Comprehensive study of back and leg pain improvements after adult spinal deformity surgery: analysis of 421 patients with 2-year follow-up and of the impact of the surgery on treatment satisfaction

Justin K. Scheer, BS,[1] Justin S. Smith, MD, PhD,[2] Aaron J. Clark, MD, PhD,[3]
Virginie Lafage, PhD,[4] Han Jo Kim, MD,[5] John D. Rolston, MD, PhD,[3] Robert Eastlack, MD,[6]
Robert A. Hart, MD,[7] Themistocles S. Protopsaltis, MD,[4] Michael P. Kelly, MD,[8]
Khaled Kebaish, MD,[9] Munish Gupta, MD,[10] Eric Klineberg, MD,[10] Richard Hostin, MD,[11]
Christopher I. Shaffrey, MD,[2] Frank Schwab, MD,[4] Christopher P. Ames, MD,[3]
and the International Spine Study Group

[1]Department of Neurological Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois; [2]Department of Neurosurgery, University of Virginia Health System, Charlottesville, Virginia; [3]Department of Neurological Surgery, University of California, San Francisco; [6]Scripps Clinic, San Diego; [10]Department of Orthopaedic Surgery, University of California, Davis, Sacramento, California; [4]Department of Orthopaedic Surgery, New York University Hospital for Joint Diseases; [5]Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, New York; [7]Department of Orthopaedic Surgery, Oregon Health & Science University, Portland, Oregon; [8]Department of Orthopedic Surgery, Washington University, St. Louis, Missouri; [9]Department of Orthopaedic Surgery, Johns Hopkins University, Baltimore, Maryland; and [11]Department of Orthopaedic Surgery, Baylor Scoliosis Center, Plano, Texas

OBJECT Back and leg pain are the primary outcomes of adult spinal deformity (ASD) and predict patients' seeking of surgical management. The authors sought to characterize changes in back and leg pain after operative or nonoperative management of ASD. Outcomes were assessed according to pain severity, type of surgical procedure, Scoliosis Research Society (SRS)–Schwab spine deformity class, and patient satisfaction.

METHODS This study retrospectively reviewed data in a prospective multicenter database of ASD patients. Inclusion criteria were the following: age > 18 years and presence of spinal deformity as defined by a scoliosis Cobb angle ≥ 20°, sagittal vertical axis length ≥ 5 cm, pelvic tilt angle ≥ 25°, or thoracic kyphosis angle ≥ 60°. Patients were grouped into nonoperated and operated subcohorts and by the type of surgical procedure, spine SRS-Schwab deformity class, preoperative pain severity, and patient satisfaction. Numerical rating scale (NRS) scores of back and leg pain, Oswestry Disability Index (ODI) scores, physical component summary (PCS) scores of the 36-Item Short Form Health Survey, minimum clinically important differences (MCIDs), and substantial clinical benefits (SCBs) were assessed.

RESULTS Patients in whom ASD had been operatively managed were 6 times more likely to have an improvement in back pain and 3 times more likely to have an improvement in leg pain than patients in whom ASD had been nonoperatively managed. Patients whose ASD had been managed nonoperatively were more likely to have their back or leg pain remain the same or worsen. The incidence of postoperative leg pain was 37.0% at 6 weeks postoperatively and 33.3% at the 2-year follow-up (FU). At the 2-year FU, among patients with any preoperative back or leg pain, 24.3% and 37.8% were free of back and leg pain, respectively, and among patients with severe (NRS scores of 7–10) preoperative back or leg pain, 21.0% and 32.8% were free of back and leg pain, respectively. Decompression resulted in more patients having an improvement in leg pain and their pain scores reaching MCID. Although osteotomies improved back pain, they were associated with a higher incidence of leg pain. Patients whose spine had an SRS-Schwab coronal curve Type N deformity (sagittal malalignment only) were least likely to report improvements in back pain. Patients with a Type L deformity were most likely to report improved back or leg pain and to have reductions in pain severity scores reaching MCID and SCB. Patients with a Type D deformity were least likely to report improved leg pain and were more likely to experience a worsening of leg pain. Preoperative pain severity affected pain improvement over 2 years because patients who had higher preoperative pain severity experienced larger improvements, and their changes in pain severity were more likely to reach MCID/SCB than for those reporting lower preoperative pain. Reductions in back pain contributed to improvements in ODI and PCS scores and to patient satisfaction more than reductions in leg pain did.

CONCLUSIONS The authors' results provide a valuable reference for counseling patients preoperatively about what improvements or worsening in back or leg pain they may experience after surgical intervention for ASD.

http://thejns.org/doi/abs/10.3171/2014.10.SPINE14475

KEY WORDS back pain; leg pain; adult spinal deformity; SRS-Schwab classification; satisfaction; scoliosis; PSO; VCR; spinal disorders

INDIVIDUALS who have adult spinal deformity (ASD) typically experience pain and disability.[2,14,26,28,29] The pain typically affects the back, legs, or both, and its etiology is multifactorial.[26,28,29] Over the last decade, most research into ASD has focused on patient-reported outcomes and on general measures of health status and function, such as the Oswestry Disability Index (ODI), the 36-Item Short Form Health Survey (SF-36), and the Scoliosis Research Society 22-question Questionnaire (SRS-22). However, pain is the primary concern for ASD patients and is often the reason for these patients to seek surgical management.[14,26] Changes in patient-reported outcomes, although helpful to physicians, may be an abstract concept to patients, who ultimately seek improvement of their pain through surgical treatment.

Despite the common use of patient-reported outcomes in the assessment of ASD, its operative management has been shown only recently to provide greater improvement of both back and leg pain than nonoperative management.[28,29] Smith et al. investigated back[28] and leg pain[29] separately in large cohorts of individuals with ASD undergoing surgical intervention and found significant improvements in numerical rating scale (NRS) pain scores. These studies were primarily designed to evaluate improvement in back and leg pain with operative management, but they did not address pain responsiveness according to initial NRS severity, spinal curve type, or use of osteotomies. Therefore, continued research into back and leg pain is still needed to identify effective ASD treatments. An increased understanding of the best practices for pain reduction and use of a pain scale that patients better understand will advance the clinical care for patients with this complex disorder.

Pain intensity has typically been assessed via an 11-point NRS.[8,10,15,18,25] This scale enables standardized measurement of pain intensity and quantitative assessment in clinical trials[8] and has been increasingly used in ASD research.[2,7,11,13,14,26,28,29] However, until recently, clinical improvement as a result of changes in the NRS was difficult to determine. A minimum clinically important difference (MCID) for both back and leg pain corresponds to a decrease in the NRS score of 1.2–1.6 points,[7,13] and a decrease by 2.5 points results in a substantial clinical benefit (SCB).[13] Thus, on the 11-point scale, small improvements in pain can lead to significant clinical improvement, indicating that patients are very sensitive even to small changes on this scale. Furthermore, pain assessed with this NRS has been categorized as mild, moderate, or severe in patients with various cancers and in those with back pain.[15,18,25] These groupings are very useful when discussing improvements or worsening in pain with patients who may find it difficult to completely understand how certain quantitative changes in pain NRS scores may relate to their experience of pain.

The purpose of the present study was to characterize back and leg pain improvement or deterioration after operative management of ASD according to pain severity. Specifically, we sought to compare pain severity after operative management with that during nonoperative management and to assess the effects on pain of the type of surgical procedure, Scoliosis Research Society (SRS)–Schwab spine deformity class,[24] preoperative pain severity, and patient satisfaction.

Methods

Patient Cohort

This study retrospectively reviewed a prospective multicenter database of ASD patients. Patients were enrolled consecutively and drawn from the International Spine Study Group (ISSG), comprising 11 sites across the United States. All patients were enrolled into an institutional review board–approved protocol by each site, and approval was obtained through each of the sites. Inclusion criteria for the ISSG database were the following: age > 18 years and presence of a spinal deformity, as defined by scoliosis

with a Cobb angle ≥ 20°, sagittal vertical axis length ≥ 5 cm, pelvic tilt angle ≥ 25°, or thoracic kyphosis angle ≥ 60°. Patients were excluded if their spinal deformity was due to a neuromuscular condition or if they had an active infection or cancer.

Patients were divided into nonoperated and operated subcohorts. The decision to manage ASD operatively was very complex and reached after individual discussions between each surgeon and patient, taking into account the patient's goal of care. Most ASD patients in our clinics were evaluated for possible surgical intervention and had received nonoperative treatment before presenting to us. Patients showing symptoms of a progressive neurological deficit, myelopathy, or bowel/bladder incontinence were generally advised to undergo operative treatment. The remaining patients were counseled about both operative and nonoperative management options.

