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Clinical Study

Outcome and safety analysis of 3D-printed patient-specific pedicle screw jigs for complex spinal deformities: a comparative study

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Abstract

BACKGROUND CONTEXT: Spinal deformities are very challenging to treat and have a great risk of neurologic complications because of hardware placement during corrective surgery. Various techniques have been introduced to ensure safe and accurate placement of pedicle screws. Patient-specific screw guides with predrawn and prevalidated trajectory seem to be an attractive option.

PURPOSE: We have focused on developing three-dimensional (3D) printing technique for complex spinal deformities in India. This study also aimed to compare the placement of pedicle screw with 3D printing and freehand technique.

STUDY DESIGN/SETTINGS: This is a retrospective comparative clinical study in an academic institutional setting.

PATIENT SAMPLE: A total of 20 patients were enrolled during the study: 10 were operated on with the help of 3D printing (Group 1) and 10 were operated on with freehand technique (Group 2). Group 1 included six patients with congenital scoliosis, three patients with adolescent idiopathic scoliosis (AIS), and one patient with post-tubercular kyphosis, and Group 2 included five patients with congenital scoliosis, four patients with AIS, and one patient with post-tubercular kyphosis.

OUTCOME MEASURES: Primary outcomes were measured in terms of screw violation, and secondary outcomes were measured in terms of surgical time, blood loss, radiation exposure (number of shoots required), and complications.

MATERIALS AND METHODS: MIMICS Base v18.0 software was used for 3D reconstruction from computed tomography scan images of all the patients. 3-Matic software was used to create a drill guide. A 3D printer from Stratasys Mojo with ABS P430 model material cartilage (a thermoplastic material) was used for the printing of the vertebra model and jigs. A two-sample test of proportion was used to compare correctly and wrongly placed pedicle screws with 3D printing and freehand technique. *t* Test with equal variance was used for operating surgical time and blood loss.

FDA device/drug status: Not applicable.

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RESULTS: No superior or inferior screw violation was observed in any of our patients in either group. We found a significant difference (p=.03) between the two groups regarding perfect screw placement in favor of 3D printing. There were 13 Grade 2 medial perforations in the freehand group and 3 in the 3D printing group. There was no Grade 3 medial perforation in either group. Six Grade 2 lateral perforations in the freehand group and seven in the 3D printing group were observed. Three Grade 3 lateral perforations in the freehand group and two in 3D printing group were observed. Analysis showed a statistically significant (p=.005) medial violation in the freehand group. Surgical time was significantly less (p=.03) in the 3D printing group compared with the freehand group. Mean blood loss was higher in the freehand group but was not statistically significant (p=.3) in the 3D printing group. Fluoroscopic shots required were less in number in the 3D printing group compared with the freehand group. There was no neurologic deficit in any of the patients in the two groups.

CONCLUSIONS: In our study, focusing on spinal deformities with statistically significant higher rates of accurate screw positioning and higher numbers of inserted screws with 3D printing was possible because of enhanced safety, particularly at apical levels. As such, spinal deformities are difficult to treat worldwide. In India, these deformities are often neglected and present at a very late and a much more deformed state when their treatment becomes even more challenging. Developing these patient-specific drill templates will enable an average spine surgeon to treat these patients with much ease and safety.

Keywords: 3D printing; Pedicle screw; Scoliosis; Screw guide; Spinal deformity; Spine surgery

Introduction

Spinal deformities are usually associated with significant morbidity and mortality [1]. These problems are very challenging to treat and have a great risk of neurologic complications because of hardware placement during corrective surgery [2]. After the introduction of pedicle screws, scoliosis correction surgeries have witnessed a revolutionary shift, necessitating the placement of a screw within the pedicle with accuracy and safety [3]. This precision is essential to avoid potential complications because of small bony geometry and the juxtaposition to the spinal cord. Various techniques have been introduced to ensure safe and accurate placement of pedicle screws [4]. Patient-specific screw guides with predrawn and prevalidated trajectory seem to be an attractive option. We have focused on developing this technique in India and have developed these patient-specific drill guides for pedicle screw placement in spinal deformities. The present study also compared the pedicle screw placements with the freehand technique.

Materials and methods

A total of 20 patients were enrolled, of which 10 were operated on with the help of three-dimensional (3D) printing (Group 1) and 10 were operated on with the freehand technique (Group 2). The study design was quasi-randomized and patients were randomized sequentially. The same surgeon performed an operation on these patients alternately. Considering the total pedicle screw misplacement rate of 5% (including Grade 2), a sample size of 120 screws was calculated to detect a significant change (confidence interval=95%, power=80). Hence, 10 patients in each group were kept to detect a statistically significant difference. An ethical clearance was obtained from the institutional ethical committee. Informed written consent was obtained from each patient.

