

The 3D Printed Template Assists Accuracy and Safety of Screw Placement in the Treatment of Pediatric Congenital Scoliosis: A Case Control Retrospective Study

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Abstract

Background: Three-dimensional (3-D) printed templates are increasingly applied in spinal surgery, but are rarely used in the treatment of congenital scoliosis. This study aimed to evaluate the accuracy and safety of 3D printed template-assisted screw placement in the treatment of congenital scoliosis.

Methods: A total of 67 patients with congenital scoliosis treated in our hospital between January 2017 to January 2019 were retrospectively included (mean age= 4.13 ± 2.66 years, range: 2-15) and divided into the template-assistant group (n=34) and the freehand group (n=33) according to the screw placement method. The accuracy rate of pedicle screw placement, surgical outcomes, and incidence of complications were compared between groups.

Results: Although the good accuracy (grade 0+ grade 1) rate of pedicle screw placement was comparable between the two groups, the excellent accuracy (grade 0) rate was significantly higher in the template-assistant group than in the freehand group (96.10% vs. 88.64%, $P=0.007$). The main curve Cobb's angle and Kyphosis' angle significantly decreased after surgery in both groups but without a significant intergroup difference. The template-assistant group had a significantly lower postoperative complication rate than the freehand group (0% vs. 18.18%; $P=0.009$). The 4 patients with postoperative complications in the freehand group all received revision surgery.

Conclusion: The 3D printed templates can improve the excellent accuracy rate of screw placement and reduce postoperative complications in the treatment of congenital scoliosis, thereby improving the therapeutic efficacy.

Background

Congenital scoliosis is defined as a lateral spinal curvature of over 10%, accounting for 10% of pediatric spine deformity [1]. The prevalence of congenital scoliosis is estimated to be approximately 0.5 to 1/1000 live births [2]. The etiology of congenital scoliosis remains not fully understood, but failure of formation/ segmentation during somitogenesis is believed to be involved in the pathogenic mechanism [3]. Congenital scoliosis has a serious impact on spinal growth [4], and up to 85% of congenital scoliosis patients would have a final curve higher than 41° after 10 years of age if left untreated [5–7].

Surgical operation remains the primary treatment for most cases of congenital scoliosis. Pedicle screw instrumentation has been widely adopted for the treatment of scoliosis due to its superior correction efficacy [8, 9]. At present, the freehand surgical approach with fluoroscopic control remains the most commonly used method of screw placement [10] but has the risk of pedicle screw misplacement [11, 12].

With the development of three-dimensional (3-D) printing technology, 3D printing guide templates are more and more commonly applied in spinal surgery, such as post-traumatic deformities, degenerative or inflammatory diseases, pathology of the craniocervical junction, and idiopathic scoliosis [13]. However, the studies on 3D printing techniques in the treatment of pediatric congenital scoliosis are extremely rare

[10]. This study aimed to evaluate the accuracy and safety of 3D printed template-assisted screw placement in the treatment of congenital scoliosis.

Methods

Study design and subjects

This study was a retrospective study. A total of 67 patients with congenital scoliosis treated in our hospital from January 2017 to January 2019 were included and divided into two groups according to the screw placement method. Inclusion criteria were: 1) congenital scoliosis; 2) comprehensive evaluation recommended surgical treatment; 3) no history of surgical treatment. The exclusion criteria were: 1) idiopathic, neuromuscular, syndrome, and non-congenital scoliosis; 2) patients with multiple system diseases intolerant to surgery; 3) the patient's parents refused to be included in the study.

In the template-assistant group (n = 34), a 3D printing anatomical model of the deformed spine was made based on preoperative CT scan data and was used for surgical planning and screw placement design. In the control group (n = 33), the freehand technique was used for intraoperative screw placement. All patients were followed up for more than 12 months.

This study was approved by the institutional review board (IRB) of our hospital and written informed consent was waived by the IRB due to the retrospective nature of this study.

