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Proximal Junctional Failure after Corrective Surgery: Focusing on Elderly Patients with Severe Sagittal Imbalance

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Background: Previous reports with proximal junctional failure (PJF) included relatively young patients or deformity without sagittal imbalance. The present study focused on the two well-known risk factors for PJF, old age and severe sagittal imbalance. With these high-risk patients, the present study aimed to identify a strategy that could prevent PJF and to investigate whether the degree of correction would really affect the PJF occurrence.

Methods: Patients who were ≥ 60 years of age and underwent long fusion (≥ 4) to the sacrum for severe sagittal imbalance (defined as pelvic incidence minus lumbar lordosis [PI–LL] ≥ 30°) were included. PJF was defined as a vertebral fracture at the uppermost instrumented vertebra (UIV) or UIV+1, failure of UIV fixation, myelopathy, or any need for proximal extension of fusion. Presumed risk factors were compared between the patients with and without PJF.

Results: Total 146 patients (mean age, 68.4 years) with preoperative mean PI–LL of 46.8° were included. PJF developed in 39 patients (26.7%) at a mean of 18.1 months after surgery. Multivariate analysis showed that osteoporosis (odds ratio [OR], 2.812; $p = 0.019$) and UIV located below T10 (OR, 3.773; $p = 0.010$) were significant risk factors for developing PJF. However, the degree of correction did not affect PJF occurrence.

Conclusions: The present study indicates that osteoporosis should be well corrected preoperatively and extending the fusion above T10 should be considered for severe imbalance in old patients. However, the amount of correction was not associated with PJF development.

Keywords: *Proximal junctional failure, Elderly, Severe sagittal imbalance*

Proximal junctional failure (PJF) following long instrumented spinal fusion for adult spinal deformity (ASD) is a well-recognized complication that may potentially worsen the clinical and radiographic outcomes and sometimes necessitates revision surgery.[1-3] As a disorder on the spectrum of proximal junctional kyphosis (PJK), PJF is a distinct clinical entity that is accompanied by the structural failure of the vertebral body or posterior ligamentous complex. The revision rate after PJF development has been reported to be as high as 47.4%.[4-9]

Previous studies have determined the risk factors associated with PJF.[2,3,7,10-15] However, numerous suggested factors showed conflicting results in those studies and remain controversial. The reason for inconsistent results among the studies might be due to heterogeneity in the definition of PJF and the patients' baseline demographics, such as age criteria and main diagnosis for surgery.

The present study focused on elderly patients with

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severe sagittal imbalance. The age itself is a well-known risk factor for the development of PJF.[3,7,13] Due to the aging society and longer life expectancy, there have been a growing number of elderly patients who undergo the long fusion surgery for ASD.[16] However, most previous studies had a study population with a relatively younger age group and a mean age ranging from 40 to 50 years.[1,11,13]

Severe sagittal imbalance is also worth consideration. A large amount of correction is required to correct severe sagittal imbalance, which is a well-known risk factor for PJF.[2,7,12,14,17,18] There are more patients with degenerative sagittal imbalance than with degenerative scoliosis in the Asian population.[19-21] However, one of the main indications for surgery in previous studies was adult scoliosis either with or without sagittal imbalance.[4-6,8,14,22]

Elderly patients with severe sagittal imbalance are inevitably more prone to have a high risk of PJF. Therefore, it is thought to be meaningful to focus on these patients to evaluate the risk factor for PJF. The objective of the present study was to identify a strategy that can prevent PJF when surgery is performed on these patients. It is necessary to see if there is a way to overcome the risk factors. In addition, focusing on these limited patients, the present study aimed to investigate whether the degree of correction would really affect the PJF development.

