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Neurologic Deficits Have A Negative Impact on Patient Related Outcomes in Primary Presentation Adult Symptomatic Lumbar Scoliosis Surgical Treatment at One-Year Follow-up

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STRUCTURED ABSTRACT

Study Design—Retrospective analysis of prospective, multicenter National Institute of Health clinical trial.

Objective—To assess the rate of neurologic complications and impact of new neurologic deficits on 1-year postoperative patient-reported outcomes (PROs).

Summary of Background Data—There are limited studies evaluating the impact of new neurologic deficits on PROs following surgery for primary presentation adult lumbar scoliosis.

Methods—Patients were divided into two groups: new postoperative neurological deficit (Def) or no deficit (NoDef). Preoperative and 1-year follow-up PROs were analyzed [Scoliosis Research Society (SRS) Questionnaire, Oswestry Disability Index (ODI), Short Form-12 Physical/Mental Health Composite Scores (PCS/MCS) and back/leg pain Numerical Rating Scale (NRS)].

Results—141 patients: 14 Def (9.9%), 127 NoDef (90.1%). No differences in demographic, radiographic or PRO data between groups preoperatively. Def group had longer surgical procedures (8.3 vs 6.9hours, $p=0.030$), greater blood loss (2832 vs 2606mL, $p=0.022$) and longer hospitalizations (10.6 vs 7.8days, $p=0.004$). NoDef group reported significant improvement in all PROs from preop to 1-year postoperative. Def group only had improvement in SRS Pain (2.7 preop to 3.4 postop, $p=0.037$) and Self-image domains (2.7 to 3.6, $p=0.004$), and NRS back pain (6.6 to 3.2, $p=0.004$) scores with significant worsening of NRS leg pain (4.1 to 6.1, $p=0.045$).

Group comparisons of 1-year postop PROs found Def group reported more NRS leg pain (6.1 vs

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1.7, $p<0.001$) and worse outcomes than NoDef group for ODI (35.7 vs 23.1, $p=0.016$) and PCS (32.6 vs 41.9, $p=0.007$).

Conclusions—We found a 9.9% rate of new neurologic deficits following surgery for symptomatic primary presentation adult lumbar scoliosis, much higher than previous studies. Most neurologic deficits improved by 1-year follow-up, but appeared to have a dramatic negative impact on PROs, with increased postoperative leg pain and greater patient-perceived pathology reported in patients experiencing neurological deficits compared to those who did not.

Keywords

adult lumbar scoliosis; degenerative scoliosis; de novo scoliosis; neurologic deficit; neurologic complication; patient-reported outcome scores

Introduction

Adult spinal deformity (ASD) surgery is complex and challenging, especially in patients with severe deformity or multiple medical comorbidities. Despite advances in surgical technique, spinal instrumentation and neuromonitoring protocols, new neurologic deficits following ASD surgery remain a major concern and feared complication. Reported rates and severity of new neurologic deficits following ASD surgery differ widely, ranging from 0.55% to 7%, with most reporting nerve root deficits and few spinal cord deficits.^{1–9} To our knowledge, no study has specifically evaluated the impact of neurologic complications on patient-reported outcomes (PROs), due to the limited studies evaluating this topic with variable methodologies (mostly retrospective in nature), small sample sizes, heterogeneous populations, and nonstandardized methods of defining and characterizing neurologic deficits. Therefore, appropriately counseling patients regarding the risk of a neurologic complication with ASD surgery and expected outcome remains a difficult task. Also, the optimal time-frame for analysis of PROs following a complication, particularly a neurologic deficit, remains unknown.

We hypothesized new neurologic deficits would negatively impact postoperative PROs and result in greater pathology compared to patients without neurologic deficits. Therefore, the purpose of this study was to assess the rate of neurologic complications encountered following surgery for primary presentation adult lumbar scoliosis, and determine the impact of these deficits on 1-year postoperative PROs.

Materials and Methods

Patient Population and Study Design

We performed a retrospective analysis of surgically treated patients from a prospective, multicenter (7 U.S. academic centers and 2 Canadian academic centers) National Institute of Health (NIH) funded clinical trial on health-related quality of life for treatment of primary presentation adult lumbar scoliosis. Institutional Review Board approval was obtained at each participating site prior to study enrollment and all patients gave informed consent to study participation. The trial was registered with clinicaltrials.gov (NCT00854828). Inclusion criteria were patients 40 to 80 years old, with primary presentation (no previous

thoracic or lumbar spinal fusion) idiopathic or denovo lumbar curve with Cobb $\geq 30^\circ$, and an Oswestry Disability Index (ODI) score ≥ 20 or Scoliosis Research Society Quality of Life instrument (SRS-QOL) score ≥ 4.0 in the Pain, Function, and/or Self-image domains.

Study Measures

Patients were divided into two groups based on the presence (Def) or absence (NoDef) of a new postoperative neurologic deficit and examined for differences in baseline demographic, medical and surgical factors. Radiographic parameters were evaluated preoperatively and at initial postoperative follow-up. PROs were completed at baseline and at 1-year postoperative follow-up. Outcome measures included SRS-QOL, ODI, Short Form-12 (SF-12) Mental and Physical Component Score (MCS/PCS), and back and leg pain Numerical Rating Scales (NRS). SRS-QOL Subscore is the average score of Pain, Function, Self-Image and Mental Health domains. Higher scores for ODI and NRS indicate more severe symptoms and pathology (positive change=worsening, negative change=improvement). Whereas, higher scores for SRS domains and SF-12 indicate less severe symptoms (positive change=improvement, negative change=worsening). Analysis of 1-year PROs was performed to best reflect a time-point when patients have sufficiently recovered from acute postoperative pain and decreased function associated with extensive spinal fusion surgery, but still be impacted by a neurologic complication. Longer follow-up may be confounded by other complications and/or adverse events (pseudarthrosis, progressive junctional deformities, traumatic fall or accident), worsening of medical comorbidities, and inevitable loss of patients to follow-up which could confound PRO.

Postoperative neurologic examination was assessed using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) from the American Spinal Injury Association (ASIA).¹⁰ New neurologic deficits were defined as events occurring at the time of or immediately after the index surgery.

