

Prospective multicenter assessment of risk factors for rod fracture following surgery for adult spinal deformity

Clinical article

JUSTIN S. SMITH, M.D., PH.D.,¹ ELLEN SHAFFREY,¹ ERIC KLINEBERG, M.D.,² CHRISTOPHER I. SHAFFREY, M.D.,¹ VIRGINIE LAFAGE, PH.D.,³ FRANK J. SCHWAB, M.D.,³ THEMISTOCLES PROTOPSALTIS, M.D.,³ JUSTIN K. SCHEER, B.S.,⁴ GREGORY M. MUNDIS JR., M.D.,⁵ KAI-MING G. FU, M.D., PH.D.,⁶ MUNISH C. GUPTA, M.D.,² RICHARD HOSTIN, M.D.,⁷ VEDAT DEVIREN, M.D.,⁸ KHALED KEBASHI, M.D.,⁹ ROBERT HART, M.D.,¹⁰ DOUGLAS C. BURTON, M.D.,¹¹ BRETON LINE, B.S.M.E.,¹² SHAY BESS, M.D.,¹² CHRISTOPHER P. AMES, M.D.,¹³ AND THE INTERNATIONAL SPINE STUDY GROUP

¹Department of Neurosurgery, University of Virginia, Charlottesville, Virginia; ²Department of Orthopaedic Surgery, University of California, Davis, Sacramento; ³University of California San Diego, School of Medicine, San Diego; ⁴San Diego Center for Spinal Disorders, La Jolla; Departments of ⁵Orthopedic Surgery and ¹³Neurological Surgery, University of California, San Francisco, San Francisco, California; ⁶Department of Orthopaedic Surgery, NYU Hospital for Joint Diseases; ⁷Department of Neurosurgery, Weill Cornell Medical College, New York, New York; ⁸Department of Orthopaedic Surgery, Baylor Spinal Center, Plano, Texas; ⁹Department of Orthopaedic Surgery, Johns Hopkins University, Baltimore, Maryland; ¹⁰Department of Orthopaedic Surgery, Oregon Health & Science University, Portland, Oregon; ¹¹Department of Orthopaedic Surgery, University of Kansas Medical Center, Kansas City, Kansas; and ¹²Rocky Mountain Hospital for Children, Denver, Colorado

Object. Improved understanding of rod fracture (RF) following adult spinal deformity (ASD) surgery could prove valuable for surgical planning, patient counseling, and implant design. The objective of this study was to prospectively assess the rates of and risk factors for RF following surgery for ASD.

Methods. This was a prospective, multicenter, consecutive series. Inclusion criteria were ASD, age > 18 years, ≥ 5 levels posterior instrumented fusion, baseline full-length standing spine radiographs, and either development of RF or full-length standing spine radiographs obtained at least 1 year after surgery that demonstrated lack of RF. ASD was defined as presence of at least one of the following: coronal Cobb angle ≥ 20°, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) ≥ 25°, and thoracic kyphosis ≥ 60°.

Results. Of 287 patients who otherwise met inclusion criteria, 200 (70%) either demonstrated RF or had radiographic imaging obtained at a minimum of 1 year after surgery showing lack of RF. The patients' mean age was 54.8 ± 15.8 years; 81% were women; 10% were smokers; the mean body mass index (BMI) was 27.1 ± 6.5; the mean number of levels fused was 12.0 ± 3.8; and 50 patients (25%) had a pedicle subtraction osteotomy (PSO). The rod material was cobalt chromium (CC) in 53%, stainless steel (SS), in 26%, or titanium alloy (TA) in 21% of cases; the rod diameters were 5.5 mm (in 68% of cases), 6.0 mm (in 13%), or 6.35 mm (in 19%). RF occurred in 18 cases (9.0%) at a mean of 14.7 months (range 3–27 months); patients without RF had a mean follow-up of 19 months (range 12–24 months). Patients with RF were older (62.3 vs 54.1 years, $p = 0.036$), had greater BMI (30.6 vs 26.7, $p = 0.019$), had greater baseline sagittal malalignment (SVA 11.8 vs 5.0 cm, $p = 0.001$; PT 29.1° vs 21.9°, $p = 0.016$; and pelvic incidence [PI]–lumbar lordosis [LL] mismatch 29.6° vs 12.0°, $p = 0.002$), and had greater sagittal alignment correction following surgery (SVA reduction by 9.6 vs 2.8 cm, $p < 0.001$; and PI–LL mismatch reduction by 26.3° vs 10.9°, $p = 0.003$). RF occurred in 22.0% of patients with PSO (10 of the 11 fractures occurred adjacent to the PSO level), with rates ranging from 10.0% to 31.6% across centers. CC rods were used in 68% of PSO cases, including all with RF. Smoking, levels fused, and rod diameter did not differ significantly between patients with and without RF ($p > 0.05$). In cases including a PSO, the rate of RF was significantly higher with CC rods than with TA or SS rods (33% vs 0%, $p = 0.010$). On multivariate analysis, only PSO was associated with RF ($p = 0.001$, OR 5.76, 95% CI 2.01–15.8).

Conclusions. Rod fracture occurred in 9.0% of ASD patients and in 22.0% of PSO patients with a minimum of 1-year follow-up. With further follow-up these rates would likely be even higher. There was a substantial range in the rate of RF with PSO across centers, suggesting potential variations in technique that warrant future investigation. Due to higher rates of RF with PSO, alternative instrumentation strategies should be considered for these cases.

