VILNIUS UNIVERSITY

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CLINICAL AND RADIOLOGICAL PROGNOSTIC FACTORS IN ACHIEVING A BALANCED CORRECTION IN PATIENTS WITH LENKE TYPE I AIS

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Biomedical Sciences, Medicine (06B)

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VILNIAUS UNIVERSITETAS

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PAAUGLIŲ IDIOPATINĖS SKOLIOZĖS CHIRURGINĖS KOREKCIJOS METODŲ LYGINAMOJI STUDIJA NUSTATANT OPTIMALŲ LAIKYSENOS PROGNOSTINĮ FAKTORIŲ

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THE AIM AND OBJECTIVES OF THE STUDY

The aim of the study:

To optimize diagnosis and operative treatment in patients with Lenke type I in AIS.

The objectives of the study:

1. To create a spinal disease recognition module in which required parameters are calculated automatically.
2. To determine the optimal fixation level for Lenke I scoliosis type.
3. To assess the prognostic risk factors that affect non-fused lumbar curve progression after surgery.
4. To identify prognostic risk factors for trunk shift after surgery.
5. To investigate the quality of life of patients 2 years after surgery according with the "touched vertebra" method.

Hypotheses

- ✓ Skeletal immaturity before surgery may affect non-fused lumbar curve progression after surgery.

- ✓ The "touched vertebra" method for scoliosis fixation is a simple and efficient solution. Selecting a fixation level at "touched vertebra" can reduce the risk of non-fused lumbat curve progression and trunk shift after surgery.

RELEVANCE AND SCIENTIFIC NOVELTY OF THE STUDY

The surgical treatment of scoliosis has changed in the past decades. The new instruments that have appeared evolved the ways of correcting this disease [1]. Technology has changed, but the goal of treating scoliosis has remained the same: to stop the progression and correct spinal deformities, to preserve as much of the non-fused segments as possible, to maintain a good balance after surgery, prevent complications and revision surgery. In 2001, Lenke classification was considered as the gold standard for the planning of scoliosis surgical treatment [2], but the question of how much of the fixation was performed in Lenke I type remains a debatable issue. In this Lenke type, only the thoracic curve is selected for fusion, but in clinical practice, mostly Lenke IB and C scoliosis type thoracic and lumbar curves are fused together [6]. One of the first analyses in finding a risk factor for selective fusion for Lenke I type was conducted by Newton et al. in 2009 [75]. Nonselective fusion, when lumbar curvature was also fixed, was 6-33%, depending on the health facilities. Significant factors were curve size before surgery, lumbar curve apex translation and the thoracic and the lumbar curvature ratio [7]. A multicenter study that highlights the importance of the issue was conducted by Crawford et. al [7], during which patients with Lenke type 1 C patterns were examined. Selective thoracic fusion was performed only on 49% of all patients [7]. In this study, the selective thoracic fusion group had smaller curvatures in both regions and had a larger thoracic curve than lumbar. Although there have been various attempts to define more precisely what the fixation should be done in Lenke I type, the dispute continues in this area.

More and more professionals approve that one of the primary idiopathic scoliosis surgical treatment goals are the appearance and posture of the patient as well as the quality of life after surgery. We should leave as many non-fused segments as possible. Spinal mobility remains after selective fusion, but there is always a risk that a non-fused lumbar curve might progress after surgery. Wang et al. [7] found that the deviation of LIV + 1 (lowest instrumented vertebra + 1) from the central sacral line (CSVL) by 10 mm and/or an intervertebral disc angulation increase of 5 degrees below fixation level is called the *Distal Adding On* phenomenon [7]. These authors showed a significant correlation between the lowest instrumented vertebra (LIV) and non-fused lumbar curve progression. Moreover, patients with skeletal immaturity had a higher LIV + 1 deviation from CSVL after surgery. In scientific literature, various authors have it established that

distal adding worsens post-operative results and increases reoperation from 2% to 51.1%. [77,124]. Suk et al. [72] showed 33.3% of the *Distal Adding On* phenomenon and risk factor was an LIV selection. Lehman et al. [2] found only 2% of this phenomenon and the risk factors were an LIV selection and a difference between neutral and end vertebra. Cho et al. [78] showed 21% of *Distal Adding On* and age, skeletal maturity were demonstrated as risk factors. However, most studies usually examined Lenke I A modifier type patterns. The question of what are the risk factors for Lenke IB and C modifiers still remains open.

One of scoliosis treatment goals is to maintain good balance after surgery. Coronal balance may be quantified by the distance between the coronal C7 and the central sacral vertical line (CSVL). However, it has been demonstrated that a patient may be *balanced* in the coronal plane, with the head centered over the pelvis, but may still manifest a significant trunk imbalance. This specified deformity was initially described by Floman in 1982 [111]. Trunk imbalance has been shown to negatively affect pelvic obliquity, function and self-image in patients with scoliosis [117]. Numerous studies have used the C7P-CSVL distance as an outcome tool for coronal balance after surgical treatment for AIS [116, 118], but there is a paucity of data commenting on the postoperative trunk balance and/or trunk shift in AIS. Trobisch et al. found 13.6% of trunk shift in their study [113]. They concluded that postoperative trunk shift is not uncommon after surgery for AIS, occurring in 13.6% of all patients in this series, of which 65% were iatrogenic. Coronal imbalance does not correlate with trunk shift. An undercorrection of the lumbar curve predisposes to the development of postoperative trunk shift. In their opinion, the real challenge lies in identifying the ideal candidate for selective thoracic fusion. The average undercorrection of the lumbar curve that was seen in patients with postoperative trunk shift may be due to a number of patients in whom the compensatory curve did not sufficiently correct after selective thoracic fusion. Although shoulder balance was initially found to be significantly different between patients with and without trunk shift, the logistic regression analysis did not confirm the findings and the correlation between shoulder balance and trunk shift was seen not to be significant. Wang et al. [115] found that both an LIV selection and the ratio of main thoracic and thoracolumbar/lumbar (MT:TL/L) curve were found to be highly correlated with the onset of postoperative trunk shift in Lenke 1C scoliosis. The amount of correction

obtained by surgery, however, did not seem to be an independent causative factor. Postoperative trunk shift is less likely to occur when selecting the lowest end vertebra (LEV) as LIV and the ratio of MT: TL/L Cobb angle of 1.2° or more.

We conclude that the study results are debatable, so researchers continue looking for a solution of optimal fixation for Lenke I type scoliosis and further search for what are the risk factors for the progression of the nonfused lumbar curve and trunk shift after surgery. Therefore, on the basis of clinical practice and literature, we performed a prospective randomized study. We suggest the "touched vertebra" method for the fixation level in Lenke I type scoliosis.

MATERIAL AND METHODS OF THE STUDY

The clinical study was carried out in the Orthopaedic-Traumatology Center of Children's Hospital, an affiliate of Vilnius University Hospital Santariskiu Klinikos. Permission No. 158200-13-609-186 to conduct this study was issued by Vilnius Regional Biomedical Research Ethics Committee on 9 April 2013. The State Data Protection Inspectorate issued the permission (No. 2R-29592.6-1) to carry out personal data processing activities. Study subjects were children who underwent surgery in the Orthopaedic-Traumatology Center of Children's Hospital, an affiliate of Vilnius University Hospital Santariskiu Klinikos for adolescent idiopathic scoliosis. The investigators informed the parents/guardians about the study objectives and methods before enrollment into the study. The investigators explained that the decision made by any parents to refuse participating in the study will not affect the medical care of any child or the quality of treatment. Parents/guardians of each patient were familiarized with the Subject's Information Form. Only patients whose parents/guardians signed the Informed Consent Form were enrolled in the study. The prospective, randomized study was carried out to assess the results of surgical treatment of Lenke type I scoliosis in applying different spine fixation methods by applying the concept of the "touched vertebra".

Study subjects, structure of the study groups

***Study inclusion criteria*:** patients 10 to 18 years old, spine deformity 45 degrees and more according to Cobb method, lumbar curve rotation from 0 to 2 (Nach Moe method), Lenke type I scoliosis, written consent as obtained from the parents/guardians to participate in the study, other surgical treatment being not applied for the patient earlier.

***Study exclusion criteria*:** diagnosis of congenital spine deformity with segmentation of vertebra formation defect, kyphoscoliosis, neuromuscular scoliosis (child cerebral palsy, syndromes), medical history of the anterior or mixed spondylodesis, patient's parents/guardians refusal of participation in the study, other surgical treatment of the spine being applied for the patient earlier.

Enrollment in the study

Randomization was carried out by applying the envelope technique with the sequence of digits 1, 2 and 3. An identification number was assigned to each patient. This number was used during the study and for data entrance into the database. After the Informed Consent to participate in the study was signed, a treating surgeon had to open the envelope to know which group the patient was assigned to and what type of spine fixation should be applied. The study subjects were randomly assigned into three groups according to the type of lumbar spine fixation method. Those having the envelope with digit 1, 2 or 3 were assigned to Group 1, Group 2 and Group 3 accordingly.

- ✓ Patients in **Group 1** had spine fixation below the last "touched vertebra" (LTV),
- ✓ Patients in **Group 2** had spine fixation above the last "touched vertebra" (LTV),
- ✓ Patients in **Group 3** had spine fixation at the level of the last "touched vertebra" (LTV).

The investigators explained in detail that the decision made by the parents or guardians to refuse participating in the study will not affect the quality of any child's scoliosis treatment or the quality of life. Each method of spine fixation offered in the study will not affect the results after the surgery, but will help optimize the surgical treatment of scoliosis.

Study stages and methods for the assessment of study results

The study consists of 3 stages: Stage I (before surgery), Stage II – 3 to 6 months after surgery, and Stage III – 2 years after surgery. All of the patients were consulted and operated by two othopeadic surgeons. During the consultation, whole spine X-ray images in coronal and sagital plane were taken in standing position. All image data were available and all measurments were performed by one of the two authors and repeated by another in picture archiving and communication systems. The mean values of the measurments by the two authors were used for final analysis and any differences found in the measurments between the two authors was considered as measurment errors.

Surgical approaches and maneuvers

Posterior pedicle-srew instrumentation was performed in all of the patients. Surgical maneuvers that were utilized intraoperatively included rod rotation, distraction on the concave side, compression on the convex side and, occasionally, in situ rod-bending.

LIV was selected after randomization according to the three "touched vertebra" groups. HIV was always selected at an "upper touched vertebra".

Radiographic measurments of the groups

Patient's skeletal age was first appointed using the Risser method. Second, we measured the thoracic and lumbar curve Cobb angle, thoracic and lumbar curve flexibility, the clavicular angle, the LIV angle and the thoracic and lumbar curve correction ratio. In each standing posteroanterior radiograph the central sacral vertical line (CSVL, the vertical line that bisects the proximal sacrum) was first drawn, followed by measurments of the distance between the CSVL and some key vertebra: LIV + 1 distance, T1-CSVL distance, thoracic and lumbar AVT distance, trunk shift. Th/L curve AVT ratio, A, B and C modifiers and the quality of life 2 years after surgery (SRS-LT questionnaire); accordingly, the "touched vertebra" group was also evaluated.

