The Value of Three-Dimensional Printing Spine Model in Severe Spine Deformity Correction Surgery

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Research

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Abstract

Objective. We aimed to evaluate the value of 3-dimensional printing (3DP) spine model in the surgical treatment of severe spinal deformity since the prosperous development of 3DP technology.

Materials and Methods. Severe scoliosis or hyper-kyphosis patients underwent posterior fixation and fusion surgery using the 3DP spine models were reviewed (3DP group). Spinal deformity surgeries operated by free-hand screw implantation during the same period were selected as the control group after propensity score matching (PSM). The correction rate, pedicle screw accuracy, and complications were analyzed. Class A and B screws were defined as accurate according to Gertzbein and Robbins criteria.

Results. 35 patients were enrolled in the 3DP group and 35 matched cases were included in the control group. The perioperative baseline data and deformity correction rate were similar between both groups ($P>0.05$). However, the operation time and blood loss were significantly less in the 3DP group (296.14±66.18 min vs. 329.43±67.16 min, 711.43±552.28 mL vs. 1322.29±828.23 mL, $P<0.05$). More three-column osteotomies (Grade 3-6) were performed in the 3DP group (30/35, 85.7% vs. 21/35, 60.0%. $P=0.016$). The screw placement accuracy was significantly higher in the 3DP group (422/582, 72.51% vs. 397/575, 69.04%. $P=0.024$). The screw misplacement related complication rate was significantly higher in the free-hand group (6/35 vs. 1/35, $P=0.046$).

Conclusion. The study provided solid evidence that 3DP spine models can enhance surgeons' confidence in performing higher grade osteotomies and improve the safety and efficiency in severe spine deformity correction surgery. 3D printing technology has a good prospect in spinal deformity surgery.

Background

Medical three-dimensional printing (3DP) is an emerging technology and a powerful tool for recreating details of human anatomy. The 3DP and computer-based simulation are becoming a routine part of pre-operative planning, intra-operative guidance and patient-specific implant modeling in many centers across the world[1, 2].

Severe spinal deformity correction is quite challenging for spine surgeons because of the complex and variable anatomical spine structure. Although spine computed tomography (CT) scan reconstruction can provide visual 3D reconstruction for doctors on the screen, the guidance of traditional medical imaging for the preoperative surgical planning and intraoperative operation is still limited. The 3DP technology based on the CT scan data can present surgeons a solid spine model in its original proportions with high precision. It not only plays an important role in teaching medical students, consulting with patients, and making surgical plans, but also assisting surgeons intraoperatively and shortening the operative time by visualizing the anatomy of organs and tissues in some recent investigations[3–5].

In this study, we aimed to analyze whether the printed model could indeed assist in the surgical treatment of severe and complex spinal deformity by reviewing the cases at our center since the beginning of the

3DP spine model application. We hope that our study will help to optimize clinical decision-making and clarify the clinical indications of 3DP technology.

Methods

Patients diagnosed with scoliosis, hyper-kyphosis or kypho-scoliosis were retrospectively reviewed following posterior pedicle screw fixation and fusion surgery. The inclusion criteria were adult scoliosis, congenital scoliosis, neuro-fibromatosis scoliosis, neuromuscular scoliosis, and scoliotic Cobb angle ≥ 80° or kyphotic angle ≥ 80°. The 3DP spine model was made voluntarily. Surgeries performed with the guidance of 3DP spine model were defined as the 3DP group. Surgeries performed by free-hand, without the guidance of 3D model or any other navigation techniques, were defined as free-hand group. Al of the cases were selected from the same center's database during the same period.

Propensity score matching (PSM) was used to compare and analyze between groups in order to eliminate confounding factors and keep the baseline data of both groups consistent. Cases in the freehand group were retrospective inconsecutive matching cohort. Group charateristics were matched after one-to-one PSM according to parameters including age, gender, diagnosis, and Cobb angle of scoliosis or kyphosis.

The spine model was printed at the original 1:1 ratio by 3DP technology (BF-SLA-600,Shanghai Blackflame Medical Technology Co., Ltd.) based on the CT scan data (DICOM format data from Siemens CT machine, SOMATOM Sensation 16, Siemens AG, Forchheim Germany) of the whole spine. Resin was used as the printing material. The print error of the model was < 0.2% per 10 cm.

