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Changes in Radiographic and Clinical Outcomes With Primary Treatment Adult Spinal Deformity Surgeries From Two Years to Three- to Five-Years Follow-up

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Study Design. Retrospective analysis of data entered prospectively into a multicenter database—clinical and radiographic outcomes assessment.

Objective. Our hypothesis is that between the 2-year and the 3- to 5-year points surgically treated adult spinal deformity patients will show significant reduction in outcomes by Scoliosis Research Society (SRS), Oswestry Disability Index (ODI), and numerical rating scale back and leg pain scores and will show increasing thoracic kyphosis, loss of lumbar lordosis, and loss of coronal and sagittal balance.

Summary of Background Data. Most analyses of primary presentation adult spinal deformity surgery assess 2-year follow-up. However, it is established that in some patients unfavorable events occur between the 2-year and 5-year points.

Methods. The cohort of 113 patients entered into a multicenter database with complete preoperative, 2-year, and 3- to 5-year data. All patients who had adult spinal deformity and surgical treatment represented their first reconstruction. Diagnoses were scoliosis (82.5%), kyphosis (10%), and scoliosis and kyphosis combined (7.5%). Outcome measures and basic radiographic parameters (curve size, thoracic and lumbar sagittal plane, coronal and sagittal balance) were assessed at those 3 time intervals. Complications (pseudarthrosis/implant failure, infection, and junctional deformities) were assessed at the 2-year and the 3- to 5-year (mean, 3.76 years) points.

Results. The mean major curve Cobb angle (preoperative, 57°; 2-year, 29°; 3–5 year, 26°); thoracic kyphosis T5 to T12 (30°, 31°, 32°) and lumbar lordosis T12 to sacrum (48°, 49°, 51°) did not change from the 2-year to ultimate follow-up. Likewise, coronal and sagittal balance parameters were the same at 2-year and ultimate follow-up. SRS total scores and modified ODI were similar at the 2 year and final follow-up (SRS: 3.89–3.88; ODI: 19–18). Preoperative SRS total score was 3.17. Six patients demonstrated complications at the 2-year point and additional 9patients demonstrated complications at the 3- to 5-year point. Those 9 patients with complications at ultimate follow-up demonstrated significant deterioration in their ODI and SRS scores when compared with the patients who did not have complications at ultimate follow-up.

Conclusion. Contrary to our hypothesis, we could not establish deterioration in mean radiographic or clinical outcomes between the 2-year and 3- to 5-year follow-up points when analyzing the group as a whole. However, for the 9 patients who experienced complications between 3- and 5-year follow-up, their outcomes were significantly worse than for the other 104 patients.

One should not anticipate an overall radiographic and clinical deterioration of the outcomes of surgically treated primary presentation adult spinal deformity patients in this studied time interval. However, close to 10% of patients will experience a new complication at the 3- to 5-year point, most commonly implant failure/nonunion and/or junctional kyphosis, which will negatively effect the patient-reported outcome.

Key words: adult spinal deformity, patient-reported outcomes, complications. **Spine 2010;35:1849–1854**

Most articles assessing outcomes in orthopedic and spine surgery are based on a minimum 2-year follow-up. A smaller number of articles assess minimum 5-year follow-up. For reconstructive spinal surgical procedures, it is not clear how much the patient's outcome changes from the 2-year point to the 3- to 5-year point. The emphasis of this investigation, which is a retrospective review of data entered prospectively into the Spinal Deformity Study Group (SDSG) database that is funded by Medtronic Spinal & Biologics (Memphis, TN).

Our hypothesis was that outcomes would substantially worsen from the 2-year point to the 3- to 5-year point. We expected significant radiographic loss of correction and deterioration of patient self-reported outcomes (scoliosis research society [SRS], Oswestry Disability Index [ODI], numerical rating scale (NRS) back and leg pain). Finally, we hypothesized that we would see more complications at the 3- to 5-year follow-up than were present at the 2-year point. Those specific compli-

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cations were pseudarthrosis/instrumentation failure, infection, and progressive junctional deformities.

