



Strap stabilization for proximal junctional kyphosis prevention in instrumented posterior spinal fusion

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Abstract

Study design This is a retrospective, single-institution, cohort study.

Objectives To evaluate the association of Mersilene tape use and risk of proximal junctional kyphosis (PJK), after surgical correction of adult spinal deformity (ASD) by posterior instrumented fusion (PIF).

Summary of background data PJK, following long spinal PIF, is a complication which often requires reoperation. Mersilene tape, strap stabilization of the supra-adjacent level to upper instrumented vertebra (UIV) seems a preventive measure.

Methods Patients who underwent PIF for ASD with Mersilene tape stabilization (case group) or without (control group) between 2006 and 2016 were analyzed preoperatively to 2-year follow-up. Matching of potential controls to each case was performed. Radiographic sagittal Cobb angle (SCA), lumbar lordosis, pelvic tilt, sacral slope, and pelvic incidence were measured pre- and postoperatively, using a deformity measuring software program. PJK was defined as progression of post-operative junctional SCA at UIV $\geq 10^\circ$.

Results Eighty patients were included: 20 cases and 60 controls. The cumulative rate of PJK $\geq 10^\circ$ at 2-year follow-up was 15% in cases versus 38% of controls (OR = 0.28; $P = 0.04$) with higher latent period in cases, (20 vs. 7.5 months), $P = 0.018$. Mersilene tape decreased risk of PJK linked with the impact of the following confounders: age, ≥ 55 years old (OR = 0.19; $0.02 \geq P \leq 0.03$); number of spinal levels fused 7–15 (OR = 0.13; $0.02 \geq P \leq 0.06$); thoracic UIV (T12–T1) (OR = 0.13; $0.02 \geq P \leq 0.06$); BMI ≥ 27 kg/m² (OR = 0.22; $0.03 \geq P \leq 0.08$); and osteoporosis (OR = 0.13; $0.02 \geq P \leq 0.08$).

Conclusions Mersilene tape at UIV + 1 level decreases the risk of PJK following PIF for ASD.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.

Key points

- In the 2-years following posterior instrumented fusion the overall incidence of proximal junctional kyphosis (PJK) was 37.3% and 45.4% of patients underwent revision surgery for PJK.
- PJK risk factors: age, ≥ 55 years-old; smoking; TLIF; fused levels ≥ 7 ; osteotomy; T1-T7 UIV; post-operative $PI \geq 26^\circ$.
- Mersilene-tape stabilization of the UIV to supra-adjacent vertebrae both decreased incidence (15% of the case-group vs 38.37% of the control-group) and prolonged time to onset (20 months for case-group vs 7.5 months for the control-group) of PJK.

Impact of Mersilene-tape on risk of PJK/PJF stratified by confounding factors

Factor	OR	95% CI	P-value
Age ≥ 55 years-old	0.19	0.02 - 0.03	0.03
Number of spinal levels fused 7–15	0.13	0.02 - 0.06	0.06
Thoracic UIV (T12–T1)	0.13	0.02 - 0.06	0.06
BMI ≥ 27 kg/m ²	0.22	0.03 - 0.08	0.08
Osteoporosis	0.13	0.02 - 0.08	0.08

Take Home Messages

- Mersilene-tape stabilization of the spine at UIV + 1 decreases the risk of PJK after correction of adult spinal deformity by long posterior instrumented fusion.
- The protective effect of strap stabilization is expected within 2 years post-operatively, especially in patients with: increased age, obesity, osteoporosis, constructs ≥ 7 levels, and thoracic UIV.
- Findings are consistent with comparative studies, suggesting stabilization of UIV and supra-adjacent levels with a soft cable or tape, have the greatest impact in mitigating the risk of PJK/PJF.

Keywords Proximal junctional kyphosis · Proximal junctional failure · Mersilene tape · Upper instrumented vertebrae · Sagittal Cobb angle

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Extended author information available on the last page of the article

Introduction

The use of posterior instrumented fusion (PIF) with pedicle screws is a standard approach for surgical correction of adult spinal deformity (ASD). Post-fusion, a change in biomechanical properties secondary to increased loading of the uppermost instrumented vertebra (UIV), may lead to proximal junctional kyphosis (PJK).

Reported PJK incidence is highly heterogeneous, ranging from 5.6 to 41%, mainly due to variable diagnostic criteria [1, 2]. Most PJK cases (76%) are diagnosed postoperatively within 3 months [3]. The most severe expression is proximal junctional failure (PJF), which may include proximal symptomatic vertebral fracture, instrumentation failure or spondylolisthesis, and has a broad incidence between 1.4 and 35% [1, 4]. Associated symptoms including mechanical spine instability, prominent instrumentation, and back or leg pain with or without neuropathy are typically present within the first postoperative year [5, 6]. Revision rates for PJK range from 13 to 55%, significantly increasing care expenditures [7].

PJK etiology involves loss of normal biomechanics [8]. Proposed mechanisms include posterior tension band disruption, paraspinal muscle dissection, improper selection of UIV, proximal disk degeneration, proximal instrumentation failure, compression fracture, and facet violation [9]. Additional factors include age > 55 years old, low bone density, high body mass index (BMI), elevated preoperative sagittal parameters, pelvic incidence (PI) > 55°, lumbar lordosis (LL) > 30°, preoperative pelvic tilt (PT) ≥ 26°, extent of curvature correction, use of pedicle screws, thoracoplasty, lumbosacral fusion, combined anterior and posterior spinal fusion, and the number of instrumented levels [2, 6, 7, 9].

