

## SURGERY

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## Correlation of Functional Outcomes and Sagittal Alignment After Long Instrumented Fusion for Degenerative Thoracolumbar Spinal Disease

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**Study Design.** A retrospective function and radiography study of the patients who have received long instrumented thoracolumbar fusion.

**Objective.** To investigate the correlation between the sagittal spinopelvic alignment and the functional outcomes after long instrumented fusion for degenerative thoracolumbar spinal disease.

**Summary of Background Data.** Restoring better sagittal alignment is known as a key factor to spine fusion surgeries. The relationship between function and radiographic results in the elderly group is barely known.

**Methods.** Between 2009 and 2013, data of 120 patients with multilevel degenerative thoracolumbar spinal disease who underwent long instrumented fusion were collected retrospectively. Perioperative radiographic and functional parameters were measured and analyzed for their correlations. Receiver operating characteristic (ROC) method was used to define ideal cutoff points of postoperative spinopelvic alignment to avoid poor outcome.

**Results.** Oswestry disability index (ODI) more than or equal to 20 or Visual analogue scale (VAS) more than or equal to 4 were

defined as poor functional outcomes. The optimal cutoff points of the radiographic parameters were found as below: the mismatch between pelvic incidence and lumbar lordosis was 16.2°, sagittal vertical axis was 38.5mm, and pelvic tilt was 23.4°. Poor functional outcomes were significantly correlated with bad sagittal alignment, older age, and poor preoperative function.

**Conclusion.** Postoperative functional outcomes were highly impacted by the spinopelvic sagittal alignment.

**Key words:** degenerative thoracolumbar spinal disease, long instrumented fusion, Oswestry disability index, pelvic incidence, sagittal vertical axis.

**Level of Evidence:** 4

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The spinal column comprises the vertebrae, intervertebral disks, and surrounding soft tissues and performs several critical functions such as protection of neural elements and maintenance of the balance and alignment of the human body. People have unique patterns of spinopelvic balance and sagittal alignment to achieve the physiological upright standing posture.<sup>1</sup> These patterns can be affected by numerous variables such as patient age, sex, weight, and especially pelvic morphology and pelvic orientation.<sup>2,3</sup> The optimal alignment of the spine and its position in relation to the pelvis and lower extremities have been observed in several studies on asymptomatic adults of different ethnic backgrounds. A significant chain of correlations exists between positional pelvic and spinal parameters and pelvic incidence.<sup>4–7</sup> The indications of spinal instrumented fusion for degenerative spinal disease are correction of deformity and prevention of additional complications after decompression of neural elements including the progression of spondylolisthesis and the supplementation of spinal stability in the absence of intact posterior elements.<sup>8,9</sup> Long instrumented fusion is required when multiple segmental lesions exist. An increased incidence of loss of sagittal plane alignment resulting from flatback deformity and adjacent segmental disease has been noted in patients who have undergone long-level spinal fusion.<sup>10,11</sup>

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Prior studies of adult scoliosis have attempted to correlate radiographic appearance with clinical symptoms.<sup>12</sup> The functional outcomes of these patients are probably closely associated with the balanced sagittal alignment of the postoperative spine; however, very few reports focus on this association, particularly in patients with degenerative thoracolumbar spinal disease. We aimed to obtain an association between sagittal parameters and Oswestry Disability Index (ODI)<sup>13</sup> and visual analog scale (VAS)<sup>14</sup> as well as to perform risk factor analysis by examining postoperative functional outcomes in long instrumented spinal fusion.

## MATERIALS AND METHODS

This retrospective cross-sectional study was conducted after receiving approval from the Research Ethics Committee of Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (IRB103-189-B). The indication of long level thoracolumbar instrumented fusion was more than four sequential levels of degenerative thoracolumbar spinal disease. Pedicle screws based system was applied for posterior fixation for all of the patients. Posterior fusion over T spine and posterolateral fusion over L spine with autogenous chipped bone graft retained from the posterior decompression procedure. Transforaminal interbody fusion (TLIF) was applied on the levels of obvious segmental instability. The inclusion criteria of this study included that the patients met the surgical indication, undergone instrumented fusion surgery involving more than four spinal motion segments that were including thoracolumbar junction and the patients who had the follow-up data of radiographic and clinical function outcomes. The exclusion criteria included that the patients with knee or hip disorders, those with postoperative complications, such as surgical site infection, the appearance of neurologic deficits, the presence of malposition screws or junctional failure, and those who had received revision spine surgery within postoperative 1 year.

