

Multicenter validation of a formula predicting postoperative spinopelvic alignment

Clinical article

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Object. Sagittal spinopelvic imbalance is a major contributor to pain and disability for patients with adult spinal deformity (ASD). Preoperative planning is essential for pedicle subtraction osteotomy (PSO) candidates; however, current methods are often inaccurate because no formula to date predicts both postoperative sagittal balance and pelvic alignment. The authors of this study aimed to evaluate the accuracy of 2 novel formulas in predicting postoperative spinopelvic alignment after PSO.

Methods. This study is a multicenter retrospective consecutive PSO case series. Adults with spinal deformity (> 21 years old) who were treated with a single-level lumbar PSO for sagittal imbalance were evaluated. All patients underwent preoperative and a minimum of 6-month postoperative radiography. Two novel formulas were used to predict the postoperative spinopelvic alignment. The results predicted by the formulas were then compared with the actual postoperative radiographic values, and the formulas' ability to identify successful (sagittal vertical axis [SVA] ≤ 50 mm and pelvic tilt [PT] ≤ 25°) and unsuccessful (SVA > 50 mm or PT > 25°) outcomes was evaluated.

Results. Ninety-nine patients met inclusion criteria. The median absolute error between the predicted and actual PT was 4.1° (interquartile range 2.0°–6.4°). The median absolute error between the predicted and actual SVA was 27 mm (interquartile range 11–47 mm). Forty-one of 54 patients with a formula that predicted a successful outcome had a successful outcome as shown by radiography (positive predictive value = 0.76). Forty-four of 45 patients with a formula that predicted an unsuccessful outcome had an unsuccessful outcome as shown by radiography (negative predictive value = 0.98).

Conclusions. The spinopelvic alignment formulas were accurate when predicting unsuccessful outcomes but less reliable when predicting successful outcomes. The preoperative surgical plan should be altered if an unsuccessful result is predicted. However, even after obtaining a predicted successful outcome, surgeons should ensure that the predicted values are not too close to unsuccessful values and should identify other variables that may affect alignment. In the near future, it is anticipated that the use of these formulas will lead to better surgical planning and improved outcomes for patients with complex ASD. (DOI: 10.3171/2011.8.SPINE11272)

KEY WORDS • pedicle subtraction osteotomy • sagittal realignment • adult spinal deformity • balance formula • pelvic tilt • degenerative

SAGITTAL spinopelvic malalignment is increasingly recognized as a cause of pain and disability in patients with ASD.^{8,11,21,22} Positive sagittal balance, de-

finied as anterior deviation of the C-7 plumb line more than 50 mm from the posterosuperior corner of the sacrum, is a reliable predictor of adverse clinical symptoms. As the magnitude of positive sagittal balance increases, HRQOL measures have been shown to worsen among patients with ASD.^{8,9,11,17} Pelvic tilt is a compensatory mechanism that

Abbreviations used in this paper: ASD = adult spinal deformity; HRQOL = health-related quality-of-life; IQR = interquartile range; NPV = negative predictive value; PI = pelvic incidence; PPV = positive predictive value; PSO = pedicle subtraction osteotomy; PT = pelvic tilt; SVA = sagittal vertical axis.

This article contains some figures that are displayed in color online but in black and white in the print edition.

reflects the body's attempt to correct sagittal alignment to maintain upright posture. Recently, increased PT has also been shown to correlate with worse HRQOL scores.¹¹

In certain cases of sagittal malalignment, a corrective osteotomy can be performed to restore balance. Pedicle subtraction osteotomy is an increasingly used technique to correct sagittal plane deformities and can obtain approximately 25° of increased lordosis when performed in the lumbar spine.^{4,12,23} One of the challenges of the PSO technique is accurately predicting the postoperative spinopelvic alignment. Achieving spinopelvic balance is dependent on multiple interdependent parameters.^{15,16,20} The complex interplay makes it difficult to determine which parameters are responsible for the deformity versus those that are compensatory.

