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# Prevalence and Indications for Unplanned Reoperations Following Index Surgery in the Adult Symptomatic Lumbar Scoliosis NIH-Sponsored Clinical Trial

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**Abstract**

**Study Design:** Longitudinal cohort.

**Objective:** To report on the prevalence and indications for unplanned reoperations following index surgery in the Adult Symptomatic Lumbar Scoliosis NIH-sponsored Clinical Trial.

**Summary of Background Data:** Reoperation following adult spinal deformity surgery exposes the patient to additional surgical risk, increases the cost of care, and decreases the potential cost-effectiveness of the intervention. Accurate data regarding the prevalence and indication for reoperation will facilitate future efforts to minimize risk.

**Methods:** A total of 153 patients underwent adult spinal deformity surgery as part of the observational, randomized, or crossover groups and were eligible for two-year follow-up. Reoperations were meticulously tracked as part of the National Institutes of Health (NIH)–mandated serious adverse event (SAE) reporting. The primary indication for reoperation was obtained from the treating surgeon's operative report.

**Results:** Thirty-two patients had one reoperation, two patients underwent two reoperations, and three patients underwent three reoperations. A total of 45 reoperations were performed in 37 patients. Eleven patients (7%) underwent reoperation within 90 days of the index surgery: two for superficial wound dehiscence, three for radiculopathy with screw removal, and six for acute proximal junctional failure (PJF). Four patients underwent reoperation for PJF more than 90 days from index surgery. Twenty-six patients underwent 28 reoperations for rod fracture/pseudoarthrosis.

**Conclusion:** In a consecutive series of adult spinal deformity surgery patients with meticulous follow-up, 24% of patients required an unplanned reoperation. The most common indication for reoperation was rod fracture/pseudoarthrosis, which occurred from 9 months to 3.7 years following the index surgery and accounted for 62% (28/45) of the reoperations. The second most common indication for reoperation was PJF, which occurred from 1 month to 1.6 years following index surgery and accounted for 22% (10/45) of the reoperations. As these complications will likely increase with longer follow-up, efforts to lower the rates of these complications are warranted.

**Level of Evidence:** Level II.



*Keywords:* Adult lumbar scoliosis; Degenerative scoliosis; Complications; Revisions; Proximal junctional kyphosis; Pseudoarthrosis

## Introduction

Although adult spinal deformity surgery has been shown to dramatically improve quality of life in well-selected patients [1-4], complication rates and unplanned reoperations continue to be a clinically significant problem [5-16]. Unplanned reoperations following adult spinal deformity surgery expose the patient to additional surgical risk, increase the cost of care, and decrease the potential cost-effectiveness of the intervention [8,9]. Efforts to avoid unplanned reoperations are warranted.

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Previous large, multi-institution database studies that have examined unplanned reoperations following adult spinal deformity surgery are limited by incomplete follow-up rates, which may misrepresent the true incidence of reoperation [11-16]. Smaller, single-institution studies may be biased by local risk factors that are not generalizable [7-9].

Accurate estimates of the incidence of reoperation and the identification of risk factors will facilitate future efforts to minimize the risk of reoperation in this patient population. The purpose of the current study was to determine an accurate prevalence and time frame for the various etiologies for unplanned reoperation following surgery in patients with adult symptomatic lumbar scoliosis. We hypothesized that prospectively collected, NIH-trial data with meticulous follow-up will provide the best available evidence regarding unplanned reoperations.

## Methods

After receiving institutional review board approval for this secondary analysis, 153 patients who underwent primary adult spinal deformity surgery as part of the observational, randomized, or crossover groups enrolled in the National Institutes of Health−sponsored Multi-Centered Prospective Study of Quality of Life in Adult Scoliosis (R01-AR-055176; NCT NCT00854828), and reached a minimum of two-year follow-up or had a revision surgery within two years after the index surgery were included in the analysis. All of the 153 patients included in the current study underwent surgery while enrolled in the NIH-monitored study. The included patients from the observational group were patients who had declined to participate in randomization, but agreed to enroll in the observational arm of the NIH study in which they were allowed to choose surgery. The included randomized patients were randomized to surgery or eventually crossed over to surgery from the nonsurgical group.

