

DEFORMITY

Under Correction of Sagittal Deformities Based on Age-adjusted Alignment Thresholds Leads to Worse Health-related Quality of Life Whereas Over Correction Provides No Additional Benefit

Justin K. Scheer, MD,* Renaud Lafage, MS,[†] Frank J. Schwab, MD,[†] Barthelemy Liabaud, MD,[†] Justin S. Smith, MD, PhD,[‡] Gregory M. Mundis, MD,[§] Richard Hostin, MD,[¶] Christopher I. Shaffrey, MD,[‡] Douglas C. Burton, MD,^{||} Robert A. Hart, MD,** Han J. Kim, MD,[†] Shay Bess, MD,^{††} Munish Gupta, MD,^{‡‡} Virginie Lafage, PhD,[†] and Christopher P. Ames, MD^{§§}, International Spine Study Group

Study Design. Retrospective review of prospectively-collected database.

Objective. This study aims to compare 2-year clinical outcomes of patients who underwent surgical reconstructions based on their achievement to age-adjusted alignment ideals.

Summary of Background Data. Recent research in sagittal plane has proposed age-adjusted alignment thresholds. However, the impact of these thresholds on postoperative health-related quality of life (HRQOL) is yet to be investigated.

Methods. Patients were included if they were more than 18-years old and underwent surgical correction of adult spinal deformity with a complete 2-year follow-up. Patients were stratified into three

groups based on achievement of age-adjusted thresholds in pelvic tilt (PT), pelvic incidence minus lumbar lordosis (PI-LL), and sagittal vertical axis (SVA). First group included patients who reached the exact age-adjusted threshold ± 10 years (MATCHED), other two groups included patients who were over corrected (OVER), and under corrected (UNDER). Clinical outcomes including actual value and offset from age-adjusted Oswestry Disability Index, Short-Form-36 (SF-36) -physical component summary, and Scoliosis Research Society-22r (SRS-22r) were compared between groups at 2 years follow-up.

Results. A total of 343 patients (mean, 57 yrs and 83% females) were included. Sagittal profile of the population was: PT = 23.6°, SVA = 65.8 mm, and PI-LL = 15.6°. At 2-year follow-up, there was significant improvement in all sagittal modifiers with 25.7%, 24.3%, and 33.1% of the patients matching their age alignment targets in terms of PT, PI-LL, and SVA, respectively. For PT and PI-LL, the three groups (MATCHED, OVER, and UNDER) had comparable values and offsets from age-adjusted PROM. However, for SVA groups, patients in UNDER had significantly worse HRQOL than the two other groups. Patients in PT, PI-LL, and SVA UNDER groups were significantly younger than the other groups, $P < 0.05$.

Conclusion. At 2 years after adult spinal deformity surgical treatment, only 24.3% to 33.1% of the patients reached age-adjusted alignment thresholds. Those under corrected in SVA demonstrated worse clinical outcomes. No significant improvements were found between matched and overcorrected patients, with overcorrection being an established risk for proximal junctional kyphosis. These results further emphasize the need for patient specific operative planning.

Key words: adult spinal deformity, age, age-adjusted alignment, threshold, health-related quality of life, sagittal alignment, sagittal balance, sagittal malalignment, spinopelvic alignment, over correction.

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From the *Department of Neurosurgery, University of Illinois at Chicago, Chicago, IL; [†]Department of Orthopedic Surgery, Hospital for Special Surgery, New York City, NY; [‡]Department of Neurosurgery, University of Virginia, Charlottesville, VA; [§]San Diego Center for Spinal Disorders, La Jolla, CA; [¶]Department of Orthopedic Surgery, Baylor Scoliosis Center, Plano, TX; ^{||}Department of Orthopedic Surgery, University of Kansas Medical Center, Kansas City, KS; **Swedish Neuroscience Institute, Seattle, WA; ^{††}Denver international spine clinic, Presbyterian St. Luke's Medical Center, Rocky Mountain hospital for children, Denver, CO; ^{‡‡}Department of Orthopedic Surgery, Washington University, St Louis, MO; and ^{§§}Department of Neurological Surgery, University of California, San Francisco, San Francisco, CA.

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J.K.S. and R.L. contributed equally to this work.

