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# Likelihood of Reaching Minimal Clinically Important Difference in Adult Spinal Deformity: A Comparison of Operative and Nonoperative Treatment

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## ABSTRACT

**Background:** Few studies have examined threshold improvements in health-related quality of life (HRQOL) by measuring minimal clinically important differences (MCIDs) in treatment of adult spinal deformity. We hypothesized that patients undergoing operative treatment would be more likely to achieve MCID threshold improvement compared with those receiving nonoperative care, although a subset of nonoperative patients may still reach threshold.

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**Methods:** We analyzed a multicenter, prospective, consecutive case series of 464 patients: 225 nonoperative and 239 operative. To be included in the study, patients had to have adult spinal deformity, be older than 18 years, and have both baseline and 1-year follow-up HRQOL measures (Oswestry Disability Index [ODI], Short Form-36 [SF-36] health survey, and Scoliosis Research Society-22 [SRS-22] questionnaire). We compared the percentages of patients achieving established MCID thresholds between operative and nonoperative groups using risk ratios (RR) with a 95% confidence interval (CI).

**Results:** Compared to nonoperative patients, surgical patients demonstrated significant mean improvement ( $P < 0.01$ ) and were more likely to achieve threshold MCID improvement across all HRQOL scores (ODI RR = 7.37 [CI 4.45, 12.21], SF-36 physical component score RR = 2.96 [CI 2.11, 4.15], SRS Activity RR = 3.16 [CI 2.32, 4.31]). Furthermore, operative patients were more likely to reach threshold MCID improvement in 2 or more HRQOL measures simultaneously and were less likely to deteriorate.

**Conclusion:** Patients in both the operative and nonoperative treatment groups demonstrated improvement in at least one HRQOL measure at 1 year. However, surgical treatment was more likely to result in threshold improvement and more likely to lead to simultaneous improvement across multiple measures of ODI, SF-36, and SRS-22. Although a subset of nonoperative patients achieved threshold improvement, nonoperative patients were significantly less likely to improve in

multiple HRQOL measures and more likely to sustain MCID deterioration or no change.

## INTRODUCTION

As the elderly population continues to increase worldwide, their associated medical conditions increase as well. Among these disease states is adult spinal deformity (ASD). Once thought to have an incidence ranging from 1.4% to 32%,<sup>1-3</sup> ASD has an actual incidence greater than 60% in patients over the age of 60 as demonstrated in recent literature.<sup>4</sup> Most healthcare providers, regardless of their specialty, are likely to encounter a patient with ASD. Although the majority of these patients will be asymptomatic, many of them may need nonoperative measures to address their symptoms or even surgical intervention in cases of severe pain and disability.<sup>5</sup> While recent studies have demonstrated the potential for surgery to improve pain and disability,<sup>6-11</sup> risks are involved and not all patients may benefit equally from surgical intervention.<sup>12</sup>

Clinical improvement after operative or nonoperative treatment for patients with ASD can be claimed with a statistically significant change in health-related quality of life (HRQOL) patient-reported clinical outcome scores. HRQOL instruments, such as the Oswestry Disability Index (ODI),<sup>13,14</sup> Short Form 36 (SF-36),<sup>15</sup> and Scoliosis Research Society (SRS)<sup>16-18</sup> questionnaires, assist physicians in tracking a patient's condition during the course of management and the patient's progress after an intervention. The patient can serve as his or her own baseline or be compared to age- and sex-matched reference populations. However, an improved HRQOL score may not necessarily mean that the patient has experienced a clinically significant benefit.<sup>5,19-23</sup>

To optimize the clinical relevance of HRQOL outcomes in adults with scoliosis, thresholds to achieve a minimal clinically important difference (MCID) have been established for the HRQOL instruments.<sup>24,25</sup> The MCID is the smallest amount of improvement on an outcome score that a patient appreciates as meaningful.<sup>19</sup> The MCID marks the absolute minimum change that can be considered a success and serves as a starting point for an analysis of actual patient improvement.<sup>19</sup> However, peer-reviewed literature on the likelihood of patients with ASD reaching threshold improvements in HRQOL by MCID is scarce and even more limited with regard to the quantification of expected improvement or deterioration after operative and nonoperative intervention.<sup>10</sup>

Many studies demonstrate increased quality of life after surgical care for ASD but poor improvement with nonoperative treatment.<sup>5,19-22</sup> Bridwell et al conducted a prospective analysis of patients with symptomatic adult lumbar scoliosis who were treated nonoperatively or surgically and found that quality of life, especially with regard to pain, was significantly better in the operative group at 2-year follow-up.<sup>10</sup> In 2 studies of patients with ASD—1 evaluating treatment outcomes in patients with back pain and 1 evaluating outcomes in patients with leg pain—Smith et al found no mean improvement in the nonoperative groups and significant improvement in the operative groups.<sup>7,8</sup> However, these improvements were reported in HRQOL measures such as lower ODI and numerical rating scale (a pain scale) scores and higher SRS scores but were not based on MCID thresholds. Although nonoperative care may not lead to mean improvement, perhaps no change in quality of life or a lack of deterioration after nonoperative care is a success in patients who are not ready for surgery.

