APPLICATION OF PATIENT-SPECIFIC 3D NAVIGATION TEMPLATES FOR PEDICLE SCREW FIXATION OF SUBAXIAL AND UPPER THORACIC VERTEBRAE

R.A. Kovalenko[1], V.V. Rudenko[2], V.A. Kashin[1], V.Yu. Cherebillo[1], D.A. Ptashnikov[2]
[1]*Almazov National Medical Research Centre, St. Petersburg, Russia;*
[2]*Russian Scientific Research Institute of Traumatology and Orthopedics n.a. R.R. Vreden, St. Petersburg, Russia*

Objective. To analyze the safety and accuracy of pedicle screw placement in the subaxial cervical and upper thoracic spine using patient-specific 3D navigation templates.

Material and Methods. The study included 16 patients who underwent transpedicular implantation of screws in the subaxial cervical and upper thoracic vertebrae using patient-specific 3D navigation templates. A total of 88 screws were installed. All patients underwent preoperative CT angiography to assess visualization of the vertebral artery. Customized vertebral models and navigation templates were created using 3D printing technology. Models and templates were sterilized and used during surgery. The results of screw implantation, as well as the safety and accuracy of the placement, were assessed by postoperative CT.

Results. The average deviation from the planned trajectory was 1.8 ± 0.9 mm. Deviation was estimated as class 1 (<2 mm) for 57 (64.77 %) screws, class 2 (2–4 mm) for 29 (32.95 %), and class 3 for two (2.27 %). The safety of screw implantation of grade 0 (the screw is completely inside the bone structure) was in 79 (89.77 %) cases, of grade 1 (<50 % of the screw diameter perforates the bone) – in 5 (5.68 %), and of grade 3 – in 2 (2.27 %).

Conclusion. Using 3D navigation templates is an affordable and safe method of installing pedicle screws in the cervical and upper thoracic spine. The method can be used as an alternative to intraoperative CT navigation.

Key Words: 3D printing, navigation, transpedicular fixation, template.

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Transpedicular fixation in the cervical spine is not a common practice. Despite the fact that this technique demonstrates the best biomechanical indicators of strength, the difficulty in implementing a correct implantation process and risks to damage neurovascular structures limit its clinical use [1–5].

Implantation of screws in the upper thoracic spine is less risky, but it is complicated due to a small diameter of pedicles and difficulty in intraoperative X-ray visualization because of the projection of the shoulder joints.

The development of various methods of spinal navigation makes it possible to reduce risks related to screw placement. The use of patient-specific navigation templates created on a 3D-printer on the basis of preoperative computer modeling is one of such methods.

The objective of the study was to analyze the safety and accuracy of transpedicular screw placement in the subaxial cervical and upper thoracic spine using patient-specific 3D navigation templates.

Material and Methods

The study included 16 patients with oncological diseases, degenerative diseases, and traumas of the cervical and thoracic spine, who had undergone transpedicular implantation of screw systems using patient-specific 3D navigation templates in 2017–2018. We assessed the screws implanted in the subaxial cervical and upper thoracic vertebrae (Table 1). All the patients signed the informed consent statement, and the study was approved by the Ethics Committee.

Design and manufacture of navigation templates. We modeled a relief of vertebra surface structures on the basis of the MSCT/CT angiography data using the Inobitec DICOM Viewer software package (v. 1.9.0). The model was finally processed using the Blender 2.78 program: secondary structures and artifacts were removed, and errors were corrected using spatial paradoxes. The same program was used to determine the optimal screw entry points and trajectory, contact faces between the navigation template and the vertebra on the basis of the ready model, and the final template was designed (Fig. 1).

In case of multisegmental fixation, templates were designed for each vertebra separately in order to avoid any displacement of landmarks and congruence breaking, if the vertebrae move relative to each other during the laying out of the patient on the operating table, during the reduction actions, and other mechanical actions.

The model and template were sliced with the Cura 3.5.1 program, and a Gcode print file was formed. The printing was performed using the technology of fused deposition modeling (Infitary M508 printer) with biodegradable PLA-plastic (lactic acid biopolymer) as a material.

