SIGNIFICANCE OF VARIOUS RISK FACTORS FOR PROXIMAL JUNCTIONAL KYPHOSIS AND INSTABILITY OF INSTRUMENTATION IN SURGICAL TREATMENT FOR ADULT SPINAL DEFORMITIES

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Objective. To analyze the significance of the influence of various risk factors on the development of proximal junctional kyphosis (PJK) and instability of instrumentation.

Material and Methods. The results of surgical treatment of 382 patients with scoliotic deformities of the lumbar spine of type I and IIIb according to Aebi were analyzed. Patients were operated on through the posterior approach using the TLIF-PLIF technique with extended rigid transpedicular instrumentation. Potential risk factors influencing the development of proximal junctional kyphosis and instability of instrumentation were analyzed.

Results. It was found that only three risk factors significantly affect the development of PJK: correction of lumbar lordosis more than 30° ($p = 0.036$) increases the likelihood of its development by 1.5 times, osteoporosis ($p = 0.001$) – by 2.5 times, and proximal junctional angle ≥10° ($p = 0.001$) – by 3.5 times. Three factors showed a statistically significant effect on the incidence of instrumentation instability: correction of lumbar lordosis more than 30° ($p = 0.034$) increases the likelihood of its occurrence by 1.7 times, osteoporosis ($p = 0.018$) – by 1.8 times, and deviation of the sagittal vertical axis by more than 50 mm ($p = 0.001$) – by 3.3 times.

Conclusion. The most significant risk factors for the occurrence of PJK and instability of instrumentation are osteoporosis, correction of lumbar lordosis more than 30°, an increase in the proximal junctional angle ≥10°, and an anterior deviation of sagittal vertical axis more than 50 mm. Consideration of these factors in the preoperative period, as well as during surgery, can decrease likelihood of the occurrence of PJK and instability of instrumentation.

Key Words: degenerative scoliosis, proximal junctional kyphosis, instability of instrumentation, risk factors, osteoporosis, deformity correction.

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Spinal deformity in adults covers a wide range of pathologies, including both stable asymptomatic and progressive and/or disabling deformities [1].

Degenerative scoliosis occurs in 65 % of the adult population over 59 years old [2]. Modern surgery for degenerative scoliosis of the lumbar spine mostly includes decompression, stabilization of the spinal motion segment, and complete deformity correction [3]. Surgical treatment of this category of patients is a technically difficult task and accompanied by a high percentage of unsatisfactory results, with a total percent of complications reaching 24.0–61.7 % [4, 5]. Among these complications, the risk of proximal junctional kyphosis (PJK) and instrumentation failure is the highest [6–8]. The incidence of PJK after surgical treatment of spinal deformities varies from 17 to 39 %, depending on the follow-up duration [9].

To date, instrumentation failure includes fracture and migration of implant elements, as well as occurrence of bone tissue resorption areas (halo effect) around the implanted screws [10].

The incidence of pedicle screw breakage ranges from 2.6 to 36.0 % [11], while the frequency of instrumentation failure resulting from bone resorption around pedicle screws is 0.6–27.0 % [11–14].

The mechanisms of PJK development and instrumentation failure have not been sufficiently studied, and no significant risk factors for the development of these complications have been identified yet.

The aim of the study is to analyze the significance of various risk factors in the development of PJK and instrumentation failure.

Material and Methods

We have analyzed the results of surgical treatment of 382 patients with degenerative scoliosis of the lumbar spine treated in 2009–2015. The average age of the patients was 57.2 ± 4.8 years (range, 48 to 70 years). There were 288 (75.4 %) females and 94 (24.6 %) males.

The inclusion criteria were the following:

1) scoliotic deformities of the lumbar spine of types I and IIIb according to the Aebi classification (2005);

2) age of < 70 years;

3) availability of imaging examination data (CT, MRI, and X-ray densitometry).

The exclusion criteria were the following:

1) systemic lupus erythematosus, systemic scleroderma, inflammatory myopathies, and rheumatoid arthritis;

2) oncological and infectious pathologies of the spine;

3) history of lumbar spine surgery;

4) severe somatic comorbidity;

5) lack of a minimum follow-up period (three years).

