.0	3/11	8[a]	5.7
Vascular	4/0		1.6	1/0		0.4	5/0		2.0
Musculoskeletal	0/0		0	2/0		0.8	2/0		0.8
Renal	1/2		1.2	0/0		0	1/2		1.2
Other	2/1		1.2	0/0		0	2/1		1.2
Total (minor/major)		240 (133/107)			167 (57/110)			407 (190/217)	
Mean complications/patient (minor/major), n		0.98 (0.54/0.43)			0.68 (0.23/0.45)			1.65 (0.77/0.88)	
Patients affected (%)		132 (53.7)			107 (43.5)			176 (71.5)	

[a]Major complications for each category that were associated with a reoperation.

lumbar Cobb angle ($P = .78$), PI-LL ($P = .50$), leg pain NRS score ($P = .71$), ODI ($P = .93$), and SRS-22 total score ($P = .84$; Tables 3 and 4). The matched groups did not differ significantly in sex, body mass index, Charlson Comorbidity Index,[38] depression, smoking, or percentage with previous spine surgery (Table 1). The nonoperative patients were modestly but significantly older than the matched operative patients (mean age, 58.0 vs 51.4 years; $P = .003$). The matched groups demonstrated similar degrees of baseline deformity, except for a modestly worse global coronal alignment among operative patients (Table 3). At

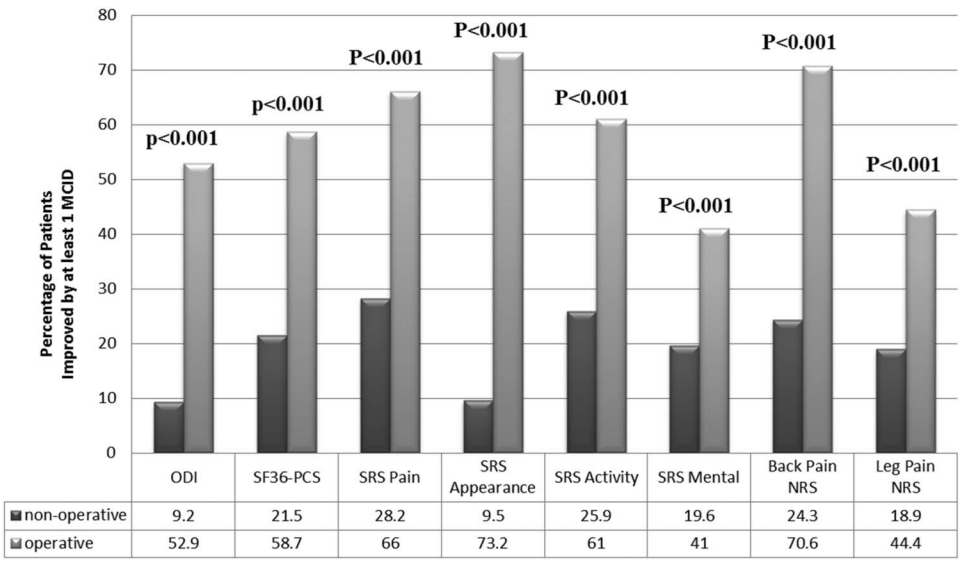

FIGURE 3. *Percentages of adult spinal deformity patients reaching at least 1 minimal clinically important difference (MCID) improvement from baseline to a minimum 2-year follow-up with either nonoperative (n = 223) or operative (n = 246) treatment. NRS, numeric rating scale; ODI, Oswestry Disability Index; SF36-PCS, Short Form-36 physical component score; SRS, Scoliosis Research Society.*

TABLE 3. Comparison of Baseline and Minimum 2-Year Follow-up Radiographic Parameters Within and Between Matched Nonoperative and Operative Treatment Groups for 97 Pairs of Adult Spinal Deformity Patients[a]

