ANALYSIS OF THE 3D PROTOTYPING IN THE SURGICAL CORRECTION OF CONGENITAL KYPHOSCOLIOSIS

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Objective. To analyze the advantages of additive technologies and 3D modeling in surgery for severe congenital spinal deformities caused by mixed and non-classified developmental anomalies, including assessing the quality of transpedicular screws.
Material and Methods. A total of 20 patients with complex spinal anatomy caused by congenital vertebral anomalies were treated. Nine patients had complex unclassifiable anomalies of the spine, 11 had mixed anomalies, 3 of them had aplasia of the structures of the spinal column. In order to assess the results, patients were divided into two groups of 10 people. In Group I, standard preoperative preparation was performed according to X-ray, CT and MRI data. In Group II, preoperative preparation was accompanied by the use of a prefabricated 3D model of the patient's spine. CT data were used to create STL-models which were printed using 3D printer. To analyze the effectiveness of 3D prototyping in preoperative planning, a survey among surgeons specializing in pathology of the spine was conducted.
Results. Survey results demonstrated that there were cases of changes in surgical treatment tactics after the 2nd stage of the survey, based on the results of applying standard methods of radiation diagnostics and 3D model of the entire spine with prototyping of the thoracic, lumbar, and sacral spine. In 25.3 % of cases, tactics were changed. Significant improvement in surgical treatment results were observed in Group II with preoperative 3D modeling (94.9 % without screw malposition), compared to Group I in which surgical correction was performed using standard methods of imaging (78.1 % without screw malposition).
Conclusion. 3D modeling allows increasing the accuracy of the placement of transpedicular screws and reducing the risk of malposition, which favorably affects the biomechanical properties of the instrumentation and reduces the risk of damage to neural structures. The use of 3D modeling can statistically significantly reduce the time taken to install one screw, and the number of x-rays required. Reducing the number of images allows you to reduce radiation exposure not only to the patient, but also to the staff of the department.
Key Words: congenital anomalies, 3D modeling, transpedicular fixation, scoliosis.
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Choosing the tactics of surgical management of congenital spine deformities in patients with mixed and unclassifiable vertebral malformations offers a number of challenging tasks to be solved by the surgeon. These problems can be solved by thorough preoperative planning using modern radiographic and non-radiographic diagnosis techniques. The currently available single-stage surgical interventions sometimes cannot be utilized. In particular, patients having multiple deformities requiring correction and a significant number of patients with congenital deformities need multi-stage surgical treatment, which makes the surgeon's work quite challenging. Precise visualization of patient's spine is extremely important. It allows the surgeon to meticulously assess the type of developmental anomaly, evaluate whether spinal instrumentation is feasible, reduce the risk of implant malposition, and choose the tactics of further interventions in this patient cohort more efficiently.

This study is relevant due to several reasons:

– there is a group of patients with severe congenital spine deformities requiring surgical treatment;

– surgical management of these patients is associated with anatomy surgical difficulties, which require novel tools for deformity visualization according to the results of preoperative examination;

– there is a need to improve the existing techniques and perform fundamental and clinical search for novel procedures, materials, and approaches to treat these patients (e.g., surgeries with 3D-printed medical models);

– the 3D modeling technologies have been improved (in particular, the precision of model manufacturing has increased, while their cost has reduced), which facilitates their launching into clinical practice.

The objective of this study was to analyze the advantages of additive manufacturing technologies and 3D modeling in surgery for severe congenital spine deformities caused by mixed and unclassifiable vertebral malformations, including performing the assessment of transpedicular screw placement accuracy.

The secondary objective was to compare the time taken to place a single screw, as well as the number of intraoperative radiographs, in Groups I and II.

The scientific novelty of this study is that it reports the experience of treating patients with the aforementioned deformities at the Department of Spine Deformities, N.N. Priorov National Medical Research Center of Traumatology and Orthopedics (Moscow, Russia).

Material and Methods

The inclusion criteria for study enrollment were as follows: age, 4–19 years; primary surgery; angular kyphoscoliotic deformity caused by mixed or unclassifiable vertebral malformations; coronal or sagittal imbalance of the spine.

Twenty patients having complex spinal anatomy caused by congenital vertebral anomalies were treated. Nine patients had complex unclassifiable anomalies of the spine; 11 patients had mixed anomalies; three of those had aplasia of the vertebral column structures.

In order to assess the outcomes, all the patients were divided into two groups consisting of 10 individuals (Table 1). In Group I, patients underwent standard preoperative preparation according to the radiographic, CT and MRI data. In Group II, preoperative preparation involved using a prefabricated 3D model of the patient's spine.

Life-size 3D printing was used for modeling; additional 3D models with the magnified regions of the most complex spinal anatomy were printed in three cases (Fig. 1).

