A Pilot Study on Posterior Polyethylene Tethers to Prevent Proximal Junctional Kyphosis After Multilevel Spinal Instrumentation for Adult Spinal Deformity

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BACKGROUND: Proximal junctional kyphosis (PJK) is a common problem after multilevel spine instrumentation.

OBJECTIVE: To determine if junctional tethers reduce PJK after multilevel instrumented surgery for adult spinal deformity (ASD).

METHODS: ASD patients who underwent posterior instrumented fusion were divided into 3 groups: no tether (NT), polyethylene tether-only (TO; tied securely through the spinous processes of the uppermost instrumented vertebra [UIV] + 1 and UIV-1), and tether with crosslink (TC; passed through the spinous process of UIV+1 and tied to a crosslink between UIV-1 and UIV-2). PJK was defined as proximal junctional angle $\geq 10^\circ$ and $\geq 10^\circ$ greater than the corresponding preoperative measurement.

RESULTS: One hundred eighty-four (96%) of 191 consecutive patients achieved minimum 3-mo follow-up (mean = 20 mo [range:3-56 mo]; mean age = 66 yr; 67.4% female). There were no significant differences between groups based on demographic, surgical, and sagittal radiographic parameters. PJK rates were 45.3% (29/64), 34.4% (22/64), and 17.9% (10/56) for NT, TO, and TC, respectively. PJK rate for all tethered patients (TO + TC; 26.7% [32/120]) was significantly lower than NT ($P = .011$). PJK rate for TC was significantly lower than NT ($P = .001$). Kaplan-Meier analysis showed significant time-dependent PJK reduction for TC vs NT (log rank test, $P = .010$). Older age and greater change in lumbar lordosis were independent predictors of PJK, while junctional tethers had a significant protective effect.

CONCLUSION: Junctional tethers significantly reduced occurrence of PJK. This difference was progressive from NT to TO to TC, but only reached pairwise significance for NT vs TC. This suggests potential benefit of tethers to reduce PJK, and that future prospective studies are warranted.

KEYWORDS: Adjacent segment disease, Adult spinal deformity, Complication, Proximal junctional angle, Proximal junctional kyphosis, Scoliosis, Spinal fusion

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Proximal junctional kyphosis (PJK) continues to be problematic after multilevel spinal instrumentation for adult spinal deformity (ASD). The reported incidence ranges from 11.0% to 52.9%.[1-8] Several risk factors have been identified and include high body mass index (BMI), older age at surgery, fusion to sacrum, low bone mineral density, larger preoperative sagittal vertical axis (SVA), postoperative proximal junctional angle (PJA) $>5^\circ$ and thoracic kyphosis $>30^\circ$, and greater correction of lumbar lordosis.[4,7,9,10]

ABBREVIATIONS: ANOVA, analysis of variance; **ASD,** adult spinal deformity; **BMI,** body mass index; **CI,** confidence interval; **LL,** lumbar lordosis; **NT,** no tether; **OR,** odds ratio; **PJA,** proximal junctional angle; **PJF,** proximal junctional failure; **PJK,** proximal junctional kyphosis; **PI,** pelvic incidence; **PT,** pelvic tilt; **SPSS,** Statistical Package for Social Science; **SVA,** sagittal vertical axis; **TC,** tether with crosslink; **TO,** tether-only; **UIV,** uppermost instrumented vertebra

Early reports of PJK were primarily focused on adolescent idiopathic scoliosis.[11] Authors used varying radiographic criteria, with abnormal PJA ranging from 5° to 15°.[11-15] More recently, for ASD, definitions of abnormal

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PJK have been more consistent.[1] PJA is measured from the caudal endplate of the uppermost instrumented vertebra (UIV) to the cephalad endplate of UIV+2 (2 supra-adjacent levels above the UIV). Abnormal PJK is defined as a proximal junction sagittal Cobb angle that is ≥10° and ≥10° greater than the corresponding preoperative measurement.[1]

Although there is increasing emphasis on PJK detection, as well as various classification systems to guide its management,[16] the question remains whether PJK is a true complication, especially in the absence of clinical symptoms.[5] Glattes and colleagues have reported no significant difference in outcome scores (Scoliosis Research Society-24 outcomes measure) between PJK and non-PJK groups.[1,2] However, a subset of patients with PJK may still require surgical revision; therefore, various preventative techniques have been proposed and include vertebral augmentation, multilevel stabilization screws, transverse process hooks at the UIV, proximal transition rods of reduced diameter, and hybrid constructs.[3,17,18] The purpose of this study was to determine if junctional tethers reduce the incidence of postoperative PJK after multilevel instrumented surgery for ASD.

METHODS

We performed a single-center, retrospective evaluation of a prospectively maintained database of patients who underwent multilevel spine instrumentation at the University of Virginia Health System (Charlottesville, Virginia). All operations were performed by the 2 senior authors (CIS, JSS) between December 31, 2011 and June 2, 2016, and the database was reviewed on December 2, 2016. The decision to use junctional tethers was not randomized; instead, CIS and JSS started utilizing junctional tethers from September 2013 and January 2015 onwards, respectively. No other technique such as vertebral augmentation, multilevel stabilization screws, transitional rods, or fusion with hybrid constructs was used that might confound PJK rates.[3,17,18] The study was approved by the University of Virginia Institutional Review Board. Patient consent was waived since data collection and analysis was retrospective and all patient-specific identifiers were removed for publication.

We searched for ASD patients with diagnosis of scoliosis and/or global sagittal malalignment (ie, abnormal SVA, thoracic kyphosis, lumbar lordosis, and/or pelvic incidence to lumbar lordosis mismatch). Inclusion criteria for the study were patient age > 18 yr, deformity correction with instrumented segmental posterior spine fusion (may have also had anterior approach procedure) at a minimum > 6 motion segments, thoracic UIV, pedicle screw instrumentation without transitional rods or hooks at the UIV, and complete radiographic data with preoperative, postoperative, and final standing long-cassette films at minimum follow-up of 3 mo.

