The unreimbursed costs of preventing revision surgery in adult spinal deformity: analysis of cost-effectiveness of proximal junctional failure prevention with ligament augmentation

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OBJECTIVE Proximal junctional kyphosis (PJK) is a well-recognized complication of surgery for adult spinal deformity and is characterized by increased kyphosis at the upper instrumented vertebra (UIV). PJK prevention strategies have the potential to decrease morbidity and cost by reducing rates of proximal junctional failure (PJF), which the authors define as radiographic PJK plus clinical sequelae requiring revision surgery.

METHODS The authors performed an analysis of 195 consecutive patients with adult spinal deformity. Age, sex, levels fused, upper instrumented vertebra (UIV), use of 3-column osteotomy, pelvic fixation, and mean time to follow-up were collected. The authors also reviewed operative reports to assess for the use of surgical adjuncts targeted toward PJK prevention, including ligament augmentation, hook fixation, and vertebroplasty. The cost of surgery, including direct and total costs, was also assessed at index surgery and revision surgery. Only revision surgery for PJF was included.

RESULTS The mean age of the cohort was 64 years (range 25–84 years); 135 (69%) patients were female. The mean number of levels fused was 10 (range 2–18) with the UIV as follows: 2 cervical (1%), 73 upper thoracic (37%), 108 lower thoracic (55%), and 12 lumbar (6%). Ligament augmentation was used in 99 cases (51%), hook fixation in 60 cases (31%), and vertebroplasty in 71 cases (36%). PJF occurred in 18 cases (9%). Univariate analysis found that ligament augmentation and hook fixation were associated with decreased rates of PJF. However, in a multivariate model that also incorporated age, sex, and UIV, only ligament augmentation maintained a significant association with PJF reduction (OR 0.196, 95% CI 0.050–0.774; $p = 0.020$). Patients with ligament augmentation, compared with those without, had a higher cost of index surgery, but ligament augmentation was overall cost effective and produced significant cost savings. In sensitivity analyses in which we independently varied the reduction in PJF, cost of ligament augmentation, and cost of reoperation by $\pm 50\%$, ligament augmentation remained a cost-effective strategy for PJF prevention.

CONCLUSIONS Prevention strategies for PJK/PJF are limited, and their cost-effectiveness has yet to be established. The authors present the results of 195 patients with adult spinal deformity and show that ligament augmentation is associated with significant reductions in PJF in both univariate and multivariate analyses, and that this intervention is cost-effective. Future studies will need to determine if these clinical results are reproducible, but for high-risk cases, these data suggest an important role of ligament augmentation for PJF prevention and cost savings.

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KEYWORDS spinal deformity; proximal junctional kyphosis; proximal junctional failure; cost-effectiveness

PROXIMAL junctional kyphosis (PJK) is a well-recognized complication in patients undergoing surgical correction for adult spinal deformity. It presents with abnormal kyphosis immediately above the upper instrumented vertebra (UIV) and is quantified by measuring

the sagittal Cobb angle between the inferior endplate of the UIV and the superior endplate of the second vertebral body above the UIV (UIV+2). The definition of PJK varies but is generally defined as an increase in kyphosis of more than 10° – 20° .^{8,10,16} We consider proximal junctional failure

ABBREVIATIONS BMP = bone morphogenetic protein; NNT = number needed to treat; PJF = proximal junctional failure; PJK = proximal junctional kyphosis; UIV = upper instrumented vertebra; UIV+1 = first vertebral body above the UIV; UIV+2 = second vertebral body above the UIV; UIV–1 = first vertebral body below the UIV.

