



Radiographic Fusion Grade Does Not Impact Health-Related Quality of Life in the Absence of Instrumentation Failure for Patients Undergoing Posterior Instrumented Fusion for Adult Spinal Deformity

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BACKGROUND: Pseudarthrosis and rod fracture (RF) remain significant concerns after fusion for adult spinal deformity (ASD). Although a radiographic system of fusion grade has been proposed, the correlation between fusion grade and health-related quality of life measures (HRQoL) is not known.

METHODS: In a retrospective review of a prospectively collected clinical database, patients that underwent ≥ 5 -level posterior instrumented arthrodesis for ASD were evaluated. Fusion grade was determined on plain films using the Lenke criteria. Patients were grouped as 1) complete fusion (grade I or II at all levels), 2) incomplete fusion (grade 3 or 4 at any level), 3) rod fracture without revision (RF), and 4) rod fracture with revision (RFR). Outcome measures were the Oswestry Disability Index, Medical Outcomes Study 36-Item Short-Form Health Survey Physical and Mental Component Summaries, Scoliosis Research Society-22r total, and Lumbar Stiffness and Disability Index.

RESULTS: There were 205 (85%) patients who achieved the minimum 2-year follow-up and were included. Complete fusion was achieved in 115 patients (56.1%), 55% patients (26.8%) had incomplete fusion, and 35% patients (17.1%) had RF. Of the 35 patients with RF, 19 (17.1%; 19/205)

underwent revision while 16 (7.8%; 16/205) had RF without revision. HRQoL measures were significantly worse in the RFR group, whereas no significant differences were found between groups 1, 2, and 3.

CONCLUSIONS: Radiographic fusion grade after ASD surgery did not significantly impact HRQoL in the absence of RF. RFR was associated with significantly worse clinical outcomes. Fusion grade may be less predictive of clinical outcomes than the occurrence of RF.

INTRODUCTION

Despite demonstrated clinical success, patients undergoing spinal reconstruction and fusion for adult spinal deformity (ASD) continue to require revision surgery in a substantial percentage of cases.¹⁻⁴ One of the more frequent complications resulting in further surgery is failure of fusion or nonunion.^{2,5,6}

Fracture of either rods or screws occurs after otherwise successful lumbar arthrodesis in 3%–10% of patients.^{2,3,7-9} In some cases, instrumentation failure and pseudarthrosis lead to recurrent or worsened back and leg pain, and loss of deformity correction. The time course of instrumentation fracture is typically within the

Key words

- Adult spinal deformity
- Complications
- Fusion
- HRQoL
- Instrumentation failure
- Lumbar spine
- Pseudarthrosis
- Quality of life
- Revision
- Rod fracture

Abbreviations and Acronyms

- ASD:** Adult spinal deformity
- HRQoL:** Health-related quality of life
- LSDI:** Lumbar Stiffness Disability Index

ODI: Oswestry Disability Index

RF: Rod fracture without revision

RFR: Rod fracture that underwent revision

SRS-22r: Scoliosis Research Society 22r

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Table 1. Criteria for Determination of Fusion Status

Grade	Classification	Anterior Fusion Criteria	Posterolateral Fusion Criteria
I	Definite fusion	Fused with remodeling and trabeculae	Solid trabeculated transverse process and facet fusions bilaterally
II	Probable fusion	Graft intact, not fully remodeled and incorporated through; no lucencies	Thick fusion mass on one side; difficult to visualize on the other
III	Probable nonunion	Graft intact, but definite lucency at top or bottom	Possible lucency or defect in the fusion mass
IV	Definite nonunion	Resorption of bone graft and collapse	Definite resorption of graft with fatigue of instrumentation

Adapted from Eck KR, Lenke LG, Bridwell KH, et al. Radiographic assessment of anterior titanium mesh cages. *J Spinal Disord.* 2000;13:501-509 [discussion: 510]¹⁰ and Lenke LG, Bridwell KH, Bullis D, et al. Results of in situ fusion for isthmic spondylolisthesis. *J Spinal Disord.* 1992;5:433-442.¹¹

postoperative range of 1–5 years; however, cases have been reported outside this time frame.^{1-3,6,9} When accompanied by increased pain, this complication is especially disheartening to patients and spine surgeons because the prospect of revision surgery develops at a point at which their clinical recovery from major surgery was seemingly complete.

