

Impact of Frailty on the Development of Proximal Junctional Failure: Does Frailty Supersede Achieving Optimal Realignment?

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STRUCTURED ABSTRACT

BACKGROUND: Patients undergoing surgery for adult spinal deformity (ASD) are often elderly, frail, and at elevated risk of adverse events perioperatively, with proximal junctional failure (PJF) occurring relatively frequently. Currently, the specific role of frailty in potentiating this outcome is poorly defined.

PURPOSE: To determine if the benefits of optimal realignment in ASD, with respect to the development of PJF, can be offset by increasing frailty.

STUDY DESIGN: Retrospective cohort

METHODS: Operative ASD patients (scoliosis $>20^\circ$, SVA $>5\text{cm}$, PT $>25^\circ$, or TK $>60^\circ$) fused to pelvis or below with available baseline (BL) and 2-year (2Y) radiographic and HRQL data were included. The Miller Frailty Index (FI) was used to stratify patients into 2 categories: Not Frail (FI <3) and Frail (>3). Proximal Junctional Failure (PJF) was defined using the Lafage criteria. “Matched” and “unmatched” refers to ideal age-adjusted alignment post-operatively.

Multivariable regression determined impact of frailty on development of PJF.

RESULTS: 284 ASD patients met inclusion criteria (62.2yrs \pm 9.9, 81%F, BMI: 27.5 kg/m² \pm 5.3, ASD-FI: 3.4 \pm 1.5, CCI: 1.7 \pm 1.6). 43% of patients were characterized as Not Frail (NF) and 57% were characterized as Frail (F). PJF development was lower in the NF group compared to the F

group, (7% vs. 18%; $p=0.002$). F patients had 3.2X higher risk of PJF development compared to NF patients (OR: 3.2, 95% CI: 1.3-7.3, $p=0.009$). Controlling for baseline factors, F unmatched patients had a higher degree of PJF (OR: 1.4, 95% CI: 1.02-1.8, $p=.03$), however, with prophylaxis there was no increased risk. Adjusted analysis shows F patients when matched post-operatively in PI-LL had no significantly higher risk of PJF.

CONCLUSIONS: An increasingly frail state is significantly associated with the development of PJF after corrective surgery for ASD. Optimal realignment may mitigate the impact of frailty on eventual PJF. Prophylaxis should be considered in frail patients who do not reach ideal alignment goals.

Key Points

1. Several studies have illustrated an association between frailty and postoperative complications like PJF, though it remains unclear whether optimal deformity correction can outweigh the degree of frailty and provide optimal outcomes while minimizing postoperative complications.
2. Optimal realignment may mitigate the impact of frailty on PJF development, and prophylaxis should be considered in frail patients who do not reach ideal alignment goals.
3. The high rates of PJF in this population warrants preoperative medical optimization and extensive patient counseling prior to surgical intervention.

INTRODUCTION

It has been well established that the restoration of sagittal balance is a pivotal component in improving pain, disability, and clinical outcomes in patients with adult spinal deformity (ASD).¹⁻⁴ Our evolving understanding of spinopelvic relationships have led to the development of postoperative realignment thresholds, that have also recently been fine-tuned to account for the chronological age of a given patient, providing a more tailored approach to preoperative surgical planning.⁵ As reported by Lafage et al., restoration of these age-adjusted alignment parameters has been shown to correlate with improvements in patient-reported outcomes.⁵

Despite these established targets, it is still relatively common for patients to develop debilitating mechanical complications, such as proximal junctional failure (PJF), even after sufficient correction of age-adjusted Schwab modifiers (SVA, PT, and PI-LL).⁵ PJF is a multifaceted and complex complication of ASD, with several known demographic, surgical, and radiographic risk factors contributing to its development.^{6,7} Undercorrection of deformity has been shown to be a powerful risk factor. Additionally, several studies have illustrated an association between frailty and postoperative complications after corrective surgery for ASD.⁸⁻¹¹ Frailty, or physiological age, comprises a broad spectrum of medical and psychosocial components of general health; thus, it serves as a better indicator of a patient's overall ability to tolerate medical and especially surgical interventions, rather than chronological age. Accordingly, Miller et al. developed the ASD Frailty Index (FI) that incorporates 40 distinct health deficits assessing physical disability, medical comorbidities, activities of daily living, mood, and cognition.¹² They reported increasing ASD-FI scores were significantly associated with increased likelihood of proximal junctional kyphosis (PJK) development, pseudarthrosis, wound dehiscence, and deep wound infection after ASD surgery.¹² Still, it remains unclear

whether optimal deformity correction can outweigh the degree of frailty and provide optimal outcomes, while minimizing postoperative complications.