The CT data of the spine were used to create STL models. The models were printed on an FDM 3D printer. Layer height was 0.2 mm. Printing time ranged between 27 and 42 hrs. The average manufacturing cycle took 2–4 days. The model embraced the thoracic, lumbar, and sacral regions of the patient's spine and pelvis to ensure the fullest imaging of all the zones involved in formation of the deformity and visualize the anatomy of bone structures of malformed vertebrae (Fig. 2).

In order to analyze the effectiveness of 3D prototyping in preoperative planning, we chose 10 clinical cases of congenital spine anomalies, including six patients with congenital kyphosis and four patients with congenital scoliosis. A survey was elaborated, which included the following criteria: osteotomy level and length; levels of spine fixation; assessment of the feasibility of implant placement; type of spine malformation; and assessment of deformity type and curvature magnitude.

To evaluate the effectiveness of 3D prototyping in preoperative planning, a survey was conducted among seven orthopedic surgeons specializing in spine pathology (two surgeons having a Doctor of Medical Sciences degree and over 28 years' experience and five surgeons having a Candidate of Medical Sciences degree and experience in spine surgery ranging from 11 to 14 years).

The survey consisted of two stages: at stage 1, the surgeons evaluated the standard radiographic diagnosis methods (radiography, CT, MRI). At stage 2, the surgeons evaluated the standard radiographic diagnosis methods supplemented with the preliminarily 3D-printed model of the spine (Fig. 3).

The following parameters were compared:

(1) extent and level of spinal osteotomy;

(2) length of spinal fixation;

(3) the feasibility of implant placement in the area of planned surgical treatment; the absence of opportunity to place implants at planned levels); and

(4) type of vertebral malformation.

In order to evaluate the effectiveness of instrumental fixation and malposition of transpedicular screws, the outcomes of surgical treatment in the study group were analyzed and compared with the group of patients who had not undergone preoperative 3D modeling. Two groups of patients who had undergone postoperative CT scanning followed by assessment of malpositioned transpedicular screws were formed. In order to minimize the influence of such factor as patient's age (and, therefore, the anatomical size of vertebral arch) on accuracy of screw placement, the patients were randomly assigned to groups using the modified method of consecutive numbers. The patients were presented as a series as their age (years) increased; each patient in this series was assigned a number. The patients having odd numbers were included into Group I (the comparison group); those having even numbers were included into Group II.

Group I consisted of 10 patients aged 4–17 years having congenital spinal deformities (unclassifiable mixed thoracic and lumbar vertebral malformations). Transpedicular screw placement was performed according to the radiographic, CT, and MRI data. A total of 169 transpedicular screws were placed. Group II consisted of 10 patients aged 5–19 years having congenital spinal deformities (unclassifiable mixed thoracic and lumbar vertebral malformations). Transpedicular screw placement was performed according to the radiographic, CT, and MRI data, as well as the 3D model. A total of 175 transpedicular screws were placed.

In all the patients, screws were inserted using the freehand technique. During the postoperative period, screw position was controlled by MSCT regardless of patients' complaints.

When analyzing the outcomes of surgical interventions in Groups I and

Table 1

Age distribution of patients in the study groups, n

Group	Age, years															
	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
I	1	–	1	2	1	1	1	–	1	1	–	–	–	1	–	–
II	–	1	–	2	2	–	2	1	–	–	1	–	–	–	–	1