The demographic data, preoperative functional status, and 12-month postoperative functional and radiographic outcomes of the patients were collected. The patients were categorized according to their body mass index (BMI) as being underweight, normal, overweight, or obese.<sup>15</sup> The patients were divided according to their T-score data of bone mineral density (BMD) into three categories: normal, osteopenia, and osteoporosis.<sup>16</sup> Postoperative functional outcomes as ODI and back pain VAS were taken at postoperative 12 months. We defined an ODI score of more than or equal to 20 as poor functional outcome.<sup>17</sup> Radiographic outcomes were evaluated with spinopelvic sagittal parameters from the whole spine standing plain films arranged at postoperative 12 months postoperatively. The radiographic parameters included pelvic incidence (PI), lumbar lordosis (LL), sacral slope (SS), pelvic tilt (PT), thoracic kyphosis (TK), and sagittal vertical axis (SVA).<sup>1</sup> SVA was calculated by the distance between C7 plumb line and posterior superior corner of sacrum and it represented the alignment of whole spine. LL was calculated as the Cobb angle between upper end plates of L1 and S1 and TK was calculated as the

Cobb angle between upper end plates of T4 and lower end plates of T12. Both of them represented the regional spine alignment. PI, SS, PT represented the spinopelvic association. The radiographic parameters mentioned above were all calculated from the lateral view of whole spine standing triple film. All of the patients had minimum 12-month follow up.

We used SPSS version 17.0 (SPSS Inc., Chicago, IL) for statistical analysis. The receiver operating characteristic (ROC) curve method<sup>18</sup> was used to determine the optimal discrimination threshold of each sagittal parameter to classify “good” or “poor” function on the basis of postoperative ODI score. We then used logistic regression analysis to identify the risk factors associated with the postoperative functional status on the basis of the ODI and VAS scores.

## RESULTS

A total of 120 patients in our outpatient clinic from January 2009 to January 2013 who met the inclusion criteria were reviewed. The demographic data of the 120 patients are shown in Table 1. The study included 32 men and 88 women with a mean age of  $65.7 \pm 8.1$  (50–80) years. Fifteen percent of the patients (mostly men) were smokers. Of the 120 patients, 69.1% were categorized as overweight or obese groups and 64.2% of them (mostly the women) were classified into osteopenia or osteoporosis groups. Sixty-five percent of the patients received the fusion involving the sacrum level and the other patients received the fusion distal to L5 level. There were 70% of the patients received 4-segment fusion and the others received 5 or more than 5-segment fusion. The proximal level of the fusion was shown in Table 1 and most of them were L1 or L2. 60% of the patients received 3-level TLIF. The mean PI was  $49.6^\circ \pm 12.0^\circ$ , with no significant difference between the men and women. The mean preoperative ODI and VAS scores were  $37.0 \pm 4.1$  and  $6.1 \pm 1.3$ , respectively. All of the patients had larger postoperative LL than PI.

The ROC method was used to determine the cutoff values of the entire spine sagittal parameters for differentiating good or poor functional status and absent or present back pain.<sup>18</sup> The area under the curve (AUC) was calculated as discrimination power. An AUC more than or equal to 0.7 was considered to indicate acceptable discrimination power.<sup>19</sup> The cutoff value of the absolute value of postoperative LL–PI mismatch was  $16.2^\circ$  with an AUC of 0.747 (Figure 1), whereas that of the absolute value of SVA was 38.5 mm with an AUC of 0.704 (Figure 2). The cutoff value of the PT was  $23.4^\circ$  with an AUC of 0.759 (Figure 3). Because all the three cutoff values had acceptable discrimination power, they were set as numerical variables for postoperative functional status in the logistic regression analysis.

