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Outcomes of Surgical Treatment for 138 Patients With Severe Sagittal Deformity at a Minimum 2-Year Follow-up: A Case Series

BACKGROUND: Operative treatment of adult spinal deformity (ASD) can be very challenging with high complication rates. It is well established that patients benefit from such treatment; however, the surgical outcomes for patients with severe sagittal deformity have not been reported.

OBJECTIVE: To report the outcomes of patients undergoing surgical correction for severe sagittal deformity.

METHODS: Retrospective review of a prospective, multicenter ASD database. Inclusion criteria: operative patients age ≥18, sagittal vertical axis (SVA) ≥15 cm, mismatch between pelvic incidence and lumbar lordosis (PI-LL) ≥30°, and/or lumbar kyphosis ≥5° with minimum 2 yr follow-up. Health-related quality of life (HRQOL) scores including minimal clinically important difference (MCID)/substantial clinical benefit (SCB), sagittal and coronal radiographic values, demographic, frailty, surgical, and complication data were collected. Comparisons between 2 yr postoperative and baseline HRQOL/radiographic data were made. $P < .05$ was significant.

RESULTS: A total of 138 patients were included from 502 operative patients (54.3% Female, Average (Avg) age 63.3 ± 11.5 yr). Avg operating room (OR) time 386.2 ± 136.5 min, estimated blood loss (EBL) 1829.8 ± 1474.6 cc. A total of 71(51.4%) had prior fusion. A total of 89.9% were posterior fusion only. Mean posterior levels fused 11.5 ± 4.1. A total of 44.9% had a 3-column osteotomy. All 2 yr postoperative radiographic parameters were significantly improved compared to baseline ($P < .001$ for all). All 2yr HRQOL measures were significantly improved compared to baseline ($P < .004$ for all). A total of 46.6% to 73.8% of patients met either MCID/SCB for all HRQOL. A total of 74.6% of patients had at least 1 complication, 11.6% had 4 or more complications, 33.3% had minimum 1 major complication, and 42(30.4%) had a postop revision.

CONCLUSION: Patients with severe sagittal malalignment benefit from surgical correction at 2 yr postoperative both radiographically and clinically despite having a high complication rate.

KEY WORDS: Adult spinal deformity, Severe, Complications, Outcomes, MCID, SCB, Sagittal malalignment

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Adult spinal deformity (ASD) patients characteristically present with pain, reduced quality of life, and disability.[1-5] The surgical management of these patients tends to be technically demanding and is associated with a high complication rate. The reported complication rates in the literature are varied and range from 14% to 71%.[6-10] However, despite these high complication rates, surgical correction does provide

ABBREVIATIONS: ANVOA, analysis of variance; **ASD,** adult spinal deformity; **Avg,** Average; **CCI,** Charlson comorbidity index; **IBF,** interbody fusion; **LL,** lumbar lordosis; **MCID,** including minimum clinically important difference; **MCS,** mental component summary; **NRS,** numeric rating scale; **ODI,** Oswestry disability index; **PCS,** physical component summary; **PI,** pelvic incidence; **PJK,** proximal junctional kyphosis; **PT,** pelvic tilt; **SCB,** substantial clinical benefit; **SPO,** Smith-Petersen osteotomy; **SRS,** Scoliosis Research Society; **SRS-22r,** Scoliosis Research Society Questionnaire; **SVA,** sagittal vertical axis; **TK,** thoracic kyphosis significant improvements in pain, disability, and health-related quality of life (HRQOL).[11-23,4]

Ever since the landmark studies by Glassman et al[24,25] demonstrating the relationship between sagittal alignment and HRQOL, there have been many studies corroborating these findings. Patients with increased sagittal malalignment resulting in a positive sagittal balance have worse baseline HRQOL and also have better postoperative outcomes.[26] There was a paradigm shift focusing on correcting global sagittal alignment at that time. The concept of sagittal alignment being a critical factor in ASD surgery was then expanded to include the pelvis.[27-29] Spino-pelvic parameters play a key role in ASD surgical planning and are closely related to HRQOL.[28]

Despite the numerous studies on ASD and outcomes, to our knowledge, a study focusing on the patients with severe sagittal deformity has yet to be conducted. Severe sagittal deformity refers to patients on the extreme end of sagittal malalignment. As there is no official definition, a group of fellowship trained attending ASD surgeons discussed a possible definition for which it was applied to the present study. Knowing the outcomes of such patients can aid in better decision making for both surgeons and patients as well as provide the groundwork for future prospective studies in this population. Our objective was to identify the patients with severe sagittal malalignment and characterize their outcomes with the hypothesis that they do well after deformity correction.

