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Personalized Three-Dimensional Printing Pedicle Screw Guide Innovation for the Surgical Management of Patients with Adolescent Idiopathic Scoliosis

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■ OBJECTIVE: **To assess the safety and efficacy of patient-specific three-dimensional (3D) rapid-prototype printing technology for pedicle screw insertion in patients with adolescent idiopathic scoliosis (AIS).**

■ METHODS: **The 3D pedicle screw guides were produced after selecting the fixation points for all individual levels to be used intraoperatively. Preoperative computed tomography images recreated 3D bone models of each vertebra specific to each patient. Safe pedicle trajectories were determined in all 3 planes on these models. 3D printed guides were modeled according to these trajectories and manufactured with a biocompatible material. Postoperatively, all screws were evaluated and scored with computed tomography as class 1 (accurate), class 2 (inaccurate), or class 3 (deviated). The mean angle between the inserted pedicle screw and the intended trajectory, and the mean distance between the central longitudinal axis of a screw and pedicle were also measured.**

■ RESULTS: **A total of 134 screws were inserted. On the concave and convex sides, the mean medial malposition was 0.5 ± 0.8 and 0.4 ± 0.6 mm, the mean lateral malposition was 1.4 ± 2.3 and 0.8 ± 1.3 mm, angle between the inserted pedicle screw and the intended trajectory was 4.2 ± 4.6 and 4.3° ± 6.0°, and distance between the central longitudinal axis of a screw and pedicle was 1.5 ± 2.1 and 0.9 ± 1.2 mm, respectively. A total of 117 screws were regarded as class 1, 14 as class 2, and 3 as class 3. Of all screws inserted, 92.5% achieved positional accuracy. There were no screw-related complications.**

■ CONCLUSIONS: **This is one of the initial reports to note the novel design and implementation of patient-specific 3D pedicle screw guides for adolescent idiopathic scoliosis surgery. Our pilot study shows that the use of these low-cost personalized 3D guides is completely safe and effective in both convex and concave sides of the curves.**

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a three-dimensional (3D) spinal deformity.[1] Pedicle screw fixation has been shown to be an effective way to obtain curve correction and fixation in patients with AIS.[2-4] Because of the rotation in the axial plain, freehand pedicle screw placement to the scoliotic spine is a technically difficult and demanding procedure that is not without potential neurologic complications.[5,6] This technique is associated with a steep and long learning period for spine surgeons. Even in experienced hands, placement of pedicle screws with this method might be challenging.

Misplacement of pedicle screws can result in devastating complications, such as injuries to the neurologic/vascular structures and to vital organs.[7] Rates of screw misplacement via the freehand technique have been reported to be between 20% and 43%.[8-15]

Key words
- 3D printing
- Adolescent idiopathic scoliosis
- Deformity
- Pedicle screw
- Spine

Abbreviations and Acronyms
3D: Three-dimensional
3DP: Three-dimensional printing
AIS: Adolescent idiopathic scoliosis
ASIT: Angle between the inserted pedicle screw and the intended trajectory
DBSP: Distance between the central longitudinal axis of a screw and pedicle
LM: Lateral malposition
MM: Medial malposition

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Therefore, improved accuracy and consistency in pedicle screw placement have led to the development of computer-assisted technologies. The indications of using such technologic devices can be given as severe (>100°) scolioses, revision cases with indistinct reference points for detecting the pedicle entry points, and complex deformities with unpredictable vertebral spatial orientations. Computer-assisted pedicle screw insertion has been shown to be more accurate, thereby decreasing the risks.[16-18] Navigation-guided techniques for pedicle screw placement comprise 1) CT-based computer-assisted surgery and 2) fluoroscopy-based computer-assisted surgery.[18] Drawbacks of these techniques consist of high radiation exposure to the young child, increased operative time and potential blood loss, and high cost, which in some countries makes acquiring such technologies a challenge.[19,20]

Additive manufacturing, so called three-dimensional printing (3DP), allows for the rapid conversion of anatomic images into physical components by the use of special printers.[21,22] This technology allows for a more personalized approach toward spine surgery. In the setting of AIS, it provides cheap and fast template production to facilitate pedicle screw insertion in patients with AIS. 3DP has been used to address several spinal disorders and/or conditions, such as the development of an intervertebral disc and vertebral bodies[23,24]; however, its application for pedicle screw insertion in patients with AIS has rarely been addressed, in particular as it pertains to a more personalized rapid prototyping approach. Therefore, this article reports a pilot study that addressed the safety and efficacy of a 3DP pedicle screw guide that was implemented in patients with AIS undergoing thoracic curve correction.

METHODS

After institutional review board approval (number 2012-KAEK-15/1905), we performed a prospective study to assess the safety and efficacy of a 3D pedicle screw drill guide in patients with AIS. Written informed consent was obtained from each patient recruited in this study.