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Address correspondence and reprint requests to Virginie Lafage, PhD, Department of Orthopedic Surgery, Spine Service, Hospital for Special Surgery, 523 East 72nd Street, New York, NY 10021; E-mail: virginie.lafage@gmail.com

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Adult spinal deformity (ASD) is associated with sagittal spinopelvic malalignment, which has been correlated with significant pain and disability.¹⁻⁷ It has been well established that increased sagittal vertical axis (SVA) is associated with poor health-related quality of life (HRQOL).^{1-4,7-9} This concept has been expanded to spinopelvic parameters including, pelvic tilt (PT) and the mismatch between pelvic incidence and lumbar lordosis (PI-LL), which also have a fundamental role in spinal alignment and HRQOL.^{5,10,11} The goal of ASD surgery is to restore sagittal and coronal alignment based on established thresholds for the primary sagittal parameters of PT, PI-LL, and SVA.

An initial attempt at defining these thresholds was based on correlation between radiographic parameters and baseline patient-reported HRQOL from a large cohort of diverse ASD patients.¹² These thresholds were calculated from a fixed Oswestry Disability Index (ODI) value of 40, representing moderate-severe disability.¹² Although, these thresholds have proven to be clinically useful in sagittal deformity correction, it is known that HRQOL scores tend to decline with age.^{13,14} In addition, there are many factors that affect spinal alignment such as patient's age, encompassing muscle atrophy, arthritis, and other degenerative changes. Therefore, age-adjusted sagittal alignment thresholds have been recently reported (Table 1)¹⁵ and calculated based on age-adjusted HRQOL scores. As patient's age, the thresholds for PT, PI-LL, and SVA related to moderate-severe disability increase.¹⁵ Thus, based on these new findings, it is now becoming important to account for the age in the preoperative planning process.

However, it has yet to be determined if surgical correction to these new age-adjusted thresholds offers an extra clinical benefit. Given that the sagittal alignment thresholds increase with age, there may be significant over-correction currently taking place by using the standard thresholds previously established. Over-correction has been associated to greater risk of proximal junctional failure¹⁶ and could lead to worse clinical outcomes, as the patients are not adapted to be in such an aligned position. Therefore, the purpose of the current study was to investigate the impact of ASD correction to the new age-adjusted thresholds for sagittal alignment on

HRQOL at 2-year follow-up. The hypothesis was that over or under-correction based the age-adjusted alignment thresholds will negatively impact HRQOL.

METHODS

Patient Population

This study is a retrospective review of a prospective multicenter ASD database, which is composed of patients from 11 sites across the United States. All patients were enrolled into an Institutional Review Board-approved protocol by each site. Inclusion criteria for the databases were: age ≥ 18 years and the presence of spinal deformity, as defined by any coronal Cobb angle ≥ 20°, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) ≥ 25°, or thoracic kyphosis (TK) ≥ 60°. Exclusion criteria included spinal deformity of a neuromuscular etiology and presence of active infection or malignancy.

Data Collection, Radiographic Assessment, and HRQOL

The demographic and clinical data collected included patient's age, sex, body mass index (BMI), and Charlson Comorbidity Index (CCI).¹⁷

Full-length posteroanterior and lateral spine radiographs (36" cassette) at baseline and 2-years follow-up were analyzed using validated software^{18,19} (Spineview, ENSAM, Laboratory of Biomechanics, Paris, France). All radiographic measures were performed at a central location based on standard techniques²⁰ and included the maximum coronal Cobb angles of thoracic and lumbar curves, coronal C7 plumbline, and TK (T4-T12); Cobb angle between superior endplate of T4 and inferior endplate of T12), SVA (offset of C7 plumbline relative to S1), PT, and the mismatch between pelvic incidence (PI) and lumbar lordosis (PI-LL). Based on the above radiographic parameters, patients were also stratified by the SRS-Schwab adult spinal deformity classification.²¹

Standardized HRQOL measures were also recorded at baseline and 2-year follow-up and included the ODI, Short-Form-36 (SF-36), and Scoliosis Research Society-22r (SRS-22r). Two standard summary scores were calculated

TABLE 1. Radiographic thresholds corresponding to an ODI of 20 (left) and 40 (right) adapted from Lafage *et al*¹⁵

