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Low-Density Pedicle Screw Constructs Are Associated with Lower Incidence of Proximal Junctional Failure in Adult Spinal Deformity Surgery

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Study Design. Retrospective cohort study.

Objective. Determine whether screws per level and rod material/ diameter are associated with incidence of proximal junctional kyphosis (PJF).

Summary of Background Data. PJF is a common and particularly adverse complication of adult spinal deformity (ASD) surgery. There is evidence that the rigidity of posterior spinal constructs may impact risk of PJF.

Methods. Patients with ASD and 2-year minimum follow-up were included. Only patients undergoing primary fusion of more than or equal to five levels with lower instrumented vertebrae (LIV) at the sacro-pelvis were included. Screws per level fused was analyzed with a cutoff of 1.8 (determined by receiver operating characteristic curve (ROC) analysis). Multivariable logistic regression was utilized, controlling for age, body mass index (BMI), 6-week postoperative change from baseline in lumbar lordosis, number of posterior levels fused, sex, Charlson comorbidity index, approach, osteotomy, upper instrumented vertebra (UIV), osteoporosis, preoperative TPA, and pedicle screw at the UIV (as opposed to hook, wire, *etc.*).

Results. In total, 504 patients were included. PJF occurred in 12.7%. The mean screws per level was 1.7, and 56.8% of patients had less than 1.8 screws per level. No differences were observed between low *versus* high screw density groups for T1-pelvic angle or magnitude of lordosis correction (both $P > 0.15$). PJF occurred in 17.0% *versus* 9.4% of patients with more than or equal to 1.8 *versus* less than 1.8 screws per level, respectively ($P < 0.05$). In multivariable analysis, patients with less than 1.8 screws per level exhibited lower odds of PJF (odds ratio (OR) 0.48, $P < 0.05$), and a continuous variable for screw density was significantly associated with PJF (OR 3.87 per 0.5 screws per level, $P < 0.05$). Rod material and diameter were not significantly associated with PJF (both $P > 0.1$).

Conclusion. Among ASD patients undergoing long-segment primary fusion to the pelvis, the risk of PJF was lower among patients with less than 1.8 screws per level. This finding may be related to construct rigidity. Residual confounding by other patient and surgeon-specific characteristics may exist. Further biomechanical and clinical studies exploring this relationship are warranted.

Key words: adult spinal deformity, pedicle screw density, proximal junctional failure.

Level of Evidence: 3

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Proximal junctional kyphosis (PJK) is a reasonably common and particularly adverse complication of adult spinal deformity (ASD) surgery. PJK is most frequently defined as the progression of kyphosis at the proximal end of construct greater than 10°.[1] The frequency of PJK after long fusion for adult scoliosis has been reported as 17% to 40%[1–7]

Risk factors for PJK have been extensively studied and reported in the literature. Preoperative risk factors include a large pre-existing thoracic kyphosis and male sex.[2,6] Select intraoperative decisions have been associated with PJK, including fusion to the sacrum, posterior fusion with segmental instrumentation,[3] and a change in lumbar lordosis more than 30°.[2] Autogenous bone graft,[5] combined anterior-posterior surgery, and increased sagittal sacral vertical line difference have also been reported as risk factors for PJK.[4] Attempting a large correction of thoracic hyperkyphosis and thoracoplasty can contribute to PJK.[5,6] The cranial and caudal limits of the construct may also be important, as choosing T1–T3 as the upper instrumented level,[4] use of pedicle screw at the top vertebra, and fusion to the lower lumbar vertebra (below L2)[5] have all been associated with PJK. Fortunately, optimal postoperative alignment of the spine was found to protect against development of PJK.[2] Fracture at the UIV is a particularly common mechanism of proximal junctional pathology.[2]

It is important to understand and consider the risk factors for PJK, as it can progress to proximal junctional failure (PJF). Risk factors for revision surgery in the setting of PJF include traumatic etiology of PJF, severity of PJK angulation, higher sagittal vertical axis, and female sex.[8] PJF has been reported to occur in approximately 6% of patients who underwent surgical correction of adult spinal deformity, with a median time to revision of 1 year.[9] Larger preoperative pelvic tilt and over correction significantly increased the risk of PJF.[9]

As surgeons identify more risk factors for PJF, we can strive towards decreasing the rate of this complication. Controllable risk factors such as operative decisions are particularly useful as they can be considered during preoperative planning. This paper aims to contribute to the existing knowledge of PJF risk factors in an effort to improve outcomes. We hypothesized that lower mean screws per level and decreased rod stiffness would be associated with lower incidence of PJF.