Therefore, the complex nature of ASD warrants further evaluation of surgical indications and assessment of nonoperative care. The purpose of our study was to evaluate the extent to which patients achieve changes large enough to reach the MCID for HRQOL measures such as ODI, SF-36, and SRS-22 in the treatment of ASD. Our hypothesis was that operative treatment would be more likely to achieve MCID threshold improvement compared with nonoperative care but that a subset of patients treated nonoperatively would also reach MCID thresholds for improvement.

## METHODS

### Study Design and Inclusion/Exclusion Criteria

This study is a retrospective analysis of a prospective multicenter, consecutive case database of patients with ASD. Institutional review board approval was obtained at each center prior to individual patient data collection and informed consent was obtained from each patient to be included in the spinal deformity database. To be included in the International Spine Study Group database, patients were required to be adults (older than 18 years) with spinal deformity defined as at least 1 of the following: coronal Cobb angle  $\geq 20$  degrees, sagittal vertical axis (SVA)  $\geq 5$  cm, pelvic tilt  $\geq 25$  degrees, or thoracic kyphosis  $\geq 60$  degrees. Both nonoperatively and operatively treated patients were enrolled and included in the database. Inclusion criteria for the current analysis consisted of any patient with complete data collection at baseline and 1-year follow-up. The assignment to operative or nonoperative treatment was not randomized; instead, assignment involved

patient input and physician counseling on the complexities of the decision and the outcomes of care.

This study population included 464 patients (397 women and 67 men) with an average age of 54.76 years ( $\pm 15.44$  years). As expected, because ASD is found in a higher proportion of females than males, the majority of our patient population was female.<sup>26</sup> In the nonoperative group ( $n=225$ ), the average age of the 193 women and 32 men was 53.43 years ( $\pm 15.82$  years). In the operative group ( $n=239$ ) the average age of the 204 women and 35 men was 55.98 years ( $\pm 15.00$  years).

### Data Collection

Patient demographic data collected included age, sex, race, body mass index (BMI), medical comorbidities, prior surgery status, smoking status, and employment status. Scores for HRQOL measures—ODI, SRS-22, and SF-36—were recorded preoperatively and at 1-year follow-up.

Patient SRS-22 scores for 4 domains—activity, pain, appearance, and mental—were compared to a reference population. Baldus et al reported normative data on the SRS instrument among sex and age groups based on 1,346 adults without scoliosis, thereby establishing a reference population for comparison of patients preoperatively and postoperatively.<sup>27</sup> We matched patients in our study by age and sex to this reference population, compared SRS-22 scores at baseline and at 1-year follow-up, and reported the difference in our patients' scores from the normative data.

The MCID for ODI, SF-36 PCS, and each SRS domain were calculated in a manner similar to prior studies.<sup>5,19–22</sup> We calculated the change in HRQOL measures from baseline to 1-year follow-up and used that data to determine the number of MCIDs gained or lost. In other words, we divided the change in each HRQOL measure by the established MCID value to determine whether patients improved, deteriorated, or remained unchanged. The MCID values for this patient population were 12.8 for the ODI, 4.9 for the SF-36 physical component score, 0.587 for SRS pain, 0.8 for SRS appearance, 0.375 for SRS activity, and 0.42 for SRS mental.<sup>20,21,25,28,29</sup>

For example, the calculation to determine MCID for SRS pain is as follows:

$$\begin{aligned} & [(SRS\ pain\ postoperatively) \\ & - (SRS\ pain\ preoperatively)] / 0.587 \\ & = \# \text{ of MCIDs gained or lost} \end{aligned}$$

An MCID change greater than +1 was considered improvement, an MCID change less than -1 was considered deterioration, and a change between -1

and +1 was considered no change. Each patient in the operative and nonoperative groups was assessed for reaching MCID threshold improvement, deterioration, or no change.

Treatment groups were also compared utilizing risk ratio (RR), calculated by contingency tables, with 95% confidence intervals. RR compared the number of patients in the operative group reaching MCID threshold improvement or no MCID improvement (no change and deterioration were grouped together) to the nonoperative group; essentially, this analysis was an assessment of the likelihood of reaching MCID and a determination of which treatment group was more likely to achieve it.

### Statistical Analysis

The data were analyzed using SPSS version 20.0 software (IBM). The operative patients and nonoperative patients were compared for differences in demographics, HRQOL scores, and likelihood of reaching MCID threshold for HRQOL measures. For categorical variables, cross-tabulations were generated. For comparison to the normative population, patients were matched by age and sex to the SRS domain scores, and the mean differences at baseline and 1-year follow-up were calculated. Normal distributions of SRS domain scores were not seen among the reference and study populations, so statistical significance of the median difference from the normative values was determined utilizing nonparametric related samples testing for nonnormally distributed data.