Age Group, Yrs	ODI = 20					ODI = 40				
	PT	PI-LL	LL-TK	SVA	TPA	PT	PI-LL	LL-TK	SVA	TPA
<35	11.3	-6.8	27.6	-17.4	6.2	13.2	1.8	24.5	5	9.8
35-44	15.1	-2.7	20.7	5.2	11.5	17	5.9	17.6	27.6	15
45-54	17.8	0.2	15.7	21.6	15.3	19.7	8.8	12.6	44	18.8
55-64	20.2	2.9	11.3	36.1	18.7	22.2	11.5	8.2	58.5	22.2
65-74	22.6	5.5	6.9	50.4	22	24.6	14.1	3.8	72.8	25.5
≥75	25.2	8.3	2.1	65.8	25.6	27.1	16.9	-1.0	88.2	29.1

LL-TK indicates lumbar lordosis minus thoracic kyphosis; ODI, Oswestry Disability Index; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SVA, sagittal vertical axis; TPA, T1 pelvic angle.

based on the SF-36, the physical component summary (PCS) and the mental component summary (MCS). The SRS-22r provides a total score and multiple subdomains, including activity, pain, appearance, mental, and satisfaction. A Numeric Rating Scale (NRS) score ranging from 0 (no pain) to 10 (most unbearable pain) was collected for back and leg pain separately.

Patients were grouped as being under-corrected (UNDER), over-corrected (OVER), or corrected to their corresponding age adjusted threshold ± 10 years (MATCHED) for 2-year postoperative PT, PI-LL, and SVA. The equations used to determine their aged adjusted sagittal parameters were the following¹⁵:

$$PT = \frac{(Age - 55)}{3} + 20, \quad PI - LL = \frac{(Age - 55)}{2} + 3, \quad SVA = 2 \times (Age - 55) + 25$$

Statistical Analysis

Continuous variables were described with the mean and standard deviation. Normality of data was determined using the Shapiro-Wilk test. Comparison of HRQOL means between the groups included one-way analysis of variance (ANOVA) with Tukey’s *post hoc* adjustment to control for Type I error or Kruskal-Wallis test, where appropriate. In addition, the offset from age-appropriate ODI, PCS, and SRS scores^{13,14} were calculated for each patient (offset = 2-year HRQOL score – the HRQOL value for age-matched normal controls) and compared between groups. Frequency analyses for categorical variables were conducted *via* Pearson χ^2 analysis. All statistical analyses were conducted using commercially available software (SPSS v22, IBM, Armonk, NY) and the level of significance was set at $P < 0.05$ for all tests.

RESULTS

Patient Population

A total of 450 patients were eligible for 2-year follow-up and of those, 343 (76.2%) had 2-year follow-up and were included in the current study. There were 284 females (82.8%) and 59 males (17.2%) with a mean age of 57.0 ± 15.1 years, mean BMI 27.3 ± 5.9 , and mean CCI of 1.7 ± 1.7 (Table 2). The following percentages of patients met the SRS-Schwab coronal curve classification criteria: Type N- 30.6%, Type T- 5.2%, Type L- 37.0%, and Type D- 27.1%. The mean of sagittal profile parameters such as PT, PI-LL, and SVA were 23.6 ± 11 degrees, 15.6 ± 21.7 degrees, and 65.8 ± 77.9 mm, respectively. The percentages of the patients meeting age-adjusted correction for the sagittal parameters are presented in Table 2. Patients in the UNDER groups for PT, PI-LL, and SVA were all significantly younger than the MATCH and OVER patients for each group ($P < 0.05$ for all, Table 2). Patients in the UNDER group for SVA had a significantly smaller mean BMI than MATCHED and OVER patients ($P < 0.05$). There were no other significant differences among the demographics of the groups ($P > 0.05$ for all, Table 2).