The spine model can be used to assist in preoperative evaluation and surgical correction, to improve the surgical plan quality, especially for increasing the accuracy of screw placement at the congenital dysplastic vertebrae and the accuracy of vertebrae resectomy. For intraoperative screws placement and correction operation, the 3DP model was carried out as the role of the materialized 3D CT scan reconstructed picture to aid the intraoperative workflow in a number of ways.

Patient clinical information, surgical data and radiographic parameters, including age, gender, diagnosis, operation time, blood loss, fusion levels, screw density, complications, Cobb angle and correction rate were collected and analyzed.

All patients underwent postoperative CT examination of the spine to check the accuracy of every pedicle screw. Gertzbein and Robbins standard was used to classify the screws and define the screw accuracy (Fig. 1). Grade A: the screw is totally inside the pedicle and does not penetrate the cortical bone of pedicle. Grade B: the screw is inserted within 2 mm or less penetration beyond the pedicle. Grade C: the screw has a penetration of 2 to 4 mm. Grade D: the screw has a penetration of 4 to 6 mm. Grade E: the penetration is > 6 mm. Grade A and B screws were defined as the accurate screws. Internal fixation related complications, such as nerve root injury, spinal cord injury, cerebrospinal fluid (CSF) leakage were recorded and analyzed.

The SPSS version 18 software (IBM Corp., Armonk, NY) was used to perform statistical analyses. Two-sample independent T test was conducted to assess the differences of continuous variables with parametric data between the 2 cohorts. Fisher's exact test was used to analyze differences of categorical variables in outcome variables, where p value of ≤ 0.05 was considered statistical significant.

Results

Thirty five spine models were printed to assist the surgery in 35 spine deformity patients, including 10 men and 25 women (Table 1). The average age at operation was 25.37 ± 11.06 (10–52) years old. The mean pre-op scoliosis Cobb angle was 96.07 ± 37.88° and the mean kyphosis angle was 94.43 ± 57.08°.

Baseline data, such as sex, age, diagnosis, Cobb angle, fusion segments, osteotomy type were matched and there was no significant difference between the groups (P < 0.05). In the control group (Table 1); there were 35 patients (9 men and 26 women) with an average age of 26.14 ± 8.73 years old, the mean pre-op Cobb angle of 104.83 ± 28.86°, and the mean kyphosis angle of 95.38 ± 37.47°.

There was no significant difference between 3DP group and control group in terms of the post-op scoliosis Cobb angle, kyphosis angle and correction rate (P > 0.05). However, the operation time was significantly shorter and blood loss was less in 3DP group (296.14 ± 66.18 min vs. 329.43 ± 67.16 min, 711.43 ± 552.28 mL vs. 1322.29 ± 828.23 mL, P < 0.05) (Table 2).

Table 1
Basic data of the included patients.

	3DP Group	Freehand Group		p
Gender (M: F)	10:25	9:26	U/595.00 (Man-Whitney)	0.790
Age	25.37 ± 11.06 (10–52)	26.14 ± 8.73 (13–56)	-0.32	0.747
ADIS	11	13	0.25	0.615
CS	14	15	0.06	0.808
NFS	6	5	0.11	0.743
NMS	4	2	0.73	0.393
ADIS:CS:NFS:NMS	11:14:6:4	13:15:5:2	0.96	0.811

ADIS: adult idiopathic scoliosis; CS: congenital scoliosis; NFS: neurofibromatosis scoliosis; NMS: neuromuscular scoliosis

Table 2
Radiologic and surgical parameters.

