TRANSPEDICULAR IMPLANTATION USING A TWO-PART NAVIGATION TEMPLATE IN EXTREMELY SMALL PEDICLES

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Objective. To explore results of transpedicular screws insertion in extremely small pedicles using two-part navigation template.
Material and Methods. Eleven consecutive patients with spinal deformities were included in the study. During surgery pedicle screws were implanted using two-part navigation templates with metallic adapter that allow to guide screw insertion as well as pedicle drilling (total of 98 screws including 60 screws in pedicle width lesser than 3.5 mm). Retrospective control group consisted of 46 patients treated using common design navigation templates that guide pedicle drilling only (total of 294 screws including 106 screws in pedicle width lesser than 3.5 mm). Malpositions with "empty" correct transpedicular channel and without one were reported separately.
Results. In extremely small pedicles malposition without "empty" transpedicular channel (due to navigation template misplacement) rates were similar in both groups (8.3 % vs. 8.5 %; $p > 0.05$). Meanwhile malposition with "empty" transpedicular channel (because of secondary screw deviation) rate was significantly less in two-part template group than in common design template group (3.6 % vs. 17.5 %; $p < 0.05$).
Conclusion. In pedicle width less than 3.5 mm application of two-part navigation template guiding transpedicular channel drilling and screw insertion allows to reduce the rate of malposition due to secondary screw deviation significantly, while the difference in malposition rate because of template misplacement is insignificant as compared with navigation template of common design.
Key Words: 3D-printing; navigation template; difficult implantation.
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Numerous studies [1–3] have confirmed the efficiency and safety of patient-specific navigation templates for bone canal formation during pedicle screw placement. However, in some series, the malposition rate reaches 7–8 % [4–6]. Analysis of our own findings showed that most malpositions occurred when screws were placed in vertebrae with extremely small pedicles (less than 3.5 mm) [7]. Two types of malposition were also revealed: with and without a clearly detectable "empty" correct transpedicular channel near the screw (Fig. 1).

This finding resulted in the following working hypothesis: deviation from the planned trajectory may occur directly during screw placement, and modification of the navigation template to control both channel formation and implant guidance would reduce the incidence of malposition at extremely small pedicles.

The objective is to explore results of pedicle screw placement in extremely small pedicles using a two-part navigation template.

Material and Methods

The study included 11 patients aged 11–17 years (all female) with spinal deformities who underwent transpedicular implantation using two-part navigation templates during surgery (a total of 98 screws, including 60 screws inserted into vertebrae with extremely small pedicles). As a control group, we used retrospective data from 46 patients aged 9–17 years (15 males, 31 females) who underwent implantation using standard design templates that controlled only transpedicular channel formation (a total of 294 screws, including 106 screws in pedicle width less than 3.5 mm). Preoperative CT imaging was used to assess the pedicle width. The implantation outcomes were evaluated on control postoperative CT scans using the 2-mm increment grading system [8]. The screws were considered to be correctly placed if they were located intraosseously or penetrated the medial cortex of the pedicle by less than 2 mm. In the case of malposition, the presence or lack of an "empty" correct transpedicular channel on CT was reported additionally.

The results were compared both as a whole for the study and control groups and separately for four intervals of pedicle width (less than 3.5 mm, 3.5–5.9 mm, 6.0–7.4 mm, 7.5 mm and more [7]). The proportion of misplaced screws without an "empty" channel out of the total number of implants was compared between the groups to account for the different types of malposition separately. When comparing the rate of malposition with the presence of an "empty" channel, cases without one were excluded from the sample. To identify the possibility of considering the occurrence of incorrect implantation in a certain interval of the pedicle width insignificant, a comparison was made with a virtual control group in which all screws were placed correctly.

A pedicle width was compared between groups as a whole and within two smaller intervals. Because of the small sample of vertebrae with pedicle width of 6 mm or more, comparisons in these intervals were not performed.

Designing a two-part navigation template. The previously described two-level navigation template [9] was taken as a basis (Fig. 2a). The tubular guides were modified to form cylinders with an axial channel with a diameter corresponding to the pedicle screw head. Notches were made in the supporting pad to prevent conflict between the screw and the navigation template (Fig. 2b).

Furthermore, an adapter was designed and manufactured of metal (SLM technology), allowing to use the same template to drill the transpedicular channel (Fig. 3).

