



Strap Stabilization Use in Posterior Instrumented Spinal Fusion for Proximal Junctional Kyphosis Prevention: A Retrospective Cohort Study

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INTRODUCTION

- Posterior instrumented fusion (PIF) with pedicle screws is a standard approach to correcting adult spinal deformities (ASD).
- Increased loading of the upper instrumented vertebrae (UIV) resulting from a number of reported destabilizing mechanisms, including compromise of the posterior ligament complex, is believed to contribute to the development of proximal junctional kyphosis (PJK).^(1, 2, 3, 4)
- PJK is an asymptomatic radiographic finding with reported incidence ranging from 5.6 to 41%.⁽⁵⁻⁷⁾ It is characterized by progression of the post-operative junctional sagittal Cobb angle (SCA) at the UIV $\geq 10^\circ$, and is usually diagnosed within 3 months post-operatively.^(8, 9)
- Proximal junctional failure (PJF) is the most severe presentation of PJK. It is associated with mechanical instability and neurological deficits with a broad incidence between 1.4% and 35%.^(2,5,10-14) It requires reoperation in 47% of cases, significantly increasing the cost of care.^(9, 5,9,15)

HYPOTHESIS

We hypothesize that strap stabilization of the UIV to the 1-2 supra-adjacent vertebrae with Mersilene-tape (Ethicon, NJ, USA) will decrease the risk of developing proximal junctional kyphosis following spine correction and PIF for ASD.

To test this hypotheses, we aimed to:

- Determine risk factors associated with the development of PJK following surgical correction and PIF for ASD.
- Compare the prevalence of PJK in patients treated for ASD by way of surgical correction and PIF with Mersilene-tape strap stabilization versus those without strap stabilization.

METHODS

Study Design: Retrospective, single institution, cohort study with matching controls.

Study Subjects: Patients who underwent thoracolumbar PIF for ASD at University of Colorado Hospital between 2006 and 2016.

- 20 subjects with Mersilene-tape strap stabilization.
- 60 subjects without Mersilene-tape strap stabilization.
- Inclusion criteria:** ≥ 18 years-old; ASD of different etiology; PIF with or without osteotomy, ≥ 3 levels fusion construct; use of pedicle screws; surgical technique including: anterior-, transforaminal-, and axial-lumbar interbody fusion (LIF); and 2-year follow-up.

Matching Criteria: age (<50, 50-60, ≥ 60); sex (male or female); osteoporosis; smoking status; operated level(s) of spine (thoracic, thoracolumbar, and lumbar); primary or revision index surgery; cement use.

Data Collection: Patient demographics were obtained by chart review. Spinopelvic parameters obtained from standing sagittal spine X-rays using Surgimap (New York, NY). Measurements taken from x-rays pre-operatively and post-operatively at 2nd-6th week, and at 6, 12 and 24 month follow-ups:

- PJK $\rightarrow \geq 10^\circ$ difference in SCA post-operatively
- PJF \rightarrow PJK with symptomatic construct failure and/or vertebral fracture

Analysis: Intergroup comparison performed with ANOVA, logistic regression, odds ratio, and survival analysis; $P \leq 0.05$ was considered statistically significant.

RESULTS

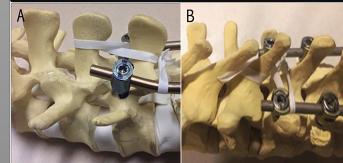


Figure 1: Mersilene-tape suture applied to lumbar (A) and thoracic (B) saw bone. Note in (B), the thoracic spinous process was drilled for facilitating the passage of suture and avoiding possible slippage.

Demographic and Clinical Characteristics of the Study Groups:

Matched characteristics:

- Average age: case = 63.2 (SD, 10.9), controls = 62.1 (SD, 11.2) ($P=0.69$)
- Gender: females were approximately 60% in both groups ($P=0.35$)
- No significant intergroup difference ($P>0.05$): osteoporosis, smoking, primary diagnosis, index operation, cause of primary operation, cause of revision/reoperation.

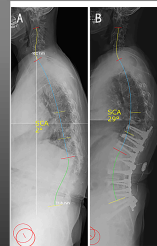


Figure 2: A 76-year-old female (control) patient that underwent T10-iliac PIF, ALIF L5-S1, L1 PSO, and iliac bolt instrumentation for symptomatic degenerative disk disease and L1 fracture..

