Rod Fracture After Apparently Solid Radiographic Fusion in Adult Spinal Deformity Patients

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■ BACKGROUND: **Rod fracture occurs with delayed fusion or pseudarthrosis after adult spinal deformity (ASD) surgery. Rod fracture after apparent radiographic fusion has not been previously investigated.**

■ METHODS: **Patients with ASD in a multicenter database were assessed for radiographic fusion by a committee of 3 spinal deformity surgeons. Fusions were rated as bilaterally fused (A), unilaterally fused (B), partially fused (C), or not fused (D). Patients with grade A or B fusion and 2-year follow-up were included. Patients with radiographic fusion were evaluated for subsequent rod fracture. Adjusted analyses were conducted with multiple logistic regression, using backwards-variable selection to a threshold of $P < 0.2$, to assess for associated factors.**

■ RESULTS: **Of 402 patients with radiographically apparent solid fusion, 9.5% (38) subsequently suffered a broken rod. On multivariate analysis, greater rates of rod fracture were seen among patients of age group 60–69 years (vs. 18-49), body mass index 30–34 and 35+ (vs. <25), stainless-steel rods (vs. titanium), patients with rods ≤5.5 mm (vs. 6.35 mm), and patients with Charlson score 0 (vs. 3+). Of the 38 patients with rod fractures, 18 (47.4%) presented with worsened pain, and 8 (21.1%) required revision at minimum 2-year follow-up.**

■ CONCLUSIONS: **Rod fracture occurred in 9.5% of patients with apparently solid radiographic fusion after ASD surgery. Advanced age, obesity, small diameter rods (5.5 mm), osteotomy, and lower comorbidity burden were significantly associated with rod fracture. Nearly one-half of these patients noted worsening pain, and 21.1% required revision surgery. Instrumentation failure may occur and may be symptomatic even in the setting of apparent fusion on plain radiographs.**

INTRODUCTION

Rod fracture after spinal deformity correction is a form of implant failure that may be associated with pain and loss of deformity correction and can require reoperation.[1-5] If it occurs early, it may increase the risk of pseudarthrosis; if it occurs late, it may result from instrumentation fatigue in the setting of pseudarthrosis.[1,6] Reported rates of rod fracture range from 6.8%[6] to 14.9%[4] in all patients with adult spinal deformity

Key words
- Adult spinal deformity
- ASD
- Fusion
- Pseudarthrosis
- Rod Fracture

Abbreviations and Acronyms
3-CO: 3-column osteotomy
ASD: Adult spinal deformity
BMI: Body mass index
LL: Lumbar lordosis
PI: Pelvic incidence
PI-LL: Spinopelvic mismatch
PSO: Pedicle subtraction osteotomy
PT: Pelvic tilt
SD: Standard deviation
SS: Sacral slope
SVA: Sagittal vertical axis

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(ASD) and 15.8%[6] to 22.0%[3] specifically in patients undergoing 3-column osteotomy (3-CO).

Rod fracture has been associated with a number of risk factors. A 2014 study of 200 patients with ASD reported 18 cases (9%) of rod fracture and found that patients with rod fracture were older, had greater body mass index (BMI), had greater baseline sagittal malalignment, and had greater sagittal malalignment correction.[3] In a subanalysis of patients who underwent pedicle subtraction osteotomy (PSO), the use of cobalt chromium rods also was associated with rod fracture.[3] However, in multivariate analysis, performance of PSO was the only significant risk factor.[3] Importantly, only 12 of the 18 cases of rod fracture presented with symptoms; all 12 had pseudarthrosis at revision surgery.[3] Of the 6 who did not have surgery, 1 had evidence of fusion on plain radiographs.[3]

Another 2015 study of 75 patients with ASD reported 7 (9.5%) cases of rod fracture and found that fusion across both thoracolumbar and lumbosacral junctions, sagittal rod contour greater than 60°, and pseudarthrosis at follow-up greater than 1 year were significant risk factors.[1] Of the 7 cases of rod fracture, 4 were symptomatic and had pseudarthrosis, 2 were asymptomatic and had solid fusion on computed tomography scan, and 1 was asymptomatic and did not have imaging.[1]

Although both of these studies examined risk factors for rod fracture, very few patients had evidence of fusion, as most cases were associated with pseudarthrosis. In this investigation, we examined rod fracture in the setting of apparent radiographic fusion. We hypothesized that advanced age, greater comorbidity burden, 3-CO, and smaller diameter rods are associated with rod fracture after apparently solid radiographic fusion.

