# 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 ≥10°, 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.[3, 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 → ≥ 10° difference in SCA post-operatively
- PJF → PJK with symptomatic construct failure and/or vertebral fracture

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

## RESULTS

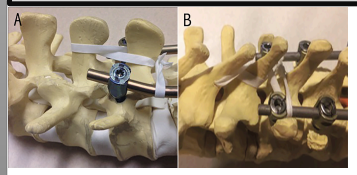


Figure 1: Mersilene-tape suture applied to lumbar (A) and thoracic (B) saw bone. Note in (B), the thoracic spinous process was drilled for facilitating the passage of suture and avoiding possible slippage.

### 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.

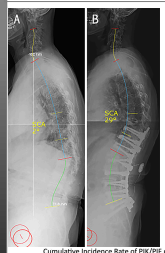


Figure 2: A 76-year-old female (control) patient that underwent T10-iliac PIF, ALIF L5-S1, L1 PSO, and iliac bolt instrumentation for symptomatic degenerative disk disease and L1 fracture..

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°.

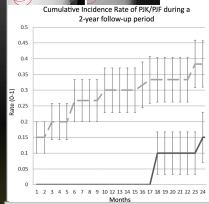


Figure 3: The Kaplan Maier curves that reflect difference in rising of the cumulative PJK/PJF risk during 2 postoperative years in 2 study groups: case (Mersilene tape use) and control (no Mersilene tape use).

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%) | | |
| | No, n | 17 | 37 | 0.28 (0.07; 1.1) | 0.045 |
| Infection | Yes, n (%) | 0 (0%) | 2 (3.3%) | | |
| | No, n | 20 | 58 | NA | 0.56 |
| Vertebral fracture | Yes, n (%) | 2 (10%) | 10 (16.7%) | | |
| | No, n | 18 | 50 | 0.56 (0.11; 2.8) | 0.37 |
| Hardware failure | Yes, n (%) | 1 (5%) | 4 (6.7%) | | |
| | No, n | 19 | 56 | 0.74 (0.08; 7.1) | 0.63 |
| Pseudoarthrosis | Yes, n (%) | 1 (5%) | 4 (6.7%) | | |
| | No, n | 19 | 56 | 0.74 (0.08; 7.1) | 0.63 |
| Inferior breakdown | Yes, n (%) | 0 (0%) | 1 (1.7%) | | |
| | No, n | 20 | 59 | NA | 0.75 |
| Post-operative revision/reoperation | Yes, n (%) | 4 (20%) | 15 (25%) | | |
| | No, n | 16 | 45 | 0.75 (0.2;2.6) | 0.45 |

Table 2: Considered Risk Factors for PJK/PJF

| Factor(s) | Subgroups | PJK/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 Technques | 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 ≥ 10° 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.
- PJK/PJF generally occurs within 2 post-operative years, particularly, in aged and obese patients, in thoracic UIV spine, if post-operative PI difference ≥11°, and if TLIF was not applied.
- Positive outcomes may be seen in patients with osteoporosis, if number of fused levels ≥7, and if expected post-operative PT ≤25°.

## 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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