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A multi-level drill guide template improves the accuracy of pedicle screw placement in lumbar spine

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Abstract. – OBJECTIVE: Free-hand technique is widely used in pedicle screw placement for lumbar spine and generally safe; however, screw malposition still occurs. To develop a novel multi-level drill guide template for pedicle screw placement in lumbar spine and evaluate its accuracy.

MATERIALS AND METHODS: Twelve lumbar cadaveric specimens were randomly allocated into guide template group (n=6) and free-hand group (n=6). Computed tomography (CT) scans were obtained for reconstruction of three-dimensional (3D) model of each lumbar vertebra, and further an individual guide template was designed. Then the templates and their corresponding vertebra were developed by rapid prototyping (RP) technology. With the guide of the templates, screws were inserted via mini-open Wiltse approach. The positions of the screws were assessed based on postoperative CT images.

RESULTS: In total, 120 pedicle screws inserted (guide template group: n=60 vs. free-hand group: n=60). For all 30 vertebras in the guide template group, all pre-designed personalized drill guide templates can be fitted into the facet joints of each vertebra well. Furthermore, our results revealed a significant improvement for the guide template group in the accuracy rate (*p*=0.026).

CONCLUSIONS: Armed with advantages of minimal invasion, enhanced accuracy and safety, the novel technique of multi-level drill guide template can be properly applied in pedicle screw placement for lumbar spine and promises to be a potential option in clinical application.

Key Words:
Pedicle screw, Three-dimensional, Guide device, Lumbar spine, Rapid prototyping.

Introduction

Pedicle screw fixation systems, as the "gold standard" technique of instrumentation, are widely used in the treatment of many spinal disorders such as degenerative spine diseases, fractures, tumors, and deformities[1-3]. In pedicle screw fixation, accurate insertion is important for ensuring good anchoring and avoiding neurological injury and weak stability[4].

At present, several techniques have been applied to improve the accuracy of screw placement, including: (1) Free-hand technique based on anatomical landmarks and averaged angular parameters; (2) Image guidance (navigation) technique based on computed tomography (CT) and fluoroscopy; (3) drill template techniques.

However, there are various caveats that should be considered: (1) Free-hand placement has the 1%-10% malposition rate, which may lead to screws loosening or nerve injury[5-7]. (2) Image navigation technique based on CT and fluoroscopy leads to longer operating time, more radiation exposure and greater infection risk[8]. (3) Different drill guide template techniques have been applied in the process of pedicle screw placement with different outcomes[9-12]. To our knowledge, limited researches[10] reported different levels using guide templates to guarantee the accuracy of pedicle screw placement.

The primary purpose of this work was to design a novel multi-level drill guide template for screw placement and to evaluate its accuracy in the cadaveric lumbar spine.

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Materials and Methods

Design of Drill Guide Templates

Three-dimensional (3D) models of the lumbar spine were reconstructed by CT scans (Light-Speed VCT, GE Healthcare, Milwaukee, IL, USA). CT images were stored in DICOM format and transferred to a workstation running MIMICS 16.0 (ImageWorks, Materialise, Belgium) software. First, based on the cross-sectional CT images, optimal trajectories for pedicle screws were pre-designed (Figure 1a). Next, 3D model was reconstructed and surface around the pedicle screw entry point was marked. Then, the bottom part of the guide template with a thickness of 1 mm was generated to be inverse the marked surface (Figure 1b), which fitted the area of the entry point well. The following step was to create hollow channels based on the pre-designed trajectories for pedicle screws (Figure 1c). At last, vertical and horizontal rods were designed to connect the bottom part with the channels together (Figure 1d-f).

Manufacture of Drill Guide Templates

The 3D spine model and the drill navigational template were exported in stereolithography (STL) format and produced by rapid prototyping (RP) technology according to a layered principle (Figure 2). Depending on this technology, we manufactured the templates from polyamide powder.