Setting of 3D printing laboratory

A 3D printer from Stratasys Mojo (Los Angeles, CA, USA) with ABS P430 model material cartilage (a thermoplastic material), soluble support material cartilages, and plastic model base were procured and installed in the 3D printing and image processing laboratory at our institution. We used MIMICS Base v18.0 software (Materialise, Technologielaan 15, Leuven, Belgium) for 3D reconstruction from computed tomography (CT) scan images. We also used the facilities at the Indian Institute of Technology, Delhi, DFM Lab, for advanced designing tools.

Development of 3D-printed drill guides

A spiral 3D volumetric CT scan was performed on all patients with a 0.625-mm slice thickness and 0.35-mm in-plane resolution. Digital Imaging and Communications in Medicine (DICOM) data were collected for each patient on the same day from the Department of Radiodiagnosis and were subsequently checked with MIMICS software compatibility (Fig. 1).

With the help of MIMICS software and these DICOM images, we created a 3D model of individual vertebrae and simultaneously saved those models in stereolithography (STL) format (required format for 3D print) (Figs. 2 and 3). We worked only on those vertebrae that were selected for instrumentation based on preoperative planning.

MIMICS Base v18.0 provides a facility to draw a primitive cylinder onto CT images, which help in determining the exact location of the drill guide. Based on the measurement of the resulting trajectory, the optimal diameter and length of the screws were determined (Fig. 4). These 3D-reconstructed vertebrae were then further imported into 3-Matic software (Materialise, Technologielaan 15, Leuven, Belgium) for computer-aided design. 3-Matic software has various features, such as Create Curve (to create a specific area of the

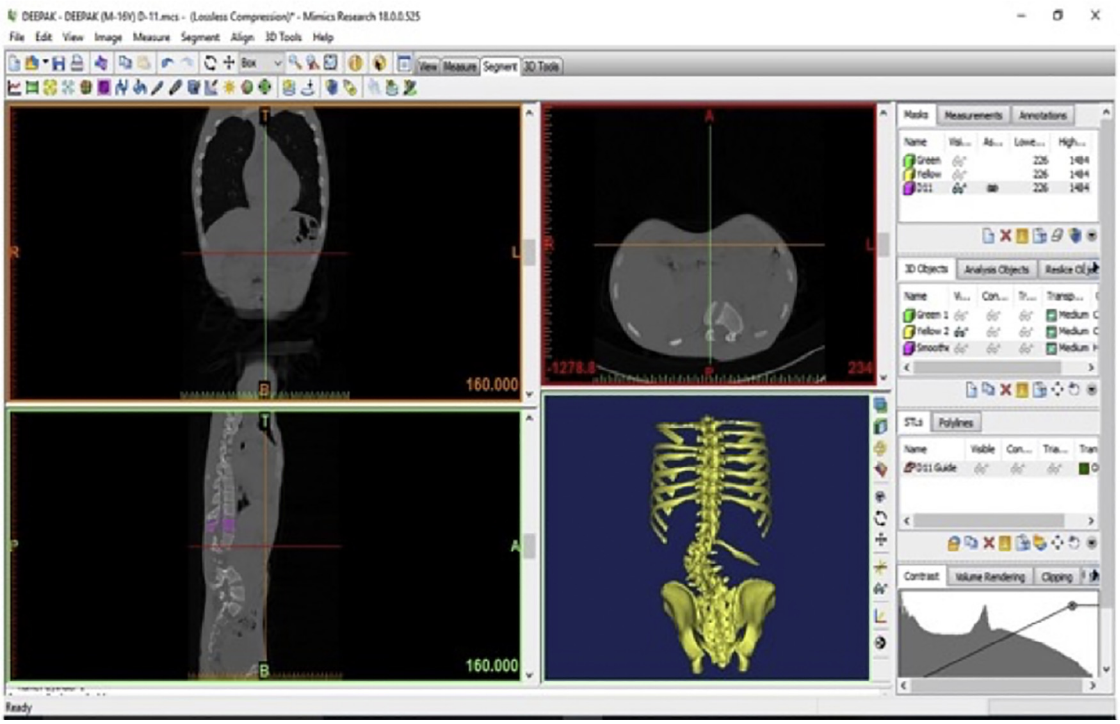

Fig. 1. Import of DICOM images of the patient. DICOM, Digital Imaging and Communications in Medicine.

vertebral body, which will act as a base surface for the guide), Hollow (to provide thickness to the selected created area), Create Cylinders (for drill guides), and Boolean function, to make the template fit in a lock-and-key fashion.

After determining and planning the proper pedicle screw trajectory, we constructed a navigational template with a drill guide on either side of the midline, as shown in Fig. 5.