METHODS

Patient Population

The present study is a case series of a retrospective review of a prospective multicenter ASD database. This database is composed of patients from 13 sites across the United States. All patients provided informed consent and each site had obtained Institutional Review Board approval. The inclusion criteria for entry into the database were the following: adults with age $\geq$ 18 yr and the presence of thoracolumbar spinal deformity defined by having 1 or more of the following—sagittal vertical axis (SVA) $\geq$ 5 cm, pelvic tilt (PT) $\geq$ 25°, scoliosis Cobb angle $\geq$ 20°, and/or thoracic kyphosis (TK) $\geq$ 60°. The exclusion criteria included either having a spinal deformity due to a neuromuscular etiology or having active infection/malignancy. Additional study inclusion criteria included if the patient had a preoperative SVA $\geq$ 15 cm, pelvic incidence-lumbar lordosis (PI-LL) $\geq$ 30°, and/or lumbar kyphosis $\geq$ 5°. These definitions were determined from a discussion among multiple senior fellowship trained attending spine surgeons.

Data Collection: Demographics, Radiographic Assessment, HRQOL, and Surgical Data

The demographic and clinical data collected included patient age, gender, comorbidity type and number, Charlson comorbidity index (CCI), and body mass index (BMI).[30] The specific surgical data collected were the following: primary vs revision index procedure, anterior or posterior fusion, the number of levels fused, whether a 3-column osteotomy (pedicle subtraction osteotomy or vertebral column resection)

TABLE 1. Demographic Information and Baseline SRS-Schwab Coronal Classification

	All patients
Number	138
Age	63.3 ± 11.5
Female:male	110:28
BMI	29 ± 6.1
ASA	2.5 ± 0.6
CCI	2.1 ± 1.8
LOS (d)	9.5 ± 5.7
Preop SRS-Schwab coronal curve	
Type N	62 (44.9%)
Type T	1 (0.7%)
Type L	55 (39.9%)
Type D	20 (14.5%)

Values are presented as the mean ± 1 standard deviation, otherwise they are the number of patients and the percent proportion.
BMI = body mass index, CCI = Charlson comorbidity index, ASA = American Society of Anesthesiologists Physical Status Classification System, LOS = length of stay, Type N: patients with no coronal curve greater than 30° (ie, no major coronal deformity), Type T: patients with a thoracic major curve of greater than 30° (apical level of T9 or higher), Type L: patients with a lumbar or thoracolumbar major curve of greater than 30° (apical level of T10 or lower), and type D: patients with a double major curve, with each curve greater than 30°.

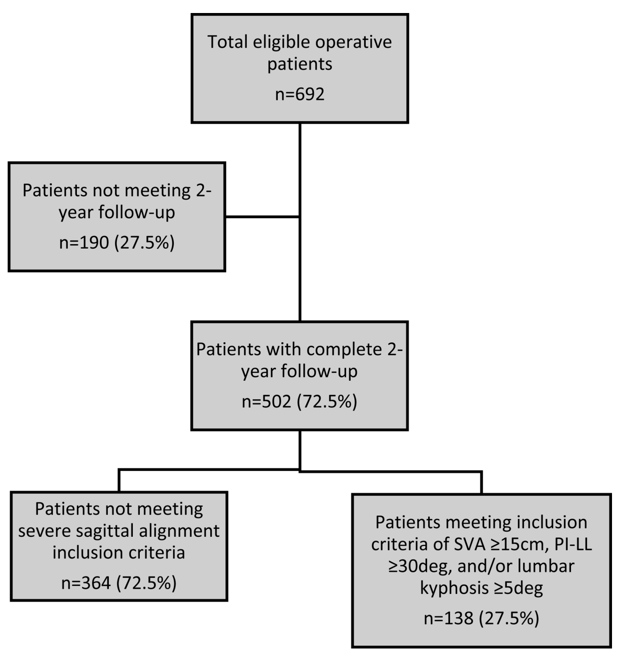

FIGURE 1. *Flowchart of patient inclusion in the study. SVA = sagittal vertical axis, PI-LL = mismatch between pelvic incidence (PI) and lumbar lordosis (LL).*

TABLE 2. Complete List of Patient Comorbidities

Parameter	All patients
Baseline frailty index	4.1 ± 1.4
≥1 comorbidity	126 (91.3%)
# of comorbidities	
0	12 (8.7%)
1	25 (18.1%)
2	27 (19.6%)
3	26 (18.8%)
4	15 (10.9%)
5	15 (10.9%)
6-8	8 (5.8%)
Types	
Arthritis	63 (45.7%)
Deep venous thrombosis	5 (3.6%)
Cancer	19 (13.8%)
Depression	46 (33.3%)
Diabetes	17 (12.3%)
Heart disease	18 (13%)
Hypertension	66 (47.8%)
Kidney disease	7 (5.1%)
Liver disease	3 (2.2%)
Pulmonary disease	9 (6.5%)
Neurological disease	5 (3.6%)
Osteoporosis	30 (21.7%)
Peripheral vascular disease	1 (0.7%)
Psychiatric disease	14 (10.1%)
Gastric ulcer	19 (13.8%)
Smoker	7 (5.1%)

Values presented are the number of patients and the percent proportion of the total cohort.