All patients were operated on through the posterior approach using the TLIF–PLIF technique with rigid transpedicular instrumentation; the fusion length was four to eight spinal motion segments. Decompression, stabilization, and deformity correction were supplemented by Schwab grade 1 and 2 osteotomies, if necessary. Distal and proximal ends of fixation were at segments L5–S1 and T10–L1, respectively. The proximal end of fixation was determined individually, with taking into account the stability and neutral position of the vertebrae relative to the frontal deformity.

During the study, we analyzed the common risk factors that, according to the literature, contribute to PJK and instrumentation failure. All of them were divided into three groups based on the same principle:

1) patient-related factors: gender, age, body mass index (BMI), smoking, and osteoporosis;

2) surgery-related factors: magnitude of lumbar lordosis correction, osteotomy type, inclusion/exclusion of the sacrum in fixation area, and the level of proximal end of fixation;

3) radiological factors: lumbar lordosis (LL), pelvic incidence (PI), the difference between pelvic incidence and lumbar lordosis (PI–LL), sagittal vertical axis (SVA), proximal junctional angle (PJA), and thoracic kyphosis (TK).

Sagittal balance parameters were calculated after assessment of radiological data obtained using Surgimap software (v. 2.2.9.9.9). Statistical data were analyzed using non-parametric methods, Cox regression model, and ROC analysis on a personal computer with installed Microsoft Excel 2010 software.

Differences between values and correlations between parameters were considered statistically significant at $p < 0.05$.

Control radiological examination was performed after three, six, 12, 24, and 36 months. Patients were indicated for thorough CT examination in case if suspicious radiological signs were detected; CT and MRI were indicated in case if PJK was diagnosed.

Results

Among 382 operated patients with degenerative scoliosis of the lumbar spine during a three-year follow-up period, there were 132 (34.6 %) cases of PJK, 74 (19.3 %) individuals with instrumentation failure, while the other 176 (46.1 %) patients had no complications.

Patient groups with diagnosed complications in the form of PJK and instrumentation failure were studied separately by comparing each of them with the group of patients without complications. For this, a statistical analysis of the effect of risk factors on development of complications was performed.

Proximal junctional kyphosis. PJK was predominantly detected on month 5–22 after the first surgical intervention; it developed due to various mechanisms. The causes and timing of PJK development, as well as PJK angle value at the time of diagnosing complications, were analyzed and established. The results are presented in Table 1.

The most severe and early-onset cause of PJK is a combination of fractures of the proximal instrumented vertebra and upper adjacent segment (average timing, 8.2 ± 3.2 months). These patients had the greatest PJA value (average value, 42.6° ± 9.3°) and the most severe clinical picture (Fig. 1).

Isolated injuries to the upper adjacent segment and proximal instrumented vertebra were diagnosed on average about two months later due to a less severe clinical picture. The latest occurring and rarest cause of PJK was intervertebral disc degeneration, which was diagnosed on average 16.2 ± 5.7 months after corrective surgery. The average PJK value in these patients was 14.4° ± 3.2°, and the clinical picture was the least pronounced. Thus, the analysis of the causes of PJK showed that this complication in 90.9 % of cases occurred due to fractures of adjacent vertebrae in the proximal fixation area.

In order to assess the correlation between PJK incidence and proximal instrumented vertebra, patients were divided into the following groups: T10 level in 123 patients, T11 in 96 individuals, T12 in 110 cases, and L1 level in 53 patients. The analysis revealed no statistically significant differences in the incidence of PJK between groups with different levels of proximal end of fixation.

A total of 15 risk factors indicated in the “Material and Methods” section were analyzed to determine their statistically significant effect on the likelihood of PJK. The significance of each risk factor was determined using the Pearson chi-square test.

The following risk factors were found to be statistically significantly associated with PJK development: osteoporosis (53–33 %; $p = 0.032$) and BMI > 25 (51–37 %; $p = 0.042$); > 30° correction of lumbar lordosis (58–30 %; $p = 0.008$) among surgery-related factors; and PI ($p = 0.012$) and PJA ($p = 0.001$) among radiological factors.

Next, statistically significant risk factors for PJK development were used as independent variables in Cox regression. Despite their statistical significance in PJK development, two out of five risk factors (PI and BMI > 25) did not have any reliable effect on its occurrence ($p = 0.065$; $p = 0.326$). Thus, only three risk factors were shown to significantly affect PJK development: osteoporosis ($p = 0.001$), PJA ($p = 0.001$), and > 30°

correction of lumbar lordosis ($p = 0.036$). Interpretation of Cox analysis results showed that the likelihood of PJK development increases 2.5-fold in the presence of osteoporosis (Exp (B) = 2.532; $p = 0.001$) and 1.5-fold in case of > 30° correction of lumbar lordosis (Exp (B) = 1.475; $p = 0.036$).