	3DP Group	Freehand Group	T	p
Pre-op main curve (°)	96.07 ± 37.88°	104.83 ± 28.86°	-1.01	0.280
Pre-op kyphosis (°)	94.43 ± 57.08°	95.38 ± 37.47°	-0.08	0.935
Post-op main curve (°)	42.26 ± 21.42°	43.90 ± 16.10°	-0.36	0.719
Post-op kyphosis (°)	50.24 ± 30.58°	51.04 ± 15.08°	-0.14	0.890
Main curve correction rate (%)	53.29 ± 20.06%	57.76 ± 13.49%	-1.01	0.278
Kyphosis correction rate (%)	44.57 ± 8.59%	42.36 ± 13.78%	0.80	0.428
Operation time (min)	296.14 ± 66.18	329.43 ± 67.16	-2.09	0.040
Estimate blood loss (ml)	711.43 ± 552.28	1322.29 ± 828.23	-3.63	0.001
Fusion segment	12.26 ± 2.82	12.49 ± 2.84	-0.34	0.737
Screws number	16.63 ± 3.65	16.66 ± 3.59	-0.03	0.974

Osteotomies were recorded according to Schwab spinal osteotomy classification system (Grade 1 to 6)[6]. As shown in the Table 3, osteotomies were performed in most of the spine deformity correction surgeries (33/35 vs. 32/35). Statistical analysis revealed that there was no significant difference in the osteotomy distribution between groups. After dividing the osteotomies into posterior column osteotomy group (Grade 0–2) and three-column osteotomy group(Grade 3–6), 3DP group exhibited a significantly higher rate of three-column osteotomy than freehand group (30/35, 85.7% vs. 21/35, 60.0%. P = 0.016), as shown in Fig. 2. Typical cases were shown in Fig. 3–5, which illustrated the application of 3DP spine model in surgical plan making.

Table 3
Osteotomy classification in the two groups.

Osteotomy Classification	3DP Group (The number of cases)	Freehand Group (The number of cases)	`x	p
None	2	3	0.22	0.643
1	1	5	2.92	0.088
2	2	6	2.26	0.133
3	7	9	0.32	0.569
4	10	6	1.30	0.255
5	8	4	1.61	0.205
6	5	2	1.43	0.232
*t	8.74			
*P	0.189			

*Comparison on the osteotomy classification distribution between 3D model group and freehand group.

A total of 582 pedicle screws were inserted in the 3DP group. According to the pedicle screw accuracy standard by Gertzbein and Robbins, there were 366 grade A (62.89%), 56 grade B (9.62%), 82 grade C (14.09%), 44 grade D (7.56%), and 4 grade E (0.69%) screws. The total accuracy rate of screw (grade A and B) was 422/582 (**72.51%**). In the control group, 575 screws were inserted, consisting of 328 grade A (57.04%), 69 grade B (12.00%), 107 grade C (18.61%), 62 grade D (10.78%), and 9 grade E (1.57%) screws. The pedicle screw accuracy rate (grade A and B) was 397/575 (**69.04%)**.

The screw accuracy was higher in the 3DP group than in the control group, and the difference was statistically significant (χ = 11.26, P = 0.02). The screw misplacement related complication rate, such as nerve root or spinal cord injury, was higher in the free-hand group (1/35 vs. 6/35), the difference was statistically significant (χ = 3.97, P = 0.046) **(**Table 4**)**.

Table 4
Accuracy of screws insertion

Gertzbein-Robbins Screw Classification	3DP Group	Freehand Group	`x	p
A	366	328	11.26	0.024
B	56	69		
C	82	107		
D	44	62		
E	4	9		
Accurate	422	397	7.78	0.005
Inaccurate	130	178		
Screws-Related Complications	1	6	3.97	0.046

Discussion

Three-dimensional printing, also known as additive manufacturing, is a kind of rapid prototyping technology. Medical 3DP is based on human anatomy to accurately make physical models of human organs and tissues[7]. The applications of 3DP for clinical purposes have grown rapidly over the past decade[8]. In the 1980s, it was first applied to engineering by Chuck Hull through computer modeling[9]. The medical application was developed in 1990, and a skull was printed based on the CT scan data[10]. Currently, 3DP plays an important role in orthopedics: in clinical teaching assistance, doctor-patient communication, diagnosis of complex diseases, preoperative planning and surgical simulation training, surgical navigation, 3DP prosthesis implantation and bone tissue engineering.[11–14]

Spinal deformity is one of the toughest challenges faced by spine surgeons and neurosurgeons. It is difficult for surgeons to evaluate and understand the exact pathological anatomical structure through traditional imaging examination, especially for congenital scoliosis caused by vertebra formation defect and failure of segmentation. However, with the emergence and development of 3DP technology, the situation has greatly improved[15, 16].