Patient Characteristics

Patients with AIS who underwent posterior instrumentation with pedicle screws consecutively between January 2016 and March 2016 in a single institution were included in this study. Patients with spinal cord anomaly, juvenile idiopathic scoliosis, one of the other scoliosis types (e.g., neuromuscular, congenital, posttraumatic, posttuberculosis, syndromic, and postlaminectomy scoliosis), history of using a cast or an orthosis, and necessity of corrective osteotomy and revision surgery were excluded from the study. Age of patients ranged from 12 to 18 years. The mean age was 15 years (standard deviation, ±1.8 years). Nine of the patients were female and 2 were male. All patients were operated on by a fellowship-trained spine surgeon (A.S.). The upper and lower levels of fusion were determined according to the radiographs of anteroposterior views in side bending, fulcrum bending, and traction under anesthesia in addition to those of standing lateral and anteroposterior views.[4,25,26] We performed alternate level pedicle screw fixation strategy.[4] After determining the fusion levels and fixation points, 3DP guides were produced for all individual levels.

Production of Guides by Using 3DP Technique

Preoperatively, we obtained 0.625-mm-thick slices and 0.35-mm in-plane resolution images with a 16-channel multidetector computed tomography scanner (BrightSpeed, GE Healthcare, Chicago, Illinois, USA), which were transferred to DICOM (Digital Imaging and Communications in Medicine) data and then to a Materialise Interactive Medical Image Control System (MIMICS) 6.3 software (Materialise, Leuven, Belgium). The images were used to create 3D bone models of each vertebra by the complex surface rendering method (**Figure 1**). These models were created as smooth mannequins, with adequate proportions and occupying as little as possible hard drive space. By this software, safe trajectories of pedicles were determined in all 3 planes (sagittal, axial, and coronal) and were planned for penetration of screws right in the center of the pedicles and if possible parallel to the upper end plate of the vertebral body. These data were transferred to a stereolithography (stl) format file and exported to the 3-Matic (version-13) (Materialise, Leuven, Belgium) software. Afterward, trajectories consistent with the left and right pedicles lying posteriorly were virtually composed by 3-Matic (**Figure 2**). Each model included the appropriate trajectory and inversely conformed to surfaces of a spinous process and 2 transverse processes were created virtually. Localization of the model on the reference points of spinous and transverse processes provided a stationary position in accordance with the related vertebra. This process was based on the principle of coordinates designating points in space. An object fixed by its 2 poles could turn around the line between those 2 points, whereas that fixed by its 3 poles remains stationary in space. The 3D reconstructed guides were transferred to a .stl format file by MIMICS 6.3 software and then transferred to Magics (Materialise, Leuven, Belgium) software. The CT scans of the patients were performed preoperatively in the outpatient clinic after the decision for surgery according to the physical examination and posteroanterior and lateral spinal radiographs of the patients. Because the decision about which levels would be instrumented was made after taking the lateral bending films, all the CT scans were planned to include the segments from T1 to L5.

The production of the 3D drill guide was planned by Magics software and the templates were prepared for additive manufacturing. The data were then exported as a .slc format file to construct models. A machine using fused deposition modeling technology, which can create endurable models to high heat, caustic materials or sterilization (Fortus 900 MC [Stratasys Ltd, Minnesota, USA]), built the computer-designed models in layers according to the .slc format file by extruding small flattened strings of molten material to form layers as the material hardens immediately after extrusion from its nozzles. The printing process was executed in 100-μm-thick layers and resulted in 100—200 μm eventual tolerance. The material used for manufacturing was acrylonitrile butadiene styrene, which is a high-strength biocompatible material (ISO 10993 USP class VI). This material was a common thermoplastic polymer with a glass transition temperature of approximately 105°C (221°F). It is an amorphous material; thus, it has no true melting point. ABS-M30i (Stratasys Ltd., Eden Prairie, Minnesota, USA), was commercially available in the market and had a tensile strength of 36 MPa, tensile modulus of

