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Original Article
Application of 3D printed models in the surgical treatment of spinal deformity

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Abstract: Objective: To test if preoperative planning with 3 dimensional (3D)-printed spine models can increase the effectiveness and safety of spinal deformity surgery. Methods: A total of 53 patients who were treated in our center for spinal deformities from January 2010 to January 2018 were included in the current study. They were divided into two groups based on whether 3D-printed models were used in the surgical planning. A total of 28 patients who were treated with 3D-printed models were assigned to the experimental group, and 25 patients who were treated with conventional methods were assigned to the control group. Duration of surgery, intraoperative hemorrhage, incidence of surgery related complications, Oswestry disability index (ODI), visual analogue scale (VAS), and Cobb's angle were compared between the two groups before and after surgery. Results: There were significant differences in the duration of surgery, intraoperative hemorrhage and intraoperative x-ray exposure between the two groups (P<0.01). Cobb's angle was smaller in the experimental group than in the control group when measured three days and a year after surgery (P<0.01). Although there was no significant difference between the experimental and control groups (P>0.05), Oswestry disability index and VAS pain scores were lower a month and a year after the surgery than before the surgery (P<0.01). Conclusion: Surgical planning using 3D-printed spine models can decrease the operation time, intraoperative hemorrhage, and x-ray exposure, and help achieve satisfactory structural restoration in patients with severe spinal deformity.

Keywords: Spinal deformity, 3D printing, osteotomy, pedicle screw

Introduction

Spinal deformity is usually caused by congenital dysplasia, trauma, vertebral infections as well as spinal tumor, which results in pain, dyskinesia, severe spinal stenosis and even paralysis. Surgery is the main option for the treatment of spinal deformity [1-3]. However, due to the complex structural abnormalities, the correction of spinal deformity presents a great challenge to orthopedic spine surgeons [4, 5]. Pedicle screws are essential in restoring and stabilizing the curvature of the spine. However, due to the deformed pedicle anatomy, pedicle walls can be easily breached by pedicle screws when using conventional methods, causing further damage to the spinal cord and the surrounding neural tissues. To circumvent this issue, novel techniques have been developed for a safe and effective screw placement over the years, and the commonly used methods for screw placement include free hand technique, screw placement with intraoperative fluoroscopic navigation and 3-dimentional (3D)-printed plate navigation [6-8]. However, the free hand technique requires advanced skill level of the surgeon and has low success rate of pedicle screw insertion. The accuracy of pedicle screw insertion ranges from 28% to 94% [9]. Although computer navigated surgery is a proven way to increase the success rate of pedicle screw insertion, but the equipment is too expensive to be widely applied [10, 11]. With the development and broad application of 3D data reconstruction, personalized 3D printing technology has been used for surgical planning. Studies have shown that 3D printing technology can significantly decrease the operation time and increase the accuracy of pedicle screw placement [12, 13]. However, there are only few studies on its application in spinal deformity correction surgeries. Here, we report our results with the application of full-scale 3D-printed spine models for planning spinal deformity surgeries.

Methods

Patient inclusion and exclusion criteria

Inclusion criteria: 1) aged 13-60 years; 2) patients with severe spinal deformity that cannot be effectively treated with palliative treatment; 3) no significant abnormalities in preoperative physical and blood check-up; 4) Cobb angle ≥40 degrees on coronal plane, and/or sagittal vertical axis (SVA) >5 cm, could not be alleviated after 3 months of conservative treatment; 5) agreed to receive surgical treatment; 6) the method of surgical treatment is internal fixation and spinal fusion using posterior surgical incision. Exclusion criteria: 1) did not fit surgical indication of spinal deformity; 2) unable to perform pedicle screw placement due to congenital dysplasia of pedicle and vertebral arch; 3) patients with contraindications to surgical treatment.

