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Comparison of the Accuracy and Safety of Pedicle Screw Placement in Thoracic Spine Between 3D Printed Navigation Templates and Free Hand Technique

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Abstract

Background. Transpedicular spine fixation is considered the gold standard for posterior stabilization of the spine in various pathological processes. The most common implantation technique is the free hand method. But today the implantation with 3D printed individual navigation templates is gaining popularity. ***Purpose*** — to compare results of the pedicle screw placement in thoracic spine with application of 3D printed navigation templates by various design and free hand technique. ***Materials and Methods.*** Results of the three group of patients were analyzed based on postoperative CT. In group 1 (free hand) 112 screws were placed to 23 patients. In group 42 screws were placed to 11 patients using bilateral monosegmental navigation templates, in group 3 (13 patients, 42 screws) — using bilateral monosegmental templates with additional support on the spinous process. The safety of implantation was assessed and compared in all groups. In groups 2 and 3 the accuracy was also evaluated based on the difference between the planned and actual screws trajectory. ***Results.*** In group 1 safety grade 0 was registered in 66,96%, safety grade 1 — in 18,75%, safety grade 2 — in 9,82%, safety grade 3 — in 4,46%. In group 2 grade 0 was registered in 85,71%, safety grade 1 — in 14,29%. In group 3 grade 0 — in 90,74%, safety grade 1 — in 9,26%. There were no cases of the cortical bone perforation for more than the half of the screw diameter in groups 2 and 3. The differences in the safety parameters are significant between free hand and both groups with application of the navigation templates. Assessment of the deviation hasn't revealed significant difference depending on the type of the templates. ***Conclusion.*** The use of the individual navigation templates for pedicular screws implantation in the thoracic spine is safer than the free hand method ($p<0.05$). Single-level bilateral matrices made by FDM technology from polylactide with support on a part of the dorsal vertebral structures make it possible to achieve the high implantation accuracy. Additional support on the spinous process does not lead to a statistically significant improvement in accuracy and safety indicators ($p<0.05$), while requiring extended dissection and resection of the ligamentous elements.

Keywords: 3D printing, navigation, transpedicular fixation, navigation template, thoracic spine, free hand technique.

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Transpedicular spine fixation is a common technique in the treatment of a wide range of diseases and injuries of the thoracic region. The most popular implantation technique is the “free hand” method, which is based on the determination of the placement trajectory by anatomical landmarks. An incorrect screw direction can adversely affect the construction stability and lead to neurovascular structures injury [1, 2, 3, 4, 5, 6, 7, 8].

To improve the implantation accuracy and reduce the number of complications, various methods of navigation were introduced into the practice of spinal surgery. Some of them are based on the data from the preoperative or intraoperative CT. For this purpose the integration of the anatomical landmarks with the CT data takes place employing a navigation mark placed on the patient's vertebra [9, 10, 11, 12, 13, 14, 15, 16].

Another method is based on the 3D printing technology. Using the preoperative CT data the customized navigation templates are made that are fixed during the surgery on the dorsal structures of the vertebra [17, 18]. Despite the growing interest in the method applying it has not reached the level of routine practice up-to-date. One of the relevant issues remains to determine is the optimal design choice for the navigation template that provides the best implantation marks and convenient usage and ease of use [19].

The purpose of this study was to compare the parameters of pedicular screw placement into the thoracic spine using two types of customized navigation templates with the “free hand” method.

Materials and Methods

The study design

This study was a prospective cohort nonrandomized trial.

Patients

The results of transpedicular implantation of 208 screws in the thoracic spine performed in 2018–2019 were analyzed. 47 patients from 23 to 75 years old were engaged in the study. There were 3 patients with scoliotic deformities, 19 – with tumors, 10 – with vertebral fractures, 15 – with degenerative lesions among them. Three groups of patients were formed: group 1 – the screws placement using the “free hand” method, group 2 – the screws placement using the bilateral templates, group 3 – the screws placement using the templates with three-point support. The patients distribution in the groups is shown in Table 1.

The scoliotic deformities were represented by 3 cases of idiopathic thoracolumbar scoliosis with a Cobb angle of 37° to 54°, 4B, 4C and 1A according to the Lenke classification. The patients with degenerative scoliosis (Cobb angle <20°) were referred to the group of the spinal degenerative process along with herniated intervertebral discs and compression myelopathies. The spinal injury was represented by high- and low-energy fractures and dislocations of the cervical, thoracic and lumbar vertebrae. The tumor lesions comprised primary and secondary malignant and benign tumors of the spinal column and the roots.

Table 1

The patients distribution by the type of pathological process

Pathology	Group 1	Group 2	Group 3
Idiopathic scoliosis	1	1	1
Degenerative process	7	3	5
Spine injury	3	4	3
Tumor lesions	12	3	4
Total	23	11	15

The patients of the 1st group underwent screws placement according to anatomical landmarks with subsequent intraoperative fluoroscopic control in the lateral plane. In groups 2 and 3, the intraoperative X-ray control was not used.