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KEY WORDS • adult • complication • deformity • instrumentation • surgery • pedicle subtraction osteotomy • rod fracture • sagittal imbalance • spine

Abbreviations used in this paper: ASD = adult spinal deformity; BMI = body mass index; BMP-2 = recombinant human bone morphogenetic protein-2; CCI = Charlson Comorbidity Index; ISSG = International Spine Study Group; LL = lumbar lordosis; PI = pelvic incidence; PSO = pedicle subtraction osteotomy; PT = pelvic tilt; SVA = sagittal vertical axis.

SUBSTANTIAL improvements in surgical techniques, instrumentation, perioperative management, and reduction of risk related to comorbid conditions

This article contains some figures that are displayed in color online but in black-and-white in the print edition.

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have broadened the indications for correction of adult spinal deformity (ASD) and have enabled correction of increasingly more complex deformities. Although data thus far seem to indicate that selected adults with spinal deformity do have significant potential for improvement with surgical treatment, overall complication rates remain high and represent areas for continued improvement^{7,8,32,39-43}. Despite great advances, an important source of complications and patient morbidity remains the inherent limitations of the durability of spinal implants.^{1,3,4,6,13-17,19-21,23,25-27,30,32,33,38,44-47,50,51}

Although development of rod fracture may have significant consequences for patients, including pain, loss of deformity correction, and the need for revision surgery, the literature regarding rod fracture remains relatively limited.^{1,4,9,11,15,19,23,29,38,49,51,52} Previous reports discussing rod fracture have many limitations, including retrospective design, inclusion of patients from only a single surgeon's cases or from a single institution, or lack of details regarding the specific type or composition of instrumentation. In addition, most previous series lack sufficient numbers of patients to enable a meaningful analysis of the subset with rod fracture.

Improved understanding of rod fracture following ASD surgery could prove valuable for surgical planning, patient counseling, and implant design. Our objective was to assess the rates of, and risk factors for, rod fracture following surgery for ASD based on a prospective, multicenter, consecutive series with a minimum of 1-year follow-up.

Methods

Patient Population

This is a prospective, multicenter, consecutive series of ASD patients treated by members of the International Spine Study Group (ISSG), which is composed of 11 sites across the United States. Patients were enrolled through a protocol approved by the institutional review boards of the participating sites. Inclusion criteria for the ISSG ASD database are patient age > 18 years and presence of at least one of the following measures of spinal deformity: coronal Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) $\geq 25^\circ$, and thoracic kyphosis $\geq 60^\circ$. Deformities resulting from neuromuscular disease, trauma, spinal infection, ankylosing spondylitis, or tumors are not included in the database. In addition to the database inclusion criteria, patients were included in the present study only if they met the following criteria: 1) ≥ 5 levels posterior instrumented arthrodesis, 2) availability of baseline full-length standing radiographs, and 3) development and documentation of rod fracture or standing radiographs obtained at a minimum of 1 year after surgery and demonstrating lack of rod fracture.

Data Collection and Radiographic Assessment

Full-length free-standing postero-anterior and lateral spine radiographs (36-inch cassette) obtained at baseline and 1-year follow-up were analyzed using validated software (Spineview, Surgiview).^{10,31} All radiographic mea-

asures were performed at a central location (NYU Hospital for Joint Diseases) based on standard techniques^{2,28} and included coronal Cobb angle, thoracic kyphosis (T4-12; Cobb angle between the superior endplate of T-4 and the inferior endplate of T-12), LL (Cobb angle between the superior endplate of L-1 and the superior endplate of S-1), SVA (C-7 plumb line relative to S-1), PT, and mismatch between pelvic incidence (PI) and lumbar lordosis (LL).

For all patients meeting inclusion criteria, demographic, clinical, operative, and follow-up data were extracted from the ISSG database. Extracted demographic and clinical data included patient age, sex, body mass index (BMI), smoking status, history of prior spine surgery, and Charlson Comorbidity Index¹² (CCI). Operative data included levels of spinal instrumented arthrodesis, whether a pedicle subtraction osteotomy (PSO) was performed, rod composition and diameter, and grafting material used for arthrodesis, including recombinant human bone morphogenetic protein-2 (BMP-2). The US Food and Drug Administration (FDA) approved BMP-2 use in the spine with an absorbable collagen sponge scaffold (INFUSE, Medtronic Sofamor Danek) for the treatment of degenerative disc disease via anterior lumbar interbody fusion in an LT-CAGE (Medtronic Sofamor Danek) in skeletally mature patients. Other uses of BMP-2 in the spine, including the majority summarized in the present study, are off-label applications.

Rod fracture occurrence and level of fracture were based on review of standardized complication assessment forms that are completed for each patient at each follow-up interval (typically, 6 weeks, 6 months, 1 year, and 2 years) and through review of follow-up full-length radiographs. Data on all rod fractures were collected and analyzed in the present study, including those that were symptomatic and those found incidentally. Rod fracture management was determined based on review of complications-reporting forms and standardized revision surgery forms.