Design and printing of navigation templates

The patient's CT data was converted to Digital Imaging and Communications in Medicine (DICOM) format file by the picture archiving and communication systems (PACS) and then was imported into the Mimics 19.0 software (Materialise, USA) (Supplementary Fig. 1). The reconstructed model was obtained through 3D reconstruction calculation. In the Analyze module, four 2.2-mm diameter cylinders were generated to simulate Kirschner wires for screw placement. The ideal nail path of the posterior pedicle screw was preliminarily designed (Supplementary Fig. 2A), and the cylinders and the reconstructed model were fitted together (Supplementary Fig. 2B).

The model (STL format) was imported into the 3-Matics software (Materialise, USA). The positioning sites for guide plates were selected on the surface of the posterior spinous process, lamina, and lateral mass of the vertebral body, and the guide plates were generated (Supplementary Fig. 3A).

With appropriate connection, all local guide plates were integrated into a navigation template (Supplementary Fig. 3B). The data of navigation template (STL format) was imported into to the 3D printing pre-processing software Magics 20.03 (Materialise, USA) for correction (Supplementary Fig. 4), followed by importing to idealmaker software (ver. 3.1.3, Raise3D, Inc. Shanghai, China) for slice (line width = 0.4 mm, layer thickness = 0.25mm, support angle = 54 °). The resulting gcode file was input into the Pro2 plus 3D printer (Raise3D, Inc) for 3D printing using Polylactic Acid (PLA) material (the nozzle

temperature = 215 °C, the hot bed temperature = 60 °C). The 2.0-mm Kirschner wire was used to clear the pinholes reserved on the printed navigation template.

Surgical procedure

All surgical treatments for congenital scoliosis were performed by posterior surgical approach. After anesthesia, the patient was placed in the prone position, and an incision was made in the middle of the posterior spine, and the paravertebral muscles were separated to expose the spinous process, lamina, upper and lower articular processes, and transverse processes.

In the template-assistant group, the sterilized navigation template was firmly buckled on the lamina. Via the reserved pinhole on the navigation template, an electric drill was used to drill pinholes for the 0.5-mm diameter Kirschner wire. After correct position of the Kirschner wire was confirmed by X-ray arm, the pedicle screw was placed. In the freehand group, the pedicle position was estimated according to the anatomical features of the exposed lamina and articular process, and Kirschner wires were placed in the corresponding position. After correct position of the Kirschner wire was confirmed by X-ray arm, the pedicle screw was placed.

After the pedicle screws were placed in both groups, the semi-vertebral body was excised and orthopedically fixed. The autogenous bone was grafted and fused, and the incision was closed.

Outcomes measurement

The data of preoperative deformity, operation time, intraoperative blood loss, and postoperative complications were recorded. After the operation, CT examination was performed and the accuracy of pedicle screw placement was evaluated by the Kawaguchi method [14] as follows:

Grade 0: The pedicle screw was completely inside the pedicle. Grade 1: The pedicle screw partially penetrated the medial or lateral pedicle, the ranging less than 2 mm. Grade 2: The pedicle screw partially penetrates the medial or lateral pedicle, the ranging between 2 and 4 mm. Grade 3: The pedicle screw partially penetrates the medial or lateral pedicle, the ranging greater than 4 mm.

Excellent accuracy rate (Grade 0 accuracy of screw positioning): $\text{Grade 0 screws} / \text{all screws} * 100\%$;

Good accuracy rate (Grade 0+ Grade 1 accuracy of screw positioning): $\text{Grade 0+ Grade 1 screws} / \text{all screws} * 100\%$.

Statistical analysis

Continuous data were indicated with mean \pm standard deviation (SD). For the comparisons between the two groups, student's independent t-test and paired t-test were used for independent and repeated measurements, respectively. Mann-Whitney U test and Wilcoxon signed-rank test would be used if normality of continuous variable was not assumed. Categorical variables were presented as numbers and

percentages and were compared using the Chi-square test or Fisher's exact test (if the expected value ≤ 5 was found). Two-way mixed-design ANOVA was used to investigate the differences of main curve Cobb's angle and Kyphosis' angle before and after surgery in both groups. Linear regression was used to investigate the association of group factors to the changing angles before and after surgery. A $P < 0.05$ would be recognized as reaching the significance of each test, two-tailed. All analyses were performed using IBM SPSS Version 25 (SPSS Statistics V25, IBM Corporation, Somers, New York).