We excluded patients with preoperative diagnosis of (1) degenerative spine disease without significant scoliosis or global sagittal malalignment, and/or (2) vertebral osteomyelitis/discitis. Patients who underwent a revision spine surgery without change in UIV were also excluded from the study.

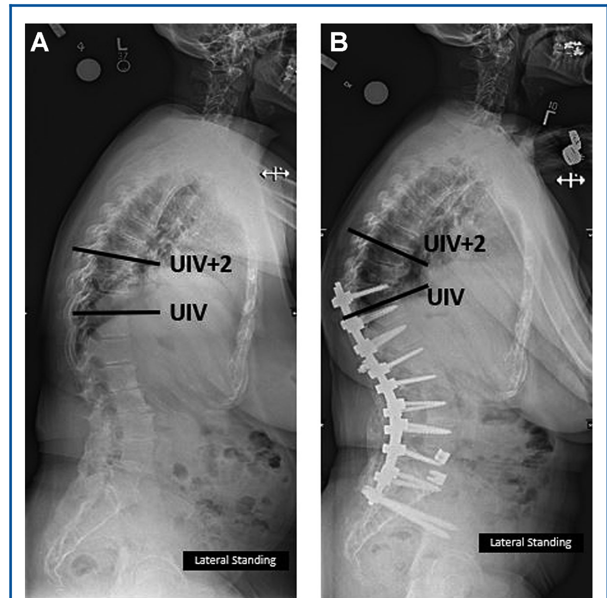

FIGURE 1. A, B, *Preoperative and postoperative standing long-cassette lateral radiographs of a 73-yr-old female with spinal deformity show the proximal junctional angle (PJA) measuring 16.2° and 29.3°, respectively. PJA was the sagittal Cobb angle measured from the caudal endplate of the uppermost instrumented vertebra (UIV) to the cephalad endplate of UIV+2 (2 supra-adjacent levels above the UIV). For this study, abnormal proximal junctional kyphosis (PJK) was defined as a PJA (1) greater than or equal to 10° and (2) at least 10° greater than the corresponding preoperative measurement. The presence of both criteria was necessary to be considered abnormal.* B, *This patient developed postoperative PJK.*

Radiographic Measurements

Subjects had standing posteroanterior and lateral long-cassette (14 × 36 inch) radiographs preoperatively, postoperatively, and at final follow-up. PJA was the sagittal Cobb angle measured from the caudal endplate of the UIV to the cephalad endplate of UIV+2 (2 supra-adjacent levels above the UIV) (Figure 1). Abnormal PJK was defined as a PJA that was ≥ 10° and ≥ 10° greater than the corresponding preoperative measurement.[1] Figure 2 depicts measurement technique for pelvic tilt (PT), pelvic incidence (PI), and lumbar lordosis (LL).

Tethering Technique

Our proximal junction posterior tether consisted of a 5-mm woven polyethylene Mersilene tape (Ethicon, Somerville, New Jersey) on a blunt needle, and in 56 patients, this was anchored to a standard crosslink. The tape-only technique first involves using a high-speed drill to create holes in the base of the UIV+1 and UIV-1 spinous processes. Then polyethylene tape is passed through these and tightened securely. An assistant holds the first knot in the polyethylene tape while the surgeon completes tying the tape for maximal tension. Our tape-crosslink technique is similar, but first involves placement of a standard crosslink between the UIV-1 and UIV-2 spinous processes. Again, using a high-speed drill, a hole is created in the base of the UIV+1 spinous process. Polyethylene tape is then passed around the crosslink and through the UIV+1 spinous process, and tied securely. Finally, the crosslink is

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FIGURE 2. *Pelvic tilt is the angle between the vertical line from the center of the femoral head and the line from the center of the femoral head to the center of the sacral endplate. Pelvic incidence is the angle between the line perpendicular to the sacral endplate and the line connecting the midpoint of the sacral endplate to the center of the femoral head. Lumbar lordosis is the Cobb angle between the inferior endplate of T12 and superior endplate of the sacrum.*

distracted inferiorly to fully tension the polyethylene tape for junctional support (Figure 3).

Statistical Analysis

Patients were divided into 3 groups based on tethering technique, which include: (1) no tether (NT), (2) polyethylene tether-only (TO), and (3) polyethylene tether with crosslink (TC). Data are presented as mean and standard deviation for continuous variables, and as frequency for categorical variables. Baseline characteristics of the cohorts, including patient demographics, surgical data, and sagittal plane radiographic parameters, were compared using Pearson's Chi square test, Fisher's exact test, and 1-way analysis of variance (ANOVA). Rates of PJK and revision surgery for proximal junctional failure (PJF), time-to-PJK, change in postoperative PJA, and total radiographic follow-up duration were analyzed using Pearson's Chi square test, Fisher's exact test, and 1-way ANOVA followed by Bonferroni post hoc test, when appropriate. Odds ratios (ORs) were calculated from 2×2 contingency tables. A Kaplan-Meier survivorship analysis was performed to analyze PJK as a time-dependent variable. After dichotomizing patients based on development of PJK at 6 mo postop, independent variables were entered in a stepwise, multivariable model using binary logistic analysis. The fit of the final model was assessed using the Hosmer-Lemeshow goodness-of-fit test.[19] For time-dependent regression, a Cox proportional hazards model was implemented.

For this study, P-values $< .05$ were considered statistically significant, and a post hoc Bonferroni adjustment was made for multiple pairwise comparisons. Statistical Package for Social Science (SPSS) version 24.0 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. IBM Corp, Armonk, New York) was used to perform all analyses.

RESULTS

Patient Demographics and Surgical Data

One hundred eighty-four (96%) of 191 consecutive patients, between December 31, 2011 and June 2, 2016, met inclusion criteria and achieved minimum 3-mo follow-up (mean = 20 mo [range: 3-56 mo]; mean age = 66 yr; 67.4% female). Patient demographics and surgical data are presented in Table 1. There were 64 NT, 64 TO, and 56 TC patients. For these 3 cohorts, there were no significant differences in patient age at surgery, gender, preoperative BMI, number of instrumented vertebrae, use of pelvic fixation, use of 3-column osteotomy, or type of approach (posterior-only vs 2-stage anterior-posterior). The majority of cases involved at least 10 motion segments with pelvic fixation, did not have 3-column osteotomies (vertebral column resection and/or pedicle subtraction osteotomy), and were posterior-only approaches. A total of 12 patients were treated via a 2-stage, combined anterior-posterior approach. No intraoperative or postoperative complication in this study could be attributed to posterior polyethylene tethers.

