



Clinical predictive model of lumbar curve Cobb angle below selective fusion for thoracic adolescent idiopathic scoliosis: a longitudinal multicenter descriptive study

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Abstract

Purpose To implement a clinically applicable, predictive model for the lumbar Cobb angle below a selective thoracic fusion in adolescent idiopathic scoliosis.

Methods A series of 146 adolescents with Lenke 1 or 2 idiopathic scoliosis, surgically treated with posterior selective fusion, and minimum follow-up of 5 years (average 7) was analyzed. The cohort was divided in 2 groups: if lumbar Cobb angle at last follow-up was, respectively, \geq or $<$ 10° . A logistic regression-based prediction model (PredictMed) was implemented to identify variables associated with the group $\geq 10^\circ$. The guidelines of the TRIPOD statement were followed.

Results Mean Cobb angle of thoracic main curve was 56° preoperatively and 25° at last follow-up. Mean lumbar Cobb angle was 33° (20; 59) preoperatively and 11° (0; 35) at last follow-up. 53 patients were in group $\geq 10^\circ$. The 2 groups had similar demographics, flexibility of both main and lumbar curves, and magnitude of the preoperative main curve, $p > 0.1$. From univariate analysis, mean magnitude of preoperative lumbar curves (35° vs. 30°), mean correction of main curve (65% vs. 58%), mean ratio of main curve/distal curve (1.9 vs. 1.6) and distribution of lumbar modifiers were statistically different between groups ($p < 0.05$).

PredictMed identified the following variables significantly associated with the group $\geq 10^\circ$: main curve % correction at last follow-up ($p = 0.01$) and distal curve angle ($p = 0.04$) with a prediction accuracy of 71%.

Conclusion The main modifiable factor influencing uninstrumented lumbar curve was the correction of main curve. The clinical model PredictMed showed an accuracy of 71% in prediction of lumbar Cobb angle $\geq 10^\circ$ at last follow-up.

Level of evidence IV Longitudinal comparative study.

Keywords Adolescent idiopathic scoliosis · Selective fusion · Uninstrumented curve · Lumbar curve · Predictive model

Introduction

The goal of surgical treatment for adolescent idiopathic scoliosis (AIS) is to correct the deformity and to maintain sagittal and coronal balance long term while minimizing number of fused vertebrae to preserve mobility and prevent spinal disk degeneration. There are two main opposing strategies: selective fusion (STF- to preserve lumbar mobility and lumbar disk below instrumentation) and non-selective fusion

(NSTF- to prevent risk of a deterioration of the curve below spinal fusion instrumentation) [1].

Various guidelines [2–4] define indications for selective fusion. However, these guidelines are not systematically applied, especially in case of lumbar modifier “C” [1, 5]. Indeed, baseline radiographic parameters significantly influence surgeons in their choice of NSTF or STF [6].

At long-term follow-up, quality of life of selective fusion patients is similar to that of healthy population with only moderate increase in the rate of disk and facet joint degeneration in the unfused segments [7, 8].

The assumption of selective thoracic fusion is by correcting the primary thoracic curve, coronal correction of the unfused lumbar curve will occur, which is reported between 34 and 63% [1, 9–12].

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In literature, the most important variables associated with uninstrumented lumbar curve correction are: percentage of main thoracic curve correction at last follow-up, preoperative flexibility of lumbar curve, and inclusion within the instrumentation of the distal neutral vertebra, the vertebra intersected by the central sacral vertical line, and the stable vertebra [13–16]. Only a few articles evaluate the long-term evolution of uninstrumented lumbar curves and those that do are single center [9–12] and do not apply machine learning models.

Machine learning (ML) is a branch of artificial intelligence adapted for complex data analysis to make predictions [14]. ML algorithms combine many features to construct an optimized, highly accurate, prediction equation [15]. Supervised ML models are suited to solve classification problems where the category of each patient is known; samples are used to train the model to classify other samples [16].

In previous studies, a supervised ML model named ‘PredictMed’ [17] was developed [18] and validated [19] to predict scoliosis in adolescents with cerebral palsy. We hypothesized that PredictMed could be used to predict the behavior of lumbar curve below thoracic selective fusion.