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(PJF) to be radiographic evidence of PJK plus clinical sequelae that require revision surgery, including pain, neurological deficit, and impaired quality of life.^{9,23}

The causes of PJK/PJF are multifactorial and include age-related degeneration, poor bone quality, ligamentous fatigue, vertebral body fractures, instrumentation failure, and degenerative disc disease.^{1,2,8,23,26} Additional surgical risk factors include older age at the time of surgery,^{3,13,15,25} preoperative sagittal imbalance,^{16,17,19,20,30–32} increased curvature correction,^{16,17,30} and disruption of the facets and posterior ligamentous complex.^{3,13,17,20} Rates of PJK vary by report and definition, but generally range from around 20% to 40%.^{8,14,15,24,31,32} Most cases occur relatively early in the postoperative period, with 66% of cases observed in the first 3 months and 80% within the first 18 months.^{30,32}

Given the morbidity and cost associated with PJK/PJF, particularly surgical revision, PJK prevention strategies are increasingly important. Surgical adjuncts, such as vertebroplasty, ligament augmentation, hook fixation at the UIV, and careful rod contouring, have been used with varying success. These adjuncts often go unreimbursed by insurance companies, despite their potential for significant cost savings. In this study, we sought to determine the efficacy of surgical adjuncts for PJK and model the cost-effectiveness in a large population of patients with adult spinal deformity.

Methods

Data Collection

A series of 200 adult spinal deformity patients undergoing instrumented fusion were included in this study. Surgeries were performed from 2010 to 2017 at a single institution by 2 surgeons (V.D. and C.P.A.). Patient demographics and surgical characteristics, including age, sex, indication for surgery, number of levels fused, use of bone morphogenetic protein (BMP), vertebroplasty (Cortoss cement, Stryker), hook fixation at the UIV (for constructs terminating in the upper thoracic spine), ligament augmentation (LigaPASS cable, Medtronic), 3-column osteotomy, and pelvic fixation, were collected.

Vertebroplasty, performed by tapping the cannulated pedicle screw trajectories and filling them with thrombin-containing hemostatic matrix to occlude venous channels, was done at the UIV and UIV+1 in a subset of lower-thoracic constructs. Cement was then injected into the vertebral bodies with a volume of 3 ml at each entry site (6 ml per vertebral body). Ligament augmentation was performed in a subset of patients throughout the thoracic and lumbar spine at the UIV–1, UIV, and UIV+1 levels. This technique involves using a matchstick burr to drill through the center of the spinous processes at these levels and then passing a soft sublaminar cable through these holes in a mirrored fashion. The cable was pulled tight on each side by hand to allow testing of the exact tension desired and then fixed to the rod using supplied connectors. Spinous processes at these levels are loaded in slight extension to resist flexion at the terminal construct. Patients with neuromuscular or neurodegenerative disorders were excluded from analysis, and only patients with at least 6 months of follow-up were included. Only patients with data on total

and direct cost of index and revision surgeries were included. PJF was defined as PJK of greater than 10° plus clinical sequelae requiring revision surgery. Upper thoracic levels were defined as T1–6, and lower thoracic levels were defined as T7–12. All activities were approved by the Committee on Human Research, our institutional review board.

Statistical Analysis

Univariate analysis was performed using the chi-square test for categorical variables and the t-test for continuous variables. Binary logistic regression was used to generate a multivariate model that included all variables that were significant on univariate analysis plus those variables with known associations with PJF. Sensitivity analyses were performed by independently varying the cost of ligament augmentation, rate of PJF prevention, and cost of reoperation to determine if the intervention remained cost-effective under each of those scenarios. Statistical significance was defined as $p < 0.05$.

Cost Analysis

Total and direct hospital costs for each hospitalization were obtained from the hospital's accounting database and are reported in US dollars. Total costs include direct costs (e.g., imaging, medications, surgical supplies, hospital room) and indirect costs (such as administrative, facilities, and overhead fees not directly attributable to an individual patient). Of note, physician payments and noninstitutional costs incurred in the care of these patients (e.g., inpatient rehabilitation stay after discharge, outpatient physical therapy) are not available in our database and therefore not included in our calculations.

Cost-benefit analyses were performed by calculating the direct cost required for ligament augmentation in the index surgery versus the prevention of the cost of reoperation surgery. Sensitivity analyses were performed by independently varying the cost of ligament augmentation, rate of PJF prevention, and cost of reoperation by $\pm 50\%$ to determine if the intervention remained cost-effective under each of those scenarios.