METHODS

Data Sources and Patient Selection

This was a retrospective cohort study of a prospectively defined database of ASD patients. All patients included in the database were age more than or equal to 18 years and at least one of the following: a diagnosis of adult degenerative or idiopathic scoliosis with a maximum Cobb angle of more than or equal to 20°, SVA more than 5 cm, PT more than 25°, or TK more than 60°. Patients less than 18 years old and those with a diagnosis of scoliosis other than degenerative or idiopathic were excluded. Only patients eligible for 2-year postoperative follow-up were included. Patients with a prior history of spinal fusion were excluded. Additional inclusion criteria were: fusion of more than or equal to five levels with LIV at the sacro-pelvis, rod diameter more than or equal to 5.0 mm (rods <5.0 mm were excluded due to low incidence), and rod material of cobalt chrome, stainless steel, or titanium (other materials were excluded due to low incidence).

Dependent Variable

The primary dependent variable in this analysis was proximal junctional failure (PJF), defined as PJ angle more than 28° and ΔPJ angle more than 22°, or more than or equal to 8 mm/more than or equal to 3 mm listhesis at upper thoracic/thoracolumbar levels.[10]

Independent Variables

The primary independent variable was the mean number of posterior screws per level fused. This was calculated as the total number of posterior screws implanted divided by the number of vertebrae from the UIV to the LIV minus the number of 3-column osteotomies performed (*i.e.*, levels with a 3-column osteotomy were not included in the denominator). Importantly, the database used in this study separates sacropelvic LIVs into separate levels of S1, S2, and ilium. To ensure consistency between patients, these levels were treated distinctly for the purpose of calculating screw density. For example, a construct from T10 to ilium (11 vertebrae fused, separating sacropelvic levels) with 15 total screws would have a density of 1.36 screws per level. An optimal cutpoint was determined by ROC analysis and the Youden index, a commonly employed method that identifies an optimal cutpoint by maximizing the sum of sensitivity and (specificity – 1).[11] We conducted a bootstrapped analysis of the optimal cutpoint, with 75% sampling and 1000 iterations. This ultimately produced screw density was also analyzed as a continuous variable. Secondary independent variables included rod diameter and material.

Statistical Analysis

Descriptive statistics were generated. Bivariable analyses using *t* tests, Wilcoxon Mann–Whitney *U* tests, and Chi-square tests, were utilized, as appropriate. Multiple logistic regression was utilized to control for a wide range of potential confounding factors, including: age, body mass index (BMI), 6-week postoperative change from baseline in lumbar lordosis, number of posterior levels fused, sex, Charlson Comorbidity Index, surgical approach, osteotomy, upper instrumented vertebra (UIV), osteoporosis, preoperative T1-pelvic angle (T1PA), and pedicle screw at the UIV (as opposed to hook, wire, *etc.*). Separate models with outcomes of binary low *versus* high density and continuous screw density were constructed. To improve fit of the continuous screw density variable to the logistic regression model, outliers were excluded by Winsorizing at 2% (10 patients) at the lower bound, corresponding to a screw density of 1.0. Statistical analysis was completed with SAS 9.4 (SAS Institute, Cary, NC) and R 3.6.3 (R Project, Vienna, Austria).

RESULTS

Descriptive Statistics

In total, 504 patients were analyzed. The mean age was 63.6 (SD 9.2) and 77.0% (n = 385) of patients were female. The mean screws per level was 1.7 (SD 0.2), and 56.8% of patients (n = 286) had constructs with less than 1.8 screws per level. PJF occurred in 12.7% of patients (n = 64). The majority of patients had 5.5 mm rods (67.5%, n = 340), though 6.0 mm (11.1%, n = 56) and 6.35 mm (21.4%, n = 108) were reasonably represented. Similarly, most rods were cobalt chrome (62.6%, n = 313), though a fair proportion had stainless steel (14.8%, n = 74) and titanium (22.6%, n = 113). There were several baseline differences between the two groups, though all variables were ultimately controlled for in multiple regression analyses. Patients with low screw density tended to have a greater proportion of 5.5 mm rods, cobalt chrome rods, UIV at T10 or lower levels, pedicle screw at the UIV, and lower number of levels fused (Table 1). Importantly, preoperative T1PA and change in lumbar lordosis at 6 weeks postoperatively from baseline were not significantly different between patients with low *versus* high screw density constructs (both $P > 0.15$). (Tables 1 and 2)