Being able to predict which patients are at risk of this surgical adverse event would be clinically useful. Although risk factors for nonunion and instrumentation failure may include high body mass index, persistent sagittal spinopelvic malalignment, greater magnitude of preoperative deformity, ongoing tobacco use, poor nutrition, metal type, diameter of rods, and type of bone graft material used, no surgical approach or patient profile ensures against this possibility.^{2,6,9}

When bilateral rod fracture occurs, it is typically assumed that pseudarthrosis exists at the implicated level. This can often be identified on dynamic plain films and/or computed tomography scan. Conversely, it is common after instrumented arthrodesis to see regions within the construct where clear radiographic evidence of fusion is lacking yet the instrumentation appears to be intact. Grading systems of both anterior and posterior fusion quality have previously been described.^{10,11} Although fusion grading is often used in reports of clinical outcomes for ASD surgery, to our knowledge no study has attempted to validate radiographic fusion grade with occurrence of rod fracture or health-related quality of life (HRQoL) measures.

Table 2. Demographics of Study Cohort (N = 205)

Demographic	Value
Age (years)	56.2 ± 14.8
Female	82.4
BMI (kg/m ²)	27.4 ± 6.0
CCI score	1.4 ± 1.6
Smoker	9.3
Diabetes	5.9

Values are mean ± SD or percentages.
BMI, body mass index; CCI, Charlson comorbidity index.

This paper presents an analysis of symptoms of pain and disability as a function of fusion grade, with and without presence of rod fracture. We hypothesized that patients with rod fracture would be more symptomatic than those with intact rods, and that fusion grade as judged on plain radiographs would be less predictive of symptom severity when instrumentation remains intact. We further hypothesized that rod fractures that ultimately required revision surgery would have the greatest impact on HRQoL, pain, and disability.

MATERIALS AND METHODS

Study Design

This is a retrospective case control study. Data were taken from a prospectively collected multicenter database on ASD surgical patients. Approval was obtained from the institutional review board at each of 11 participating centers in the United States.

Baseline demographic and surgical data and HRQoL outcome measures at 2- and 3-year follow-up were recorded based on self-reported questionnaires and interviews with research assistants at participating centers. Demographic variables included patient age, sex, Charlson comorbidity index, body mass index, smoking status, and history of diabetes. HRQoL outcome measures included Oswestry Disability Index (ODI),¹² Medical Outcomes Study 36-Item Short-Form Health Survey Physical Component Summary and Mental Component Summary,¹³ Scoliosis Research Society 22r (SRS-22r),¹⁴ back and leg pain numerical rating scale score, and Lumbar Stiffness Disability Index (LSDI).¹⁵ HRQoL at last clinical follow-up (2 or 3 years) comprised the primary outcome measures.

Fusion status at last radiographic follow-up was assessed centrally on standing long-cassette radiographs by 2 surgeons blinded to the patients' outcome using previously reported scales for anterior¹⁰ and posterior fusion¹¹ (Table 1). Patients were considered to have achieved fusion if they met criteria for a grade I or II fusion in either the anterior or posterior construct at all instrumented levels and incomplete fusion if they received a grade of III or IV at ≥ 1 levels. Criterion for surgical revision was symptomatic rod fracture as determined by the treating surgeon's clinical discussion with individual patients. Symptoms of back and leg pain, and recurrent deformity, were considered in deciding for or against revision surgery. Incidence of rod fractures and associated revision procedures during the study

Table 3. Demographics of Study Cohort Stratified by Fusion and Rod Fracture Status

Demographic	Complete Fusion	Incomplete Fusion	Rod Fracture, No Revision	Rod Fracture, Revision
Number of patients (%)	115 (56.1)	55 (26.8)	16 (7.8)	19 (9.3)
Age (years)	55.2 ± 14.3	55.5 ± 17.7	62.8 ± 5.6	58.0 ± 12.9
Female (%)	87.8	81.8	81.3	55.6
BMI (kg/m ²)	27.2 ± 6.1	26.4 ± 4.9	28.1 ± 5.7	31.6 ± 6.8
CCI score	1.2 ± 1.4	1.7 ± 1.8	1.6 ± 1.5	1.3 ± 1.6
Smoker (%)	11.1	11.5	0	5.9
Diabetes (%)	3.5	7.3	18.8	5.9

Values are mean ± SD or as otherwise indicated.

BMI, body mass index; CCI, Charlson comorbidity index.

period were reported by the treating surgeon on standardized complication assessment forms and verified by the independent review team radiographically. The patient cohort was stratified into 4 groups as follows: 1) complete fusion throughout the entire construct, no evidence of rod fracture; 2) incomplete fusion at ≥ 1 segments, no evidence of rod fracture; 3) rod fracture without revision (RF); and 4) rod fracture that underwent revision (RFR).