Results

Patient Demographics

A total of 200 patients were identified; 5 were excluded due to lack of cost data, leaving 195 patients in our final analysis. The mean age was 64 years (range 25–84 years), and 135 patients (69%) were women. The mean number of levels fused was 10 (range 2–18). The UIV was cervical in 2 cases (1%), upper thoracic in 73 cases (37%), lower thoracic in 108 cases (55%), and lumbar in 12 cases (6%). Three-column osteotomies were used in 82 patients (42%). Pelvic fixation was used in 190 cases (97%). Surgical adjuncts were also quantified: ligament augmentation was used in 99 cases (51%), hook fixation at the UIV in 60 cases (31%), vertebroplasty in 71 cases (36%), BMP in 133 cases (68%), and 4-rod constructs with 3-column osteotomies in 78 cases (40%). PJF occurred in 18 cases (9%). The mean total cost of index surgery was $\$129,953 \pm \$32,177$ ($\$80,368 \pm \$19,882$ in direct cost). The mean cost

TABLE 1. Patient demographics and surgical characteristics

Variable	Value
No. of patients	195
Mean age in yrs (range)	64 (25–84)
Sex	
Male	60 (31)
Female	135 (69)
Surgical characteristic	
Mean levels fused (range)	10 (2–18)
UIV	
Cervical	2 (1)
Upper thoracic	73 (37)
Lower thoracic	108 (55)
Lumbar	12 (6)
3CO	82 (42)
Pelvic fixation	190 (97)
Surgical adjuncts	
Ligament augmentation	99 (51)
Hook fixation at UIV	60 (31)
Vertebroplasty	71 (36)
BMP	133 (68)
4-rod construct w/ 3CO*	78 (40)
PJF	18 (9)
Mean cost	
Primary surgery	
Direct cost	\$80,368 ± 19,882
Total cost	\$129,953 ± 32,177
Revision surgery for PJF	
Direct cost	\$119,217 ± 94,212
Total cost	\$193,277 ± 152,613
Mean FU duration in mos (range)	22 (6–78)

3CO = 3-column osteotomy; FU = follow-up.

Values are presented as the number of patients (%) unless stated otherwise.

* The 4-rod construct was used in 40% of all patients and 95% of patients who underwent 3-column osteotomy (78 of 82).

of the revision surgery was \$193,277 ± \$152,613 (\$119,217 ± \$94,212 in direct cost). The mean length of follow-up was 22 months (range 6–78 months). These data are summarized in Table 1.

Statistical Analysis of PJF Rates

The effect of individual PJF prevention techniques was first assessed by univariate analysis. Ligament augmentation was associated with a 4% rate of PJF (4 of 99), compared with 15% (14 of 96) in patients without ligament augmentation ($p = 0.011$). Hook fixation at the UIV was associated with a PJF rate of 2% (1 of 60), compared with 13% (17 of 135) in those without ($p = 0.014$). Neither vertebroplasty nor BMP was associated with reduced rates of PJF ($p = 0.819$ and $p = 0.498$, respectively). These data are summarized in Table 2.

Since hook fixation is only used in upper thoracic con-

TABLE 2. PJF rates with surgical adjuncts

Surgical Adjunct	Rate of PJF w/ Intervention	Rate of PJF w/o Intervention	p Value
Ligament augmentation	4/99 (4)	14/96 (15)	0.011
Hook fixation	1/60 (2)	17/135 (13)	0.014
Vertebroplasty	7/71 (10)	11/124 (9)	0.819
BMP	11/133 (8)	7/62 (11)	0.498

structs and vertebroplasty in lower thoracic constructs, we generated a multivariate model to control for other important confounders, including age, sex, and UIV, since hook fixation is only used in upper thoracic levels. In this multivariate model, only ligament augmentation was significantly associated with a reduction in PJF (OR 0.196, 95% CI 0.050–0.774; $p = 0.020$). Age, sex, UIV, and hook fixation were not associated with a reduction in PJF. Results of multivariate analysis are summarized in Table 3.

