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Original Article

Soft Landing technique as a possible prevention strategy for proximal junctional failure following adult spinal deformity surgery

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Background: This cross sectional study describes a "Soft Landing" strategy utilizing hooks for minimizing proximal junctional kyphosis (PJK) and proximal junctional failure (PJF). The technique creates a gradual transition from a rigid segmental construct to unilateral hooks at the upper instrumented level and preservation of the soft tissue attachments on the contralateral side of the hooks. Authors devise a novel classification system for better grading of PJK severity.

Methods: Thirty-nine consecutive adult spinal deformity (ASD) patients at a single institution received the "Soft Landing" technique. The proximal junctional angle was measured preoperatively and at last follow-up using standing 36-inch spinal radiographs. Changes in proximal junctional angle and rates of PJK and PJF were measured and used to create a novel classification system for evaluating and categorizing ASD patients postoperatively.

Results: The mean age of the cohort was 61.4 years, and 90% of patients were women. Average follow up was 2.2 years. The mean change in proximal junctional angle was 8° (SD 7.4°) with the majority of patients (53%) experiencing less than 10° and only 1 patients with proximal junctional angle over 20°. Four patients (10%) needed additional surgery for proximal extension of the uppermost instrumented vertebra (UIV) secondary to PJF.

Conclusions: Soft Landing technique is a possibly effective treatment strategy to prevent PJK and PJF following ASD that requires further evaluation. The described classification system provides management framework for better grading of PJK. The "Soft Landing" technique warrants further comparison to other techniques currently used to prevent both PJK and failure.

Keywords: Adult scoliosis; spinal deformity; proximal junctional kyphosis (PJK); proximal junctional failure (PJF); adult spinal deformity (ASD); supra laminar hook

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Introduction

Proximal junctional kyphosis (PJK) continues to be a challenging complication following adult spinal deformity (ASD) surgery with an incidence ranging from 17% to 39% (1-3). PJK refers to the development of kyphosis at the segments immediately cephalad to a spinal fusion construct. PJK manifests as a spectrum of disease severity, ranging from asymptomatic to significant pain and deformity. Most cases of PJK occur within 3 months of the postoperative period (4), and a second peak is seen after the 12-month postoperative period (5).

There is currently no consensus radiographic definition of PJK. Glattes *et al.* originally defined PJK as a sagittal Cobb angle between the uppermost instrumented vertebra (UIV) with two pedicle screws and two levels above the UIV (UIV+2) of 10° or greater and at least 10° greater than the preoperative measurement (6). To date, this is the most repeatedly used definition of PJK in the literature (1,7,8). There are authors who use 15° (7) or 20° (8) to define PJK, however, in this paper we used a stringent cut off of greater than 10°.

Within the spectrum of PJK, proximal junctional failure (PJF) is a more serious complication characterized by an acute structural failure such as vertebral fracture, implant failure, posterior ligament complex failure, or vertebral subluxation resulting in revision surgery (4). Its incidence was reported between 1.4% and 35% (9,10). PJF is defined in this paper as a PJK that requires extension of the construct.

The causes of PJK/PJF are not fully understood but are believed to be multifactorial. They can be categorized into surgical, radiographic, and patient-related risk factors. The surgical risk factors include among others, injury of the posterior soft tissues and variability among pedicle screw constructs. Previous investigators reasoned that ligamentous failure of the posterior interspinous ligament and paraspinal musculature damage may contribute biomechanically to increased rates of PJK (11,12). The exclusive usage of pedicles screws from the pelvis to the highest level of instrumentation results in overly rigid and stiff constructs and has been definitively shown to be a risk factor for PJK/PJF (13-15).

The purpose of this study is to report our results with the "Soft Landing" technique for ASD. This technique includes a combination of unilateral preservation of the soft tissue sleeve and contralateral instrumentation with a single hook or multiple hooks. We hypothesize the "Soft Landing" may reduce the risk of PJK/PJF by creating a less rigid transition between the pedicle screw construct and the non-instrumented upper level of the spine when compared to rates in the literature. In this study we also report a novel classification system for describing the spectrum of PJK/PJF.

We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/jss-20-622).