Sagittal Plane Radiographic Parameters

Sagittal plane radiographic parameters are presented in Table 2. There were no significant differences in the pre- and postoperative SVA, PT, PI, LL, PI-LL mismatch, and thoracic kyphosis among cohorts. The amount of deformity correction, measured by the postoperative change in SVA and LL, was comparable among cohorts.

PJK in Non-tethered vs Tethered Patients

Univariate comparison of non-tethered vs all tethered patients for the primary outcome of postoperative PJK is presented in Table 3. The overall PJK rate for non-tethered patients (NT) was significantly higher compared to the tethered cohort (TO + TC): 45.3% (29/64) vs 26.7% (32/120; $P = .011$).

Secondary Analyses After Stratifying Tethered Patients Based on Use of an Anchoring Crosslink

Secondary analyses after stratification of tethered patients into TO and TC subgroups is presented in Tables 4-6. Overall PJK

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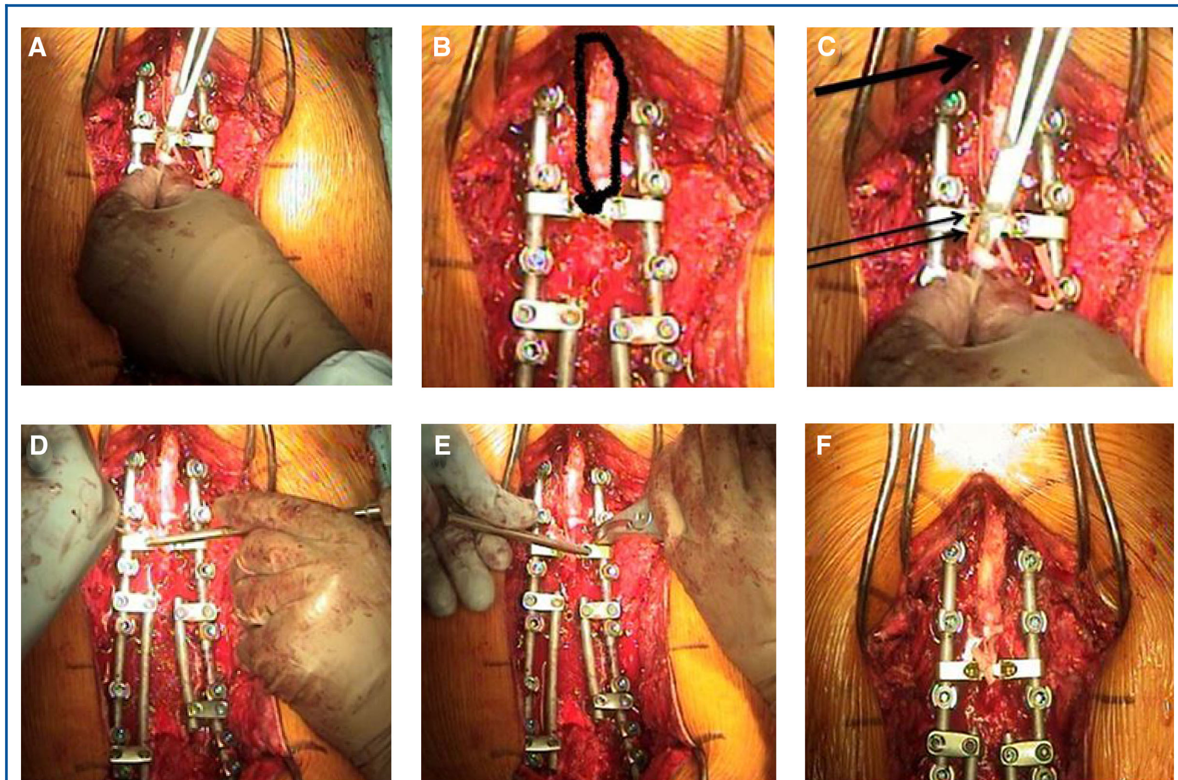

FIGURE 3. *The polyethylene tape-crosslink tethering technique first involves placement of a standard crosslink between the base of UIV-1 and UIV-2 spinous processes. Using a high-speed drill, a hole is created in the base of the UIV+1 spinous process.* **A**, *Next, a 5-mm woven polyethylene tape is passed around the crosslink and through the UIV+1 spinous process, and* **B**, *then tightened securely (the black line traces the polyethylene tether).* **C**, *The single arrow and double arrows indicate the superior and inferior attachments of the polyethylene tape.* **D**, **E**, *Finally, the crosslink is distracted inferiorly to fully tension the tape for junctional support.* **F**, *The final result is aimed to reduce the risk of developing PJK.*

TABLE 1. Patient Demographics and Surgical Data Separated by Tethering Technique[a]

	No tether (NT, n = 64)	Tape-only (TO, n = 64)	Tape-crosslink (TC, n = 56)	P^b
Age at surgery (years)	66.06 ± 8.47	66.27 ± 10.92	66.64 ± 8.59	.944
Gender (female/male)	42/22	43/21	39/17	.895 ($\chi^2 = 0.221$)
Body mass index (kg/m^2)	28.83 ± 5.88	30.23 ± 4.76	30.76 ± 6.02	.144
Number of instrumented vertebrae	11.75 ± 3.21	11.20 ± 2.76	12.23 ± 3.30	.192
Pelvic fixation (yes/no)	62/2	56/8	52/4	.136
3-column osteotomy (yes/no)	18/46	17/47	8/48	.153 ($\chi^2 = 3.753$)
Approach				
Posterior-only	57	61	54	.252
Anterior-posterior	7	3	2	

[a]Values are expressed as the mean ± standard deviation or frequency for continuous and categorical variables, respectively.
[b]Comparison of the 3 tethering groups analyzed with Pearson's chi square test, Fisher's exact test, or one-way analysis of variance.