Data Collection, Radiographic Assessment, and Health-Related Quality of Life

The demographic and clinical data included patient age, sex, body mass index, and Charlson comorbidity index scores.[6] Surgical data collected included American Society of Anesthesiologists physical status classification, length of hospital stay, operating room time, estimated blood loss, and surgery type. Operated patients were grouped according to surgery type as described in the following: 1) patients who had neither decompression nor osteotomy (Other); 2) patients who underwent decompression and no osteotomy (D); 3) patients who underwent no decompression and an osteotomy, including Smith-Petersen osteotomy and 3-column osteotomies such as pedicle subtraction osteotomy and vertebral column resection (O); and 4) patients who underwent both osteotomy and decompression (D+O).

Standardized health-related quality of life (HRQOL) measures included the ODI, SF-36, and SRS-22 scores. Two standard summary scores were based on the SF-36: the physical component summary (PCS) score and the mental component summary score. The SRS-22 provides a total score and multiple subdomains, including activity, pain, appearance, mental, and satisfaction. Responses to Questions 21 and 22 on the SRS-22 were evaluated separately from the total subscores. The SRS-22 Question 21 states, "Are you satisfied with the results of your back management?" and Question 22 states, "Would you have the same management again if you had the same condition?" An NRS score ranging from 0 (no pain) to 10 (most unbearable pain) was collected for back pain and leg pain separately.

Patients were categorized according to the severity of their back or leg pain. The severity scale used was based on previous studies and included the following: no pain (NRS Score 0), mild pain (NRS Scores 1–4), moderate pain (NRS Scores 5–6), and severe pain (NRS Scores 7–10).[15,25] To place HRQOL outcomes in a clinically relevant context, MCID values have been established for the HRQOL measures.[3,13] Analyses of the differences in the proportions of patients whose HRQOL measures reached an MCID were also performed. Substantial clinical benefit values for ODI, PCS, and back and leg pain NRS scores

were also determined.[13] The MCID and SCB values used in the present study included the following: for ODI scores, an MCID of −15 and an SCB of −18.8; for PCS scores, an MCID of +5.2 and an SCB of +6.2; and for back and leg pain NRS scores, an MCID of −2 and an SCB of −3.[3,4,7,13]

Full-length, free-standing lateral spine radiographs (obtained with a 91.4-cm cassette) at baseline and at 6-week, 3-month, 1-year, and 2-year follow-up (FU) visits were analyzed using validated software (Spineview, EN-SAM, Laboratory of Biomechanics).[5,21] All radiographic measures were performed with standard techniques[20] at a central location and included the following: coronal Cobb angles of thoracic and lumbar curves, thoracic kyphosis (that is, at T2–12 with Cobb angle measured between the superior endplate of T-2 and the inferior endplate of T-12), lumbar lordosis (Cobb angle measured between the superior endplate of L-1 and the superior endplate of S-1), length of sagittal vertical axis (C-7 plumb line relative to S-1), pelvic tilt, and a pelvic incidence–lumbar lordosis mismatch.

On the basis of the above radiographic parameters, cases were additionally stratified by the coronal deformity of their spines according to the SRS-Schwab ASD classification (Fig. 1).[24] In this classification, the coronal curve type is determined by the maximal coronal angle of the spine measured according to standard Cobb technique. The 4 curve types were as follows: a Type T spine with a thoracic major curve > 30° (the spinal level of the curve apex was at T-9 or above) and a lumbar curve < 30°; Type L with a lumbar or thoracolumbar major curve > 30° (the spinal level of the curve apex was at T-10 or lower) and a thoracic curve < 30°; Type D with a double major curve (that is, 1 Type T and 1 Type L curve), with each curve >

FIG. 1. The SRS-Schwab classification includes 4 coronal curve types and 3 sagittal modifiers of pelvic tilt, sagittal vertical axis (SVA), and the difference between pelvic incidence (PI) and lumbar lordosis (LL). TL = thoracolumbar.

30°; and Type N with no coronal curve > 30° (that is, no major coronal deformity).

Statistical Analyses

Continuous variables are described as the mean ± SD. To minimize the likelihood of a Type I error, group comparisons initially included an ANOVA or Kruskal-Wallis test for assessing the effects of the factors under consideration. According to statistical significance identified in these analyses, we performed Student t-tests or Wilcoxon rank-sum tests to assess statistical significance between individual means. Differences in group means were analyzed with nonpaired t-tests, while changes in means between baseline and the postoperative time points were evaluated with paired t-tests.

Frequency analysis was used to analyze categorical variables. To evaluate changes in pain severity during the 2-year FU period or for assessing rates of meeting MCID or SCB, we performed chi-square analyses. As above, we first conducted chi-square tests with all factors and then individual comparisons, if appropriate, to minimize the likelihood of a Type I error. Univariate and multivariate linear regressions were used to assess the relationship between the severity of back and leg pain and the improvement/worsening of ODI scores. All statistical analyses were conducted with JMP (v7.0, SAS Institute, Inc.), and the level of statistical significance was set at $p < 0.05$ for all analyses.

Results

Patient Cohort

In total, 286 operated patients and 403 nonoperated patients were eligible for inclusion in this study. Of those, 235 operated patients (82.2%) and 186 nonoperated patients (46.2%) had completed 2-year clinical and radiographic FUs, resulting in a total of 421 patients whose data formed the basis of this study. The cohort included 358 women and 63 men, whose mean age was 54.0 ± 15.8 years (range 25–84 years). Among all of these patients, the percentages of those whose spines had 1 of 4 SRS-Schwab coronal curve types were as follows: 23.3% with Type N, 37.1% with Type T, 13.1% with Type L, and 26.4% with Type D. Additional demographics and SRS-Schwab coronal curve classifications of operated and nonoperated patients are presented in Table 1.

Operative Versus Nonoperative Management

Among patients who received operative management, a significantly higher percentage had severe (NRS Scores 7–10) pain in the back and legs preoperatively (that is, at baseline), and a significantly lower percentage had mild (NRS Scores 1–4) preoperative back and leg pain than among patients who received nonoperative management ($p < 0.0001$ for both comparisons, Table 2). Among the operated patients, a significantly higher percentage than among the nonoperated patients reported improvement in both back and leg pain by at least 1 pain severity category at the 2-year FU ($p < 0.05$, Table 2). Furthermore, significantly more nonoperated patients experienced worsening of their back and leg pain by at least 1 pain severity category at the 2-year FU than operated patients, and signifi-

TABLE 1. Demographics for operated and nonoperated patients and SRS-Schwab classification of the coronal curve deformity at baseline*

Variable	Patients		p Value
	Operated	Nonoperated	
No. of patients	235	186	
Age (yrs)	55 ± 15.4	52.7 ± 16.2	0.0934
Female sex (%)	197 (83.8)	161 (86.6)	
Baseline BMI	27.1 ± 5.9	25.3 ± 5.7	0.0001
Baseline CCI score	1.4 ± 1.5	0.9 ± 1.1	0.0073
Baseline SRS-Schwab spine coronal curve type†			
N	58 (24.8)	40 (21.5)	
T	82 (35)	74 (39.8)	>0.05
L	34 (14.5)	21 (11.3)	
D	60 (25.5)	51 (27.4)	

BMI = body mass index; CCI = Charlson comorbidity index.
* The values in this table show mean ± SD, unless indicated otherwise; p values < 0.05 were considered statistically significant.
† The values indicate number of patients (%); 1 patient could not be categorized by coronal curve type. Please see *Methods* for detailed description of the 4 coronal curve types.

cantly more nonoperated patients remained in the same back pain severity category 2 years after surgery than operated patients ($p < 0.0001$ for all, Table 2).

Patients who underwent surgery were 6.2 times (95% CI 4.0–9.7 times) more likely to experience an improvement in back pain than patients who did not undergo surgery. Surgery was also 3.0 times (95% CI 1.9–4.8 times) more likely to improve leg pain than nonoperative management. Patients who underwent nonoperative treatment were 11 times (95% CI 4.8–25.0 times) more likely to experience worsening back pain and 2.0 times (95% CI 1.2–3.3 times) more likely to experience worsening leg pain by the 2-year FU than patients who underwent surgery for ASD. Nonoperated patients were also 1.9 times (95% CI 1.2–2.9 times) more likely to remain in the same category of back pain severity during the 2 years posttreatment than operated patients.

The operated patients had significantly higher mean baseline NRS scores of back and leg pain than the nonoperated patients (7.1 ± 2.3 vs 4.4 ± 2.6 and 4.2 ± 3.3 vs 2.3 ± 2.8, respectively, $p < 0.0001$ for both comparisons) and significantly lower average back pain NRS scores at the 2-year FU (3.5 ± 3 vs 4.5 ± 2.9, $p = 0.0004$; Fig. 2). The operated and nonoperated patients had similar mean NRS scores for leg pain at the 2-year FU (2.5 ± 2.9 and 2.7 ± 3.0, respectively, $p = 0.6448$); however, at this time, the operated patients had a significantly greater mean decrease in back and leg pain NRS scores than the nonoperated patients (−3.6 ± 3.2 vs 0.1 ± 2.7 and −1.8 ± 3.6 vs 0.4 ± 3, respectively, $p < 0.0001$ for both comparisons).