Statistical analysis

The sample size of the study was calculated according to the data of a pilot retrospective study where the main radiographic findings were the LIV + 1 distance, thoracic curve Cobb angle and lumbar curve Cobb angle. 30 cases were included into each analyzed group. After statistical analysis in the prospective study, we included 25 patients in each study groups.

Statistical analysis was performed using the software IBM SPSS 20 for Windows, Microsoft Excel and MedCalc (version 16.8.4). The data was described by such statistical characteristics: qualitative variables absolute data (n) and percentage (percent.); Quantitative variables mean and standard deviation (SD), standard error (SE).

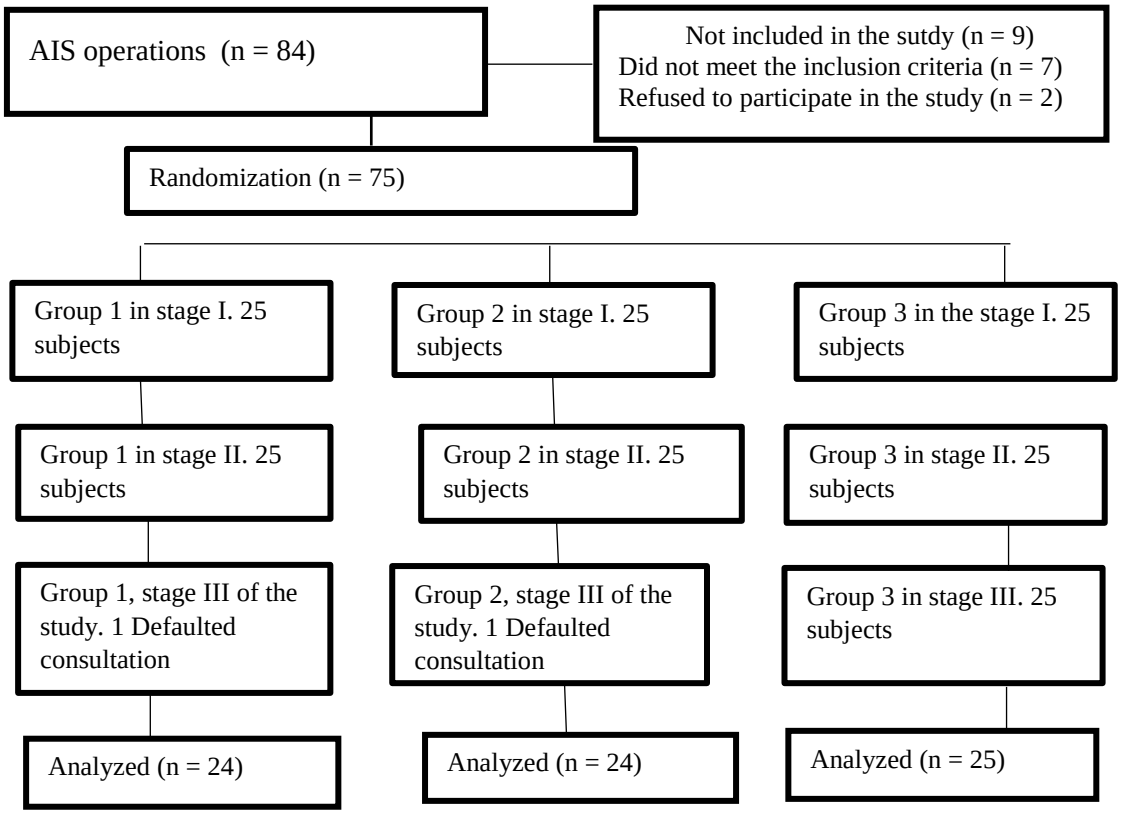
The Student t test was employed for comparison of the means between two groups with normal distribution (Kolmogorov-Smirnov test), and two-factorial dispersion analysis (ANOVA) was used for the comparison of the means between more than two groups. The Bonferonni test was applied for quantitative variable repeated paired comparisons. a A non-parametric Mann-Whitney U test was used for a comparison between two groups of quantitative variables with non-normal distribution; a Kruskal Wallis test was applied

for a comparison between more than two groups. The Wilcoxon test was used for a paired comparison of dependent samples between two groups. Various independent variables diagnostic and prognostic performances were determined using the ROC curve analysis, evaluating the sensitivity, specificity, positive predictive value of the test and a negative predictive value of the test. A binary logistic regression was performed in assessing the relationship between the variables. The difference or association between variables was considered statistically significant when the significance of applied tests was $p < 0.05$.

RESULTS

114 patients underwent surgery for adolescent idiopathic scoliosis at the Orthopaedic-Traumatology Center of Children Hospital, an affiliation of Santariskiu Clinics at Vilnius University Hospital. 30 patients were enrolled in the retrospective pilot study. Parents/guardians of the patients were familiarized with the Study Subject's Information Form and gave their consent to take part in the study. The size of the study sample for the prospective research was defined in the pilot study. Patients' data used for the prospective study were not used elsewhere. 84 patients participated in the prospective study, 9 of them (10.7%) were not enrolled in the study. Seven patients did not meet inclusion criteria for spine deformity characteristics. In two of the patients, X-ray and CT images of the entire spine spondylosis were diagnosed, which could have influenced the further course of the treatment and distort test results. Parents/guardians of the two patients refused to take part in the study. 75 patients met the inclusion criteria and the parents/guardians of the patients gave their consent to take part in the study after reading the Subject's Information Form. As there were no dropped out patients in Group 3 who underwent spine fixation at the level of the last “touched vertebra”, in aiming to ensure proper enrollment not exceeding the defined number of study subjects group 3 envelopes were replaced with the additional envelopes of one of the two first groups accordingly. During the course of study, two patients out of 75 (2.7 %) did not come to the consultation after 2 years and thus were excluded from the final study analysis.

Summary of the study



62 girls (84.9%) and 11 boys (15%) were included in the study. The most common LIV fixation level was L1 vertebrae, 26 (35.6%) cases, the most common HIV fixation level was TH 4.37 (50.7%) cases.

A spinal disease recognition module

In this study, we used the information data system as a radiology information system (RIS) and an image archiving and communication system (PACS). All stages of the investigation required to make a lot of measurements – this can only be done manually and may thus increase errors in measurement. Together with information technology specialists, in cooperation with Vilnius University, we have developed a spinal disease recognition module which carried out the necessary calculations automatically. In the e-mail created portal sending (JPG, DICOM, and other formats), we acquired the findings with the necessary parameters. This backbone recognition and modelling method combines some classical techniques (Hough transformation, GVF snakes) with some novelties (a method for initial curvature detection, which they call the *Falling Ball* method). The result enables us to identify high-quality features of the spine and to detect the major deformities of backbone: the intercrestal line, Center sacral vertical line, C7

plumbline; we are able to perceive certain angles as well: the proximal thoracic curve, main thoracic curve, thoracolumbar/lumbar. These features are used for measure in adolescent idiopathic scoliosis, especially in the case of treatment. Input data are just radiographic images that are met in everyday practice.

When the recognition model detects a curvature of the spine and sets additional points, biomechanical parameter calculations are carried out. Distances are calculated in accordance with two necessary points. The angles are calculated through the right point drawn sections. The distances and angles and the rendering of necessary plot points are marked on the X-rays and the required measurements are calculated automatically.

Fig. No. 3 *Necessary points for calculation and spine curve imaging*

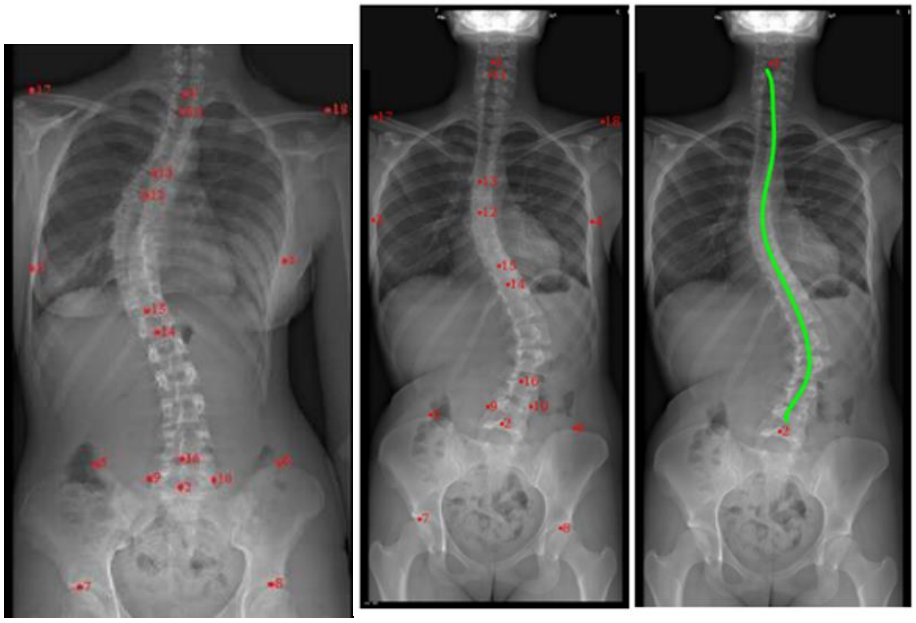
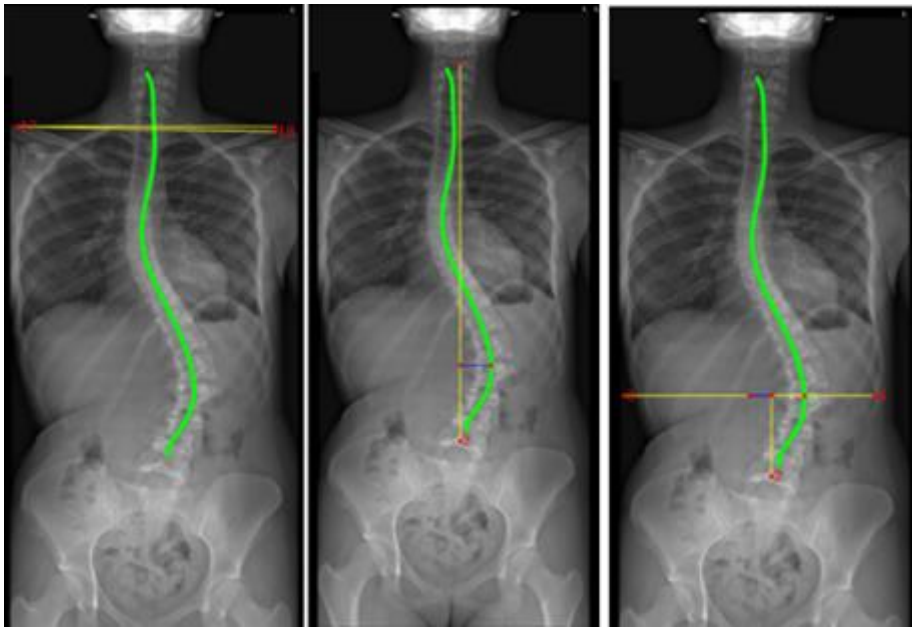


Fig. No. 4 *Automatic calculations of required parameters*



The module reliability testing

30 patients were investigated by measuring the thoracic and lumbar curve Cobb angle and the LIV + 1 distance. The automatic measurement and manual measurement results were compared. These two groups, which were of normal distribution, were also compared and the Student's t-test was used. Automatic measurement results did not differ significantly from the control manual measurements ($p > 0.05$) and have significantly correlated with each other ($p < 0.05$).

