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Authors
Rodnoi, Pope
Le, Hai
Hiatt, Luke
et al.

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Corresponding Author
Eric O. Klineberg
https://orcid.org/0000-0003-1408-106X

Department of Orthopedic Surgery, University of California, Davis, 4860 Y Street, Suite 3800, Sacramento, CA 95817, USA
Email: eoklineberg@ucdavis.edu

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Ligament Augmentation With Mersilene Tape Reduces the Rates of Proximal Junctional Kyphosis and Failure in Adult Spinal Deformity

Pope Rodnoi, Hai Le, Luke Hiatt, Joseph Wick, Joshua Barber, Yashar Javidan, Rolando Roberto, Eric O. Klineberg

Department of Orthopedic Surgery, University of California, Davis, Sacramento, CA, USA

Objective: To investigate prevention of proximal junctional kyphosis (PJK) and failure (PJF) following adult spinal deformity (ASD) surgery utilizing a novel technique of posterior ligament augmentation with polyester fiber tether.
Methods: This study evaluated ASD adult patients who underwent posterior decompression and instrumented fusion from the thoracolumbar junction (T9–L1) to the pelvis from 2011–2017. Basic demographic data were obtained. Radiographic outcomes included proximal junctional angle (PJA), sagittal vertical axis, PJK, and PJF. The study population was divided into patients who had ASD surgery with and without ligamentous augmentation.
Results: A total of 43 subjects were evaluated, including 20 without and 23 with ligamentous augmentation. PJA increased over time for both groups. PJA was smaller for the augmented group, and rate of increase in PJA was slower in the augmented group ($p < 0.0001$). The rate of PJK was significantly higher in the nonaugmented group ($p = 0.01$). PJF was significantly less common in the augmented group ($p = 0.003$). Time to revision surgery was lower in the nonaugmented group ($p = 0.003$).
Conclusion: Our novel ligament augmentation technique utilizing polyethylene tape is an effective technique to slow progression of the PJA and lower the risk for proximal junctional disease in ASD surgery.

Keywords: Adult spinal deformity, Adjacent segment disease, Proximal junction disease, Proximal junctional kyphosis, Proximal junctional failure, Proximal junctional angle

INTRODUCTION

Patients with thoracolumbar adult spinal deformity (ASD) present with significant pain and disability as they expend supraphysiologic energy to maintain their global alignment.[1,2] Many patients require major spinal reconstructive surgery to correct their coronal and sagittal balance.[2] Surgery greatly improves quality of life and health status,[3] yet poses significant complication risks,[4] with complication rates as high as 69.8%.[5] Proximal junctional disease (PJD), including proximal junctional kyphosis (PJK) and proximal junctional failure (PJF), is a major delayed complication of ASD surgery.[4-8] PJK typically occurs within 2 years of surgery, with rates ranging from 17% to 39%.[9] Radiographic PJK can progress to PJF, necessitating revision surgery for hardware failure, vertebral body fracture, neurologic injury, and/or pain and disability.[7,8] Rates of progression to PJF range between 1.4%–5.6%.[10,11]

Substantial efforts in ASD research have focused on PJD prevention and treatment. Multiple risk factors have been identified and prevention strategies proposed.[8] Specifically, one of the major PJD risk factors is instrumentation rigidity at the upper instrumented vertebra (UIV). Sudden transition from a rigid posterior spinal instrumented fusion construct to flexible noninstrumented vertebrae places significant mechanical stress on the UIV and its adjacent vertebrae. Over time, this predisposes the transition zone to PJD. Many techniques have been developed to lessen instrumentation rigidity and suddenness of transition at the UIV, including use of hook fixation, transition rods, and ligament augmentation.[8,12,13] Since 2016, we have performed ligament augmentation at the level above the UIV (UIV+1) for all ASD surgeries using a braided, nonabsorbable 5-mm suture made of polyethylene-terephthalate polyester fiber tape (Mersilene, Ethicon, Somerville, NJ, USA) tensioned over a crosslink. Herein, we describe our technique and evaluate the rates of PJK and PJF following ASD surgery with and without ligament augmentation.