Methods

Data collection

A consecutive series of 39 ASD patients undergoing instrumented fusion were included in this study. Preoperative standard standing 36-inch radiographs were utilized for radiographic measurements. Surgeries were performed from 2012 to 2018 at a single institution by the senior surgeon. Patient demographics including age, sex, BMI, indication for surgery, number of levels fused posteriorly and anteriorly, anterior and posterior approaches, bone density, use of vertebroplasty, use of cement, hook fixation type at the UIV, and 3-column osteotomy were collected. The proximal junctional angle (PJA) was measured preoperatively and at the last follow-up on standing 36-inch radiographs. Preoperative imaging was not available for 5 patients, so immediate postoperative imaging in the operating room or the post anesthesia care unit (PACU) was utilized as the reference image for PJA comparison. PJA was measured from the caudal endplate of the upper instrumented vertebra (UIV) to the cranial end plate of the vertebra two levels cranial to the upper instrumented level (UIV+2) (*Figures 1,2*). Two independent reviewers performed the measurements in order to minimize bias. PJK was defined as a difference in the preoperative and postoperative PJA of greater than 10°. PJF was defined as PJK that resulted in revision surgery as a direct consequence of the PJK, other causes for revision surgery such as trauma, were not considered PJF. PJF was further subdivided into two cohorts: patients requiring construct extension and those who did not. Spinopelvic parameters of sagittal alignment were measured on preoperative and most recent postoperative imaging. Measurements included pelvic tilt (PT), sagittal vertical axis (SVA), pelvic incidence-lumbar lordosis (PI-LL) mismatch, and T1 pelvic angle (TPA).

