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DEFORMITY

What Factors Predict the Risk of Proximal Junctional Failure in the Long Term, Demographic, Surgical, or Radiographic?

Results From a Time-dependent ROC Curve

Jingyan Yang, MHS,[*,†] Marc Khalifé, MD,[‡] Renaud Lafage, MS,[*] Han Jo Kim, MD,[*] Justin Smith, MD,[§] Christopher I. Shaffrey, MD,[§] Douglas C. Burton, MD,[¶] Christopher P. Ames, MD,[||] Gregory M. Mundis Jr., MD,[**] Richard Hostin, MD,[††] Shay Bess, MD,[‡‡] Eric O. Klineberg, MD,[§§] Robert A. A Hart, MD,[¶¶] Frank J. Schwab, MD,[*] and Virginie Lafage, PhD[*], International Spine Study Group (ISSG)

Study Design. Retrospective review of prospective multicenter database.

Objective. To identify an optimal set of factors predicting the risk of proximal junctional failure (PJF) while taking the time dependency of PJF and those factors into account.

Summary of Background Data. Surgical correction of adult spinal deformity (ASD) can be complex and therefore, may come with high revision rates due to PJF.

Methods. Seven hundred sixty-three operative ASD patients with a minimum of 1-year follow-up were included. PJF was defined as any type of proximal junctional kyphosis (PJK) requiring revision surgery. Time-dependent ROC curves were estimated with corresponding Cox proportional hazard models. The predictive abilities of demographic, surgical, radiographic parameters, and their possible combinations were assessed sequentially. The area under the curve (AUC) was used to evaluate models' performance.

Results. PJF occurred in 42 patients (6%), with a median time to revision of approximately 1 year. Larger preoperative pelvic tilt (PT) (hazard ratio [HR]=1.044, $P=0.034$) significantly increased the risk of PJF. With respect to changes in the radiographic parameters at 6-week postsurgery, larger differences in pelvic incidence-lumbar lordosis (PI-LL) mismatch (HR = 0.924, $P=0.002$) decreased risk of PJF. The combination of demographic, surgical, and radiographic parameters has the best predictive ability for the occurrence of PJF (AUC = 0.863), followed by demographic along with radiographic parameters (AUC = 0.859). Both models' predictive ability was preserved over time.

Conclusions. Over correction increased the risk of PJF. Radiographic along with demographic parameters have shown the approximately equivalent predictive ability for PJF over time as with the addition of surgical parameters. Radiographic rather than surgical factors may be of particular importance in predicting the development of PJF over time. These results set the groundwork for risk stratification and corresponding prophylactic interventions for patients undergoing ASD surgery.

Key words: adult spinal deformity, prediction, proximal junctional failure, proximal junctional kyphosis, revision surgery, sagittal balance, spinopelvic parameters.

Level of Evidence: 4

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From the [*]Department of Orthopedic Surgery, Hospital for Special Surgery, New York, NY; [†]Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY; [‡]Saint Joseph Hospital, Paris, France; [§]Department of Neurosurgery, University of Virginia Medical Center, Charlottesville, VA; [¶]Department of Orthopedic Surgery, The University of Kansas Hospital Marc A. Asher, MD Comprehensive Spine Center, Kansas City, KS; [||]Department of Neurological Surgery, University of California San Francisco, San Francisco, CA; [**]The San Diego Center for Spinal Disorders, San Diego, CA; [††]Baylor Scott & White Scoliosis Center, Plano, TX; [‡‡]Denver International Spine Center, Denver, CO; [§§]Department of Orthopedic Surgery, School of Medicine, University of California, Davis, CA; and [¶¶]Swedish Medical Center, Seattle, WA.