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TABLE 2. Sagittal Plane Radiographic Parameters[a]

	No tether (NT, n = 64)	Tape-only (TO, n = 64)	Tape-crosslink (TC, n = 56)	P^b
Preoperative				
Sagittal vertical axis (cm)	8.65 ± 6.43	9.23 ± 7.87	8.66 ± 7.33	.876
Pelvic tilt (°)	24.97 ± 10.16	28.14 ± 9.85	25.71 ± 9.39	.167
Pelvic incidence (°)	51.91 ± 11.46	53.92 ± 10.70	51.21 ± 11.07	.374
Lumbar lordosis (°)	30.47 ± 20.09	26.92 ± 25.14	30.71 ± 16.78	.534
PI-LL mismatch (°)	21.03 ± 19.07	25.81 ± 24.41	20.05 ± 19.42	.273
Thoracic kyphosis (°)	25.34 ± 21.37	32.13 ± 18.96	33.41 ± 20.60	.063
Postoperative				
Sagittal vertical axis (cm)	3.85 ± 4.36	4.26 ± 4.66	3.20 ± 4.06	.412
Pelvic tilt (°)	22.14 ± 8.47	23.91 ± 9.54	22.20 ± 8.86	.458
Pelvic incidence (°)	52.38 ± 11.21	51.77 ± 10.82	48.91 ± 10.08	.179
Lumbar lordosis (°)	48.39 ± 9.90	47.66 ± 17.17	46.93 ± 8.79	.819
PI-LL mismatch (°)	3.98 ± 11.33	4.11 ± 18.78	1.98 ± 12.79	.682
Thoracic kyphosis (°)	36.98 ± 12.09	40.14 ± 17.22	39.14 ± 17.30	.509
Amount of correction				
Sagittal vertical axis (cm)	4.80 ± 5.46	4.32 ± 7.86	5.46 ± 6.78	.653
Lumbar lordosis (°)	17.92 ± 19.31	19.52 ± 25.20	16.21 ± 17.07	.691

PI = pelvic incidence, LL = lumbar lordosis.
[a]Values are expressed as the mean ± SD for continuous variables.
[b]Comparison of the 3 tethering groups analyzed with one-way analysis of variance.

TABLE 3. Postoperative Development of PJK in 184 ASD Patients Dichotomized Based on Use of Polyethylene Tethers[a]

	No tether (NT, n = 64)	Tether[b] (TO + TC, n = 120)	P
Overall PJK[a] (%)	45.3	26.7	**.011** ($\chi^2 = 6.548$)
Yes	29	32	
No	35	88	

[a]Analyzed using Pearson's chi square test with 2 × 2 contingency table.
[b]Tether patients with polyethylene tape only (TO) or tape with crosslink (TC) were grouped into a single cohort.

rates were 45.3% (29/64), 34.4% (22/64), and 17.9% (10/56) for NT, TO, and TC patients, respectively (Table 4). The PJK rate for TC tethers was significantly lower than NT at the Bonferroni-adjusted alpha level (P = .001). Based on the OR, the odds of developing PJK was 3.81 times higher for NT compared to TC patients. There was a nonsignificant trend in PJK reduction for TC compared to TO, and TO compared to NT. The rate of revision surgery for PJF was lowest for TC (3.6% [2/56]) compared to TO (9.4% [6/64]) and NT (4.7% [3/64]); however, pairwise comparisons did not reach statistical significance.

Table 5 presents pairwise comparisons of the postoperative change in PJA between NT, TO, and TC subgroups. The postoperative change in PJA was calculated using preoperative and final long-cassette lateral radiographs. If revision surgery for PJF was performed, the final PJA was measured using the long-cassette radiograph taken just prior to revision surgery. Postoperative change in PJA for TC was significantly less than both TO and NT using post hoc ANOVA with Bonferroni correction (P = .026 and P = .024, respectively). There was no significant difference in postoperative PJA change for TO compared to NT (P = 1.000).

Time-Dependent PJK and Kaplan-Meier Survivorship Analysis

Time-to-PJK among NT, TO, and TC subgroups was not significantly different (P = .530). NT, TO, and TC patients developed PJK at 17.02 ± 23.44, 11.59 ± 12.58, and 11.40 ± 14.88 wk, respectively. Comparison of postoperative radiographic follow-up duration was significantly different among all cohorts using post hoc ANOVA with Bonferroni-adjusted analysis (P < .001). NT, TO, and TC patients had total radiographic follow-up of 115.59 ± 50.91, 79.47 ± 41.66, and 41.42 ± 18.48 wk, respectively.

Owing to the difference in follow-up duration among NT, TO, and TC subgroups, 3- and 6-mo PJK rates were calculated and Kaplan-Meier analysis was performed. Table 6 presents PJK rates at 3- and 6-mo following multilevel spine instrumentation. At 3 mo, there is a nonsignificant trend in PJK reduction with TC compared to TO and NT. At 6 mo, there is significant PJK reduction for TC compared to NT at the Bonferroni-adjusted alpha level (16.1% compared to 39.1%, P = .005).

Kaplan-Meier analysis demonstrated a significant difference in the time-dependent rate of PJK (log rank test, P = .030). Using pairwise comparisons, Kaplan-Meier analysis demonstrated a significant reduction in PJK for TC compared to NT (log rank test, P = .010) at the Bonferroni-corrected alpha level (Figure 4).