Radiographic Parameter (SD)	Treatment Group (Matched)		*P* Value (Operative vs Nonoperative)
	Nonoperative (n = 97)	Operative (n = 97)	
Global positive sagittal malalignment, % with C7-S1 SVA >5 cm			
Baseline	28.3	35.4	.35
Minimum 2-y follow-up	29.2	19.8	.18
P value (baseline vs 2 y)	>.99	.02[b]	—
Mean pelvic tilt, degrees			
Baseline	21.0 (10.0)	21.0 (11.7)	.78
Minimum 2-y follow-up	21.5 (10.8)	19.9 (10.8)	.29
P value (baseline vs 2 y)	.20	.10	—
Mean PI-LL mismatch, degrees			
Baseline	7.7 (17.7)	9.6 (20.3)	.50[c]
Minimum 2-y follow-up	10.2 (19.6)	1.4 (14.2)	<.001[b]
P value (baseline vs 2 y)	<.001[b]	<.001[b]	—
Mean maximum TL/L coronal Cobb angle, degrees			
Baseline	29.2 (16.1)	28.1 (19.7)	.78[c]
Minimum 2-y follow-up	30.3 (16.6)	13.0 (11.9)	<.001[b]
P value (baseline vs 2 y)	.08	<.001[b]	—
Mean coronal alignment, magnitude, mm			
Baseline	23.4 (19.5)	34.2 (37.8)	.03[b]
Minimum 2-y follow-up	27.9 (27.6)	26.6 (22.5)	.61
P value (baseline vs 2 y)	.02[b]	.04[b]	—
Mean thoracic kyphosis (T4-T12), degrees			
Baseline	34.1 (16.3)	30.4 (16.6)	.15
Minimum 2-y follow-up	32.7 (17.0)	36.7 (15.7)	.11
P value (baseline vs 2 y)	.13	<.001[b]	—

[a]LL, lumbar lordosis; PI, pelvic incidence; SVA, sagittal vertical axis.
[b]Significant.
[c]*P* value reflects comparison of parameter used for baseline propensity matching of operative and nonoperative patient pairs.

follow-up, the operative patients had significant improvement in maximum thoracolumbar/lumbar Cobb angle, global coronal alignment, proportion of patients with SVA >5 cm, and PI-LL ($P \leq .04$; Table 3). Nonoperative patients had significantly worse global coronal alignment ($P = .02$) and worse PI-LL ($P < .001$) at follow-up (Table 3).

At follow-up, the matched operative patients had significant improvement in all HRQOL measures assessed ($P < .001$), except for SF-36 mental component score ($P = .05$), and for each of the measures with reported values for MCID, the improvement was at least 1 MCID (Table 4). In contrast, the matched nonoperative patients lacked significant improvement in HRQOL measures, except for modest improvements in SRS-22r total score and SRS-22r pain and satisfaction domains (Table 4). The percentages of propensity matched patients reaching at least 1 MCID improvement from baseline to the minimum 2-year follow-up with either nonoperative or operative treatment are summarized in Figure 4. At follow-up, compared with the nonoperative matched patients, the operative patients had significantly better scores for all measures of HRQOL assessed ($P \leq .001$), except for SF-36 mental component score ($P = .06$) (Table 4). Plots illustrating the baseline and follow-up mean HRQOL and NRS pain scores for the matched groups are shown in Figure 5.

DISCUSSION

The present study provides a prospective, multicenter assessment of outcomes for operative vs nonoperative treatment for ASD based on both unmatched and propensity-matched analyses at a minimum 2-year follow-up. The unmatched cohort analyses provided broad comparisons of outcomes between all nonoperative and operative patients enrolled and allowed assessment of baseline factors that differed between patients opting for operative vs nonoperative treatment. The matched cohort analyses provided groups of operative and nonoperative patients with similar baseline radiographic and clinical features to better define the impact of operative vs nonoperative treatment. Collectively, both unmatched and matched assessments demonstrated improvement in HRQOL with surgical treatment, whereas nonoperative treatment maintained baseline levels of pain and disability.

A propensity-matched operative-nonoperative cohort was generated to control for potentially confounding factors that may

TABLE 4. Comparison of Baseline and Minimum 2-Year Follow-up Clinical Outcomes Parameters Within and Between Matched Nonoperative and Operative Treatment Groups for 97 Pairs of Adult Spinal Deformity Patients[a]

