

RESULTS OF SURGICAL TREATMENT OF EARLY-ONSET SCOLIOSIS USING GROWTH-FRIENDLY IMPLANTS: ANALYSIS OF A 10-YEAR MONOCENTRIC COHORT

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Objective. To evaluate early and medium-term results of surgical treatment of early-onset scoliosis using the principle of growth-friendly systems. **Material and Methods.** A retrospective analysis of the medical records of 54 patients treated using surgical distractible metal implants was carried out. Patients were divided into 4 etiological groups: congenital (n = 17), systemic (n = 12), idiopathic (n = 16) and neurogenic scoliosis (9). The boy/girl ratio was 11/43. The average age at which patients started treatment was 9.6 years, and at the end of treatment -13.2 years.

Results. Radiometric parameters were assessed during and after completion of treatment. The Cobb angle of the main curve of deformity before treatment averaged 56.1° , after the primary operation -31.8° , and after completion of treatment -23.2° . Correction of the main deformity curve for the entire period of multi-stage surgical treatment was 57.8° . The highest initial magnitude of deformity was noted in the group of neuromuscular scoliosis (67.6°), and the lowest in the group of congenital pathology (50.4°). In the groups of systemic and idiopathic scoliosis, the preoperative values were very close: 53.4° for systemic scoliosis and 57.6° for idiopathic scoliosis. According to the results of staged treatment in the neuromuscular scoliosis group, the residual curvature of the main curve was the lowest, and the percentage of its correction was the highest -18.9° and 73.6° , respectively, versus 24.5° and 49.7° in the congenital scoliosis group. The effectiveness of treatment with an assessment of the percentage of correction after final instrumentation in groups of idiopathic and systemic scoliosis was close: 23.0° and 62.3° , and 28.5° and 51.5° , respectively. Identical average values of the main curve angle after final instrumentation were noted in all four etiological groups (on average, 23.2°). Changes in thoracic kyphosis and lumbar lordosis were insignificant. During the treatment, 22° unplanned surgical interventions were performed in 15° patients.

Conclusion. This study revealed a number of key points that in the future may help in the formation of clearer algorithms of selecting the most optimal technique: neurogenic scoliosis is most successfully corrected by growing systems, and congenital scoliosis shows less pronounced correction of deformity and a greater relative number of complications per patient with a single use of growing systems, which requires caution during staged surgical treatment.

Key Words: scoliosis, growth-friendly systems, surgical treatment, children, TGR, VEPTR.

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As defined by the Growing Spine Study Group (GSSG), Chest Wall and Spine Deformity Study Group (CWSDSG) and Scoliosis Research Society (SRS), as well as established by the Pediatric Orthopedic Society of North America (POSNA), the concept of "early-onset scoliosis" includes a wide range of spinal deformities that develop in children under 10 years of age, regardless of the etiology [1].

In present-day pediatric vertebrology, treatment for scoliosis deformities is performed, first of all, using conserva-

tive methods; only if they are not effective, the question of surgical treatment raises. Decision on surgical correction is based on the angle of the primary deformity curve – Cobb angle more than 40° [2–4], the disease progression, the grade of vertebral torsion, the mobility of the primary and secondary curve, as well as the severity of clinical signs and cosmetic defect that results in the decreased patient's quality of life. Despite the variety of options described, the decision on a treatment method is made on an individual basis. At that, the determining fac-

tor in choosing surgical intervention is the surgeon's knowledge of the possible efficacy and the structure of complications for a specific technique.

The central principle of surgical treatment for scoliosis in children and adolescents using growing systems is spinal deformity correction along with maintaining growth potential [5].

One of the most common techniques is the use of spinal systems elongated by external actions. The most common growing distractible systems in Russia are traditional connector systems, i.e.,

Traditional Growing Rods (hereinafter: TGR), and modular distractors, i.e. Vertical Expandable Prosthetic Titanium Rib (hereinafter: VEPTR)

The objective is to evaluate the early and medium-term results of surgical treatment for early-onset scoliosis using growing systems.

Material and Methods

It was a cohort, ambispective, nonrandomized trial. Patients were selected in two stages. The first stage was a retrospective review of the medical histories of patients who underwent posterior instrumented spinal fixation after a course of reconstruction using distractible systems in Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics in 2012-2022. At the second stage, 54 patients with early-onset scoliosis (age under 10 years at the time of scoliosis deformity onset) were selected who received treatment using systems elongated by external actions (surgical intervention) with subsequent staged corrections of deformity until the bone maturity of the axial skeleton was confirmed.

Inclusion criteria:

- patients with early-onset scoliosis of any etiology (age under 10 years at the time of scoliotic deformity onset);
- patients treated using growing spinal systems (TGR and/or VEPTR);
- patients who underwent a full cycle of surgical correction using growing distractible systems (initial correction multi-stage surgical correction final posterior instrumental transpedicular screw fixation with a multi-anchor system);
- all stages of surgical treatment were performed at the Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics;
- the follow-up period after the final fixation was at least 1 year.