Data and Statistical Analysis

The mean and standard deviation were used to describe continuous variables, and frequency analyses were used for categorical variables. For categorical variables, cross-tabulations were generated, and the Fisher exact or Pearson chi-square test was used to compare distributions. For continuous variables, t-tests were used to investigate differences between subsets of patients classified by categorical data. Changes in radiographic measures between baseline and 1-year follow-up were evaluated using a paired t-test analysis, and group comparison was performed using an unpaired t-test analysis. Patients were stratified into one of two groups, those who did and those who did not develop rod fracture during a minimum of 1-year follow-up. Demographic, clinical, surgical, and radiographic parameters were compared both within and between these groups. Time to rod fracture was calculated based on the time elapsed between surgery and definitive demonstration of rod fracture on imaging. Stepwise binary logistic regression analysis was performed to assess for independent demographic, clinical, radiographic, and operative differences between patients who did or did

not develop rod fracture. Statistical analyses were 2-sided, and $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS software (version 21, SPSS Inc).

Results

Patient Population

Of the 287 patients who otherwise met inclusion criteria, 200 (70%) either demonstrated rod fracture or had radiographic imaging at a minimum of 1 year after surgery that was available for review and showed lack of rod fracture. The 87 patients who did not meet inclusion criteria did not differ significantly from those meeting inclusion criteria with regard to age ($p = 0.531$), sex ($p = 0.616$), CCI ($p = 0.709$), smoking status ($p = 1.00$), baseline sagittal spinopelvic alignment (SVA, $p = 0.843$; PT, $p = 0.793$; or PI-LL mismatch, $p = 0.688$), whether an osteotomy was performed ($p = 0.892$), or number of vertebral levels fused (11.1 vs 11.8, respectively; $p = 0.075$).

The baseline demographic characteristics of the 200 patients who met the inclusion criteria are summarized in Table 1. Their mean age at the time of surgery was 54.8 years (SD 15.8 years), and 81% of the patients were women. The mean BMI was 27.1 (SD 6.5), which corresponds to a BMI category of overweight, and the mean CCI was 1.4 (SD 1.6). Overall, 10% of the patients were smokers, and 42% of patients had a history of prior spine surgery. The mean number of vertebral levels fused was 12 (SD 4), and the procedure for 50 (25%) of the patients included a PSO. The rod material was cobalt chromium (CC, in 53% of cases), stainless steel (SS, in 26%), or titanium alloy (TA, in 21%), and the rod diameters were 5.5 mm (in 68% of cases), 6.0 mm (in 13%), or 6.35 mm (in 19%).

Rod fracture occurred in 18 patients (9.0%) at a mean of 14.7 months (range 3–27 months, Figs. 1–3); patients without rod fracture had a mean follow-up of 19 months (range 12–24 months). For 6 patients with rod fracture (2 with bilateral and 4 with unilateral rod fracture), the fracture was found incidentally on routine imaging, and there were no apparent clinical symptoms attributed to the fracture. The remaining 12 patients with rod fracture all presented with new onset of pain that was primarily located in the back. Rod fracture was unilateral in 11 patients (incidentally found in 4 cases and symptomatic in

7) and was bilateral in 7 patients (2 incidentally found in 2 cases and symptomatic in 5) ($p = 1.00$).

As of last follow-up, 12 of the 18 patients with rod fracture had undergone revision surgery, primarily consisting of rod replacement and re-arthrodesis. Pseudarthrosis was confirmed intraoperatively for each of the 12 patients who underwent revision. Of the 6 patients who had not undergone revision surgery, 4 (Patients 6, 9, 16, and 17; Fig. 3) had incidentally found unilateral rod fractures, 1 (Patient 11; Fig. 3) had a unilateral rod fracture with some increase in back pain but clear evidence of bony fusion on plain radiograph, and 1 (Patient 5; Fig. 3) had bilateral rod fracture but was asymptomatic, had maintained alignment, and did not want revision.

Assessment of Rod Fracture Patients and Risk Factors

Compared with patients who did not develop rod fracture, the group with rod fracture had a significantly higher mean age (62.3 vs 54.1 years, $p = 0.036$), had a significantly greater BMI (30.6 vs 26.7, $p = 0.019$), and included a significantly higher proportion of patients with a history of previous spine surgery (67% vs 39%, $p = 0.042$; Table 1). Sex, smoking, and severity of comorbidities (based on CCI) were not significantly associated with occurrence of rod fracture (Table 1).

With regard to surgical parameters, the occurrence of rod fracture was not significantly associated with the number of vertebral levels fused ($p = 0.645$), the mean rod diameter (0.396), or the proportion of rods that were at least 6.0 mm in diameter ($p = 0.189$; Table 2). Performance of a PSO was associated with a significantly higher rate of rod fracture compared with cases in which a PSO was not performed (22.0% vs 4.7%, $p = 0.001$). PSO was performed in 21.4% of the patients who did not develop rod fracture and was performed in 61.1% of the cases in which rod fracture occurred ($p = 0.001$; Table 2). Type of rod material was also significantly associated with rod fracture rates, with CC, SS, and TA rods having fracture rates of 14.2% (15 of 106), 3.8% (2 of 52), and 2.4% (1 of 42) ($p = 0.025$; Table 2). Notably, there was a significant preference for the use of CC rods in the more biomechanically demanding PSO cases compared with the use of SS or TA rods; specifically, CC rods were used in 68.0% of cases in which a PSO was performed and in 47.3% of cases in which a PSO was not performed ($p = 0.014$).