Cadaveric Specimens

Twelve lumbar cadaveric specimens were randomly categorized into guide template group (n=6) and free-hand group (n=6). Preoperative conventional radiographs of the lumbar spine (L1-L5) for all specimens were obtained to exclude metastatic disease, metabolic bone disease, or fracture. For guide template group, preoperative CT scans were acquired to design and manufacture the individual navigational templates. This study was approved by the Ethics Committee of Nanjing Medical University.

Surgical Procedure

In guide template group, small incisions were made and bone surface around the entry point was exposed *via* Wiltse approach (Figure 3a). After sufficient exposure, the template was fixed on the lumbar vertebra via the incisions and Kirschner wires were inserted into the pedicles through guide channels (Figure 3b). Then, the C-arm was applied to evaluate the positions of the K-wires. On the premise of ensuring safety and accuracy, screws were then inserted (Figure 3c).

In free-hand group, the entry point and averaged angular parameters were chosen according to anatomical landmarks following a previous described protocol[13]. Detailed process was consistent with our previous report[14].

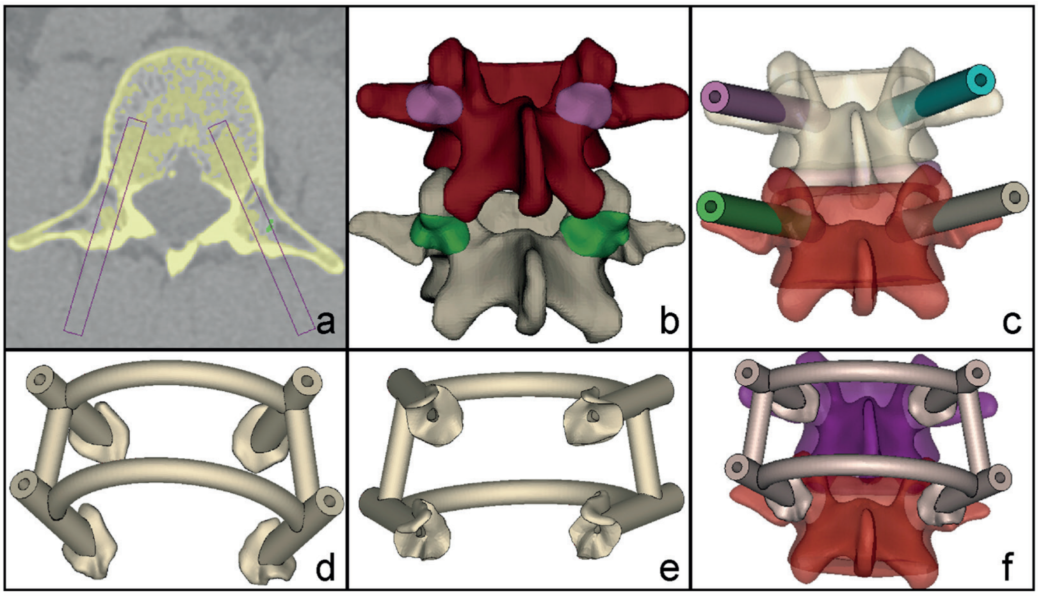

Figure 1. Design process of a multi-level drill guide template. ***(a)*** Design of precise trajectory for pedicle screws based on CT image; ***(b)*** Design of the bottom of the guide template based on "Key-Lock technique"; ***(c)*** Channels for pedicle screws insertion; ***(d)*** Guide template (top view); ***(e)*** Guide template (bottom view); ***(f)*** Guide template placed virtually on the lumbar spine.