Li et al.[17] made 3DP models of 22 patients with cervical deformations, and simulated posterior cervical operations were conducted on the models to obtain accurate screw placement routes and angles. The screw accuracy was improved and no vertebral artery was injured. Sixteen severe scoliosis patients were treated with the help of 3DP technology, and the best screw placement angle and depth were obtained in the simulated surgery on the 3DP spine models before operation[18]. Li et al. randomly divided 53 patients with scoliosis into the control and 3DP groups, and the statistical data showed that the operation time was shorter and screw placement accuracy was better in the 3DP group.

It is challenging for surgeons to implant pedicle screws accurately in the deformed spine, which is usually accompanied by vertebra rotation, thin pedicle, hemivertebra, unsegmented vertebra, or multi-segment fused vertebra. Severe spine deformity cases treated by posterior pedicle screw fixation and fusion in our center were comprehensively compared between 3DP spine model-assisted group and free-hand group using PSM method in this study, and the results showed that pedicle screw placement was more accurate and operation time was much shorter with the guidance of the printed model. The operation time was shortened by 33 minutes on average, which would reduce surgery-related and anaesthesia-related complications and improve the efficiency of operating room staff.

The severe spine deformity often requires spinal osteotomies to achieve good correction. The higher the osteotomy grade, the better the correction effect, but also comes with a higher risk. The osteotomy plan was made by the surgeon based on cognition of the spinal anatomy structure. It has been reported that preoperative familiarity of oncologic pathology based on 3D models in orthopaedics helps to increase the accuracy of bone resection and to decrease operative time.[19] In this study, surgeons were more inclined to performed more advanced osteotomies with the help of 3DP spine models. In the meanwhile, neurological complications rate was reduced and operation time was shortened significantly.

Traditionally, CT scan and reconstraction images help us a lot to evaluate the spine deformity. Zheng et al. reported that compared with reconstructed 3D-rendered images in preoperative planning, the utilizing of 3DP models could significantly improve surgical plan quality[20]. The authors postulated that the 3DP models may have improved the understanding of the anatomically complex sites of skeletal structure. 3DP models allowed surgeons to appreciate the structure and relations of the relevant anatomy much better than the visualization provided by two-dimensional CT images conventionally used.[5] Inspection of these models also revealed structural abnormalities not appreciated on CT which altered the surgical approach in a significant number of cases.[21] Luo et al. demonstrated that accuracy of the surgical technique using spinal 3D printing technology in patients with severe congenital scoliosis was higher than that of the free-hand technique, and it appeared to shorten operative time.[22]

It is reported that the intraoperative navigation system or robotic assistant system have been used to enhance the accuracy of pedical screw insertion in the treatment of spine degenerative and some spine deformity disease,[23] and it turns out to be fesiable and effective.[24, 25] However, in severe spine deformity surgery, the evidence was unpowered and insufficient.[26] Yang et al. reported that 3D technology could reduce the misplacement rate, operating time and blood loss in patients with preoperative mean Cobb angle only > 50°.[27] According to our experience, the application of robotic navigation technology in the operation of severe spinal deformity was not accurate and convenient enough.

The cost of 3DP full spine model varies from $400 to $500, which is much less than the surgical robot or surgical navigation. Thus, in the area of severe spine deformity surgery exhibiting the advantage of cost-effectiveness and reducing radiation exposure.[28, 29]

Currently, the progress of the surgeons' surgical skill learning curve mainly depends on clinical practice, cadaveric simulation, and digital imaging technology training, such as virtual reality and augmented reality. For surgeons in training, getting a chance to operate is competitive, especially in the developing countries where medical resources are inadequate, and this limits the training of surgeons. In addition, cadaveric training has significant limitations in cost, quality, and availability.