Within the operative and nonoperative patient groups, analyses were performed to compare the baseline and 1-year HRQOL scores and the likelihood of reaching threshold MCID. Frequencies for reaching threshold improvement in 1 or more HRQOL measures in the operative and nonoperative groups were calculated. For continuous variables in which data were collected preoperatively and postoperatively within a group, paired *t* tests were used to determine if a significant change occurred between time points. A Student *t* test was used to assess the difference of continuous measures across operatively and nonoperatively treated patient groups. RR tests were used for dichotomous data analysis. A *P* value  $< 0.05$  was considered statistically significant.

## RESULTS

### Demographics

The comparison of demographic data between patients in the operative ( $n=239$ ) and nonoperative ( $n=225$ ) groups revealed no significant differences in age or sex (Table 1). Patients in the operative group had a higher rate of prior surgery (43%) compared to

**Table 1. Patient Demographics in the Operative and Nonoperative Groups**

Variable	n	Operative Group	n	Nonoperative Group	P value
Mean age, years	239	55.98	225	53.43	0.07
Sex, female	204	85%	193	86%	0.90
Mean body mass index, kg/m <sup>2</sup>	239	26.9	225	25.4	<0.01
Prior surgery	103	43%	46	20%	<0.01

patients in the nonoperative group (20%) ( $P<0.01$ ). Patients in the operative group also had a higher average BMI at 26.9 kg/m<sup>2</sup> compared to the average in the nonoperative group of 25.4 kg/m<sup>2</sup> ( $P<0.01$ ).

**Baseline HRQOL Outcomes**

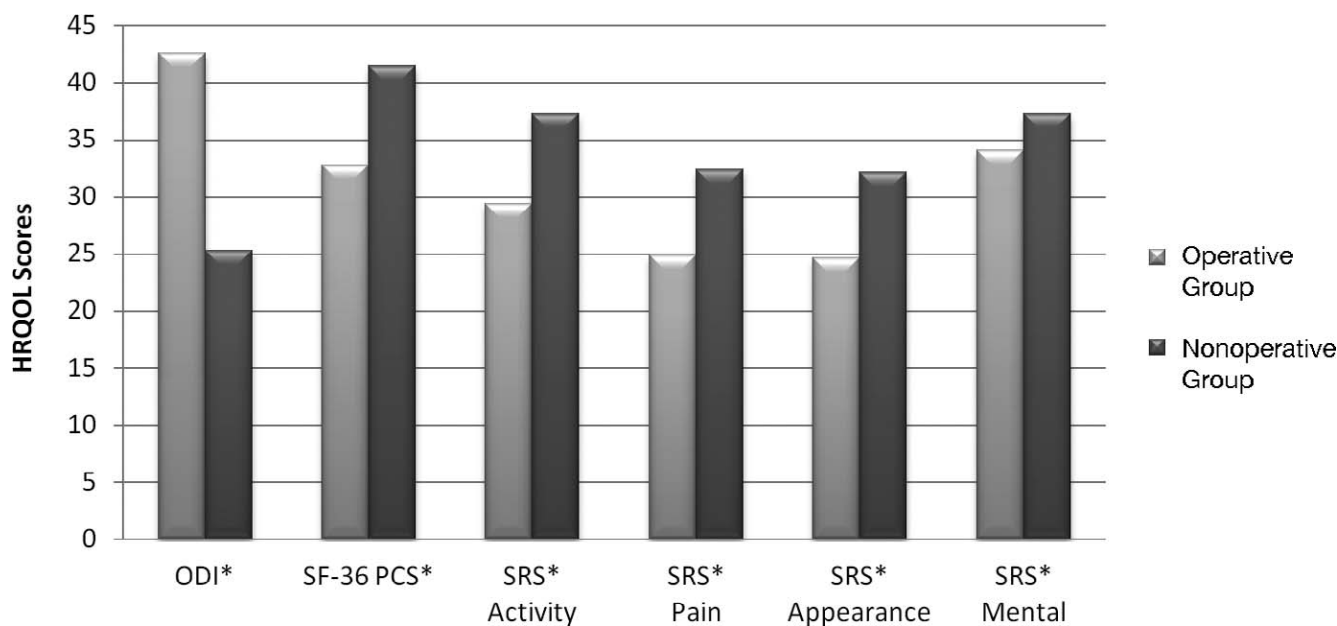
At baseline, the analysis of patient-reported outcomes revealed that patients in the operative group had significantly poorer HRQOL scores (all  $P<0.01$ ) across all measures compared to patients in the nonoperative group (Figure 1).

At baseline, values for all SRS domains in the nonoperative and operative groups were significantly different compared to the reference population values (Table 2). All the differences from the normative values were statistically significant ( $P<0.05$ ) across

all 4 SRS domains: activity, pain, appearance, and mental. At baseline, patients in the nonoperative group tended to have SRS domain scores closer to the reference population normative value, while patients in the surgical group had significantly greater baseline differences from the reference population normative value for each SRS domain.

