Revision Surgery Due to Proximal Junctional Failure and Rod Fracture in Adult Deformity Surgery at a Single Institution in Japan

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Abstract:

Introduction: Proximal junctional failure (PJF) and rod fracture (RF) are the primary reasons for revision surgery after a long corrective fusion for the adult spinal deformity (ASD). However, many recent studies on ASD are multicenter studies from the US and European racial characteristics may differ from those of Asians. Therefore, the risk factors for revision surgery because of PJF and RF after ASD surgery were evaluated in Japanese patients.

Methods: Patients with ASD who underwent corrective surgery from the thoracic vertebrae to the ilium at the authors' institution were reviewed. Demographic, surgical, and radiographic parameters were included in the analysis. Univariate and multivariate regression models were used to analyze the risk factors for PJF and RF.

Results: Two hundred and fifty-nine patients were included in the study. A total of 73 patients (28.1%) required revision surgery because of mechanical complications and 15 patients (5.7%) required revision surgery because of PJF on average 380 days after surgery. In PJF cases, body mass index (BMI) and pelvic tilt were significantly higher (p=0.01, p=0.048, respectively). BMI was an independent risk factor for revision owing to PJF (odds ratio [OR], 1.16; p=0.013). A total of 49 patients (18.9%) required revision owing to RF on average 867 days after surgery. Three-column osteotomy (p<0.001), significant blood loss (p=0.048), number of fusion segments (p=0.023), absence of lateral lumbar interbody fusion (p<0.001), and sagittal imbalance (p=0.033) were risk factors for revision surgery owing to RF in the univariate analysis. Three-column osteotomy (OR 4.41; p<0.001) and number of fusion segments (OR 1.21; p<0.009) were independent factors for revision surgery owing to RF.

Conclusions: PJF occurred in a relatively early phase (approximately 1 year) after surgery in patients with ASD with high BMI. Conversely, RF occurred approximately 2.5 years after surgery in three-column osteotomy and spinal fusion cases that involvedlonger fusion range.

Keywords:

adult spinal deformity, rod fracture, proximal junctional failure, revision surgery, mechanical complication

Spine Surg Relat Res 2022; 6(5): 497-502
dx.doi.org/10.22603/ssrr.2021-0199

Introduction

Patients with adult spinal deformity (ASD) experience back pain and disability, and their quality of life is significantly worse than that of age-matched patients. However, when adequately indicated, surgery has been shown to improve the quality of life compared with conservative treatment[1]. As such, the number of adults undergoing surgery has increased[2]. Additionally, surgery for ASD frequently involves long fusion constructs to achieve optimal sagittal and coronal alignment.

Long spinal fusion with iliac screws or sacral ala iliac screws is a recent trend in spinal surgery for ASD[3-5]. The advantage of long spinal fusion is the maintenance of appropriate spinal alignment, which resulted in decreased spinal motion. However, loss of spinal motion leads to increased

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Received: October 5, 2021, Accepted: December 1, 2021, Advance Publication: February 10, 2022

mechanical failure due to concentrated load stress to adjacent levels or implants. Mechanical complications are the topic of interest in spinal deformity surgery. The European Spine Study Group proposed a global alignment and proportion (GAP) score as a risk factor simulator for mechanical complications in patients with ASD[6].

Proximal junctional failure (PJF) and rod fracture (RF) are the primary reasons for revision surgery due to mechanical complications[7,8]. Although PJF and RF are mechanical complications, their risk factor are thought to be different. Some of the risk factors for PJF and RF have been reported in recent multicenter studies; however, it can be inferred that patient background, such as race, is diverse and that surgical techniques are often not standardized because of multicenter studies. It would be useful to investigate risk factors for PJF and RF in a group of cases with standardized patient background and surgical technique.

This study evaluated the difference in risk factors for PJF and RF after long spinal fusion for ASD at a single institution in Japan.