Several authors have developed predictive formulas for lumbar lordosis that are based on morphological parameters such as PI, but also include compensatory values such as PT, sacral slope, and T-9 tilt.^{3,16} These formulas are accurate in predicting lumbar lordosis, but their utility in preoperative planning for a lumbar PSO is questionable. One challenge when applying these formulas to lumbar PSO is that the compensatory parameters (PT and T-9 tilt) included in these formulas cannot be directly controlled in surgery. Therefore, it is not possible to predict lumbar lordosis because there is no way to determine how these compensatory parameters will change after surgery. A simple mathematical model has also been developed for use in planning PSOs.¹⁸ A tangent function is used to calculate the angle of the resection needed to restore the SVA to normal. The weakness of this method is that it does not take PT into account when calculating the angle of resection. Consequently, a large compensatory PT may be undercorrected. A multilinear regression analysis was previously used to develop 2 spinopelvic alignment formulas that predict PT and SVA based on lumbar lordosis, thoracic kyphosis, and PI.¹³ The strength of these formulas is that they rely on a fixed parameter (PI) and factors controllable by the surgeon (lumbar lordosis and thoracic kyphosis). The formulas are intended to aid surgeons in preoperative planning with any realignment technique.

This paper is a multicenter validation of these spinopelvic alignment formulas in adult patients undergoing lumbar PSO. The aim was to determine the accuracy of the formulas in predicting postoperative PT and SVA. Additionally, the ability of the formulas to predict successful versus unsuccessful radiographic outcomes following lumbar PSO was evaluated. This multicenter validation should enable surgeons to know when the spinopelvic alignment formulas are beneficial in preoperative planning and allow researchers to see where the formulas need further refinement.

Methods

Study Design and Ethics

This study was a multicenter retrospective analysis of consecutive patients treated between 2006 and 2009. Data were gathered from 8 spinal deformity referral centers across the US. Institutional review board approval was obtained by each participating site.

Study Patients

The study inclusion criteria included ASD patients older than 21 years of age who were surgically treated by lumbar PSO and spinal fusion for sagittal imbalance. All patients must have undergone a single-level PSO in the lumbar spine (L1–5) with complete preoperative and at least 6-month postoperative anteroposterior and sagittal radiography. Patients with underlying neurological or neuromuscular conditions were excluded from this study, as were patients with established hip, knee, ankle, and foot pathology that could have affected joint position. Patients were also excluded if multilevel PSO was performed or if the femoral heads were not visible on sagittal radiographs.

Radiographic Analysis and Data Extraction

All patients underwent radiography of the spinal axis (including the pelvis) using 36-in full-length films. Patients were instructed to assume a free-standing posture, with elbows flexed at approximately 45° and their fingertips on the clavicles. Anteroposterior and lateral radiographs were digitized using a Vidar scanner (Vidar Systems Corp.) with 75 dpi resolution and 12 gray levels. Sagittal and frontal spinopelvic parameters were assessed using SpineView (Surgiview), a validated computer-based tool that enables quantitative measurements of the spine and pelvis.^{5,19}

For the purpose of this study, a restricted set of parameters was extracted from SpineView. The spinal sagittal plane (Fig. 1) was described by calculating the maximal lumbar lordosis, the maximal thoracic kyphosis, and the SVA (the offset between a plumb line drawn from C-7 to the posterosuperior corner of S-1). The sagittal pelvic morphology and orientation (Fig. 2) were described by the pelvic tilt, which is the angle between the vertical and the line through the midpoint of the sacral plate to the axis of the femoral heads (retroversion is then measured as a PT increase, anteversion as a PT decrease); the pelvic incidence was defined as the angle between the perpendicular to the sacral plate at its midpoint and the line connecting this point to the axis of the femoral heads.

Spinopelvic Alignment Formulas

The methodology used in the development of the spinopelvic alignment formulas has been previously presented¹³ with the key points summarized below. A multilinear regression analysis was conducted on a set of 218 patients with ASD to develop a method to predict postoperative sagittal alignment (SVA) and pelvic rotation (PT). The goal of this study was to create a formula based on only morphological parameters (that is, PI) and parameters controllable during surgery (regional curvatures: lumbar lordosis and thoracic kyphosis). The subsequently created spinopelvic alignment formulas are as follows: $PT = 1.14 + 0.71 \times (PI) - 0.52 \times (\text{maximal lumbar lordosis}) - 0.19 \times (\text{maximal thoracic kyphosis})$, and $SVA = -52.87 + 5.90 \times (PI) - 5.13 \times (\text{maximal lumbar lordosis}) - 4.45 \times (PT) - 2.09 \times (\text{maximal thoracic kyphosis}) + 0.513 \times (\text{age})$.