MATERIALS AND METHODS

1. Patient Enrollment

This study received approval from the Institutional Review Board (IRB) of University of California, Davis (approval number: 1156618-1). Since this was a retrospective study with no direct patient interaction, informed consent was exempted. After IRB approval was obtained, patients ≥ 18 years who had undergone posterior decompression and instrumented fusion from the thoracolumbar junction (T9–L1) to the pelvis for ASD between 2011 to 2017 were identified in a single-center ASD database. The minimum follow-up was 2 years. All patients underwent surgery by the senior author. The study population was divided into patients who had ASD surgery without ligamentous augmentation (nonaugmented group) versus with ligamentous augmentation (augmented group). Patients who underwent surgery between 2011 and 2015 were part of the nonaugmented group whereas patients who underwent surgery between 2016 and 2017 were part of the augmented group. The study's sample size was calculated based on previously published studies on the incidence of PJF in augmented versus nonaugmented cohorts. Two independent study groups were used, and the primary endpoint was dichotomous (i.e., was there PJF or

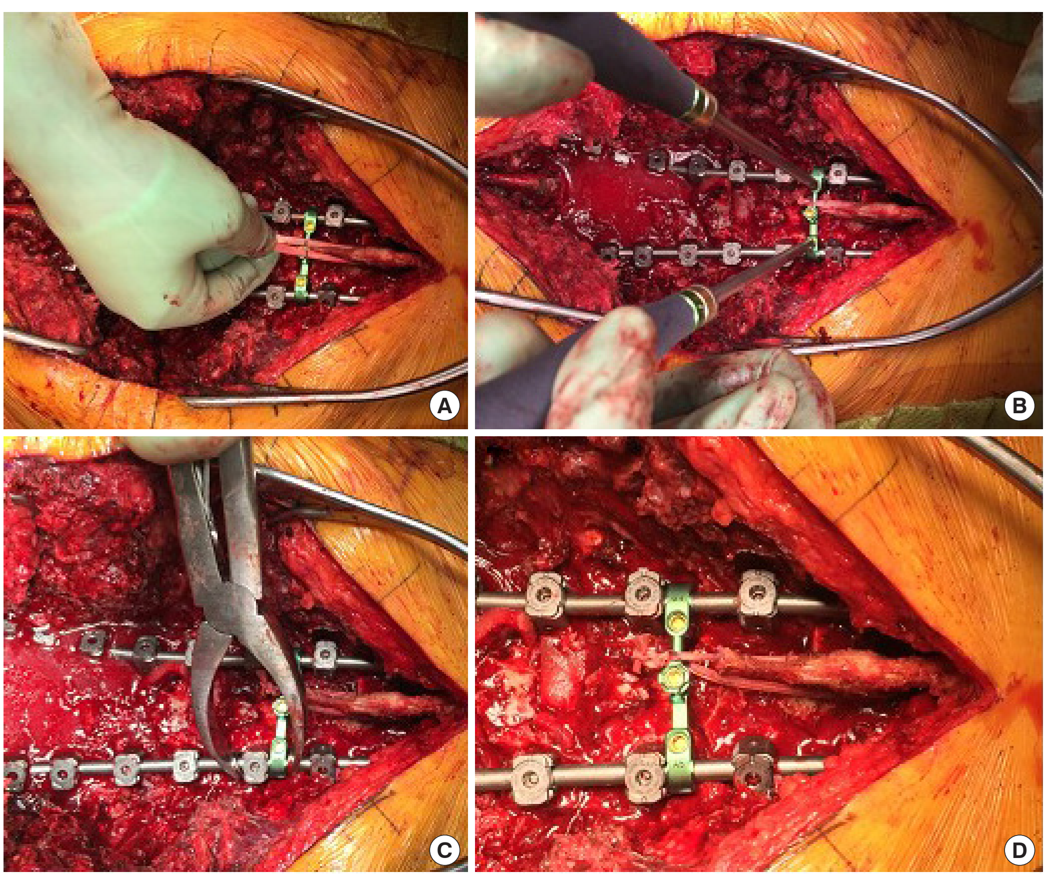

Fig. 1. Intraoperative photos demonstrating ligament augmentation. (A) Polyethylene suture tape is passed through base of spinous process of UIV+1 and appropriate length is measured and marked. (B) Tape is tied around crosslink and ends cut. (C) Compression through crosslink is performed to tension tape. (D) Final tightening of crosslink is performed.

not), with alpha set at 0.05 and power set at 0.80. The number of patients required to detect statistically significant differences was calculated to be 154 patients, or 77 patients in each cohort.

