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ORIGINAL ARTICLE

Proximal junctional kyphosis is a rebalancing spinal phenomenon due to insufficient postoperative thoracic kyphosis after adolescent idiopathic scoliosis surgery

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Abstract

Purpose Many authors tried to explain proximal junctional kyphosis (PJK) after adolescent idiopathic scoliosis (AIS) surgery by looking for risk factors. Latest publications focus on sagittal alignment. Each healthy adolescent has a specific thoracic kyphosis (TK) depending on their pelvic parameters and lumbar lordosis (LL). The objective of this work is to determine if the difference between TK at follow-up (TKFU) and the patient-specific TK (PSTK) plays a role in PJK occurrence after AIS surgery. The secondary objective was to find other risk factors.

Methods We analyzed retrospectively 570 thoracic AIS who underwent a posterior thoracic fusion from nine centers. The series was separated in two groups: with and without PJK. PSTK was calculated with the formula PSTK = 2(PT + LL-PI). TK Gap was the difference between TKFU and PSTK. Logistic regression was utilized to test the impact of TK Gap and other known risk factors on PJK occurrence.

Results Univariate analysis showed 15 factors significantly different between the groups. In a multivariate analysis, three factors had a strong significant influence on PJK: TKFU, TK Gain and TK Gap. Four additional factors affected the rate of PJK: Posterior translation on two rods, preoperative TK, preoperative LL and number of instrumented vertebrae.

Conclusion PJK is related to the insufficient TK at follow-up, compared to the specific TK that every patient should have according to their pelvic parameters. PJK incidence is significantly reduced by a strong gain in TK and a thoracic selective fusion which leaves the proximal lumbar vertebrae free.

Level of evidence I Diagnostic: individual cross-sectional studies with consistently applied reference standard and blinding

Keywords Proximal junctional kyphosis · Thoracic kyphosis · Patient-specific thoracic kyphosis · Postero-medial translation · Adolescent idiopathic scoliosis

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Introduction

Since the first publications on proximal junctional kyphosis (PJK) [1–3], the overall reported incidence ranges from 0 to 46%. Several authors have tried to explain PJK by looking for the risk factors: patient related factors like age, gender, body mass index; surgery-related factors like density, length of the instrumentation, anchors type, rod diameter, thoracoplasty, combined anterior and posterior surgery; X-ray related factors like Lenke type, pre-operative thoracic kyphosis (TK), loss of kyphosis, high pelvic incidence (PI), post-operative sagittal vertical axis > 5 cm [1–7]. However, these factors remain controversial as they are not reported by all authors [8]. Moreover, many factors lose significance with multivariate analysis [9] and some authors have not found any risk factors [10].

The most recent publications focus on sagittal alignment. PJK could be due to postoperative posterior imbalance by increased lumbar lordosis (LL), insufficient TK, or a mismatch between thoracic and lumbar alignment [7, 8, 11]. he occurrence of PJK has been described as a compensatory mechanism to keep the head above the pelvis [12].

A good postoperative sagittal alignment requires that the sagittal curvatures be in accordance with the pelvic parameters. The role of TK seems essential. Although there is a wide range of normal values [13], some authors are currently looking for the optimal TK value [14–17].

It has recently been shown that each healthy adolescent has a specific kyphosis depending on pelvic tilt (PT), PI and LL. The formula for calculating this "patient specific thoracic kyphosis" (PSTK) is PSTK = 2(PT + LL-PI) [17]. Therefore, there is not one TK optimal value for all, but a specific value for each subject. The objective of this work was to determine if the difference between TK at follow-up (TKFU) and the PSTK, played a role in the occurrence of PJK. The secondary objective was to find other factors, focusing on the correction technique, that may explain PJK.

Methods

Hypothesis

The occurrence of PJK in adolescent idiopathic scoliosis (AIS) is a consequence of a sagittal balance disorder due to insufficient TKFU compared to the kyphosis that the patient should have.

Patients

The data from AIS patients treated by posterior thoracic fusion, was collected from nine centers in a shared database (KEOPS-SMAIO-France). All patients had full spine, standing radiographs (coronal and sagittal) preoperatively, postoperatively and at least minimum 2 years follow-up. Patients with selective lumbar fusion (Lenke 5), previous spine surgery, anterior release and incomplete files were excluded. After application of the exclusion criteria, 570 files remained for retrospective analysis.