Bivariable and Multivariable Analyses

The optimal cutpoint for screw density was determined to be 1.8 screws per level (95% CI 1.7–1.8) (Figure 1). PJF occurred in 17.0% of patients with high screw density constructs and in 9.4% of patients with low screw density constructs ($P = 0.0119$) (Table 3). Similarly, patients experiencing PJF exhibited higher mean screw density (1.76 *vs.* 1.70, $P = 0.0020$, Table 4). In multivariable analyses, low *versus* high screw density construct were associated with lower odds of PJF (odds ratio (OR) 0.45, $P = 0.0230$) (Table 5). A continuous variable for screw density was significantly associated with PJF (OR 3.87 per 0.5 screws per level, $P = 0.0118$). No significant difference was observed in the risk of PJF by rod diameter or material in both bivariable and multivariable analyses (all $P > 0.15$). In a subanalysis that stratified screw density into the region adjacent to the UIV (UIV to UIV-4) and the remainder of the construct, a continuous variable for screw density adjacent to the UIV was not significantly associated with PJF ($P = 0.31$). A case example of these findings is presented in Figure 2.

DISCUSSION

This study found that adult spinal deformity patients undergoing primary, long-segment fusion to the sacro-pelvis with low pedicle screw density constructs (<1.8 screws per level) were less likely to experience PJF than patients with high density constructs. Pedicle screw density modeled as a continuous variable was also significantly associated with PJF. Rod material and diameter were not significantly related to PJF.

Previous studies have supported that posterior construct stiffness can influence risk of complications at the proximal junction. Han *et al*[12] conducted a study of 54 ASD patients undergoing fusion to the sacro-pelvis to compare stiff cobalt-chrome multiple-rod constructs (CoCr-MRC) with less stiff titanium alloy two-rod constructs (Ti-TRC). The CoCr-MRC and Ti-TRC groups exhibited similar distribution of age, sex, use of 3-CO, levels fused, and pre-/postoperative alignment. PJK occurred in 60% (n = 12) of the CoCr-MRC group and 26.5% (n = 9) of the Ti-TRC group ($P < 0.05$). Bony failure accounted for the vast majority of PJK events. Importantly, rod fracture occurred at a significantly higher rate in the Ti-TRC group *versus* the CoCr-MRC group. Greater screw density of a posterior spinal construct is very likely associated with increased construct stiffness, though we are unable to find literature attesting to this specific concept at the present time. It is possible that decreased construct stiffness the both Ha *et al*'s study as well as the present investigation allows for greater flexibility at the proximal junction, reducing stress concentration at the proximal junction.[13] We hope to undertake biomechanical studies to further investigate this point.

It is interesting to note that this study found a significant association between PJF and screw density, but did not observe such an association between PJF and rod material/diameter. This may argue against a possible connection between screw density, posterior construct stiffness, and PJF. However, it is also possible that the range of variability in construct stiffness imparted by modulating material and diameter of posterior rods may be less than that imparted by modulating screw density. As above, these questions deserve further investigation via biomechanical studies. In the meantime, this study highlights the potentially important role of posterior implant density in adult spinal deformity—a role that has to this point received relatively little attention.

A randomized clinical trial of implant density in adult spinal deformity surgery may also potentially be warranted. The Minimizing Implants Maximizing Outcomes (MIMO) Study Group conducted a survey of parent/patient willingness to participate in a randomized controlled surgical trial. They found that 63% of patients and parents were willing to enroll in such a trial.[14] Willingness among adult spinal deformity patients may be comparable. Interestingly, the MIMO Clinical Trial selected more than or equal to 1.8 implants per level fused as the cutoff for high-implant density—this is the precise cutoff determined empirically in the present study.[15] Comparison of the present results to the MIMO study may yield fascinating insights when that trial is published.