Considering the observed effect of PJA, which statistically significantly increased the likelihood of PJK development, additional analysis was required to determine PJA threshold significance.

Threshold PJA value was determined using the ROC analysis. Mathematical calculations yielded threshold PJA of 9.5° at 76.5 % sensitivity and 71.0 % specificity. This cut-off means that 76.5 % of patients with a PJA > 9.5° develop PJK.

The obtained data made it possible to calculate the PJA value, which was 10°; it was further analyzed using the Cox regression model. The analysis revealed that a PJA of ⩾ 10° increases the likelihood of developing PJK 3.5-fold (Exp (B) = 3.487; $p = 0.001$). Furthermore, in case of a PJA of ⩾ 10°, the risk of PJK development increases 1.258-fold (or 25.8 %) per each additional 1° (Exp (B) = 1.258; $p = 0.001$).

Instrumentation failure. There were 75 patients with instrumentation failure and 176 individuals without it. It should be noted that the diagnosis of instrumentation failure was made in cases of obligatory presence of both radiological and clinical manifestations of failure.

Instrumentation failure was detected a little earlier than PJK: 2–8 months after surgery on average. There were two main causes of failure: mechanical failure of instrumentation elements and osteolysis (Fig. 2).

Clinical manifestations almost coincided with the timing of radiological diagnosis of failure in cases of instrumentation fractures and occurred with a delay in case of osteolysis. Data on the type of failure and timing of its development are presented in Table 2.

The significance of the risk factors indicated in the "Material and Methods" section in the development of instrumentation failure was studied using the Pearson chi-square test, which made it possible to determine potential risk factors.

The performed analysis revealed a higher incidence of instrumentation failure in patients with osteoporosis (40–20 %; $p = 0.015$), after > 30° correction of lumbar lordosis (46–17 %; $p = 0.004$), individuals with postoperative difference between PI and LL values ($p = 0.042$) and SVA displacement value ($p = 0.002$). The rest of the risk factors did not have any statistical significance in the development of instrumentation failure.

Next, statistically significant risk factors were included in the Cox regression analysis to determine a correlation between them, independent significance of the variables, and their influence on the likelihood of instrumentation failure.

The analysis revealed that all the variables weakly correlated with each other; for this reason, they were subsequently used as independent variables in regression. Three factors were shown to have a statistically significant effect on the incidence of instrumentation failure: osteoporosis ($p = 0.018$), >30° correction of lumbar lordosis ($p = 0.034$), and SVA displacement value ($p = 0.001$).

Interpretation of the results of Cox regression analysis showed that the likelihood of instrumentation failure increases 1.8-fold in the presence of osteoporosis (Exp (B) = 1.812; $p = 0.018$) and 1.7-fold after > 30° correction of lumbar lordosis (Exp (B) = 1.722; $p = 0.034$).

Since displacement of SVA anteriorly from the theoretical boundaries showed a statistically significant effect on the likelihood of instrumentation failure, determination of the threshold value of this parameter was further required. In order to do this, a ROC analysis was carried out, which revealed the threshold SVA value of 50 mm at 75.7 % sensitivity and 75.0 % specificity. Thus, interpretation of the obtained data suggests that 75.7 % of patients with an SVA > 50 mm develop instrumentation failure.

Analysis of the resulting SVA viable (50 mm) using Cox regression analysis showed that the risk of instrumentation failure for this parameter increases 3.3-fold (Exp (B) = 3.292; $p = 0.001$). In addition, each subsequent 1 mm of SVA displacement anteriorly increases this likelihood 1.088-fold, or by 8.8 % (Exp (B) = 1.088; $p = 0.001$). The risk of developing instrumentation failure increases 2.3-fold (1.08810 = 2.324) with an increase in SVA by 1 cm.