Patient Population

Consecutively enrolled adult (≥ 18 years of age) patients with spinal deformity that underwent operative management and reached a minimum of 2-year clinical and radiographic follow-up at the time of analysis were included. Spinal deformity was defined as at least one of the following criteria present on baseline long-cassette radiographs: scoliosis $\geq 20^\circ$, sagittal vertical axis ≥ 5 cm, pelvic tilt $\geq 25^\circ$, or thoracic kyphosis $\geq 60^\circ$. Patients who underwent revision surgery during the study interval for an indication other than to address rod fracture were excluded. Patients were included if they had ≥ 5 -levels posterior instrumented arthrodesis (with or without anterior fusion) and availability of full-length standing radiographs and HRQoL scores with minimum 2-year follow-up.

Data and Statistical Analysis

Frequency distributions and summary statistics were tabulated for all baseline and outcome variables. We assessed the impact of fusion and rod fracture status on each outcome variable using analysis of variance to compare mean values across the four groups previously outlined. Between-group differences were assessed post hoc with Tukey honest significant difference test to correct for multiple comparisons.

RESULTS

Study Cohort

Of 240 eligible patients, a total of 205 (85%) achieved minimum 2-year radiographic and clinical follow-up and were included in this analysis. Demographic features of the study cohort are presented in **Table 2**. The same patients, stratified by fusion and rod

fracture status, are shown in **Table 3**. At last radiographic follow-up, complete fusion at all levels was achieved in 115 patients (56.1%), whereas 55 patients (26.8%) had ≥ 1 levels at which fusion grade was III or IV. Thirty-five patients (17.0%) experienced a rod fracture, of which over half ($n = 19$, 54.3%) required revision surgery to address this complication. Therefore, the overall revision rate for rod fracture was 9.3%. Rod fracture was diagnosed at a mean of 18.3 (range, 2–35) months after the index procedure.

Rod Fractures

The timing and location of rod fractures are shown in **Table 4**. Most (74.3%) were identified at 1- or 2-year follow-up. The most common sites were L3, L4, and L5, cumulatively comprising 25 (71.4%) of the rod fractures. Of 15 patients with bilateral rod fractures identified on standard radiographs, 10 underwent revision compared with 8 of 20 with unilateral fractures.

HRQoL Outcome Measures

Figure 1 demonstrates the impact of fusion and rod fracture status on the ODI, Physical Component Summary, Mental Component Summary, and LSDI. For each outcome measure, patients with RFR tended to fare the worst, followed by the other groups. For ODI and LSDI, this reached statistical significance. Post hoc analysis of between-group differences revealed that, with respect to the ODI and LSDI, the RFR group had significantly worse outcome than the complete and incomplete fusion groups but did not differ significantly from the RF group.

SRS-22r total score and the activity and appearance subdomains differed according to fusion/rod fracture group, whereas the mental, pain, and satisfaction domains did not (**Figure 2**). Between-group comparisons revealed that the RFR group had significantly lower SRS-22r total and activity subdomain scores than the complete and incomplete fusion groups; no such between-group differences were found to be significant for the appearance subdomain.

DISCUSSION

This study demonstrated a substantial rate of rod fracture among ASD patients at minimum 2-year follow-up, with over half of these