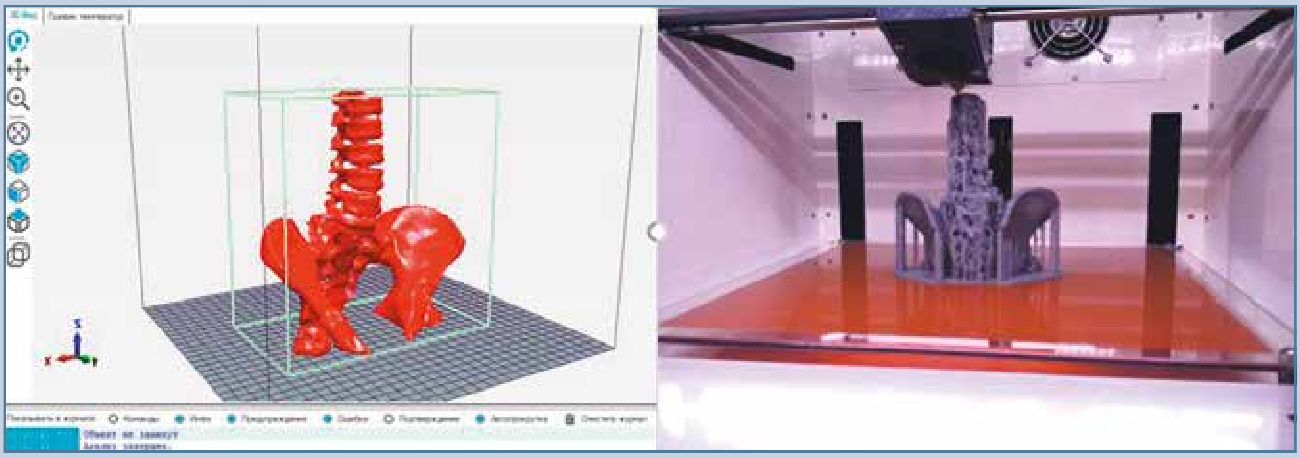

Fig. 1
3D printing of a plastic model of the spine

II, the following aspects were evaluated: the rate of accurate screw placement (the absolute number and the percentage of the total number of screws inserted); the absolute number and percentage of screws whose trajectory was displaced. In turn, the distribution of malpositioned screws was evaluated within this data set (B – malposition <2 mm; C – malposition 2–4 mm; D – malposition >4 mm; subgroup A corresponded to patients without malpositioned screws) both as the absolute number and the percentage of the total number of patients [1].

Statistical analysis of screw placement accuracy was performed using the Pearson's chi-squared test. The SPSS Statistics 22 software was used for final data processing and analysis. Malpositional (tangential) displacement with respect to the accurate position (mm) was determined for each screw. For the assigned task, it was reasonable to use viewers of electronic MSCT data, which allowed one to measure the distance between two points with a 0.1 mm accuracy. A displacement value measured with the given accuracy was found for each screw. For the accurately placed screws, displacement was assumed to be 0 mm. In order to eliminate errors, the same images were viewed using three different programs. If one measurement mismatched the other two, it was regarded as a software error. The value for which two matched results had been obtained was used for further analysis. The critical value was $p = 0.05$. The statement that screw displacement is the same in two groups was the null hypothesis. The comparison was performed twice: for the two screw samples and only for the malpositioned screws.

The time spent for placing a single screw for the patients in each group, as well as the number of required images obtained using an electron-optical image converter (EOC), were compared using the Student's t-test and the Mann – Whitney U test. The statements that there are no differences between screw samples for the key parameters were the null hypotheses.

It was not relevant to compare many key osteotomy parameters (the degree of correction, the level of osteotomy performed) because the size of comparison groups was small and there were differences in patients' age. Meanwhile, it would be extremely difficult to perform comparison in certain age groups (e.g., <7 years; 7–14 years; etc.) because of the small sample size in these groups. However, future studies (including the multicenter ones) can focus on this aspect.

The extents of instrumented fixation were compared using the Mann – Whitney U test; the number of fixed levels (between the upper and lower poles of the instrumentation, inclusive) were used as units of measurement.

Results

The survey results showed that the tactics of surgical treatment were changed from the second stage of the survey based on the standard radiographic methods and using the 3D model of the entire spine with prototyping of the thoracic, lumbar, and sacral spine regions (Table 2).

Fig. 2
The appearance of the 3D printed spine model

Fig. 3
The stage of preoperative planning using radiographic diagnosis methods and the 3D model

In order to correct the coronal and sagittal balance, deformity correction was performed involving the segments that had retained their natural mobility. In the angular deformation zone where vertebral segmentation was disrupted, correction was performed by spinal osteotomy using the SPO (9 cases), PSO (8 cases), and VCR (3 cases) procedures. According to the results of the survey, the level and extent of planned osteotomy were changed in 2.7 (range, 0–4) cases on average. The extent and levels of spinal fixation changed in two (range, 0–4) cases on average; direct visualization of the entire spine allows more comprehensive evaluation of bone structures and the overall patient's anatomy and can affect the selection of optimal points for implant placement during instrumentation planning. At the second stage of the survey, assessment of the feasibility of implant placement was reconsidered in 5 (range, 2–7) cases on average; assessment and the type of spine malformation involved in the deformity, in 0.4 (range, 0–1). The survey results infer that 3D modeling plays the greatest role in choosing the instrumentation area and determining the extent of spinal osteotomy required to achieve the more successful outcome of surgical treatment.