3DP technology has also been adopted for the surgeons' training and teaching purposes, whereby the design flexibility in terms of geometry and material properties (tissue density, hardness, flexibility) enables simulation of a range of clinical scenarios for surgical training[30, 31] or anatomical learning[32] without the associated ethical and cost barriers, as well as anatomical variation, that can be present in cadaveric study. Especially for the complex spinal deformities, printed models can improve the junior doctors' understanding of the pathological structure of the spine. Zhao et al.[33] trained junior surgeons by conducting simulated surgery with 3DP models. The accuracy of screw placement on the model reached 93.75% after 3-months of training. After 6 months of training, all junior surgeons could implant pedicle screw accurately and independently, which greatly reduced the training time. Besides, many studies have indicated that 3DP spine model could promote surgical education, team communication and patient understanding.[34–37]

In conclusion, it is worthwile to apply the 3DP technology in severe spinal deformity surgery concerning the following advantages. Firstly, 3DP spine model improves the understanding of the anatomical structure of the surgical site and can be used for surgical rehearsal to accelerate the learning curve of surgeons and improve the quality of clinical education. Secondly, it improves surgical safety by increasing screw accuracy and reducing fluoroscopy exposure[17, 18, 38, 39]. Thirdly, it improves surgical efficiency by shortening the operation time. At last, 3D-printed spinal models make it easier for doctors to convince the patients and families about treatment plan, surgical complications, and rehabilitation program.

We suggest that 3DP models should be incorporated into the workflow in the surgical treatment of complex and severe spine deformity. It is believed that 3DP technology has great potential to become popular in the field of orthopedics. The medical 3DP industry may experience a period of rapid development.

Conclusions

The study provided solid evidence that 3DP spine models can enhance surgeons' confidence in performing higher grade osteotomies and improve the safety and efficiency in severe spine deformity correction surgery. 3D printing technology has a good prospect in spinal deformity surgery.

Abbreviations

3DP, 3-dimensional printing

PSM, propensity score matching

CT, computed tomography

ADIS, adult idiopathic scoliosis

CS, congenital scoliosis

NFS, neurofibromatosis scoliosis

NMS, neuromuscular scoliosis

Declarations

Ethics approval and consent to participate

We have received the approval of the ethics committee of Beijing Chaoyang hospital, CCMU, and the study was performed in accordance with the Helsinki Declaration of

1964, and its later amendments. Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Aixing Pan, Hongtao Ding, Junrui Jonathan Hai and Bo Han analyzed and interpreted the patient data regarding the correction surgery of spine deformity. Aixing Pan, Yong Hai and Peng Yin performed the correction surgery. Aixing Pan and Hongtao Ding were major contributors in writing the manuscript. All authors read and approved the final manuscript.