Results

Patient's demographic and clinical characteristics

A total of 67 patients with congenital scoliosis were included (43 males and 24 females, mean age = 4.13 ± 2.66 years, range: 2–15 years) and divided into the template-assistant group ($n = 34$) and the freehand group ($n = 33$) according to the screw placement method. The demographic and clinical characteristics were summarized in Table 1. There was no significant difference in age, gender, scoliosis types, combined malformation, malformation type, scoliosis location, and scoliosis side between the two groups (all $P > 0.05$), indicating that the two groups were comparable.

Table 1
Patient's demographic and clinical characteristics

Parameters	Template-assistant group (n = 34)	Freehand group (n = 33)	All (n = 67)	P
Age, year	4.06 ± 2.28	4.21 ± 3.04	4.13 ± 2.66	0.816
Sex				0.548
Male	23 (67.65%)	20 (60.61%)	43 (64.18%)	
Female	11 (32.35%)	13 (39.39%)	24 (35.82%)	
Scoliosis types				0.206
Defects of formation	12 (35.29%)	18 (54.55%)	34 (50.75%)	
Defects of segmentation	2 (5.88%)	2 (6.06%)	4 (5.97%)	
Mixed type	20 (58.82%)	13 (39.39%)	33 (49.25%)	
Combined malformation				0.323
No	22 (64.71%)	25 (75.76%)	47 (70.15%)	
Yes	12 (35.29%)	8 (24.24%)	20 (29.85%)	
Malformation type				0.067
Single	13 (38.24%)	20 (60.61%)	33 (49.25%)	
Multiple	21 (61.76%)	13 (39.39%)	34 (50.75%)	
Scoliosis side				0.216
Left	18 (52.94%)	18 (54.55%)	36 (53.73%)	
Right	16 (47.06%)	13 (39.39%)	29 (43.28%)	
Kyphosis	0	2 (6.06%)	2 (2.99%)	

Surgical information

All patients successfully underwent posterior fusion surgery for congenital scoliosis. Table 2 demonstrated the surgical information and outcomes of both groups. there was no significant difference in surgical time and intraoperative bleeding between groups (both $P > 0.05$).

Table 2
Surgical information and outcomes

Parameters	Template-assistant group (n = 34)	Freehand group (n = 33)	All (n = 67)	P
Surgical time, min	160.44 ± 46.03	156.82 ± 55.21	158.66 ± 50.40	0.771
Intraoperative bleeding, mL	368.53 ± 254.64	306.15 ± 232.24	337.81 ± 244.05	0.299
Screw placement outcomes				
Number of screws	6.59 ± 2.72	5.24 ± 2.05	5.93 ± 2.49	0.026
Excellent accuracy rate	96.10%±7.02%	88.64%±13.91%	92.42% ±11.51%	0.007
Good accuracy rate	99.02%±3.28%	97.14%±7.20%	98.09% ±5.60%	0.171
Number of fused level	3.47 ± 1.58	2.70 ± 1.13	3.09 ± 1.42	0.025
Main curve Cobb's angle				
Preoperative	38.77 ± 13.59	32.91 ± 11.87	35.88 ± 13.02	0.065
Postoperative	8.94 ± 9.20*	5.86 ± 7.30*	7.42 ± 8.40	0.135
Kyphosis' angle				
Preoperative	20.33 ± 14.77	19.68 ± 16.17	20.01 ± 15.36	0.864
Postoperative	8.87 ± 7.45*	4.70 ± 9.56*	6.82 ± 8.75	0.073
Complication	0	6 (18.18%)	6 (8.96%)	0.009
*, both main curve Cobb's angle and Kyphosis' angle significantly decreased after surgery in both groups (all $P < 0.001$).				

The template-assistant group had a significantly higher number of screws and fused level than the freehand group (all $P < 0.05$).