Outcome Parameter (SD)	Treatment Group (Matched)		*P* Value (Operative vs Nonoperative)
	Nonoperative (n = 97)	Operative (n = 97)	
ODI			
Baseline	30.0 (14.8)	30.1 (16.3)	.93[b]
Minimum 2-y follow-up	30.8 (18.0)	17.1 (17.3)	<.001[c]
P value (baseline vs 2 y)	.59	<.001[c,d]	—
SF-36 physical component score			
Baseline	39.1 (8.9)	37.4 (10.5)	.11
Minimum 2-y follow-up	37.6 (9.9)	46.9 (10.7)	<.001[c]
P value (baseline vs 2 y)	.16	<.001[c,d]	—
SF-36 mental component score			
Baseline	47.3 (11.9)	50.9 (11.5)	.01[c]
Minimum 2-y follow-up	48.9 (13.2)	52.7 (11.2)	.06
P value (baseline vs 2 y)	.25	.05	—
SRS-22r total score			
Baseline	3.2 (0.6)	3.2 (0.5)	.84[b]
Minimum 2-y follow-up	3.3 (0.7)	4.0 (0.7)	<.001[c]
P value (baseline vs 2 y)	.02[c]	<.001[c]	—
SRS-22r activity domain			
Baseline	3.5 (0.8)	3.4 (0.8)	.15
Minimum 2-y follow-up	3.6 (0.9)	4.0 (0.9)	<.001[c]
P value (baseline vs 2 y)	.37	<.001[c,d]	—
SRS-22r pain domain			
Baseline	2.9 (0.8)	2.9 (0.8)	.96
Minimum 2-y follow-up	3.1 (0.9)	3.9 (0.9)	<.001[c]
P value (baseline vs 2 y)	.03[c]	<.001[c,d]	—
SRS-22r appearance domain			
Baseline	3.0 (0.7)	2.8 (0.7)	.012[c]
Minimum 2-y follow-up	3.0 (0.7)	4.0 (0.8)	<.001[c]
P value (baseline vs 2 y)	.82	<.001[c,d]	—
SRS-22r mental domain			
Baseline	3.5 (0.8)	3.9 (0.7)	.001[c]
Minimum 2-y follow-up	3.6 (0.9)	4.1 (0.7)	<.001[c]
P value (baseline vs 2 y)	.13	.001[c]	—
SRS-22r satisfaction domain			
Baseline	3.2 (1.0)	2.9 (1.0)	.046[c]
Minimum 2-y follow-up	3.6 (1.0)	4.4 (0.9)	<.001[c]
P value (baseline vs 2 y)	.001[c]	<.001[c]	—
NRS back pain score			
Baseline	5.1 (2.4)	6.4 (2.3)	<.001[c]
Minimum 2-y follow-up	5.5 (2.7)	2.7 (2.8)	<.001[c]
P value (baseline vs 2 y)	.20	<.001[c,d]	—
NRS leg pain score			
Baseline	3.2 (2.9)	3.1 (3.2)	.708[b]
Minimum 2-y follow-up	3.7 (3.1)	1.8 (2.5)	<.001[c]
P value (baseline vs 2 y)	.21	<.001[c,d]	—

[a]NRS, numeric rating scale; ODI, Oswestry Disability Index; SF-36, Short-Form, 36; SRS, Scoliosis Research Society.
[b]*P* value reflects comparison of parameter used for baseline propensity matching of operative and nonoperative patient pairs.
[c]Significant.
[d]Average change in score from baseline to follow-up is at least 1 minimal clinically important difference (MCID) for the respective health-related quality-of-life measure. Note that relevant values for MCID have not been reported for SF-36 mental component score, SRS total score, or SRS satisfaction domain.

affect comparisons between each treatment approach. Five parameters were selected for propensity scoring. Baseline ODI and SRS-22r total score were selected to help control for the baseline impact of the spinal deformity on a standardized measure of disability (ODI) and on a disease-specific measure of HRQOL (SRS-22r). Baseline thoracolumbar/lumbar coronal Cobb angle

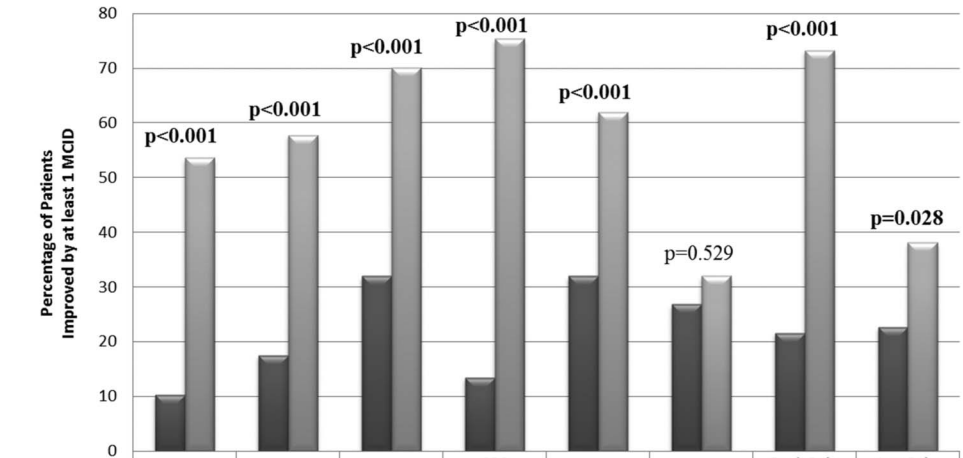

FIGURE 4. *Percentages of adult spinal deformity patients from the propensity-matched cohort reaching at least 1 minimal clinically important difference (MCID) improvement from baseline to a minimum 2-year follow-up with either nonoperative (n = 97) or operative (n = 97) treatment. Significant P values are shown in bold. NRS, numeric rating scale; ODI, Oswestry Disability Index; SF36-PCS, Short Form-36 physical component score; SRS, Scoliosis Research Society.*