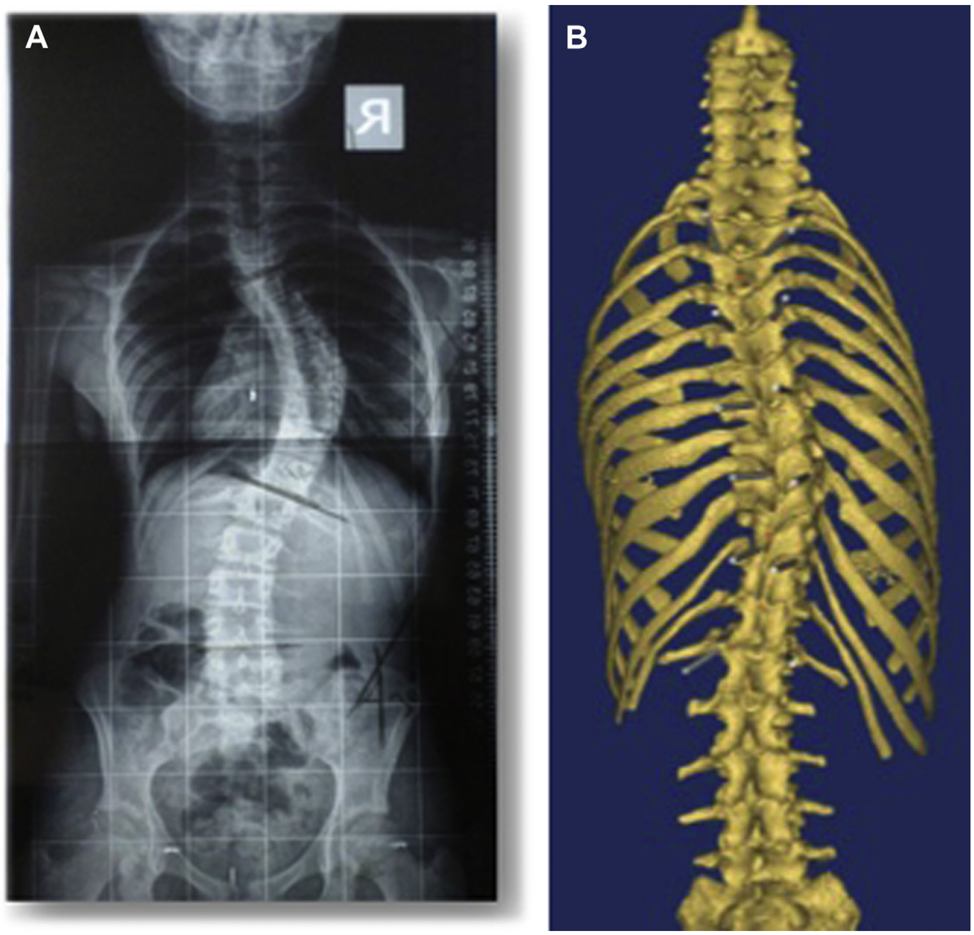

Figure 1. (**A**) Anteroposterior standing plain radiograph of a 13-year-old girl who was classified as having Lenke type 1. (**B**) A three-dimensional model of the patient produced from the DICOM images.

2.413 MPa, tensile elongation of 4%, and a flexural stress of 61 MPa. After being manufactured by the techniques outlined, the guides were then sterilized with ethylene oxide to be ready for operative use (Figure 3A).

Surgical Technique

Multimodal intraoperative spinal cord monitoring was used during all surgeries. After the proper posterior midline approach, transverse processes and spinous processes were prepared by removing all soft tissues to accommodate the guides correctly. This step is crucial because any small alteration in the position of guides causes severe pedicle screw misplacement. First, a pilot hole was constituted by a Kirschner wire through the ports of guides, and wires were advanced 2 cm deep into the pedicles. After the establishment of pilot holes and trajectories by these wires, the guides were removed, leaving the wires in place. Thereafter, the pedicle trajectories were drilled and tapped in accordance with the guidance of Kirschner wires (Figure 3B). Instead of using Kirschner wires, thinner pedicle awls can also be used for constituting the preliminary pedicle screw preliminary tracts. Care was taken in this step to avoid irrelevant drilling of the spine, which could be caused by a mistake in manufacturing those guides. All screws were placed in the same manner (Figure 3C).

Follow-Up Evaluation

A musculoskeletal radiologist performed all the measurements on the transverse images of postoperative CT studies (Figure 4). A medial malposition (MM) of a screw was determined by measuring the distance between the medial aspect of the pedicle wall and the medial margin of the screw. The lateral malposition (LM) was measured as the distance between the lateral margin of the screw and the lateral aspect of the vertebral body. An unacceptable screw position was rated where a screw violated >2 mm medially or 6 mm laterally.[7] The following criteria were also used for classifying the penetration amounts of screws: class 1 (accurate), screw axis deviates by <2 mm from the planned trajectory; class 2 (inaccurate), screw axis deviates by ≥2 mm but <4 mm; and class 3 (deviated), screw axis deviates by ≥4 mm.[27] The distance between the central longitudinal axis of a screw and pedicle (DBSP) was measured