METHODS

Study Design

All experimental protocols in the present study were approved by the Institutional Review Board of Samsung Medical Center (No. 2021-04-007). All methods were used in accordance with relevant guidelines and regulations. The requirement for informed consent was waived by the institutional review board as the study used existing clinical data. This study was a retrospective case series, with records retrieved from a prospective ASD database at our institution. Eligible individuals for this study included ASD patients ≥ 60 years of age who had undergone a greater than four-level fusion including the sacrum. Among the 266 patients who underwent surgery between 2005 and 2018, we selected those with a preoperative pelvic incidence (PI)–lumbar lordosis (LL) ≥ 30°, which was our definition of severe sagittal imbalance. We excluded patients with ankylosing spondylitis or neuromuscular scoliosis and patients who had undergone revision surgery for reasons other than PJF, i.e., postoperative infection and rod fracture. Patients whose follow-up duration was less than two years were also excluded. A total of 146 patients met the inclusion and exclusion criteria and constituted the study cohort.

The primary goal of the surgery was to restore the optimal LL relative to the PI. An ideal LL was determined using Lee's formula and the Scoliosis Research Society-Schwab classification.[23,24] The surgical methods were chosen based on the severity and flexibility of sagittal deformity to get the desired LL. All patients underwent pedicle screw-based instrumentation and fusion. The material of the pedicle screws and rods was titanium alloy in all cases. Since 2011, iliac fixation has been routinely performed in all cases with a greater than four-level fusion including the sacrum to prevent nonunion at the L5–S1 levels. Other preventive techniques against PJF, such as prophylactic cement augmentation or ligament augmentation, were not used. However, transverse process hooks above the uppermost instrumented vertebra (UIV) have been implemented in the case of UIV located at thoracic levels since 2016. The patients were followed up at 1, 3, and 6 months postoperatively and then every 6 months thereafter.

Definition of PJF

PJF was defined as structural failures, such as vertebral fracture at the UIV or UIV+1, failure of UIV fixation, myelopathy, or any need for proximal extension of fusion as described in previous studies.[4] In making a definition of PJF, a few authors have included PJK, which refers to ligamentous failure and is represented by a proximal junctional angle (PJA) of 10°, 15°, or 20°.[4,13,15,25] However, in our study, PJK with ligamentous failure was excluded from the definition of PJF because it is well-known that benign PJK does not negatively affect clinical outcomes[2,12,13] and rarely necessitates revision surgery.[2,6,7] In our study, three patients underwent revision surgery for progressive PJK, and they were placed in the PJF group. We focused only on PJF accompanied by structural failure because the main interests among surgeons are acute catastrophic PJF rather than later-developing benign PJK.

Risk Factor Analysis

The presumed risk factors were analyzed between the PJF and non-PJF groups using the three categories of patient, surgical, and radiographic factors. Patient factors included age, sex, body mass index (kg/m^2), osteoporosis, smoking, diabetes mellitus, and the American Society of Anesthesiologists physical status classification grade. Surgical factors included the number of total fused segments, history of prior fusion surgery, the UIV level below T10, the surgical approach (posterior-alone vs. combined anteroposterior approach), pedicle subtraction osteotomy, and iliac fixation. Radiographic factors were the values of PI, LL (L1–

S1), sacral slope, PT, thoracic kyphosis (TK, T5–T12), sagittal vertical axis (SVA), and PJA as assessed preoperatively and at 4 to 6 weeks postoperatively. The PJA was measured from the caudal endplate of the UIV to the cranial endplate of the two supra-adjacent vertebrae. Positive values of PJA and TK indicated kyphotic curvature, while positive values of LL suggested lordotic curvature.

Statistical Analysis

Data are presented as frequencies with percentages for categorical variables and as means with standard deviations for continuous variables. A univariate analysis was performed using Fisher's exact tests to compare the categorical variables and Student *t*-tests to assess differences in the means of the continuous variables between the two groups. Multivariate analyses were performed using binary logistic regression. Non-radiographic variables with *p*-values less than 0.05 in the univariate analyses were included. Among radiographic parameters, preoperative PI, postoperative LL, and change in LL were included. The correction amount was evaluated using postoperative LL and change in LL. PI was included as LL needs to be adjusted with PI. Different from LL, any other radiographic parameters, including SVA or PT, were excluded from multivariate analysis as the parameters were the results of PJF, not the causes. Statistical analyses were carried out by professional statisticians using the SPSS ver. 25.0.0 (IBM Corp., Armonk, NY, USA). A *p*-value < 0.05 was considered statistically significant.