Exclusion criteria:

- patients who voluntarily withdrew from the study (lost contact);
- patients who did not undergo final fixation for any reason.

The research was approved by Ethics Committees of the organizations in

accordance with the recommendations of the Declaration of Helsinki [6].

Evaluation criteria

Registered general and demographic cohort parameters included age, gender, length of hospital stay, time interval between surgical interventions, the total number of planned and unscheduled interventions, and the number and severity of adverse events. Data on complications and adverse events were obtained from medical records. Infectious complications, instability of metal implants (rod/screw/connector breakage), and neurological complications were of the major interest among other adverse events and were assessed using the Clavien –Dindo classification [7] that is widely used in present-day research literature and was validated for the surgical management of spinal deformities (Fig. 1).

Patients underwent radiological examinations (radiological telemetry of the spine in two planes, vertical) at all treatment stages. Radiological images were assessed by three spinal surgeons with 3, 9, and 16 years of experience. The following parameters were measured in the frontal and sagittal planes using Surgimap software: (1) Cobb angle for the primary deformity curve; (2) cranial and caudal compensatory curves (if any); (3) T1-T12 thoracic kyphosis; (4) and L1-L5 lumbar lordosis. Based on radiological results, the percentage of deformity correction in the postoperative period (including after each intervention stage) and after the treatment completion was calculated. In addition, the levels of metal implant location and the type of system used were identified.

Statistical processing

The hypothesis of normal data distribution was checked using the Shapiro-Wilk test. Data with normal distribution are provided as mean value \pm standard deviation (M \pm SD), other data – as mean value / median (Q1; Q3) (M/MED (Q1; Q3)). Comparisons of Cobb angles before treatment and after final correction were performed using a two-tailed Student's t-test for dependent samples. The value of statistical significance was p = 0.05. Box and whisker plots were

used to demonstrate the results with the median, interquartile range, min/max sample value within 1.5 x interquartile range, and outliers. Data processing was carried out using R software, version 4.3.2 [8].

Results

Analysis of general and demographic data, as well as results of instrumental examinations and laboratory tests is provided in Table 1.

Patients were divided into 4 groups by disease etiology: congenital scoliosis, systemic scoliosis, idiopathic scoliosis, and neurogenic scoliosis.

The mean age at the start of surgical treatment was 9.6 (±2.66) years, and at the end of treatment – 13.2 (±1.51). All patients previously received care and a course of conservative treatment by orthopedists on an outpatient basis in local clinics. Their scoliosis was first detected by their parents and diagnosed by physicians at an early age (<10 years); all these facts fully correspond to the concept of "early-onset scoliosis" [1].

All patients completed treatment between 2015 and 2021 (Fig. 2): for more than half of them, the follow-up period was more than three years after the treatment completion. The mean follow-up period was 4.8 (±1.87) years.

At this point, the period of staged distractions was completed and the "final spinal fusion" was performed. All patients underwent surgical intervention when the growing implant was replaced with a rigid one; the residual deformity underwent the maximum possible correction, as well as posterior transpedicular fixation with posterior spinal fusion was performed.

The mean number of distraction stages was $3.6 (\pm 1.95)$ for the entire treatment period, and the mean interval between surgeries was 9.9 months for all patient groups.

During the treatment process, TGR and VEPTR metal implants were used in different versions and combinations (Table 2).

The mean number of planned distractions (3.60 ± 1.95) demonstrated no significant difference between all four

groups: this value in the idiopathic scoliosis group was 2.90 ± 1.39 ; in the neuromuscular scoliosis group – 3.00 ± 2.12 ; in the congenital scoliosis group – 4.10 ± 2.02 ; and in the systemic scoliosis group – 4.10 ± 2.20 . However, there was a longer interval between surgical interventions in the congenital scoliosis group (11.40 ± 6.79 months), while in the groups of idiopathic, neuromuscular and systemic scoliosis, this interval was 9.10 ± 6.82 months, 9.31 ± 3.32 months, and 8.50 ± 3.36 months, respectively.

The mean length of hospital stay for the initial placement of metal implant was 17.40 ± 6.30 days for all groups of patients (Table 3).

Before treatment start and after its completion, several patients underwent the quality of life assessment using the SRS-22 questionnaire (Table 4). Considering the long follow-up period, SRS-22 results are available not for all patients. 25 patients were interviewed (10 patients with idiopathic scoliosis, 3 patients with neuromuscular scoliosis, 7 patients with congenital scoliosis, and 5 patients with systemic scoliosis).