Therefore, the main purpose of the present study was to adapt and validate PredictMed to identify the variables influencing uninstrumented lumbar curve Cobb angle at minimum of 5 years follow-up after selective instrumentation for thoracic AIS. The secondary purpose was to highlight factors when the lumbar uninstrumented Cobb angle worsened between immediately postoperative and last follow-up.

Materials and methods

This longitudinal, double-blinded, descriptive study included 9 centers from a European scoliosis study group. A total of 111 AIS surgical patients were included with Lenke 1 ($n=84$) and Lenke 2 ($n=27$), who underwent posterior selective fusion with ≥ 5 -year follow-up (average 7 y) and younger than 20 years old at time of surgery (average 14 y) were included. Cobb angle exceeding 50 degrees was considered as an indication for surgery. Curves with Cobb angles between 40 and 50 degrees were operated on in case of at least two of the following features: rapid curve progression, coronal imbalance, and hypokyphosis $< 10^\circ$.

Selective fusion was defined if lower instrumented vertebrae (LIV) were the neutral vertebrae (NV) of the main thoracic curve or the last touching vertebra, but not caudal to L1. Exclusion criteria consisted of non-idiopathic etiology, open triradiate cartilage, lumbar curve $< 20^\circ$, Lenke 1AR curve, all hook construct, previous spine surgery, or anterior fusion.

Patients were enrolled between June 2007 and June 2015. Assessments and data collection were collected prospectively from the medical records.

The study was approved by the appropriate ethics committee (“*Commission de Protection des Personnes*”) and by the French Data Protection Authority. All procedures performed in this study were in accordance with the 1964 Helsinki declaration and its later amendments.

Operative techniques

Ninety-two percent of patients had hybrid hooks-screws instrumentation, and 8% had hybrid screws-hooks and sublaminar bands. The mean number of instrumented vertebrae was 10 (min. 8, max. 13), and the mean implant density was 56% (40/100). The LIV was between T11 and L2 (T11 = 6, T12 = 28, L1 = 77). Main technique of curve correction was postero-medial translation ($n=77$), concave side rod rotation ($n=22$), cantilever ($n=5$), and in situ bending ($n=5$).

Study variables

Anterior–posterior and lateral full-spine radiographs were obtained preoperatively, postoperatively (before the 40th postoperative day), and at last follow-up. The clinical and radiographic data were entered into the KEOPS-Spine database [20]. The measurements were then performed automatically by the Keops-Analyzer software after a senior surgeon (JLC) identified each vertebra, as well as the neutral vertebra (NV) of the main curve and the last touching vertebra (LTV) [13]. The position of the LIV relative to the NV was recorded as follows: NV-1 if the LIV was the vertebra immediately cephalad to the NV, NV-2 if the LIV was the second vertebra cephalad to the NV, and NV + 1 if the LIV was the first vertebra distal to the NV [13]. The same notation was used to record the position of the LIV relative to the LTV.

Percentage of correction, preoperative flexibility and density of implant were calculated per the standard [21].

To build a multiple logistic regression model, the follow-up measure utilized was lumbar curve Cobb angle with a cut-off of 10° to separate cases and controls after observation of the series and calculation of median values [22].

Statistical analyses

The variables were entered into the electronic database “PredictMed” [17–19]. R programs were used for the statistical analysis. P values lower than 0.05 were taken to indicate significant differences [23]. Mean values were compared by applying the T -test or analysis of variance (ANOVA) and percentages by applying the exact Fisher’s test. Pearson’s

test was chosen to assess correlations among quantitative variables [23].

The groups were compared for age, gender, Risser sign, type of curve according with Lenke's classification [3], magnitude and flexibility of both main and lumbar curves to determine if comparable (Table 1).

Based on published studies, personal opinion, and results of the univariate analysis, seven variables were used to build a multiple logistic regression model: age, sex, preoperative main curve Cobb angle, preoperative lumbar curve Cobb angle, correction of main curve at follow-up (%), lumbar modifier (A, B, or C), Risser sign, flexibility of both main and lumbar curve %, ratio between main and lumbar curve..