Following the NIH-approved protocol, patients were enrolled by nine centers from 2010 to 2014. Inclusion criteria were as follows: 40−80 years old, lumbar Cobb $\geqslant 30^{\circ}$ and Scoliosis Research Society−22R (SRS-22R) score $\leqslant$ 4.0 in Pain, Function or Self-Image domains or Oswestry Disability Index (ODI) $\geqslant$ 20. Patients were excluded from the trial if they had undergone prior spinal deformity surgery or prior instrumented fusion. Reoperations were meticulously tracked as part of the NIH-mandated Serious Adverse Event reporting. The primary indication for reoperation was obtained from review of the treating surgeon's operative report.

## Results

One hundred fifty-three patients met inclusion criteria. Mean age at index surgery was 59.91 $\pm$ 8.81 years with 136 females and 17 males. The majority of patients (141, 92%) had a posterior-only surgery. The mean number of surgical levels fused posteriorly was 10.64 $\pm$ 3.93 levels with transforaminal interbody fusions in 1.05 $\pm$ 1.0 levels. There were 85 (56%) Smith-Petersen osteotomies, 3 pedicle subtraction osteotomies, and 2 vertebral column resections. In the 12 patients who had a combined anteroposterior approach, the mean number of surgical levels fused anteriorly was 2.20 $\pm$ 1.81. Thirty-two patients had one reoperation, two patients had two reoperations, and three patients had three reoperations. Therefore, a total of 45 unplanned reoperations in 37 (24%) of the 153 (Table). The multiple reoperation patients had early reoperation for malpositioned screws or early proximal junctional

Table 1
Indications for revision and prevalence.

| Indication for reoperation | Time postoperation | Prevalence, n (%) (n = 153) |
|---|---|---|
| Rod fracture/pseudoarthrosis | 9–44 months | 26 (17) |
| Proximal junctional failure | 1–19 months | 10 (7) |
| Radiculopathy/screw removal | <90 days | 3 (2) |
| Wound dehiscence/drainage | <90 days | 2 (1) |
| Total | 0–44 months | 37 (24) |

failure (PJF) followed by later reoperations for pseudoarthrosis.

Eleven patients (7%) had reoperations within 90 days of the index surgery: two (1.3%) for superficial wound dehiscence, three (1.9%) for radiculopathy with screw removal, and six (3.9%) for acute PJF. Four (2.6%) patients underwent reoperation for PJF more than 90 days from index surgery. A total of 10 patients (7%) underwent reoperation for PJF. A total of 26 patients (17%) underwent 28 reoperations for rod fracture/pseudoarthrosis. As five patients had multiple surgeries, 45 unplanned surgeries occurred in 37 of the 153 patients in the study.

The most common indication for reoperation was rod fracture/pseudoarthrosis, which occurred from 9 to 44 months following the index surgery and accounted for 62% (28/45) of the reoperations. By the two-year follow-up visit, 85% (22/26) of the rod fractures were identified, whereas 15% (4/26) were identified after the two-year follow-up visit. The second most common indication for reoperation was proximal junctional failure that occurred from 1 to 19 months after index surgery and accounted for 22% (10/45) of the reoperations.

## Discussion

In this consecutive series of 153 adult scoliosis surgery patients from the NIH-sponsored trial, the most common indication for reoperation was rod fracture/pseudoarthrosis in 26 (17%) patients from 9 to 44 months following index surgery. The second most common indication for reoperation was proximal junctional failure in 10 (7%) patients from 1 to 19 months after index surgery. As the prevalence of these complications will likely increase with longer follow-up, efforts to follow these patients over a longer time frame are warranted.

Comparison of the current study results to previous literature is somewhat limited by the heterogeneity of ‘‘adult spinal deformity’’ surgery. In 2009, Mok et al. reported a single-institution series of 89 patients who underwent at minimum of four-level fusion for adult spinal deformity. With 91% follow-up, the cumulative reoperation rate was 26%. Infection was the most common indication for reoperation, followed by adjacent segment problems, then implant failure and pseudoarthrosis. On multivariate analysis, smoking was more common in the reoperation group [7].