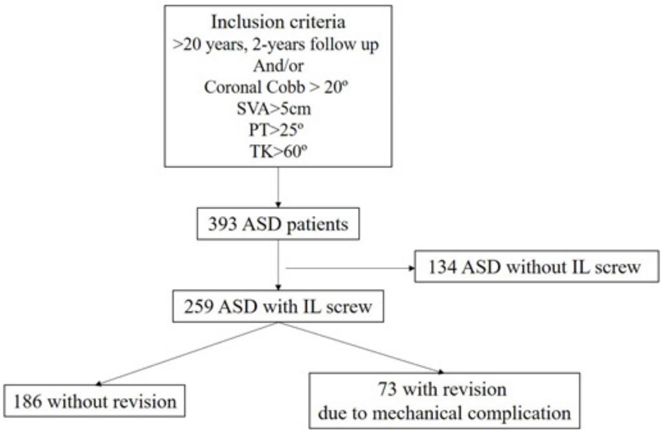

Figure 1. Flowchart of patient inclusion criteria. A total of 259 patients were included in this study and 73 patients underwent revision surgery owing to mechanical complications.

Materials and Methods

ASD databases (>20 years and coronal Cobb >20°, sagittal vertical axis [SVA] >5 cm, pelvic tilt [PT] >25°, or thoracic kyphosis >60°) of the authors' institution were queried for Japanese patients with ASD who underwent spinal fusion from the thoracic vertebrae to the ilium with more than 2 years of follow-up since 2010. Demographic, surgical, and radiological variables were prospectively recorded and analyzed.

Demographic variables included age, sex, and body mass index (BMI). Moreover, total blood loss during surgery, total operative time, number of fusion segments, three-column osteotomy (3-CO), lateral lumbar body fusion (LLIF), and number of rods were evaluated as surgical variables. SVA, PT, pelvic incidence minus lumbar lordosis, the distance between the central sacral vertical line and C7, and scoliosis Cobb angle were measured as radiographic parameters before surgery and at first standing after surgery. The GAP alignment score was entered categorically (proportionate, moderately disproportionate, severely disproportionate) and as a compound score.

Revision surgery was recommended for patients with severe pain or neurological symptoms due to PJF or RF or with a progressive loss of correction. In this series, only cases with revision surgery were included in the PJF and RF groups, respectively. First, revision surgeries and reoperations were identified. To examine potential risk factors for revision surgery for PJF and RF, demographic data, surgical data, radiological parameters, and GAP categories were compared between patients who had undergone revision surgery and those who did not. Risk factors for revision of PJF and RF were identified using univariate analysis for each variable. The identified potential risk factors were then further examined using multiple logistic regression analyses to isolate independent risk factors for revision surgery.

All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). Descriptive and bivariate comparisons of demographic variables were performed between the two groups using the independent *t*-test for continuous variables and Fisher's exact test for categorical variables. The level of statistical significance was set at $p<0.05$.

Results

Of the 393 patients with ASD included in the database with a 2-year follow-up, 259 underwent fusion from the thoracic vertebrae to the ilium. The average age was 68.4 years, and 83.8% were female. A total of 73 patients (28.1%) required revision surgery owing to mechanical complications (Fig. 1). In patients who underwent revision surgery, the average age was 67.7 years and 83.3% were female. The most common cause of revision was RF in 49 cases, followed by PJF in 15 cases.

Proximal junctional failure

A total of 15 patients (5.7%) required revision surgeries because of PJF at 380 days (41-1123 days) after surgery. The variables for patients with and without PJF are summarized in Table 1. Regarding demographic variables, BMI in PJF cases was significantly higher (25.5 vs. 23.0, p=0.01). There was no significant difference in the surgical variables between the two groups. The upper instrumented vertebra in PJF cases was one case each in T2, T4, and T8, two cases in T9, eight cases in T10, and one case in T12. There was no significant difference in the number of fusion segments between the two groups. Regarding radiographic parameters, PT in PJF cases was significantly higher (25.4% vs. 20.4%, p=0.048). In the GAP category, there were no significant differences between the two groups. BMI was an independ-

Table 1. Comparison of PJF and Non-PJF.