Given the role of ligament augmentation in PJF prevention, we compared demographics, surgical characteristics, and both total and direct costs between patients who received ligament augmentation and those who did not. Age was significantly older in the ligament augmentation group (66 vs 63 years, $p = 0.025$), as were the number of levels fused (11 vs 10 levels, $p = 0.043$). The UIV did not significantly differ with respect to upper and lower thoracic constructs; however, there were more lumbar UIVs in the group without ligament augmentation (11% vs 1%, $p = 0.002$). We compared the UIV in patients with and without ligament augmentation who developed PJF. In the group with ligament augmentation, 4 patients developed PJF. The UIV levels in these patients were as follows: 1 at C-7 and 3 at T-10. In the group without ligament augmentation, the UIV levels were as follows: 3 each at T-10 and T-12, 2 each at T-11 and L-1, and 1 each at T-3, T-4, T-9, and L-2.

Rates of PJF were lower in the ligament augmentation group (4% vs 15%, $p = 0.011$), but the mean follow-up was also shorter in the ligament augmentation group (16 vs 29 months, $p < 0.001$). The cost of index surgery was significantly higher for patients with ligament augmentation, and the cost of revision surgery for patients with ligament augmentation was notably lower; however, the difference did not reach statistical significance. These data are summarized in Table 4.

TABLE 3. Multivariate analysis of variables associated with PJF

Variable	OR (95% CI)	Significance (p value)
Age	1.038 (0.979–1.100)	0.216
Female sex	2.301 (0.603–8.780)	0.223
UIV		
Upper thoracic	1.000 (reference)	0.365
Lower thoracic	3.217 (0.467–22.157)	0.235
Lumbar	5.096 (0.526–49.363)	0.160
Ligament augmentation	0.196 (0.050–0.774)	0.020
Hook fixation	0.544 (0.034–5.894)	0.544

TABLE 4. Comparison of patients with and without ligament augmentation

Variable	w/ Ligament Augmentation (n = 99)	w/o Ligament Augmentation (n = 96)	p Value
Mean age in yrs	66	63	0.025
Female sex	67 (68)	68 (71)	0.633
Surgical features			
Mean no. of levels fused	11	10	0.043
UIV			
Cervical	1 (1)	1 (1)	0.983
Upper thoracic	42 (42)	31 (32)	0.144
Lower thoracic	55 (56)	53 (55)	0.961
Lumbar	1 (1)	11 (11)	0.002
Hook fixation	42 (42)	18 (19)	<0.001
Vertebroplasty	47 (47)	24 (25)	0.001
3CO	39 (39)	43 (45)	0.445
Pelvic fixation	97 (98)	93 (97)	0.626
PJF	4 (4)	14 (15)	0.011
Mean cost			
Primary op			
Direct cost	\$85,449 ± 17,504	\$75,128 ± 20,893	<0.001
Total cost	\$139,131 ± 27,842	\$120,488 ± 33,711	<0.001
Reop			
Direct cost	\$74,586 ± 23,606	\$131,968 ± 103,395	0.296
Total cost	\$122,661 ± 41,246	\$213,453 ± 167,607	0.308

Values are presented as the number of patients (%) unless stated otherwise.

Cost-Benefit Analysis

We then performed a cost-benefit analysis for ligament augmentation in the prevention of PJF. Specifically, we compared the cost of ligament augmentation in the index case (\$1100) versus the cost of reoperation for PJF (\$119,217). Since ligament augmentation produced a 10.5% reduction in the rate of PJF in our patient cohort, we calculated that 9.5 patients had to receive ligament augmentation in their index surgery in order to prevent 1 reoperation for PJF (this is the number needed to treat [NNT]). This means that we spent \$10,450 for ligament augmentation upfront in 9.5 patients in order to prevent a \$119,217 revision surgery in 1 patient. Scaled to a theoretical cohort of 100 patients receiving ligament augmentation, the estimated savings would be \$1,144,916.

To assess the robustness and generalizability of our results, we performed sensitivity analyses for the cost-benefit of ligament augmentation for PJF prevention. The value of each parameter (PJF reduction rate, cost of ligament augmentation, and cost of reoperation) was independently varied by ± 50%. At baseline, \$108,767 was saved by using ligament augmentation upfront to prevent reoperation for PJF. The use of ligament augmentation remained cost-effective, with savings per 100 patients ranging from \$515,889 to \$1,772,374, in all variations. These data are summarized in Table 5.