**One-Year HRQOL Outcomes**

At 1-year follow-up, the comparison of patient-reported outcomes between patients in the operative and nonoperative group revealed statistically significant differences ( $P<0.01$ ) in only 2 SRS domains: activity and appearance (Figure 2). Patients in the operative group demonstrated lower scores in activity and higher scores in appearance compared to



**Figure 1. Baseline health-related quality-of-life (HRQOL) measures for patients in the operative and nonoperative groups. Operative patients demonstrated a higher baseline disability across all HRQOL measures, with a higher average Oswestry Disability Index (ODI) score and lower average Scoliosis Research Society (SRS) and Short Form 36 physical component score (SF-36 PCS) scores compared to nonoperative patients.**

\*All differences were statistically significant ( $P<0.01$ ). The range for ODI is 0 to 100, with higher numbers reflecting greater disability. The range for SF-36 is 0 to 100, with 100 indicating the highest level of health. The range for SRS is 0 to 5, with higher scores reflecting better health status. The SRS scores were multiplied by 10 for the purposes of the figure.



**Table 2. Scoliosis Research Society (SRS) Questionnaire Domain Score Difference from Reference Population at Baseline for Patients in the Operative and Nonoperative Groups**

SRS Domain	Operative Group <sup>a</sup> n=239	Nonoperative Group <sup>a</sup> n=225
Activity	1.20	0.43
Pain	1.77	1.09
Appearance	1.70	0.94
Mental	0.65	0.29

All differences are reported as means.

<sup>a</sup>All median differences were statistically significant with  $P < 0.05$  by nonparametric related samples testing.

patients in the nonoperative group. The differences in disability, SF-36 physical component score, and other SRS domains were not significant.

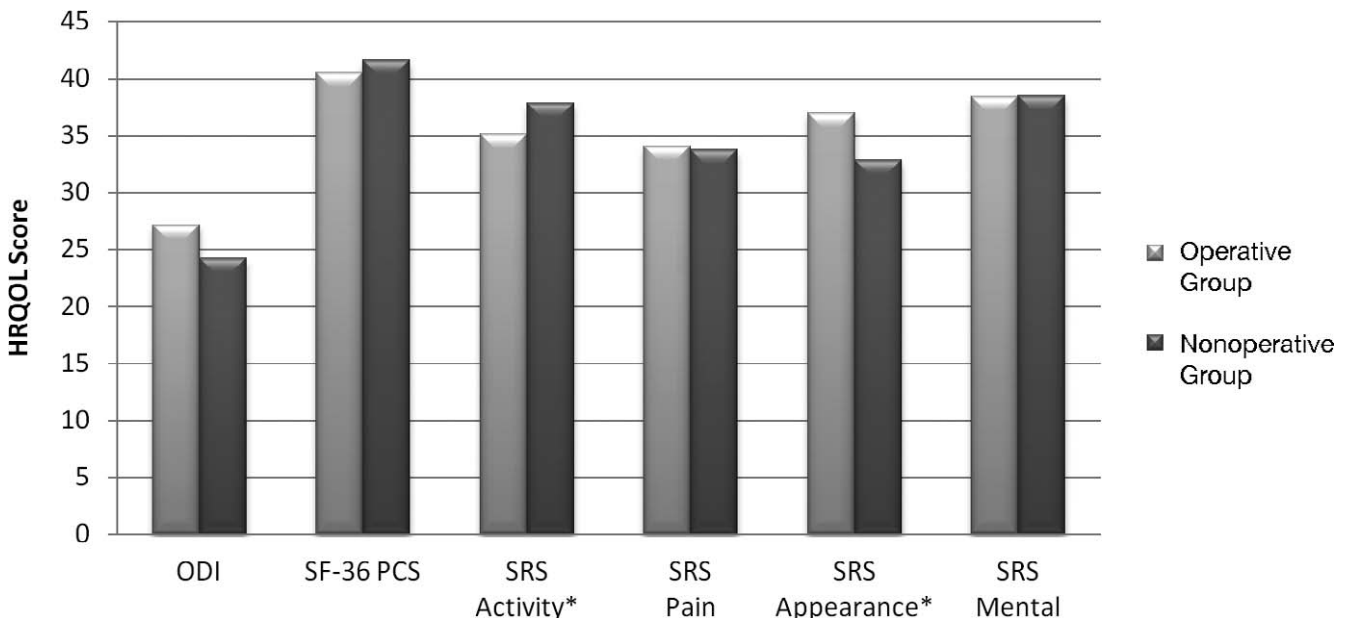
Significant differences also occurred between the nonoperative and operative groups compared to the reference population after 1 year. Nonoperative patients had an SRS activity score closer to the reference population compared to the operative group, while patients in the operative group had an SRS appearance score closer to the reference population compared to the nonoperative group (Table 3). Scores for the pain and mental SRS

domains also revealed significant differences from the reference population in the operative and nonoperative groups, but both were about equally distant from the normative values.

### Mean Change in HRQOL Scores from Baseline to 1-Year Follow-Up

Over the course of 1 year, surgical patients demonstrated significant improvement ( $P < 0.01$ ) in ODI, SF-36 physical component score, and all 4 SRS domain scores (Table 4). Patients in the nonoperative group had a statistically significant mean improvement in SRS pain only ( $P < 0.01$ ) and no significant mean improvement or decline in the other SRS domains, ODI, and SF-36. Overall, the operative group demonstrated a larger change in HRQOL measures at 1 year compared to the nonoperative group. The differences between the HRQOL changes from baseline to 1 year were statistically significant between the operative and nonoperative group ( $P < 0.01$ ).

