TRANSPEDICULAR FIXATION OF THE SPINE WITH TWO-LEVEL NAVIGATION TEMPLATES FOR NARROW PEDICLES

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Objective. To assess the correctness of transpedicular screw insertion in thoracic and lumbar vertebrae using two-level navigation templates for narrow pedicles.

Material and Methods. Two-level navigation templates were used in surgical treatment of four patients aged 14–17 years with scoliotic deformity and multiple pedicles of small width (less than 4.35 mm). In each patient, the least favorable zones were selected for implantation using navigation templates. The rest of planned pedicle screws were inserted using free-hand technique. All patients underwent CT scanning postoperatively. Screws inserted to pedicles less than 4.35 mm in width were classified as correctly placed if they did not extend beyond the medial cortical layer by more than 2 mm.

Results. Out of 68 pedicles planned for screw placement, 42 were narrower than 4.35 mm. In the pedicles difficult for implantation, 29 screws were inserted using navigation templates and 13 by free-hand technique. Screws classified as correctly placed were 28 from those inserted with navigation templates and 9 from those implanted by free-hand technique. Difference in results of screw placement in narrow pedicles with navigation templates and by free-hand technique was statistically significant (exact Fisher test, $p < 0.05$).

Conclusion. Transpedicular screw placement with two-level navigation templates in narrow pedicles is more correct than insertion by free hand technique.

Key Words: 3D-printing, navigation template, scoliosis, difficult implantation.

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Transpedicular screw fixation is a widespread method of inserting supporting elements in the treatment of spinal deformities. The narrow pedicles may be considered as a limiting factor for the application of this technique [1, 2]. Morphometric analyses indicate a wide prevalence of difficult implantation areas in spinal deformities, especially in adolescent idiopathic scoliosis [3–5]. For overcoming this limitation, a planned in-out-in technique of screw insertion was suggested [1]. Its realization by the free-hand method is considered to be technically challenging and requires a high qualification of the operating surgeon. According to Akazawa et al. [2], the use of navigation surgery has some limits if it is treated for some morphometric features of the pedicle. An alternative method of transpedicular screw precise positioning is the application of individual navigation templates generated by 3D printing.

The aim of the paper is to evaluate the correctness of the transpedicular screws implantation using two-level navigation templates in the vertebrae of the thoracic and lumbar spine with narrow pedicles.

Material and Methods

Two-level navigation templates were used in surgical treatment of four patients aged 14–17 years with scoliotic deformities. Their preoperative examination revealed multiple areas difficult for implantation (at least 50 % of the pedicles' width was less than 4.35 mm, corresponding to the minimum diameter of the transpedicular screw of the standard kit). Demographic, clinical, and radiological data on patients are provided in Table1.

In the preoperative planning, the width of pedicles planned for implantation was calculated according to the CT data. If the pedicle width was less than 4.35 mm, the implantation was considered to be technically difficult (Fig. 1). Two pairs of adjacent vertebrae with the lowest anatomical features were identified in each case. In order to insert transpedicular screws in these vertebrae, navigation templates were used.

DICOM data processing, design of selected adjacent vertebrae virtual models, determination of optimal trajectories, and creation of navigation templates were made using free access software (Slicer, Autodesk MeshMixer, and Blender). A two-level template was created in the form of a base plate carrying the impress of the laminae of the corresponding vertebrae (spinous, transverse and articular processes were not used as a contact area), and four guide tubes of 60 mm in length (Fig. 2). The guide tubes were disposed to leave a gap of at least 2 mm between the tube and the surface of the vertebra. Models of the vertebrae and navigation templates were printed on a fused deposition modeling

Table 1

Summary of sex and age and clinical and radiological characteristics of patients included in the study

Patient	Sex	Age, years	Diagnosis	Magnitude of primary curve (Cobb's degrees)
1st	F	17	Adolescent idiopathic scoliosis (Lenke 5BN)	43
2ns	F	14	Type 1 neurofibromatosis	55
3rd	F	14	Smith – Lemli – Opitz syndrome	48
4th	F	14	Atypical idiopathic scoliosis	38

(FDM) 3D printer from polylactic acid (PLA) filament.

