

## Proximal junctional failure in primary thoracolumbar fusion/fixation to the sacrum/pelvis for adult symptomatic lumbar scoliosis: long-term follow-up of a prospective multicenter cohort of 160 patients

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**OBJECTIVE** Proximal junctional failure (PJF) is a severe form of proximal junctional kyphosis. Previous reports on PJF have been limited by heterogeneous cohorts and relatively short follow-ups. The authors' objectives herein were to identify risk factors for PJF and to assess its long-term incidence and revision rates in a homogeneous cohort.

**METHODS** The authors reviewed data from the Adult Symptomatic Lumbar Scoliosis 1 trial (ASLS-1), a National Institutes of Health–sponsored prospective multicenter study. Inclusion criteria were an age  $\geq 40$  years, ASLS (Cobb angle  $\geq 30^\circ$  and Oswestry Disability Index [ODI]  $\geq 20$  or Scoliosis Research Society revised 22-item questionnaire [SRS-22r] score  $\leq 4.0$  in pain, function, or self-image domains), and primary thoracolumbar fusion/fixation to the sacrum/pelvis of  $\geq 7$  levels. PJF was defined as a postoperative proximal junctional angle (PJA) change  $> 20^\circ$ , fracture of the uppermost instrumented vertebra (UIV) or UIV+1 with  $> 20\%$  vertebral height loss, spondylolisthesis of UIV/UIV+1  $> 3$  mm, or UIV screw dislodgment.

**RESULTS** One hundred sixty patients (141 women) were included in this analysis and had a median age of 62 years and a mean follow-up of 4.3 years (range 0.1–6.1 years). Forty-six patients (28.8%) had PJF at a median of 0.92 years (IQR 0.14, 1.23 years) following surgery. Based on Kaplan-Meier analyses, PJF rates at 1, 2, 3, and 4 years were 14.4%, 21.9%, 25.9%, and 27.4%, respectively. On univariate analysis, PJF was associated with greater age ( $p = 0.0316$ ), greater body mass index (BMI;  $p = 0.0319$ ), worse baseline patient-reported outcome measures (PROMs; ODI, SRS-22r, and SF-12 Physical Component Summary [PCS]; all  $p < 0.04$ ), the use of posterior column osteotomies (PCOs;  $p = 0.0039$ ), and greater postoperative thoracic kyphosis (TK;  $p = 0.0031$ ) and PJA ( $p < 0.001$ ). The use of UIV hooks was protective against PJF ( $p = 0.0340$ ). On regression analysis (without postoperative measures), PJF was associated with greater BMI (HR 1.077, 95% CI 1.007–1.153,  $p = 0.0317$ ), lower preoperative PJA (HR 0.607, 95% CI 0.407–0.906,  $p = 0.0146$ ), and greater preoperative TK (HR 1.362, 95% CI 1.082–1.715,  $p = 0.0085$ ). Patients with PJF had worse PROMs at the last follow-up (ODI, SRS-22r subscore and self-image, and SF-12 PCS;  $p < 0.04$ ). Sixteen PJF patients (34.8%) underwent revision, and PJF recurred in 3 (18.8%).

**CONCLUSIONS** Among 160 primary ASLS patients with a median age of 62 years and predominant coronal deformity, the PJF rate was 28.8% at a mean 4.3-year follow-up, with a revision rate of 34.8%. On univariate analysis, PJF was as-

**ABBREVIATIONS** ASD = adult spinal deformity; ASLS = adult symptomatic lumbar scoliosis; BMI = body mass index; LL = lumbar lordosis; MCS = Mental Component Summary; ODI = Oswestry Disability Index; PCO = posterior column osteotomy; PCS = Physical Component Summary; PI = pelvic incidence; PI-LL = mismatch between PI and LL; PJA = proximal junctional angle; PJF = proximal junctional failure; PJK = proximal junctional kyphosis; PROM = patient-reported outcome measure; SRS-22r = Scoliosis Research Society revised 22-item questionnaire; SVA = sagittal vertical axis; TK = thoracic kyphosis; UIV = uppermost instrumented vertebra.

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sociated with a greater age and BMI, worse baseline PROMs, the use of PCOs, and greater postoperative TK and PJA. The use of UIV hooks was protective against PJF. On multivariate analysis (without postoperative measures), a higher risk of PJF was associated with greater BMI and preoperative TK and lower preoperative PJA.

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**KEYWORDS** adult scoliosis; complications; proximal junctional failure; proximal junctional kyphosis; spinal alignment; spine deformity; spinal instrumentation; spine surgery; lumbar

**P**ROXIMAL junctional kyphosis (PJK) is a well-recognized phenomenon following posterior segmental instrumentation for spinal deformity.<sup>1–5</sup> The reported incidence ranges from 5.8% to 59%,<sup>6</sup> with most reports favoring a 20%–40% range.<sup>3,7–9</sup> PJK is a complex, multifactorial issue that requires a multifaceted approach to address.<sup>10</sup> However, given the widely used definition of PJK proposed by Glattes and colleagues,<sup>6</sup> the majority of patients with PJK do not appear to have symptoms or a need for revision surgery.<sup>6,11</sup>

The term “proximal junctional failure” (PJF) has since been advanced to reflect more clinically significant junctional pathology.<sup>8,12–17</sup> Although the definition of PJF remains unsettled, patients with PJF typically not only meet the PJK Glattes criteria but also exhibit a combination of more significant junctional kyphosis, bony fracture, posterior ligamentous complex disruption, or instrumentation failure. PJF has a reported incidence ranging from 1.4% to 19%.<sup>1,9,13–16</sup> and is arguably the greatest unsolved problem in adult spinal deformity (ASD) surgery. The development of PJF can be associated with pain, disability, and neurological deficits and frequently requires extensive revision surgery.<sup>8,18</sup>

Previous studies on PJF have been limited by relatively short follow-ups, limited follow-up rates, single-center or single-surgeon cohorts, and heterogeneous deformity populations.<sup>9,13–16,19,20</sup> Further study is needed to better define the long-term incidence of PJF and factors associated with its occurrence. In the present study, we aimed to define the prevalence of PJF and to assess the risk factors for PJF using a longer-term follow-up in a relatively homogeneous patient population from a multicenter, prospective database (from the Adult Symptomatic Lumbar Scoliosis 1 trial [ASLS-1]).<sup>21–23</sup>

## Methods

### Study Design and Inclusion Criteria

This is a retrospective review of a prospective, multicenter, consecutive series of patients from a National Institutes of Health–sponsored study (ASLS-1) designed to assess operative versus nonoperative treatment of adults with symptomatic lumbar scoliosis.<sup>21,22</sup> Patients were enrolled at 9 sites in North America through a protocol approved by the institutional review boards of each contributing center. Inclusion criteria were as follows: no prior spine fusion or multilevel decompression, age 40–80 years, and ASLS defined on the basis of the presence of a lumbar curve with a coronal Cobb angle  $\geq 30^\circ$  and an Oswestry Disability Index (ODI)  $\geq 20$  or Scoliosis Research Society revised 22-item questionnaire (SRS-22r) score  $\leq 4.0$  in the domains of pain, function, or self-image. Patients with neuromuscular scoliosis (e.g., Parkinson’s disease) were excluded from

study enrollment. The present study focused on the subset of ASLS-1 patients who had been operatively treated with posterior instrumented fusion/fixation of  $\geq 7$  vertebral levels that included the sacrum/pelvis.