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Address correspondence and reprint requests to Virginie Lafage, PhD, Department of Orthopedic Surgery, Hospital for Special Surgery, 525 E 71st Street, 4TH FL, New York, NY 10021; E-mail: lafagev@hss.edu

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Despite advances in the surgical treatment of adult spinal deformity (ASD), these procedures have been reported to have a considerable rate of complications requiring revision surgery.[1–3] Proximal junctional failure (PJF), defined as any type of symptomatic proximal junctional kyphosis (PJK) requiring surgery, is a well-recognized postoperative phenomenon in adults following deformity surgery.[4–6] PJF involves not only kyphosis but also structural failure of the vertebral body and/or posterior ligament complex.[4,7,8] PJF is therefore commonly symptomatic, leading to a significant burden for the patients' quality of life, characterized by intolerable pain,[9] neurological deficit,[9,10] progressive trunk deformity,[11] and inability to maintain horizontal gaze.[12] Results from a systematic review have shown that the incidence of PJK requiring revision surgery ranged from 13% to 55% in patients who underwent spinal instrumentation for deformity, depending on the study population and the length of follow-up.[13]

Risk factors for developing PJF have been reported inconsistently across studies. Major risk factors included severity of the preoperative deformity,[6,14,15] the amount of surgical correction,[9,16,17] fusion to the lower lumber vertebra and sacrum,[9,18–22] age at operation,[23,24] and use of combined anterior-posterior approach.[7,8,22,23] However, Glattes *et al*[25] found that none of the patients' demographic, radiographic, or instrumentation variables were predictive for developing PJK. The onset of PJK generally starts early in the patients' postoperative course. PJK was identified as early as 8 weeks postoperatively,[23] though the majority of the patients have developed PJK within 3 to 18 months after surgery.[20,26] Smith *et al*[27] conducted a retrospective review and reported that 49 of 197 patients (25%) who had preoperative sagittal imbalance developed PJF within 6 months of surgery and 16 patients (33%) required revision surgery within the first year. Similarly, Hostin *et al*[4] reviewed a total of 1218 consecutive surgically-treated ASD patients and 68 patients experienced junctional failures, among whom 28 had revision surgery within 6 months postoperatively. It was worth noting that for those who underwent revision surgery, they had earlier manifestation of junctional changes identified compared with those who did not have revision surgery. Hence, understanding the natural course of PJK may help better manage the postoperative complications.

However, previous studies that identified risk factors for PJF did not take the time dependence of those failures into account,[16,19,25,27–29] which may shed light on the management of junctional failures following ASD surgery. The purpose of the present study is to, first, identify a set of factors, including demographic, radiographic, and surgical factors, that optimally predict the development of PJF after spinal deformity surgery while taking the time dependence of those failures into consideration; second, in the long term following ASD surgery, to evaluate the predictive abilities of different sets of variables, namely, demographic, radiographic, and surgical.

METHODS

Study Population

The present study is a multicenter, retrospective analysis of prospectively collected data of ASD patients from 11 sites across the United States. Inclusion criteria of the cohort were age $\geq$ 18 years and a radiographic diagnosis of ASD defined by at least one of the following: coronal Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT)$\geq 25^\circ$, and/or thoracic kyphosis (TK) $\geq 60^\circ$. Based on the initial management approach, patients were divided into operative and nonoperative groups at the time of enrollment. The present study included only operatively treated ASD patients with a minimum of 1-year follow-up after surgery. Patients who had pre-existing neuromuscular, syndromic, autoimmune, infectious, posttraumatic conditions, or tumor were excluded. Also, those who required revision surgeries due to complications other than junctional failures were excluded (N = 81). The study protocol was approved by the institutional review board at each site. Informed consent was obtained from all patients.

Data Collection

Demographic characteristics including age, sex, body mass index (BMI), Charlson comorbidity index, smoking, frailty index,[30] and fusion history of prior spine surgery were collected at the time of enrollment. Standing postero-anterior and lateral spine radiographs (36″ cassette) were analyzed at baseline and 6-week postoperative follow-up using a dedicated and validated software[31,32] (Spineview, Surgiview, Paris). Radiographic parameters consisted of pelvic incidence (PI), lumbar lordosis (LL), sagittal vertical axis (SVA), pelvic tilt (PT), and T1 pelvic angle (TPA). Surgical parameters included extended fusion in present surgery, the use of bone morphogenic protein (BMP), the lowest instrumented vertebrae (LIV) to sacrum/pelvis, the upper-most instrumented vertebrae (UIV) at T10 or below, PI-LL mismatch, the use of iliac crest bone graft and if 3-column osteotomy (3CO) was performed.