The key points of these formulas were that the prediction of PT was based on PI and regional sagittal curvatures, while the prediction of the SVA required the addi-

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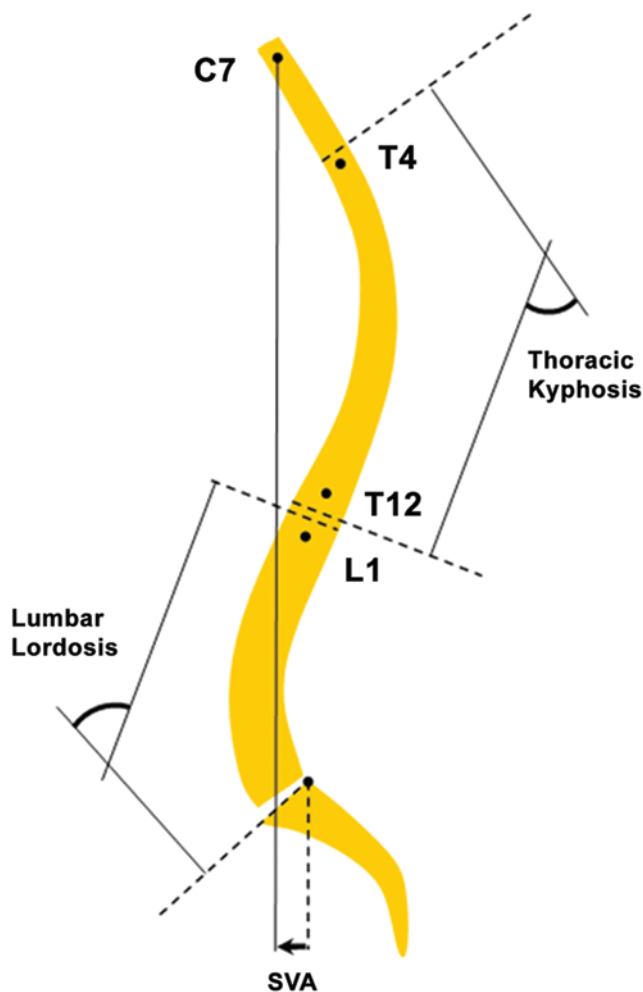


Fig. 1. Sagittal spinal radiological parameters. Positive values for sagittal curvatures denote a lordotic alignment, while negative values denote a kyphotic alignment.

tion of the predicted PT and age at surgery to the existing set of parameters.

Validation of the Spinopelvic Alignment Formulas

The spinopelvic alignment formulas were applied to the current set of patients in an attempt to predict postoperative PT and postoperative SVA. The values used in the formulas were obtained from the postoperative radiographs. Radiographic outcomes predicted by the formulas were classified as “successful” if the predicted SVA was less than or equal to 50 mm and the predicted PT was less than or equal to 25°. If either of these conditions was not met (SVA > 50 mm or PT > 25°), the predicted radiographic outcome was classified as “unsuccessful.” Postoperative radiographs were again classified as successful or unsuccessful according to the same criteria but based on the actual postoperative PT and SVA values.

Statistical Analysis

Patient demographics and PSO characteristics were summarized using descriptive statistics (such as mean, standard deviation, and range). Paired t-tests, using SPSS