Statistical Analysis

Baseline demographic, medical, surgical, radiographic and PRO parameters were compared between the two groups (Def versus NoDef), as well as subset analysis of the deficit group (Major [MajDef: ASIA B/C] versus Minor [MinDef: ASIA D]) deficit, using Fisher's exact or chi-square test (for categorical variables) and Mann-Whitney U analysis (for non-parametric continuous variables). Within group comparison of PROs from baseline to 1-year postoperative time points were analyzed using Wilcoxin signed-rank test (for non-parametric continuous variables). When a variable was significantly associated with the occurrence of a neurologic deficit, an odds ratio (OR) for developing a neurologic deficit was calculated. A p-value <0.05 , based on a two-sided hypothesis test, was considered significant.

Results

A total of 141 patients met inclusion criteria and were included in the current analysis. All patients had postoperative radiographs(range:1-week to 4-months) and 140 patients had complete 1-year PRO data. One patient did not have 1-year PRO data due to death at 8-month follow-up.

Fourteen patients (9.9%) experienced a new neurologic deficit related to surgical intervention: 4 major (ASIA B/C) and 10 minor (ASIA D) deficits. One patient with a major deficit died before 1-year follow-up. The three remaining major deficit patients improved to ASIA D and 6 of the 10 minor deficit patients improved to ASIA E by 1-year follow-up. Two of the minor deficits were patients with sensory only deficits. Both patients were still symptomatic (parasthesia/dysesthesia) at 1-year follow-up. There were 127 patients (90.1%) in the NoDef group (Appendix 1).

Demographic/Clinical/Surgical Variables—There were no differences in demographic or medical characteristics between the NoDef and Def groups, nor between the MinDef and MajDef groups (Table 1, Appendix 2). The Def group had significantly longer surgical procedures (8.3 vs 6.9 hours, $p=0.030$), greater estimated blood loss (EBL; 2832.1 vs 2606.2mL, $p=0.022$) and longer hospitalizations (10.6 vs 7.8 days, $p=0.004$) compared to the NoDef group. Twenty-nine percent of the patients in the Def group had neuromonitoring changes compared to only 6.3% in the NoDef group ($p=0.020$) (Table 1).

Risk Factor Analysis—We found the Def group was significantly associated with intraoperative dural tear/ cerebrospinal fluid (CSF) leak compared to the NoDef group [21.4% vs 3.9%, $p=0.033$; OR 6.655 (1.400–31.626)] and were more likely to have other intraoperative (35.7% vs 10.2%, $p=0.019$; OR 4.829 (1.405–16.60)] and post-operative complications (78.6% vs 14.2%, $p<0.001$), specifically DVT (14.3% vs 1.6%, $p=0.007$; OR 10.417 (1.344–80.715)] (Table 1).

Radiographic Parameters

No Deficit versus Deficit—There were no differences in radiographic parameters between the NoDef and Def groups at baseline or at initial postoperative follow-up (Appendix 3); nor were there any differences in the mean change from baseline to initial follow-up between the two groups.

Minor/Major Deficit—There were significant differences in the mean baseline sagittal vertical axis (SVA) of the MinDef and MajDef groups (10.9 vs 125.0mm, $p=0.016$), as well as the NoDef and both the MinDef (32.1 vs 10.9mm, 0.039) and MajDef (32.1 vs 125mm, $p=0.003$) groups (Table 2). There were significant baseline differences between the MinDef and MajDef groups mean lumbar lordosis (-42.0 vs -6.5° , $p=0.011$) and pelvic incidence-lumbar lordosis (PI-LL) mismatch (13.3 vs 43.0° , $p=0.02$). There were also baseline differences in the mean lumbar lordosis and PI-LL mismatch between the NoDef and the MajDef groups (-38.8 vs -6.5° , $p=0.007$ and 17.4 vs 43.0° , $p=0.015$ respectively) (Table 2).

Initial postoperative radiographic measurements demonstrated significant differences between the MinDef and MajDef groups mean lumbar lordosis (-55.0 vs -34.0° , $p=0.023$) and SVA (-6.6 vs 69.3 mm, $p=0.018$). There were also differences in both the mean lumbar lordosis and SVA of the NoDef and the MajDef groups (-50.9 vs -34.0° , $p=0.022$ and 10.7 vs 69.3° , $p=0.011$, respectively). There were no differences in the mean change from baseline to initial follow-up between the two groups lumbar lordosis (T12-sacrum), SVA, or lumbar Cobb measurements (Table 2).

Patient Related Outcomes Scores

No Deficit versus Deficit—There were no differences in PROs between the two groups at baseline. At 1-year postoperative follow-up the Def group reported more NRS leg pain (6.1 vs 1.7, $p<0.001$) and more disability on ODI (35.7 vs 23.1, $p=0.016$) and SF-12 PCS (32.6 vs 41.9, $p=0.007$) than the NoDef group (Table 3). Analysis of mean change in PROs found the Def group had worsened NRS leg pain compared to NoDef group ($p<0.001$) as well as significantly less improvement in SRS Subscore ($p=0.049$) and SF-12 PCS ($p=0.016$) (Figures 1–3). Paired analysis of baseline to 1-year postoperative PROs found the NoDef group demonstrated significant improvement in all PROs (Table 4). Whereas the Def group only demonstrated improvement in the SRS Pain, SRS Self-Image and NRS back pain scores and had a significant worsening of NRS leg pain scores. The Def group had no differences in the paired analysis for SRS Function, SRS Mental Health, SF-12, or ODI scores (Table 4).

Minor/Major Deficit—At baseline the MajDef group had worse ODI compared to the NoDef group (53.5 vs 37.0, $p=0.015$). There were no differences between MinDef and NoDef groups at baseline (Table 5). At 1-year postoperative the MajDef group reported significantly worse SRS Function (1.9 vs 3.5, $p=0.002$), SRS Self-image (2.7 vs 4.0, $p=0.007$), ODI (48.0 vs 23.1, $p=0.025$), SF-12 MCS (37.5 vs 53.0, $p=0.044$), and NRS leg pain (7.3 vs 1.7, $p=0.001$) scores compared to the NoDef group. In addition, the MinDef group had worse NRS leg pain (5.7 vs 1.7, $p<0.001$) and SF-12 PCS (33.0 vs 41.9, $p=0.029$) compared to the NoDef group (Table 5).