The tactics of surgical treatment have been changed in 25.3 % of cases (the modifications were evaluated using the criteria of the second stage of survey). These modifications were related to the technical aspects of surgical intervention and its planning:

– a decision not to insert screws through pedicles of one or two vertebrae adjacent to the most deformed one based on measurements of their parameters (including pedicle's size and shape), as well as their anatomical and topographic orientation with respect to the spinal canal;

– a decision to place additional screws and correct the levels of screw placement in order to retain the functional and biomechanical properties of the instrumentation;

– other modifications of the instrumentation configuration, including reinforcement with inter-rod coupling; attachment of additional rods to the lumbar segment of instrumentation (which is exposed to the greatest load) via connectors; in case of undifferentiated developmental anomalies, placing the rods to bypass the significantly large osseous structures and bulges, which require excessive bending and therefore applying excessive tangential load onto the rods. These modifications were suggested in response to the primary conclusion whether screw placement is feasible in the most altered zone (the apical level ± 2 sub- and superjacent levels). It should be mentioned that a decision whether to place additional elements (couplings etc.) or not is often made during the surgery; however, application of the 3D model allowed one to think through using them as early as at the preoperative stage (including not only the localization and the putative number of additional elements, but also the volume of implant beds that need to be formed at the sites where it is anatomically feasible). The final decision regarding this modification of the instrumentation configuration was made in 8 (80 %) patients in the study group and one (10 %) patient in the control group, since the CT data (even when 3D reconstruction was applied) did not allow one to efficiently plan this technical aspect;

– in two (20 %) patients, the osteotomy level was reconsidered. Because of the volume and configuration of osseous tissue in the anatomically changed posterior vertebral elements, it was possible to perform the surgery at the previously planned level only if operative time and blood loss volume were significantly increased. Therefore, a decision was made for each patient to perform osteotomy at the subjacent level.

Further intervention was conducted according to the operating surgeon' final decision.

Although 3D prototyping is more an applied technical method rather than a clinical one and is intended for planning a surgical intervention and performing intraoperative visual assisting, the outcomes of using it are encouraging. In Group I, 169 transpedicular screws were implanted. The following outcomes were obtained according to the CT data: 132 (78.1 %) implants were placed properly; 37 (21.9 %) implants were malpositioned (type B, C, and D displacement was revealed in 16 (9.4 %), 17 (10.0 %), and 4 (2.3 %) cases).

In Group II, 175 transpedicular screws were implanted. The following outcomes were obtained according to the CT data: 166 (94.9 %) implants were placed properly; 9 (5.1 %) implants were malpositioned (type B, C, and D displacement was revealed in 3 (1.7 %), 4 (2.3 %), and 2 (1.1 %) cases).

Significant intergroup differences were revealed for such parameter as time spent for placing a single screw. Because of the large number of screws placed (n = 344) and the hypothesis about normal distribution, the Student's t-test was used. In Group I, the mean screw placement time was 135.00 ± 10.41 s; in Group II, this parameter was 117.00 ± 8.27 s; the differences were statistically significant ($p < 0.05$). When comparing only the malpositioned screws, it was statistically impossible to perform subgroup analysis (for subgroups B, C, and D) because of the small number of malpositioned screws in the study group. The mean time spent for placing a single screw (for malpositioned screws) was 132.00 ± 13.15 s in Group I and 120.00 ± 9.47 s in Group II; the differences were also statistically significant ($p < 0.05$; Mann – Whitney U test). No statistically significant differences between the subgroup of properly placed screws and the malpositioned ones within one Group (I or II) were revealed ($p < 0.05$).

The number of images recorded for the EOC control was 2.9 ± 0.8 per screw in Group I and 2.1 ± 0.5 per screw in Group II (Student's t-test). The differences are statistically significant ($p < 0.05$).

According to the literature data, medial malposition < 4 mm does not cause neurological disorders, since it refers to the so-called safe zone. This rule is especially applicable for the thoracic spine, where 2 mm corresponds to the epidural space and another 2 mm, to the subarachnoid space, so no direct spinal cord compression takes place.

The study demonstrated that the outcomes have been significantly improved in the group where 3D prototyping was used (94.9 % of properly placed screws) compared to the group where surgical correction was performed using the standard radiographic diagnosis methods only: 78.1 % of properly placed screws (Fig. 4). The total number of malpositioned implants in Group I was 37; of those, 24 screws were inserted into the thoracic spine and 13 screws, into the lumbar spine. In Group II, 9 screws were malpositioned; of those, six screws were inserted into the thoracic spine and three screws, into the lumbar spine.

No significant differences were revealed for the extent of instrumentations in two groups analyzed using the Mann – Whitney U test ($p > 0.05$) due to the commonly used tactics where screws were placed at least three levels above and below the instrumentation. When making a decision regarding changing the extent of fixation in these patients, the instrumentation extent was increased no more than by one level in the distal direction.