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TABLE 4. PJK and Revision Surgery for PJF: NT vs TO vs TC

	No tether (NT, n = 64)	Tape-only (TO, n = 64)	Tape-crosslink (TC, n = 56)	P^{*} P^{**} P^{***} χ^2
Overall PJK[a] (%)	45.3	34.4	17.9	.206, .041, **.001**
Yes	29	22	10	1.597, 4.167, 10.263
No	35	42	46	
Revision for PJF[b] (%)	4.7	9.4	3.6	.492, .281, 1.00
Yes	3	6	2	
No	61	58	54	

PJK, proximal junctional kyphosis; PJF, proximal junctional failure.
[a]Analyzed with Pearson's chi square test with 2 × 2 contingency tables.
[b]Analyzed with Fisher's exact test with 2 × 2 contingency tables.
*TO compared to NT.
**TC compared to TO.
***TC compared to NT.
***P* = .001** is the only significant pairwise comparison at the Bonferroni-adjusted alpha level.

TABLE 5. Postoperative Change in Proximal Junctional Angle (PJA): NT vs TO vs TC[a]

	No tether (NT n = 64)	Tape-only (TO, n = 64)	Tape-crosslink (TC, n = 56)	P^b
Change in PJA (°)	12.68 ± 9.34	12.63 ± 9.94	8.18 ± 8.01	**.011***

[a]Change in PJA at last follow-up (or prior to revision for proximal junctional failure) compared to preoperative PJA.
[b]Comparison of the 3 tethering groups analyzed with one-way analysis of variance (ANOVA) followed by Bonferroni post hoc test.
*Post hoc ANOVA with Bonferroni correction TO compared to NT ($P = 1.000$), TC compared to TO ($P = .026$), TC compared to NT ($P = .024$).

Although not significant, there was a trend suggestive of PJK reduction for TC compared to TO (log rank test, $P = .074$). There was no significant difference in PJK rates for TO compared to NT (log rank test, $P = .337$).

Multivariable Analyses With Patients Dichotomized Based on PJK

Variables included in multivariable binary logistic and Cox regression models were age at surgery, female gender, BMI, number of instrumented vertebrae, use of pelvic fixation, use of 3-column osteotomy, use of polyethylene tether (including both TO and TC), preoperative SVA, change in SVA, and amount of LL correction. Results of binary logistic regression are presented in Table 7. Older age at surgery and greater correction of LL were independent predictors of PJK. Use of a polyethylene tether was a significant predictor of reduced PJK risk (OR = 0.422, 95% confidence interval [CI] 0.205-0.868, $P = .019$). Based on the Hosmer-Lemeshow goodness-of-fit test, the regression was not statistically different from a null model without the explanatory variables, indicating a good fit ($P = .963$).

Results of Cox proportional hazards regression are presented in Table 8. Use of a polyethylene tether remained a significant independent factor for avoiding PJK (hazards ratio = 0.532, 95%

TABLE 6. Time-Dependent Proximal Junctional Kyphosis (PJK): NT vs TO vs TC

	No tether (NT, n = 64)	Tape-only (TO, n = 64)	Tape-crosslink (TC, n = 56)	P^{*} P^{**} P^{***} χ^2
3-mo PJK[a] (%)	29.7	26.6	14.3	.694, .099, .044
Yes	19	17	8	.155, 2.729, 4.063
No	45	47	48	
6-mo PJK[a] (%)	39.1	32.8	16.1	.461, .035, **.005**
Yes	25	21	9	.543, 4.464, 7.775
No	39	43	47	

[a]Pearson's chi square test with 2 × 2 contingency tables.
*TO compared to NT.
**TC compared to TO.
***TC compared to NT.
***P* = .005** is the only significant pairwise comparison at the Bonferroni-adjusted alpha level.

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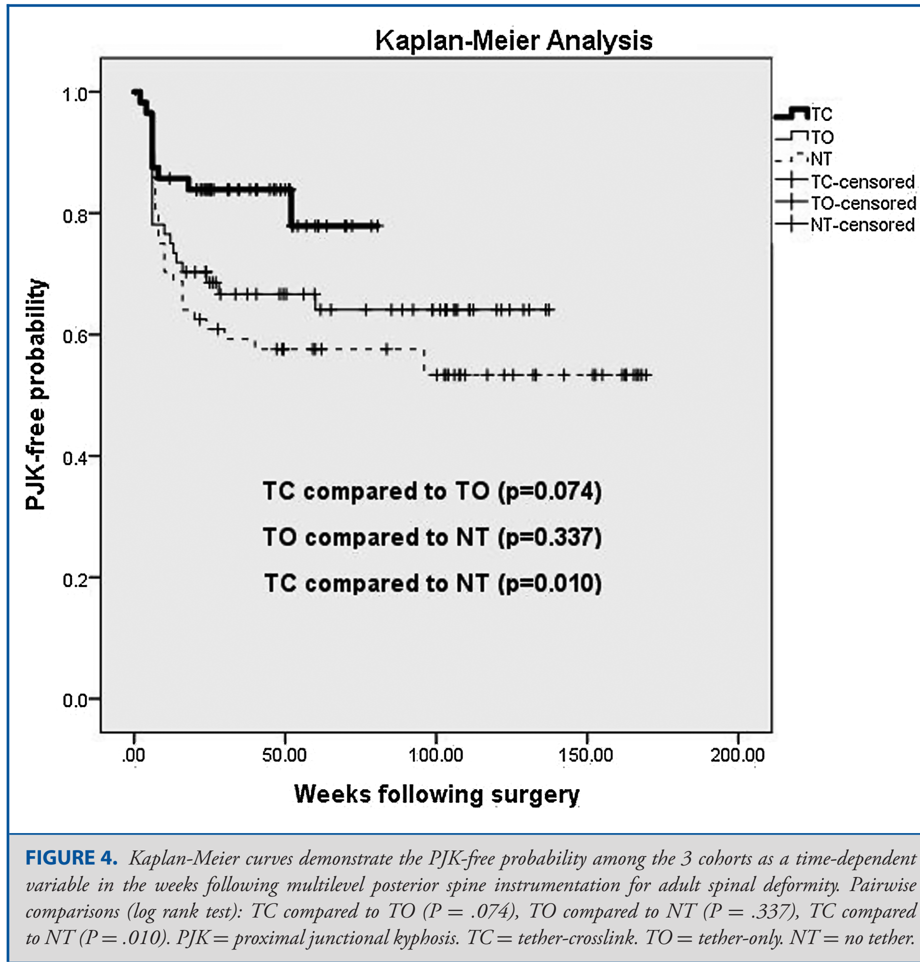