RESULTS

A total of 146 patients made up the final study cohort (Table 1). The length of follow-up duration was 51.0 ± 35.7 months. The mean age at the time of surgery was 68.4 ± 6.6 years and there were 134 women (91.8%) in the study population. In terms of the preoperative radiographic parameters, PI was 56.0° ± 11.9°, LL was 9.3° ± 18.5°, PI–LL was 46.8° ± 14.3°, and SVA was 90.3 ± 54.6 mm. Further demographic and baseline data are listed in Table 1.

PJF developed in 39 patients (26.7%) at a mean of 18.1 ± 29.5 months postoperatively. There were 31 patients with vertebral fractures at UIV or UIV+1, 5 patients with failure of UIV fixation, and 3 patients with PJK progression. There were no patients with myelopathy. In patients with PJF, the PJA significantly increased from 21.3° ± 10.6° at the initial diagnosis of PJF to 32.2° ± 16.1° at the final follow-up ($p < 0.001$), but did not significantly differ according to failure modes ($p = 0.532$) (Fig. 1). The final PJA in the non-PJF group was 8.8° ± 9.2°. Ten patients underwent revision surgery for vertebral fractures (n = 6), fixation failure (n = 1), and PJK progression (n = 3).

Risk Factor Analysis

In the univariate analysis, there were more patients with osteoporosis in the PJF group than in the non-PJF group (41.0% vs. 17.8%, $p = 0.008$) (Table 2). There were signifi-

Table 1. Demographic and Baseline Data

Characteristics	Value
Age (yr)	68.4 ± 6.6 (60.0 to 83.0)
Female	134 (91.8)
BMI (kg/m^2)	25.4 ± 3.7 (14.9 to 38.6)
Osteoporosis	35 (24.0)
DM	23 (15.8)
ASA grade	2.0 ± 0.5
Number of total fused segments	6.3 ± 2.2 (4 to 15)
Prior fusion surgery	49 (33.8)
UIV below T10	95 (65.1)
Follow-up duration (mo)	51.0 ± 35.7
Surgical technique	
TLIF : OLIF	36 (24.7) : 67 (45.9)
PSO : ACR	25 (17.1) : 18 (12.3)
TP hook*	22 (34.9)
Iliac fixation	87 (59.6)
Radiographic variable	
Preoperative PI (°)	56.0 ± 11.9 (22.0 to 82.6)
Preoperative LL (°)	9.3 ± 18.5 (–61.0 to 47.0)
Preoperative PI–LL (°)	46.8 ± 14.3 (30 to 93.8)
Preoperative PT (°)	36.0 ± 9.6 (14.0 to 64.8)
Preoperative TK (°)	8.3 ± 12.5 (–28.0 to 37.5)
Preoperative SVA (mm)	90.3 ± 54.6 (–73.1 to 236.7)
Preoperative PJA (°)	–1.0 ± 7.0 (–16.5 to 15.2)

Values are presented as mean ± SD (range), number of patients (%), or mean ± SD.
BMI: body mass index, DM: diabetes mellitus, ASA: American Society of Anesthesiologists, UIV: uppermost instrumented vertebra, TLIF: transforaminal lumbar interbody fusion, OLIF: oblique lumbar interbody fusion, PSO: pedicle subtraction osteotomy, ACR: anterior column realignment, TP: transverse process, PI: pelvic incidence, LL: lumbar lordosis, PT: pelvic tilt, TK: thoracic kyphosis, SVA: sagittal vertical axis, PJA: proximal junctional angle, SD: standard deviation.
*TP hook was implemented for patients with UIV at or above T11.