Discussion

Despite advances in modern medicine, ASD surgery continues to have an inherent risk of complications and one of the most concerning postoperative complications is a new neurologic deficit.¹¹ To our knowledge, there are limited studies that report rates of new neurologic deficits following ASD surgery,^{1–9} and none that we could find specifically evaluating the impact of a new neurologic deficit on patient-reported outcomes. In 1995, Albert and colleagues¹² prospectively evaluated the impact of complications and health outcomes after adult deformity surgery in 68 patients and found no difference in self-reported health function parameters (SF-36) at 1 and 2 years between patients with and without complications. However, controversy remains and various other studies have demonstrated the occurrence of a complication can be detrimental to health outcomes and functional results after ASD surgery.^{13–15}

Previously reported rates of neurologic complications after ASD surgery have averaged 3.1% [1.84% Hamilton;³ 2.4% Cho;⁹ 2.9% (7% long deformity) Pateder;⁴ 7.5% Charosky;² 11% (revision/PSO) Buckowski et al;⁷ 1% Swank⁵], but vary due to differences in inclusion criteria (i.e. primary versus revision), case complexity, and methods for determining and reporting neurologic deficits. The largest reported series evaluating neurologic deficits following spine surgery by Hamilton et al³ retrospectively analyzed the SRS Morbidity and Mortality database (108,419 spine procedures), with a subset analysis of 26,226 adult patients undergoing surgery for a primary diagnosis of scoliosis. The authors found a 1.84%

rate of new neurologic deficits (1.52% nerve root, 0.07% cauda, 0.26% spinal cord). Regardless of deficit severity, approximately 45% of patients in each group had complete recovery, 45% partial, and 5–10% (4.8% nerve root, 10% spinal cord) with no recovery.³ In addition, Charosky and colleagues² performed a multicenter, retrospective analysis of primary adult scoliosis patients over age 50 undergoing surgery and found a 7.5% rate of neurologic complications, with risk factors for neurologic complication including: number of instrumented vertebra, fusion to the sacrum, PSO, and high preoperative pelvic tilt of 26°. However, this study including 3 patients with dural tears without neurologic deficits and 2 patients with late cord-level (>2 years postoperative) deficits.²

In the current study, we report the highest rate (10%) of neurologic deficits following surgical treatment of primary presentation adult symptomatic lumbar scoliosis in the literature. While most neurologic deficits were nerve root deficits (69% of MinDef patients) and had improvement at 1-year follow-up without additional surgery or treatment, our hypothesis was confirmed that new neurologic deficits negatively impact PROs, with greater patient-perceived pathology and higher postoperative leg pain than those without neurologic deficits. Our study also found patients with new postoperative neurologic deficits had longer length of surgery, larger EBL, and longer hospitalizations. We further subanalyzed patients with Minor (ASIA D) versus Major (ASIA B/C) neurologic deficits and found the MajDef group demonstrated significantly worse PROs and more postoperative leg pain compared to the NoDef group, although the MajDef group had a higher ODI score at baseline. Interestingly, the MinDef group demonstrated worse postoperative leg pain compared to the NoDef group, but had no difference in other PROs, except SF-12 PCS. Therefore, our results suggest MajDef have a greater negative impact on PROs compared to MinDef, but both MinDef and MajDef groups experienced worse postoperative leg pain compared to the NoDef group.

Our study also demonstrated patients with intraoperative dural tear/CSF leak were six times more likely to have new neurologic deficits. Patients with neurologic deficits also trended toward a greater mean number of decompression levels per patients (3.0 vs 1.9, $p=0.061$) and more staged procedures (21.4% vs 5.5%, $p=0.062$) compared to the no deficit group. We postulate patients with more complex, rigid deformed segments causing stenosis of the neural elements increases the risk of dural tear/CSF leak, which in our study was associated with a higher likelihood of a postoperative neurologic deficit. Intuitively, patients not requiring exposure of the spinal canal or manipulation of the neural elements would be less likely to have a dural tear/CSF leak. However, dural tear/CSF leak occurred in 5 patients (3.9%) from the NoDef group, and while magnitude of the tear or repair technique may be factors associated with risk of neurologic deficit, these were not specifically evaluated in this study.

Although there were no differences in radiographic parameters at baseline or initial postoperative follow-up between the NoDef and Def groups, subanalysis demonstrated the MajDef group had significantly greater sagittal imbalance, less lumbar lordosis, and higher PI-LL mismatch at baseline compared to the NoDef and MinDef Groups. This again highlights that the baseline characteristics of the MajDef group may have contributed to the risk of a new neurologic deficit. Also of importance, patients with new neurologic deficits

were at significantly increased risk for having other non-neurologic postoperative complications (OR 22.2), in particular for having a deep vein thrombosis (OR 10.4). An important point is that our study also found the NoDef group had a substantial rate of intraoperative (10%) and postoperative complications (14%).

Surprisingly, we did not find any differences between patients with and without new neurologic deficits in regards to various demographic variables (age, gender, body mass index, diabetes mellitus), number of levels fused/instrumented, number/type of interbody fusion, and number/type of osteotomy. Also, neuromonitoring changes were only present in 29% of the Def group, which was significantly greater than the NoDef group (6%) in our univariate analysis, but was not found to be an independent predictor of postoperative neurologic deficit in multivariate analysis. Hamilton et al² reported in their series that neuromonitoring was only used in 65% of cases, with changes in neuromonitoring signals reported in 11% for nerve root deficits, 8% for cauda equina deficits and 40% for spinal cord deficits. In the current study, most of the reported neurologic deficits, similar to previous studies,^{2,3} were nerve root level, therefore controversy remains regarding the utility of neuromonitoring in this setting. In addition, surgical decision making in the presence of neuromonitoring changes was determined by the individual surgeon and subsequent intraoperative response (ie, performance of a Stagnara wake-up test prior to proceeding) or changes to the surgical plan were not specifically analyzed.