Definition of PJF

PJK is considered present when the proximal junctional sagittal Cobb angle, that is, the angle between the lower endplate of the UIV and the upper endplate of the two supra-adjacent vertebrae, $\geq 10^\circ$ and at least 10° greater compared with the preoperative measurement, according to Glattes *et al*, which is the most commonly used definition of PJK in the literature.[25] In the present study, PJF was defined as any type of symptomatic PJK requiring revision surgery.

Statistical Analysis

Demographic, surgical, and radiographic parameters were compared between those who experienced PJF *versus* not, using Student *t* test for normally distributed variables (means), Kruskal–Wallis test for skewed-distributed variables (medians), and Chi-squared test for categorical variables (proportions). Cox proportional hazard model was performed to estimate hazard ratios (HRs) with corresponding 95% confidence interval (CI) to identify risk factors associated with the development of PJF. Proportionality assumption was assessed using the interaction between time and case status. To evaluate the predictive capability of demographic, surgical, and radiographic parameters while taking the time dependence of PJF into consideration, time-dependent receiver operating characteristic (ROC) curves were estimated sequentially for Cox models including different combinations of demographic, surgical, and radiographic parameters. Area under the curve (AUC) was used to measure the discriminative ability across models. Time-dependent ROC curve was estimated using R. The rest of the analyses were performed using Stata SE 14.0 (StataCorp, College Station, TX).

RESULTS

Patient Population

In total, we identified 867 surgically-treated ASD patients with a minimum of 1-year follow-up who were eligible. In the present study, 736 patients who had complete information on demographic, surgical, and radiographic parameters were contributed to the analysis. During the follow-up, 42 (6%) patients developed PJK requiring revision surgery. The earliest case was identified 8 days after surgery with a mean of approximately 1 year (1.1 ± 0.9 yr) to receive reoperation due to PJF. Patients who had PJF were older at operation (No PJF, aged$\geq$ 65 yr: 38%; PJF: 62%, $P = 0.003$), more frail (No PJF, frailty index: 3.32 ± 1.61; PJF: 3.94 ± 1.27, $P = 0.016$), had fusion extended to the sacrum or pelvis (No PJF: 77.4%; PJF: 95.2%, $P = 0.006$), larger preoperative SVA (No PJF: 64.6 ± 73.3 mm; PJF: 92.1 ± 74.1 mm, $P = 0.018$), larger preoperative T1PA (No PJF: $22.6 \pm 13.2^{\circ}$; PJF: $27.3 \pm 12.3^{\circ}$, $P = 0.023$), larger changes of PI-LL mismatch (No PJF: $-12.8 \pm 20.5^{\circ}$; PJF: $-23.4 \pm 17.3^{\circ}$, $P = 0.001$) and SVA (No PJF: -38.5 ± 70.4 mm; PJF: -65.6 ± 73.4 mm, $P = 0.016$) at 6-week postsurgery, compared with those who did not have PJF (Table 1).

Survival Analysis

Three Cox proportional hazard models were built sequentially with the inclusion of demographic, surgical, and radiographic parameters. In the first model with demographic variables only, age above 65 years (hazard ratio [HR] = 2.342, $P = 0.010$) was found significantly associated with the incidence of PJF (data not shown). In the second model with addition of surgical parameters, the above relationships still held. Furthermore, female sex (HR = 2.781, $P = 0.037$) significantly increased the risk of PJF (data not shown). In the last model with radiographic variables taken into account, larger preoperative PT (HR = 1.044, $P = 0.034$) significantly increased the risk of PJF. With respect to changes in the radiographic parameters at 6-week postsurgery, larger differences in PI-LL mismatch (HR = 0.924, $P = 0.002$) decreased risk of PJF. No surgical and demographic characters were statistically significant (Table 2).

Time-dependent ROC Curves

Time-dependent ROC curves were estimated with corresponding Cox proportional hazard models described above, along with all the possible combinations of different sets of variables (Figure 1). The model with demographic, surgical, as well as radiographic parameters has the best predictive capability (the area under the curve [AUC] = 0.863), followed by the model with both demographics and radiographic parameters (AUC = 0.859) and the model with radiographic and surgical parameters (AUC = 0.817). The model that included only surgical parameters has the worst performance.