The operated patients had worse mean baseline ODI and PCS scores ($p < 0.0001$ for both comparisons, Fig. 3) than the nonoperated patients. At the 1- and 2-year FUs, the patients in the 2 groups had similar ODI and PCS scores ($p > 0.05$). However, the operated patients had significantly greater improvements in both scores at the 1-

TABLE 2. Number of operated and nonoperated patients in each pain severity category at baseline and changes in pain severity during the 2-year FU period*

Variable	Patients w/ Back Pain			Patients w/ Leg Pain		
	Operated	Nonoperated	p Value	Operated	Nonoperated	p Value
Pain severity at baseline†						
None (0)	1 (0.4)	14 (7.7)	<0.0001	60 (26.9)	76 (43.9)	0.0004
Mild (1–4)	30 (13.3)	79 (43.6)	<0.0001	48 (21.5)	55 (31.8)	0.0213
Moderate (5–6)	46 (20.4)	46 (25.4)	0.2344	44 (19.7)	18 (10.4)	0.0100
Severe (7–10)	148 (65.8)	42 (23.2)	<0.0001	71 (31.8)	24 (13.9)	<0.0001
Back pain > leg pain	124 (55.1)	104 (57.5)	0.7007	NA	NA	NA
Leg pain > back pain	NA	NA	NA	18 (8.1)	16 (9.2)	0.6784
2-yr change in pain‡						
Improvement	144 (68.2)	46 (25.7)	<0.0001	95 (45.9)	37 (21.9)	<0.0001
Worsening	7 (3.3)	49 (27.4)	<0.0001	34 (16.4)	48 (28.4)	0.0051
No change	60 (25.2)	77 (43.0)	0.0026	39 (18.8)	30 (17.8)	0.7859
New onset	1 (100)	7 (50.0)	0.0009	20 (33.3)	20 (27.0)	0.4967
Back pain but not leg pain improved	41 (25.5)	6 (6.5)	<0.0001	NA	NA	NA
Leg pain but not back pain improved	NA	NA	NA	21 (14.3)	20 (21.3)	0.6011

* The values in this table indicate number (%) of patients, unless indicated otherwise (patient numbers in each group may vary because of missing data for some patients and because of different groups being compared); p values < 0.05 were considered statistically significant for comparisons of back and leg pain severity between operated and nonoperated patients.

† The ranges represent the NRS scores for each of the 3 pain severity categories.

‡ A change in pain was defined as improvement or worsening by at least 1 pain category. The "worsening" group included the patients with new-onset pain. The percentages were calculated from the available patients within each group with those for the "new-onset" group calculated from the patients with no preoperative pain within each respective group and from both the "back pain but not leg pain improved" and "leg pain but not back pain improved" groups from patients with baseline back and leg pain. Note that percentages may not add up to 100%. The "no change" group represents patients whose baseline pain did not change in severity; "back pain but not leg pain improved" represents patients whose back pain improved by at least 1 pain category and whose leg pain either worsened by at least 1 pain category (including new-onset leg pain postoperatively) or those whose leg pain did not change (excluding patients without preoperative leg pain); "leg pain but not back pain improved" represents patients whose leg pain improved by at least 1 pain category and whose back pain either worsened by at least 1 pain category (including new-onset back pain postoperatively) or those whose back pain did not change (excluding patients without preoperative back pain); and "new onset" represents patients who had no pain preoperatively and reported new pain postoperatively.

and 2-year FUs than the nonoperated patients (p < 0.0001 for all comparisons).

The ODI, PCS, and back and leg pain NRS scores of the operated patients were significantly more likely to reach MCID and SCB than the scores of the nonoperated patients (p < 0.05 for all comparisons, Fig. 4).

Operated Patients

Incidence of Leg Pain and Improvement or Worsening of Pain by Surgical Procedure

Sixty operated patients (26.9%) did not have preoperative leg pain (Table 2); 20 of these patients (33.3%) had
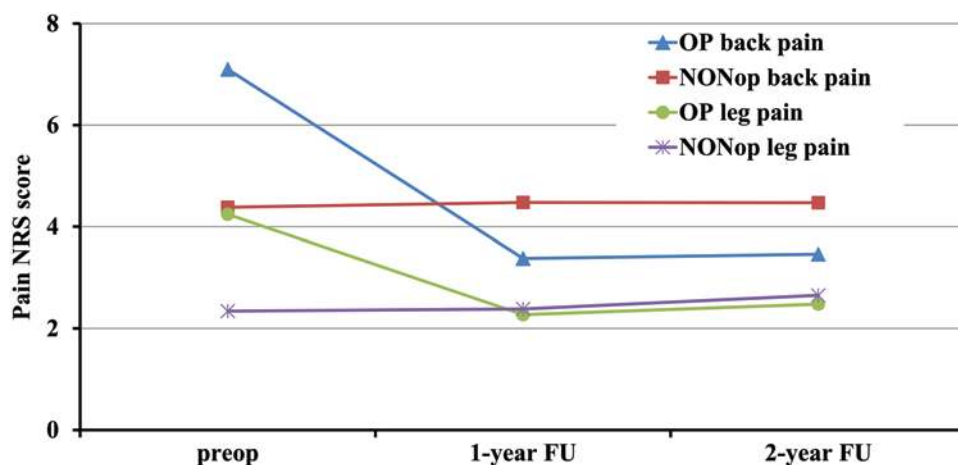

FIG. 2. Changes in mean NRS scores for back and leg pain over a 2-year FU period for both operated (OP) and nonoperated (NONop) patients. Figure is available in color online only.
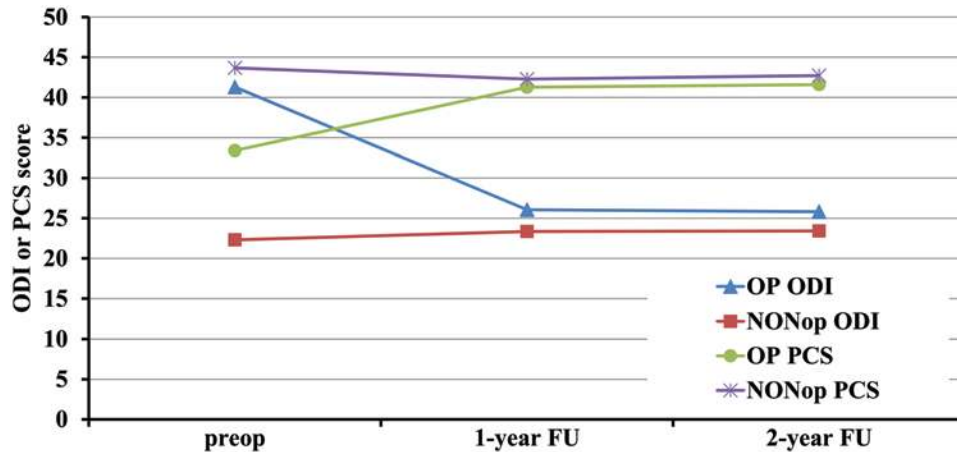
FIG. 3. Mean ODI and PCS scores from SF-36 across 2 years for both operated (OP) and nonoperated (NONop) patients. Figure is available in color online only.

new leg pain at the 2-year FU, with 14 having mild pain, 3 moderate pain, and 3 severe pain (Table 2). Among all 60 patients without preoperative leg pain, 46 (76.7%) had available data for 6-week postoperative NRS scores for leg pain. Of these patients, 17 (37.0%) had new leg pain (9 mild, 4 moderate, and 4 severe pain), and the remainder reported no leg pain (that is, an NRS score of 0). Among the 17 patients with new postoperative leg pain, 10 (58.8%) the pain persisted to the 2-year FU, and 7 (41.2%) had complete resolution of the pain by that time. Among the 10 patients with persistent leg pain, the pain improved by 1 pain category in 2 patients (20%), worsened by at least 1 pain category in 2 patients (20%), and remained the same in 6 patients (60%).

In total, 40 patients underwent surgeries not involving decompression or osteotomy (Other), 54 underwent osteotomy (O), 41 decompression (D), and 100 both decompression and osteotomy (D+O). At baseline, a higher percentage of patients in Group Other reported mild or moderate

back pain, and a higher percentage of patients in Group D reported severe back pain (p < 0.05, Table 3). No other differences in baseline severity of back pain were observed (p > 0.05 for all comparisons). Baseline leg pain severity in the patients in the D and D+O groups significantly differed from that in patients in both Other and O groups (p < 0.05 for all comparisons). Decompression resulted in a higher percentage of patients reporting at the 2-year FU that their leg pain had improved than among Group Other patients (p < 0.05). Among the patients in Group O, a higher percentage reported improvement in back pain at the 2-year FU than among those in Group Other (p < 0.05). However, a higher percentage of Group O patients reported new-onset leg pain than among Group D patients (p < 0.05).