TABLE 3. Surgical Data for All of the Patients

Surgical data	All patients
Number	138
OR time (min)	386.2 ± 136.5
EBL (ml)	1829.8 ± 1474.6
Revision (% patients of total)	71 (51.4%)
Mean surgical invasiveness score (range)	116.2 ± 37.4 (10.6-213.2)
Aproach	
Anterior fusion (% patients of total)	1 (0.7%)
Posterior fusion (% patients of total)	124 (89.9%)
Combined anterior-posterior (% patients of total)	13 (9.4%)
Mean number posterior levels fused (range)	11.5 ± 4.1 (1-19)
Upper-most instrumented vertebra category	
T1-T6	50 (36.2%)
T7-T12	76 (55.1%)
Lumbar	12 (8.7%)
Lower-most instrumented vertebra category	
Thoracic	0 (0%)
Lumbar	7 (5.1%)
Sacroiliac	131 (94.9%)
Decompression (% patients of total)	104 (75.4%)
Mean number decompression levels (range)	1.1 ± 0.3 (1-2)
SPO (% patients of total)	72 (52.2%)
Mean number SPO levels (range)	4.6 ± 2.1 (1-12)
3-column osteotomy (% patients of total)	62 (44.9%)
Mean number of 3-column osteotomy levels (range)	1 (1)
Interbody fusion (% patients of total)	95 (68.8%)
Mean number of IBF levels (range)	2.3 ± 1.4 (1-6)

OR = operating room, EBL = estimated blood loss, SPO = Smith-Petersen osteotomy, IBF = interbody fusion.

was used, the upper- (UIV) and lower-most instrumented vertebra (LIV), and the ASD surgical invasiveness score.[31] Additionally, the number of levels for the following: direct decompression, Smith-Petersen osteotomies (SPOs), and interbody fusion (IBF) were recorded.

Each patient had full-length free-standing lateral spine radiographs (36" cassette) and were analyzed using validated software[32-34] (Spineview®, ENSAM, Laboratory of Biomechanics, Paris, France). In order to standardize the radiographic measurements and insure quality, reliable values, all radiographic measurements were performed at a central location based on standard techniques.[33] These included the following coronal measurement: Cobb angles of thoracic and lumbar curves (including the maximum Cobb angle) and coronal plumbline distance (C7-S1). The sagittal measurements included: TK (T4-T12; the Cobb angle between T4 superior endplate and T12 inferior endplate), LL (the Cobb angle between L1 superior endplate and S1 superior endplate), SVA (C7 plumbline distance to S1), PT, and the mismatch between PI and LL (PI-LL). Each patient was also classified by the Scoliosis Research Society (SRS)-Schwab Adult Spinal Deformity Classification system.[35]

The clinical outcomes measured included standardized HRQOL measures. They were the following: Oswestry disability index (ODI), Short-Form-36 (SF-36), and Scoliosis Research Society Questionnaire (SRS-22r). Within the SF36, 2 standard summary scores are calculated which include the physical component summary (PCS) and the mental component summary (MCS). Furthermore, each patient was classified according to the ASD frailty index.[36,37] The SRS-22r scores provide a total score and multiple subdomain scores: mental, activity, appearance, pain, and satisfaction. To evaluate back and leg pain, a numeric rating scale (NRS) score ranging from 0 (no pain) to 10 (most unbearable pain) was collected. In order to place HRQOL outcomes in a clinically relevant context, minimal clinically important difference (MCID) values have been established for the HRQOL instruments.[35,38] The proportions of patients reaching MCID for each HRQOL measure were also considered. Substantial clinical benefit (SCB) values for ODI, PCS, and back and leg pain NRS have also been established.[38] The MCID/SCB values used in the present study included: ODI (−16/−18.8), PCS (+5.2/+6.2), back and leg pain NRS (−2/−3).[35,38-40]

Statistics and Predictive Model Construction

Data that are recorded as continuous variables were reported with the mean and standard deviation. The normality of data was evaluated via the Shapiro-Wilk test. Comparisons between baseline preoperative and 2-yr variables were conducted. These comparisons were initially performed by an analysis of variance (ANVOA) or Kruskal-Wallis test when appropriate. A pairwise Tukey's Honest Significant Difference test to control for type I error or Wilcoxon summed ranked tests where done following the ANOVA where appropriate. Any categorical variables were evaluated by frequency analyses via Pearson's $\chi 2$ analysis. All above mentioned statistical analyses were performed using commercially available software (SPSS v22, IBM, Armonk, New York). The level of significance for all tests was set at $P < .05$.