When the models were compared over time following surgery, the predictive capability of each model preserved well. In the early phase after surgery, the model with only surgical parameters had the worst performance, followed by the model with radiographic parameters only, while the rest of the models had similar performance. Over time, the performance of the model with demographic, surgical, and radiographic parameters was still the best, although the model with demographic and radiographic parameters alone has shown an equivalent performance. The predictive ability remained constant for all the models after 3-year postoperatively (Figure 2).

DISCUSSION

Our results have demonstrated that radiographic along with demographic parameters have shown the approximately equivalent predictive ability for PJF as with the addition of surgical parameters, and the model's predictive ability reserved well over time after surgery. Hence, radiographic parameters appear to play the most important role in predicting PJF after surgery. To our knowledge, this is the first study examining risk factors for PJF while taking the time-dependency of junctional failures and risk factors into consideration. The incorporation of time component is of particular importance in optimizing postoperative patient care, given the burden associated with early revision surgery for junctional failures.

Our results supported that severe preoperative sagittal malalignment increased the risk of PJF, which have been observed in previous studies.[9,16,20,26,33] For example, Maruo *et al*[16] conducted a retrospective study that consisted of 90 ASD patients who underwent long instrumented fusion to the sacrum and 13.3% had revision surgery due to PJK. They found that preoperative thoracic kyphosis more than 30°, proximal junctional angle more than 10°, and PI more than 55° were risk factors for PJK.[16] However, the effect of PI was not observed in current study. It is possible that when the TK correction is planned according to preoperative PI values, the PI effect may no longer be observed. Measure of preoperative sagittal parameters quantifies the severity of deformity, which may explain the elevated risk of junctional failures among those patients.

Moreover, our data revealed that the global sagittal realignment due to surgery was significantly associated with the risk of PJF. In other words, over surgical correction of sagittal alignment can lead to PJF, which was consistent with what have been reported.[16,22,24,34,35] Maruo *et al*[16] conclude that achievement of ideal global sagittal realignment ($SVA < 50$ mm, $PT < 20^{\circ}$, and PI-LL mismatch between -10° and 10°) reduced the risk of PJF. Kim

TABLE 1. Patients' Characteristics, Stratifying by Whether Developed PJF or Not

Characteristics	No PJF (N = 694)	PJF (N = 42)	*P* Value
Time to revision, yrs	–	1.14 ± 0.89	
Age, yrs, N (%)			
<65	428 (61.7)	16 (38.1)	
≥65	266 (38.3)	26 (61.9)	0.003
BMI, N (%)			
Underweight/normal	246 (35.4)	13 (31.0)	
Overweight	244 (35.2)	21 (50.0)	
Obese	204 (29.4)	8 (19.0)	0.150
Charlson comorbidity index, N (%)			
0	230 (33.1)	8 (19.0)	
≥1	464 (66.9)	34 (81.0)	0.062
Sex, N (%)			
Male	174 (25.1)	5 (11.9)	
Female	520 (74.9)	37 (88.1)	0.063
Prior surgery, cervical fusion	57 (8.2)	6 (14.3)	0.161
Prior surgery, thoracic fusion	190 (27.4)	10 (23.8)	0.722
Prior surgery, lumbar fusion	106 (15.3)	8 (19.1)	0.510
Fragility index, mean (SD)	3.32 ± 1.61	3.94 ± 1.27	0.016
3-column osteotomy, N (%)	146 (21.0)	9 (21.4)	0.952
IBF, N (%)	426 (61.4)	26 (61.9)	0.946
BMP use, N (%)	477 (68.7)	28 (66.7)	0.779
LIV (pelvis/sacrum), N (%)	537 (77.4)	40 (95.2)	0.006
UIV at T10 or below, N (%)	333 (48.0)	27 (64.3)	0.055
Extended fusion in present surgery	141 (20.3)	9 (21.4)	0.844
Preoperative PI, mean (SD)	54.9 ± 15.2	52.8 ± 10.7	0.379
Preoperative PT, mean (SD)	23.7 ± 11.0	27.2 ± 9.5	0.040
Preoperative PI-LL, mean (SD)	14.9 ± 22.7	21.8 ± 21.8	0.058
Preoperative T1PA, mean (SD)	22.6 ± 13.2	27.3 ± 12.3	0.023
Preoperative SVA, mean (SD)	64.6 ± 73.3	92.1 ± 74.1	0.018
Changes in PT at 6 wk, mean (SD)	−4.0 ± 8.3	−4.5 ± 7.4	0.751
Changes in PI-LL at 6 wk, mean (SD)	−12.8 ± 20.5	−23.4 ± 17.3	0.001
Changes in T1PA at 6 wk, mean (SD)	−6.8 ± 11.1	−9.6 ± 9.5	0.113
Changes in SVA at 6 wk, mean (SD)	−38.5 ± 70.4	−65.6 ± 73.4	0.016