Patients who underwent decompression (that is, those in the D and D+O groups) were significantly more likely to have their leg pain NRS and ODI scores reach MCID at the 2-year FU than those who did not undergo decompression (p < 0.05 for all comparisons, Fig. 5). The leg pain
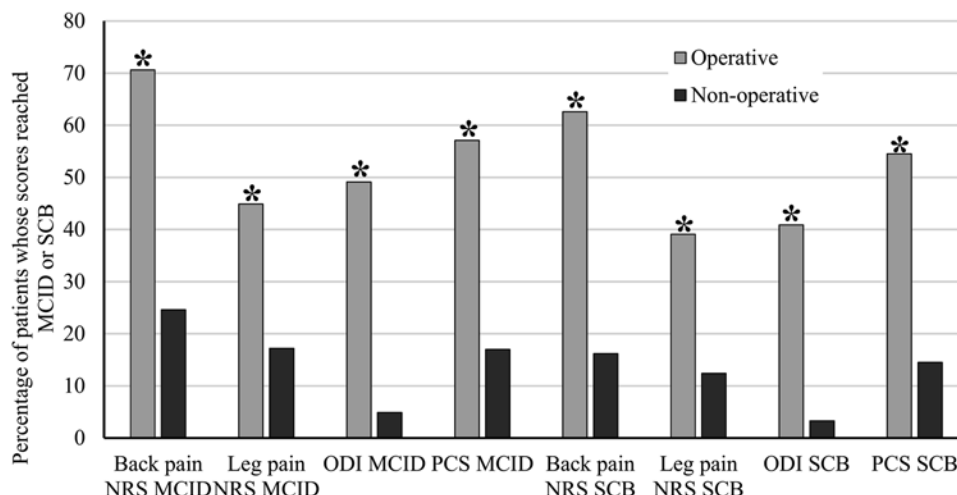

FIG. 4. The percentage of patients whose scores reached MCID and SCB in the HRQOL measures indicated for operated and nonoperated patients. All differences in the percentages between operated and nonoperated patients were statistically significant (*p < 0.05).

TABLE 3. Pain severity at baseline and the change in pain severity from baseline to the 2-year FU for all 4 types of ASD surgeries*

Variable	Patients w/ Back Pain				Patients w/ Leg Pain			
	Other	O	D	D+O	Other	O	D	D+O
Pain at baseline†								
None (0)	1 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	18 (48.6)	20 (39.2)	6 (15.8)	16 (16.7)
Mild (1–4)	9 (24.3)	8 (15.4)	2 (5.3)	11 (11.3)	6 (16.2)	13 (25.5)	5 (13.2)	24 (25.0)
Moderate (5–6)	8 (21.6)	9 (17.3)	6 (15.8)	23 (23.7)	7 (18.9)	8 (15.7)	5 (13.2)	23 (24.0)
Severe (7–10)	19 (51.4)	35 (67.3)	30 (78.9)	63 (64.9)	6 (16.2)	10 (19.6)	22 (57.9)	33 (34.4)
Back pain > leg pain	26 (70.3)	35 (67.3)	14 (36.8)	48 (49.5)	NA	NA	NA	NA
Leg pain > back pain	NA	NA	NA	NA	3 (8.1)	2 (3.9)	3 (7.9)	10 (10.4)
2-yr change in pain‡								
Improvement	16 (50.0)	37 (74.0)	24 (64.9)	67 (72.8)	8 (40.0)	17 (37.0)	19 (57.6)	50 (56.8)
Worsening	1 (3.1)	3 (6.0)	1 (2.7)	2 (2.2)	4 (20.0)	11 (23.9)	4 (12.1)	15 (17.0)
No change	14 (43.8)	10 (20.0)	12 (32.4)	23 (25.0)	5 (25.0)	9 (19.6)	9 (27.3)	16 (18.2)
New onset	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)	3 (17.6)	9 (45.0)	1 (16.7)	7 (43.8)
Back pain but not leg pain improved	3 (17.6)	13 (39.4)	6 (19.3)	19 (23.8)	NA	NA	NA	NA
Leg pain but not back pain improved	NA	NA	NA	NA	4 (26.7)	2 (7.1)	4 (13.3)	10 (13.5)

D = patients undergoing only decompression; D+O = patients undergoing both osteotomy and decompression; NA = not applicable; O = patients undergoing only osteotomy (includes Smith-Petersen osteotomy and 3-column osteotomies such as pedicle subtraction osteotomy and vertebral column resection); Other = patients undergoing surgery other than decompression or osteotomy.

* The values in this table indicate number (%) of patients.

† The ranges represent the NRS scores for each of the pain severity categories.

‡ See footnote in Table 2 for descriptions of the 2-year changes in pain.

NRS scores of patients in the D+O group were significantly more likely to reach SCB at the 2-year FU than those of the patients in the Other group, and back pain NRS scores of patients in the D+O group were significantly more likely to reach MCID than were those of the patients in the D group (p < 0.05 for all comparisons, Fig. 5).

In total, 163 operated patients had reported preoperative leg pain, and data for leg pain NRS scores at the 2-year FU were available for 148 (90.8%) of these patients. Of these, 28 patients (18.9%) had curve correction only without decompression (that is, those in the O group). In 17 (60.7%) of these 28 patients, the leg pain had improved by at least 1 pain category at the 2-year FU. Seventy-four (61.7%) of the remaining 120 patients underwent both curve correction and decompression (that is, all patients in the D+O surgery group), and in 50 (67.6%) of these patients, the leg pain improved by at least 1 pain category at the 2-year FU.

SRS-Schwab Coronal Deformity Classification

Preoperatively, patients with SRS-Schwab coronal deformity Type N reported back pain NRS scores (7.8 ± 1.6) that were similar to those reported by patients with Type
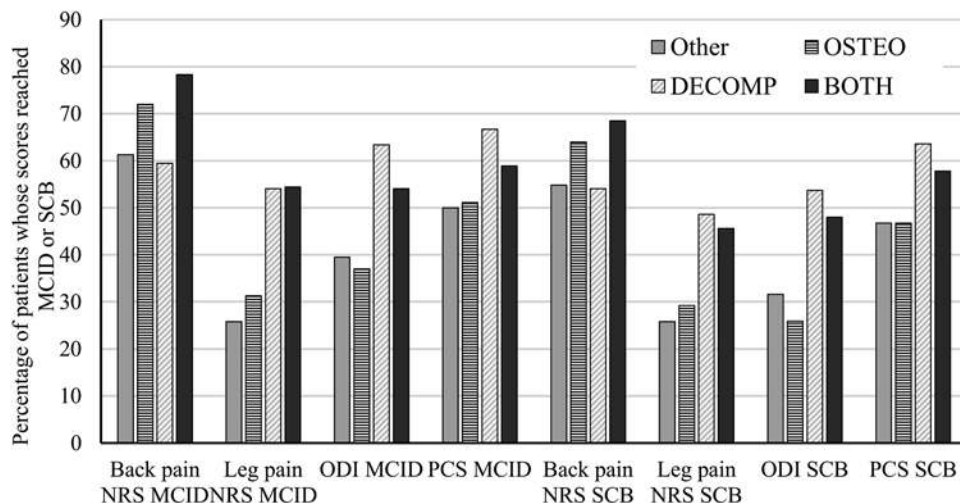

FIG. 5. The percentage of patients in each of the 4 main surgery groups whose scores reached MCID and SCB in the 8 HRQOL measures. BOTH = both decompression and osteotomy; DECOMP = decompression; Other = neither decompression nor osteotomy; OSTEO = osteotomy.

L (7.2 ± 2.7, p > 0.05), but significantly higher than those of patients with Type T (6.7 ± 2.5) or Type D (6.9 ± 2.2) (p < 0.05 for both comparisons). The preoperative back pain NRS score was similar among the patients with predominately coronal curve deformities (Types T, L, and D, p > 0.05 for all comparisons). The average preoperative leg pain NRS score was significantly higher in patients with Types N (5.2 ± 3.1) and L (5.4 ± 3.4) than in those with Types T (3.9 ± 3.3) and D (3.0 ± 3.1) (p < 0.05 for all comparisons).