Radiological results

Cobb angle of the primary deformity curve before treatment was at mean $56.0^{\circ} \pm 19.5^{\circ}$, after the first intervention $-28.9^{\circ} \pm 15.2^{\circ}$, and after the treatment completion $-23.6^{\circ} \pm 10.7^{\circ}$. Correction of the primary deformity curve over the entire period of multi-stage surgical treatment in the analyzed group was 58.0 ± 21.2 %. Summarized values by stages are provided in Table 5.

Radiological data in regard to the disease etiology are of particular interest (Fig. 3, 4).

Angle of primary deformity curve. The highest initial magnitude of the deformity was observed in the neuromuscular scoliosis group ($67.6^{\circ} \pm 17.5^{\circ}$), the lowest one - in the congenital scoliosis group ($50.4^{\circ} \pm 18.4^{\circ}$). Angle of the primary deformity curve in the systemic and idiopathic scoliosis groups was $53.4^{\circ} \pm 16.2^{\circ}$ and $57.6^{\circ} \pm 17.5^{\circ}$, respectively. Moreover, according to the results of staged treatment, the residual deformity magnitude of the primary curve was the lowest in the neuromuscular scoliosis group – $18.9^{\circ} \pm 12.2^{\circ}$. In other groups, Cobb angle values for the residual deformity curve after completion of treatment

were similar (Table 5). However, considering the differences in mean deformity angle before treatment, the magnitude of corrected deformity was different. In the congenital scoliosis group, both percentage and numerical value (Cobb angle in degrees) for the correction of the primary deformity curve turned out to be the lowest, 49.9 % and 25.8° \pm 17.5°, while patients with neuromuscular scoliosis demonstrated the most significant values, 73.6% and $48.7^{\circ} \pm 11.2^{\circ}$. Radiological parameters of the scoliosis deformity curve correction in the idiopathic scoliosis group at the end of treatment were 62.3% and $34.6^{\circ} \pm 13.8^{\circ}$. In patients with systemic scoliosis after final instrumentation, the correction amounted to 51.5% and $28.5^{\circ} \pm 19.5^{\circ}$. The final changes in the primary curve of scoliotic deformity in regard to Cobb angle in all groups of patients were statistically significant (p < 0.0004).

Changes in the parameters of thoracic kyphosis and lumbar lordosis during treatment were insignificant. Thoracic kyphosis was 28.4°/24.5° (16.2°; 36.0°) before surgery and 23.3°/22.0° (15.0°; 29.0°) after the treatment completion; lumbar lordosis was 38.9°/37.0° (28.0°;

Grade	Description
I	Any deviation from the normal course of the postoperative period without the need for pharmacological treatment
	or surgical, endoscopic, or radiological interventions
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
	Blood transfusion and total parenteral nutrition are also included
III	Requiring surgical, endoscopic, or radiological interventions
IIIA	Interventions without general anesthesia
IIIB	Interventions under general anesthesia
IV	Life-threatening complications (including CNS complications)* requiring treatment in intensive care
	units/resuscitation units
IVA	Single organ dysfunction (including hemodialysis)
IVB	Multi-organ dysfunction
V	Death of a patient
Suffix "d"	If a patient had complications at discharge (resulted in disability), the suffix "d" is added to the corresponding
	complication grade.

Fig. 1
Adverse events and complications according to the Clavien – Dindo classification [7]

44.5°) before treatment and 37.2°/35.0° (28.8°; 44.5°) after the final correction.

Fig. 5 demonstrates radiological images of a typical course of multi-stage treatment for scoliosis using growing metal implants. A female patient was diagnosed with severe systemic progressive scoliosis according to James classification associated with undifferentiated connective tissue dysplasia. She received treatment at the Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics during three years (from March 26, 2018 to January 25, 2021). During this period, four planned surgical interventions were performed within staged spinal distraction followed by final deformity correction and posterior transpedicular fixation.

A case of patient I., female, with congenital structural scoliosis that was treated using a growing VEPTR implant is provided in Fig. 6. The patient received treatment for seven years (from January 14, 2009 to August 2, 2016) and underwent six planned surgical interventions performed for staged spinal distraction; at the last stage, VEPTR was replaced with a unilateral TGR system because of malposition of the rib anchor. Treatment was completed with the final correction of the deformity and bilateral posterior transpedicular fixation.

Adverse events and complications

A total of 22 unscheduled surgical interventions were performed in 15 patients: 9 patients with idiopathic scoliosis, 2 patients with neuromuscular scoliosis, 9 patients with congenital scoliosis, and 2 patients with systemic scoliosis. Four patients required repeated unscheduled surgeries.

Moreover, there were many adverse events that required no urgent surgical intervention but caused changes in the planned treatment process. Thus, 26 causes of adverse events were eliminated during planned surgeries and had no significant impact on the treatment course (Table 6).