Although the good accuracy rate of pedicle screw placement was comparable between the two groups (99.02% vs. 97.14%, $P = 0.171$), the excellent accuracy rate was significantly higher in the template-assistant group than in the freehand group (96.10% vs. 88.64%, $P = 0.007$).

Clinical outcomes

In both preoperative or postoperative results, no significant difference was found in the main curve Cobb's angle and Kyphosis' angle between the two groups (all $P > 0.05$, Table 2). However, in ANOVA results, both groups' main curve Cobb's angle and Kyphosis' angle significantly decreased after surgery (all $P < 0.001$).

The changing angle of the main curve Cobb's angle (-29.84 ± 10.88 vs. -27.05 ± 10.77 ; $P = 0.295$) and Kyphosis' angle (-11.46 ± 15.11 vs. -14.98 ± 16.20 ; $P = 0.361$) were not significantly different between groups. The linear regression of group factor to the changing angles also showed no significant difference between groups (both $P > 0.05$). These results indicated the comparative treatment effect between groups.

Two representative cases of the template-assistant group were shown in Figs. 1 and 2.

Postoperative complication

The template-assistant group had a significantly lower postoperative complication rate than the freehand group (0% vs. 18.18%; $P = 0.009$). No patients in the template-assistant group had a postoperative complication. In the freehand group, 2 patients had transiently reduced muscle strength after surgery, and 2 patients had internal fixation-related complications. All of them received revision surgery.

Discussion

Current screw placement methods include freehand, navigation system [15], and robot-assisted pedicle screw placement [16]. Conventional freehand technology has low accuracy [11, 12]. Especially in pediatric scoliosis patients, pedicle screw misplacement is more likely to occur due to the presence of small pedicles and severely rotated vertebrae. For congenital scoliosis patients at an early age (3–5 years), hemivertebra excision and short segment fusion are a safe and effective procedure for a single or two-level congenital vertebral defect [17]. To reduce the fixation of segments, short segment fusion (fixation of the vertebra above and below the hemivertebrae) is frequently performed. However, this procedure is often associated with instrument complications. In pediatric scoliosis patients, pedicle screw misplacement may occur due to the presence of small pedicles and severely rotated vertebrae, leading to severe complications, such as injuries of the nerve roots, spinal cord, major vessels and pedicle fracture [18–20]. An intraoperative pedicle fracture causes the fused level to be extended, while an unidentified pedicle fracture may lead to loss of postoperative correction effects and neurological complications. Ledonio et al. have conducted a systematic review including 13,536 pedicle screws placed in 1353 pediatric patients with spinal deformity and found that the overall accuracy of pedicle screw placement by freehand technique was 94.5% and the accuracy would decrease in severe spinal deformity [21]. Therefore, the accuracy of screw placement is important for reducing complications and improving prognosis.

The 3D printing technique has been increasingly used in guiding templates for screw placement in spinal orthopedics [22, 23]. However, most of these studies focusing on adult patients, and studies on 3D printing techniques in the treatment of congenital scoliosis are scarce. Very recently, Vissarionov et al. have reported that the screw placement with 3D-printed guiding templates during surgical treatment of congenital scoliosis is more accurate than using a freehand technique (94.4% vs. 53.8%) [10]. Nevertheless, Vissarionov et al.'s study only compared the accuracy of screw placement but not corrective efficacy and postoperative complications. Therefore, the effect of 3D printing technique in the treatment of congenital scoliosis is needed to further investigation.

In this study, we evaluated the accuracy and safety of 3D printed template-assisted screw placement in the treatment of congenital scoliosis. The results showed that the template-assistant group had significantly more screws and fused level than the freehand group. The 3D printed navigation templates were more commonly used in patients with complex deformities, and these patients had more severe scoliosis and complex anatomical structures. Therefore, the template-assistant group had more screws (for fixation) and more fused levels.