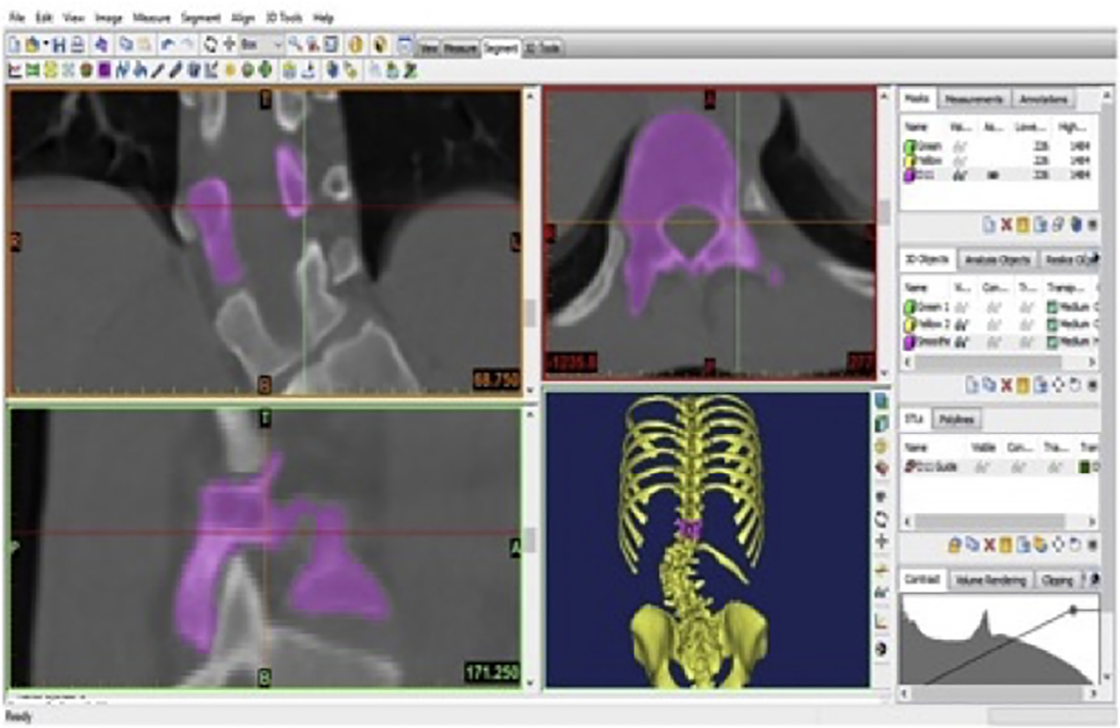

Fig. 2. Separation of particular vertebrae from the whole spine.

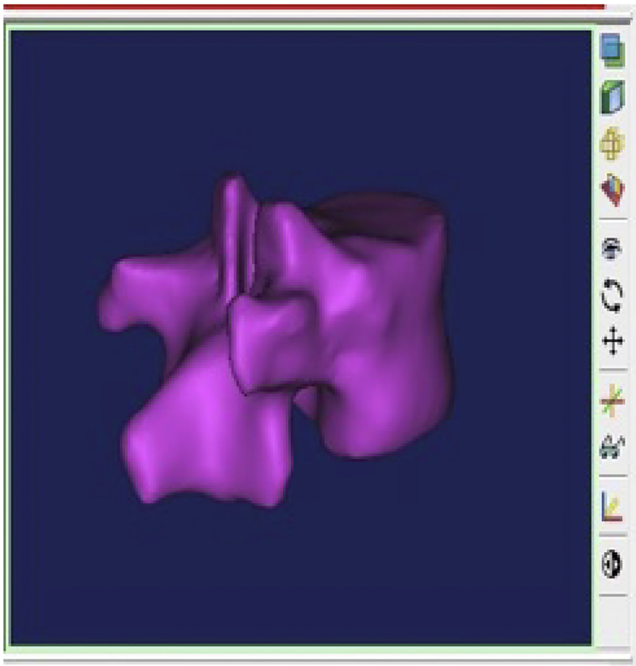

Fig. 3. Separated vertebrae.

The template surface was created as the inverse of the vertebral posterior surface, thus potentially enabling a near-perfect fit. Hence, in this way, we created the drill guides and saved the file in STL file format (Figs. 6 and 7). These STL guides were further imported onto the 3D-reconstructed vertebrae in MIMICS Base v18.0 to check their accuracy. Lastly, these STL files were exported for 3D print. Finally, the biomodel of the desired vertebra and its corresponding navigational template was produced for each level (Fig. 8).

We used a rapid prototyping technique to manufacture each vertebra and respective navigational screw guides. We rehearsed and tested each individual guide for accuracy and any violation (Fig. 9). To test violation, each biomodel of the vertebra was placed along with the tightly fit respective navigational screw guides, and a 3.5-mm drill bit was used to drill the screw trajectory into each vertebra through the holes of the navigational screw guide. Each model was inspected in detail to identify any violation. Each guide and corresponding vertebra were marked, sterilized, and kept on the operating table for use (Fig. 10).

After confirming their validity, these navigational screw guides were placed during surgery to the posterior aspect of the respective lamina and spinal process. A conscious and careful effort was made to make each template fit snugly in the vertebra, then the screw guide was used to drill and prepare the screw trajectory. After this pedicle screws were inserted (Figs. 11 and 12). All standard safety measures, including neuromonitoring and C-arm (when thought necessary), were used in each patient. Two cases were used as a check initially to familiarize and to look for subtle changes required and were not included in the study. Fig. 13 shows the pre- and postoperative x-rays of the patient operated on with the help of 3D printing.