As such, in this study we sought to characterize the relationship between frailty and the development of PJF, in patients undergoing corrective surgery for ASD. We also sought to evaluate whether optimal deformity correction could offset, to some degree, the risk of PJF development in patients with frailty. We hypothesized that increasingly frail patients would develop PJF at a higher rate and that optimal correction would influence PJF development in these individuals.

MATERIALS AND METHODS

Design and Data Source

This study was a retrospective cohort study of consecutively enrolled ASD patients presenting to a single academic spine center from November 2013 to May 2018. Institutional Review Board approval was obtained for this study, and patient consent was not required due to the de-identified nature of the data and retrospective study design.

Study Inclusion Criteria

Patients included for analysis were greater than or equal to 18 years of age at the time of surgery, had a diagnosis of ASD utilizing SRS-Schwab radiographic criteria (SVA > 5cm, PI-LL > 10°, or PT > 20°).¹³ All included patients had complete baseline full-body stereographic imaging and baseline + 2-year health-related quality of life (HRQL) outcomes recorded and had lower instrumented level of at least pelvis.

Data Collection

Demographic data, including age, body mass index (BMI), and gender were abstracted from the registry, as well as surgical characteristics, including operative time, estimated blood loss (EBL), levels fused, whether an osteotomy was performed, intraoperative complications, use of PJK prophylaxis (cement, hooks, or tethers), and others. HRQL outcome measure tools included the Oswestry disability index (ODI) questionnaire and The Miller Frailty index. The ODI questionnaire is an assessment of disability and physical limitations imposed by lower back pain, scored on a scale from 0 to 100. The Miller frailty index (FI) is composed of a 40-item list, including BMI, medical comorbidities, neurological exam findings, and responses to HRQL questions. We utilized the Miller FI scale, described in **Table 1**, to stratify patients into not frail (NF) based on a score <3 , or frail (F) based on a score >3 .¹²

Biplanar Radiographic System and Measurement

The standardized protocol for imaging acquisition entailed weight-bearing, free-standing position with arms contracted at 45° and fingertips resting on the clavicles, to avoid superimposition of the sagittal spine view. This position has previously been demonstrated to not alter a patient's center of gravity in the standing position.¹⁴ Two source-detector pairs positioned orthogonally captured the position simultaneously, enabling the acquisition of anteroposterior and lateral images, vertically translated without distortion. Images were measured with validated software (Surgimap, Nemaris Inc., New York, NY) at a single center.

Outcomes

Proximal junctional failure (PJF) was defined using the *Lafage et al.* criteria of a 2-year PJK angle of < -28 degrees, a 2-year difference in PJK angle of < -22 degrees, or revision surgery for PJK before 2 years postoperatively.¹⁵ Patients considered “matched” in this analysis met the ideal Schwab age-adjusted alignment category, as per the *Lafage et al.* criteria.¹⁵

Statistical Analysis

All statistical analyses were performed utilizing SPSS software (version 23.0, Armonk, NY, USA). The level of statistical significance for all tests was set at $p < 0.05$. Multivariable logistic regressions were used to evaluate the association between FI (NF and F states), and PJF development, adjusting for other covariates abstracted.

RESULTS

Overall Cohort Overview, Baseline Radiographic Profile, and Surgical Profile

284 ASD patients met inclusion criteria. Mean patient age was 62.2 ± 9.9 years, mean BMI was $27.5 \pm 5.3 \text{ kg/m}^2$, mean Charlson Comorbidity Index (CCI) was 1.7 ± 1.6 , mean baseline ASD FI was 3.4 ± 1.5 . 81% of patients were female. With respect to radiographic parameters, at baseline, mean pelvic tilt (PT) was $26.2 \pm 10.1^\circ$, mean PI-LL was $20.9 \pm 19.5^\circ$, mean SVA was $77.7 \pm 71.4 \text{ mm}$, and mean T4-T12 kyphosis was $-31.4 \pm 18.6^\circ$. Mean length of stay (LOS) was 7.7 ± 4.1 days, mean levels fused was 11.7 ± 4.5 , mean EBL was $1706 \pm 1319 \text{ mL}$, and mean operative time was 354 ± 122 minutes. 67% of patients underwent an osteotomy. In terms of surgical approach, 58% of patients underwent a posterior-only approach and 42% underwent a combined approach. Overall, 30.5% of patients received some sort of prophylaxis which was 5.6% cement, 7.7% hooks, 10.9% tethers, and the rest being other or mixed. Comparison of