Table 4. Timing and Location of Rod Fractures

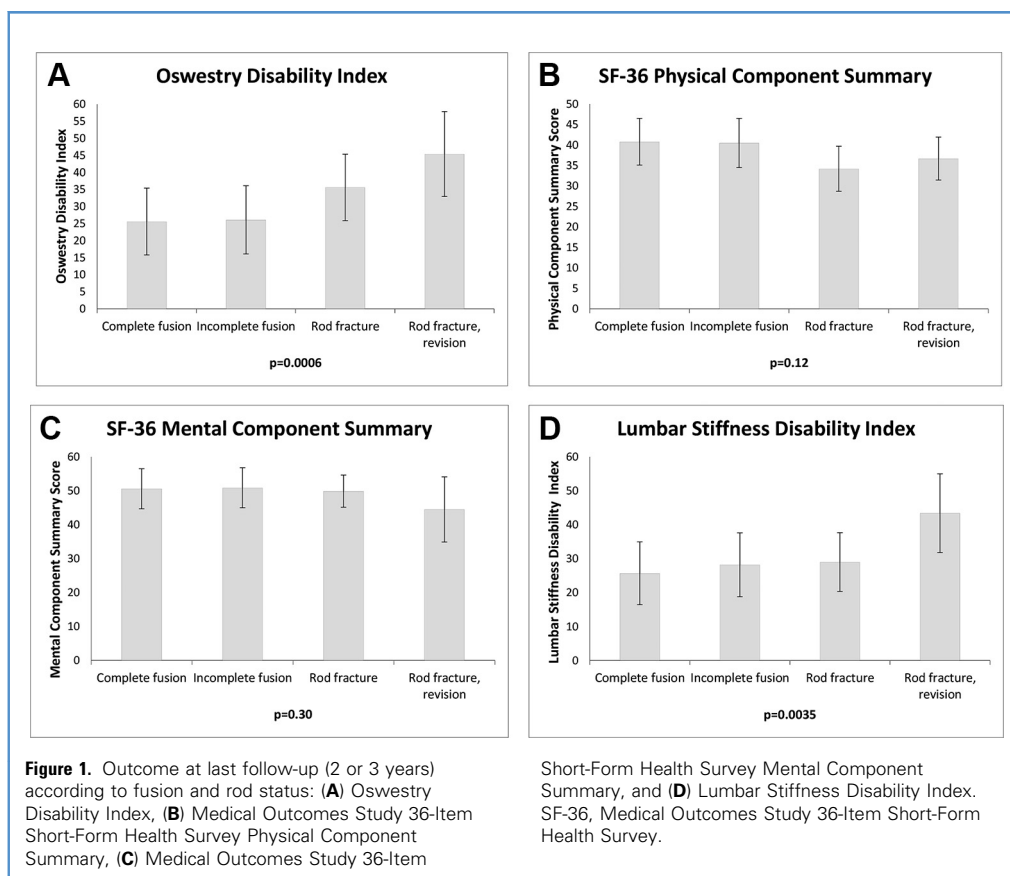
Number	Time of Failure*	Unilateral/Bilateral	Level	Revised (Yes/No)†
1	3 years	Unilateral	L3	Yes
2	2 years	Bilateral	L2	Yes
3	3 years	Unilateral	T12	Yes
4	3 years	Unilateral	S1	No
5	2 years	Unilateral	L4	No
6	2 years	Unilateral	S1	No
7	3 years	Unilateral	L4	No
8	1 year	Unilateral	L4	No
9	2 years	Bilateral	L3	No
10	6 weeks	Unilateral	L3	No
11	2 years	Bilateral	Ilium	No
12	2 years	Unilateral	L4	Yes
13	1 year	Unilateral	L4	Yes
14	3 years	Unilateral	L4	No
15	2 years	Bilateral	L5	Yes
16	6 weeks	Unilateral	T11	Yes
17	1 year	Bilateral	L3	Yes
18	3 years	Bilateral	L4	No
19	3 years	Bilateral	Unknown	Yes
20	1 year	Bilateral	Unknown	Yes
21	1 year	Unilateral	L5	Yes
22	1 year	Bilateral	L3	Yes
23	2 years	Unilateral	L5	No
24	2 years	Unilateral	L5	No
25	2 years	Bilateral	L5	No
26	2 years	Unilateral	L3	No
27	2 years	Bilateral	L5	Yes
28	2 years	Unilateral	L3	Yes
29	1 year	Bilateral	L5	No
30	2 years	Bilateral	L5	Yes
31	2 years	Unilateral	L2	Yes
32	2 years	Bilateral	L5	Yes
33	1 year	Bilateral	T11	Yes
34	1 year	Unilateral	L5	No
35	2 years	Unilateral	L4	No

*Refers to standard follow-up time point at which rod fracture was identified.

†Refers to whether a patient had undergone revision surgery for rod fracture by their last clinical follow-up.

patients undergoing a revision procedure. The overall rate of rod fracture is near the upper end of that previously reported in the literature (4%–15%).^{1-3,5,9} This may in part be explained by the

inclusion in the present study of all rod fractures, regardless of clinical impact. In addition, we analyzed patients with a minimum follow-up of 2 years and an average follow-up time of >50 months.



This relatively long follow-up may also explain the higher incidence of RF reported.