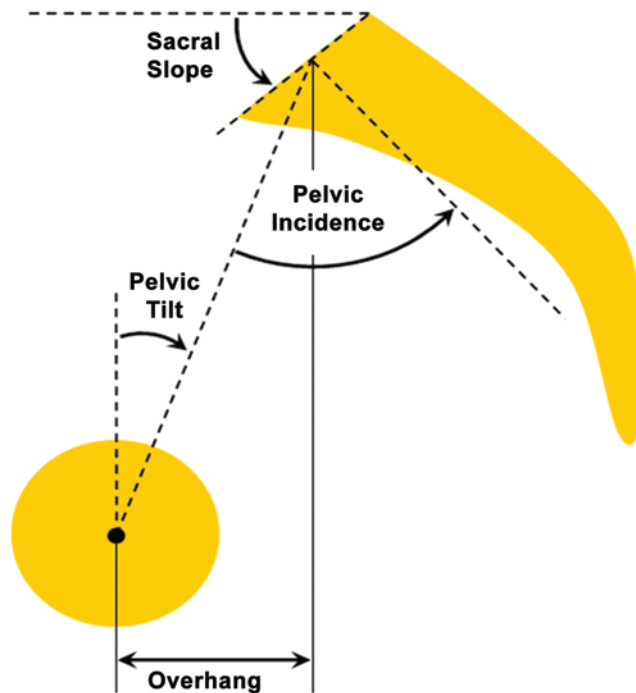


Fig. 2. Pelvic radiological parameters.

statistical software (version 17.0, SPSS, Inc.), were run to determine the difference between preoperative and postoperative PT and SVA. The median absolute error and IQRs for the absolute differences between the predicted values and actual values for the PT and SVA were calculated. The PPV and the NPV of the spinopelvic alignment formulas were calculated based on their ability to correctly predict whether the patient would fall into the successful category (SVA ≤ 50 mm and PT ≤ 25°) or the unsuccessful category (SVA > 50 mm or PT > 25°). The PPV was defined as the probability of a successful outcome when the formulas predicted a successful outcome. The NPV was defined as the probability of an unsuccessful outcome when the formulas predicted an unsuccessful outcome.

Results

Study Sample and Surgical Corrections

Ninety-nine patients met inclusion criteria. There were 80 women and 19 men, and the mean age was 55.5 ± 11.7 years (± SD; range 35–81 years) (Fig. 3). The most common site of PSO was L-3 (Fig. 4), and the mean degree of resection was 23° (range 16°–39°). Overall, the mean SVA improved from 140 ± 80 mm preoperatively to 43 ± 56 mm postoperatively (p < 0.01). The mean PT improved from 34° ± 12° preoperatively to 25° ± 12° postoperatively (p < 0.01). Based strictly on the actual SVA and PT from the postoperative radiographs, 42 (42%) of 99 patients had successful radiographic outcomes, and 57 (57%) of 99 patients had unsuccessful radiographic outcomes (Tables 1 and 2).

Prediction Accuracy of Spinopelvic Alignment Formulas

The median absolute error between the formula-pre-

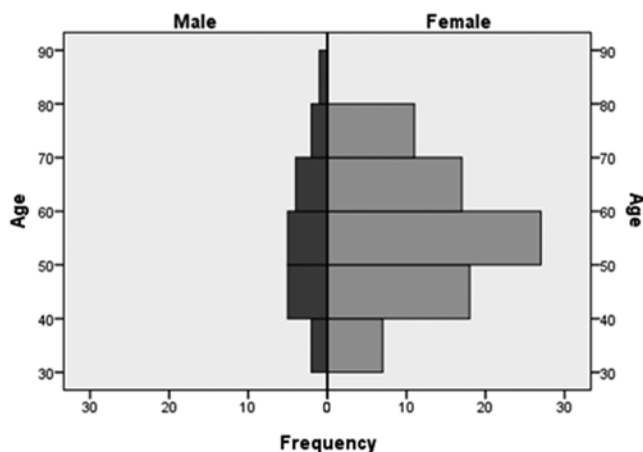


Fig. 3. Population pyramid illustrating the age (in years) and sex distribution of the 99 study patients.

dicted PT and actual postoperative PT was 4.1° (IQR 2.0° – 6.4°). The median absolute error between the formula-predicted SVA and actual postoperative SVA was 27 mm (IQR 11–47 mm). The calculated PPV of the spinopelvic alignment formula was 0.76, which signifies that if the formulas predict a successful outcome, there is a 76% chance that the postoperative result will be successful. The calculated NPV was 0.98, which signifies that if the alignment formulas predict an unsuccessful outcome, there is a 98% chance that the postoperative result will be unsuccessful.