2. Surgical Technique

Ligament augmentation (Fig. 1) was performed after completion of posterior decompression and instrumented posterolateral spinal fusion. First, the base of the UIV+1 spinous process was exposed, taking care to not violate the posterior ligamentous complex and paraspinal musculature. A sharp towel clamp was used to create a hole across the base of the spinous process, through which the polyester tape was passed. The ends of the tape were marked, cut, and securely tied over a crosslink such that the crosslink would be positioned between the spinous processes of the UIV and UIV-1 after final tensioning. After crosslink insertion on the rods, a compressor was used to appropriately tension the tape, and the crosslink was final-tightened. A UIV hook was not used on patients in the ligamentous augmentation group. As PJK is a result of flexion deforming forces, we tension enough to maintain neutral alignment between the spinous processes of the UIV and UIV+1. In our experience, tensioning the tape by compressing the crosslink provides greater force and is more reliable than tensioning by knot tying alone. At present, we do not have a reliable way to objectively measure the amount of tension force on the tether.

3. Covariates and Data Collection

Demographic data, including age, sex, and body mass index, as well as operative data, including anterior fusion and 3-column osteotomy, were collected. The proportion of patients with preoperative diagnosis of osteoporosis was also determined for each cohort. Radiographic parameters were measured on full-length standing scoliosis films obtained at the preoperative, immediate postoperative, 6-week, 3-month, and 24-month postoperative timepoints. Radiographic parameters included sagittal Cobb proximal junction angle (PJA), sagittal vertical axis (SVA), lumbar lordosis (LL), and pelvic incidence. PJA was defined as the sagittal Cobb angle of the UIV+1 superior endplate and the UIV inferior endplate. PJK was defined as PJA $\geq 10°$ and at least 10° greater than the preoperative angle. The primary clinical outcome of interest was PJF, defined as need for revision surgery for PJD including symptomatic PJK and fracture or hardware failure at the UIV or its adjacent vertebrae. In our study, PJF included ligamentous failure, bone failure (fracture), and implant/bone interface failure (hardware fracture, hook pull-out).

4. Statistical Analysis

Two-sample t-tests were used to compare quantitative variables between cohorts. Chi-square tests and Fisher exact tests were used to compare categorical variables. A linear mixed-effect model was used to model PJA versus main effects for each group (augmented vs. nonaugmented), time in days since surgery, and the interaction between groups and the time terms. Several functional forms for the relationship between PJA and time were considered, including a logarithmic term. Models were compared based on Akaike Information Criteria (AIC). For the logarithmic time value, 0.1 was added to days since surgery because the logarithm of 0, which was the baseline time of surgery, is undefined. A random intercept was included for each subject to account for correlation of values within the same subject. The trajectory of SVA values over time was similarly analyzed. Kaplan-Meier survival curves were constructed for time to revision surgery and compared using a log-rank test. Statistical analyses were performed using R version 3.4.0 (R Foundation for Statistical Computing, Vienna, Austria), and PROC MIXED in SAS 9.4 (SAS Institute Inc., Cary, NC, USA). All hypothesis testing was 2-sided based on a significance level of 0.05.

RESULTS

1. PJA and PJK

A total of 43 subjects were evaluated, including 20 patients without and 23 with ligament augmentation. Patient characteristics and demographics did not differ significantly between the groups (Table 1). In our study, 3 of 20 (15%) of nonaugmented patients had documented osteoporosis, while 7 of 23 (30%) of augmented patients had documented osteoporosis. In the nonaugmented group, 2 of the patients with osteoporosis required revision surgery during the 2-year follow-up period. In the augmented group, none of the patients with osteoporosis required revision surgery during the 2-year follow-up period. The UIV for the augmented group was between T9–L1, while the UIV for the nonaugmented group was between T9–12. Preoperative PJA was lower in the augmented group but not statistically significant. Preoperative SVA was significantly higher in the augmented group ($p = 0.001$).