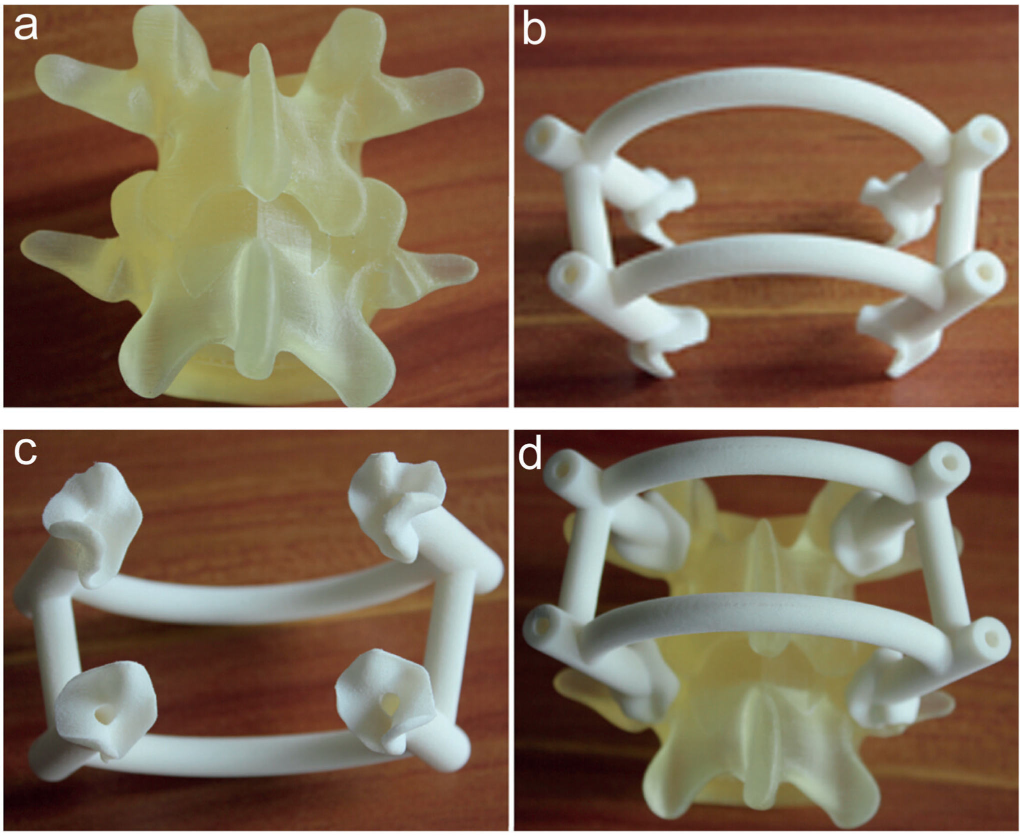

Figure 2. Rapid prototyping (RP) model of lumbar vertebrae and guide template. ***(a)*** RP model of lumbar vertebrae; ***(b)*** RP model of guide template (top view); ***(c)*** RP model of guide template (bottom view); ***(d)*** Guide template fits RP model of vertebrae perfectly.

Operations of pedicle screw placement for both groups were completed by the same surgeon. Postoperative radiographs and CT scans for both groups were needed for evaluation of the accuracy of each pedicle screw (Figure 3d).

Evaluation of Screw Position

After operation, the positions of the screws were assessed based on CT images. We graded the position of each screw according to the classification by Louis Philippe Amiot[2]. All screws were independently evaluated by two investigators.

Statistical Analysis

SPSS 19.0 software (IBM, Armonk, NY, USA) was used for statistical analysis. The significance of differences in the accuracy rates of pedicle screws was analyzed using the χ^2-test. Differences were considered statistically significant at $p < 0.05$.

Results

Data of 12 lumbar cadaver specimens were collected for analysis. A total of 120 pedicle screws were placed (navigational template group: n=60 *vs.* free-hand group: n=60). For all 30 vertebras in the guide group, all pre-designed personalized drill guide templates can be fitted into the facet joints of each vertebrae well.

According to the classification by Louis Philippe Amiot, only screws in Grade 1 were considered as completely accurate insertion.