Surgical procedures

The constructs carried out between 1983 and 2017 were double rods with either hybrid or all screws anchorages. Five correction techniques were used depending on surgeon preferences:

- rod rotation (RR) with screws and hooks hybrid constructs,
- in situ bending (ISB) with all screw constructs, [18].
- cantilever correction (C) with screws and hooks hybrid constructs, [19].
- postero-medial translation on one rod (1-rod PMT) with screws, sublaminar bands and self-stabilizing proximal hooks hybrid constructs, [20].
- PMT on two rods (2-rod PMT) with screws and self-stabilizing proximal claws hybrid constructs [21].

Scoliosis Lenke type 1 and 2 had selective or non-selective thoracic fusions depending on surgeons' preferences. Scoliosis Lenke type 3, 4 and 6 had posterior thoracic and lumbar fusions. Upper instrumented vertebrae (UIV) were not different for the five correction techniques (T2, T3 or T4).

Radiographic measurements

All the measurements were performed automatically by the software "Keops Analyser" after graphical identification of anatomical landmarks and sagittal curves and relied on a consensus between two surgeons. Global TK and global LL were measured, corresponding to all vertebrae which were in kyphosis or lordosis independently of a predefined vertebral level (Fig. 1) [17].

Several variables were defined as follows (Table 1):

- PJA: Proximal sagittal Junctional Angle as the cobb angle between the proximal endplate of the UIV and

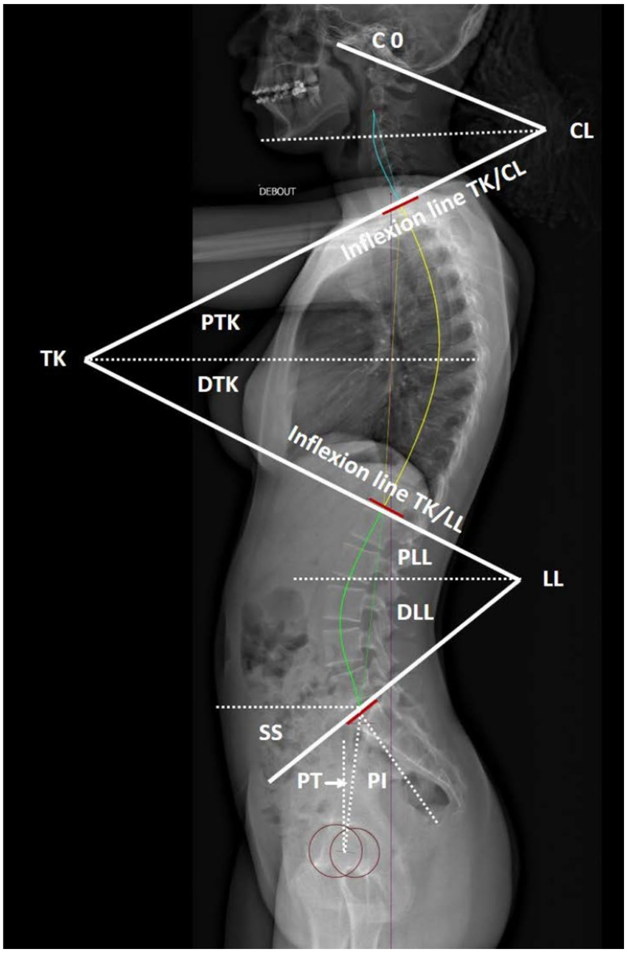

Fig. 1 TK and LL global measurements: TK and LL are separated by an inflection line defined by the change of curvature between the thoracic and lumbar regions. Global LL was measured between sacral slope and the inflection line TK/LL, and global TK between this inflection line and the inflection line TK/CL between the thoracic and cervical regions. CL: Cervical Lordosis; TK: Thoracic Kyphosis; PTK: Proximal Thoracic Kyphosis; DTK: Distal Thoracic Kyphosis; LL: Lumbar Lordosis; PLL: Proximal Lumbar Lordosis; DLL: Distal Lumbar Lordosis; SS: Sacral Slope, PT: Pelvic Tilt; PI: Pelvic Incidence

the superior endplate of the two supra-adjacent vertebrae above the UIV.