The study was conducted in accordance with the

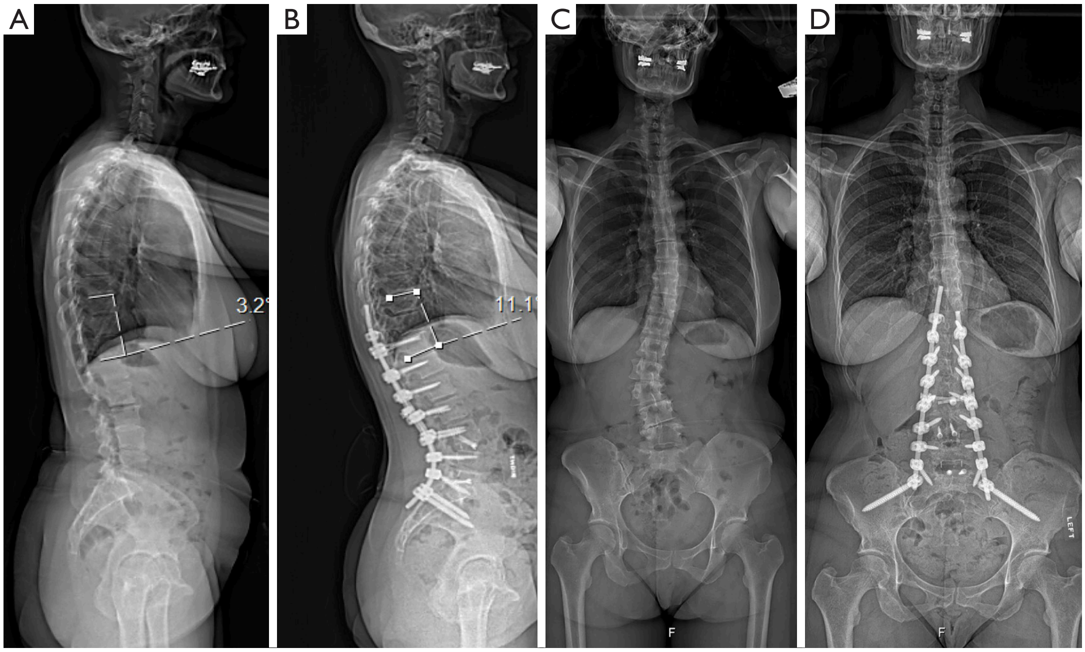

Figure 1 Preoperative and postoperative imaging of the Soft Landing technique in a patient undergoing their primary surgery for ASD. (A) Preoperative lateral standing EOS film demonstrating a PJA of 3.2° in a primary spinal fusion surgery. PJA was measured from the caudal vertebral endplate of the UIV (2 pedicle screws at the same level) to the cephalad vertebral endplate 2 levels caudal to the UIV (UIV+2). (B) Two-year postoperative lateral standing EOS film of patient in (A) with a PJA of 11.1°, delta PJA of 7.9°. (C) Preoperative AP standing EOS film. (D) Two-year postoperative AP standing EOS film. ASD, adult spinal deformity; PJA, proximal junctional angle; UIV, uppermost instrumented vertebra; AP, anteroposterior.

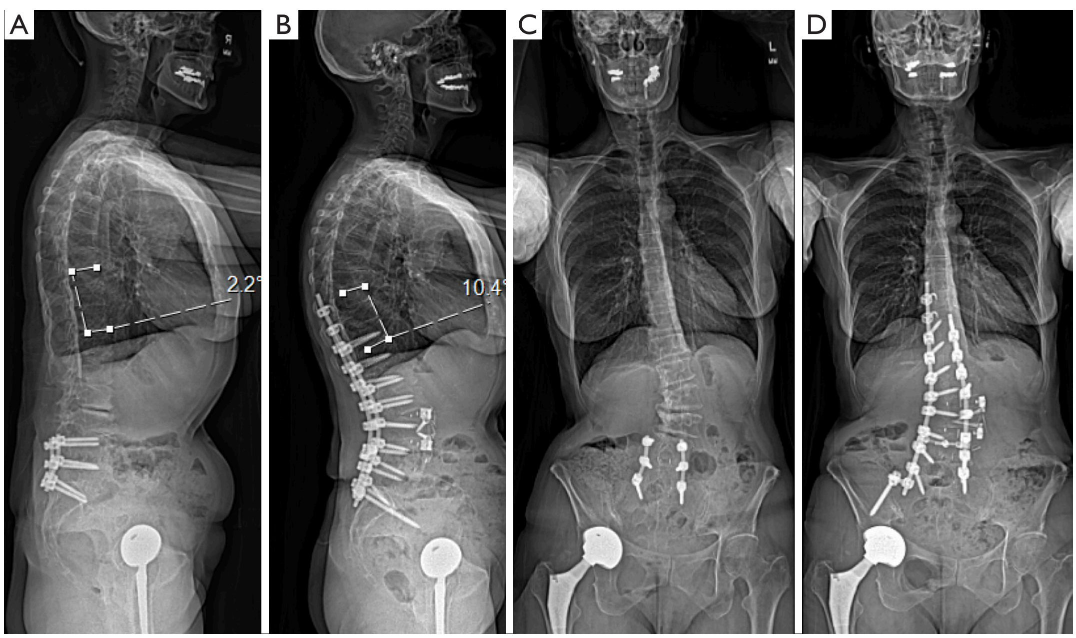

Figure 2 Preoperative and postoperative imaging of the Soft Landing technique in a patient who had previously undergone lumbar spinal fusion for ASD. (A) Preoperative lateral standing EOS film demonstrating a PJA of 2.2° in a patient with a previous lumbar spinal fusion. (B) Two-year postoperative lateral standing EOS film of patient in (A) with a PJA of 10.4°, delta PJA of 8.2°. (C) Preoperative AP standing EOS film. (D) Two-year postoperative AP standing EOS film. ASD, adult spinal deformity; PJA, proximal junctional angle; AP, anteroposterior.