- A) Pre-operatively: SCA, 2°; Sacral Slope, 9°; Lumbar Lordosis, 2°; Pelvic Tilt, 46°; and Pelvic Incidence, 55°.
- B) Post-operatively: the patient develops PJK at 6 weeks secondary to vertebral fracture at T9: SCA, 29°; Sacral Slope, 23°; Lumbar Lordosis, 44°; Pelvic Tilt, 32°; and Pelvic Incidence 55°.

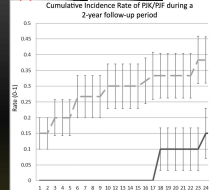


Figure 3: The Kaplan Maier curves that reflect difference in rising of the cumulative PJK/PJF risk during 2 postoperative years in 2 study groups: case (Mersilene tape use) and control (no Mersilene tape use).

Table 1: Risk of Post-Operative Complications

Complication	Subgroups	Study group		Odds ratio (95% confidence limits)	P-value (case vs control)
		Cases	Controls		
PJK/PJF	Yes, n (%)	3 (15%)	23 (38%)	0.28 (0.07; 1.1)	0.045
	No, n (%)	17	37		
Infection	Yes, n (%)	0 (0%)	2 (3.3%)	NA	0.56
	No, n (%)	20	58		
Vertebral fracture	Yes, n (%)	2 (10%)	10 (16.7%)	0.56 (0.11; 2.8)	0.37
	No, n (%)	18	50		
Hardware failure	Yes, n (%)	1 (5%)	4 (6.7%)	0.74 (0.08; 7.1)	0.63
	No, n (%)	19	56		
Pseudarthrosis	Yes, n (%)	1 (5%)	4 (6.7%)	0.74 (0.08; 7.1)	0.63
	No, n (%)	19	56		
Inferior breakdown	Yes, n (%)	0 (0%)	1 (1.7%)	NA	0.75
	No, n (%)	20	59		
Post-operative revision/reoperation	Yes, n (%)	4 (20%)	15 (25%)	0.75 (0.2; 2.6)	0.45
	No, n (%)	16	45		

Table 2: Considered Risk Factors for PJK/PJF

Factor(s)	Subgroups	PIK/PJF		Odds ratio (95% confidence limits)	P-value (case vs control)
		Yes, N (%)	No, N		
Smoking	Yes	4 (80%)	1	5.3(0.6;51.9)	0.05
	No	18 (33%)	36		
Surgical technique	PIF	14 (33%)	28	1.0(0.4;2.8)	1.0
	PIF + Other Techniques	12 (32%)	26		
Number of levels fused	7-15	19 (44%)	24	3.4(1.2; 9.4)	0.01
	3-6	7 (19%)	30		
Level of osteotomy	Lumbar/Lumbosacral	8 (23%)	27	27.0 (4.2; 175.5)	0.01
	Thoracolumbar/Thoracic	8 (67%)	4		
Revision after index operation	Yes	13 (68%)	6	8.0 (2.6; 25.1)	<0.001
	No	13 (21%)	48		
Postoperative PT (degree)*	26-51	11 (55%)	9	3.7 (1.3; 10.6)	0.03
	2-25	15 (25%)	45		

MAJOR FINDINGS:

- The cumulative rate of PJK $\geq 10^\circ$ at 2-year follow-up was 15% in cases vs. 38% of controls ($P=0.045$).
- Mersilene-tape patients had an OR=0.33 ($P=0.09$) and higher latent period (20 vs. 7.5 months $P=0.018$).
- Mersilene-tape significantly decreased risk of PJK in the following conditions:
 - Age, ≥ 55 years-old (OR=0.19, $P=0.03$)
 - UIV, T1-T12 (OR=0.13, $P=0.04$)
 - Number of levels fused, 7-15 (OR=0.13, $P=0.045$)

CONCLUSION

- Mersilene-tape stabilization of the spine at UIV and 1-2 supra-adjacent levels likely decreases the risk of PJK after correction of ASD by long PIF.
- PIK/PJF generally occurs within 2 post-operative years, particularly, in aged and obese patients, in thoracic UIV spine, if post-operative PI difference $\geq 11^\circ$, and if T1W was not applied.
- Positive outcomes may be seen in patients with osteoporosis, if number of fused levels ≥ 7 , and if expected post-operative PT $\leq 25^\circ$.

FUTURE DIRECTIONS

- Correlate effectiveness of strap stabilization with Biomechanical study.
- Compare effectiveness of strap stabilization with other techniques.
- Examine difference between strap stabilization to 1 vs 2 supra-adjacent vertebrae.

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