Preservation of the posterior ligament complex above the UIV is paramount in maintaining natural stability [10]. To provide additional support to the UIV and supra-adjacent levels, we proposed the use of Mersilene tape (Ethicon, Somerville, NJ), a nonabsorbable braided polyethylene-terephthalate 5-mm-wide suture. It is recognized as a safe and useful appliance in spine surgery [11]. In preclinical and clinical studies, Mersilene tape was a safe supplemental option for segmental fixation [11, 12]. Our previous case-series study with supplemental Mersilene tape revealed no PJK complications during the first postoperative year following PIF for ASD [13]. This noncomparative study prompted the hypothesis that strap stabilization of supra-adjacent vertebrae decreases the risk of PJK.

The purpose of this study was to evaluate the impact Mersilene tape stabilization of the UIV to the supra-adjacent vertebrae has on PJK risk following spine correction and PIF for ASD.

Materials and methods

A retrospective, single-institution, matched cohort study was performed with Institutional Review Board approval. The medical records and radiographic images from an electronic database were analyzed for patients who underwent thoracolumbar PIF for ASD between 2006 and 2016 at the University of Colorado Hospital, Anschutz Medical Campus, Aurora, CO, USA. Inclusion criteria were: age, ≥ 18 years old; primary or revision surgery for ASD secondary to degenerative disk disease or idiopathic scoliosis; ≥ three-level PIF construct, with or without combination of: anterior–lumbar interbody fusion (ALIF), transforaminal–lumbar interbody fusion (TLIF), axial–lumbar interbody fusion (Axial LIF), osteotomy (Smith-Peterson, pedicle subtraction, and vertebral column resection); with or without Mersilene tape; and postoperative observation of at least 2 years or revision/reoperation due to severe complication (s). The applied exclusion criteria were: < 18 years old; < three-level spinal fusion construct; malignancy; pregnancy; infection; autoimmune diseases; no use of pedicle screws; and less than 2-year follow-up with no reoperation due to severe complications.

Revealed subjects were classified into two groups: cases (Mersilene tape) and controls (no Mersilene tape) (Figs. 1–2). In the group which had been intervened with Mersilene tape, the construct was reinforced at the UIV and one level above. There was no drilling of the spinous process (Fig. 2). These were matched in two stages: 1) by age (< 50, 50–60, > 60); sex; osteoporosis measured at the spine; smoking status; spinal operated level (s) (thoracic, thoracolumbar, and lumbar); primary or revision index surgery; and use of cement. The outcomes of the index operation were the ones taken into consideration in the current study. 2) At least two and up to three controls were matched to each case depending on the number of relevant participants identified in the control group; if more than three participants in the control group were found to match a single case, an independent nonparticipant of the study randomly selected only three of the controls to be matched to the case and the nonselected controls were not included in the matched analysis. Considered potential confounders were: BMI, > 26 or ≤ 26 kg/m²; age, ≥ 55 or < 55 years old; number of levels fused; level of UIV; surgical technique; osteotomy use, type, and level (s); lumbar or lumbosacral fusion, with and without sacroiliac fixation by iliac bolts; and postoperative complications listed below. The following parameters were obtained from standing sagittal spine X-rays using Surgimap (New York, NY, USA) and defined preoperatively as well as postoperatively at 1.5, 6, 12, and 24 months: sagittal Cobb angle (SCA), LL, PI, PT, and sacral slope (SS). The normal range of these was defined as: LL 42°–67°, SS 24°–48°, PI 39°–62°, and PT 3°–22°

Fig. 1 Mersilene tape suture applied to lumbar (a) and thoracic (b) saw bone. Note in (b) the thoracic spinous process was drilled (optional) for facilitating the passage of suture and avoiding possible slippage

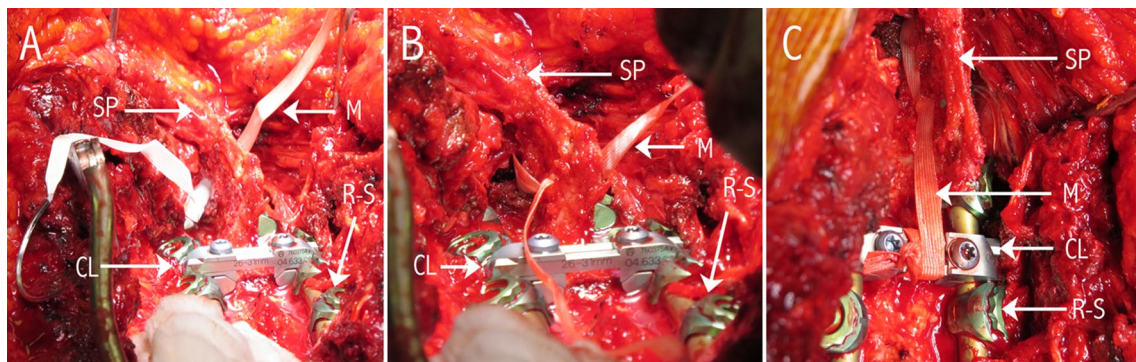
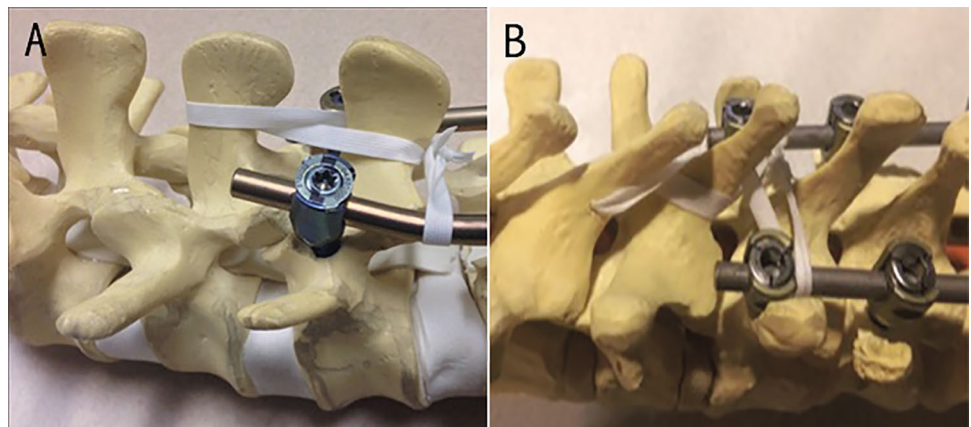