Design and printing of navigation templates. The navigation templates design was carried out using the DICOM-MSCT data with a slice thickness of 1 mm. The files preprocessing and the stereolithography (STL) model production were carried out in the program "Inobitec Web DICOM-Viewer 1.15.1". The final processing of the model and the choice of the implantation trajectory, contact areas, auxiliary structures production and guide tubes were carried out in the Blender 2.78. The Gcode print file was produced in Cura 4.4. The printing was carried out by the technology of inkjet overlays fused deposition modeling (FDM) from polylactide (PLA).

Two different types of navigation templates were used in this study. The 1st type was represented by a bilateral single-level template. A part of the dorsal structures of the vertebra was used as a support platform, namely the dorsal surface of the arch, the inferior articular process, and the medial part of the transverse process (Fig. 1).The removal of periosteum of these dorsal structures is usually carried out during the standard approach for posterior decompression and spinal fusion. The two basic elements - the support platform and the guide tube were connected by a transverse beam reinforced with stiffeners.

In the 3rd group, modified double-sided templates were used with a similar support zone, a rigid frame, and an additional supporting fixation element connected to the apex of the spinous process in a key-to-lock manner (Fig. 2). This design increased the stability of the template, allowing the control of the midline, but requiring an additional dissection zone with resection of the supraspinatus ligament.

A drill with a diameter of 3 mm was used to form the stroke for the screw. The inner diameter of the tube was 4 mm, and the outer diameter – 6 mm.

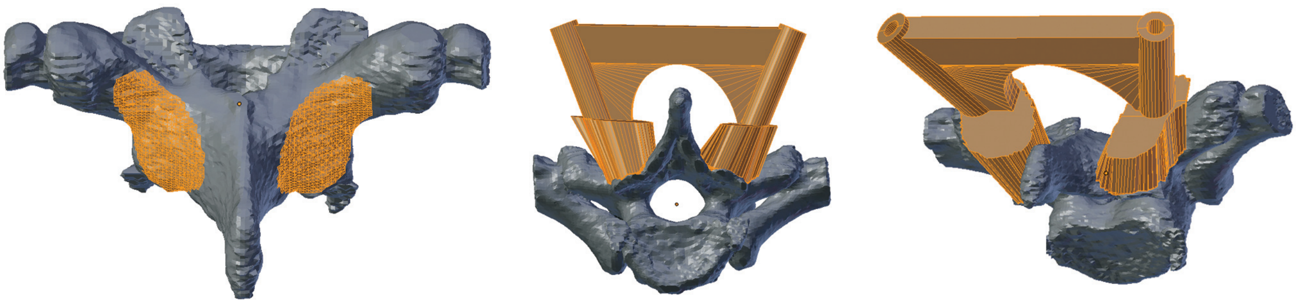

Figure1. The support zone localization and template design in the 2nd group.

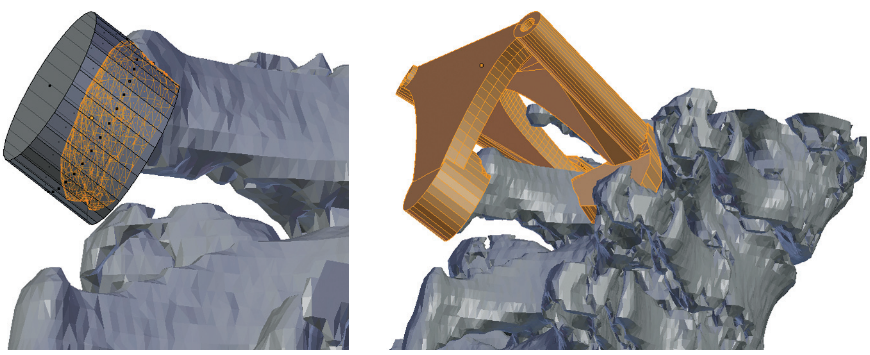

Figure 2. The navigation matrices design in the 3rd group with a support-fixing element at the spinous process tip.

The study results assessment. The implantation safety at the level of the pedicle was assessed in all groups according to the criteria proposed by S. Kaneyama et al. [20], namely grade 0 – the screw was completely inside the bone structures; grade 1 – the screw partially perforated the bone structure, but more than 50% of the screw diameter was inside the bone; grade 2 – the screw perforated the bone structure, with more than 50% of the screw diameter outside the bone; grade 3 (penetration) – the screw was completely outside the bone (Fig. 3).

The additional misplacement assessment was carried out by the K. Abul-Kasim scheme [21], Table 2.

The criterion of accuracy was the deviation assessment (mm) between the planned and actual screw trajectories at the point of entry into the vertebra (Entry point) and at the screw axis intersection with the anterior cortical layer of the vertebral body (End point) by layering axial and sagittal sections of postoperative multispiral CT with planned trajectories of implantation in the Mimics Research 21.0 program (Fig. 4).The accuracy was assessed in groups 2 and 3.

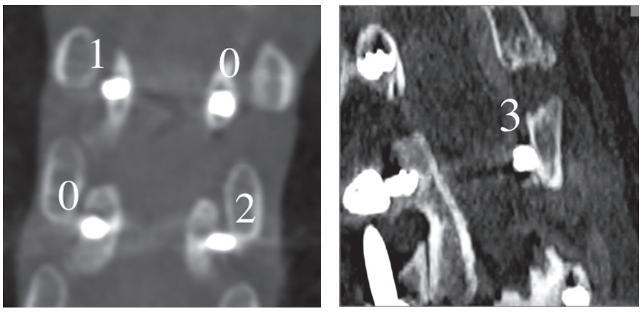

Figure 3. Examples of safety assessment by grades 0 to 3.