The best-fitting model for PJA based on AIC values was the logarithmic model. Predicted trajectories with each model and observed PJA are shown in Fig. 2. The PJA changed significantly over time, and the trajectories differed between the 2 groups ($p < 0.0001$). Parameter estimates showed the augmented group changed less than the nonaugmented group ($p < 0.0001$). Fig. 2

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Table 1. Patient baseline preoperative characteristics

Characteristic	Nonaugmented (n = 20)	Augmented (n = 23)	p-value
Female sex	13 (65)	15 (65.2)	1.00
Age (yr)	68.0 ± 5.8	69.1 ± 6.7	0.57
Body mass index (kg/m²)	27.4 ± 5.5	28.4 ± 6.0	0.58
Anterior procedure	2 (10)	1 (4)	0.59
3-Column osteotomy	3 (15)	2 (8.7)	0.65
Pelvic incidence (PI)	56.1 ± 10.0	58.8 ± 11.8	0.42
Delta lumbar lordosis (LL)	16.6 ± 15.1	24.0 ± 14.0	0.11
Preoperative PI–LL	-0.2 ± 9.8	3.2 ± 6.1	0.19
Preoperative PJA	5.2 ± 4.8	3.0 ± 6.4	0.21
Preoperative SVA	44.8 ± 31.6	88.1 ± 50.7	0.001

Values are presented as number (%) or mean ± standard deviation.
PJA, proximal junctional angle; SVA, sagittal vertical axis.

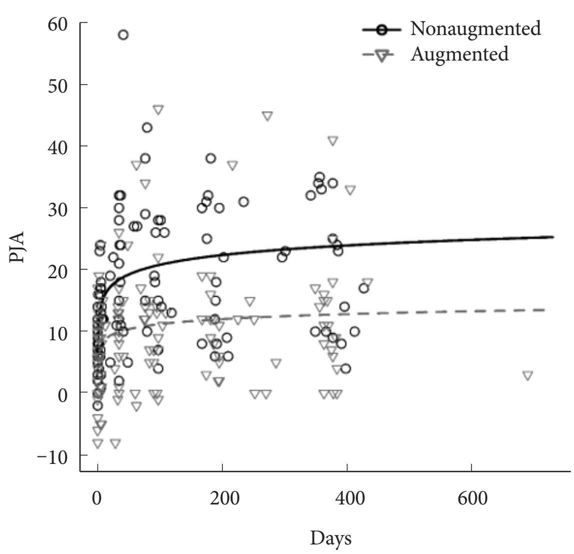

Fig. 2. Observed (specific data points) and predicted (logarithmic curves) proximal junctional angle (PJA) over time by group assuming a logarithmic relationship between PJA and days since surgery. Grey indicates the augmented group while black indicates the nonaugmented group.

illustrates the pattern of changes in PJA deviation from baseline over time for the 2 groups under the fitted model. While PJA increased over time for both groups, on average, the PJA was smaller for the augmented group, and rate of increase in PJA was slower in the augmented compared to the nonaugmented group ($p < 0.0001$). The rate of PJK was significantly higher in the nonaugmented group (17 of 20 patients, 85%) compared to the augmented group (10 of 23 patients, 43.5%) ($p = 0.01$). The median UIV for PJK in the nonaugmented group was T10. The median UIV for PJK in the augmented group was T11.

Table 2. Patient surgical characteristics and outcomes

Outcome	Nonaugmented (n = 20)	Augmented (n = 23)	p-value
Postoperative SVA	40.6 ± 42.4	51.3 ± 40.0	0.4
Revision surgery within 2 years of surgery	7	0	0.003
Mean time to revision surgery (day)	462.9	N/A	0.003
Fracture	5	3	-
Symptomatic PJK	1	0	-
Hook pull-out	7	0	-

Values are presented as mean ± standard deviation or number.
SVA, sagittal vertical axis; PJK, proximal junctional kyphosis; N/A, not applicable.