Prediction model

The supervised learning model with internal and cross-validation was used to predict the binary outcome that each patient would have a lumbar curve Cobb angle \geq or $< 10^\circ$ at follow-up. In accordance with the statistical learning theory described by Vapnik [24], we split the patients' data in a "training set" of about 80% of the cohort (116 patients) and a "test set" of about 20% (30 patients) of the cohort [24]. We trained the logistic regression algorithm utilizing the

"training set" to predict the probability of an angle \geq or $< 10^\circ$ for a new patient (in the "test set") by using the values of the selected independent variables: age, sex, Risser sign, type of curve according with Lenke's classification [10], and magnitude and flexibility of both main and lumbar curves. To minimize the dependency from the compositions of training and testing sets, we used cross-validation by randomly generating 20 different couples of training and testing sets, i.e., the training and test set compositions were randomly changed in 20 rounds of cross-validation. We calculated the accuracy, sensitivity, and specificity of the predictions for each couple and calculated the average values [25–27]. This was done with open source software 'R' using the 'glm()' function [17]. The prediction accuracy was calculated as: Prediction accuracy = (TP + TN)/(TP + TN + FP + FN) (TP = true positive, TN = true negative, FP = false positive, FN = false negative). The best logistic regression model was selected according to the highest value of accuracy. A linear regression was also performed with the same independent parameters to predict the continuous values of lumbar Cobb angle at follow-up.

The evolution of the lumbar curve Cobb angle change was calculated between the immediate postoperative and last follow-up X-ray. Multivariate linear regression model was

Table 1 Demographic data and results: comparison between groups

Parameters	Whole series	Group ≥ 10 degrees*	Group < 10 degrees**	P-value***
Number of patients	111	53	58	–
Sex (males, females)	8; 103	8; 45	0; 58	0.002
Age (year)	14.8 (11; 20)	14.6 (11; 20)	15 (12; 19)	0.41
Follow-up	7 (5; 12)	7 (5; 12)	7 (5; 11)	0.56
Risser sign (0, 1, 2, 3, 4, 5)	21; 12; 23; 31; 38; 17	4; 4; 6; 19; 10; 10	5; 7; 9; 11; 14; 10	0.51
Lenke type of scoliosis (1, 2)	84; 27	39; 14	46; 12	0.65
Lumbar modifier (A, B, C)	61, 26, 24	21, 15, 17	40, 11, 7	0.0002
Cobb angle of preoperative main thoracic curve	56 (40; 92)	56 (40; 92)	56 (40; 85)	0.88
Flexibility of main thoracic curve %	48 (21; 98)	42 (21; 85)	55 (28; 98)	0.16
Cobb angle of main thoracic curve at 1 st -standing X-ray	21 (1; 49)	23 (1; 49)	19 (3; 41)	0.002
Cobb angle of main thoracic curve at last follow-up	25 (1; 71)	27 (8; 71)	20 (1; 40)	E-5
Correction of main thoracic curve at last follow-up %	62 (7; 98)	58 (0; 80)	65 (0; 96)	0.0003
Cobb angle of preoperative lumbar curve	33 (20; 59)	35 (20; 59)	30 (20; 42)	E-4
Flexibility of lumbar curve %	71% (9; 98)	70 (9; 99)	71 (9; 95)	0.55
Ratio main curve/lumbar curve	1.9 (1.1; 3)	1.6 (1.1; 2.8)	1.9 (1.1; 3)	E-4
Cobb angle of lumbar curve at first-standing X-ray	12 (0; 37)	16 (0; 37)	7 (0; 18)	E-13
Cobb angle of lumbar curve at last follow-up	11 (0; 35)	18 (10; 35)	5 (0; 9)	E-30
Correction of lumbar curve at last follow-up	67 (5; 98)	48 (4; 75)	83 (5; 98)	0.001

Quantitative variables are presented as follows: average (minimum, maximum) angles are expressed in degrees

Bold indicates p value < 0.05

LIV = Last instrumented vertebra (distal), NV: distal neutral vertebra of main thoracic curve, LTV: Last vertebra touching the sacral vertical midline

*Group ≥ 10 and ** group < 10 indicate Cobb angle of lumbar curve at last follow-up ≥ 10 degrees or < 10 degrees

***Comparison between group $\geq 10^\circ$ and group $< 10^\circ$

utilized to understand the impact of other variables on the lumbar curve change.