demographic factors, surgical details, and HRQL outcomes among frailty groups are displayed in **Table 2.**

Frailty and the Association with Proximal Junctional Failure

43% of patients (138) were characterized as Not Frail (NF) and 57% (107) were characterized as Frail (F). The rate of PJF development for the overall cohort was 13% and the rate of PJK development was 59%. A combined approach was found to have no differences in rates of PJF (12% in combined approach vs. 14% in single approach, $p=.575$) or PJK (57% in combined approach vs. 62% in single approach, $p=.378$). The F group had a higher rate of PJF development overall (18% compared to 7% in the NF group, $p=0.002$). Multivariable (MVA) logistic regression analysis, controlling for age, baseline deformity, UIV, osteoporosis, and surgical invasiveness, demonstrated a higher baseline FI correlated with an increased risk of PJF development (OR: 1.4, 95% CI: 1.03-1.8, $p=0.31$). MVA logistic regression analysis showed a 3.2X higher risk of PJF development for F patients compared to NF patients (OR: 3.2, 95% CI: 1.3-7.3, $p=0.009$), controlling for the aforementioned variables. Controlling for age, BL deformity, UIV, osteoporosis, and surgical invasiveness, F unmatched patients had a higher degree of PJF (OR: 1.4, 95% CI: 1.02-1.8, $p=.03$), however, with prophylaxis there was no increased risk. Adjusted analysis shows F patients when matched post-operatively in PI-LL had no significantly higher risk of PJF.

Osteoporosis and the Association with Proximal Junctional Failure

The rate of osteoporosis in the overall cohort was 18.7%. Patients with osteoporosis received PJK prophylaxis at higher rates than those without osteoporosis (41% vs. 27%, $p=.040$). Patients

with osteoporosis trended towards higher rates of PJF though this was not significant (17% vs 12%, $p=.351$). Osteoporosis patients did have lower PJF rates when prophylaxis was used (0% vs. 31%, $p<.001$). Utilizing prophylaxis was predictive of not developing PJK by 2 years in patients with osteoporosis (OR: 0.173 [.044-.685], $p=.012$). A subgroup analysis of only frail patients found similar PJF rates when comparing those with versus without osteoporosis (23% vs. 16%, $p=.421$).

DISCUSSION

Current treatment principles and surgical goals in the management of ASD are centered on the restoration of sagittal balance and spinopelvic relationships. *Lafage et al.* suggested that patients who are matched according to age-adjusted alignment thresholds may have a reduced likelihood of developing complications such as PJK.¹⁶ However, the incidence of PJK remains quite high, ranging from 5% to >40%, and several studies have demonstrated an association with patient frailty.¹⁷⁻²² To what extent, if any, optimal surgical correction of baseline deformity in ASD can offset the increased risk of mechanical complications in frail patients, has not previously been investigated. We believe our study is novel in its exploration of these parameters using a sizeable ASD database of 245 patients, with broad variation in baseline frailty and spinal deformity.

As assessed by the ASD FI, we found frailty to be significantly associated with the eventual development of PJF. Strikingly, this association remained present, even after accounting for the effects of other variables such as baseline deformity or surgical invasiveness. Our findings are well aligned with those of *Miller et al.*, who previously reported that the odds of PJK development were higher in frail patients compared to non-frail patients.¹² The large association between frailty and the development of PJF in our cohort raises the question of which

factors, in particular, may predispose frail patients to PJF development. Frailty, defined as a loss in functional capacity, is closely linked with sarcopenia, which is a decline in muscle mass, strength and endurance.²⁵ It has been shown that after ASD surgery, muscle degeneration is closely associated with dysregulation of sagittal alignment and subsequent loss of postural control, negatively affecting balance and functional tasks in elderly patients.^{29,30} *Bao et al.* previously quantified the relationship between spino-femoral muscle degeneration and sagittal malalignment. They identified a close relationship between gluteal and hamstring muscles and radiographic parameters, such as PT and SVA.³²