Fig. 2 Mersilene tape is applied after PIF. **a** Proximally passed through the supra-adjacent level spinous process. **b** Looped in a Fig. 8 way around the infra-adjacent spinous process. **c** Passed under the rods bilaterally, or cross-link and knotted. Minimal proximal exposure is needed as the Mersilene tape comes attached to a nee-

dle and the adjacent level spinous process projects downward, hence facilitating the grasp of the needle. *UIV* upper instrumented vertebrae, *SP* spinous process, *CL* cross-link; *R-S* rod and screws, *M* Mersilene tape

[14]. PJK was defined as pre- versus postoperative SCA difference $\geq 10^\circ$ without clinical symptoms. PJF was considered symptomatic PJK (e.g., recurrent back pain, neurologic claudication) with or without instrumentation failure and or vertebral fracture at $UIV + 2$ spinal levels [15].

The data were extracted by two experienced researchers under the principal investigator's (PI) supervision. An inter-measurement reliability analysis was performed. Final decision concerning diagnosis of PJK/PJF and other complications was made by three blinded experienced orthopedic surgeons (co-authors) following detailed clinical and radiographic analysis. The following complications were considered: postoperative PJK or PJF, spondylolisthesis, vertebral fracture (s), pseudoarthrosis, infection, and distal segment degeneration/failure [16].

The analysis of variance (ANOVA) was applied for intergroup comparison utilizing JMP 7.0.1 (SAS Institute Inc.; <http://www.jmp.com>). The differences of the continuous variables were defined using mean values, the standard deviation (SD) and the standard error of the mean (SE).

The statistical significance of the revealed differences was assessed using the two-sided Student's *t* test after testing of the distribution for normality. The categorical variables were compared using rates (%). The comparison of risks for the studied events was performed using the odds ratio (OR) with 95% confidence interval limits. The statistical significance was assessed using the Pearson's Chi-square test and, additionally the Fisher exact test if the compared subgroups and number of the studied outcomes were small ($n < 5$). The inter-measurement reliability of the studied radiographic parameters was defined by the Pearson correlation coefficient (*r*), the coefficient of determination (R^2), and the root-mean-square error (RMSE) of the linear fit of the two independent measurements for the same characteristics of the same randomly selected images. The risk of postoperative complications including PJK/PJF in the studied groups was defined by the comparison of the cumulative rates during the whole (2-year) period of observation. The impact of confounding factors on the risk of PJK/PJF and the preventive effect of the Mersilene tape use was studied by

stratification [2]. The statistical significance was considered as $P < 0.05$.

Results

A total of eighty patients were included: 20 cases and 60 controls. The mean age was 62.3 years old (SD 11.1) and 63.8% were female. Two significant intergroup differences were identified: (1) BMI, case group 30.2 kg/m² (SD, 4.8) versus control group 26.1 kg/m² (SD, 5.4) ($P = 0.003$). (2) Surgical technique, PIF alone or combined with ALIF or TLIF, predominated in the control group, while PIF alone or combined with Axial LIF prevailed in the case group (Tables 1 and 2). Revision/reoperation following the index operation was not significantly different between groups and occurred in 19 of 80 patients (23.8%): four cases (20%) and 15 controls (25%). These 19 cases were excluded from further analysis after the revision.

The inter-measurement reliability of studied radiographic characteristics was strong: $P < 0.0001$.

The mean LL was $< 42^\circ$ preoperatively and remained significantly increased throughout the postoperative course in both groups (Table 3). The mean preoperative SS had optimal values in both groups and remained within the defined normal range postoperatively (Table 3). The mean preoperative PT exceeded the optimal upper threshold in both groups and tended to decrease postoperatively (Table 3). The mean preoperative PI was within normal range in both groups and remained normal postoperatively (Table 3).

The mean preoperative SCA did not differ significantly in the case and control groups (Table 3). The mean immediate

postoperative changes were different: decreased in the case group (-1.8°) and increased in the control group (0.7°), $P = 0.01$ (Table 3). This difference was much more substantial at 2-year follow-up: The mean decreased in the case group (-1.7°) and the mean increased in the control group (9.0°), $P = 0.001$ (Table 3). The changes in the mean SCA at 1.5 months versus 2-year postoperatively were also different: 1.4° in the cases and 6.9° in the controls, $P = 0.04$ (Table 3).

The total cumulative rate of PJK/PJF in the whole studied population at 2-year follow-up was 26/80 (32.5%): three of 20 (15%) with Mersilene tape and 23 of 60 (38.37%) without. PJK occurred in 14 patients (17.5%) and PJF in 12 patients (15%, two from case group, ten from control group). In the 26 patients who underwent reoperation, 12 were diagnosed with PJK or PJF (46.2%; four PJK, eight PJF).

