



# Comparing the Treatment of Congenital Spine Deformity Using Freehand Techniques In Vivo and 3D-Printed Templates In Vitro (Prospective–Retrospective Single-Center Analytical Single-Cohort Study)

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## ABSTRACT

**Introduction:** Hemivertebrae excision with local posterior instrumentation is the most common technique for treatment of patients with congenital spine deformity—it is performed at a very young age. We conducted a comparative analysis for accuracy of pedicle screw positioning in infants with congenital scoliosis of the thoracolumbar area inserted using freehand technique in vivo and 3D-printed guiding templates in vitro.

**Methods:** The study analyzes the results of 10 surgically treated patients with congenital deformity of the thoracolumbar spine due to vertebrae failure of formation. These patients were included in group 1 (in vivo) comprising six boys and four girls with a mean age of 3 years 8 months (2 years 2 months–6 years 8 months). Group 2 (in vitro) consisted of 27 plastic 3D-printed models of congenitally deformed spine of the same 10 patients in which screws were placed using 3D-printed guiding templates. The accuracy of screw position was assessed using computer tomography data performed postoperatively with Gertzbein–Robbins classification.

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**Results:** Results of our study show that screw insertion using 3D-printed guiding templates during surgical treatment of infants with congenital spine deformities is more accurate than using freehand technique (96.3% vs. 78.8%  $p = 0.011$ ).

**Conclusion:** The data show that this method of screw insertion is very promising and can be used in surgical treatment of infants with congenital spine deformities.

**Keywords:** 3D prototyping; Children; Congenital scoliosis; Guiding templates; Hemivertebrae; Pedicle screws

### Key Summary Points

#### *Why carry out this study?*

Surgical treatment of infants with congenital spine deformities is the most complicated surgery in terms of neurological deterioration and postoperative implant failure. Malalignment of the implant can lead to chronic spinal issues, the necessity for surgical revision, and other adverse outcomes

This study aimed to evaluate a better option for treating spinal deformity. In the usual procedure with infants, the surgeon uses a “freehand” technique that can result in misaligned screws. The use of 3D-printed templates offers the potential to ensure correct alignment in a higher percentage of cases, which, in turn, is a more effective treatment with fewer side effects and improved outcomes for patients

The research question is simply, “Do 3D-printed templates improve the accuracy of screw placement?” The evaluation of accuracy was with respect to pedicle screw positioning in infants with congenital scoliosis of the thoracolumbar area. The comparison groups had implants inserted using the commonplace freehand technique in vivo and 3D-printed templates in vitro

#### *What was learned from the study?*

The data analysis revealed that using 3D-printed templates is quite promising. It is a viable means to improve surgical treatment of infants with congenital spine deformities. Specifically, using 3D-printed templates is statistically more accurate than using freehand techniques (96.3% vs. 78.8%  $p = 0.011$ ). More importantly, the accuracy of using 3D-printed templates also is practically important

3D templates overall have higher accuracy, but mistakes remain possible. The surgeon still needs to be competent using the freehand technique. Nonetheless, instances of surgeries for complex cases with abnormal anatomy can benefit from the use of 3D-printed templates. Avoiding implant malalignment is critical in reducing the odds of further neurological deterioration

## INTRODUCTION

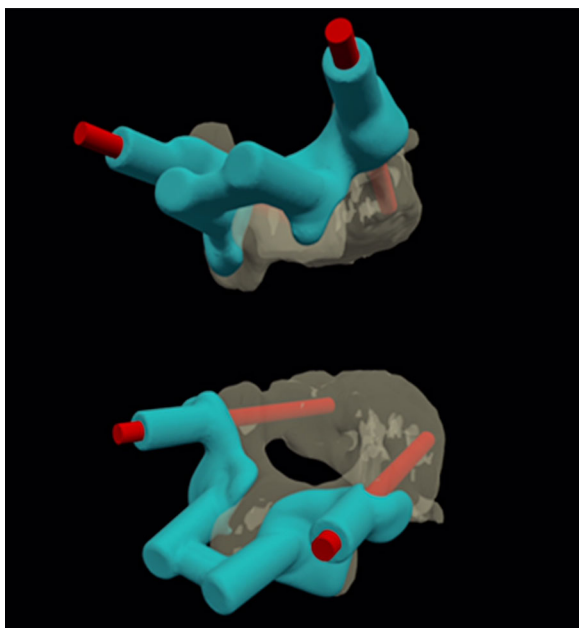
Hemivertebrae excision with local posterior instrumentation is the most common technique for treatment of patients with congenital spine deformity—it is performed at a very young age [1–5]. Surgical treatment in older patients does not achieve full correction of the deformity [6]. Compared to laminar hooks, pedicle screws have advantages from a biomechanical point of view but risk malpositioning due to anatomical changes of the deformed vertebrae [7]. Therefore, carefully controlled positioning of the screw is highly important. The freehand technique with fluoroscopic control remains the basic and most commonly used method of insertion [8]. There are only a few reports in the literature on screw positioning accuracy using intraoperative computed tomography (O-arm) or active spine navigation system [9].