Given that different hospitals have various implant prices, we performed a continuous sensitivity analysis for ligament augmentation implant price (Fig. 1). The threshold price under which ligament augmentation remained

cost-effective in preventing PJF was \$12,549, which is a significant increase from the price currently negotiated at our center (\$1100) and more than the cost difference between patients with and without ligament augmentation (\$11,035).

Discussion

Prevention strategies for PJK/PJF are of increasing importance in adult spinal deformity. In addition to the significant morbidity and clinical impact on patients, the cost of revision surgery carries a significant economic impact.¹⁸ Reducing rates of PJF therefore has the potential to produce significant cost savings.²⁹ Several techniques believed to reduce the risk of PJK/PJF include extending fusion constructs to include levels with baseline segmental kyphosis of more than 5°, using composite metals with greater flexibility, minimizing the destruction of soft tissue at the UIV, achieving optimal spinal balance post-operatively, and using transition rods.^{2,4,5,8,19,20} The use of hook fixation at the UIV, as shown in our data, is also associated with decreased rates of PJK/PJF. This technique provides a theoretical advantage since the hooks require less violation of the facet joint and provide more dynamic fixation at the top of the construct.^{10,12,16} Several studies have compared PJK rates in patients with spinal hooks to those with pedicle screws at the UIV; rates of PJK in those with hooks ranged from 0% to 30%, compared with 30% to 35% in those with pedicle screw constructs.^{10,16}

Our clinical practice has evolved over the past 5 years,

TABLE 5. Sensitivity analysis for cost-benefit analysis of ligament augmentation for PJF prevention (direct costs)

Parameter	Cost of Reop	NNT	Cost of LA	Cost to Prevent Single PJF	Cost Savings w/ LA Per 100 Pts
Base case	\$119,217	9.5	\$1,100	\$10,450	\$1,144,916
Varied parameters					
Reduction in PJF					
5.25%	\$119,217	19.0	\$1,100	\$20,952	\$515,889
15.75%	\$119,217	6.3	\$1,100	\$6,984	\$1,767,668
Cost of LA					
\$550	\$119,217	9.5	\$550	\$5,225	\$1,199,916
\$1650	\$119,217	9.5	\$1,650	\$15,675	\$1,089,916
Cost of reop					
\$59,609	\$59,609	9.5	\$1,100	\$10,450	\$517,458
\$178,826	\$178,826	9.5	\$1,100	\$10,450	\$1,772,374

LA = ligament augmentation; pts = patients.

with PJF prevention becoming a significant priority for all deformity cases.²⁸ Since the proposed mechanism of PJK in the upper thoracic spine is ligamentous fatigue, we use hook fixation at the UIV for all constructs terminating at those levels. We also introduce terminal kyphosis into the rod so it is never forced into place, which prevents additional loading forces to the construct and minimizes the risk for screw pullout or junctional stress. For constructs terminating in the lower thoracic spine, we perform vertebroplasty at the UIV and UIV-1 levels since failures at the thoracolumbar spine are often due to fractures. We use ligament augmentation in all cases, as it is an emerging strategy for PJF prevention. The goal of this technique is to reinforce the junction between the UIV and adjacent noninstrumented vertebrae while minimizing facet joint violation.²⁷ Our data indicate that this strategy is highly effective in reducing the rate of PJF after surgery for adult spinal deformity, producing a 10.5% reduction in PJF in

patients with ligament augmentation compared with those without ligament augmentation.

Prior studies have demonstrated that readmissions and reoperations in patients with adult spinal deformity are associated with a significant increase in costs and reduction in the cost-effectiveness of deformity correction.^{6,22,29} Reoperations for PJF often require large surgeries with extension of instrumentation, making PJF a particularly costly complication. In this context, our analysis suggests that the use of ligament augmentation is highly cost-effective. Implant costs associated with ligament augmentation total approximately \$1100, or 1.4% of the direct cost of the primary surgery. Given the NNT of 9.5, the cost of preventing 1 reoperation is \$10,450, which is \$108,767 less than the mean cost of a reoperation for PJF. The potential cost savings are thus substantial. Recent estimates suggest that rates of patients undergoing fusion for adult spinal deformity are increasing, with 6728 cases in 2013 at a rate