BMI indicates body mass index; PJF, proximal junctional failure.

et al[24] have conducted a case control study that included 3 groups of ASD patients, namely, those without PJK, with PJK but not requiring revision and with PJK requiring revision surgery. The results have shown that larger postoperative LL and sagittal balance correction were related to the development of PJK requiring revision surgery.[24] However, it is worth mentioning that the ideal SVA curvature corrections should be tailored to individual patient characteristics such as age. This is also true for the reduction of LL, which should be planned according to patients' preoperative PI values. Given the complexity of these procedures, individualized ideal sagittal realignment should be pursued in order to minimize the risk of postoperative PJF.

None of the surgical-related parameters were found to be associated with an increased risk of PJF after accounting for radiographic variables, though the literature has mixed results. In a total of 98 patients with degenerative lumbar scoliosis (DLS), no specific surgical parameters were related to the incidence of PJK, except that the UIV at thoracolumbar junction were more common in patients with PJK.[36] A few studies reported that a long fusion to the lower lumber vertebra and sacrum greatly increased the risk of PJF.[9,19,20,26] Specifically, O'Shaughnessy concluded that compared with patients with short fusion, long fusions to the sacrum may result in more revision surgery.[37] Furthermore, Kim *et al*[19] have pointed out that a combined anterior-

TABLE 2. Cox Proportional Hazard Model Including Demographic, Surgical, and Radiographic Parameters

	Hazard Ratio	95% CI	*P* Value
Age, yrs			
<65	Ref		
≥65	1.753	0.887, 3.461	0.106
Sex			
Male	Ref		
Female	2.204	0.821, 5.921	0.117
BMI			
Underweight/normal	Ref		
Overweight	1.401	0.676, 2.904	0.364
Obese	0.534	0.202, 1.413	0.206
Charlson index			
0	Ref		
≥1	1.548	0.622, 3.852	0.348
Prior surgery, cervical fusion	1.421	0.566, 3.566	0.454
Prior surgery, thoracic fusion	0.549	0.087, 3.463	0.523
Prior surgery, lumbar fusion	1.147	0.133, 9.850	0.901
Fragility index	1.082	0.843, 1.389	0.535
3-column osteotomy	0.570	0.215, 1.508	0.258
IBF	0.754	0.388, 1.467	0.406
BMP use	0.570	0.278, 1.168	0.124
LIV (pelvis/sacrum)	2.342	0.503, 10.910	0.278
UIV at T10 or below	1.106	0.540, 2.265	0.784
Extended fusion in present surgery	1.242	0.095, 16.216	0.869
Preoperative PI	1.001	0.976, 1.027	0.950
Preoperative PT	1.044	1.003, 1.086	0.034
Preoperative PI-LL	0.981	0.956, 1.008	0.161
Preoperative SVA	1.002	0.994, 1.010	0.640
Diff6wk PT	1.029	0.803, 1.318	0.821
Diff6wk PI-LL	0.924	0.878, 0.972	0.002
Diff6wk T1PA	1.115	0.816, 1.524	0.495
Diff6wk SVA	0.995	0.967, 1.024	0.749

posterior approach surgery is the strongest risk factor for PJK. It is possible that when surgical approaches allow excessive correction of the sagittal plane, they may lead to increased stress concentrations at the proximal end of the fusion and therefore PJF occurs.[23]

Importantly, we found that radiographic parameters have superior predictive ability over surgical parameters in the long term for the development of PJF. Although most of the PJF were observed to occur within 2 years after ASD surgery,[23,27] long-term follow-up of those patients is needed to better understand the nature course of the disease. Therefore, the identification of radiographic factors that has the best predictive capacity while taking the time-dependent long-term proximal junctional change into consideration is of particular clinical importance. A retrospective study that included patients with minimum 2-year follow-up (range 2–10 yr) treated with revision surgery due to PJK has shown that patients with PI-LL mismatch $< 11^\circ$ were more likely to have late-onset PJK requiring surgery than those with PI-LL mismatch $\geq 11^\circ$.[38] In another long-term review of adult scoliosis patients treated with long spinal fusion, the authors found that inappropriate global spine alignment and greater SVA change postoperatively were associated with increased risk for PJK.[26] An individualized perioperative planning and surgical execution may help achieve an optimal postoperative alignment, which therefore reduces the risk of PJF.