The risk of PJK/PJF was more than two times less in the case group: OR = 0.28 (95% CI: 0.07; 1.1), $\chi^2 = 4.8$; $P = 0.045$ (Table 4). The risk of other complications did not differ significantly between the cases and controls (Table 4). PJK/PJF was manifested earlier in the control group (mean = 7.5 months; SD 8.3) than the case group (mean = 20.0 months; SD 3.5), $T = 4.8$, $P = 0.018$ (Figs. 3, 4).

Whole group analysis found the following factors to be significantly associated with development of PJK/PJF: revision/reoperation, OR = 8.0 (95% CI 2.5; 25.1), $\chi^2 = 13.9$, $P < 0.001$; fusion \geq seven levels, OR = 3.58 (95% CI 1.2; 9.4), $\chi^2 = 4.7$, $P = 0.01$; thoracic/thoracolumbar versus lumbar/lumbosacral osteotomy, OR = 27.0 (95% CI 4.2; 175.5), $\chi^2 = 4.4$, $P = 0.01$; thoracic (T1-9) UIV, OR = 3.3 (95% CI 1.2; 9.6), $\chi^2 = 5.5$, $P = 0.03$; PT $\geq 26^\circ$ within 3 months postoperatively, OR = 3.7 (95% CI 1.3; 10.6), $\chi^2 = 4.9$, $P = 0.03$ (Table 5).

Table 1 Demographic and clinical characteristics of the studied groups

Characteristic	Statistical indices/subgroups	Study group		Statistical test value	P value
		Cases (N=20)	Controls (N=60)		
Age	Mean (SD)	63.2 (10.9)	62.1 (11.2)	$T = -0.39$	0.69
Sex	Male (n)	9 (45%)	20 (33.3%)	$\chi^2 = 0.88$	0.35
	Female (n)	11 (55%)	40 (66.7%)		
BMI	Mean (SD)	30.2 (4.9)	26.1 (5.4)	$T = 3.19$	0.003
Osteoporosis	Yes (n)	7 (35%)	21 (35%)	$\chi^2 = 0.0$	1.0
	No (n)	13 (65%)	39 (65%)		
Smoking	Yes (n)	1 (5%)	6 (10%)	$\chi^2 = 0.47$	0.49
	No (n)	19 (95%)	54 (90%)		
Primary diagnosis	DDD (n)	10 (50%)	38 (63.3%)	$\chi^2 = 1.11$	0.29
	DS (n)	10 (50%)	22 (36.7%)		
Index operation	Primary (n)	4 (20%)	17 (28.3%)	$\chi^2 = 0.54$	0.43
	Revision/reoperation (n)	16 (80%)	43 (71.7%)		

Cases Mersilene tape used, Controls no Mersilene tape used, N number of subjects, n number of events, SD standard deviation, DDD degenerative disk disease, DS degenerative scoliosis, n number of cases in subgroups, BMI body mass index (kg/m²), T the Student's *t* test, two-tailed, two-sample unequal variance coefficient, χ^2 the Pearson's Chi-square test coefficient

Table 2 Characteristics of the index operation in the studied groups

Characteristic	Statistical indices/subgroups	Study group		Statistical test value	P value
		Cases (N=20)	Controls (N=60)		
Index operation	Primary, n (%)	4 (20%)	17 (28.3%)	$\chi^2=0.54$	0.45
	Revision/reoperation, n (%)	16 (80%)	43 (71.7%)		
UIV	T1–T9, n (%)	4 (20%)	17 (28.3%)	$\chi^2=2.08$	0.35
	T10–T12, n (%)	5 (25%)	21 (35%)		
	L1–L4, n (%)	11 (55%)	13 (36.7%)		
Cement use	Yes, n (%)	1 (5%)	6 (10%)	$\chi^2=1.3$	0.26
Osteotomy	Yes, n (%)	10 (50%)	37 (61.6%)	$\chi^2=1.39$	0.20
Spinal level (s) of osteotomy	Lumbar and lumbosacral (S1–L1), n (%)	8 (40%)	27 (45.0%)	$\chi^2=1.3$	0.51
	Thoracolumbar (L4–T9), n (%)	0 (0%)	5 (8.3%)		
	Thoracic (T12–T3), n (%)	2 (10%)	5 (8.3%)		
Levels with osteotomy	Mean (SD)	1.8 (1.2)	1.8 (1.5)	T=0.08	0.94
Levels fused	Mean (SD)	6.7 (3.8)	7.5 (3.3)	T=0.95	0.32
Fixation to sacrum/pelvic	Yes, n (%)	17 (85%)	41 (68.3%)	$\chi^2=2.27$	0.13
	No, n (%)	3 (15%)	19 (31.7%)		
Surgical intervention	PIF combined with interbody fusion by different technique (s), n (%)	9 (45%)	18 (30%)	$\chi^2=0.91$	0.30

Cases Mersilene tape, controls no Mersilene tape, N number of subjects, n number of events, BMI body mass index, SD standard deviation, PIF posterior instrumented fusion, UIV upper instrumented vertebrae, T Student's two-tailed test for two-sample unequal variance, χ^2 the Pearson's Chi-square test

Table 3 Preoperative radiographic characteristics and their postoperative dynamics in the studied groups

