Rapid prototyping drill guide template for lumbar pedicle screw placement

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Objective: To develop a novel method of spinal pedical stereotaxy by reverse engineering and rapid prototyping techniques, and to validate its accuracy by experimental and clinical studies.

Methods: A 3D reconstruction model for the desired lumbar vertebra was generated by using the Mimics 10.11 software, and the optimal screw size and orientation were determined using the reverse engineering software. Afterwards, a drill template was created by reverse engineering principle, whose surface was the antitemplate of the vertebral surface. The drill template and its corresponding vertebra were manufactured using the rapid prototyping technique.

Results: The accuracy of the drill template was confirmed by drilling screw trajectory into the vertebral biomodel preoperatively. This method also showed its ability to customize the placement and size of each screw based on the unique morphology of the lumbar vertebra. The drill template fits the postural surface of the vertebra very well in the cadaver experiment. Postoperative CT scans for controlling the pedicle bore showed that the personalized template had a high precision in cadaver experiment and clinical application. No misplacement occurred by using the personalized template. During surgery, no additional computer assistance was needed.

Conclusions: The authors have developed a novel drill template for lumbar pedicle screw placement with good applicability and high accuracy. The potential use of drill templates to place lumbar pedicle screws is promising. Our methodology appears to provide an accurate technique and trajectory for pedicle screw placement in the lumbar spine.

Key words: Neuronavigation; Template; Lumbar vertebrae; Bone screws

The major complications of pedicle screw placement include a high risk of bone instability or lesions of the spinal cord, nerve roots or blood vessels.1,2 The modern concept of computer-assisted orthopedic surgery may cause intraoperative problems and need additional technical facilities for intraoperative registration of bone structures and spatial arrangement of displays, sensors, and robot systems.3,4 Only a few hospitals can bear the costs of the sensor or robot-based systems. The current study was conducted to assess the feasibility and accuracy of a new method.5

METHODS

Design of computer assistant navigational template

A spiral three-dimensional CT scan (GE Company, LightSpeed 64 Row VCT, USA) was performed on lumbar spine with 0.625-mm slice thickness and 0.35-mm in-plane resolution. The images were stored in DICOM format, and transferred to a workstation running MIMICS 10.11 software (Materialise Company, Belgium) to generate a 3D reconstruction model for the targeted lumbar vertebra.

The 3D vertebral model was exported in STL format, and then opened in a workstation running UG imageware12.0 (EDS Company, US) for the optimal
screw size and orientation. The optimal screw size was also determined according to the size of pedicle shaft. Then, a 3D vertebral model was reconstructed with a virtual screw placed on both sides. Afterwards, a drill template was constructed by reverse engineering principle. The template surface was used as the antitemplate of the vertebral surface, and thus potentially produced matching relation in a lock-and-key fashion similar to a physical casting of the vertebral surface, and specifically avoided overlap onto adjacent segments (Fig. 1).

The computer model was then exported in a STL format, and the vertebra biomodel and the drill template were both produced with acrylate resin (Stereocol by Avecia, Manchester, UK) using the stereolithography rapid prototyping technique.

Specimen experiment

Three randomly chosen human cadavers were obtained. Their lumbar spines (L₁-L₃) were examined with conventional radiographs in two planes (AP and lateral) to exclude anomalies, tumors or severe multisegmental changes other than osteoporosis and moderate spondylosis. Preoperative CT scans (L₁-L₃) were acquired using a standard algorithm with a slice thickness of 0.625 mm. The computer assistant navigational template was made according to the personalized lumbar vertebrae.

Clinical application

From September 2007 to September 2008, 6 patients (5 male, 1 female, aged 28-68 years) with lumbar spinal pathology requiring internal fixation underwent posterior fixation of the lumbar spine. The template was sterilized and used intraoperatively to navigate and confirm anatomic relationships. Intraoperative radiograph was used only once after the pedicle screw had been inserted. Postoperative radiograph and CT scanning was used to validate an accurate screw placement.

RESULTS

Choosing an optimal entry point for the bore and thus determining the optimal entry point and the direction for the pedicle screw (Figs. 3, 4), we created the drill template to fit the postural surface of the vertebra very well in the cadaver experiment (Fig.2).