The study followed the guidelines of the “Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis” (TRIPOD) Statement [28].

Results

Mean main curve Cobb angle was 56° preoperatively, 21° postoperatively and 25° at last follow-up. At last follow-up, mean correction of main thoracic curve was 62%. Mean lumbar Cobb angle was 33° (20; 52) preoperatively, 12° postoperatively (0–37) and 11° (0; 36) at last follow-up.

Differences between preoperative and last follow-up Cobb angles, as well as between preoperative and immediate postoperative values, were significant ($p < 0.01$) for both lumbar and thoracic curves; conversely, postoperative and follow-up values were not significantly different ($p > 0.4$). Fifty-three patients out of 112 had a final Cobb angle of lumbar curve $> 10^\circ$ (Figs. 1, 2, 3). In the group $\geq 10^\circ$ (Figs. 4, 5, 6), 6 had a final Cobb angle of lumbar curve between 25° and 35°; two of them underwent secondary fusion of lumbar curve: one for adding-on



Fig. 1 Patient 1, 13 y.o. boy with Lenke 2 B idiopathic scoliosis: preoperative X-ray. Patient 1: 13 y.o. boy; Lenke 2 B idiopathic scoliosis Cobb angles: 53 degrees (main thoracic curve); 37 degrees (lumbar curve); Risser sign: 0

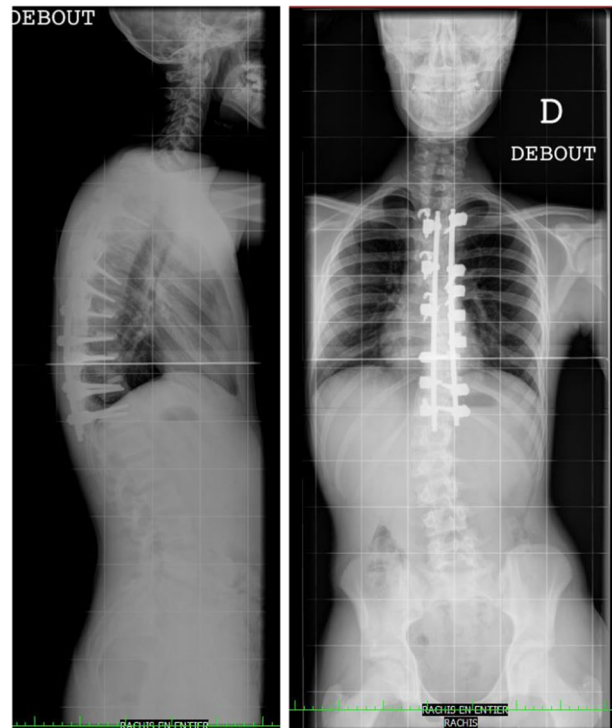


Fig. 2 Patient 1, 13 y.o. boy with Lenke 2 B idiopathic scoliosis: X-ray at 30th postoperative day; T2-T11 Hybrid construct with pedicle screws and claws. Correction through simultaneous translation on 2 rods. Patient 1: x-ray at 30th postoperative day; T2-T11 Hybrid construct with pedicle screws and claws. Correction through simultaneous translation on 2 rods Cobb angles: 4 degrees (main curve), 11 degrees (lumbar curve)

of main curve and one for decompensation of lumbar curve and symptomatic coronal imbalance.

The two groups were similar concerning age, sex, Risser sign, main and lumbar curve flexibility, Lenke classification (type 1 or 2), technique of correction, and preoperative magnitude of main curve, $p > 0.1$.

From univariate analysis, mean magnitude of preoperative lumbar curves (35° vs. 30°), mean correction of main curve (65% vs. 58%), mean ratio of main curve/distal curve (1.9 vs. 1.6) and distribution of lumbar modifiers were statistically different between groups ($p < 0.05$).

The percentage of various positions of LIV regarding neutral vertebra or last touching vertebra was not different between groups ($p > 0.1$).

The correction techniques were equally distributed among groups ($p > 0.1$).