Logistic regression analysis was used for finding the risk factors of poor postoperative functional status according to ODI or VAS score. The risk factors included age, sex, smoking status, BMI, BMD, preoperative functional status, PI, postoperative TK, involvement of sacrum level in fusion, the numbers of instrumented fusion segments and the cutoff

**TABLE 1. Demographic Data of the 120 Included Patients**

	Male	Female	Total	P
N	32	88	120	
Age	64.0 ± 7.9	66.4 ± 8.2	65.7 ± 8.1	0.158
Smoke	–	–	–	<0.001*
No	19 (59.4%)	83 (94.3%)	102 (85.0%)	
Yes	13 (40.6%)	5 (5.7%)	18 (15.0%)	
BMI group	–	–	–	0.170
Normal	5 (15.6%)	29 (33.0%)	34 (28.3%)	
Underweight	0 (0.0%)	3 (3.4%)	3 (2.5%)	
Overweight	13 (40.6%)	27 (30.7%)	40 (33.3%)	
Obese	14 (43.8%)	29 (33.0%)	43 (35.8%)	
TST	–	–	–	<0.001*
Normal	21 (65.6%)	22 (25.0%)	43 (35.8%)	
Osteopenia	11 (34.4%)	42 (47.7%)	53 (44.2%)	
Osteoporosis	0 (0.0%)	24 (27.3%)	24 (20.0%)	
S1 involvement	–	–	–	0.280
No	14 (43.8%)	28 (31.8%)	42 (35.0%)	
Yes	18 (56.3%)	60 (68.2%)	78 (65.0%)	
Instrumented fusion segments	–	–	–	0.653
4	21 (65.6%)	63 (71.6%)	84 (70.0%)	
≥5	11 (34.4%)	25 (28.4%)	36 (30.0%)	
Proximal fusion level	–	–	–	0.479
L1	17 (53.1%)	36 (40.9%)	53 (44.2%)	
L2	9 (28.1%)	36 (40.9%)	45 (37.5%)	
T10	4 (12.5%)	6 (6.8%)	10 (8.3%)	
T11	0 (0.0%)	1 (1.1%)	1 (0.8%)	
T12	2 (6.3%)	2 (2.3%)	4 (3.3%)	
T4	0 (0.0%)	1 (1.1%)	1 (0.8%)	
T8	0 (0.0%)	4 (4.5%)	4 (3.3%)	
T9	0 (0.0%)	2 (2.3%)	2 (1.7%)	
Interbody fusion segment	–	–	–	<0.001*
≤2	2 (6.3%)	13 (14.8%)	15 (12.5%)	
3	28 (87.5%)	44 (50.0%)	72 (60.0%)	
4	2 (6.3%)	31 (35.23%)	33 (27.5%)	
PI	48.4 ± 8.2	50.1 ± 13.2	49.6 ± 12.0	0.401
PreOP VAS	6.1 ± 1.2	6.2 ± 1.3	6.1 ± 1.3	0.681
PreOP ODI	35.8 ± 3.6	37.4 ± 4.2	37.0 ± 4.1	0.050*

\* $P < 0.05$  was considered statistically significant after test.

