The likelihood of reaching minimum clinically important difference and substantial clinical benefit at 2 years following a 3-column osteotomy: analysis of 140 patients

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OBJECT Three-column osteotomies (3COs) are technically challenging techniques for correcting severe rigid spinal deformities. The impact of these interventions on outcomes reaching minimum clinically important difference (MCID) or substantial clinical benefit (SCB) is unclear. The objective of this study was to determine the rates of MCID and SCB in standard health-related quality of life (HRQOL) measures after 3COs in patients with adult spinal deformity (ASD). The impacts of location of the uppermost instrumented vertebra (UIV) on clinical outcomes and of maintenance on sagittal correction at 2 years postoperatively were also examined.

METHODS The authors conducted a retrospective multicenter analysis of the records from adult patients who underwent 3CO with complete 2-year radiographic and clinical follow-ups. Cases were categorized according to established radiographic thresholds for pelvic tilt ($> 22^\circ$), sagittal vertical axis (> 4.7 cm), and the mismatch between pelvic incidence and lumbar lordosis ($> 11^\circ$). The cases were also analyzed on the basis of a UIV in the upper thoracic (T1–6) or thoracolumbar (T9–L1) region. Patient-reported outcome measures evaluated preoperatively and 2 years postoperatively included Oswestry Disability Index (ODI) scores, the Physical Component Summary and Mental Component Summary (MCS) scores of the 36-Item Short Form Health Survey, and Scoliosis Research Society-22 questionnaire (SRS-22) scores. The percentages of patients whose outcomes for these measures met MCID and SCB were compared among the groups.

ABBREVIATIONS ASD = adult spinal deformity; HRQOL = health-related quality of life; ISSG = International Spine Study Group; MCID = minimum clinically important difference; MCS = Mental Component Summary; ODI = Oswestry Disability Index; PCS = Physical Component Summary; PI-LL = mismatch between pelvic incidence and lumbar lordosis; PSO = pedicle subtraction osteotomy; SCB = substantial clinical benefit; SRS-22 = Scoliosis Research Society-22 questionnaire; SF-36 = 36-Item Short Form Health Survey; SVA = sagittal vertical axis; UIV = uppermost instrumented vertebra; VCR = vertebral column resection; 3CO = 3-column osteotomy.

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RESULTS Data from 140 patients (101 women and 39 men) were included in the analysis; the average patient age was 57.3 ± 12.4 years (range 20–82 years). Of these patients, 94 had undergone only pedicle subtraction osteotomy (PSO) and 42 only vertebral column resection (VCR); 113 patients had a UIV in the upper thoracic ($n = 63$) or thoracolumbar region ($n = 50$). On average, 2 years postoperatively the patients had significantly improved in all HRQOL measures except the MCS score. For the entire patient cohort, the improvements ranged from 57.6% for the SRS-22 pain score MCID to 24.4% for the ODI score SCB. For patients undergoing PSO or VCR, the likelihood of their outcomes reaching MCID or SCB ranged from 24.3% to 62.3% and from 16.2% to 47.8%, respectively. The SRS-22 self-image score of patients who had a UIV in the upper thoracic region reached MCID significantly more than that of patients who had a UIV in the thoracolumbar region (70.6% vs 41.9%, $p = 0.0281$). All other outcomes were similar for UIVs of upper thoracic and thoracolumbar regions. Comparison of patients whose spines were above or below the radiographic thresholds associated with disability indicated similar rates of meeting MCID and SCB for HRQOL at the 2-year follow-up.

CONCLUSIONS Outcomes for patients having UIVs in the upper thoracic region were no more likely to meet MCID or SCB than for those having UIVs in the thoracolumbar region, except for the MCID in the SRS-22 self-image measure. The HRQOL outcomes in patients who had optimal sagittal correction according to radiographic thresholds determined preoperatively were not significantly more likely to reach MCID or SCB at the 2-year follow-up. Future work needs to determine whether the Schwab preoperative radiographic thresholds for severe disability apply in postoperative settings.

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KEY WORDS 3-column osteotomy; pedicle subtraction osteotomy; vertebral column resection; spinal deformity; minimum clinically important difference; substantial clinical benefit; spinal disorders

RIGID adult spinal deformity (ASD) may be surgically corrected with 3-column osteotomy (3CO) techniques such as pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR).^{4,5,8,17,35,38} These techniques allow for significant correction of severe rigid spinal deformity in the sagittal, coronal, and axial planes simultaneously through a posterior-only approach.^{1,4,8,17,18,35,36,38} Both 3CO procedures are technically challenging and are associated with significant morbidity rates, but have resulted in significant improvements in clinical and radiographic outcomes for patients with ASD.^{1,4,6,8,11,12,14,17,21,26} Despite these improvements, suboptimal spinal correction has been reported in 22%–42% of patients undergoing 3COs for ASD.^{3,20,33}