The reporting and study of new neurologic deficits is a difficult topic for various reasons, mostly because the occurrence of catastrophic neurologic complications are seemingly uncommon. Most studies that have reported new neurologic deficits have been retrospective in nature and the data is dependent on accurate recording of the deficit during the hospital admission and at subsequent follow-up visits. Our study is unique because of its high quality prospectively collected data from an NIH-funded study, with excellent clinical and radiographic follow-up, standardized neurologic assessment methods using ISNCSCI at all enrollment sites, and detailed documentation of all serious adverse events and neurologic complications with oversight by a Data Safety Monitoring Board. Therefore, previous studies may have significantly under-reported new neurologic deficits, and when assessed across the spectrum of spine surgeons (inexperienced to experienced) performing ASD surgery in a heterogeneous population, the rate of new neurologic deficits may be higher than 10%.

In addition, any study evaluating multiple variables and outcomes may be limited by the potential for both type-1 and type-2 error. When multiple univariate comparisons are made, there is the risk of finding a difference between groups due to random chance rather than a true difference (type-1 error). Also, as previously discussed regarding the use of 1-year follow-up, we believe this to be more reflective than an earlier or later time-point. However, there was one of our patients, with a major neurologic deficit, who did not have 1-year PROs due to death during the follow-up period. Therefore, our results may be biased toward underestimating the impact of neurologic deficit on 1-year PROs. Another possible confounding variable is the use of immediate post-operative radiographic parameters, as deterioration of deformity correction (e.g., proximal junctional kyphosis, coronal decompensation) by 1-year follow-up may have impacted PROs. However, the main purpose

of using immediate postoperative radiographic parameters was to evaluate the association between amount of deformity correction and new neurologic deficits. Additional analysis of this ongoing prospective NIH trial may provide information regarding the impact of neurologic deficits at later time points, and the change in PROs from the current 1-year analysis.

In conclusion, our study found a 9.9% rate of neurologic deficit following surgery for primary presentation adult lumbar scoliosis, much higher than previous studies. Most neurologic deficits improved by 1-year postoperative follow-up, but appear to dramatically negatively impact 1-year postoperative PROs, with more postoperative leg pain and greater pathology in most patient-reported parameters than those without neurologic deficits.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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APPENDIX 1. Neurologic Deficit Characteristics and Recovery

Patient	Age at OR	ASIA Initial Deficit	ASIA 1-year Postop	Neurologic Deficit		Bowel/Bladder Intact	Recovery of Deficit
				LEFT	RIGHT		
Major Deficits							
1	63.9	B	D	L2 4/5 L3 2/5 L4 4/5 L5 3/5 S1 3/5	L2 4/5 L3 2/5 L4 4/5 L5 3/5 S1 3/5	No	Still present w/treatment
2	58.5	C	D	L2 4/5 L3 4/5 L4 0/5 L5 0/5 S1 0/5	L2 4/5 L3 4/5 L4 0/5 L5 0/5 S1 0/5	Yes	Still present w/treatment
3	69.6	C	D	L5 2/5 S1 2/5	L2 2/5 L3 2/5 L4 3/5 L5 0/5 S1 4/5	Yes	Still present w/treatment
4	72.9	C	C	L2 3/5 L3 4/5	L2 3/5 L3 4/5 L4 2/5 L5 2/5 S1 4/5	Yes	Death
Minor Deficits							
5	70.2	D	D	L4 4/5 L5 4/5 S1 3/5		Yes	Still present w/o treatment
6	58.6	D	D	L4 3/5 L5 3/5		Yes	Still present w/o treatment
7	64.6	D	E		L4 3/5 L5 3/5	Yes	Recovered w/o treatment
8	53.5	D	E		L2 3/5 L3 3/5 L4 4/5 L5 4/5	Yes	Still present w/o treatment
9	58.6	D	E	L2 4/5 L3 4/5		Yes	Recovered w/o treatment
10	59.3	D	E	L5 2/5		Yes	Recovered w/treatment
11	57.2	D	E	L2 4/5	L2 2/5	Yes	Recovered w/o treatment

Patient	Age at OR	ASIA Initial Deficit	ASIA 1-year Postop	Neurologic Deficit		Bowel/Bladder Intact	Recovery of Deficit
				LEFT	RIGHT		
				L3 4/5 L5 3/5 S1 3/5	L3 3/5 L5 4/5 S1 4/5		
12	62.1	D	E	L2 3/5 L4 4/5	L2 4/5	Yes	Recovered w/o treatment
13	63.0	D	D	Sensory Deficit Parasthesia Right L5 Right S1		Yes	Still present w/o treatment
14	40.3	D	D	Sensory Deficit Parasthesia Left L5		Yes	Still present w/o treatment

* ASIA (American Spinal Injury Association); L2 (Iliopsoas); L3 (Quadriceps); L4 (Tibialis Anterior); L5 (Extensor Hallucis Longus); S1 (Gastroc-Soleus); L5-S1 (Hamstring); w/ (with); w/o (without)

APPENDIX 2. Comparison of Demographic and Medical Variables Between Minor and Major Deficits

	Minor Deficit (Min)			Major Deficit (Maj)			p-value Min vs Maj
	N	Mean	SD	N	Mean	SD	
Age at Surgery	10	58.7	7.9	4	66.2	6.4	0.157
BMI	10	27.0	3.7	4	27.1	4.8	1.000
Gender: Female	8			3			1.000
Gender: Male	2			1			
Diabetes: No	10			3			0.286
Diabetes: Diet Controlled	0			0			
Diabetes: Oral Medication	0			1			
Diabetes: Insulin Dependent	0			0			
Smoker: No	7			3			1.000
Smoker: Yes	1			0			
Femoral Neck T-score	6	-0.4	1.2	4	-0.7	1.3	0.915
Length of Surgery (hours)	10	8.2	2.8	4	8.4	2.8	0.941
Length of Hospital Stay (days)	10	9.6	4.0	4	13.3	2.4	0.076
Estimated Blood Loss (mL)	10	2700.0	1099.5	4	3162.5	1376.8	0.454
# Decompression Levels (per pt)	4	3.3	1.9	2	2.5	0.7	0.803
# Posterior Spinal Fusion Levels (per pt)	10	11.4	3.2	4	12.0	4.6	0.667
# Anterior Spinal Fusion Levels (per pt)	2	1.5	0.7	0	0.0	0.0	1.000
# Fixation Points (per pt)	10	24.2	5.7	4	26.8	10.2	0.671
Implant Density (# fixation points/PSF levels)	10	2.0	0.2	4	2.0	0.2	0.733
PLIF/TLIF (# of pts)	7			4			0.505
SPO/PCO (# of pts)	7			2			0.580
PSO (# of pts)	0			0			N/A