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Not applicable

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Figures

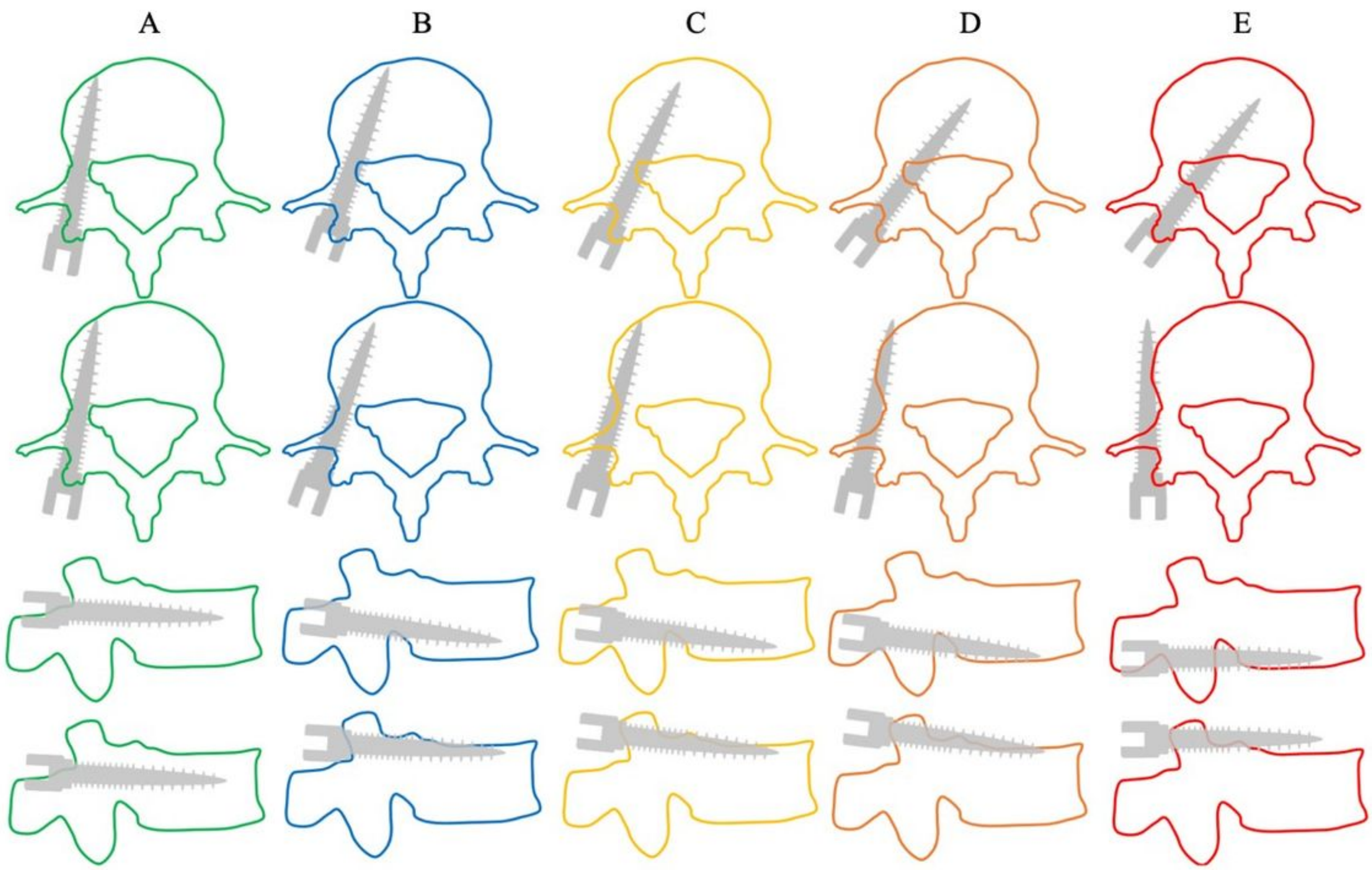

Figure 1

Illustration of Gertzbein-Robbins pedicle screw classification.