Index (units)	Follow-up	Statistical indices/subgroups	Study group		Case vs. control	
			Cases (N=20)	Controls (N=60)	T	P
LL (°)	Pre-op.	Mean (SD)	39.7 (16.7)	37.5 (15.9)	0.5	0.60
	Immediate post-op. vs. pre-op.	Mean difference (SE)	13.4 (2.8)	9.9 (2.1)	1.0	0.79
SS (°)	Pre-op.	Mean (SD)	31.8 (11.6)	28.9 (11.1)	0.94	0.34
	Immediate post-op. vs. pre-op.	Mean difference (SE)	4.9 (1.9)	5.6 (1.3)	0.30	0.65
PT (°)	Pre-op.	Mean (SD)	24.3 (9.0)	25.4 (10.5)	0.69	0.49
	Immediate post-op. vs. pre-op.	Mean difference (SE)	-1.6 (1.6)	-5.2 (1.2)	1.8	0.07
PI (°)	Pre-op.	Mean (SD)	55.6 (16.1)	54.4 (12.6)	0.28	0.74
	Immediate post-op. vs. pre-op.	Mean difference (SE)	3.3 (1.9)	0.5 (0.9)	1.4	0.19
SCA (°)	Preoperative	Mean (SD)	13.5 (7.8)	10.8 (8.5)	1.29	0.21
	Immediate post-op. vs. pre-op.	Mean difference (SE)	-1.8 (1.5)	0.7 (0.8)	1.74	0.1
	Post-op. at last follow-up vs. pre-op.	Mean difference (SE)	-1.7 (2.3)	9.0 (1.7)	3.7	0.001
	Post-op. at last follow-up vs. immediate post-op.	Mean difference (SE)	1.4 (2.3)	6.9 (1.3)	2.08	0.04

Cases Mersilene tape, Controls no Mersilene tape, N number of subjects, SD standard deviation, SE standard error of the mean, SCA sagittal Cobb angle, measure of proximal junctional kyphosis (°), LL lumbar lordosis (°), SS sacral slope (°), PT pelvic tilt (°), PI pelvic incidence (°), N number of cases in the study groups, T t ratio calculated as a two-sample unequal variance two-tailed t test, P P value defined by the result of the t test

The stratification of confounding factors demonstrated that the use of Mersilene tape significantly decreased the risk of PJK/PJF linked with the impact of the following factors: age, ≥ 55 years old, OR = 0.19 (95% CI 0.04; 0.9), $\chi^2 = 6.2$, $0.02 \geq P \leq 0.03$; the number of spinal levels fused 7–15, OR = 0.13 (95% CI 0.01; 1.2), $\chi^2 = 5.7$, $0.02 \geq P \leq 0.06$;

the thoracic UIV (T12–T1), OR = 0.13 (95% CI 0.01; 1.2), $\chi^2 = 5.9$, $0.02 \geq P \leq 0.06$; BMI ≥ 27 kg/m², OR = 0.22 (95% CI 0.01; 1.2), $\chi^2 = 4.9$, $0.03 \geq P \leq 0.08$; and osteoporosis, OR = 0.13 (95% CI 0.01; 1.2), $\chi^2 = 5.8$, $0.02 \geq P \leq 0.08$ (Table 6).

Table 4 Risk of postoperative complications

Complication	Subgroups	Study group		Odds ratio (95% confidence limits) ^a cases vs. controls	Fisher's exact test, one-tailed (<i>P</i> value)
		Cases (<i>N</i> =20)	Controls (<i>N</i> =60)		
PJK/PJF	Yes, <i>n</i> (%)	3 (15%)	23 (38%)	0.28 (0.07; 1.1)	0.045
	No, <i>n</i> (%)	17 (85%)	37 (62%)		
Infection	Yes, <i>n</i> (%)	0 (0%)	2 (3.3%)	NA	0.56
	No, <i>n</i> (%)	20 (100%)	58 (96.7%)		
Vertebral fracture	Yes, <i>n</i> (%)	2 (10%)	10 (16.7%)	0.56 (0.11; 2.8)	0.37
	No, <i>n</i> (%)	18 (90%)	50 (83.3%)		
Hardware failure	Yes, <i>n</i> (%)	1 (5%)	4 (6.7%)	0.74 (0.08; 7.1)	0.63
	No, <i>n</i> (%)	19 (95%)	56 (93.3)		
Pseudoarthrosis	Yes, <i>n</i> (%)	1 (5%)	4 (6.7%)	0.74 (0.08; 7.1)	0.63
	No, <i>n</i> (%)	19 (95%)	56 (93.3)		
Distal segment degeneration/failure	Yes, <i>n</i> (%)	0 (0%)	1 (1.7%)	NA	0.75
	No, <i>n</i> (%)	20 (100%)	59 (98.3%)		
Postoperative revision/reoperation	Yes, <i>n</i> (%)	4 (20%)	15 (25%)	0.75 (0.2; 2.6)	0.45
	No, <i>n</i> (%)	16 (80%)	45 (75%)		

The Fisher's exact one-tailed test specifically tested the 0-hypothesis that the risk of complication in the control group does not higher than in the case group; $P \leq 0.05$ enables to reject this 0-hypothesis

Cases Mersilene tape, Controls no Mersilene tape, *N* number of subjects, *n*, number of events, PJK/PJF proximal junctional kyphosis and/or failure, NA not applicable