The use of guiding templates is becoming more popular in surgical treatment of different spine pathologies including post-traumatic deformities, degenerative or inflammatory diseases, pathology of the cranio-cervical junction, and idiopathic scoliosis. Studies on this topic show the importance of high accuracy of screw positioning after insertion at different areas of the spine [10–13]. On the basis of a careful review of the literature, we found no reported studies that investigate the use of guiding templates in the surgical treatment of infants with congenital spinal deformities. Here, we provide the comparative analysis of the screw position accuracy in infants with congenital scoliosis at the thoracolumbar area using two methods: freehand technique *in vivo* and 3D guiding templates *in vitro* (Fig. 1).

## METHODS

### Study Design

Retrospective and prospective single-center analytical single-cohort study evaluating the outcome due to exposure.



**Fig. 1** Computed planning of the screws and guiding templates using PME Planner software

This study is based on the retrospective part which includes analysis of the results of surgically treated infants with congenital scoliosis due failure of vertebrae formation (hemivertebrae at the thoracolumbar area) during the period of 2016–2017. There were 10 patients with a mean age of 3 years 8 months (ranging from 2 years 2 months to 6 years 8 months): six were male and four were female. The prospective part consisted of laboratory study in which 27 3D-printed plastic vertebrae models of congenitally deformed spine of the same patients were used for screw insertion with guiding templates (Figs. 2 and 3).

### Ethics Approval and Consent to Participate

The study protocol was approved by the Turner Scientific and Research Institute for Children's Orthopaedics (within the Department of Spinal Pathology and Neurosurgery), Pushkin, Saint Petersburg, Russia. All research was performed in accordance with Turner Scientific and Research Institute guidelines and regulations, and the respective authors declare a statement confirming that informed consent was obtained



**Fig. 2** 3D-printed guiding templates for screw insertion

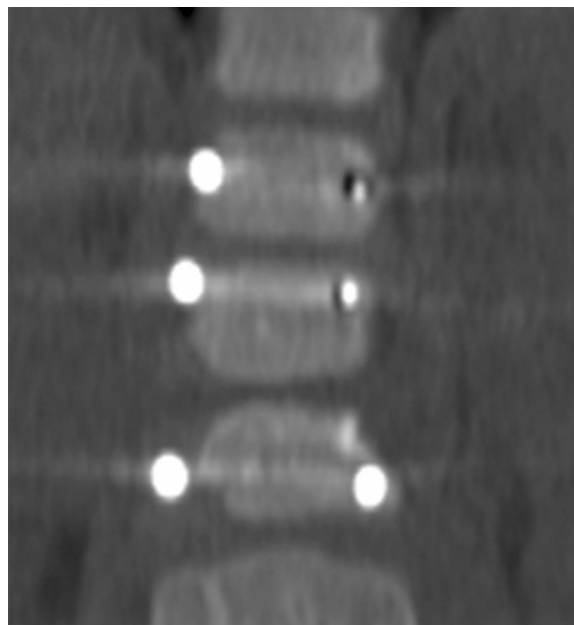


**Fig. 3** Plastic model with the screws inserted using guiding templates. Properly placed screws

from all of the participants' parents and/or their legal guardians. In addition to the guidelines described above, the authors of these study dealing with human transplantation research attested that no organs/tissues were procured from prisoners. No animals were used for the studies that are the basis of this research. All research on humans was in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013 (<http://ethics.iit.edu/ecodes/node/3931>).

All patients were examined preoperatively and postoperatively using CT scans of the thoracolumbar spine. Surgical treatment included hemivertebrae excision, correction of the deformity using a pedicle screw spinal system, and anterior and posterior fusion using bone autografts. On the basis of the data of preoperative CT, 27 plastic vertebrae models of the congenitally deformed spine of the same patients were printed and screws were inserted in those models in the laboratory using guiding templates.

3D modeling was performed using CT data of the same 10 patients with congenital spine