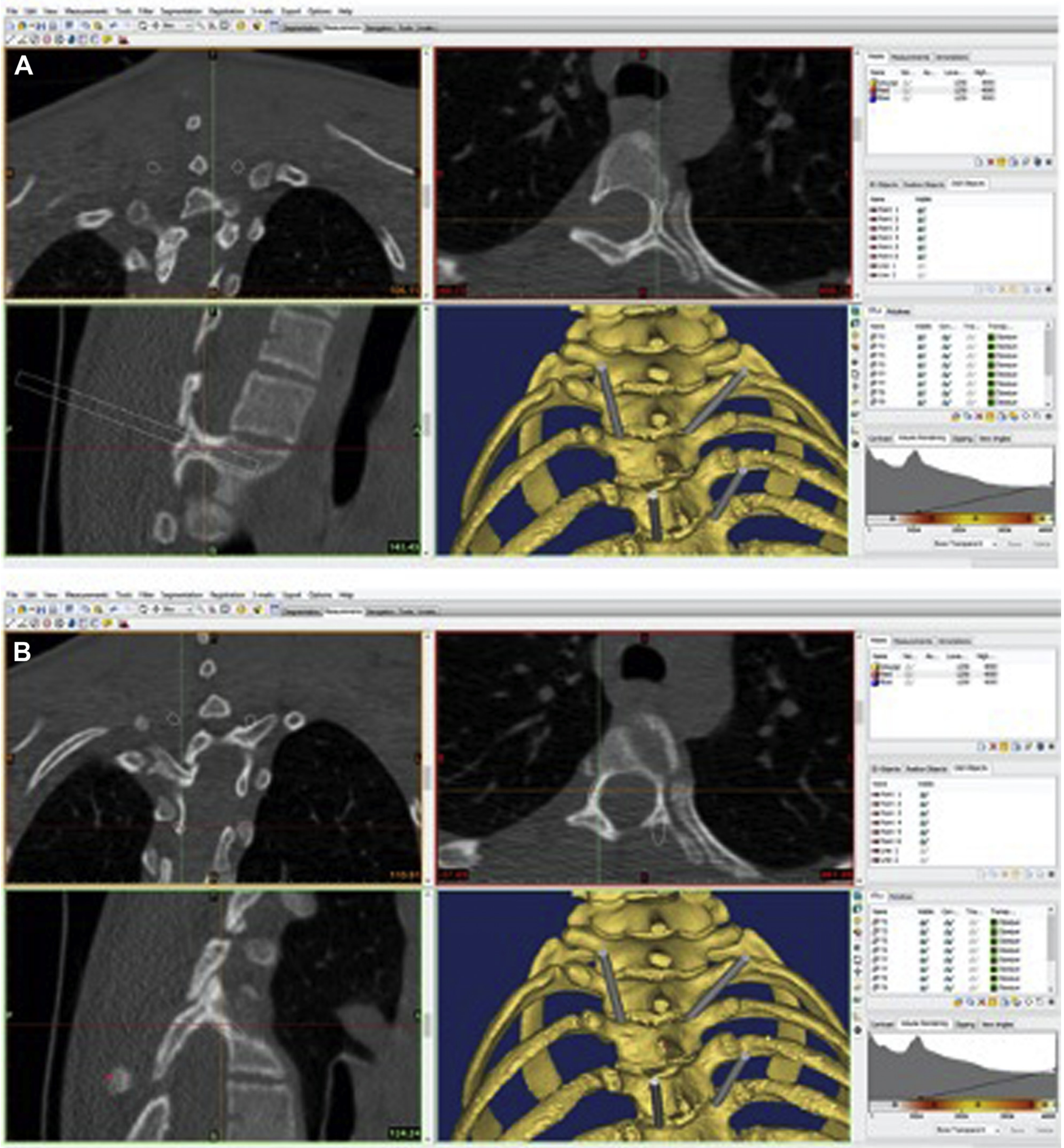

Figure 2. (**A**) Pedicle screw trajectory of the left pedicle of T5 is visible on 3 planes. (**B**) Pedicle screw trajectory of the right pedicle of the same level is also seen on 3 planes.

right in the middle of the pedicle anteroposteriorly and mediolaterally. The pedicle sizes were noted as the narrowest width of the pedicle. The angle between the inserted pedicle screw and the intended trajectory (ASIT) of the screw through the pedicle was also measured.[28] The vertebrae were classified as upper thoracic, midthoracic, lower thoracic, and lumbar.

