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ORIGINAL ARTICLE

Accuracy of thoracic pedicle screw placement in adolescent patients with severe spinal deformities: a retrospective study comparing drill guide template with free-hand technique

Yue Pan[1] · G. H. Lü[1] · Lei Kuang[1] · Bing Wang[1]

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Abstract

Purpose Patients with severe spinal deformities often have small pedicle diameters, and pedicle dimensions vary between segments and individuals. Free-hand pedicle screw placement can be inaccurate. Individualized drill guide templates may be used, but the accuracy of pedicle screw placement in severe scoliosis remains unknown. The accuracy of drill guide templates and free-hand technique for the treatment of adolescent patients with severe idiopathic scoliosis are compared in this study.

Methods This study included 37 adolescent patients (mean age 16.4 ± 1.3 years) with severe idiopathic scoliosis treated surgically at a single spine center between January 2014 and June 2017. Spinal deformities were corrected using posterior pedicle screw fixation. Patients in group I were treated with rapid prototype drill guide template technique (20 patients; 396 screws) and patients in group II were treated with free-hand technique (17 patients; 312 screws). Outcomes that included operative time, correction rate, and the incidence and distribution of screw misplacement were evaluated.

Results Operative time in group I was 283 ± 22.7 min compared to 285 ± 25.8 min in group II ($p = 0.89$). The scoliosis correction rate was 55.0% in group I and 52.9% in group II ($p = 0.33$). Based on both axial and sagittal reconstruction images, the accuracy rate of pedicle screw placement was 96.7% in group I and 86.9% in group II ($p = 0.000$).

Conclusion The drill guide template technique has potential to offer more accurate and thus safer placement of pedicle screws than free-hand technique in the treatment of severe scoliosis in adolescents.

Keywords Pedicle screws · Severe spinal deformities · Drill guide template

Introduction

Severe spinal deformity manifests as scoliosis, defined as a Cobb angle greater than 90° or flexibility, and/or a curve improvement on an X-ray acquired with the patient bending or a curve on an X-ray acquired with the patient standing up less than 20% in association with complex deformities such as kyphosis and vertebral deformity [1]. The etiology of severe spinal deformity includes idiopathic scoliosis and congenital spinal malformations, as well as neurofibromatosis, and neuromuscular diseases. Idiopathic scoliosis is the most common type among them. Severe scoliosis may result in cosmetic deformity, compromised cardiopulmonary function, and neurological damage.

The use of thoracic pedicle screws in the management of adolescent idiopathic scoliosis was first described by Suk et al. [2]. In this patient population, pedicle screws enable enhanced three-dimensional deformity correction. Recently, pedicle screw instrumentation has gained popularity for the correction of all types of spinal deformity. However, in severe scoliosis, correction is often challenging. Patients often have small pedicle diameters, and pedicle dimensions vary between segments and individuals. The deformed thoracic spine, aorta and inferior vena cava have a close anatomical relationship, which means surgeons must proceed with caution [3–5]. Pedicle screw insertion in severe scoliosis is a challenging procedure due to difficult placement techniques and the potential to cause serious complications. Indeed, the rates of misplaced pedicle screws using the free-hand technique range from 5% to between 28 and 43% [6, 7].

✉ Lei Kuang
leikuangcs@sohu.com

[1] Department of Spine Surgery, The Second Xiangya Hospital of Central South University, Changsha 410011, China

Safety and accuracy in pedicle screw placement in severe scoliosis have been investigated in cadaveric and clinical studies [6, 8–10], which found that computer-assisted pedicle screw navigation results in a decreased incidence of misplaced screws. However, this technique involves surface registration of each vertebra, which increases the potential for registration-based errors and may lengthen operative time. Furthermore, this process also requires additional personnel during surgery, and is associated with risk for intraoperative infection and prohibitively expensive equipment costs [6, 11–13].