Interestingly, surgical site infection requiring a return to the operating room was not reported in the current study population. Two patients (1.3%) did have early reoperation for superficial wound dehiscence. It is unclear if these two patients would have been later classified as a surgical site infection without the early reoperation. Future studies are needed to determine which factors may have contributed to the very low wound complication rate. Infection prevention protocols were not standardized among centers, nor were data collected for the current study. Possible strategies in current use may include avoiding high-risk patients (eg, poorly controlled diabetics or smokers), perioperative glycemic control, perioperative antibiotics, intraoperative irrigation with or without betadine, and intrawound vancomycin powder.

In 2010, Pichelmann et al. reported a large, single-institution series of 643 patients who underwent a minimum of five-level fusion for adult spinal deformity. The reoperation rate was relatively low at 9%, with pseudoarthrosis reported as the most common cause. Of note, the mean age of the group was significantly lower than the current study (38 vs. 60 years) and the group was more heterogeneous by diagnosis [6]. In 2014, Sánchez-Mariscal et al. reported 59 patients who underwent a minimum four-level fusion for adult scoliosis. The reoperation rate was relatively high at 36%, with painful/prominent implants reported as the most common cause. Of note, length of follow-up was 8.5 years with 41% of the patients having greater than 10-year follow-up [7]. In 2015, Barton et al. reported risk for rod fracture following posterior correction of adult spinal deformity in 75 consecutive patients. The overall incidence was 9.3%. Risk factors for rod fracture included crossing both the thoracolumbar and lumbosacral junction, sagittal rod contour $>60^{\circ}$, rod connectors at the site of failure, and pseudoarthrosis at > 1-year follow-up [10].

Several previous reports have used patient samples from the International Spine Study Group (ISSG), which is a multicenter, prospective database of adult spinal deformity patients with a more heterogeneous inclusion criteria when compared the inclusion criteria of the current study. Additionally, variations in study design and follow-up rates have provided a range of reoperation rates from 17% to 28%. In 2013, Scheer et al. reported reoperation rates from the ISSG database. The reoperation rate was 17% and the most common indications for reoperation included instrumentation complications and radiographic failure not otherwise specified [14]. In 2015, Soroceanu et al. reported ‘‘radiographic and implant-related complications’’ in a sample of adult spinal deformity surgery patients from the ISSG. All patients with complete 2-year follow-up were included. The incidence of radiographic and implant-related complications was 32% with 53% requiring reoperation. Rod breakage and proximal junctional kyphosis were also common indications for reoperation [15]. In 2016, Smith et al. reported complication rates associated

with adult spinal deformity surgery in a sample of patients from ISSG. At least one revision was required in 28% of the patients who reached the 2-year minimum follow-up [16]. Also in 2016, Passias et al. reported on revision surgical procedures in a sample of adult spinal deformity patients from ISSG. The authors intentionally excluded wound complications. With two years of follow-up, they reported a 16.5% incidence, with nearly half of the revision occurring between the one- and two-year follow-ups. Implant complications including rod failure and proximal junctional kyphosis were the most common indications for revision.

Recently, a non-ISSG study was published in 2016. Puvanesarajah et al. used the PearlDiver database (2005−2012) to estimate revision surgery following primary adult spinal deformity surgery (posterolateral fusion of eight or more levels) in patients 65 years and older. The authors reported a 10.5% revision rate at the one-year follow-up and an 18.5% revision rate at the five-year follow-up [16].

The results of the current study support the previous literature showing clinically significant reoperation rates in adult spinal deformity patients. The precise prevalence varies in the literature because of the heterogeneity of ‘‘adult spinal deformity surgery,’’ as well as the heterogeneity of study design and follow-up rates. Although a multivariate analysis to identify risk factors associated with unplanned surgery would have been ideal, the sample size in the current study is too small and the number of variables to consider too many to produce valid results. The current study suggests that efforts to decrease the incidence of proximal junctional failure and rod fracture/pseudoarthrosis appear to be the most promising areas for improvement. Future studies are needed to more clearly understand the various risk factors and prevention strategies for rod fracture/pseudoarthrosis and proximal junctional failure in the adult spinal deformity population.