Discussion

Considering the high risk of PJK and instrumentation failure after surgical treatment of patients with degenerative scoliosis of the lumbar spine, the main

Table 1

Mechanisms of development and timing of the onset of PJK

Mechanism	Incidence, n (%)	Average development time, months	Average PJA, deg.
Intervertebral disc degeneration	12 (9.1)	16.2 ± 5.7	14.4 ± 3.2
UAS fracture	67 (50.8)	11.2 ± 3.8	34.2 ± 6.2
PIV fracture	39 (29.5)	10.3 ± 4.1	32.1 ± 7.1
UAS + PIV fracture	14 (10.6)	8.2 ± 3.2	42.6 ± 9.3
Total	132 (100.0)	–	–

UAS – upper adjacent segment; PIV – proximal instrumented vertebra.

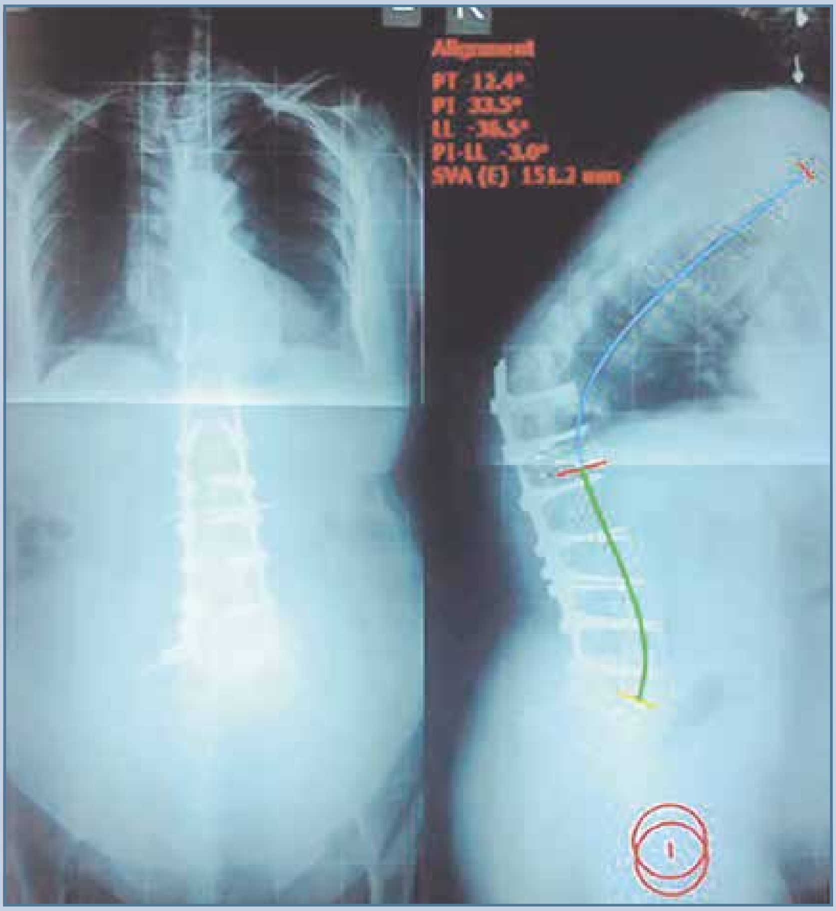

Fig. 1
Spine teleroentgenogram in frontal and lateral projections of patient A., aged 64 years: four months after surgery; PJK, T10 fracture

task should be reducing the number of cases of these complications. For this, along with careful selection of patients, the risk factors contributing to the occurrence of complications should be taken into account. Their consideration can significantly improve surgical outcomes.

To date, a rather large number of risk factors for the occurrence of PJK and instrumentation failure are mentioned in the literature. The most common demographic factors contributing to PJK are gender, age, patent's BMI, the presence of osteoporosis or osteopenia, and smoking. Numerous studies show that the patients who subsequently developed PJK were older than individuals without this complication [15–18]. Bridwell et al. [2] note that the average age in the group of patients with PJK is 10 years older than that in the group without PJK. At the same time, there are many works demonstrating that age is not a risk factor for the occurrence of PJK [19–22]. We found no statistically significant relationship between the patient's age and PJA development in our study. According to the systematic meta-analysis by Zhao et al. [23], women are more likely to develop PJK after extended fixation than men. Bridwell et al. [2], Ha et al. [24], and Lafage et al. [25] came to the same conclusion. This is most likely due to osteoporosis, which is more common among older women and increases the risk of PJK. In our study, the patient's gender had no statistically significant effect on PJK development. The same results were obtained when assessing the effect of smoking on PJK occurrence, which were also confirmed in other works [2, 19, 22].