and PI-LL were selected to control for the severity of the deformity and to help control for the type of deformity. Baseline leg pain NRS score was selected for propensity matching as a means of partially controlling for the presence of stenosis, which is significantly more prevalent in degenerative spinal deformities compared with adult idiopathic scoliosis.[4] Assessment of the propensity-matched cohort suggested that the groups were well matched, with no significant differences between the groups on the basis of any of the matching parameters. In addition, beyond the matching parameters, the groups were well matched for body mass index, comorbidities, depression, and smoking status. Instead of matching patients on the basis of age, the focus was instead placed on matching by deformity severity and impact of the deformity on standardized measures of pain and disability.

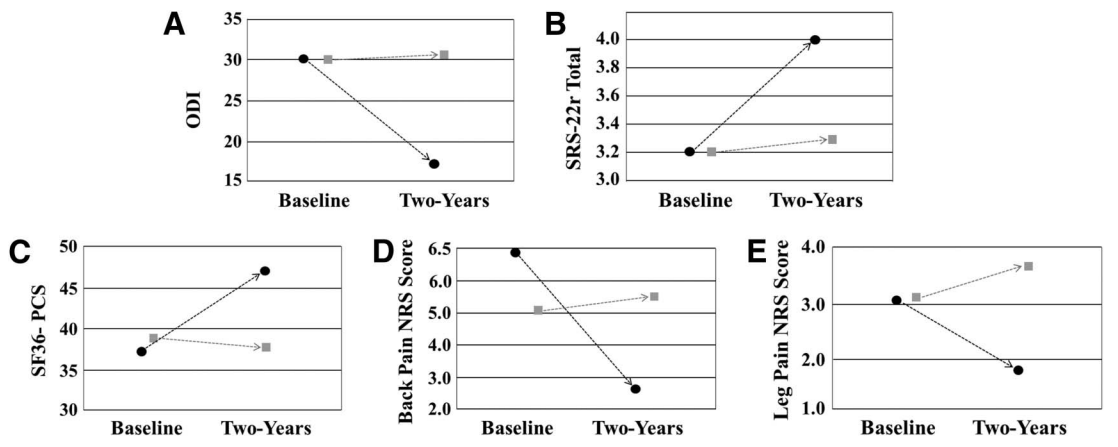

FIGURE 5. *Plots illustrating the preoperative and follow-up mean health-related quality-of-life scores for matched operative and nonoperative groups (97 in each group) based on the Oswestry Disability Index (ODI; A), Scoliosis Research Society (SRS)-22r total score (B), Short Form-36 physical component score (SF36-PCS; C), back pain numeric rating scale (NRS) score (D), and leg pain NRS score (E). Black circles and gray squares indicate operative and nonoperative patient groups, respectively.*

This resulted in a matched nonoperative cohort that was modestly but significantly older than the matched operative cohort.

The present study supports the findings of Bridwell and colleagues.[3] In their report, propensity matching was used to generate operative and nonoperative treatment groups for adults with symptomatic lumbar scoliosis (41 patients in each group). They reported that the operative cohort significantly improved in all HRQOL measures, that the nonoperative cohort did not improve, and that a nonsignificant decline in HRQOL scores was common in the nonoperative cohort. Both the present study and that of Bridwell and colleagues used matching parameters reflective of deformity severity and baseline pain and disability. The present study also incorporated matching based on the PI-LL mismatch, which may have facilitated better matching for sagittal spinal malalignment, a finding that has been strongly correlated with pain and disability.[7] Notably, similar to the present study, Bridwell and colleagues also had a relatively low (45%) follow-up rate for nonoperative patients. Despite great efforts in both studies to achieve >80% follow-up for nonoperative patients, many did not return, and this was entirely a function of patient choice.