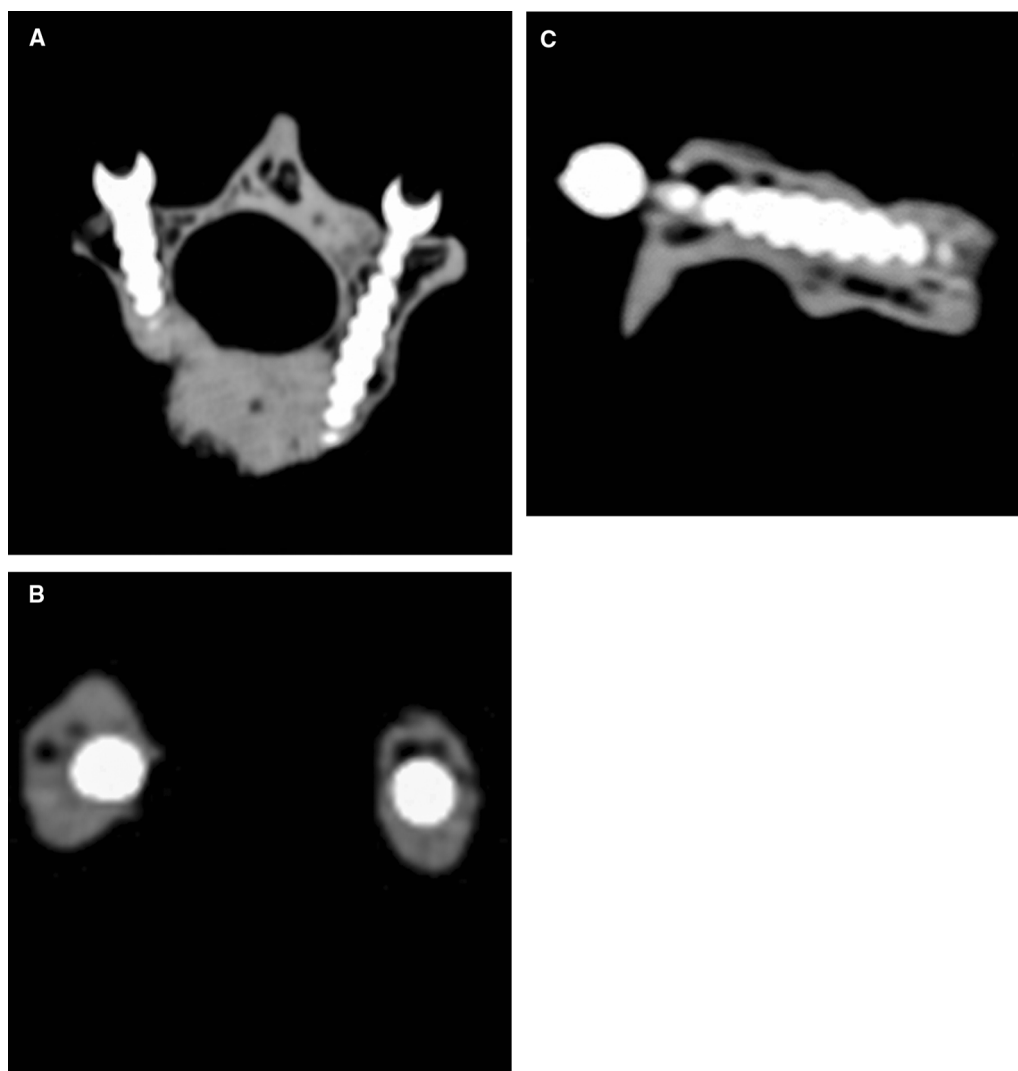


**Fig. 4** Postoperative CT scan in the coronal plane in a patient with congenital scoliosis after the posterior L2 hemivertebrae excision. Malpositioning of the screws is noted: Th12–V2 (body wall penetration, grade II), L1 and L3–V3 (body wall penetration grade III)

deformity and software for the computed planning of the surgical treatment. PME Planner (Polygon Medical Engineering, [polygonmed.ru](http://polygonmed.ru)) software was developed for the evaluation of anatomical landmarks at the area of implantation in 3D format. This enabled surgeons to identify the size and optimal positioning of screws to be implanted. Guiding templates were made using position and direction of the previously created virtual screws and aligned with the dorsal bony structures features of the evaluated vertebrae (Fig. 4).

### 3-Dimensional Printing

3D printing of the guiding templates was performed using a Formlabs Form 2 (SLA technology) 3D printer (Fig. 5). Plastic vertebrae models were printed using a PICASO DESINGER PRO 250 (FDM technology) 3D printer. Previously printed guiding templates were placed over the dorsal surface of the plastic models and with the 2.5-mm drill bit a pedicle canal was made in the direction indicated by the template. After this



**Fig. 5** Axial (a), coronal (b), and sagittal (c) CT views presenting correct position of the screw inserted using guiding templates in the plastic models

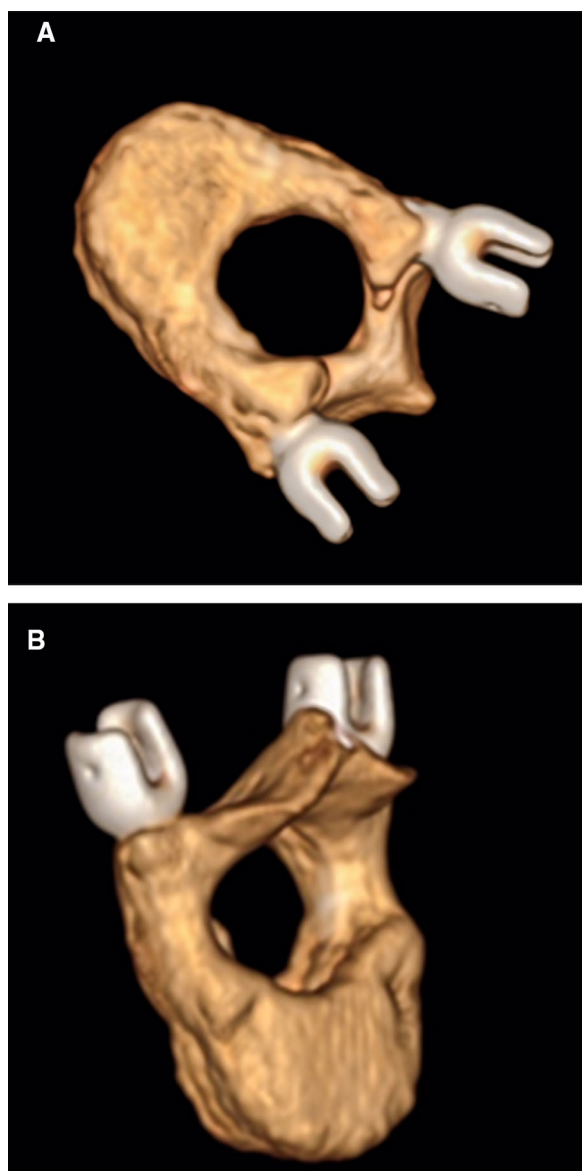
step, the templates were removed and standard 3.5-mm screws were inserted. Lastly visual evaluation of screw positioning was performed (Fig. 6).