### Data Collection

Patient demographic, clinical, and operative parameters were collected from standardized study forms. Patient-reported outcome measures (PROMs) included the SRS-22r, SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS), ODI, and numeric rating scale for back and legs.

Full-length free-standing posteroanterior and lateral radiographs were obtained at baseline, 3 months postoperatively, and at subsequent clinical visits. Radiographs were measured using Surgimap software (Nemaris Inc.). Sagittal parameters included lumbar lordosis (LL), thoracic kyphosis (TK), sagittal vertical axis (SVA), pelvic tilt, pelvic incidence (PI), mismatch between PI and LL (PI-LL), and T1 pelvic angle, as previously described.<sup>24,25</sup> Proximal junctional angle (PJA) was measured as the angle between the inferior endplate of the uppermost instrumented vertebra (UIV) and the superior endplate of the second vertebra above the UIV (UIV+2). Coronal parameters included Cobb angles and global coronal alignment measured as the distance from the midsacral point to the plumbline drawn from the center of C7.<sup>25</sup>

Radiographic PJK was defined on the basis of the Glattes criteria:<sup>6</sup> 1) PJA  $\geq +10^\circ$  and 2) PJA at least  $10^\circ$  greater than the preoperative measurement. Based on previous reports,<sup>8,9,12,13,16,18,26</sup> PJF was defined as the presence of at least one of the following on postoperative imaging: change in PJA  $> 20^\circ$  compared with the preoperative measurement, fracture of UIV and/or UIV+1 with  $> 20\%$  vertebral height loss, screw dislodgment, or spondylolisthesis of UIV+1 relative to UIV of  $> 3$  mm.

### Data and Statistical Analysis

Follow-up started on the date of the index surgical treatment and ended at the first loss to follow-up or death. Kaplan-Meier curves were used to estimate the proportion of patients with PJF across the follow-up period. Demographic, clinical, surgical, and radiographic parameters were compared for patients with and without PJF using the Wilcoxon rank-sum test for continuous variables and the chi-square test and Fisher’s exact test for categorical data according to the sample size. Differences were considered statistically significant if  $p < 0.05$ .

Multivariate Cox models were used to determine a subset of risk factors independently associated with PJF. Initial multivariate models included all variables with  $p < 0.1$  from the univariate comparisons. Variables that did

not retain a  $p < 0.1$  in the multivariate analysis were then removed, and additional variables known to be potentially important confounders were considered for inclusion before determining the final multivariate model.

Among patients who had PJF, Kaplan-Meier curves were used to estimate the proportion of patients with a revision across the time after PJF. Associations between each parameter used to define PJF and the need for revision surgery were assessed using the chi-square test and Fisher's exact test for categorical data according to the sample size. Statistical analyses were performed using SAS software (SAS Institute Inc.).

## Results

### Clinical and Radiographic Characteristics of the Patient Population

A total of 286 patients were enrolled in ASLS-1 between 2010 and 2014, including 182 patients who underwent surgery. Of these 182 patients, 22 were excluded from the present study because of a lack of instrumentation extending to the pelvis ( $n = 10$ ),  $< 7$  levels fused ( $n = 11$ ), or a lack of radiographic follow-up ( $n = 1$ ). The mean total follow-up for the remaining 160 patients included in the study was 4.3 years (range 0.1–6.1 years).

Baseline demographics, radiographic measures, and PROMs are summarized in Table 1. The median age was 62 years (IQR 55.7, 67.9), and 141 of the patients (88.1%) were women. On baseline radiographs, the median PI-LL was  $19^\circ$  (IQR 8, 32), median C7–S1 SVA was 31.5 mm (IQR 13, 66), and median coronal Cobb angle was  $51^\circ$  (IQR 41.5, 67). Baseline PROMs reflected moderate to severe disability and pain.

Operative parameters are summarized in Table 2. The mean number of vertebral levels fused posteriorly was 11.5 (IQR 8, 14), with 67 patients (41.9%) having an upper thoracic UIV, 20 (12.5%) having a UIV in the mid-thoracic spine, and 73 (45.6%) having a UIV in the lower thoracic spine. The most common rod material used was cobalt chromium (84.4%), followed by titanium (10%) and stainless steel (4.4%). Most rods were 5.5 mm in diameter (94.4%). Eighteen patients had supplemental rods.<sup>27,28</sup> Posterior column osteotomies (PCOs) were used in the majority of patients, and three-column osteotomies (pedicle subtraction osteotomy or vertebral column resection) were used in 9 patients. PJF prophylaxis measures included hooks at the UIV in 39 patients (24.4%) and cement at the UIV and/or UIV+1 in 7 patients (4.4%). The two most common UIV hook constructs were bilateral transverse process hooks and a pedicle screw on one side with a pedicle hook on the other side. Postoperative radiographic measures, changes in radiographic measurements from baseline, and PROMs obtained at the last follow-up are summarized in Table 3.

### Characteristics of Patients Presenting With PJF

A total of 46 patients (28.8%) had PJF at a median of 335 days (IQR 51, 449 days) from the index surgery (Table 4). Based on Kaplan-Meier analyses, PJF rates at 1, 2, 3, and 4 years were 14.4%, 21.9%, 25.9%, and 27.4%, respectively (Fig. 1 left). Among these 46 patients, the UIV

was in the upper thoracic spine in 18 (39.1%), midthoracic spine in 4 (8.7%), and lower thoracic spine in 24 (52.2%). The median PJA at the 3-month follow-up was  $19.2^\circ$  (IQR  $14.3^\circ$ ,  $26.8^\circ$ ), and 39 patients (84.8%) ultimately had a PJA  $> 20^\circ$ . Fracture of the UIV and UIV+1 was found in 18 (39.1%) and 7 (15.2%) patients, respectively. Screw dislodgment and spondylolisthesis of UIV+1 relative to the UIV were seen in 7 (15.2%) and 2 (4.3%) patients, respectively (Table 4).

### Assessment of Risk Factors for PJF

On univariate analysis, baseline demographic and radiographic measures were similar between those who did and those who did not have PJF, except for age and body mass index (BMI; Table 1). Patients with PJF were significantly older (median age 64 vs 60 years,  $p = 0.0316$ ), and had a significantly greater BMI (median 28.0 vs 25.8,  $p = 0.0319$ ). Patients with PJF also had significantly worse baseline PROM scores for ODI, SRS-22r subscore, SRS-22r pain, SRS-22r function, SRS-22r mental health, and SF-12 PCS (all  $p < 0.04$ ).

