Development of a Dual-trajectory Guide Plate Using Additive Manufacturing for Patients with Osteoporosis

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(Received 2 May 2018; Accepted 25 June 2018; Published on line 1 December 2018)

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DOI: [10.5875/ausmt.v8i4.1830](https://doi.org/10.5875/ausmt.v8i4.1830)

Abstract: Pedicle screw fixation is a surgical procedure performed by clinically experienced physicians, and requires the precise placement of the screws in specific locations. The use of additive manufacturing in surgical procedures has gradually increased in recent years. Advantages of this technique include reduced difficulty of surgery and burden on physicians. The spinal dual-trajectory technique (DT) is a newly developed screw placement technology that is mainly used in patients with osteoporosis, and provides stable and strong spinal fixation to increase screw bonding strength. However, DT requires the placement of two screws oriented in different directions at the narrow pedicle, making the surgery more difficult and riskier than traditional pedicle fixation. This study integrates computer-aided design and additive manufacturing techniques to propose a complete design method for the DT guide plate. The developed guide plate was then installed in a three-dimensional vertebral model and the screw fixation process was implemented to verify the feasibility of the proposed method. The results show that the guide plate was able to implant screws in predefined directions without penetrating the structure of the vertebral body.

Keywords: Spine dual-trajectory technique; Surgical guide plate; Additive manufacturing; Spine surgery; Osteoporosis

Introduction

Global population aging is being accompanied by gradual calcium loss, thus increasing the risk of various osteoporosis-related spinal conditions. Patients with osteoporosis have reduced bone mass and density, resulting in increased bone porosity and decreased bone strength. This leads to an increased risk of fractures, progressive spinal deformities, and nerve damage [1].

Pedicle screw fixation [2] is one of the most widely used spinal correction surgeries. Different screw fixation techniques have been developed according to variations in the orientation and angle of the screw chosen for implantation in the pedicle. Traditional trajectory (TT) drives the screw towards the chain line of the spinous process along the pedicle from the lower end of the vertebrae. The aim is to relieve nerve compression and pain and to maintain the stability of the vertebral

structure.

Previous studies have reported a strong correlation between bone density and screw fixation strength in the pedicle [3, 4]. In patients with osteoporosis, reduced trabecular bone density provides less bone to affix to the screws using TT. Hence, there is an increased risk of screw loosening that can lead to difficulties in healing for the affected part of the spine [5].

Cortical bone trajectory (CBT) is an effective alternative to TT for screw implantation into the spines of patients with osteoporosis [6]. In CBT, bone screws are implanted from the lower end to the upper end of the vertebrae, in a medial-to-lateral direction. In comparison to TT, CBT can maximize the contact surface area between screws and cortical bone to enhance tensile loading and bending resistance of the implant. However, when the intervertebral disc is intact or a transforaminal lumbar interbody fusion implant is used, TT can improve the rigidity and other mechanical

properties of the screws [7, 8].

In the last decade, the use of the dual-trajectory technique (DT) has gradually increased among surgeons in treating patients with osteoporosis [9-11]. This novel spinal fixation involves the implantation of two screws in a single pedicle. The screws lock in two different directions using TT and CBT fixed at the pedicle. The combined strength of these two screws is greater than their individual counterparts and can reduce the number of vertebral bodies implanted by the screws [11].

In traditional spinal surgery, surgeons often depend on their personal experience to determine the entry point and direction of the bone screw based on specific features of the patient's spine. With the advancement of medical imaging techniques, computer-aided systems have become widely used in various surgical procedures to assist physicians in patient diagnosis and treatment. Three-dimensional (3D) digital models of the affected area can be reconstructed using computer tomography (CT) scan images. Coupled with additive manufacturing (AM, commonly known as 3D printing) technology, physicians can use this technique to quickly produce 3D

physical models of the affected area to obtain more information about the fracture.

Previous reports confirm that AM can be used to produce guide plates, assisting surgeons in the positioning of the bone screws [12, 13]. The improvement in accuracy of screw implantation using the AM-produced guide plate complements the ease of operation for this technique [14]. However, most studies only focused on the TT method of screw implantation. DT implants two screws with different orientations within the same pedicle for spinal fixation, which is a more difficult implantation method than TT.

Utilizing AM to produce DT guide plates is a feasible approach to address this difficulty. The key point is to configure guide holes for the TT and CBT screws in the guide plate such that these four screws do not interfere with each other during the implantation process, while allowing the screws to be accurately fixed on the vertebrae. The following describes the methodology used to integrate computer-aided design (CAD) and AM technology to develop a design method for the DT guide plate.

Material and Methods

Computer-Aided Design for Dual-trajectory Guide Plate

The DT guide plate design flow can be divided into four steps (Fig. 1). First, the 3D mesh model of the patient's spine is reconstructed from CT scan images using the commercial software Amira 5.4.3 (Visage Imaging, USA). The entry point and orientation of the TT and CBT screws are then planned using the 3D mesh model in the commercial software Magics 13.0 (Materialise, Belgium). To align the screw guide holes with the correct positions on the target vertebra, six degrees of freedom of the guide plate are required to fix onto the target vertebra. This can be achieved by selecting a suitable mesh from the vertebral mesh model as the contact area between the guide plate and the vertebrae. The guide plate is based on this contact area (mesh surface only, not volume) and the 3D mesh model of the guide plate is constructed by growing a certain thickness laterally from the outer vertebrae.