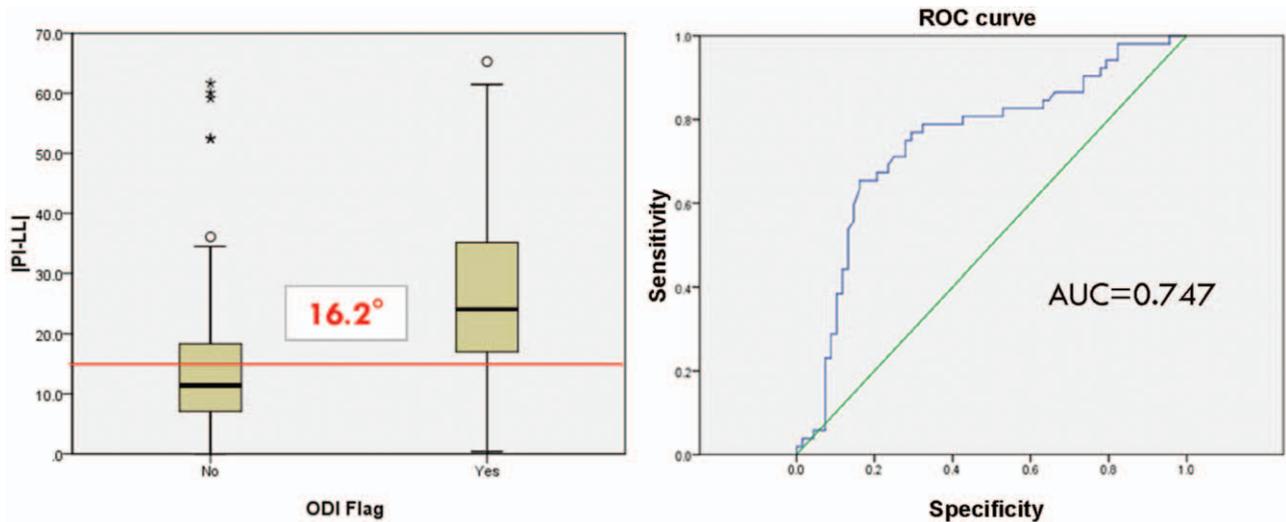
Data are presented as *n* or mean ± standard deviation. BMI indicates body mass index; ODI, Oswestry disability index; PI, pelvic incidence; TST, total spine T score; VAS, visual analogue scale.

values of postoperative PT, LL – PI, and SVA. On the basis of multivariate analysis, we found that old age, poor preoperative ODI, PT more than or equal to 23.4°, and fusion involving the sacrum level was significantly correlated with poor postoperative ODI score (Table 2), whereas old age, female, with smoking habit, LL – PI mismatch more than 16.2°, and poor preoperative ODI was related to poor postoperative VAS score (Table 3). Osteoporosis and overweight was related to poor postoperative functional scores in only univariate analysis. The 5 and more than 5 instrumented fusion segments were significantly risky to poor postoperative ODI and VAS in univariate analysis and

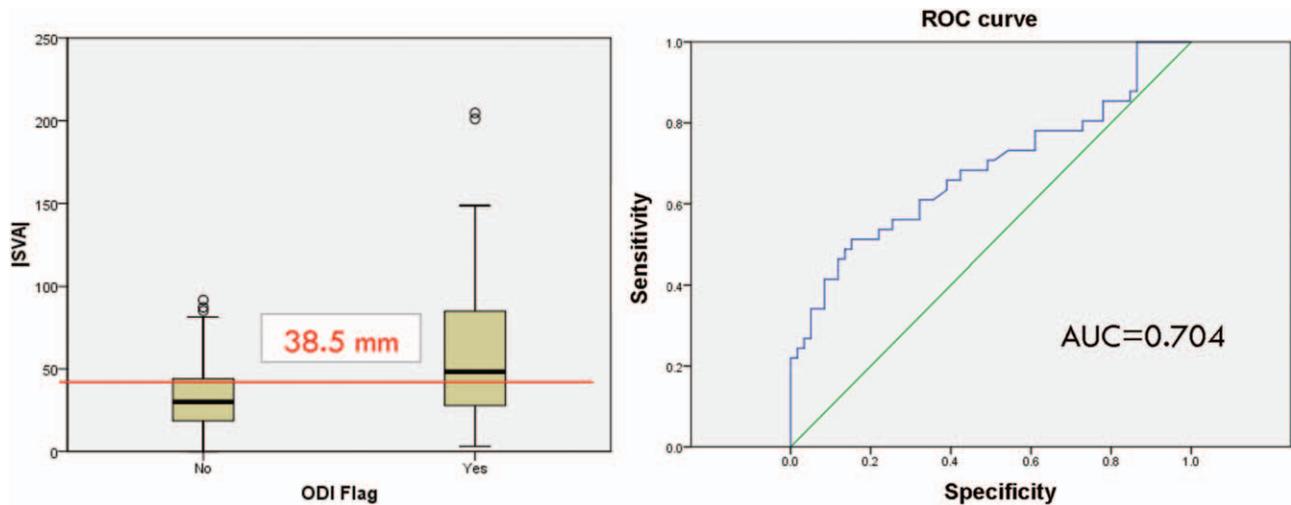
marginally risky to poor postoperative ODI in multivariate analysis.