Table 4 also shows the mean change in number of MCIDs for each outcome measure. Calculations were based on established MCID values as described in the Methods section. The surgical group demonstrated larger changes in MCID compared to the nonoperative group. On average, patients in the operative arm improved more than 1 MCID, while patients in the



**Figure 2. Health-related quality-of-life (HRQOL) measures for patients in the operative and nonoperative groups at 1-year follow-up.**

\*Only Scoliosis Research Society (SRS) domains activity and appearance were statistically significant ( $P < 0.01$ ). Oswestry Disability Index (ODI), Short Form 36 physical component score (SF-36 PCS), and other SRS domain scores were not statistically significant. SRS scores range from 0 to 5 and were multiplied by 10 for the purposes of the figure. The range for ODI is 0 to 100, with higher numbers reflecting greater disability. The range for SF-36 is 0 to 100, with 100 indicating the highest level of health.

**Table 3. Scoliosis Research Society (SRS) Questionnaire Domain Score Difference from Reference Population at 1-Year Follow-Up for Patients in the Operative and Nonoperative Groups**

SRS Domain	Operative Group <sup>a</sup> n=239	Nonoperative Group <sup>a</sup> n=225
Activity	0.68	0.45
Pain	0.90	0.96
Appearance	0.47	0.91
Mental	0.26	0.26

All differences are reported as means.

<sup>a</sup>All median differences were statistically significant with  $P < 0.05$  by nonparametric related samples testing.

nonoperative arm improved less than 0.25 MCID. On average, the patients who underwent surgery reached the MCID threshold improvement.

**Likelihood of Reaching MCID Threshold**

Table 5 shows the analysis of the patients who reached MCID threshold improvement. Within the operative arm, patients had the highest rate of achieving threshold improvement in the SRS appearance domain (74%) and the lowest rate of achieving threshold improvement in the SRS mental domain (43%). Within the nonoperative arm, patients had the highest rate of achieving threshold improvement in

the SRS pain domain (24%) and the lowest rate of threshold improvement in ODI (7%).

The likelihood of achieving MCID threshold improvement was favorable for the operative group for all measures of HRQOL assessed in the present study; in particular, the likelihood was highest for the SRS appearance domain with an RR of 5.55 (95% confidence interval [CI]: 3.74 to 8.25).

We analyzed both operative and nonoperative treatment groups for reaching threshold in at least 1 or more HRQOL measures, 2 or more HRQOL measures, and 4-6 HRQOL measures. More than 50% of patients in each group reached threshold improvement in at least 1 HRQOL measure; however, no statistically significant difference in relative risk occurred at 1 HRQOL measure although patients in the operative group were significantly more likely to achieve MCID thresholds for improvement in multiple measures.

We also evaluated the patients who reached the threshold for MCID deterioration (Table 6). Patients in the operative group reached MCID threshold deterioration in 15% or fewer cases for each HRQOL measure. In contrast, patients in the nonoperative group had higher rates of threshold deterioration (6% to 25%) for all HRQOL measures compared with patients in the operative group ( $P < 0.01$ ). Further analysis with risk ratios revealed that nonoperative patients demonstrated a higher risk of reaching threshold deterioration with a 95% confidence interval

**Table 4: Mean Change in Health-Related Quality-of-Life Scores at 1 Year Compared to Baseline**

Patient-Reported Outcome Measure	Operative Group n=239			Nonoperative Group n=225			Comparison of Change P Value
	Mean Change at 1 Year	P Value	Mean MCID Gained/Lost <sup>a</sup>	Mean Change at 1 Year	P Value	Mean MCID Gained/Lost <sup>a</sup>	
ODI <sup>b</sup>	-13.64	<0.01	1.07	-0.74	0.28	0.06	<0.01
SF-36 PCS <sup>c</sup>	6.90	<0.01	1.41	-0.46	0.28	-0.09	<0.01
SRS Activity <sup>d</sup>	0.50	<0.01	1.34	-0.03	0.42	-0.07	<0.01
SRS Pain <sup>e</sup>	0.86	<0.01	1.47	0.13	<0.01	0.22	<0.01
SRS Appearance <sup>f</sup>	1.22	<0.01	1.52	0.04	0.35	0.05	<0.01
SRS Mental <sup>g</sup>	0.39	<0.01	1.01	0.03	0.49	0.08	<0.01

MCID, minimal clinically important difference; ODI, Oswestry Disability Index; SF-36 PCS, Short Form 36 physical component score; SRS, Scoliosis Research Society.

<sup>a</sup>Mean MCID gained/lost = (Postoperative score – preoperative score)/MCID reference value. MCID >1 is considered improvement; MCID <-1 is considered deterioration; MCID of -1 to +1 is considered no change.

<sup>b</sup>MCID reference value for ODI = 12.8.