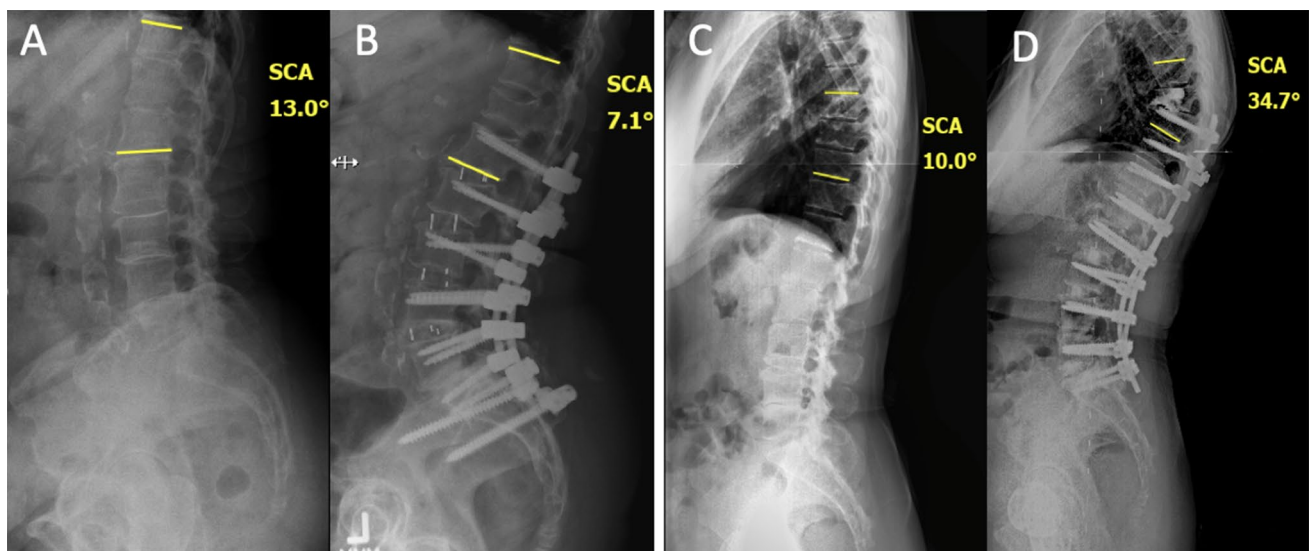


Fig. 3 a, b Pre- and postoperatively at 6 months the SCA of a 73-year-old female (case) that underwent L1-iliac PIF, XLIF L1–L5, TLIF L5–S1 for symptomatic degenerative disk disease. c, d Pre- and postoperatively at 6 months the SCA of a 69-year-old female (con-

rol) that underwent T10–L4 PIF, TLIF L2–4 for symptomatic degenerative disk disease. The patient developed PJF, requiring a vertebroplasty of T9

Discussion

The goal of this study was to evaluate the association between Mersilene tape use and risk of PJK/PJF, after surgical correction of ASD by PIF. Our incidence of PJK/PJF

(32.5%) and revision rate of the index operation (46.2%) correspond with previous findings [1, 2, 5–7, 17].

Prior studies have associated older age (>55 years old), high BMI (e.g., ≥ 25 kg/m²), and low bone density, as PJK/PJF risk factors [3, 5, 18–20]. Age above 55 shows trends of increased risk, but was not significantly associated. Our

Fig. 4 Dynamics of cumulative incidence rate curves reflect the difference in rising of the cumulative PJK/PJF risk during 2 postoperative years in both studied groups: case (Mersilene tape) and control (no Mersilene tape). Note: expressed in months ± SE