In addition, the planned and actual angles between the axes of the screws in two planes were measured, which was necessary to analyze the causes of the deviation (Fig. 5).

Statistical analysis. The statistical processing of the data was carried out using the Statistica 10 software. The results were assessed for distribution normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The accuracy of implantation in groups 2 and 3 was subjected to statistical analysis by the Kruskal – Wallis and Mann – Whitney tests for paired independent non-parametric samples. The planned (β) and actual (β) axial angles were analyzed using Wilcoxon's test for paired dependent nonparametric samples. In order to compare the safety of implantation in the 3 groups the Pearson $\chi 2$ test was used corrected for likelihood. The data distribution in the groups was presented as median and 25–75% quartiles in the format Me (25%; 75%).

Table 2

Implantation safety assessment system according to K. Abul-Kasim [21]

Misplacement direction	Misplacement degree
Medial cortical perforation (MCP) of the pedicle	Grade 0: The screw is completely embedded in the bone structures or perforates the medial wall of the pedicle less than ½ the screw diameter
	Grade 1: Partial medial perforation (more than 1/2 of the screw diameter)
	Grade 2: The screw passes completely medially of the pedicle
Lateral cortical perforation (LCP) of the pedicle	Grade 0: The screw is completely embedded in the bone structures or perforates the lateral wall of the pedicle less than ½ the screw diameter
	Grade 1: Partial lateral perforation (more than 1/2 of the screw diameter)
	Grade 2: The screw passes completely paravertebrally
Anterior cortical perforation of the vertebral body (ACP)	Grade 0: The end of the screw is in the vertebral body
	Grade 1: The end of the screw perforates the anterior wall of the vertebral body. The degree of perforation is indicated in millimeters
Endplate perforation (EPP)	Grade 0: The end of the screw is in the vertebral body
	Grade 1: The end of the screw perforates the top or bottom endplate into the disc cavity
Foraminal perforation (FP)	Grade 0: The screw is completely in the bone structures
	Grade 1: The screw perforates the pedicle into the superior or inferior foramen

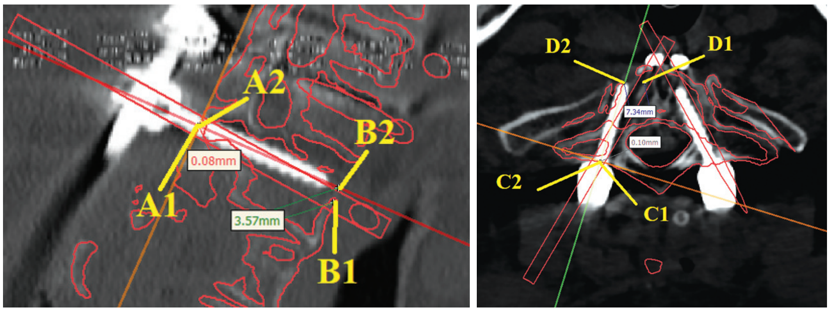

Figure 4. Deviation assessment method:
A1, C1 – planned entry points;
A2, C2 –actual entry points;
B1, D1 – planned end point;
B2, D2 – actual end point.

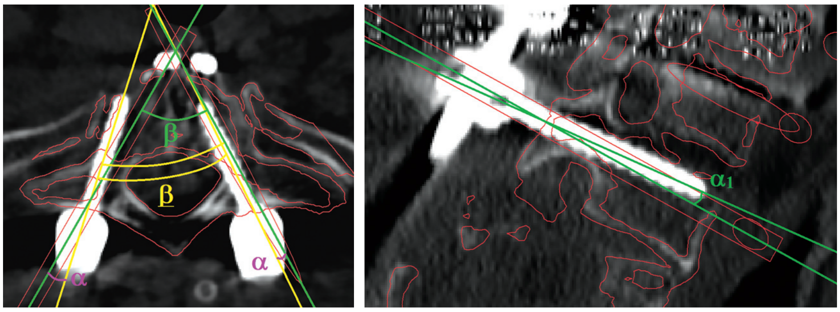

Figure 5. Deviation of the angles assessment, planned vs actual trajectories in the axial and sagittal planes:
α — the angle formed by the planned and actual axes of implantation of one screw in the axial plane;
β — the angle formed by the planned axes of implantation in the axial plane;
$\underline{\beta}$ — the angle formed by the actual axes of implantation in the axial plane;
α_1 — the angle formed by the planned and actual axes of implantation of one screw in the sagittal plane.

Results

23 patients of the 1st group underwent 112 transpedicular screw placements by the "open" method using free-hand technology. In the 2nd group (11 patients, 42 screws), the placement was performed using bilateral single-level templates, and in the 3rd group (13 patients, 54 screws) – using bilateral single-level templates with support on the spinous process. The distribution of implanted screws by the groups is shown in Table 3. The free-hand technigue was less commonly used for implantation in the upper thoracic region for the reason that it was more difficult and risky at these levels. Moreover, it increased the risks for the patient in the case of no navigation applying.