Technique of transpedicular implantation. After skeletonization of the posterior vertebral structures planned for implantation, the supporting pad of a template was placed on them. An adapter was placed in each navigation guide in turn, and transpedicular channels were formed using a drill (Fig. 4a). After the adapter was removed, screws were placed along the guides (Fig. 4b).

Statistical processing of the data. The Mann–Whitney U test was used to compare the pedicle width in the study groups. The comparison of implantation outcomes was performed using Pearson's chi-squared test and Fisher's exact test.

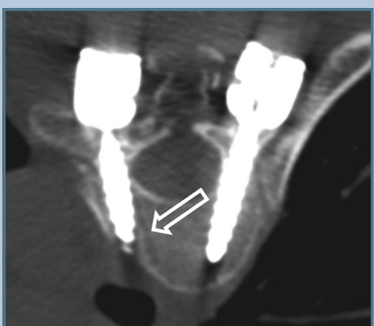

Fig. 1
Malposition with an "empty" correct transpedicular channel (marked with an arrow)

Results

Differences in the incidence of malposition between groups were generally insignificant; significant differences were proved only for the interval of pedicle width less than 3.5 mm (Table 1). The incidence of incorrect implantation in the interval of 3.5-5.9 mm was found to be negligible in both groups (when compared to virtual control groups without malposition; $p > 0.05$).

Comparison of the width of the vertebral arch pedicle in the groups showed that the size of the pedicles was significantly larger in the group with the navigation template of conventional design than in the study group. No significant differences were confirmed when comparing the pedicle width in the intervals less than 3.5 mm and 3.5–5.9 mm (Table 2).

Matching of the incidence of different types of malposition with a pedicle width of less than 3.5 mm showed that malposition with an "empty" transpedicular channel was significantly less frequent in the group using the two-part navigation template, while the incidence of malposition without this phenomenon was comparable (Table 3).

Discussion

According to the postoperative CT scans, the various types of malposition are likely to be based on two different mechanisms. In malposition without an "empty" correct transpedicular channel, the drill initially deviates from the planned trajectory that probably associated with a failure to position the navigation template. The incidence of this phenomenon at a pedicle width of less than 3.5 mm is almost identical in both groups (8.3 % and 8.5 %; $p > 0.05$), while it is negligibly rare at greater vertebral pedicle width. Thus, if the pedicle width is sufficient, the possible shift of the template is acceptable and does not result in malposition. In this regard, it is worth noting that a number of previously reported series of 3D-assisted implantations, in which 99–100 % of the screws were appropriately placed, were performed in elderly individuals suffering from degenerative conditions for which the occurrence of small-sized pedicles is uncommon [10–12]. The presence of an "empty" correct transpedicular channel indicates that the position of the template and the drill progression were correct, but the inserted screw subsequently deviated from the intended trajectory. In order to more correctly account for the incidence of this malposition mechanism, we compared the proportion of successfully placed screws to successfully formed transpedicular channels (the first type of malposition was excluded from the sample). A possible explanation for the screw deflection from the correct trajectory is as follows: although the use of a navigation template provides for the formation of a transpedicular channel under unfavorable anatomical conditions in more than 90 % of cases, this results in perforation or significant thinning of both the medial and lateral cortex of the pedicle. Consequently, in the most narrow area medial and lateral to the correct transpedicular channel, false passages separated by dense, sharpened areas of bone tissue appear. And the screw may slip into these passages during subsequent implantation (Fig. 5).

The implementation of this mechanism is particularly typical for screw placement at extremely small values of the pedicle width, but it is also possible when placing into larger vertebral pedicles. The use of a two-part navigation template that controlled both the formation of the transpedicular channel and subsequent screw placement significantly reduced the incidence of type II malposition compared with the control group (3.6 % vs. 17.5 %; $p < 0.05$).

A number of classifications of the vertebral arch pedicle based on preoperative measurements of their morphological parameters reflect a decrease in the probability of successful implantation when the dimensions of the pedicle decrease [13–17]. This correlates with the data obtained in this study. It is noteworthy that the differences in implantation results between the groups as a whole were not statistically significant.