An ANOVA compared the lumbar modifiers (A, B, or C) with final lumbar Cobb angles, lumbar coronal correction, and lumbar flexibility. The final lumbar Cobb angles were significantly different between modifiers (9°, 12°, and 15° respectively; $p = E-5$), while lumbar coronal correction

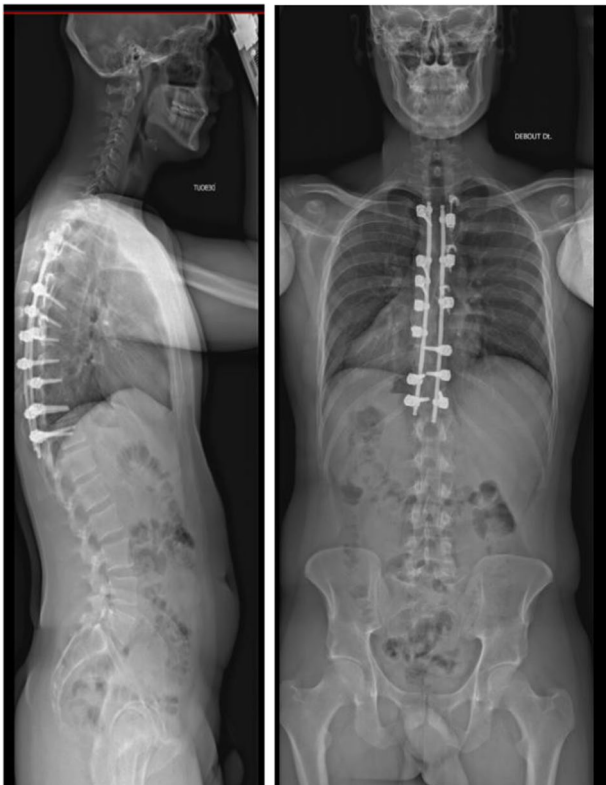


Fig. 3 Patient 1, 15 y, 3y follow-up X-ray. Patient 1: 14 y follow-up; Cobb angles: 4° (Main curve), 5° (lumbar curve)

(57%, 63%, and 58%, respectively; $p = 0.37$) and lumbar flexibility were not significant ($p = 0.43$).

The supervised ML model identified preoperative lumbar curve angle ($p = 0.047$) and main curve correction % ($p = 0.0146$) significantly associated with lumbar curve Cobb angle $\geq 10^\circ$ at follow-up.

The prediction score showed an average of 71% accuracy.

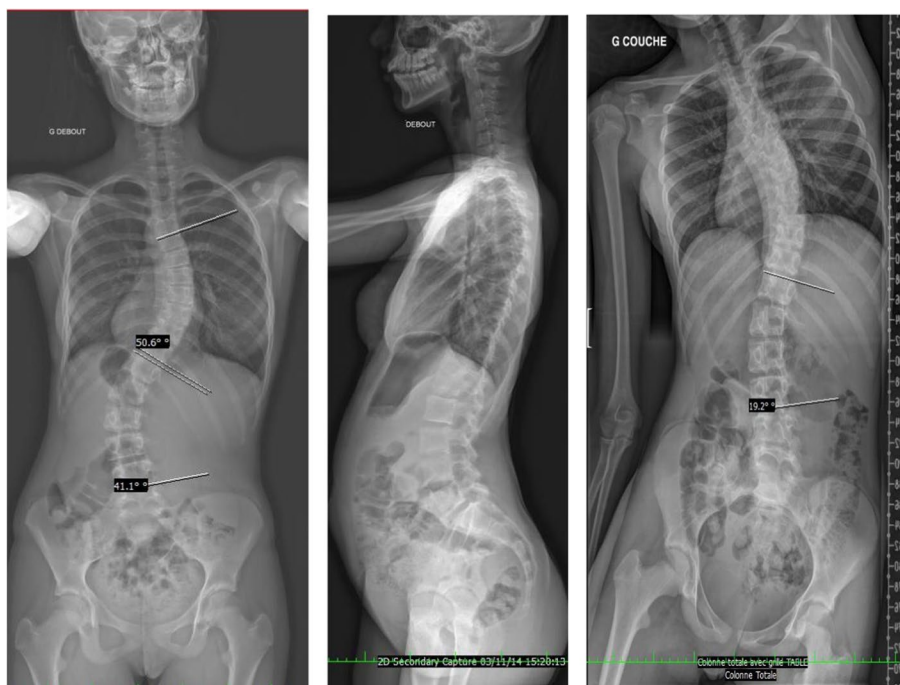
The linear regression model predicted the following equation ($R^2 = 0.48$, $p < 0.001$):

Follow-up lumbar Cobb = $14 + 0.4 * \text{preoperative lumbar Cobb} - 22 * \text{main curve correction at follow-up} - 3 * \text{lumbar modifier A}$.