To properly assess spinopelvic alignment, radiographic thresholds indicating severe disability have been established.³² These thresholds have enabled the creation of the validated and clinically relevant Scoliosis Research Society–Schwab classification system for ASD.^{2,31,34,37} It is well documented that patients with ASDs above these thresholds preoperatively have worse health-related quality of life (HRQOL) scores, and a change in the Scoliosis Research Society–Schwab classification score predicts these HRQOL outcomes.³⁴ However, information is lacking about whether meeting these thresholds after a 3CO has an impact on HRQOL. Furthermore, to increase the clinical applicability of the established HRQOL measures, minimum clinically important difference (MCID) and substantial clinical benefit (SCB) values have been established.^{9,10,12} However, there is a paucity of studies investigating the likelihood of surgical correction of ASD leading to outcomes that meet MCID and SCB, and even fewer studies have examined these outcome changes in patients undergoing 3CO. Liu et al., studying MCID among surgical and nonsurgical ASD cohorts, reported that in surgical

patients, outcomes were more likely to reach MCID than in nonsurgical patients.^{10,22}

The optimal proximal termination for long-length posterior fixations continues to be debated. An uppermost instrumented vertebra (UIV) in the upper thoracic region is often used for correcting large coronal curves in the thoracic region, for thoracolumbar kyphosis, and for sagittal malalignment.^{9,18,26} Alternatively, in cases with well-balanced curves, a UIV in the thoracolumbar region is often used.^{9,18,26} A proximal termination in the upper thoracic region may maintain postoperative alignment, but longer operation times and a risk for more complications with this procedure may offset its benefits. To our best knowledge, few studies have investigated the impact of UIV on HRQOL.^{9,28} In a large population of patients with ASD, previous studies have reported that UIV treatment does not influence HRQOL outcomes.^{9,28} However, it is unknown how many patients in these 2 study cohorts underwent a 3CO because the authors did not stratify the patients by osteotomy type. As such, it still remains unclear whether a UIV has an impact on the likelihood of outcomes meeting MCID or SCB for patients undergoing a 3CO.

The current literature focuses on comparing postoperative improvements with respect to preoperative values, averaged across the entire cohort. This comparison includes patients who have poor maintenance of postoperative spinal alignment and suboptimal correction. To our best knowledge, the rates at which patients' outcomes after 3CO reach MCID or SCB are unknown, and it is unclear whether factors such as optimal spinal correction or the location of the UIV influence those rates. Thus, the objective of the present study was to describe the rates of MCID and SCB in patients undergoing 3COs and to evaluate these rates with respect to UIV and to optimal or suboptimal radiographic correction at 2 years postoperatively.

Methods

Patient Population

Using a multicenter ASD database, we conducted a retrospective review of the medical records of 140 patients who underwent a 3CO. Patients were drawn from the International Spine Study Group (ISSG), which is composed of 11 sites across the United States. Internal review board approval was obtained through each of the member sites contributing patients' records. Inclusion criteria for the ISSG database were the following: age ≥ 18 years and presence of spinal deformity, defined by a scoliotic Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt $\geq 25^\circ$, or thoracic kyphosis $\geq 60^\circ$. Exclusion criteria included spinal deformity stemming from a neuromuscular etiology and presence of an active infection or malignant disease.

Patients were categorized into 2 groups according to the anatomical location of their UIV procedure as upper thoracic or thoracolumbar. A UIV in the upper thoracic region was defined as a fixation terminating between T-1 and T-6 and a UIV in the thoracolumbar region as a fixation between T-9 and L-1. Patients were also categorized according to the type of 3CO they received, that is, either a PSO or a VCR. All patients underwent complete baseline examinations and 2-year clinical and radiographic follow-ups.

Data Collection, Radiographic Assessment, and Classification

Demographic and surgical data collected included patient age, sex, body mass index, fixation levels, PSO/VCR sites, operating room time, estimated blood loss, and revision surgery indications. All radiographic measures were performed at a central location with standard techniques²⁵ (Spineview, ENSAM, Laboratory of Biomechanics) and included SVA (that is, C-7 plumb line relative to S-1), pelvic tilt, and the mismatch between pelvic incidence and lumbar lordosis (PI-LL, that is, the Cobb angle between the superior endplate of L-1 and the superior endplate of S-1). Proximal junctional kyphosis was also considered, and its angle was defined as the Cobb measurement between the caudal endplate of the UIV to the cranial endplate 2 vertebrae above. Abnormal radiographic proximal junctional kyphosis was defined as a proximal junctional angle $> 10^\circ$ and at least 10° greater than the corresponding preoperative angle.

Radiographic thresholds that predict severe disability (that is, an Oswestry Disability Index [ODI] score ≥ 40) have been previously established and include an SVA of 4.7 cm, a pelvic tilt of 22° , and PI-LL of 11° .^{19,32,34} On the basis of these thresholds, patients who underwent a PSO were grouped as follows: 1) being either above or below the pelvic tilt threshold at the 2-year follow-up for patients whose spine was above the pelvic tilt threshold preoperatively, 2) being either above or below the SVA threshold at the 2-year follow-up for patients whose spine was above the SVA threshold preoperatively, 3) being either above or below the PI-LL threshold at the 2-year follow-up for patients whose spine was above the PI-LL threshold preoperatively, and 4) being either above or below all 3 of the thresholds at the 2-year follow-up for patients whose spine was above all 3 of the thresholds preoperatively.

