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Original Study Article

Evaluation of the efficacy of a novel customized guide with visual control function in children with congenital spinal deformity

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ABSTRACT

BACKGROUND: The use of customized surgical guides for transpedicular screw placement improves the accuracy and safety of the procedure in children with congenital spinal deformities.

AIM: This study aimed to perform a comparative analysis of the effectiveness of a new surgical guide with cutouts for visual control during transpedicular screw placement in pediatric patients with congenital spinal deformities associated with thoracic curvatures.

MATERIALS AND METHODS: The study included 30 patients with congenital thoracic spine deformities who underwent surgery between June 2022 and June 2023. The patients were divided into groups that used the new guide and freehand technique. Screw placement accuracy was assessed using the Gertzbein scale based on postoperative computed tomography data. Results were compared using Student's *t*-test for independent samples because the data were normally distributed, as verified by the Shapiro–Wilk test. Statistical significance was defined as a $p < 0.05$.

RESULTS: The new guide demonstrated high accuracy, with 97.7% of the screws placed without deviation (Grade 0). Only 2.3% of the screws deviated up to 2 mm (Grade I), which did not affect the complication rates. The freehand technique had lower accuracy rates; approximately 89.7% of the screws were placed correctly (Grade 0), 7.5% had a deviation of up to 2 mm (Grade I), and 2.8% had a deviation of >2 mm (Grade ⩾ II).

CONCLUSIONS: A new customized guide with visual control cutouts provides high accuracy, reliability, and ease of use, making it a promising clinical tool for treating congenital spinal deformities.

Keywords: spinal developmental abnormalities; congenital spinal deformities; surgical guides; transpedicular screws; surgical procedures; implantation accuracy.

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Оригинальное исследование

Оценка эффективности применения нового типа индивидуального шаблона-направителя с функцией визуального контроля у детей с врожденной деформацией позвоночника

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АННОТАЦИЯ

Обоснование. Использование индивидуальных хирургических шаблонов для установки транспедикулярных винтов улучшает точность и безопасность операций при врожденных деформациях позвоночника у детей.

Цель — разработать и провести сравнительный анализ эффективности нового хирургического шаблона-направителя с вырезами для визуального контроля при установке транспедикулярных винтов у пациентов детского возраста с врожденными деформациями позвоночника, сопровождающимися искривлениями грудной клетки.

Материалы и методы. В исследование включены 30 пациентов с врожденной деформацией позвоночника и грудной клетки, которые проходили хирургическое лечение с июня 2022 по июнь 2023 г. Пациенты были разделены на две группы: с использованием нового навигационного шаблона и с применением метода «свободной руки». Точность установки винтов оценивали по шкале S.D. Gertzbein на основе данных послеоперационных компьютерных томографий. Результаты сравнивали с помощью *t*-теста Стьюдента для независимых выборок, так как данные имели нормальное распределение, что проверяли с помощью теста Шапиро – Уилка. Значение $p < 0,05$ считали статистически значимым.

Результаты. Новый шаблон продемонстрировал высокую точность — 97,7 % винтов были установлены без отклонений (Grade 0). Только для 2,3 % винтов отклонение составило до 2 мм (Grade I), что не повлияло на развитие осложнений. При применении метода «свободной руки» отмечены более низкие показатели точности: около 89,7 % винтов были установлены корректно (Grade 0), для 7,5 % отклонение составило до 2 мм (Grade I) и для 2,8 % — более 2 мм (Grade II и выше).

Заключение. Новый индивидуальный навигационный шаблон с вырезами для визуального контроля обеспечивает высокую точность, надежность и удобство использования, что делает его перспективным инструментом для клинической практики при лечении врожденных деформаций позвоночника.

Ключевые слова: аномалии развития позвоночника; врожденная деформация позвоночника; шаблоны-направители; транспедикулярные винты; хирургическое лечение; точность имплантации.

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BACKGROUND

The surgical treatment of pediatric patients with congenital spinal deformities remains a critical and challenging issue in modern cerebrology. Congenital spinal pathologies account for 2%–3% of all scoliotic deformities [1]. A study of the natural progression of congenital spinal deformities indicated that the risk of kyphotic and scoliotic curves increasing by up to 40° over 10 years is significant [2]. The steady progression of such deformities can profoundly affect the respiratory, cardiovascular, and nervous systems, ultimately leading to cardiopulmonary insufficiency syndrome [3]. Over time, these conditions resulted in severe functional impairments of the spinal column, cosmetic deformities, reduced motor activity, and considerable decline in the quality of life of pediatric patients [4]. In many cases, this progression leads to early-onset disability.