Subgroup Analysis of Inaccurate Formula Predictions

Analysis of the 13 patients who were predicted to have a successful radiographic outcome but had an unsuccessful postoperative result demonstrated that 6 patients (46%) had a postoperative PT greater than 25° and an SVA less than 50 mm, 6 patients (46%) had a postoperative SVA greater than 50 mm and a PT less than 25° , and 1 patient (8%) had a PT greater than 25° and an SVA greater than 50 mm. Of the 6 patients who had the postoperative PT inaccurately predicted, the predicted values were 14° , 21° , 21° ,

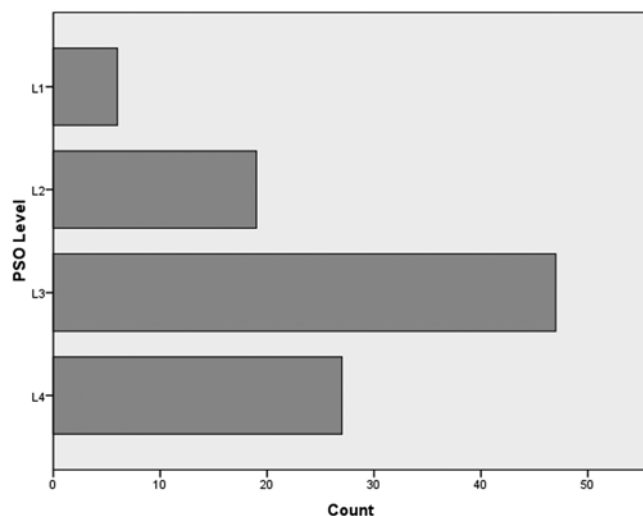


Fig. 4. Histogram of PSO levels illustrating the number of PSO resections performed at each lumbar vertebral level.

TABLE 1: Comparison of predicted outcome versus actual outcome*

Category Predicted	Predicted (no. of patients)	Actual Category	
		Successful	Suboptimal
successful	54	41	13
suboptimal	45	1	44
total	99	42	57

* Successful outcome is defined as SVA ≤ 50 mm and PT $\leq 25^\circ$. Suboptimal outcome is defined as SVA > 50 mm and/or PT $> 25^\circ$.

20° , 25° , and 21° with an actual postoperative PT of 33° , 28° , 31° , 26° , 26° , and 33° , respectively. Of the 6 patients who had the postoperative SVA inaccurately predicted, the predicted values were 13, 18, 39, 39, 47, and 50 mm with an actual postoperative SVA of 124, 129, 70, 85, 120, and 132 mm, respectively. Among this latter group, 2 patients had implant failures with associated kyphosis, 1 patient had a proximal junctional kyphosis leading to high postoperative SVA, and 3 patients were unable to compensate for their spinal alignment by retroverting their pelvis. The patient who had both the postoperative PT and SVA inaccurately predicted also had a proximal junctional kyphosis. For this patient, the predicted PT and SVA were 23° and 36 mm, respectively, and the actual postoperative PT and SVA were 26° and 73 mm, respectively. When patients presenting with a postoperative junctional failure and/or implant failure were excluded from the analysis, the PPV of the formula was 0.84 (instead of 0.76) and the NPV was the same (0.98) (Table 3).

Illustrative Cases

Case 1: Successful Realignment Surgery

The process by which the postoperative PT and SVA can be estimated is illustrated with this case. According to the preoperative measurements (Fig. 5 and Table 4), the patient presented with substantial sagittal malalignment, and surgical correction through a PSO was pursued. With a preoperative lordosis of 33° and a PI of 65° , the surgeon might wish to pursue an osteotomy that would increase the lordosis by approximately 35° to achieve a postoperative lordosis of 68° . During this process, kyphosis might be restored by approximately 10° to be 55° . The postoperative PT and SVA could then be predicted by using the following values: PT = $1.14 + 0.71 \times (65) - 0.52 \times (68) - 0.19 \times (-55) = 22^\circ$, and SVA = $-52.87 + 5.90 \times (65) - 5.13 \times (68) - 4.45 \times (22) - 2.09 \times (-55) + 0.513 \times (55) = 27$ mm.