It is possible to model templates with additional support on enlarged spinous processes of some vertebrae, thus increasing the template stability and, consequently, the implantation accuracy and safety. The model was used for preoperative planning, detailed examination of the 3D anatomy, and determining the surgical approach. The implantation and the estimation of the planned screw positions were also simulated (Fig. 2).

The models and templates were sterilized with hydrogen peroxide plasma.

Intraoperative use. A conventional posteromedial approach was used. Thorough skeletonization of the contacting faces of the template and vertebra is an important factor in this case. The template placement should be accompanied by a certain tactile sensation of a firm contact. At any moment, the surgeon can remove the template out of the wound and compare it with the 3D-model for the visual and tactile confirmation of the accuracy of its positioning. The canal for the screw insertion was shaped with a drill or a Kirschner's wire through the tube guides (Fig. 3).

The safety grade of screw implantation was determined by the data of postoperative CT at the level of pedicle in the coronal and axial projections according to the following criteria [6]: Grade 0: the screw is completely inside the bone structure; Grade 1: the screw partially perforates the bone structure, but >50 % of the screw diameter is inside the bone; Grade 2: the screw perforates the bone structure, and >50 % of the screw diameter is outside the bone, Grade 3 (penetration): the screw is completely outside the bone (Fig. 4).

Implantation accuracy class was determined in two planes (axial and sagittal) at the most distal points of the intersection of the planned trajectory and the screw axis extension with the vertebral body by means of the CT images overlapping (of the planned preoperative trajectory and of the actual screw axis) using the DICOM format of the Mimics 3D software package (Fig. 5).

Implantation accuracy was assessed according to the following criteria [6]: Class 1: the screw axis deviates by < 2 mm from the planned trajectory; Class 2: the screw axis deviates by >2 mm but not less than by 4 mm; Class 3: the deviation is more than 4 mm.

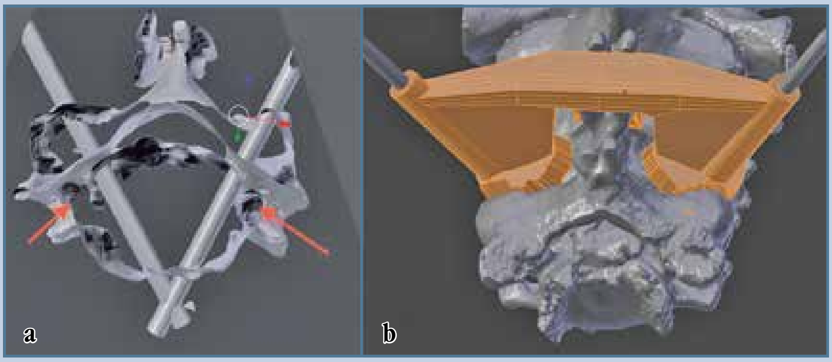

Fig. 1
Stages of the navigation templates design: **a** – determining the screw insertion trajectory in 3D format of the processed STL file, red arrows point to *ff. vertebrales*; **b** – creating the final design of the navigation templates

Results and Discussion

The mean deviation grade of the inserted screws was 1.8 ± 0.9 mm. According to accuracy assessment, 97 % of the screws were inserted in accordance with Classes 1 and 2. The deviation of Class 2 was observed in 29 cases (32.95 %), that of Class 3 in 2 cases (2.27 %; Table 2).

Safety grade was estimated as satisfactory (Grades 0 and 1) in 84 cases (95.5 %). Grade 2 was determined for three screws (3.41 %), and Grade 3 was determined for one screw (1.14 %). No neurovascular complications related to screw implantation were revealed. The safety estimation results are given in Table 3.

The performed studies demonstrate the safety of transpedicular fixation in the cervical spine, thus allowing reduction maneuvers depending on types of deformities. At the same time, this technique is risky and complicated for execution because of a small diameter of pedicles, close proximity to the vertebral artery, the spinal cord, spinal roots, and other factors [1–5]. Due to these reasons, the researchers still continue to search for technical solutions, which would be able to increase implantation accuracy and safety.