Surgery procedure

In the control group, 0.5 mm thick preoperative computed tomography (CT) scans were used to construct a two-dimensional image of the operation region for surgical planning. Transpedicular vertebral osteotomy was used for deformity correction in our patients. Preoperative planning included the segments of fixation, site of osteotomy, estimated correction of Cobb's angle, and the size of implants. The patient was placed in the prone position on the operating table after general anesthesia. The posterior spinal structure was exposed to bilateral transverse processes through a posterior central incision. Pedicle screws were inserted using preplanned trajectory. Transpedicular vertebral osteotomy was carried out as planned by using our patented Tian's osteotome. Spinal cord and nerve roots were carefully protected throughout the surgery and were monitored with somatosensory evoke potential and motor evoke potential. The rods were shaped intraoperatively according to the correction of Cobb's angle.

In the experimental group, 0.5 mm thick computed tomography (CT) scans were used to construct the 3D image of the whole spine using Mimics software, which was printed using epoxy resin by 3D printer. The trajectory and length of pedicle screw and the site and method of osteotomy were designed on Mimics software and confirmed on the 3D-printed model. The connecting rods of pedicle screws were pre-shaped to safely reduce spinal deformity and save operation time. All the other procedures were the same as the control group.

Outcome assessment

The following parameters were used to assess the outcome: 1) surgery related outcomes such as intraoperative time, hemorrhage, time of x-ray exposure; 2) the accuracy of screw placement evaluated by CT scans 3 days after surgery. The screw placement accuracy was graded as "0" if the screw was within the pedicle all the time, "1" if the screw breached the pedicle within 2 mm without any complications, and "2" if the screw breached the pedicle more than 2 mm [14]; 3) deformity correction was determined by anteroposterior and lateral x-rays before surgery, 3 days after surgery, and one year after surgery. Cobb's angle and correction of Cobb's angle: (Cobb's angle after surgery - Cobb's angle before surgery)/Cobb's angle before surgery *100%; 4) visual analogue scale (VAS) pain score and Oswestry disability index (ODI) before surgery, 4 weeks after surgery, and a year after surgery. VAS pain scores (0-10 points, with 0 meaning no pain, and 10 meaning extreme pain) were used to assess the back pain in patients. ODI was used to assess the functional recovery after surgery. It measured pain intensity, personal care, sleeping, sitting, standing, walking, traveling, sex and social life, as well as lifting. Scores ranged from 0 (normal) to 10 (complete inability) in each subclass; 5) complications: surgery related complications such as incidence of neural injury, spinal fluid leakage, infection as well as the incidence of deep vein thrombosis during follow up were recorded and compared between the two groups.

Statistical analysis

SPSS 24.0 (IBM, Chicago, IL) was used for the statistical analysis in the current study. Duration

Table 1. Intraoperative time, hemorrhage, and the pedicle screw placement accuracy of patients in the two groups

		Experimental	Control	T/X^2	P
Time (min)		375±80	456±107	7.24	<0.01
Hemorrhage (ml)		363±75	442±85	7.51	<0.01
x-ray (s)		13.3±4.1	18.2±5.8	4.03	<0.01
Instrumentation accuracy	0	361	305	48.69	<0.01
	1	48	89		
	2	6	14		

of surgery, intraoperative hemorrhage, time of x ray exposure, Cobb's angles, VAS and DOI scores were compared between the groups using independent sample t-tests. Paired t-tests were used for comparison of indicators before and after treatment within the same group. The count data such as the incidence of surgery related complications was analyzed using chi-squared analysis. The data was expressed by mean ± standard deviation. The difference was considered significant when P<0.05.

Results

According to the inclusion and exclusion criteria, a total of 53 patients (23 men, 30 women, average age of 27.5±11.8 years ranging from 13-59) were enrolled in our study. They were divided into experimental and control groups according to the treatment they have received. In the experimental group, there were 13 men and 15 women, with the average age of 25.6±9.2 years (range 15-54 years). In the control group, there were 10 men and 15 women, with the average age of 29.1±12.4 years (range 13-59 years).