The transpedicular implant was inserted using the freehand approach in all the cases. In addition to analyzing implant malposition, the time spent for inserting the implant, the rate of re-insertion of pedicle punch, and the number of repeatedly taken radiographs, were also evaluated. The following results were obtained: the mean time taken to place an implant (between the instant when a pedicle canal started to be formed and the time of final screw fixation in the vertebral body) was 3 min 11 s (±49 s) in Group I and 2 min 22 s (±41 s) in Group II. The differences assessed using the Mann – Whitney U test are statistically significant ($p = 0.045$); the differences evaluated using the Student's t-test are statistically highly significant ($p < 0.001$). The mean number of times when the pedicle punch was placed to form the channel in Group I was 1.8 (range, 1–7). In Group II, the mean number of attempts was 1.3 (range, 1–4). This made it possible to use the radiographic control less frequently: in Group I, mean ± SD was 1.4 ± 0.2 images per placement of a single implant and in Group II, 0.9 ± 0.15 images (the differences are not statistically significant according to the Mann – Whitney U test at $p = 0.8$ and significant according to Student's t-test at $p = 0.004$).

Analysis of the degree of screw malposition revealed statistically significant differences between the two screw samples (Groups I and II, respectively) evaluated using the Student's t- test ($p = 0.037$). The differences measured using the non-

Table 2

Assessment of modifications of the surgical treatment tactics according to the data obtained in the second stage of survey among surgeons

Parameters being assessed	Surgeons						
	1st	2nd	3rd	4th	5th	6th	7th
Extent and level of planned osteotomy	2	3	1	4	3	4	3
Length and levels of spinal fixation	1	4	2	0	2	3	2
Assessment of the feasibility of implant placement	5	7	2	4	6	5	6
Type of vertebral malformation	1	0	0	0	1	1	0
Total	9	14	5	8	12	13	11

parametric Mann – Whitney U test are less significant (p = 0.071), which can be attributed to the limitations related to application of nonparametric methods for large (>100 elements) samples. This factor should be taken into account when working with other specified parameters (the number of radiographs taken and time spent to place a single screw).

When comparing the samples consisting of malpositioned screws only (displacement types B, C, and D), the differences were significant for both tests: p = 0.031 (for the Mann – Whitney U test) and p = 0.022 (for the Student's t-test).

It should be mentioned for these findings that it took significantly less time to place a single screw in the group where the 3D model was used. In Group II, the severity of injury to bone tissues made by the pedicle punch when forming a channel in complex anatomy cases was much lower, which reduces the risk of damaging the spinal canal content and the risk of complications. Furthermore, it allows one to decrease the frequency of using intraoperative radiographic control and, therefore, reduce the radiation exposure to the patient and the operating surgeon.

Case report. A 5-year-old patient with congenital lumbar kyphoscoliosis, mixed malformation of the thoracic and lumbar spine, and aplasia of the posterior elements of the lumbar spine (Fig. 5).

Analysis of the patient's past medical history showed that at birth the patient had spinal cord herniation and malformation of the lumbar spine, osseous form of diastematomyelia, and aplasia of lumbar (L1–L5) and lower thoracic (T9–T12) pedicles. Surgical treatment involved dissection of spinal cord herniation by a neurosurgeon. The nonhealing skin defect within the surgical area was managed by plastic reconstruction via closure with a skin flap.

Abrupt progression of the lumbar kyphotic deformity caused by aplasia of the posterior vertebral elements occurred at patient's age between 4 and 5 years,. Detailed CT scanning revealed a combination of congenital hemivertebrae and defect of thoracic segmentation, pedicle aplasia in the lumbar and sacral spine, and heterogeneous cicatricial changes within the skin flap area. Clinical examination revealed such neurological disorders as flaccid lower extremity paraparesis and pelvic floor dysfunction (incontinence, Frenkel grade B). Ultrasonography of soft tissues in the areas above the spinal canal content and thoracic pedicles was conducted (the ultrasonography data were compared to the results of lumbar spine MRI) to evaluate whether the spine can be accessed intraoperatively. Skin thickness at the apex of deformity was 1.5 mm; heterogeneous changes in the dural sheath structures were observed. On the left-hand side, at the apex of deformity, the thickness of skin and soft tissues above the vertebral pedicles was > 3 mm; on the right-hand side, >4 mm (Fig. 6).

Because of the complexity of anatomical structures encountered during the preoperative period and the challenges related to accessing the spine via the posterior midline approach, after ultrasonography it was decided to perform 3D modeling of the patient's spine. Spine model was built from PLA material using the CT data (Fig. 7).

A number of technical problems were overcome in this patient due to 3D prototyping. It allowed one to rationally select screw size and type and precisely determine screw placement angles, which is especially important because of the size of anatomical structures at patient's age. Due to this preoperative planning, 100 % of screws (12 out of 12) were properly inserted at the first attempt. Intraoperatively, the operating surgeon and the assistant could see the model aligned parallel to the patient's anatomical structures, which additionally eased the screw placement. Several varieties (configurations) of the instrumentation were discussed preoperatively using the model, and the optimal one was chosen.