Polycarbonate drill guide templates were first used for lumbar pedicle screw placement in 1998 [14]. Subsequently, a template that incorporates clamps that interface with the posterior cervical vertebrae was developed in 2001 [15]. The three-dimensional shape of this template assures that screw placement is not affected by changes in spinal alignment, such as torsion during drilling and screw insertion. This template is especially useful for patients with small pedicles or severe spinal misalignment. However, most studies using this template were performed on cadavers [16–18]. Furthermore, there were few studies reported on the use of a drill guide template for screw placement in patients with thoracic spine deformities [19–21]. Currently, there are no studies comparing the accuracy of drill guide templates with the free-hand technique for pedicle screw insertion in severe idiopathic spinal deformities.

Here, we present a retrospective study that compares the accuracy of pedicle screw placement with individualized drill guide templates and the free-hand technique in adolescent patients with severe kyphoscoliosis.

Materials and methods

Study design

This study included adolescent patients with severe idiopathic scoliosis, defined as a Cobb angle > 90°, who were treated surgically at a single spine center between January 2014 and June 2017. Inclusion criteria were: (1) patients who were 10–18 years old; (2) patients who were diagnosed as adolescent idiopathic scoliosis or had been diagnosed as early onset idiopathic scoliosis; (3) patients who was treated with pedicle screw-based posterior instrumentation. Patients who had received previous spinal surgeries or with diagnosis other than idiopathic scoliosis such as congenital scoliosis, secondary scoliosis, neuromuscular or syndromic scoliosis were excluded. This study was approved by the institutional review board. Written informed consent was obtained from all patients and their legal guardians.

Spinal deformities were corrected using posterior pedicle screw fixation. All surgeries were performed by a single surgeon (Dr. Kuang). Patients in group I were treated with a rapid prototype drill guide template and patients in group II were treated with the free-hand technique. There was no techinique cross-over between the two groups. Selection of patients for the guide template versus the free-hand technique was non random, according to which treatment they were willing to receive. Outcomes included operative time, correction rate, and the incidence and distribution of pedicle screw misplacement evaluated by computed tomography (CT).

Design of the drill guide template

A three-dimensional full-scale model of each patient's spine was developed from CT data using stereolithography as a rapid prototyping technique. A spiral three-dimensional CT scan was performed on the whole spine of each patient using the following specifications: 0.625 mm slice thickness, 0.35 mm in-plane resolution. MIMICS 19.01 software (Materialize Company, Belgium) was used to generate a 3-D reconstruction model. Autodesk Max 2010 software was used to design optimal screw size and orientation. The screw positions were designed by technicians and validated by the surgeon, including the orientation on coronal, sagittal, and axial planes, as well as the screw length and diameter, then a list of screw size on different levels was produced accordingly. If the pedicle calibre was too small for a 4.5-mm-diameter pedicle screw, an extrapedicular thoracic pedicle screw fixation technique was adopted in the screw trajectory designed process. The drill guide template specific to each level and the corresponding bone model was produced for each vertebra based on the validated screw trajectory (Fig. 1a, b). The template surface was developed as the inverse of the spinous process, lamina and transverse process, which facilitated a lock-and-key type fit and identified a specific entry point (Fig. 1c).

Drill guide template technique

Both sides of the spine were exposed subperiosteally. The soft tissues around the facet joints and the transverse processes were carefully cleaned to reveal the bony landmarks. The drill guide template was placed onto the spinous process, lamina process, and transverse process and was fixed to the corresponding spinous process with a clamp (Fig. 2a). A high-speed burr was used to drill the trajectory of each pedicle screw by hand, to a depth that was in accordance with the preoperative plan [9] (Fig. 2b). The length and diameter of the pedicle screw was also selected according to the size list determined before the operation. A probe was used to examine the integrity of the pedicle after tapping (Fig. 2c). The pedicle screw was inserted along the same trajectory without fluoroscopic control. A pedicle screw was not inserted if