TABLE 4. Mean ± 1 Standard Deviation (in Degrees Unless Specified) for the Preoperative, 2-yr, and 2-yr Differences Compared With Preoperative Values Radiographic Parameters

Time	Maximum coronal Cobb	Coronal C7 plumb	PT	PI-LL	LL	TK	SVA
Preop	35.7 ± 20.1	46.6 ± 42	33.5 ± 10	40.3 ± 11.8	17.3 ± 15.4	23.9 ± 16.8	143.1 ± 67.1
2 yr	20.2 ± 16.3	30.2 ± 22.9	26.6 ± 9.8	12.6 ± 14.6	45.3 ± 15.2	41.7 ± 15.7	58.7 ± 57.8
2 yr changes	−17.7 ± 12.9	−16.6 ± 42.8	−6.8 ± 7.8	−27.7 ± 15.1	28 ± 15.3	17.8 ± 15.6	−84.4 ± 73.4
P value	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

P values in bold represent a statistically significant difference between the preoperative and 2-yr postoperative values.
PT = pelvic tilt, PI-LL = mismatch between pelvic incidence (PI) and lumbar lordosis (LL), TK = thoracic kyphosis, SVA = sagittal vertical axis.

TABLE 5. Health-Related Quality of Life (HRQOL) Measures for All Patients at Preoperative and 2-yr Times Points With 2-yr Differences Compared With Preoperative Values

	ODI	PCS	MCS	SRS activity	SRS pain	SRS appearance	SRS mental	SRS satis-faction	SRS total	Back pain NRS	Leg pain NRS
Preop	51.3 ± 16.3	27.9 ± 8.2	43.4 ± 15.2	2.6 ± 0.9	2.1 ± 0.8	2.1 ± 0.8	3.3 ± 1	2.7 ± 1.1	2.5 ± 0.7	7.6 ± 2.1	5.2 ± 3.2
2 yr	33.3 ± 21.3	36.7 ± 10.5	48.8 ± 13.4	3.2 ± 1	3.3 ± 1.1	3.4 ± 1	3.8 ± 0.9	4.2 ± 1	3.5 ± 0.8	3.7 ± 3.1	2.9 ± 3.1
2 yr change	−17.9 ± 18.1	9.2 ± 9.4	5.8 ± 12.3	0.7 ± 0.8	1.2 ± 1	1.3 ± 1	0.5 ± 0.8	1.5 ± 1.4	1 ± 0.7	−3.9 ± 3.2	−2.3 ± 3.9
P value	**<.001**	**<.001**	**.003**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

Values are presented as the mean ± 1 standard deviation.
P values in bold represent a statistically significant difference between preoperative and 2-yr postoperative values.
ODI = Oswestry disability index, PCS = physical component summary score of the Medical Short Form 36 (SF-36), MCS = mental component summary score of the SF-36, SRS = Scoliosis Research Society-22 questionnaire, NRS = numeric rating scale score.