Modern surgical approaches for progressive congenital scoliosis aim to correct the spinal curvature while maintaining the achieved correction as the child grows. In recent years, correction techniques for congenital spinal deformities utilizing transpedicular screw fixation with metal constructs have become prevalent [5]. These constructs enable the highly effective correction of congenital curvatures, provide biomechanical stability, and ensure long-term postoperative outcomes. The accurate placement and positioning of the metal construct's supporting elements are critical determinants of the effectiveness and safety of transpedicular screw fixation. The safety and accuracy of transpedicular screw placement are critical for assessing the quality of surgical treatment and minimizing potential complications. To increase the accuracy of transpedicular screw placement, various navigation methods are employed in clinical practice, including anatomical landmark visualization (freehand technique), specialized navigation systems, and template-guided techniques [6, 7]. However, commonly used techniques, such as the freehand method, are often less accurate and are associated with a high risk of screw malposition, which may result in severe complications, including damage to vascular and nervous structures [8–10]. Navigation systems, such as multislice computed tomography (CT) or fluoroscopic stepwise guidance, offer greater precision but have significant drawbacks. These include high radiation exposure for pediatric patients and surgical teams, high equipment costs, prolonged procedural time, and risk of infectious complications [11].

In recent years, additive technologies have emerged as a promising solution to enhance the personalization of surgical interventions. These technologies have the potential to improve the safety and efficacy of procedures in pediatric patients with spinal deformities [12].

This **study aimed** to conduct a comparative analysis of the effectiveness of a novel surgical guide template with visual control cutouts for transpedicular screw placement in pediatric patients with congenital spinal deformities and thoracic cage deformities.

MATERIALS AND METHODS

Design and development of a novel navigation template

The navigation template with visual control cutouts (Fig. 1) was developed as a monolithic structure using 3D printing with biocompatible plastic. The frame of the template features a support platform that precisely matches the contours of the posterior vertebral structures, including arches, spinous processes, and facet joints. It is equipped with two contralateral guiding tubes. The frame includes visual control cutouts: one at the level of the spinous process apex and two at the projection of the facet joints. These cutouts enable the verification of the accurate positioning of the template and adherence to the posterior bony structures of the vertebrae.

The template ensures stable fixation to the dorsal vertebral structures, eliminating the risk of displacement in the axial and sagittal planes. In addition, it allows for the visual assessment of the accuracy of positioning and precise fit before forming bone channels for transpedicular screw placement.

Intraoperative application

Intraoperatively, after the skeletonization of the posterior vertebral structures, the individualized navigation template is placed on the vertebra's posterior bony structures, ensuring that the support platform conforms precisely to the anatomical contours. Then, the visual control cutouts were utilized to confirm the accurate positioning and precise fit of the template. Once the guide template is securely and accurately fitted to the posterior bony structures, bone channels for transpedicular screw placement are created

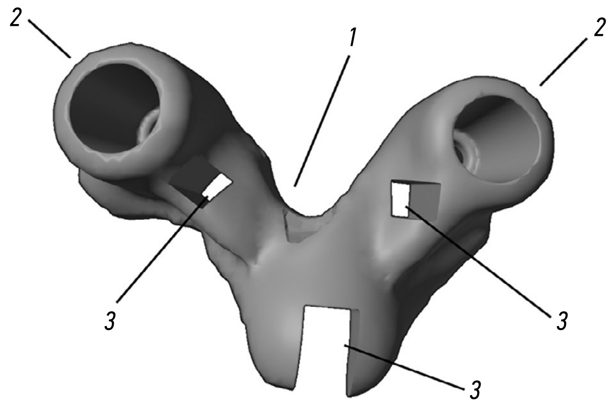

Fig. 1. Top view of the navigation template: *1*, template body; *2*, guiding tubes; *3*, visual control cutouts

in the vertebral body using a high-speed drill through the guide tubes integrated into the template frame.

After the removal of the template, the transpedicular screws are inserted into the prepared bone channels.