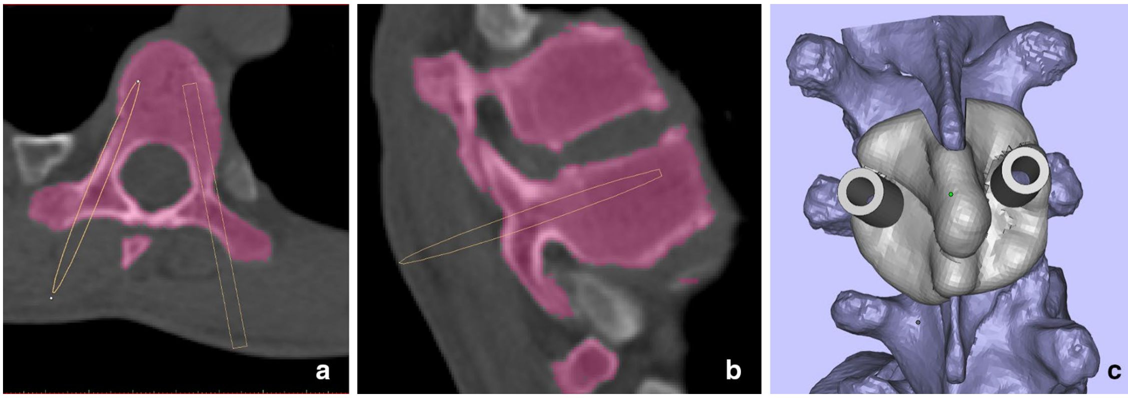

Fig. 1 Screw orientation designed by Autodesk Max 2010 software: **a** axial view of the pedicle screws trajectory; **b** lateral view of the pedicle screws trajectory; **c** the drill guide template

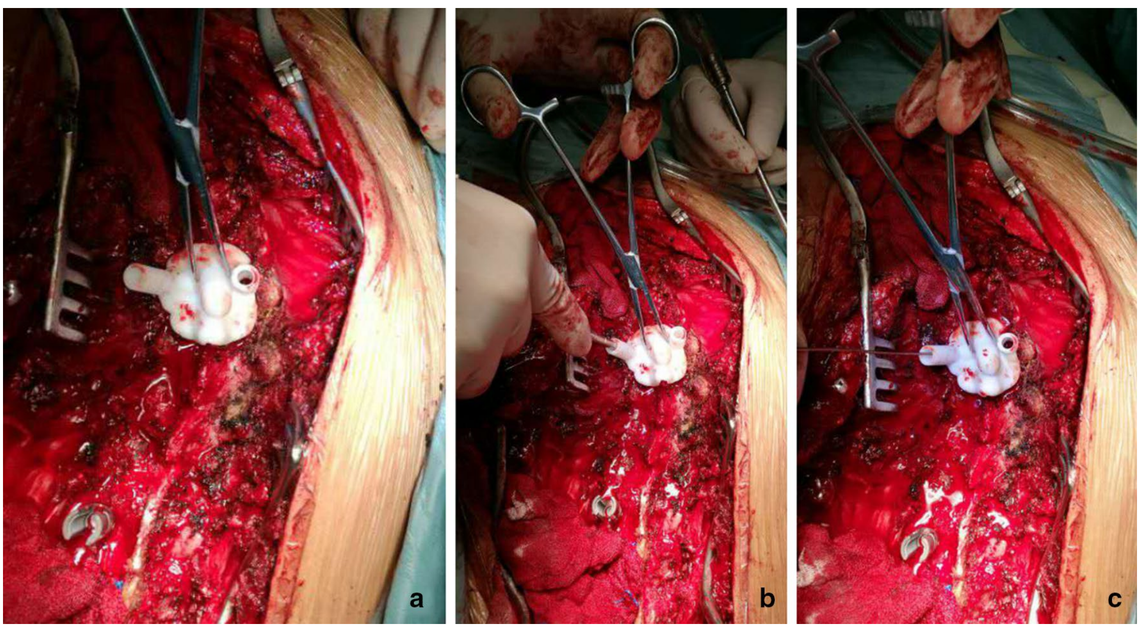

Fig. 2 Using the drill guide template for pedicle screw placement: **a** the drill guide template and the corresponding spinous process were fitted and fixed by a clamp; **b** the trajectory of the pedicle screw was carefully drilled by a hand drill to a pre-determined depth; **c** a probe was used to detect the integrity of the pedicle

there was a breach, and it was recorded as Grade 2 misplacement. If an extrapedicular thoracic pedicle screw fixation technique was adopted, the screw was recorded as Grade 2 misplacement.