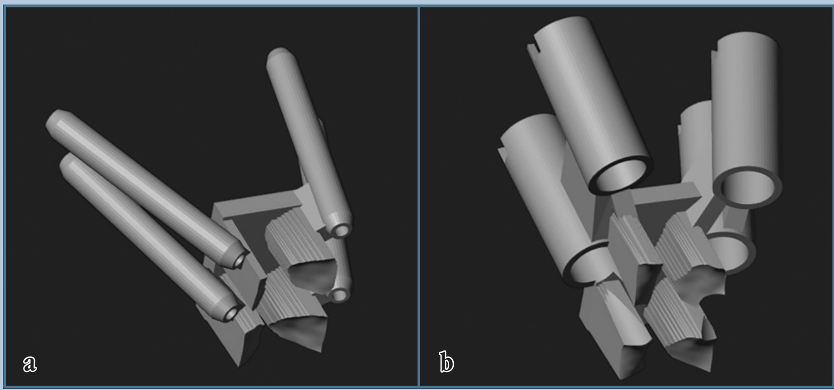

Fig. 2
Models of navigation templates: **a** – a template of a conventional design; **b** – modified navigation template

Fig. 3
Metal adapter for forming a transpedicular channel

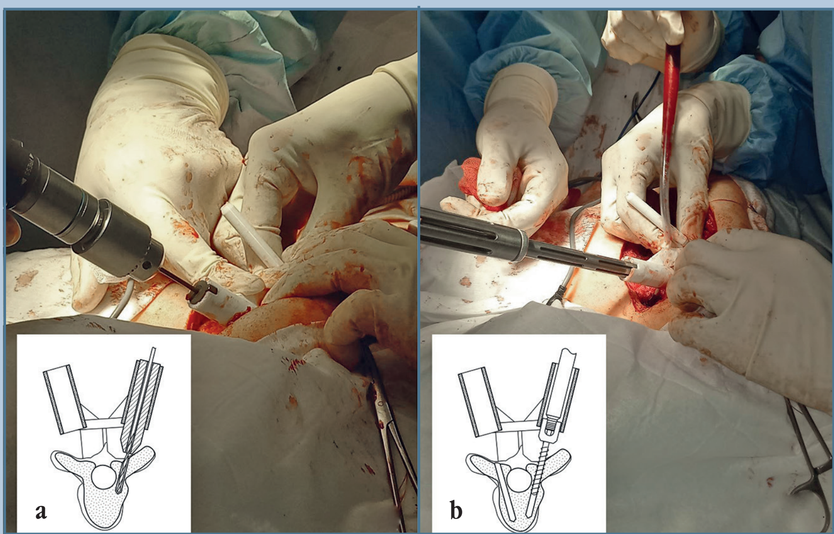

Fig. 4
Application a two-part navigation template: **a** – formation of a transpedicular channel using an adapter; **b** – screw implantation

However, a comparison of the width of pedicles between the groups showed that the width of the instrumented vertebral pedicles was significantly greater in the control group than in the study group: 3.90 [2.90–5.60] mm vs. 3.10 [2.50–4.10] mm ($p < 0.05$). Meanwhile, when the pedicle width was less than 3.5 mm, the differences in morphometric parameters between the groups were insignificant that provided a reliable assessment of the differences in the malposition rate. This circumstance necessitates a cautious approach to the results of comparative studies which do not report the absence of significant differences in the morphology of the instrumented vertebrae. However, even in the absence of differences in gender, age, pathology, and deformity extent, the comparability of pedicle width is an assumption that does not guarantee against sampling bias.

The vast majority of authors consider 3D assistance as applied only to transpedicular channel formation. Nevertheless, during the initial spread of 3D printing in spine surgery, Sugawara et al. [18] proposed an additional template for assisted screw placement, which did not become widespread. It was presumably due to the need to prepare a duplicate number of three-dimensional objects, as well as the generally satisfactory results of using navigation templates that do not control the implant direction. The current study provides grounds to say that under unfavorable anatomical conditions, 3D-assisted screw placement is necessary, and the use of an adapter provides an opportunity to use a single template both for transpedicular channel formation and directly for placement.

One of the potential disadvantages of plastic-made navigation templates is the interaction of the relatively fragile material with a metal drill that can disrupt directional accuracy as well as result in contamination of the surgical wound with plastic chips. Despite the lack of reports of complications associated with partial destruction of the template by the drill, some surgeons prefer to supplement three-dimensional objects with metal inserts in the area of the burr holes [19, 20]. In our opinion, this approach

Table 1

Incidence of malpositions in groups with application of navigation templates of different designs

Interval of pedicle width	Two-part navigation template	Template of conventional design	Statistically significant difference
Less than 3.5 mm	7/60 (11.7 %)	26/106 (24.5 %)	$p < 0.05$
3.5–5.9 mm	2/32 (6.2 %)	4/108 (3.7 %)	$p > 0.05$
6.0–7.4 mm	0/3	0/39	–
7.5 mm and more	0/1	0/20	–
Total	9/98 (9.2 %)	30/273 (11.0 %)	$p > 0.05$