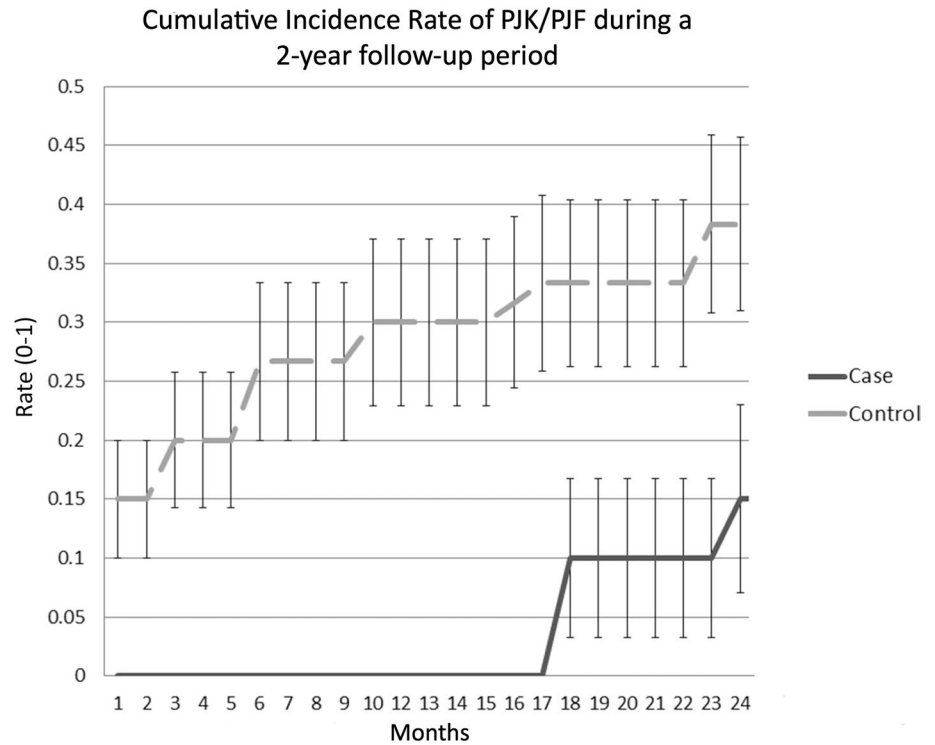


Table 5 Considered risk factors for PJK/PJF

Factor (s)	Subgroups	PJK/PJF		Odds ratio (95% confidence limits)	Fisher's exact test, two-tailed (P value)
		Yes, n (%)	No, n (%)		
Age ≥ 55 years old	Yes	23 (37%)	39 (63%)	3.0 (0.8; 11.3)	0.15
	No	3 (17%)	15 (83%)		
Body mass index (BMI)	27–42	12 (31%)	27 (69%)	0.86 (0.3; 2.2)	0.81
	16–26.9	14 (34%)	27 (66%)		
Osteoporosis	Yes	13 (46%)	15 (54%)	2.6 (0.9; 6.8)	0.08
	No	13 (25%)	39 (75%)		
Smoking	Yes	4 (57%)	3 (43%)	3.1 (0.6; 14.9)	0.21
	No	22 (30%)	51 (70%)		
Surgical technique	PIF	14 (33%)	28 (67%)	1.0 (0.4; 2.8)	1.0
	PIF + other techniques	12 (32%)	26 (68%)		
Number of levels fused	7–15	19 (44%)	24 (56%)	3.4 (1.2; 9.4)	0.01
	3–6	7 (19%)	30 (81%)		
Level of osteotomy	Lumbar/lumbosacral	8 (23%)	27 (77%)	27.0 (4.2; 175.5)	0.01
	Thoracolumbar/thoracic	8 (67%)	4 (33%)		
UIV	(L4–L1)/T12–T10	6 (18%)	27 (82%)	3.3 (1.2; 9.6)	0.03
	T9–T1	20 (43%)	27 (57%)		
Lumbosacral fusion	Yes	18 (31%)	40 (69%)	0.8 (0.3; 2.2)	0.79
	No	8 (36%)	14 (64%)		
Revision after index operation	Yes	13 (68%)	6 (32%)	8.0 (2.6; 25.1)	<0.001
	No	13 (21%)	48 (79%)		
Postoperative PT (degree)°	26–51	11 (55%)	9 (45%)	3.7 (1.3; 10.6)	0.03
	2–25	15 (25%)	45 (75%)		

Cases Mersilene tape used, Controls no Mersilene tape used, N number of subjects, PJK/PJF proximal junctional kyphosis (> 10°) and/or vertebral failure with clinical symptoms, UIV upper instrumented vertebrae, PT pelvic tilt, BMI body mass index, PIF posterior instrumented fusion

Table 6 Impact of Mersilene tape on risk of PJK/PJF stratified by confounding factors

Confounding factor	Subgroups	PJK/PJF	Group		OR (95% CI)	Fisher's exact test, one-tailed (<i>P</i> value)
			Cases (<i>N</i> =20)	Controls (<i>N</i> =60)		
Age	24–54	Yes, <i>n</i> (%)	1 (20%)	2 (15%)	1.4 (0.1; 19.6)	1.0
		No, <i>n</i> (%)	4 (80%)	11 (85%)		
	55–83	Yes, <i>n</i> (%)	2 (13%)	21 (45%)	0.19 (0.04; 0.9)	0.03
		No, <i>n</i> (%)	13 (87%)	26 (55%)		
BMI	16–26.9	Yes, <i>n</i> (%)	1 (20%)	13 (36%)	0.44 (0.6; 4.49)	0.64
		No, <i>n</i> (%)	4 (80%)	23 (64%)		
	27–42	Yes, <i>n</i> (%)	2 (13%)	10 (42%)	0.22 (0.04; 1.2)	0.08
		No, <i>n</i> (%)	13 (87%)	14 (58%)		
Osteoporosis	No	Yes, <i>n</i> (%)	2 (15%)	11 (28%)	0.46 (0.09; 2.4)	0.29
		No, <i>n</i> (%)	11 (85%)	28 (72%)		
	Yes	Yes, <i>n</i> (%)	1 (14%)	12 (57%)	0.13 (0.01; 1.2)	0.06
		No, <i>n</i> (%)	6 (86%)	9 (43%)		
Number of levels fused	3–6	Yes, <i>n</i> (%)	2 (17%)	5 (20%)	0.8 (0.13; 4.9)	0.59
		No, <i>n</i>	10 (83%)	20 (80%)		
	7–15	Yes, <i>n</i> (%)	1 (13%)	18 (51%)	0.13 (0.01; 1.2)	0.045
		No, <i>n</i>	7 (87%)	17 (49%)		
UIV	Lumbar (L4–L1)	Yes, <i>n</i> (%)	2 (18%)	4 (19%)	0.94 (0.2; 6.9)	0.67
		No, <i>n</i>	9 (82%)	17 (81%)		
	Thoracic (T12–T1)	Yes, <i>n</i> (%)	1 (11%)	19 (49%)	0.13 (0.01; 1.2)	0.04
		No, <i>n</i>	8 (89%)	20 (51%)		

The Fisher's exact one-tailed test specifically tested the 0-hypothesis that the risk of PJK/PJF in the control group does not higher than in the case group; $P \leq 0.05$ enables to reject this 0-hypothesis, $0.1 < P > 0.05$ shows a borderline significance

Cases Mersilene tape, Controls no Mersilene tape, *N* number of subjects, *n* number of events, *PJK/PJF* proximal junctional kyphosis $> 10^\circ$ with or without vertebral failure and/or clinical symptoms, *BMI* body mass index, *UIV* upper instrumented vertebrae, *OR* the odds ratio, *95% CI* the 95% confidence limits

study did not reveal a significant association with PJK/PJF for these factors. Age > 55 years old is well documented in previous studies that increases the risk for PJK. However, it is also seen in adolescents with idiopathic scoliosis undergoing surgery. We propose these differences are due to the heterogeneity of the studied populations and size of the studies.