Study subjects according to the concept of "touched vertebra"

All quantitative variables, except the clavicular angle and types A, B and C, according with the Lenke classification, satisfied the normality condition, when $p > 0.05$. At the beginning of the study, all groups were homogeneous according with the following variables: age ($p = 0.18$), skeletal maturity Risser ($p = 0.23$), thoracic Cobb angle ($p = 0.62$), lumbar Cobb angle ($p = 0.46$), thoracic curve flexibility ($p = 0.59$), lumbar curve flexibility ($p = 0.27$), thoracic curve AVT distance ($p = 0.92$), lumbar curve AVT distance ($p = 0.12$), thoracic and lumbar curves AVT ratio ($p = 0.22$).

Changes of thoracic and lumbar curves in time according with the selected fixation method of the spine

We further calculated the change in thoracic scoliosis 3 to 6 months and 2 years after the surgery. The deformity of the thoracic spine was assessed in degrees applying Cobb's

technique. The deformity of the thoracic spine in Group 3 (fixation was performed at the level of the "touched vertebra") was 19.53 ± 8.08 degrees after 3-6 months and 20.06 ± 9.14 degrees after 2 years. The largest variations of the thoracic spine deformity during Stage II and III of the study were reported in Group I; however, significant differences between the groups in 3-6 months ($p = 0.86$) and 2 years ($p = 0,31$) after surgery were not detected. The deformity of the lumbar spine in Group 3 of "touched vertebra" was 9.14 ± 7.03 degrees after 3-6 months and only insignificant changes were reported after 2 years. The deformity of the lumbar spine in Group 1 was 11.74 ± 6.43 degrees and increased to 15.21 ± 8.04 degrees after 2 years. The same measurements in Group 2 after 3–6 months were 9.32 ± 5.87 degrees and 12.49 ± 8.15 degrees 2 years after surgery. A comparison of the deformities of the lumbar part between the groups during Stage II and III of the study did not reveal any significant differences in 3-6 months and 2 years after the surgery with $p = 0.29$ and $p = 0.06$, accordingly.

Progression of the non-fused lumbar curve in Lenke I type

One of the factors in determining the changes of posture after surgery is the progression of the non-fused lumbar curve (NFLC) after surgery. Such progressions after surgery impair the patient's satisfaction with the result of surgical treatment and increase the risk of repeated surgery. We composed two groups of patients with regard to the non-fixated deformity of the lumbar spine. The first group was made up from patients with a progressing non-fixated deformity of the lumbar spine, n = 16 (21.92%) and the second group included patients in whom the progression of a non-fixated deformity of the lumbar spine was not reported in 2 years after the surgery, n = 57 (78.08%). The progression of NFLC was assessed by calculating Cobb's angle. Progression was reported if a non-fixated deformity of the lumbar spine increased by 5 degrees and more during the period of 3–6 months and 2 years after the surgery. All parameters and identified risk factors that might have influenced the progression of NFLC after the surgery were compared in these groups.

The identification NFLC progression risk factors

Risk factors before the surgery were established on the basis of the obtained study results. We applied the Student's t-test for the comparison of mean values before the surgery. Among the groups, significant differences were discovered in age ($p = 0.004$), skeletal maturity Risser ($p = 0.001$), trunk shift ($p = 0.044$), flexibility of lumbar

deformity before the surgery (p = 0.003), LIV + 1 distance (p = 0.005) and thoracic AVT distance (p = 0.03). An ROC test helps to estimate the parameters of the threshold values that are significantly influenced by a non-fused lumbar spinal curve progression before surgery: age ≤ 13 (AUC 0.71, p = 0,003), Risser ≤ 3 (AUC 0.74, p < 0.001), LIV + 1 distance > 20.75 mm (AUC 0.69, p = 0.02), trunk shift ≤7 mm (AUC 0.67, p = 0.02), lumbar curve flexibility ≤ 55% (AUC 0.69, p = 0.01).

Establishment of risk factors during Stage II and III of the study

A significant difference in the NFLC groups of 3-6 month after surgery was discovered in the lumbar curve correction ratio (p = 0.03), LIV angle (p = 0.045) and LIV + 1 distance (p < 0.001) after 3-6 months after surgery. An ROC test for any risk factors demonstrated the following: lumbar curve correction ratio ≤ 63% (AUC 0.67, p = 0.029), LIV angle > 4 degrees (AUC 0.68, p = 0.001), LIV + 1 distance > 12,6 mm (AUC 0.90, p < 0.0001). Significant differences in the progression of NFLC of the lumbar spine groups after 2 years follow-up were the lumbar curve and LIV angle. An ROC test revealed the following: lumbar curve > 17.8 degrees (AUC 0.71, p = 0.004), LIV angle > 4.5 degrees (AUC 0.72, p = 0.0008).

Shoulder balance and progression of the non-fused lumbar curve

As we examined the changes of posture in our study, we analyzed whether the progression of the non-fused deformity of the lumbar spine was associated with the differences in variation of the shoulders' line. The clavicular angle was chosen to assess these variations. As this parameter did not satisfy normality requirements, we applied a non-parametric Mann-Whithney U test to compare the obtained values in the groups. Angular differences of the clavicular angle before the surgery were not reported in the NFLC groups. Before surgery, p = 0.82; 3-6 months after the surgery, p = 0.87; finally, 2 years after the surgery, p = 0.71.

The “touched vertebra” method and progression of the non-fused lumbar curve

During this stage of the study, we assessed whether the chosen method of spine fixation, in applying the concept of a “touched vertebra”, has any influence on the changes in the non-fused lumbar curve. Out of 16 patients with a progression of NFLC after surgery, even 12 patients (75 %) were from Group 2 and underwent fixation of the spine above the “touched vertebra”. One (6.25 %) patient was from Group 1 and had spinal fixation performed below the “touched vertebra”. Three (18.75 %) patients were from Group 3,

in which fixation of the spine ended at the level of the "touched vertebra". We have chosen a distance between the first non-fixated vertebra of the lumbar spine (LIV + 1) to the middle sacral line as a measure to assess the change in the study groups. A comparison of LIV distance between the groups at all stages of the study did not reveal any statistically significant differences, $p > 0.05$. Data in table no. 1 are mean values with a standard deviation (± SD) and confidence interval (CI: ± 95).

***Table No. 1**. LIV + 1 distance depending on the method of fixation by the "touched vertebra" approach at all stages*

LIV + 1 distance (mm) *(n = 73)*		***Mean, ± SD***	***± 95%. CI***		***P***
Before surgery	*Group 1*	*11.27 ± 7.02*	*7.69*	*12.24*	*0.64*
	Group 2	*9.94 ± 7.34*	*7.00*	*13.68*	
	Group 3	*9.59 ± 8.76*	*7.35*	*14.43*	
	Total	*10.42 ± 7.58*	*8.71*	*11.96*	
3-6 months after surgery	*Group 1*	*10.85 ± 6.64*	*7.79*	*12.10*	*0.13*
	Group 2	*8.52 ± 4.44*	*6.34*	*10.51*	
	Group 3	*7.77 ± 7.30*	*5.99*	*11.77*	
	Total	*9.31 ± 6.39*	*7.88*	*10.63*	
2 years follow-up	*Group 1*	*8.84 ± 6.65*	*6.69*	*11.00*	*0.85*
	Group 2	*9.85 ± 6.13*	*7.00*	*12.59*	
	Group 3	*9.53 ± 8.07*	*6.42*	*12.69*	
	Total	*9.30 ± 6.96*	*7.82*	*10.77*	

We also performed separate calculations on whether the modifiers A, B and C have any influence on the progression of the non-fused curve of the lumbar spine after surgery. However, significant differences of the LIV + 1 distance were not reported, $p > 0.05$. Data in table no. 2 are mean values with a standard deviation (± SD) and confidence interval (CI: ± 95 %)

Table No. 2. *Lenke I A, B and C type influences of fixation level and non-fused lumbar curve progression.*

LIV + 1 distance (mm) 2 years follow-up (mean value and ± SD)				
	Lenke IA modifier	***Lenke IB modifier***	***Lenke IC modifier***	***P***
Group 1	*7.98 ± 6.29*	*9.12 ± 4.27*	*9.67 ± 7.9*	*0.77*
Group 2	*10.94 ± 7.15*	*9.54 ± 5.04*	*8.82 ± 6.28*	*0.8*
Group 3	*10.81 ± 9.4*	*9.25± 8.15*	*7.78 ± 6.05*	*0.72*

A previous ROC test helps to estimate parameters of the threshold values that are significantly influenced by the non-fused lumbar spinal curve progression before surgery and skeletal maturity Risser was ≤ 3 (AUC 0.74, $p < 0.001$). We observed that LIV + 1 distance significantly progressed at group 2, where LTV was above the "touched vertebra" and patients had less skeletal maturity before surgery, $p = 0.02$. The data presented in table no. 3 are provided with an average and standard deviation (± SD).

Table No. 3. *Skeletal maturity and the non-fused lumbar curve progression*

LIV + 1 distance (mm)	***Skeletal maturity (Risser)***	***Mean***	***± SD***	***P***
Before surgery	*≤3*	*9.70*	*6.83*	*0.44*
	>3	*10.96*	*8.11*	
3-6 months	*≤3*	*8.27*	*6.19*	*0.19*
	>3	*10.10*	*6.59*	
2 years follow-up	*≤3*	*11.18*	*7.35*	*0.03**
	>3	*7.88*	*6.31*	

**mean value is significant at the level <0.05*

However, the assessment of skeletal maturation of the patients before surgery and the chosen method of fixation revealed that LIV + 1 distance from the middle sacral line in Group 2 in patients with lower skeletal maturity was the highest among the groups in 2 years after surgery and had reached a level of significance, $p = 0.005$. The LIV + 1

distance in other groups, in respect of the method of fixation and skeletal maturation after 2 years, did not reach a level of significance, $p > 0.05$. Data presented in table no. 4 are mean values with a standard deviation (± SD).

Table No. 4. *Fixation methods dependence on patient skeletal maturity*

LIV + 1 distance 2 years follow up (mm)			
	Skeletal maturity	***Mean ± SD***	***P***
Group 1	*Risser ≤ 3*	*10.64 ± 8.13*	*0.10*
	Risser > 3	*7.15 ± 4.45*	
Group 2	*Risser ≤ 3*	*14.78 ± 3.59*	*0.005**
	Risser > 3	*7.31 ± 5.66*	
Group 3	*Risser ≤ 3*	*9.91 ± 7.48*	*0.84*
	Risser > 3	*9.29 ± 8.73*	

**mean value is significant at the level <0.05*

The skeletal maturation of patients was analyzed in detail. We estimated that patients who had acquired their skeletal maturity before surgery had scored 0 points according with Risser and underwent fixation above the "touched vertebra" (Group 2); the LIV + 1 distance to the middle sacral line increased from 9.49 ± 5.92 mm (measurements before) to 19.22 ± 3.01 mm after surgery in the 2 years follow-up. This difference was statistically significant, $p = 0.03$. In the cases when fixation of the spine ended at the "touched vertebra" (Group 3) and skeletal maturity was acquired before surgery, 3 points were scored according to Risser; in these cases, too, the LIV + 1 distance was reduced from 18.41 ± 9.33 mm before surgery to 9.45 ± 8.04 mm. This difference reached the level of statistical significance, $p = 0.018$. Data presented in table no. 5 are mean values with standard deviation (± SD).

