Early Patient-Reported Outcomes Predict 3-Year Outcomes in Operatively Treated Patients with Adult Spinal Deformity

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BACKGROUND: **For patients with adult spinal deformity (ASD), surgical treatment may improve their health-related quality of life. This study investigates when the greatest improvement in outcomes occurs and whether incremental improvements in patient-reported outcomes during the first postoperative year predict outcomes at 3 years.**

METHODS: **Using a multicenter registry, we identified 84 adults with ASD treated surgically from 2008 to 2012 with complete 3-year follow-up. Pairwise *t* tests and multivariate regression were used for analysis. Significance was set at $P < 0.01$.**

RESULTS: **Mean Oswestry Disability Index (ODI) and Scoliosis Research Society-22r total (SRS-22r) scores improved by 13 and 0.8 points, respectively, from preoperatively to 3 years (both $P < 0.001$). From preoperatively to 6 weeks postoperatively, ODI scores worsened by 5 points ($P = 0.049$) and SRS-22r scores improved by 0.3 points ($P < 0.001$). Between 6 weeks and 1 year, ODI and SRS-22r scores improved by 19 and 0.5 points, respectively (both $P < 0.001$). Incremental improvements during the first postoperative year predicted 3-year outcomes in ODI and SRS-22r scores (adjusted $R^2 = 0.52$ and 0.42, respectively). There were no significant differences in the measured or predicted 3-year ODI ($P = 0.991$) or SRS-22r scores ($P = 0.986$).**

CONCLUSIONS: **In surgically treated patients with ASD, the greatest improvements in outcomes occurred between 6 weeks and 1 year postoperatively. A model with incremental improvements from baseline to 6 weeks and from 6 weeks to 1 year can be used to predict ODI and SRS-22r scores at 3 years.**

INTRODUCTION

Operative treatment of patients with adult spinal deformity (ASD) has been associated with significant improvements in radiographic and patient-reported outcomes, despite risk of major complications.[1-5] Studies have shown that the Scoliosis Research Society-22r (SRS-22r) patient questionnaire and the Oswestry Disability Index (ODI) are responsive tools for measuring improvements in patient-reported outcomes after ASD surgery.[6-8]

Glassman et al.[9] showed that in operatively treated patients with ASD, changes in patient-reported outcomes occurred during the first postoperative year and stabilized at the 1-year postoperative interval. The investigators concluded that for most patients, 1 year after surgery was a reasonable time frame to anticipate maximal improvement. In contrast, Bridwell et al.[10] hypothesized that longer follow-up may show a deterioration of patient-reported outcomes. However, these investigators found that radiographic and clinical outcomes did not deteriorate after 2 years for most patients.[10] To our knowledge, few studies have focused on ASD with longer than 2-year patient-reported outcome data,[10-14] and no study has investigated whether the incremental improvements

Key words
- Adult spinal deformity
- Oswestry Disability Index
- Patient-reported outcomes
- Scoliosis Research Society-22r

Abbreviations and Acronyms
ASD: Adult spinal deformity
MCID: Minimum clinically important difference
ODI: Oswestry Disability Index
SRS-22r: Scoliosis Research Society-22r

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obtained in patient-reported outcomes persist during the 3-year time frame.

The aims of our study were to investigate when the greatest improvements in patient outcomes occur after surgery for ASD and if incremental improvements in patient-reported outcomes during the first postoperative year predict outcomes at 3 years.

METHODS

Institutional review board approval was received at each participating institution.

Database Query Criteria

A multicenter registry of patients with ASD was queried to identify all patients 18 years or older who were surgically treated for ASD from 2008 to 2012 and had at least 3 years of clinical and radiographic follow-up. ASD was defined as occurring in patients who were ≥18 years old and had scoliosis Cobb angle ≥20°, sagittal vertical axis ≥5 cm, pelvic tilt ≥25°, and/or thoracic kyphosis ≥60°. Patients with spinal deformity in the setting of neuromuscular causes, active infection, or malignancy were excluded. The primary indication for surgery was correction of spinal deformity, but at least 56% of patients had additional neurologic symptoms such as history of lower extremity paresthesias and/or weakness.