Health-Related Quality of Life

The HRQOL measures included the scores from the ODI, the 36-Item Short Form Health Survey (SF-36), and the Scoliosis Research Society–22 questionnaire (SRS-22). Two standard summary scores were calculated according to the SF-36: the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores. The SRS-22 provides a total score and those from 5 subdomains, including activity, pain, self-image, mental, and satisfaction. To increase the clinical applicability of the HRQOL outcomes, MCID values for these measures have been previously established.^{4,9,10,12} The SCB values for the ODI score and the PCS score have also been established and were considered for the current study.¹² The MCID and SCB values used in the present study were as follows: an ODI score MCID of -15 and an ODI score SCB of -18.8 , a PCS score MCID of 5.2 and a PCS score SCB of 6.2, an SRS activity score MCID of 0.375, an SRS pain score MCID of 0.587, an SRS self-image score MCID of 0.8, and an SRS mental score MCID of $+0.42$.

Statistical Analyses

Continuous variables are presented as the mean and SD. An ANOVA or the Kruskal-Wallis test and the Student t-test or Wilcoxon rank-sum test were used as appropriate. Frequency analysis was used for categorical variables. The percentages of patients whose outcomes met MCID or SCB for the HRQOL measures were compared among the respective study groups (above or below the radiographic thresholds) with chi-square analyses. The upper thoracic and thoracolumbar analyses, as well as the postoperative threshold analysis, were conducted with patients who underwent only PSO, as most of these patients underwent correction for sagittal malalignment. A preliminary analysis revealed that data from only a few VCR patients were available for analysis because most of these patients had no preoperative sagittal malalignment, and these patients were therefore omitted from further analyses. The level of statistical significance for all comparisons was set at $p < 0.05$. All data were analyzed with commercially available statistical software (JMP v11.0, SAS Institute, Inc.).

Results

Patients and Procedures

In total, data from 140 patients were analyzed in this study (101 women and 39 men); the average age of these patients was 57.3 ± 12.4 years (range 20–82 years). Complete baseline and 2-year radiographic and HRQOL data were available for all patients; 95 of the patients underwent a PSO performed between T-7 and L-5, and 45 underwent a VCR between T-4 and L-5. Among the patients who underwent a PSO, 3 underwent a second 3CO (2 underwent another PSO at L-4, and 1 underwent a VCR at L-5); thus, 94 patients underwent 1 or more PSOs. Of the patients who underwent a VCR, 6 underwent a second 3CO (3 patients underwent a PSO at T-11, L-5, or S-1, and 3 had another VCR at T-7, T-11, or L-4); thus, in total 42 patients underwent 1 or more VCRs. In total, 113 (80.7%) of the 140 patients underwent a UIV procedure terminating in either the upper thoracic or the thoracolumbar

region; patients who underwent a UIV procedure not in one of these regions were excluded from the analysis. Of the included UIV patients, 78 (69.0%) were women and 35 (31.0%) were men, with an average age of 58.7 ± 11.7 years (range 21–82 years); 63 patients fell into the upper thoracic group and 50 into the thoracolumbar group. Average age, body mass index, operating time, and estimated blood loss are reported in Table 1.

In total, 53 patients (37.9%) underwent at least 1 revision surgery (range 1–6 revisions) within 2 years after the initial 3CO, resulting in a total of 97 revisions. Of these, 54 (55.7%) were performed for mechanical reasons, which included implant failure, pseudarthrosis, and proximal junctional kyphosis. The remaining 43 revisions addressed neurological deficits, sagittal malalignment, wound infection, or instrumentation pain. Thirty-three patients (35.1%) in the PSO group had at least 1 revision (range 1–3 revisions), resulting in a total of 46 revisions, and 18 patients (42.9%) in the VCR subpopulation underwent at least one revision (range 1–6 revisions), resulting in a total of 43 revisions.

Twelve patients (8.6% of all patients) underwent a revision surgery for abnormal proximal junctional kyphosis, 8 (66.7%) of whom were patients who underwent a PSO (8.4% of the PSO subcohort) and 2 of whom were patients who underwent a VCR (4.8% of the VCR subcohort). A similar proportion of patients in the upper thoracic and thoracolumbar surgery groups underwent a revision surgery ($p > 0.05$). Eight patients underwent a revision for abnormal proximal junctional kyphosis. Of these patients, 5 (62.5%) underwent revision in the thoracolumbar region, and 3 (37.5%) in the upper thoracic region ($p > 0.05$); 2 of the 5 patients with thoracolumbar revisions for proximal junctional kyphosis underwent revision twice.

Overall HRQOL Scores and MCID and SCB

At the 2-year follow-up, the combined data from the patients who underwent POS or VCR indicated a significant ($p < 0.05$) improvement in all HRQOL measures with the exception of the MCS score ($p > 0.05$, Table 2). Broken down by type of surgery, patients who underwent a PSO significantly improved in all HRQOL measures ($p < 0.05$)

with the exception of the MCS score and the SRS mental score ($p > 0.05$ for both). The VCR patients significantly improved only in the SRS self-image, satisfaction, and total scores ($p < 0.05$ for all 3 scores).

For patients undergoing PSO only, the HRQOL measure that reached MCID in the greatest percentage of patients was the SRS pain score (62.3%) (Table 3), and the measure that reached MCID least frequently was the ODI score (34.9%). Moreover, in 45.9% of the PSO patients, the PCS score met SCB, but only in 26.5% of these patients did the ODI score meet SCB. For patients undergoing only VCR, the HRQOL measure that reached MCID most frequently (in 57.9% of the patients) was the SRS self-image score. Similar to the PSO group, among the patients who underwent VCR, a greater percentage had PCS scores meeting SCB than ODI scores meeting SCB. Compared with patients who did not undergo revisions, similar percentages of patients in both surgical groups who underwent revision surgery within the 2-year postoperative period had HRQOL outcomes that reached MCID and SCB ($p > 0.05$ for all).