The freehand technique was used in a standard manner in 10 other patients. Postoperatively, all patients underwent detailed imaging in the form of x-rays and CT scans to evaluate the placement of the pedicle screws. We specifically looked for an axial image for each screw to include the whole length (Fig. 14). All pedicle screws were analyzed for any violations. We classified all screws on the basis of axial CT scans

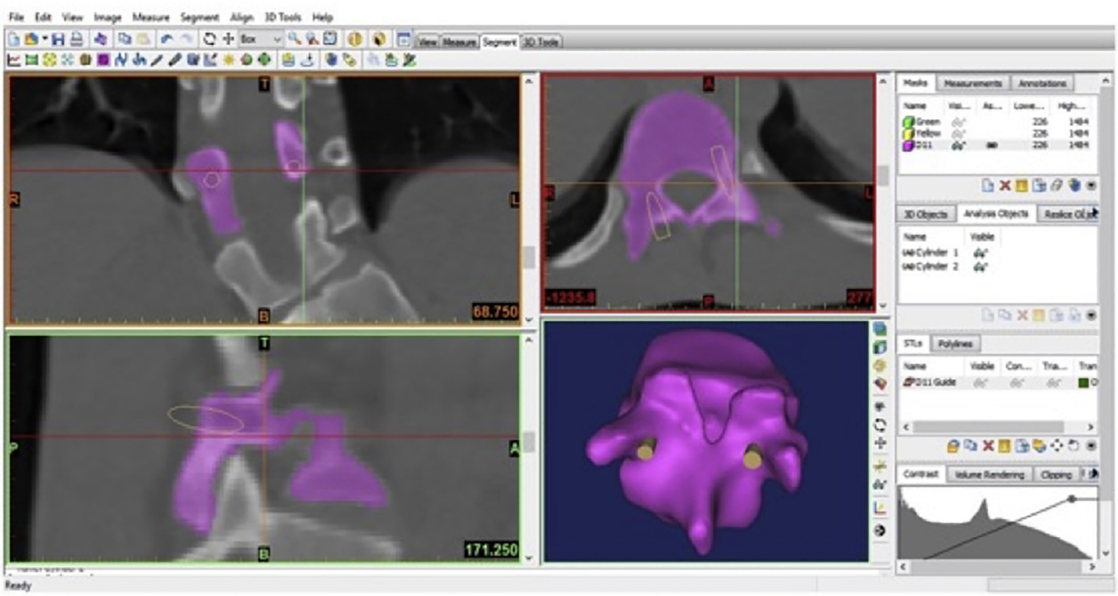

Fig. 4. Created guideways on which template has to be made.

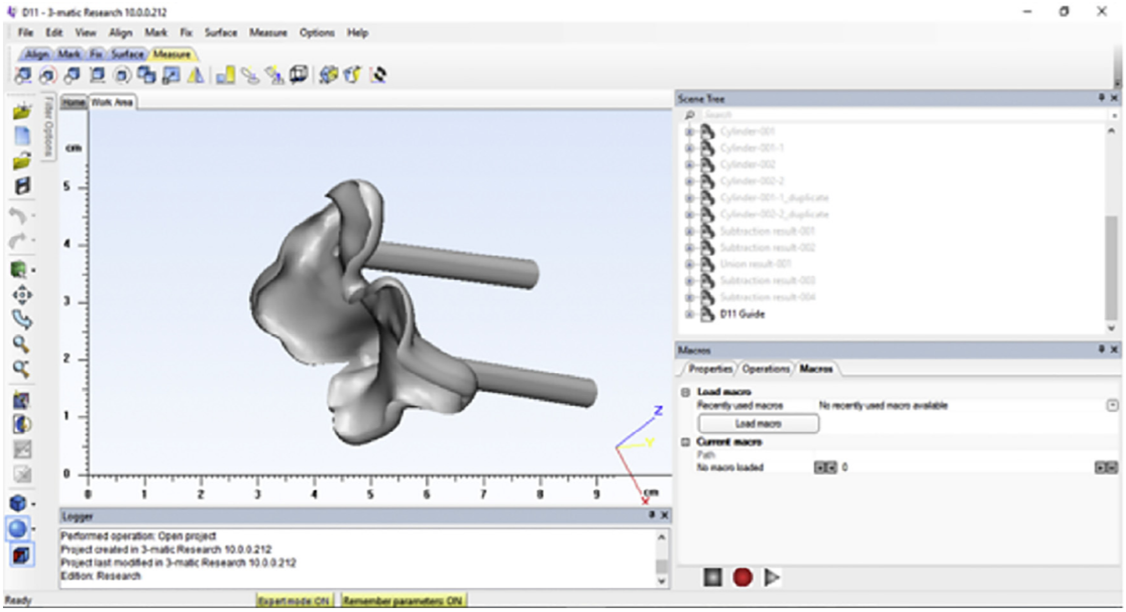

Fig. 5. 3-Matic file of the final vertebral guide template.

in three grades: Grade 1, perfectly placed screws; Grade 2, <4-mm medial or lateral violation; and Grade 3, >4-mm violation.