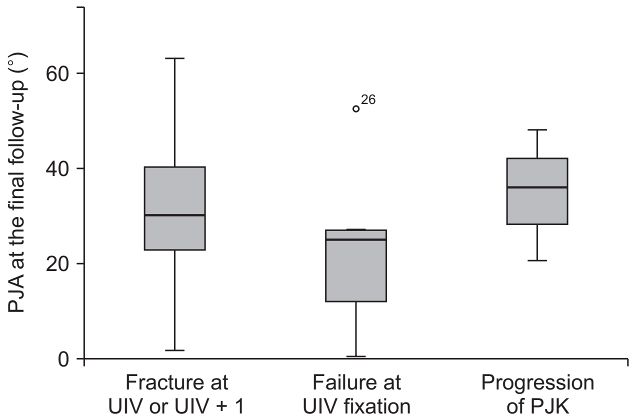

Fig. 1. The proximal junctional angle (PJA) at the final follow-up according to the failure mode. UIV: uppermost instrumented vertebra, PJK: proximal junctional kyphosis.

Table 2. Univariate Analysis of Demographic Risk Factors for PJF

Risk factor	Non-PJF (n = 107)	PJF (n = 39)	*p*-value
Age (yr)	67.9 ± 6.1	69.9 ± 7.6	0.112
Female	97 (90.7)	37 (94.9)	0.516
BMI (kg/m²)	25.1 ± 3.6	26.2 ± 4.0	0.101
Osteoporosis	19 (17.8)	16 (41.0)	0.008*
DM	16 (15.0)	7 (17.9)	0.619
ASA grade	2.0 ± 0.6	2.0 ± 0.5	0.838
Prior fusion surgery	38 (35.5)	11 (28.9)	0.551
UIV below T10	63 (58.9)	32 (82.1)	0.011*
Surgical technique			0.800
TLIF	28 (26.2)	8 (20.5)	
PSO	17 (15.9)	8 (20.5)	
OLIF	48 (44.9)	19 (48.7)	
ACR	14 (13.1)	4 (10.3)	
TP hook†	20 (37.0)	2 (22.2)	0.476
Iliac fixation	60 (56.1)	27 (69.2)	0.184

Values are presented as mean ± standard deviation or number of patients (%).
PJF: proximal junctional failure, BMI: body mass index, DM: diabetes mellitus, ASA: American Society of Anesthesiologists, UIV: uppermost instrumented vertebra, TLIF: transforaminal lumbar interbody fusion, PSO: pedicle subtraction osteotomy, OLIF: oblique lumbar interbody fusion, ACR: anterior column realignment, TP: transverse process.
*Indicates statistical significance. †Analysis about TP hook was conducted for patients with UIV at or above T11.

Table 3. Univariate Analysis of Radiographic Risk Factors for PJF

Variable	Non-PJF (n = 107)	PJF (n = 39)	*p*-value
Preoperative PI (°)	54.7 ± 12.2	59.6 ± 10.6	0.029*
Preoperative LL (°)	8.6 ± 18.4	11.5 ± 18.8	0.402
Preoperative PI–LL (°)	46.2 ± 15.2	48.5 ± 15.2	0.390
Preoperative SS (°)	19.2 ± 12.4	22.3 ± 12.1	0.180
Preoperative PT (°)	35.5 ± 9.2	37.3 ± 10.6	0.311
Preoperative TK (°)	8.2 ± 12.7	8.3 ± 11.9	0.987
Preoperative SVA (mm)	89.4 ± 54.4	92.7 ± 55.8	0.755
Preoperative PJA (°)	–0.4 ± 6.9	–2.5 ± 7.3	0.140
Postoperative LL (°)	40.2 ± 12.0	44.3 ± 13.2	0.078
Postoperative PI–LL (°)	13.9 ± 13.1	15.0 ± 13.7	0.682
Postoperative SS (°)	31.3 ± 9.9	33.1 ± 9.5	0.330
Postoperative PT (°)	22.8 ± 9.9	26.0 ± 11.3	0.091
Postoperative TK (°)	22.1 ± 10.4	22.2 ± 10.8	0.955
Postoperative SVA (mm)	28.4 ± 32.6	22.9 ± 25.6	0.348
Optimal correction†	40 (37.4)	13 (33.3)	0.701
Change in LL (°)	31.6 ± 17.6	32.8 ± 20.8	0.732
Change in SS (°)	12.7 ± 10.3	11.3 ± 11.3	0.460
Change in PT (°)	–12.7 ± 10.3	–11.3 ± 11.3	0.460
Change in TK (°)	13.8 ± 10.0	13.9 ± 10.6	0.969
Change in SVA	– 61.1 ± 51.3	–69.7 ± 61.3	0.394