## DISCUSSION

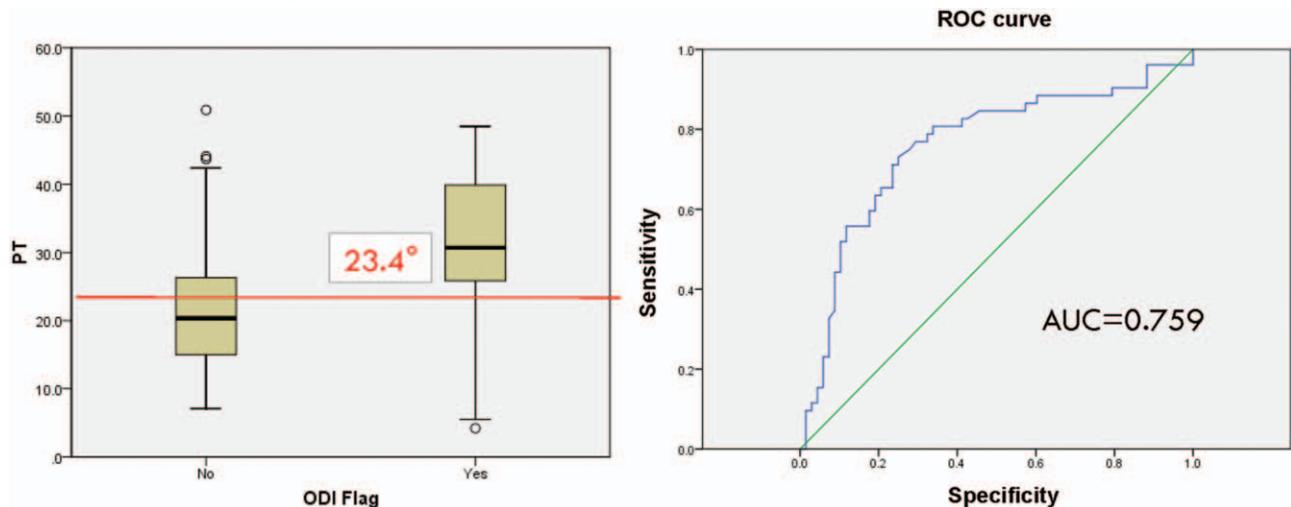
This is the first study to determine the cutoff values of the sagittal parameters associated with postoperative function and to perform risk factor analysis of poor functional status for patients who were diagnosed with degenerative spinal disease and received long-segment instrumented fusion that included thoracolumbar junction. The change of regional sagittal parameters can influence the other regional parameters and subsequently the entire alignment



**Figure 1.** Receiving operation curve (ROC) method was used for finding the cutoff value of PI – LL for differentiating between good and worse ODI score. Area under curve (AUC) is 0.747 as acceptable discrimination power of absolute value of PI – LL < 16.2°. LL indicates lumbar lordosis; ODI, Oswestry disability index; PI, pelvic incidence.



**Figure 2.** Receiving operation curve (ROC) method was used for finding the cutoff value of SVA for differentiating between good and worse ODI score. Area under curve (AUC) is 0.702 as acceptable discrimination power of absolute value of SVA less than 38.5 mm. ODI indicates Oswestry disability index; SVA, sagittal vertical axis.



**Figure 3.** Receiving operation curve (ROC) method was used for finding the cutoff value of SVA for differentiating between good and worse ODI score. Area under curve (AUC) is 0.759 as acceptable discrimination power of absolute value of PT is less than 23.4°. ODI indicates Oswestry disability index; PT, pelvic tilt; SVA, sagittal vertical axis.