On univariate analysis, operative parameters were similar between those who did and those who did not have PJF, except for the use of PCOs and hooks at the UIV (Table 2). More patients with PJF had been treated with PCOs than those without PJF (80.4% vs 56.1%,  $p = 0.0039$ ), and fewer patients with hooks at the UIV had PJF (28.9% vs 13.0%,  $p = 0.0340$ ). Notably, surgical approach, rod material and diameter, number of fused levels, and level of UIV were not associated with PJF.

On univariate analysis, 3-month postoperative radiographic parameters and changes in radiographic alignment (3-month postoperative compared with preoperative) were not different between patients who did and those who did not have PJF, except for postoperative TK, postoperative PJA, and change in PJA (Table 3). Patients with PJF had greater postoperative TK ( $46.8^\circ$  vs  $40.0^\circ$ ,  $p = 0.0031$ ), greater postoperative PJA ( $19.2^\circ$  vs  $9.5^\circ$ ,  $p < 0.0001$ ), and greater postoperative change in PJA ( $14.3^\circ$  vs  $4.4^\circ$ ,  $p < 0.0001$ ). Notably, patients with PJF had significantly worse scores on multiple PROMs at the last follow-up (Table 3).

Multivariate assessment of baseline parameters associated with the development of PJF demonstrated significant associations with BMI, baseline PJA, and baseline TK (Table 5). The occurrence of PJF was associated with greater BMI (HR 1.077, 95% CI 1.007–1.153,  $p = 0.0317$ ), lower baseline PJA (HR 0.607, 95% CI 0.407–0.906, modeled by  $5^\circ$  increments), and greater baseline TK (HR 1.362, 95% CI 1.082–1.715,  $p = 0.0085$ , modeled by  $10^\circ$  increments). Factors that were adjusted for but were not significant in the final model included age, osteopenia/osteoporosis, level of UIV, hooks at the UIV, and baseline C7–S1 SVA (Table 5).

### Revision Surgery for PJF and PJF Recurrence Rates

Of the 46 patients with PJF, 16 (34.8%) had undergone revision surgery as of the last follow-up (Table 4). The median follow-up after PJF was 902 days (IQR 135, 1363 days; Fig. 1 right). Extension of fusion was performed in

**TABLE 1. Summary of baseline characteristics of 160 ASLS patients stratified based on the development of PJJ**

Characteristic	All Patients	No PJJ	PJJ	p Value (no vs yes)
No. of patients	160	114	46	
Age in yrs	62 (56, 68)	60 (56, 66)	64 (59, 72)	<b>0.0316*</b>
Female sex	141 (88.1)	100 (87.7)	41 (89.1)	0.8028†
Race				0.8121‡
White	153 (95.6)	109 (95.6)	44 (95.7)	
Black	5 (3.1)	4 (3.5)	1 (2.2)	
Other	2 (1.3)	1 (0.9)	1 (2.2)	
Tobacco use				0.4629‡
Current	2 (1.3)	2 (1.8)	0 (0.0)	
Former	62 (38.8)	41 (36.0)	21 (45.7)	
Never	96 (60.0)	71 (62.3)	25 (54.3)	
BMI	26.0 (23.4, 29.5)	25.8 (23.4, 28.2)	28.0 (24.2, 31.2)	<b>0.0319*</b>
Osteopenia/osteoporosis				0.2914‡
None/NA	53 (33.1)	41 (36.0)	12 (26.1)	
T-score -1 to -1.5	46 (28.8)	28 (24.6)	18 (39.1)	
T-score -1.6 to -2.4	46 (28.8)	33 (28.9)	13 (28.3)	
T-score -2.5 or worse§	15 (9.4)	12 (10.5)	3 (6.5)	
Diabetes				0.1278‡
No	150 (93.8)	107 (93.9)	43 (93.5)	
Yes, controlled w/ diet	1 (0.6)	1 (0.9)	0 (0.0)	
Yes, controlled w/ oral hypoglycemic	7 (4.4)	6 (5.3)	1 (2.2)	
Yes, insulin dependent	2 (1.3)	0 (0.0)	2 (4.3)	
Radiographic measures				
C7-S1 SVA in mm	31.5 (13, 66)	31.5 (13, 60)	29.5 (16, 87)	0.4263*
TPA in °	20.8 (14.4, 28)	20.8 (14.5, 27.9)	20.3 (14.4, 29.9)	0.6477*
TK (T4-T12) in °	30.7 (19.4, 42.5)	30 (18.1, 41)	36.5 (27, 44.4)	0.1*
LL (T12-sacrum) in °	36.3 (25, 49)	37 (27, 47)	32.8 (20, 58)	0.7672*
PI in °	54 (48, 63)	54 (48, 63)	53 (45.1, 63)	0.8766*
PI-LL in °	19 (8, 32)	18.5 (8.5, 31.1)	20 (8, 34)	0.762*
PT in °	24 (20, 30)	24 (19, 28)	24 (21, 31)	0.3591*
Lumbar Cobb angle in °	51 (41.5, 67)	55 (43, 68)	49 (38, 61)	0.1497*
Coronal alignment absolute value in mm	21 (9, 38.6)	21 (10, 39.2)	20 (8, 34)	0.6307*
PJA in °	5.0 (3.0, 8.6)	5.2 (3, 9)	4.7 (2, 7.9)	0.1226*
Baseline PROMs				
ODI	38 (28, 50)	36 (26, 46)	47 (36, 54)	<b>0.0026*</b>
SRS-22r subscore	3.0 (2.6, 3.5)	3.1 (2.7, 3.5)	2.7 (2.4, 3.4)	<b>0.0063*</b>
SRS-22r pain	2.8 (2.2, 3.4)	2.8 (2.4, 3.4)	2.6 (2, 3.2)	<b>0.0386*</b>
SRS-22r function	3.2 (2.5, 3.6)	3.2 (2.8, 3.8)	2.7 (2.2, 3.4)	<b>0.0046*</b>
SRS-22r self-image	2.7 (2.1, 3.2)	2.8 (2.2, 3.2)	2.5 (2, 3)	0.0657*
SRS-22r mental health	3.7 (3.0, 4.2)	3.8 (3.2, 4.4)	3.4 (2.8, 4)	<b>0.0283*</b>
SRS-22r satisfaction	3.0 (2.0, 3.5)	3 (2, 3.5)	2.8 (2, 3.5)	0.3145*
NRS back pain	7 (5, 8)	7 (5, 8)	7 (6, 8)	0.2615*
NRS leg pain	4 (1, 7)	4 (1, 7)	4.5 (2, 7)	0.0816*
SF-12 MCS	51.7 (41.5, 59.6)	53.2 (41.5, 59.9)	47 (40.5, 58.3)	0.0835*
SF-12 PCS	31.9 (25.8, 39.3)	33.9 (27.5, 41.7)	26.7 (22.8, 33.5)	<b>0.0005*</b>

NA = not applicable; NRS = numeric rating scale; PT = pelvic tilt; TPA = T1 pelvic angle.