Primary outcome measure: screw violation

Secondary outcome measures

The secondary outcome measures included surgical time, blood loss, radiation exposure in terms of the number of shoots required, and complications.

Statistical analysis

Screw-wise analysis was performed. A two-sample test of proportion was used to compare correct and wrong pedicle screw placements with the 3D printing and the freehand technique. *t* Test with equal variance was used to compare operating surgical time and blood loss. Statistical analysis was carried out using STATA version 14.0 statistical software (StataCorp LLC, College Station, TX, USA). A p-value of <.05 was considered statistically significant.

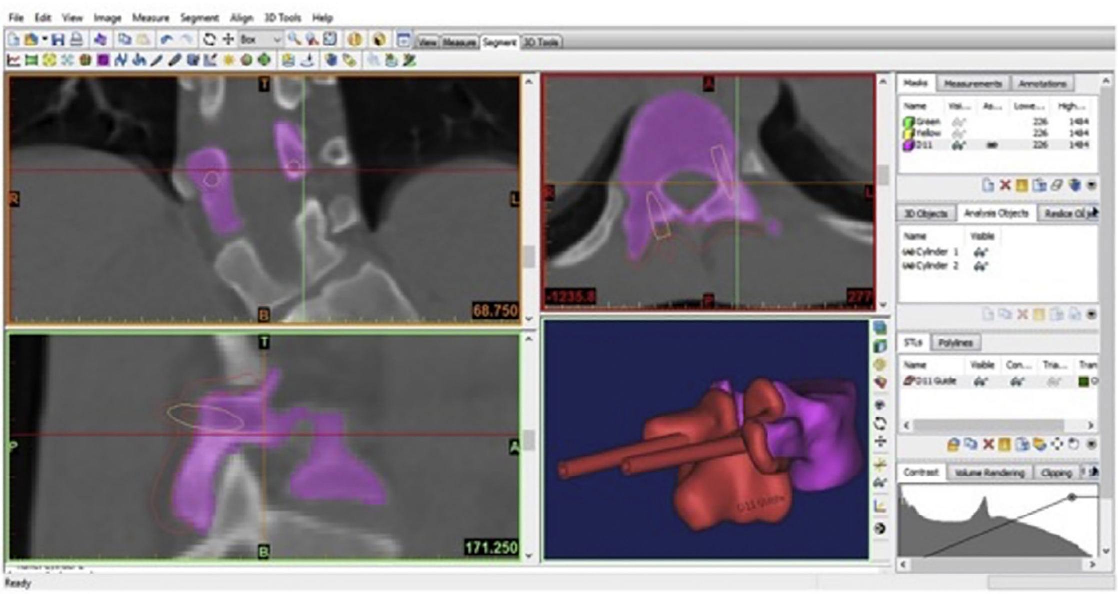

Fig. 6. Checking the accuracy and the precision of the guide.

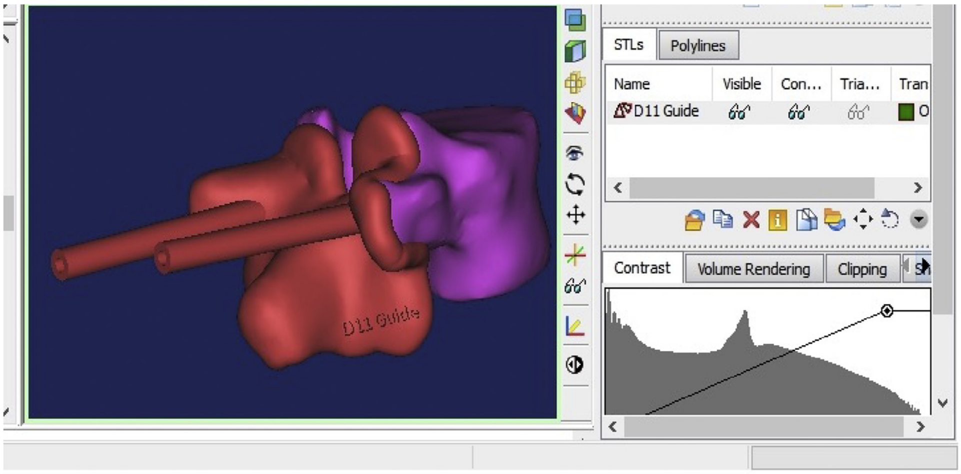

Fig. 7. Final vertebral guide.

Fig. 8. 3D-printed vertebrae and jig. 3D, three-dimensional.