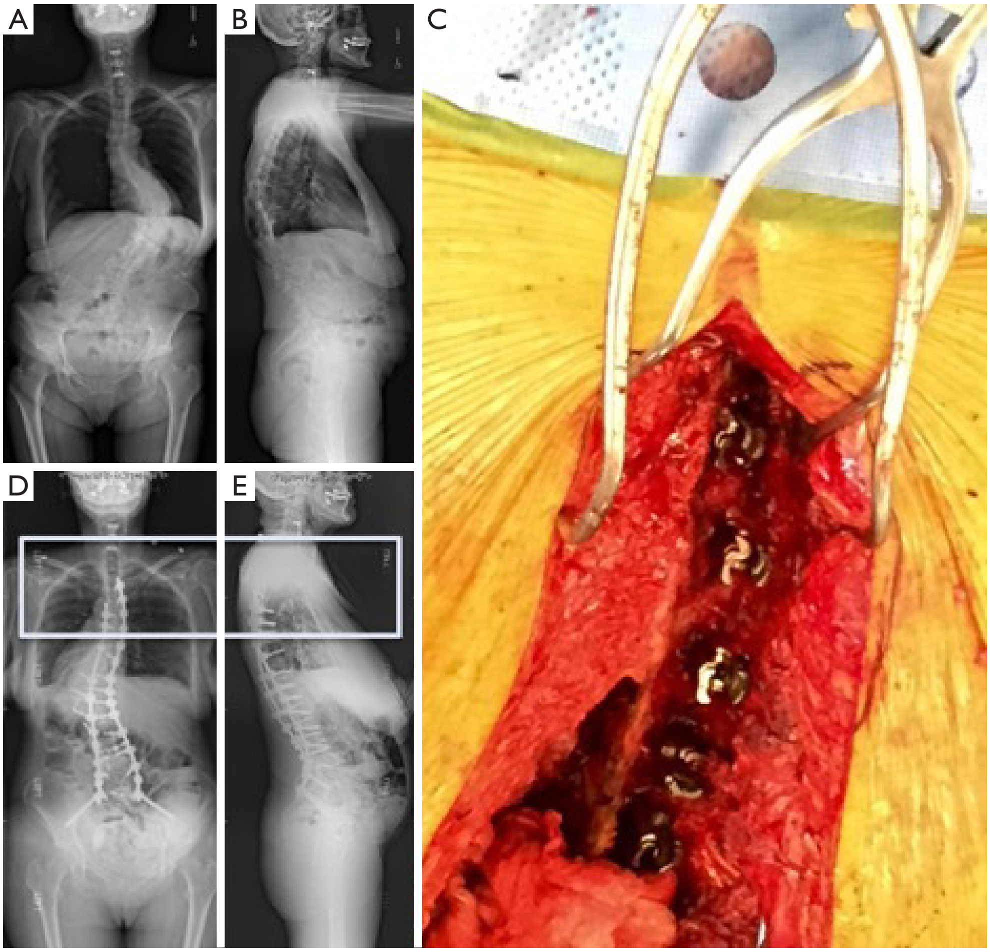

Figure 3 Intraoperative imaging of the Soft Landing technique. (A) Preoperative AP and (B) lateral standing radiographs of a patient that will undergo the Soft Landing technique. (C) Intraoperative image of the Soft Landing technique. On the right side, 3 supra laminar hooks were positioned, while the left side was maintained intact. (D) Postoperative AP and (E) lateral standing radiographs of a patient that underwent the Soft Landing technique with boxed area representing the location of the image taken in (C). Radiographs were taken 6 months postoperatively, with PJK measuring 6.7° at that time. PJK, proximal junctional kyphosis; AP, anteroposterior.

Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of The University of Pennsylvania (#827321) and individual consent for this retrospective analysis was waived.

Soft Landing technique

The goal of Soft Landing is to create a gradual transition from the rigid segmental instrumentation (using pedicle screws) to the native spine at the top of the construct in order to reduce the quantity of junctional stress. After deciding which levels would be the UIV, a unilateral subfascial approach of the spine is performed above the UIV. The soft tissues, including muscle and ligament attachments, are left intact on the controlateral side (*Figure 3*). On the spinal exposure side, one or several supralaminar (SL), infralaminar (IL) or transverse process (TP) hooks were used. A claw construct made up of a pedicle screw and hooks was also used was in some instances. The spinal tension band must always be preserved on the contralateral side when creating the contruct.