Our results showed no significant differences in the intraoperative bleeding amount and surgical duration between the template-assistant group and the freehand group. This is mainly because correction surgery for congenital scoliosis often requires hemivertebra resection, which takes a long surgical time and causes much bleeding. In contrast, the surgical time and blood loss saved by the 3D printed navigation templates were too small to affect the overall difference. In this study, although the good accuracy rate of pedicle screw placement was comparable between the two groups, the template-assistant group had a significantly higher excellent accuracy rate of pedicle screw placement as compared with the freehand group (96.10% vs. 88.64%, $P = 0.007$). Consistent with our finding, Vissarionov et al.'s study shows that compared to the freehand technique, the 3D-printed guiding templates markedly improve the accuracy of screw placement in the surgical treatment of congenital scoliosis (94.4% vs. 53.8%) [10]. These results suggest that the application of 3D printed navigation templates can significantly improve the accuracy of screw placement in the surgical treatment of congenital scoliosis. Congenital scoliosis often combines with posterior lumbar fusion, making a larger contact area between the posterior lamina and the navigation template and allowing more accurate screw placement.

In this study, the main curve Cobb's angle and Kyphosis' angle significantly decreased after surgery in both groups. However, no significant difference was observed between groups. This data indicated that both the 3D-printing technique and freehand technique had high therapeutic efficacy for the surgical treatment of congenital scoliosis. The template-assistant group had a significantly lower incidence of postoperative complication as compared with the freehand group (0% vs. 18.18%; $P = 0.009$). The 4 patients with postoperative complications in the freehand group all received revision surgery. This finding demonstrated that 3D-printing templates can effectively reduce postoperative complication rate in the treatment of congenital scoliosis as compared with the freehand technique.

There are still some limitations to this study. first, this study was limited by its small sample size and retrospective nature. In addition, the primary outcome of this study was the accuracy of screw placement, which can be assessed from postoperative CT, hence the follow-up duration of this study was relatively short. Continued follow-up is necessary for side effects, postoperative complications, and long-term effects. Moreover, we did not compare the outcomes between 3D printed template-assisted and robot-assisted pedicle screw placement. In the future, a well-designed, large prospective trial should be conducted to validate the findings of this study.

Conclusions

In summary, our study suggested that The 3D printed templates can improve the excellent accuracy rate of screw placement and reduce postoperative complications in the treatment of congenital scoliosis, thereby improving the therapeutic efficacy.

Abbreviations

DICOM: Digital Imaging and Communications in Medicine

PACS: picture archiving and communication systems

Declarations

Ethics approval:

This study was approved by the institutional review board (IRB) of the Beijing Children's Hospital and written informed consent was waived by the IRB due to the retrospective nature of this study.

Consent for publication:

Not applicable.

Availability of data and material:

All data generated or analysed during this study are included in this published article.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions

JC collected, analyzed and interpreted the patient data, and was a major contributor

in writing the manuscript. XJZ analyzed and interpreted the patient data and revised the manuscript. HNL and ZMY collected and analyzed the patient data. YSB, DG,LF searched literatures. All authors read and approved the final manuscript.