A CT scan of the plastic model was performed to evaluate the accuracy of screw positioning. The Gertzbein–Robbins classification was used to evaluate the accuracy of screw positioning. This classification includes grade 0—fully correct position positioning with the screw placed in the pedicle and not in contact with the surrounding soft tissues; grade I—displacement of the screw no more

than 2.0 mm out of the pedicle cortex; grade II—displacement of the screw between 2.0 and 4.0 mm; and grade III—displacement of the screw by more than 4.0 mm [14].

### Statistical Analysis

To assess the accuracy of the screw position in both groups, we used the so-called SLIM + V system. This mnemonic describes the position of the screw in relation to the cortex of the pedicle: S—superior cortex, L—lateral, I—inferior, and M—medial. The “+ V” describes



**Fig. 6 a, b** 3D CT reconstruction of the plastic vertebrae model with the screws inserted using guiding templates (different screw position)

whether or not there is penetration of the anterior body wall [15]. Statistical analysis was performed using Statistica 10. Descriptive statistics (histogram analysis) was used for the assessment of the data in terms of its fit with the normal distribution. Data were described using the median and the range. Group differences were assessed using the Wilcoxon–Mann–Whitney test with an a priori

decision to use an alpha level of 0.05 ( $p < 0.05$ ) as statistically significant).

## RESULTS

### Pattern of Congenital Scoliosis in Infants

CT data presenting the anatomical, anthropometric characteristics of the vertebrae of the thoracolumbar and lumbar areas in infants with congenital scoliosis due to failure of formation are listed in Table 1.

These data were used for planning before the insertion of the screws into the plastic models. In infants with congenital deformity (due to a single hemivertebrae in the lumbar spine), all vertebrae parameters were similar to the parameters of the lumbar spine in children without spine pathology [16]. Table 2 presents data on the accuracy of screw position in group 1 where the screws were inserted freehand.

### Accuracy of Pedicle Screw Position

The total number of screws placed in group 1 was 52. Correct screw position in relation to the bony structures was observed in 53.8% of cases (28 screws); 24 screws (46.2% of cases) were placed incorrectly according to postoperative CT: 25% (13 screws) were of grade I malposition, 11.6% (6 screws) were grade II, and 9.6% (5 screws) were grade III. V-type malpositioning occurred in 69.2% (18 screws), type L in 23.1% (6 screws), and type I and type M in 3.85% (one screw in each type). Thus the total number of screws with grade 0 + grade I was 41 (78.8%) (for more detail, see next section and Fig. 4).

Table 3 shows the data on the accuracy of the screw position in group 2 where the screws were inserted using guiding templates.

### Correct Screw Position in Relation to Structures of Plastic Model

Total number of inserted screws in group 2 was 54. Correct screw position in relation to the structures of the plastic model was observed in