- PJKA: Proximal Junctional Kyphosis Angle as PJA at follow-up minus PJA pre-op.
- PJK was defined by two criteria: PJA > 10° and PJKA > 10° at follow-up [2]. Patients were separated into two groups: PJK and Non-PJK groups.
- TKFU was calculated by removing PJKA from global TK at follow-up. PJKA represents the kyphosis due to PJK; this allowed to control for the increase in TK due to PJK.
- TK Gain was calculated from TKFU minus pre-operative TK. It corresponds to the gain in TK linked to the instrumentation.
- PSTK was calculated with the preoperative values of PT, PI and LL with the formula PSTK = 2(PT + LL-PI) [17].
- TK Gap was the difference between TKFU and PSTK.

The influence of TKFU, TK Gain and TK Gap on the occurrence of PJK was tested.

Other potential influencers were also tested: general factors (gender, age and Risser sign at the time of surgery), sagittal radiologic factors (PI, SS, PT, TK, LL and their gain, proximal lordosis, C7-tilt) coronal radiologic factors (angulation of main, proximal and distal curves, correction percentage, Lenke type, lumbar modifiers), and surgical factors (number of instrumented vertebrae (NIV), implant density, anchor type, and correction technique.

Statistical analysis

Mean values were compared through unpaired T test or analysis of variance. Categorical variables were analyzed through Fisher's exact test and logistic regressions. Multivariate analysis was performed through logistic regression where the dependent factor was the occurrence of PJK. The significance level was set at 0.05 [22]. All analyses were performed with XLStat Addinsoft®.

Results

General results

We analyzed 570 patients, 482 girls and 88 boys with an average age of 15 years (10–21) and a mean follow-up of 49 months (24–356). Overall 102 patients (18%) developed PJK. Only 10 patients required revision surgery due to pain or morphological disorder.

In the coronal plane, the main thoracic Cobb decreased from 58° (± 11.9°) to 22° (± 11.5°) at last follow-up which corresponded to an average correction of 63% (± 17.1%).

Univariate analysis

15 factors were significantly different between the two groups on univariate analysis. Three factors, Global TK at follow-up, PJA at follow-up and PJKA were different due to the definition of the 2 groups. The percentage of PJK was significantly different between the five correction techniques ($p = 0.03$). All other factors, including those not listed in Table 2, were not significantly different.

Table 1 Table of abbreviations in alphabetical order

AIS	Adolescent idiopathic scoliosis	PMT	Postero medial translation
C	Cantilever	PSTK	Patient-specific kyphosis = 2(PT + LL-PI)
ISB	In situ bending	PT	Pelvic tilt
LL	Lumbar lordosis	RR	Rod rotation
NIV	Number of instrumented vertebrae	SS	Sacral slope
PI	Pelvic incidence	TK	Thoracic kyphosis
PJA	Proximal junctional angle	TK Gain	= TKFU—TK Pre-op
PJK	Proximal junctional kyphosis defined by PJA > 10° and PJKA > 10°	TK Gap	= TKFU—PSTK
PJKA	Proximal junctional kyphosis Angle = PJA at follow-up—PJA pre-op	TKFU	Thoracic kyphosis at follow-up = Global TK—PJKA
PLL	Proximal lumbar lordosis	UIV	Upper instrumented vertebra

Multivariate analysis

All significant univariate factors were tested on multiple logistic regression. Ten of them lost their significance. Three factors had a strong influence on PJK: TKFU, TK Gain and TK Gap. Preoperative TK and PMT on two rods were also significant. Two additional factors interfered with an interdependent effect: LL at follow-up with NIV and NIV with TK Gap (Table 3).

Correction technique influence

Table 4 gives the sagittal spinopelvic parameter values and surgical parameters for the five correction techniques. The PMT on two rods showed a significantly lower PJK rate (4.5%) compared to the four other techniques ($p < 0.001$).

Discussion

TKFU, TK Gain, and TK Gap

The occurrence of PJK depended mainly on three factors: TKFU, TK Gain and TK Gap. Those factors express the variation of TK after surgery: absolute value for TKFU and relative values for TK Gain and TK Gap. In the PJK group, the loss of TK between preoperative and last control (average − 5°) and the negative TK Gap (average − 9°) showed that TKFU (average 28°) was insufficient, compared to the PSTK (average 37°). Conversely, the 10° TK Gain in the Non-PJK group with the positive TK Gap (average 6°) showed that restoration of TKFU (average 37°) at least equal or superior to PSTK (average 31°) was a protective mechanism against PJK. The main hypothesis is therefore confirmed: PJK was related to insufficient TKFU, which remained lower than PSTK.