■ Materials and Methods

This is an analysis of patients who were prospectively entered into a multicenter database, which was started in 2002. The organization sponsoring the database is the SDSG, which is funded by Medtronic Spinal and Biologics (Memphis, TN). The purpose of the SDSG is to assess patient outcomes. There are 3 limbs to the SDSG: pediatric, spondylolisthesis, and adult outcomes. The adult outcomes limb represents the study population for this project.

Data were entered by 13 surgeons from 10 centers. Every effort at the 10 centers was made to consecutively enroll patients in the database. However, we did not keep a list of those patients who declined to have their data enrolled. All data entered into the database were included. Patients analyzed were those with a primary adult spinal deformity surgery. Spinal deformity was defined as a scoliosis curve of more than 30°, a kyphosis of greater than 70°, or a coronal or sagittal imbalance treated with a spinal fusion and instrumentation of 5 or more segments. A total of 113 patients met enrollment criteria and had both 2-year and 3- to 5-year follow-up data. A total of 145 patients met enrollment criteria before surgery, but 32 patients either did not have 2-year follow-up or a follow-up in the range of 3 to 5 years postoperative. Therein, the retrieval rate was 78%. Twenty-seven patients were 18 to 39 years old, 58 were 40 to 60 years old, and 28 were more than 60 years old at the time of surgery. Fifty-seven of these patients were fused to the sacrum; 14 were fused to L5; 16 were fused to L4; 43 were stopped proximally in the distal thoracic spine, and 49 were stopped proximally in the upper thoracic spine. Others had fusion that ended in the mid thoracic or upper lumbar spine. Fifteen patients had decompression performed; 8 patients done at 1 level, 5 at 2 levels, and 2 at 3 levels.

We then made an assessment of radiographic outcomes, patient-reported outcomes, and complications identified at the 2-year point and those same parameters at the 3- to 5-year point. The mean follow-up was 3.76 years and 43 patients were observed for 5 years. The purpose of this study was not to assess early complications, but rather complications identified at those longer follow-up points.

Patient-reported outcome measures used were SRS (SRS-23 preoperative and SRS-30 postoperative) instrument, the ODI, and the NRS back and leg pain scores. The primary outcomes measures were the SRS and ODI. The NRS back and leg pain scores were the secondary measures. Recorded radiographic parameters in the coronal plane were Cobb measurements for thoracic and lumbar curves and in the sagittal plane thoracic kyphosis from T5T12 and lumbar lordosis T12 to the sacrum. Alignment parameters judged radiographically were C7 coronal plumb and C7 sagittal plumb relative to the sacrum. Complications studied were pseudarthrosis/implant failure, wound infection, and any other complication that might result in an additional return to the operating room, including proximal or distal junctional kyphosis >20°. Pseudarthrosis was defined as implant failure consisting of either halo around a fixation point, pullout of a fixation point, failure of a rod, loss of correction of ≥10%, or what appeared to be nonunion based on coned-down coronal, sagittal and oblique radiographs of the fusion mass. If a complication was identified at the 2-year point it was not counted again as a complication at the 3- to 5-year point. Our intent was to identify new complications at the 2-year point and also new complications noted in the 3- to 5-year postoperative period.

Table 1. Radiographic Results

Variable	Mean	Standard Deviation	*P*
Major curve (°)			
Preoperative	56.55	16.89	0.0128*
2 yr	29.21	13.06	
Final	26.22	11.50	
Coronal balance (mm)			
Preoperative	22.85	21.12	0.0997
2 yr	20.14	16.70	
Final	18.09	14.15	
Sagittal balance (mm)			
Preoperative	35.66	41.02	0.6195
2 yr	34.53	33.70	
Final	35.69	37.44	
Thoracic kyphosis (°)			
Preoperative	29.76	18.60	0.2315
2 yr	31.01	13.84	
Final	31.77	12.90	
Lumbar lordosis (°)			
Preoperative	48.05	21.65	0.0491*
2 yr	49.48	16.40	
Final	51.31	15.61	

No significant deterioration occurred between the 2-year and final (3–5 year) follow-up for the total group of 113 patients. *P* values assessed whether a significant difference existed between 2-year and 3- to 5-year follow-up.
*Changes are statistically significant, but they represent improvements, not deteriorations, and are clearly not of any clinical importance. They are within the realm of measurement error.