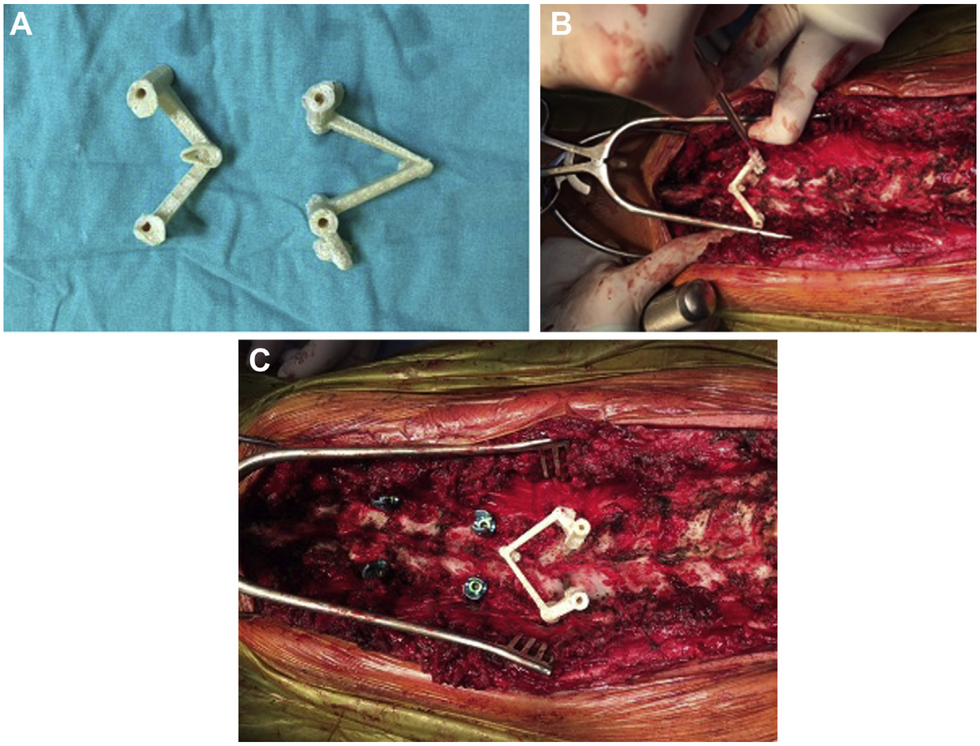

Figure 3. (**A**) Three-dimensional printed guides for pedicle screw fixation of predetermined levels. (**B**, **C**) Intraoperative pictures show the three-dimensionally printed guide use.

Statistical Analyses

The frequency and descriptive analyses, Student t test, and χ^2 analyses were performed where applicable. Statistical significance was set at the value of $P < 0.05$. Statistical analyses were performed with SPSS version 21 (IBM Corp., Armonk, New York, USA).

RESULTS

There were 134 screws (67 convex and 67 concave) inserted in 11 patients with AIS. The demographic characteristics, scoliosis types according to Lenke classification, and detailed Cobb angle measurements of the patients are shown in Table 1.[29] In addition, the cost of these patient-specific 3DP guide templates (for one level-2 pedicle screw) was approximately €2. For 5 levels of fixation (10 pedicle screws inserted with alternate pedicle screw fixation for T4-T12 fusion), the total cost of screw guide templates was just €10.

Five screws medially penetrated >2 mm and 5 screws laterally penetrated >6 mm. Of those 10 screws, only 1 was at the apex of a major curve that showed L3 convex medial wall violation. Of the screws, 92.5% were in an acceptable position. The perforation grades greater than class 1 were 87.3%. The perforation grade and mean deviation in millimeters per level are shown in Table 2. There were 29 screws with no penetration (15 convex and 14 concave). On concave and convex sides, the mean MM was 0.5 ± 0.8 and 0.4 ± 0.6 mm, the mean LM was 1.4 ± 2.3 and 0.8 ± 1.3 mm, the mean ASIT was 4.2 ± 4.6 and 4.3° ± 6.0°, and the mean DBSP was 1.5 ± 2.1 and 0.9 ± 1.2 mm, respectively. There was no statistically significant difference between the concave and convex sides in terms of measurements ($P < 0.05$). Measurements of the parameters for each level are presented in Table 3. No screw-related injury to vascular, neurogenic, or other vital structures was encountered in our series of patients. There was no complication related to screw placement and no revision surgeries were performed.

DISCUSSION

The success rate of our patient-specific 3DP pedicle guide was 92.5%, which was comparable to the other computer/navigation-based techniques described in the literature.[18-20] The mean MM and LM on concave and convex sides (0.5—0.4 and 1.43—0.83 mm, respectively) were under the thresholds of acceptability criteria. The most remarkable feature of the guide was taking ≥3 distinct landmarks of the related vertebra as reference points to indicate the pilot hole and the trajectory of the pedicle. These guides were also safe to be in contact with the local tissue; contact usually does not last more than 3 minutes. The material used to manufacture these templates is biocompatible and thus does not have any adverse effect on patients. The reproducibility of this technique was robust, and even less experienced spine surgeons could use it.

The mean ASIT values of the concave and convex sides were 4.2° and 4.3°, respectively. These values indicate only 0.7 mm