According to a number of authors [9, 26, 27], osteoporosis is a significant risk factor for PJK development in patients with spinal deformities. In our study, the incidence of PJK increased 2.5-fold in the presence of osteoporosis. It should be noted that BMI plays an important role in PJK development; however, the literature data on this issue are ambiguous and sometimes contradictive. Wang et al. [9] note that BMI is higher in patients developing PJK. The same results were obtained by Yagi et al. [27]. However, there is another information that BMI is lower in the group of PJK patients and that BMI is not a statistically significant factor in PJK development [15, 20, 28].

The most common radiological factors contributing to PJK are LL, PI, PI–LL, SVA, PJA, and TK. According to the meta-analysis by Zhao et al. [23], the preoperative SVA, PT, and PI–LL values are higher in patients who developed PJK, while LL and sacral slope are lower. More than 50-mm displacement of preoperative SVA is most often reported as a risk factor for PJK occurrence. However, there are a number of studies reporting that SVA displacement is not a risk factor for PJK [29]. Whether thoracic kyphosis value is a risk factor for PJK occurrence is currently a subject of discussion. In our study, thoracic kyphosis was not a statistically significant risk factor for PJK development. TK values in the groups with and without PJK before surgery were 34.2 ± 8.1 and 31.8 ± 7.9 ($p = 0.097$), respectively. After surgical treatment, this parameter had the following values: 38.4 ± 8.6 in PJK group and 33.1 ± 7.1 in the group without PJK ($p = 0.178$). Meanwhile, Buell et al. [20] reported that the TK value in PJK patients was 14° higher than in individuals without PJK. Maruo et al. [30] also note that the TK value is significantly higher in PJK patients. The work by Ghandi et al. [31] is the only study reporting that TK is statistically significantly lower in PJK patients (31.64° ± 8.63° in PJK patients versus 40.37° ± 14.08° in individuals without PJK; $p = 0.031$).

Fig. 2
CT of the lumbar spine of patient M., aged 56 years, 11 months after surgery: failure of S1 pedicle screws (halo effect)

Among surgery-related factors capable of provoking PJK, attention should be paid to the amount of lumbar lordosis correction, osteotomy type, inclusion of the sacrum in fixation area, and proximal instrumented vertebra.

The amount of lumbar lordosis correction is a significant risk factor for PJK development. Mauro et al. [30] state that >30° correction of lumbar lordosis is an independent risk factor for postoperative PJK. Kim et al. [28] report that overcorrection of lumbar lordosis and SVA (more than 80 mm) significantly increases the risk of revision surgery for PJK.

According to numerous studies, the type of osteotomy has no effect on the risk of PJK development. For instance, these data were obtained by Zhao et al. [21]. Most authors note an increased risk of developing PJK in case of inclusion of the sacrum in fixation area. According to Bridwell et al. [2], the incidence of PJK is higher in patients with fusion to the sacrum. A meta-analysis of 14 studies also showed that fusion to the sacrum is a risk factor for PJK development [32]. According to Park et al. [33], the incidence of PJK is significantly higher in patients with the proximal end of fixation at T11–L1. Bridwell et al. [2] reported that positioning the proximal fixation end lower than T8 vertebra can significantly enhance the likelihood of PJK. A study of O'Shaughnessy et al. [34] should be also mentioned; it demonstrated a sharp increase in the incidence of postoperative complications in case of positioning the proximal fixation end above T10. The authors rightly point out the inadvisability of extending the fusion to the upper thoracic spine only in order to prevent PJK occurrence. We found no differences in the incidence of PJK between groups with different levels of proximal fixation end in our study.

Most authors consider a decrease in bone mineral density and an increase in BMI as patient-related risk factors for instrumentation failure [35–37]. The number of instrumented segments is the most significant surgical risk factor for the development of instrumentation failure. The higher incidence of instrumentation failure has been repeatedly demonstrated for multilevel fixation compared to stabilization of one spinal motion segment [35, 38]. The main radiological risk factors for instrumentation failure are spinopelvic parameter disorders [28].

We performed a multivariate analysis, which has demonstrated that only five of the 16 main risk factors considered had statistical significance in PJK development, and three factors had a significant contribution to its occurrence: osteoporosis ($p = 0.001$), > 30° correction of lumbar lordosis ($p = 0.036$), and ⩾ 10° postoperative PJA ($p = 0.001$). Osteoporosis increases the likelihood of developing PJK 2.5-fold, while > 30° restoration of lumbar lordosis and ⩾ 10° increase in PJA enhance the risk 1.5- and 3.5-fold, respectively.