There were 7 complications of grade I, 6 complications of grade II, and 55 complications of grade IIIB. There were no complications associated with infection and/or delayed healing of surgical

Table 1 Summary demographic data of patients in the study group								
Etiological groups of scoliosis	Patients, n	Gender (male/female), n	Mean age at the start/end of treatment, years	Mean number of planned distractions, n	Mean period between surgeries, months			
Idiopathic	16	2/14	10.6/13.7	2.9	9.2			
Neuromuscular	9	0/9	10.1/13.8	3.4	9.7			
Congenital	17	5/12	7.5/12.4	4.1	11.4			
Systemic	12	4/8	10.0/13.4	3.9	8.7			
Total	54	11/43	9.6/13.2	3.6	9.9			

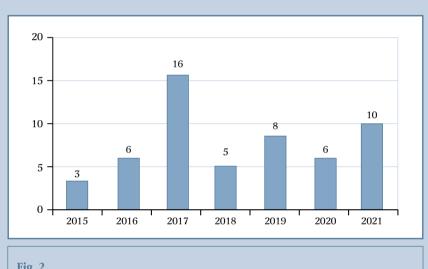


Fig. 2
Patients who completed multi-stage treatment

wounds in the analyzed group. Most (36) adverse events were associated with either malposition or damage to metal implant elements. There were 7 cases of complications associated with the nervous system, including 4 cases of liquorrhea eliminated intraoperatively with no consequences, and 3 cases of temporary neurological deficit eliminated in the postoperative period with no consequences. We registered 11 cases of deformity progression outside the fixation area. In addition, 1 case of pneumothorax was registered that developed during the placement of a subclavian venous catheter and had no effect on the treatment results. There were no patients in the analyzed group with intraoperative blood loss over 1,000 mL and/or who

required blood transfusion for postoperative post-hemorrhagic anemia. The mean number of complications was 1.19 per a patient. At that, the highest value was registered in the group of patients with congenital scoliosis (1.47 complications per a patient), and the lowest one in the neurogenic scoliosis group (0.66 complications per a patient). For systemic and idiopathic scoliosis groups, this value was 0.75 and 1.25 complications per a patient, respectively.

Discussion

Management of early-onset scoliosis in children and adolescents is a challenging task of the present-day spine medicine. Non-treatment in such patients leads to

Table 2
Use of fixation systems in different etiological groups

Type of metal implant	Etiological groups of scoliosis					
	Idiopathic	Neuromuscular	Congenital	Systemic		
Unilateral application of the TGR	9	1	9	3	22	
Bilateral application of the TGR	9	8	7	9	33	
Application of the VEPTR system in various configurations	2	-	6	_	8	
(rib - spine; rib - rib; rib - pelvis)						
Hybrid application of the VEPTR \pm	-	-	1	-	1	
dual unilateral TGR						
Conversion during treatment from the unilateral TGR	2	-	2	-	4	
system to a bilateral one						
Conversion from the VEPTR system to the unilateral TGR-2 $$	-	-	2	_	2	

Table 3
Mean bedday number at treatment stages

Etiological groups of scoliosis	First surgery	Planned staged distraction	Unplanned surgery	Final instrumentation	Total
Idiopathic	13.90 ± 4.40	7.30 ± 3.06		15.50 ± 5.22	10.30 ± 5.22
Neuromuscular	18.70 ± 6.61	8.40 ± 2.57	16.00 ± 8.48	23.90 ± 14.09	13.50 ± 9.46
Congenital	23.00 ± 5.04	8.90 ± 4.16		17.90 ± 6.85	12.50 ± 7.40
Systemic	16.40 ± 5.90	8.40 ± 3.36		14.80 ± 3.59	10.90 ± 5.13
Total	17.40 ± 6.30	8.20 ± 3.50		17.50 ± 8.03	11.70 ± 6.86

Mean assessment values of the condition of patients with scoliosis according to the SRS-22 questionnaire