<sup>c</sup>MCID reference value for SF-36 PCS = 4.9.

<sup>d</sup>MCID reference value for SRS Activity = 0.375.

<sup>e</sup>MCID reference value for SRS Pain = 0.587.

<sup>f</sup>MCID reference value for SRS Appearance = 0.8.

<sup>g</sup>MCID reference value for SRS Mental = 0.42.

All mean changes in the operative group were statistically significant ( $P < 0.01$ ); in the nonoperative group, only mean change in SRS Pain ( $P < 0.01$ ) was statistically significant. Mean changes between the operative and nonoperative groups in all HRQOL scores from baseline to 1 year were statistically significant ( $P < 0.01$ ).

**Table 5. Patients Reaching Minimal Clinically Important Difference Threshold Improvement**

Patient-Reported Outcome Measure	n	Operative Group <sup>a</sup> n=239	n	Nonoperative Group <sup>a</sup> n=225	Risk Ratio <sup>b</sup>	Confidence Interval
ODI	118	49%	15	7%	7.37	(4.45, 12.21)
SF-36 PCS	107	45%	34	15%	2.96	(2.11, 4.15)
SRS Activity	151	63%	45	20%	3.16	(2.32, 4.31)
SRS Pain	154	64%	54	24%	2.68	(2.01, 3.58)
SRS Appearance	177	74%	30	13%	5.55	(3.74, 8.25)
SRS Mental	103	43%	39	17%	2.49	(1.83, 3.38)
≥1 HRQOL measures	175	73%	117	52%	1.41	(0.95, 2.09)
≥2 HRQOL measures	161	67%	50	22%	3.03	(1.97, 4.68)
4-6 HRQOL measures	103	43%	3	1%	32.32	(10.04, 104.07)

HRQOL, health-related quality of life; ODI, Oswestry Disability Index; SF-36 PCS, Short Form 36 physical component score; SRS, Scoliosis Research Society.

<sup>a</sup>All percentages of patients achieving threshold improvement are statistically significant ( $P < 0.01$ ).

<sup>b</sup>Risk ratio reflects the difference in reaching threshold minimal clinically important difference improvement between the operative and nonoperative group (employing a 95% confidence interval). It was significant across all HRQOL scores and 2 or more simultaneous HRQOL measures.

in all HRQOL measures except ODI. The highest percentage of threshold deterioration in the nonoperative group was for the SRS activity measure (25%). When comparing the 2 groups for the likelihood of MCID deterioration, patients in the operative group were approximately one-half as likely to deteriorate compared to patients in the nonoperative group, especially for the SRS domains of activity, pain, appearance, and mental as well as the SF-36 physical component score.

Some patients in both the operative and nonoperative groups reached neither threshold improvement nor threshold deterioration and were classified as having not reached MCID change (Table 7). In the operative group, 23%-48% of patients did not sustain an MCID change in the HRQOL measures. Among patients in the nonoperative group, 55%-87% of patients did not sustain an MCID change. When

comparing the nonoperative to operative group for not reaching MCID threshold deterioration or improvement, the operative group had a lower relative risk—ranging from 0.31 to 0.73—across all HRQOL measures and was thus less likely to remain unchanged. Stated another way, patients in the nonoperative group were up to 3 times as likely to show neither MCID improvement nor deterioration with a 95% CI.

## DISCUSSION

In this study, we attempted to analyze and quantify clinically noticeable change that patients with ASD experience during their nonsurgical management or after their operative care. We used the MCID to further describe changes in HRQOL scores and place them in the context of clinical gain or loss. We

**Table 6. Patients Reaching Minimal Clinically Important Difference Threshold Deterioration**

Patient-Reported Outcome Measure	n	Operative Group <sup>a</sup> n=239	n	Nonoperative Group <sup>a</sup> n=225	Risk Ratio <sup>b</sup>	Confidence Interval
ODI	12	5%	14	6%	0.80	(0.48, 1.34)
SF-36 PCS	30	13%	47	21%	0.60	(0.46, 0.78)
SRS Activity	37	15%	56	25%	0.62	(0.49, 0.79)
SRS Pain	14	6%	32	14%	0.41	(0.30, 0.57)
SRS Appearance	9	4%	21	9%	0.40	(0.27, 0.61)
SRS Mental	26	11%	37	16%	0.66	(0.49, 0.89)

ODI, Oswestry Disability Index; SF-36 PCS, Short Form 36 physical component score; SRS, Scoliosis Research Society.

<sup>a</sup>All percentages of patients reaching threshold deterioration are statistically significant ( $P < 0.01$ ).

<sup>b</sup>Risk ratios reflect the difference in reaching threshold minimal clinically important difference deterioration between the operative and nonoperative group (employing a 95% confidence interval). They were significant for SF-36 PCS and all SRS domains.