TABLE 2: Comparison of predicted outcome versus actual outcome when excluding patients with junctional failure or implant problem

Category Predicted	Predicted (no. of patients)	Actual Category	
		Successful	Suboptimal
successful	49	41	8
suboptimal	45	1	44
total	99	42	57

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TABLE 3: The PPV and NPV of the spinopelvic alignment formulas

Study Sample	PPV	NPV
entire cohort	76%	98%
entire cohort (excluding junctional & implant failures)	84%	98%

Thus, the formula predicts a successful surgery based on an increase in lordosis by approximately 35°, with a postoperative PT of 22° and an SVA of 27 mm. Indeed, this patient had a successful outcome following an increase in lordosis by 33°, with a postoperative PT of 24° and a postoperative SVA of 26 mm (Fig. 5 and Table 4).

Case 2: Unsuccessful Realignment Surgery

The patient in this case presented with severe sagittal malalignment (Fig. 6 and Table 4). Realignment surgery planning for such a patient might involve aggressive osteotomies targeting an introduction of an additional 45° of lordosis. With this change in alignment, a concurrent restoration of kyphosis would also be expected, of perhaps 10°. The formula can be used in the planning stages to determine if 45° of lordosis would be sufficient to achieve a successful outcome. The predicted values for PT and SVA would be as follows: $PT = 1.14 + 0.71 \times (64) - 0.52 \times (51) - 0.19 \times (-60) = 31^\circ$, and $SVA = -52.87 + 5.90 \times (64) - 5.13 \times (51) - 4.45 \times (31) - 2.09 \times (-60) + 0.513 \times (75) = 89 \text{ mm}$.

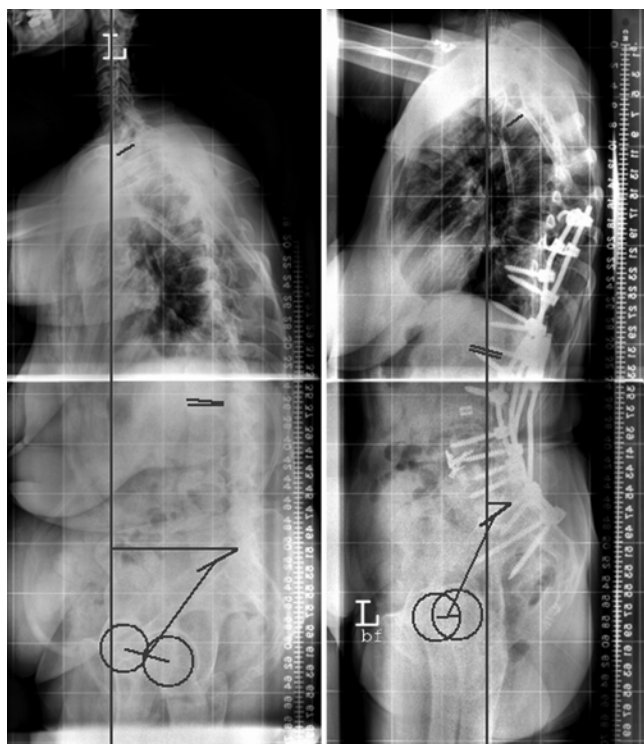


Fig. 5. Case 1. Preoperative (left) and postoperative (right) radiographs obtained in a patient who underwent sagittal realignment surgery, showing a successful realignment surgery.

According to the formula's prediction, osteotomies achieving lordosis correction of approximately 45° would not be sufficient for a successful outcome. In fact, the patient received 51° of lordosis correction, with the outcome of 32° (PT) and 98 mm (SVA) (Fig. 6 and Table 4).

Discussion

Positive sagittal balance has been demonstrated to strongly correlate with poor HRQOL scores.⁸ Several studies have shown that proper restoration of sagittal plane alignment is critical in improving clinical outcome and avoiding pseudarthrosis.^{1,2,6} High PT has also been shown to correlate with poor HRQOL scores and increased pain.^{11,14} An ideal preoperative planning method would predict how a given operative plan would affect both SVA and PT.