Domains	Period		Etiological gro	ups of scoliosis		Total
		Idiopathic	Neuromuscular	Congenital	Systemic	(n = 25)
		(n = 10)	(n = 3)	(n = 7)	(n = 5)	
Pain	Before treatment	3.10 ± 0.83	3.30 ± 0.57	3.60 ± 0.78	3.00 ± 0.70	3.20 ± 0.76
	After final	4.20 ± 0.98	4.30 ± 0.57	4.30 ± 0.75	4.20 ± 0.44	4.20 ± 0.76
	instrumentation					
Self-image	Before treatment	2.80 ± 0.98	2.30 ± 0.57	3.00 ± 0.57	3.00 ± 0.70	2.90 ± 0.78
	After final	4.00 ± 0.63	3.30 ± 0.57	4.00 ± 0.81	4.00 ± 1.00	3.90 ± 0.74
	instrumentation					
Function	Before treatment	3.60 ± 0.67	2.00 ± 1.00	2.80 ± 0.69	3.4 ± 0.54	3.20 ± 0.84
		4.50 ± 0.63	$2.30\ \pm0.57$	3.80 ± 0.69	4.00 ± 1.22	4.00 ± 0.97
Mental health	Before treatment	3.10 ± 1.04	2.60 ± 0.57	3.30 ± 0.95	3.60 ± 0.54	3.20 ± 0.89
	After final	4.00 ± 0.63	3.30 ± 0.57	4.40 ± 0.78	3.80 ± 0.83	4.00 ± 0.74
	instrumentation					
Satisfaction	Before treatment	-	-	-	-	_
	After final	4.70 ± 0.46	4.00 ± 1.00	3.30 ± 0.75	4.60 ± 0.54	4.20 ± 0.86
	instrumentation					
Total value	Before treatment	3.20 ± 0.59	2.60 ± 0.52	3.20 ± 0.37	3.20 ± 0.46	3.10 ± 0.52
	After final	4.30 ± 0.38	3.50 ± 0.23	4.00 ± 0.39	4.10 ± 0.22	4.00 ± 0.41
	instrumentation					

The magnitude of the main curve of scoliotic deformity according to Cobb in groups of patients with scoliosis, degree

Etiological groups of scoliosis	Before treatment	After first surgery	Before final instrumentation	After final instrumentation	Correction	Correction (mean), %
Idiopathic	57.6 ± 17.5	28.7 ± 14.0	39.7 ± 16.2	23.0 ± 15.4	34.6 ± 13.8	62.3
Neuromuscular	67.6 ± 17.5	30.4 ± 15.1	30.7 ± 15.4	18.9 ± 12.2	48.7 ± 11.2	73.6
Congenital	50.4 ± 18.4	37.1 ± 14.3	37.9 ± 17.1	24.5 ± 15.6	25.8 ± 17.5	49.7
Systemic	$53.4\ \pm16.2$	29.5 ± 20.2	37.9 ± 18.8	24.9 ± 18.0	28.5 ± 19.5	51.5
Total	56.1 ± 18.0	31.8 ± 15.8	37.2 ± 16.6	23.2 ± 15.3	32.8 ± 17.5	57.8
Literature date (mean)	71.6	41.2	Not available	40.8	30.8	42.1

a significant decrease in the quality of life associated with severe cardiorespiratory disorders, as well as increased mortality [9, 10]. With the obvious final goal of treatment, i.e. maximum correction of spinal deformity and achievement of a balanced torso in three planes with a minimum number of interventions and with no complications, it is important to consider the specific aspects of scoliosis management in growing patients. Planning of treatment and outcomes should be performed considering growth of the chest and maturation of lung tissue by the age of 8 years [11, 12].

Growing systems may be used for different applications. The traditional growth modulation system based on distraction was popularized by Akbarnia et al. [2–4] and is the global standard for the management of early-onset scoliosis. The wide variety of anchor types, hooks, sublaminar fixation with wires and tapes, pedicle screws, as well as different types of connectors by different manufacturers provide a huge variety of combinations available in countries with different healthcare management models. Despite the convincing evidence that bilateral growing systems demonstrate better results in comparison to unilateral ones, the perfect configuration of the system is still debatable. In Russia, variations and combinations of the TGR and VEP-TR systems are most common [13], since other options for growth-friendly systems (Vertebral Body Stapling, Vertebral Body Tethering, Magnetically Controlled Growing Rods [14], Shilla Growth Guidance System, Modern Luque Trolley, etc.)

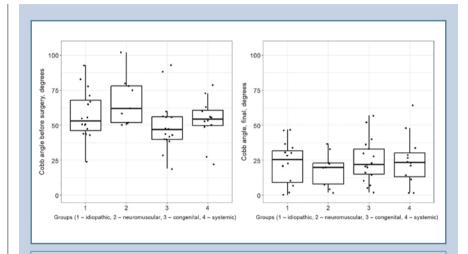


Fig. 3
Scoliotic deformity angles before treatment (left) and after final instrumentation (right)

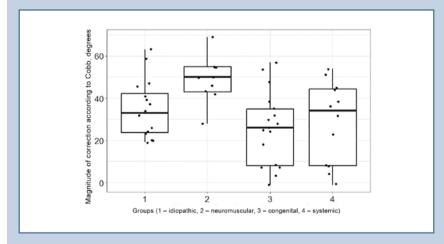


Fig. 4
The magnitude of correction of the main curve of deformity, degree

are not registered in the Russian Federation, and there is much less reliable evidence of their efficacy. Moreover, there are several latest dynamic fixation systems that require less invasive interventions and reduce the cost of treatment. One of the current trends is the use of a ratchet mechanism. Researchers from different countries develop various options for fixators that allow distraction to be performed either with no surgery at all, or with mini-

mally invasive planned interventions. Examples of such systems are One-Way Self-Expanding Rod [15], Self-Adaptive Ratchet Growing Rod [16], and Api-Fix posterior dynamic deformity correction device [17]; all these systems are based on a principle of a connector with ratchet mechanism. This method allows eliminating or significantly reducing invasive planned distraction that should apparently lead to the decreased number of complications.