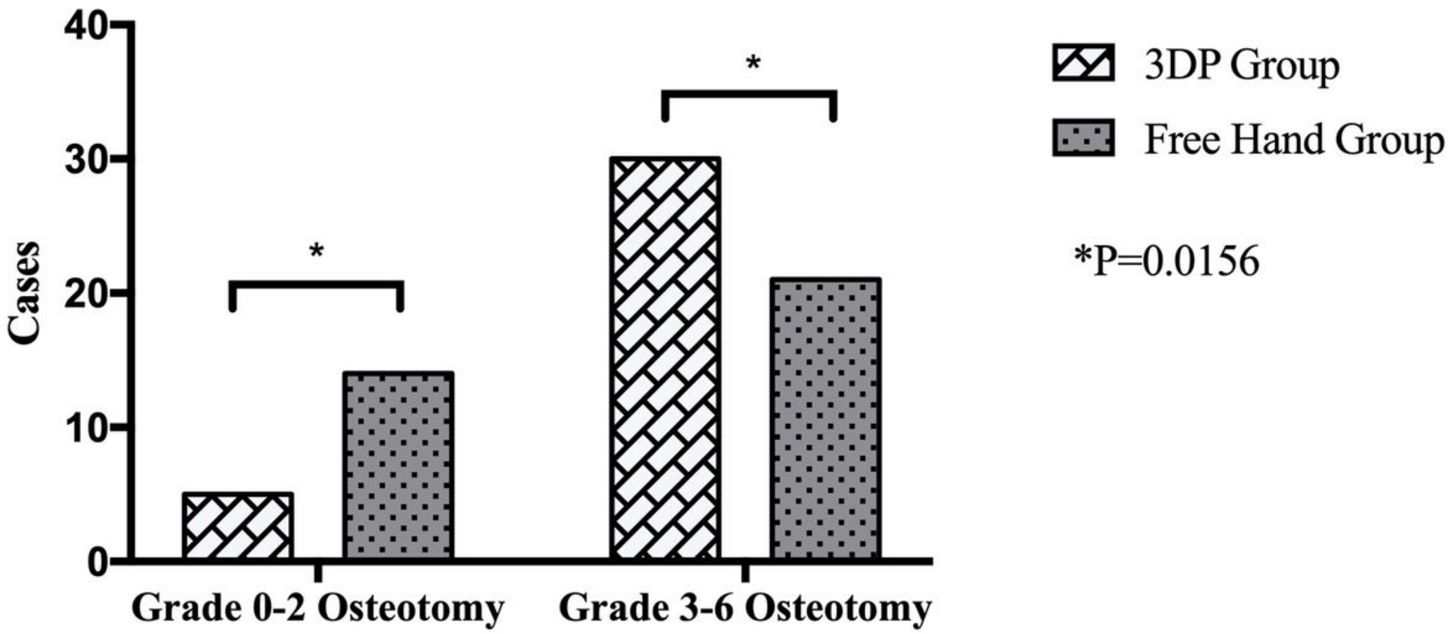

Figure 2

Comparison of three-column osteotomies (Grade 3-6) and non-three-column (Grade 0-2) osteotomies between the two groups.