Values are presented as mean ± standard deviation or number of patients (%).
PJF: proximal junctional failure, PI: pelvic incidence, LL: lumbar lordosis, SS: sacral slope, PT: pelvic tilt, TK: thoracic kyphosis, SVA: sagittal vertical axis, PJA: proximal junctional angle.
*Indicates statistical significance. †Optimal correction was defined as the postoperative SVA less than 50 mm, PT less than 25°, and PI–LL less than ± 10°.

cantly more patients with a UIV located below T10 in the PJF group than in the non-PJF group (82.1% vs. 58.9%, $p = 0.011$). The number of total fused segments was 6.6 for PJF group and 5.5 for non-PJF group. Regarding the radiographic parameters (Table 3), only the preoperative PI was significantly different between the two groups (54.7° for non-PJF group vs. 59.6° for PJF group; $p = 0.029$). The multivariate analysis revealed that only osteoporosis (odds ratio [OR], 2.812; 95% confidence interval [CI], 1.187–6.662; $p = 0.019$) and the UIV located below T10 (OR, 3.773; 95% CI, 1.371–10.380; $p = 0.010$) were significant risk factors (Table 4). All the included radiographic parameters, preoperative PI, postoperative LL, and change in LL were not significantly related to PJF development.

Although age was not a significant risk factor in this

Table 4. Multivariate Analysis of Risk Factors for PJF

Variable	Odds ratio	95% CI	*p*-value
Osteoporosis	2.812	1.187–6.662	0.019*
UIV below T10	3.773	1.371–10.380	0.010*
Preoperative PI	1.046	0.996–1.099	0.069
Postoperative LL	0.988	0.945–1.034	0.609
Change in LL	1.019	0.991–1.048	0.176

PJF: proximal junctional failure, CI: confidence interval, UIV: uppermost instrumented vertebra, PI: pelvic incidence, LL: lumbar lordosis.
*Indicates statistical significance.

Table 5. Probability of PJF Development According to the Number of Risk Factors

Age	Risk factor	PJF development	*p*-value
< 70 yr (n = 76)	Osteoporosis + UIV below T10	4 / 8 (50.0)	0.024*
	UIV below T10 or osteoporosis	11 / 41 (26.8)	
	None	2 / 27 (7.4)	
≥ 70 yr (n = 70)	Osteoporosis + UIV below T10	10 / 16 (62.5)	0.010*
	UIV below T10 or osteoporosis	10 / 40 (24.4)	
	None	2 / 13 (15.4)	

PJF: proximal junctional failure, UIV: uppermost instrumented vertebra.
*Indicates statistical significance.

study, we grouped patients into < 70 years old and ≥ 70 years old to calculate the probability of PJF development according to the number of risk factors (Table 5). Among patients with both risk factors, PJF developed in 50% (age < 70 years) and in 62.5% (age ≥ 70 years). A representative case with both risk factors of osteoporosis and UIV of T11 or below is illustrated in Fig. 2. If a patient did not have both risk factors, the risk of PJF development was 7.4% in patients < 70 years and 15.4% in patients ≥ 70 years. A representative case without those risk factors is illustrated in Fig. 3.