Effect of PSO-UIV Surgery on HRQOL

On average, the cohort undergoing only PSOs ($n = 94$, both upper thoracic and thoracolumbar groups) significantly improved in all HRQOL outcomes ($p < 0.05$ for both groups) except in the MCS score and the SRS function score; the thoracolumbar patients also had no improvement in the SRS mental score ($p > 0.05$). Both the upper thoracic and thoracolumbar groups had similar HRQOL values for all outcomes measured preoperatively (Fig. 1). The upper thoracic and thoracolumbar groups had similar percentages of patients whose outcomes met MCID and SCB ($p > 0.05$ for all), except for the SRS self-image score for which a significantly greater percentage of patients undergoing operations in the upper thoracic regions had outcomes that reached MCID (71.9% vs 46.0%, $p = 0.0281$; Table 4).

Postoperative Spinal Alignment and HRQOL Scores and MCID and SCB in PSO Patients

Of the patients who underwent only PSO ($n = 94$), 78 (83.0%) had spines that were above the pelvic tilt threshold related to disability (that is, an angle $> 22^\circ$) preoperatively, 78 (83.0%) above the SVA threshold of 4.7 cm, 75 (79.8%) above the PI-LL threshold of $> 11^\circ$, and 67 (71.3%) were above all 3 thresholds. The patient numbers and percentages in each of these 3 groups whose spines remained above or were corrected below the thresholds at the 2-year follow-up are listed in Table 5. Most operated spines remained above the thresholds for all groups with the exception of the PI-LL group in which most spines (62.7%) were corrected to below these thresholds.

A comparison of patients whose spines were preoperatively above the radiographic thresholds related to disability and were above or below these thresholds at the 2-year follow-up revealed that those with spines above the pelvic tilt threshold of 22° at the 2-year follow-up had significantly worse preoperative ODI scores (50.6 ± 17.8 vs 41.1 ± 16.4 , $p = 0.039$; Fig. 2). For SVA, those whose spines were

TABLE 1. Demographic data and operative results for patients who underwent either PSO or VCR*

Factor	PSO	VCR
No. of pts	94	42
Age in yrs	59.7 ± 12.3	52.3 ± 11.4
M/F ratio	26:68	11:31
BMI	29.9 ± 7.1	27.4 ± 5.5
Op time (mins)	458.4 ± 145.5	457.9 ± 137.4
EBL (L)	3.0 ± 2.1	2.9 ± 1.6
No. of pts w/ UT UIV	41	22
No. of pts w/ TL UIV	43	5

BMI = body mass index, EBL = estimated blood loss; pts = patients; TL = thoracolumbar; UT = upper thoracic.

* Patients in these 2 groups underwent the indicated procedure both in the initial operation and in any revisions. Values represent mean $\pm$ SD, unless indicated otherwise.

TABLE 2. The mean preoperative and 2-year follow-up HRQOL scores for the patients who underwent either a single-level PSO or a VCR

Procedure & Time Point	MCS Score	PCS Score*	Mean ± SD SRS Score						
			Pain*	Function*	Self-Image†	Mental	Satisfaction†	Total†	ODI Score*
PSO									
Preop	44.8 ± 14.2	30.0 ± 9.2	2.4 ± 0.8	2.7 ± 0.8	2.2 ± 0.8	3.3 ± 1.0	2.7 ± 1.1	2.7 ± 0.7	46.3 ± 18.3
2-yr FU	46.0 ± 13.3	36.9 ± 11.1	3.1 ± 1.0	3.1 ± 1.0	3.3 ± 1.0	3.6 ± 0.9	3.9 ± 1.1	3.3 ± 0.8	35.8 ± 21.0
VCR									
Preop	45.0 ± 14.0	33.7 ± 10.3	2.8 ± 0.9	3.1 ± 1.0	2.3 ± 0.7	3.5 ± 0.9	2.7 ± 1.2	2.9 ± 0.7	33.8 ± 17.8
2-yr FU	47.2 ± 12.0	38.3 ± 10.2	3.1 ± 1.0	3.2 ± 1.1	3.3 ± 1.0	3.8 ± 0.8	3.9 ± 1.0	3.4 ± 0.8	30.4 ± 17.6

FU = follow-up.

* PSO patients showed statistically significant improvement in this score ($p < 0.05$).† Both PSO and VCR patients showed statistically significant improvement in this score ($p < 0.05$).

above the thresholds had significantly worse preoperative ODI scores (52.6 ± 14.6 vs 42.7 ± 18.0 , $p = 0.019$; Fig. 2) and SRS pain scores (2.1 ± 0.7 vs 2.5 ± 0.8 , $p = 0.023$). No significant preoperative differences were observed between above and below the radiographic thresholds for the PI-LL group and all patients ($p > 0.05$ for all comparisons). Moreover, no significant differences were observed in any of the groups for the PCS score (Fig. 3) or other the HRQOL scores ($p > 0.05$ for all comparisons).