Density of implants was weakly correlated with the main curve correction ($p = E-7$ coefficient = 0.4, CI 95% = 0.3; 0.5) and loss of correction ($p = 0.01$, coefficient = -0.2, CI 95% = -0.3; -0.1).

The worsening of the lumbar curve was inversely related to postoperative lumbar curve angles (i.e., lesser postoperative lumbar curve angle increased at follow-up, coefficient = -0.1, CI 95% = -0.1; -0.1, $p = 0.001$) and directly related to main curve loss of correction (i.e., higher loss of correction increased lumbar Cobb angle at follow-up, coefficient = 0.2, CI 95% = 0.1; 0.2, $p = 0.001$). Position of LIV, preoperative lumbar reducibility and lumbar modifier were not significant ($p > 0.2$).

Fig. 4 Patient 2: Lenke 2 A, 15 y, Risser grade: 4. Cobb angles: T6-T11 = 51°, T1-T5 = 29°, T12-L4 = 41°



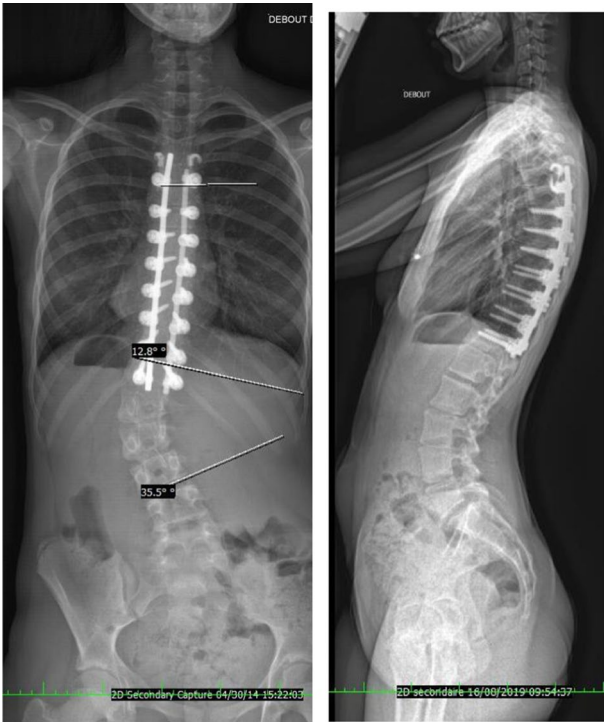


Fig. 5 Patient 2: X-ray at 30th postoperative day T4-T12. Hybrid construct with pedicle screws and hooks. Correction through simultaneous translation on 2 rods. Cobb angles: 13 degrees (main curve), 35 degrees (lumbar curve). Patient 2: x-ray at 30th postoperative day T4-T12. Hybrid construct with pedicle screws and hooks. Correction through simultaneous translation on 2 rods. Cobb angles: 13 degrees (main curve), 35 degrees (lumbar curve)

Discussion

We developed and validated a supervised machine learning model able to predict the final lumbar Cobb angle (as a quantitative, continuous values and a binary, \geq or $<$ 10° , value) after selective instrumentation for thoracic AIS. Previous studies have used predictive models but not machine learning methods [29].

The present study highlighted that lumbar, uninstrumented, coronal Cobb angle at follow-up was mostly related to a lesser correction of main thoracic curve and bigger preoperative lumbar curve angle. Lumbar modifier C and ratio between main and lumbar curve were significant only from univariate analysis. The relevance of these parameters is consistent with Lenke classification and recent literature [1, 3–12, 29, 30].

Further, Risser sign was not significant, which is consistent with previous literature [31].

Surprisingly, our results do not provide significant findings concerning the best choice of LIV, since position of the LIV relative to neutral or last touching vertebra was not significant, which contradicts previous literature [11, 13].