## References

[1] Bridwell KH, Glassman S, Horton W, et al. Does treatment (nonoperative and operative) improve the two-year quality of life in patients with adult symptomatic lumbar scoliosis: a prospective multicenter evidence-based medicine study. *Spine (Phila Pa 1976)* 2009;34:2171−8.

[2] Li G, Passias P, Kozanek M, et al. Adult scoliosis in patients over sixty-five years of age: outcomes of operative versus nonoperative treatment at a minimum two-year follow-up. *Spine (Phila Pa 1976)* 2009;34:2165−70.

[3] Yadla S, Maltenfort MG, Ratliff JK, Harrop JS. Adult scoliosis surgery outcomes: a systematic review. *Neurosurg Focus* 2010;28:E3.

[4] Theis J, Gerdhem P, Abbott A. Quality of life outcomes in surgically treated adult scoliosis patients: a systematic review. *Eur Spine J* 2015;24:1343−55.

[5] Mok JM, Cloyd JM, Bradford DS, et al. Reoperation after primary fusion for adult spinal deformity: rate, reason, and timing. *Spine (Phila Pa 1976)* 2009;34:832−9.

[6] Pichelmann MA, Lenke LG, Bridwell KH, et al. Revision rates following primary adult spinal deformity surgery: six hundred forty-three consecutive patients followed-up to twenty-two years postoperative. *Spine (Phila Pa 1976)* 2010;35:219−26.

[7] Sánchez-Mariscal F, Gomez-Rice A, Izquierdo E, et al. Survivorship analysis after primary fusion for adult scoliosis. Prognostic factors for reoperation. *Spine J* 2014;14:1629−34.

[8] Paulus MC, Kalantar SB, Radcliff K. Cost and value of spinal deformity surgery. *Spine (Phila Pa 1976)* 2014;39:388−93.

[9] McCarthy I, O'Brien M, Ames C, et al. International Spine Study Group. Incremental cost-effectiveness of adult spinal deformity surgery: observed quality-adjusted life years with surgery compared with predicted quality-adjusted life years without surgery. *Neurosurg Focus* 2014;36:E3.

[10] Barton C, Noshchenko A, Patel V, et al. Risk factors for rod fracture after posterior correction of adult spinal deformity with osteotomy: a retrospective case-series. *Scoliosis* 2015;10:30.

[11] Hart R, McCarthy I, O'brien M, et al. International Spine Study Group. Identification of decision criteria for revision surgery among patients with proximal junctional failure after surgical treatment of spinal deformity. *Spine (Phila Pa 1976)* 2013;38:E1223−7.

[12] Scheer JK, Tang JA, Smith JS, et al. Reoperation rates and impact on outcome in a large, prospective, multicenter, adult spinal deformity database: clinical article. *J Neurosurg Spine* 2013;19:464−70.

[13] Soroceanu A, Diebo BG, Burton D, et al. International Spine Study Group. Radiographical and implant-related complications in adult spinal deformity surgery: incidence, patient risk factors, and impact on health-related quality of life. *Spine (Phila PA 1976)* 2015;40:1414−21.

[14] Smith JS, Klineberg E, Lafage V, et al. International Spine Study Group. Prospective multicenter assessment of perioperative and minimum 2-year postoperative complications rates associated with adult spinal deformity surgery. *J Neurosurg Spine* 2016;25:1−14.

[15] Passias PG, Soroceanu A, Yang S, et al. Predictors of revision surgical procedure excluding wound complications in adult spinal deformity and impact on patient-reported outcomes and satisfaction: a two-year follow-up. *J Bone Joint Surg Am* 2016;98:536−43.

[16] Puvanesarajah V, Shen FH, Cancienne JM, et al. Risk factors for revision surgery following primary adult spinal deformity surgery in patients 65 years and older. *J Neurosurg Spine* 2016;25:486−93.