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Figures

Fig. 1

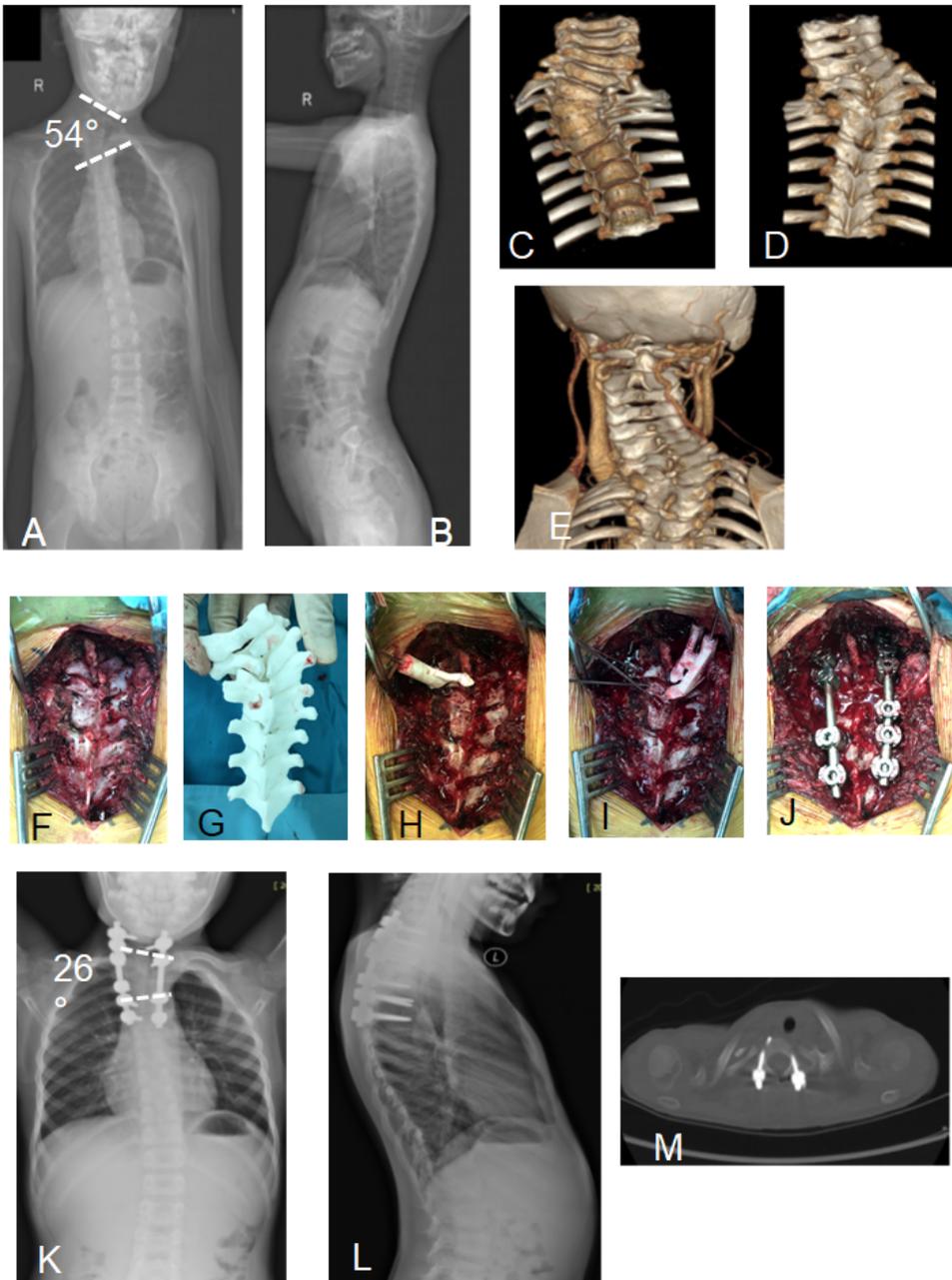


Figure 1

A 7-year-old male patient visited due to a worsening neck skew. (A-B) X-rays showed congenital scoliosis. There were multiple vertebral deformities in the cervical and upper thoracic spine. The angle of scoliosis was about 72° and the trunk was offset by 2.7 cm. (C-E) CT showed multiple vertebral malformations in

the upper thoracic spine. CTA was performed to understand the condition of the carotid artery. (F-J) The spine was exposed during the operation. The premade 3D printed navigation template was placed on the vertebral body, and the spinous process and transverse process anatomical landmarks were used to confirm the fixation. Along the navigation template, the Kirschner wires were placed, followed by the screws. (K-L) Postoperative anterolateral radiographs of the spine showed correction of scoliosis to 26°. (M) Postoperative CT showed that the screws were placed in the center of the pedicle.