Some identified demographic factors that were associated with PJF, such as older age,[8,22–24] greater BMI,[8,22] and presence of comorbidities,[22] were not seen in our data. Our study has some limitations. First, we only captured PJF that occurred in the early phase following spine surgery. However, the focus of present study is to demonstrate the predictive capacity of different risk factors for PJK in the long term using statistical modeling. Second, some of the less-recognized risk factors, including bone mineral density (BMD),[26] were not considered. Future studies are needed

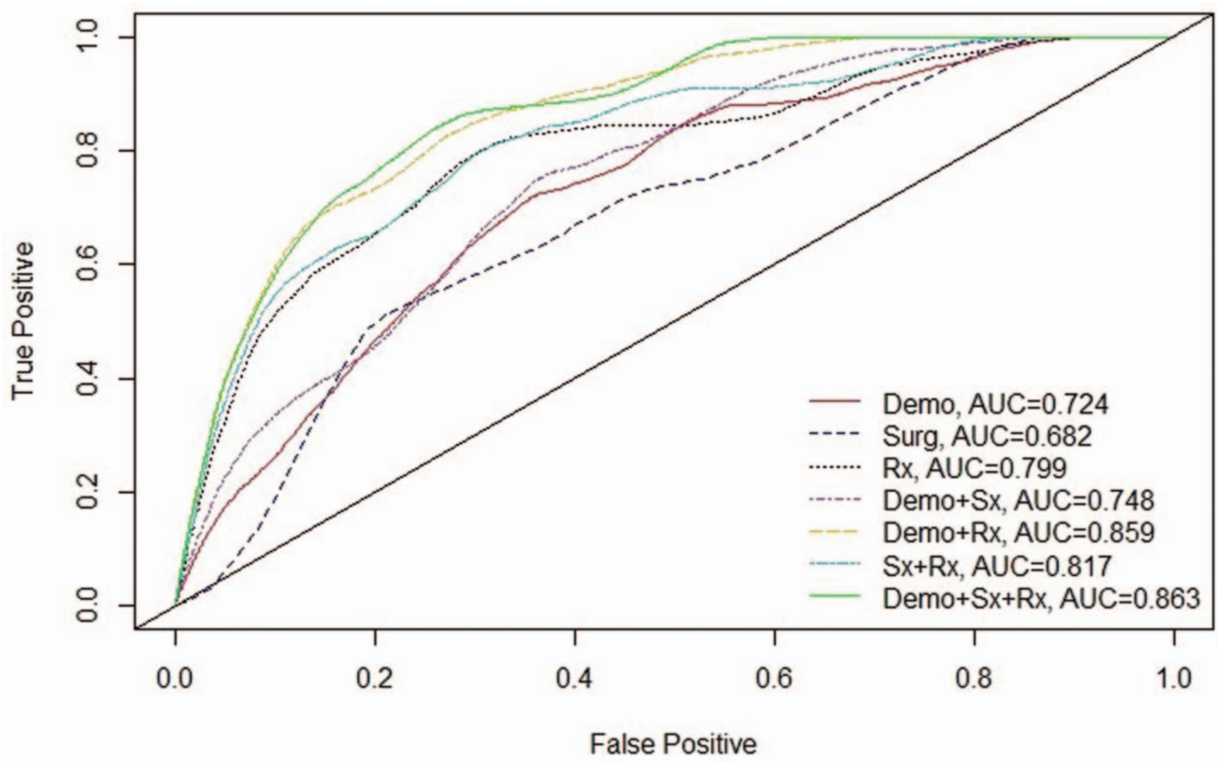

Figure 1. The AUCs based on time-dependent ROC curves of different sets of risk factors. AUC indicates area under the curve; ROC, receiver operating characteristic.