Radiographic and Patient-Reported Outcomes

Free-standing, full-length anteroposterior and lateral spine radiographs were obtained on 91.4-cm (36-inch) cassettes at baseline and at 6-week, 1-year, 2-year, and 3-year follow-up and were analyzed in a central location. Radiographic parameters of interest were measured using validated software (Spineview [ENSAM, Laboratory of Biomechanics, Paris, France]). Each patient also completed the SRS-22r and the ODI before surgery and at 6 weeks, 1 year, 2 years, and 3 years postoperatively.

Statistical Methods

Pairwise t tests were used to compare preoperative (baseline) and 3-year postoperative radiographic outcomes, as well as patient-reported outcomes at various postoperative intervals.

Multivariate regression models were constructed to assess the relationship between changes in baseline and 3-year postoperative outcomes as a function of incremental improvements from baseline to 6 weeks and from 6 weeks to 1 year. Pairwise t tests and Pearson correlation coefficients were used to compare predicted and measured 3-year postoperative scores. Significance was set at a P value less than 0.01 for all analyses.

RESULTS

Patient and Radiographic Characteristics

We identified 141 patients, of whom 84 (60%) had complete radiographic and patient-reported outcome data at 3-year follow-up and were included in the analysis. Patient and surgical characteristics are reported in Table 1. Mean age at surgery was 54 ± 17 years, and 85% of patients were women. The mean number of levels fused was 10.5 ± 4.5. Forty-three patients (51%) were fused to the pelvis.

Table 1. Characteristics of 84 Operatively Treated Patients with Adult Spinal Deformity

Characteristic	Mean ± Standard Deviation	Number (%)
Age at surgery (years)	54 ± 17	
Female sex		71 (85)
Body mass index (kg/m^2)	26.8 ± 6.4	
History of spine surgery		38 (45)
Charlson Comorbidity Index	1.2 ± 1.4	
American Society of Anesthesiologists physical status classification		
I		17 (20)
II		38 (45)
III		23 (27)
IV		2 (2)
Operative time (minutes)	389 ± 139	
Estimated blood loss (L)	1.98 ± 1.83	
Number of levels fused	10.5 ± 4.5	
Length of hospital stay (days)	8.3 ± 4.0	

Patients were stratified using the SRS-Schwab ASD classification. Preoperatively, 26% patients had SRS-Schwab T-type curves, 6% had L-type curves, 37% had D-type curves, and 32% had N-type curves. When classifying by Schwab pelvic tilt modifier, 42% of patients had a 0 modifier, 33% had a + modifier, and 25% had a ++ modifier. When classifying by Schwab global alignment modifier, 45% of patients had a 0 modifier, 25% had a + modifier, and 30% had a ++ modifier. Compared with baseline, at 3 years, there were significant improvements in mean thoracic Cobb angle ($P = 0.016$), lumbar Cobb angle ($P = 0.001$), T2-T12 thoracic kyphosis ($P < 0.001$), T12-S1 lumbar lordosis ($P < 0.001$), pelvic incidence—lumbar lordosis ($P < 0.001$), and sagittal alignment ($P = 0.001$) (Table 2).

Changes in ODI and SRS-22r

The mean improvements from baseline to 3 years in ODI and SRS-22r total scores were 13 ± 16 and 0.8 ± 0.7 points, respectively (both $P < 0.001$). There were also significant improvements in all SRS-22r domains (function, pain, self-image, mental health, and satisfaction; all $P < 0.001$) (Table 3).

From baseline to 6 weeks, the mean ODI score worsened by 5 points ($P = 0.049$) and the mean SRS total score improved by 0.3 points ($P < 0.001$). The greatest improvements occurred between 6 weeks and 1 year, with mean ODI score improvement of 19 points, and mean SRS-22r total score improvement of 0.5 points (both $P < 0.001$) (Table 3).

There were no significant changes in mean postoperative ODI scores from 1 year to 2 years ($P = 0.898$) or from 2 years to 3 years ($P = 0.373$). Similarly, there were no significant changes in the mean postoperative SRS-22r total scores from 1 year to 2 years ($P = 0.986$) or from 2 years to 3 years ($P = 0.228$).