Proximal junctional classification system

The proximal junctional classification system describes changes in PJA (UIV+2) as well as outcomes following ASD surgery at most recent follow up. Type 1 are patients with less than 10°, type 2 are patients with 10°–20° and type 3 are patients with over 20°. Modifiers A, B, or C describe whether they needed repeat surgery. Modifier A did not require repeat surgery, B required a repeat surgery but no extension, and C required an extension. Therefore patients can be 1A, 2A, 3A, 1B, 2B, 3B, 1C, 2C, 3C. According to this new classification system any patient with types 2 and 3 met the criteria for PJK. Finally, patients in group 2C and 3C met the traditional criteria for PJF.

Statistical analysis

Student *t*-test was utilized to perform univariate analysis of continuous variables. Chi-square test was utilized to perform univariate analysis of categorial variables. Linear regression and binary logistic regression was performed for multivariate analyses. Variables were included in the multivariate model if they were found to demonstrate a statistically significant relationship or were known factors associated with PJK and PJF. For purposes of the multivariate analysis, the UIV was categorized as upper thoracic (T1–T5) or lower thoracic (T6–T12). Statistical significance was defined as $P<0.05$. All analyses were performed using IBM SPSS (version 24, IBM Corp.).

Results

Patient and surgical demographics

Thirty-nine patients were included in this analysis. The mean age and BMI at the time of surgery were 61 years (range, 41–83 years) and 26.5 (range, 19–43), respectively. There were 4 men and 35 women. Twenty-five out of 39 patients had a documented Dual-energy X-ray absorptiometry (DEXA) scan in their chart, 21/25 (84%) had osteopenia/osteoporosis according to their T-score. Indications for surgery varied, with many patients having more than one diagnosis. These indications included meeting all the criteria for the ASD (scoliosis with significant coronal decompensation and/or neurogenic claudication, significant sagittal imbalance, iatrogenic flat back, adjacent-segment disease, PJK, and an extensive degenerative spinal disease). Over half (54%) of the patients underwent previous spine surgeries, and a combined anterior/lateral and posterior approach was used in 27 patients. Staged approaches were utilized in 33% of cases, with an average of 2.1 days separating the anterior/lateral and posterior surgeries. Three out of the 13 patients had the second stage after 5, 7, and 11 months due to their medical condition and were excluded from the calculation of average days between staged procedures. The mean number of levels fused posteriorly was 10 (range, 7–15), excluding the pelvis. Thirty-seven out of 39 cases were fused to the pelvis, the other two patients were both fused to L5. The UIV was upper thoracic (T1–5) in 10 cases and lower thoracic (T6–12) in 29 cases. A three-column osteotomy was performed in one case (L4 level). Sixty-nine percent of patients had anterior lumbar interbody fusion (ALIF). Vertebroplasty of the UIV was used in 9 cases. Demographics, presurgical, and surgical data are summarized in *Tables 1,2*. The composition of the unilateral Soft Landing at the top of the construct was diverse and is summarized in *Table 3*.

Surgical outcomes

The mean change in PJA was 8° (SD 7.4°); 23 patients had a change of less than 10°. Fifteen patients had a change in PJA of 10°–20°, and 1 patient had a change in PJA of greater than 20°. Given the accepted criteria of greater than 10° of change in PJA, 16/39 (41%) patients had radiographic PJK at most recent follow up (*Table 4*). Therefore there were 23 type 1 patients, 15 type 2 patients, and 1 type 3 patient. The mean time of follow-up was 2.2 years (range, 118–2,640 days). Thirty-five patients and 30 patients had at least 6 months and one-year follow-up, respectively.

The majority of patients (69%) did not require any return to the OR following soft landing procedure, including patients who met the radiographic definition of PJK. These patients who did not require repeat surgery fall into modifier A. Eight patients (21%) had modifier B and needed to return to the OR because of various complications but did not require extension of construct (broken instrumentation =4, hook removal =3, lumbar stenosis =1). Four patients (10%) required a return to the OR with extension of construct past the original level of instrumentation as well as radiographic PJK, therefore meeting the criteria for PJF (*Table 4*) and warranted the most serious modifer, C. The breakdown of patients into their respective classifications is demonstrated in *Table 4*. Mean time from index surgery to revision was 404 days.