All patients studied were those having primary surgery. If a patient had a prior fusion or instrumentation to address any region of the thoracic or lumbar spine, then that patient was excluded. Patients were only included if they did not have a prior spinal deformity surgery. If they had a discectomy at 1 lumbar level, they were still a candidate for this study. Statistical analysis included descriptive statistics, means, and standard deviations. Differences between outcomes were assessed using paired *t* tests of the differences between the 2 year and the 3- to 5-year measures. Because the outcome measures did not approximate a normal distribution, the results of parametric tests were compared with nonparametric tests. The results of the parametric tests are presented as the results between the 2 methods yielded similar results. Beverly Diamond, PhD, at PhDx (Albuquerque, NM) performed this statistical analysis.

■ Results

Table 1 summarizes the radiographic results. There was not a significant or identifiable change in any of the coronal Cobb parameters for the major curve from the 2-year to the 3- to 5-year point. The segmental sagittal measurements were statistically the same and appear identical at the 2-year *versus* 3- to 5-year point. The coronal and sagittal C7 plumb, as measures of coronal and sagittal balance, were not different at the 2-year *versus* the 3- to 5-year point.

Table 2 summarizes the patient-based outcome measures. For the SRS data, in terms of individual domains and total score, there was no difference at 2 years *versus* 3 to 5 years. For the ODI data, scores at 2 years *versus* 3

Table 2. Patient-Reported Outcome Results

Variable	Mean	Standard Deviation	*P*
ODI			
Preoperative	30.59	17.72	0.2241
2 yr	19.54	16.44	
Final	18.29	17.27	
SRS total score			
Preoperative	3.17	0.62	0.9692
2 yr	3.89	0.70	
Final	3.88	0.71	
SRS satisfaction			
Preoperative	3.03	0.97	0.2891
2 yr	4.35	0.79	
Final	4.27	0.82	
NRS back pain			
Preoperative	5.71	2.43	0.5192
2 yr	2.54	2.45	
Final	2.41	2.59	
NRS leg pain			
Preoperative	3.35	3.40	0.0009
2 yr	1.45	2.38	
Final	1.81	2.69	

No significant deteriorations were identified other than NRS leg pain for the whole group of 113 patients. *P* values assessed whether a significant difference existed between 2-year and 3- to 5-year follow-up. There was a significant deterioration in NRS leg pain score between 2-year and 3- to 5-year follow-up.

to 5 years were not statistically different and appear to be identical. Note the same findings for the NRS back pain scores, which are the same at the 2-year *versus* 3- to 5-year point. NRS leg pain scores significantly deteriorated ($P = 0.0009$).

Table 3 identifies the complications at the 2-year *versus* the 3- to 5-year point. Table 4 describes the demographics of the complication groups. The intent was not to identify all adverse events that the patients experienced after surgery. The purpose was to identify complications commonly seen at a later longer follow-up. Four instrumentation failures and/or pseudarthrosis were identified at the 2-year point and 5 were identified at the 3- to 5-year point. Two infections were identified at the 2-year point and 1 additional one was identified at the 3- to 5-year point. No junctional deformities were identified at the 2-year point and 3 were identified at the 3- to 5-year point. Two patients underwent reoperation at the 2-year point and 5 patients underwent reoperation at the 3- to 5-year point. These complications identified at the 3- to 5-year point were not present at the 2-year point (Table 3). Mean follow-up for the 9 patients with complications at ultimate follow-up was 3.67 years and was 3.77 years for the other 104 patients.

Table 5 shows the effect of complications at final fol-

Table 3. Complications Identified

Complications Identified	2 Year	Final Follow-up (3–5 yr)
Instrumentation failure/pseudarthrosis	4*	5†
Junctional deformity	0	3
Infection-deep wound	2	1
Complications requiring further surgery	2‡	5§
Total complications	6	9

*Two iliac screw fractures; 2 unilateral rod fractures.
†Four bilateral rod fractures; 1 iliac screw fracture.
‡The 2 patients with deep wound infection.
§Four of the 5 patients with implant failure; the 1 patient with deep wound infection.