The loss of thoracic kyphosis after surgery has been described as a risk factor with TK segmental measurements (T5-T12) [4, 6]. With a global TK measurement, Ferrero et al. observed that TKFU was similar in the two groups and since PJK was responsible for a TK increase at the non-instrumented upper junction, it may be associated with a reduced TK in the instrumented part [7]. They therefore included upper thoracic kyphosis due to PJK in global TK, while the measurement between T5 and T12 does not. In our study, we took care to remove PJKA from the global TK at follow-up to avoid accounting for TK increase due to PJK.

The definition of insufficient TK implies that the optimal value of TK is known. There is a wide range of normal kyphosis in the literature ranging from 7 to 63° with a large standard deviation (10°) [13]. Rothenfluh et al. defined a critical thoracic kyphosis of 23° to potentially avoid postoperative sagittal plane deterioration [16]. Liu et al. demonstrated that the predictive adult sagittal alignment formula TK = 2(LL-10)-PI was not applicable in adolescents [15]. It has recently been proposed that each normal subject has a specific TK according to the formula PSTK = 2(PT + LL-PI) [17]. This formula allows for calculating preoperatively the PSTK for the correction of AIS, given that the preoperative pelvic parameters will be the same at follow-up (Table 2) [23–25]. Concerning LL in the formula, Clement et al. showed that the surgical increase in TK led to an increase in the uninstrumented LL through the increase in proximal lumbar lordosis (PLL) [23]. The LL gain was 40% of the TK gain. For this study, we used this formula to calculate PSTK with the pre-operative LL and without the LL increase. Therefore, PSTK was underestimated. This explains why TKFU is superior to PSTK with a positive TK Gap in the non-PJK group.

Table 2 Univariate analysis: Role of risk factors on PJK occurrence

Univariate analysis mean value (± SD)	Cohort *n* = 570	Non-PJK group *n* = 468	PJK group *n* = 102 (18%)	p PJK/Non-PJK
General factors				
Age (years)	15.2	15.1	15.6	**0.012**
Gender (F/M)	482/88	402/66	80/22	NS
Follow-up (months)	49	51	40	**0.037**
Risser (0, 1, 2, 3, 4, 5)	47, 59, 73, 138, 124, 129	11, 7, 13, 25, 18	36, 52, 60, 113, 106, 101	NS
Lenke type (1, 2, 3, 4, 6)	351, 149, 27, 10, 33	292, 125, 19, 9, 23	59, 24, 8, 1, 10	NS
Modifiers (A, B, C)	342, 78, 150	281, 67, 120	61, 11, 30	NS
Coronal radiological factors (*Cobb*°)				
Main Curve (pre-op)	58° (± 12)	58° (± 12)	57° (± 12)	0.9
Main Curve (follow-up)	22° (± 12)	22° (± 11)	23° (± 12	0.32
Correction (%)	63% (± 17)	63% (± 17)	61% (± 18)	0.21
Sagittal radiological factors (°)				
PI (pre-op)	51° (± 12)	51° (± 12)	51° (± 12)	0.67
PI (follow-up)	50° (± 12)	50° (± 12)	50° (± 12)	0.53
SS (pre-op)	42° (± 9)	42° (± 9)	43° (± 9)	0.54
SS (follow-up)	42° (± 9)	42° (± 9)	42° (± 8)	0.85
PT (pre-op)	9° (± 8)	9° (± 8)	8° (± 7)	0.19
PT (follow-up)	9° (± 9)	9° (± 9)	8° (± 8)	0.27
Global LL Pre -op	58° (± 11)	58° (± 11)	61° (± 11)	**0.006**
Global LL Follow-up	62° (± 11)	62° (± 12)	64° (± 9)	0.054
LL Gain	4° (± 10)	4° (± 10)	3° (± 10)	0.38
Global TK Pre-op	28° (± 14)	27° (± 16)	33° (± 16)	**0.0015**
Global TK Follow-up	39° (± 16)	38° (± 15)	45° (± 18)	**< 0.0001**
PJA Pre-op	3° (± 6)	3° (± 6)	1° (± 6)	**0.0035**
PJA Follow-up	6° (± 8)	4° (± 6)	18° (± 6)	**< 0.0001**
PJKA	4° (± 9)	1° (± 6)	17° (± 5)	**< 0.0001**
TKFU = Global TK-PJKA	35° (± 17)	37° (± 16)	28° (± 18)	**< 0.0001**
TK Gain	7° (± 20)	10° (± 19)	− 5° (± 22)	**< 0.0001**
PSTK = 2(PT + LL-PI)	32° (± 15)	31° (± 14)	37° (± 15)	**0.0005**
TK Gap = TKFU-PSTK	3° (± 21)	6° (± 20)	− 9° (± 22)	**< 0.0001**
C7 Tilt (follow-up)	3° (± 3)	3° (± 3)	4° (± 4)	0.8
Surgical factors				
NIV (*n*)	11.9 (± 1.8)	11.8 (± 1.9)	12.3 (± 1.7)	**0.01**
Anchorages density (%)	70.8% (± 14.8)	71.4% (± 15.2)	68.0% (± 12.9)	**0.04**
Correction techniques: Fisher exact test: *p* = *0.03*				P (PJK/Cohort)
RR (*n*)	117	96	21 (18%)	NS
ISB (*n*)	66	53	13 (20%)	NS
C (*n*)	43	31	12 (28%)	NS
1-rod PMT (*n*)	167	119	48 (29%)	NS
2-rod PMT (*n*)	177	169	8 (4.5%)	**0.001**