Several methods have been used in surgical planning for PSO. A common method has involved the use of radiograph tracing with paper and applying cutouts.^{2,7,10} Although the reported results of this technique have been good, the method is cumbersome, does not take into account pelvic version in response to alignment changes, and requires printed films (increasingly rare given digital systems). Recently, Ondra et al.¹⁸ described a method that uses a tangent function to calculate the size of the desired osteotomy. Although this method permits an estimation of SVA, it fails to take pelvic parameters into account. Accordingly, even if the SVA is within the normal range, patients may still be compensating for a loss of lordosis through the pelvis, which can lead to decompensation and a poor clinical outcome.²² We are unaware of any published formulas that predict postoperative sagittal spinopelvic alignment.

The current study describes 2 spinopelvic alignment formulas that can be used to predict postoperative PT and SVA following lumbar PSO, the radiographic parameters most closely related to clinical outcome. Use of the formulas focuses on predicting immediate alignment changes rather than longitudinal ones. The formulas accurately predicted SVA and PT following lumbar PSO. They were effective in predicting good spinopelvic alignment (SVA ≤ 50 mm and PT ≤ 25°; PPV 76% for the entire database and 84% when removing patients with junctional and/or implant failure) and were even more accurate in predicting negative outcomes (SVA > 50 mm or PT > 25°; NPV 98%). One of the major advantages of the described formulas is the ease of use. All initial predictors are either fixed (PI and patient age) or are theoretically controllable by the surgeon (thoracic kyphosis and lumbar lordosis) as long as the entire spine is instrumented. Additionally, by classifying the predicted results as being successful versus unsuccessful, the surgeon can then use the spinopelvic alignment formulas to determine when adjustments must be made to the preoperative plan. In the case of a patient who is predicted to have an unsuccessful outcome, it is likely that this is the result of the surgical planning not fully accounting for elevated pelvic retroversion. Consequently, the change in lordosis that is planned to result from the osteotomy is not great enough. If an unsuccessful outcome is predicted, then another plan should be pursued in which the resection has a greater angle.

TABLE 4: Preoperative, postoperative, and planned/predicted radiographic parameters in the 2 illustrative cases

Parameter	Case 1			Case 2		
	Preop	Planned/Predicted	Actual Postop	Preop	Planned/Predicted	Actual Postop
PI (°)	65	65	64	64	64	65
max lordosis (°)	33	68	66	6	51	57
max kyphosis (°)	-45	-55	-54	-50	-60	-54
PT (°)	36	22	24	45	31	32
SVA (mm)	150	27	26	252	89	98
age (yrs)	55	55	55	75	75	75

One concern may be that 13 patients who were predicted to have a successful outcome had unsuccessful postoperative results. A detailed analysis of these patients showed that 5 patients had predicted PT and SVA values that bordered the cutoff for unacceptable values (SVA > 50 mm and PT > 25°), 5 patients demonstrated a junctional failure or implant failure postoperatively, and 3 patients were unable to retrovert their pelvis to compensate for their large SVA. These 3 scenarios illustrate the limitations of the formulas as follows: 1) Borderline predictions. When the formulas predict PT and SVA values that border the cutoff for unacceptable values (SVA > 50 mm and PT > 25°), alternative preoperative planning should be considered to help ensure that the necessary correction is achieved. 2) Reciprocal changes. The formulas require both the lumbar lordosis and the thoracic kyphosis to be completely controllable by the surgeon, a scenario that is only possible when the entire spine is instrumented. Although thoracic kyphosis

may change when the thoracic spine is uninstrumented, our experience has shown that these changes are minor in the stiff curves normally associated with ASD. Results of the current study suggest that the formulas are still applicable in this context. On the other hand, results also demonstrated that the formulas are not intended to predict implant failures or junctional failure, and research is still needed to identify patients at risk for these complications. 3) Ability to compensate. Since the formulas were obtained using a multilinear regression analysis, they are intended to model the most common behavior in terms of compensatory mechanisms. In the setting of sagittal malalignment, a loss of lumbar lordosis is usually accompanied by pelvic retroversion and an increase in SVA. Interestingly, a small number of patients had a mismatch between PT and SVA and did not compensate through the pelvis for their spinal malalignment. It is possible that these patients had undiagnosed hip pathology or soft-tissue contractures that prevented them from compensating with their pelvis, leading to a normal PT even in the presence of positive sagittal balance. A future refinement of the formula should include provisions that account for hip pathology. One possible approach would be to define an individual formula for each patient based on his or her preoperative use of compensatory mechanisms.