Values are expressed as the median (Q1, Q3) or number (%), unless indicated otherwise. Boldface type indicates statistical significance.

\* Wilcoxon rank-sum test.

† Chi-square test.

‡ Fisher's exact test.

§ Or vertebral compression fracture.

**TABLE 2. Index operative parameters for 160 ASLS patients stratified based on the development of PJF**

Parameter	All Patients	No PJF	PJF	p Value (no vs yes)
No. of patients	160	114	46	
Estimated blood loss in ml	1750 (975, 3000)	1700 (1000, 2600)	1875 (900, 3500)	0.6092*
Operative time in hrs	6.5 (5.8, 7.5)	6.6 (6, 7.7)	6.5 (5.3, 7)	0.1415*
Surgical approach				
Pst only	144 (90.0)	104 (91.2)	40 (87.0)	0.4150†
Combined ant-pst	16 (10.0)	10 (8.8)	6 (13.0)	
Pst approach details				
Rod material				0.1301‡
Titanium	16 (10.0)	13 (11.4)	3 (6.5)	
Stainless steel	7 (4.4)	6 (5.3)	1 (2.2)	
Cobalt chromium	135 (84.4)	95 (83.3)	40 (87.0)	
Other	2 (1.3)	0 (0.0)	2 (4.3)	
Rod diameter				
Rod 1 diameter				0.6905‡
5.5 mm	152 (95.0)	109 (95.6)	43 (93.5)	
6.0 mm	8 (5.0)	5 (4.4)	3 (6.5)	
Rod 2 diameter				0.2096‡
5.5 mm	150 (93.8)	109 (95.6)	41 (89.1)	
6.0 mm	7 (4.4)	4 (3.5)	3 (6.5)	
7.0 mm	3 (1.9)	1 (0.9)	2 (4.3)	
Rod 3 diameter				>0.99‡
5.5 mm	17 (94.4)	14 (93.3)	3 (100.0)	
6.0 mm	1 (5.6)	1 (6.7)	0 (0.0)	
Accessory/satellite rod(s)				0.2804‡
No	142 (88.8)	99 (86.8)	43 (93.5)	
Yes	18 (11.3)	15 (13.2)	3 (6.5)	
No. of fused levels	11.5 (8, 14)	13 (8, 15)	9 (8, 14)	0.4354*
UIV				
Upper thoracic spine (T1–4)	67 (41.9)	49 (43.0)	18 (39.1)	
Mid thoracic spine (T5–8)	20 (12.5)	16 (14.0)	4 (8.7)	
Lower thoracic spine (T9–12)	73 (45.6)	49 (43.0)	24 (52.2)	
Type of pelvic fixation				0.5964†
Iliac screws	147 (91.9)	106 (93.0)	41 (89.1)	
S2-alar-iliac screws	13 (8.1)	8 (7.0)	5 (10.9)	
Osteotomies				
PCO	101 (63.1)	64 (56.1)	37 (80.4)	<b>0.0039†</b>
Three-column osteotomy	9 (5.6)	7 (6.1)	2 (4.3)	>0.99‡
PSO	6 (3.8)	6 (5.3)	0 (0.0)	0.1832‡
VCR	3 (1.9)	1 (0.9)	2 (4.3)	0.1988‡
PJF prophylaxis measures				
Hooks at UIV	39 (24.4)	33 (28.9)	6 (13.0)	<b>0.0340†</b>
Cement at UIV &/or UIV+1	7 (4.4)	5 (4.4)	2 (4.3)	>0.99‡
Ant/lat approach details				
ALIF				0.4248‡
1	8 (50.0)	6 (60.0)	2 (33.3)	
2	7 (43.8)	3 (30.0)	4 (66.7)	
3	1 (6.3)	1 (10.0)	0 (0.0)	

ALIF = anterior lumbar interbody fusion; ant = anterior; PSO = pedicle subtraction osteotomy; pst = posterior; VCR = vertebral column resection. Values are expressed as the median (Q1, Q3) or number (%), unless indicated otherwise. Boldface type indicates statistical significance.

\* Wilcoxon rank-sum test.

† Chi-square test.

‡ Fisher's exact test.

**TABLE 3. Postoperative radiographic outcome measures and PROMs for 160 ASLS patients stratified based on the development of PJF**

Parameter	All Patients	No PJF	PJF	p Value (no vs yes)*
No. of patients	160	114	46	
Postop (3-mo radiographs)				
C7–S1 SVA in mm	24.7 (12, 39)	22.4 (11, 35.8)	29.6 (16.1, 43.1)	0.0562
TPA in °	16 (9, 23)	16 (10.4, 23)	17 (8, 25)	0.8201
TK (T4–12) in °	42 (31.3, 48.1)	40 (31, 46)	46.8 (36.5, 56.4)	<b>0.0031</b>
LL (T12–sacrum) in °	51 (43.5, 61)	50.5 (43, 60)	53 (46, 61)	0.3836
PI in °	54 (47, 61)	54 (46, 61)	53.5 (47.4, 61)	0.8342
PI-LL in °	7 (3.6, 13)	6.6 (3, 13)	8.5 (5, 13)	0.2014
PT in °	21.9 (15.9, 27)	21.4 (15.7, 25.2)	23 (16, 29)	0.6132
Lumbar Cobb angle in °	19.2 (12, 29)	21 (11.2, 30.2)	17.3 (12.7, 22)	0.2449
Coronal alignment absolute value in mm	15.7 (8, 25.4)	15.4 (8, 25.4)	15.8 (8.7, 26.8)	0.8188
PJA in °	11.5 (7.2, 16.9)	9.5 (6.6, 13.2)	19.2 (14.3, 26.8)	<b>&lt;0.0001</b>
Change (postop – baseline)				
C7–S1 SVA in mm	41 (15.1, 71)	41 (17.8, 67.2)	41.6 (12.7, 92.4)	0.7177
TPA in °	8.4 (4.2, 13.1)	7.6 (4.2, 12.1)	9.7 (4.3, 14.5)	0.3947
TK (T4–12) in °	13.4 (7.2, 21)	12.5 (6.9, 21)	15.9 (8.5, 21.1)	0.2143
LL (T12–sacrum) in °	17 (8, 27)	16.5 (8, 26.6)	18 (11, 31.5)	0.2485
PI in °	3 (1.6, 4)	3 (1, 4)	3 (2, 4)	0.6699
PI-LL in °	18 (9, 29)	17.4 (9, 26.9)	21 (11, 31)	0.3193
PT in °	6 (3, 11.6)	6 (3, 11.8)	6 (3.5, 11)	0.3638
Lumbar Cobb in °	34 (24, 41.8)	34.5 (24.5, 42.7)	30.6 (19.6, 40)	0.4993
Coronal alignment absolute value in mm	25 (10, 46)	25.7 (13, 46)	19.9 (7.5, 45.4)	0.3487
PJA in °	6 (3.1, 11.0)	4.4 (2.2, 7.5)	14.3 (9.7, 19.9)	<b>&lt;0.0001</b>
PROMs at last follow-up				
ODI	22 (8, 38)	18 (8, 36)	27 (16, 48)	<b>0.0091</b>
SRS-22r subscore	3.9 (3.3, 4.3)	4 (3.4, 4.4)	3.6 (3.2, 4.1)	<b>0.0379</b>
SRS-22r pain	3.8 (3, 4.4)	3.8 (3.2, 4.6)	3.9 (2.5, 4.4)	0.1378
SRS-22r function	3.6 (3, 4.2)	3.8 (3, 4.2)	3.4 (2.8, 4)	0.0682
SRS-22r self-image	4 (3.4, 4.5)	4.2 (3.5, 4.5)	3.7 (3.2, 4.3)	<b>0.0221</b>
SRS-22r mental health	4 (3.4, 4.6)	4.2 (3.6, 4.6)	4 (3.4, 4.6)	0.4612
SRS-22r satisfaction	4.5 (4, 5)	4.5 (4, 5)	4.5 (3.5, 5)	0.5686
NRS back pain	2 (1, 5)	2 (0, 5)	3 (1, 5)	0.1266
NRS leg pain	1 (0, 4)	1 (0, 4)	2 (1, 5)	0.0554
SF-12 MCS	52.5 (40.4, 58.9)	53.7 (41.7, 59.7)	49.7 (37.6, 57.7)	0.1350
SF-12 PCS	43.2 (31.9, 52.1)	45.3 (33.3, 53.3)	37.5 (29.3, 47.6)	<b>0.0238</b>