Assessment of the adequacy of radiographic correction at the 2-year follow-up revealed that, in cases in which the spines were adequately corrected, most HRQOL measures reached MCID and SCB at the 2-year follow-up; however, this difference did not reach statistical significance ($p > 0.05$; Table 6), except for 3 comparisons: statistically significant differences in the percentage of patients whose outcomes reached MCID were observed for the SRS self-image score in the pelvic tilt group ($p = 0.0419$), the SRS pain score in the PI-LL group ($p = 0.0056$), and for the SRS function score in the All group ($p = 0.0312$). No significant differences in HRQOL outcomes were detected in the SVA group ($p > 0.05$ for all comparisons).

Discussion

Adult spinal deformity remains a serious clinical challenge, and the current surgical techniques for managing this condition are technically demanding. Techniques such as 3COs, including PSO and VCR, improve function, quality of life, and overall health for patients having an ASD.^{17,19,23–25,27,29,30,39} However, these technically demanding and complex procedures may result in complications or in loss of spinal correction over time.^{6–8,15,17,35} The results of the present study indicate that rates of HRQOL measures reaching MCID or SCB after a 3CO are low; the highest rate was 62.3% for the SRS pain score MCID in patients who underwent PSO and the lowest was 24.3% for the ODI score MCID in patients undergoing VCR. The SCB range was even lower at 16.2%–47.8%. In addition, our results suggest that termination of the UIV in either the upper thoracic or the thoracolumbar region does not influence the rate of outcomes meeting MCID or SCB, with the exception of the SRS self-image score. Moreover, patients with optimal spinal correction had better HRQOL scores at 2 years postoperatively. However, outcomes in patients with suboptimal spinal correction had rates of

meeting MCID and SCB in HRQOL measures that were similar to those in patients whose spines maintained correction at 2 years. In addition, we observed that revision surgery for major complications had no detectable impact on these outcomes meeting MCID or SCB.

Ultimately, the percentage of patients undergoing 3CO whose HRQOL measures reached MCID or SCB was less than satisfactory. This may be a result of several factors. First, the thresholds for MCID and SCB in HRQOL were established in a population of patients with lumbar degenerative disease and adolescent idiopathic scoliosis, limiting their use in other patient populations. No study to date has determined MCID and SCB values in ASD patients or in adults undergoing 3COs. Thus, it is possible that the rates of reaching MCID or SCB could have been higher had we used threshold values for these outcome indicators specific for the present population. However, because these specific thresholds have yet to be determined, the currently available values were the best clinical instruments for the present study and may permit comparison with other ASD studies that have used them.

The positive outcome rates reported here are lower than previously reported rates for ASD patients. Liu et al., studying surgical outcomes in 464 ASD patients, showed that surgical intervention significantly increases the likelihood of patients improving across multiple HRQOL measures and their outcomes meeting MCID relative to pa-

TABLE 3. The percentages of patients whose outcomes reached MCID or SCB for the various HRQOL measures, broken down by surgical procedure

Measure	PSO (%)	VCR (%)
MCID		
PCS score	50.0	47.8
SRS score		
Pain	62.3	47.4
Function	56.4	37.8
Self-image	56.4	57.9
Mental	42.9	41.7
ODI score	34.9	24.3
SCB		
PCS score	45.9	47.8
ODI score	26.5	16.2

FIG. 1. Mean preoperative HRQOL scores for patients in the upper thoracic and thoracolumbar surgery groups. Note, the SRS scores were multiplied by 10. Error bars denote 1 SD around the mean. UT = upper thoracic (fixation terminating between T1–6); TL = thoracolumbar (fixation terminating between T9–L1).

tients undergoing nonsurgical treatments.^{10,22} The number of 3CO procedures in the cohort studied by Copay et al. is unclear; however, in the surgical cohort, the maximum MCID rate among patients was 74% for the SRS self-image score, and the lowest was 43% for the SRS mental score.¹⁰ In the present study, across the entire patient cohort we observed a maximum MCID rate of 57.6% for the SRS pain score and a minimum MCID rate of 24.4% for the ODI score. The reasons for the lower MCID rates in patients who underwent 3COs may include a larger magnitude of the spinal deformity than in patients not requiring a 3CO, undergoing a more extensive operation with a possibly longer and more complicated postoperative course, and poor maintenance of spinal correction in the PSO group. Most

patients above a certain radiographic threshold remained above that threshold at the 2-year follow-up. The present study did not attempt to study the above possibilities, but rather serves as a groundwork to report initial MCID and SCB values in populations of spine patients such as 3CO patients.

Schwab et al. have previously established radiographic thresholds indicating severe disability.³² These values were determined according to baseline HRQOL values in surgical and nonsurgical patients, and the impact of surgical correction on these thresholds is unclear. Thresholds for postoperative correction and how they may affect HRQOL may be beneficial for assessing the clinical course of ASD patients. Here, we have shed some light on the applicability of the existing radiographic thresholds for severe disability and their role in influencing HRQOL values. Future work should be aimed at determining whether postoperative thresholds for severe disability differ from those existing preoperatively.