Compression fractures at the UIV were seen in 2 cases and at the UIV+1 in 1 case for a total of 3 cases out of 39 (7.7%). Two of patients with compression fracture

Table 1 Patient demographics stratified by proximal junctional angle

Proximal junctional angle	Total (n=39)	<10 (n=23)	≥10 (n=16)	P values
Age at surgery	61.4 (±9.7)	61.1 (±9.7)	61.8 (±10.0)	0.824
Gender				0.046
Female	35 (89.7%)	23 (100.0%)	12 (75.0%)	
Male	4 (10.3%)	0 (0.0%)	4 (25.0%)	
Body mass index	26.5 (±5.5)	25.8 (±6.2)	27.6 (±4.3)	0.282
Diabetes	2 (5.1%)	2 (8.7%)	0 (0.0%)	0.636
Hypertension	20 (51.3%)	14 (60.9%)	6 (37.5%)	0.267
Coronary heart disease	3 (7.7%)	0 (0.0%)	3 (18.8%)	0.121
Hypercholesterolemia	15 (38.5%)	10 (43.5%)	5 (31.2%)	0.662
Smoking	3 (7.7%)	2 (8.7%)	1 (6.3%)	1
Osteoporosis or osteopenia	21 (53.8%)	10 (43.5%)	11 (68.8%)	0.277
ASA score	2.4 (±0.5)	2.3 (±0.5)	2.4 (±0.5)	0.416
T-score	–1.5 (±0.9)	–1.5 (±1.0)	–1.6 (±0.8)	0.841
Previous spine surgery	23 (59.0%)	12 (52.2%)	11 (68.8%)	0.481

ASA, American Society of Anesthesiologist.

were asymptomatic and did not require revision surgery. The third patient with a compression fracture also had a concurrent pseudomeningocele, which required revision surgery. Spondylolisthesis was observed in one case (T2/T3 level).

There was no statistically significant difference in the change of spinopelvic parameters between patients with PJK and patients without PJK. Average change in SVA, PT, PI-LL mismatch, and TPA are reported in *Table 5*.

Conclusions

The Soft Landing technique warrants further study to evaluate its impact on PJK and PJF. The use of hooks in lieu of pedicle screws at the UIV is a well-recognized PJK prevention strategy (16). Hooks provide a theoretical biomechanical advantage since they require less violation of the facet joint and provide more dynamic fixation at the cranial aspect of the construct (17,18). However, most of the hooks currently inserted in the literature are TP hooks. Because of weakened TPs in patients with pseudoarthrosis, sublaminar (SL) hooks were utilized in most cases. TP and IL hooks were utilized for 8 patients in this study only when SL hooks could not be inserted for technical reasons. Several studies have compared PJK rates in patients with spinal hooks to those with pedicle screws at the UIV (7,15,19). For example, Kim *et al.* reported improved rates of PJK in procedures that included hooks as compared to pedicle screws, however they did not comment on rates of PJF (15). Additionally, Helgeson *et al.* found a trend towards decreased rates of PJK when using hooks but never achieved significance (7). The limitations of these studies demonstrate the need for more conclusive evidence. These studies also did not utilize the technique of unilateral soft tissue dissection at the cranial end of the construct, as described in the present study. Ultimately, the make-up of the construct was determined by the senior surgeon based on clinical judgement. In future studies, a more defined methodology for construct composition will allow for more robust conclusions to be made on the benefits of Soft Landing.

It is thought that preserving the soft tissues with the Soft Landing technique as well as utilizing hooks may lower the rate of PJF. In this case series, the rate of PJF was 10% with an average follow up of 2.2 years. The senior author also performed the Soft Landing technique on patients considered to be high risk for PJK/PJF who had poor bone quality or high levels of spinal deformity preoperatively. Although, according to the literature there are certain drawbacks; similar published cases report PJF in 1.4–35%