Implant density has been extensively studied in the adolescent idiopathic scoliosis (AIS) literature. The MIMO Group found in a retrospective study that high *versus* low implant density constructs were associated with greater curve correction among Lenke 1 and 2 curves, but not Lenke 5 curves, and with inconsistent effects on health-related quality of life.[16] Chen *et al*[17] studied 35 patients with Lenke type 5 AIS and found no association between implant density and either correction index or magnitude of sagittal

TABLE 1. Descriptive Statistics (Categorical)

Variable	All Patients		Screw Density		
	N	%	Low (%)	High (%)	*P*-Value
All patients	**504**	–			
Average screws per level					–
High (≥1.8)	218	43.3	–	–	
Low (<1.8)	286	56.8	–	–	
Rod diameter					**<0.0001**
5.5 mm	340	67.5	71.1	64.7	
6.0 mm	56	11.1	16.1	7.3	
6.35 mm/quarter inch	108	21.4	12.8	28.0	
Rod material					**0.0034**
Cobalt chrome	313	62.6	69.6	57.2	
Stainless steel	74	14.8	9.2	19.1	
Titanium	113	22.6	21.2	23.7	
Frequency missing = 4					
Gender					0.7770
Male	115	23.0	23.6	22.5	
Female	385	77.0	76.4	77.5	
Frequency missing = 4					
CCI					0.8935
0	124	24.6	26.2	23.4	
1	126	25.0	23.9	25.9	
2	122	24.2	24.3	24.1	
≥3	132	26.2	25.7	26.6	
Pedicle screw at UIV					**<0.0001**
No	96	19.1	1.4	32.5	
Yes	408	81.0	98.6	67.5	
Approach					0.1303
Posterior only	307	60.9	64.7	58.0	
Anterior-posterior (APSF)	197	39.1	35.3	42.0	
Osteotomy					0.1110
No	124	24.6	21.1	27.3	
Yes	380	75.4	78.9	72.7	
UIV					**0.0017**
T5 or higher	177	35.1	27.5	40.9	
T6–T9	51	10.1	8.7	11.2	
T10 or lower	276	54.8	63.8	47.9	
Osteoporosis					0.3950
No	413	81.9	80.3	83.2	
Yes	91	18.1	19.7	16.8	

UIV indicates upper instrumented vertebra. Bold values are those with P < .05.

curve correction. Gebhart *et al*[18] similarly studied 119 AIS patients treated with posterior spinal fusion and found that implant density was significantly related to length of stay and implant charges, but not curve correction magnitude, complications, infection, or estimated blood loss. Kemppainen *et al*[19] found similar results in their study of 52 AIS patients, namely that sagittal alignment, coronal balance, and magnitude of correction was similar between high and low implant density constructs. None of these studies, however, examined PJF as an outcome, possibly due to low incidence among the AIS population. These studies were all retrospective reviews, and it is therefore difficult to determine the influence of preoperative surgical planning based on curve morphology and surgeon experience. It is also challenging to extrapolate these data from AIS to ASD. Nevertheless, they suggest that screw density may have less influence on the immediate intra- and postoperative period. Our results support the idea that the effects of implant density may manifest over months-to-years postoperatively. Further study of this topic is strongly warranted.

There were potential limitations to this study. First, this was a retrospective investigation, and it is very possible that occult confounding variables exist. Pedicle screw placement is a complex decision that is influenced by a wide range of

TABLE 2. Descriptive Statistics (Continuous)

Variable	All Patients			Screw Density		
	Mean	SD	Missing	Low (SD)	High (SD)	*P*-Value
Average screws per level	1.7	0.2	0	–	–	–
Age	63.6	9.2	0	62.9 (9.6)	64.1 (8.9)	0.1697
BMI	27.8	5.3	3	28.2 (5.4)	27.5 (5.2)	0.1129
Change in LL (6wk—baseline)	17.6	16.3	10	17.2 (15.8)	18 (16.7)	0.6006
Number of levels fused	12.0	3.5	0	11.5 (3.2)	12.4 (3.6)	0.0025
Baseline T1-PA	23.6	11.3	4	22.8 (11.2)	24.2 (11.3)	0.1844

BMI indicates body mass index.