**Table 7. Patients Who Did Not Reach Minimal Clinically Important Difference Change (No Improvement, No Deterioration)**

Patient-Reported Outcome Measure	n	Operative Group <sup>a</sup> n=239	n	Nonoperative Group <sup>a</sup> n=225	Risk Ratio <sup>b</sup>	Confidence Interval
ODI	104	44%	195	87%	0.50	(0.44, 0.57)
SF-36 PCS	65	27%	123	55%	0.50	(0.43, 0.58)
SRS activity	56	23%	124	55%	0.43	(0.37, 0.49)
SRS pain	76	32%	139	62%	0.51	(0.45, 0.59)
SRS appearance	58	24%	174	77%	0.31	(0.28, 0.35)
SRS mental	115	48%	149	66%	0.73	(0.62, 0.84)

ODI, Oswestry Disability Index; SF-36 PCS, Short Form 36 physical component score; SRS, Scoliosis Research Society.

<sup>a</sup>All percentages of patients who did not reach threshold change are statistically significant ( $P < 0.01$ ).

<sup>b</sup>Risk ratios reflect the difference in reaching no minimal clinically important difference change between the operative and nonoperative group (employing a 95% confidence interval). All health-related quality-of-life scores were statistically significant.

also analyzed MCID distribution within subgroups to better refine potentially broad conclusions.

In general, patients in the operative group showed significantly greater improvements in HRQOL measures and also had a higher likelihood of reaching MCID threshold improvement compared to patients in the nonoperative group. Comparatively, patients in the nonoperative group showed only minor improvements in SRS pain scores, were less likely to reach MCID threshold improvement, and were more likely to reach threshold deterioration or have no change in their scores.

The improvements in HRQOL measures for operative treatment of ASD that we used in this study are similar to those in the literature. Prior studies evaluating operative treatment in ASD most commonly use HRQOL measures. Only one study that we were able to identify, investigated by Blondel et al, used MCID to analyze clinical outcomes after surgery.<sup>28</sup> Blondel and colleagues found that a greater magnitude of correction in SVA up to 120 mm results in a significantly greater chance of achieving MCID with regard to disability only (ODI). However, no prior reports include a comparison of operative and nonoperative patients who achieved MCID threshold changes across multiple HRQOL measures, including ODI, SF-36, and SRS-22 domains. The findings of our study are further distinguished from those of the previous reports by inclusion of the percentage of nonoperative patients who also demonstrated MCID threshold improvement.

In a grouped analysis of the HRQOL measures, it may be easy to generalize the mean data and conclude that because patients in the operative group as a whole improved significantly more than patients in the nonoperative group, surgery trumps nonoperative management with regard to clinical decision making (Table 4). However, because all patients contribute to the mean, the distribution of patients

who improve, deteriorate, and remain the same must also be investigated.

When HRQOL measures are analyzed by subsets and not as means, the subgroups with improvements and deterioration are more readily seen. Fifty-two percent of patients in the nonoperative group reached MCID threshold improvement in at least 1 HRQOL measure (Table 5), a percentage much higher than might be expected given the prior literature on HRQOL measures. Additional scrutiny reveals that the percentage of patients reaching MCID threshold improvements in the nonoperative group was as high as 24% in the SRS pain measure and as low as 7% in ODI. A grouped analysis indicates that nonoperative patients improve minimally, but a closer look indicates that the mean may actually be masking a subset of patients who have improved, albeit not as broadly across the spectrum of HRQOL measures as the operatively treated patients.

The 3 categories of MCID change are MCID improvement, MCID no change, and MCID deterioration. The first category is composed of patients who reached MCID threshold improvement. Although more than half of all operative and nonoperative patients achieved threshold improvement in at least 1 HRQOL measure, the impact of improvement was more considerable in the operative group. Only 22% of patients in the nonoperative group improved in 2 or more measures compared to 67% of patients in the operative group. In fact, surgical patients were 3 times more likely to achieve MCID improvement in 2 or more measures than nonoperative patients (95% CI: 1.97 to 4.68). Furthermore, less than 2% of nonoperative patients reached MCID threshold improvement for 4-6 of the HRQOL measures compared to 43% of operative patients, demonstrating that when operative patients achieve MCID threshold, they tend to achieve it across multiple quality-of-life domains.

Regarding specific measures, more than 40% of all patients in the operative group reached threshold MCID improvement in ODI, SF-36, and the SRS domains, compared to less than 25% of all patients in the nonoperative group (Table 5). Among the patients in the nonoperative group, the highest percentage reaching MCID improvement was in the SRS pain measure, while the lowest percentage was in ODI. The surgical group reached the highest percentage of threshold improvement in the SRS appearance measure (74%) and the lowest in the SRS mental measure (43%).

Only 43% of surgical patients achieved MCID improvement in SRS mental—the lowest of all the HRQOL measures reached within that group. This could be due to the fact that baseline SRS mental scores did not start far from the reference values. This could also, in part, reflect the chronic psychosocial impact of spinal deformity on a person. One year might not provide enough time for the mental impact of spinal deformity to be assuaged, even if surgery restores anatomy and aesthetics.

Nonetheless, even the surgical group's lowest percentage of patients reaching MCID threshold improvement was still higher than the nonoperative group's highest percentage—although the greater initial difference from the reference population may be the reason for the MCID improvement in the surgical group. Statistically significant RRs ranged from 2.49 to 7.37 with 95% CIs for the likelihood of improvement in the surgical group compared to the nonoperative group across all HRQOL measures, further supporting the impact of surgery with regard to clinically meaningful changes in quality of life.