**TABLE 2. Risk Factors Associated with Postoperative ODI Score (n = 120)**

	Univariate		Multivariate	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
Age	1.10 (1.05–1.16)	<0.001*	1.13 (1.01–1.28)	0.040*
Gender	–	–	–	–
Female	References	NA	References	NA
Male	0.60 (0.26–1.39)	0.235	0.45 (0.05–3.68)	0.454
Smoke	–	–	–	–
No	References	NA	References	NA
Yes	1.06 (0.39–2.89)	0.918	2.21 (0.29–17.01)	0.447
BMI	–	–	–	–
Normal	References	NA	References	NA
Underweight	4.18 (0.34–51.24)	0.263	0.89 (0.00–4.39E8)	0.991
Overweight	1.55 (0.60–4.01)	0.371	3.04 (0.43–21.70)	0.268
Obese	2.19 (0.86–5.58)	0.100	1.12 (0.14–8.89)	0.918
BMD	–	–	–	–
Normal	References	NA	References	NA
Osteopenia	0.79 (0.34–1.81)	0.573	0.31 (0.05–1.92)	0.206
Osteoporosis	3.71 (1.27–10.85)	0.016*	1.19 (0.13–10.89)	0.875
PreOP VAS	1.72 (1.22–2.43)	0.002*	1.47 (0.76–2.82)	0.253
PreOP ODI	1.30 (1.16–1.46)	<0.001*	1.23 (1.01–1.54)	0.047*
LL – PI <16.2°	–	–	–	–
No	References	NA	References	NA
Yes	0.13 (0.06–0.30)	<0.001*	1.08 (0.13–8.81)	0.945
SVA  <38.5 mm	–	–	–	–
No	References	NA	References	NA
Yes	0.28 (0.13–0.60)	0.001*	0.35 (0.07–1.64)	0.182
PT <23.4°	–	–	–	–
No	References	NA	References	NA
Yes	0.12 (0.05–0.29)	<0.001*	0.13 (0.02–0.80)	0.027*
S1 involvement	–	–	–	–
No	References	NA	References	NA
Yes	5.50 (2.26–13.40)	<0.001*	6.00 (1.06–34.11)	0.043*
Instrumented fusion segments	–	–	–	–
4	References	NA	References	NA
≥5	25.6 (8.07–81.20)	<0.001*	6.86 (0.72–65.46)	0.094
PI	1.06 (1.02–1.09)	0.002*	0.99 (0.90–1.10)	0.965
TK	0.99 (0.96–1.02)	0.550	1.02 (0.96–1.09)	0.568

\*P < 0.05 was considered statistically significant after test.

Data are presented as odds ratio (95% CI). BMI indicates body mass index; BMD, bone mineral density; CI, confidence interval; LL, lumbar lordosis; NA, not applicable; ODI, Oswestry disability index; PI, pelvic incidence; PT, pelvic tilt; SVA, sagittal vertical axis; TK, thoracic kyphosis; VAS, visual analogue scale.

by compensation. The compensatory mechanisms occur in spine, pelvis, and lower limb areas when people age, to rebalance the axis of gravity; this ability of rebalancing decreases when spinal segments are surgically fused. Considering an acceptable postoperative spinopelvic sagittal alignment while deciding to perform long-segment instrumented fusion in addition to adequate decompression has received tremendous attention in the past decade. Positive sagittal balance is strongly correlated with poor health-related quality of life scores and the proper restoration of sagittal plane alignment is critical for improving the clinical outcome and avoiding pseudarthrosis in patients

with adult spinal deformity.<sup>10,12,20,21</sup> Lafage *et al*<sup>22,23</sup> investigated the spinopelvic alignment formulas that can be used to predict postoperative PT and SVA following lumbar pedicle subtraction osteotomy. The radiographic parameters were most closely related to clinical outcome, and the study demonstrated a mismatch between PI and LL as being the key factor associated with pain and disability in the patients with adult spinal deformity. Boulay *et al*<sup>24</sup> proposed the formula  $LL = PI \pm 9^\circ$  on the basis of the data of 75 asymptomatic adults with a mean age of 48 years. Schwab *et al*<sup>25</sup> reported SVA is less than or equal to 50 mm, PT less than or equal to 20°, and