Patients who developed rod fracture had significantly

TABLE 1: Baseline demographic parameters for 200 adults treated surgically for spinal deformity*

Parameter	All Patients (n = 200)	Rod Fracture		p Value†
		No (n = 182)	Yes (n = 18)	
mean age, yrs	54.8 ± 15.8	54.1 ± 16.0	62.3 ± 11.3	0.036
female sex	81%	82%	72%	0.340
mean BMI	27.1 ± 6.5	26.7 ± 6.4	30.6 ± 5.9	0.019
mean CCI	1.4 ± 1.6	1.4 ± 1.6	1.8 ± 2.1	0.349
smokers	10%	12%	0%	0.224
prior spine surgery	42%	39%	67%	0.042

* Mean values are presented ± SD. Bold type indicates statistical significance.

† Comparison of groups with and without rod fracture.

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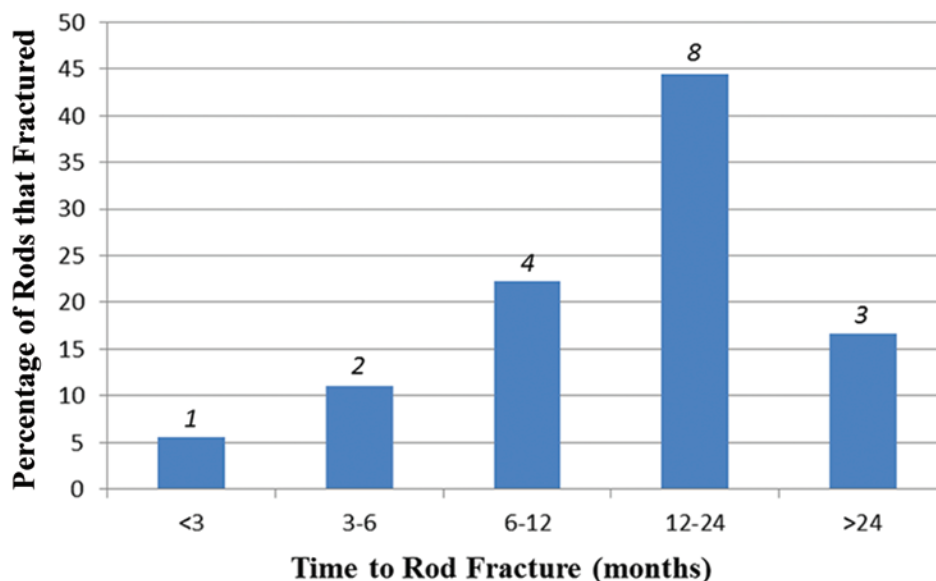


Fig. 1. Time interval of rod fracture for 18 adults treated surgically for spinal deformity. The italicized number above each bar reflects the number of fractures corresponding to the time interval.

greater preoperative sagittal spinopelvic malalignment compared with those who did not develop rod fracture. These baseline differences included SVA (11.8 cm vs 5.0 cm, $p = 0.001$), PT (29.1° vs 21.9° , $p = 0.016$), and PI-LL mismatch (29.6° vs 12.0° , $p = 0.002$) (Table 3). Following surgical treatment, measures of mean sagittal spinopelvic alignment (thoracic kyphosis, SVA, PT, and PI-LL mismatch) did not differ significantly between the patients who subsequently developed rod fracture and those who did not (Table 3). Thus, the patients who developed rod fracture had significantly greater magnitudes of sagittal spinopelvic realignment changes with surgical treat-

ment, including SVA (reduction by 9.6 cm vs 2.8 cm, $p < 0.001$) and PI-LL mismatch (reduction by 26.3° vs 10.9° , $p = 0.003$) (Table 3). In contrast, patients who did not develop rod fracture had greater coronal deformity, compared with patients who developed rod fracture (mean maximum coronal Cobb angle 46.3° vs 25.2° , $p < 0.001$) (Table 3). On multivariate analysis of risk factors for rod fracture, only performance of PSO remained in the best-fit model ($p = 0.001$, OR 5.76, 95% CI 2.01–15.8).

Assessments for associations between the rates of rod fracture and the type of grafting material used for arthrodesis were performed separately for cases that did

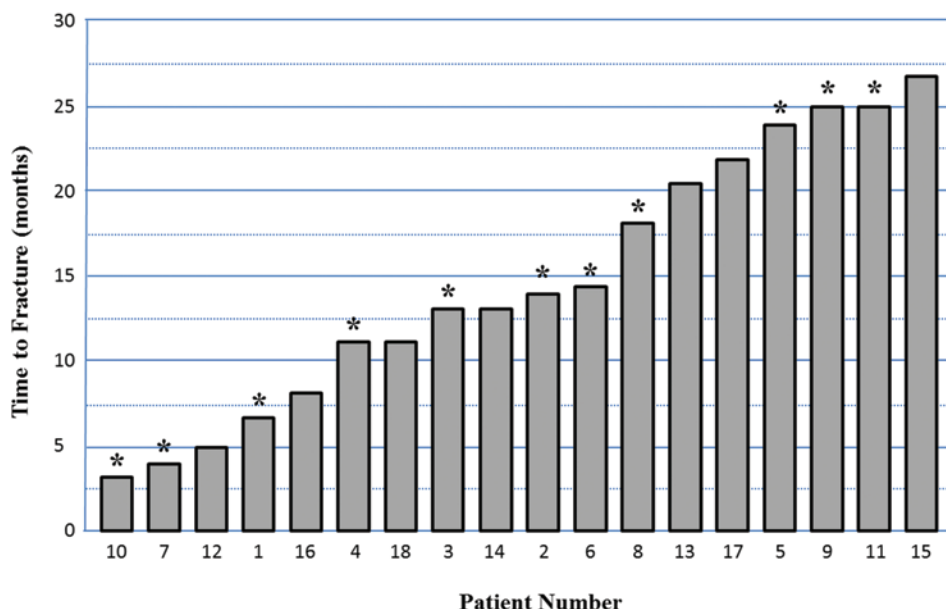


Fig. 2. Summary of time to rod fracture (months) for 18 adults treated surgically for spinal deformity. Cases are ordered based on shortest to longest interval between surgery and rod fracture, with case numbers corresponding to those shown in Fig. 1. Asterisks denote cases in which a pedicle subtraction was performed.