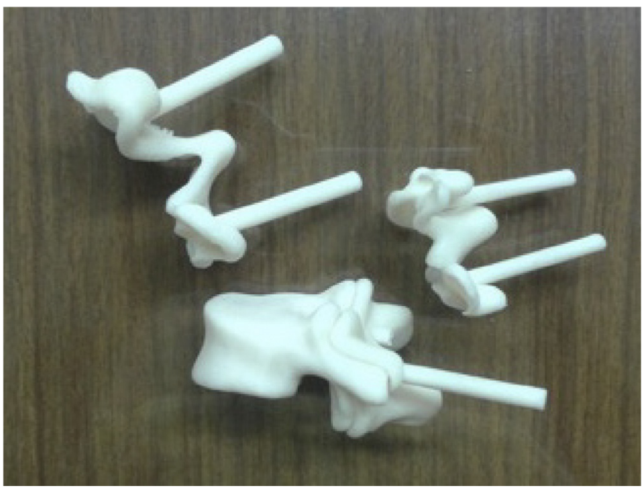

Fig. 9. Navigational template fit the vertebra perfectly.

Fig. 10. Sterile marked templates on the operating table.

Results

A total of 10 patients in each group were operated on. The two groups were similar in age and gender distribution. Group 1 included six patients with congenital scoliosis, three patients with adolescent idiopathic scoliosis, and one patient with post-tubercular kyphosis. Group 2 included five patients with congenital scoliosis, four patients with adolescent idiopathic scoliosis, and one patient with post-tubercular kyphosis. The mean Cobb angle was 90.4 in Group 1 and 85.3 in Group 2. The mean numbers of vertebra included in the fusion were 12.6 in Group 1 and 12.4 in Group 2 (Table 1). A total of

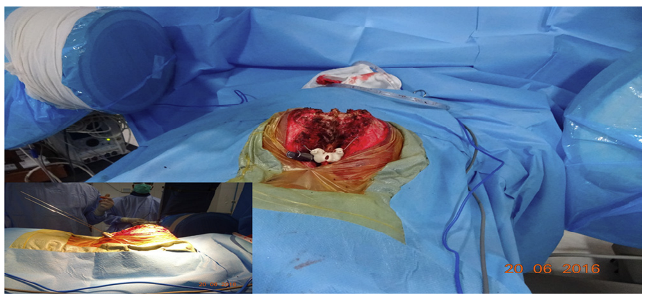

Fig. 11. Guide wires through the templates.

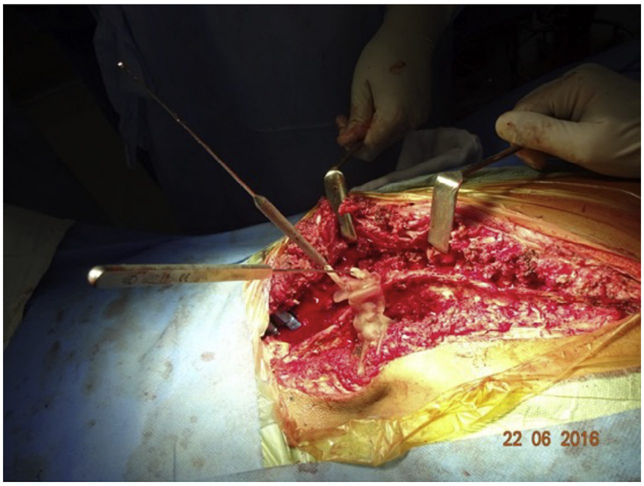

Fig. 12. Difference in directions of pedicle screws as judged with these guides.

137 screws were placed in the 3D printing group and 126 screws were placed in the freehand group. There was no superior or inferior violation in any of our patients in either group.

Screw grading

Grade 1 screw

We found a statistically significant difference between the two groups regarding perfect screw placement in favor of 3D printing (Table 2) (p=.03). There were 13 Grade 2 medial perforations in the freehand group and 3 in the 3D printing group. There was no Grade 3 medial perforation in either group. There were six Grade 2 lateral perforations in the freehand group and seven in the 3D printing group. There were three Grade 3 lateral perforations in the freehand group and two in the 3D printing group. Analysis showed a statistically significant medial violation in the freehand group (p=.005).

Surgical time

Surgical time was significantly less in the 3D printing group compared with the freehand group (Table 1) (p=.03).

Blood loss

Mean blood loss was higher in the freehand group but not statistically significant (Table 1 (p=.3).

Other outcomes

A total of 57 fluoroscopic shots were obtained in the 3D printing group (5.7 per patient), whereas 119 fluoroscopic shots were obtained in the freehand group, which was significantly higher. There was no neurologic deficit in any of the patients in the two groups. There were two superficial wound infections in each group, which were managed with the change of antibiotics only.

Discussion

It is of utmost importance to understand the 3D morphology of each vertebra for an optimum placement of pedicle screws in patients with spinal deformities. Various studies have described several techniques for ideal pedicle screw placement, as well as their advantages and disadvantages. Broadly, we can classify them into five types, as described by Lu et al. [5]: (1) techniques relying on anatomical landmarks and averaged angular dimensions; (2) techniques with direct exposure of the pedicle (eg, by laminotomy); (3) CT-based computer-assisted surgery; (4) fluoroscopy-based computer-assisted surgery techniques; and (5) drill template techniques.