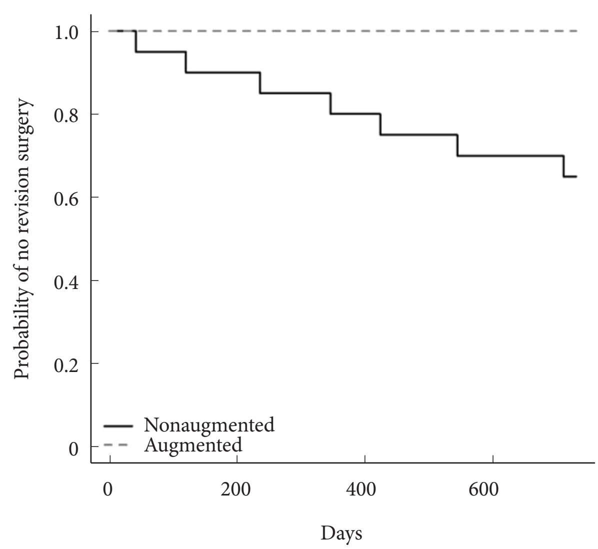

Fig. 3. Kaplan-Meier survival curves for time to revision surgery for augmented and nonaugmented groups.

2. Proximal Junctional Failure

PJF was significantly less common in the augmented group (0 of 23 patients, 0%) than the nonaugmented group (7 of 20 patients, 35%) ($p = 0.003$) as shown in Table 2. This resulted in the nonaugmented group having 7 revision surgeries within the first 2 years due to fracture, hook pull-outs, or symptomatic PJK. Kaplan-Meier curves were generated for time to revision surgery for each group (Fig. 3), and a log-rank test was performed to compare times between groups. Time to revision surgery differed significantly between the 2 groups ($p = 0.003$).

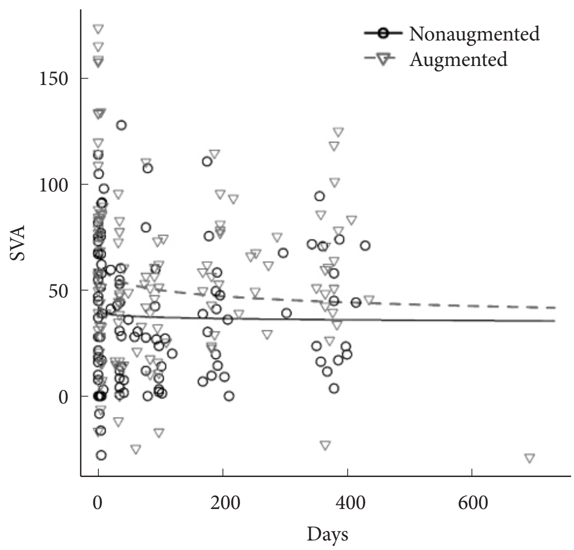

Fig. 4. Observed (specific data points) and predicted (logarithmic curves) sagittal vertical axis (SVA) over time by group assuming a logarithmic relationship between SVA and days since surgery. Grey indicates the augmented group while black indicates the nonaugmented group.

3. SVA Over Time

The best-fitting model for SVA based on AIC values was the logarithmic model (AIC of 1,619.8). The logarithmic model best represented the original data in regard to explaining the greatest amount of variation in our dataset. Predicted trajectories with each model and observed SVA are shown in Fig. 4. SVA values did not change significantly over time in the nonaugmented group ($p=0.61$) or in the augmented group ($p=0.20$). Preoperatively, SVA was significantly higher in the augmented group ($p<0.0001$). Postoperatively, SVA was not significantly different between the groups (Table 2).

DISCUSSION

In this study, we compared rates of PJK, PJF, and SVA over time, as well as need for revision surgery, between patients who underwent surgical correction of ASD both with and without posterior ligament augmentation with a novel polyethylene tape technique. Patients who underwent augmentation were found to have a significantly slower increase in PJA and significantly lower rate of PJK. Similarly, development of PJF was significantly lower, and time to revision surgery was significantly longer amongst patients who underwent augmentation.

Results of this study suggest that our novel technique may be employed to successfully reduce rates of PJD, in turn reducing the need for revision surgery. The benefits of decreasing revision rates following ASD surgery include avoiding the morbidity and costs associated with additional surgical procedures.[14] Additionally, ligament augmentation slows the progression of the PJA such that patients who go on to develop PJK typically develop it much later than patients who are not augmented. It is important to note that the only significant difference between the 2 cohorts in our study was the preoperative SVA, with the augmented group having a greater preoperative SVA. However, the degree of sagittal imbalance did not impact the need for anterior procedures or 3-column osteotomies, and no significant difference was noted in the postoperative SVA. Furthermore, while the augmented group had higher baseline SVA, the development of PJF was lower in this cohort, which further supports the advantage of ligament augmentation.