MCID deterioration and MCID no change comprise the other categories for MCID change. Overall, 38% (n=86) of all patients in the nonoperative group demonstrated deterioration or no change, while 10% (n=24) of all patients in the operative group deteriorated or did not show any clinically meaningful change. Within each HRQOL measure, 15% or fewer surgical patients showed any MCID deterioration, with the highest deterioration occurring in the SRS activity domain (Table 6).

Patients in the surgical arm were less likely to exhibit deterioration in the SF-36 physical component score and SRS activity domain compared to patients in the nonoperative arm, with RRs of 0.60 (95% CI: 0.46 to 0.78) and 0.62 (95% CI: 0.49 to 0.79), respectively. The surgical patients were also less likely to exhibit deterioration in the other SRS domains. While a lower likelihood of reaching MCID deterioration in the surgical group is noteworthy, it needs to be understood in the context of clinical decisionmaking and patient expectations—deteriora-

tion is a possible outcome of both nonoperative and operative management.

Only ODI exhibited a lower risk of deterioration among the surgical group compared to the nonoperative group that was not completely supported by the confidence interval, with an RR of 0.80 (95% CI: 0.48 to 1.34). The wide CI (crossing 1) suggests a greater uncertainty in drawing conclusions about this potential outcome. Although further information may be needed about ODI, we can confidently conclude based on our data that patients in the operative group are about half (0.4 to 0.6) as likely to deteriorate in SF-36 and SRS domains.

The RRs are exaggerated even more when we look at patients who did not reach any MCID change (Table 7). Patients in the nonoperative group were more likely to deteriorate or exhibit neither improvement nor deterioration compared to surgical patients. Although this outcome may not be surprising, it is important to note that no MCID change in the nonoperative arm may be a positive outcome, while no MCID change in the operative arm is an unacceptable outcome. Notably, however, the patients in our study were sufficiently symptomatic to have warranted referral for surgical evaluation, suggesting that their baseline levels of pain and disability were not satisfactory.

The primary limitation of this study is the short-term follow-up of 1 year. Surgical patients achieve a high rate of MCID threshold improvement at short-term follow-up; at longer term follow-up, few additional patients would be expected to reach threshold improvement given that most changes in HRQOL measures appear to take place during the first year after surgery.<sup>30</sup> The nonsurgical patients were more likely to sustain MCID deterioration or no change, possibly because their HRQOL scores were not as poor as the operative patients at baseline; at longer term follow-up, perhaps more patients will deteriorate or will plateau. Once a patient plateaus, the natural course of the disease, being progressive, will commence. Moreover, improvements in pain may be short lived as a result of decreasing opiate efficacy over time—especially if patients have recently entered the system for treatment.

Additionally, this study does not delve into the characteristics of the subset population of patients in the nonoperative group who demonstrated MCID improvement. This population requires further study. Assessing the details of this population could provide information on how to select patients for nonoperative management and maximize their potential for improvement. Furthermore, while the data were prospectively collected, this study is still limited by the retrospective design and lack of randomization. Patients may improve based on their choices, causing an inherent

bias because the scores may reflect the patient's interest in pursuing surgery or not pursuing surgery.

The future directions of this study are to evaluate if certain factors are predictive of which patients are most likely to achieve MCID threshold improvement with operative and nonoperative management. The literature presents factors that are more important in surgical decision making in adult scoliosis. Glassman et al<sup>31</sup> found that surgical patients had more frequent leg pain, a higher mean level of daily back pain, and more moderate to severe back pain over the past 6 months. Pekmezci et al<sup>32</sup> found that functional domain scores, such as walking in the ODI and vitality in the SRS-30, were significantly worse in the operative group compared to the nonoperative group. These 2 studies indicate that some pain or functional preoperative factors may be predictive of MCID threshold improvement or deterioration.

## CONCLUSION

Previous studies have used HRQOL measures to assess improvement and compare treatment options in patients with adult spinal deformity, but perhaps a more precise way of identifying clinically important change and confirming trends in HRQOL across time involves utilizing MCID.

This study demonstrates that patients undergoing surgery were significantly more likely to achieve MCID threshold improvement across multiple measures of HRQOL scores compared to patients who elected nonoperative management. While patients in the nonoperative group were more likely to sustain no change or reach threshold deterioration, more than 50% of them reached MCID improvement in at least 1 HRQOL measure, demonstrating that in some cases nonoperative management can address some aspects of symptoms and disease. All physicians involved in the care of patients with ASD, regardless of medical specialty, should be aware of the nonoperative options available and expected outcomes so they can properly educate and guide their patients.

Despite the MCID improvement rate of surgically treated patients, a subset of patients either show no change or decline, and these outcomes are unacceptable after such a major intervention. Therefore, careful consideration of the risks, complications, and all possible outcomes of surgery must occur when patients seek to take the next step from nonoperative to operative care.

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