2-Year HRQOL Analysis

Patients improved for all mean HRQOL measures at 2-years compared with preoperative values ($P < 0.05$ for all). For PT and PI-LL, all three groups had statistically similar mean values for 2-year HRQOL ($P > 0.05$ for all, Table 3). For the SVA groups, patients in the UNDER group had significantly worse mean ODI, PCS, and SRS Total at 2 years compared with those patients that were matched or over-corrected ($P < 0.05$ for all, Table 3). In addition, MATCHED and OVER demonstrated similar HRQOL at 2 years (ODI: 26.5 ± 19.4 vs. 24.5 ± 18.6 ;

TABLE 2. Demographics for Different Study Groups

Group	Number	%	Age, Yrs	Female: Male	BMI	CCI
All Patients	343	100	57.0 ± 15.1	284:59	27.3 ± 5.9	1.7 ± 1.7
PT						
Under	133	38.9	53.7 ± 14.2	113:20	27.5 ± 6	1.5 ± 1.7
Match	88	25.7	56.2 ± 15.5	71:17	27.1 ± 5.2	1.7 ± 1.9
Over	121	35.4	61.1 ± 14.8	99:22	27.1 ± 6.3	1.8 ± 1.6
<i>P</i>	–	–	<0.001	0.673	0.633	0.166
PI-LL						
Under	126	36.8	51.4 ± 15.9	102:24	27.5 ± 6	1.6 ± 1.8
Match	83	24.3	57.2 ± 13.8	68:15	28.1 ± 6.5	1.6 ± 1.8
Over	133	38.9	62.1 ± 13.2	113:20	26.6 ± 5.4	1.8 ± 1.6
<i>P</i>	–	–	<0.001	0.677	0.199	0.31
SVA						
Under	112	32.8	53.9 ± 16.7	87:25	28.7 ± 6.6	1.8 ± 1.9
Match	113	33.1	54.4 ± 14.6	94:19	26.8 ± 5.5	1.5 ± 1.7
Over	116	34.0	62.7 ± 11.7	101:15	26.4 ± 5.4	1.7 ± 1.6
<i>P</i>	–	–	<0.001	0.170	0.009	0.243

BMI indicates body mass index; *CCI*, Charlson Comorbidity Index; *PI-LL*, pelvic incidence minus lumbar lordosis; *PT*, pelvic tilt; *SVA*, sagittal vertical axis.

TABLE 3. Mean 2-Year Postoperative ODI, PCS score, and SRS Total Score for Groups of Patients Who Were Under-corrected, Matched, or Over-corrected Based on Their Age-adjusted Alignment Thresholds

Group	%	2-Year ODI	2-Year PCS	2-Year SRS Total
PT				
Under	38.9	29.5 ± 21.5	40.2 ± 11.7	3.6 ± 0.9
Match	25.7	24.5 ± 20	41.3 ± 11.4	3.7 ± 0.8
Over	35.4	29.1 ± 19.8	38.9 ± 11.7	3.6 ± 0.8
<i>P</i>	–	0.159	0.367	0.418
PI-LL				
Under	36.8	29.3 ± 22.2	40.8 ± 11.9	3.6 ± 0.9
Match	24.3	27.8 ± 20	40 ± 12	3.7 ± 0.8
Over	38.9	27.3 ± 19.3	39.3 ± 11.2	3.7 ± 0.7
<i>P</i>	–	0.861	0.653	0.714
SVA				
Under	32.8	33 ± 22.8	37.9 ± 12.5	3.4 ± 0.9
Match	33.1	26.5 ± 19.4	41.7 ± 11.3	3.7 ± 0.8
Over	34	24.5 ± 18.6	40.6 ± 10.9	3.8 ± 0.7
<i>P</i>	–	0.016	0.04	0.006

ODI indicates Oswestry Disability Index; PCS, Physical Component Summary; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SRS, Scoliosis Research Society; SVA, sagittal vertical axis.

PCS: 41.7 ± 11.3 *vs.* 40.6 ± 10.9; SRS Total: 3.7 ± 0.8 *vs.* 3.8 ± 0.7; all *P* > 0.1 for all).

2-Year HRQOL Offsets From an Age-matched Normative Population

The HRQOL offsets for PT and PI-LL were statistically similar among the correction groups (*P* > 0.05 for all, Table 4). Similar to the mean HRQOL results above, the UNDER patients in the SVA group had significantly larger

ODI, PCS, and SRS total offsets from age-matched normal patients than the MATCHED or OVER patients (*P* < 0.05 for all, Table 4) without significant difference between MATCHED and OVER (*P* > 0.05 for all).