The largest percentage of patients reporting an improvement in back pain at the 2-year FU was among those with Type L deformity, significantly larger than among those with Type N (p < 0.05, Table 4), who exhibited the least improvement in back pain among the 4 SRS-Schwab groups. In all other groups, similar percentages of patients experienced an improvement in back pain (p > 0.05 for all comparisons). The Type D deformity group had the highest percentage of patients experiencing improvement in back pain without experiencing improvement in leg pain, reaching statistically significant differences in improvement with patients with Type N or T (p < 0.05 for both comparisons), but not with Type L (p > 0.05). The Type N group had the highest percentage of patients whose back pain did not change from baseline to the 2-year FU (p < 0.05 for all differences). All 4 groups had similar percentages of patients whose back pain worsened postoperatively (p > 0.05 for all comparisons).

The Type L deformity group also had the largest percentage of patients whose leg pain improved, and this improvement was significantly larger than for patients with Type T or D (p < 0.05 for both comparisons, Table 4). A significantly higher percentage of patients in the Type N group experienced improvement in leg pain than among patients in the Type D group (p < 0.05), which had the lowest percentage of patients whose leg pain had improved. The Type D group had the highest percentage of patients whose leg pain worsened, and the percentage of these patients statistically significantly differed from that in the Type T group (p < 0.05). Patients in the Type T group were significantly less likely to have new-onset leg pain at the 2-year FU than the patients in the other 3 groups (p < 0.05 for all comparisons).

Within the Type N group, no significant differences were detected in the percentages of patients whose back or leg pain improved, worsened, or had no change for those who underwent a 3-column osteotomy (pedicle subtraction or vertebral column resection) and all other surgery types (p > 0.05 for all comparisons). Moreover, 3-column osteotomy and Smith-Petersen osteotomy did not result in any significant differences in the change of pain severity preoperatively to the 2-year FU (p > 0.05).

Patients with Type L were significantly more likely to have leg pain NRS scores that reached both MCID and SCB at the 2-year FU than patients with Type D (p < 0.05 for both comparisons, Table 5). Patients with Type N were significantly more likely to have leg pain ODI scores that reached SCB at the 2-year FU than patients with Type T or D (p < 0.05 for both comparisons). Patients with Type L were significantly more likely to have leg pain ODI scores reaching SCB at the 2-year FU than patients with Type T (p < 0.05).

Pain Severity, HRQOL, and Patient Satisfaction
Pain Severity
In total, 71 patients had severe (NRS Scores 7–10)

TABLE 4. The change in pain severity from baseline to the 2-year FU for patients grouped according to the SRS-Schwab coronal curve deformity of their spine*

Variable	SRS-Schwab Coronal Curve Type†			
	N	T	L	D
Back pain				
Improvement	28 (57.1)	49 (65.3)	25 (80.6)	41 (73.2)
Worsening	0 (0.0)	4 (5.3)	1 (3.2)	2 (3.6)
No change	21 (42.9)	21 (28.0)	5 (16.1)	13 (23.2)
New onset‡	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)
Back pain but not leg pain improved	5 (12.2)	9 (18.0)	6 (22.2)	21 (50.0)
Leg pain				
Improvement	26 (57.8)	31 (60.8)	20 (71.4)	17 (39.5)
Worsening	8 (17.8)	7 (13.7)	4 (14.3)	15 (34.9)
No change	11 (24.4)	13 (25.5)	4 (14.3)	11 (25.6)
New onset‡	4 (50)	1 (4.3)	3 (50)	12 (54.5)
Leg pain but not back pain improved	5 (12.5)	7 (14.0)	4 (16.0)	5 (16.1)

* The values in this table indicate number (%) of patients. A change in pain severity from baseline to the 2-year FU was defined as improvement or worsening by at least 1 pain category. See footnote for Table 1 for descriptions of the changes in pain.
† See *Methods* and Fig. 1 for a description of the 4 coronal curve deformity types.
‡ The percentages for new-onset pain were calculated with the total number of patients in each coronal curve group who reported no pain at baseline. See footnote in Table 2 for the description of the 2-year changes in pain.

TABLE 5. The effect of SRS-Schwab coronal curve type on ODI, PCS, and NRS scores reaching an MCID or SCB at the 2-year FU*

Score	SRS-Schwab Coronal Curve Type			
	N	T	L	D
MCID				
Back pain NRS	32 (65.3)	52 (70.3)	26 (83.9)	38 (67.9)
Leg pain NRS	24 (49.0)	32 (43.8)	19 (61.3)	17 (32.1)
ODI	29 (50.9)	38 (47.5)	21 (61.8)	25 (41.7)
PCS	25 (53.2)	39 (54.9)	20 (69.0)	28 (56.0)
SCB				
Back pain NRS	28 (57.1)	48 (64.9)	22 (71.0)	33 (58.9)
Leg pain NRS	23 (46.9)	26 (35.6)	16 (51.6)	15 (28.3)
ODI	45 (78.9)	44 (55.0)	27 (79.4)	37 (61.7)
PCS	25 (53.2)	38 (53.5)	19 (65.5)	25 (50.0)

* The values in this table indicate number (%) of patients whose HRQOL scores reached an MCID or SCB; the percentages were calculated with the number of patients whose scores met MCID or SCB and the total number of patients in each curve type group.

leg pain preoperatively, and leg pain NRS scores at the 2-year FU were available for 67 (94.4%) of these patients. Among these patients, 16 (23.9%) reported severe leg pain, 11 (16.4%) improved to moderate pain, 18 (26.9%) improved to mild pain, and 22 (32.8%) had no pain. At baseline, 148 patients reported severe back pain, and back pain NRS scores at the 2-year FU were available for 138 of these patients. Among these patients, 39 (28.3%) reported severe back pain, 28 (20.3%) improved to moderate pain, 42 (30.4%) improved to mild pain, and 29 (21.0%) had no back pain.

A significantly higher percentage of patients with preoperative severe back pain (NRS Scores 7–10) or moderate back pain (NRS Scores 5–6) improved by at least 1 back pain category than among those with preoperative mild back pain (NRS Scores 1–4, $p < 0.05$ for both comparisons; Table 6). Moreover, patients with preoperative severe and moderate back pain were 3.6 times (95% CI 1.6–8.2) and 4.7 times (95% CI 1.7–13.0) more likely, respectively, to have improved by at least 1 pain severity category at the 2-year FU than patients with mild preoperative pain. At the 2-year FU, a significantly higher percentage of patients with preoperative mild (NRS Scores 1–4) back pain had not experienced a change in the severity of their pain than among patients with severe back pain ($p < 0.05$, Table 6). A significantly higher percentage of patients with preoperative severe or moderate leg pain improved by at least 1 pain category than among those with preoperative mild leg pain ($p < 0.05$ for both comparisons). Moreover, patients with preoperative severe and moderate leg pain were 4.5 times (95% CI 1.9–9.7) and 2.7 times (95% CI 1.1–6.6) more likely, respectively, to experience improvement by at least 1 pain severity category by the 2-year FU than patients with mild preoperative pain.

Among all operated patients, 210 (89.4%) had at least mild back pain and 148 (63.0%) had at least mild leg pain, and pain severity scores at the 2-year FU were available for all of these patients. Among these patients, 51 (24.3%) and 56 (37.8%) were free of back or leg pain, respectively, at the 2-year FU, among whom a significantly higher percentage with preoperative severe back pain (29 patients [13.8%]) did not have back pain at the 2-year FU than among the patients with moderate (10 patients [4.8%]) or mild (12 patients [5.7%]) preoperative pain ($p < 0.05$ for both comparisons). Of the 56 patients who had no leg pain at the 2-year FU, the numbers and percentages of patients in each of the preoperative leg pain categories were all similar ($p > 0.05$ for all comparisons) and were as follows: severe pain (22 patients [14.9%]), moderate pain (16 patients [10.8%]), and mild pain (18 patients [12.2%]).

To assess the impact of preoperative back and leg pain severity on the changes in back or leg pain from baseline to the 2-year FU, linear regression analyses were conducted. Univariate linear regression analysis identified preoperative back pain and leg pain as significant predictors of the changes in back pain (r^2 0.18, $p < 0.0001$) and leg pain (r^2 0.43, $p < 0.0001$), respectively, over the 2-year FU period.

Pain Severity and HRQOL

The patients who had severe preoperative back pain had significantly worse preoperative ODI and PCS scores than those who had moderate or mild pain preoperatively ($p < 0.05$ for both comparisons, Table 7), and the patients with moderate preoperative back pain had worse preoperative ODI and PCS scores than those with mild back pain ($p < 0.05$). The patients with severe preoperative leg pain had worse preoperative PCS scores than those whose leg pain was moderate or mild ($p < 0.05$ for both comparisons) and worse preoperative ODI scores than the patients with mild leg pain ($p < 0.05$). The patients with severe or moderate preoperative back pain had a significantly greater 2-year improvement in ODI and PCS scores than the patients with mild pain ($p < 0.05$ for both scores). Patients with severe preoperative leg pain had a significantly greater 2-year improvement in ODI scores than patients with mild pain ($p < 0.05$), but no greater improvement in PCS scores ($p > 0.05$).