MATERIALS AND METHODS

This study is a retrospective review of a multicenter, consecutive series of patients with ASD treated by members of the International Spine Study Group, which is composed of 11 sites across the United States. Patient enrollment protocols were approved by the institutional review boards of the participating institutions. Inclusions criteria for the database are patient age >18 years and at least 1 of the following: sagittal vertical axis (SVA) ≥5 cm, coronal Cobb angle ≥20°, thoracic kyphosis ≥60°, or pelvic tilt ≥25°. Deformities resulting from trauma, infection, ankylosing spondylitis, or neuromuscular disorders are not included.

Plain films of each patient in the database were assessed for fusion by a committee of 3 spinal deformity surgeons; fusions were rated as bilateral solid fusions (A), unilateral solid fusions (B), partial fusions (C), or no fusion (D) posteriorly or anteriorly. In the present study, patients were included only if they had radiographically confirmed fusion (grade A or B) and 2-year clinical and radiographic follow-up data were available.

For all patients meeting inclusion criteria, demographic, clinical, operative, and follow-up data were extracted from the International Spine Study Group database. Extracted demographic and clinical data included patient age, sex, BMI, history of previous spine surgery, American Society of Anesthesiologists score, Charlson Comorbidity Index,[7] smoking status, and baseline and 2-year postoperative sagittal alignment parameters including SVA, sacral slope (SS), pelvic tilt (PT), pelvic incidence (PI), lumbar lordosis (LL), and spinopelvic mismatch (PI-LL). Operative data included levels of spinal instrumented arthrodesis, whether a 3-CO was performed, where an interbody fusion was performed, rod composition and diameter, use of a supplemental rod, use of recombinant human bone morphogenetic protein-2, operative duration, and whether the procedure was staged.

Rod fracture occurrence was determined based on review of follow-up full-length radiographs. Patients were defined as exhibiting rod fracture after fusion if their rod fracture was documented concurrently with or after confirmed fusion. The database was queried for pain on presentation at the time of rod fracture diagnosis as well as any revision surgeries occurring after rod fracture.

Demographic, clinical, and operative data for patients who had rod fracture were compared with those with intact hardware. Unadjusted comparisons of categorical variables were conducted with χ^2 and Fisher exact tests, as appropriate. Unadjusted comparisons of continuous variable were conducted with the Wilcoxon signed-rank test. Adjusted analyses were conducted with multiple logistic regression, using backwards variable selection to a threshold of $P < 0.2$ to assess for factors associated with rod fracture. All statistical tests were performed with SAS 9.4 (SAS Institute, Cary, North Carolina, USA), and $P < 0.05$ was considered statistically significant.

RESULTS

In total, 402 patients met inclusion criteria and had apparent radiographically solid fusion on postoperative radiographs. Mean age was 57.4 (standard deviation [SD] 14.8) years, 320 (79.8%) were female, the mean BMI was 27.4 kg/m^2 (SD 6.0), and the mean Charlson Comorbidity Index was 1.6 (SD 1.7). A total of 28 (7.5%) of patients were smokers, and 185 (46.3%) patients had previous spine surgery that required revision (Table 1).

During the deformity correction, the mean levels fused was 11.1 (SD 4.1), 260 (64.7%) patients required decompression, 282 (70.2%) required osteotomy, 246 (61.2%) underwent interbody fusion, and 42 (10.5%) had supplemental rods placed. Cobalt chrome rods were used in 241 (61.2%), stainless steel was used in 85 (21.6%), and titanium was used in 68 (17.3%); 6.35-mm rods were used in 108 (27.1%), 6.0-mm rods were used in 26 (6.5%), and 5.5-mm or smaller rods were used in 264 (66.3%) (Table 1).

In total, 38 of 402 patients with apparent radiographic fusion sustained rod fractures (9.5%) (Figure 1). Patients who sustained a rod fracture had greater mean baseline SVA ($P = 0.0014$), PT ($P = 0.0046$), and PI-LL ($P = 0.0037$) than those who did not sustain rod fracture. The mean baseline SS ($P = 0.0035$) and LL ($P = 0.0030$) were lower in those who sustained rod facture. At 2 years, those in the rod fracture group had a greater mean SVA ($P = 0.0007$), PT ($P = 0.0133$), and PI-LL ($P = 0.0223$), whereas their mean 2-year SS ($P = 0.0035$) and LL ($P = 0.0033$) measurements were lower on average. There were no significant differences between groups in terms of baseline or 2-year follow-up PI ($P = 0.8300$, $P = 0.6419$, respectively), Table 1.