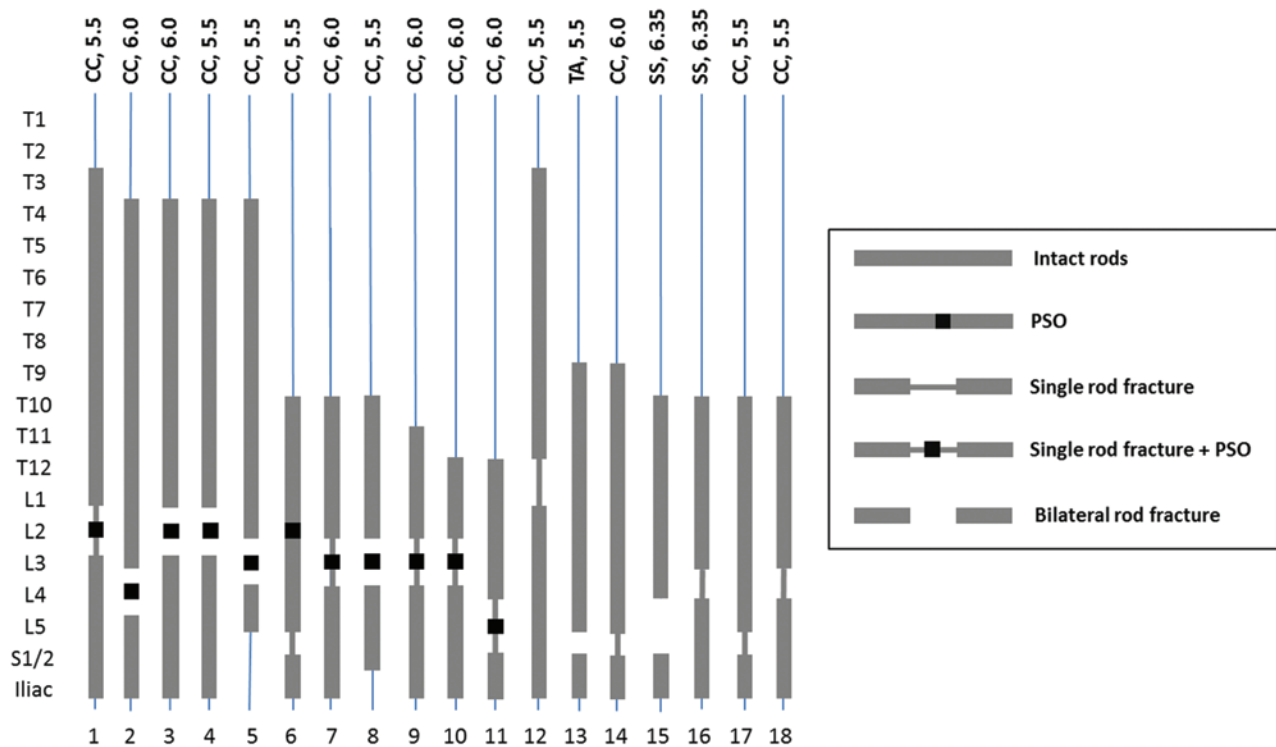


FIG. 3. Summary of rod composition, diameter, and location of rod fracture among 18 adults treated surgically for spinal deformity. Spinopelvic levels are distributed along the left side, including thoracic (T), lumbar (L), sacral (S), and ilium (I). Each vertical bar represents a single case, with the extent of the bar reflecting the instrumented and arthrodesed levels. Gaps within the vertical bars represent locations of rod fracture. Complete gaps indicate bilateral rod fracture and gaps spanned by a vertical line reflect unilateral rod fracture. Black squares denote the location of a pedicle subtraction osteotomy. Shown along the top of each vertical line are the rod diameter (mm) and composition. Patient 15 developed unilateral rod fracture at L4–5 and contralateral rod fracture at L5–S1. CC = cobalt chromium; SS = stainless steel; TA = titanium alloy.

and did not include a PSO due to the significantly different rates of rod fracture between these two groups. Among the cases with a PSO, the posterior grafting material included allograft in 50%, iliac crest autograft in 52%, locally harvested autograft in 74%, demineralized bone matrix in 40%, and BMP-2 in 44%. For the cases

that included a PSO, BMP-2 was used in an interbody location (anterior and/or posterior approach) in 30%. None of these grafting materials demonstrated a significant association with the occurrence of rod fracture among these cases ($p > 0.05$).

TABLE 2: Comparison of surgical parameters for 200 adults with spinal deformity, stratified based on the occurrence of rod fracture*

Radiographic Parameter	Rod Fracture		p Value
	No (n = 182)	Yes (n = 18)	
mean no. of vertebral levels fused	12.0 ± 3.8	11.6 ± 3.3	0.645
performance of PSO	21.4%	61.1%	0.001
rod material			0.025
CC	50.0%	83.3%	
TA	22.5%	5.6%	
SS	27.5%	11.1%	
mean rod diameter (mm)	5.7 ± 0.3	5.8 ± 0.3	0.396
rod diameter ≥6.0 mm	31.9%	50.0%	0.189

* Mean values are presented ± SD. Bold type indicates statistical significance. CC = cobalt chromium; PSO = pedicle subtraction osteotomy; SS = stainless steel; TA = titanium alloy.