Compared with nonoperative treatment, operative treatment provided a significantly greater likelihood of reaching or exceeding MCID improvement for the HRQOL measures used in the present study (Figures 3 and 4). The percentages of operative patients achieving at least 1 MCID improvement varied on the basis of the outcome measure, ranging from 41% to 73.2%. These findings may prove particularly valuable for patient counseling because simple averages of outcomes measures may not fully reveal the range of outcomes.[39]

It is noteworthy that nonoperative treatment appeared to provide benefit to a subset of patients. Of the patients treated nonoperatively, 10% achieved MCID improvement for ODI, and approximately 25% to 30% achieved MCID improvement for SRS pain and activity domains (Figures 3 and 4). Further study is warranted to define ASD patients who may benefit from nonoperative treatment and to assess the durability of these therapies over longer-term follow-up.

In unmatched assessments, operative patients had significantly poorer baseline health status, including greater comorbidities, higher body mass index, and higher prevalence of depression, compared with the nonoperative patients. The operative patients also had significantly greater severity of deformity and had significantly worse HRQOL as indicated by all measures used in this study. The poorer health status among the operatively treated patients may reflect a more advanced spinal deformity disease state. For example, patients with greater severity of deformity and worse pain and disability may tend to be more sedentary and have greater tendencies toward comorbidities such as obesity, heart disease, and depression. Although patients with greater comorbidities may potentially have greater risks of complications, if they also have the greatest impact on HRQOL, they may stand to gain the most from surgical treatment.[13] Notably, the matching process that accounted for deformity severity and baseline HRQOL measures produced operative and nonoperative patient groups with statistically similar Charlson Comorbidity Index scores. These findings are consistent with those reported in a study by Fu et al[5] in which elderly patients with degenerative scoliosis opting for operative treatment had poorer health status (Charlson Comorbidity Index) and worse ODI, SRS-30, and Short Form-12 scores compared with those opting for nonoperative treatment. Although the decision of whether and when to pursue operative treatment for ASD is complex, these findings suggest that self-assessment measures of HRQOL may prove useful in identifying patients who are disabled and are nearing the threshold of pursuing surgical treatment.

Reflective of the length of follow-up and study design, the numbers and rates of operative complications identified in the present study are substantially higher than in previous reports. Overall, a total of 407 complications (190 minor and 217 major) at a minimum 2-year follow-up were identified, and 71.5% of patients were affected by ≥1 complications. When these findings are interpreted, it is important to recognize that not all complications are equally impactful[40] and that many, if not most, likely have minimal or no effect on ultimate patient outcome. However, it is also important to recognize that some of the complications that do not affect long-term outcome may have an impact on length of hospital stay, need for invasive procedures (including reoperation), and the rates at which patients recover.[41,42]

Limitations

Strengths of this study include the prospective multicenter design that includes unmatched and matched cohorts; the use of multiple standardized measures of HRQOL; the standardized approach to radiographic assessment, including assessment of pelvic parameters; and the relatively large patient population. In addition, patients were drawn from the practices of multiple surgeons across the United States, which enhances the generalizability of the findings. Limitations of this study include the relatively lower follow-up rate for nonoperative compared with operative patients, a challenge that has been reported in multiple previous studies.[2,3,11-13] It is possible that some of the nonoperatively treated patients lost to follow-up may have achieved symptomatic improvement, whether temporary or durable, which could bias the sample. Another potential source of bias may have resulted from the matching process from which the resulting matched nonoperative patients were modestly but significantly older than the matched operative patients. Because for the entire operative and nonoperative patient cohorts the nonoperative patients had significantly less pain and disability, it is possible that the matching process generally needed older nonoperative patients (presumably with more degenerative changes, pain, and disability) as matches for the operative patients. In addition, although efforts were made to maximize nonoperative treatment, no standardized protocols were used. Another limitation of this study results from the lack of treatment randomization and the inability to blind to treatment approach. Patients had a choice with regard to whether to pursue surgical treatment, and it is

possible that those who made the commitment to surgery were more likely to think that they should get better, which could have introduced bias. In addition, compared with the nonoperatively treated patients, a significantly higher percentage of operatively treated patients had a history of previous spine surgery, which could have introduced bias. Furthermore, no attempt was made to control for the type of operative or nonoperative treatment provided, and patients were evaluated in a prospective observational manner, not randomized.

CONCLUSION

This multicenter, prospective case-control analysis of operative and nonoperative treatment for ASD demonstrated that operative treatment for ASD can provide significant improvement in HRQOL at a minimum 2-year follow-up. In contrast, nonoperative treatment on average does not alter presenting levels of pain and disability. Further work is needed to define specific types of spinal deformity that are most responsive to operative and nonoperative treatment.