Surgical technique and fusion construct were also previously shown as potential risk factors for PJK/PJF [6, 9]. The partial disruption of the posterior ligamentous complex is one of the many factors, if not one of the most important factors in increasing the risk of PJK. In our case, at the UIV and level above the construct, the supraspinous ligament is sacrificed and the interspinous ligament is only partially disrupted. However, this is the area being reinforced by the Mersilene tape. Our approach is not minimally invasive, and the paravertebral muscles are affected at some level as well. Currently, we are working on how minimal invasive approaches may decrease the risk of PJK. The applied surgical techniques were preserved between study groups. Consistent with prior studies, longer constructs were found to have a higher PJK risk. Other factors significantly associated with PJK/PJF were thoracic UIV, specifically upper

thoracic (T1-9), thoracolumbar osteotomy, and previous spine surgery. These findings correspond well with previous publications [1, 18, 19]. Contrary to some studies, we did not find a significant association between the risk of PJK/PJF and lumbar, lumbosacral, and sacroiliac fusion [3, 6, 18, 19]. We also contribute this discrepancy to variety of the studied populations.

Spinopelvic parameters corresponding with increased risk of PJK were described by Charosky et al. as preoperative $PT > 26^\circ$ and Mauro et al. as $PI > 55^\circ$ and postoperative change of $LL > 30^\circ$ [2, 21]. Our study revealed the same risk for preoperative $PT \geq 26^\circ$; however, 10% of study patients had postoperative correction of $LL > 30^\circ$ and did not demonstrate an increased incidence of PJK ($OR = 1.4$; $P = 0.41$). Theoretically, this phenomenon can be explained by a compensatory increase in LL to reach a more stable balance, $PI-LL < 10^\circ$ since PI is considered constant. This compensatory lordosis likely increases stress at UIV, hence contributing to the progression of PJK.

The current study revealed strap stabilization of the UIV + 1 with the Mersilene tape significantly decreased the risk of PJK/PJF in the 2 years following PIF for surgical

correction of ASD. Stratification of confounders demonstrated independent benefit of Mersilene tape in the following: age > 55 years old; \geq seven-level construct; and UIV at the thoracic spine (T1–12).

Mersilene tape strap stabilization of the UIV + 1 to the fusion construct is one of many proposed methods to prevent PJK/PJF following spine surgery. The preventive effect of comparative studies was reviewed and standardized by calculation of OR and corresponding *P* value. Of note, all of these studies were retrospective, did not have uniform diagnostic criteria for PJK/PJF, and had highly heterogeneous study populations (i.e., age, sex), clinical (i.e., diagnosis) and follow-up periods, among other characteristics. Therefore, the results should be regarded as preliminary due to the high risk of bias and low level of evidence [22]. A significant preventive effect was demonstrated with pedicle screws as compared to all hook constructs in adolescents with idiopathic scoliosis (AIS): $OR \leq 0.53$, $0.01 \geq P \leq 0.03$ [23]. The effect of hybrid constructs versus pedicle screws lacked clear preventative benefit: $0.26 \geq OR \leq 0.76$, $0.02 \geq P \leq 0.44$ [23]. The outcomes concerning supplemental hooks at UIV with pedicle screws also demonstrated unclear benefit: $0.19 \geq OR \leq 0.67$, $0.001 \geq P \leq 0.68$ [23]. Interestingly, Safaee et al. found a preventive effect for PJK through stabilization of UIV ± 2 using a soft cable passed through drill holes in the proximal spinous processes: $OR = 0.19$, $P = 0.001$ [24]. Similarly, Buell et al. [25] found a decreased incidence (10/46; 17.9%; $P = 0.01$) and later presentation (11.4 ± 14.8 weeks; ~ 3 months; $P > 0.05$) of PJK in patients treated for ASD with the use of Mersilene tape (both unanchored and anchored to the proximal cross-link) versus control group. These two studies and the current findings suggest that stabilization of UIV and supra-adjacent levels with a soft device such as cable or tape are approaches that diminish the risk of PJK/PJF. Currently, there are few polyethylene tape augmentations that have been tested for this purpose and an optimal technique has yet to emerge.

The present study had some limitations. The retrospective design of the study increases the risk of selection bias, which was minimized by randomization. To minimize the risk of confounding factors influence, we matched cases and controls by the main demographic and clinical characteristics. Unfortunately, the sample size did not allow for identification of more risk factors that were recognized in other studies (e.g., additional spinopelvic parameters, sacroiliac fusion), which should not be disregarded. Age, BMI, and bone density were not found to be significantly associated with increased risk of PJK/PJF in this study, contrary to prior publications. Although these factors were not different between study groups, additional analysis could not completely reject potential influence on the obtained results. Therefore, the presented results should be regarded

as preliminary which require further confirmation, presumably with a prospective study.

Conclusion

Mersilene tape stabilization of the spine at UIV + 1 decreases the risk of PJK after correction of ASD by long PIF. This protective effect is expected within 2 years postoperatively, especially in patients with: increased age, obesity, osteoporosis, constructs \geq seven levels, and thoracic UIV. This is an early pilot study proposing Mersilene tape stabilization for PJK prevention in \geq three-level PIF constructs and highlights patient characteristics that confer the greatest benefit.

Authors' contribution We, the undersigned, certify that each author has participated in and has contributed sufficiently to the work to take public responsibility for the appropriateness of the experimental design and method, and the collection, analysis and interpretation of the data and that this final version has been reviewed and approved for submission and/or publication. The sequence of authorship below is identical to that on the submitted manuscript. FRF, DOY, CK, CC, EB and VV were involved in conception/design of the work. FRF, BR, AN, DOY, CK, CC, EB and VV were involved in acquisition of data.

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Conflict of interest The authors declare that they have no conflict of interest.

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