Significant *p* in bold

SD: Standard Deviation

PJK as a compensatory mechanism

If TK is insufficient, the patients will regain their new balance by mobilizing the proximal portion of the spine that is still mobile above the instrumentation and develop PJK and/or distal cervical kyphosis (Fig. 2). If TK is too large, which is less frequent, the patients can recover their balance by reducing their proximal thoracic kyphosis and/or by increasing their distal cervical lordosis. The post-operative C7 sagittal tilt which is similar between the 2 groups (Table 2),

Table 3 Multivariate analysis: Multiple logistic regression

Multiple logistic regression	Values	*p*	Odds ratio	Odds ratio lower bound (95%)	Odds ratio upper bound (95%)
TKFU	0.043	< 0.0001	1.044	1.028	1.059
TK Gain	0.043	< 0.0001	0.958	0.944	0.972
TK Gap	− 0.045	< 0.0001	0.956	0.944	0.969
2-rod PMT	1.339	0.001	3.814	1.687	8.619
TK Pre-op	− 0.016	0.042	0.984	0.97	0.999
Multiple logistic regression with interaction effects					
NIV/LL Pre-op	0.002	0.018	1.002	1	1.003
NIV/TK Gap	0.007	0.024	1.007	1.001	1.013

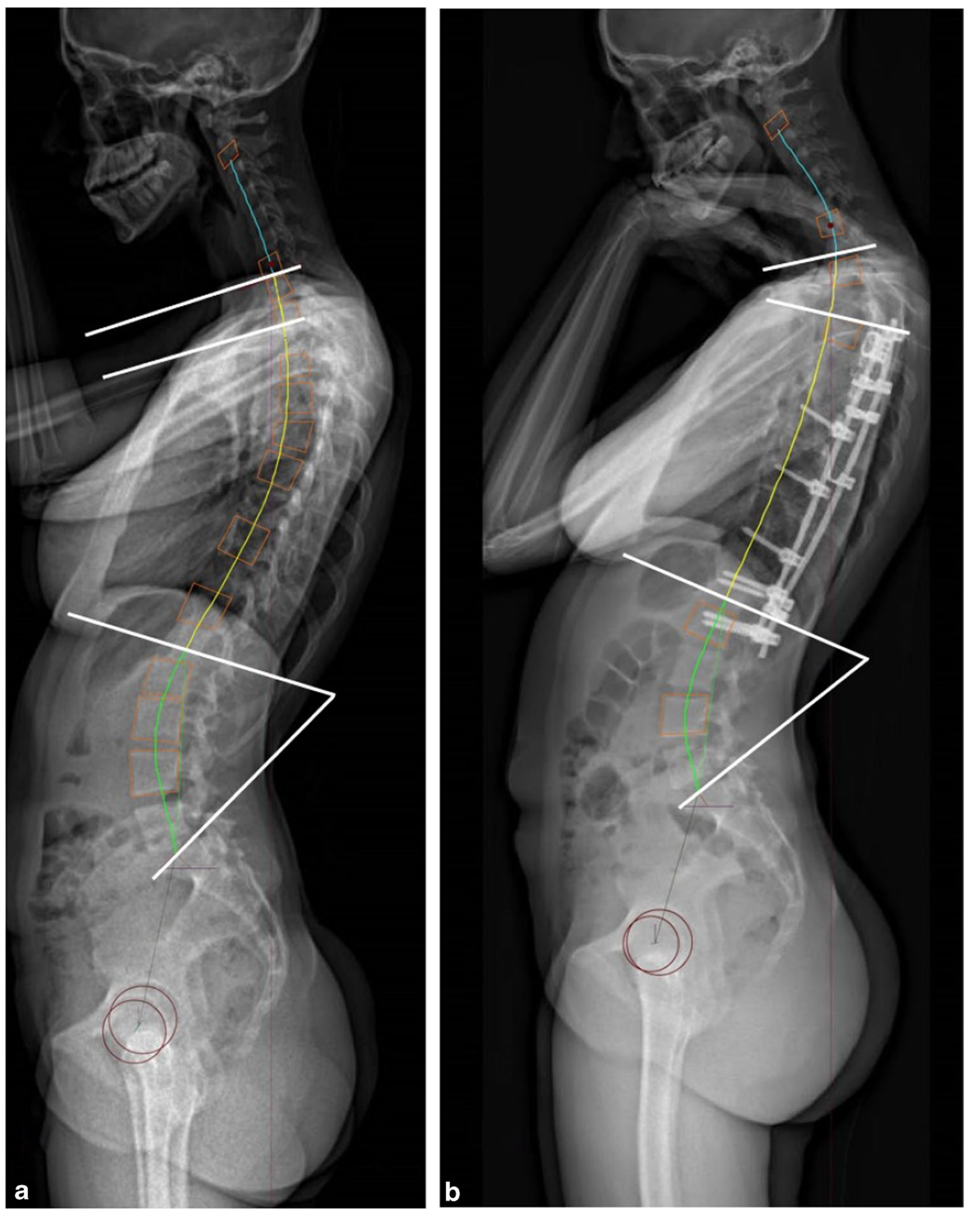

Fig. 2 PJK due to insufficient TK. **a**: Pre-operative X-ray: PT = 12°, PI = 57°, LL = 72°, PSTK = 2(PT + LL PI) = 54°, TK = 35°, PJA = 2°. **b:** X-ray at follow-up (28 months). Global TK at follow-up = 37°, PJA = 27°, PJKA = 25° (27–2°), TKFU = 12°, TK Gap (TKFU-PSTK) = − 42°. The spine is rebalancing by PJK