factors. While we attempted to control for a broad array of potential confounders, the non-randomized nature of this study inherently limited the scope to known variables that may interact with both screw density and PJF. Second, the database that we used separated sacropelvic LIVs into S1, S2, and ilium as separate levels. To ensure consistency, each sacropelvic level was counted separately in our calculation of the denominator for screw density per vertebra fused. This approach meant that a patient instrumented from T10-ilium (11 vertebrae, including sacropelvic levels separately) with bilateral pedicle screws at T10-S1 and bilateral iliac screws (20 screws) would have a screw density of 1.81. Had we elected to exclude the S2 level from the count of instrumented vertebrae, the screw density in the above example would have been 2.0 (20 screws over 10 vertebrae). This calculation should be taken into account when considering our results. Nevertheless, while the inclusion of separate sacropelvic levels in the denominator vertebrae influenced the absolute pedicle screw density for each patient, it will likely have had little effect on the relative distribution of screw densities across our cohort. It was for this reason that we also analyzed screw density as a continuous variable, the significance of which suggested that our results were not biased by this accounting of vertebrae. Finally, our continuous screw density analysis indicated a significant but relatively small difference in mean screws per level between patients experiencing *versus* not experiencing PJF. This is at least partially attributable to the markedly non-normal

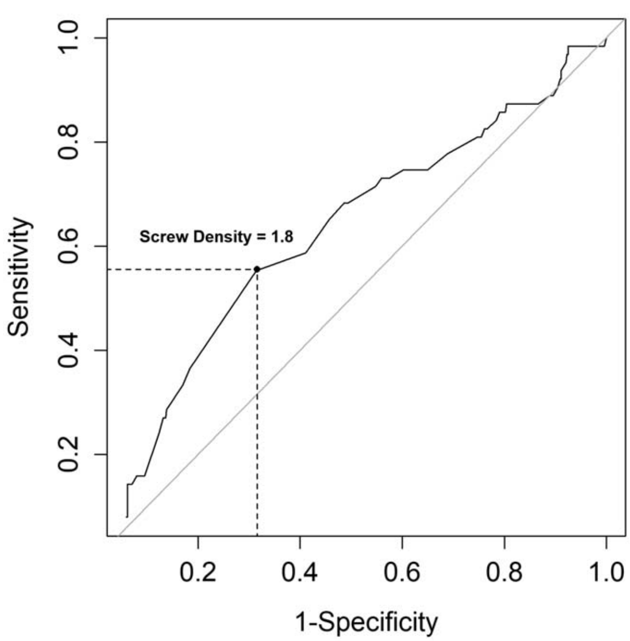

Figure 1. ROC curve for screw density and proximal junctional failure, with the optimal cutpoint of 1.8 screws per level identified using the Youden method.

TABLE 3. Bivariable Categorical Analysis

	PJF (%)	*P*-Value
Screw density		0.0119
High (≥1.8)	17.0	
Low (<1.8)	9.4	
Rod diameter		0.7543
5.5 mm	12.1	
6.0 mm	12.5	
6.35 mm /quarter inch	14.8	
Rod material		0.3023
Cobalt chrome	13.1	
Stainless steel	16.2	
Titanium	8.9	

TABLE 4. Bivariable Comparison of Screw Density by PJK/PJF

	Mean	SD	*P*-Value
PJF			0.0020
No	1.70	0.18	
Yes	1.76	0.18	

PJF indicates proximal junctional kyphosis.

TABLE 5. Multivariable Analysis

Variable	OR	95% CI		*P*-Value
Low density (<1.8)	0.48	0.25	0.90	0.0230
Screw density (per 0.5 screws per level)	3.87	1.35	11.09	0.0118