Navigation templates and 3D models of the selected pairs of vertebrae were subjected to low-temperature sterilization. Then, they were used intraoperatively. After careful skeletonization of the posterior structures, pairs of vertebrae planned for navigated implantation were identified by bone markers. The base plate of the navigation template was placed on the posterior structures of the corresponding vertebrae. The stability was checked, and transpedicular routes were formed via guide tubes with a drill of 100 mm in length. A probe was used to control the integrity of the bone walls.

Transpedicular screws, 4.35 mm in diameter, were inserted on the formed routes. The remaining planned screws were inserted by free-hand technique.

Following the surgery, all patients underwent CT scans. The position of the screws was evaluated according to the 2 mm increment grading system [6]: class 0 – intraosseous screw insertion; class 1 – the screw penetrates the cortical layer no more than 2 mm; class 2 – the screw penetrates the cortical layer by 2–4 mm; class 3 – the screw penetrates the cortical layer more than 4 mm. If the pedicle width was more than 4.35 mm, the correctness criterion was regarded to be of classes 0 and 1. Screws inserted to pedicles less than 4.35 mm in width were classified as correctly placed if they did not extend beyond the medial cortical layer by more than 2 mm (Fig. 3).

The statistical analysis was carried out on the Statistica 12 software (StatSoft. Inc). The statistical significance of differences in the correctness of implantation using a navigation template and free-hand technique with pedicle width less than 4.35 mm was defined using Fisher exact test. Statistically significant differences were shown by the value of the exact Fisher criterion less than 0.05.

Results

The data concerning the dimensional parameters of the pedicles planned for implantation during preoperative planning, as well as the pairs of vertebrae selected for navigation templates, is given in Table 2. The insertion of two supra-laminar hooks was also planned (patient 2: T4 and T5 vertebrae in the right).

Forty two out of 68 pedicles planned for insertion of transpedicular screws had width less than 4.35 mm. Two pairs of adjacent vertebrae (32 screws in total) were chosen for implantation using navigation templates in each patient. It should be noted that in three cases the pedicle width was more than 4.35 mm. Thirty six screws were planned for implantation using the free-hand technique. In this group of support elements, the pedicle width was less than 4.35 mm in 13 cases. Therefore, 29 screws implanted using a navigation template and 13 screws inserted by the free-hand technique were ranked as difficult for implantation.

In the course of surgical interventions, all the planned transpedicular screws were inserted (Fig. 4). There were no evidence of neurological or other implantation-related complications.

According to the 2-mm increments grading system, 68 installed screws were divided as follows: class 0 – 11; class 1 – 44; class 2 – 8; class 3 – 5. During the assessment of the insertion correctness, considering the pedicle width less than 4.35 mm, the position of 61 screws was determined to be correct. 7 screws were found to be placed incorrectly.

The distribution of 2-mm increments system by classes and the correctness evaluation of transpedicular screws