Table 3

Distribution of the screw implantation methods by the thoracic spine levels and by the study groups

The method of implantation	The level of implantation			Total
	Th1-4	Th5-8	Th9-12	
Free-hand technology (group 1)	18	48	46	112
Bilateral single-level templates (group 2)	24	12	6	42
Three-points support template (group 3)	32	20	2	54

The assessment of the implantation safety according to S. Kaneyama showed statistically significant differences between the free-hand group and the both groups with navigation templates ($p < 0.05$). No differences were found between the 2nd and 3rd groups (Table 4). The safety grades 2 and 3 were observed only in the 1st group. All screws with grade 3 were placed paravertebrally (LCP2). There were no cases of the spinal cord and great vessels injury.

The types of misplacement according to K. Abul-Kasim for each group are presented in Table 5. In the 1st group, 2 revisions with screws replacement were performed - in 1st case when the screw contacted the thoracic aorta wall, in the 2nd – due to insufficient stability of the structure.

There were no significant differences in the indicators of entry points and end points deviation in groups 2 and 3 (Table 6, Fig. 6).

Table 4

Implantation safety by S. Kaneyama

Safety degree	Free-hand technique (group 1)	Bilateral single-level templates (group 2)	Three-points support templates (group 3)
0	75 (67%)	36 (85.71%)	49 (90.74%)
1	21 (18.8%)	6 (14.29%)	5 (9.26%)
2	11 (9.8%)	–	–
3	11 (9.8%)	–	–

Table 5

Types of misplacement according to K. Abul-Kasim

Types of misplacement	Free-hand technique (group 1)	Bilateral single-level templates (group 2)	Three-points support templates (group 3)
MCP1	2	–	–
MCP2	–	–	–
LCP1	9	–	–
LCP2	5	–	–
ACP1	–	–	–
EPP	10	3	1
FF	–	–	–

Table 6

The deviation of planned and actual trajectories

Type of template	Entry point			End point		
	Axial	Sagittal	Average	Axial	Sagittal	Average
Bilateral single-level templates (group 2)	0.97 (0.59; 1.27)	0.77 (0.53; 1.31)	0.93 (0.66; 1.22)	2.49 (0.84; 5.43)	2.94 (1.89; 4.12)	2.83 (1.95; 4.81)
3-points support templates (group 3)	1.01 (0.44; 1.45)	0.89 (0.55; 1.34)	1,04 (0,64; 1,37)	3.13 (1.54; 4.57)	2.58 (1.33; 4.03)	2.88 (1.81; 4.07)

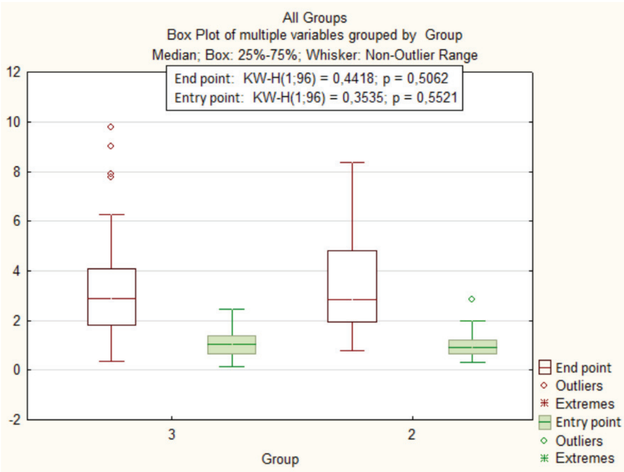

Figure 6. Diagram of implantation accuracy distribution at Entry point and End point for groups 2 and 3.

The deviation of the planned implantation trajectory from the actual one did not differ significantly between the compared groups. Although, there were significant differences between the planned (<β) and actual (<β) axial angles in both groups (Table 7). The actual angle was less than the planned one, that indicated a predominantly lateral deviation of the implantation axis. This is the most likely due to the pressure of the paravertebral muscles on the screwdriver during screw implantation.

Table 7

Deviation between the planned and the actual implantation angles

Angle	Group 1	Group 2
Angle α	5.87 (3.47; 8.51)	5.17 (1.97; 8.,58)
Angle α1	3.71 (2.19; 5.66)	4.48 (2.27; 6.64)
Difference between angles β and β	5.91 (2.91; 8.37)	7.71 (5.37; 11.01)

Discussion

Customized navigation templates are a spinal navigation technique that is rapidly gaining popularity around the world, which is reflected in a growing increasing number of publications. A search of literary sources in the databases PubMed, Scopus, Web of Science, Google Scholar and eLibrary identified 22 publications, including experimental, preclinical and clinical studies. This technology appeared 20 years ago, but its active implementation began only in the last decade. This can be explained by the progress of 3D printing, namely the improvement of printers, the development of special software, cheaper materials and other factors. The analysis of world literature upon this topic allows to evaluate the method as an effective and inexpensive mode of spinal navigation.