Among the 28 patients in the experimental group, 13 patients had congenital scoliosis, while 7 patients had neuromuscular type scoliosis and 8 patients had idiopathic scoliosis. Twelve patients had thoracolumbar deformity; 12 patients had lumbar deformity, and 4 patients had upper thoracic deformity. In the control group of 25 patients, there were 11 patients with congenital scoliosis, 6 patients with neuromuscular type scoliosis, and 8 patients with idiopathic scoliosis. A total of 11 patients had thoracolumbar deformity; 10 patients had lumbar deformity, and 4 patients had upper thoracic deformity. There were no significant differences in age, gender, type of scoliosis, and the segment of deformity between the two groups (P>0.05).

Screw insertion accuracy

Screw insertion accuracy was evaluated using postoperative CT scans. It was considered accurate when the screw was located in the pedicle wall and vertebral body. Any breach of the pedicle wall was considered screw placement failure. A total of 415 screws were inserted in the experimental group, and 408 screws were inserted in the control group. The number of medial and lateral breaches were 2 and 4, respectively, in the experimental group, and 4 and 10, respectively, in the control group. The screw insertion accuracy was 87% in the experimental group and 75% in the control group. There was no symptomatic breakage of the pedicle wall and no screw loosening or pull out during follow up.

The follow up time was 12-24 months with an average of 16.2±4.5 months. Importantly, there was a significant difference in the duration of surgery, intraoperative hemorrhage, and the time of x-ray exposure between the two groups. All these parameters were lower in the experimental group than in the control group (**Table 1**).

Correction of deformity

There was no significant difference in thoracic and lumbar Cobb's angle at coronal and sagittal planes before the surgery between the two groups (P>0.05), and as expected, the Cobb's angle was smaller in patients 4 weeks after surgery in both groups compared to that before surgery. However, Cobb's angle was smaller in the experimental group than in the control group (P<0.01) (**Table 2**).

VAS pain scores and ODI scores

The VAS pain scores and ODI scores were significantly improved one month after surgery (P<0.01), and further improved at the last follow up (P<0.01). There was no significant difference in VAS pain scores and ODI scores be-

Table 2. Sagittal and coronal plane Cobb's angle in thoracic and lumbar spine of two groups of patients before and after surgery

Cobb's Angle		Time	Experimental	Control	P
Thoracic spine	Sagittal Plane	Before	70.1±13.8	68.3±13.2	0.71
		After	20.6±7.8#	31.9±6.5#	<0.01
		A year	26.4±6.4#	34.1±7.1#	<0.01
	Coronal Plane	Before	39.3±12.1	40.2±11.6	0.26
		After	9.1±6.2#	16.3±7.3#	<0.01
		A year	9.8±7.0#	17.7±8.4#	<0.01
Lumbar spine	Sagittal Plane	Before	53.9±22.1	57.0±15.2	0.66
		After	21.7±9.8#	32.9±5.3#	<0.01
		A year	26.0±7.6#	35.6±6.4#	<0.01
	Coronal Plane	Before	37.6±17.1	39.2±13.6	0.73
		After	6.3±6.5#	11.9±7.3#	0.01
		A year	6.4±6.6#	13.9±8.9#	<0.01

#: P<0.01 compared with before surgery within the same group.

Table 3. VAS pain scores and ODI functional recovery scores in two groups of patients

		Experimental	Control	P
VAS	Before	7.8±2.3	7.5±1.9	0.36
	4 weeks	3.4±1.1#	3.6±1.3#	0.55
	A year	1.5±0.6#,*	1.6±0.7#,*	0.58
ODI	Before	52.6±15.3	50.8±14.7	0.54
	4 weeks	40.3±12.6#	38.8±10.5#	0.64
	A year	28.5±8.0#,*	26.7±7.5#,*	0.40

#: P<0.01 compared to before surgery within the same group; *: P<0.01 compared to 4 weeks after surgery within the same group.

fore the surgery, after the surgery, and during follow up between the two groups (P>0.05, **Table 3**).

Complications

One patient in the control group experienced incomplete paraplegia after surgery. An emergency surgery was scheduled, and all the screws and rods were removed. Patient started sensory recovery a week after surgery, and the muscle strength was recovered significantly a month after surgery. The patient achieved near normal functional and sensory recovery a year after the surgery. One patient in the experimental group showed partial sensory impairment in the left leg, which was recovered within three months without intervention. One patient in the control group was found with spinal fluid leakage, which was treated by prolonged drainage and antibiotic treatment (ceftriaxone 1 g, bid). No other surgery related complications were found in either group.