Because there was a high risk of wound nonhealing and developing trophic disorders, the approach was performed through two incisions 1 cm lateral to the projection line from pedicles on the left and right sides. Transpedicular screws were inserted at the T11–L5 levels according to the CT data and the intraoperative 3D model. Spinal wedge osteotomy of the L2 vertebra was performed using the PSO procedure; posterior fusion was formed using autologous and alloplastic bone grafts. The total blood loss was 250 ml. The operative time was 4 hrs 35 min. Instrumentation consisting of 12 screws was implanted. CT scanning revealed no malpositioned screws (Fig. 8).

The patient was verticalized on day 3 after the drainage system had been removed. On day 7, it was revealed that an element of the instrumentation had perforated skin; skin trophicity within the sutures was disturbed. Secondary sutures were applied; the subcutaneous tissue of the skin flap was mobilized, and the necrotic zone was dissected. The sutures were removed on day 12. The control radiographs showed that the instrumentation position was stable.

We would like to mention for this case report that preoperative planning of surgical treatment is very important for the patient having a complex and severe congenital kyphotic deformity having a high risk of pathological growth in combination with undifferentiated cicatri-

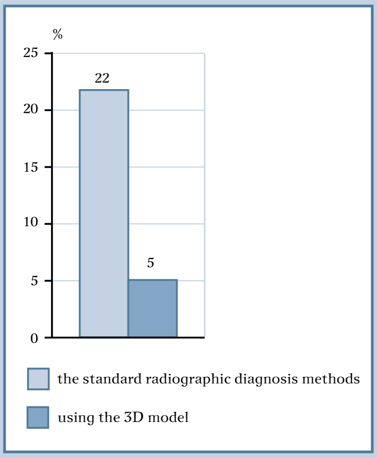

Fig. 4
The diagram showing the probability of screw malposition (types B, C, and D) with respect to the total number of implants

cial tissue at the apex of deformity above the spinal canal contents as this factor not only makes it difficult to choose the optimal type of surgical treatment but also limits the surgeon's methods as it is difficult to access the spine. 3D prototyping has made it possible to develop the surgical tactics and understand the extent of spine fixation and the level at which osteotomy needs to be performed, as well as to choose the approach for accessing the spine.

Discussion

There currently are many studies focused on the methods used for surgical treatment of isolated anomalies; however, only few publications on surgical tactics in patients with multiple vertebral malformations (combinations of various types of anomalies, including the unclassifiable ones) are available.

The key surgeon's objectives is to form a proper coronal and sagittal balance of the spine, prevent neurological symptoms, and limit the pathological growth that causes further progression of spine deformity. Despite all the risks, surgeons nowadays need to conduct early surgeries to avoid secondary changes that can subsequently affect patient's quality of life.

To obtain the maximally thorough health record, patients having anomalies of spinal development undergo comprehensive examination using the modern radiographic diagnosis methods (radiographic assessment of spine posture in the upright position, MSCT, and MRI of all spinal regions involved in the formation of the deformity). However, even detailed examination of the images often does not provide a complete overview to choose the optimal combination of surgical procedures. Additive 3D manufacturing technologies allow one to broaden the surgeon's capabilities to plan surgeries in this group of patients.

The reports on this subject are rather sparse. Searching across the PubMed database performed in November, 2018 (keywords: 3D printing, kyphosis, scoliosis) revealed only two reviews evaluating the current state-of-the-art [2, 3]. Many case reports are available in literature; however, the main focus has been placed on characteristics of the deformity and the number of screws placed, as well as the overall experience of using the technology by different surgeons to treat an individual deformity or vertebral malformation [4, 5]. These studies often specify only the degrees of malposition (e.g., type B – displacement <2 mm; type C – displacement by 2–4 mm; and type D – displacement >4 mm) [6] or the number of accurately placed or malpositioned screws [7, 8]. Case series include a rather small number of patients [9, 10]. We would not like to detract from the merits of the available studies (namely, the evaluation of deformity correction involving thorough examination of vertebral column geometry and meticulous description of clinical outcomes and the structure of emerging complications). However, it should be noted that, with few exceptions [11], no detailed information regarding quantitative parameters of tangential displacement of screws or time spent to insert each screw is available (only the total duration of surgical intervention being reported).

According to numerous literature data, the degree of screw malposition in the thoracic and lumbar spine ranges from 1 to 58 % for freehand correction of spinal deformities.