Values are expressed as the median (Q1, Q3), unless indicated otherwise. Boldface type indicates statistical significance.

\* Wilcoxon rank-sum test.

all but 1 patient, including 1–2 levels (1 patient), 3–5 levels (6 patients), or 6–10 levels (8 patients). Five (31.3%) of the 16 patients who had undergone revision for PJF had a laminectomy/decompression at the junction and extension of fusion, 7 (43.8%) had a partial or complete vertebrectomy and extension of fusion, 3 (18.8%) had only extension of fusion, and 1 (6.3%) had partial removal of instrumentation (Table 4). A case example of PJF requiring revision surgery is shown in Fig. 2.

The percentage of patients with PJF who met each of the 4 criteria used to define PJF, with stratification based on whether revision surgery was performed, is summa-

rized in Table 6. Each criterion was significantly associated with the need for revision except for spondylolisthesis of UIV+1, which was only present in 2 patients. A change in PJA > 20° was more common among patients who did not undergo revision for PJF (93.3% vs 68.8%,  $p = 0.040$ ). In contrast, patients who had undergone revision had a higher rate of fracture of the UIV and/or UIV+1 (93.8% vs 20.0%,  $p < 0.001$ ) and a higher rate of screw dislodgment (37.5% vs 3.3%,  $p = 0.005$ ) than those who had not undergone revision surgery. Recurrent PJF developed at the new UIV in 3 (18.8%) of the 16 patients treated for PJF (Table 4).

**TABLE 4. Characteristics and management of ASLS patients with PJF**

Parameter	Value
No. of patients	46/160 (28.8)
Time to PJF from index surgery in days	335 (51, 449)
UIV	
T1–4	18/46 (39.1)
T5–8	4/46 (8.7)
T9–12	24/46 (52.2)
Radiographic findings	
PJA >20°	39/46 (84.8)
Fracture of UIV	18/46 (39.1)
Fracture of UIV+1	7/46 (15.2)
Screw dislodgment	7/46 (15.2)
Spondylolisthesis of UIV+1 relative to UIV	2/46 (4.3)
Treatment for PJF	
None to date	30/46 (65.2)
Revision surgery	16/46 (34.8)
Proximal extension of fusion	15/16 (93.8)
1–2 vertebral levels	1/16 (6.3)
3–5 vertebral levels	6/16 (37.5)
6–10 vertebral levels	8/16 (50.0)
>10 vertebral levels	0/16 (0)
Decompression (laminectomy) at level of PJF	5/16 (31.3)
Complete/partial vertebrectomy at level of PJF	7/16 (43.8)
Partial removal of instrumentation	1/16 (6.3)
Recurrent PJF	
None	13/16 (81.3)
Recurred	3/16 (18.8)

Values are expressed as number/total number (%) or median (Q1, Q3).

### Rates of PJK and Overlap With PJF

Of the study cohort of 160 patients, 74 (46.3%) had PJK based on Glattes criteria<sup>6</sup> at a median of 122 days (IQR 30, 950 days) after surgery. All but 1 of the 46 patients (97.8%) who met the criteria for PJF also met the criteria for PJK. In contrast, there were 29 patients who developed PJK but did not develop PJF, and none of these 29 patients underwent revision surgery. Of the 16 patients who had undergone revision surgery for junctional issues, all met the criteria for PJF and 15 met the criteria for PJK.