**Table 1** Anatomical, anthropometric characteristics of the vertebrae of the thoracolumbar and lumbar areas

V	Dextra				Sinistra			
	W	H	L	A	W	H	L	A
Th10	6.0 (5.7–6.3)	10.3 (10.1–10.5)	31.6 (29.9–33.2)	11.5 (10.3–12.7)	5.9 (5.7–6.0)	9.8 (9.2–10.4)	30.5 (30.0–31.0)	12.9 (10.5–15.3)
Th11	5.6 (4.5–6.6)	10.0 (8.6–10.9)	31.4 (29.7–34.9)	11.6 (5.7–17.6)	5.6 (4.0–6.5)	9.8 (9.0–11.4)	32.8 (31.2–35.2)	13.2 (10.2–16.5)
Th12	5.3 (4.9–7.9)	9.8 (9.4–11.0)	31.9 (30.5–35.4)	12.1 (7.7–18.1)	5.6 (3.7–8.3)	10.0 (8.7–11.4)	32.9 (30.2–35.1)	12.3 (8.8–15.7)
Th13	6.0 (5.7–6.9)	10.4 (9.1–11.4)	33.1 (30.5–33.3)	10.7 (10.5–11.6)	6.2 (5.8–6.5)	9.7 (9.6–10.1)	34.1 (32.1–34.7)	12.7 (11.4–15.0)
L1	5.7 (4.6–8.9)	9.9 (7.2–10.8)	32.7 (31.3–36.8)	12.0 (8.2–13.6)	5.3 (3.9–6.1)	9.5 (7.8–10.6)	32.6 (26.2–36.2)	12.1 (4.6–16.3)
L2	5.8 (4.1–7.7)	8.7 (7.1–11.0)	34.0 (30.0–36.2)	11.5 (9.7–23.0)	5.8 (4.5–7.4)	9.2 (7.4–10.6)	34.0 (31.8–39.8)	16.2 (13.2–20.2)
L3	6.5 (4.3–7.9)	9.4 (6.8–10.8)	33.0 (28.6–39.5)	14.7 (11.8–25.4)	5.7 (3.7–7.6)	9.4 (0.1–11.6)	33.6 (31.9–40.4)	15.2 (11.5–24.2)
L4	6.8 (5.4–12.4)	9.0 (6.0–9.7)	34.5 (28.4–37.9)	17.0 (7.8–26.0)	7.0 (4.1–9.8)	9.3 (6.8–10.3)	35.0 (32.2–39.3)	15.8 (14.4–23.1)
L5	9.1 (7.2–11.9)	7.7 (6.0–9.1)	32.8 (29.3–35.3)	23.7 (13.5–41.2)	7.8 (5.5–10.4)	8.4 (7.0–10.5)	33.7 (32.5–37.8)	18.5 (12.2–28.7)
L6	11.1 (9.5–13.7)	6.9 (5.3–10.0)	34.2 (30.3–35.5)	31.2 (19.6–41.5)	8.4 (7.0–11.9)	7.4 (4.2–7.8)	34.0 (27.2–35.7)	29.8 (19.4–40.7)
L7	10.3	6.9	31.1	36.0	13.3	7.1	33.4	32.1

Data are presented as mean (min–max)

V vertebrae, W pedicle width, H pedicle height, L length of the screw canal, A pedicular angle in the axial plane

**Table 2** Accuracy of the pedicle screw position in group 1 (in vivo)

UO	Vert.	Th10	Th11	Th12	Th13	L1	L2	L3	L4	L5	L6	L7
1	Dex	–	–	V2	N	V3	HV	V3	–	–	–	–
	Sin	–	–	0	N	0		0	–	–	–	–
2	Dex	–	–	–	–	–	0	HV	V1	–	–	–
	Sin	–	–	–	L2	–	V3		0	–	–	–
3	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		V1	–	–	–
4	Dex	–	–	0	V2	HV	0	–	–	–	–	–
	Sin	–	–	V1	V1		0	–	–	–	–	–
5	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	V2	N	NS		NS	–	–	–	–
6	Dex	–	–	–	–	–	–	–	–	V3	HV	V3
	Sin	–	–	–	–	–	–	–	–	I2		0
7	Dex	–	–	–	0	0	HV	M1	–	–	–	–
	Sin	–	–	–	V2	V1		0	–	–	–	–
8	Dex	0	0	HV	–	–	–	–	–	–	–	–
	Sin	V1	L1, V1		V1	–	–	–	–	–	–	–
9	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
10	Dex	–	L1	L1	N	HV	0	–	–	–	–	–
	Sin	–	L1	L1, V2	N		0	–	–	–	–	–
TScrew		2	4	10	8	5	10	5	4	2	0	2
Mal		1	3	5	5	2	1	2	2	2	0	1

UO patient number, *Vert.* vertebrae, *Dex* screws on the right side, *Sin* screws on the left side, *TScrew* total number of screws placed, *HV* hemivertebrae, *N* absence of the screw with mentioned number, – vertebrae which were not included in fusion, *NS* screws were not placed during fusion; *SLIM* + *V*, *S* superior, *L* lateral, *I* inferior and *M* medial cortex, *V* anterior wall of the vertebral body (0, 1, 2, 3—grade of malposition)

94.4% of cases (51 screws). Incorrect screw position was observed in 5.6% (three screws): grade II malpositioning occurred in two screws (3.7%) and grade I in one screw (1.9%). There was one case of type L and two cases of type V malpositioning. Thus total number of screws with grade 0 + grade I malposition was 52 (96.3%, Figs. 5 and 6).

Thus the number of cases with improperly placed screws was significantly lower in group 2

where guiding templates were used compared to group 1 where freehand techniques were used as a method of insertion: 5.6% versus 46.2% ( $p = 0.011$ ).