Free-hand technique

Pedicle screws were inserted according to Lenke's method [7, 22]. Following exposure of the posterior elements, soft tissue was cleaned from the facet joints. The entry point was identified and opened with an awl, the pedicle was drilled and the drill canal was probed to feel if the pedicle cortices were intact after tapping. A pedicle screw was not inserted if there was a breach, and it was recorded as Grade 2 misplacement. A screw of an appropriate length and diameter was inserted along the same trajectory without fluoroscopic control in the absence of a breach.

Analysis of pedicle screw insertion

Pedicle screw placement was analyzed on postoperative CT images (axial and sagittal) of the instrumented segments independently by a surgeon who was not involved in the operations, as well as a radiologist. The position of the screws was evaluated according to Gertzbein's classification [23]. In this classification, there are four categories for screw placement: Grade 0, screws are completely within the pedicle; Grade 1, perforation < 2 mm; Grade 2, perforation between 2 and 4 mm; Grade 3, perforation > 4 mm (Fig. 3). In the current study, Grade 0 and Grade 1 were considered satisfactory, while Grade 2 and Grade 3 were regarded as perforated.

Statistical analysis

SPSS (version 17.0.1; Chicago, IL, USA) was used for statistical analysis. Data are presented as mean ± standard deviation (SD). Between-group differences in baseline characteristics, accuracy rate, and misplaced screws on the concavity and convexity of the curve were evaluated with Chi-squared, Fisher exact test, as well as the rank sum test. A p value < 0.05 was statistically significant.

Results

A total of 708 screws were implanted in 37 patients (17 males, 20 females; mean age, 16.4 ± 1.3 years; age range, 10–18 years). In group I, 396 pedicle screws were implanted in 20 patients (7 males, 13 females; mean age, 16.3 ± 1.8 years; mean Cobb angle, 96.0° ± 4.4°) using a rapid prototype drill guide template. In group II, 312 pedicle screws were implanted in 17 patients (6 males, 11 females; mean age, 16.5 ± 1.4 years; mean Cobb angle, 94.2° ± 5.0°) using the free-hand technique. Patient's baseline demographic and radiographic data are shown in Table 1.

Operative time in group I was 283 ± 22.7 min compared to 285 ± 25.8 min in group II; there were no significant differences between groups ($p = 0.89$). In groups I and II, the major curve was corrected from 96.0° ± 4.4° to 43.1° ± 3.8° and 94.2° ± 5.0° to 44.4° ± 4.4°, respectively. In groups I and II, the scoliosis correction rate was 55.0 and 52.9%, respectively; there were no significant differences between groups ($p = 0.33$).

Based on axial and sagittal reconstruction images, the accuracy rate of pedicle screw placement (Grade 0 and 1) in group I was 96.7% compared to 86.9% in group II (Table 2). Analyzing axial reconstruction images alone, the overall perforation rate was 10.6% in group I compared to 23.4% in group II. The minor perforation rate (Grade 1, < 2 mm) was 7.3% (29/396) in group I compared to 11.9% (37/312) in group II. The moderate perforation rate (Grade 2, 2-4 mm) was 3.3% (13/396) in group I compared to 11.5% (36/312) in group II. The severe perforation rate (Grade 3, > 4 mm) was 1.6% (5/312) in group II; however, misplaced screws were not associated with neurological deficits (Table 2).