On bivariate analysis, older age ($P = 0.014$), larger BMI ($P = 0.005$), performance of osteotomy ($P = 0.047$), and performance of an interbody fusion ($P = 0.044$) were associated with rod

Table 1. Descriptive Statistics and Bivariate Analyses

Variable	*N*	%	Rod Fracture (%)	*P* Value
Rod fracture				—
No	364	90.6	—	
Yes	38	9.5	—	
Age group, years				**0.0144**
18–49	89	22.2	4.5	
50–59	105	26.2	7.6	
60–69	130	32.4	16.2	
70+	77	19.2	6.5	
Missing = 1				
Sex				0.0663
Male	81	20.2	14.8	
Female	320	79.8	8.1	
Missing = 1				
BMI				**0.0049**
<25	141	35.3	4.3	
25.0–29.9	148	37.0	8.8	
30.0–34.9	72	18.0	15.3	
35+	39	9.8	20.5	
Missing = 2				
Charlson Comorbidity Index				0.8713
0	133	33.2	9.8	
1	93	23.2	10.8	
2	80	20.0	10.0	
3+	95	23.7	7.4	
Missing = 1				
ASA				0.0821
Grade I	34	8.9	2.9	
Grade II	191	50.0	9.4	
Grade III	152	39.8	11.2	
Grade IV	5	1.3	40.0	
Missing = 20				
Smoker				0.5042
Yes	28	7.5	5.7	
No	348	92.6	94.3	
Revision				0.1302
No	215	53.8	7.4	
Yes	185	46.3	11.9	
Missing = 2				
Levels fused				0.1902
<9	82	20.6	4.9	

Continues

Table 1. Continued

Variable	*N*	%	Rod Fracture (%)	*P* Value
9–10	129	32.4	10.9	
11–15	93	23.4	7.5	
16+	94	23.6	13.8	
Missing = 4				
Staged				0.8752
Same day	342	85.1	9.4	
Staged	60	14.9	10.0	
Approach				0.5461
Anterior only	2	0.5	0.0	
Posterior only	291	72.4	10.3	
Combined	109	27.1	7.3	
Decompression				0.1147
No	142	35.3	6.3	
Yes	260	64.7	11.2	
Osteotomy				**0.0465**
No	120	29.9	5.0	
Yes	282	70.2	11.4	
BMP-2				0.8712
No	91	22.6	9.9	
Yes	311	77.4	9.3	
Interbody fusion				**0.0444**
No	156	38.8	5.8	
Yes	246	61.2	11.8	
Supplemental rod				1.0000
No	360	89.6	9.4	
Yes	42	10.5	9.5	
Operative duration				0.4779
<5	75	18.9	8.0	
5–6	128	32.3	7.0	
7–8	106	26.8	11.3	
9+	87	22.0	12.6	
Missing = 6				
Rod material				0.2182
Cobalt chrome	241	61.2	11.2	
Stainless steel	85	21.6	8.2	
Titanium	68	17.3	4.4	
Missing = 8				
Rod diameter				0.2117

Bold value indicates statistical significance.

BMI, body mass index; ASA, American Society of Anesthesiologists; BMP-2, bone morphogenetic protein-2; SD, standard deviation; SVA, sagittal vertical axis; SS, sacral slope; PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis; PI-LL, spinopelvic mismatch.

Continues

Table 1. Continued

Variable	*N*	%	Rod Fracture (%)	*P* Value
5.5 mm or less	264	66.3	11.4	
6.0 mm	26	6.5	7.7	
6.35 mm	108	27.1	5.6	
Missing = 4				

	No Rod Fracture, Mean (SD)	Rod Fracture, Mean (SD)	*P* Value
Baseline SVA	60.84 (72.09)	107.12 (86.16)	**0.0014**
2-year SVA	27.96 (53.21)	62.75 (60.09)	**0.0007**
Baseline SS	30.81 (15.07)	21.39 (28.05)	**0.0035**
2-year SS	33.84 (10.32)	24.20 (27.48)	**0.0016**
Baseline PT	23.18 (10.46)	29.55 (11.70)	**0.0046**
2-year PT	20.83 (9.65)	26.20 (11.18)	**0.0133**
Baseline PI	54.00 (14.24)	50.94 (29.23)	0.8300
2-year PI	54.66 (12.19)	50.40 (29.54)	0.6419
Baseline LL	39.61 (22.63)	27.32 (22.44)	**0.0030**
2-year LL	52.03 (13.77)	44.01 (15.73)	**0.0033**
Baseline PI-LL	14.39 (23.41)	23.61 (34.95)	**0.0037**
2-year PI-LL	2.63 (14.68)	6.39 (33.60)	**0.0223**

Bold value indicates statistical significance.