## DISCUSSION

Table 4 provides literature references on the efficacy of templates during insertion of the



**Table 3** Accuracy of the pedicle screw position in group 2 (in vitro)

UO	Vert	Th10	Th11	Th12	Th13	L1	L2	L3	L4	L5	L6	L7
1	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	V2	N	0		0	–	–	–	–
2	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		0	–	–	–
3	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		0	–	–	–
4	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
5	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	0	N	0**		0**	–	–	–	–
6	Dex	–	–	–	–	–	–	–	–	0	HV	0
	Sin	–	–	–	–	–	–	–	–	0		0
7	Dex	–	–	–	0	0	HV	0	–	–	–	–
	Sin	–	–	–	V2	0		0	–	–	–	–
8	Dex	0	0	HV	0	–	–	–	–	–	–	–
	Sin	0	L1		0	–	–	–	–	–	–	–
9	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
10	Dex	–	0	0	N	HV	0	–	–	–	–	–
	Sin	–	0	0	N		0	–	–	–	–	–
TScrew		2	4	10	8	6**	10	6**	4	2	0	2
Mal		0	1	1	1	0	0	0	0	0	0	0

UO patient number, *Vert.* vertebrae, *Dex* screws on the right side, *Sin* screws on the left side, *TScrew* total number of screws placed, *HV* hemivertebrae, *N* absence of the screw with mentioned number, – vertebrae which were not included in fusion, *NS* screws were not placed during fusion; *SLIM + VS* superior, *L* lateral, *I* inferior and *M* medial cortex, *V* anterior wall of the vertebral body (0, 1, 2, 3—grade of malposition)

\*\* screws which were able to be additionally inserted in group 2

screws in cervical [17–20], thoracic [21, 22], and lumbar areas [18, 27, 28]. Some authors performed cadaveric studies with CT scanning of the cadaveric vertebrae and following computed evaluation and 3D printing of guiding templates which were then used in cadavers for screw insertion [17–19, 22–24, 27]. There is also a study where authors used 3D-printed models of normal vertebrae with insertion of the screws

using guiding templates [25]. In several studies, screws were inserted in cadaveric vertebrae after development of the guiding template design based on previously 3D-printed plastic models [20, 21]. Our findings reveal that the number of inserted screws using guiding templates in vitro varied from 4 to 240 (total number 646) [17–28].

Accuracy of the screw positioning according to literature review was distributed as follows:

**Table 4** Literature highlighting the topic of guiding templates used in vitro

Spine area	Year	Author	Type of study	Age (years)	No. of screws	CorScrew, grade, %/(total)				CorScrew, %/ (total)
						0	1	2	3	
Ct	2011	Lu et al. [17]	CS	> 18	84	97.6% (82)	2.4% (2)	-	-	-
CA	2005	Berry et al. [18]	CS	> 18	4	-	-	-	-	100%
	2009	Ryken et al. [19]	CS	> 18	20	-	-	-	-	95% (19)
	2017	Bundoc et al. [20]	PM + CS	> 18	50	-	-	-	-	94% (47)
	2012	Ma et al. [21]	PM + CS	> 18	GT-240	93.4% (224)	6.6% (16)	-	-	100%
T			GT vs. FH							
					FH-240	65% (156)	24.2% (58)	4.2% (10)	-	89.2% (214)
L	2016	Chen et al. [22]	CS	> 18	50	-	-	-	-	100% (50)
	1998	Radermacher et al. [23]	CS	> 18	-	-	-	-	-	100%
	2001	Birnbaum et al. [24]	CS	> 18	-	-	-	-	-	100%
	2017	Shao et al. [25]	PM	Teens	30	-	-	-	-	100% (30)
	2017	Wang et al. [26]	CS	6–13	GT-20	-	-	-	-	100% (20)
				GT vs. FH						
T + L	2005	Berry et al. [18]	CS	> 18	46	-	-	-	-	85% (17)
	2015	Lamartina et al. [27]	CS	-	54	77.8% (42)	13.5% (7)	8.7% (5)	-	91.3% (49)
	2017	Farshad et al. [28]	CS	> 18	GT-48	58.33%	39.58%	2.08%	-	97.92%
			GT vs. FH							
					FH-48	43.75%	37.5%	10.42%	8.33%	81.25%

*Ct* all cervical area, *SA* subaxial segment, *T* thoracic area, *L* lumbar area, *T + L* thoracic and lumbar area, *GT* guiding template, *FH* freehand technique, *PM* plastic model of the vertebrae, *CS* cadaveric study, *GT vs. FH* comparative analysis of screw position accuracy using guiding templates and freehand technique, *CorScrew* correctness of screw position

grade 0 from 58.3% to 97.6%, grade I from 2.4% to 39.5%, and grade II 8.7%. Grade 0 + grade I accuracy varied from 91.3% to 100%. Grade III malpositioning was not observed in any case [17, 21, 27, 28]. In comparison, several studies that evaluated the grade of malposition ranged from 71.7% to 100% (mean 96%) [18–20, 22–26]. Some authors estimated the accuracy of screw position as a function of the method of insertion: freehand versus using templates. Correct screw position in the templates group varied from 97.9% to 100%; in the freehand group it ranged from 81.3% to 89.2%, which is statistically significant ( $p < 0.05$ ) [21, 26, 28]. These data reflect the process of constant evolution of surgical techniques in an attempt to provide more safety for the patient—that is the main reason for our current study.

These studies generally reported data from patients older than 18 years [17–25, 27, 28]. We found only one study describing the use of guiding templates in pediatric patients at the age of 6–13 years. The authors of that study printed 10 guiding templates and used them to insert 20 screws in the lumbar area. There were zero cases of screw malpositioning [26].