Table 2. Mean ± Standard Deviation Radiographic Characteristics of 84 Operatively Treated Patients with Adult Spinal Deformity

Characteristic	Preoperative	3-Year Follow-Up	*P* Value*
Alignment parameters (mm)			
Coronal	8 ± 50	8 ± 31	0.258
Sagittal	61 ± 85	35 ± 55	0.001
Coronal curve parameters (°)			
Thoracic	29 ± 32	18 ± 17	0.016
Lumbar	20 ± 31	9 ± 18	0.001
Sagittal curve parameters (°)			
T2-T12 thoracic kyphosis	34 ± 20	48 ± 20	<0.001
T12-S1 lumbar lordosis	38 ± 24	49 ± 14	<0.001
Pelvic parameters (°)			
Obliquity	0.4 ± 2.5	0.7 ± 2.3	0.247
Incidence	55 ± 14	55 ± 13	0.146
Tilt	23 ± 12	21 ± 10	0.141
Incidence: lumbar lordosis	13 ± 22	5 ± 15	<0.001
Sacral slope (°)	33 ± 12	34 ± 10	0.053

*Statistical significance set at $P < 0.01$.

There was no significant difference in the mean change in ODI or the SRS total score from preoperatively to 3-year follow-up between patients who had primary surgery (P = 0.08) versus those who had revision spinal surgery (P = 0.03). Similarly, there was no significant difference in the mean change in the ODI or the SRS total score from preoperatively to 3-year follow-up between patients who had fusion to the pelvis (P = 0.104) versus those fused short of the pelvis (P = 0.262).

Modeling 3-Year Patient-Reported Outcomes

Because the greatest change in ODI score occurred in the first postoperative year, we created a linear regression model for the change in ODI score from baseline to 3-year follow-up as a function of change in ODI score from baseline to 6-week follow-up and change in ODI score from 6-week to 1-year follow-up. The resulting model had an adjusted R^2 of 0.52. There was no significant difference between the predicted and measured 3-year postoperative ODI scores (P = 0.991; r = 0.732) (Figure 1).

Similarly, the change in SRS-22r total score from baseline to 3-year follow-up was modeled as a function of changes in SRS-22r total scores from baseline to 6-week follow-up and from 6-week to 1-year follow-up. The resulting model had an adjusted R^2 of 0.40. There was no significant difference between the predicted and measured 3-year postoperative SRS-22r total scores (P = 0.986; r = 0.651) (Figure 2).

Similar linear regression models were created for changes from baseline to 3-year postoperative scores in all the SRS-22r domains as a function of the changes in scores from baseline to 6-week follow-up and from 6-week to 1-year follow-up. There were no significant differences in the mean predicted and measured 3-year postoperative scores for any of the following SRS-22r domains: function (P = 0.99), pain (P = 0.987), self-image (P = 0.998), mental health (P = 0.979), and satisfaction (P = 0.966). The correlation between the predicted and measured 3-year postoperative scores for the domains were as follows: function (r = 0.647), pain (r = 0.661), self-image (r = 0.782), mental health (r = 0.618), and satisfaction (r = 0.821).

To test whether the 40% of patients (57 of 141 patients) who were lost to follow-up after 2 years had worse outcomes than those with complete 3-year follow-up, we compared ODI scores at earlier time points between the 2 groups. There were no significant differences in 1-year (P = 0.28) and 2-year (P = 0.07) postoperative ODI scores between groups. Nor were there differences in SRS-22r total scores at the 1-year (P = 0.125) and at the 2-year follow-up periods (P = 0.10) between patients who had complete 3-year follow-up versus those who did not.