Various modifications of the free-hand method (laminotomy involving direct visualization of the pedicle, determination of the optimal coordinates of the entrance point and trajectory angles, pedicle cannulation, etc.) do not ensure sufficient safety and greatly depend on the experience and personal skills of the surgeon [7–10].

Intraoperative CT navigation is considered to ensure better safety, nevertheless, many researchers show different types of screw malpositioning, when this method is used. Uehara et al. [11] analyzed the screw implantation accuracy in the C2–L5 vertebrae using intraoperative CT navigation. Of 3413 screws that were

Table 1
Inserted screws distribution (n = 88) by implantation levels

Level	Screws, n
C4	4
C5	12
C6	12
C7	16
T1	20
T2	20
T3	4

inserted, 6.9 % were judged as Grade 2 or 3 of perforations (5.0 % for C2, 11.4 % for C3–C5, 7.0 % for C6–C7, and 10.4 % for T1–T4).

Shimokawa et al. [6] described the results of comparing navigation methods using preoperative (first group) and intraoperative (second group) CT data. A total of 762 screws were inserted in the spine level of C2 to T3. Safety Grade 0 (the screw was completely contained within the bone) was 93.6 % for the first group and 97.1 % for the second group. The perforation of more than half of the screw diameter was observed in 3.3 % cases in the first group and 0.6 % in the second group. In total, 5.0 % of screws were found to perforate the cortex of the pedicle.

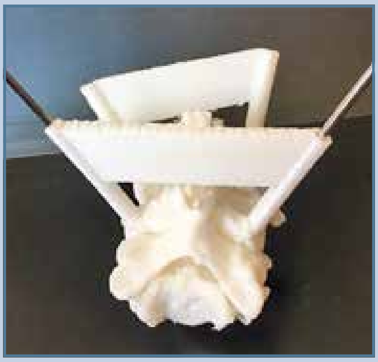

Fig. 2
Preoperative computer modeling of screw insertion using the 3D model

Fig. 3
Intraoperative use of the template

The use of computer-modeled drill guide templates is one of the methods of the 3D printing technologies in the spinal surgery. This technique has been actively developed for the last ten years. In 2007, Owen et al. [12] demonstrated the potential use of customized drill guide templates for transpedicular implantation in the cervical spine. The drill template was used to guide drilling of a pilot hole, and a pedicle screw was placed in the pilot hole in the C5 vertebra on a cadaver cervical spine.

In 2009, Lu et al. [13] published their results, when in total, 88 screws were inserted transpedicularly in 25 patients into levels C2–C7 using navigation templates. Of 88 screws, 71 screws were inserted with safety Grade 0, fourteen screws were inserted with Grade 1, and three screws were inserted with Grade 2. No complications were observed. Radiography was used only for screw insertion control after the surgery. The required average time of one screw implantation was about 80 s.

In 2012, Kawaguchi et al. [14] presented their study results describing transpedicular screw implantation in the cervical spine using navigational templates. The first part of the study analyzed the accuracy of screw insertions using 3D full-scale models of the patient's spine. The penetration of the lateral part of the C3 pedicle was observed in one case due to its small diameter. The second part of the study described clinical trials. The authors analyzed this method in 11 patients. In total, 44 screws were implanted: 16 screws were inserted in C2, ten screws were inserted in C3, two screws were inserted in C4, five screws were inserted in C5, three screws were inserted in C6, and eight screws were inserted in C7. The analysis showed that 42 screws were completely inside the bone structures, two screws perforated the bone wall by <2 mm without injury of the vascular or nerve structures. No complications were recorded.