It should be noted that several studies address in vivo screw placement with guiding templates in the cervical spine [10, 29–36]. Very close attention must be paid to the treatment in this area, dictated by critical anatomical features (small pedicle size, close approximation of the vertebral arteries). Highly precise and correct screw placement is essential. Some authors investigate the problem of application of guiding template in the whole cervical spine including both atlanto-axial and subaxial areas [10, 29, 30]. Others studies solely reported screw insertion in the atlanto-axial area [31–35]. There is scarce literature about the application of guiding templates in subaxial cervical spine [36]. In addition, there are reports using guiding templates at the thoracic [11, 37–40] and lumbar areas [12, 41, 42] separately and together [13, 43] (Table 5).

Mostly studies were designed as follows: firstly, 3D models of the patients' vertebrae were printed with later insertion of the screws in prototyped models using guiding templates. Secondly the same guiding templates for screw

insertion were used in vivo with further evaluation of screw position relative to patient bony structures [10, 11, 13, 29, 30, 32, 33, 35–38, 42]. Some studies used models from plaster of Paris instead of plastic [39]. One author used results of cadaveric pre-study to develop the technique of screw insertion with guiding templates [12, 31]. Others placed the screws using templates directly during the surgery without preparation stage of prototyping of the vertebrae model [34, 40, 41, 43].

According to the literature review the number of screws inserted with guiding templates in vivo varied from 5 to 582 (2323 in total) [10–13, 29–43]. The analysis of screw position accuracy data showed that grade 0 (fully correct) varied from 80.7% to 98.4% (mean 92.2%); grade I from 1.4% to 15.9% (mean 6.8%); grade II from 0.2% to 4.0% (mean 2.7%); grade 0 + grade I from 96.1% to 100% (mean 98.8%). Screw malpositioning classified as grade III was not observed in any case [10, 13, 29, 34, 36, 37, 39–41, 43]. Studies which evaluated malposition of the screws without grading showed that correct positioning was observed in 96.1–100% (mean 99.4%) [11, 12, 30–33, 35, 38, 42].

Comparative analysis of freehand technique and guiding templates in relation to accuracy of screw position was performed in a few studies. Correct position of screws (grade 0) inserted with guiding templates was observed in 92.6–96%. In patients treated with freehand technique percentage of correctness varied from 75% to 88.8%. The combined number of grade 0 + grade 1 screws in patients treated with guiding templates was significantly higher ( $p < 0.05$ ) compared to in patients treated with freehand technique: 96.7–100% and 86.9–98.1%, respectively [34, 40, 41, 43].

Fewer studies related to the efficacy of guiding template application in pediatric patients. These mostly address the problems of surgical treatment in idiopathic scoliosis, systemic and congenital deformities in adolescents [13, 30, 37, 39, 40, 43]. Our literature search did not find studies related to the topic of guiding template application in infants with congenital scoliosis. Comparing the literature and results of our study, the accuracy of screw placement using guiding templates both

**Table 5** Literature data highlighting the topic of guiding templates usage in vivo

Spine area	Year	Author	Type of study	N of cases, type of pathology	Mean age; range	No. of screws	CorScrew, Grade, %/(total)				CorScrew, %/(total)
							0	1	2	3	
Ct	2009	Lu et al. [10]	PM + in vivo	25: trauma (10), spondylogenic myelopathy (4), basilar invagination (11)	17–53	88	80.7% (71)	15.9% (14)	3.4% (3)	–	96.6% (85)
	2012	Kawaguchi et al. [29]	PM + in vivo	11: RA (7), congenital anomalies (3), cerebral palsy (1)	57.4; 14–78	44	95.4% (42)	4.6% (2)	–	–	100%
	2018	Burtsev et al. [30]	PM + in vivo	1: C2 tumor	<18	6	–	–	–	–	100%
AA	2001	Goffin et al. [31]	CS + in vivo	RA C1–C2, congenital deformity C0–C2, AA instability	59–64	–	–	–	–	–	100%
	2009	Lu et al. [32]	CS + in vivo	9: basilar invagination	17–53	19	–	–	–	–	100%
	2014	Kaneyama et al. [33]	CS + in vivo	23: cervical kyphosis (7), basilar impression (5), RA (4), OPLL (2), os odontoidum (2), secondary tumor (1), spondyloarthropathy (1), ankylosing spondylitis (1)	69.4; 54–86	48	–	–	–	–	97.9% (47)
	2017	Jiang et al. [34]	In vivo GT versus FH	54: congenital (26), trauma (22), RA (6)	45.3; 12–54	GT- 100 FH- 116	96% (96)	4% (4)	–	–	100% (100)
	2017	Sugawara et al. [35]	PM + in vivo	12: AA dislocation (11), os odontoidum (1)	42–77	48	–	–	–	–	100%