Table 4. Demographics of Complication Groups

	No Complications* (n = 104 Patients)	2-Year Complications (n = 6 Patients)	3–5-Year Complications (n = 9 Patients)
Age (mean; yr)	53	62	60
No. patients with decompressions	14	1	1
No. levels fused (mean)	10	13	12
No. patients fused to the sacrum	48	3	6

A higher number of patients in the ultimate complication group were fused to the sacrum, but the difference in the 2 complication groups was not significant.
*At ultimate follow-up.

Table 5. Effect of Complications on Outcome at Final Follow-up (3–5 Year) Point

Complications	Variable	Mean	Standard Deviation	*P*
No	Lumbar lordosis (°)			
	Preoperative	48.39	21.91	0.0652
	2 yr	49.90	15.63	
	Final	52.12	15.13	
Yes	Lumbar lordosis (°)			
	Preoperative	44.38	19.49	
	2 yr	44.75	24.29	
	Final	42.25	19.02	
No	ODI			
	Preoperative	30.25	17.67	0.0068
	2 yr	19.23	16.66	
	Final	17.24	17.04	
Yes	ODI			
	Preoperative	34.44	18.99	
	2 yr	23.11	13.86	
	Final	30.27	16.06	
No	SRS total score			
	Preoperative	3.19	0.61	0.0025
	2 yr	3.90	0.72	
	Final	3.93	0.69	
Yes	SRS total score			
	Preoperative	2.96	0.75	
	2 yr	3.75	0.48	
	Final	3.40	0.81	
No	NRS leg pain			
	Preoperative	3.39	3.44	0.1732
	2 yr	1.42	2.42	
	Final	1.70	2.64	
Yes	NRS leg pain			
	Preoperative	2.71	2.93	
	2 yr	1.88	1.89	
	Final	3.13	3.09	

There was a trend toward loss of lumbar lordosis in those patients having complications (n = 9) at final follow-up. There was a significant deterioration in both ODI score and SRS total score at final follow-up. There was also a notable deterioration in NRS leg pain score for those patients without and with complications. The comparison between those with and without complications at final follow-up was not statistically significant. *P* values assessed whether there was a significant difference in the change from 2 year to final follow-up in the group that did not have complications (n = 104) to those who did have complications (n = 9). For the complications patients the radiographic values, ODI, SRS, and NRS leg pain scores at final follow-up represent the values at the point the complication was noted and before any additional revision surgery.

low-up on outcomes. This table compares parameters preoperative, at the 2-year point, and at ultimate follow-up. The *P* values represent comparison of the 2-year point to ultimate follow-up. Those patients at ultimate follow-up were queried before having additional treatment to address their complications. The "no" group means no complications at ultimate follow-up and "yes" group means complications at ultimate follow-up. We were able to identify 3 areas in which there was a significant or nearly significant deterioration in patient outcomes from the 2-year to final follow-up. Those having complications lost 2.5° of lumbar lordosis, as opposed to those who did not have a complication who showed a gain of lumbar lordosis of just over 2°. The difference between these 2 outcomes represented a strong trend ($P = 0.06$). For those patients having complications, Oswestry scores deteriorated 7 points, as opposed to those without complications improved by 2 points, a significant decrease ($P = 0.007$). For total SRS score at final follow-up, those without complications were unchanged from 3.90 to 3.93; those with complications deteriorated by 0.35 points, which was significant ($P = 0.0025$). We also found there was a notable deterioration in the NRS leg pain at final follow-up in those patients with and without complications. The deterioration was 0.32 for those without complications. For patients with complications, the NRS leg pain score increased by 1.25. However, this comparison was not statistically significant ($P = 0.17$) because of the high standard deviations.