BMI, body mass index; ASA, American Society of Anesthesiologists; BMP-2, bone morphogenetic protein-2; SD, standard deviation; SVA, sagittal vertical axis; SS, sacral slope; PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis; PI-LL, spinopelvic mismatch.

fracture (Table 1). There was no significant association between smoking status and rod fracture ($P = 0.5042$).

On multivariate analysis, rod fracture was associated with patients of age group 60–69 years (vs. 18–49) ($P = 0.009$), patients with BMI 30-34 and 35+ (vs. <25) ($P < 0.016$), patients with Charlson score 0 (vs. 3+) ($P = 0.006$), a posterior approach (vs. combined) ($P = 0.039$), performance of an osteotomy ($P = 0.039$), performance of an interbody fusion ($P = 0.041$), use of stainless-steel rods (vs. titanium) ($P = 0.018$), and use of rods ≤5.5 mm (vs. 6.35 mm) ($P = 0.015$) (Table 2).

Of the 38 patients who sustained rod fractures after fusion, 18 (47.4%) presented with worsened pain relative to previous follow-up visits, and 8 (21.1%) required revision with minimum 2-year follow-up.

DISCUSSION

This investigation revealed that rod fracture occurred in 9.5% of patients with apparently solid fusion on plain radiographs after surgery for ASD. Advanced age, obesity, lower comorbidity burden, posterior-only approaches, performance of an osteotomy, interbody fusion procedure, stainless-steel rods, and small-diameter rods (5.5 mm) were significantly associated with rod fracture on multivariable analysis. Patients with more severe baseline and corrected sagittal imbalance also were noted to be at increased risk of rod fracture.

The association of advanced age and greater BMI with rod fracture is consistent with the findings of Smith et al.[3] Conversely, Barton et al.[1] did not find any association between rod fracture and patient variables, although the authors speculate that their study may have been underpowered. It is interesting that our analysis also identified lower comorbidity burden as a risk factor. Although 1 of 18 patients with rod fracture in the study of Smith et al.[3] exhibited radiographic fusion, all patients in the present study appeared fused in either the anterior or posterior spine on radiographs. As healthier patients are likely to be more active, it is possible that the risk of rod fracture in the setting of radiographic fusion is more dependent on activity level than in the setting of radiographic pseudoarthrosis.

Performance of osteotomy was associated with rod fracture, which is again consistent with the study by Smith et al.,[3] which found a rod fracture rate of 22.0% and 4.7% in cases that did or did not include a PSO. Barton et al.,[1] in contrast, reported a rate of 8.1% post-PSO and found no significant association with PSO. The authors note that the decreased incidence of rod fracture after PSO in their study could be due to their increased use of anterior support including interbody fusions, which may reduce bending moments along the rod.[8] This observation may explain our finding that combined approaches were associated with a reduced risk of rod fracture compared with posterior-only approaches. However, it would not explain why we found an

Figure 1. (**A**) Patient who underwent L3 pedicle subtraction osteotomy and T3—ilium fusion with apparent radiographic fusion at 2-year follow-up. (**B**) Three-year follow-up radiograph revealed left rod fracture.

association between rod fracture and interbody fusion. It is possible that patients who were at greater risk of pseudarthrosis, as gauged by the surgeon, underwent posterior approach interbody fusion (transforaminal lumbar interbody fusion or posterior lumbar interbody fusion) in an effort to increase the chance of fusion, thus explaining the correlation between both posterior approach surgery and interbody placement and rod fracture. It is also possible that patients undergoing facet resection for

Table 2. Multivariate Analysis

Variable	OR	95% CI		*P* Value
Age group, years (ref = 18–49)				
50–59	1.84	0.45	7.59	0.3965
60–69	6.28	1.58	24.99	**0.0091**
70+	3.03	0.55	16.73	0.2037
BMI (ref = <25)				
25.0–29.9	2.37	0.76	7.42	0.1388
30.0–34.9	4.66	1.34	16.24	**0.0158**
35.0+	13.03	3.04	55.75	**0.0005**
CCI (ref = 0)				
1	0.49	0.16	1.45	0.1966
2	0.47	0.15	1.53	0.2102
3+	0.15	0.04	0.57	**0.0055**
Approach (ref = posterior only)				
Combined	0.27		0.94	**0.0394**
Osteotomy (ref = no)				
Yes	3.10	1.06	9.04	**0.0389**
BMP-2 (ref = no)				
Yes	0.43	0.15	1.18	0.1018
Interbody fusion (ref = no)				
Yes	2.99	1.04	8.57	**0.0413**
Supplemental rod (ref = No)				
Yes	0.32	0.08	1.26	0.1029
Operative duration (ref = <5)				
5–6	0.46	0.12	1.68	0.2375
7–8	0.83	0.23	2.96	0.7752
9+	2.90	0.67	12.58	0.1559
Rod material (ref = titanium)				
Cobalt chrome	2.87	0.69	11.98	0.1490
Stainless steel	12.28	1.54	98.05	**0.0180**
Rod diameter (ref = 6.35mm)				
6.0 mm	1.57	0.11	21.80	0.7356
5.5 mm	10.53	1.57	70.43	**0.0152**
Revision surgery (ref = no)				
Yes	1.89	0.82	4.38	0.1370