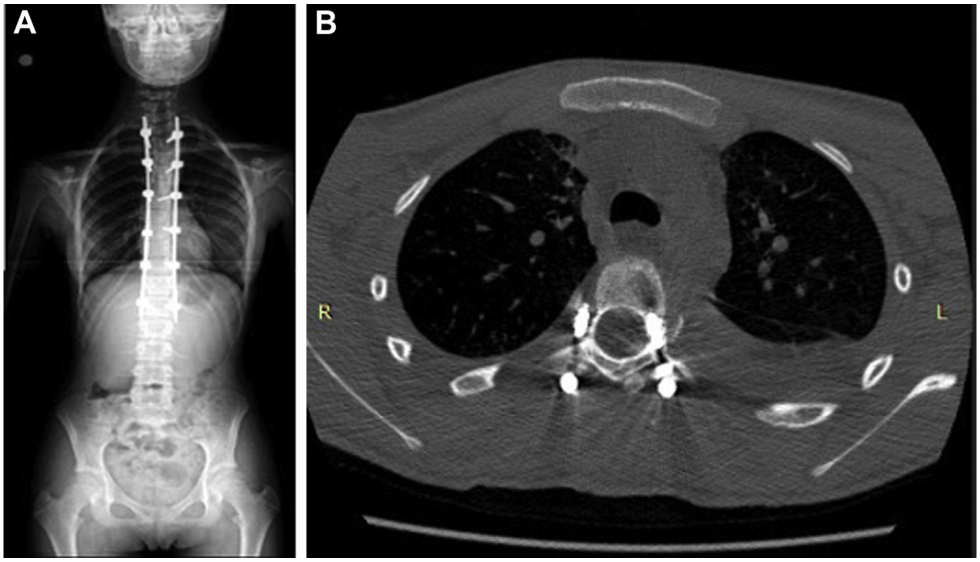

Figure 4. (**A**) Postoperative anteroposterior standing plain radiograph of the same patient as shown in Figure 1. The patient underwent alternate level pedicle screw fixation strategy. (**B**) Computed tomography evaluation of the T5 level. The right pedicle screw seems to have lateral penetration. However, the pedicle diameter is narrow, preventing pedicle screw insertion within the cortical walls.

distortion in the middle of the pedicle between the screw and the intended trajectory (the midpoint is assumed to be 10 mm away from the pilot hole), because the 4° tangent is 0.0699, which is not a limiting factor and could be deemed as possessing a perfect accuracy (Figure 4B). Therefore, these guides provided pedicle insertion with accuracy and with a mean deviation of ±0.7 mm.

3D guides were not 100% successful in our series. Several reasons may exist for the misplacement of the screws inserted with the 3D drill guides. For instance, changing parameters during the scan reconstruction, segmentation, filtering, and surface extraction steps have an effect on the dimensions of the final model. These factors need to be quantified that rely on the accuracy of 3DP models for a more accurate screw trajectory delineation.[30] However, we investigated the unacceptable screws and found that all misplaced screws were larger in diameter than the installed pedicles (Table 4). None of those screws triggered an undesired sensorimotor or motor-evoked potential intraoperatively, and thus, there was no need to revise them. Of the

Table 1. Characteristics of the Patients

Patient Number	Age (years)	Gender	Lenke Type	Preoperative UT Cobb's	Preoperative MT Cobb's	Preoperative TL/L Cobb's	Postoperative UT Cobb	Postoperative MT Cobb	Postoperative TL/L Cobb
1	16	F	1A	42.7	48.2	24.7	6.2	7.5	6
2	16	M	4B	34	43	33	13	16	20
3	16	M	4B	67	86	57	28	21	29
4	15	F	1A	28.9	55.6	32.5	17	15.7	13.4
5	14	F	5C	4	29	44	6	16	12
6	13	F	2A	26	47	25	12.4	12	5
7	17	F	2A	57	74	42	29.6	38.7	18
8	12	F	3C	24.3	40	39	13	24.6	18.4
9	15	F	3B	26	59	43	16	24	21
10	18	F	1B	21.4	41	38	5	19	29
11	12	F	5C	27.7	69	23	18.4	20.1	6.5

UT, upper thoracic; MT, midthoracic; TL/L, thoracolumbar/lumbar; F, female; M, male.

Table 2. Pedicle Wall Violation Classification and Screw Insertion Accuracy Rates for Each Level

	Class 1 (<2 mm)	Class 2 (2–4 mm)	Class 3 (≥4 mm)	Accuracy, n (%)	Wall Violation (mm), Mean± Standard Deviation
T2	3	1	0	3/4 (75)	1.36 ± 0.72
T3	6	2	0	6/8 (75)	2.36 ± 2.91
T4	8	0	0	8/8 (100)	1.72 ± 1.39
T5	7	3	0	7/10 (70)	2.44 ± 2.17
T6	9	1	0	9/10 (90)	1.93 ± 1.25
T7	4	3	1	4/8 (50)	2.39 ± 2.38
T8	11	1	0	11/12 (91.6)	2.07 ± 1.60
T9	10	0	2	10/12 (83.3)	2.10 ± 3.06
T10	10	0	0	10/10 (100)	1.03 ± 1.00
T11	12	2	0	12/14 (85.7)	1.20 ± 1.11
T12	10	0	0	10/10 (100)	1.23 ± 1.80
L1	11	1	0	11/12 (91.6)	0.72 ± 0.95
L2	6	0	0	6/6 (100)	1.10 ± 1.15
L3	8	0	0	8/8 (100)	0.73 ± 0.52
L4	2	0	0	2/2 (100)	0 ± 0

screws, 87.3% had only class 1 perforation. These results were comparable to previous studies in the literature. Another reason was that the surgeon created the pedicle screw tracts with an awl. The pedicle tracts are shown by the guides, and the tracts are constituted by the hand of the surgeon, which is still susceptible to misangulation. However, as seen on postoperative CT images,