■ Discussion

Relatively few peer-reviewed articles assessing adult spinal deformity treatment have been addressed, not only radiographic but patient-reported outcomes.[1–4] Most studies suggest that the ODI and SRS instrument are the most useful patient-reported outcomes for adult deformity patients.[2,4–7] To some extent whether a 1-year, 2-year, or longer outcome approaching 4 to 5 years is adequate is debatable.[2] The most common late complications seem to be delayed wound infection, proximal junctional kyphosis, and pseudarthrosis.[4,6,8–13] Very specific to adult spinal deformity, pseudarthrosis/implant failure is often not detected at the 2-year postoperative point, but presents at 3 to 4 years postoperative point. Unlike surgical treatment of degenerative spondylolisthesis and teenage idiopathic scoliosis, if there is no pseudarthrosis/implant failure at 2-year postoperative, very commonly implant failure will occur at the 3- or 4-year postoperative point.[9,10] Delayed wound infection can occur anywhere from 1 year to 10 years postoperatively. Proximal junctional kyphosis usually presents fairly soon after surgical treatment, but may progress up to 5 years postoperatively.[11–13] Therein, we used standard radiographic measures and NRS back pain, NRS leg pain, ODI, and SRS patient-reported results to assess the patient outcome at 2 year *versus* ultimate follow-up, which ranged 3 to 5 years and averaged just under 4 years. Forty-three patients achieved a 5-year follow-up. The complications we recorded and analyzed were deep wound infection, implant failure/pseudarthrosis, and junctional kyphosis.

The strength of our study is the complete data we collected on these 113 patients at the 3 time points. We expected to see deterioration in the patient self-reported outcomes and radiographic measures between the 2-year point and ultimate follow-up. However, analyzing the entire group of 113 patients we saw no evidence of either patient-reported outcomes or radiographic deterioration from the 2-year point to ultimate follow-up, except for NRS leg pain scores. A very substantial number of patients did present with new complications at ultimate follow-up. Nine of 113 patients presented with implant failure/pseudarthrosis, infection, or junctional kyphosis. Five of these 9 patients underwent revision surgery. A total of 9 patients had complications at ultimate follow-up, as opposed to only 6 patients at the 2-year point. This data suggest that notable late complications may occur more frequently at final follow-up than at the 2-year point. Further, the complications may be more substantial as the ultimate follow-up patients more commonly went on to revision surgery than those patients whose complications presented at the 2-year follow-up point. However, the comparative numbers of the 2 groups are small enough that no statistical conclusions can be made.

Further, for those patients with complications at final follow-up their outcomes demonstrated deterioration of lumbar lordosis, ODI score, total SRS score, and NRS leg pain scores from the 2-year point to ultimate follow-up. Other parameters were not changed. Deterioration in the SRS and ODI scores was of statistical significance. Deterioration in lumbar lordosis and NRS leg pain were not of significance. The deterioration in lumbar lordosis was a change of 4.5°, which may not be of clinical importance. Nonetheless, the deterioration in lumbar lordosis and NRS leg pain is noteworthy and of concern. The other measures studied (major curve, coronal balance, sagittal balance, thoracic kyphosis, SRS satisfaction score, and NRS back pain score) did not deteriorate from the 2-year point to ultimate follow-up in those 9 patients who presented with complications at ultimate follow-up.

This was a group of patients who had predominantly more back pain than leg pain. Only a small number of patients in this study had spinal stenosis substantial enough to warrant decompression procedures (15/113). Before surgery the mean NRS back pain score was 5.71 and mean NRS leg pain score was only 3.35. For the plenary group at follow-up the NRS back pain score was 2.41 and the NRS leg pain score was 1.81. At ultimate follow-up the NRS back pain score was higher than the NRS leg pain score. There was a nonsignificant improvement in NRS back pain score from 2-year to final follow-up, but a significant deterioration in NRS leg pain score from 1.45 to 1.81 ($P = 0.0009$). Exactly what this means is hard to discern. Leg pain can be referable to spinal radiculopathy and can also be referable to arthritic conditions in the hips or knees or ankles and feet. An instru-

mented fusion of the spine should protect patients from recurrent spinal stenosis or disc herniation within the instrumented fusion. Our follow-up period was not long enough to expect a substantial number of patients with proximal or distal junctional spinal canal problems. The meaning and cause of the significant deterioration in leg pain from the 2-year point to ultimate follow-up is not a finding that we can easily explain based on the data we collected to perform this study. For those patients having complications at ultimate follow-up, the deterioration in NRS leg pain score was seemingly even more dramatic from 1.88 to 3.13, which was worse than the preoperative value of 2.71. However, the standard deviations were quite high and therein these changes were not of statistical significance as described in Table 4.