FIGURE 4. *Kaplan-Meier curves demonstrate the PJK-free probability among the 3 cohorts as a time-dependent variable in the weeks following multilevel posterior spine instrumentation for adult spinal deformity. Pairwise comparisons (log rank test): TC compared to TO (P = .074), TO compared to NT (P = .337), TC compared to NT (P = .010). PJK = proximal junctional kyphosis. TC = tether-crosslink. TO = tether-only. NT = no tether.*

TABLE 7. Multivariable Analysis of ASD Patients Dichotomized Based on Development of PJK 6 mo After the Index Operation[a]

	OR (95% CI)	*P*
Age at surgery	1.068 (1.020-1.119)	**.005**
Female	1.975 (0.888-4.392)	.095
Body mass index	1.014 (0.953-1.078)	.671
Number of instrumented vertebrae	1.050 (0.930-1.185)	.434
Pelvic fixation	1.605 (0.303-8.506)	.578
3-column osteotomy	1.059 (0.456-2.458)	.895
Use of polyethylene tether[b]	0.422 (0.205-0.868)	**.019**
Preoperative sagittal vertical axis	1.007 (0.935-1.085)	.849
Amount of correction		
Sagittal vertical axis	1.050 (0.967-1.141)	.246
Lumbar lordosis	1.030 (1.006-1.055)	**.014**

CI, confidence interval; OR, odds ratio.
[a]Explanatory variables were entered in a stepwise, multivariable model using binary logistic regression.
[b]Polyethylene tape only and tape with crosslink tethers were grouped into a single cohort.

TABLE 8. Cox Proportional Hazards Regression for ASD Patients and Postoperative PJK

	HR (95% CI)	*P*
Age at surgery	1.051 (1.016-1.088)	**.004**
Female	1.570 (0.855-2.883)	.145
Body mass index	1.019 (0.976-1.063)	.395
Number of instrumented vertebrae	1.035 (0.948-1.131)	.438
Pelvic fixation	1.213 (0.365-4.023)	.753
3-column osteotomy	0.949 (0.515-1.752)	.868
Use of polyethylene tether[a]	0.532 (0.318-0.892)	**.017**
Preoperative sagittal vertical axis	0.990 (0.935-1.048)	.737
Amount of correction		
Sagittal vertical axis	1.030 (0.966-1.099)	.363
Lumbar lordosis	1.022 (1.005-1.039)	**.013**

CI, confidence interval; HR, hazards ratio.
[a]Polyethylene tape only and tape with crosslink tethers were grouped into a single cohort.

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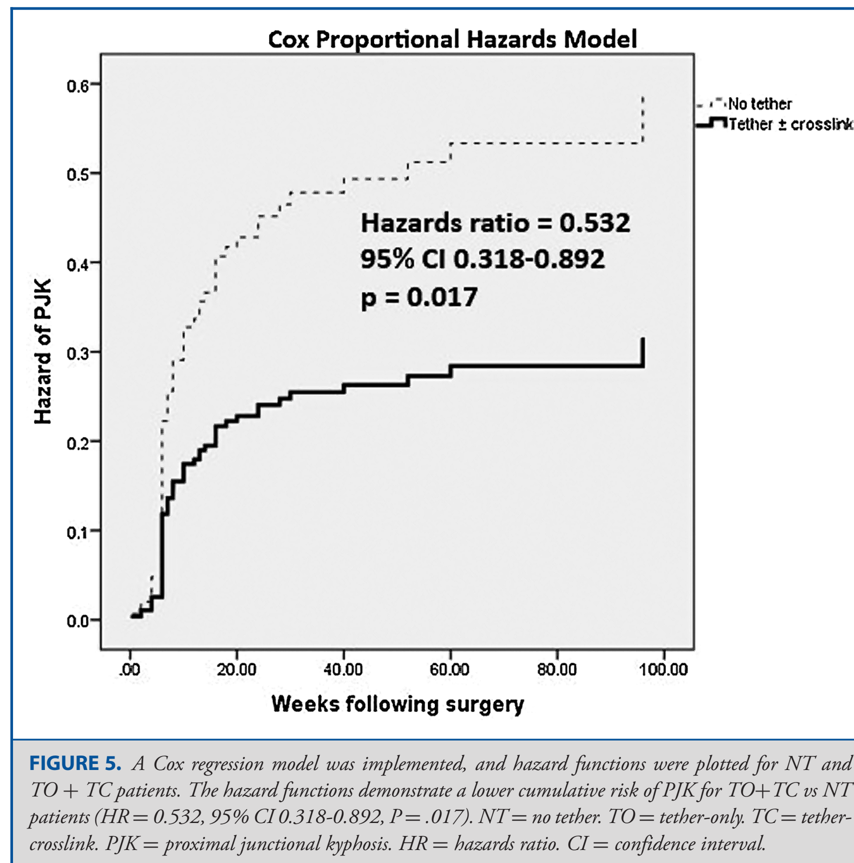

FIGURE 5. *A Cox regression model was implemented, and hazard functions were plotted for NT and TO + TC patients. The hazard functions demonstrate a lower cumulative risk of PJK for TO+TC vs NT patients (HR = 0.532, 95% CI 0.318-0.892, P = .017). NT = no tether. TO = tether-only. TC = tether-crosslink. PJK = proximal junctional kyphosis. HR = hazards ratio. CI = confidence interval.*

CI 0.318-0.892, P = .017). Cumulative hazard functions for tethered and nontethered patients are plotted in Figure 5.