Table 5 continued

Spine area	Year	Author	Type of study	N of cases, type of pathology	Mean age; range	No. of screws	CorScrew, Grade, %/(total)				CorScrew, %/(total)
							0	1	2	3	
CA	2015	Kaneyama et al. [36]	PM + in vivo	20: cervical kyphosis (7), RA (5), CP (4), trauma (1), OPLL (1), myelopathy (1), secondary tumor (1)	66.9; 49–86	80	97.5% (78)	2.5% (2)	–	–	100% (80)
T	2012	Lu et al. [37]	PM + in vivo	16: AIS (14), congenital (2)	5–18	168	93.5% (157)	6.5% (11)	–	–	100% (168)
	2013	Sugawara et al. [38]	PM + in vivo	10: OPLL (5), oncology (3), DDD (2)	44–65	58	–	–	–	–	100% (58)
	2016	Hu et al. [11]	PM + in vivo	151: trauma (76), oncology (20), DDD (55)	52; 36–67	582	–	–	–	–	96.1% (559)
	2016	Takemoto et al. [39]	PM + in vivo	36: AIS (34), Marphan syndrome (2) 4: OPLL	15.0; 11–19 55.3; 43–77	420 46	98.4% (408)	1.4% (6)	0.2% (1)	–	99.8% (414) 100% (46)
	2018	Pan et al. [40]	In vivo GT versus FH	37: AIS (deformity > 90°)	16.4; 10–18	GT- 396 FH- 312	89.4% (354)	7.3% (29)	3.3% (13)	–	96.7% (383) 86.9% (271)

**Table 5** continued

Spine area	Year	Author	Type of study	N of cases, type of pathology	Mean age; range	No. of screws	CorScrew, Grade, %/(total)					CorScrew, %/(total)
							0	1	2	3	0 + 1	
L	2009	Lu et al. [12]	CS + PM + in vivo	6: DDD (2), trauma (4)	28–68	22	–	–	–	–	–	100% (22)
	2013	Merc et al. [41]	In vivo GT versus FH	20	> 50	GT- 54	92.6% (50)	7.4% (4)	–	–	100% (54)	–
						FH- 54	83.3% (45)	14.8% (8)	1.9% (1)	–	98.1% (53)	–
	2017	Azimifar et al. [42]	PM + in vivo	20	> 18	20	–	–	–	–	–	100% (20)
T + L	2017	Liu et al. [43]	In vivo GT versus FH	10 (deformity > 70°): AIS (3), congenital (7)	17.7; 13–23	GT- 48	93.8% (45)	6.2% (3)	–	–	100% (48)	–
						FH- 104	78.8% (82)	18.3% (19)	–	97.1% (101)	–	–
								2.9% (3)				
	2017	Putzier et al. [13]	PM + in vivo	4: AIS (3), neuromuscular scoliosis (1)	17; 13–25	76	84.2% (64)	11.8% (9)	4% (3)	–	96.1% (73)	–

CS all cervical area, AA atlanto-axial segment, SA subaxial segment, T thoracic area, L lumbar area, T + L thoracic and lumbar area, GT guiding template, FH freehand technique, PM plastic model of the vertebrae, CS cadaveric study, *in vivo* screw insertion in a patient using guiding template, GT vs. FH comparative analysis of screw position accuracy using guiding templates and freehand technique, OPPL ossification of the posterior longitudinal ligament, DDD degenerative disk disease, RA rheumatoid arthritis, CorScrew correctness of screw position, AIS adolescent idiopathic scoliosis

in vitro (grade 0 + I, 91.3–100%) and in vivo (grade 0 + I, 96.1–100%) was very precise. Compared to the accuracy of freehand screw positioning, it may be concluded that it did not differ significantly: grade 0 + I, 78.8% in group 1 of our study and 86.9–98.1% in patients reported by other authors.

On the basis of results of our literature review, we found there were no studies with a design similar to ours. The advantage of our chosen study design is the possibility of comparative evaluation of the screw position in the same cohort of patients using two different techniques which is impossible in clinical practice. The salient finding is that using guiding templates allow the surgeon to improve the accuracy of insertion. There was not only greater precision of screw insertion in group 2 (in vitro) but also significantly more screws could be placed.

Limitations of the current study are the small sample size in group 1 and differences in conditions of screw insertion in group 1 (live surgery) and group 2 (lab study on a plastic model) which might affect the results.

## CONCLUSIONS

The data from our comparative analysis show that the number of correctly placed pedicle screws was significantly higher in group 2 where the guiding templates were used in relation to the group 1 where screws were placed with freehand technique (96.3% versus 78.8%,  $p = 0.011$ ). The data obtained highlight the high accuracy of screw placement with guiding templates in vitro, which is encouraging with respect to the further development and refinement of this method. It also is promising with respect to the wider application of this approach in surgical treatment of infants with congenital spine deformities.

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**Compliance with Ethics Guidelines.** The study protocol was approved by the Turner Scientific and Research Institute for Children’s Orthopaedics (within the Department of Spinal Pathology and Neurosurgery), Pushkin, Saint Petersburg, Russia. All research was performed in accordance with Turner Scientific and Research Institute guidelines and regulations, and the respective authors declare a statement confirming that informed consent was obtained from all of the participants’ parents and/or their legal guardians. In addition to the guidelines described above, the authors of these study dealing with human transplantation research attested that no organs/tissues were procured from prisoners. No animals were used for studies that are the basis of this research. All research on humans was in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013 (<http://ethics.iit.edu/ecodes/node/3931>).

**Data Availability.** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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