The study population was not a purely homogenous group. The majority of patients had scoliosis; a smaller number had kyphosis, and some had a combination of both with a component of sagittal imbalance. Therefore, the population is not as homogenous as the one that is purely scoliosis or purely kyphosis. Although our follow-up numbers were not 100%, they were very competitive with other clinical studies attempting to follow patients at 2-year points and beyond. We might be criticized for only capturing 3 complications at the 3- to 5-year point, but those are the complications that spinal deformity surgeons view at this time point. If patients present with urinary tract infections, deep venous thrombosis, or myocardial infarction at 4-year follow-up, this cannot be ascribed to the surgical treatment. Another potential limitation of this article is that the average follow-up was 3.76 years. However, many patients were observed to the 5-year point. If we had followed all of these patients until the 5-year point, we might have missed their 4-year complications and therein our 5-year reporting would have been the outcome after revision for the complication. There is good and bad to having essentially a 4-year follow-up on an average *versus* a 5-year follow-up on average. We would need substantially more patients in the database to be able to make further comparisons about the complication *versus* no complication groups in terms of whether factors such as decompression, age, length of fusion, comorbidities, and diagnosis impacted the complications and final outcome. This is a very substantial series of patients. No study comes close to following 113 patients at preoperative, 2-year follow-up, and 3- to 5-year follow-up in the literature. Data were recruited from 10 centers. A database of 150 to 300 patients would be required to answer some of those questions and is therefore beyond the scope of this article.

Based on this data, our suggestion is that it is important to follow all these patients to at least the 3- to 5-year point. A 2-year follow-up is not adequate. The overall results do not appear different at final follow-up, but between 2-year and final follow-up it can be anticipated that close to 10% (8% in this study) of patients will have additional complications. The conclusions of this article are somewhat paradoxical. If you analyze the plenary group, there is not a change from 2 year to ultimate follow-up in outcomes or radiographic parameters. However, if you analyze the subset of patients who had new complications, those patients were impacted negatively in terms of outcomes and radiographic parameters. This points out that when analysis is performed on patients with additional follow-up, both the plenary group and the subgroup with complications should be carefully studied. It is not adequate to simply study the plenary group and comment there is not deterioration. There was no deterioration for patients who did not have complications, but there clearly was deterioration for patients who did have complications. Patients who did have complications represented a small enough sample that this did not affect the overall plenary results. Those patients experiencing complications at final follow-up will demonstrate deterioration in ODI and SRS scores and potentially deterioration in lumbar lordosis and NRS leg pain score. At least one article suggested that perioperative complications do not effect the 2-year patient-reported outcomes.[2] The apparent contradiction in conclusions may be explained by the fact that in that study the patients were treated for complications which then resolved. Patients studied at ultimate follow-up in this study were at a point when the complication was identified but not yet treated to the point of resolution. It may be that complications that have subsequently been treated and resolved will not affect the ultimate outcome, but complications that have not yet led to further treatment and revision will impact the patient-reported outcome.

■ Key Points

- For the plenary group of 113 patients followed between 3 and 5 years, there was no deterioration in radiographic or clinical outcomes from the 2-year point, except NRS leg pain.
- However, 9 of 113 patients presented with new complications at final follow-up that were not present at the 2-year point. These new complications were implant failure/pseudarthrosis, infection, and junctional kyphosis.
- Those patients who experienced new complications at ultimate follow-up demonstrated deterioration in ODI and total SRS scores that were significant and deterioration in lumbar lordosis and NRS leg pain scores that were notable.

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