	Minor Deficit (Min)			Major Deficit (Maj)			p-value Min vs Maj
	N	Mean	SD	N	Mean	SD	
VCR (# of pts)	0			0			N/A
Laminectomy-Decompression	4			2			1.000
Anterior Approach/Fusion	2			0			1.000
Pelvic Fixation	9			4			1.000
Staged Procedure	2			1			1.000
SCM Changes: Yes	0			1			1.000
SCM Changes: No	7			3			
Total Intra-Op Complications (Non-neurologic)	3			2			0.580
CSF Leak	2			1			1.000
Total Post-op Complications (Non-neurologic)	7			4			0.505
DVT	1			1			0.505

No differences in demographic and medical characteristics between the major versus minor deficit groups at baseline.

* denotes significant difference with p-value <0.05, BMI (Body Mass Index), F/U (follow-up), mL (milliliters), # (number), pt (patient), PSF (posterior spinal fusion), PLIF (posterior lumbar interbody fusion), TLIF (transforaminal interbody fusion), SPO (Smith-Peterson osteotomy), PCO (posterior column osteotomy), PSO (pedicle subtraction osteotomy), VCR (vertebral column resection), deg (degree), N (number), SD (standard deviation), CSF (cerebral spinal fluid), SCM (Spinal Cord Monitoring), DVT (deep vein thrombosis), N/A (not applicable), min (minor), maj (major)

APPENDIX 3. Comparison of Radiographic Measurements No Deficit vs Deficit Groups

	No Neuro Deficit (No Def)			Deficit (Def)			MWU p-value No Def v Def
	N	Mean	SD	N	Mean	SD	
Baseline Radiographic Measurements							
Lumbar Coronal Cobb (deg)	127	55.2	15.1	14	62.1	13.8	0.109
Fractional Cobb (deg)	124	22.7	9.9	14	26.7	13.8	0.352
Coronal Vertical Axis (mm)	127	0.4	35.7	14	−2.3	50.8	0.764
T2-T5 Sagittal Cobb (deg)	124	9.1	7.7	13	6.6	7.7	0.156
T2-T12 Sagittal Cobb (deg)	125	34.8	18.4	13	26.5	16.6	0.146
T5 - T12 Sagittal Cobb (deg)	126	28.4	16.7	14	25.4	19.1	0.516
T10 - L2 Sagittal Cobb (deg)	127	17.0	16.2	14	21.1	14.1	0.331
T12-S1 Sagittal Cobb (deg)	127	−38.8	19.2	14	−31.9	21.7	0.391
Sagittal Vertical Axis-SVA (mm)	127	32.1	41.8	14	43.5	70.1	0.855
Pelvic Incidence-PI (deg)	121	55.6	10.5	13	53.4	9.4	0.532
Sacral Slope (deg)	121	32.3	10.4	13	31.1	7.7	0.562
Pelvic Tilt (deg)	121	23.5	9.0	13	22.8	7.6	0.886
PI-LL Mismatch (deg)	121	17.4	18.1	13	22.5	21.7	0.491
Initial Postop Radiographic Measurements							
Lumbar Coronal Cobb (deg)	127	25.4	13.0	14	27.7	17.1	0.820

	No Neuro Deficit (No Def)			Deficit (Def)			MWU p-value No Def v Def
	N	Mean	SD	N	Mean	SD	
Fractional Cobb (deg)	125	10.0	7.4	14	10.1	6.5	0.729
Coronal Vertical Axis (mm)	125	-3.5	24.7	13	3.8	23.5	0.223
T2-T5 Sagittal Cobb (deg)	127	13.3	8.8	13	11.8	14.3	0.165
T2-T12 Sagittal Cobb (deg)	127	46.2	15.2	13	43.2	12.4	0.493
T5 - T12 Sagittal Cobb (deg)	127	35.5	14.9	14	33.0	11.3	0.682
T10 - L2 Sagittal Cobb (deg)	127	5.8	13.0	14	5.4	13.8	0.656
T12-S1 Sagittal Cobb (deg)	127	-50.9	12.3	14	-49.0	14.9	0.890
Sagittal Vertical Axis-SVA (mm)	126	10.7	39.6	13	10.9	43.8	0.783
Sacral Slope (deg)	117	34.7	9.5	12	33.6	9.1	0.833
Pelvic Tilt (deg)	117	20.3	9.3	12	19.9	8.1	0.974
PI-LL Mismatch (deg)	117	3.6	13.1	12	-2.3	14.7	0.207

There were no differences in radiographic measurements between the No Neuro Deficit and Deficit groups at baseline and initial postoperative follow-up.

* denotes significant difference with p-value <0.05, deg (degree), mm (millimeter), PI-LL (Pelvic Incidence-Lumbar Lordosis), N (number), SD (standard deviation), MWU (Mann-Whitney U), NoDef (No Deficit Group), Def (Deficit Group)

Figure 1. Mean change in NRS Back/Leg Pain Baseline to 1-Year Post-op

Chart of mean change in NRS (Numerical Rating Scale) Back and Leg Pain from preoperative to 1-year postoperative, with comparison between groups. There was no difference in mean change in NRS Back Pain between groups, however there was a significant difference in mean change in NRS Leg Pain with NoDef cohort demonstrating a mean 2.3 point improvement compared to Def cohort demonstrating a mean 2.4 point worsening of NRS Leg Pain.

Figure 2. Mean change in SRS Score Baseline to 1-Year Post-op

Chart of mean change in SRS-QOL (Scoliosis Research Society-Quality of Life)

Questionnaire score from preoperative to 1-year postoperative, with comparison between groups. There was no difference in mean change in SRS Score between groups for Pain and Mental Health domains, however there was a significant difference in mean change for Function, Self Image and Subscore domains, with the NoDef cohort demonstrating greater pathology compared to Def cohort.