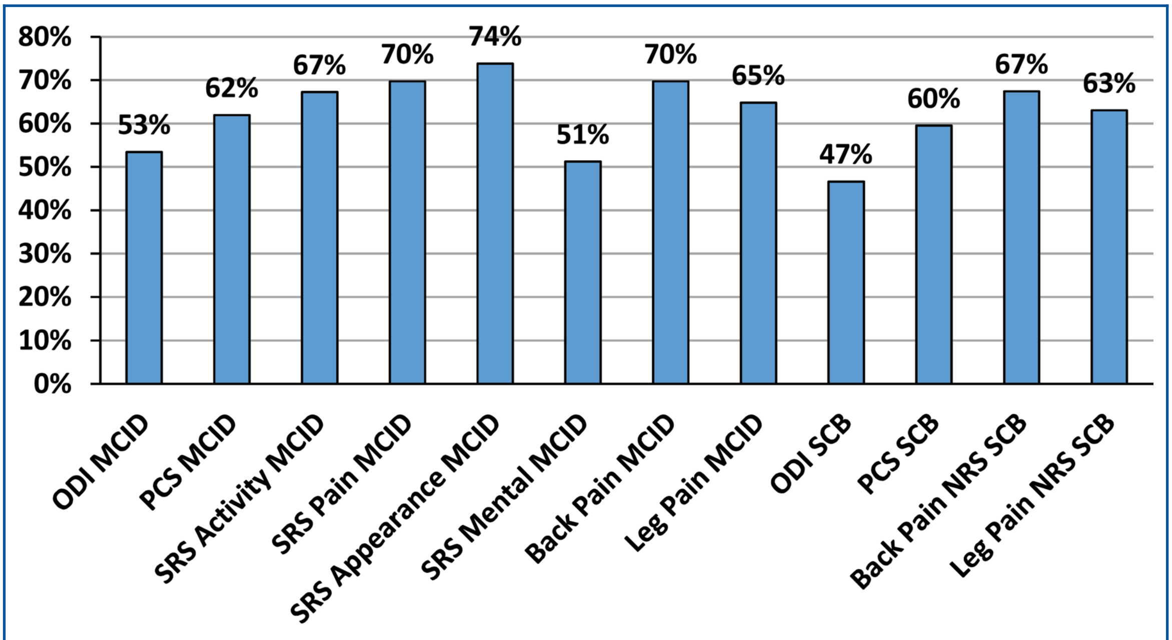

FIGURE 2. *The number and percentage of patients that reached minimal clinically important difference (MCID) and substantial clinical benefit (SCB) from baseline (BL) to 2-yr postoperative. The number of eligible patients is the number of patients with available data to compute the MCID or SCB. ODI = Oswestry disability index, PCS = physical component summary score of the Medical Short Form 36 (SF-36), MCS = mental component summary score of the SF-36, SRS = Scoliosis Research Society-22 questionnaire, NRS = numerical rating scale.*

TABLE 6. MCI and SCB for All Patients and Those That had a 3-Column Osteotomy

HRQOL measure	# Eligible patients	# (%)	3-Column osteotomy patients	# (%)
MCID				
ODI	134	71 (53.4%)	61	31 (50.8%)
PCS	all	78 (61.9%)	60	34 (56.7%)
SRS activity	135	88 (67.2%)	61	40 (65.6%)
SRS pain	136	92 (69.7%)	61	43 (70.5%)
SRS appearance	134	96 (73.8%)	61	46 (75.4%)
SRS mental	132	66 (51.2%)	61	38 (62.3%)
Back pain	137	63 (69.7%)	62	23 (69.4%)
Leg pain	113	92 (64.8%)	61	43 (54.1%)
SCB				
ODI	134	62 (46.6%)	61	26 (42.6%)
PCS	all	75 (59.5%)	60	32 (53.3%)
Back pain NRS	134	87 (67.4%)	62	41 (66.1%)
Leg pain NRS	108	63 (63.0%)	61	31 (50.8%)

ODI = Oswestry disability index, PCS = physical component summary score of the Medical Short Form 36 (SF-36), MCS = mental component summary score of the SF-36, SRS = Scoliosis Research Society-22 questionnaire, NRS = numeric rating scale score.

TABLE 7. Distribution of Complication Number and Types

	All patients
Total # of patients	138
# patients with minimum 1 complication	103 (74.6%)
# patients with minimum 1 intraoperative	38 (27.5%)
# patients with minimum 1 perioperative	23 (16.7%)
# patients with minimum 1 postoperative	76 (55.1%)
# patients with minimum 1 reoperations	48 (34.8%)
# patients with minimum 1 revision of index spine surgery	42 (30.4%)
Major	46 (33.3%)
Minor	76 (55.1%)
Number of complications	
1	46 (33.3%)
2	26 (18.8%)
3	15 (10.9%)
4	8 (5.8%)
5 or greater	8 (5.8%)

RESULTS

A total of 692 operative patients were eligible for inclusion and of those, 502 patients had 2-yr follow-up (72.5%). Of the 502 patients, 138 (27.5%) met these additional inclusion criteria (79.7% female, mean age 63.3 ± 11.5 yr; Table 1, Figure 1). Mean baseline frailty score was 4.4 ± 1.4 indicating that patients were frail. The majority of study patients had a prior fusion (51.4%). The rates of medical comorbidities ranged from 0.7% to 47.8% (Table 2). Most of the patients underwent a posterior-only fusion (89.9%), with mean number of levels fused being 11.5 ± 4.1, 44.9% had a 3-column osteotomy, and 68.8% underwent at least 1 IBF (Table 3).

The mean SVA of the study cohort was 143.1 ± 67.1, with a mean PT of 33.5 ± 10°. All 2-yr postoperative radiographic parameters were significantly improved compared to baseline ($P < .001$, Table 4). The mean SVA change was −84.4 ± 73.3 mm.

All 2-yr HRQOL measures were significantly improved compared to baseline ($P < .001$, Table 5). Many patients either met MCID or SCB at 2 yr follow-up (47%-74%, Figure 2). The greatest percentage of patients that met MCID was for SRS appearance at 74%. And for patients that underwent a 3-column osteotomy, they met MCI/SCB at rates of 42.6% to 75.4% (Table 6).