Disclosures

The International Spine Study Group is funded through research grants from DePuy Synthes and individual donations. Dr Lafage reports receiving grants from SRS, National Institutes of Health, and DePuy Synthes; having speaking/teaching arrangements with Nemaris Inc, DePuy Synthes, MSD, and Medicre; and being on the Board of Directors of and a shareholder in Nemaris Inc. Dr Shaffrey reports receiving consultancy, patents, or royalties from Biomet, Medtronic, NuVasive, and K2M; being a stockholder for K2M; and serving as consultant for Stryker. Dr Schwab reports grants from SRS, DePuy Synthesis Spine, and AO; speaking/teaching arrangements and consulting for K2M, NuVasive, Biomet Zimmer, Medicrea, and MSD; and being on the Board of Directors and a shareholder for Nemaris Inc. Dr Hostin has been a consultant for DePuy Spine. Dr Akbarnia reports royalties from DePuy Spine, K2M, and NuVasive and consulting fees from NuVasive and K2M; NuVasive has provided grants to institution. Dr Mundis reports receiving consultancy fees, honorarium, royalties, and research support from NuVasive; consultancy fees and royalties from K2M; consultancy fees from Medicrea; and honorarium from Misonix and Ellipse. Dr Kim has been a consultant for K2M and ZimmerBiomet. Dr Protopsaltis has been a consultant for Medicrea and has received international research support from Zimmer Spine. Dr Line has been a consultant for the International Spine Study Group. Dr Klineberg reports receiving consulting fees from DePuy Synthes and Stryker, honorarium from AOSpine and K2M, and a fellowship grant from AOSpine. Dr Gupta reports consultancy fees and royalties from DePuy Synthes; being a stockholder in Pfizer, Johnson & Johnson, Medicrea, and Proctor & Gamble; and being a consultant for Medtronic and Orthofix; grant paid to University of California Davis. Dr Hart has been a board member of the CSRS Board ISSLS International Spine Study Group Executive Committee; reports receiving consultancy fees from DepuySynthes Globus Medtronic, grants from Medtronic International Spine Study Group Foundation, royalties from Seaspine DePuy Synthes, and speaking bureau/honoraria from DePuy Synthes; and has owned stock in Spine Connect. Dr Burton has received research support and royalties from DePuy Spine. Dr Bess reports the following: research grant from DePuy Spine, research grant and consultant fees from NuVasive, Stryker research grant, Medtronic research grant, and k2 research grant and consultant fees. Dr Ames reports the following: DePuy, Medtronic, and Stryker, consultancy; Biomet Spine and Stryker, royalties; Doctors Research Group, stock/stock options; and Fish & Richardson, PC, patent. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES

1. Bess S, Boachie-Adjei O, Burton D, et al. Pain and disability determine treatment modality for older patients with adult scoliosis, while deformity guides treatment for younger patients. *Spine (Phila Pa 1976).* 2009;34(20):2186-2190.
2. Bridwell KH, Baldus C, Berven S, et al. Changes in radiographic and clinical outcomes with primary treatment adult spinal deformity surgeries from two years to three- to five-years follow-up. *Spine (Phila Pa 1976).* 2010;35(20):1849-1854.
3. Bridwell KH, Glassman S, Horton W, et al. Does treatment (nonoperative and operative) improve the two-year quality of life in patients with adult symptomatic lumbar scoliosis: a prospective multicenter evidence-based medicine study. *Spine (Phila Pa 1976).* 2009;34(20):2171-2178.
4. Fu KM, Rhagavan P, Shaffrey CI, Chernavvsky DR, Smith JS. Prevalence, severity, and impact of foraminal and canal stenosis among adults with degenerative scoliosis. *Neurosurgery*. 2011;69(6):1181-1187.
5. Fu KM, Smith JS, Sansur CA, Shaffrey CI. Standardized measures of health status and disability and the decision to pursue operative treatment in elderly patients with degenerative scoliosis. *Neurosurgery*. 2010;66(1):42-47; discussion 47.
6. Glassman SD, Bridwell K, Dimar JR, Horton W, Berven S, Schwab F. The impact of positive sagittal balance in adult spinal deformity. *Spine (Phila Pa 1976).* 2005;30(18):2024-2029.
7. Schwab FJ, Blondel B, Bess S, et al. Radiographic spino-pelvic parameters and disability in the setting of adult spinal deformity: a prospective multicenter analysis. *Spine (Phila Pa 1976).* 2013;38(13):E803-E812.
8. Smith JS, Fu KM, Urban P, Shaffrey CI. Neurological symptoms and deficits in adults with scoliosis who present to a surgical clinic: incidence and association with the choice of operative versus nonoperative management. *J Neurosurg Spine.* 2008;9(4):326-331.
9. Smith JS, Kasliwal MK, Crawford A, Shaffrey CI. Outcomes, expectations, and complications overview for the surgical treatment of adult and pediatric spinal deformity. *Spine Deform.* 2012;Preview Issue:4-14.
10. Smith JS, Klineberg E, Schwab F, et al. Change in classification grade by the SRS-Schwab adult spinal deformity classification predicts impact on health-related quality of life measures: prospective analysis of operative and nonoperative treatment. *Spine (Phila Pa 1976).* 2013;38(19):1663-1671.
11. Smith JS, Shaffrey CI, Berven S, et al. Operative versus nonoperative treatment of leg pain in adults with scoliosis: a retrospective review of a prospective multicenter database with two-year follow-up. *Spine (Phila Pa 1976).* 2009;34(16):1693-1698.
12. Smith JS, Shaffrey CI, Berven S, et al. Improvement of back pain with operative and nonoperative treatment in adults with scoliosis. *Neurosurgery*. 2009;65(1):86-93; discussion 93-94.
13. Smith JS, Shaffrey CI, Glassman SD, et al. Risk-benefit assessment of surgery for adult scoliosis: an analysis based on patient age. *Spine (Phila Pa 1976).* 2011;36(10):817-824.
14. Smith JS, Singh M, Klineberg E, et al. Surgical treatment of pathological loss of lumbar lordosis (flatback) in the setting of normal sagittal vertical axis (SVA) achieves similar clinical improvement as surgical treatment of elevated SVA: clinical article. *J Neurosurg Spine.* 2014;21(2):160-170.
15. Terran J, Schwab F, Shaffrey CI, et al. The SRS-Schwab adult spinal deformity classification: assessment and clinical correlations based on a prospective operative and nonoperative cohort. *Neurosurgery*. 2013;73(4):559-568.
16. Aebi M. The adult scoliosis. *Eur Spine J.* 2005;14(10):925-948.
17. Smith JS, Shaffrey CI, Fu KM, et al. Clinical and radiographic evaluation of the adult spinal deformity patient. *Neurosurg Clin N Am.* 2013;24(2):143-156.
18. Glassman SD, Carreon LY, Shaffrey CI, et al. The costs and benefits of nonoperative management for adult scoliosis. *Spine (Phila Pa 1976).* 2010;35(5):578-582.
19. Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Phys Ther.* 2001;81(2):776-788.
20. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. *Physiotherapy*. 1980;66(8):271-273.
21. Bridwell KH, Berven S, Glassman S, et al. Is the SRS-22 instrument responsive to change in adult scoliosis patients having primary spinal deformity surgery? *Spine (Phila Pa 1976).* 2007;32(20):2220-2225.
22. Asher MA, Lai SM, Glattes RC, Burton DC, Alanay A, Bago J. Refinement of the SRS-22 health-related quality of life questionnaire function domain. *Spine (Phila Pa 1976).* 2006;31(5):593-597.