**TABLE 3. Risk Factors Associated With Postoperative Back Pain VAS Score (n = 120)**

	Univariate		Multivariate	
	Odds Ratio (95% CI)	P	Odds ratio (95% CI)	P
Age	1.10 (1.05–1.16)	<0.001*	1.13 (1.03–1.25)	0.012*
Gender	–	–	–	–
Female	References	NA	References	NA
Male	0.28 (0.12–0.65)	0.003*	0.15 (0.03–0.71)	0.017*
Smoke	–	–	–	–
No	References	NA	References	NA
Yes	1.40 (0.49–4.03)	0.532	30.11 (3.82–237.49)	0.001*
BMI group	–	–	–	–
Normal	References	NA	References	NA
Underweight	5.82E8 (NA)	0.999	1.01E9 (NA)	0.999
Overweight	0.24 (0.09–0.65)	0.005*	0.19 (0.04–0.97)	0.046*
Obese	0.67 (0.25–1.80)	0.430	0.76 (0.15–3.79)	0.736
TST group	–	–	–	–
Normal	References	NA	References	NA
Osteopenia	0.87 (0.33–2.26)	0.773	0.92 (0.20–4.25)	0.911
Osteoporosis	2.02 (0.54–7.61)	0.297	0.44 (0.07–3.03)	0.407
PreOP VAS	1.42 (1.03–1.96)	0.033*	0.95 (0.57–1.59)	0.854
PreOP ODI	1.26 (1.11–1.41)	<0.001*	1.33 (1.09–1.61)	0.004*
LL – PI <16.2°	–	–	–	–
No	References	NA	References	NA
Yes	0.28 (0.11–0.70)	0.006*	0.27 (0.05–0.82)	0.044*
SVA  <38.5 mm	–	–	–	–
No	References	NA	References	NA
Yes	0.73 (0.31–1.73)	0.476	1.54 (0.41–5.76)	0.518
PT <23.4°	–	–	–	–
No	References	NA	References	NA
Yes	0.43 (0.20–0.90)	0.026*	0.55 (0.11–2.80)	0.473
S1 involvement	–	–	–	–
No	References	NA	References	NA
Yes	1.20 (0.56–2.57)	0.639	0.51 (0.12–2.19)	0.364
Instrumented fusion segments	–	–	–	–
4	References	NA	References	NA
≥5	3.18 (1.30–7.79)	0.011*	2.81 (0.12–5.63)	0.380
PI	1.01 (0.98–1.04)	0.527	0.93 (0.85–1.02)	0.114
TK	1.02 (0.99–1.06)	0.218	1.02 (0.96–1.09)	0.504

\*P < 0.05 was considered statistically significant after test.

Data are presented as odds ratio (95% CI). BMI indicates body mass index; BMD, bone mineral density; CI, confidence interval; LL, lumbar lordosis; NA, not applicable; ODI, Oswestry disability index; PI, pelvic incidence; PT, pelvic tilt; SVA, sagittal vertical axis; TK, thoracic kyphosis; TST, total spine T score; VAS, visual analogue scale.