With the help of the novel guide technique, 60 pedicle screws were inserted in guide template group. Among these 60 screws, 55 were classified in Grade 1, 5 in Grade 2, none in Grade 3 or Grade 4 or Grade 5. The percentage of Grade 1 was calculated to be 91.7%, representing the completely accuracy rate.

Meanwhile, a total of 60 pedicle screws were placed by the same surgeon using free-hand tech-

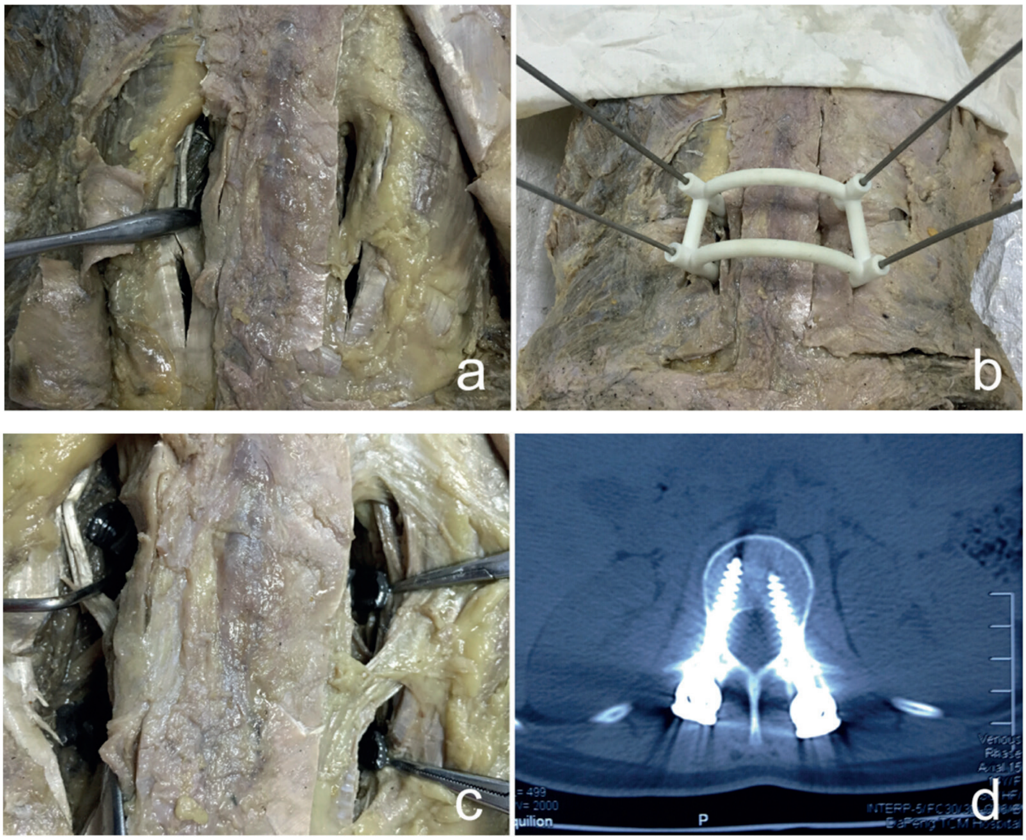

Figure 3. Pedicle screw insertion using the guide template. ***(a)*** Four mini-incisions were made; ***(b)*** The template was placed on the spine via the incisions and K-wires were inserted through navigational channels into the pedicles; ***(c)*** Four pedicle screws were successfully inserted into the pedicles; ***(d)*** Postoperative CT scans were taken to evaluate the accuracy.

nique. After CT scan evaluation, 47 were classified in Grade 1, 12 in Grade 2, 1 in Grade 3, none in Grade 4 or Grade 5. Accuracy rate of this group was calculated to be 75%.

The results revealed a significant improvement for the navigational template group in the accuracy rate (χ^2=6.000, p=0.026) (Table I).

Discussion

Many methods have been investigated for pedicle screw placement in lumbar spine. Among them, free-hand technique is still the main method in lumbar surgery. However, it was associated with a high rate of unplanned pedicle malposition (14%)[2], which may cause screws loosening, radicular pain or neurological deficits.