Six patients were treated using this drill guide system. The concept of a template fitting to the combined posterior lumbar worked very well. No misplacement occurred by using the personalized template. During surgery, no additional computer assistance was needed. After placing the autoclaved personalized template in its predefined position, the optimal position could be found easily and bare handedly because no evident motion of the template occurred when it was pressed slightly against the bone (Fig.3).

Postoperative CT scans showed that the personalized template had a high precision. Exact preparation of the bone surface, thorough removal of the attached muscle and fat tissue without damaging the bony surface structure are important.

DISCUSSION

Various methods have been explored for pedicle screw placement in the lumbar vertebra. Traditional methods of intraoperative spinal localization still have an important role to play in the field of spine surgery; however, it is clear that shortcomings of these method exist, which lead to the use of image-guided placement. Image-guided technique provides detailed views of hidden spinal anatomy that can be used for surgical planning and navigation.

Computer-assisted orthopedic surgery may cause intraoperative problems and needs additional technical facilities for intraoperative registration of bone structures and spatial arrangement of displays, sensors, and robot systems. There are several weak points that should be considered: (1) The learning curves for these techniques are obvious. (2) Errors may occur when adjacent segments of the spine shift intraoperatively or if the registration frame and optical array shift. (3) The tracking of optical array devices can be obscured by the surgeons or tools. (4) The technology is expensive. (5) The techniques can prolong the time of surgical procedures.

Personalized templates eliminate the need for complex equipment and time-consuming procedures in the operating room. A preoperative CT scan is mandatory to generate the personalized templates and for a precise spatial correspondence between the personalized bony structure in situ and the intended position of the
The goal of this study is to evaluate practicability and accuracy of the image-based personalized templates. These templates are a simple and low-cost solution that provides an exact, safe, and fast implementation of elective surgery on bone structures.

Fig. 1. Analysis of pedicle screw channel and the 3-D model of drill template. A: Pedicle and its positive projection. B: Pedicle screw channel of pedicle projection. C: Confirmation of pedicle screw channel. D: The 3-D model of drill template and vertebrae.

Fig. 2. Experimental study of the navigational template. A: Construction of lumbar vertebrae. B, C: Placement of pedicle screw. D: An accurate pedicle screw placement confirmed by CT scan.

Fig. 3. Design and manufacture of navigational template. A: The 3-D model of navigational template. B: The solid model of navigational template and vertebra. C and D: Navigational template used during operation. E, F, and G: CT scan showing the accurate trajectory of pedicle screw after operation.
The technique may also have potential errors. Since 3D model of the vertebra is constructed manually or automatically, there is potential error on the procedure. Furthermore, the RP model may deviate from the computer 3D model because the present RP technology allows 0.1 mm error. Finally, geometric accuracy alone does not ensure an accurate screw placement. In the real clinical setting, a template should be used as drill guide, and any movement between the bones will affect the accuracy. Berry et al. designed a three V-shaped drill template. An advantage of using this design is devoid of excessive soft-tissue dissection from the vertebra. However, with the four trajectories tested in the cervical spine, the surgeons are not always confident of the screw positioning. Goffin et al. designed a template featured in a number of clamps to contact the posterior part of the cervical vertebra. More recently, Owen et al. constructed a drill template to match the posterior surface of the cervical vertebra. With a greater contact area to the vertebra, this template is supposed to provide greater stability.

Our template design is unique in that it is based on reverse engineering principle, and therefore can match the postural surface of the vertebra perfectly. In the clinical situation, however, soft tissues around the spine make the surface vary. Fortunately, after thorough removal of the attached muscle and fat tissues without damaging the bony surface structure, all our templates can be easily and securely held in place.

The personalized-manufactured template can be produced at a reasonable price compared with the intraoperative navigation systems. If a service provider produces the template on the basis of the measuring data via operation, no further technical instruments are necessary during operation.

Our study shows that using a template with drill guide can simplify surgical procedures and enhance the accuracy of pedicle screw positioning. The planning of the screw trajectory is completely finished before operation. Intraoperative planning, based on the preoperative stored data, as is done in actual stereotactic guidance systems, can be avoided. This shortens operation time and obviates possible intraoperative positioning. The screw size is selected according to the size of pedicel shaft.

In summary, the personalized template is easy to use and has a high accuracy. By using it in a cadaveric study and clinical application, we have verified its accuracy and efficiency. A further study will certificate the accuracy of template on the thoracic and cervical pedicle.

REFERENCES


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