TABLE 4. The percentages of patients who underwent a PSO and whose HRQOL measures met an MCID or a SCB at the 2-year follow-up, broken down by location of the operation (upper thoracic or thoracolumbar)

Measure	UT (%)	TL (%)	p Value
MCID			
PCS score	43.3	58.8	0.215
SRS score			
Pain	65.6	66.7	0.928
Function	53.1	59.5	0.597
Self-image*	71.9	46.0	0.028
Mental	46.9	41.7	0.666
ODI score	31.4	41.0	0.391
SCB			
PCS score	43.3	50.0	0.594
ODI score	25.7	28.2	0.810

* The percentages for both groups were statistically significantly different from the preoperative percentages.

TABLE 5. The number and percentage of PSO patients (n = 94) above or below the radiographic-measure thresholds associated with severe disability (ODI score of ≥ 40) preoperatively and at 2 years postoperatively*

Radiographic Measure	Preop Above	2-Yr FU	
		Above Threshold	Below Threshold
PT	78	53 (67.9)	25 (32.1)
SVA	78	40 (51.3)	38 (48.7)
PI-LL	75	28 (37.3)	47 (62.7)
All	67	18 (26.9)	12 (17.9)

PT = pelvic tilt; All = patients either above all 3 thresholds or below all 3 thresholds.

* Percentages are given in parentheses and were calculated on the basis of the number of patients whose spines were above the indicated threshold preoperatively.

FIG. 2. Mean preoperative ODI scores for patients who underwent PSO and who had scores either above or below the 3 radiographic thresholds associated with severe disability (ODI score ≥ 40) at 2 years postoperatively. The patients analyzed were above the indicated threshold preoperatively. Above = above the radiographic threshold; Below = below the radiographic threshold; PT = pelvic tilt; All = patients either above all 3 thresholds (for pelvic tilt, SVA, and PI-LL) or below all 3 thresholds.

The optimal proximal stopping point for long posterior fixations continues to be debated. Despite many studies demonstrating that ASD correction improves HRQOL, few reports have investigated the effects of the UIV on HRQOL.^{9,13} Moreover, to our best knowledge, ours is the first study investigating both UIV and SCB in patients undergoing 3COs. Ha et al., studying HRQOL outcomes among 89 ASD patients undergoing proximal and distal UIV for treating proximal junctional kyphosis and who were followed up for at least 2 years, reported similar clinical outcomes for the distal and proximal UIV groups.¹³ However, the study included only 19 patients who underwent PSOs and none who underwent VCRs, and MCIDs and SCBs were not reported. Similarly, Kim et al. specifically investigated UIV and HRQOL outcomes in a large ASD population.^{9,16} The authors showed that 91 patients with UIVs terminating in the upper thoracic region (that is, in T2–4) and 107 patients with UIVs terminating in the lower thoracic regions (that is, in T10–L2), had similar clinical outcomes at the 2-year follow-up.⁹ The only postoperative difference the authors noted was the 1-year SRS image score, which was higher in the patients undergoing a UIV procedure in the upper thoracic region. However, these differences had been normalized by the 2-year follow-up.

Our results were similar to those reported previously in that all HRQOL values were similar among the groups, with patients in the upper thoracic group having a higher SRS self-image score both at 2-year follow-up and having a greater likelihood of their outcomes reaching MCID. That outcomes in our patient cohort did not normalize by the 2-year follow-up can likely be attributed to our study's strict focus on patients undergoing PSO, a surgical intervention used for those with severely sagittally malaligned spines. Furthermore, this is a reasonable result, as patients requiring fixation terminating in the upper thoracic region may generally have a greater coronal deformity or overall sagittal malalignment of their spine. Thus, a large spinal correction greatly improves a patient's reported HRQOL in regards to self-image. Unfortunately, the location and

FIG. 3. Mean preoperative PCS score for patients undergoing PSO either above or below the 3 radiographic thresholds associated with severe disability (ODI ≥ 40) at 2 years postoperatively. The patients analyzed were above the indicated threshold preoperatively. Above = above the radiographic threshold; Below = below the radiographic threshold.

magnitudes of any coronal curves was not available from the data, and this lack of data represents a limitation of this study.

The present study attempted to evaluate the importance of optimal sagittal correction on improving clinical status. To date, no study has directly investigated the Schwab radiographic thresholds postoperatively or in patients who underwent a PSO. A study similar to ours by Blondel et al. involved 76 patients whose outcomes were analyzed on the basis of the magnitude of SVA correction and its impact on the likelihood of these patients' outcomes exceeding MCID.⁴ These authors found that substantial or complete correction of an SVA significantly improved the rates of reaching MCID for the ODI and PCS scores and the SCB for the ODI score.

Blondel et al. set substantial curve correction as a 66% or greater improvement from preoperative SVA. However, it is unclear how many of the patients in that study underwent a 3CO, and the authors examined only the SVA. The SVA is often considered the most influential radiographic parameter for HRQOL measures, but because total sagittal alignment is the ultimate goal of 3COs, it is crucial to correlate clinical outcomes with more extensive radiographic measures. Therefore, the present study examined the 3 thresholds most associated with disability, that is, pelvic tilt, SVA, and PI-LL.³² In contrast to the study by Blondel and colleagues, we did not observe any statistical significant difference among the MCID and SCB rates when comparing patients' outcomes either above or below each of these 3 radiographic thresholds at the 2-year follow-up. However, more often than not, patients below 1 of the 3 thresholds at 2 years postoperatively had higher rates of outcomes meeting MCID or SCB for a given HRQOL measure, especially in the All group. It is therefore possible that these radiographic thresholds commonly used preoperatively may not have the same effects postoperatively or that the ODI score cutoff to determine these thresholds may not be ≥ 40 as originally established in the literature.³²