Figure 3. Mean change ODI and SF-12 MCS/PCS Baseline to 1-Year Post-op

Chart of mean change in ODI (Oswestry Disability Index) and SF-12 MCS/PCS (Short Form 12, Mental Component Score/Physical Component Score) from preoperative to 1-year postoperative, with comparison between groups. There was a significant difference in mean change ODI, SF-12 MCS and PCS, with the NoDef cohort demonstrating greater pathology compared to Def cohort.

Table 1

Comparison of Demographic and Medical Variables Between Groups

	No Deficit (NoDef)			Deficit (Def)			p-value NoDef vs Def
	N	Mean	SD	N	Mean	SD	
Age at Surgery	127	59.1	8.8	14	60.9	8.1	0.352
BMI	127	27.1	5.2	14	27.0	3.9	0.791
Gender: Female	115			11			0.172
Gender: Male	12			3			
Diabetes: No	120			13			
Diabetes: Diet Controlled	1			0			
Diabetes: Oral Medication	5			1			
Diabetes: Insulin Dependent	0			0			0.913
Smoker: No	126			13			
Smoker: Yes	1			1			
Femoral Neck T-score	96	-1.1	0.9	10	-0.6	1.2	0.105
Length of Surgery (hours)	127	6.9	2.0	14	8.3	2.7	0.030*
Length of Hospital Stay (days)	127	7.8	3.7	14	10.6	3.9	0.004*
Estimated Blood Loss (mL)	127	2606.2	5701.9	14	2832.1	1149.5	0.022*
# Decompression Levels (per pt)	57	1.9	1.0	6	3.0	1.5	0.061
# Posterior Spinal Fusion Levels (per pt)	127	10.7	3.7	14	11.6	3.5	0.296
# Anterior Spinal Fusion Levels (per pt)	13	2.2	1.6	2	1.5	0.7	0.643
# Fixation Points (per pt)	127	23.6	7.0	14	24.9	6.9	0.643
Implant Density (# fixation points/PSF levels)	127	2.0	0.2	14	2.0	0.2	0.311
PLIF/TLIF (# of pts)	74			11			0.163
SPO/PCO (# of pts)	71			9			0.586
PSO (# of pts)	3			0			1.000
VCR (# of pts)	2			0			1.000
Laminectomy-Decompression	57			6			0.885
Anterior Approach/Fusion	12			2			0.633

	No Deficit (NoDef)			Deficit (Def)			p-value NoDef vs Def
	N	Mean	SD	N	Mean	SD	
Pelvic Fixation	113			13			0.923
Staged Procedure	7			3			0.062
SCM Changes: Yes	8			4			0.02 *
SCM Changes: No	118			10			
Total IntraOp Complications (Non-neurologic)	13			5			
CSF Leak	5			3			0.019 * [OR 4.829 (1.405–16.60)]
Total Postop Complications (Non-neurologic)	18			11			0.033 * [OR 6.655 (1.400–31.626)]
DVT	2			2			<0.001 * [OR 22.2 (5.639–87.426)]
							0.007 * [OR 10.417 (1.344–80.715)]

No differences in demographic and medical characteristics between the no neuro deficit versus neuro deficit groups. Patients in the Deficit group had significantly longer surgical procedures (8.3 vs 6.9 hours, $p=0.030$), greater volume EBL (2832cc vs 2606, $p=0.022$) and longer length of stays (10.6 vs 7.8 days, $p=0.004$) compared to the No Neuro Deficit group. Deficit group had significantly greater Spinal Cord Monitoring changes, more non-neurologic intraop and postop complications, particularly dural tear/CSF leak and DVT. Risk factor analysis, deficit group demonstrated significant association with additional non-neurologic intraop (CSF leak) and postop complications (DVT).

* denotes significant difference with p-value <0.05, BMI (Body Mass Index), F/U (follow-up), mL (milliliters), # (number), pt (patient), PSF (posterior spinal fusion), PLIF (posterior lumbar interbody fusion), TLIF (transforaminal interbody fusion), SPO (Smith-Peterson osteotomy), PCO (posterior column osteotomy), PSO (pedicle subtraction osteotomy), VCR (vertebral column resection), deg (degree), N (number), SD (standard deviation), CSF (cerebral spinal fluid), SCM (Spinal Cord Monitoring), DVT (deep vein thrombosis), N/A (not applicable), min (minor), maj (major), OR (Odds Ratio, with 95% Confidence Interval)

Table 2
Comparison of Radiographic Measurements No Deficit vs Minor and No Deficit vs Major Deficit Groups