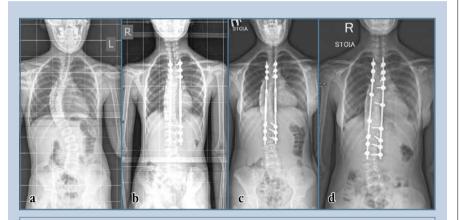


Fig. 5
Typical course of multi-stage treatment of scoliosis using a growing metal implants: **a** – before the start of treatment, a female patient of 10 years old; **b** – after the initial installation of the growing system; **c** – before the final stage of treatment; **d** – after completion of treatment (final instrumentation), the patient is 13 years old

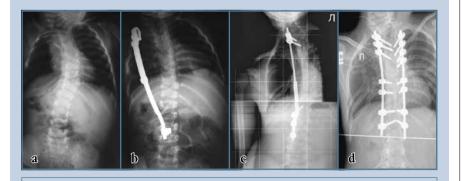


Fig. 6Radiological images of patient I., female, with congenital structural scoliosis: **a** – before the start of multi-stage surgical treatment using VEPTR, the patient is 2 years old; **b** – after installation of the primary metal implant – the unilateral VEPTR system; **c** – before installation of the final rigid metal implant, after 6 planned surgical distractions with replacement of VEPTR with a unilateral TGR system at one of the stages; **d** – after completion of treatment (final instrumentation), the patient is 9 years old

Moreover, there is another idea implemented in the use of spring mechanisms that provide passive tensile force, for example, Spring Distraction System [18].

Most of these systems are still undergoing clinical testing or have only recently been implemented in clinical practice. Despite the high-potential short-term results of such treatment, small number of patients and short follow-up period do not allow objective assessing of their reliability and efficacy. There are also a number of new "self-distracting" systems; however, most of these developments are at the testing stage.

We have earlier conducted a large study of current research publications on the efficacy of growth-friendly systems in the treatment for early-onset scoliosis [19]. In accordance with the PICOS criteria [20], over the past 10 years, 38 current research publications have been selected out of more than 800 articles on this issue and analyzed in detail [21-58]. The literature analysis performed gave reliable data for comparison. It was found that the results of this study significantly differed in several aspects from those reported in the current research literature. Gender ratio demonstrated a definite predominance of girls over boys, 80/20 %, compared to the literature data where this ratio is close to 50/50 (41.5/58.5 % for TGR and 51.5/48.5 % for VEPTR). The mean age of children at the time of treatment start in our research was higher than the mean age provided in literature sources (6.6 years for TGR and 4.9 years for VEPTR), and was 9.6 years (Table 7). Since scoliotic spinal deformity is a syndrome that develops over a long period of time, it takes several months or sometimes several years from the moment of detection of the spinal deformity until the time of its progression to a condition that requires surgical intervention. During this period, in accordance with the approach to the management of early-onset scoliosis approved in present-day spine medicine, patients receive a course of conservative outpatient treatment (including brace treatment) to slow down the progression of spinal and chest deformity [59]. In cases of failure of conservative treatment,

Table 6
Distribution of complications and adverse events (according to Clavien — Dindo) by etiological groups, n

Clavien — Dindo grade		Total			
	Idiopathic	Neuromuscular	Congenital	Systemic	
I	5	1	1	_	7
II	-	2	4	_	6
IIIA	_	-	_	_	_
IIIB	13	3	20	9	55
IV-V	_	_	_	_	_
Number of complications / patients with complications	18/10	6/4	25/11	9/6	68/31

a decision is made to switch to surgical interventions. A specialist can evaluate changes over time and the efficacy of conservative treatment only over a quite long time period, usually six months or more. Moreover, the Russian Federation has several specific organizational factors (including those determined by geography) that increase the time period from the moment of diagnosis with "earlyonset scoliosis" to the first surgery. All these factors are most likely to have an effect on the difference in the mean age at the time of placement of the first metal implant between data in our research and various data in recent literature.