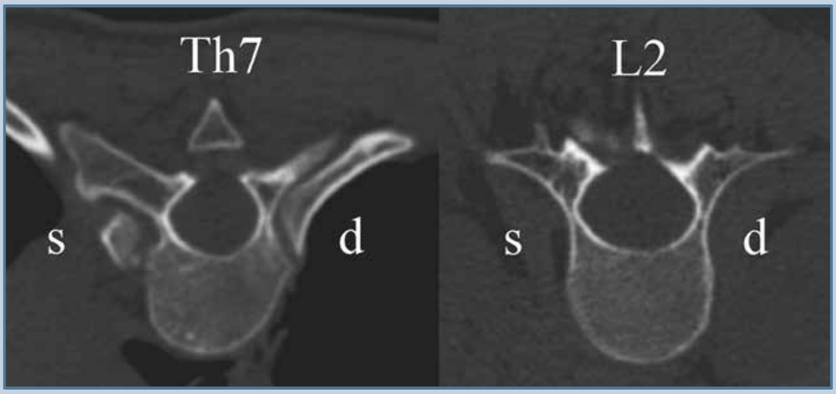

Fig. 1
Preoperative CT scans of vertebrae with small width of pedicle

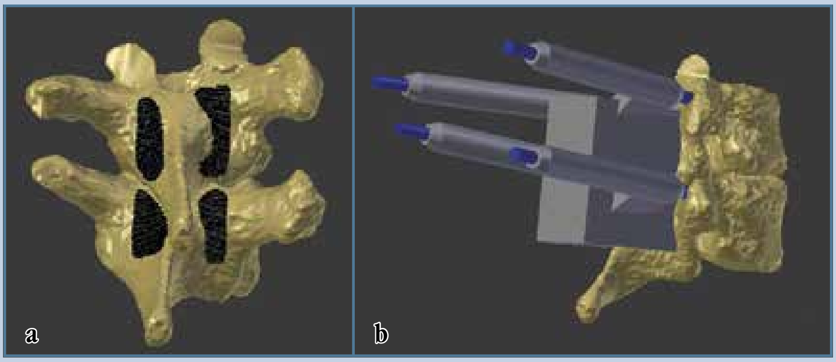

Fig. 2
Navigation template design: **a** – contact area; **b** – ready-made virtual model

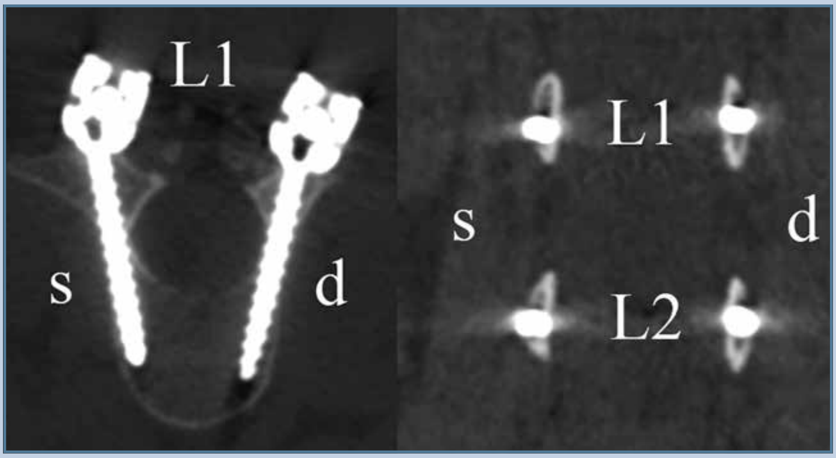

Fig. 3
Results of screw implantation using navigation template

positioned in difficult areas are given in Table 3.

Statistical analysis of screws insertion in difficult areas showed the significant difference in use of the navigation template and free-hand technique (Fisher's exact test, $p < 0.05$).

Discussion

Today, a wide experience has been collected of using navigation templates in spinal surgery. It should be noted that most of the research is dedicated to the instrumental fixation of the cervical spine. The data concerning 3D printing used in surgeries on the thoracic and lumbar spine is less widely presented [7–9]. However, a number of papers report on the successful application of this approach in the treatment of adolescent idiopathic scoliosis [10–17], deformities associated with malformations [12–15, 18, 19], neuromuscular diseases [13, 20], post-tuberculosis kyphosis [12], Strumpell-Marie disease [21], ossification of the posterior longitudinal ligament [22], as well as in oncological [22, 23] and degenerative [24] lesions and fractures of the vertebrae [23, 25].

Comparative studies prove the advantages of implantation using navigation templates over the free-hand technique [12, 14, 16, 23, 26, 27].