A similar study was carried out by Kaneyama et al. [15]. They placed 80 midcervical pedicle screws in the subaxial cervical spine for 20 patients using patient-specific 3D screw guide templates. The mean screw deviation from the planned trajectory was 0.29 ± 0.31 mm (0.0–1.6 mm); 78 screws were completely inside the bone, and two screws were outside the bone structure by less than half a diameter. The authors proposed to use the following three types of templates for each screw: location template for determining the entrance point, drill guide template for drilling holes for

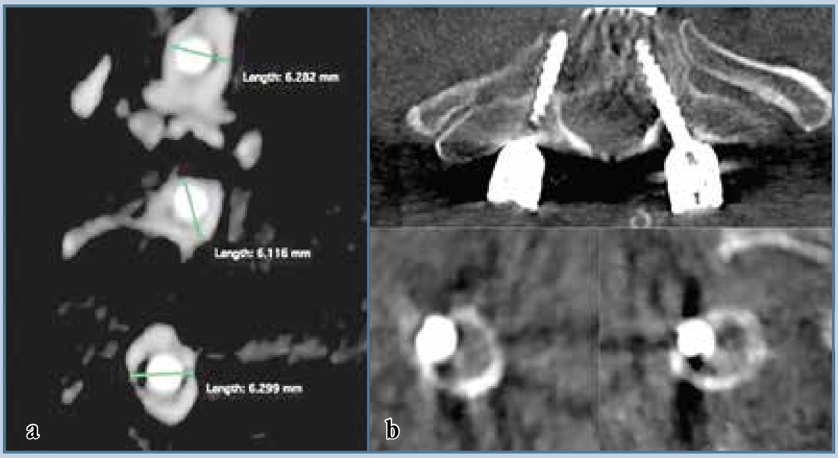

Fig. 4
Assessing the implantation safety according to the postoperative CT data: **a** – transpedicular screws are in C4–C5–C6 (Grade 0); **b** – screws are in T1 (Grade 1)

Fig. 5
Assessing the implanted screws deviation from the planned trajectory by comparing the postoperative CT data and the preoperative computer modeling

Table 2
Screw distribution by deviation grade according to the SGT system, n (%)

Level of implantation	Class 1 (<2 mm)	Class 2 (2–4 mm)	Class 3 (>4 mm)
C4	3 (75.0)	1 (25.0)	–
C5	3 (25.0)	9 (75.0)	–
C6	6 (50.0)	5 (41.7)	1 (8.3)
C7	12 (75.0)	3 (18.8)	1 (6.3)
T1	13 (65.0)	7 (35.0)	–
T2	17 (85.0)	3 (15.0)	–
T3	3 (75.0)	1 (25.0)	–

Table 3
Screw distribution by the placement safety grade, n (%)

Level of implantation	Grade 0	Grade 1	Grade 2	Grade 3 (penetration)
C4	4 (100.0)	–	–	–
C5	9 (75.0)	2 (16.7)	1 (8.3)	–
C6	10 (83.3)	1 (8.3)	1 (8.3)	–
C7	14 (87.5)	1 (6.3)	–	1 (6.3)
T1	19 (95.0)	1 (5.0)	–	–
T2	19 (95.0)	–	1 (5.0)	–
T3	20 (100.0)	–	–	–

screws, and screw guide template for screw inserting.

In 2017, a group of researchers from the Philippines [16] presented the results of assessing the accuracy of screw insertions in the cervical spine *in vitro*. Contrary to the above mentioned studies, the authors did not design computer-modeled navigational templates, they molded them manually from polymethylmethacrylate dental cement over the 3D printed models of the vertebrae from cadaveric material. Fifty subaxial screws were inserted in C3–C7 vertebrae. Forty seven screws were inserted with the deviation of Grade 0, two screws were inserted with Grade 1, and one screw was inserted with Grade 2. According to the authors' opinion, the deviation was caused by incomplete skeletonization of the vertebrae and, consequently, there was no snug fit between the template and vertebra, which led to the displacement of the planned entrance point. It should be mentioned that such approach is performed without any virtual planning of the insertion trajectory: a wire or a drill is inserted into the model of the vertebra under visual control, and afterwards a mold is taken. On the other side, the process is simplified because there is no necessity of a computer modeling of templates, which requires good skills in 3D design and specialized computer software. The function to create STL-models of the spine based on the DICOM data of MSCT is incorporated in many programs.