Although studies have reported enhanced safety margins with the use of the first four methods, these methods are not always accurate. Even after the use of these technological advances, studies have reported pedicle perforation rates of 1.2%–8.0%. Lu et al. [6] also reported several issues with these technologies, such as significant learning curve, errors caused by intraoperative shifting of spinal segments, registration errors, optical array dislodgement, erratic tracking of optical array devices, high cost, and increased surgical time.

The use of patient-specific drill and osteotomy templates has emerged as a promising and much safer tool for pedicle screw placement. Lu et al. [7] reported the use of these templates for 88 cervical pedicle screw placement and no misplacement was found. Lu et al. [8] also reported placement

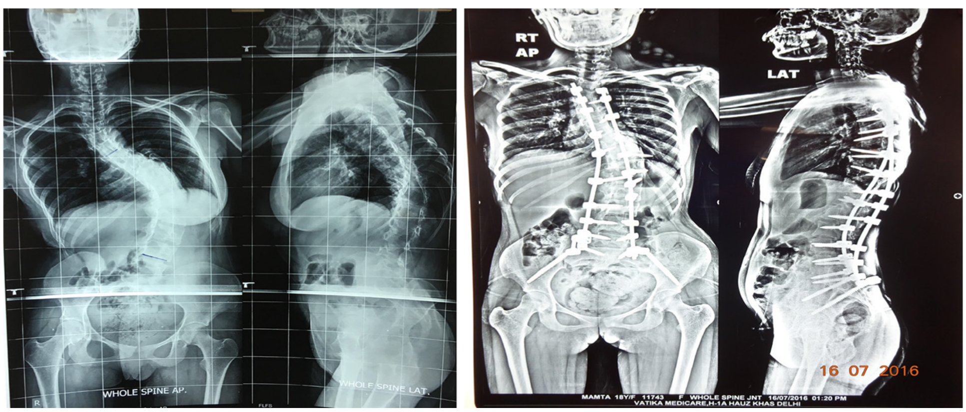

Fig. 13. Pre- and postoperative x-rays of one patient with congenital scoliosis operated on with the help of 3D printing. 3D, three-dimensional.