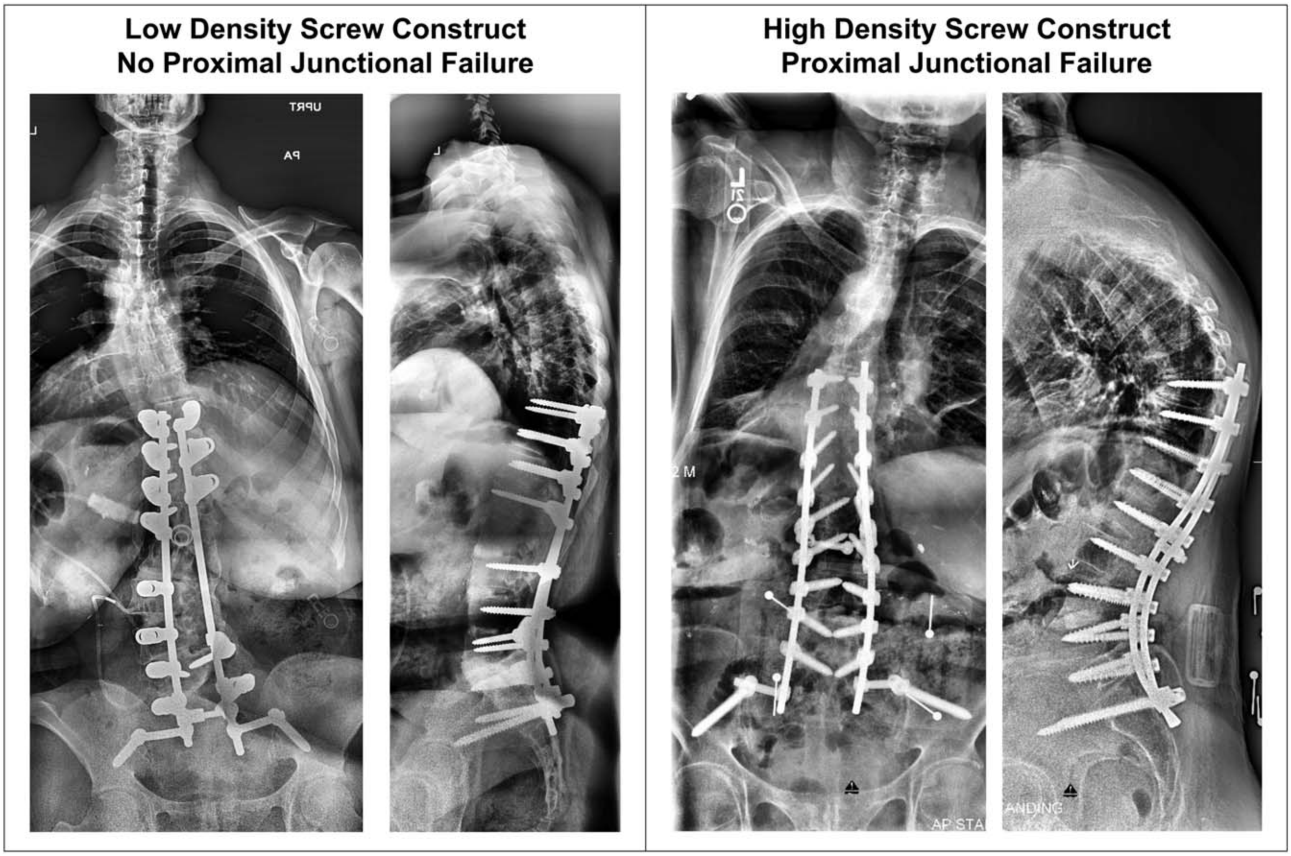

Figure 2. On the left, a 61-year-old female underwent primary fusion with a low screw density construct (1.36 screws per level) from T10-ilium, with no PJF at follow-up. On the right, a 73-year-old female underwent primary fusion with a high screw density construct (2.00 screws per level) from T10-ilium, with PJF at follow-up. PJF indicates proximal junctional kyphosis.

distribution of screw density. Our categorical analysis confirms the existence of two groups of patients with highly distinct associations between screw density and PJF.

CONCLUSION

Among ASD patients undergoing long-segment primary fusion to the pelvis, the risk of PJF was lower among patients with less than 1.8 screws per level. This finding may be related to construct rigidity. Rod material and diameter, however, were not significantly associated with PJF. Residual confounding by other patient and surgeon-specific characteristics may exist. Further biomechanical and clinical studies exploring this relationship are warranted.

➢ Key Points

- ❑ Among ASD patients undergoing long-segment primary fusion to the pelvis, the risk of PJF was lower among patients with less than 1.8 screws per level. This finding may be related to construct rigidity.
- ❑ Pedicle screw density modeled as a continuous variable was also significantly associated with PJF.
- ❑ Rod material and diameter were not significantly related to PJF.

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