In Russia, there was a report [17] on the use of 3D navigational templates for cervical screw insertion in three patients. According to the CT control the screws deviated from the planned trajectory by <2 mm, no perforation of bone structures was observed.

Previous publications and our study demonstrate a sufficiently high safety of transpedicular fixation in the cervical spine using navigational templates. This technique simplifies and standardizes complicated types of implantation, thus making them less dependent on the experience and personal skills of the surgeon as compared with the freehand method. Safety Grades 0 and 1 are achieved in 95.5 % of cases, which in general corresponds to the results of intraoperative CT navigation.

Navigation guide templates can be designed and produced within 24 hours. In comparison with CT navigation, the cost of the necessary equipment is substantially lower, and guides can be used in any operating room, distantly from the production place. This is an additional advantage in terms of logistics. It should be also mentioned that the absorbed radiation dose of the personnel and patients is reduced, because the navigation is not based on intraoperative radiology data. Nevertheless, some important conditions should be observed for a correct use of this technique. A template should be designed in order to minimize the probability of its intraoperative deformation, breakdown or displacement. We prefer to create templates with the support upon the vertebral arches and joints, as well as upon the spinous processes, and to fasten guiding tubes with stiffening ribs. In order to avoid landmark displacements in case the vertebrae move relative to each other, separate templates should be designed for each vertebra with the support points only upon the vertebra, where the screw would be inserted. While forming a drilling channel, the assistant should thoroughly press the template to the vertebra in order to avoid any sliding at the moment, when the wire passes through the cortical layer. Special attention should be paid to soft tissues extraction at the contact zone between the template and structures of the vertebra, this must be done more carefully than through the conventional approach, and it takes more time.

Conclusion

Using 3D navigational templates is an affordable and safe method of inserting transpedicular screws in the cervical and upper thoracic spine. The method can be used as an alternative to intraoperative CT navigation, because according to earlier published studies, the parameters of the insertion safety are similar and even exceed those as compared with the free-hand method. In order to increase the accuracy of the efficiency and safety parameters of the method, comparative randomized studies should be carried out involving more patients.

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Address correspondence to:
Kovalenko Roman Aleksandrovich
2 Akkuratova str., St. Petersburg, 197341, Russia,
Almazov National Medical Research Centre,
roman.kovalenko@my.com

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Roman Aleksandrovich Kovalenko, MD, PhD, neurosurgeon, Neurosurgery Department 6, Almazov National Medical Research Centre, 2 Akkuratova str., St. Petersburg, 197341, Russia, ORCID: 0000-0002-7940-7086, roman.kovalenko@my.com;
Viktor Vadimovich Rudenko, MD, PhD, head of the Neurosurgery Department 3, Russian Scientific Research Institute of Traumatology and Orthopedics n.a. R.R. Vreden, 8 Akademika Baykova str., St. Petersburg, 195427, Russia, VictorRudenko@mail.ru;
Vasily Andreyevich Kashin, resident, Chair of Neurosurgery, Almazov National Medical Research Centre, 2 Akkuratova str., St. Petersburg, 197341, Russia, ORCID: 0000-0002-0626-1565, spin3d@yandex.ru;
Vladislav Yuryevich Cherebillo, DMSc, Prof., scientific director of the Neurosurgery Department 6, Almazov National Medical Research Centre, 2 Akkuratova str., St. Petersburg, 197341, Russia, ORCID: 0000-0001-6803-9954, cherebillo@mail.ru;
Dmitry Aleksandrovich Ptashnikov, DMSc, Prof., Head of the Department of Spinal Pathology, head of the Department of Neuroorthopaedics and Bone Oncology, Russian Scientific Research Institute of Traumatology and Orthopedics n.a. R.R. Vreden, 8 Akademika Baykova str., St. Petersburg, 195427, Russia, ORCID: 0000-0001-5765-3158, drptashnikov@yandex.ru.