Among the cases that did not include a PSO, the posterior grafting material included allograft in 80%, iliac crest autograft in 27%, locally harvested autograft in 59%, demineralized bone matrix in 35%, and BMP-2 in 65%. For the cases that did not include a PSO, BMP-2 was used in an interbody location (anterior and/or posterior approach) in 43%. None of these grafting materials demonstrated a significant association with the occurrence of rod fracture in this patient group ($p > 0.05$).

Subanalysis of PSO Cases

The rate of rod fracture among cases that included a PSO was 22.0%, and in 10 of the 11 cases of PSO with a rod fracture, the fracture(s) occurred at or adjacent to the level of the PSO (Fig. 3). The mean time to rod fracture for PSO cases was 14.4 months. The rate of rod fracture for PSO cases ranged from 10.0% to 31.6% across contributing centers. CC rods were used in 68% of PSO cases, including all with rod fracture (Fig. 3), and among cases including a PSO, the rate of rod fracture was significantly higher compared with cases in which TA or SS rods were used (33% vs 0%, $p = 0.010$). Univariate analysis did not

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TABLE 3: Comparison of baseline and postoperative (after surgical correction) radiographic measures for 200 adults with spinal deformity, stratified based on the occurrence of rod fracture*

Radiographic Parameter	Rod Fracture		p Value
	No (n = 182)	Yes (n = 18)	
mean max coronal Cobb angle (°)			
baseline	46.3 ± 21.6	25.2 ± 25.0	<0.001
following surgical treatment	21.3 ± 15.4	16.2 ± 19.1	0.206
change following surgery	-27.0 ± 17.1	-9.9 ± 12.8	<0.001
p value†	<0.001	0.004	—
mean thoracic kyphosis, T4–12 (°)			
baseline	-30.4 ± 17.7	-25.7 ± 22.6	0.322
following surgical treatment	-37.4 ± 14.5	-38.9 ± 18.3	0.693
change following surgery	-7.0 ± 14.5	-13.3 ± 15.1	0.101
p value†	<0.001	0.003	—
mean C7–S1 SVA (cm)			
baseline	5.0 ± 7.7	11.8 ± 7.7	0.001
following surgical treatment	2.4 ± 5.4	2.2 ± 2.9	0.883
change following surgery	-2.8 ± 6.7	-9.6 ± 7.9	<0.001
p value†	<0.001	<0.001	—
mean PT (°)			
baseline	21.9 ± 11.3	29.1 ± 7.9	0.016
following surgical treatment	18.8 ± 10.4	23.4 ± 8.3	0.089
change following surgery	-3.6 ± 9.1	-5.7 ± 9.8	0.407
p value†	<0.001	0.042	—
mean PI-LL mismatch (°)			
baseline	12.0 ± 21.0	29.6 ± 21.0	0.002
following surgical treatment	1.8 ± 13.6	3.2 ± 15.2	0.706
change following surgery	-10.9 ± 18.7	-26.3 ± 22.9	0.003
p value†	<0.001	0.001	—

* Mean values are presented ± SD. Bold type indicates statistical significance. Change following surgery was calculated as the postoperative value minus the baseline value. LL = lumbar lordosis; PI = pelvic incidence; PT = pelvic tilt; SVA = sagittal vertical axis.

† The p value represents paired t-test comparisons between baseline and postoperative values.

identify any significant differences between the PSO cases in which rod fracture did develop and those in which it did not develop with regard to patient age ($p = 0.989$), CCI ($p = 0.378$), baseline BMI ($p = 0.370$), number of spinal levels fused ($p = 0.878$), baseline maximum coronal Cobb angle ($p = 0.404$), baseline SVA ($p = 0.578$), baseline PT ($p = 0.742$), baseline PI-LL mismatch ($p = 0.801$), postoperative SVA ($p = 0.346$), postoperative PT ($p = 0.817$), postoperative PI-LL mismatch ($p = 0.872$), magnitude of SVA correction ($p = 0.447$), magnitude of PT correction ($p = 0.148$), or magnitude of PI-LL mismatch correction ($p = 0.691$).

For deformity corrections that did not include a PSO, 2 fixation rods were used with only rare exception. In contrast, for 6 (12%) of the cases that included a PSO, additional satellite rods were placed to span the PSO level (3 total rods in 4 cases and 4 total rods in 2 cases). None of the cases with supplemental satellite rod(s) across the PSO level demonstrated rod fracture during the follow-up period, compared with 11 of 44 (25%) of the cases with only

2 rods; however, this did not reach statistical significance ($p = 0.317$). Supplemental interbody devices were placed at the level immediate cephalad, caudal, or both cephalad and caudal in 12, 1, and 8 cases, respectively. The rate of rod fracture did not differ significantly between the cases in which no interbody spacer was placed adjacent to the PSO level versus cases in which an interbody spacer was placed at either or both the cephalad and caudal levels (fracture rate of 24.1% vs 19.0%, respectively; $p = 0.741$).