While our study did not specifically characterize muscle bulk or degeneration, “frailer” patients would be expected to have lower muscle bulk and/or more muscle degeneration. This could potentially contribute to their overall worse radiographic parameters, and furthermore, explain the higher incidence of PJF seen in the frail compared to non-frail groups of our cohort. Further studies investigating the association between sarcopenia and frailty, independently as well as in combination, are warranted. In the interim, it may be worthwhile to include muscle strength and control as part of the perioperative risk assessment for mechanical complications in patients undergoing ASD surgery.

Patients with a higher FI who were matched in their age-adjusted alignment thresholds for PI-LL showed a reduction in PJF, while in patients without “ideal” age-adjusted sagittal alignment, prophylaxis may have provided a counterbalancing effect on PJF development, further emphasizing the complexity and intricacy of PJF as an entity. Several risk factors have been associated with the development of PJF postoperatively. Age, poor preoperative alignment, and the severity of deformity correction at the time of surgery have all been identified. *Hart et*

al., in their analysis of risk factors for PJF development after ASD surgery, reported a higher association with preoperative malalignment in SVA, PI-LL, and thoracic kyphosis.^{33,34,35,36}

Park et al similarly identified age and preoperative malalignment in SVA as significant risk factors for PJK development. Their study additionally echoed the importance of bone health with respect to mechanical complications such as PJK, as they reported an increased risk associated with osteoporosis and a UIV at T11, T12, or L1.³⁷ *Kim* et al, in their retrospective study of 206 adult scoliosis patients, demonstrated similar findings, as they reported an association of a greater degree of sagittal imbalance correction with PJF.³⁸ *Maruo* et al, in their retrospective cohort study of 90 patients who underwent long fusion (≥ 6 vertebrae) to sacrum, described minimizing PJF occurrence by restoring radiographic parameters, including SVA, PI-LL, and anterior pelvic tilt, to age-adjusted “balanced” or “corrected” targets.³⁹ Additionally, osteoporosis has been previously shown to increase risk for PJF, however the subset of this cohort with osteoporosis was not found to have statistically higher rates of PJF as compared to those without osteoporosis.³⁷ A potential explanation for this interesting finding is that patients preoperatively diagnosed with osteoporosis received prophylaxis at higher rates than those without osteoporosis. The decision for which patient should be given prophylaxis is multifaceted and one must consider cost effectiveness as well as numerous patient-specific factors such as medical comorbidities, risk for suboptimal alignment if not a candidate for aggressive realignment, frailty status, risk for revision, and history of recurrent junctional failure.³⁷⁻³⁹

A patient-specific approach should be undertaken when it comes to preoperative planning for ASD patients who are deemed surgical candidates. A comprehensive profile should be defined, one that includes baseline clinical and radiographic alignment parameters, baseline physiologic factors (such as frailty), and specific targets during surgical correction.

We recognize several limitations. First, this remains a retrospective investigation conducted using a surgical registry and suffers from the typical drawbacks associated with research using such an approach, including the prospect of selection and indication bias. There may also be cluster bias due to the use of data from patients treated within a single center. Additionally, data was collected over an 8-year period, which potentiates heterogeneity in terms of perioperative management protocols as well as surgical techniques. Lastly, the FI used in this study did not incorporate radiographic measurements or laboratory values within the calculation itself. Clinicians who use varying frailty calculators that incorporate different parameters, may be limited in their application of these findings to their patient populations. Nevertheless, we believe our findings are novel and relevant in the context of the ASD-FI, and future work can build upon these preliminary findings.

CONCLUSIONS

We utilized a large, single-center database with wide variation in baseline frailty and spinal deformity to characterize the effect of baseline frailty and realignment on the development of PJF after corrective surgery for ASD. Optimal realignment may mitigate the impact of frailty on PJF development, and prophylaxis should be considered in frail patients who do not reach ideal alignment goals. The high rates of PJF in this population warrants preoperative medical optimization and extensive patient counseling prior to surgical intervention. Future research is also necessary to characterize which subset of frail patients may benefit the most from surgical intervention.