It should be mentioned that the extreme values of this parameter in our research (start of treatment at 15 years and its completion at 8 years) are single and unique cases. The decision on treatment that was non-typical for the specific age was made by a team of experts based on the individual characteristics of patients. Patient G., male, who received staged surgical treatment using a growing TGR implant at the age of 15 to 16 years, had an undifferentiated genetic defect in addition to the congenital abnormality. The exact diagnosis was not established despite a genetic analysis performed. This defect caused a significant decrease in the weight and height of the child, as well as high mobility of the scoliotic deformity curve. For this reason, the patient was under outpatient followup for seven years (from 8 to 15 years) and received conservative treatment, including brace treatment. The main obstacle to the surgery at an earlier age

was the patient's excessively low height and weight. Only by the age of 15, his weight and height were comparable to those of a normal child aged 8–10 years and were close to the acceptable parameters for surgical intervention. These specific features determined choosing the method of growing systems despite the age. The patient underwent a total of 3 interventions: initial placement of a TGR metal implant, surgery for distraction of this metal implant, as well as correction of deformity and posterior transpedicular screw fixation with a satisfactory result.

Patient E., female, received a rigid metal implant that replaced a growing one at the age of 8 years. She had a congenital spinal abnormality with high structural complexity; therefore, it was decided to change the treatment strategy for vertebrotomy with short posterior fixation. Refusal to further use the growing implant at that time seemed to be the right decision, since the state of the corrected primary deformity curve looked very satisfactory immediately after vertebrotomy with short posterior fixation. However, at the present moment, a post-hoc analysis of this case allows assessing this approach as wrong, since short fixation was not enough to prevent further progression of deformity. As a result, this approach led to unsatisfactory delayed results, since in subsequent years the patient experienced adverse events, i.e. malposition of metal construction elements and progression of the deformity above and below the fixation area. Several additional interventions were required, so, the surgical

treatment was actually completed with a satisfactory result at the age of 11 years. In total, the patient underwent 9 surgical interventions: initial placement of a unilateral VEPTR metal implant at the age of 2 years; 4 planned staged distractions at the age of 2 to 6 years with the replacement of VEPTR with a unilateral TGR implant; vertebrotomy at the apex of the deformity with the correction of deformity, and short posterior instrumental fixation at the age of 8 years. From 8 to 11 years, the patient underwent 3 more unscheduled surgeries for repeated placement and elongation of the metal implant for the correction of progressive spinal deformity.

Although these patients were included in our research in accordance with the inclusion/exclusion criteria, we should mention that these cases were single and non-indicative, and they in general have no effect on the mean values in the analyzed group.

Radiological data of the cohort in our research also revealed discrepancies with the information provided in recent publications. Cobb angle of the primary deformity curve before treatment was mean 56.1° that is less than in the literature – 71.6°. Similar mean values of the angle of the primary curve after initial surgery in the groups of idiopathic, neuromuscular and systemic scoliosis are also of interest (28.7°; 30.4°; and 29.5°, respectively), while the group of congenital scoliosis after the initial placement of a metal implant had higher values of the residual deformity curve (37.1°). Mean residual primary curve after the initial surgery for

Table 7
Summary demographic data presented in current literature

(male/female), % start, years n (male/female), % start, years	TGR				VEPTR	
	Patients, n		· ·	,		Mean age at the treatment start, years
76.5 41.5/58.5 6.6 78.0 51.5/48.5 4.9	76.5	41.5/58.5	6.6	78.0	51.5/48.5	4.9

all groups was 31.8°, and after the treatment completion – 23.2° that is also less than the values mentioned in the literature sources (41.2° and 40.8°, respectively). Correction of the primary deformity curve after the treatment completion in the presented research was greater than in the international literature sources, 57.8 % vs 42.1 %. Despite the discrepancy in percentages, the degrees of primary curve correction turned out to be comparable, 32.8° in our research vs 30.8° in the literature. On this basis, it can be noted that in regard to the percentage in the cohort of patients in this research, a better result was achieved than the one presented in the international literature. however, upon that, the degrees of correction turned out to be almost similar and amounted to approximately 30°. Discrepancies with literature data can probably be explained by the single-center design of our research.

Correlation between the correction of deformity and the etiology of scoliosis is of special interest. The highest deformity correction in the neuromuscular scoliosis group can be explained by the high mobility of the curves in this deformity type. At that, the lowest deformity correction was registered in the congenital scoliosis group. This was associated with the increased structural complexity of this abnormality and the reduced growth potential of such patients. However, in addition to the percentage of deformity correction, the absolute values for this parameter should be also considered. Thus, over the entire treatment period, the mean magnitude of correction was 34.6° in the idiopathic scoliosis group, 48.7° – in the neuromuscular scoliosis group, 25.8° – in the congenital scoliosis group, and 28.5° - in the systemic scoliosis group. Based on this, it was registered

that the correction potential in neuromuscular scoliosis patients is apparently more significant than in other groups, while in the congenital pathology group, on the contrary, it turned out to be significantly lower.