Discussion

Surgical treatment is the only effective option for patients with severe spinal deformities. However, due to the complex anatomical pathologies in patients with severe spinal deformities, placement of pedicle screws can be challenging [15-17]. Application of 3D printing technology makes it possible to anticipate and prepare for the challenges that need to be addressed during the procedure and simplifies the preoperative surgical planning [18, 19]. The personalized full-scale 3D-printed spine models help accurately analyze the surgical anatomy of the patient and plan more effective and safe approaches for osteotomy and screw placement [20, 21].

After the first report of 3D printing by Hull in 1986, 3D printing technology has been gaining increasing popularity in orthopedic spine surgery [22]. Application of accurate 3D printing in spinal surgery improves the preoperative planning and reduces the complexity and duration of operation [23, 24]. Accurate 3D models enable the surgeon to plan and practice a safe surgical corridor or approach preoperatively, which helps reduce the complexity of the surgery and decrease the operation time for complex cases [25-27].

In our participants, we used 3D-printed models in the preoperative planning of spinal deformity (**Figures 1-3**). Our study showed that using 3D-printed spinal deformity models could significantly reduce the operation time, intraoperative hemorrhage, and x-ray exposure. We first built 3D models and reconstructed the anatomical relations among the segments of deformed spine to directly assess the severity of deformity. Next, using those 3D models, we decided the position, direction and depth of pedicle screw placement, and pre-bent the connecting rods, and planned the location and method of osteotomy. The 3D model-based