Concerning the definition of selective fusion, we included LIV equal to NV or LTV and above L2, to allow a “reasonable” number of uninstrumented segments below the construct. We chose to focus on NV or LTV because we think a “distal” thoracic curve with apex at T10 and NV on L1 is selectively fused if fusion stops on L1. However, we had to exclude very distal thoracic curves with neutral vertebra on L2 or L3. The concept of selective fusion is variously defined in literature; for some authors, it simply means fusion above L2 [6, 9, 10]. Conversely, we chose a more strict and precise definition.

The main limitation is the potential loss to follow-up¹⁹. Moreover, we did not analyze the patient’s quality of life since questionnaires were not available for all. In addition, the cut-off of 10° to separate good and poor results on lumbar Cobb angle at follow-up is a severe and somewhat arbitrary criterion. We have chosen it after observation of the final lumbar Cobb angle, whose median and average were around 10° , thus separating into two equal sized groups for the logistic regression analysis. Moreover, 10° is a “crux” value in scoliosis literature because it separates scoliotic curves from non-scoliotic [32], therefore defining a curve below 10° as clinically negligible.

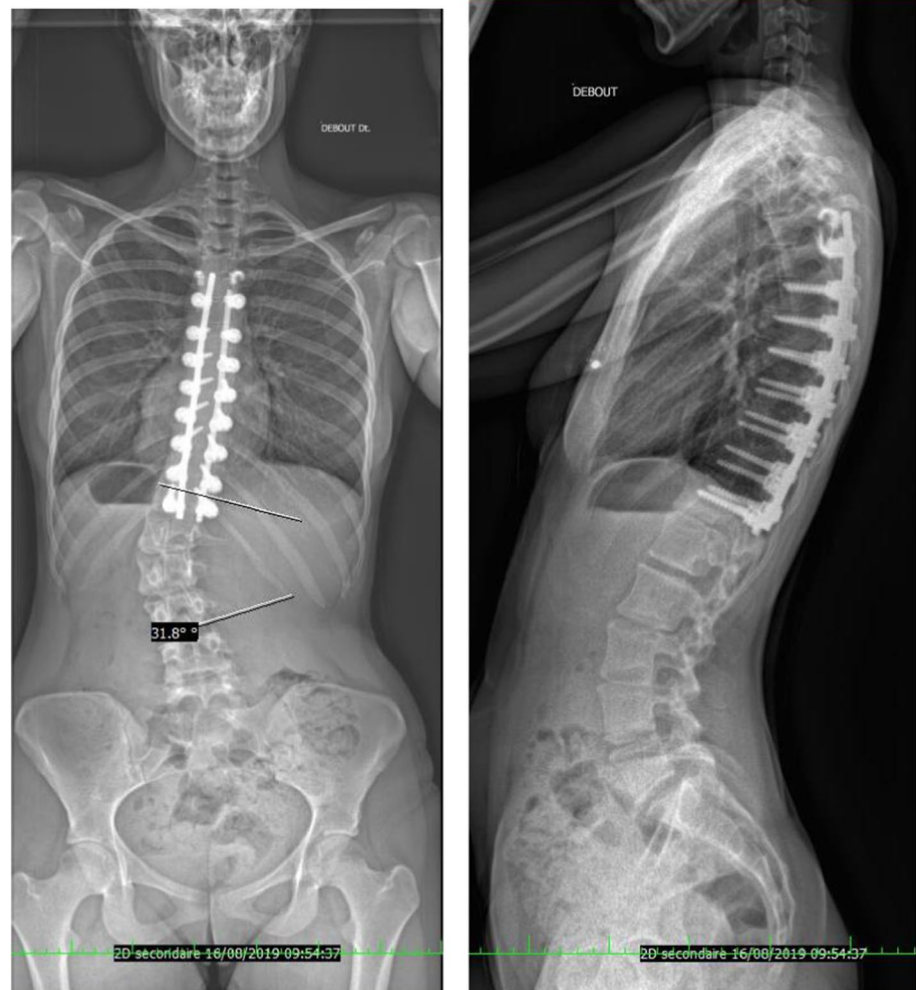
Also, measuring lateral vertebral translation in mm requires calibration of the radiographs, and unfortunately, was not available for all patients in the series.