The design of navigation templates is presented by a considerable number of options. The classification proposed by Kim et al. [25] distinguishes unilateral and bilateral templates, considering the variant of contact with the laminae (platnar and in the form of a hook), the degree of contact with the spinous process (no contact, limited contact, full contact), as well as the use of one or more templates during implantation of each screw. It should be noted that we were able to find only two papers describing the use of unilateral navigation templates in the thoracic and lumbar areas [14, 25]. The data were published in 2016–2017. In other papers, only bilateral designs were mentioned. Apparently, unilateral navigation templates are not used today.

In our opinion, it is more relevant to systematize the design of navigation templates depending on the construction of the base plate and the guide element. The base plate should provide stable and unambiguous positioning of the template on the posterior vertebral structures. The stability is mainly driven by the length of the template along two axes: transverse and craniocaudal. In that way, Kokushin et al. [18] reached a stable position of the template with a limited contact area only in 5 out of 10 cases. On the other hand, the excess contact area requires extensive dissection of soft tissues and complicates visualization [18]. The inclusion of the spinous process edges, with its certain configuration, in the contact area may result in the inability to place the template on the posterior structures [13]. Many authors have successfully used the top of the spinous process as a support point [12, 13, 15, 27–29]. Practically all the researchers used single-level templates [12, 13, 15–18, 22–24, 26, 27, 29], since the risk of positioning inaccuracy is minimized due to the displacement of adjacent vertebrae. Moreover, there is data concerning the successful use of templates covering two [10, 14], and under certain conditions – three [19] and more levels [11]. We believe that the best way to ensure a sufficient length of the

Table 2

The width of pedicles planned for the spinal implantation

Vertebra	The width of a pedicle, mm							
	patient 1		patient 2		patient 3		patient 4	
	in the left	in the right	in the left	in the right	in the left	in the right	in the left	in the right
T4	–	–	**4.0**	*	–	–	–	–
T5	–	–	**3.5**	*	–	–	–	–
T6	–	–	**2.4**	**2.5**	–	–	–	–
T7	**3.1**	**2.9**	**1.4**	**1.6**	–	–	–	–
T8	**3.3**	**3.3**	**1.6**	**2.1**	–	–	–	–
T9	**3.5**	**2.6**	**3.1**	**3.4**	**1.4**	**3.2**	**2.6**	**2.7**
T10	4.6	**3.9**	**4.2**	**4.2**	**2.9**	4.4	**3.4**	**3.0**
T11	**3.5**	6.8	6.3	7.0	4.5	6.5	5.4	**4.3**
T12	**2.0**	6.2	7.8	6.2	**4.0**	**3.8**	4.4	4.7
L1	**2.1**	**3.1**	**3.8**	5.1	4.4	**2.5**	**2.9**	**2.3**
L2	**3.3**	**3.7**	4.5	6.1	**4.3**	4.9	**2.8**	**2.3**
L3	4.7	5.7	–	–	7.1	7.8	5.8	5.1
L4	–	–	–	–	–	–	5.5	6.6
Areas planned for implantation, n	18		20		14		16	
Difficult areas for implantation, n	13		13		7		9	

The pedicles with a width less than 4.35 mm are highlighted in bold, the cells corresponding to the vertebrae planned for implantation via the navigation template are highlighted by the background, the areas planned for the supra-laminar hooks' insertion are marked with*.