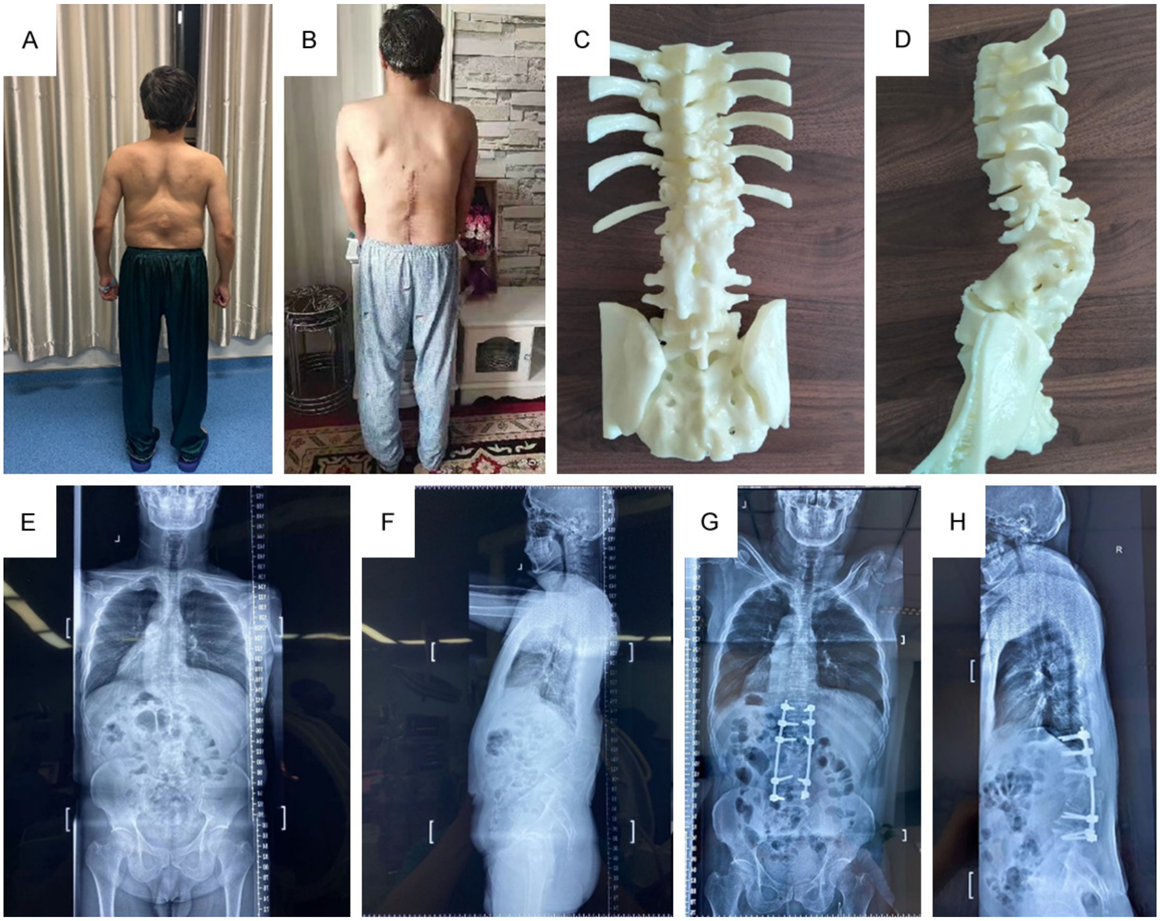

Figure 1. A 49-year-old patient with congenital scoliosis (A, B). The preoperative sagittal cobb angle was 85 degrees and 40 degrees on coronal plane (E, F). 3D-printed spine models were used for preoperative planning (C, D). The sagittal cobb angle was reduced to 42 degrees, and the coronal cobb angle was reduced to 15 degrees after surgery (G, H).

planning of screw placement, osteotomy and bone fusion avoided excessive trauma and hemorrhage from excessive exposure during surgery, leaving more time for accurate osteotomy and screw positioning. As consistent with our results, Garg et al. [28] found that 3D printing-aided surgery can significantly decrease the intraoperative time, hemorrhage, x-ray exposure, and achieve more accurate screw placement than the control group.

Previous studies have reported that, besides reducing operation time and hemorrhage, preoperative planning using 3D-printed spinal deformity models could also increase the correction of Cobb's angle and alleviate the symptoms associated with spinal deformity in patients [29]. In our current study, correction of both thoracic and lumbar regions at coronal and sagittal plane Cobb's angles was significantly better in the experimental group than in the control group. However, we did not observe any difference in VAS pain scores and ODI scores between the two groups, albeit both parameters were significantly improved after the surgery and during follow up, probably due to patients in both groups achieving satisfactory recovery after the surgery, as the final VAS and ODI scores were both significantly improved. Our results supported the findings by Tan et al. [30] that 3D-printed model-assisted surgical planning significantly increased the accuracy of screw placement and the efficacy of deformity correction and decreased the incidence of surgery related complications. Although the 3D printing technique can be a valuable addition to the surgical planning of spinal deformity treatment, its relatively high cost and low accuracy hamper its wider application. With the increasing quality and decreasing cost