Fig. 2

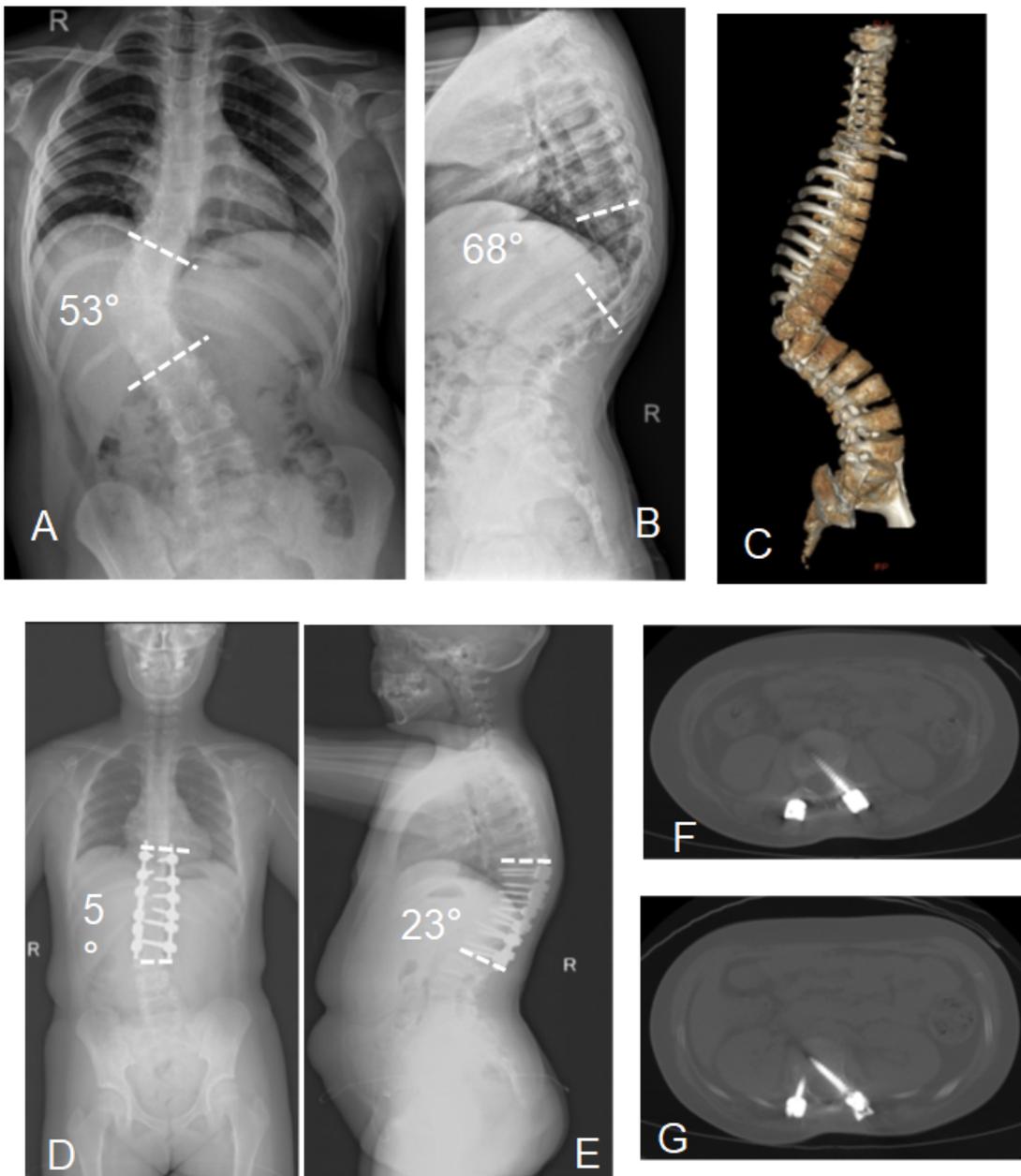


Figure 2

A 9-year-old female patient presented with a bulging back. (A-C) X-ray showed congenital scoliosis, thoracolumbar hemivertebral deformity, with the scoliosis angle of about 53° and kyphosis of 68°. (D-E) Postoperatively, the scoliosis was corrected to 5° and the kyphosis was 23°. After the operation, the patient's lower limb muscle strength decreased and returned to normal after one month. (F-G) CT showed that the left L1 and L2 pedicle screws were offset into the spinal canal.

Supplementary Files

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