Table 2 Preoperative and surgical data stratified by proximal junctional angle

Proximal junctional angle	Total (n=39)	<10 (n=23)	≥10 (n=16)	P value
Staged	13 (33.3%)	5 (21.7%)	8 (50%)	0.135
Vertebroplasty	9 (23.1%)	7 (30.4%)	2 (12.5%)	0.357
Osteotomy				0.477
SPO	4 (10.3%)	2 (8.7%)	2 (12.5%)	
Multiple SPO	10 (25.6%)	5 (21.7%)	5 (31.2%)	
PSO	24 (61.5%)	16 (69.6%)	8 (50%)	
VCR	1 (2.56%)	0 (0%)	1 (6.25%)	
Length of stay	7.42 (±4.27)	7.48 (±4.79)	7.33 (±3.5)	0.915
Surgery approach				0.765
Anterior/posterior	27 (69.2%)	15 (65.2%)	12 (75%)	
Posterior	12 (30.8%)	8 (34.8%)	4 (25%)	
Estimated blood lose	1,483 (±740)	1,338 (±621)	1,691 (±863)	0.173
Intra-operative PRBC	2.82 (±2.04)	2.93 (±2.04)	2.67 (±2.09)	0.705
Surgery duration	554 (±141)	529 (±138)	591 (±142)	0.194
Below T6	29 (74.4%)	17 (73.9%)	12 (75%)	1
Posterior levels fused	10.3 (±2.78)	10.3 (±2.72)	10.4 (±2.94)	0.94
Anterior levels fused	1.96 (±0.71)	1.87 (±0.74)	2.08 (±0.669)	0.434
Number of hooks used	1.44 (±0.68)	1.39 (±0.58)	1.5 (±0.816)	0.651
Surgical complications	10 (25.6%)	6 (26.1%)	4 (25%)	1
Medical complications	17 (43.6%)	10 (43.5%)	7 (43.8%)	1
ALIF	27 (69.2%)	15 (65.2%)	12 (75%)	0.765

SPO, Smith Peterson osteotomy; PSO, pedicle subtraction osteotomy; VCR, vertebral column resection; PRBC, packed red blood cells; ALIF, anterior lumbar interbody fusion.

Table 3 Composition of hook constructs

Hook construct	Number of cases
1 supralaminar hook	21
1 transverse process hook	1
2 supralaminar hooks	7
2 transverse process hooks	3
1 supralaminar and 1 transverse process hook	1
1 supralaminar and 1 infra-laminar hook	1
1 supralaminar hook and 1 pedicle screw	2
1 transverse process hook and 1 pedicle screw	1
3 transverse process hooks and 1 supralaminar hook	1
1 supralaminar, 1 transverse process, and 1 infra-laminar hook	1

Table 4 Change in proximal junctional angle (PJA) and repeat surgery comparison

PJA (°)	Proximal junctional kyphosis repeat surgery categories			
	A: no repeat surgery	B: repeat surgery	C: extension of hardware	Total
1: <10°	51% (20/39)	8% (3/39)	0% (0/39)	59% (23/39)
2: 10–20°	18% (7/39)	13% (5/39)	7% (3/39)	38% (15/39)
3: >20°	0% (0/39)	0% (0/39)	3% (1/39)	3% (1/39)
Total	69% (27/39)	21% (8/39)	10% (4/39)	

Table 5 Average change in spinal parameters (preoperative-postoperative) stratified by change in proximal junctional angel at most recent follow up. Statistical analysis performed with Fischer *t*-test

Variables	PJA <10°	PJA >10°	P value
Sagittal vertical axis	74.5	66.5	0.352
Pelvic tilt	5.0	5.7	0.389
Pelvic incidence—lumbar lordosis mismatch	25.8	25.2	0.456
T1 pelvic angle	11.0	10.8	0.470

of cases (9,10,19). The difference between PJF and PJK highlights the importance of clinical outcomes as compared to radiographic outcomes. Although many of these patients had PJK as defined as PJA >10°, they did not meet the criteria for PJF, which is the more clinically relevant. A technique that has the potential to prevent reoperation warrants close inspection and further evaluation, as the complication rate following reoperation for ASD remains high.

In this paper we propose a new classification system to define the spectrum of PJK/PJK, which we call The Proximal Junctional Classification System. This system allows authors to more rigorously define PJK and PJF. The system stratifies patients based off of change in the UIV+2 and the type of repeat surgeries required. We felt that this system was necessary because patients often need to return to the OR but those return trips do not fall into the category of PJF. Many of these surgeries were outpatient surgeries that are not as difficult or time intensive as traditional PJF surgeries with an extension of the construct. According to this new classification system any patient with types 2 and 3 met the criteria for PJK. Finally, patients in group 2C and 3C met the traditional criteria for PJF. A full explanation of the system appears in the methods section. We propose that this new system will allow improved investigation, greater transparency, and clarity.