On multivariate analysis of risk factors for rod fracture among PSO cases, only use of CC rods entered the best-fit model; however, since all of the fractured rods among PSO cases were CC, neither an odds ratio nor confidence intervals could be estimated.

Discussion

This study provides a prospective, multicenter assessment of rod fracture rates and risk factors for rod fracture among adults surgically treated for spinal deformity. The

overall rate of rod fracture was 9.0%; the rate was 22.0% and 4.7% among cases that either did or did not include a PSO, respectively. With further follow-up these rates would likely be even higher. Several significant associations with higher rates of rod fracture were identified, including older age, greater BMI, history of previous spine surgery, performance of a PSO, use of CC rods, greater baseline sagittal spinopelvic malalignment (SVA, PT, and PI-LL mismatch), and greater magnitude of sagittal spinopelvic malalignment correction with surgery (SVA and PI-LL mismatch). Among these potential risk factors for rod fracture, performance of a PSO was the only factor to be incorporated into the best-fit linear regression model. Notably, the substantial range in the rate of rod fracture with PSO (10.0% to 31.6%) across contributing centers suggests potential variations in technique that warrant future investigation. Collectively, these data suggest that for ASD cases that aim to provide substantial correction of sagittal spinopelvic malalignment, and especially for cases including a PSO, alternative strategies beyond the traditional 2-rod configuration should be considered to reduce the risk of rod fracture.

Although the present study did not demonstrate any significant associations between the use of BMP-2 and the occurrence of rod fracture, there are several previous reports that have demonstrated significantly higher fusion rates with use of this osteobiologic.^{18,22} It is possible that the apparent lack of a protective effect of BMP-2 on rod fracture through promotion of arthrodesis may relate to subtleties of application or dosing that are beyond the scope of the present study. In addition, that many of the rod fractures occurred relatively early in the postoperative course before a robust arthrodesis may have been expected suggests that these failures may relate, at least in part, to mechanical compromise of the instrumentation.

Our group has previously reported on rod fracture rates based on a retrospective review of ASD patients from 3 centers.³⁸ Based on 442 patients, the overall rate of symptomatic rod fracture was 6.8%, and the rate of rod fracture in cases in which PSO was performed was 15.8%. These rates are somewhat lower than those of the present study (9.0% and 22.0%, respectively), which may reflect the inclusion of both asymptomatic and symptomatic rod fractures in the present study. The previous retrospective study had several important limitations; most notable was the lack of assessment of demographic, clinical, or sagittal spinopelvic alignment parameters for the patients who did not have rod fracture, which prohibited any detailed assessment of risk factors for rod fracture. Nevertheless, based on the assessment of patients with rod fracture, the retrospective study suggested that residual postoperative sagittal malalignment and greater BMI may be associated with greater risk of rod fracture. The present prospective study confirms the added risk of rod fracture with greater BMI and confirms that sagittal spinopelvic alignment may also be a risk factor, but instead of postoperative residual sagittal malalignment, the present study suggests that it is the magnitude of sagittal alignment correction that may be a more important factor.

The findings of the present study demonstrate a markedly higher rod fracture rate in cases with a PSO.

PSO is a powerful technique that can provide substantial correction of sagittal spinopelvic malalignment, and it is likely that these added forces contribute to the higher rates of rod fracture seen in these cases. In addition, fixation rods in the setting of PSO are often bent to angles of 20° to 60° and may be notched by the bending instruments. Previous studies have demonstrated that CC and TA have greater fatigue life than SS,^{27,45} that TA is very notch sensitive,^{14,27} and that bending rods lowers their performance.^{5,21,25,30} Compared with TA and SS, CC has the greatest elastic modulus and displays the greatest ultimate stress.^{16,25,27} Furthermore, Tang and colleagues assessed the severity of rod contour on posterior rod failure in the setting of lumbar PSO based on a biomechanical study.⁴⁷ They demonstrated that with 5.5-mm CC rods in a cadaveric model of lumbar PSO, the fatigue life of the rods was largely dependent on the severity of the rod contour, with greater contouring producing shorter fatigue life.⁴⁷ In the present study, CC rods were preferentially used in the setting of the more biomechanically demanding PSO, which could appear to bias rod fracture rates against CC; however, when PSO cases were analyzed as a subset, use of CC rods, as compared with TA or SS rods, was associated with significantly higher rates of rod fracture, even though the patient groups did not differ based on demographic or radiographic parameters. Collectively, these findings suggest that although CC rods may exhibit many favorable biomechanical properties, they are not infallible and may be more vulnerable following the significant contouring that is often involved in correction of marked sagittal spinopelvic malalignment with PSO.

Although the present study suggests that more aggressive correction of sagittal spinopelvic malalignment may result in higher risk of rod fracture, there continues to be increasing recognition of the importance of restoring sagittal spinopelvic alignment in the setting of ASD surgery.^{2,24,34–37,43,48} Based on the findings of our previous retrospective study and of the present study, many surgeons in our study group have expanded the use of alternative strategies for PSO cases (Fig. 4). These strategies have included placement of interbody spacers adjacent to the PSO level through posterior or lateral techniques (Fig. 4A) and use of either unilateral or bilateral satellite rods (Fig. 4B). Although both of these techniques may reduce the risk of rod fracture, fractures have been encountered with both techniques. The present study did not demonstrate a significant reduction in the rate of rod fracture with either of these techniques; however, in the limited number of cases in which supplemental satellite rods were used in this series, no patient had a rod fracture during the follow-up interval. Future studies are warranted to further explore the potential protective benefits of supplemental rods in a larger number of patients. A newer technique, the deep short rod technique (Fig. 4C; Ames, Deviren, and Gupta, unpublished data), has been subsequently performed in a small subset of cases, without a rod fracture encountered to date based on short follow-up.

