SELECTIVE APPLICATION OF NAVIGATION TEMPLATES IN IDIOPATHIC SCOLIOSIS: TECHNICAL AND CHRONOMETRIC FEATURES

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Objective. To evaluate short-term result of selective navigation templates application in idiopathic scoliosis surgery.
Material and Methods. A total of 12 patients aged 14—17 years with idiopathic scoliosis were included in the study. Group A included 6 patients treated with selective application of navigation templates for pedicle screws insertion in the most difficult zones. Group B (control) included 6 patients in whom all the pedicle screws were placed with free-hand technique. Number of screws inserted was 16—20 per patient. There was no significant difference between the groups in sex, age, Cobb angle, number of vertebrae instrumented, number of pedicle screws and laminar hooks. Surgery duration, blood loss, absolute and relative correction were compared. In Group A, duration of the 3D-objects fabrication and printing, as well as pedicle screw accuracy based on 2-mm increment grading system were evaluated.
Results. Selective application of navigation templates as compared with total free-hand screw placement significantly reduced surgery duration. Difference in blood loss and deformity correction was not significant. A total of 107 pedicle screws were placed in Group A, 48 of them with navigation templates and 59 by free-hand technique. Average pedicle width in screw installation with navigation templates was 4.28 ± 1.43 mm, and in that with free-hand technique 6.53 ± 1.72 mm, with significant difference. Accurate screw placement with navigation templates and by free-hand technique were 93.7 % and 88.0 %, respectively, with no significant difference. Duration of 3D-objects manufacturing was 1419 ± 190 minutes. Active operator's involvement was required in about 10 % of the while.
Conclusion. Selective application of a pair of two-level navigation templates for most difficult pedicles in idiopathic scoliosis significantly reduces surgery duration. Difference in blood loss and deformity correction is insignificant. Refusal of total templates usage for combination of navigation templates for selected difficult pedicles and free-hand technique for the rest is an option for shortening the preoperative preparation, but provides screw placement accuracy comparable with total templates usage (92.5—97.6 % as reported).
Key Words: 3D-printing, navigation template, pedicle screw, idiopathic scoliosis.
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A high accuracy of pedicle screw placement using patient-specific navigation templates is proven by numerous modern studies [1–5]. The manufacture of such templates requires specific financial, technical, and time resources [6–9]. They are especially significant when planning an extended fixation with numerous screws. Meanwhile, it is reasonable to make them only for those spine regions in which the insertion of pedicle screws can be difficult.

Despite of the correlation between the small pedicle width and the malposition of pedicle screws confirmed in a number of publications [10, 11], there is currently no consensus on the critical pedicle width for free-hand screw placement. The most suitable criterion is a comparison of the pedicle width and the screw diameter. If the diameter of the screw exceeds the width of the pedicle, placement is considered to be difficult [12]. Morphometric analyses of vertebrae in idiopathic scoliosis have shown the gradual decrease in the width of the pedicles both on the convex and, to a greater extent, on the concave side of the deformity when approaching the apex of the curve [13, 14]. Therefore, the regions difficult for pedicle screw placement most often comprise 2–3 segments (Fig. 1).

The results of surgical treatment of idiopathic scoliosis using navigation templates were assessed in this study in terms of determining pedicle screws difficult for placement, including objectification of the time spent on preparation of the 3D objects.

Design: a retrospective cohort study.

The objective is to evaluate short-term result of selective navigation templates application in idiopathic scoliosis surgery.

Material and Methods

Patients

A total of 12 patients aged 14–17 years with idiopathic scoliosis who underwent posterior instrumented fusion were included in the study. The patients were retrospectively divided into 2 groups.

Group A included 6 patients treated with navigation templates for pedicle screw insertion in the most difficult zones.

Group B (control) included 6 patients selected by the propensity score matching among those in whom all the pedicle screws were placed with free-hand technique.

There was no significant difference between the groups in sex, age, Cobb angle, number of vertebrae instrumented, number of pedicle screws inserted and laminar hooks installed (Table 1).