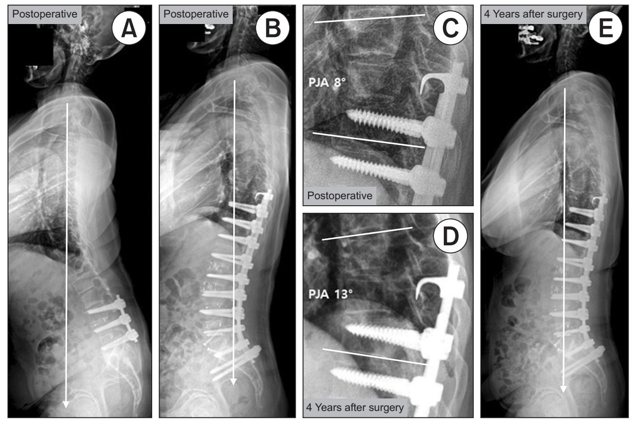

Fig. 2. (A) A 72-year-old woman with severe deformity without osteoporosis (T-score: –1.5) underwent reconstructive surgery (T10–S1). (B, C) Postoperative changes of lumbar lordosis and sagittal vertical axis were 65° and –95 mm, respectively. (D, E) The construct was well maintained without proximal junctional failure development 4 years after surgery. PJA: proximal junctional angle.

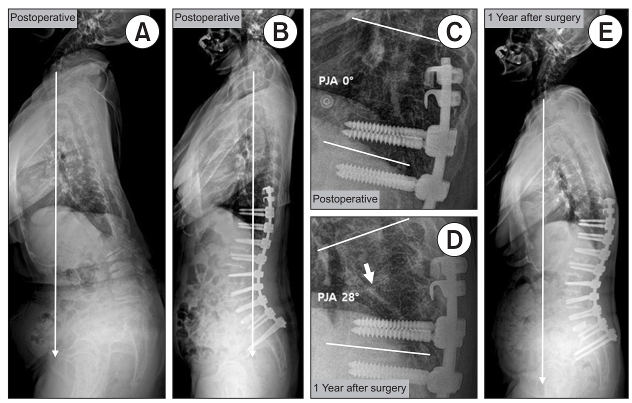

Fig. 3. (A) A 65-year-old woman with severe deformity and osteoporosis (T-score: –2.6) underwent reconstructive surgery (T11–S1). (B, C) Postoperative changes of lumbar lordosis and sagittal vertical axis were 71° and –150 mm, respectively. (D, E) However, 1 year later, a vertebral fracture developed at T10 (white arrow). PJA: proximal junctional angle.

DISCUSSION

Given that PJF can negatively affect clinical outcomes, identifying its risk factors is important as the first step in determining strategies against PJF development. During the past few decades, several risk factors for PJF have been suggested in the literature. Although there is a general consensus on these risk factors, they were not uniformly reported in the studies. For example, older age at the time of surgery is a well-documented risk factor for the development of PJF.[7,10,26,27] However, Maruo et al. did not observe any differences in age groups between the patients with and without failure.[14] In Smith's study, it was also found that age just trended higher without statistical significance in patients who developed PJF.[5] These inconsistent results among studies might result from the diversity of study populations and also different PJF definitions. Therefore, to derive clinically relevant risk factors, we need to focus on a specific patient group using a clearly delineated definition of PJF. Due to the aging society, a growing number of elderly patients are expected to have long fusion surgery to treat ASD. The reason why we focused on elderly patients was that they would be more vulnerable to mechanical failures and could experience greater disability or pain with a similar-degree deformity compared to younger adults.[28,29] Mechanical failures that develop at the proximal junction would be more problematic particularly in patients with severe sagittal imbalance because a large amount of correction in the sagittal plane has been recognized as a risk factor for PJF.[2,4,14,15,27] Therefore, we investigated the risk factors for PJF with a focus on elderly patients whose main problem was severe sagittal imbalance. In this study, a more clinically relevant definition of PJF had to be established. According to previous studies, PJF was defined variously such as only bony failure,[10,26,27] PJA > 10° plus bony failure,[8,14] or PJA > 15° plus bony failure.[4,5,30] The authors thought that the ligamentous type of PJF, which was defined as a PJA > 10° or > 15°, is the continuum of the PJK spectrum. Unlike PJF, PJK is usually considered to be a benign form that occurs relatively later and rarely worsens the clinical outcomes.[2,3,11,13] PJF with bony failure, myelopathy, or revision surgery would be the main interest among surgeons; therefore, we excluded the PJA criteria from the PJF definition.