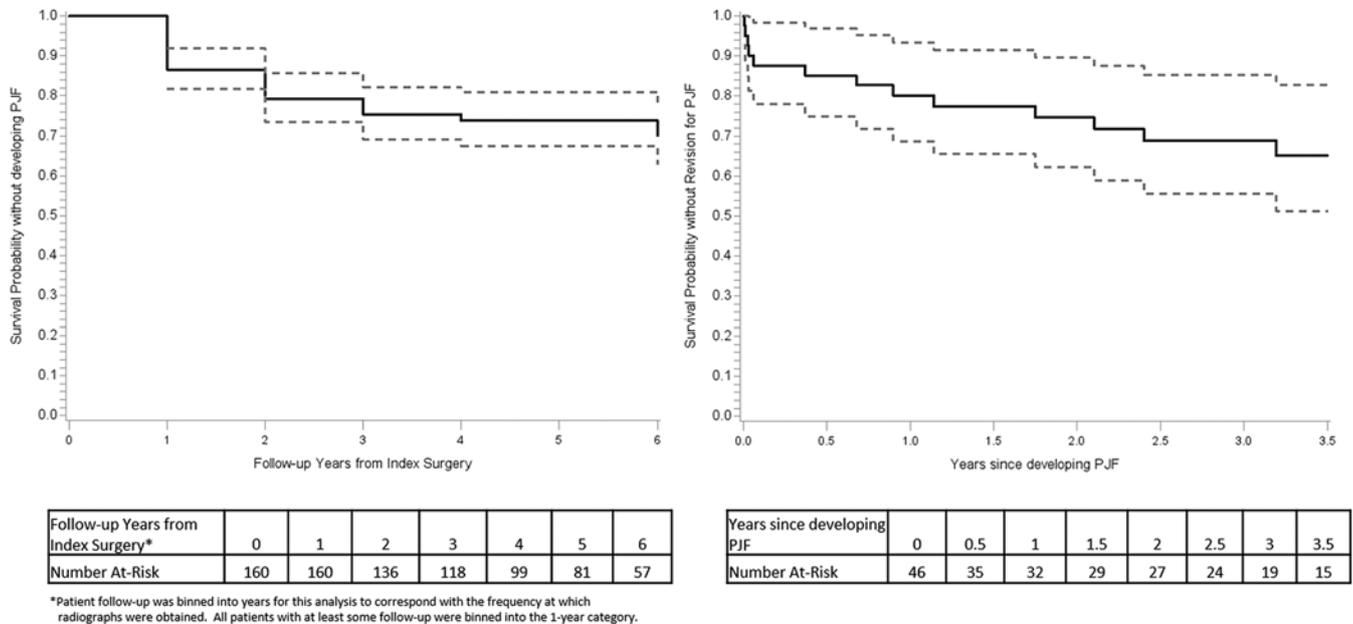
### Discussion

PJK is most commonly defined on the basis of the criteria established by Glattes and colleagues.<sup>6</sup> Among 81 ASD patients, they noted a PJK rate of 26%, but none of these patients underwent revision surgery for PJK, and there was no apparent impact on PROMs. Subsequent studies have reported rates of PJK ranging from 17% to 61.7%,<sup>3,8</sup> but significant associations with clinical outcomes have been limited.<sup>7</sup> More recently, the term “PJF” was coined to help distinguish the subset of clinically significant PJK patients.<sup>18</sup> In the present study, although we report rates of PJK, we focused on PJF. Our definition of PJF is similar

to that of Hart et al.,<sup>18</sup> with the addition of PJA > 20°.<sup>16</sup> We provide assessment of PJF rates, risk factors, and revisions in a multicenter, prospectively collected, relatively homogeneous series of primary ASLS patients with a mean follow-up of more than 4 years. To our knowledge, this study provides the highest quality data to date on rates of PJF following primary ASLS surgery.

In our cohort of 160 patients, 46 (28.7%) had PJF. Based on Kaplan-Meier analyses, PJF rates at 1, 2, 3, and 4 years were 14.4%, 21.9%, 25.9%, and 27.4%, respectively. This suggests that the majority of PJF cases develop within 2 years of surgery. The rate of PJF in this study is higher than those in previous reports, in which the rates have ranged from 1.4% to 19%.<sup>1,9,13–16,18</sup> This likely reflects a number of factors, including differences in how PJF was defined across studies, differences in the length of follow-up, variations in surgical technique and correction goals, and marked heterogeneity in patient pathologies. To help ensure the homogeneity of our study population, only patients undergoing primary thoracolumbar fusion/fixation to the sacrum/pelvis of  $\geq 7$  levels were included. In addition, the spinal pathologies in our study population consisted of coronal deformities, with limited representation of sagittal malalignment.

Although the literature on PJK is extensive, there are few studies that have focused on PJF. Based on a retrospective review of 1668 patients with ASD who were followed for a mean of 4.0 years after surgery, Yagi and colleagues<sup>9</sup> reported a PJF rate of 1.4%. They defined PJF as symptomatic PJK requiring surgery, and their cohort was very heterogeneous, including primary and revision cases, with pathologies ranging from adult idiopathic scoliosis to fixed sagittal imbalance, and not all patients received instrumentation to the pelvis. Hart and colleagues<sup>18</sup> defined PJF on the basis of meeting the Glattes PJK criteria<sup>6</sup> and at least one of the following: fracture of the UIV/UIV+1, disruption of the posterior osseoligamentous complex, or UIV instrumentation pullout. They reported PJF in 57 (4.7%) of 1218 ASD patients whose cases included primary and revision procedures, a mixture of coronal and sagittal plane deformities, no minimum length of instrumentation construct, and variable inclusion of pelvic instrumentation. Hostin and colleagues<sup>13</sup> reported a 5.6% rate of acute PJF (within 28 weeks of surgery) among 1218 ASD patients with a broad range of deformities. They defined acute PJF as any one of the following within 28 weeks of surgery:  $\geq 15^\circ$  increase in PJA, fracture of the UIV/UIV+1, failure of UIV fixation, or the need for proximal extension of fusion. Using a definition of PJF as PJK requiring revision surgery, Scheer and colleagues<sup>15</sup> reported a 7.3% rate of PJF among 510 ASD patients with a broad range of coronal and sagittal pathologies. Park and colleagues<sup>14</sup> retrospectively reviewed 160 ASD patients treated with long instrumented fusion to the sacrum (with or without iliac fixation) and reported a PJF rate of 18.1%. They defined PJF as the presence of PJK (Glattes criteria<sup>6</sup>) and structural failure, such as UIV/UIV+1 fracture, screw pullout, or implant breakage. Yagi and colleagues<sup>16</sup> reported a PJF rate of 19% among 113 surgically treated ASD patients whose cases included primary and revision procedures and a variety of sagittal and coronal deformities. They defined PJF as an



**FIG. 1.** Survival plot for the occurrence of P.J.F. following surgical treatment of ASLS in 160 patients (*left*). Survival plot for revision surgery following the development of P.J.F. (*right*). *Dashed lines* represent the 95% confidence interval.

increase in the PJA  $\geq 20^\circ$  from baseline and concomitant deterioration of at least one SRS-Schwab<sup>29</sup> sagittal modifier grade, or any type of PJK requiring revision. Notably, the P.J.F. rate in the present study is closest to those reported by Yagi et al.<sup>16</sup> and Park et al.<sup>14</sup> Although the definition of P.J.F. in those studies only partially overlaps with the definition in the present study, both of those studies had high proportions of patients with instrumentation extending to the sacrum/pelvis, which likely adds considerable stiffness to the proximal junction and potentially increases the risk of P.J.F.

Risk factors for P.J.F. on univariate analysis in the present study included greater age, greater BMI, worse base-

line PROMs, the use of PCOs, greater postoperative TK and PJA, and greater change in PJA following surgery. In addition, hooks were used in a greater proportion of patients who did not have P.J.F. Multivariate analyses to identify risk factors for P.J.F. based only on parameters available preoperatively revealed a greater BMI, lower preoperative PJA, and greater preoperative TK as significant factors. Age has been identified as a risk factor for PJK/P.J.F. in several previous studies<sup>3,7,8,14,15</sup> and may reflect an overall greater frailty. BMI has also been reported as a risk factor for PJK/P.J.F.<sup>14,15,26,30</sup> and may relate to increased biomechanical stress at the proximal junction. For example, based on the hazard ratio for BMI (1.077) in the present study, the risk of P.J.F. increases by 210% for a patient with a BMI of 35 compared to that of a patient with a BMI of 25. (Hazard ratios are relative measures, so increases in the risk for multiple units are calculated as  $HR^N$  units; thus, a 10-point increase in BMI corresponds to  $1.077^{10}$ .) Since BMI is a potentially modifiable factor, this finding may offer an opportunity for preoperative optimization to mitigate P.J.F. risk. Previous reports have also noted the potential protective effects of hooks at the UIV for reducing PJK/P.J.F.<sup>19,31</sup> It is possible that hooks may facilitate UIV fixation with less soft tissue disruption than pedicle screws. However, the present study is limited in providing a definitive assessment of hooks since they were used in a relatively small subset of patients (39 of 160). The reasons that worse baseline PROMs and the use of PCOs were associated with P.J.F. occurrence are unclear. It is possible that patients with greater pain and disability at baseline may be less active and more deconditioned, which could contribute to sarcopenia and a greater P.J.F. risk.<sup>32</sup>