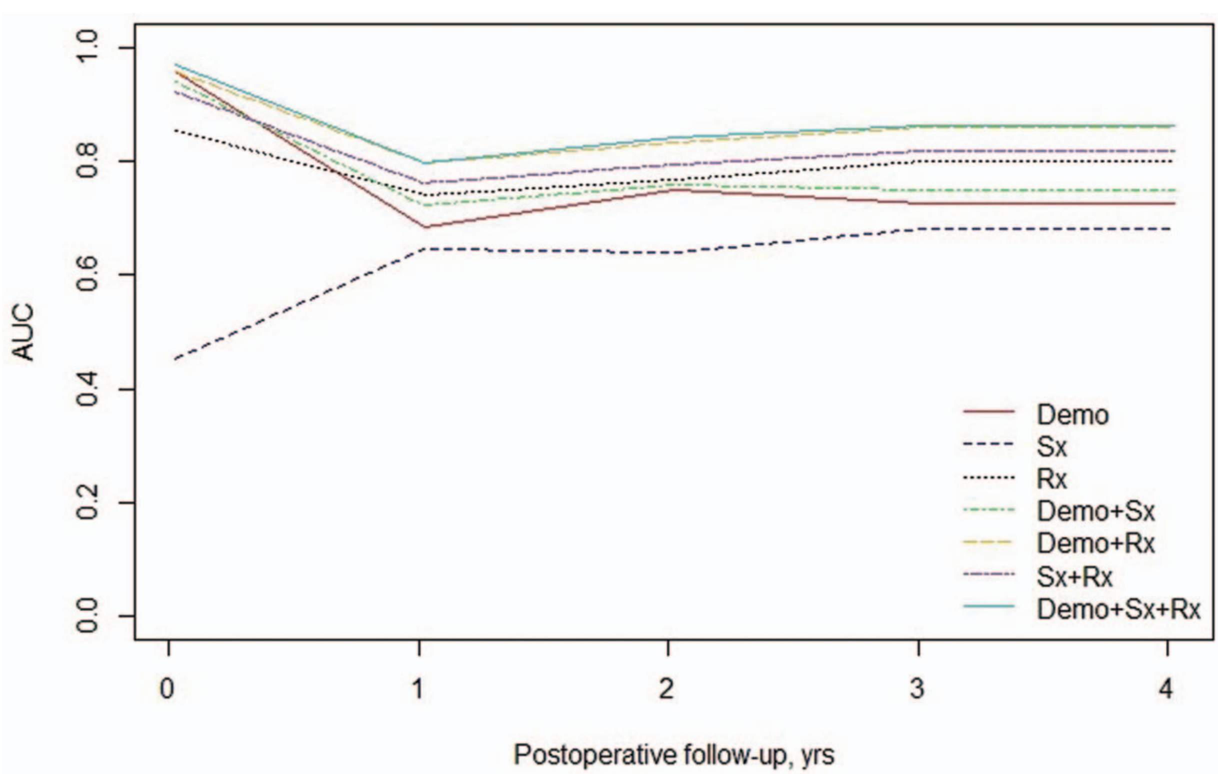

Figure 2. The AUCs over time based on different sets of risk factors.

with more comprehensive data to better understand patients with PJF.

CONCLUSION

Our analytic approach demonstrates an important methodological alternative to describe PJF associated risk factors by taking the time dependence of junctional failures and factors into consideration. Our study has highlighted the importance of radiographic parameters in predicting the development of PJF among surgically-treated ASD patients both in the acute phase and in the long term. Understanding the heterogeneity of patients' sagittal alignment may provide insights to develop individualized surgical plans and stratify postoperative risk of junctional failures.

➢ Key Points

- ❑ Over surgical correction increased the risk of PJF following ASD surgery.
- ❑ Over time, radiographic rather than surgical parameters appear to play the most important role in predicting the development of PJF after surgery.
- ❑ Our analytic approach demonstrates an important alternative to describe PJF-associated risk factors by taking the time dependence of junctional failures and those factors into account.
- ❑ Our results set the groundwork for risk stratification and corresponding interventions for patients undergoing ASD surgery.

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