The strengths of the current study include its multicenter design and complete 2-year follow-up of the patients. The patients included in this study were from 11

TABLE 6. Percentages of the patients who underwent a PSO and whose outcomes reached an MCID or a SCB at 2 years postoperatively above or below the radiographic thresholds associated with disability*

Measure	PT		SVA		PI-LL		All	
	Above	Below	Above	Below	Above	Below	Above	Below
MCID								
PCS score	52.4	60.0	59.4	58.6	42.9	61.5	54.6	66.7
SRS score								
Pain	58.5	81.8	62.9	75.9	45.0	80.5	46.2	80.0
Function	57.1	72.7	55.6	65.5	52.4	68.3	50.0	90.0
Self-image	57.1	81.8	55.6	72.4	57.1	68.3	64.3	90.0
Mental	48.8	36.4	45.7	48.3	55.0	39.0	46.2	40.0
ODI score	40.4	39.1	42.9	38.2	33.3	43.2	35.7	40.0
SCB								
PCS score	50.0	55.0	53.1	55.2	38.1	59.0	45.5	55.6
ODI score	29.8	30.4	31.4	29.4	25.0	31.8	28.6	30.0

* Patients included only those whose scores were above the indicated thresholds preoperatively; all differences between the "above" and "below" groups did not reach statistical significance ($p > 0.05$), except for the SRS self-image score MCID in the PT group, SRS pain score MCID in the PI-LL group, and for the SRS function score MCID in the All group ($p < 0.05$).

different sites across the country and underwent procedures performed by multiple surgeons, indicating generalizability of the results. Potential variation in the radiographic measurements was minimized because all of them were performed at a single center with standardized image analysis software. However, this study is not without limitations. These include its retrospective design and that the MCID values used in this study were originally established in a population of patients with lumbar degenerative disease and adolescent idiopathic scoliosis. As a result, the generalizability of these MCID values is limited, but until a prospective study defining MCID values for HRQOL in ASD patients is produced, the current values are the best clinical instruments for studies such as ours. In addition, the lack of information about the location and magnitude of any coronal curves is a limitation, as this information may have played a role in patient selection for upper thoracic or thoracolumbar UIV. Looking ahead, additional insight into the importance of optimal correction on clinical outcomes may be gained from a prospective study with a larger patient cohort.

Conclusions

For patients who underwent a 3CO, the likelihood of their HRQOL measures reaching an MCID and a SCB ranged from 24.3% to 62.3% and 16.2% to 47.8%, respectively. Patients who underwent a UIV procedure terminating in the upper thoracic region were no more likely to have outcomes reaching MCID or SCB compared with patients who underwent a UIV procedure in the thoracolumbar region, except for the MCID in the SRS self-image score. In addition, outcomes in patients whose spines had optimal sagittal correction according to radiographic thresholds determined pre- and postoperatively were not significantly more likely to reach MCIDs or SCBs. Future work is needed to determine whether the Schwab preoperative radiographic thresholds for severe disability apply in postoperative settings.

References

1. Auerbach JD, Lenke LG, Bridwell KH, Sehn JK, Milby AH, Bumpass D, et al: Major complications and comparison between 3-column osteotomy techniques in 105 consecutive spinal deformity procedures. *Spine (Phila Pa 1976)* **37**:1198–1210, 2012
2. Bess S, Schwab F, Lafage V, Shaffrey CI, Ames CP: Classifications for adult spinal deformity and use of the Scoliosis Research Society-Schwab Adult Spinal Deformity Classification. *Neurosurg Clin N Am* **24**:185–193, 2013
3. Blondel B, Schwab F, Bess S, Ames C, Mummaneni PV, Hart R, et al: Posterior global malalignment after osteotomy for sagittal plane deformity: it happens and here is why. *Spine (Phila Pa 1976)* **38**:E394–E401, 2013
4. 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
5. Boachie-Adjei O, Bradford DS: Vertebral column resection and arthrodesis for complex spinal deformities. *J Spinal Disord* **4**:193–202, 1991
6. Bridwell KH: Decision making regarding Smith-Petersen vs. pedicle subtraction osteotomy vs. vertebral column resection for spinal deformity. *Spine (Phila Pa 1976)* **31** (19 Suppl):S171–S178, 2006
7. Bridwell KH, Lewis SJ, Edwards C, Lenke LG, Iffrig TM, Berra A, et al: Complications and outcomes of pedicle subtraction osteotomies for fixed sagittal imbalance. *Spine (Phila Pa 1976)* **28**:2093–2101, 2003
8. Bridwell KH, Lewis SJ, Lenke LG, Baldus C, Blanke K: Pedicle subtraction osteotomy for the treatment of fixed sagittal imbalance. *J Bone Joint Surg Am* **85**:454–463, 2003
9. 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
10. 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