In group I, 23/396 (5.8%) screws were misplaced on the concavity of the curve, and 19/396 (4.8%) screws were misplaced on the convexity of the curve. In group II, 40/312 (12.8%) screws were misplaced on the concavity of the curve, and 38/312 (12.2%) screws were misplaced on the convexity of the curve. In group I, the incidence of lateral and medial penetration was 22/396 (5.6%) and 20/936 (5.1%), respectively. In group II, the incidence of lateral and

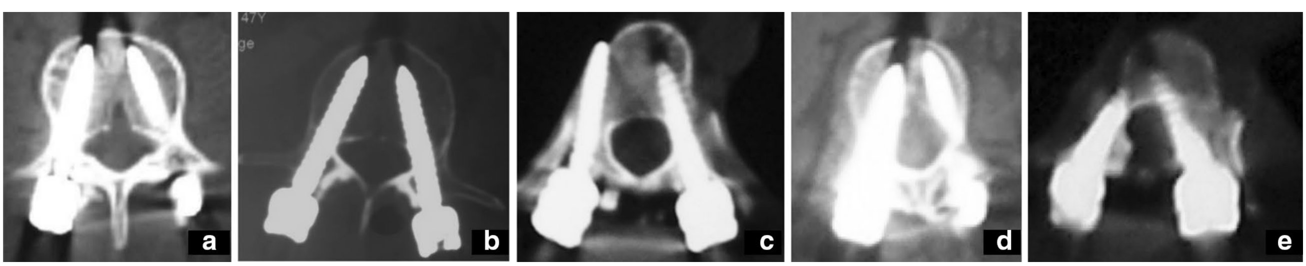

Fig. 3 Gertzbein's classification of screw misplacement in axial CT images: **a** Grade 0, screws are completely within the pedicle; **b** Grade 1, perforation < 2 mm (lateral); **c** Grade 1, perforation < 2 mm (medial); **d** Grade 2, perforation between 2 and 4 mm; **e** Grade 3, perforation > 4 mm

Table 1 Demographic and radiographic data of the patients in two groups

	Group I	Group II	p value*
Number of patients	20	17	
Sex	7 male/13 female	6 male/11 female	0.071
Age at admission (years)	16.4 ± 1.4	16.3 ± 1.1	$p = 0.182$
Cobb angle of thoracic curve (°)	96.0 ± 4.4	94.2 ± 5.0	0.250
Cobb angle of thoracic kyphosis (°)	60.9 ± 8.1	57.0 ± 9.3	0.181

*Compared between Group I and Group II

Table 2 Analysis of pedicle screw misplacement

Misplacement (according to Gertzbein's classification)	Group I ($n = 396$ screws)	Group II ($n = 312$ screws)
Grade 0 (screws are completely within the pedicle)	354	234
Grade 1 (screw perforation < 2 mm)	29	37
Grade 2 (screw perforation between 2 and 4 mm)	13	36
Grade 3 (screw perforation > 4 mm)	0	5
Accuracy	96.7%	86.9%

Accuracy = (Grade 0 + Grade 1)/n × 100%

The difference in overall accuracy rates between the two groups was significant ($p = 0.000$)

medial penetration was 37/312 (11.9%) and 41/312 (13.1%), respectively (Table 3).

Discussion

The insertion of pedicle screws is an important step in the treatment of severe spinal deformities. Screw-related complications are minimized by ensuring that the starting point and trajectory within the pedicle are accurate. Surgeons performing scoliosis correction must be skilled and experienced in the procedure [2, 7, 24]. Published evidence suggests that pedicle violation rates resulting from free-hand screw placement ranges from 3 to 54.7% [22, 25–27], and complications associated with screw misplacement, including nerve damage, occur in 0–7% of patients [22]. Screw misplacement may also damage adjacent blood vessels and surrounding organs, weaken reduction and fixation, and require revision surgery [22, 25]. Free-hand thoracic pedicle screw insertion results in a rate of 25–43% cortical perforation of the pedicles, even by experienced surgeons [28–30]. In our study, a pedicle screw was not inserted if there was a breach. It was recorded as Grade 2 misplacement as it is not possible to accurately measure the distance of perforation according to Gertzbein's classification. The authors of this study have extensive clinical experience with the free-hand technique, and the accuracy of screw placement in this study of severe adolescent scoliosis was 86.9%; these findings are in accordance with previous reports [29, 30]. Preoperative image-based or CT-based computer navigation systems have been introduced to guide the insertion of pedicle screws in spine surgery, but the accuracy of the systems is questionable and the failure rate remains high (8.5–11%) [31, 32]. These failures are largely attributed to anatomical variations in the thoracic spine, suggesting that screw insertion should be individualized. Recently developed intraoperative CT-based navigation is thought to improve the accuracy of screw placement in patients in the supine position. However, the rates of thoracolumbar and sacral pedicle perforation remain 3.2–4.8% [33, 34], and may result from changes in spinal alignment, such as torsion during drilling and screw placement.