DISCUSSION

Recently, new age-adjusted thresholds related to moderate to severe disability have been determined,¹⁵ but it remains unknown if correcting to the new age-adjusted thresholds

TABLE 4. Mean 2-Year Postoperative ODI, PCS score, and SRS Total Score Offsets From Age-matched Normal Controls for the Groups of Patients Who Were Under-corrected, Matched, or Over-corrected Based on Their Age-adjusted Alignment Thresholds

Group	%	2-Year ODI	2-Year PCS	2-Year SRS Total
PT				
Under	38.9	11.1 ± 21.6	−7.4 ± 11.5	−0.7 ± 0.9
Match	25.7	4.9 ± 20.3	−5.6 ± 11.1	−0.5 ± 0.8
Over	35.4	7.4 ± 19.2	−6.5 ± 10.9	−0.6 ± 0.8
<i>P</i>	36.8	0.143	0.550	0.418
PI-LL				
Under	24.3	11.4 ± 22.1	−7.3 ± 11.5	−0.7 ± 0.9
Match	38.9	8.2 ± 18.7	−6.8 ± 11	−0.6 ± 0.8
Over	32.8	5.3 ± 19.8	−5.9 ± 11	−0.5 ± 0.7
<i>P</i>	33.1	0.133	0.553	0.527
SVA				
Under	34	14.2 ± 22.4	−9.6 ± 11.4	−0.8 ± 0.9
Match	37.4	7.9 ± 18.9	−5.7 ± 10.9	−0.5 ± 0.8
Over	22.7	2.5 ± 18.5	−4.5 ± 10.4	−0.4 ± 0.7
<i>P</i>	39.9	<0.001	0.002	0.002

ODI indicates Oswestry Disability Index; PCS, Physical Component Summary; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SRS, Scoliosis Research Society; SVA, sagittal vertical axis.

results in an additional clinical benefit. Therefore, we have performed a large retrospective analysis to investigate the impact of meeting the age-adjusted thresholds on ODI, PCS, and SRS Total. Only 24.3% to 33.1% of the patients met age-adjusted thresholds and thus, it appears most patients may actually be over-corrected based on the prior thresholds for sagittal spinal deformity. This was expected as the surgical plan did not intend to correct the patients to their age-adjusted threshold.

For PT and PI-LL, there were no significant differences in HRQOL for any of the groups. However, the patients that were under-corrected for SVA had significantly worse HRQOL scores than those that were matched to their age-adjusted threshold or to those over-corrected. This finding is not surprising and within the current literature that elevated SVA results in worse HRQOL.^{1-3,22-25} However, under-correction as defined in the current study represents a larger postoperative SVA than the patients respective age-adjusted SVA, thus, under-correction will vary based on their age. For example, in the younger patients (age <44 yrs), an SVA of 5 cm may still be considered under-corrected (Table 1).¹⁵ Thus, it is very important to have a detailed preoperative plan accounting for patients' age and baseline reported HRQOL.

Of more interest is the finding that there were no significant differences in 2-year HRQOL for the patients that were corrected to within their age-matched range and those that were over-corrected based on their age-adjusted threshold for all three of the sagittal parameters. It was initially thought that over-correction may lead to either improved or worse HRQOL as sagittal alignment increases as age increases for a given level of reported disability (Table 1). The older patients have a larger range of sagittal alignment in which their disability is reported as moderate to severe compared to the younger patients that have a much narrower range. For instance, the age-adjusted SVA thresholds based on ODI have been calculated as the following: age < 35 years: 5 mm, 35–44 years: 27.6 mm, 45–54 years: 44 mm, 55–64 years: 58.5 mm, 65–74 years: 72.8 mm, and ≥75 years: 88.2 mm. As older patients require a larger sagittal malalignment to meet severe disability, it is reasonable to infer that over-correction to an SVA <50 mm could result in worse HRQOL. In addition, greater correction may have improved their reported HRQOL, which has been shown repeatedly in the literature, supporting the standard practice to correct to the initial age-independent thresholds of SVA <50 mm; however, neither occurred in the current study. It is critical to keep in mind that for older patients, there appears to be no decrease in HRQOL score and no incremental benefit in correcting their SVA below the value currently defined as the standard threshold (< 50 mm). However, there is an association with over-correction and a larger incidence of PJK development.¹⁶ Therefore, surgery may still be considered a success for older patients even with correction to an SVA higher than 50 mm. Moreover, there is no clinical need to overcorrect based on HRQOL, especially given the potential increased risk of PJK. The goal of surgery

should be to reduce sagittal malalignment to below the new age-adjusted thresholds but without aggressive over-correction if not indicated for another clinically appropriate reason.