Table 3. The Mean Values of Pedicle Size, Medial Malposition, Lateral Malposition, Angle Between the Inserted Pedicle Screw and the Intended Trajectory, and Distance Between the Central Longitudinal Axis of a Screw and Pedicle for Each Level

	Pedicle Size ±SD	Medial Malposition ±SD	Lateral Malposition ±SD	Angle Between the Inserted Pedicle Screw and the Intended Trajectory ±SD	Distance Between the Central Longitudinal Axis of a Screw and Pedicle ±SD
T2	4.92 ± 0.66	0.1 ± 0.2	1.26 ± 0.91	3.29 ± 2.44	0.8 ± 1.08
T3	4.28 ± 1.60	0.5 ± 0.14	2.31 ± 2.95	5.52 ± 5.51	1.83 ± 2.54
T4	3.72 ± 1.21	0.62 ± 0.78	1.10 ± 1.64	4.63 ± 4.70	0.72 ± 1.08
T5	3.56 ± 1.13	0.30 ± 0.35	2.13 ± 2.43	5.63 ± 5.27	1.75 ± 1.75
T6	3.89 ± 1.46	1.15 ± 1.14	0.84 ± 1.49	2.97 ± 2.53	1.14 ± 1.27
T7	4.08 ± 0.86	0.43 ± 1.23	1.95 ± 2.47	6.13 ± 4.12	2.38 ± 2.23
T8	4.46 ± 1.22	0.74 ± 0.85	1.32 ± 1.95	3.21 ± 2.88	1.87 ± 2.10
T9	3.82 ± 0.93	0.48 ± 0.48	1.70 ± 3.22	4.62 ± 6.80	1.54 ± 2.92
T10	5.09 ± 1.41	0.32 ± 0.42	0.71 ± 1.01	2.81 ± 2.86	0.79 ± 1.27
T11	5.7 ± 1.16	0.28 ± 0.46	0.91 ± 1.21	4.83 ± 7.01	1.17 ± 1.45
T12	6.46 ± 1.08	0.35 ± 0.75	0.88 ± 1.83	5.83 ± 10.55	0.96 ± 2.03
L1	5.75 ± 0.93	0.28 ± 0.49	0.44 ± 0.88	2.05 ± 1.96	0.31 ± 0.31
L2	5.60 ± 1.47	0.65 ± 0.81	0.45 ± 0.71	6.8 ± 7.25	0.68 ± 1.21
L3	7.47 ± 0.95	0.58 ± 0.62	0.15 ± 0.27	2.74 ± 2.95	0.71 ± 0.66
L4	10.0 ± 4.38	0.0 ± 0.0	0.0 ± 0.0	1.45 ± 2.05	0.0 ± 0.0

SD, standard deviation.

Table 4. Screw Failures Including Unacceptable Screws, Pedicle Sizes, and Degree of Pedicle Wall Violations

Unacceptable Screw Number	Screw Size (mm)	Pedicle Size (mm)	Lateral Malposition	Medial Malposition
1	4.5	2.8	7.7	0
2	5.5	2.2	6.44	0
3	5.5	3.6	0	3.25
4	5.5	2.5	6.45	0
5	4.5	4.2	0	3.5
6	5.5	3	0	2.5
7	4.5	2.8	9.3	0
8	5.5	2.3	7.7	0
9	5.5	3	0	2.4
10	6.5	5.4	0	2.4

the pedicle screw entry point was still completely accurate (Figure 4B).

Yang et al.[31] found 16.9% of misplacement with 3D rapid prototyping assisted surgery in a group of Lenke type 1 patients with AIS. Wu et al.[32] reported a success rate of 97.9% with 3D technology for screw placement in patients who underwent hemivertebra resection, assuming the safe zone as ≤4 mm LM and ≤2 mm MM. However, both studies used 3D technology by printing a copy of the whole vertebral column of the patient and were just haptic formats of the 3D reconstructed CT images of the vertebral column. The studies used 3D physical components to determine the trajectories perioperatively. So, the pedicle screws were still inserted with a freehand technique, whereas our 3D guides were placed on the related vertebra in a fit-and-lock manner. Afterward, the surgeon created the pilot holes with a Kirschner wire through the guide holes.