The PCS and ODI scores of patients with severe preoperative back pain were significantly more likely to reach an MCID and SCB at the 2-year FU than those of patients with mild back pain ($p < 0.05$ for both measures, Table 8),

TABLE 6. The change in pain categories from baseline to the 2-year FU for all preoperative back and leg pain severity groups*

Variable	Back Pain†			Leg Pain†		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Back						
Improvement	12 (41.4)	33 (76.7)	99 (71.7)	30 (71.4)	25 (64.1)	47 (69.1)
Worsening	4 (13.8)	2 (4.7)	NA	0 (0.0)	1 (2.6)	2 (2.9)
No change	13 (44.8)	8 (18.6)	39 (28.3)	12 (28.6)	13 (33.3)	19 (27.9)
Back pain but not leg pain improved	11 (37.9)	13 (30.2)	44 (31.9)	15 (35.7)	5 (12.8)	7 (10.3)
Leg						
Improvement	6 (40)	25 (73.5)	63 (53.4)	18 (42.9)	26 (66.7)	51 (76.1)
Worsening	2 (13.3)	4 (11.8)	28 (23.7)	10 (23.8)	4 (10.3)	NA
No change	7 (46.7)	5 (14.7)	27 (22.9)	14 (33.3)	9 (23.1)	16 (23.9)
Leg pain but not back pain improved	5 (33.3)	5 (14.7)	11 (9.3)	3 (7.1)	6 (15.4)	12 (17.9)

* The values in this table indicate number (%) of patients. See footnote for Table 2 for descriptions of the 3 pain severity groups.

† The ranges represent the NRS scores preoperatively for each of the pain severity categories.

TABLE 7. ODI and PCS scores for all operated patients and for all operated patients grouped according to the 3 pain categories of back or leg pain*

Time/Change	Pts/Pain Category	ODI Score	PCS Score
At baseline	All operated pts	41.3 ± 19.3	33.4 ± 10.2
	Back		
	Mild	22.3 ± 16.9	43.2 ± 11.7
	Moderate	34.4 ± 16.1	35.7 ± 9.7
	Severe	47.4 ± 17.2	30.8 ± 8.4
	Leg		
	Mild	39.9 ± 16.3	32.9 ± 9.2
	Moderate	43.7 ± 19.0	33.5 ± 7.7
	Severe	50.7 ± 16.2	28.1 ± 7.6
At 2-yr FU	All operated pts	25.8 ± 20.2	41.6 ± 11.6
	Back		
	Mild	13.1 ± 14.2	47.0 ± 11.6
	Moderate	16.5 ± 14.2	45.8 ± 10.9
	Severe	31.4 ± 21.0	39.5 ± 11.3
	Leg		
	Mild	26.9 ± 19.8	42.5 ± 11.7
	Moderate	27.8 ± 20.4	39.7 ± 11.3
	Severe	29.4 ± 21.0	39.2 ± 11.0
2-yr change	All operated pts	−8.2 ± 17.5	4.1 ± 10.1
	Back		
	Mild	−9.2 ± 15.8	4.0 ± 7.9
	Moderate	−17.9 ± 18.3	9.5 ± 11.5
	Severe	−16.0 ± 18.2	8.6 ± 10.4
	Leg		
	Mild	−13.1 ± 15.8	9.6 ± 10.1
	Moderate	−16.4 ± 17.6	6.0 ± 9.7
	Severe	−21.1 ± 19.1	10.8 ± 10.6

Pts = patients.
* The values in this table indicate mean ± SD. The changes were calculated from the listed time point to baseline. Negative values indicate a decrease and positive values an increase in score.

and the PCS scores of patients with moderate preoperative back pain were significantly more likely to reach an MICD and SCB at the 2-year FU (p < 0.05). Similarly for leg pain, the PCS scores of patients with severe preoperative pain were significantly more likely to reach an MCID and SCB at the 2-year FU than the PCS scores of the patients with moderate pain (p < 0.05 for both measures), and their ODI scores were significantly more likely to reach an MCID and SCB than those of the patients with mild leg pain (p < 0.05). Furthermore, the PCS scores of patients with moderate preoperative leg pain were significantly more likely to reach an MCID and SCB at the 2-year FU than the PCS scores of the patients with mild leg pain (p < 0.05 for both scores).

To assess the impact of back and leg pain severity on the 2-year changes in ODI and PCS scores, linear regression analyses were conducted. Univariate linear regression analyses identified the 2-year change in back pain and leg

pain severities as significant predictors of the changes in ODI scores from baseline to the 2-year FU (p < 0.0001, r^2 0.22 and p < 0.0001, r^2 0.17, respectively). For the regression of the 2-year change in both back and leg pain with the change in ODI score, the r^2 was 0.32 (p < 0.0001). The univariate linear regressions also indicated that the changes in back pain, in leg pain, and in both back and leg pain were also significant predictors of the change in PCS scores from baseline to the 2-year FU (r^2 0.20, r^2 0.17, and r^2 0.28, respectively; p < 0.0001 for all analyses).

For the patients whose ODI (n = 114) and PCS (n = 113) scores met MCID at 2 years, the decrease in back pain NRS scores was significantly larger than the decrease in leg pain NRS scores (−5.1 ± 2.7 vs −3.0 ± 3.5 and −4.8 ± 2.7 vs −2.6 ± 3.5, respectively, p < 0.0001 for both comparisons).

Pain and Patient Satisfaction

Among the operated patients who had both preoperative back and leg pain and 2-year scores (n = 147), in 27 (18.4%) the back pain improved by at least 1 pain category but the leg pain did not improve (that is, the leg pain persisted or worsened), and in 21 (14.3%) leg pain but not back pain improved (Table 2). The patients whose back pain but not their leg pain improved were significantly more satisfied with their surgical management than those whose leg pain but not back pain improved: they had a significantly higher SRS-22 Question 21 score (4.2 vs 3.5, p = 0.0231), Question 22 score (4.5 vs 3.7, p = 0.0075), and overall SRS-22 satisfaction score (4.3 vs 3.7, p = 0.0401) than those whose back pain did not improved. Both groups had statistically similar preoperative, 1-, and 2-year changes in ODI and PCS scores (p > 0.05 for all). However, patients whose leg pain but not back pain improved had significantly higher preoperative leg pain (p < 0.05). Among the patients whose back pain but not leg pain improved a higher percentage had ODI and PCS scores that met MCID or SCB than among the patients whose leg pain but not back pain improved (39.0%/34.2% vs 28.6%/23.8, respectively, for ODI scores and 62.2%/54.1% vs 41.2%/41.2%, respectively, for PCS scores); however, these differences did not reach statistical significance (p > 0.05 for all comparisons).

Discussion

To the best of our knowledge, no reports on a patient series as large as the one in the present study have investigated the effect of surgical intervention on back and leg pain in ASD. Moreover, we are not aware of any previous studies addressing back and leg pain in terms of pain severity according to surgical versus nonsurgical management, surgery type, SRS-Schwab deformity classification, and patient satisfaction in ASD. As the largest series published to date, the present study may serve as a valuable reference for counseling patients preoperatively about how ASD surgery may improve or worsen their pain. Surgical management resulted in significantly greater improvement in both back and leg pain severity than nonsurgical management (Figs. 2–5). Moreover, patients whose ASD was managed nonsurgically were more likely to experience no improvement or worsening of their pain. Although operative management significantly improved leg pain, there

TABLE 8. Patients whose ODI or PCS scores had reached MCID or SCB at the 2-year FU*

Score	All Operated Pts	Pts w/ Back Pain†			Pts w/ Leg Pain†		
		Mild	Moderate	Severe	Mild	Moderate	Severe
MCDI							
ODI	114 (49.1)	11 (36.7)	26 (56.5)	73 (50.3)	18 (37.5)	20 (47.6)	45 (64.3)
PCS	113 (57.1)	8 (30.8)	24 (64.9)	79 (60.3)	29 (65.9)	14 (41.2)	44 (71.0)
SCB							
ODI	95 (40.9)	8 (26.7)	23 (50.0)	62 (42.8)	15 (31.3)	15 (35.7)	42 (60.0)
PCS	108 (54.5)	8 (30.8)	22 (59.5)	76 (58.0)	28 (63.6)	14 (41.2)	41 (66.1)

* The values in this table indicate number (%) of patients; the percentages were calculated with the number of patients whose scores met an MCID or SCB and the total number of patients in each pain group.