The largest number of implanted screws in the thoracic region in the cadaver experiment on 20 preparations was presented by T. Ma et al. Bilateral guides were made from acrylic resin using the STL, the support platform included a part of the vertebral arches, intervertebral joints and the spinous process. The time spent on the one guide design and manufacture was about 1 hour, the cost was $50 excluding the cost of computer programs. The authors compared the studied navigation technique with free hand method. 240 screws were implanted in each group. In the free hand group there were 156 (65%) screws completely surrounded by bone (Grade 0). Of the 84 cases of bone perforation, 58 (24.2%), 16 (6.6%) and 10 (4.2%) were classified as grade 1 (<2 mm or <1/2 screw diameter), grade 2 (deviation 2 to 4 mm or 0.5 to 1 screw diameter) and grade 3 (> 4 mm screw diameter, respectively. Although, only 16 (6.6%) screws perforated the bone wall with grade 1 in the group of guided placement. In the free hand group, the screws protruded beyond the bone by an average of 3.29 ± 1.84 mm, and in the group of guided placement – by 0.95 ± 0.49 mm. The differences were statistically significant [22].

S.B. Kim et al. conducted a cadaver study with 80 screws placed in the thoracoabdominal region (Th11–L5) along the subcortical trajectory. A separate screw was used to fix the guide; bilateral templates were designed with support on the arches and spinous process with continuous contact over almost the entire area of the dorsal structures. Deviation less than 2 mm was estimated for 76 screws (95%, average deviation 0.94 ± 0.42 mm), 2 to 4 mm – for 4 screws (5%, average deviation 2.75 ± 0.64 mm) [23]. In another article the authors described a clinical case of Th4-5 fracture dislocation with 10 screws placement. The work focuses on the design features of the guides. The authors proposed an original design: the unilateral template without support on the spinous process, but with hook-type gripping of the arch instead. The authors emphasized as an advantage the presence of a small support zone, allowing preserving the supra- and interspinous ligament and reducing the time spent on skeletonizing. Also, the authors proposed a classification of templates depending on the type of spinous process embracing [24].

S. Lu et al. studied the effectiveness of templates in scoliotic deformities. 16 patients were installed 168 screws at the Th2 to Th12 level. 157 screws were placed fully totally intrapedicular, 11 protruded in the 0 to 2 mm range (1 medially, 10 laterally). Among these 11 cases penetration in 8 cases was planned due to the small diameter of the pedicle, the rate of misplacement was 1.8%. The authors believed that the pedicle penetration up to 2 mm was safe, so the overall safety level was 100% [25].

F. Azimifar et al. presented the results of applying the technology for scoliotic deformities. The customized bilateral guides were designed for each level. Printing was carried out using FDM technology. The support was carried out on 4 points in the area of the superior and inferior articular processes base, not according to the principle of mirroring the surface. The spinous and transverse processes were not considered as the basic support for two reasons: the exact anatomical size of the supraspinous ligament covering the bone is not clear, and the use of the transverse processes would require a larger volume of dissection [26]. Attention was drawn to the massive matrix frame required more material than other design options. Out of 110 screws placed in Th1 to S1 level (51 of them in the thoracic region) the percentage of correct implantation in patients with scoliosis was 94%.

M. Takemoto et al. presented the data on of the technique applying in the thoracic region with 36 scoliosis patients and 4 patients with posterior longitudinal ligament ossification. The article emphasized the importance of reducing the contact zone. Based on the segmentation analysis, 7 points of support were identified out of the initially selected 14 points, including a small support on the spinous process to increase the stability. The guides were manufactured by a relatively expensive method made from titanium by laser melting in an argon atmosphere. 420 transpedicular screws were implanted in the patients with scoliosis. Among them 408 were (98.4%) with a safety degree of 0, 6 (1.4%) with a degree of 1, 1 (0.2%) with a degree of 2. The patients with ossification of the posterior longitudinal ligaments were placed implanted 46 screws with safety grade 0 [27].

M. Putzier et al. presented the results of a pilot study dedicated to the implantation of 76 screws (56 in the thoracic and 20 in the lumbar spine) in 4 patients with idiopathic or acquired scoliosis. For 2 screws a malposition was detected during the surgery with correct replacement under fluoroscopic control. The safety degree was 0 in 84%, 0 and 1 in 96.1%. All lumbar screws were installed with a security grade of 0. The diameter of 14 pedicles in the thoracic region was less than 4.5 mm, and therefore the screw protrusion beyond the stem was predictable, and the trajectory was planned so that the malposition was lateral [28].

A randomized study of dislocated thoracic spine fractures was performed by C. Wu et al. 42 patients were divided into 2 groups. In the 1st group 24 patients underwent the standard free-hand technique with fluoroscopic control. In the 2nd group 18 patient underwent the surgery with customized guides. The operative time, blood loss, degree of dislocation and sagittal angle were significantly better in the 2nd group ($p < 0.05$). Also, the significant differences were obtained in the accuracy of screw placement, the angles between the screws in the sagittal plane and the difference between the actual entry points compared with those planned before the surgery and the assessment of deformity according to the Frankel scale during the follow-up [29].