Four risk factors had a statistically significant effect on the biomechanical aspect of instrumentation failure, and three factors significantly contributed to it: osteoporosis ($p = 0.018$), > 30° correction of lumbar lordosis ($p = 0.034$), and >50-mm displacement of SVA anteriorly ($p = 0.001$). Furthermore, the presence of osteoporosis, > 30° restoration of lumbar lordosis, and > 50-mm displacement of SVA anteriorly increase the likelihood of PJK development 1.8-, 1.7-, and 3.3-fold, respectively.

Considering the preoperative data obtained, special attention should be paid to the bone mineral density. In case of osteoporosis, its correction and the use of bone cement to anchor the implanted screws are required in the preoperative period. Studies have shown that this method not only increases instrumentation life but also prevents the occurrence of fractures in the proximal zone of fixation leading to PJK [39, 40].

The amount of lumbar lordosis correction is equally important for the risk of complications. Complete restoration of the sagittal balance with maximum lordosis correction, especially in cases with a pronounced loss of correction,

Table 2
Instrumentation failure and average timing of its development

Failure type	Failure, n (%)	Average timing of radiological manifestations, months	Average timing of clinical manifestations, months	p
Osteolysis	56 (75.7)	4.1 ± 2.1	5.3 ± 2.1	0.031
Migration	6 (8.1)	4.3 ± 1.8	4.4 ± 1.6	0.633
Fracture	12 (16.2)	6.4 ± 2.6	6.8 ± 2.6	0.213

significantly increases the lateral tension, which may result in not only destabilization of instrumentation but also increased loads on the proximal instrumented vertebra. This is especially noted in cases of rigid thoracic spine. As shown by the current study, > 30° correction of lumbar lordosis significantly increases the risk of both PJK occurrence and instrumentation failure regardless of initial lordosis parameters. In the absence of a pronounced sagittal imbalance, > 30° correction of lumbar lordosis allows for a complete restoration of the patient's sagittal balance in most cases. In cases of either gross imbalance with complete lordosis correction loss or kyphosis in the lumbar spine, partial correction is usually not enough to restore all spinal and pelvic parameters. However, in our opinion, the mathematical model should be neglected in this case in order to just reduce the risk of severe orthopedic complications such as PJK and instrumentation failure.

The risk of PJK also increases significantly with a ⩾ 10° increase in PJA after surgery. Therefore, it is extremely important to control this parameter, primarily intraoperatively. Surgical methods that allow for correction of the occurred changes and improvement of the long-term treatment outcomes should be used.

More than 50-mm displacement of SVA is one of the most important biomechanical risk factors for instrumentation failure. In addition, the calculations showed that each subsequent 1 cm of SVA displacement anteriorly increases the risk of complication by 23.2 %. Thus, the surgeon's task for reducing the risk of instrumentation failure is to maximize body anterior displacement. This is difficult because a compromise between the amount of lumbar lordosis correction and the rate of SVA restoration must be achieved. Both parameters are known to have a direct correlation; it is the lordosis correction rate that determines the rate of SVA restoration. It is quite difficult to prioritize the extent of surgical correction in such case. In our opinion, the combination of factors favors the need for partial correction of lordosis (up to 30°), since this parameter largely determines the patient's quality of life after surgery and anticipates the development of complications. In this regard, our understanding of the SVA restoration rate is based on the principles of the maximum acceptable correction of lumbar lordosis in order to best restore SVA and reduce the negative impact of sagittal imbalance on instrumentation stability.

Conclusion

The performed retrospective study showed that osteoporosis, > 30° correction of lumbar lordosis, > 10° increase in PJA, and displacement of the vertical sagittal axis > 50-mm anteriorly are the most significant risk factors for the occurrence of proximal junctional kyphosis and instrumentation failure after corrective surgery in patients with degenerative scoliosis. Consideration of these factors in the preoperative period and during surgery can reduce the risk of PJK development and instrumentation failure. A randomized prospective multicenter study is required to assess clinical significance of the identified risk factors and find the optimal methods for preventing complications after surgical treatment of patients with lumbar spine deformities.

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