DISCUSSION

PJK is common following multilevel spine instrumentation for ASD, with a reported incidence of 11.0% to 52.9%.[1-8] The exact pathophysiological mechanism of PJK is unclear; however, most authors agree it is likely multifactorial.[20,21] PJK may in part be secondary to an iatrogenic effect of altered spinal biomechanics, which produce pathologic flexion-loading forces at the proximal fusion segment. This includes compensatory changes following operative correction of thoracic kyphosis and sagittal malalignment, which are further exacerbated by posterior tension band disruption and the creation of a moment arm at the proximal segment of long, rigid fusion constructs.[13,22,23]

PJF is considered a distinct entity in the spectrum of PJK that involves mechanical failure at the UIV or just above and/or proximal junctional posterior discoligamentous failure.[20,24] The most common modes of failure in the upper thoracic spine compared to the thoracolumbar region are soft tissue disruption and mechanical fracture, respectively.[25] Patients with PJF may present with progressively worsening pain, focal neurological deficits, and ambulatory difficulty—resulting in significantly worse standardized outcome scores.[16] Therefore, PJK and PJF prevention is, and should be, among the principal goals for optimizing clinical outcomes after spinal deformity surgery.

Posterior polyethylene junctional tethers at the UIV in multilevel spine instrumentation may be an effective anti-PJK technique. Bess and colleagues,[26] using finite element analysis, demonstrated more gradual changes in segmental range-of-motion and reduction in proximal segment intradiscal pressures, pedicle screw loads, and posterior ligament complex forces with increasing number of posterior tethers. The authors hypothesized that posterior polyethylene tethers may reduce biomechanical risk factors for PJK.

A literature search for posterior tethers, and their clinical use as an anti-PJK device after spine surgery, produced only a single clinical report by Zaghloul and colleagues.[27] The authors reported no case of PJK in 18 patients with polyethylene tape–based strap stabilization at the proximal end of fusion constructs. However, this relatively small case series, with average 11.9 mo of follow-up, lacked specific inclusion and exclusion criteria for spinal deformity surgery or long-segment fusion—12 patients had fusion constructs of 6 or less motion segments, and 4 patients were fused at a single segment.[27]

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We present the first large clinical study of posterior polyethylene junctional tethers as an anti-PJK device for multilevel spine instrumentation (>6 fused segments) in ASD patients with scoliosis and/or global sagittal malalignment. Our results show that junctional tethers (both TO and TC) are a significant negative predictor of PJK, and that there are significantly reduced overall crude and time-dependent PJK rates when polyethylene tape is anchored to a crosslink. Additionally, TC tethers significantly reduced the postoperative change in PJA at last follow-up. Pairwise comparisons showed no significant effect of polyethylene tethering without utilization of an anchoring crosslink, although trends still suggested a reduction in PJK. To explain this difference, we hypothesize that anchoring polyethylene tape to a crosslink between UIV-1 and UIV-2, and then distracting the crosslink inferiorly, produces additional tension and increased junctional support compared to polyethylene tape-only tethers.

In this study, the decision to use junctional tethers was not randomized; instead, the 2 senior authors (CIS, JSS) started utilizing junctional tethers from September 2013 and January 2015 onwards, respectively. No other change in surgical technique (vertebral augmentation, multilevel stabilization screws, transverse process hooks at the UIV, proximal transition rods of reduced diameter, hybrid constructs)[3,17,18] was identified that may confound PJK rates. However, we still attempted to limit potential bias from practice variability and nonrandomization by controlling for baseline patient demographic, surgical data, as well as pre- and postoperative sagittal plane radiographic parameters in multivariable models (Tables 7 and 8) and performing time-dependent analyses (Figures 4 and 5). In addition, the confounding effect of possible practice variability was limited by our decision not to extend the inclusion start date to an earlier time. This produced relatively balanced cohorts with 64 NT, 64 TO, and 56 TC patients.

Limitations

The limitations of this study include its nonblinded retrospective design, the experience level and technical ability of the surgeons at a single center, the different follow-up duration among cohorts, and the relatively short minimum follow-up duration of 3 mo. To account for differences in follow-up, we calculated 3- and 6-mo PJK rates, performed multivariable regression using 6-mo PJK rates, implemented a Cox regression model, and performed a life-table survival analysis (Kaplan-Meier estimation). Kaplan-Meier analysis was congruent with the overall crude rates and demonstrated a significant time-dependent reduction in PJK for TC compared to NT (log rank test, $P = .010$) at the Bonferroni-corrected alpha level (Figure 4). Although minimum radiographic follow-up of 3 mo may seem relatively short, prior studies have reported up to 76% of PJK occurs within 3 mo postoperatively, and that new PJK after 6 mo may be rare.[2,3,22,28,29] Also, Kim and colleagues[2] showed that the average PJA increase at 2 mo postoperation accounts for the majority of total PJA increase at 5 yr postoperation. In our study, 93% (171/184) of patients had at least 6 mo of follow-up, and the vast majority of patients who developed PJK did so within 3 mo of the index operation.

Although TC tethers significantly reduced PJK, rates of revision surgery for PJF were comparable across all cohorts. However, the small number of patients who underwent revision surgery limits meaningful comparison of revision rates; therefore, a larger tether study with longer follow-up duration may be warranted. We are currently accruing more patients in a prospectively maintained database, with longer follow-up and clinical outcome scores, to further elucidate the clinical impact of posterior polyethylene tethers in spinal deformity surgery. Additionally, future studies are necessary to determine if our findings are generalizable to other spine surgery patients without ASD, particularly those without scoliosis and/or global sagittal malalignment, or who have 6 or less fused motion segments.

CONCLUSION

PJK is a common problem after multilevel spine instrumentation for spinal deformity correction, and in a subset of patients, may require surgical revision. Posterior junctional tethers, consisting of polyethylene tape anchored to a crosslink at the superior aspect of fusion constructs, may represent a novel anti-PJK device for ASD patients. In this study, use of junctional tethers for long-segment posterior fusion for ASD significantly reduced the occurrence of PJK. This difference was progressive from NT to TO to TC cohorts, but only reached statistical significance on pairwise comparisons for NT vs TC. These findings suggest potential benefit of junctional tethers to reduce PJK, and that future prospective studies with longer-term follow-up are warranted.