There was a high complication rate within the study cohort. Almost three fourths of patients (74.6%) had at least 1 complication with 11.6% having 4 or more complications (Tables 7 and 8). A total of 33.3% had a minimum of 1 major complication, and 30.4% had a postoperative revision (Table 7). The most common type of complication was implant related at 30.4% with the second and third most common being operative (25.4%) and radiographic (25.4%, Table 7). A detailed listing of complication types is in Table 8.

Case example: The patient is a 73-yr-old female with severe sagittal malalignment (Figure 3) with baseline HRQOL scores—back pain NRS: 8, Leg pain NRS: 6, ODI: 62, PCS: 25.3, SRS Activity: 2.6, Pain 1.2, appearance: 2, Mental: 2.2, and Satisfaction: 1. She underwent a T11-pelvis posterior instrumented fusion with 3 SPOs and an L4-5 transforaminal lumbar interbody fusion (TLIF) with significant correction of her sagittal deformity (Figure 4). She had 3 minor complications (cardiopulmonary, gastrointestinal, and radiographic (proximal junctional kyphosis [PJK]). Despite this, at 2-yr postoperative she met MCID and SCB for all HRQOL measures. She did not require surgery for the PJK and was followed.

TABLE 8. Complication Types

Cardiopulmonary	19 (13.8%)	Neurological	26 (18.8%)
Acute respiratory syndrome (ARDS)	0	Bowel-bladder deficit	0
Arrhythmia	2	Epidural hematoma	0
Atelectasis	0	Mental status	2
Cardiac arrest	0	Motor deficit	11
Congestive heart failure	2	Ophthalmological injury	0
Deep venous thrombosis	3	Radiculopathy	8
Myocardial infarction	2	Spinal cord injury/myelopathy	2
Pulmonary embolus	6	Seizure	0
Pleural effusion	4	Sensory deficit	0
		Stroke	3
Gastrointestinal	9 (6.5%)		
Cholecystitis	2	Operative	35 (25.4%)
Hemorrhage	1	Bowel perforation	1
Ileus	6	Dural tear	17
Dysphagia		Excessive bleeding	10
		Lymphocele	1
Implant	42 (30.4%)	Neuromonitoring anomaly	2
Interbody dislodge	1	Pleural injury	0
Loose	8	Positioning	1
Painful implant	4	Vertebra fracture	1
Implant prominence	2	Visceral injury	0
Rod fracture	21	Vascular injury	2
Rod dislodge	0		
Screw break	5	Radiographic	35 (25.4%)
Screw medial breach	1	Adjacent segment disease	1
Screw nerve impinge	0	Coronal imbalance	2
Screw vascular impinge	0	Distal junctional kyphosis	1
		PJK	22
Infection	16 (11.6%)	Pseudarthosis	9
Clostridium difficile	0		
Deep	4	Wound	2 (1.4%)
Pneumonia	4	Dehiscence	0
Sepsis	1	Drainage	0
Superficial	3	Hematoma seroma	2
Urinary tract infection	4	Incisional hernia	0
Renal	1 (0.7%)	Vascular	0 (0%)
Renal failure	1		

DISCUSSION

This is the first study of its kind investigating patients with severe sagittal malalignment and 2-yr postoperative outcomes. The study demonstrated that patients with severe sagittal deformity overall do well both radiographically and by HRQOL measures. Most of the patients met MCID or SCB at 2-yr postoperative indicating a significant clinical improvement. The positive postoperative gains in HRQOL were in the setting of a relatively high complication rate of 74.6% for any complication and a 33.3% rate for a major complication.

Severe Sagittal Deformity and HRQOL

The results of this study have large clinical implications on multiple levels. First, these patients have very poor baseline HRQOL status. The mean ODI was 51.3 and the mean PCS was 27.9. A study by Bess et al[41] compared HRQOL of patients with ASD to US population norms and other chronic diseases. The authors found that the norm-based PCS value for the ASD population between ages 55 and 64 yr was 38.7 and the US population norm was 47.4, both much higher than the current study population with severe sagittal malalignment. In addition, the mean PCS for the US population were the following for