It is important to recognize the limitations of the present study. Specific assessment of fusion status for all patients was not performed, and it is likely that the occurrences of rod fracture reflect a combination of mechani-

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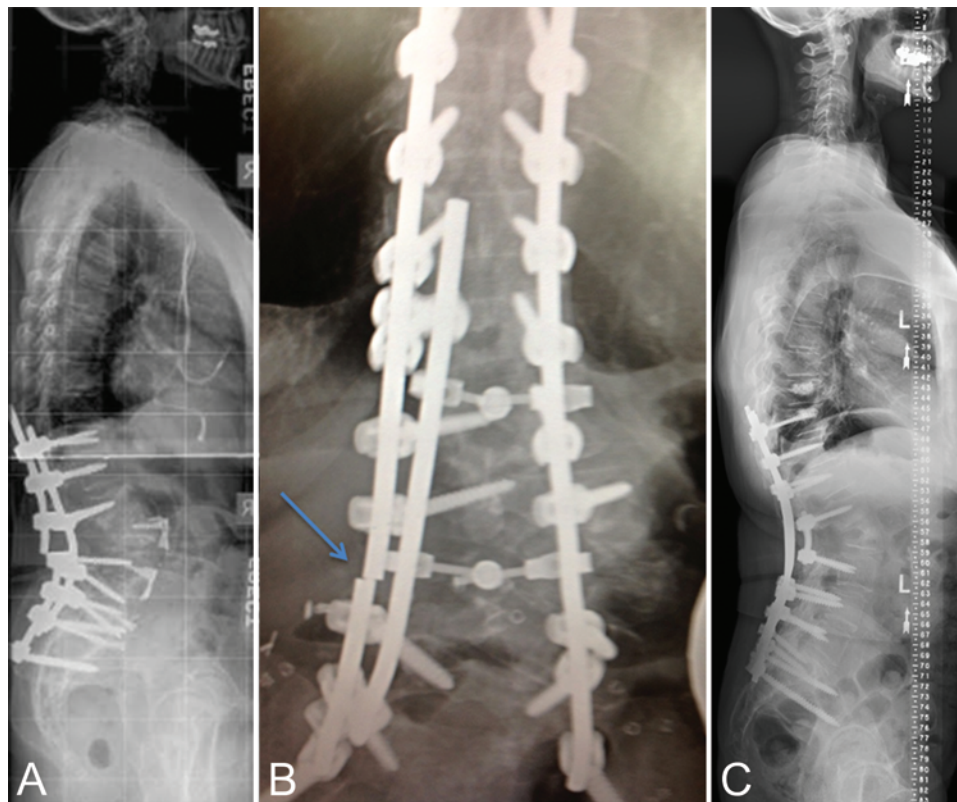


Fig. 4. Rod techniques for PSO. **A:** Standard 2-rod technique, with single rods connecting the screw heads on the left and right sides. Note that one of the rods has fractured. **B:** Satellite rod technique in which a third rod (satellite rod) has been attached to the left primary rod via side connectors to span the level of a PSO. In addition, cross-links have been placed to attach the satellite rod to the contralateral (right) primary rod. Note that the left primary rod has fractured (arrow). **C:** Ames-Deviren short rod technique in which a short rod spanning only the level of the PSO is placed, followed by placement of rods spanning all instrumented and arthrodesed levels, but not connecting to the screws connected by the short rod. Note that this technique does not require sharp bending of the primary rods to seat into the heads of the screws adjacent to the PSO level.

cal instrumentation failure and pseudarthrosis; however, a substantial portion of the fractures occurred sufficiently early to suggest that at least some component of mechanical failure was contributory. In addition, the mean follow-up period for the patients who did not develop rod fracture was moderate (19 months), but additional follow-up time could demonstrate additional rod fractures. Although not the objective of the study, the potential impact on health-related quality of life measures related to rod fracture was not assessed. Detailed assessment of differences in surgeon techniques that may have contributed to differing rates of rod fracture across centers has not been performed; however, since the time of this study many of the contributing centers have substantially changed their techniques, including addition of satellite rods or use of the deep short rod technique.

Conclusions

The overall rate of rod fracture for ASD surgery was 9.0%; the rates were 22.0% and 4.7% for cases that either did or did not include a PSO, respectively. Several significant associations with higher rates of rod fracture were identified, including older age, greater BMI, history of previous spine surgery, performance of a PSO, use of CC

rods, greater baseline sagittal spinopelvic malalignment (SVA, PT, and PI-LL mismatch), and greater magnitude of sagittal spinopelvic malalignment correction with surgery (SVA and PI-LL mismatch). There was a substantial range in the rate of rod fracture with PSO across centers (10.0%–31.6%), suggesting potential variations in technique that warrant future investigation. Collectively, these data suggest that for ASD cases that aim to provide substantial correction of sagittal spinopelvic malalignment, and especially for cases including a PSO, alternative strategies beyond the traditional 2-rod configuration should be considered to reduce the risk of rod fracture.

Disclosure

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Address correspondence to: Justin S. Smith, M.D., Ph.D., University of Virginia Health Sciences Center, Department of Neurosurgery, Box 800212, Charlottesville, VA 22908. email: jss7f@virginia.edu.