† See Table 2 for NRS scores corresponding to "mild," "moderate," and "severe" back or leg pain.

was still a 37.0% incidence of leg pain 6 weeks postoperatively and a 33.3% incidence of leg pain at the 2-year FU. Patients who underwent decompression were more likely to experience an improvement in leg pain and to have NRS and ODI scores for leg pain that reached MCID and ODI scores that reached SCB at the 2-year FU than those who did not undergo decompression. Interestingly, patients who underwent osteotomy for curve correction were more likely to have an improvement in back pain; however, they were also more likely to have new-onset leg pain.

Patients with different coronal curve deformities differed in the level of reported baseline pain and in the improvement of their pain. The patients whose spines had primarily sagittal malalignment (Type N) had worse baseline back pain, and those with dominant lumbar curve deformities (Type L) had worse leg pain. In addition, back pain was least likely to improve in patients with coronal curve Type N. The addition of a 3-column osteotomy to the surgical management of Type N spines neither improved nor worsened back or leg pain. However, patients with a Type L deformity were most likely to experience improvement in back and leg pain and more likely to have NRS scores that reached MCID and SCB for leg pain than patients with double curve deformities (Type D). Patients with Type D were more likely to have an improvement in back pain but not in leg pain, were least likely to have leg pain improvement, and were more likely to have leg pain worsening. Among the patients with severe preoperative back or leg pain, 21.0% were free of back pain and 32.8% were free of leg pain at the 2-year FU. Of the patients with any preoperative back or leg pain, 24.3% were free of back pain and 37.8% were free of leg pain at the 2-year FU.

Patients with severe preoperative back or leg pain were more likely to experience an improvement in severity of both back and leg pain and their PCS and ODI scores were more likely to reach MCID or SCB than for patients with less severe preoperative pain. An improvement in back pain contributed to greater improvements in ODI and PCS scores than improvements in leg pain did. Patients whose ODI or PCS scores met MCID experienced greater improvements in back pain than in leg pain. Improvement in back pain contributed more to a patient's satisfaction of back management than an improvement in leg pain did. The patients whose back pain but not leg pain improved were significantly more satisfied with the management of

their back pain than those whose leg pain but not back pain improved.

Numerous studies have established that surgical correction of ASD results in improved HRQOL and decreased disability.[16,17,19,27,29–32] However, a paucity of data still exists for pain improvements, especially for leg pain improvement. Back and leg pain have been largely overshadowed by the large focus on standard disability measures such as ODI, SRS-22, and SF-36 scores. Recent reports have identified both back and leg pain as independent predictors of a patients' preference for operative rather than nonoperative care.[14,26] Thus, in addition to the standard HRQOL measures, back and leg pain should be strongly considered for disability in the management of ASD.

Few studies have directly investigated improvements in back and leg pain in individuals with ASD. Smith et al.[28] studied NRS scores for back pain in 317 ASD patients (147 operated and 170 nonoperated patients). Operative treatment significantly improved back pain relative to nonoperative management despite the surgically treated patients having higher baseline back pain NRS scores. The results of the present study indicated a similar trend: the operated patients were 6.2 times more likely to improve by at least 1 back pain severity category than the nonoperated patients. Smith et al. also found that the back pain NRS scores in the nonoperated patients did not significantly change from baseline to 2 years postoperatively.[28] Similarly, the present study found that nonoperated patients were 1.9 times more likely to remain in the same pain severity category than the operated patients.

In addition, the authors assessed the effect of laminectomy on pain improvement and found that patients undergoing laminectomy had a greater improvement in back pain than those who did not. However, the results of the present study show that those patients undergoing an osteotomy (Smith-Petersen osteotomy, 3-column osteotomy, or both) were more likely to experience improvement in back pain than those undergoing decompression. In addition, decompression alone did not improve back pain, but rather resulted in improvement of leg pain. The improved back pain with osteotomy is likely the result of the curve correction allowing the patients to maintain a more upright posture and to decrease the use of extensor muscles.

Smith et al.[29] also investigated the effect of operative and nonoperative ASD management on leg pain with 208

patients (96 operated and 112 nonoperated patients). Similar to back pain, leg pain significantly improved after surgical treatment relative to nonsurgical treatment despite the operated patients having higher baseline leg pain. In addition, patients undergoing laminectomy had a significantly larger decrease in leg pain 2 years postoperatively than those who did not undergo laminectomy. In the present study, operated patients were 3 times more likely to have an improvement in leg pain severity than nonoperated patients. Furthermore, patients who underwent a direct decompression were more likely to have their leg pain improve and have their change in pain severity reach MCID at 2 years postoperatively. However, patients undergoing an osteotomy were more likely to have new-onset leg pain than those undergoing only decompression. This was likely a result of patients having less new leg pain with decompression because this surgery aims to reduce leg pain. For patients who underwent both a decompression and an osteotomy, the incidences of new leg pain were similar.

Smith et al.[28] did not find an association with baseline back pain NRS scores and curve location, a finding similar to that in our study, which showed that all patients with predominantly coronal curves (Types T, L, and D) had similar back pain severity at baseline. However, the authors did not conduct an analysis of pain improvements because the primary objective of the study was to assess the outcomes of operative versus nonoperative treatment. In the present study, the different curve types were assessed, and patients whose spine was Type N had the highest preoperative back pain and were least likely to experience an improvement in back pain. This is not surprising because sagittal malalignment has been repeatedly shown to be associated with back pain.[1,3,12,22,23] The results of the coronal curve analysis indicated that patients with Type L spinal deformities experienced the greatest improvement in back pain. The reason for this finding is not entirely clear. Patients whose spines had both thoracic and lumbar coronal curves (Type D) had the same preoperative leg pain, but experienced the least improvement in leg pain and the highest incidence of worsening or new-onset leg pain at the 2-year FU. This may be a result of spines of these patients having more pronounced lumbar coronal curves than those of the patients with Type L deformities. However, our data did not provide enough evidence to support this hypothesis.

This is the first study to investigate the preoperative severity of back and leg pain and its relationship with improvements in pain and of the relationships among back and leg pain and improvements in ODI and PCS scores. Smith et al.[30] investigated clinical and radiographic parameters in a large group of individuals with ASD to distinguish the best and worst outcomes after surgical correction and found that patients with worst outcomes (ODI Scores > 40 at 2 years postoperation) had had higher preoperative back pain. This observation is in contrast to the findings of the present study in which patients with more severe preoperative back or leg pain were more likely to experience an improvement in both back and leg pain and to have their ODI and PCS scores reach MCID at the 2-year FU. Because of the design of the pain NRS, this observation could be the result of patients with more severe pain having a greater likelihood of moving to a lower pain score than those with

milder pain. Patients who have more severe pain at baseline have more opportunity to improve than patients with less severe pain at baseline. However, patients with severe pain were less likely to remain in severe pain than patients with mild pain remaining in mild pain.

The questions of the ODI questionnaire refer to limitations due only to back pain and not to leg pain.[9] However, it was previously unknown whether leg pain plays a role in the ODI score, and the present study attempted to answer this question. It appears that back pain is the dominant driver of the ODI score as evidenced by the patients whose ODI scores reached MCID and who reported a significantly larger improvement in back pain than in leg pain. Moreover, the results of the linear regression analyses indicated that both improvements in back and leg pain were significant predictors of improvement in ODI scores, but the r^2 was higher for back pain. However, when the 2 variables were combined, the r^2 was higher than that for either individual variable. This may imply that even though back pain was the main driver of ODI scores, leg pain also contributed. Future work may warrant incorporating leg pain into disability scales.

This is the first study to evaluate the role of back and leg pain in patient satisfaction. According to our results, improvement in back pain appears to be a larger driver of patient satisfaction than leg pain. Patients whose back pain but not leg pain improved were more likely to be satisfied at the 2-year FU than patients whose leg pain but not back pain improved. This result was not surprising because most ASD patients have preoperative back pain, and back pain is an independent predictor for a patient's choice of operative management. Furthermore, larger decreases in back pain were associated with meeting MCID for disability HRQOL than improvements in leg pain. It is worth noting, however, that leg pain also has been shown to be an independent driver toward undergoing surgical treatment.[26]

The strengths of the current study include the multicenter participation, the largest number of ASD patients being studied for back and leg pain to date, and the complete preoperative and 2-year FU of the patients assessed for both operative and nonoperative treatments. Furthermore, patients were enrolled from multiple surgical centers comprising 11 different sites across the United States, which improved the generalizability of the results. Other strengths of this study included the self-reported nature of the back and leg pain NRS scores as well as the categorization of the pain by mild, moderate, and severe. Moreover, the addition of the MCID and SCB measures allowed for additional characterization of the impact of the parameters studied on patients' clinical improvement.