We estimated that in the cases when skeletal maturity reached a score of 0 points according with Risser, the LIV + 1 distance was increased by 10 mm in two years after the surgery. We had 7 patients (9.5 %) of such type. All these patients were from Group 2, in which the patients had the last fixated vertebra above the "touched vertebra" and met criteria of the *Distal Adding On* phenomenon.

Table No. 5. *Patient skeletal maturity, LIV + 1 distance according fixation level*

LIV + 1 distance (mm) (mean value and ± SD)		***RISSER 0***	***RISSER 2***	***RISSER 3***	***RISSER 5***
Group 1	*Before op.*	*7.27 ± 2.14*	*10.57 ± 8.62*	*13.89 ± 8.02*	*8.7 ± 7.05*
	2 years follow-up	*9.24 ± 4.33*	*10.12 ± 10.49*	*12.51±7.6*	*8.24 ± 6.5*
		p > 0.05	*p > 0.05*	*p > 0.05*	*p > 0.05*
Group 2	*Before op.*	*9.49 ± 5.92*	*10.1 ± 1.6*	*9.79 ± 7.3*	*10.62 ± 9.22*
	2 years follow-up	*19.22 ± 3.01*	*14.36 ± 1.6*	*12.75 ± 1.94*	*5.17 ± 4.3*
		**p = 0.03*	*p > 0.05*	*p > 0.05*	*p > 0.05*
Group 3	*Before op.*	*8.02 ± 10.42*	*15.74 ± 9.4*	*18.41 ± 9.33*	*14.72 ± 11.39*
	2 years follow-up	*10.54 ± 11.17*	*10.96 ± 7.28*	*9.45 ± 8.04*	*11.47 ± 6.4*
		p > 0.05	*p > 0.05*	**p = 0.018*	*p > 0.05*

**mean value is significant at the level <0.05*

We used logistic regression to find the connection between the fixation level according with the "touched vertebra" method and the non-fused lumbar curve progression. We found that an NFLC progression occured when fixation was above the "touched vertebra" (the second group) and the Odds ratio (OR) was 0.4 (95% CI, 0.1679 to 0.8374, p = 0.02). In the final stage, we entered the *stepwise* logistic regression model of all significant prognostic parameters, aiming to find the strongest correlation between the risk factors and progression of non-fused lumbar curve. We identified 3 prognostic factors for an NFLC progression:

- ✓ Skeletal maturity before operation,
- ✓ LIV + 1 distance from CSVL 3-6 months after surgery,
- ✓ LIV angle 2 years follow-up.

If skeletal maturity is Risser score 0 before surgery, the OR for progression is 68.03 (95% CI 3.4325 to 1348.3010, p = 0.006), the LIV + 1 distance > 12.6 mm is within 3-6 months after surgery, the OR for progression is 1.59 (95% PI 1.2587 to 2.031, p = 0.0001) and the LIV angle is at > 4.5 degrees at 2 years follow-up, the OR is 1.31 (1.0265 to 1.6629, p = 0.03). Total area under ROC curve of this logistic regression model is 0.95. Data are presented in table no. 6.

Table No. 6. *The logistic regression model and Odds ratio, $\chi 2=50.74$, $p < 0.0001$,* ***Nagelkerke $R^2 = 0.7153$***

Variable	*Coefficient*	*Wald*	*Odds ratio*	*95% ± CI*	*P*
Skeletal maturity Risser=0	*4.2199*	*7.6692*	*68.03*	*3.4325-1348.3010*	*0.006*
LIV+1 distance 3-6 month post op.	*0.4649*	*15.0579*	*1.59*	*1.2587-2.031*	*<0.001*
LIV angle 2 years follow up	*0.2674*	*4.7213*	*1.31*	*1.0265-1.6629*	*0.03*
Constant	*-9.8938*	*15.8773*			*0.0001*

Trunk shift and fixation level according with the "touched vertebra" method

Trunk shift also worsens treatment results and a patient's posture after surgery. We compared chest displacement between the study groups according to a chosen method of spine fixation. A two-factor dispersion analysis (ANOVA) was used to compare mean values, as we had three groups in the study. We estimated that trunk shift at all study stages according with a chosen method of spine fixation was not statistically significant. The total mean value of chest displacement before surgery was 10.84 ± 7.9 mm, p = 0.72, 3-6 months after the surgery saw the value at

12.34 ± 7.23 mm, p = 0.26 and the chest displacement value for 2 years after surgery was 11.32 ± 6.88 mm, p = 0.86.

Establishment of risk factors of trunk shift

Trunk shift, if it reaches 2 cm or more with regard to pelvis, significantly worsens the posture of patients and the results after surgery. We made up two subgroups to identify risk factors.

• Subgroup I – patients with trunk shift > 20 mm after 2 years. We had 18 patients (24.7 %) of such type.

• Subgroup II – patients with trunk shift < 20 mm after 2 years. We had 55 patients (75.3 %) of such type.

Risk factors for trunk shift before and 3-6 months after surgery (during Stage I and II).

We used the same potential risk factors that were used for identifying the progression of non-fused curve of the lumbar spine. Thoracic curve AVT distance was statistically significantly different among the subgroups of trunk shift before surgery. This difference was 46.70 ± 18.53 mm in the group with trunk shift > 20 mm and 36.75 ± 15.93 mm in the group with trunk shift < 20 mm. This difference reached the level of statistical significance, p = 0.025. Coronal balance (T1-CSVL distance) was significantly different in 3-6 months after surgery between the subgroups of trunk shift. This difference was 13.58 ± 7.22 mm in the group with trunk shift > 20 mm and 9.37 ± 5.81 mm in the group with trunk shift < 20 mm. This difference reached the level of statistical significance, p = 0.01.

Risk factors for trunk shift during Stage III of the study

When trunk shift within 2 years follow-up reached > 20 mm, coronal balance (T1-CSVL distance) was 16.13 ± 5.23 mm. If trunk shift was < 20 mm, T1-CSVL distance was only 8.03 ± 6.61 mm. This difference reached the level of statistical significance, p = 0.001. The threshold values of prognostic parameters were calculated at the next stage. We established that the T1-CSVL distance before the surgery > 19.69 mm (AUC 0.66, p = 0.047) and the thoracic curve AVT distance before the surgery > 45 mm (AUC 0.67, p = 0.036) would increase the risk for a trunk shift development after surgery.

Shoulder balance and trunk shift

The clavicular angle was chosen to assess changes in shoulder balance in the case of trunk shift. As the clavicular angle did not satisfy normality requirements, we applied a non-parametric Mann-Whitney U test to compare the obtained values in the groups. Differences in the clavicular angle in the subgroups of trunk shift were not reported at all study stages. Before surgery, $p = 0.99$; 3-6 months after surgery, $p = 0.74$; 2 years after surgery, $p = 0.79$.

Prognosis of trunk shift and risk factors

We applied logistic regression to establish the correlations with trunk shift progression. We included risk factors with significantly different mean values into the model. Methods of spine fixation according with the concept of the "touched vertebra" were included additionally. We estimated, by applying the *stepwise* method, that the Odd ratio for trunk shift after surgery was 1.04 (95 % CI 1.0065 to 1.0754, $p = 0.019$), when the thoracic curve AVT distance was > 45 mm before surgery. If the T1-CSVL distance before the surgery was > 19.69 mm, the Odds ratio for trunk shift > 20 mm would be 1.1 (95 % CI 1.0209-1.1955, $p = 0.01$) in the 2 years follow-up (table no. 7). The prognostic risk factors for trunk shift after a 2 years follow-up was the distance between the apex of deformity of the thoracic spine and coronal balance before surgery rather than the chosen method of spine fixation according with the concept of the "touched vertebra". As we demonstrated a significant difference of coronal balance in the subgroups of trunk shift, we used the Pearson's correlation coefficient to assess the strength of correlation. We demonstrated a statistically significant longitudinal correlation of moderate strength, $r = 0.5$, $p < 0.001$. Trunk shift increases with increased coronal imbalance.

Table No. 7*. The logistic regression model and Odds ratio, $\chi 2=13.481$, $p=0.02$,* ***Nagelkerke $R^2 = 0.2230$***

Variable	*Coefficient*	*Wald*	*Odds ratio*	*95% ± CI*	*P*
Thoracic curve AVT distance CSVL (mm) before op.	*0.0396*	*5.4979*	*1.0404*	*1.0065 – 1.0754*	*0.019*
Coronal balance (T1-CSVL distance) (mm) before op.	*0.0996*	*6.1191*	*1.1048*	*1.0209 – 1.1955*	*0.013*
Constant	*-5.0091*	*12.5939*			*0.0004*

Assessment for quality of life according with the chosen method of fixation in 2 years after surgery

A validated international questionnaire SRS 22 was used for a more detailed analysis of post-surgical results and for an assessment of the quality of life in 2 years after surgery. The patients, according to the study groups, completed the questionnaire SRS-22 LT at a 2 years follow-up and in the scale from 0 to 5 points assessed:

- ✓ Function/activity (5 questions);
- ✓ Pain (5 questions);
- ✓ Self-image/appearance (5 questions);
- ✓ Mental health (5 questions);
- ✓ Satisfaction with management (2 questions).

The higher score was indicated, the better results of surgery were perceived to be.

The *Function/activity* category in Group 1, in which patients underwent fixation of the spine below the "touched vertebra", was 4.28 ± 0.59 points. This score was 4.13 ± 0.63 points in Group 2, in which patients underwent fixation of the spine above the "touched

vertebra". This score was 4.53 ± 0.53 points in Group 3. Patients in this group had underwent fixation of the spine at the level of the "touched vertebra". Statistically significant differences between the groups were not reported, p = 0.46. The *Pain* category assessment arranged according with the method of the "touched vertebra" revealed the following results: pain ratings were 4.80 ± 0.23 points in Group 1, 4.13 ± 0.72 points in Group 2 and 4.56 ± 0.48 points in Group 3. Significant differences between the groups according with the method of fixation were not reported, p = 0.07. The category *self-image/appearance* was evaluated by patients only in 2 years after surgery. Ratings were 4.05 ± 0.59 points in Group 1, 3.75 ± 0.73 points and 4.06 ± 0.78 points in Group 3. Significant differences between the groups in the assessment of appearance were not reported, p = 0.62. The ratings of the *mental health* category were 4.11 ± 0.34 points in Group 1, 3.75 ± 0.40 points and 3.96 ± 0.92 points in Group 3. Significant differences between the groups in the assessment of general condition were not reported, p = 0.47. Ratings in the *Satisfaction with management* category, done by patients in 2 years after surgery, were as follows: 4.87 ± 0.24 points in Group I, 4.50 ± 0.82 points in group 2 and 4.66 ± 0.51 points in group 3. We did not find any significant differences between the groups in the *satisfaction with management* category, p = 0.53.