Our results are consistent with previous studies, which have shown that disruption of the posterior soft tissues in ASD surgery is a major risk factor for PJD.[7,15-17] These results have led to the relatively new technique of ligamentous augmentation. In cadaveric models, violation of the posterior soft tissue structures has been shown to destabilize the posterior column and decrease thoracic motion segment flexion stiffness.[18] Therefore, the objective of ligament augmentation is to reproduce the tethering effect of the posterior ligamentous structures, specifically the interspinous and supraspinous ligaments. In theory, ligament augmentation helps maintain flexion stability, thereby reducing PJD risk.[19]

Ligament augmentation can be achieved with various tethering materials and techniques. Overall, we found higher rates of PJK in both the nonaugmented (85%) and augmented (43.5%) cohorts compared to prior published studies.[12,20] Zaghloul et al.[13] were among the first to describe check-rein strap stabilization using Mersilene tape. However, their application was slightly different from ours. In their technical description, the authors placed the tape above or through the spinous process of the UIV+1 and made a figure of 8 loop under the spinous process of the UIV. The tape was then passed under the rods or around a crosslink, and the ends were subsequently tied together.[13] They reported no development of PJD in their series of 18 patients at a mean follow-up of 11.9 months (range, 2–31 months).[13] In a follow-up study from the same group, the rate of PJK at 2 years was lower with polyethylene tape stabilization compared to the matched control cohort (15% vs. 38%, $p=0.04$).[20] Their results suggest that ligament augmentation lowers, but does not eliminate the risk for PJD. Similarly, Safaee et al.[12] reported their experience tensioning soft sublaminar cables through the spinous processes and anchoring them to rods using special connectors.

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Surgical nylon tape and semitendinosus allograft have also been used to reinforce the posterior ligamentous structures.[21,22] Similar to our results, Rodriguez-Fontan et al.[20] reported an increased latent period to development of PJD of 20 months in an augmented cohort, compared to 7.5 months in the control group ($p = 0.018$).

This study is not without limitations. First, this study was a retrospective review of patients treated by a single surgeon at a single institution, which limits generalizability. Our study populations were small and therefore underpowered, potentially predisposing our statistical analyses to type II error. Additionally, there was no "washout period" between the change in practice between groups when the tether technique was introduced. The senior author transitioned directly from using a nonaugmented technique to using an augmented technique in 2016. Indeed, an initial surgeon learning curve associated with implementing the tethering technique may have biased results to show a lesser effect size of the tethering technique described in the latter group. A period of time between the 2 treatment options may have reduced a "carryover" effect, or at least provided enough experience with the technique to demonstrate a greater effect size, which may be expected after the surgeon has gained more experience with the technique. Although there was no transition period between cohorts, these were consecutive patients and there was no self-selection for treatment. Once switched to ligamentous augmentation, all patients received ligamentous augmentation. Moreover, T12 and L1 are often avoided as choices for the UIV as they tend to be located at the transition from thoracic kyphosis to LL. Overall, only 2 patients from the augmented group developed PJK at these UIV positions so this should not take away from our results. Moreover, this should not affect the interpretation of the results as patients in the nonaugmented group had UIV ranges between T9–12.

Additionally, the patient cohorts had different preoperative SVAs. Greater baseline SVA, reflecting greater baseline deformity in the augmented group, may have masked the effect size of the tethering, as patients with greater baseline deformity may be at increased risk of developing PJD.[23] If preoperative SVAs were similar, there likely would be a greater effect seen in this study. Lastly, follow-up timing for proximal junctional failure is limited by 2 years for our given data set at this time. However, even at the 2-year mark, we see that there is a significant difference in PJF between the 2 treatment groups. Similarly, Zaghloul et al.[13] show that 1-year follow-up may be short, but at 2 years they found higher rates of PJF. Improving upon this data may lead to contributions of time to PJF in ligament augmentation if it were to eventually occur. With this limitation on follow-up time, we still gain insight on resistance to PJF in our ligament augmentation technique.

CONCLUSION

In summary, our results show that ligament augmentation in ASD surgery utilizing a novel technique with polyethylene tape is effective in slowing the progression of the PJA and lowering the risk for PJF and revision surgery. In turn, this may help patients avoid the risks and morbidity associated with revision surgery, while providing substantial cost savings to the healthcare system.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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