LL = PI ± 9° as yielding a successfully balanced spinopelvic alignment according to the data from a retrospective review of the clinical outcomes of 125 patients. Sagittal parameters in the older patients are much different from other age groups. Hammerberg and Wood<sup>26</sup> revealed average TK as 52°, LL as 57°, C7–S1 SVA as 40 mm in the group of 50 asymptomatic volunteers at 70 to 85 years of age, while as Iyer *et al*<sup>27</sup> found that C7–S1 SVA was 5 ± 34.4 mm, PT was 14.4 ± 7.2°, and PI–LL was –4.7 ± 12.3° over 61 to 70 y/o asymptomatic volunteers. Our study focused on these known key sagittal parameters and used the ROC method to determine the cutoff values based on the

patients' functional status. We found that the postoperative radiographic alignment with SVA less than 38.5 mm, PT less than 23.4°, and LL – PI mismatch less than 16.2° was related to good function and that the discrimination powers of these cutoff values were acceptable. The difference in the values of the key sagittal parameters between this and the previous studies may originate from the different characteristics of the patient groups. The patients included in our study were all older than 50 years old and with degenerative spine disease who received fusion for more than four motion segments and the compensatory ability of them was not the same as that

of patients who have adult spinal deformity, so that the cutoff values of the spinopelvic sagittal alignment parameters were not in the same range between the two groups.

The logistic regression analysis results of the risk factors related to poor ODI scores and back pain VAS revealed that these key sagittal alignment parameters were strongly correlated with the functional status according to our cutoff points, even after multivariate adjustments. The result was consistent with those of previous studies, specifically that clinical outcomes were immensely influenced by the radiographic alignment parameters in the patients who received spinal surgery.<sup>4,12,28</sup> PT more than 23.4° significantly correlates to poor ODI and the mismatch between PI and LL more than 16.2 significantly correlates to poor back pain VAS, while the values of SVA have no significant correlation on both the functional outcomes according to our logistical regression analysis. An adequate correction of LL and PT can restore the entire spinal balance and improve clinical outcomes. Older age and fusion to the sacrum were also both important risk factors for poor functional status. The indication of long spinal instrumented fusion and lumbosacral fusion should be more carefully assessed for the elderly. A program to enable patients to quit smoking may also be beneficial to these patients during the 12-month postoperative period. Although osteoporosis and overweight did not tend to significantly aggravate clinical outcomes, preoperative weight reduction and antiosteoporotic medication has been shown to play a crucial role in improving the surgical results of elderly patients who received spinal instrumentation and fusion.<sup>16</sup>

The limitations of this study are its retrospective design and cross-sectional analysis. We didn't collect the preoperative spinopelvic sagittal parameters, which could be an influential factor to the functional outcomes, because the whole spine standing lateral plain films were seldom checked preoperatively until August 2014. The extents of disk degeneration and nerve compression were also not recorded, which may influence the surgical results in addition to the sagittal alignment. Furthermore, prospective cohort studies for different types of correction methods should examine degenerative spinal disorders. Longer-term follow-up of large populations to check the incidence of diseases in the adjacent segment is one of our future objectives. Despite the aforementioned limitations, this study revealed the importance of sagittal alignment change on postoperative functional outcomes for degenerative spinal disease.

## CONCLUSION

The results of this study support previous findings that functional outcomes are closely associated with sagittal radiographic parameters in the patients with degenerative thoracolumbar spinal disease who received long-segment fusion. The achievement of global and regional sagittal alignment balance is a crucial factor for improved postoperative functional outcomes. In addition, improved

functional outcomes for long-instrumented thoracolumbar are closely associated with the plan for desired postoperative sagittal alignment and careful assessment of the necessity of fusion extending to the sacrum. The surgical indication of long-segment spinal fusion for the older patients and smokers should be closely examined because they may have poor postoperative functional outcomes.

## ➤ Key Points

- ❑ Region spinal alignment parameters, such as PT and mismatch between PI and LL, influence functional outcomes more than whole spine alignment one, such as SVA.
- ❑ Postoperative radiographic alignment with SVA less than 38.5 mm, PT less than 23.4°, and LL – PI mismatch less than 16.2° was related to good function and that the discrimination powers of these cutoff values were acceptable.
- ❑ Improved outcomes for long instrumented thoracolumbar fusion are associated with postop spinopelvic sagittal alignment parameters
- ❑ The necessity of fusion extending to the sacrum should be considered because it may be related to poor functional outcomes.
- ❑ The surgical indication of long-segment spinal fusion for the older patients and smokers should be closely examined because they may have poor postoperative functional outcomes.

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