		Non-PJF		PJF		
N		244	(%, SD)	15	(%, SD)	p-value
Demographic Variables						
Age		68.45	9.58	67.47	11.26	0.704
Gender	F	206	84.4	11	73.3	0.276
	M	38	15.6	4	26.7	
BMI		22.97	3.7	25.53	3.97	0.01
Surgical Variables						
Total blood loss (ml)		1635.43	1060.2	1605.87	1107.16	0.917
Total surgical time (min)		440.98	83.14	423.67	103.98	0.441
No. of fusion segments		9.48	2.28	9.07	2.58	0.504
Three-column osteotomy		88	36.1	7	46.7	0.419
LLIF		86	35.2	4	26.7	0.587
No. of rods	2	135	55.8	11	73.3	0.278
	3	32	13.2	0	0.0	
	4	75	31	4	26.7	
Preoperative Radiographic Parameters						
PI-LL (°)		34.52	17.10	28.60	22.16	0.202
SVA (mm)		128.59	82.59	125.34	87.11	0.886
PT (°)		35.86	10.88	34.47	14.93	0.639
C7CSVL (mm)		31.35	32.41	33.05	35.12	0.849
Cobb (°)		29.27	21.61	27.67	24.73	0.576
Postoperative Radiographic Parameters						
PI-LL (°)		7.57	12.91	11	17.47	0.331
SVA (mm)		49.11	41.43	44.95	47.27	0.709
PT (°)		20.37	9.43	25.4	10.26	0.047
C7CSVL (mm)		17.73	17.37	20.93	20.5	0.508
Cobb (°)		9.42	8.99	6.79	6.19	0.282
Global Alignment and Proportional (GAP) Parameters						
GAP score		5.1	3.27	6.07	4.92	0.302
Proportioned		52	24.4	4	28.6	0.214
Moderately disproportional		93	43.7	3	21.4	
Severely disproportional		68	31.9	7	50	

PJF: proximal junctional failure; SD: standard deviation; BMI: body mass index; PI-LL: pelvic incidence minus lumbar lordosis; SVA: surgical vertical axis; PT: pelvic tilt; C7CSVL: distance between C7 plumb line and central sacral vertical line

Table 2. Risk Factors for Revision Due to PJF (Multivariate Analysis).

	Odds ratio	95% CI	p-value
BMI	1.16	1.030–1.300	0.013
PT (°)	1.04	0.988–1.100	0.127

BMI: body mass index; PT: pelvic tilt; CI: confidence interval

ent risk factor for revision due to PJF (odds ratio [OR], 1.16; p=0.013) in the logistic regression analysis (Table 2).

Rod fracture

A total of 33 patients with RF received nonsurgical care because of mild symptoms and 49 patients (18.9%) required revision surgery owing to RF at an average of 867 days (181-1738 days) after surgery. In this series, RF cases with revision surgery were defined as the RF group. The variables for the patients with RF and without RF are summarized in Table 3. There was no significant difference in the demographic variables between the two groups. Significantly higher total blood loss (1905 mL vs. 1568 mL, p=0.048), longer fusion segments (10.1% vs. 9.3%, p=0.023), higher rate of three-column osteotomy, and lower rate of LLIF (63.3% vs. 30.5%, p<0.001) were observed in RF cases. With regard to radiographic parameters, preoperative SVA was significantly higher in the RF group. There were no significant differences between the two groups in the GAP category. Both 3-CO (OR, 4.16; p<0.001) and number of fusion segments (OR, 1.20; p<0.012) were independent factors for revision surgery because of RF (Table 4).

RF occurred at the site of 3-CO in 18 cases, posterolateral

Table 3. Comparison of RF and Non-RF.