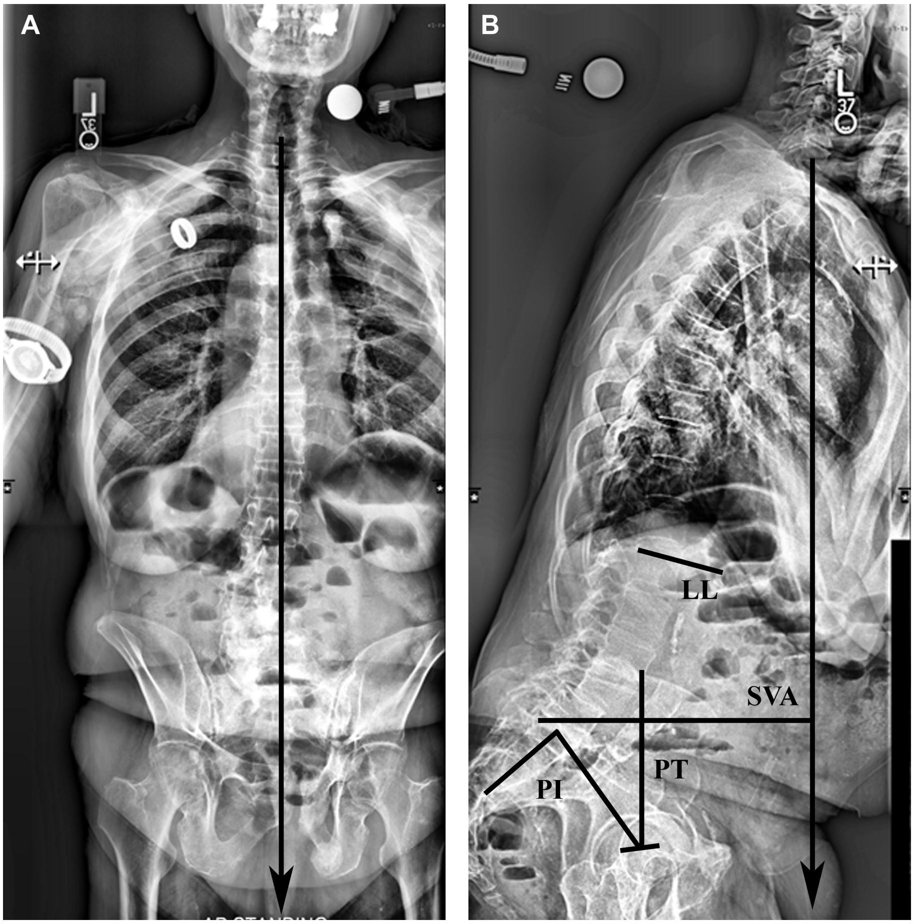

FIGURE 3. *Case example. Preoperative anteroposterior* **A** *and lateral* **B** *radiographs demonstrating the coronal and sagittal spinal alignment parameters. The arrow in the left image represents the coronal C7-plumb line (4 mm). SVA = sagittal vertical axis (23.4cm), PI = pelvic incidence, LL = lumbar lordosis (PI-LL = 46.3º), PT = pelvic tilt (34.1º).*

various chronic diseases: back pain 45.7, depression 45.4, diabetes 41.1, cancer 40.9, heart disease 38.9, and the lowest being lung disease at 38.3.[41] Our current population of patients with severe sagittal malalignment has a much lower PCS than all of those in comparison.

Complication Rate

Second, the complication rate for the present study is very high compared with the means presented in the literature for ASD. Sciubba et al[42] performed a large systematic review of complications for ASD surgery (93 articles) and found that the mean overall complication rate was 55% with a major complication rate of 18.5%. The present study found an overall complication rate of 74.6% with a major complication rate of 33.3%. Both of which are much higher than the reported means in the literature. This is likely a result of the more extensive surgery the patients underwent to correct the severe sagittal deformity. The mean posterior levels fused was 11.5 and 44.9% of the patients underwent a 3-column osteotomy. Complications increase in patients that undergo 3-column osteotomies.[42] There was also a high revision rate of 30.4%. This is likely explained from the highest complication type being implant related.

Two-Year Outcomes

Lastly and most importantly, the 2-yr outcomes of the patients are surprisingly very positive in lieu of a really high complication rate. A study by Liu et al[12] investigating the MCID outcomes for ASD patients undergoing operative treatment compared with nonoperative treatment was conducted demonstrating that the operative patients met MCID for the following HRQOL measures: ODI 49%, PCS 45%, SRS activity 63%, SRS pain 64%, SRS appearance 74%, and SRS mental 43%. The MCID values for each of those HRQOL values for the current population was higher than all of them, with the largest difference being