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Table 1. Factors included in the Miller ASD-FI

Health deficits
Documented by physician
>3 medical problems
Body mass index <18.5 or >30 kg/m ²
Cancer
Cardiac disease
Currently on disability
Depression
Diabetes
Hypertension
Liver disease
Lung disease
Osteoporosis
Peripheral vascular disease
Previous blood clot (deep vein thrombosis/pulmonary embolism/stroke)
Smoking status
Patient-reported (questionnaire, question no.)
Bladder incontinence
Bowel incontinence
Deteriorating health this yr (SF-36v2, 2)
Difficulty climbing 1 flight of stairs (SF-36v2, 3e)
Difficulty driving a car (LSDI, 3)
Difficulty getting dressed (SF-36v2, 3j; LSDI, 1 & 2)
Difficulty getting in/out of bed (LSDI, 6)
Difficulty sleeping >6 hrs (ODI, 7)
Difficulty walking 100 yards (SF-36v2, 3i)
Difficulty w/ light activity (SF-36v2, 3b)
Feeling downhearted/depressed most of the time (SF-36v2, 9f; SRS-22r, 16)
Feeling tired most of the time (SF-36v2, 9i)

Feeling worn out most of the time (SF-36v2, 9g)

General health: fair/poor (SF-36v2, 1)

Inability to bathe w/o assistance (SF-36v2, 3j; LSDI, 8)

Inability to cheer up often (SF-36v2, 9c; SRS-22r, 7)

Inability to do normal work/schoolwork/housework (ODI, 10; SRS-22r, 9 & 12)

Inability to lift heavy objects (SF-36v2, 3c; ODI, 3)

Inability to travel >1 hr (ODI, 9)

Inability to walk w/o assistive device (ODI, 4)

Leg weakness

Loss of balance

Not in excellent health (SF-36v2, 11d)

Personal care dependency (ODI, 2)

Restricted activity level (SRS-22r, 5)

Restricted social life (ODI, 8; SRS-22r, 14 & 18)

LSDI = Lumbar Stiffness Disability Index; ODI = Oswestry Disability Index; SF-36v2 = 36-Item Short-Form Health Survey, version 2; SRS-22r = Scoliosis Research Society-22r questionnaire.

Taken from: Miller EK, Neuman BJ, Jain A, et al. An assessment of frailty as a tool for risk stratification in adult spinal deformity surgery. *Neurosurg Focus*. 2017;43(6):E3.

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Table 2. Comparison of demographic factors, surgical details and HRQL outcomes among frailty groups.

	Frail	Not Frail	p-value
Demographic Details			
Age (years)	64±10.7	61±10.8	p=.060
Gender (% Female)	77%	86%	p=.085
BMI (kg/m ²)	28±5.4	25±4.5	p<0.001
Charlson Comorbidity Index	2.1±1.7	1.1±1.3	p<0.001
Radiographic Parameters			
Pelvic tilt	28°	24°	p=.010
PI-LL	25°	15°	p<0.001
Thoracic kyphosis at T4-T12	-31°	-33°	p=0.414
SVA C7-S1	9.2 cm	5.7 cm	p<0.001
Sacral slope	29.2°	29.8°	p=0.646
Surgical Details			
ISSG Surgical Invasiveness	103	97	p=0.194
Estimated blood loss (mL)	1742	1661	p=0.620
Length of stay	7.7 days	7.6 days	p=.815
Baseline HRQL Scores			
SF-36 Physical Component Score	27.3±6.6	36.4±8.8	p<0.001
SF-36 Mental	38.5±13.3	53.4±9.0	p<0.001
SRS-Activity	2.4±.68	3.4±.67	p<0.001
SRS-Pain	2.1±.73	2.9±.73	p<0.001
SRS-Appearance	2.1±.66	2.8±.70	p<0.001
SRS-Mental	3.0±.82	4.0±.66	p<0.001
SRS-Satisfaction	2.6±1.1	2.8±1.1	p=0.035
SRS-Total	2.4±.51	3.2±.48	p<0.001
ODI	54±14	32±12	p<0.001

BMI = body mass index; PI-LL = pelvic incidence minus lumbar lordosis; SVA = sagittal vertical axis; SF-36 = Short Form 36; SRS = Scoliosis Research Society; ODI = Oswestry Disability Index