		Non-RF		RF		
N		210	(%, SD)	49	(%, SD)	p-value
Demographic Variables						
Age		68.41	9.81	68.29	9.09	0.933
Gender	F	177	84.3	40	81.6	0.668
	M	33	15.7	9	18.4	
BMI		23.08	3.74	23.28	3.87	0.73
Surgical Variables						
Total blood loss (ml)		1568.71	1041.12	1905.6	112.24	0.048
Total surgical time (min)		441.64	85.08	432.84	81.54	0.512
Number of fusion segments		9.3	2.24	10.12	2.42	0.023
Three column osteotomy		64	30.5	31	63.3	<0.001
Lateral lumbar interbody fusion		84	40.0	6	12.2	<0.001
Number of rods	2	135	55.0	31	64.6	0.104
	3	24	11.5	8	16.7	
	4	70	33.5	9	18.8	
Preoperative Radiographic Parameters						
PI-LL (°)		34.30	17.62	33.67	16.83	0.822
SVA (ml)		122.94	17.62	150.98	81.86	0.033
PT (°)		35.18	11.08	38.33	11.08	0.075
C7CSVL (ml)		32.37	32.35	27.85	33.23	0.397
Cobb (°)		30.34	21.36	23.85	22.74	0.063
Postoperative Radiographic Parameters						
PI-LL (°)		7.11	13.45	10.47	11.96	0.111
SVA (ml)		48.9	41.35	48.7	43.58	0.977
PT (°)		20.4	9.78	21.78	8.45	0.368
C7CSVL (ml)		38.79	15.24	44.53	15	0.019
Cobb (°)		9.52	8.49	8.23	10.29	0.367
Global Alignment and Proportional (GAP) Parameters						
GAP score		5.07	3.34	5.54	3.59	0.395
Proportioned		44	24.3	12	26.1	0.144
Moderately disproportional		82	45.3	14	30.4	
Severely disproportional		55	30.4	20	43.5	

SD: standard deviation; BMI: body mass index; PI-LL: pelvic incidence minus lumbar lordosis; SVA: surgical vertical axis; PT: pelvic tilt; C7CSVL: distance between C7 plumb line and central sacral vertical line

Table 4. Risk Factors for Revision Due to RF (Multivariate Analysis).

	Odds ratio	95% CI	p-value
Total blood loss	1.00	1.000–1.000	0.789
No. of fusion segments	1.21	1.050–1.390	0.009
Three-column osteotomy	4.41	2.230–8.720	<0.001
LLIF	0.39	0.123–1.100	0.094
Preoperative SVA	1.00	0.006–0.174	0.858

RF: rod fracture; LLIF: lateral lumbar interbody fusion; SVA: sagittal vertical axis; CI: confidence interval

fusion in 13 cases, posterior interbody fusion in 13 cases, LLIF in 1 case, and sacroiliac joint in 4 cases. RF levels (except in cases of 3-CO) were L1-2 in 1 case, L3-4 in 4 cases, L4-5 in 6 cases, L5-S1 in 16 cases, and sacroiliac joint in 4 cases. RF at the site of 3-CO was observed in 2 cases for the three-rod construct and in 16 cases for the two-rod construct. Although additional rods were used in 11 of the 27 cases (posterolateral fusion, posterior interbody fusion, and LLIF), RF occurred outside the range of the additional rod in 10 cases.

Discussion

The revision rate for mechanical failure after ASD surgery was relatively high (28.1%). PJF and RF were the leading causes for mechanical revision surgery and each had different characteristics. PJF occurred in a relatively early phase (approximately one year) after surgery. High BMI was an independent risk factor for PJF. Alternatively, revision surgery for RF was performed approximately 2.5 years after surgery. Extended spinal fusion and 3-CO were independent risk factors for RF.

Many recent studies on adult spinal deformities have been conducted in the US and Europe. Multicenter studies have the advantage of accumulating a large number of cases and eliminating bias in the target population. However, they also have disadvantages, such as a lack of uniformity in surgical methods. The advantage of this series is that the surgical techniques were standardized because of their single-center nature. Furthermore, racial differences in spinal alignment have been reported[9], and studies that focus on specific racial groups would be more revealing.