Y. Pan et al. conducted a comparative study upon the navigation templates applying (20 patients, 396 screws) and the free-hand method (17 patients, 312 screws) in the adolescents with severe spinal deformities. The templates were designed according to the principle of arches, spinous and transverse processes inversion with almost complete coverage of the dorsal elements. The operative time and the degree of correction did not differ significantly in the groups, while the safety of implantation was statistically higher with the use of templates. Grade 1 perforation was observed in 7.3%, grade 2 – in 3.3%. In free hand group, grade 1 perforation was noted in 11.9%, grade 2 – in 11.5%, grade 3 – in 1.6%, $p = 0.000$ [18].

Similarly, K. Shah et al. compared two methods for complex kyphoscoliotic deformities in children with previous placement of sublaminar wire constructions, which complicated the process of modeling the guides due to metal artifacts and required more careful segmentation. Bilateral templates with partial support were predominantly designed without the involvement of the spinous process. The malposition rate for free-hand was 36.21%, for templates – 24.56%. The mean operative time and the time of one screw placement did not differ significantly [30].

In most majority of the works the authors used single-level mono- or bilateral templates. Support only on the vertebra structures, into which the screws are placed, eliminates the factor of intersegmental mobility as a predictor of malposition. For rigid deformations the multilevel guides can be used. A.V. Kosulin et al. demonstrated the high precision of implantation in the thoracic and lumbar spine in children using a multilevel bilateral navigation template [32].

Thus, in a number of works dedictated to the study of 3D navigation templates, the authors paid a great attention to the technical aspects of the design, printing of guides and the search for design options that ensure high accuracy of implantation at with minimal costs.

The requirements can be summarized as following:

– minimization of the support zone to reduce the skeletonization area;

– preservation of ligamentous elements;

– reduction in of financial costs due to less material and of less expensive 3D printing options applying.

In previous studies the authors did not compare different types of navigation templates, while these templates could differ significantly in design (mono- or bilateral, one- or multilevel, etc.). It should also kept in mind that differences in the anatomy and mobility of various parts of the spine require a separate study of the implementation of technology in various segments. Previously, we conducted a study on cadaver preparations of the cervical and upper thoracic regions comparing three different variants of navigation templates. According to the results of this study the best indicators were revealed as using bilateral templates with three-point support with a separate abutting element in the spinous process apex [33]. In this study, we obtained the results similar to the publications presented above. We found the statistically significant differences in the level of safety for the employment of the templates in the thoracic spine in comparison with the free-hand method. This fact emphasizes the usefulness of the templates once again. There were no differences between the groups with various guides either in the degree of safety or in the parameters of deviation. Perhaps this was due to the larger area of the support zones in the arch and articular processes in the thoracic region as compared with the cervical region. This difference provides the sufficient templates stability even with two-point support with partial coverage of the dorsal structures.

A significant difference in the angle between the trajectories (<β – <β) in both groups in case of using navigation could be associated with the technique of screws placement. A high-speed drill was used only for passing the pedicle, the drill was immersed into a depth of approximately 1 cm under control of a set limiter. Then the standard instruments were used, including a curved awl, which could, to some extent, change the implantation trajectory without violating of the cortical layer integrity.

Thus, the presence of additional support on the spinous process in the thoracic region does not affect the accuracy and safety parameters and is not an obligatory structural element. This makes it possible not to skeletonize the spinous process zone, reducing the time for surface preparation and preservating the elements of the ligamentous apparatus. It also provides the use of templates after previous laminectomy or spinal trauma with spinous process injury. The localization and area of the support zone used in this study in the process of templates design are sufficient for high safety level implantation. It has increased significantly in comparison with the free-hand method. The obtained results demonstrated that the guides created on the FDM-printer from PLA allowed to achieve the similar results of pedicle screw placement in comparison with more expensive technologies, for example, STL or laser sintering, used by a number of authors [22, 25, 27].

The use of customized navigation templates for the transpedicular screws placement in the thoracic spine is safer than the free-hand method ($p < 0.05$). Single-level bilateral templates based on a part of vertebra dorsal structures, manufactured from PLA by FDM technology, allow to achieve a high implantation accuracy. The additional support on the spinous process did not lead to a statistically significant improvement in accuracy and safety indicators ($p < 0.05$), while required extended dissection and resection of the ligamentous elements.

Consent

The patients gave a voluntary informed consent for the participation in this study and publication of its results

Competing interests: The authors declare no conflict of interest.

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Authors' contributions

R.A. Kovalenko – research concept and design, text preparation.

D.A. Ptashnikov – research concept and design.

V.Yu. Cherebillo – text editing.

V.A. Kashin – design and manufacture of navigation guides, collection and processing of material and its statistical processing.