As reported by Kuklo et al. [12], when correcting scoliotic deformities with the Cobb angle >90°, 96.3 % of screws inserted using the freehand procedure [13, 14] were positioned properly. According to other data, the number of malpositioned screws in the thoracic and lumbar spine is as high as 31.6 % and 10.6 %, respectively. Up to 48.0 malpositioned screws in the thoracic spine affect the T1–T6 level because of smaller pedicle diameter [15]. Approximately 56 % of malpositioned screws are located on the concave side of the deformity, which can be attributed to structural dysplasia of pedicles and apical torsion. Meanwhile, the malposition degree is less than 2 mm for 81–86 % of screws and not greater than 4 mm for 68 % of screws. It is noteworthy that these studies mostly focus on idiopathic and dysplastic scoliotic deformities, while congenital deformities of the vertebral column, which are directly related to malformations, remain poorly studied.

Searching for the methods that would reduce the rate of malpositions is currently ongoing. One of the approaches is to stop using the original freehand procedure or develop assisting devices. Thus, Kokushin et al. [16] described the method for manufacturing transpedicular drill guides using 3D prototyping, which has rather encouraging outcomes: the application of a guide in addition to 3D prototyping of the spine (similar to that described in this study) increases the rate of proper screw placement to

Fig. 5
Preoperative appearance and radiographs of the spine of the 5-year-old patient

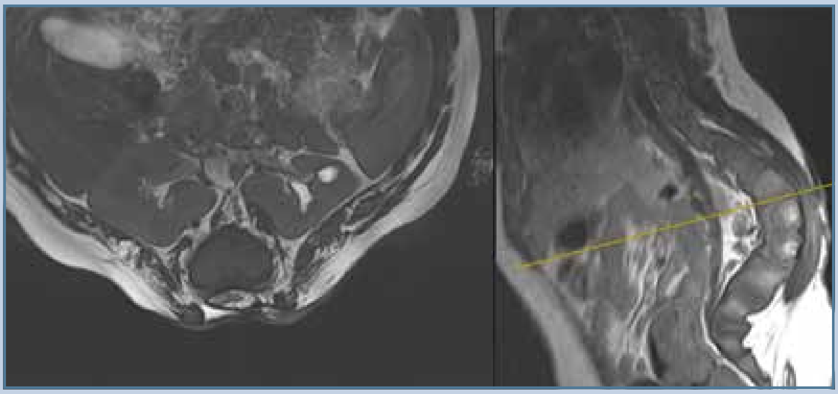

Fig. 6
MRI scan of the lumbar spine of the 5-year-old patient

96.3 % (while this figure without using the guides is 80.8 %; p = 0.011). Moreover, because of economic reasons or because certain materials and technologies are available, the «freehand + 3D prototyping of the spine only» technology can be rational, so it should be further discussed.

Detailed visualization of the posterior structures and implantation points in combination with the freehand procedure under EMG control increases screw placement accuracy to 98 % [17, 18]. The PediGuard (ECD) device is a rather reliable method for forming a proper transpedicular channel. The principle of action of this device is based on impedancemetry, which significantly reduces the risk of dangerous malpositions.

Surgeon's experience and skills are the most important variables determining the number of malpositioned screws in each clinical case, which requires a more informative visualization of the object of surgical intervention.

Screw placement accuracy increases when MSCT and 3D prototyping is used in preoperative planning, which allows one to determine the points of screw insertion more precisely. According to the literature data, the use of this technique to manage thoracolumbar deformities with the Cobb angle of 42–78° increases the accuracy of screw placement to 94.1 % versus 84.5 % achieved without using MSCT + 3D prototyping, which reliably demonstrates that 3D modeling and prototyping are quite relevant methods for modern surgery, especially in the cases with complex deformities caused by spine development anomalies.

High-precision methods (both radiographic diagnosis and intraoperative control techniques) are widely used in modern vertebrology to improve quality and accuracy of instrumentation placement [19, 20].

As mentioned earlier, surgeon's experience and manual (operative) skills play a crucial role in successful implementation of the freehand procedure. Meanwhile, the 3D model substantially simplifies this task even for a well-seasoned surgeon. This can be reached due to a number of aspects.

At the stage of preoperative planning, it is possible to precisely select transpedicular screws having a certain size and type, as well as the angle at which they are inserted into the vertebral pedicles. Furthermore, when working with a 3D model, it is possible to discuss the use and arrangement of other fixed elements if hybrid instrumentation is supposed to be used.