In this study, we found only two significant risk factors for PJF: osteoporosis and the UIV below T10. It may seem that our results have nothing new to offer because osteoporosis and the UIV located in the lower thoracic area are already well-known risk factors for PJF.[4,5,15,27] However, when evaluating patients before surgery, we cannot take all risk factors into consideration. Therefore, it is necessary to determine what risk factors should be taken into account for each patient. In this sense, these two risk factors could be considered most important particularly when planning a corrective surgery for elderly patients with severe sagittal imbalance. Unlike previous studies that have reported older age increases the risk of PJF,[7,10,26,27] this study showed that age was not significantly different between the two groups even upon univariate analysis. The potential risk related to age was already embedded in our study cohort because we set the age criteria as more than 60 years. Our results also suggest that in elderly patients ≥ 60 years, the coexistence of osteoporosis is more important in the development of PJF than the chronological age itself. If a patient had both risk factors, the probability of developing PJF was 50%–62.5% (Table 5). Meanwhile, in cases with no risk factors, the probability of developing PJF decreased to 7.4%–15.4%. The positive relationship between the PJF probability and the number of risk factors was also confirmed even in the two age groups of < 70 years and ≥ 70 years.

Although the radiographic parameters were not significant in our study, they should be addressed because radiographic risk factors have been extensively reported in the literature. In this study, the values and changes of all radiographic parameters did not differ between patients with and without PJF, except for the preoperative PI, which was greater in the PJF group upon the univariate analysis, but was not significant in the multivariate analysis. Our findings might conflict with those of the previous studies that have reported that more severe preoperative sagittal imbalance status,[6,8,26,27] a higher postoperative LL,[5,7] and a greater amount of correction in LL (≥ 30°) or SVA (≥ 50 mm) increase the risk for PJF.[2,7,12,14,26] Given that the optimal correction should be always pursued based on each PI value for better clinical outcomes,[24] there would be a contradiction among the previous concepts regarding the large correction and the optimal correction. For patients with a severe sagittal imbalance, larger corrections, i.e., ≥ 30° LL, are frequently necessary to achieve optimal sagittal balance; however, according to previous concepts, these large corrections can be a risk factor for PJF. Therefore, according to our results, the optimal correction should always be pursued even when a great correction is required for the sagittal imbalance because a greater correction will not cause PJF development. Similar to our results, more recent studies have also demonstrated that PJF development was not affected by the severity of the preoperative sagittal imbalance, postoperative balance status, or amount of correction.[15,27,30] These debatable radiographic issues must be further investigated in future studies.

Several limitations of this study should be acknowledged. First, our definition of PJF cannot cover all types of PJF. Although the ligamentous type of PJF might negatively affect the clinical outcome during long-term follow-up, we focused more on relatively acute-onset bony failures. Second, this study lacked a long-term follow-up period. However, considering that most bony failures develop early in the postoperative period, a minimum 2-year follow-up would be enough for this study. Despite its retrospective nature and limitations, this study is unique in that it is the first study to provide specific risk factors for PJF in elderly patients with severe sagittal imbalance who are vulnerable to the development of PJF.

In conclusion, osteoporosis should be well corrected preoperatively and extending the fusion above T10 should be considered in old patients with severe imbalance. However, the amount of correction was not related to PJF development.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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