	No Neuro Deficit (NoDef)			Minor Deficit (Min)			Major Deficit (Maj)			MWU p-values	
	N	Mean	SD	N	Mean	SD	N	Mean	SD	No Def v Minor	No Def v Major
Baseline Radiographic Measurements											
Lumbar Coronal Cobb (deg)	127	55.2	15.1	10	60.4	13.8	4	66.3	15	0.295	0.156
Fractional Cobb (deg)	124	22.7	9.9	10	24.8	14.5	4	31.5	12.2	0.809	0.156
Coronal Vertical Axis (mm)	127	0.4	35.7	10	0.6	35.7	4	-9.5	85.2	0.908	0.442
T2-T5 Sagittal Cobb (deg)	124	9.1	7.7	9	6.7	7.9	4	6.5	8.4	0.223	0.434
T2-T12 Sagittal Cobb (deg)	125	34.8	18.4	9	28.3	12.9	4	22.5	25	0.307	0.251
T5 - T12 Sagittal Cobb (deg)	126	28.4	16.7	10	27.5	19.1	4	20.3	20.9	0.802	0.392
T10 - L2 Sagittal Cobb (deg)	127	17	16.2	10	21.3	12.9	4	20.8	18.9	0.369	0.664
T12-S1 Sagittal Cobb (deg)	127	-38.8	19.2	10	-42	10.3	4	-6.5	22.8	0.529	0.007*
Sagittal Vertical Axis-SVA (mm)	127	32.1	41.8	10	10.9	42.8	4	125	58.3	0.039*	0.003*
Pelvic Incidence-PI (deg)	121	55.6	10.5	9	55.1	10.4	4	49.5	5.7	0.989	0.236
Sacral Slope (deg)	121	32.3	10.4	9	33.2	6.8	4	26.3	8.4	0.88	0.189
Pelvic Tilt (deg)	121	23.5	9	9	22.2	9.1	4	24	2.9	0.724	0.784
PI-LL Mismatch (deg)	121	17.4	18.1	9	13.3	17	4	43	17.6	0.452	0.015*
Initial Postop Radiographic Measurements											
Lumbar Coronal Cobb (deg)	127	25.4	13	10	25.7	16.9	4	32.8	19.1	0.823	0.422
Fractional Cobb (deg)	125	10	7.4	10	8.1	6.2	4	15	4.8	0.512	0.083
Coronal Vertical Axis (mm)	125	-3.5	24.7	10	-1.9	20	3	22.7	28.5	0.556	0.126
T2-T5 Sagittal Cobb (deg)	127	13.3	8.8	9	7	6.5	4	22.8	21.8	0.026*	0.41
T2-T12 Sagittal Cobb (deg)	127	46.2	15.2	9	41	12.3	4	48.3	12.7	0.329	0.83
T5 - T12 Sagittal Cobb (deg)	127	35.5	14.9	10	35.2	12.1	4	27.5	7.3	0.82	0.244
T10 - L2 Sagittal Cobb (deg)	127	5.8	13	10	3.1	9.4	4	11.3	22.3	0.429	0.678
T12-S1 Sagittal Cobb (deg)	127	-50.9	12.3	10	-55	10.9	4	-34	13.7	0.211	0.022*
Sagittal Vertical Axis-SVA (mm)	126	10.7	39.6	10	-6.6	31.4	3	69.3	20.4	0.094	0.011*
Sacral Slope (deg)	117	34.7	9.5	9	35.8	8	3	27	10.8	0.687	0.249

	No Neuro Deficit (NoDef)			Minor Deficit (Min)			Major Deficit (Maj)			MWU p-values	
	N	Mean	SD	N	Mean	SD	N	Mean	SD	No Def v Minor	Minor v Major
Pelvic Tilt (deg)	117	20.3	9.3	9	18	7.6	3	25.7	7.6	0.532	0.297
PI-LL Mismatch (deg)	117	3.6	13.1	9	-4.4	9.8	3	4	26.9	0.076	0.596

* denotes significant difference with p-value <0.05, deg (degree), mm (millimeter), PI-LL (Pelvic Incidence-Lumbar Lordosis), N (number), SD (standard deviation), MWU (Mann-Whitney U), Min (minor), Maj (major)

At baseline, there were significant differences between the No Def and Major Deficit groups for T12-S1 Sagittal Cobb, SVA, and PI-LL, similarly between the Minor and Major Deficit groups. Also, at baseline there was a significant difference between the No Def and Minor Deficit groups for SVA. Initial post-operative follow-up demonstrated a significant difference between the No Def and Major Deficit groups for T12-S1 Sagittal Cobb and SVA, similarly between the Minor and Major Deficit groups.

Table 3

Comparison of Patient Outcomes at Baseline and 1-Year Postop Between Groups

	No Neuro Deficit (NoDef)			Deficit (Def)			MWU p-value NoDef vs. Def
	N	Mean	SD	N	Mean	SD	
Baseline PROs							
SRS Pain Domain	127	2.8	0.8	14	2.7	0.7	0.740
SRS Function Domain	127	3.1	0.7	14	3.1	0.6	0.793
SRS Self Image Domain	127	2.7	0.7	14	2.7	0.6	0.761
SRS Mental Health Domain	127	3.6	0.8	14	3.6	0.7	0.666
SRS Subscore	127	3.0	0.6	14	3.0	0.6	0.796
ODI	127	37.0	15.3	14	41.1	14.2	0.312
SF-12 MCS	126	49.8	11.2	14	50.1	11.4	0.763
SF-12 PCS	126	33.5	9.4	14	31.2	9.6	0.445
Back Pain NRS	127	6.2	2.2	14	6.6	1.5	0.724
Leg Pain NRS	127	4.0	3.0	14	4.1	3.2	0.945
1-Year Postop PROs							
SRS Pain Domain	127	3.7	0.9	13	3.4	0.7	0.088
SRS Function Domain	127	3.5	0.8	13	3.1	1.0	0.219
SRS Self Image Domain	127	4.0	0.8	13	3.6	1.0	0.148
SRS Mental Health Domain	127	4.0	0.8	13	3.8	1.0	0.446
SRS Subscore	127	3.8	0.7	13	3.5	0.8	0.116
ODI	127	23.1	17.7	13	35.7	17.8	0.016*
SF-12 MCS	122	53.0	9.9	11	51.8	13.1	0.870
SF-12 PCS	122	41.9	10.4	11	32.6	10.9	0.007*
Back Pain NRS	127	2.9	2.6	13	3.2	2.7	0.564
Leg Pain NRS	127	1.7	2.4	13	6.1	2.1	<0.001*

No difference in PROs between the two groups at baseline. At 1-year post-op the Deficit group reported significantly more Leg Pain (6.1 vs 1.7, $p<0.001$) on NRS than the no deficit group and more disability on ODI (35.7 vs 23.1, $p=0.016$) and on SF 12 PCS (32.6 vs 41.9, $p=0.007$).