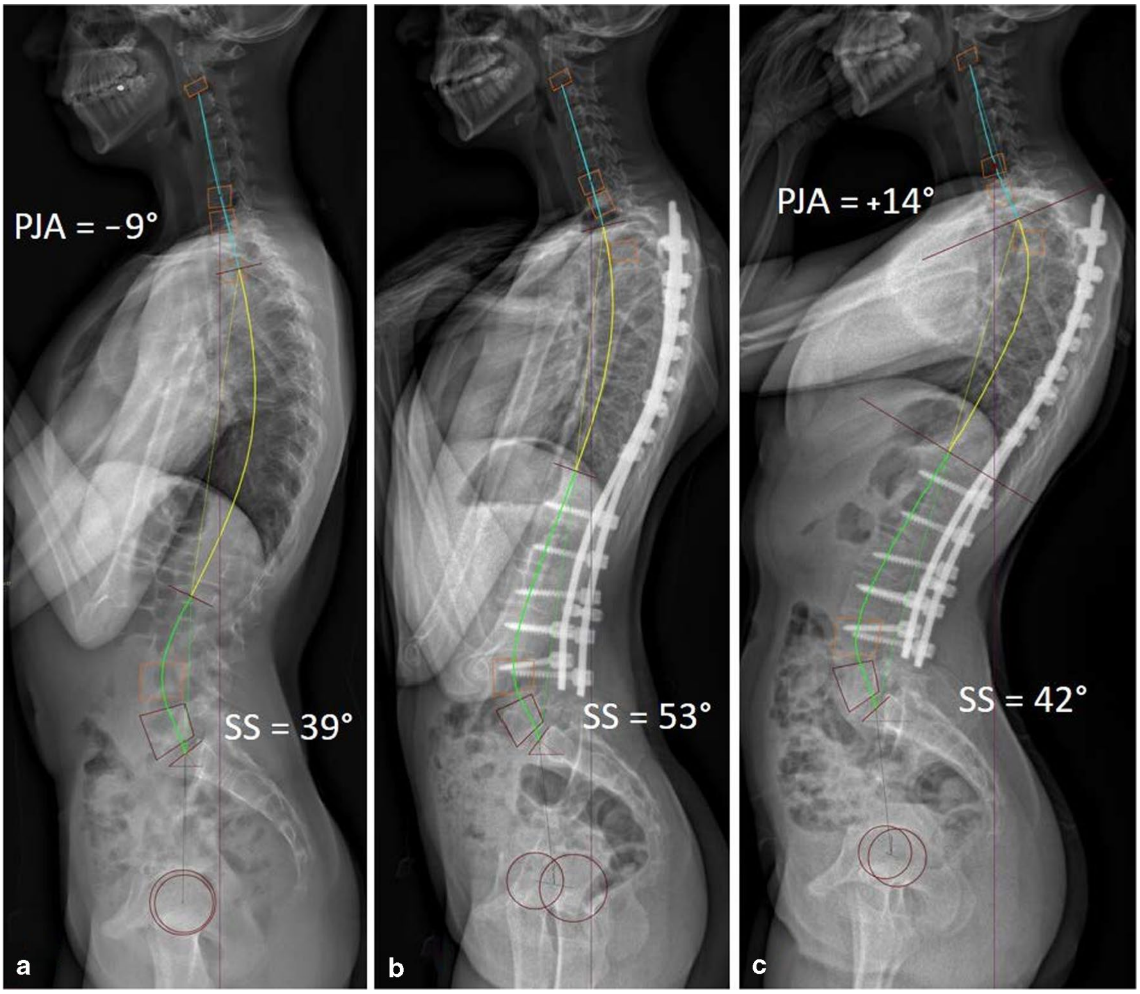

Fig. 3 PJK in a long construct. **a**: Pre-operative X-ray. PT = 1°; PI = 40°; LL = 65°; PSTK = 52°. **b**: Post-operative X-ray. The pelvic anteversion compensates for insufficient TK and ensures spine balance. **c**: X-ray at follow-up. TKFU = 31°. TK Gap = −21°. After returning to the initial pelvic orientation, PJK helps achieve the patient rebalancing

clearly shows that all the patients were balanced, either due to a good instrumented TK or due to PJK. [12]. Thus, PJK appears as a compensation method to rebalance the patient following insufficient TK. Most of the time, PJK will be well tolerated but can become, in some severe TK insufficiencies, a proximal adjacent disease requiring revision surgery (10 revision surgeries/102 PJK).

Another solution to recover a balanced spine would be to modify the sagittal post-operative pelvic orientation. A pelvic anteversion can compensates for the insufficiency of TK (Fig. 3). However, this situation does not last over time because not economical. The patients recover their initial pelvic orientation and regain their balance by increasing proximal kyphosis (Table 2) [23–25].

A distal junctional kyphosis could also be a process of rebalancing. However, this was not observed in this cohort.

Either way, the best method to achieve good sagittal alignment and avoid PJK, is to get TKFU at least equal to PSTK. PSTK must be calculated before surgery to set the target and give to the rods, the correct thoracic and lumbar curvature. The use of specific pre-bent rods is perhaps one of the solutions to achieve this objective.