Several other surgical techniques have been proposed to help reduce the rates of PJK including utilization of cemented vertebroplasty, combined anterior and posterior approach, fusion constructs extending above T6, and the use of an ALIF. The use of vertebroplasty has demonstrated advantageous biomechanical properties but also leads to issues such as adjacent level collapse (20-24). A combined anterior and posterior approach was theorized to increase construct stability but failed to reduce the rates of PJK (25). Similarly, it was theorized that extending fusion constructs to the more rigid vertebral segments above T6 would help prevent PJK, but these results never met statistical significance (26). More recently, the use of ALIFs to restore overall alignment was thought to help reduce PJK but this technique also failed to achieve improvement (27). As has been concluded in several studies, our data demonstrated that these techniques did not have a significant effect on PJK or PJF.

The optimum number and combination of hooks utilized for the Soft Landing technique still needs to be identified. In our current cohort the average number of hooks was 1.5 in patients with PJK and 1.4 in patients who did not meet the criteria for PJK. The number of hooks utilized was determined intraoperatively and occasionally included a combination of pedicles screws and hooks. Ten different types of constructs were utilized in this case series, although the majority of cases (54%) utilized only 1 supralaminar hook. Establishing a framework for determining the optimal construct requires further investigation. It is the senior author's belief that the soft tissue landing may work best if the unilateral soft tissue sleeve is left intact for the two contiguous upper instrumented levels and that on the instrumented sides two hooks should probably be inserted. Future studies should focus on one variation of the fusion construct, with a specific number of hooks in a particular conformation in order to determine efficacy.

There are several limitations to this study, most notably the retrospective case series study design lacking a control group, modest follow-up, and diversity of the patient population and surgical techniques. Future studies should include longer follow-up, but we believe it is important to note that most cases of PJK occur within 3 months from surgery (4). Furthermore, as the study is a case series, there is no control group without the Soft Landing technique to compare our results to. Prospective controlled trials including a larger number of patients comparing traditional constructs to the novel Soft Landing technique, described here, will help to elucidate the benefits of reducing construct rigidity at the UIV in order to prevent PJK/PJF. Because of the study design, we are unable to draw conclusions from these data, but they provide evidence that Soft Landing warrants further investigation. Other limitations of this study included the diversity of the patient population. Over half of the patients (54%) had osteoporosis, which often complicates surgical procedures in the spine. Additionally, the Soft landing was not the index procedure for over half of the patients because 54% of patients were undergoing revision surgery. Finally, the variability in surgical technique demonstrates the need for a more rigorous algorithm for treatment. Twenty-seven of these patients had combined anterior/lateral and posterior approaches and 33% of these cases were staged between the two approaches. Several different hook constructs were included in this study as well, which limits its wider applicability until a definition of Soft Landing is formalized. Future studies should occur in a more uniform patient population with a specific approach, hook construct, use of interbody, and other variables determined prior to study inclusion.

PJK and PJF are well-reported complications following ASD surgery. A new classification system has been developed to describe different grades of PJK/PJF based on PJA and need for repeat surgery. The Soft Landing technique, described here, demonstrated a mean change in PJA of 8° with 23 patients experiencing a change of less than 10° (type 1). 10% of patients included in the study required revision surgery for PJF (type 2C and 3C) with a mean follow up of 813 days. Authors believe that this new classification system has enabled them to better categorize and treat PJK/PJF. Although further evaluation is required, the Soft Landing technique represents a potential and effective prevention strategy for PJK and PJF.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/jss-20-622

Data Sharing Statement: Available at http://dx.doi.org/10.21037/jss-20-622

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/jss-20-622). CS has stock ownership of Vertera Spine. VA is a paid consultant for Depuy, Zimmer, Nuvasive, Medtronic, and Camber. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of The University of Pennsylvania (#827321) and individual consent for this retrospective analysis was waived.

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