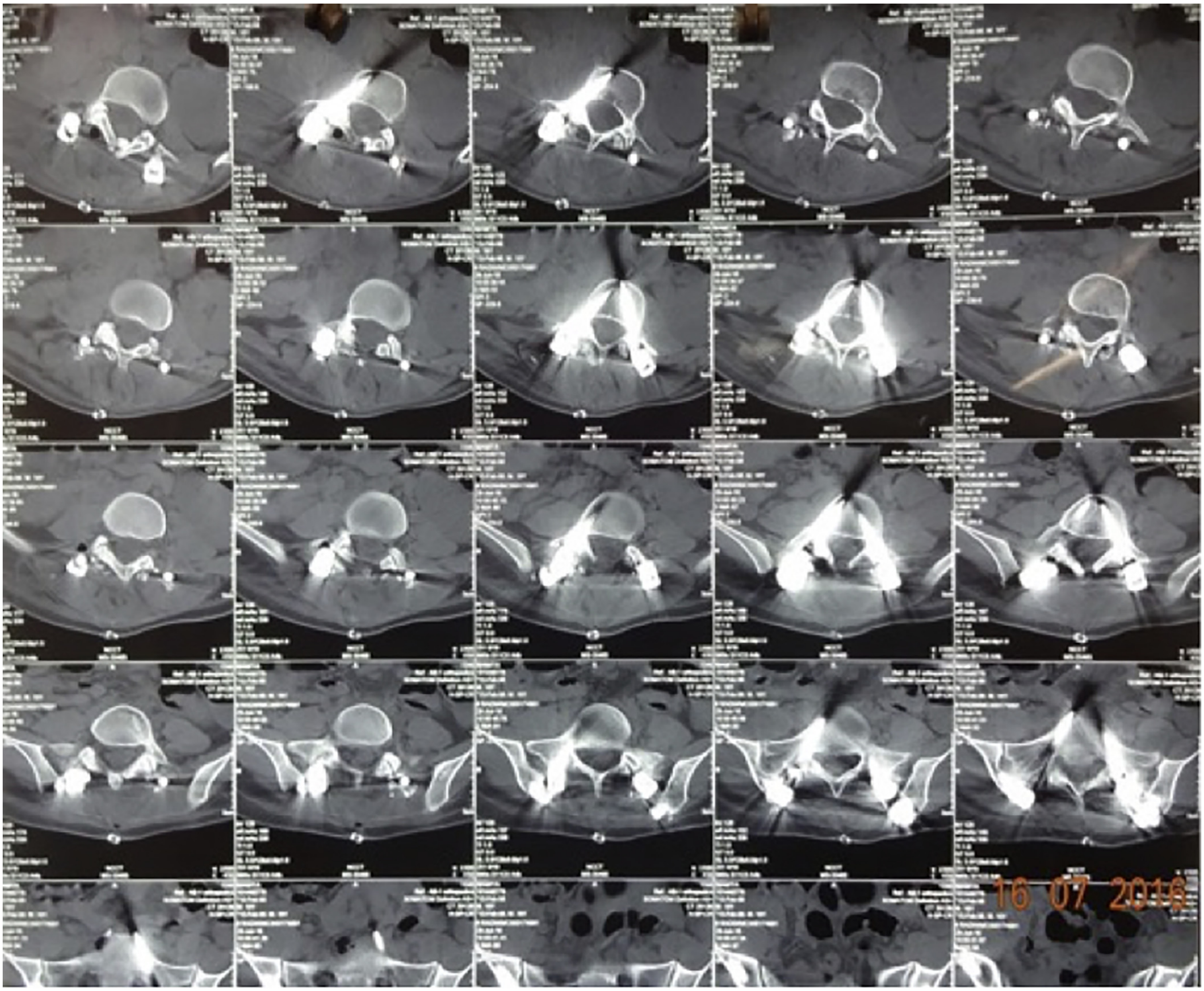

Fig. 14. Axial CT scan showing perfect placement of all screws in the patient, operated on with the help of 3D printing. 3D, three-dimensional; CT, computed tomography.

Table 1
Comparative demographic and surgical data of both groups

	Group 1: non-3D printing	Group 2: 3D printing	p-Value
N	10	10	
Type of scoliosis, n (%)			
Congenital	6 (60)	5 (50)	.5
Adolescent idiopathic scoliosis	3 (30)	4 (40)	
Post-tubercular kyphosis	1 (10)	1 (10)	
Gender, n (%)			
Female	7 (70)	6 (60)	.5
Male	3 (3)	4 (40)	
Age (y)	15.5 (3.8)	16.6 (4.9)	.6
Cobb angle (degree)	90.4	85.3	
Vertebrae included in fusion	12.6	12.4	
No. of screws	137	126	
Surgical time (min)	298.5 (59.3)	235.5 (55.7)	.03
Surgical blood loss (mL)	840 (533.3)	630 (227.6)	.3

3D, three-dimensional.

Table 2
Count or proportion of correctly or wrongly placed screws in patients with spinal deformity operated on with 3D printing and non–3D printing technique

	Group 1: non-3D printing	Group 2: 3D printing	p-Value
Total screws placed	126	137	.5
Correctly placed (Grade 1), n (%)	104 (82.6)	125 (91.2)	.03
Incorrectly placed (Grade 2 or Grade 3 violations), n (%)	22 (17.6)	12 (8.8)	
Medial violations (total), n (%)	13 (10.3)	3 (2.2)	.005
Grade 2: <4 mm	13	3	
Grade 3: >4 mm	0	0	
Lateral violation (total), n (%)	9 (7.1)	9 (6.6)	.85
Grade 2: <4 mm	6	7	
Grade 3: >4 mm	3	2	

3D, three-dimensional.

of C2 laminar screws using the same technique in another study and found all screws in perfect placement. Ma et al. [9] reported the use of patient-specific drill templates for thoracic screw placement in cadavers and found a much higher accuracy compared with the conventional technique. None of these, in particular, looked at the use of these techniques in spinal deformities, which magnifies the potential of this technique in terms of accuracy and safety.

In our study, focusing on spinal deformities, we found a statistically significant higher rate of accurate screw positioning with 3D printing. In spite of a similar vertebral fusion span, more screws were inserted in the 3D printing group, which was possible because of enhanced safety, particularly at apical levels. We had more lateral breaches in the 3D printing group, especially around apical concavity.

We also found some limitations. Soft tissues have to be stripped completely to make templates fit. Preoperative preparation of these templates takes around 10–12 hours per patient; however, the preoperative preparation is justified in view of statistically significant less surgical time and radiation exposure. Because bigger and less rotated pedicles do not require much surgical expertise and time compared with difficult ones, we are now using this technique only for difficult pedicles to save time and cost.

We had an almost similar accuracy with all pedicles; however, a larger sample size may reveal a statistically significant difference.

As such, spinal deformities are difficult to treat worldwide. In India, these deformities are often neglected and present at a very late and a much more deformed state when their treatment becomes even more challenging. Only very few centers treat these deformities in India, and the waiting list itself runs into years in these centers because of patient overload. Surgical treatment of these disorders carries a high risk of neurologic complications, and the majority of these complications occur because of misplaced pedicle screws caused by a deformed anatomy. Developing these patient-specific drill templates will enable an average spine surgeon to treat these patients with much ease and safety. This step will create a further platform to extend this technology for other orthopedic disorders, especially in the management of neglected injuries and deformities of other bones, which are again fairly common in India compared with the Western world.

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