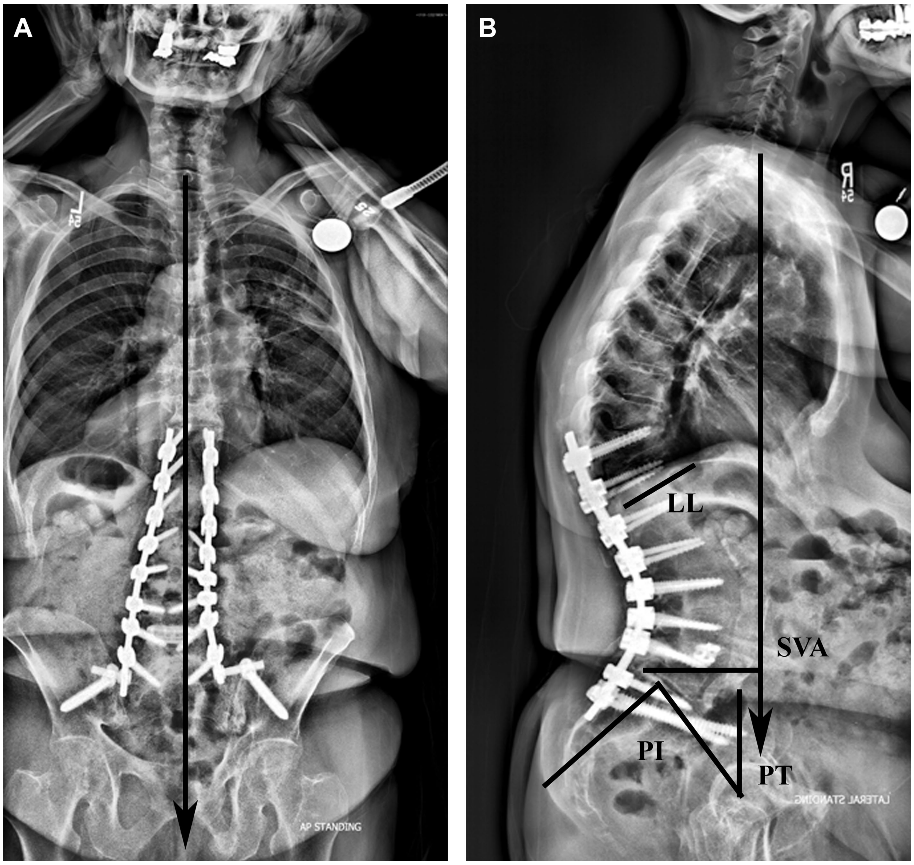

FIGURE 4. *Case example. Two-year postoperative anteroposterior* **A** *and lateral* **B** *radiographs demonstrating the coronal and sagittal spinal alignment parameters. The arrow in* **A** *represents the coronal C7-plumb line (1.8cm). SVA = sagittal vertical axis (9.5cm), PI = pelvic incidence, LL = lumbar lordosis (PI-LL = 6.2º), PT = pelvic tilt (34.5º).*

62% for PCS. For back and leg pain, a study by Scheer et al[13] showed though a large deformity population the 2-yr MICD rates for back and leg pain were 71% and 46%, respectively. In the present study, the MCID values were 70% and 65%, respectively. As for SCB, the patients in the Scheer et al[13] study had a rate of 62% for back pain and 39% for leg pain, whereas the current study has rates of 67% and 63%, respectively. Despite a large deformity correction, they had a large improvement in back and leg pain. And given that half the patients in the present study underwent a 3-column osteotomy, comparison of MCID to the literature shows that a study by Fakurnejad et al[43] had reported MCID values for the following: ODI 34.9% and PCS 50.0%. The current study had rates of 50.8% and 56.7% for the patients that underwent a 3-column osteotomy, again higher. Patients with severe sagittal deformity significantly improve compared to baseline but also to other populations of patients with ASD in the literature. Moreover, this is the setting of most of these patients being frail with a mean score of 4.4.

Strengths and Limitations

The study strengths include the multicenter design and a large number of ASD patients with severe sagittal malalignment, 138 in total. The multicenter design with 13 different sites across the United States allows for better generalizability of the results. This study used complete 2-yr follow-up of the patients, which is also a large strength.

However, there are limitations to this study, one of which includes the retrospective design which may have introduced selection or information biases. Additionally, the definitions of severe sagittal deformity were defined as 1 standard deviation above the mean for a large cohort of ASD patients. This definition is arbitrary but does provide a mathematical framework to study this population. The definition of "severe sagittal deformity" may vary across different populations of ASD patients. In the present study, the mean SVA for this population was 14.3 cm, which we feel most deformity fellowship trained surgeons would agree is "severe". Despite the arbitrary definitions for the inclusion criteria, this study provides a starting point for addressing this particular severe deformity population.

CONCLUSION

Patients with severe sagittal malalignment have very poor baseline health status and are frail but benefit from surgical correction at 2-yr postoperative; both radiographically and clinically despite having a high complication rate. This data can aid in the preoperative discussions between patient and surgeon to allow for more accurate and realistic expectations following large sagittal deformity correction.

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The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENT

The authors have examined a subset of patients with severe sagittal deformities who were part of a large adult spinal deformity (ASD) database. Many of these patients required 3 column osteotomies for correction of their deformity. The outcomes for this subset of patients is overall positive with considerable improvements noted in both clinical and radiographic metrics. The key take-home message is that this complex deformity correction surgery in patients with severe sagittal deformity does not come without a cost in the form of increased complication rates. I think that this cost is expected and justified for these types of procedures often involving 3-column osteotomies. The authors have shown that these patients can benefit from good outcomes in the final analysis.

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