Patients and clinical study

The study included 30 pediatric patients with congenital thoracic spine deformities and associated thoracic cage deformities who underwent surgical correction and stabilization at the Department of Spinal Pathology and Neurosurgery, H. Turner National Medical Research Center for Children's Orthopedics and Trauma Surgery, between June 2022 and June 2023. The patients were divided into two groups: Group 1 (n = 15) received surgical treatment using the novel navigation template with visual control cutouts, whereas Group 2 (n = 15) received surgical treatment using the freehand method for placing the supporting elements.

Inclusion criteria: patients with congenital thoracic spine deformities with associated thoracic cage deformities and aged 5–9 years. Exclusion criteria: previous surgical interventions in the area of the congenital deformity, developmental anomalies of the spinal canal or spinal cord.

The following parameters were evaluated:

- Patient age and sex.
- Magnitude of the scoliotic deformity (measured using the Cobb method).
- Pre- and post-operative CT data.
- Number of formed channels and inserted screws.
- Time required for bone channel formation.
- Postoperative complications, including infections, neurological issues, and construct destabilization, over a follow-up period of 1.5 years.

Evaluation of the surgical outcomes

The accuracy of the transpedicular screw placement was visually evaluated on postoperative radiographs and CT scans using the Gertzbein scale [13]. To evaluate the effectiveness of the navigation template versus the freehand method, the time required for bone channel formation was compared between the two groups.

Data were analyzed using Student's t-test for independent samples. The normality of the data distribution was verified using the Shapiro–Wilk test. A p value of <0.05 was considered significant.

RESULTS

Clinical data of the patients

The clinical characteristics of the patients included in the study are summarized in Table 1.

Group 1 (n = 5) underwent surgery using the new navigation template with visual control windows. The mean age of the patients was 6.93 ± 1.28 years, and the group included six boys and nine girls. The average preoperative scoliotic curve was 32.47° ± 6.12°, and the average local kyphosis was 17.27° ± 2.37°. A total of 88 transpedicular screws were placed, and the number of fixation points per patient ranged from 4 to 8.

Group 2 (n = 15) underwent surgery using the freehand method for transpedicular screw placement. The mean age of the patients was 7.4 ± 1.45 years, and the group included 4 boys and 11 girls. The average preoperative scoliotic curve was 32.6° ± 5.67°, and the average local kyphosis was 16.47° ± 3.29°. A total of 78 transpedicular screws were placed, and the number of fixation points per patient ranged from 4 to 6.

Both groups had comparable baseline clinical characteristics, ensuring the validity of outcome comparisons and allowing for an accurate assessment of the efficacy and accuracy of the new navigation template with visual control windows compared with the traditional freehand method.

Analysis of the bone channel formation time

In both groups, a quantitative statistical analysis was performed on the time required to form bone channels before transpedicular screw placement. The mean times to create a single channel were 52.6 ± 2.6 and 134.7 ± 5.3 in Groups 1 and 2, respectively (p < 0.005). Thus, compared with the traditional method, the navigation template with visual control windows significantly reduced the time required for channel formation.

Notably, the time required for the formation of a single bone channel may vary significantly because of individual anatomical differences in patients' bone structures.

Analysis of the accuracy of the transpedicular screw placement

The results of the assessment of the accuracy of transpedicular screw positioning, performed using the Gertzbein scale, are presented in Table 2.

The results show the higher accuracy of then new navigation template when used in placing the transpedicular screws compared with the freehand method. Moreover, 97.7% of the transpedicular screws were correctly placed (Grade 0) in the navigation template group. In the freehand group, the proportion of correctly placed screws was 84.6%. Screw displacement within 2 mm (Grade I) occurred in 2.3% and 11.5% of cases using the navigation template and freehand method, respectively. In the freehand group, displacement exceeding 2 mm (Grade II) was observed in 3.8% of the cases.

During the postoperative follow-up, no complications were recorded in either group.