Table 3. Mean ± Standard Deviation Patient-Reported Outcome Scores of 84 Operatively Treated Patients with Adult Spinal Deformity

		Postoperative			
Outcome Measure	Preoperative	6 Weeks	1 Year	2 Years	3 Years
Oswestry Disability Index	38 ± 20	43 ± 19	24 ± 19	25 ± 19	25 ± 19
Scoliosis Research Society-22r					
Function	3.1 ± 1.0	2.7 ± 0.7	3.7 ± 1.0	3.8 ± 1.0	3.6 ± 1.0
Pain	2.6 ± 0.9	2.5 ± 0.8	3.5 ± 1.0	3.5 ± 1.0	3.4 ± 1.1
Self-image	2.6 ± 0.8	3.6 ± 0.9	3.7 ± 0.9	3.7 ± 0.9	3.7 ± 1.0
Mental health	3.5 ± 1.0	3.6 ± 0.9	3.8 ± 0.9	3.9 ± 0.9	3.9 ± 0.9
Satisfaction	2.7 ± 0.9	4.3 ± 0.8	4.3 ± 0.8	4.2 ± 1.0	4.1 ± 1.0
Total	2.9 ± 0.7	3.2 ± 0.6	3.7 ± 0.8	3.8 ± 0.8	3.7 ± 0.8

Values are rounded to the nearest figure.

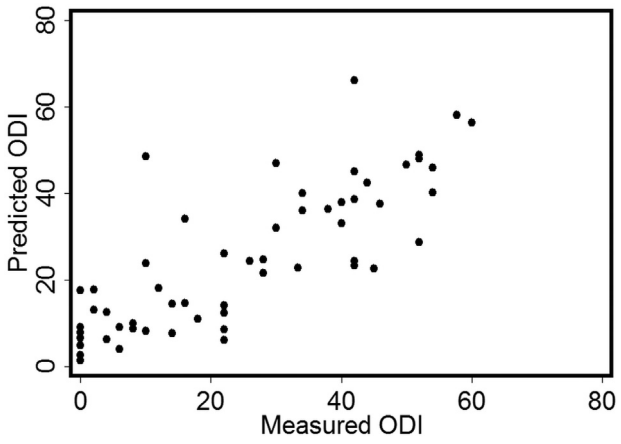

Figure 1. Scatter plot of predicted (using linear regression) versus measured 3-year Oswestry Disability Index (ODI) scores in 84 adults who underwent operative treatment for adult spinal deformity.

DISCUSSION

Operative treatment for ASD is associated with significant improvements in patient-reported outcomes.[2,4,5,15-17] In the present study, we found that the greatest changes in ODI and SRS-22r scores occurred during the first postoperative year. We also found that incremental improvements during the first postoperative year predicted patient-reported outcomes at 3 years.

The results of our study are consistent with those in the literature. In a study of 283 patients, Glassman et al.[9] found that the maximal improvements in patient-reported outcomes had occurred by 1-year follow-up and found no significant improvements in ODI and SRS-22 scores between 1-year and 2-year follow-up. In another study of patients with ASD, Bridwell et al.[10] did not find a deterioration in mean radiographic or clinical outcomes between 2-year and 3-year to 5-year follow-up. These investigators reported that 10% of patients in their cohort developed instrumentation problems/nonunion and junctional problems during the 3-year to 5-year follow-up. However, neither study specifically investigated the relationship between 1-year and 3-year outcomes.

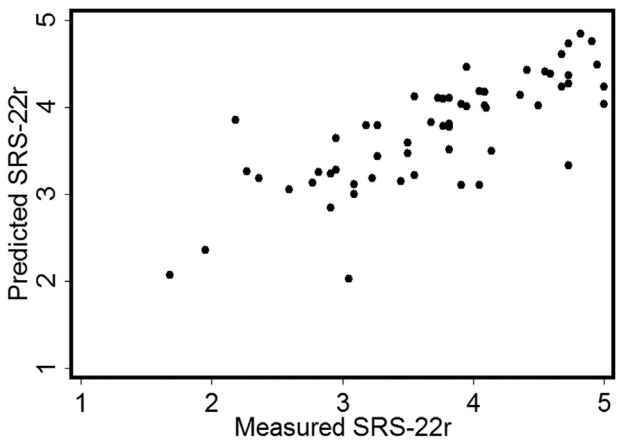

Figure 2. Scatter plot of predicted (using linear regression) versus measured 3-year Scoliosis Research Society-22r (SRS-22r) total scores in 84 adults who underwent operative treatment for adult spinal deformity.