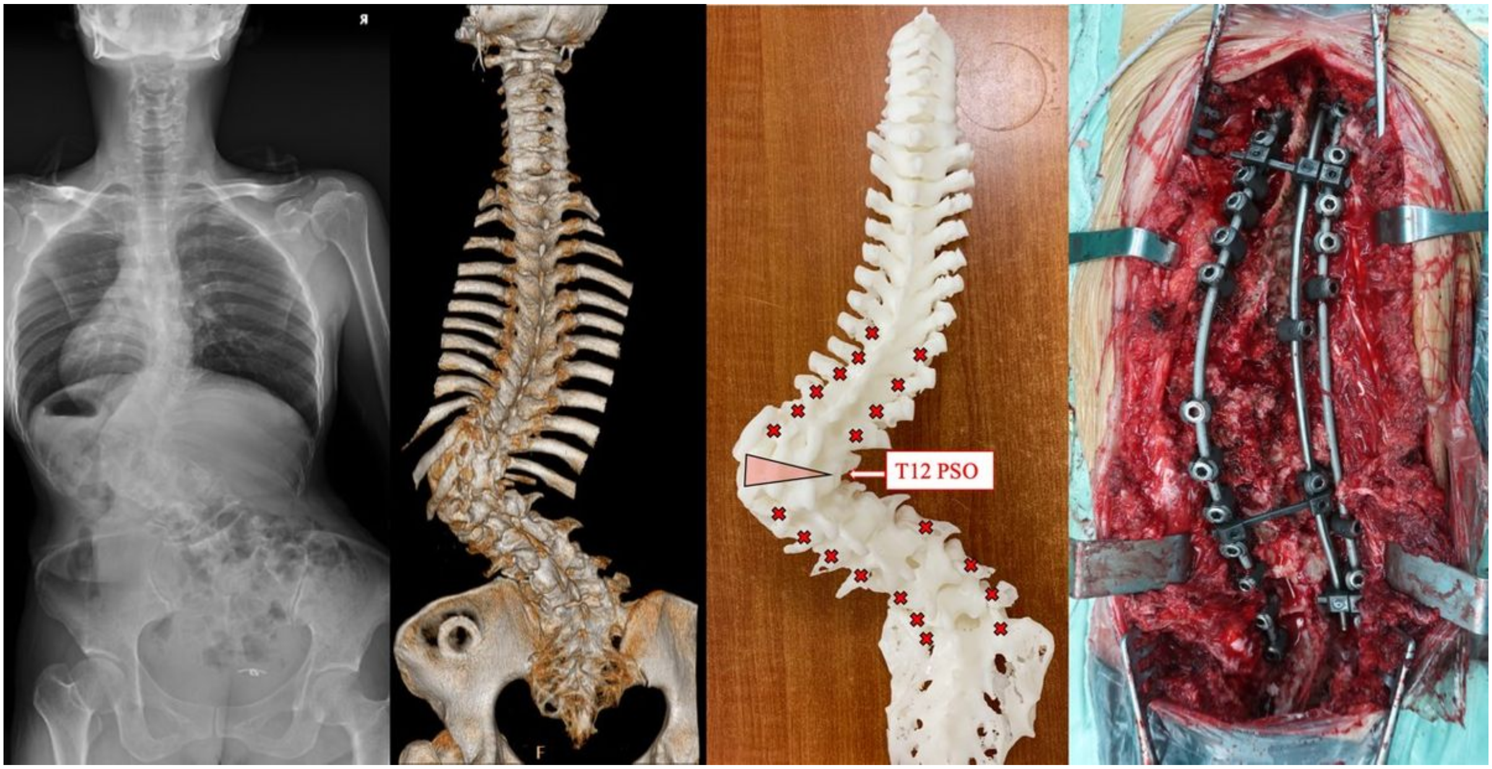

Figure 3

It is a 44-year-old congenital scoliosis female patient. 3DP spine model was made to assist the pre-operative plan making, intra-operative screw implantation and osteotomy at the apex vertebrae.

Figure 4

A 14-year-old congenital kypho-scoliosis female patient. Multi-level failure of segmentation (T11-L1). 3D spine model was printed to assess the bony structure of the spine precisely and provide the guidance on the osteotomy plan.

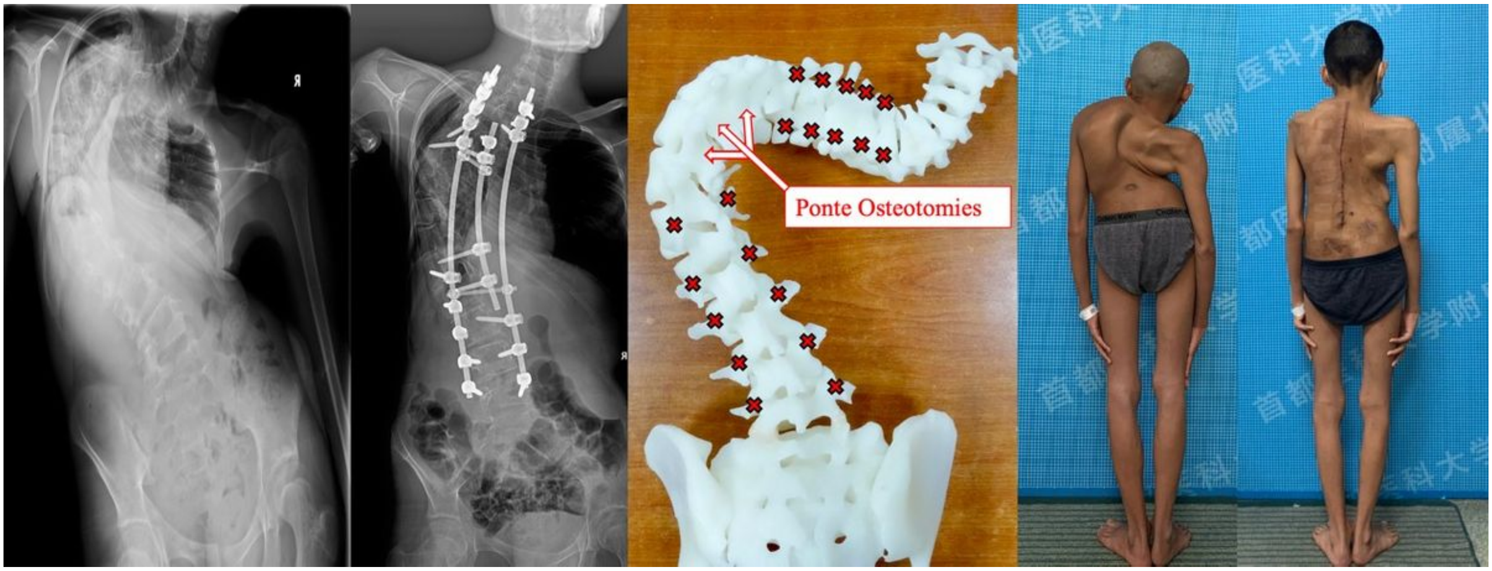

Figure 5

A 16-year-old severe adolescent idiopathic scoliosis male patient. The 3D spine model was printed to assess the spinal rotation and variation. The whole spine model can guide surgical planning and intraoperative correction.