Patients who had underwent fixation in applying the "touched vertebra" concept above LTV have demonstrated a lower difference in scores according with the SRS-LT questionnaire, but this difference was not statistically significant, p> 0.05.

Complications

Complications were reported in 12 patients (16.4 %) out of 73 study subjects, who underwent surgery for adolescent idiopathic scoliosis. The *Distal Adding On* phenomenon was diagnosed in 7 patients (9.5 %) and two of them (2.7 %) underwent repeated surgery one year after the first surgical intervention. Posterior spondylodesis was performed and fixation of the spine was extended by one vertebra downward. A loosing of the rove of the right inferior screw and a migration of the rod was noticed in one patient (1.4 %) after 1.5 years during the consultation when an X-ray image of the entire spine was taken. This patient underwent repeated surgery as well. The loose rove was replaced with a new one. Superficial skin and a subcutaneous tissues infection of the upper part of a surgical cut were diagnosed in two patients (2.7%). The wound

healed per secundam after change of dressings. Neurological complications or lesions of the dural sack were not reported during the study.

DISCUSSION

The “touched vertebra” concept

Our study is one of the first prospective studies of spine fixation methods in applying the “touched vertebra” concept for Lenke I type deformity of the thoracic spine, including the analysis of post-operative results. A review of published materials revealed a large number of retrospective studies in analyzing fixation methods for spine deformities and using different landmarks. Therefore, the suggestion made in our study to carry out a fixation of the spine by applying the concept of the “touched vertebra” is simple, convenient and effective. There are only few publications on the concept of the “touched vertebra” available and this is a rather new concept in surgical treatment of idiopathic scoliosis. Qin X. et al. [117] conducted a retrospective study in which patients were assigned in two groups in applying the concept of the “touched vertebra”. In 23 patients out of 104 (22.1 %), a progression of the non-fused lumbar curve was diagnosed after spine surgery. It was found that a fixation above the “touched vertebra” is a significant prognostic factor of the *Distal Adding On* phenomenon. L. G. Lenke and Harms study group, on the basis of 5-year follow-up data gathered after surgery, proved in the SRS congress in Prague in 2016 that the selection of the “touched vertebra” as the last fixated vertebra to treat type I and II Lenke deformities is the optimal choice. An analysis of a type I Lenke deformity demonstrated that an LIV + 1 distance was significantly larger in the group of patients with the fixation above the “touched vertebra”. An analysis of Lenke IB and C type deformities in this study did not reveal any significant changes in the LIV + 1 distance from CSVL. A comparison of groups according Lenke I A, B and C modifiers and LIV + 1 distance in our study did not demonstrate any statistically significant differences, as $p = 0.77$, $p = 0.8$ and $p = 0.72$, respectively.

Spine fixation at the level of the "touched vertebra". Correction options and deformity changes in time.

We compared the spine deformities between the groups. A successful correction of the deformity of the lumbar spine was reported in 74.04% (± 17.62) of cases in the group, in which fixation of the pine ended at the “touched vertebra”. However, when fixation was

done below the “touched vertebra”, a successful correction of the deformity of the lumbar spine was reported in 65.65 (± 18.68) % of cases and in 66.52 (± 24.73) % of cases with a fixation one vertebra above. It could be suggested from the clinical point of view that the best fixation of the lumbar spine deformity is reached when fixation ends at the level of the “touched vertebra”; however, a statistically significant difference between the groups was not reported, $p = 0.21$. When the deformity of the thoracic spine was assessed during Stage II and III of the study, it was found that a minimal loss of correction occurred in the cases when correction ended at the level of the “touched vertebra” and one vertebra above the “touched vertebra”; however, a statistically significant difference was not reported, $p = 0.31$. The loss of correction of the deformity of the lumbar spine during Stage II and III of the study was of 1 degree when fixation ended at the level of the “touched vertebra”. On the other hand, 4 degrees of correction were lost when the fixation was performed below the “touched vertebra”. Finally, 3 degrees of correction were lost when the fixation was performed above the “touched vertebra”. It could be also suggested from the clinical point of view that the smallest loss of correction of the lumbar spine deformity occurred when the fixation ended at the level of the “touched vertebra”; however, a statistically significant difference between groups was not reported, $p = 0.06$. We think that in the cases when fixation of spine ends at the level of the “touched vertebra” both at the lower and upper part of the deformity, the best correction of lumbar deformity and stabilization is reached after surgery. We did not find any publications on this topic.

The progression of the non-fused deformity of the lumbar spine. Risk factors and prognosis

Out of the 13 before-surgery parameters in our study, we selected 5 prognostic factors that were most important in determining the progression of the deformity of non-fixated lumbar spine. We performed an ROC test and established the threshold values of the parameters. Factors having the most important impact on the progression of NFLC were age ≤ 13 years old (AUC 0.712, $p = 0.003$), skeletal maturity ≤ 3 (AUC 0.742, $p < 0.001$), LIV + 1 distance from CSVL was > 20.75 mm (AUC 0.69,$p = 0.017$), lumbar curve flexibility ≤ 55 % (AUC 0.69, $p = 0.01$), trunk shift ≤ 7 mm (AUC 0.67, $p = 0.02$). Out of 6 potential risk factors, a significant difference in 3-6 months after the surgery was reported for the LIV + 1 distance and the LIV angle. The threshold values calculated

in applying an ROC test are the following: LIV + 1 distance > 12.6 mm (AUC 0.90, $p < 0.001$) and LIV > 4 degrees (AUC 0.68, $p = 0.001$). Out of the same 6 risk factors, we found some in the category of 2 years after surgery; it was that the lumbar curve Cobb angle at > 17.76 degrees (AUC 0.71, $p = 0.004$) and the LIV angle at > 4.5 degrees had a significant impact on the progression of the deformity of non-fixated lumbar spine.

We cite a recent retrospective study completed in 2016 by Murhy et al. [80], in which the treatment of the type I Lenke deformity of the thoracic spine was compared by the fixation methods according with the concept of the "touched vertebra". The inferior dislocation phenomenon was diagnosed in 27 patients (17 %) out of 89. The authors discovered that a fixation of the spine above the "touched vertebra" (OR 3.63; $p = 0.01$), a lower skeletal maturity before surgery when the Risser score was 0 (OR 4.93; $p = 0.02$) and the distance of the 7th cervical (C7) vertebra from the middle sacral line at < 2 cm before surgery (OR 3.97; $p = 0.01$) all had significant impact on the progression of the non-fused lumbar curve. Similar results were obtained in our study. We found that in patients of 2 years after surgery that were assigned to Group 2, who underwent fixation of the spine above the "touched vertebra", the LIV + 1 distance was 14.78 ± 3.59 mm in the patients with lower skeletal maturity. At the same time, the LIV + 1 distance for adolescents with higher skeletal maturity was only 7.31 ± 5.66 mm. This difference reached the level of statistical significance, $p = 0.005$. A comparison of skeletal maturity revealed no significant changes of the LIV + 1 distance in Group 1 and Group 3, despite the different method of the "touched vertebra", $p > 0.05$. We also found thatthe LIV + 1 distance, when the Risser score was 0, increased from 9.49 ± 5.92 mm to 19.22 ± 3.01 mm in 2 years after surgery in Group 2, in which patients underwent fixation of the spine one vertebra above the "touched vertebra". We had 7 patients (9.6%) of such type and they were diagnosed with the *Distal Adding On* phenomenon.

Our prognoses revealed that the Odds ratio (OR) for the progression of NFLC in Group 2, in which patients underwent fixation of the spine one vertebra above the "touched vertebra", was 0.4 (95% CI 0.1679-0.8374, $p = 0.02$). We also established, at the final stage, the three prognostic factors for the progression of NFLC: the skeletal maturity of patients before surgery, the LIV + 1 distance from CSVL 3-6 months after surgery and the LIV angle in the 2 years follow-up. The total area under the ROC curve of this logistic regression model was 0.95 and Nagelkerke $R^2 = 0.7153$. When the Risser score

was 0 before surgery, the OR was 68,03 (95 % CI 3.4325 -1348.3010, p = 0.006), when the LIV + 1 distance from the middle sacral line was > 12 6 mm in 3-6 months after surgery, the OR was 1.59 (95 % CI 1.2587-2.031, p = 0.0001) and when the LIV angle in 2 years after surgery was > 4.5 degrees, the OR was 1.31 (1.0265-1.6629, p = 0.03) for the progression the of non-fused lumbar curve. In conclusion, a patient's skeletal maturity before surgery is the main prognostic factor of the progression of non-fused lumbar curve after the surgery in AIS patients.

Shoulder balance by the chosen method of fixation.

Watanabe et al. [96] analyzed factors that could have influence on shoulder imbalance after surgery in the case of the type I Lenke deformity of the thoracic spine. The investigators assigned patients into different groups by the upper end vertebra (UEV) for the fixation of the thoracic spine. The first group involved patients who underwent fixation above UEV; patients who had fixation done at the level of UEV were assigned to the second group and those who had fixation done below UEV were assigned to the third group. The clavicular angle and declination of T1 were chosen to define the balance of shoulders' line after the surgery. The authors concluded that the imbalance of the shoulder line was usually found in patients after scoliosis correction and stated that the imbalance of the shoulders' line could have impact on the progression of deformity of the non-fused lumbar spine. It is still unclear which of the parameters were chosen for the selection of the spine fixation level. Criteria for selecting the upper fixation of the spine were clearly defined in our study. Spine fixation for all patients participating in the study was done at the level of the upper “touched vertebra”. We did not find any significant differences in the clavicular angle during the entire study by the chosen spine fixation method. Before surgery, p = 0.77; 3-6 months after the surgery, p = 0.32; 2 years after the surgery, p = 0.14. In case of the NFLC progression and trunk shift, no significant differences in shoulder imbalance were reported, p > 0.05.

Trunk shift by the chosen method of fixation and the establishment of risk factors

We made estimations in our study regarding the changes in trunk shift by the method of spine fixation in applying the concept of the “touched vertebra”. Significant changes in trunk shift were not reported by the chosen spine fixation method before surgery, p = 0.72, and 3-6 months after surgery, p = 0.26. Mean trunk shift by the chosen spine fixation method in 2 years after surgery was 11.32 ± 6.88 mm, p = 0.72. At the next

stage of the study, we established risk factors that have impact on trunk shift > 20 mm. Our data was similar with Wang et al. [115] and showed that the thoracic curve AVT distance and thoracic and lumbar AVT distance ratio before surgery reached a significant difference between the subgroups by trunk shift ($p = 0.025$ and $p = 0.03$, respectively). Significant differences in spine balance in the coronal plane (T1-CSVL distance) were also discovered at the stages II and III of our study ($p = 0.01$ and $p < 0.01$, respectively). We discovered a longitudinal correlation as in the Richards et al. [114] study group between trunk shift and coronal balance; this correlation was of moderate strength and statistically significant ($r = 0.5$, $p < 0.001$). Trunk shift increases with increased coronal imbalance. An ROC test and a logistic regression model were used for the prognosis of trunk shift. Methods of spine fixation, according with the concept of a "touched vertebra", were included additionally. We estimated, by applying the *stepwise* method, that the Odds ratio for trunk shift after surgery was 1.04 (95 % CI 1.0065–1.0754, $p = 0.019$) when the thoracic curve AVT distance was > 45 mm before surgery. If the T1-CSVL distance before surgery was > 19.69 mm, the Odds ratio for trunk shift > 20 mm is 1.1 (95% CI 1.0209-1.1955, $p = 0.01$), Nagelkerke $R^2 = 0.2230$.