Conclusions

This study has validated the use of the spinopelvic alignment formulas in predicting postoperative PT and SVA following lumbar PSO. The results of this study indicate that if the current formulas predict an unsuccessful outcome, changes should be made to the surgical plan to obtain a predicted successful result. However, even after obtaining a predicted successful outcome, further evaluation is still necessary. Surgeons should ensure that the predicted values are not too close to the cutoffs (SVA = 50 mm or PT = 25°) and should identify any hip or lower-extremity pathology that may affect alignment. It is anticipated that the use of the spinopelvic alignment formulas will lead to better surgical planning and improved outcomes for patients with complex ASD.

Disclosure

Dr. Hart is a consultant for DePuy and Medtronic; has direct stock ownership in SpineConnect; is on the Speakers' Bureau for DePuy; is a patent holder with SeaSpine; and receives support of

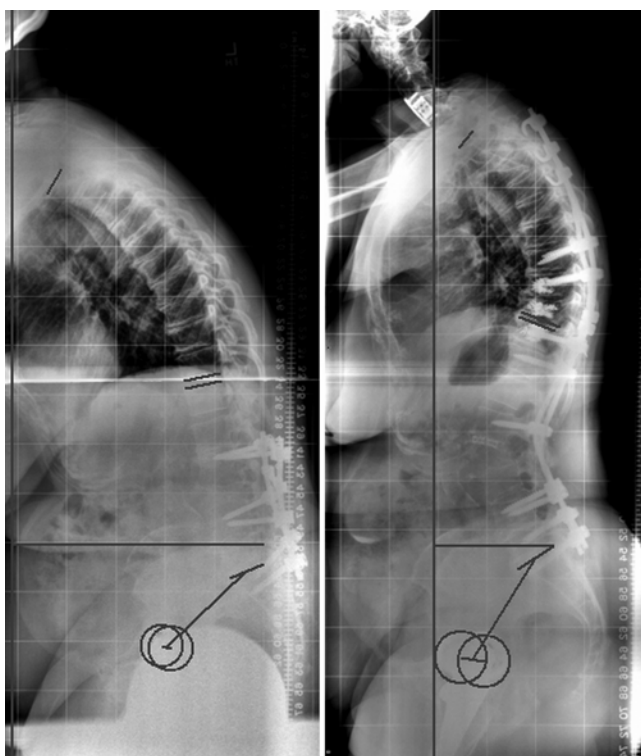


FIG. 6. Case 2. Preoperative (left) and postoperative (right) radiographs obtained in a patient who underwent sagittal realignment surgery, showing an unsuccessful realignment surgery.

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non-study-related clinical or research effort from DePuy, Medtronic, OREF, and Synthes. Dr. Burton is a consultant for and patent holder with DePuy Spine. Dr. Boachie-Adjei is a consultant for DePuy, K2M, Osteotech, and Trans1; received clinical or research support for the study described from DePuy, K2M, and Osteotech; and receives grant and research support and is on the Speakers' Bureau for DePuy, K2M, Trans1, and Osteotech. Dr. Smith states that the International Spine Study Group is funded through research grants from DePuy Spine. Dr. Shaffrey is a consultant for Medtronic and is a patent holder with Medtronic and Biomet. Dr. Gupta is a consultant for DePuy, Osteotech, and Lanx, and receives royalties from DePuy. Dr. Akbarnia is a consultant for NuVasive, K2M, DePuy Spine, Ellipse Technology, and KSpine; has direct stock ownership in Phygien; and received clinical or research support for the study described from NuVasive and K2M. Dr. Bess is a consultant for DePuy Spine and Allosource, and received clinical or research support for the study described from DePuy Spine.

Author contributions to the study and manuscript preparation include the following. Conception and design: Lafage, Schwab. Acquisition of data: Lafage. Analysis and interpretation of data: Lafage, Smith, Shaffrey, Bess. Drafting the article: Lafage, Bharucha. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Lafage. Statistical analysis: Lafage, Bharucha. Administrative/technical/material support: Lafage, Schwab. Study supervision: Lafage, Schwab.

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