11. Daubs MD, Lenke LG, Cheh G, Stobbs G, Bridwell KH: Adult spinal deformity surgery: complications and outcomes in patients over age 60. **Spine (Phila Pa 1976)** **32**:2238–2244, 2007
12. 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
13. Ha Y, Maruo K, Racine L, Schairer WW, Hu SS, Deviren V, et al: Proximal junctional kyphosis and clinical outcomes in adult spinal deformity surgery with fusion from the thoracic spine to the sacrum: a comparison of proximal and distal upper instrumented vertebrae. **J Neurosurg Spine** **19**:360–369, 2013
14. Hassanzadeh H, Jain A, El Dafrawy MH, Ain MC, Mesfin A, Skolasky RL, et al: Three-column osteotomies in the treatment of spinal deformity in adult patients 60 years old and older: outcome and complications. **Spine (Phila Pa 1976)** **38**:726–731, 2013
15. 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
16. Kim HJ, Boachie-Adjei O, Shaffrey CI, Schwab F, Lafage V, Bess S, et al: Upper thoracic versus lower thoracic upper Instrumented vertebrae endpoints have similar outcomes and complications in adult scoliosis. **Spine (Phila Pa 1976)** **39**(13):E795–E799, 2014
17. Kim YJ, Bridwell KH, Lenke LG, Cheh G, Baldus C: Results of lumbar pedicle subtraction osteotomies for fixed sagittal imbalance: a minimum 5-year follow-up study. **Spine (Phila Pa 1976)** **32**:2189–2197, 2007
18. Kostuik JP, Hall BB: Spinal fusions to the sacrum in adults with scoliosis. **Spine (Phila Pa 1976)** **8**:489–500, 1983
19. Lafage V, Schwab F, Patel A, Hawkinson N, Farcy JP: Pelvic tilt and truncal inclination: two key radiographic parameters in the setting of adults with spinal deformity. **Spine (Phila Pa 1976)** **34**:E599–E606, 2009
20. Lafage V, Smith JS, Bess S, Schwab FJ, Ames CP, Klineberg E, et al: Sagittal spino-pelvic alignment failures following three column thoracic osteotomy for adult spinal deformity. **Eur Spine J** **21**:698–704, 2012
21. Li G, Passias P, Kozanek M, Fu E, Wang S, Xia Q, et al: Adult scoliosis in patients over sixty-five years of age: outcomes of operative versus nonoperative treatment at a minimum two-year follow-up. **Spine (Phila Pa 1976)** **34**:2165–2170, 2009
22. 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
23. Mummaneni PV, Dhall SS, Ondra SL, Mummaneni VP, Berven S: Pedicle subtraction osteotomy. **Neurosurgery** **63** (3 Suppl):171–176, 2008
24. Murrey DB, Brigham CD, Kiebzak GM, Finger F, Chewning SJ: Transpedicular decompression and pedicle subtraction osteotomy (eggshell procedure): a retrospective review of 59 patients. **Spine (Phila Pa 1976)** **27**:2338–2345, 2002
25. O'Brien MF, Kuklo TR, Blanke K, Lenke LG (eds): **Spinal Deformity Study Group Radiographic Measurement Manual**. Minneapolis: Medtronic Sofamor Danek, 2005
26. O'Shaughnessy BA, Bridwell KH, Lenke LG, Cho W, Baldus C, Chang MS, et al: Does a long-fusion "T3-sacrum" portend a worse outcome than a short-fusion "T10-sacrum" in primary surgery for adult scoliosis? **Spine (Phila Pa 1976)** **37**:884–890, 2012
27. Rose PS, Bridwell KH, Lenke LG, Cronen GA, Mulconrey DS, Buchowski JM, et al: Role of pelvic incidence, thoracic kyphosis, and patient factors on sagittal plane correction following pedicle subtraction osteotomy. **Spine (Phila Pa 1976)** **34**:785–791, 2009
28. Scheer JK, Lafage V, Smith JS, Deviren V, Hostin R, McCarthy IM, et al: Maintenance of radiographic correction at 2 years following lumbar pedicle subtraction osteotomy is superior with upper thoracic compared with thoracolumbar junction upper instrumented vertebra. **Eur Spine J** **24** (Suppl 1):S121–S130, 2015
29. 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
30. 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
31. 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
32. Schwab FJ, Blondel B, Bess S, Hostin R, Shaffrey CI, Smith JS, et al: Radiographical spinopelvic parameters and disability in the setting of adult spinal deformity: a prospective multicenter analysis. **Spine (Phila Pa 1976)** **38**:E803–E812, 2013
33. Schwab FJ, Patel A, Shaffrey CI, Smith JS, Farcy JP, Boachie-Adjei O, et al: Sagittal realignment failures following pedicle subtraction osteotomy surgery: are we doing enough? **J Neurosurg Spine** **16**:539–546, 2012
34. 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 non-operative treatment. **Spine (Phila Pa 1976)** **38**:1663–1671, 2013
35. Smith JS, Wang VY, Ames CP: Vertebral column resection for rigid spinal deformity. **Neurosurgery** **63** (3 Suppl):177–182, 2008
36. Suk SI, Kim JH, Kim WJ, Lee SM, Chung ER, Nah KH: Posterior vertebral column resection for severe spinal deformities. **Spine (Phila Pa 1976)** **27**:2374–2382, 2002
37. 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
38. Wang MY, Berven SH: Lumbar pedicle subtraction osteotomy. **Neurosurgery** **60** (2 Suppl 1):ONS140–146, 2007
39. 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

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