Techniques

Two pairs of adjacent vertebrae with pedicle width less than 4.35 mm (minimum screw diameter; Fig. 1) were chosen for the design of navigation templates. Using Slicer 4.8.1 software, virtual 3D models of selected pairs of vertebrae (regions of interest) were created; then pedicle screw placement planning and design of two-level navigation templates were performed in Blender 2.78. Each template was a contact plate with four guide tubes [12]. Physical three-dimensional models of regions of interest and navigation templates were printed from a PLA filament on a 3D printer (FDM technology). The time spent on the creation of virtual objects, as well as the operating time of the 3D printer, were counted during the preparatory work.

Printed models of vertebral pairs and navigation templates were subjected to a low-temperature sterilization. During the surgery, after skeletonization of the posterior structures, navigation templates were set on the dorsal surface of the vertebrae. Transpedicular channels were formed using a drill (Fig. 2), through which the screws were inserted. Free-hand technique was applied to implant all the other supporting elements. The patients underwent CT scanning in the postoperative period.

In Group A patients, screws inserted were evaluated using 2-mm increment grading system [15]: intraosseous screws or the ones perforating the pedicle by no more than 2 mm were considered as correctly inserted. If the pedicle width was less than the screw diameter, only medial perforations were taken into account.

Surgery duration, blood loss, absolute and relative correction of the major curve were compared between the group with selective application of navigation templates and the control group. Since the patients of the control group were selected retrospectively, postoperative CT scan in 5 of them was not available for analysis. Thus, a comparative assessment of the accuracy of pedicle screw insertion between the groups was not performed. These issues were discussed in previously published papers [1–5].

Statistical analysis

Statistical data processing was done using Jamovi 2.2.5 software. Comparison of qualitative data depending on the minimum value of the expected phenomenon was fulfilled using Fisher's exact test or continuity-corrected Pearson's chi-squared test with continuity correction. The quantitative data were verified for normality of distribution using Shapiro – Wilk (at $n < 50$) and Kolmogorov – Smirnov (at $n > 50$) tests. Student's T-test or Mann – Whitney U-test were used for the comparison. The differences were considered statistically significant at a significance level of $p < 0.05$. While identifying significant differences, considering the small number of cases, the effect size was evaluated using Hedges' g and the power of the test was determined. If the power was 80 %, it was considered acceptable.

Results

All planned screws were inserted during the procedures. Fig. 3 shows the distribution of pedicle screws by the placement technique depending on the spine level, in Group A. No screw-related complications were noted.

As mentioned above, the groups did not differ significantly by Cobb angle and the number of laminar hooks (Mann-Whitney U-test), by age, the number of vertebrae fused, the number of pedicle screws inserted (Student's T-test), as well as by gender (Fisher's exact test) (Table 1).

The comparison of the surgery duration, blood loss, absolute and relative correction between the groups using the

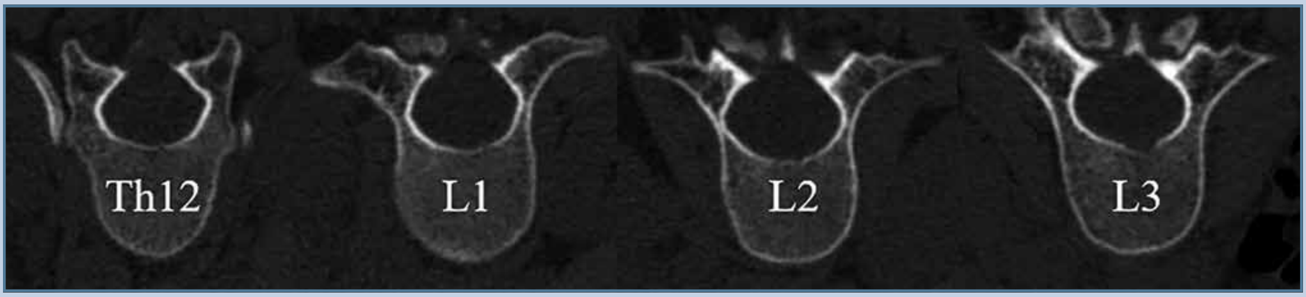

Fig 1
Pedicles of four adjacent vertebrae included in the planned fusion: difficult zones (pedicle width less than 4.35 mm) are two adjacent segments L1 and L2