FIG. 1. Sensitivity analysis of ligament augmentation price. When varying the price of ligament augmentation, the intervention remains cost-effective as long as the price is less than \$12,549. The current negotiated price at our center is \$1100.

of 13.9 per 100,000 adults per year in the United States.³³ Based on an NNT of 9.5, ligament augmentation has the potential to prevent 10.5 reoperations per 100 patients with a savings of over \$1.25 million. When scaled to 6728 cases annually, this results in a savings of over \$84 million per year. Although not all of these cases are large deformity corrections that are generalizable to the population included in this study, even a conservative estimate using one-third of all deformity corrections (approximately 2241 patients per year), would result in a savings of over \$28 million annually by using ligament augmentation in primary index surgeries for deformity.

Direct costs associated with the primary surgery, ligament augmentation, and reoperation for PJF are likely to vary by center based on negotiated prices with implant manufacturers and other determinants of surgical cost, including patient factors, surgeon preferences, hospital practices, and regional variability.^{6,7,11,21,22} Along similar lines, a relative paucity of data exists regarding the reduction in PJF produced by ligament augmentation,²⁷ and it is possible that the reduction in PJF achieved with ligament augmentation may vary as this technique is adopted at other centers. Our sensitivity analysis indicates that even if ligament augmentation produced half the reduction in PJF we observed at our institution, it would still be highly cost-effective in these settings.

There are certain limitations to the present study that are inherent to its retrospective design, such as selection bias and moderate sample size. Although this was a cohort of purely adult spinal deformity patients, they were not randomized to PJF prevention strategy or surgical plan. The retrospective design also limits the ability to control for confounding variables such as bone mineral density scores or other clinical factors that can contribute to increased risk of PJF. This study design also limits our ability to capture postoperative events, including revision surgery, since patients were not included in a prospective cohort where adverse events or revision surgeries are more completely captured. These cohorts have some inherent heterogeneity since ligament augmentation is a more recent technique. Our practice pattern has evolved in a fluid manner, so that patients who underwent ligament augmentation were also more likely to have hook fixation (for constructs terminating in the upper thoracic spine), vertebroplasty (for constructs terminating in the lower thoracic spine or thoracolumbar junction), BMP, and gentle contouring of the rods, which could not be retrospectively assessed. The use of these additional surgical adjuncts helps explain the nearly \$10,000 difference in the direct cost of primary surgery in the ligament augmentation group compared with the group without ligament augmentation, since the price of ligament augmentation alone is only \$1100. We utilized a multivariate model to help control for these differences, but future studies should utilize an entirely contemporary cohort across multiple centers to determine the reproducibility of these data. In addition, it is important to note that our cost data do not include outpatient costs, such as physical therapy or rehabilitation. We would expect that PJF reoperation costs also including outpatient costs would be even higher than those calculated here, making ligament augmentation even more cost-effective for these patients.

Conclusions

Ligament augmentation is a novel strategy for PJK/PJF prevention. Even when controlling for age, sex, UIV, and use of other surgical adjuncts, ligament augmentation continues to demonstrate a significant reduction in PJF and the need for revision surgery. Using sensitivity analysis, we showed that even dramatic variations in the reduction of PJF rates, cost of ligament augmentation, and cost of reoperation do not change the significant cost-effectiveness of this treatment. Future studies will need to determine if these data are reproducible in large cohorts of adult spinal deformity patients and control for other important confounders including bone mineral density. However, given the current cost of ligament augmentation and relative ease of implementing this strategy in the operating room, this technique warrants consideration for all adult spinal deformity cases, particularly for patients at high risk for PJK/PJF.

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Conception and design: Deviren, Ames. Acquisition of data: Safaee, Dalle Ore, Zygourakis. Analysis and interpretation of data: Safaee, Dalle Ore, Zygourakis, Ames. Drafting the article: Safaee, Dalle Ore. Critically revising the article: Safaee, Dalle Ore, Zygourakis, Ames. Reviewed submitted version of manuscript: Safaee, Dalle Ore, Ames. Approved the final version of the manuscript on behalf of all authors: Safaee. Statistical analysis: Safaee, Dalle Ore. Administrative/technical/material support: Deviren, Ames.

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