In addition to the holistic main model, the same CT data can be used to build several additional models, with slice planes running through the structures

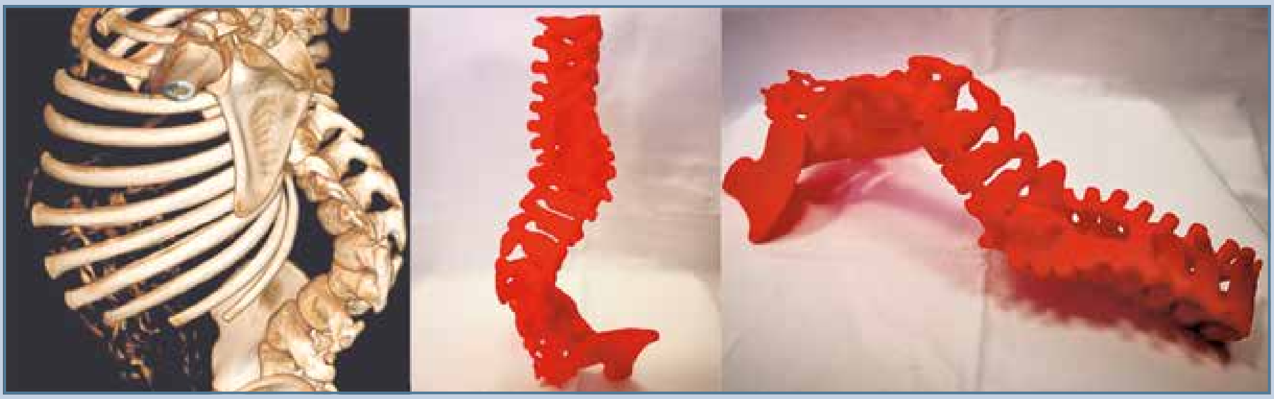

Fig. 7
Building the plastic (PLA) model according to the CT data

Fig. 8
Postoperative appearance and radiographs of the spine of the 5-year-old patient

of interest (e.g., the fused posterior vertebral elements in case of disrupted vertebral segmentation). Provided that quality of 3D printing is sufficiently good, this will allow one to evaluate parameters (thickness, arrangement, and other anatomical and topographic features) of the cortical and spongy layers in these structures. This property can be useful in the following cases:

– when evaluating labor intensity, the anatomical volume, and technical specifications of certain osteotomy variants;

– when evaluating the osteotomy level according to the anatomical criteria (the arrangement of bone masses, great vessels and other structures, for which the conventional CT imaging is challenging);

– when it is necessary to place transpedicular screws and other fixation elements into the severely changed anatomical bone structures (different from the vertebral pedicle). This technology can also be used to choose proper type and size of screws in similar cases.

Intraoperatively, the 3D model can be placed so as the operating surgeon and the assistants could see it and aligned with respect to the patient's spine, which allows them to better follow the position of the anatomical structures (mainly the deformed ones at the apex of deformity). This property becomes especially valuable when the surgery is performed through unconventional approaches, including the short-length ones. This very situation was described in this case report. The reasons for such situation were both the profound lack of soft tissues within the surgical area along with the features of the deformity per se, which abruptly increased the risk of wound nonhealing when the standard posterior approach was used and forced us to use an alternative approach.

Such area of spinal surgery as using various navigation systems and surgical guides is currently being developed. The implant placement methods using navigation systems allow one to sufficiently accurately choose the spine fixation points. However, the technical equipment is expensive and requires precise positioning of the inserted landmarks. Intraoperative neurophysiological monitoring and systems to control screw position (PediGuard) can be regarded only as an additional technique used to supplement the major navigation methods during implant placement.

Building the 3D model of the spine allows a surgeon to have a thorough visual control and compare the shape and anatomy of the skeletonized spine to the structures shown by the model. In turn, this makes it possible to simultaneously choose the fixation point and set a required angle of implant placement. This method reduces the risk of injury to the anatomical spine structures that may be caused by excessive manipulations made when an implant is inserted and significantly reduces the radiation exposure to the staff and the patient.

Conclusions

1. 3D modeling increases the accuracy of transpedicular screw placement and reduces the risk of malposition, which favorably affects the biomechanical properties of instrumentation and reduces the risk of damaging neural structures.

2. Preoperative 3D modeling can help perform technical planning of the intervention aspects for which the CT data are either insufficient or difficult to interpret. These aspects include ensuring precise 3D configuration of instrumentation, using of additional elements, determining the anatomical capabilities of forming bone beds to insert instrumentation elements.

3. 3D modeling allows one to refine and improve the surgical procedure proposed by operating spine surgeons having different experience. Because there were only few (two) spine surgeons whose working experience was more than 25 years, the correlation between working experience and frequency of modifying the surgery plan described in this study is a promising topic for future multicenter studies where rather large comparison groups can be enrolled.

4. An additional advantage of using the 3D models is that they can be placed so that the operating surgeon and the assistants could see them. This will allow the surgical team to properly arrange the screws intraoperatively under complex topographic anatomical conditions that are typical of congenital spine deformities. Furthermore, the 3D model simultaneously provides all the information obtained by CT scanning as opposed to digital or printed images.

5. Application of 3D modeling will allow one to statistically significantly reduce the time taken to install one screw and the number of radiographs (EOC images) that need to be taken. Fewer number of radiographs reduces the radiation exposure both to the patients and staff of the department.

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