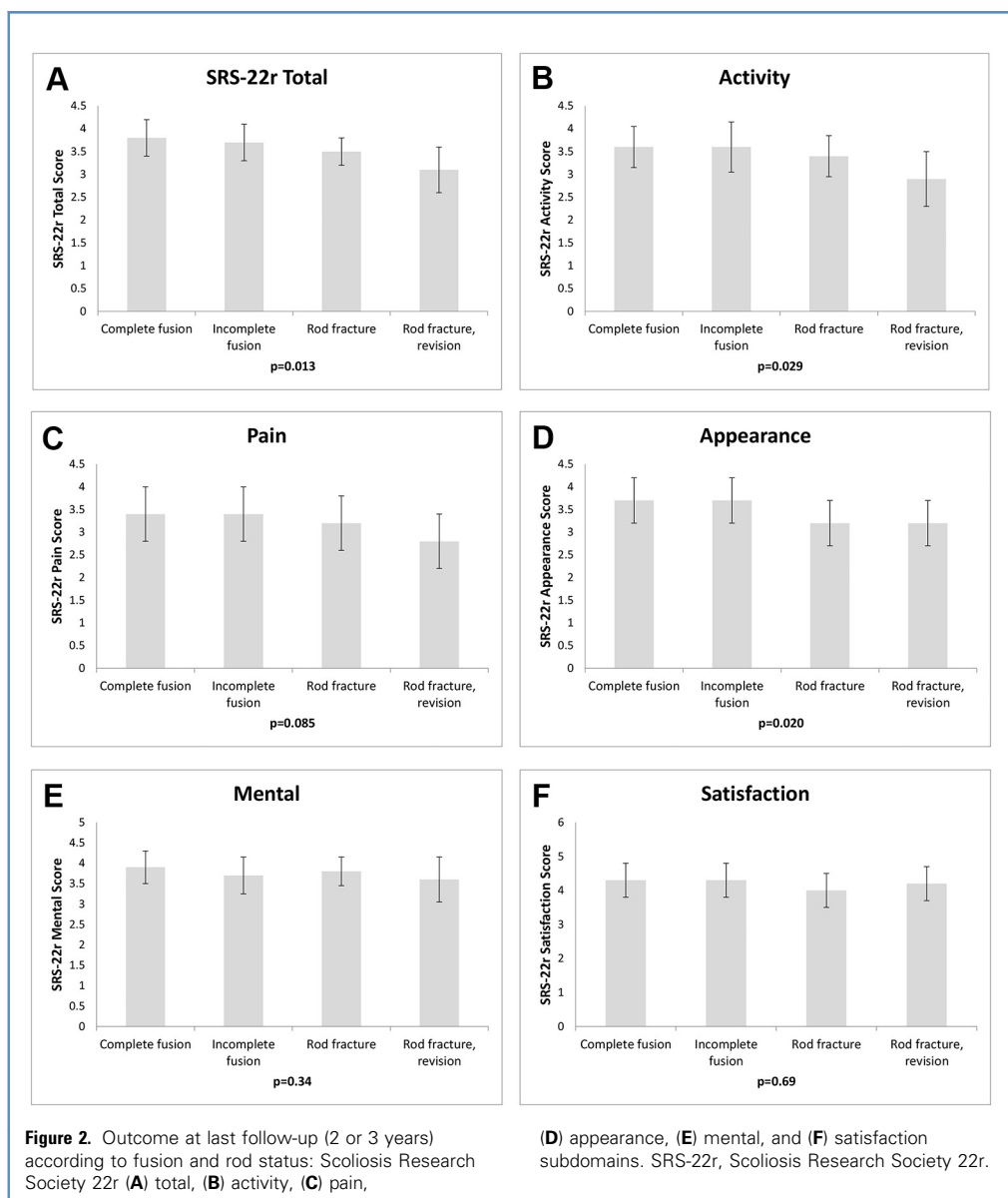
The rate of RF patients undergoing revision was 9.3%, which is within the previously reported range. Because patients undergoing revision were likely suffering from increased symptoms of pain and/or recurrent deformity, this group of patients may be more akin to those reported in other studies. Indeed, Smith et al.³ reported a rate of symptomatic rod fracture of 6.8% in a similar population to that of the present study, and also identified a higher incidence of RF after pedicle subtraction osteotomy (15.8%). Our study population included 45 patients who underwent one or more 3-column osteotomies, which may also explain the higher rate of RF.