Crawford et al.[18] estimated the minimum clinically important difference (MCID) as 0.4 for SRS-22r total and domain scores. In our study, we found that this MCID in SRS-22r total score and in all domains except mental health was achieved by 1 year. Further, we found that outcome scores stabilized at 1 year, and that between the 1-year to 2-year and the 2-year to 3-year postoperative intervals there were no significant changes in ODI or SRS-22r total scores.

We found that between baseline and 6-week follow-up, SRS-22r scores improved, whereas ODI scores deteriorated. The deterioration in ODI score can be attributed to the fact that the Oswestry Low Back Pain Questionnaire[19] includes questions specifically addressing pain intensity and how pain affects activities, and thus, it is more sensitive to postoperative pain than is the SRS-22r. Despite the deterioration in ODI scores in the early postoperative period, there was a 14-point improvement in the mean ODI score by 1 year compared with preoperatively. This result is greater than the MCID of 12.8 reported by Copay et al.[20] for ODI scores of patients undergoing lumbar spine surgery. To our knowledge, the MCID for the ODI in the context of ASD has not been reported. Further, like the SRS-22r, improvements in the ODI were maintained at the 3-year follow-up.

We found that, compared with before surgery, the greatest improvements in mean 1-year postoperative SRS-22r domain scores were in the satisfaction domain (1.6 points), followed by self-image (1.1 points), pain (0.9 points), and function (0.6 points). The SRS-22r mental health domain showed the least improvement at 1 year (0.3 points). These findings are consistent with recent research, which suggests that the operative treatment of ASD is associated with the greatest improvements in the SRS-22r self-image domain and that the self-image domain correlates most with patient satisfaction in long-term follow-up.[14]

The results of our study have important implications for preoperative counseling of patients with ASD. Glassman et al.[9] reported that maximal improvements in self-reported outcomes occurred by 1-year follow-up, and that in most patients these were maintained up to the 2-year follow-up. Our study takes these results a step further, providing evidence that most patients can expect to maintain improvements in health-related quality-of-life outcomes for at least 3 years after surgery. Another important finding from our study is that the satisfaction, self-image, and pain domains had the greatest improvements. An understanding of the relative improvements that a patient can expect in various domains is an important aspect of preoperative counseling.

Our study has several limitations. First, although our 2-year follow-up rate was 79%, the 3-year follow-up rate was only 60%. It is possible that this factor may lead to bias in our results. It is possible that patients who were dissatisfied may not have returned for follow-up. However, we found that there was no significant difference in 1-year and 2-year patient-reported outcomes between the group lost to follow-up and those with complete 3-year

follow-up. Another limitation is that the follow-up intervals were not evenly distributed. Most of the improvement in patient-reported outcomes occurred between 6 weeks and 1 year. We did not capture data at the 3-month, 6-month, and 9-month postoperative intervals, which would help elucidate the incremental changes that occur in patient-reported outcomes. Further, patients in our study had a wide range of spinal deformities across the spectrum of Schwab types. The heterogeneity of our sample may dilute the applicability of our results to more specific patient populations. Although our results suggest that most patients improve during the first year after surgery and that these improvements are maintained over 3-year follow-up, our study did not identify factors that predict whether a patient will experience improvement in health-related quality of life. Assessment of factors that predict postoperative improvement (or lack thereof) is an important aspect of preoperative risk stratification and patient counseling. Despite these limitations, this is the largest study to correlate patient-reported outcomes at early follow-up with those at 3 years. Future studies are needed with longer follow-up and more homogenous patient populations.

CONCLUSIONS

We found that for operatively treated patients with ASD, the most significant changes in ODI and SRS-22r total scores occurred between 6 weeks and 1 year postoperatively. By 1 year, the patient-reported outcomes stabilized and were maintained at 3 years. We also found that the incremental changes from baseline to 6 weeks and from 6 weeks to 1 year could be used to predict outcomes at 3 years.

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