The strengths of our study are: long follow-up, multicenter recruitment, predictive statistical analysis performed according with advanced models by 2 independent operators (CB and FS), and automatic computer-assisted assessment of radiographic parameters, which provides better repeatability and reproducibility than do conventional measurements.

The performance of the prediction model was in accordance with recent literature about clinical studies for comparable samples [18, 19, 25–27]. This study uniquely addresses the predictive results in terms of accuracy. The choice of accuracy, rather than p -value, Akaike index or R^2 , allows easier evaluation of the regression model performance [18, 19].

The formula we found for calculating the final lumbar Cobb angle should be confirmed through larger studies, but it could be applied before surgery to provide a reasonable estimate of the final lumbar Cobb angle if the scoliosis surgeons know their average correction of main curve. This highlights the need for continuous evaluation of each scoliosis surgeon’s results. Our results suggests, when choosing a selective thoracic fusion, a possible way to improve lumbar Cobb angle is by increasing main curve correction and by maintaining its stability over time. From literature, this can be done through increasing density and stability of anchors, mechanical properties of the rods, spine release, and bone graft [13, 21, 33, 34].

Fig. 6 Patient 2: Lenke 2 A, 19y (4y follow-up), Risser grade: 5. Cobb angles: T6-T11 = 11 degrees, T12-L4 = 32 degrees



Concerning the evolution of lumbar curve between postoperative and last follow-up values, surprisingly higher postoperative lumbar Cobb angles tend to decrease. This finding suggests that the first-standing lumbar Cobb angle should not alarm the surgeon and spontaneous decrease in lumbar curve is very common. We also found that the loss of correction of main curve strongly influenced the increase in lumbar curve, which is consistent with previous literature [9, 13].

The strengths of this study are the conformity to TRIPOD Statement, and the implement of new ML algorithm with all possible combinations of independent variables.

The main implications of our findings include:

- A selective fusion can be indicated with ease if the surgeon knows the predicted outcome;
- Longer fusion should be considered in the case of a high risk of persistent lumbar curve, and consequently a higher risk of lumbar degenerative evolution;
- Information to patients about the risk of a persistent lumbar curve will be more precise, e.g., in case of selective fusion despite relevant risk of persistent lumbar curve, the

eventuality of revision surgery to fuse lumbar curve should be described.

Conclusion

In selective thoracic fusion for AIS, a higher lumbar uninstrumented coronal Cobb angle at follow-up was mostly associated with the low correction of the main thoracic curve and larger preoperative lumbar curve angle.

Decrease in the lumbar Cobb angle between immediate postoperative X-ray and last follow-up occurred more frequently in case of higher postoperative lumbar Cobb angle and correlated with the stability of main curve correction. The clinical model PredictMed showed an accuracy of 71% in prediction of lumbar Cobb angle $\geq 10^\circ$ at last follow-up.

Author contributions FS: Conception or design of the work, Acquisition, analysis, or interpretation of data, Drafted the work, Approved the version to be published, Agree to be accountable for all aspects of

the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. WL: Acquisition, analysis, or interpretation of data, Drafted the work, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. CM: Conception or design of the work, Acquisition, analysis, or interpretation of data, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JSdG: Acquisition, analysis, or interpretation of data, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. IO: Acquisition, analysis, or interpretation of data, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. HFP: Acquisition, analysis, or interpretation of data, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JL: Acquisition, analysis, or interpretation of data, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JLC: Conception or design of the work, Acquisition, analysis, or interpretation of data, Drafted the work, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. CMB: Conception or design of the work, Acquisition, analysis, or interpretation of data, Drafted the work, Revised it critically for important intellectual content, Approved the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declarations

Conflict of interest FS received financial support for attending symposia and congresses from Medicea Int. and Euros. JLC is consultant for Medicea Int. JSdG received financial support for attending symposia and congresses from Medtronic and Implanet. IO and WL received financial support for attending symposia and congresses from Medtronic and Spineart. JL, HP et SW received financial support for attending symposia and congresses from Medtronic. CMB, CM, GK: no conflicts.

Ethical approval All procedures described in this work have been approved by the IRB of the leading center (Nice) with number

2017728v0, 14th September 2016; all patients and parents provided formal consent.


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