Radiographic alignment measures, including greater global sagittal malalignment, greater correction of global sagittal malalignment, and greater correction of

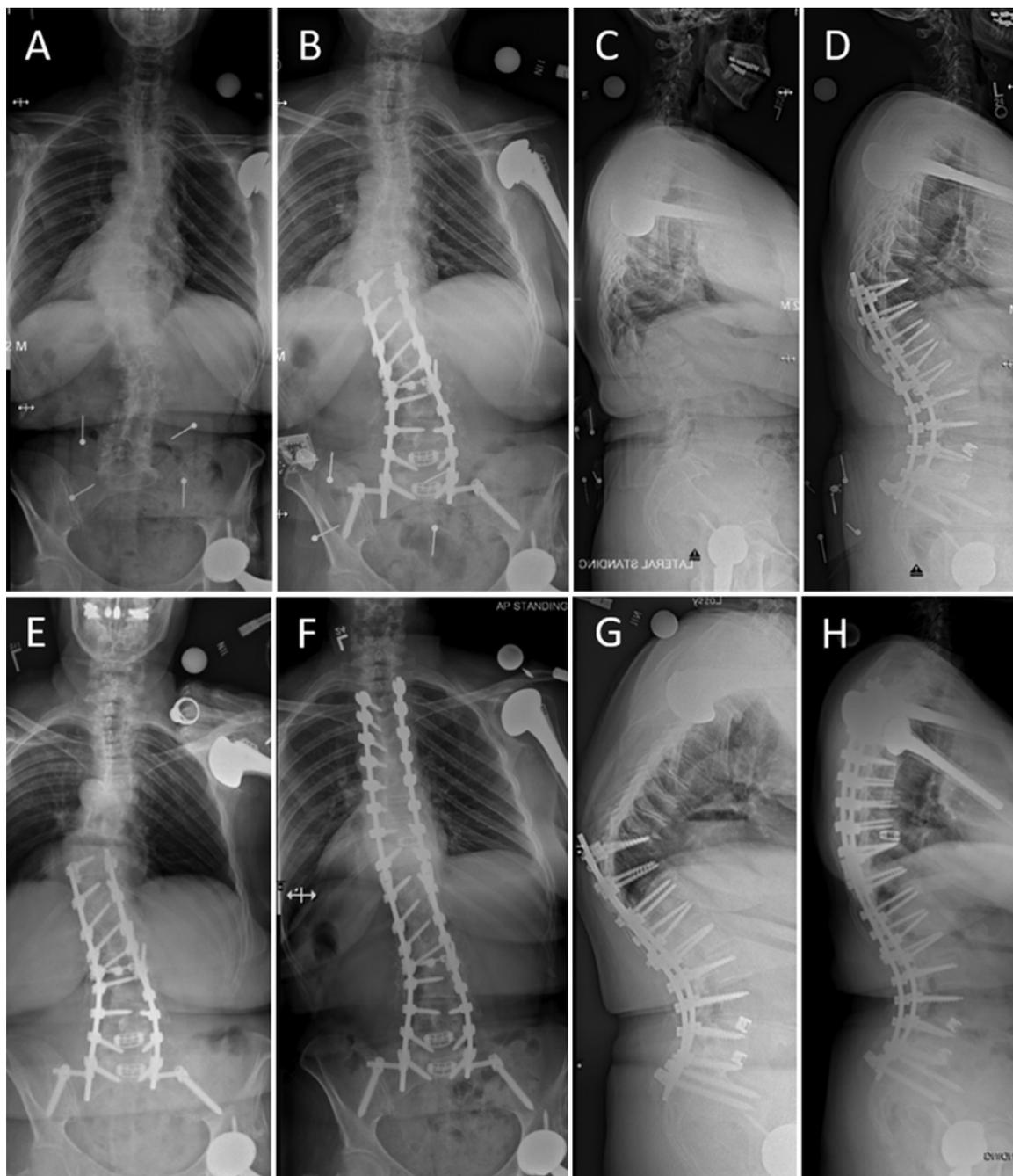
**TABLE 5. Baseline parameters associated with the risk for P.J.F. based on multivariate modeling**

Parameter	HR	95% CI	p Value
Age at index surgery	1.438	0.921–2.246	0.1097
BMI	1.077	1.007–1.153	<b>0.0317</b>
Osteopenia/osteoporosis	1.667	0.794–3.499	0.1768
UIV			
T9–12	Ref	Ref	Ref
T5–8	0.637	0.2–2.032	0.4459
T1–4	0.632	0.288–1.386	0.2525
Hooks at UIV	0.486	0.19–1.241	0.1315
Baseline PJA*	0.607	0.407–0.906	<b>0.0146</b>
Baseline TK (T4–12)†	1.362	1.082–1.715	<b>0.0085</b>
Baseline C7–S1 SVA†	1.043	0.971–1.121	0.2465

Boldface type indicates statistical significance.

\* Modeled by 5° increments.

† Modeled by 10° increments.



**FIG. 2.** Case example of a 62-year-old woman with ASLS who underwent surgical correction consisting of T10–S1 posterior instrumented arthrodesis with T12–S1 PCOs, L4–S1 transforaminal lumbar interbody fusions, and placement of iliac screws. Full-length free-standing posteroanterior and lateral radiographs at preoperative baseline (**A** and **C**, respectively) and at the 3-month postoperative follow-up (**B** and **D**, respectively). Following operative treatment, she had marked improvement of her preoperative symptoms; however, she developed a compression fracture at T10 with progressive PJK and positive sagittal malalignment. At approximately 18 months following the index surgery, she underwent revision surgery consisting of partial T9 and T10 vertebral column resections with titanium cage placement and extension of the posterior instrumentation to T3. Full-spine standing posteroanterior and lateral radiographs at approximately 18 months following the index surgery (**E** and **G**, respectively) and following the revision surgery (**F** and **H**, respectively). Note the T10 compression fracture and markedly increased PJA, which measures 42° (**G**).