On the basis of our study results and in conclusion of the discussion we can say that the results of automatized measurements, with a proper selection of the coordinated measurement points, are very precise, can be obtained instantaneously and do not practically depend on an investigator's experience. We have further plans to develop a parametric general model of the spine. It would allow to reduce the exposure to ionizing radiation required for the diagnostic and to find patterns of efficacy and usefulness of the applied treatment methods. A selection of spine fixation methods according with the concept of the "touched vertebra" are simple and effective. From a clinical point of view, the selection of a spine fixation at the upper and lower part of spine deformity at the level of the "touched vertebra" has the strongest correlation with and ensures the best stability of the lumbar deformity after spine surgery and does not have any influence on the progression of the deformity of non-fused lumbar curve and trunk shift after the surgery in Lenke I type AIS patients.

Conclusions

1. A spinal disease recognition module optimizes scoliosis diagnosis and improves the results of evaluation objectivity.

2. A fixation of the spine at the level of the “touched vertebra” is the optimal fixation in Lenke I type AIS.

3. Skeletal immaturity before surgery is associated with an increased risk of the progression of the non-fused lumbar curve after surgery.

4. Trunk shift increases in the case of any higher extent of the apical displacement of the thoracic curve and in the presence of spine imbalance in the coronal plane.

5. Quality of life after two years was the same, irrespective of which fixation method was applied when according with the concept of the “touched vertebra”.

Methodical recommendations

1. We recommend using software for spine model detection during surgery planning and making calculations according with X-ray images.

2. When the risk factors are assessed, the Lenke I type curve fixation distal level can be done above the “touched vertebra” and thus save more non-fused vertebrae.

3. The biggest concern in the planning of surgical treatment for AIS should be the skeletal maturity of a patient before surgery. In the case of lower skeletal maturity of a patient, there still is a likelihood of intensive growth of the spine and progression of the non-fused curve of the lumbar spine; therefore, fixation of the spine should end at the level of the “touched vertebra”.

AKTUALUMAS

Kai yra Lenke I tipo stuburo iškrypimas, viena iš pagrindinių užduočių, planuojant idiopatinės paauglių skoliozės chirurginį gydymą, yra nustatyti fiksacijos lygį. Netinkamai pasirinkta stuburo fiksacija blogina pacientų laikyseną ir didina pakartotinės operacijos tikimybę. Chirurginis stuburo iškrypimo gydymas per pastaruosius dešimtmečius smarkiai pakito. Atsirandant naujų instrumentų, keitėsi deformacijos korekcijos būdai, tačiau pagrindiniai principai išliko. Vis daugiau specialistų pasaulyje sutinka, kad vienas iš pagrindinių idiopatinės paauglių skoliozės chirurginės korekcijos uždavinių tampa pacientų išvaizda ir laikysena po operacijos. Vieni iš pagrindinių faktorių, lemiančių laikysenos pokyčius po operacijos,– tai nefiksuoto stuburo juosmens iškrypimo progresavimas ir krūtinės poslinkis po operacijos. Studijų rezultatai nėra vienareikšmiški, todėl tyrėjai ir toliau ieško sprendimo, kokio ilgio fiksacija ir kokie faktoriai turi įtakos nefiksuoto stuburo juosmens iškrypimo progresavimui ir krūtinės poslinkiui po operacijos.

DARBO TIKSLAS IR UŽDAVINIAI

Darbo tikslas – optimizuoti krūtininės stuburo dalies Lenke I tipo skoliozės diagnostiką ir chirurginį gydymą.

Darbo uždaviniai

1. Sukurti stuburo ligų atpažinimo modulį, kuris leistų reikiamus parametrus apskaičiuoti automatiškai.
2. Pagal „paliesto slankstelio“ metodą nustatyti optimalius taškus stuburo fiksacijai atlikti.
3. Nustatyti rizikos faktorius, kurie turi įtakos skoliozei progresuoti juosmens srityje po operacijos.
4. Išanalizuoti krūtinės poslinkio priežastis po operacijos.
5. Ištirti pacientų gyvenimo kokybę pagal pasirinktą fiksacijos būdą praėjus 2 metams po operacijos.

Darbo naujumas

Atlikta įvairių, tačiau tik retrospektyvių studijų, kuriose nagrinėjama stuburo fiksacijos ilgio pasirinkimas bei rizikos faktoriai, lemiantys laikysenos pokyčius po operacijos. Daugumoje studijų nagrinėjamas tik Lenke I A tipo iškrypimas. Studijų rezultatai nėra

vienareikšmiški. Todėl, remdamiesi klinikine praktika ir literatūros duomenimis, atlikome perspektyvinį randomizuotą tyrimą, kuriame stuburo fiksacijos lygiui nustatyti naudojome „paliesto slankstelio“ metodą. Tai gali būti optimali ir saugi metodika, kuri neleidžia nefiksuotam stuburo iškrypimui progresuoti ir krūtinės poslinkiui atsirasti po operacijos. Remdamiesi šio tyrimo duomenimis, gydytojai praktikai galės efektyviau planuoti chirurginį paauglių skoliozės gydymą bei pasirinkti tinkamesnį stuburo fiksacijos lygį.

Ginamieji disertacijos teiginiai

- Planuojant operaciją labai svarbi kaulinė pacientų branda prieš operaciją, nes ji turi įtakos stuburo iškrypimui progresuoti po operacijos.
- „Paliesto slankstelio“ metodas pasirenkant stuburo fiksaciją yra paprastas ir veiksmingas, gali sumažinti riziką progresuoti stuburo iškrypimui ir krūtinės poslinkiui atsirasti po operacijos.

METODIKA

Klinikinis tyrimas buvo atliktas 2013–2016 metais VšĮ Vilniaus universiteto Santariškių klinikos Vaikų ligoninėje. Tyrimui atlikti 2013-04-09 gautas regioninio Biomedicininių tyrimų etikos komiteto leidimas (Nr. 158200-13-609-186). Valstybinė duomenų apsaugos inspekcija išdavė leidimą (Nr.2R-29592.6-1) atlikti asmens duomenų tvarkymo veiksmus. Tyrimą sudarė 2 dalys: retrospektyvinė ir perspektyvinė. Retrospektyvinis tyrimas (žvalgomoji studija) atliktas tik perspektyvinio tyrimo imties dydžiui nustatyti.

Tiriamieji: ne vyresni kaip 18 metų pacientai, kurie dėl idiopatinės paauglių skoliozės buvo operuoti VšĮ Vilniaus universiteto Santariškių klinikos Vaikų ligoninėje; atitinkantys įtraukimo į tyrimą kriterijus; kai nėra atmetimo kriterijų; pasirašę informuoto asmens sutikimo dalyvauti biomedicinininiame tyrime formą.

Įtraukimo į tyrimą kriterijai: pacientai 10–18 metų amžiaus, stuburo iškrypimas 45 laipsniai pagal Cobb ir daugiau, nustatytas Lenke I iškrypimo tipas prieš operaciją, rotacija stuburo juosmens dalyje nuo 0 iki 2 pagal Nach Moe metodiką, iš paciento tėvų / globėjų gautas rašytinis sutikimas dalyvauti tyrime, prieš tai netaikytas skoliozės operacinis gydymas.

Neįtraukimo į tyrimą kriterijai: diagnozuota įgimta stuburo deformacija, kai yra segmentacijos ar slankstelių formavimo yda, kifoskoliozė, neuroraumeninė skoliozė (vaikų cerebrinis paralyžius, sindromai), paciento tėvai / globėjai atsisako dalyvauti tyrime, prieš tai taikytas skoliozės operacinis gydymas.

Tiriamųjų atsitiktinis įtraukimas į tyrimą

Randomizacija tyrime atlikta naudojant vokų, kuriems suteikta skaičių seka 1, 2, 3, metodą. Kiekvienam pacientui suteiktas identifikacinis numeris, kuris naudotas atliekant tyrimą ir suvedant duomenis į duomenų bazę. Pasirašius informuotą sutikimą dalyvauti tyrime ir įtraukus ligonį į studiją, voką atplėšia operuojantis chirurgas ir nustato, kuriai grupei priklausys ligonis ir kokia stuburo fiksacija bus atliekama. Tiriamieji suskirstyti į tris grupes: pagal fiksacijos būdo pasirinkimą stuburo juosmens srityje. Ištraukę skaičių 1 tiriamieji pateko į pirmą grupę, ištraukę skaičių 2 tiriamieji įtraukti į antrą grupę, ir ištraukę skaičių 3 –į trečią grupę.

- pirma grupė, kai stuburo fiksacija pasirinkta žemiau „paliesto slankstelio“,
- antra grupė, kai stuburo fiksacija pasirinkta aukščiau „paliesto slankstelio“,
- trečia grupė, kai stuburo fiksacija pasirinkta ties „paliestu slanksteliu“.

Tyrėjai išsamiai paaiškino, kad tėvų ar globėjų apsisprendimas dalyvauti tyrime nedaro įtakos vaiko skoliozės gydymo ir gyvenimo kokybei. Tyrime kiekvienas pasiūlytas stuburo fiksacijos būdas nepakenks rezultatams po operacijos, o padės optimizuoti skoliozės chirurginį gydymą.

Tyrimo eiga ir tiriamųjų rezultatų vertinimo metodika

Išskirti trys tyrimo etapai: I (priešoperacinis) etapas, II etapas (3–6 mėnesiai po operacijos) ir III etapas (2 metai po operacijos).

Tiriamųjų vertinimas I etapo metu: amžius ir lytis. Iš atliktos viso stuburo priekinės rentgeno nuotraukos prieš operaciją vertinta: kaulinis pacientų subrendimas pagal Risser, stuburo iškrypimo kampas krūtininėje ir juosmens dalyje pagal Cobb, stuburo krūtininio ir juosmens iškrypimo lankstumas procentais, abiejų raktikaulių kampas, krūtinės poslinkis, stuburo balansas (krūtininio I slankstelio poslinkis nuo centrinės kryžkaulio linijos (CSVL), krūtinės dalies ir juosmens stuburo dalies iškrypimo viršūnės poslinkis nuo CSVL ir jų santykis.

Tiriamųjų vertinimas II etapo metu: krūtininis ir juosmens stuburo iškrypimas pagal Cobb metodą, stuburo krūtininio ir juosmens iškrypimo atkūrimas procentais, abiejų

raktikaulių kampas, krūtinės poslinkis nuo centrinės kryžkaulio linijos (CSVL), stuburo balansas (krūtininio I slankstelio poslinkis nuo CSVL) , LIV+1 atstumas (paskutinio fiksuoto slankstelio poslinkis) nuo CSVL prieš operaciją ir po 3–6 mėnesių, LIV kampas prieš operaciją ir po 3–6 mėnesių, krūtinės ir juosmens dalies stuburo iškrypimo viršūnės poslinkis nuo CSVL.