All authors made a significant contribution to the research and preparation of the article and read and approved the final version before its publication. They agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. Parker S.L., McGirt M.J., Farber S.H., Amin A.G., Rick A.M., Suk I., Witham T.F. Accuracy of free-hand pedicle screws in the thoracic and lumbar spine: analysis of 6816 consecutive screws. *Neurosurgery*. 2011;68(1): 170-178. doi: 10.1227/NEU.0b013e3181fdfaf4.
2. Di Silvestre M., Parisini P., Lolli F., Bakaloudis G. Complications of thoracic pedicle screws in scoliosis treatment. *Spine (Phila Pa 1976)*. 2007;32(15):1655-1661. doi: 10.1097/BRS.0b013e318074d604.
3. Hicks J.M., Singla A., Shen F.H., Arlet V. Complications of pedicle screw fixation in scoliosis surgery: a systematic review. *Spine (Phila Pa 1976)*. 2010;35(11):E465-E470. doi: 10.1097/BRS.0b013e3181d1021a.
4. Modi H.N., Suh S.W., Fernandez H., Yang J.H., Song H.R. Accuracy and safety of pedicle screw placement in neuromuscular scoliosis with free-hand technique. *Eur Spine J*. 2008;17(12):1686-1696. doi: 10.1007/s00586-008-0795-6.
5. Gubin A.V., Ryabykh S.O., Burtsev A.V. [Retrospective analysis of screw malposition following instrumented correction of thoracic and lumbar spine deformities]. *Hirurgia pozvonocnika* [Spine Surgery]. 2015;12(1):8-13. (In Russian). doi: 10.14531/ss2015.1.8-13.
6. Karapinar L., Erel N., Ozturk H., Altay T., Kaya A. Pedicle screw placement with a free hand technique in thoracolumbar spine: is it safe? *J Spinal Disord Tech*. 2008;21(1):63-67. doi: 10.1097/BSD.0b013e3181453dc6.
7. Kim Y.J., Lenke L.G., Bridwell K.H., Cho Y.S., Riew K.D. Free hand pedicle screw placement in the thoracic spine: is it safe? *Spine (Phila Pa 1976)*. 2004;29(3):333-342. doi: 10.1097/01.brs.0000109983.12113.9b.
8. Fichtner J., Hofmann N., Rienmüller A., Buchmann N., Gempt J., Kirschke J.S. et al. Revision Rate of Misplaced Pedicle Screws of the Thoracolumbar Spine-Comparison of Three-Dimensional Fluoroscopy Navigation With Freehand Placement: A Systematic Analysis and Review of the Literature. *World Neurosurg*. 2018;109:e24-e32. doi: 10.1016/j.wneu.2017.09.091.
9. Kotani T., Akazawa T., Sakuma T., Koyama K., Nemoto T., Nawata K. et al. Accuracy of Pedicle Screw Placement in Scoliosis Surgery: A Comparison between Conventional Computed Tomography-Based and O-Arm-Based Navigation Techniques. *Asian Spine J*. 2014;8(3):331-338. doi: 10.4184/asj.2014.8.3.331.
10. Perdomo-Pantoja A., Ishida W., Zygourakis C., Holmes C., Iyer R.R., Cottrill E. et al. Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis of 51,161 Screws. *World Neurosurg*. 2019;126:664-678.e3. doi: 10.1016/j.wneu.2019.02.217.
11. Shree Kumar D., Ampar N., Wee Lim L. Accuracy and reliability of spinal navigation: An analysis of over 1000 pedicle screws. *J Orthop*. 2019;18:197-203. doi: 10.1016/j.jor.2019.10.002.
12. Feng W., Wang W., Chen S., Wu K., Wang H. O-arm navigation versus C-arm guidance for pedicle screw placement in spine surgery: a systematic review and meta-analysis. *Int Orthop*. 2020;44(5):919-926. doi: 10.1007/s00264-019-04470-3.
13. Gelalis I.D., Paschos N.K., Pakos E.E., Politis A.N., Arnaoutoglou C.M., Karageorgos A.C. et al. Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. *Eur Spine J*. 2012;21(2):247-55. doi: 10.1007/s00586-011-2011-3.
14. Ling J.M., Dinesh S.K., Pang B.C., Chen M.W., Lim H.L., Louange D.T. et al. Routine spinal navigation for thoraco–lumbar pedicle screw insertion using the O-arm three-dimensional imaging system improves placement accuracy. *J Clin Neurosci*. 2014;21(3):493-498. doi: 10.1016/j.jocn.2013.02.034.
15. Shin B.J., James A.R., Njoku I.U., Härtl R. Pedicle screw navigation: a systematic review and meta-analysis of perforation risk for computer-navigated versus free-hand insertion. *J Neurosurg Spine*. 2012;17(2):113-122. doi: 10.3171/2012.5.SPINE11399.
16. Tian N.F., Huang Q.S., Zhou P., Zhou Y., Wu R.K., Lou Y., Xu H.Z. Pedicle screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies. *Eur Spine J*. 2011;20(6):846-859. doi: 10.1007/s00586-010-1577-5.
17. Kosulin A.V., Elyakin D.V., Lebedeva K.D., Sukhomlinova A.E., Kozlova E.A. [Navigation template for vertebral pedicle passage in transpedicular screw fixation]. *Pediatr* [Pediatrician]. 2019;10(3);45-50. (In Russian). doi: 10.17816/PED10345-50.
18. Pan Y., Lü G.H., Kuang L., Wang B. Accuracy of thoracic pedicle screw placement in adolescent patients with severe spinal deformities: a retrospective study comparing drill guide template with free-hand technique. *Eur Spine J*. 2018;27(2):319-326. doi: 10.1007/s00586-017-5410-2.
19. Ferrari V., Parchi P., Condino S., Carbone M., Baluganti A., Ferrari M. et al. An optimal design for patient-specific templates for pedicle spine screws placement. *Int J Med Robot*. 2013;9(3):298-304. doi: 10.1002/rcs.1439.
20. Kaneyama S., Sugawara T., Sumi M. Safe and accurate midcervical pedicle screw insertion procedure with the patient-specific screw guide template system. *Spine (Phila Pa 1976)*. 2015;40(6):E341-E348. doi: 10.1097/BRS.0000000000000772.
21. Abul-Kasim K., Strömbeck A., Ohlin A., Maly P., Sundgren P.C. Reliability of Low-Radiation Dose CT in the Assessment of Screw Placement After Posterior Scoliosis Surgery, Evaluated With a New Grading System. *Spine*. 2009;34(9):941-948. doi: 10.1097/brs.0b013e31819b22a4.
22. Ma T., Xu Y.Q., Cheng Y.B., Jiang M.Y., Xu X.M., Xie L., Lu S. A novel computer-assisted drill guide template for thoracic pedicle screw placement: a cadaveric study. *Arch Orthop Trauma Surg*. 2012;132(1):65-72. doi: 10.1007/s00402-011-1383-5.
23. Kim S.B., Rhee J.M., Lee G.S., Lee H.Y., Kim T., Won Y. Computer-assisted Patient-specific Prototype Template for Thoracolumbar Cortical Bone Trajectory Screw Placement: A Cadaveric Study. *Send to Tech Orthop*. 2018;33(4):246-250. doi: 10.1097/BTO.0000000000000285.
24. Kim S.B., Won Y., Yoo H.J. Unilateral Spinous Process Noncovering Hook Type Patient-specific Drill Template for Thoracic Pedicle Screw Fixation: A Pilot Clinical Trial and Template Classification.