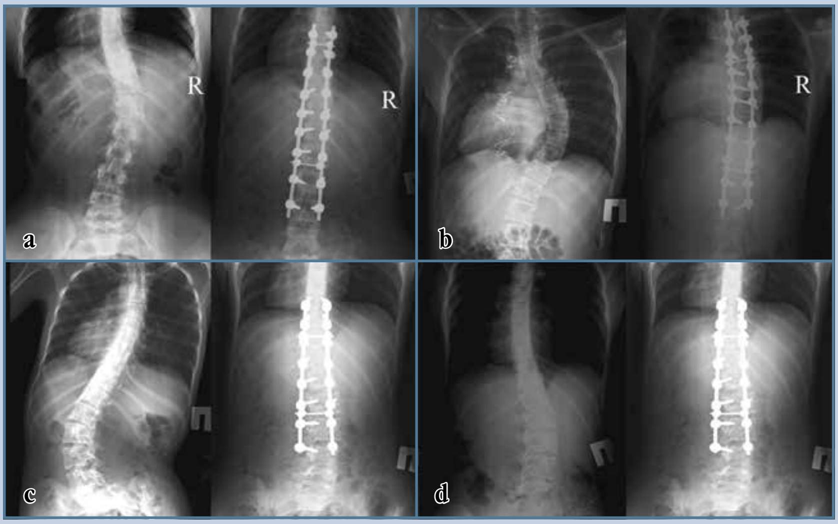

Fig. 4

Pre- and postoperative spondylograms of patients included in the study: **a** – patient 1; **b** – patient 2; **c** – patient 3; **d** – patient 4

base plate along the craniocaudal axis is to use a two-level template contacting the laminae of two adjacent vertebrae.

The guide element design depends on the instrument used by the operating surgeons to form the transpedicular route. Most of the authors are in favor of a drill equipped with a burr [12, 13, 15, 18, 19, 23–25, 28] or Kirschner wire [17, 27]. An awl application is described by a smaller number of papers [10, 14, 16, 26, 29]. As a rule, the guide is a hollow cylinder, the diameter of which matches the working part of the instrument used. We use a cylinder of specific length and position on the template to prevent passage the drill to a depth exceeding the planned one. If for some reason it is preferable to use an awl, a guide element of this type inevitably disrupts the tactile sensation of the operating surgeon [10]. In this regard, the one should consider a construction by Chen et al. [30] for atlantoaxial fixation consisting of a ring surrounding the entrance point and a narrow cylinder located parallel to a given route. In the papers of 2013 and 2017, it is reported about the sequential use of two or more templates for different stages of the surgery [11, 22]. However, this practice is not mentioned in later papers. It makes way for modifiable directional elements: a cylinder with a

Table 3

Assessment of the position of transpedicular screws implanted in vertebrae with pedicle width less than 4.35 mm

Technique of screw insertion	Screw position according to 2-mm increment grading system				Screw position correctness		Total
	class 0	class 1	class 2	class 3	correct	incorrect	
Navigation template	–	25	4	–	28	1	29
Free-hand	–	6	4	3	9	4	13
Total	0	31	8	3	37	5	42

wide hole (for screw insertion) and a removable adapter for the awl [26] or an open cylinder with a twisted-off external part [29]. Most authors use the template only for the formation of the bone canal into which the transpedicular screw is inserted without additional equipment [10, 12–19, 23–25, 27, 28].

Various 3D printing techniques are used for the production of navigation templates: fused deposition modeling [12, 17, 23, 28], selective laser sintering [20], stereolithography [11, 14, 15, 18], and PolyJet dusting [13, 22, 25]. From our point of view, the use of fused deposition modeling is most economically rational. Specific position is taken by the production of navigation templates of titanium [21, 31]. Due to different physical features of the metal template it should be compared with plastic products with caution. During the virtual model design of the navigation template, a number of authors use various non-specialized (universal) 3D editing tools [14, 16, 17, 19, 23, 26, 28, 29]. It is obvious that the choice of a specific software does not make a significant difference. Most papers do not describe the degree of involvement of the surgeon in the navigation template development. There are recommendations on the interaction between the medical and engineering teams [21]. From our point of view, the development of 3D modeling skills by the operating surgeon to the required level will make the preparation for the surgery faster and more effective.

Conclusion

In case of a narrow pedicle, the implantation of transpedicular screws using two-level navigation templates is more correct comparing to the free-hand technique.

Limitations of the study: a small number of cases and a retrospective design.

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