LL, have been suggested as risk factors for PJK/PJF in multiple studies.<sup>8,14,15</sup> Similar associations were not observed in the present study, which may be attributable to differences in patient populations. In the present study, spinal deformities were primarily in the coronal plane,

and three-column osteotomies were rarely used. This contrasts with previous studies in which the cohorts were heterogeneous and included primary sagittal deformities and a greater use of three-column osteotomies.<sup>1,13,16,18</sup> It may seem counterintuitive that the greater use of PCOs,

**TABLE 6. Association between each factor used for the definition of PJF and the need for revision surgery**

Parameter	No Revision	Revision	p Value
No. of patients	30	16	
Change in PJA >20°	28 (93.3)	11 (68.8)	<b>0.040</b>
Fracture of UIV &/or UIV+1 >20%	6 (20.0)	15 (93.8)	<b>&lt;0.001</b>
Screw dislodgment	1 (3.3)	6 (37.5)	<b>0.005</b>
Spondylolisthesis of UIV+1 by >3 mm	1 (3.3)	1 (6.3)	>0.99

Values are expressed as number (%), unless indicated otherwise. Boldface type indicates statistical significance.

but not greater sagittal correction, would be associated with an increased occurrence of PJF since PCOs are often employed to provide sagittal correction. However, in the present study cohort, since the primary deformity was in the coronal plane, PCOs may have served a greater role in the segmental release of scoliosis than in increasing segmental lordosis.

In the present study, the association between PJF and the development of greater postoperative TK and PJA and a greater change in PJA following surgery may reflect a combination of early junctional kyphosis/failure and greater relaxation of preoperative thoracic compensation.<sup>33</sup> Although in the univariate analysis preoperative TK and PJA were not significantly predictive of PJF, both parameters met the threshold for inclusion in the multivariate models and each was significantly associated with PJF occurrence in these models. The increased risk of PJF in patients with greater preoperative TK has been noted in multiple studies<sup>8,15</sup> and may result from increased biomechanical stress at the junction and could reflect increased overall frailty and sarcopenia.<sup>32</sup> For example, based on the hazard ratio for preoperative TK (1.362, modeled per 10°) in the present study, the risk of PJF increases 2.5-fold (calculated as  $1.362^3 = 2.53$ ) for a patient with a preoperative TK of 60° compared to that of a patient with a TK of 30°. The association between greater preoperative TK and an increased risk of PJF may have implications for patient counseling and may impact surgical planning with regard to UIV selection.

In the present series, 16 (34.8%) of 46 patients with PJF had undergone revision as of the last follow-up. Thus, even when selecting for patients with more severe proximal junctional pathology (PJF vs Glattes PJK<sup>6</sup>), only approximately one-third of cases resulted in revision surgery. The decision of whether to pursue revision surgery for PJF is multifactorial and often driven by back and/or radicular pain not relieved by nonoperative treatment, the development of a neurological deficit or myelopathy, increased kyphosis significantly impacting function and/or appearance, and concerns about instability or the progression of junctional failure that may threaten neurological compromise. The mechanism of failure was significantly associated with the need for revision surgery (Table 6), with revision performed in 6 (85.6%) of the 7 patients with screw dislodgment, 15 (71.4%) of the 21 with UIV/UIV+1 fracture, 1 (50.0%) of the 2 with spondylolisthesis of UIV+1, and

11 (28.2%) of the 39 with PJA > 20°. Few previous studies have specifically reported revision rates for PJF, and some studies have defined PJF based on the need for revision surgery.<sup>9,15</sup> Hart and colleagues<sup>18</sup> reported that 27 (47.4%) of 57 patients with PJF in their cohort underwent revision surgery within 6 months of the index operation. They also identified several factors that seemed to influence the decision to perform revision surgery for PJF, including traumatic etiology of PJF, severity of PJA, higher SVA, and female sex. In the series from Park and colleagues,<sup>14</sup> of the 29 patients who had PJF, revision surgery was recommended for 13, only 2 of whom had revision surgery and 11 of whom underwent vertebroplasties at the UIV/UIV+1 as a means of palliative care because the patients had declined revision surgery. In the series from Hostin and colleagues,<sup>13</sup> 28 (41.2%) of 68 patients with acute PJF underwent revision surgery. In the present series, 3 (18.8%) of 16 patients who had undergone revision for PJF later developed recurrent PJF. This compares with the previously reported rates of recurrent PJK of 31% by Funao and colleagues<sup>34</sup> and 44% by Kim and colleagues.<sup>35</sup>

Strengths of the present study include the prospective multicenter design, relative homogeneity of the patient population, and length of the follow-up. It is also important to recognize the limitations. Although the homogeneity of the cohort is a strength, it is also a limitation since the patients had primarily coronal deformities, which limits the ability to assess the potential impact of sagittal realignment on the risk of PJF. The relatively small number of three-column osteotomies in this cohort limited meaningful analysis of this subgroup with regard to PJF risk. Since the time that patients were enrolled in the ASLS-1 study, there have been advances in our understanding of PJK/PJF prevention that were not employed in and cannot be assessed using the present cohort. For example, the use of proximal junctional tethers<sup>19,36-42</sup> and an improved understanding of age-adjusted alignment goals<sup>43-45</sup> have been suggested to reduce rates of PJK/PJF. Finally, since there were multiple surgeons from several institutions, there was a potential selection and performance bias that could have influenced the decision for revision surgery.

## Conclusions

We used data from the multicenter, prospective ASLS-1 to define rates of PJF based on longer-term follow-up in a relatively homogeneous cohort and to assess risk factors for PJF. In this cohort, the overall PJF rate was 28.8% at a mean 4.3-year follow-up. Based on Kaplan-Meier analyses, PJF rates at 1, 2, 3, and 4 years were 14.4%, 21.9%, 25.9%, and 27.4%, respectively. On univariate analysis, a higher risk of PJF was associated with a greater age and BMI, the use of PCOs, and worse baseline PROMs. The use of hooks at the UIV was protective against PJF. On multivariate analysis, an increased risk of PJF was associated with a greater BMI and preoperative TK and lower preoperative PJA. Sixteen patients (34.8%) underwent revision surgery for PJF, and PJF recurred in 3 of the patients (18.8%). Collectively, this study provides the highest quality data to date on rates of PJF following primary ASLS surgery.

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Conception and design: Smith, Kelly, Shaffrey, Bridwell. Acquisition of data: Smith, Kelly, Dial, Hills, Baldus, Lafage, Schwab, Shaffrey, Bridwell. Analysis and interpretation of data: Smith, Lazaro, Sardi, Kelly, Yanik, Gupta, Yen, Ames, Bess, Bridwell. Drafting the article: Smith, Lazaro, Sardi. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Smith. Statistical analysis: Yanik. Administrative/technical/material support: Baldus, Bess, Shaffrey, Bridwell. Study supervision: Bridwell.

### Supplemental Information

#### Previous Presentations

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### Disclosures

Dr. Smith is a consultant for Zimmer Biomet, Carlsmed, DePuy Synthes, NuVasive, Stryker, SeaSpine, and Cerepedics; receives royalties from Zimmer Biomet, NuVasive, and Thieme; owns