There are a few limitations to this study, one of which includes its retrospective design. Despite this retrospective analysis, the data used were obtained from a large multicenter prospective database of ASD patients. Loss to FU in the nonoperated subcohort may have caused an overestimation of the prevalence of disability among patients in this subcohort, which may have exaggerated the potential benefits of surgery. In addition, we did not evaluate the etiology and duration of the back or leg pain at baseline. Both of these variables could have had an influence on the

possible outcomes assessed. Moreover, the baseline deformity severity of the different surgical groups was also not evaluated and could have had an effect on the surgical recommendations for each group. Future work is necessary to provide greater insight into pain management in ASD surgery. Lastly, the MCID/SCB values used in the present study were from studies in which these outcomes were examined in lumbar arthrodesis patients, and these values have not been validated with data from patients with spinal deformities. Thus, the generalizability of these MCID/SCB values was limited, but a strong prospective ASD study defining MCID/SCB values for HRQOL is currently unavailable. The results of this study are still valid as there were clear differences between the parameters studied when the same MCID/SCB cutoff values were used as those previously reported.

Conclusions

Patients undergoing operative management were 6.2 times more likely to experience an improvement in back pain and 3.0 times more likely to have an improvement in leg pain than patients undergoing nonoperative management of ASD. Moreover, individuals whose ASD was managed nonoperatively were more likely to experience no change in or worsening of their back or leg pain than individuals undergoing operative ASD management. The incidence of postoperative leg pain was 37.0% at the 6-week FU and 33.3% at the 2-year FU. Among patients with any preoperative back or leg pain, 24.3% and 37.8% were free of back and leg pain, respectively, 2 years postoperatively. Among patients with severe (NRS Scores 7–10) preoperative pain in the back or leg, 21.0% and 32.8% were free of back and leg pain, respectively, at the 2-year FU. Decompression resulted in more patients having an improvement in leg pain and having HRQOL scores reaching MCID. Osteotomies improved back pain, but they were associated with a higher incidence of leg pain.

Individuals who had an SRS-Schwab coronal curve Type N deformity (sagittal malalignment only) were least likely to experience an improvement in back pain after surgery. Individuals with coronal curve Type L deformity were the most likely to experience an improvement in back and leg pain and to have HRQOL scores that reached an MCID and SCB. Individuals with Type D were least likely to have leg pain improvement and were more likely to experience worsening of leg pain. Preoperative pain severity affected the improvement in pain over 2 years postoperatively; patients whose pain was more severe experienced greater improvements in both back and leg pain and were more likely to have HRQOL scores that reached an MCID or SCB. Improvements in back pain contributed more to improvements in ODI and PCS scores and patient satisfaction than improvements in leg pain did. Our results provide a valuable reference for counseling patients preoperatively about what improvements or worsening of back and leg pain they can expect after undergoing surgery for ASD.

References

1. Ames CP, Smith JS, Scheer JK, Bess S, Bederman SS, Deviren V, et al: Impact of spinopelvic alignment on decision making in deformity surgery in adults. A review. **J Neurosurg Spine 16:**547–564, 2012
2. Bess S, Boachie-Adjei O, Burton D, Cunningham M, Shaffrey C, Shelokov A, 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) 34:**2186–2190, 2009
3. Blondel B, Schwab F, Ungar B, Smith J, Bridwell K, Glassman S, et al: Impact of magnitude and percentage of global sagittal plane correction on health-related quality of life at 2-years follow-up. **Neurosurgery 71:**341–348, 2012
4. Carreon LY, Sanders JO, Diab M, Sucato DJ, Sturm PF, Glassman SD: The minimum clinically important difference in Scoliosis Research Society-22 Appearance, Activity, and Pain domains after surgical correction of adolescent idiopathic scoliosis. **Spine (Phila Pa 1976) 35:**2079–2083, 2010
5. 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 15:**982–991, 2006
6. Charlson M, Szatrowski TP, Peterson J, Gold J: Validation of a combined comorbidity index. **J Clin Epidemiol 47:**1245–1251, 1994
7. 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 8:**968–974, 2008
8. Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al: Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. **Pain 113:**9–19, 2005
9. Fairbank JC, Pynsent PB: The Oswestry Disability Index. **Spine (Phila Pa 1976) 25:**2940–2952, 2000
10. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM: Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. **Pain 94:**149–158, 2001
11. 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 69:**1181–1187, 2011
12. 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) 30:**2024–2029, 2005
13. 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 90:**1839–1847, 2008
14. Glassman SD, Schwab FJ, Bridwell KH, Ondra SL, Berven S, Lenke LG: The selection of operative versus nonoperative treatment in patients with adult scoliosis. **Spine (Phila Pa 1976) 32:**93–97, 2007
15. Hirschfeld G, Zernikow B: Variability of "optimal" cut points for mild, moderate, and severe pain: neglected problems when comparing groups. **Pain 154:**154–159, 2013
16. Hyun SJ, Rhim SC: Clinical outcomes and complications after pedicle subtraction osteotomy for fixed sagittal imbalance patients: a long-term follow-up data. **J Korean Neurosurg Soc 47:**95–101, 2010
17. Ikenaga M, Shikata J, Takemoto M, Tanaka C: Clinical outcomes and complications after pedicle subtraction osteotomy for correction of thoracolumbar kyphosis. **J Neurosurg Spine 6:**330–336, 2007
18. Jensen MP, Smith DG, Ehde DM, Robinsin LR: Pain site and the effects of amputation pain: further clarification of the meaning of mild, moderate, and severe pain. **Pain 91:**317–322, 2001

19. Liu S, Schwab F, Smith JS, Klineberg E, Ames CP, Mundis G, et al: Likelihood of reaching minimal clinically important difference in adult spinal deformity: a comparison of operative and nonoperative treatment. **Ochsner J 14:**67–77, 2014

20. O'Brien MF, Kuklo TR, Blanke KM, Lenke LG (eds): **Spinal Deformity Study Group Radiographic Measurement Manual.** Memphis, TN: Medtronic Sofamor Danek, 2004

21. Rillardon L, Levassor N, Guigui P, Wodecki P, Cardinne L, Templier A, et al: [Validation of a tool to measure pelvic and spinal parameters of sagittal balance.] **Rev Chir Orthop Reparatrice Appar Mot 89:**218–227, 2003 (Fr)

22. Schwab F, Lafage V, Patel A, Farcy JP: Sagittal plane considerations and the pelvis in the adult patient. **Spine (Phila Pa 1976) 34:**1828–1833, 2009

23. Schwab F, Patel A, Ungar B, Farcy JP, Lafage V: Adult spinal deformity-postoperative standing imbalance: how much can you tolerate? An overview of key parameters in assessing alignment and planning corrective surgery. **Spine (Phila Pa 1976) 35:**2224–2231, 2010

24. Schwab F, Ungar B, Blondel B, Buchowski J, Coe J, Deinlein D, et al: Scoliosis Research Society-Schwab adult spinal deformity classification: a validation study. **Spine (Phila Pa 1976) 37:**1077–1082, 2012

25. Serlin RC, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS: When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function. **Pain 61:**277–284, 1995

26. 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 9:**326–331, 2008

27. Smith JS, Klineberg E, Schwab F, Shaffrey CI, Moal B, Ames CP, 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) 38:**1663–1671, 2013

28. Smith JS, Shaffrey CI, Berven S, Glassman S, Hamill C, Horton W, et al: Improvement of back pain with operative and nonoperative treatment in adults with scoliosis. **Neurosurgery 65:**86–94, 2009

29. Smith JS, Shaffrey CI, Berven S, Glassman S, Hamill C, Horton W, 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) 34:**1693–1698, 2009

30. Smith JS, Shaffrey CI, Glassman SD, Carreon LY, Schwab FJ, Lafage V, et al: Clinical and radiographic parameters that distinguish between the best and worst outcomes of scoliosis surgery for adults. **Eur Spine J 22:**402–410, 2013

31. Terran J, Schwab F, Shaffrey CI, Smith JS, Devos P, Ames CP, et al: The SRS-Schwab adult spinal deformity classification: assessment and clinical correlations based on a prospective operative and nonoperative cohort. **Neurosurgery 73:**559–568, 2013

32. Yang BP, Ondra SL, Chen LA, Jung HS, Koski TR, Salehi SA: Clinical and radiographic outcomes of thoracic and lumbar pedicle subtraction osteotomy for fixed sagittal imbalance. **J Neurosurg Spine 5:**9–17, 2006

Author Contributions

Conception and design: Ames. Acquisition of data: Lafage. Analysis and interpretation of data: Scheer. Drafting the article: Scheer. Critically revising the article: Scheer, Smith, Lafage, Rolston, Kelly, Gupta, Ames. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Scheer. Statistical analysis: Scheer. Study supervision: Ames.

Correspondence

Justin K. Scheer, Department of Neurological Surgery, Northwestern University Feinberg School of Medicine, 676 N. St. Clair St., Ste. 2210, Chicago, IL 60611. email: jscheer@ucsd.edu.