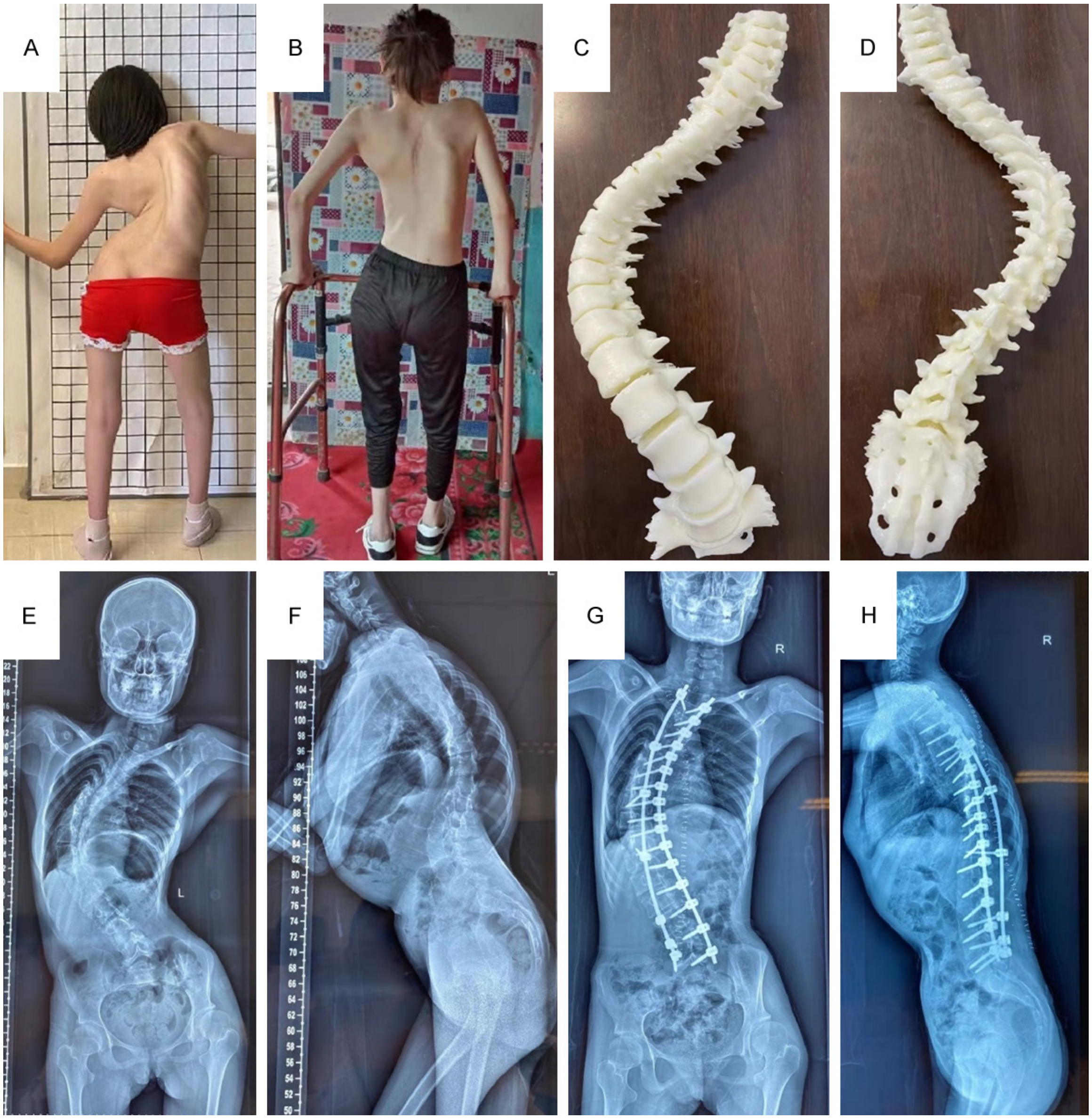

Figure 2. A 13-year-old patient with neuromuscular scoliosis (A, B). The preoperative cobb angle was 96 degrees and 88 degrees on coronal and sagittal planes (E, F). 3D-printed spine models were used for preoperative planning (C, D). After Smith-Peterson osteotomy at T11, T12 and reduction with internal fixation, the cobb angle was reduced to 39 degrees and 30 degrees on coronal and sagittal planes after surgery (G, H).

of 3D printers and printing materials, those limitations can be overcome in the future.

We have shown the advantages of using 3D-printed spine models in surgical planning of spinal deformity; however, the current study has some limitations. First, its retrospective nature makes the results prone to patient selection bias, although we did not find significant differences in the demographic patient characteristics and the severity of deformity before surgery between the two groups. Future prospective study will more convincingly demonstrate the beneficial effects of using 3D-printed spine models. Second, our current study used subjects from one center, and the sample size of was relatively small. Multi-center studies and larger sample sizes will further validate our results.