Previous studies have described various risk factors for PJF after corrective fusion for ASD[10-15]. Damage to the posterior soft tissues and use of pedicle screw constructs were reported as risk factors for PJF related to surgical technique[10,12,14-16]. In this report, surgical variables were not identified as risk factors. Surgical averaging due to the single-center study design might have caused surgical variables were not risk factors for PJF. In agreement with this study, BMI has been reported in previous studies to be a risk factor for PJF[17,18]. Moreover, several studies reported that low bone density was also a risk factor for PJF[19] however, the lack of data is a significant limitation of this study Based on these results, PJF might be caused by a high load applied to a fragile adjacent fixed end. In cases where surgical techniques are standardized, patient factors, such as BMI and bone density, may be responsible for PJF. Even in recent revisions of the GAP score, BMI and bone density were independent risk factors for mechanical failure[20]. The importance of BMI and bone density in the prevention of PJF should be noted.

Previous studies have reported many risk factors for RF after ASD surgery. The use of 3-CO was reported as a risk factor for RF, similar to the results of this study[21,22]. Additionally, several studies reported that a small diameter (<6 mm) was also a risk factor for RF[23,24]. Rod diameter was not analyzed because rods of only 6.00 or 6.35 mm in diameter were used. Based on the results, RF might be caused by a high load applied to an unstable area of the fixation segment in 3-CO cases.

In this study, the number of fusion segments was an independent risk factor for RF. This could be attributed to decrease trunk mobility from the more extended fusion, which increased the load on the rods. Unlike PJF, RF was caused by the influence of surgical planning such as 3-CO and more extended fusion and not by patient factors. Therefore, surgeries should be planned to reduce the range of fusion segments and areas of instability as much as possible to prevent RF. In this study, the additional rod could not reduce the incidence of RF, which may be because several RFs occurred outside the range of the additional rod. Therefore, additional rods should be included in the range from the thoracic vertebrae to the iliac level[25,26]. Moreover, LLIF is a dependent risk factor for RF prevention. LLIF using large-sized spacers was considered biomechanically stable and advantageous for the prevention of RF.

The GAP score is a method used to predict mechanical complications[6]. However, a few recent studies have reported no correlation between the GAP score and mechanical complications[27,28]. The results of this study also indicated that the GAP score did not correlate with RF and PJF. Furthermore, ideal alignment is thought to differ depending on age, sex, and race. Thus, the cut-off value of the GAP score should be modified depending on the characteristics of the patient group.

Only surgical revision cases were evaluated in this study, but there were several cases of PJF or RF without revision surgery. The indication for revision surgery with PJF or RF was considered on a case-by-case basis without clear criteria. Thus, the risk factors for PJF and RF in this study might be inaccurate as risk factors for developing complications included non-revision surgery, which is a limitation of the study.

Conclusion

PJF and RF were the leading causes of mechanical complication, and each had different characteristics. PJF occurred in a relatively early phase (approximately 1 year) after surgery in patients with ASD with high BMI. Conversely, revision surgery for RF occurred approximately 2.5 years after surgery in 3-CO and spinal fusion cases that involved more levels.

Conflicts of Interest: Yu Yamato and Shin Oe belong to the donated fund laboratory called Division of Geriatric Musculoskeletal Health. The laboratory funded by below organizations.

Sources of Funding:
Medtronic Sofamor Danek Inc.
Japan Medical Dynamic Marketing Inc.
Meitoku Medical Institution Jyuzen Memorial Hospital
We have not received funding from the NIH, HHMI, or others.

Author Contributions: Tatsuya Yasuda wrote and prepared the manuscript, and all authors participated in the study design. All authors have read, reviewed, and approved the article.

Ethical Approval: The study protocol was approved by the Institutional Review Board of the Hamamatsu University School of Medicine, Shizuoka, Japan (No.14-306).

Informed Consent: Informed consent for publication was obtained from all participants in this study.

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