Tiriamųjų vertinimas III etapo metu: krūtinės stuburo ir juosmens srities iškrypimas pagal Cobb metodą, abiejų raktikaulių kampas, krūtinės poslinkis nuo centrinės kryžkaulio linijos (CSVL), stuburo balansas (krūtininio I slankstelio poslinkis nuo CSVL), LIV+1 slankstelio atstumas nuo CSVL, LIV kampas, krūtinės ir stuburo juosmens stuburo dalies iškrypimo viršūnės poslinkis nuo CSVL (mm), SRS-22 LT klausimynas gyvenimo kokybei įvertinti praėjus 2 metams po operacijos. Įvertinami pacientų nusiskundimai. Duomenys suvedami į duomenų bazę.

Statistinė duomenų analizė ir imties dydis

Statistinė duomenų analizė atlikta pagal programą IBM SPSS 20 for Windows, Microsoft Excel, MedCalc (16.8.4 versija). Duomenims aprašyti taikytos šios statistinės charakteristikos: kokybiniams kintamiesiems – absoliutūs duomenų skaičiai (n) ir jų procentinė išraiška (proc.), kiekybiniams kintamiesiems – vidurkis ir standartinis nuokrypis (SD), standartinė paklaida (SE).

Kintamųjų normalumui nustatyti taikytas Kolmogorovo ir Smirnovo kriterijus. Dviejų grupių, kurių skirstinys buvo normalusis, vidurkiams palyginti taikytas Stjudento t kriterijus. O daugiau nei dviejų grupių – dvifaktorinė dispersinė analizė (ANOVA). Daugkartiniams poriniams palyginimams taikytas Bonferoni kriterijus. Dviejų grupių kiekybiniams kintamiesiems, kurių skirstinys nebuvo normalusis, palyginti taikytas neparametrinis Mann-Whitney U kriterijus. Poriniams palyginimams tarp dviejų grupių priklausomoms imtims taikytas Wilkoksono kriterijus.

Vertinant kintamųjų ryšį naudota vienmatė ir daugiamatė dvinarė logistinė regresija. Įvairių nepriklausomų kintamųjų diagnostinis ir prognostinis efektyvumas nustatytas naudojant ROC kreivių analizę, rastas plotas po ROC kreive (angl. *area under the receiver-operating characteristic* (AUC)), įvertintas tyrimo jautrumas, specifiškumas, prognostinė teigiamo testo vertė ir prognostinė neigiamo testo vertė. Naudotas statistinio reikšmingumo lygmuo $\alpha = 0,05$; skirtumas statistiškai reikšmingas, kai $p < 0,05$.

Numatomo tyrimo imtis apskaičiuota remiantis bandomojo retrospektyvinio tyrimo, kuriame buvo stebėti pagrindiniai rentgenologiniai parametrai: LIV+1 atstumas nuo centrinės kryžkaulio linijos, krūtininės stuburo dalies ir juosmens stuburo dalies iškrypimas pagal Cobb po operacijos, duomenimis. Tai vieni iš svarbiausių rentgenologinių parametrų, apibūdinančių skoliozės operacinio gydymo rezultatus. Retrospektyviai pasirinkta 30 operuotų pacientų. Atlikus imties tūrio skaičiavimus, į tiriamųjų grupes įtraukta po 25 pacientus.

REZULTATAI

Per tiriamąjį laikotarpį VšĮ Vilniaus universiteto Santariškių klinikų Ortopedijos-traumatologijos centre dėl idiopatinės paauglių skoliozės operuota 114 pacientų. Retrospektyviniame tyrime dalyvavo 30 pacientų. Pacientų tėvai / globėjai susipažino su retrospektyvinio tyrimo asmens informavimo forma ir sutiko dalyvauti tyrime. Žvalgomojoje studijoje nustatytas imties dydis perspektyviniam tyrimui ir toliau retrospektyvinio tyrimo duomenys nebuvo naudoti. Perspektyviniame tyrime dalyvavo 84 pacientai, iš kurių 9 (10,7 proc.) nebuvo įtraukti į tyrimą. Septyni pacientai neatitiko įtraukimo kriterijų dėl stuburo iškrypimo charakteristikų, iš kurių dviem pacientams, atlikus viso stuburo rentgeno nuotraukas, o paskui patikslinus KT tyrimu, nustatyta spondilolizė, kuri galėjo turėti įtakos tolesnei gydymo eigai ir rezultatams. Dviejų pacientų tėvai atsisakė dalyvauti tyrime. 75 pacientai atitiko įtraukimo kriterijus ir pacientų tėvai / globėjai, susipažinę su perspektyvinio tyrimo asmens informavimo forma, sutiko dalyvauti tyrime. Pirmoje grupėje, kai stuburo fiksacija buvo numatyta vienu slanksteliu žemiau ir šis slankstelis buvo L5, šių pacientų stuburas buvo fiksuotas ties L4 slanksteliu t. y. ties „paliestu slanksteliu“. Tokių atvejų buvo 3 (4,1 proc.). Siekiant įtraukti ir neviršyti leidžiamo tiriamųjų skaičiaus trečioje grupėje, skirstant tiriamuosius trečia grupė buvo atitinkamai pakeista viena iš pirmų dviejų grupių papildomu numeriu. Tyrimo eigoje iš 75 tiriamųjų du pacientai (2,7proc.) neatvyko konsultacijos po 2 metų, todėl nebuvo įtraukti į galutinę tyrimo analizę. Perspektyviniame tyrime dalyvavo 62 mergaitės (84,9 proc.) ir 11 berniukų (15 proc.). Pagal stuburo fiksaciją apačioje dažniausiai fiksuotas L1 stuburo slankstelis, 26 (35,6 proc.) atvejai. Pagal stuburo fiksaciją viršuje dažniausiai fiksuotas TH 4 slankstelis, 37 atvejai (50,7 proc.).

Stuburo modelio atpažinimo programa

Visų tyrimo etapų metu reikia atlikti daug matavimų. Tyrime buvo naudojamos tokios informacinės duomenų sistemos: radiologijos informacinė sistema (RIS) bei vaizdų archyvavimo ir perdavimo sistema (PACS) Pacs. Šiose sistemose matavimus galima daryti tik rankiniu būdu, todėl atsiranda didesnės matavimo paklaidos tikimybė. Kartu su informacinių technologijų specialistais bendradarbiaujant su Vilniaus universitetu buvo sukurtas stuburo ligų atpažinimo modulis, kuris leidžia reikiamus skaičiavimus atlikti automatiškai. Atlikta 30 kontrolinių lyginamųjų testų. Matuoti parametrai reikalingi vertinant stuburo iškrypimo dydį, balansavimo kriterijus, liemens postūmio matavimus. Lyginti automatinio matavimo ir rankinio matavimo rezultatai. Automatinio matavimo rezultatai patikimai susiję su kontroliniais rankiniais matavimais ($p < 0,05$).

Visi kiekybiniai kintamieji, išskyrus abiejų raktikaulių kampą bei Lenke klasifikacijos A, B ir C tipus, visais tyrimo etapais tenkino normalumo sąlygą, kai $p > 0,05$. Kadangi lyginti trys fiksacijos būdai pagal „paliesto slankstelio“ metodiką, įvertintas grupių homogeniškumas pagal: amžių, kaulinę brandą (Risser), stuburo krūtinės ir juosmens dalies iškrypimą prieš operaciją, stuburo krūtininio ir juosmens iškrypimo lankstumą prieš operaciją, stuburo krūtinės dalies iškrypimo viršūnės atstumą nuo centrinės kryžkaulio linijos, stuburo juosmens dalies iškrypimo viršūnės atstumą nuo centrinės kryžkaulio linijos, stuburo krūtinės ir juosmens dalies viršūnių atstumo santykį. Tiriamosios grupės buvo panašios pagal visus parametrus.

Stuburo iškrypimo korekcija ir kitimas laiko atžvilgiu pagal „paliesto slankstelio“ metodą

Stuburo iškrypimo atkūrimo krūtininėje dalyje grupių bendras vidurkis buvo 64,71 ± 13,29 proc., statistiškai reikšmingai nesiskyrė, $p = 0,29$. Pirmoje grupėje stuburo iškrypimo atkūrimas juosmens srityje buvo 65,65 ± 18,68 proc., o antroje grupėje – 66,52 ± 24,73 procentų. Stuburo iškrypimo atkūrimas juosmens srityje buvo didžiausias trečioje grupėje, kai stuburo fiksacija pabaigta ties „paliestu slanksteliu“ ir sudarė 74,04 ± 17,62 proc., tačiau statistiškai reikšmingai nesiskyrė, $p = 0,21$. Toliau skaičiuotas krūtininės dalies skoliozės kitimas po 3–6 mėnesių ir 2 metai po operacijos. Krūtininės dalies stuburo iškrypimo laipsnis vertintas pagal Cobb metodą. Trečioje grupėje, kai stuburo fiksacija atlikta ties „paliestu slanksteliu“, stuburo krūtininės dalies iškrypimas po 3–6 mėnesių buvo 19,53 ± 8,08 laipsnių, po 2 metų 20,06 ± 9,14 laipsnių. Pirmoje

grupėje krūtinės dalies stuburo iškrypimas II ir III tyrimo etapais kito labiausiai, tačiau reikšmingo skirtumo grupėse po 3–6 mėnesių (p = 0,86) ir 2 metai po operacijos (p = 0,31) nenustatyta. Stuburo juosmens iškrypimas po 3–6 mėnesių „paliesto slankstelio“ trečioje grupėje buvo 9,14 ± 7,03 laipsnių ir po 2 metų kito nežymiai. Pirmoje grupėje juosmens stuburo iškrypimas nuo 11,74 ± 6,43 laipsnių po 2 metų padidėjo iki 15,21 ± 8,04 laipsnių. Antroje grupėje – 9,32 ± 5,87 laipsniai po 3–6 mėnesių ir 12,49 ± 8,15 laipsnių po 2 metų. Lyginant stuburo juosmens iškrypimą grupėse II ir III tyrimo etapo metu reikšmingo skirtumo nenustatyta, p = 0,29 po 3–6 mėnesių ir p = 0,06 po 2 metų.

Stuburo fiksacijos būdai ir nefiksuoto stuburo juosmens iškrypimo (NSJS) progresavimas

NSJS progresavimas vertintas skaičiuojant Cobb'o kampą. Progresavimas nustatytas, jei nefiksuotas stuburo juosmens iškrypimas po 3–6 mėnesių ir per 2 metus po operacijos padidėjo 5 laipsniais ir daugiau. Šių grupių palyginti visi parametrai ir identifikuoti rizikos faktoriai, kurie gali turėti įtakos NSJS progresuoti po operacijos. Pagal nefiksuotą stuburo juosmens iškrypimą sudarytos dvi grupės. I grupė, kai nefiksuotas stuburo juosmens iškrypimas progresavo, n = 16 (21,92 proc.), ir II grupė, kai nefiksuotas stuburo juosmens iškrypimas neprogresavo 2 metai po operacijos, n = 57 (78,08 proc.). Šių grupių palyginti visi parametrai ir identifikuoti rizikos faktoriai visais tyrimo etapais, kurie gali turėti įtakos NSJS progresuoti po operacijos.