Conclusion

3D-printed spine model assisted surgical planning significantly decreases the duration of sur-

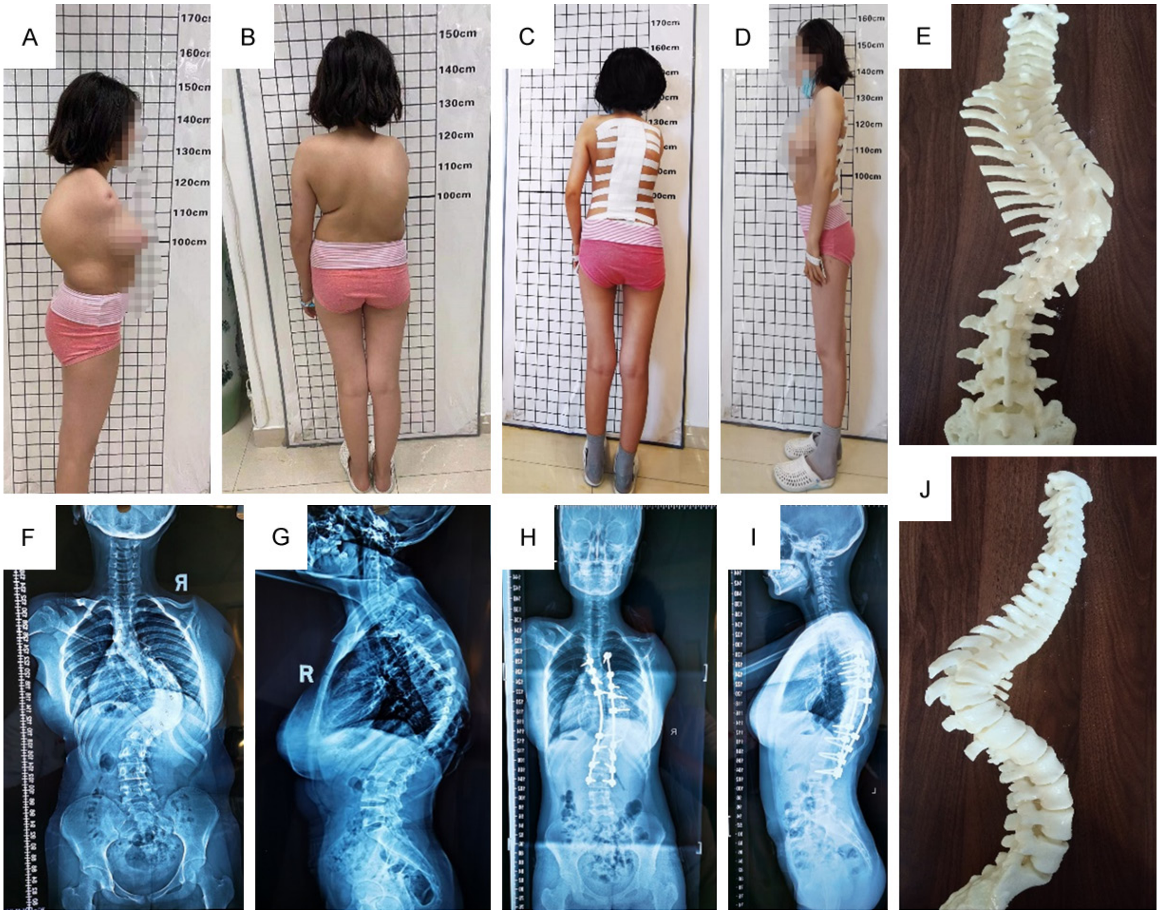

Figure 3. A 19-year-old patient with idiopathic scoliosis (A-D). The preoperative cobb angle was 100 degrees and 58 degrees on coronal and sagittal planes (F, G). 3D-printed spine models were used for preoperative planning (E, J). The sagittal cobb angle was reduced to 22 degrees and 15 degrees on coronal and sagittal planes after surgery (H, I).

gery and intraoperative hemorrhage while increases the accuracy of screw placement and the efficacy of deformity correction, leading to further alleviation of back pain and better functional recovery after surgery. This technique should be used to guide spinal deformity surgeries, especially in medical centers that are not equipped with computer assisted intraoperative surgical navigation system.

Disclosure of conflict of interest

None.

Abbreviations

3D, 3-dimentional; CT, Computed tomography; ODI, Oswestry disability index; VAS, Visual analogue scale.

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