To overcome these shortcomings of free-hand techniques, image-guided techniques of computer-assisted placement were introduced. With the help of navigation systems, the incidence of incorrectly positioned pedicle screws decreased remarkably and satisfactory clinical outcomes were achieved[15,16]. However, there are still some disadvantages associated with navigation systems which should be considered, including high-cost, longer surgical time, significant learning curve and more radiation exposure, etc.

To date, some individualized navigational templates have been designed to solve these problems with the purpose of low cost, simple operation, safety, and accuracy. Radermacher et al[9,17] firstly explored an individualized drill navigational template builted from polycarbonate by a milling machine for pedicle screws placement in lumbar spine and confirmed its satisfactory effect on orthopedic surgery. Berry et al[10] upgraded the template for personalized vertebrae, manufactured by the selective laser sintering, and achieved 100 percent success rate.

For greater contact with the surface of the vertebra, guide channels of templates could provide more stability[11]. Lu et al[12,18-20] applied stereoli-

Table I. Grading of adopted lumbar screw placement.

Classification (Louis Philippe Amiot)	Navigational template group: Number of screws (N=60)	Navigational template group: Accuracy rate (%)	Free-hand group: Number of screws (N=60)	Free-hand group: Accuracy rate (%)
Grade 1 (%)	55	91.7	47	78.3
Grade 2 (%)	5	8.3	12	20
Grade 3 (%)	0	0	1	1.7
Grade 4 (%)	0	0	0	0
Grade 5 (%)	0	0	0	0

Screws in Grade 1 were fully contained in the pedicle without misplacement. In order, cortical breach of screws in Grade 2-5 was within 2 mm, 2-4 mm, 4-6 mm, and over 6 mm.

thography technique to design a series of templates to match the posterior vertebral surface precisely and improved the accuracy of pedicle screws placement. Merc et al[21] used the rapid prototyping technology to create a multi-level drill guide template for pedicle screw placement in lumbar and the first sacral spine and its lower incidence of cortex perforation was validated in the clinical study.

In the present study, we applied a "lock-and-key" mechanism to design a novel drill guide template that fits into posterior area of the facet joint. A "bridge" crossing the spinous processes was designed to connect the both sides of guide channels. To fix more stably and simply, the parts of guide channel were linked to each other in both transversal and sagittal plane, which resulted in a multi-level template. The template was designed to allow four or more screws placement at once. Our findings confirm that the novel navigational template improves the accuracy rate of pedicle screw placement significantly compared to the conventional free-hand technique.

As a new alternative for pedicle screws placement in lumbar spine, our guide template system does not have long learning curves, which is fit for beginners well. Furthermore, due to the mini-open Wiltse incision and the connected structure, the navigational template does not require paraspinal muscle stripping and interspinous ligament removing, thus resulting in less damage and blood loss, lower prevalence of postoperative back pain and shorter hospitalization time[22,23].

It must be mentioned, however, that several limitations of the study warrant discussion. First, more stripping of the bone surface around entry points was required. Any inappropriate preparation could result in inaccuracy and pedicle violation. Second, narrow exposure is another limitation of the surgery with mini-open Wiltse incision. Fortunately, with mini-retractors designed by ourselves, the surgery field can be clearly exposed[14]. Third, the technique also has some potential of errors, which may influence the accuracy of screw placement, including parameter errors of CT scan during virtual construction and RP technology and RP materials when producing the physical template.

Conclusions

We designed a novel multi-level drill guide template for pedicle screws placement in lumbar spine. Our study confirmed that use of the guide device can significantly enhance the accuracy rate of pedicle screw placement. Armed with advantages of short learning curves, minimal invasion, enhanced accuracy and safety, our novel technique promises to be a potential option in lumbar pedicle screw placement.

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Conflict of Interest

The Authors declare that they have no conflict of interest.

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