Table 1

Background data of patients included in the study

Parameters	Group A	Group B	Significance level p
Age, years	16.00 ± 1.26	15.20 ± 1.33	0.292
Gender (male : female), n	0 : 6	2 : 4	0.455
Major curve Cobb angle, degree	45.0 (43.5–45.8)	47.5 (39.8–53.8)	0.872
Vertebrae included in fusion, n	9.67 ± 1.21	10.80 ± 0.75	0.073
Pedicle screws inserted, n	17.80 ± 1.33	17.30 ± 1.97	0.617
Laminar hooks installed, n	0.00 (0.00–0.00)	0.00 (0.00–0.00)*	0.405

* Two laminar hooks were installed during the treatment of one patient of Group B, and therefore the median is zero.

Student's T-test confirmed the statistical significance of the difference for the duration of surgery only. Meanwhile, for the rest of the tests, the differences were not significant (Table 2). For this comparison, the statistical power of the Student's T-test was 97 %.

The time spent on preparing 3D objects included the time of virtual 3D modeling, 3D printing of two regions of interest, and 3D printing of two navigation templates. The chronometry findings of each of these stages were considered separately (Table 3).

A total of 107 pedicle screws (from 16 to 20 per surgery) were inserted in patients of Group A, and 8 screws in each case were placed using two two-level navigation templates. Out of them 48 screws were inserted with templates; 59 – by free-hand technique. Using preoperative CT scans, the pedicles were grouped according to screw placement technique. The width of pedicles instrumented with navigation templates was 4.28 ± 1.43 mm (minimum – 1.9 mm), which turned out to be significantly less than the width of pedicles instrumented by free-hand technique (6.53 ± 1.72 mm; $p < 0.05$, Student's T-test). According to the postoperative CT scan, accurate placement was confirmed for 96 (89.7 %) screws; out of them 45 and 51 screws (93.7 and 88.0 %, respectively) were inserted without malposition using navigation templates and the free-hand technique, respectively. Difference in screw placement accuracy between the groups was insignificant. (Pearson's chi-squared test with continuity correction).

Discussion

Most researchers who apply 3D printing for extended spinal surgery use navigation templates to insert all screws during a single procedure [2–5, 16–20], reporting accurate placement of 92.5–97.6 % of screws in idiopathic scoliosis [17, 19]. Comparative studies have demonstrated the following advantages of total navigation templates over the free-hand technique: lower frequency of malposition [2–5], a shorter surgery duration [3], and less time required to insert a single screw [4]. The differences in absolute (the difference between the pre- and postoperative Cobb angle) [3] and relative correction (the ratio of absolute correction to the initial Cobb value [2] had no statistical significance.

Meanwhile, 3D-assisted screw placement requires an amount of time for preparatory work, consisting of 3D modeling phase requiring the active operator participation, and 3D printing performed by the printer automatically. The production of a set of models, depending on the number of planned screws, can take from one to three days [2, 21]. If a procedure requires the use of multiple objects, the preparation time can be reduced by modeling one object while another one is being printed and/or using several printers. It is possible to significantly reduce the duration of preparatory work by rejecting the printing region of inter-