Changes in thoracic kyphosis and lumbar lordosis in our research and in the literature data turned out to be insignificant. In this research, thoracic kyphosis was 28.4° before surgery and 23.3° after the treatment completion, and lumbar lordosis was 38.9° before treatment and 37.2° after final instrumental fixation. According to the literature, thoracic kyphosis was 46.2° before surgery and 59.4° after the treatment completion, and lumbar lordosis was 47.7° before treatment and 50.1° after the final surgical intervention. Although the values of these parameters in the recent publications are significantly higher than in our research, these changes over time are equally minimal in all groups. Consequently, it can be stated that the use of growing systems has no pronounced effect on the sagittal balance of a child's body. Due to its high adaptability, a growing organism manages to adapt and compensate for the sagittal deformity during growth, with no disorders of the global balance. In addition, a rigid metal implant placed at the end of treatment allows further correcting the found sagittal disorders at the level of fixation.

Therefore, this research helped to evaluate the early results of treatment for scoliosis in children and adolescents using TGR and VEPTR systems and to identify several specific features that are typical for their use.

The biomechanics of growing rods differs significantly from that of a rigid metal implant. Cyclic loads on the less rigid bridge-like construction of growing rods combined with the smaller size of rods and screws of Ø4.5 during initial placement increase the risk of complications associated with damage and/or breakage of the implant during child's growth and weight gain. One should also consider the rather high motor activity of children. This requires the sequential performance of several planned surgical interventions to elongate the structure (on mean, 3.5-fold), with regular hospitalization of a patient and his/her caregivers (parents, guardians, relatives, etc.). Moreover, it is necessary to monitor the efficacy of the primary curve correction, the presence and progression of secondary curves outside the fixation area, as well as patient's weight, height, and motor activity. This predetermines a high percentage of implant-related complications in this research: up to 65 % of the total number of adverse events. No development or worsening of neurological symptoms was observed during the research, and transient disorders in 7 patients (13 % of the total number of adverse events) did not lead to long-term negative consequences. Rather high (11) number of complications associated with the progression of deformity outside the fixation area (20 % of the total number of adverse events) attracts the attention; it indicates the high growth potential of this cohort of patients and changes in biomechanical relationships over time that can be adjusted during staged treatment. Another type for the development of these complications (possible incorrect choice of the level of metal implant placement and/or incorrect choice of the type of anchor points) seems to be unlikely. These aspects require additional preoperative planning to correctly determine the instrumentation area, as well as careful postoperative follow-up in order to identify trends and analyze them.

In this research, congenital scoliosis demonstrated lower deformity correction because of its greater rigidity. This highlights the reasonability of using three-column osteotomy for spinal correction followed by short posterior instrumental fixation to obtain a local bone union at an early age, with no serious damage to the axial growth of a child. However, this issue requires much more detailed research with the assessment of long-term results. Moreover, there is evidence in the literature that an optimal technique is the hybrid one [60] that combines apical vertebrotomy with short posterior instrumental fixation and simultaneous placement of a growing TGR system. This approach allows achieving better correction of spinal deformity and reducing the number of complications. The use of dynamic systems in this situation is possible if there are contraindications to a more aggressive spinal osteotomy.

Conclusion

Currently, there is no established standard for the use of dynamic, surgically distractible growing systems. A wide range of options and configurations of growing implants along with a large number of additional factors related with etiology, age, severity of deformity,

combined and concomitant pathology in various patients have significant effect on the results of treatment.

This research highlighted several key ideas that may help in the development of clear algorithms to choose the optimal technique: neurogenic scoliosis is more successfully treated using growing systems; congenital scoliosis demonstrates less significant deformity correction and a higher relative number of complications per a patient when using standalone growing systems what requires caution during staged surgical treatment.

The relatively high number of complications and adverse events (most were caused by issues with metal implants) indicates the need for further development and improvement of both the constructions and the techniques and algorithms for their use.

The choice of one or another technique depends on a large number of factors and should be made only on an individual basis based on experience and expert opinion. The heterogeneity of causal factors results in a wide range of planning and assessment criteria that significantly limits the possibility of algorithmization and machine analysis to justify a protocol for medical decision support.

Limitations of the research

This research has a number of limitations that do not allow interpreting its results with absolute confidence and reliability.

- 1. Small sample of patients. A larger number of patients will allow more accurate calculating demographic and radiological parameters.
- 2. Short follow-up period after the final treatment stage. A longer minimum follow-up period after the treatment completion (5 or 10 years) will allow better understanding and assessing of the persistence of the achieved result and changes of patients' condition over time.
- 3. Limited information on the quality of life during treatment stages. To assess patients' quality of life, regular analysis using validated questionnaires (SRS-22/24) at different stages of treatment is required. Understanding individual factors that have an effect on the quality of life will allow adjusting the treatment process what can significantly increase patient satisfaction.

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