The first clinical trial using individualized drill guide templates on the lumbar spine was performed in China in 2009 by Lu et al. [8], in which personalized templates were carefully designed to exactly match the posterior surface of patients' lumbar vertebrae. In another clinical study, Lu et al. [9] used the same template technique for placement of 168 screws in scoliosis patients. Of these, 11 screws were considered to have a 0–2 mm breach, but no pedicle screw breached > 2 mm, the accuracy rate of pedicle screw placement was 93.4%. Matjaz Merc et al. [21] assessed the accuracy of drill guide template pedicle screw placement versus the free-hand technique in the degenerative lumbar and sacral spine. In patients with degenerative lumbar disease, the accuracy rate of pedicle screw placement was 90% in the template group and 74% in the free-hand group. Putzier et al. [20] designed a navigational template for pedicle screw placement in four patients with severe scoliosis, and 76 pedicle screws implanted (56 thoracic, 20 lumbar) with only two screws (2.6%) were misplaced intraoperatively and repositioned. Eighty-four percent of the pedicle screws were completely intrapedicular, 96.1% within less than 2 mm cortical breach. Lamartina et al. [17] used a patient-matched

Table 3 Screw misplacement on concave side and convex side in two groups

	Group I			Group II		
	Concave side	Convex side	Total	Concave side	Convex side	Total
Lateral	8	12	20	16	21	37
Medial	15	7	22	24	17	41
Total	23	19	42	40	38	78

pedicle targeting guide in three cadaveric spine specimens. Of the 46 inserted screws eligible for assessment, 91.3% were fully inside the pedicle. There were no cases of Grade B (2–4 mm) or C (> 4 mm) pedicle perforation. In the current study, the accuracy of pedicle screw placement was greater in patients treated with a drill guide template compared to patients treated with the free-hand technique. The misplacement rate with the drill guide template was 10.6%, which was higher than the 1.8% misplacement rate reported by Lu et al. [9]. The discrepancy may be explained by differences in the severity of scoliosis between studies, which may have affected the difficulty of screw placement. In our study, all pedicle screws using extrapedicular technique in group 1 were recorded as Grade 2 misplacement and may be attributed to the higher misplacement rate. However, drill guide templates were associated with a 96.7% overall accuracy rate of screw placement, which was significantly higher than the free-hand technique. Significant improvement was achieved in postoperative scoliosis correction in all patients. In addition, there was no significant difference in mean operative time between the two groups; use of the drill guide template did not take a significantly longer time than the free-hand technique. Farshad et al. [18] randomly compared the accuracy of patient-specific targeting guides and free-hand technique for pedicle screw placement from Th2–L5 in three cadaveric specimens by three surgeons with different experience levels. The author concluded that template-guided pedicle screw placement is faster considering intraoperative instrumentation time, has a higher accuracy (97.9%) particularly in the thoracic spine and creates less intraoperative radiation exposure compared to the free-hand technique.