Correction technique

Among the five surgical correction techniques analyzed, PMT on two rods resulted in the lowest PJK rate (4.5%) (Table 4). This is mainly explained by the technique's efficiency to increase TK, which carries out a postero-medial translation of the vertebrae toward the rods [21], whereas RR, ISB and C did not significantly improve TK.

However, patients from 2-rod PMT subgroup combines a larger TK Gain (17.2° vs 11°; $p = 0.003$) and positive TK Gap (13.2° vs 7.4°; $p < 0.0001$) than patients from 1-rod PMT subgroup and resulted in less PJK. Therefore, the spine translation seems more efficient on TK if correction

Table 4 Correction techniques influence on PJK and difference between the 2 translation techniques

Correction techniques mean value ± SD	RR (*n* = 117)	ISB (*n* = 66)	C (*n* = 43)	1-rod PMT (*n* = 167)	2-rod PMT (*n* = 177)	P 2-rod PMT/1-rod PMT
PJK group (%) (*n*)	18% (21)	20% (13)	28% (12)	29% (48)	4.5% (8)	0.006
LL Pre-op	56° ± 13	60° ± 11	59° ± 12	60° ± 9	58° ± 10	NS
TK Pre-op	25° ± 17	33° ± 18	32° ± 18	29° ± 15	27° ± 16	NS
TKFU	29° ± 15	26° ± 19	16° ± 20	40° ± 14	44° ± 11	0.007
TK Gain (°)	4° ± 18	− 7° ± 19	− 16° ± 21	11° ± 17	17° ± 16	0.033
PSTK (°)	30° ± 20	39° ± 18	35° ± 16	33° ± 13	31° ± 13	NS
TK Gap (°)	− 1° ± 21	− 13° ± 20	− 19° ± 19	7° ± 18	13° ± 15	< 0.0001
NIV	10.8 ± 2.1	12.7 ± 1.6	13.7 ± 1.8	13.0 ± 1.0	10.9 ± 1.3	0.045