23. Ware JE Jr. SF-36 health survey update. *Spine (Phila Pa 1976).* 2000;25(24): 3130-3139.
24. Champain S, Benchikh K, Nogier A, Mazel C, Guise JD, Skalli W. Validation of new clinical quantitative analysis software applicable in spine orthopaedic studies. *Eur Spine J.* 2006;15(6):982-991.
25. Rillardon L, Levassor N, Guigui P, et al. Validation of a tool to measure pelvic and spinal parameters of sagittal balance [in French]. *Rev Chir Orthop Reparatrice Appar Mot.* 2003;89(3):218-227.
26. O'Brien MF, Kuklo TR, Blanke K, Lenke L, eds. *Spinal Deformity Study Group Radiographic Measurement Manual*. Memphis, TN: Medtronic Sofamor Danek; 2005.
27. Ames CP, Smith JS, Scheer JK, et al. Impact of spinopelvic alignment on decision making in deformity surgery in adults: a review. *J Neurosurg Spine.* 2012;16(6): 547-564.
28. Schwab F, Ungar B, Blondel B, et al. Scoliosis Research Society-Schwab adult spinal deformity classification: a validation study. *Spine (Phila Pa 1976).* 2012;37 (12):1077-1082.
29. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behav Res.* 2011;46(3):399-424.
30. Kasliwal MK, Smith JS, Shaffrey CI, et al. Does prior short-segment surgery for adult scoliosis impact perioperative complication rates and clinical outcome among patients undergoing scoliosis correction? *J Neurosurg Spine.* 2012;17(2):128-133.
31. Lambat MP, Glassman SD, Carreon LY. Impact of perioperative complications on clinical outcome scores in lumbar fusion surgery. *J Neurosurg Spine.* 2013;18(3): 265-268.
32. Glassman SD, Copay AG, Berven SH, Polly DW, Subach BR, Carreon LY. Defining substantial clinical benefit following lumbar spine arthrodesis. *J Bone Joint Surg Am.* 2008;90(9):1839-1847.
33. Liu S, Schwab F, Smith JS, et al. Likelihood of reaching minimal clinically important difference in adult spinal deformity: a comparison of operative and nonoperative treatment. *Ochsner J.* 2014;14(1):67-77.
34. Berven SH, Deviren V, Demir-Deviren SH, Hu S, Bradford DS. *Minimal clinically important difference in adult spinal deformity: how much change is significant?* Paper presented at: International Meeting for Advanced Spine Techniques; July 7-9, 2005; Banff, Canada.
35. Blondel B, Schwab F, Ungar B, et al. Impact of magnitude and percentage of global sagittal plane correction on health-related quality of life at 2-years follow-up. *Neurosurgery*. 2012;71(2):341-348.
36. Copay AG, Glassman SD, Subach BR, Berven S, Schuler TC, Carreon LY. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and pain scales. *Spine J.* 2008;8(6):968-974.
37. Copay AG, Subach BR, Glassman SD, Polly DW Jr, Schuler TC. Understanding the minimum clinically important difference: a review of concepts and methods. *Spine J.* 2007;7(5):541-546.
38. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
39. Smith JS, Shaffrey CI, Glassman SD, et al. Clinical and radiographic parameters that distinguish between the best and worst outcomes of scoliosis surgery for adults. *Eur Spine J.* 2013;22(2):402-410.
40. Glassman SD, Hamill CL, Bridwell KH, Schwab FJ, Dimar JR, Lowe TG. The impact of perioperative complications on clinical outcome in adult deformity surgery. *Spine (Phila Pa 1976).* 2007;32(24):2764-2770.
41. Liu S, Tetreault L, Fehlings M, et al. A novel method using baseline normalization and area under the curve to evaluate differences in outcome between treatment groups and application to patients with cervical spondylotic myelopathy undergoing anterior versus posterior surgery. *Spine (Phila Pa 1976).* 2015 [in press].
42. Scheer JK, Mundis GM, Klineberg E, et al. Post-Operative recovery following adult spinal deformity surgery: comparative analysis of age in 149 patients during 2 year follow up. *Spine (Phila Pa 1976).* 2015;40(19):1505-1515.

COMMENTS

This is a prospective multicenter study comparing operative and nonoperative management of adult spinal deformity. Given the relative lack of comparative studies involving symptomatic adult deformity in the literature and the large number of patients evaluated in this investigation, this study is particularly relevant. The findings suggest that surgery results in better clinical outcomes than nonoperative management. It is noteworthy that total complications were very high (71.5%) and represent a realistic risk for surgery that is typically complex and technically demanding. However, even with this high complication rate, patients did well after recovery, as reflected in the 2-year clinical outcomes. The Discussion section appropriately describes the significant limitations of this study, including the poor follow-up in the nonoperative group, nonstandardized medical management, and nonrandomized study design.

Paul Park
Ann Arbor, Michigan

This is a well-conceived study investigating an important patient population in spine surgery. The authors prospectively compared the outcomes of adult spinal deformity (ASD) patients undergoing either operative or nonoperative treatment. Operative (97) and nonoperative (97) patients were matched with the use of several health-related quality-of-life (HRQOL) assessments and deformity measures with a minimum 2-year follow-up. They found that operative patients had significantly better HRQOL at follow-up for all measures assessed, except Short Form-36 mental component score. However, 71.5% of the patients who were operated on had at least $\geq$1 complications within the 2-year follow-up. The authors concluded that operative treatment for patients with ASD can lead to significantly improved HRQOL at 2 year follow-up, whereas nonoperative management of ASD neither improves nor worsens baseline levels of pain and deformity at the 2-year follow-up.

Steven Spitz
Daniel Refai
Atlanta, Georgia