Table 1. Clinical data of the patients

Patient	Sex	Age	Number of screws	Magnitude of scoliotic deformity, °, Cobb method)	Magnitude of local kyphosis, °
Group 1					
1	M	5	4	34	19
2	M	7	4	30	20
3	F	7	5	37	19
4	F	7	6	26	21
5	F	9	8	34	19
6	F	6	4	29	17
7	M	9	5	39	14
8	M	9	7	39	14
9	F	6	7	23	19
10	M	6	4	33	17
11	F	6	8	22	14
12	F	8	8	42	15
13	F	7	8	27	15
14	M	6	5	34	19
15	F	6	5	38	17
Group 2					
1	M	8	4	36	17
2	M	8	6	35	19
3	F	8	6	25	12
4	F	9	5	31	18
5	F	7	4	41	12
6	F	5	5	29	20
7	F	8	6	28	12
8	F	8	6	38	21
9	F	9	5	40	13
10	F	8	4	33	14
11	M	5	6	39	18
12	F	9	6	27	15
13	F	5	5	23	21
14	M	6	5	29	19
15	F	8	5	35	16

Table 2. Accuracy of transpedicular screw placement according to the Gertzbein Scale

Grade	Number of screws (Group 1)	Proportion (Group 1), %	Number of screws (Group 2)	Proportion (Group 2), %
0	86	97.7	66	84.6
1	2	2.3	9	11.5
2	0	0	3	3.8
3	0	0	0	0
Total	88	100	78	100

DISCUSSION

The results demonstrate the high efficiency, precision, and usability of the new navigation template with visual control cutouts in the surgical treatment of pediatric patients with congenital spinal deformities. Of the 88 transpedicular screws placed, 97.7% (86 screws) were positioned correctly (Grade 0), reflecting the exceptional accuracy of the method. Only 2 (2.3%) screws demonstrated a displacement of up to 2 mm (Grade I), which may be considered a satisfactory outcome that did not lead to malposition-associated complications.

The inclusion of visual control cutouts did not compromise the fit of the template to the bone structures, ensuring reliable adherence to the posterior bony anatomy and facilitating precise transpedicular screw placement. These findings are consistent with the results of previous studies highlighting the advantages of customized navigation templates [14–18]. For instance, Pijpker et al. demonstrated high precision and accuracy of transpedicular screw placement using guide templates. Their analysis of 3D deviations revealed mean entry point and mean angular deviations of 1.40 ± 0.81 and 6.70° ± 3.77°, respectively. Notably, angular deviations were significantly greater in the sagittal plane than in the axial plane ($p = 0.02$). Importantly, all screws were classified as safe (100%), with no damage to neurovascular structures or breaches of the pedicle walls, underscoring the reliability of this method [19].

In contrast, many studies have reported lower accuracy, slower screw placement, reduced positioning precision, and higher incidence of complications with traditional methods compared with guide templates. For example, with the freehand method, the overall screw placement accuracy is approximately 73% [20], and 11.9% of cases exhibit screw deviations >2 mm, significantly increasing the risk of complications [21].

The developed customized guide template demonstrated exceptional accuracy of adherence to the posterior bony structures of the vertebrae. It ensured optimal stability during bone channel formation for the construction of support elements, enabling precise transpedicular screw placement. In the study, no patients had guide template displacement during the creation of channels for spinal system anchors, confirming the stability and reliability of this innovation.

The new guide template with visualization windows provides high precision for transpedicular screw placement, reliability, and ease of use during surgical procedures for correcting congenital spinal deformities, which can significantly improve surgical results.

CONCLUSION

This study evaluated the application of a customized navigation template with visual control cutouts. The new template demonstrated high positioning accuracy on the posterior bony structures of the vertebrae, precise transpedicular screw placement, and significant reductions in bone channel formation time. The results indicate that the developed navigation template has substantial potential to improve the quality of surgical care for children with congenital spinal deformities. The introduction of this navigation template into clinical practice emphasizes the potential for additive technologies to enhance the safety and efficacy of surgical procedures, particularly in complex cases.

ADDITIONAL INFORMATION

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Competing interests. The authors declare that they have no competing interests.

Ethics approval. The study was approved by the Local Ethics Committee of the H. Turner National Medical Research Center for Children’s Orthopedics and Trauma Surgery, Ministry of Health of Russia (Protocol No. 24-3-1, May 17, 2024).

Consent for publication. Written consent was obtained from legally acceptable representatives of patients for the publication of medical data.

Author contribution. All authors made a significant contribution to the study and preparation of the article, and each read and approved the final version before it was published.

Major contributions were distributed as follows: *V.G. Toriya* wrote sections of the article, collected data, analyzed the literature, and created the figures. *S.V. Vissarionov* conducted the staged editing of the manuscript. *P.A. Pershina* wrote sections of the article, conducted statistical data analysis, and conducted a literature review.

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