To further investigate the relationship between age-adjusted alignment thresholds and HRQOL, the offsets from an age-matched normative population were analyzed, as HRQOL scores decline as age increases. The offset was defined as the difference between the patients' 2-year HRQOL score and their corresponding age-matched normative controls previously published. The results were similar to the mean HRQOL score analyses with no differences between the correction groups for PT and PI-LL. And in the SVA group, the under-corrected patients had significantly larger HRQOL offsets than the other groups without significant differences between the matched and over-corrected patients. This reinforces the results discussed above and adds an additional view on HRQOL analyses. A previous Danish study was also not able to find differences in HRQOL in PT groups; however, statistical significance was revealed in PI-LL and SVA groups, in comparison to only SVA groups in our study.²⁶ The reason being that the relationship between alignment and HRQOL is also confounded by other factors like stenosis, compression, comorbidities, and so on. Moreover, this study grouped patients preoperatively, in contrast to 2-year time point in our analyses.²⁶ Having a larger offset from age-matched normative controls suggests that the HRQOL scores are worse than those patients without spinal deformity. Even though, the goal would be to have patients' HRQOL return to their age-matched normative values postoperatively, it is unlikely to be achieved, given that they have spinal deformity and have undergone a large surgery to correct it. Despite this limitation, approaching the HRQOL normative values is another measure of surgical success and in the current study cohort; under-correction leads to increased offsets, whereas over-correction provides no additional benefit.

Ultimately, the results of this study suggest important implications for future practice. Specifically, it is crucial to determine an age-appropriate threshold of SVA for each patient population in the preoperative planning stage. Furthermore, there is no incremental benefit and not always necessary to over-correct sagittal spinal deformity as defined by SVA for the older population.

The strengths of the current study include the multicenter design with patients enrolled from multiple surgeons comprising 11 different sites across the United States, which allows for better generalizability of the results. Other strength of this study is the complete baseline and 2-year follow-up for the analyzed patients. However, there are a few limitations of this study, one of which includes the retrospective design. Despite the retrospective nature of this study, the data were obtained from a large multicenter prospective database with strict quality control measures. Another limitation is that the preoperative planning did not attempt to correct to age-adjusted thresholds but rather the previously general alignment thresholds. Therefore, the prevalence values for under, matched, and over-correction are limited as they were calculated retrospectively. There were a limited number of patients that were

corrected to their age-adjusted alignment threshold. Furthermore, the MATCHED group was determined based on a range of thresholds between -10 and $+10$ years of their actual age. This is relatively large range, however, it offers a sufficient starting point to investigate the definition of age-matched alignment and the difference between a patient's chronological and biological age is generally within this range. A smaller range did not offer an appropriate amount of patients for analysis. A large, prospective study attempting to correct to age-adjusted alignment thresholds is warranted and will provide significant information on its impact for HRQOL. The current results should not be discounted, as it sets the groundwork and provides insight into the impact of age-adjusted sagittal alignment correction on clinical outcomes.

CONCLUSION

At 2-year follow-up after ASD surgical correction only 22.7% to 38.9% of the patients reached age-adjusted alignment thresholds. The patients that were under-corrected based on age-adjusted SVA demonstrated worse clinical outcomes for ODI, PCS, and SRS Total at 2-year follow-up. No significant improvements were found between matched and over-corrected patients. In the operative management of ASD, over-correction is an established risk for junctional breakdown and these results further emphasize the need for patient specific operative planning. Correction beyond the age-adjusted thresholds does not have a significant clinical benefit.

➤ Key Points

- At 2 years after ASD surgical correction, only 22.7% to 38.9% of the patients reached age-adjusted alignment thresholds.
- The patients that were under corrected based on age-adjusted SVA demonstrated worse clinical outcomes for ODI, PCS, and SRS total at 2-year follow-up.
- There were no significant improvements found between patients who met age-adjusted alignment thresholds and those that were overcorrected.

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