In the literature, the results of a freehand technique for pedicle screw insertion vary; however, our reported rate remains relatively accurate in comparison.[6,33] We believe that the difference will be more obvious when these 3D guides are used in complex deformities or revision surgeries, because determining the reference landmarks for freehand will be more challenging in those cases. Alternatively, for an appropriate screw installation, determining the pilot hole is crucial. Revision surgeries may be most challenging for screw insertion cases, in which determining the pilot hole in the pedicle is an almost impossible challenge. The freehand technique may be affected by the difficulty level of the deformity, whereas 3D guides may not. So, we believe that our 3D guides would maintain their accuracy in complex deformities and revision cases. Furthermore, the mean ASIT, DBSP, LM, and MM were statistically similar between the concave and convex sides. Because of the resulting similarity between such parameters in the concave and convex sides, there would be similar screw insertion accuracies with these 3D guides in different types of deformities.

A similar technique was used by Fu et al.[34] for cervical anterior transpedicular screw insertion. These investigators created cervical vertebral models with predrilled pedicles and placed 2-mm K-wires anteriorly. Afterward, they used polymethyl methacrylate bone cement to create drill guides by enveloping the K-wires and waited for them to solidify to take the shape of the anterior vertebral corpus and the K-wires. In their technique, the drill guides referenced the smooth surface of the anterior vertebral body, which may cause sliding of the guide on the body when constituting the pedicle path. Second, the K-wire may move in the cement during the solidifying process. A few degrees of K-wire movement may cause pedicle wall penetration during screw insertion. The more industrial the step used for guide creation, the greater the industrial error rate. In contrast with Fu et al., we created the guides with reverse engineering technology and printed out the drill guides with ≥3 reference points (2 transverse and 1 spinous processes). The most significant drawback of our guides was the high flexibility with bending forces. This factor might have resulted in distortion of the pedicle path constitutions, which could easily be averted by using harder materials.

A guide more similar to ours was used by Lu et al.[35] by producing with the stereolithographic 3D technique using acrylate resin. These investigators claimed that their guides took reference from 2 transverse processes and 1 spinous process and also fitting to the lamina. However, the guides were not fitting and locked to the transverse processes as in our study. Our guides have accessory processes to fit and lock to the transverse and spinous processes. Thus, this feature prevents the risk of sliding on the lamina while constituting the pedicle path. Apart from preliminary studies for this technique, several studies have also been reported describing similar guides to that in the current study.[36-38] However, most of these studies were not conducted on patients with deformity.

Compared with intraoperative CT-assisted or fluoroscopy-assisted navigation systems, 3DP guides do not require any additional preparation process intraoperatively while the patient is under general anesthesia. The guides are modeled and manufactured before surgery and prepared in packages ready to use in a sterile fashion. We have not seen any problem while using these guides; however, there are several shortcomings in other navigation systems (e.g., synchronization, struggling in reference point recognition by the navigation device, and potential risk of reference point device movement during the surgery). Besides, it sometimes becomes difficult and risky to insert the pedicle screw while viewing the screen instead of the surgical field. It also causes an additional risk for infection as a result of unintended contact of the navigation device with the sterile area. Furthermore, the pedicle screws are not more accurate. Modi et al.[39] reported 27.1% misplacement of pedicle screws with freehand technique in patients with scoliosis. Most of the studies in the literature report a misplacement rate between 28% and 43%.[40] Therefore, navigational systems have been promoted recently. In a systematic review reported by Gelalis et al.,[18] the percentage of the screws fully contained in the pedicle ranged from 28% to 85% with the aid of fluoroscopy, from 89% to 100% using CT navigation, and from 81% to 92% using fluoroscopy-based navigation. According to Gelalis et al.s' study, there is no further accuracy with navigation compared with the 3DP guides described in this study.

The most significant limitation of our current study was the absence of a control group. However, high accuracy rates are comparable to or higher than they are in historical cohorts. Besides, our study did not address complex deformities and revision surgeries, and we anticipate these 3D guides to be more advantageous in such cases. Another disadvantage may be the high radiation exposure of the patients, which was required for 3D modeling. However, we are assessing the usefulness of magnetic resonance imaging scans for 3D modeling to prevent radiation-related drawback, and the CT scans are already indicated for all severe, complicated, or revision cases for better understanding the features of the deformity and bony anatomy.

CONCLUSIONS

Based on our knowledge, our study is one of the first to address patient-specific 3D manufactured pedicle screw guides for patients with AIS. Our pilot study showed these guides to be completely safe and effective in both convex and concave sides of the curves when facilitating pedicle screw insertion in patients with scoliosis. These inexpensive guides have potential use for complex deformities and revision cases. However, larger studies are needed to further validate our findings.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Alpaslan Senkoylu: Conceptualization, Methodology, Project administration, Supervision, Visualization, Writing - review & editing, Resources. **Mehmet Cetinkaya:** Writing - original draft, Writing - review & editing, Formal analysis, Data curation, Resources, Visualization. **Ismail Daldal:** Resources, Visualization. **Elsan Necefov:** Resources, Visualization. **Ali Eren:** Resources, Visualization. **Dino Samartzis:** Writing - review & editing.

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