* denotes significant difference (worsened) with p-value <0.05 , PROs (Patient Related Outcomes Scores), SRS (Scoliosis Research Society), ODI (Oswestry Disability Index), SF-12 MCS/PCS (Short Form Mental Component Score/Physical Component Score), NRS (Numerical Rating Score), N (number), SD (standard deviation), MWU (Mann-Whitney U)

Table 4

Paired Comparison Patient Outcomes Baseline to 1-Year Postop

	Baseline			1-Year Postop			p-value Pre- to 1-year Postop
	N	Mean	SD	N	Mean	SD	
No Neuro Deficit Group (NoDef)							
SRS Pain Domain	127	2.8	0.8	127	3.7	0.9	<0.001 *
SRS Function Domain	127	3.1	0.7	127	3.5	0.8	<0.001 *
SRS Self Image Domain	127	2.7	0.7	127	4.0	0.8	<0.001 *
SRS Mental Health Domain	127	3.6	0.8	127	4.0	0.8	<0.001 *
SRS Subscore	127	3.0	0.6	127	3.8	0.7	<0.001 *
ODI	127	37.0	15.3	127	23.1	17.7	<0.001 *
SF-12 MCS	126	49.8	11.2	122	53.0	9.9	0.003 *
SF-12 PCS	126	33.5	9.4	122	41.9	10.4	<0.001 *
Back Pain NRS	127	6.2	2.2	127	2.9	2.6	<0.001 *
Leg Pain NRS	127	4.0	3.0	127	1.7	2.4	<0.001 *
Deficit Group (Def)							
SRS Pain Domain	14	2.7	0.7	13	3.4	0.7	0.037 *
SRS Function Domain	14	3.1	0.6	13	3.1	1.0	0.937
SRS Self Image Domain	14	2.7	0.6	13	3.6	1.0	0.004 *
SRS Mental Health Domain	14	3.6	0.7	13	3.8	1.0	0.719
SRS Subscore	14	3.0	0.6	13	3.5	0.8	0.033 *
ODI	14	41.1	14.2	13	35.7	17.8	0.328
SF-12 MCS	14	50.1	11.4	11	51.8	13.1	0.929
SF-12 PCS	14	31.2	9.6	11	32.6	10.9	0.657
Back Pain NRS	14	6.6	1.5	13	3.2	2.7	0.004 *
Leg Pain NRS	14	4.1	3.2	13	6.1	2.1	0.045**

For the paired Baseline to 1-Year Post-op PROs comparison, the No neuro deficit group demonstrated significant improvement in all Pre-op to 1-Year post-op PROs. The Deficit group demonstrated significant improvement in Back NRS and SRS Pain and Self Image domain scores, with worsening of Leg NRS.

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denotes significant difference (improvement) with p-value <0.05, *denotes significant difference (worsened) with p-value <0.05, PROs (Patient Reported Outcome Scores), SRS (Scoliosis Research Society), ODI (Oswestry Disability Index), SF-12 MCS/PCS (Short Form Mental Component Score/Physical Component Score), N (number), SD (standard deviation)

Table 5
Comparison of Patient Outcomes at Baseline and 1-Year Postop Minor versus Major Deficit Groups

	No Neuro Deficit (No Def)			Minor Deficit (Min)			MWU p-value No Def v Minor		Major Deficit (Maj)			MWU p-value No Def v Major
	N	Mean	SD	N	Mean	SD	N	Mean	SD			
Baseline PROs												
SRS Pain Domain	127	2.8	0.8	10	2.8	0.8		0.762	4	2.4	0.4	0.256
SRS Function Domain	127	3.1	0.7	10	3.3	0.6		0.397	4	2.5	0.1	0.060
SRS Self Image Domain	127	2.7	0.7	10	2.9	0.6		0.301	4	2.3	0.6	0.280
SRS Mental Health Domain	127	3.6	0.8	10	3.8	0.8		0.703	4	3.2	0.3	0.145
SRS Subscore	127	3.0	0.6	10	3.2	0.6		0.425	4	2.6	0.2	0.073
ODI Score	127	37.0	15.3	10	36.2	13.9		0.766	4	53.5	4.1	* 0.015
SF-12 MCS	126	49.8	11.2	10	52.1	13.0		0.366	4	45.3	3.3	0.381
SF-12 PCS	126	33.5	9.4	10	33.5	10.1		0.914	4	25.6	6.1	0.097
Back NRS	127	6.2	2.2	10	6.3	1.6		0.817	4	7.5	0.6	0.289
Leg NRS	127	4.0	3.0	10	3.3	2.7		0.492	4	6.0	4.1	0.213
1-Year Postop PROs												
SRS Pain Domain	127	3.7	0.9	10	3.3	0.7		0.098	3	3.5	0.8	0.585
SRS Function Domain	127	3.5	0.8	10	3.5	0.8		0.987	3	1.9	0.6	* 0.002
SRS Self Image Domain	127	4.0	0.8	10	3.9	0.9		0.724	3	2.7	0.6	* 0.007
SRS Mental Health Domain	127	4.0	0.8	10	3.9	0.9		0.977	3	3.1	1.0	0.094
SRS Subscore	127	3.8	0.7	10	3.7	0.7		0.505	3	3.7	0.7	* 0.027
ODI	127	23.1	17.7	10	32.0	17.3		0.103	3	48.0	16.4	* 0.025
SF-12 MCS	122	53.0	9.9	9	55.0	11.9		0.283	2	37.5	8.7	* 0.044
SF-12 PCS	122	41.9	10.4	9	33.3	12.0		* 0.029	2	29.0	4.5	0.067
Back NRS	127	2.9	2.6	10	3.8	2.7		0.248	3	1.3	1.2	0.386
Leg NRS	127	1.7	2.4	10	5.7	2.3		* <0.001	3	7.3	1.2	* 0.001

At baseline the Major deficit group had worse ODI compared to the No deficit group. At 1-year postoperative the Major deficit group when compared to the No deficit group had significantly worse SRS Function (1.9 v 3.5, p=0.002) and SRS Self-Image (2.7 v 4.0, p=0.007) component scores, as well as SF-12 MCS (53.0 v 37.5, p=0.044) and ODI (29.0 v 48.0, p=0.025). In addition, at 1-year postoperative, both the Minor (5.7 v 1.7, p<0.001) and Major (7.3 v 5.7, p=0.001) deficit groups demonstrated significant worse Leg NRS compared to the No deficit group.

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* denotes significant difference (worsened) with p-value <0.05,

PROs (Patient-Related Outcomes Scores), SRS (Scoliosis Research Society), ODI (Oswestry Disability Index), SF-12 MCS/PCS (Short Form Mental Component Score/Physical Component Score), NRS (Numerical Rating Score), N (number), SD (standard deviation), MWU (Mann-Whitney U)