Table 2

Pedicle width of instrumented vertebrae

Interval of pedicle width	Two-part navigation template	Template of conventional design	Statistically significant difference
Less than 3.5 mm	2.60 [2.00–3.10]	2.65 [2.20–3.00]	$p > 0.05$
3.5–5.9 mm	4.30 [4.00–4.95]	4.50 [3.88–5.10]	$p > 0.05$
Total	3.10 [2.50–4.10]	3.90 [2.90–5.60]	$p < 0.05$

Table 3

Incidence of different types of malposition during implantation into the pedicles with width of less than 3.5 mm

Type of malposition	Two-part navigation template	Template of conventional design	Statistically significant difference
Without an “empty” transpedicular channel	5/60 (8.3 %)	9/106 (8.5 %)	$p > 0.05$
With an “empty” transpedicular channel	2/55 (3.6 %)	17/97 (17.5 %)	$p < 0.05$

unnecessarily complicates the technology of the production of navigation templates, and the use of a reusable metallic adapter is a better solution.

The modification of the navigation template that prevents conflict between the implanted screws and the support pad involves the creation of cylindrical notches in the latter that capture the contact surface, thereby reducing the surface area of the support. Yet, the absence of significant differences between the groups in the malposition rate associated with template dislocation indicate that this modification does not affect the stability of the navigation device.

The most considerable limitation of the two-part navigation template is the dependence of its feasibility on the use of a specific model of pedicle screws with a certain head diameter. The reusable metallic adapter can be replaced with the required number of disposable plastic ones, that, however, will require additional time and material in preparation for surgery. Remarkably, the metallic adapter was manufactured using additive SLM technology, and the same tools were used for its development as for the design of the patient-specific templates. Therefore, additive manufacturing provides both the possibility of producing patient-specific navigation devices, plastic materials [21], and implants [22] with unique properties and offers a wide range of opportunities for the development of tools to meet the special tasks of spine surgery.

Limitations of study validity: small sample, retrospective control group data.

Conclusion

In pedicle width less than 3.5 mm, the application of a two-part navigation template (that guides pedicle screw insertion through a previously formed channel using a reusable metal adapter) allows to reduce significantly the rate of malposition associated with screw deviation from defined trajectory, without significant influence on the incidence of inappropriate implantation because of template misplacement.

The study had no sponsors. The authors declare that they have no conflict of interest.
The study was approved by local ethics committee of the institution. All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

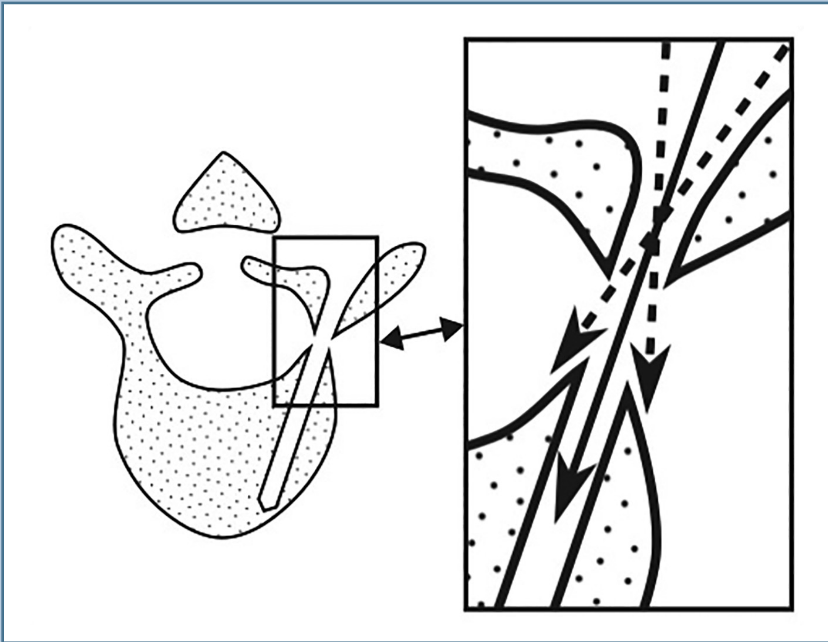

Fig. 5
Schematic drawing of the malposition mechanism with an "empty" transpedicular channel

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