Bold value indicates statistical significance.
OR, odds ratio; CI, confidence interval; BMI, body mass index; CCI, Charlson Comorbidity Index; BMP-2, bone morphogenetic protein-2.

transforaminal lumbar interbody fusion suffered increased rod fracture rate due to the lack of facet fusion, as patients with a combined approach with lateral lumbar interbody fusion or anterior lumbar interbody fusion experienced lower rod fracture rates.

Neither Barton et al. nor Smith et al. found an association between rod fracture and rod diameter,[1,3] whereas in our study 5.5-mm rods were a risk factor when compared with larger-diameter rods. Similar to the association with lower comorbidity burden, it is possible that this finding is explained by

fatigue failure in our sample of radiographically fused spines. This mechanism also could explain why we found that stainless steel was associated with rod fracture, whereas Smith et al.[3] found that cobalt chromium was a risk factor. Studies have shown that both cobalt chromium and titanium have greater fatigue life than stainless steel,[9] whereas cobalt chromium displays the greatest ultimate stress.[9] In the setting of apparent radiographic fusion, fatigue life likely becomes more important than ultimate stress.

It is also possible that rod fracture in the setting of apparent radiographic fusion may represent small gaps in the fusion mass or failure of the fusion mass to completely anchor to the underlying vertebrae and transverse processes. Although small fusion mass defects or hairline pseudarthroses may be difficult to appreciate on plain radiographs, they may nonetheless affect the biomechanical strength of the construct and result in increased bending forces on the rods. In addition, patients with worse preoperative and corrected sagittal imbalances were at increased risk of rod fracture. This may be due to an increase in bending forces with poor postoperative sagittal balance or secondary to an increased use of osteotomies and subtle pseudarthroses through the osteotomy sites in these patients. Despite radiographic fusion, nearly one-half of the patients with rod fracture presented with worsening pain, and 21.1% required revision surgery. Although this percentage is lower than those reported in the studies examining rod fracture in the setting of pseudoarthrosis,[1,3,5] it demonstrates that rod fracture in the setting of apparent fusion may not be benign. In addition, some of the patients with radiographically solid fusion and rod fracture who reported no symptoms at the 2-year follow up point may eventually develop symptoms that warrant revision with longer-term follow up. A recent study by Yamato et al.[5] found that revision surgery was performed in 36 of 54 (66.7%) cases of rod fracture and that there were no signs of mobility near the fracture site during surgery in 8 patients. The authors found that symptoms improved in all revisions, which suggests that surgery in the setting of symptomatic rod fracture, even if fusion is suspected, may be beneficial.[5] However, it is noteworthy that 17 of 18 patients with asymptomatic rod fracture in that cohort experienced no symptom development or loss of correction with nonoperative treatment.[5]

This study has several potential limitations, including its retrospective design and lack of standardized follow-up. However, it is the first study to specifically assess rod fracture in patients with radiographically apparent fused ASD surgery, adding important data regarding the lack of sensitivity regarding plain radiographs for assessing fusion. Additional factors that may have influenced the results of this study include subtle rod fracture not observed on radiographs that may have been present before fusion occurred, as well as rod fracture through truly solid arthrodesis due to plastic deformation of the fusion mass.

CONCLUSIONS

Rod fracture occurred in 9.5% of patients with apparently solid radiographic solid fusion after ASD surgery. Advanced age, obesity, small-diameter rods (5.5 mm), performance of an osteotomy, and lower comorbidity burden were significantly associated with rod fracture. Plain radiographs may not be sensitive enough to reliably assess solid fusion in patients with ASD. Of the 38 patients who sustained rod fractures after fusion, 18 (47.4%) presented with worsened pain relative to previous follow-up visits, and 8 (21.1%) required revision at minimum 2-year follow-up.

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