Reikšmingai prognozuojamų parametrų slenkstinės reikšmės prieš operaciją: amžius ≤ 13 metų (AUC 0,71, p = 0,003), Risser ≤ 3 (AUC 0,74, p < 0,001), LIV+1 atstumas > 20,75mm (AUC 0,69, p = 0,02), juosmens stuburo iškrypimo atkūrimas ≤ 63 proc. (AUC 0,67, p = 0,03), krūtinės poslinkis ≤ 7 mm (AUC 0,67, p = 0,02) ir juosmens stuburo lankstumas ≤ 55 proc. (AUC 0,69, p = 0,01).

Reikšmingai prognozuojamų parametrų slenkstinės reikšmės II etapo metu (po 3–6 mėnesių): LIV kampas > 4 laipsnių (AUC 0,68, p = 0,001) ir LIV+1 atstumas >12,6 mm (AUC 0,90, p < 0,0001).

Reikšmingai prognozuojamų parametrų slenkstinės reikšmės III etapo metu (po 2 metų): stuburo juosmens iškrypimas >17,76 laipsnių (AUC 0,71, p = 0,004) ir LIV kampas > 4,5 laipsniai (AUC 0,72, p = 0,0008).

Stuburo fiksacijai palyginti grupėse pasirinktas pirmo nefiksuoto slankstelio juosmens dalyje (LIV+1) atstumas nuo centrinės kryžkaulio linijos. Apskaičiuota, kad LIV+1

atstumas trečioje grupėje buvo 10,89 ± 8,76 (mm) prieš operaciją, po 3–6 mėnesių buvo 8,88 ± 7,30 (mm), o po 2 metų buvo 9,55 ± 8,07 (mm). Palyginus visas grupes pagal LIV+1 atstumą visais tyrimo etapais, statistiškai reikšmingo skirtumo nerasta, p = 0,64, p = 0,13, p = 0,85. Atskirai apskaičiuota, ar A, B ir C iškrypimo potypiai (angl. *modifier*) turi įtakos nefiksuoto stuburo juosmens iškrypimui progresuoti po operacijos, tačiau reikšmingo LIV+1 atstumo vidurkių skirtumo nerasta, p = 0,77, p = 0,8, p = 0,72. Nustatyta, kad esant mažesniam kauliniam subrendimui antroje grupėje LIV+1 atstumas 2 metai po operacijos buvo didžiausias ir reikšmingai skyrėsi, p = 0,005. Kitose grupėse LIV+1 atstumas po 2 metų pagal fiksacijos būdą ir kaulinę brandą reikšmingai nesiskyrė, p = 0,10 ir p = 0,84.

Nefiksuoto stuburo juosmens iškrypimo progresavimo prognozė

Logistinė regresija. Nefiksuoto stuburo juosmens iškrypimo ryšiui su stuburo fiksacijos būdais pagal „paliesto slankstelio“ metodą naudota logistinė regresija. Nustatyta, kad NSJS progresuoti, kai stuburo fiksacija atlikta aukščiau „paliesto slankstelio“ ŠS yra 0,4(95 % PI 0,1679-0,8374, p = 0,02), kai $\chi 2$ = 7,211, p = 0,007 ir Nagelkerke R^2 = 0,13. Ieškant didžiausio rizikos faktorių ryšio, kartu su fiksacijos būdais pagal „paliesto slankstelio“ metodą į logistinės *stepwise* regresijos modelį įtraukti visi reikšmingai prognozuojami parametrai. Nustatyti 3 prognostiniai faktoriai: kaulinė pacientų branda prieš operaciją, LIV+1 poslinkis nuo centrinės kryžkaulio linijos po 3–6 mėnesių, kampas po paskutinio fiksuoto slankstelio (LIV) po 2 metų. Esant Risser 0 prieš operaciją, ŠS yra 68,03 (95 % PI 3,4325 -1348,3010, p = 0,006), LIV+1 poslinkiui esant >12,6 mm po 3–6 mėnesių, ŠS yra 1,59 (95 % PI 1,2587-2,031, p = 0,0001) ir LIV kampui po 2 metų esant > 4,5 laipsnių, ŠS yra 1,31 (1,0265-1,6629 , p = 0,03) progresuoti nefiksuotam stuburo juosmens iškrypimui po operacijos. Bendras šio logistinės regresijos modelio plotas po ROC kreive yra 0,95. Nagelkerke R^2 = *0,7153*.

Krūtinės poslinkis ir tiriamosios grupės pagal „paliesto slankstelio“ metodą

Apskaičiuota, kad krūtinės poslinkis visais tyrimo etapais pagal pasirinktą fiksacijos būdą statistiškai reikšmingai nesiskyrė. Bendras krūtinės poslinkio vidurkis prieš operaciją grupėse buvo 10,84 ± 7,9 mm, p = 0,72, 3–6 mėnesiai po operacijos – 12,34 ± 7,23 mm, p = 0,26 ir po 2 metų – 11,32 ± 6,88 mm, p = 0,86. Krūtinės poslinkis labai pablogina pacientų laikyseną bei pooperacinius rezultatus, kai pasislenka dubens atžvilgiu 2 cm ir daugiau [113]. Rizikos faktoriams nustatyti sudaryti du pogrupiai. I

pogrupis, kai krūtinės poslinkis > 20 mm po 2 metų. Tokių ligonių buvo 18 (24,7 proc.). II pogrupis, kai krūtinės poslinkis < 20 mm po 2 metų. Šio pogrupio ligonių buvo 55 (75,3 proc.).

Krūtinės poslinkio rizikos faktoriai

Prieš operaciją krūtinės poslinkio grupėse statistiškai reikšmingai skyrėsi krūtininės dalies iškrypimo viršūnės atstumas, p = 0,025. Šis atstumas krūtinės poslinkio grupėje buvo 46,70 ± 18,53 mm ir 36,75 ± 15,93 mm grupėje, kur krūtinės poslinkis buvo < 20 mm. Pagal krūtinės poslinkio pogrupius po 3–6 mėnesių reikšmingai skyrėsi T1-CSVL atstumas, p = 0,01. Šis atstumas krūtinės poslinkio grupėje buvo 13,58 ± 7,22 mm ir 9,37 ± 5,81 mm, kai krūtinės poslinkis buvo < 20 mm. Krūtinės poslinkiui po 2 metų po operacijos, kai jis > 20 mm, T1-CSVL atstumas buvo 16,13 ± 5,23 mm. Krūtinės poslinkiui esant < 20mm, T1-CSVL atstumas buvo tik 8,03 ± 6,61 mm. Šis skirtumas buvo statistiškai reikšmingas, p < 0,001.

Krūtinės poslinkio ir rizikos faktorių prognozė

Reikšmingai prognozuojamų parametrų slenkstinės reikšmės visais tyrimo etapais: T1-CSVL atstumas prieš operaciją > 19,69 mm (AUC 0,66, p = 0,047) ir krūtininės dalies iškrypimo viršūnės atstumas nuo CSVL (mm) prieš operaciją > 45 mm (AUC 0,67, p = 0,036).

Logistinė regresija: *stepwise* metodu apskaičiuota, kad krūtinės poslinkiui atsirasti po operacijos, kai krūtininės dalies iškrypimo viršūnės atstumas > 45 mm prieš operaciją, šansų santykis yra 1,04 (95 %PI 1,0065-1,0754, p = 0,019). Kai T1-CSVL atstumas prieš operaciją yra >19,69 mm, šansų santykis krūtinės poslinkiui > 20 mm yra 1,1 (95 % PI 1,0209-1,1955, p = 0,01).

Gyvenimo kokybės įvertinimas pagal pasirinktą fiksacijos būdą

Pacientai, kuriems stuburo fiksacija atlikta aukščiau „paliesto slankstelio“, visuose pogrupiuose pagal *skausmą, funkciją, išvaizdą, bendrą savijautą bei pasitenkinimą gydymu* skyrėsi mažesniu balu, tačiau šis skirtumas nebuvo statistiškai reikšmingas, p > 0,05. Pacientų, kuriems buvo nustatytas NSJS progresavimas, bendras SRS klausimyno balas buvo 4,36 ± 0,57 ir 4,8 ± 0,32, kai NSJS progresavimo nebuvo nustatyta. Šis skirtumas nebuvo statistiškai reikšmingas, p = 0,09. Šios grupės pacientai savo *funkciją* po operacijos įvertino mažesniu balu, nors bendras balų skirtumas nebuvo statistiškai reikšmingas, p = 0,06. Palyginta gyvenimo kokybė krūtinės poslinkio grupėse. Nors

bendras grupių balų skirtumas nebuvo statistiškai reikšmingas, p = 0,1, tačiau pacientai, kuriems nustatytas krūtinės poslinkis >20 mm po 2 metų, *pasitenkinimą gydymu* įvertino mažesniu balu negu tie, kuriems krūtinės poslinkio nebuvo nustatyta. Šis balų skirtumas buvo statistiškai reikšmingas, p = 0,01.

Komplikacijos

Iš 73 tiriamųjų, operuotų dėl idiopatinės paauglių skoliozės, komplikacijos nustatytos 12(16,4 proc.) pacientų.

IŠVADOS

1. Sukurtas stuburo ligų atpažinimo modulis palengvina skoliozės diagnostiką bei pagerina rezultatų vertinimo objektyvumą.

2. Stuburo fiksaciją ties „paliestu slanksteliu“ yra optimali stuburo fiksacija.

3. Mažesnė kaulinė branda prieš operaciją didina tikimybę progresuoti nefiksuotam stuburo juosmens iškrypimui po operacijos.

4. Krūtinės poslinkis didėja, kai yra didesnis krūtinės iškrypimo viršūnės poslinkis ir stuburo disbalansas tiesinėje plokštumoje.

5. Gyvenimo kokybė naudojant skirtingus fiksacijos būdus pagal „paliesto slankstelio“ metodiką nesiskiria po 2 metų.

METODINĖS REKOMENDACIJOS

1. Planuojant stuburo operaciją ir norint atlikti rentgenologinius skaičiavimus, rekomenduojama naudotis stuburo modelio atpažinimo programa.

2. Įvertinus prognostinius rizikos faktorius, stuburo fiksaciją galima pabaigti aukščiau „paliesto slankstelio“ ir tokiu būdu išsaugoti daugiau nefiksuotų slankstelių.

3. Daugiausia dėmesio planuojant idiopatinės paauglių skoliozės operacinį gydymą reikia skirti pacientų kaulinei brandai prieš operaciją. Kai pacientų kaulinė branda mažesnė, išlieka tikimybė intensyviai augti stuburui ir didėti nefiksuotam stuburo juosmens iškrypimui, todėl stuburo fiksaciją būtina pabaigti ties „paliestu slanksteliu“.