Fig 2
Application of a navigation template during a surgery

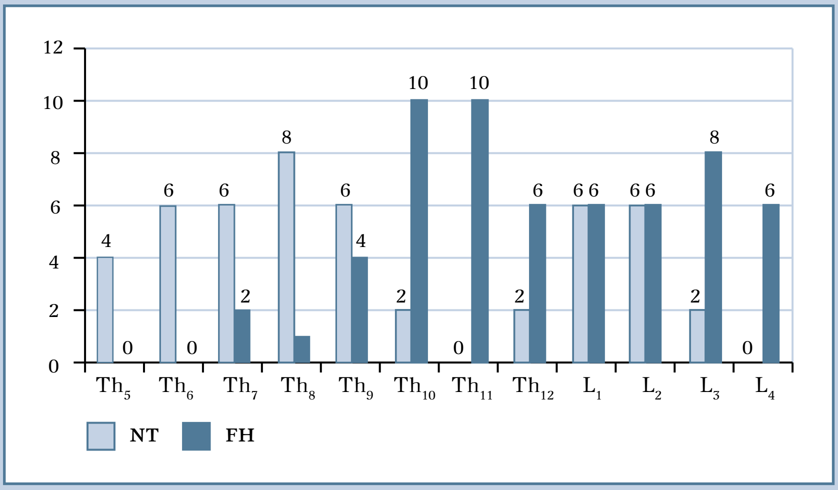

Fig 3
Distribution of pedicle screws in Group A according to the placement technique depending on the level: NT – navigation templates; FH – free-hand technique

est model. Nevertheless, it is undesirable since the model eases orientation in the surgical wound, and in case of a change in the surgery plan, it can serve as a highly informative reference object [22, 23].

Another option to decrease the time for preoperative preparation may be to refuse the total use of templates and combinate 3D-assisted placement and the free-hand technique. The use of such a technique with the production of templates for vertebrae with the least favorable features was reported in two small case series only [12, 21].

The greatest frequency of pedicle screw malposition is observed in the small transverse dimensions of the pedicles [10, 11], which are more common in idiopathic scoliosis than in the normal spine [14, 24]. The presence of regions difficult for screw placement in the thoracic region on the concave side of the curve is most typical [25, 26]; pedicle screw placement in the upper instrumented vertebra is the most difficult [27, 28]. It is consistent with our data. However, the differences in the frequency of malposition between the screws inserted by two different techniques appeared to be statistically insignificant.

On average, the total duration of 3D models production was 1.419 ± 190 minutes. It should be noted that the active operator's participation was required only in the 3D modeling stage, which did not exceed 10 % (126.0 ± 19.2 min) of the total time spent.

In our study, a selective application of navigation templates for pedicle screw placement in the most difficult regions significantly reduced the surgery duration in comparison with the total use of free-hand pedicle screw placement. Thus, the use of two two-level navigation templates during extended (8 or more levels) instrumented fusion enables the preparation of all necessary 3D objects within one day. Moreover, it is possible to achieve a significant reduction in surgery duration without increasing the risk of malposition of screws inserted without an additional equipment.

Conclusion

The selective application of navigation templates that cover 2 pairs of segments with the narrowest pedicles, in comparison with the free-hand technique in idiopathic scoliosis surgery significantly reduces the duration of procedure without significant affecting correction and blood loss.

In comparison with the total 3D modeling of the spine, the selective application of templates also reduces the time required for their production with a similar accuracy of the screw placement. No more than 10 % of the total time spent on the modeling and production requires the active operator's participation.

The study was not aimed at analyzing financial costs. Nevertheless, a priori, the costs of the filament and the application of technological equipment in the selective model are lower than in the total model.

Limitations of the study: a small number of cases and a retrospective design; the lack of CT control and an assessment of the frequency of malpositions in the control group (free-hand – reported in the literature); the lack of the second control group with the total application of navigation templates (the use of literature data).

Table 2
Postoperative data of patients included in the study

Parameters	Group A	Group B	Significance level p
Surgery duration, min	357.00 ± 57.20	470.00 ± 35.80	0.002
Blood loss, % of total blood volume	16.00 ± 2.90	18.80 ± 4.26	0.208
Absolute correction, degree	31.30 ± 5.85	26.70 ± 6.98	0.238
Relative correction, %	65.50 ± 13.70	55.90 ± 13.10	0.244

Table 3

Time spent preparing for surgery with application of navigation templates

Stages of preparatory work	Duration, min
3D modeling	126.0 ± 19.2
3D printing of regions of interest	766.0 ± 175.0
3D printing of navigation templates	527.0 ± 28.8
Total	1419.0 ± 190.0

The study had no sponsors. The authors declare that they have no conflict of interest.

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