Spine (Phila Pa 1976). 2017;42(18):E1050-E1057. doi: 10.1097/BRS.0000000000002067.
25. Lu S., Zhang Y.Z., Wang Z., Shi J.H., Chen Y.B., Xu X.M., Xu Y.Q. Accuracy and efficacy of thoracic pedicle screws in scoliosis with patient-specific drill template. *Med Biol Eng Comput.* 2012;50(7):751-758. doi: 10.1007/s11517-012-0900-1.
26. Azimifar F., Hassani K., Saveh A.H., Ghomsheh F.T. A medium invasiveness multi-level patient's specific template for pedicle screw placement in the scoliosis surgery. *Biomed Eng Online.* 2017;16(1):130. doi: 10.1186/s12938-017-0421-0.
27. Takemoto M., Fujibayashi S., Ota E., Otsuki B., Kimura H., Sakamoto T. et al. Additive-manufactured patient-specific titanium templates for thoracic pedicle screw placement: novel design with reduced contact area. *Eur Spine J.* 2016;25(6):1698-1705. doi: 10.1007/s00586-015-3908-z.
28. Putzier M., Strube P., Cecchinato R., Lamartina C., Hoff E.K. A New Navigational Tool for Pedicle Screw Placement in Patients With Severe Scoliosis: A Pilot Study to Prove Feasibility, Accuracy, and Identify Operative Challenges. *Clin Spine Surg.* 2017;30(4):E430-E439. doi: 10.1097/BSD.0000000000000220.
29. Cecchinato R., Berjano P., Zerbi A., Damilano M., Redaelli A., Lamartina C. Pedicle screw insertion with patient-specific 3D-printed guides based on low-dose CT scan is more accurate than free-hand technique in spine deformity patients: a prospective, randomized clinical trial. *Eur Spine J.* 2019;28(7):1712-1723. doi: 10.1007/s00586-019-05978-3.
30. Wu C., Tan L., Lin X., Hu H. [Clinical application of individualized reference model of sagittal curves and navigation templates of pedicle screw by three-dimensional printing technique for thoracolumbar fracture with dislocation]. *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi.* 2015;29(11):1381-1388. (In Chinese).
31. Shah K., Gadiya A., Shah M., Vyas D., Patel P., Bhojraj S., Nene A. Does Three-Dimensional Printed Patient-Specific Templates Add Benefit in Revision Surgeries for Complex Pediatric Kyphoscoliosis Deformity with Sublaminar Wires in Situ? A Clinical Study. *Asian Spine J.* 2020 Mar 30. doi: 10.31616/asj.2019.0021.
32. Kosulin A.V., Elyakin D.V., Kornievskiy L.A., Darkovskaya A.M., Bulatova I.A., Pashko A.A. [Application of three-level navigation template in surgery for hemivertebrae in adolescents]. *Hirurgia pozvonocnika* [Spine Surgery]. 2020;17(1):54-60. (In Russian). doi: 10.14531/ss2020.1.54-60.
33. Kovalenko R.A., Kashin V.A., Cherebillo V.Y., Sharifov R.M., Mironchuk R.R., Akopov A.L., Ivanov V.A. [Determination of optimal design of navigation templates for transpedicular implantation in the cervical and thoracic spine: results of cadaveric studies]. *Hirurgia pozvonocnika* [Spine Surgery]. 2019;16(4):77-83. (In Russian). doi: 10.14531/ss2019.4.77-83.

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