Disclosures

Dr Bess receives research support from K2M, Innovasis, Nuvasive, Medtronic, DePuy Synthes, Stryker, and Zimmer-Biomet; is a consultant for K2M and Allosource; and holds patents with K2M and Innovasis. Mr Line, BSME, is a consultant for ISSGF. Dr Ames is a consultant for Medtronic, DePuy Synthes, and Stryker; receives royalties from Zimmer-Biomet and Stryker; has research support from UCSF; and holds a patent with Fish & Richardson PC. Dr Schwab is a consultant for Zimmer-Biomet, K2M, Nuvasive, Medicrea, and MSD; receives research support from SRS, AOSpine, DePuy Spine Synthesis, and ISSGF; and is a stock holder in Nemaris Inc. Dr Lafage is a consultant for Nemaris Inc, Nuvasive, Medicrea, and DePuy Synthes; is a stock holder in Nemaris Inc; and receives non-study-related support from SRS, NIH, DePuy Synthes, and ISSGF. Dr Shaffrey is a consultant for Medtronic, Nuvasive, Zimmer-Biomet, and K2M; receives royalties from Medtronic, Nuvasive, and Zimmer-Biomet; is a stock holder in Nuvasive; and has grants from NIH, DOD, and NACTN. Dr Smith receives royalties from Zimmer Biomet, is a consultant for Zimmer Biomet, Cerapedics, Nuvasive, K2M, and AlloSource; receives honoraria from Zimmer Biomet, Nuvasive, and K2M; has research support from DePuy Synthes, and ISSGF; and receives fellowship support from NREF and AOSpine. The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENTS

The authors present the results of their retrospective, single-center, comparative cohort study of 184 patients who underwent surgery for adult spinal deformity between 2012 and 2016. During that period, the authors' surgical techniques at the proximal junction changed from not using a polyethylene tether, to placing a tether that was secured to the spinous processes, and finally to placing a tether that was secured to a crosslink. In their primary analysis, they found that the incidence of PJK without a tether was 45% and with a tether, using either technique, it was 27%. Secondary analyses were generally consistent with the primary finding. The crude odds ratio (OR) for developing PJK with a tether was 0.44; controlling for factors such as BMI, pelvic fixation, and amount of correction using multivariable regression, the odds ratio for PJK with the use of a tether was 0.53.

This study includes 3 cohorts made up of patients treated by different techniques as the surgical practices at a single center evolved over time. The 2 surgeons may have changed their techniques in response to a perceived problem with PJK, perhaps as the result of a particularly high incidence of PJK in the period prior to instituting the technical change. There is evidence that this may, in fact, be the case, as the "no tether" cohort had a 45% incidence of PJK, which is toward the upper end of the range reported in the literature.[1] This raises the possibility that some of the observed difference in the incidence of PJK is due to regression to the mean. If aspects of the surgical technique (reduced application of corrective forces near the UIV, more limited proximal soft tissue dissection) or decision-making (selection of the construct levels) were changed in response to a particularly high incidence of PJK, one would expect the incidence to subsequently decline independent of other changes.

Assessing "statistical significance" is only 1 part of analyzing a study; one should also critically evaluate the estimate of the effect size, the degree of uncertainty regarding the estimate, and how the study design may

affect the estimate.[2] In this study, the absolute reduction of 18% in the incidence of PJK with tether use is very likely to be an overestimate of the effect size. Regression to the mean and other changes in management, as discussed above, are 2 likely explanations for some of the observed difference in the incidence of PJK between the subgroups in this case series.

These considerations must be weighed against the potential risks of the intervention. In this case the procedure likely adds little risk to the procedure itself and probably does not put the patient at increased risk of delayed adverse events, although these aspects need further study. Even if the effect size of 0.18 is exaggerated by a factor of 3, with a standard error of approximately 0.05, it is unlikely (less than 1% probability) that the incidence of PJK with a tether is actually higher than without a tether.[3] If revision for PJK is necessary, the presence of a tether probably would not interfere with the subsequent surgery or alter its outcome. This technique may therefore be an option that spinal deformity surgeons should consider but with more modest expectations for outcome than reported in this paper. Follow-up reports and studies by other groups should be performed help to further refine our knowledge of the effectiveness and safety of this procedure.

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Proximal junctional kyphosis (PJK) is a common entity that develops after long-segment fusions for adult spinal deformity (ASD). The authors propose an interesting technique to reduce the incidence of PJK by incorporating *junctional tether* at the proximal junction. For this purpose, the authors retrospectively reviewed the data and radiographic images of 184 patients that underwent posterior or anteroposterior fixation at a single institute for ASD between 2012 and 2016. The authors compared between 3 different techniques: *no proximal tether*, 64 patients; *polyethylene tether in isolation*, 64 patients; and *polyethylene tether in conjunction with a crosslin*k, 56 patients.

After a mean follow-up of 20 months, the authors found that the rate of PJK was significantly higher in the nontethered group compared to the tethered group (45% vs 27%, $P = .011$). Based on Kaplan-Meier survivorship analysis, there was a significant reduction in PJK rate for tethered group vs nontethered group (log-rank test, $P = .010$). The revision surgery rate for proximal junctional failure (PJF) was lower in the tethered group as well, although this difference did not reach a statistical significance.

This article is well-written and novel in terms of using a new, safe, and effective technique to improve the surgical outcomes of long-segment fusions in ASD. The authors should be commended for this important addition to our understanding of the junctional tethers and their effect on PJK. Moving forward, it will be interesting to utilize the findings of this study in future prospective randomized studies, with a longer follow-up duration, to investigate long-term outcomes, such as PJF, associated with junctional tethers.

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The authors have presented initial data on the novel use of polyethelene tethers placed 1 level past the proximal end of a fusion construct in an attempt to help prevent proximal junctional kyphosis (PJK). The idea of stress sharing is not new, but this particular use of an "elastic band" is of interest to anybody who has had to deal with PJK. As with many studies such as this, there are potential systemic biases in how the 2 cohorts were created and in surgical technique that may have adapted over time. Though this paper offers an attractive adjunct device to implant with many fusions, it still needs more study and investigation to justify its use.

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