Insertion of pedicle screws in severe scoliosis is associated with risk of neurological injury. The drill guide template enables the entry point to deformed pedicles, which may be abnormal in shape and size due to rotation and wedging, to be individualized to the patient. This facilitates accurate screw placement and minimizes neurological complications [35]. Drill guide templates originate from a preoperative supine CT scan; however, these three-dimensional templates are applied to patients in the prone position on the operating table. As multi-level drill guide templates can be affected by changes in spinal alignment, especially in flexible scoliosis with smaller Cobb angle, but may not be affected in rigid and severe scoliosis. However, we designed a single segment template to minimize potential errors. Resistance to deformation may be decreased in some templates due to the thickness and hardness of the material that are used for manufacture, which can lead to changes in the guide-hole angle during drilling. In the current study, the thickness of the template was 15 mm and we used a novel triangle design to reinforce stability, avoiding torque-related deformation during drilling and screw placement. This method is especially useful for patients with small pedicles or severe spinal misalignment. Azimifar et al. [21] used the inferior articular process and superior articular process as fitting areas of the template, for it is easy to be presented and it is not necessary to remove extra soft tissue. However, the articular process of superior is too close to the entry point for thoracic pedicle screw insertion. Risk of template migration still exists. In our study, the design of lock-and-key type of the template makes it easy and stable to fix on the spinous process without movement in all directions, which facilitates the drilling procedure.

For severe scoliosis, pedicle dysplasia has a significant impact on screw misplacement, especially in highly rotated vertebrae with pedicles < 2–3 mm in diameter. Dvorak et al. [36] developed an extrapedicular thoracic pedicle screw fixation technique to overcome complications associated with screw misplacement in patients with pedicle dysplasia [37–39]. However, the technique is technically demanding and is associated with the risk of vascular or visceral injury in surgeons with little experience. In our study, a drill guide template with extrapedicular fixation was used in 34 dysplastic pedicles. All of them were recorded as Grade 2 misplacement because it is not possible to assess the distance of perforation after the surgery. Nevertheless, the final result demonstrated it a safe and simple method.

However, the drill guide template has several limitations. First, the template is manufactured using a three-dimensional printer, which has limited precision; therefore, there is a potential error. Second, the slice thickness in CT may be insufficient, which may significantly affect the accuracy of the drill guide template. Third, drill guide templates originate from a preoperative CT scan with patients in the supine position; however, the templates are applied to patients in the prone position. This may affect the veracity of the drill guide template, and may, therefore, fail to correspond with the spinous process. This is especially pertinent in young patients who have a higher degree of spinal flexibility. Fourth, drill guide template designs are based on a CT scan, and the scan surface is parallel to the horizon, which may affect the accuracy of pedicle screw placement. Our template design was based on a CT scan that selected an image plane parallel to the pedicle, so the accuracy of the screw trajectory was higher. Fifth, high temperature sterilization process is applied to the template, which may change the geometric shape of the template and influence accuracy. Notably, accurate screw placement is not dependent on geometric accuracy alone. A template should as act as a drill guide, but movement between the spine and the template will affect accuracy in the clinical setting. Putzier et al. [12] showed that a 4-cm skin incision provided a stable docking positioning for a template at the most superior spinal segment. Use of such a template requires careful preparation of soft tissues close to the facets and as well as an exact fit and fixing of the template. To avoid inaccurate placement, the trajectory of each pedicle screw should be drilled with a high-speed burr used along the navigational channel. Finally, the investment of the three-dimensional printing machines (usually exceeds 250,000 US dollars), the expenses of the printing material, and the extra investment on human resources, manufacture and disinfection time of the template and model (usually takes 3 days)should be taken into consideration.

Conclusions

In our study, we compared the accuracy of pedicle screw placement using a drill guide template with the free-hand technique in severe scoliosis. However, unavoidable limitations are the retrospective study design and the small sample size in a single center with single surgeon. A prospective study including a larger patient population is required to further explore the superiority of the drill guide template. Nevertheless, the current study demonstrates that the drill guide template has a potential to offer more accurate and thus safer, pedicle screw placement than the free-hand technique in the treatment of severe scoliosis in adolescents without extra time consumption.

Compliance with ethical standards

Conflict of interest Nothing to disclose.

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