In this patient cohort, rod fractures were diagnosed at an average of 18.3 months after the index procedure with a range of 2–35 months. This timing is in keeping with previous reports. Smith et al.³ found RFs to occur between 2 and 73 months after the index procedure, with a mean time to early (<12 months) and late (>12 months) RF of 6.4 and 31.8 months, respectively. In a subsequent prospective study, the same group demonstrated an average time to RF of 14.7 months (range, 3–27 months).² Finally, Akazawa et al.⁹ reported a mean time to and range to RF of 18.1 and 2–37 months, respectively. Although most RFs appear to occur within the first 3 years, they can occur at >5 years from surgery. It is therefore likely that longer follow-up

would identify a greater incidence of late RF. It is also possible that the etiology of early versus late RF may differ (e.g., early failures may represent greater instability or a mechanical deficiency of the rods, whereas late RFs may represent failure or even fatigue fracture of a solid bony fusion). Evaluating this question may be of further clinical value.

It is interesting that measures of lumbar spinal stiffness (LSDI) correlated strongly with measures of low back pain (ODI) in our study. Presumably, rod fracture increases available motion through pseudarthrotic segments. The fact that patients perceived an increase in functional stiffness reconfirms prior demonstrations that lumbar stiffness and low back pain are related, perhaps indicating that patients with low back pain do not make efforts to functionally use available spinal mobility.^{15–18}

Perhaps the most striking aspect of our study is our inability to find a correlation between radiographic fusion grade and HRQoL scores in the absence of rod fracture. Further, it appears that at least for some patients, rod fracture has relatively limited clinical impact. In this sense, we are led to question the value of fusion scoring systems based solely on plain radiographs. Although we cannot exclude the possibility that lower fusion grade may correlate with eventual occurrence of rod fracture, the limited clinical impact does at least raise the question of whether grading of spinal fusion in the absence of obvious evidence of fusion failure is clinically relevant.



In many circumstances, rod fracture implies failure of fusion; however, this did not always appear to be the case. For example, patients may experience a unilateral rod fracture through a segment that subsequently fuses. In long constructs, it is not uncommon to observe rod fractures between the S1 pedicle and iliac screws, which is an unfused portion of the construct. Established grading systems do not adequately account for such nuances, which further highlights the need to incorporate clinical and HRQoL measures into the assessment of potential pseudarthrosis. To this end, Klineberg et al.¹⁹ demonstrated that ASD patients that underwent surgery and developed pseudarthrosis failed to achieve significant improvement in the SRS-22r and ODI. Their counterparts that achieved a complete fusion improved in both of these domains at 1 year after their operation.

The grading of posterolateral fusion remains challenging. According to the scale we used,¹¹ instrumentation failure is assigned a grade of IV. In the setting of isthmic spondylolisthesis for which the grading scale was originally proposed, this is likely appropriate. However, as previously noted, in ASD, there are potential scenarios where rod fracture can occur despite achieving a solid fusion. Interpreting our finding that fusion grade is less clinically relevant than rod fracture must be done in light of this limitation in the fusion grading scale.

This study shares the limitations of all retrospective analyses. The cohort may have lacked sufficient statistical power to detect actual differences because of relatively small numbers within groups. Specifically, our failure to show a difference in HRQoL outcomes between the RF and RFR groups may represent a type II

error because of lack of power. The RFR group presumably comprised patients with symptomatic nonunion and would therefore be expected to have fared poorer than those with rod fracture that did not require revision.

The timing of assessment of HRQoL relative to the timing of rod fracture and revision surgery could have impacted our results. HRQoL was determined at prespecified intervals irrespective of when rod failure occurred. We attempted to mitigate any potential confounding by using HRQoL measures recorded at the last available clinical follow-up in our analysis to capture the ultimate impact of fusion status, rod fracture, and revision status. Future prospective studies that capture HRQoL at the time that rod fracture is identified and, when revision is performed, pre- and postoperatively, would help elucidate the impact of these events and the time course of changes in HRQoL.

Despite these limitations, this is the first study, to our knowledge, that attempts to validate radiographic fusion grade using

clinical impact measures in a cohort of ASD patients. Our failure to do so suggests a need to improve fusion assessments or modify current grading systems to focus on more clinically relevant measures. Unfortunately, although our study does demonstrate that current fusion grading may lack clinical validity, the work of suggesting a better alternative remains for future efforts.

CONCLUSIONS

Radiographic fusion grade after ASD surgery did not significantly correlate with patient 2-year HRQoL, independent of occurrence of rod fracture. Patients with RFR did report significantly worse HRQoL outcomes at last follow-up compared with patients with complete fusion, incomplete fusion, or RF. Fusion grade itself appears to be less sensitive to clinical outcomes than the occurrence of RF, especially for patients requiring revision surgery.

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