SD: Standard deviation

is carried out simultaneously on two rods than on one, the second rod being in the latter technique, only stabilizer.

Moreover, patients from the 2-rod PMT subgroup had also shorter constructs (NIV = 11 vs 13) with non-selective thoracic fusion in Lenke type 1 and 2 for patients from 1-rod PMT subgroup and selective thoracic fusions for patients from 2-rod PMT subgroup.

From our result, the shorter the construct, the lower the risk of PJK. This has already been reported in adults [2, 5]. This can be explained by the formula PSTK = 2(PT + LL-PI), as follows: LL being the sum of the sacral slope (SS) and PLL, the formula can be written PSTK = 2(PT + SS + PLL-PI); TK therefore depends on 3 pelvic parameters and one spinal parameter. Since pelvic parameters will not be changed by surgery [23–25], only PLL will change and adapt to the new post-operative TK. If the construct is short, the proximal lumbar spine is free and can move toward the "best" PLL value which will ensure adequate sagittal alignment. If the construct is long, PLL is imposed by the rod and there is risk of not providing the optimum PLL value, becoming a source of imbalance and rebalancing by PJK (Fig. 3). The optimal PLL value is PLL = TK/2 (replacing in the formula, PT + SS by PI, leads to TK = 2PLL). For long instrumentations, it is necessary to bend the rod so that PLL is half of TK. Therefore, PLL appears to be a key element for regulating postoperative sagittal alignment.

Other factors

Most known factors associated with PJK did not play a significant role in this multicenter cohort on multivariate analysis. However, two known factors were found to impact PJK: preoperative TK and NIV (Table 3).

Preoperative TK was higher in the PJK group (32.7 vs 27.1°). This was previously published [3, 6, 7]. A large preoperative TK is usually associated with a large LL like in your cohort (Table 2). Since LL enters the calculation of PSTK = 2(PT + LL-PI), a high LL leads to a high PSTK. The surgical objective of achieving larger PSTK is therefore more demanding and increases the PJK risk.

The NIV is a risk factor when combined with either preoperative LL or TK Gap. Long constructs increase the PJK risk if LL is high and therefore the target TK. Likewise, a long construct increases the PJK risk if TK Gap is negative due to insufficient TK.

Strength and study limitations

This study is the first to evaluate the role of TK surgical correction on the occurrence of PJK. PJK depends on TKFU, which can be also measured by the TK Gain or the TK Gap, difference between TKFU and PSTK. PMT on two rods also impacts PJK rates through the gain on TK it provides. NIV appears to be an additional aggravating factor.

Retrospective analysis with elimination of all incomplete multicentric files are the weak points of this study. A strong point is the large number of patients (*n* = 570) with an average follow-up of 4 years.

Conclusion

After surgical correction of AIS, PJK is a phenomenon of rebalancing, due to the insufficient correction of thoracic kyphosis when compared to the patient-specific thoracic kyphosis. Its incidence is significantly reduced by a large thoracic kyphosis gain and a short instrumentation which leaves the proximal lumbar lordosis free. Patient-specific thoracic kyphosis restoration should therefore represent a major target when correcting thoracic scoliosis. The choice of correction technique appears crucial for increasing thoracic kyphosis. Pre-bent patient-specific rods could help achieve patient-specific thoracic kyphosis.

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Author contributions All authors contributed to the study conception, design, and follow-up of the patients. Material preparation, data collection and analysis were performed by JLC and SP. The statistical analysis was performed by FS. The first draft of the manuscript was written by JLC, the final manuscript by JLC, FS and SP. All authors read and approved the final manuscript.

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Declaration

Conflict of interest All procedures were in accordance with the ethical standards of the authors' Institutional Review Board (CPP: Committee for the Protection of Persons; n°2017728v0) and with the 1964 Helsinki declaration and its later amendments. The authors declare that they have no competing interests related to this work.

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