Reconstruction of a 3D Mesh Model of the Spine

For more consistent results, an artificial lumbar vertebrae model (SKU #1352-44, Sawbones Inc., USA) was used as a source to reconstruct the 3D mesh model using image-processing software. The selected Sawbones model has radiopaque properties to enable CT imaging. During the process of reconstructing the 3D mesh model, it is necessary to adjust the threshold value to select the

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clearest bone-segmented image. However, there is no standard to adjust the threshold value and thus it will depend on the user's experience. In general, better input parameters can be found by means of error analysis between the image model and the 3D mesh model.

The 3D mesh model reconstructed from CT scan images will also consist of the neighboring vertebrae, producing excessive image information and requiring long processing times. Therefore, only the target vertebra and its adjacent parts are processed to minimize computing time.

Figure 1. Design flow chart of DT guide plate.

Screw Positioning

In this study, the criteria for positioning the TT and CBT screws were determined by the physician based on the 3D digital model of the patient's spine. The angle and depth of the implantation were then determined based on the entry point and position of the pedicle. Screw positioning was based on the following steps:

Step 1: CBT screw positioning

The appropriate screw size and length were chosen according to the size of the pedicle and the physician's choice of entry point. The entry point for CBT was located at the lateral aspect of the *pars interarticularis* projecting in the 5 o'clock direction (left pedicle) and the 7 o'clock direction (right pedicle). The CBT was directed 10° laterally in the axial plane and 25° cranially in the sagittal plane along the inferior border of the pedicle [15]. The CBT screw should not penetrate the vertebral endplate or vertebral structure, as shown in Fig. 2a.

Step 2: TT screw positioning

An appropriately sized TT screw was selected and

positioned following Weinstein's technique [16]. The entry point was selected to utilize the upper residual space in the pedicle along the superior border of the pedicle, as shown in Fig. 2b. The primary restrictions are that the screws should not interfere with each other bilaterally and should remain parallel to the vertebral endplate without penetrating it.

Figure 2. Screw positioning rules for (a) CBT and (b) TT screws.

Determination of Contact Region between Vertebral Bone and Guide Plate

After positioning the screws, a contact region between the vertebral body and the guide plate was selected based on the apparent features of the vertebra. Five features were chosen in this study: spinous process, pedicle of vertebral arch, accessory process, transverse process, and the screw entry point (see Fig. 3). The spinous and accessory processes allow the surgeon to easily determine whether the DT guide plate has been installed correctly on the spine during surgery. Meanwhile at the transverse process, the mesh was selected to form the hook structure (as shown in magnified view of Fig. 3). This hook structure provides a locking effect so that the guide plate was completely attached to the vertebra and unlikely to loosen.

Figure 3. Contact region (green) between the vertebral body and guide plate.

3D Mesh Model Generation of DT Guide Plates

Since the contact area of the guide plate chosen in the previous step was a surface mesh, it was volume-less. An AM machine cannot produce a volume-less object. Therefore, a mesh model of the guide plate was created that extruded 3 mm from the surface mesh. The screw entry direction was also defined by the generation of tubular guide holes in this step, which in turn were integrated into the mesh model of the guide plate.

Production of Dual-trajectory Guide Plate by Additive Manufacturing Technique

AM is a technique that creates products by accumulating materials layer by layer. There are different types of AM machines that can be classified easily by their accumulation methods, such as inkjet, extrusion, and photopolymerization. This study used a stereolithography (SLA) 3D printer (Form 2, formlabs, USA) to manufacture the DT guide plate. The SLA-type 3D printer uses a laser light source to cure photosensitive resins in specific areas by photo-polymerization. SLA products have higher surface quality and are more delicate than those produced using other AM techniques.

In this study, the DT guide plate was formed layer-by-layer with a thickness of 0.05 mm. DT guide plates must withstand brief periods of stress or strain; therefore, a tough resin was selected (Form 2, formlabs, USA). Upon completion of the model, a solution of

isopropanol was used to clean uncured resin from the model surface. To obtain maximum mechanical properties from the DT guide plate, the cleaned model was UV-cured then for 2 minutes (LQ-BOX, Rolence, Taiwan).

Simulation of Screw Implantation

To simulate screw implantation, an L1 vertebral model was designed using human bone data. Vertebral bone is primarily comprised of cortical and cancellous bone. Human cortical bone has an average thickness of 0.35 mm, with a thin, dense, and hard shell. The internal core is mainly cancellous bone, a loose structure with many pores. The average thickness of the vertebral endplate is 0.5 mm. Healthy human bone mineral density is about 100 mg/cm³, and a density of less than 80 mg/cm³ is characteristic of osteoporosis [17]. Similarly, the porosity of healthy cancellous bone ranges from 75–95%, with values below 68% typical of osteoporosis [18].

The L1 vertebral mesh model was thinned for this study (shell thickness 0.5 mm) to compare the cortical bone and vertebral endplate. The thinned vertebral model had a meshed inner structure, with a preconfigured porosity of 50% to simulate cancellous bone. This new model was named the L1 vertebral AM model and was made with the SLA 3D printer. To visualize postimplantation of the L1 model, a clear resin was chosen (Form 2, Formlabs, USA).

Figure 4. DT guide plates for L1-L5 designed by the proposed method. (a-e) Spatial relations between vertebral bones L1-L5 and DT guide plates for L1-L5. (f) DT guide plates of L1-L5 placed on artificial lumbar vertebrae model.

Table 1. Average processing time of the DT guide plate for L1 by the proposed method.

Stage	Step	Average processing time (min)	Percentage
Design	Reconstruction of 3D spine model	3	
	Screw positioning	10	8.5%
	3D model generation of DT guide plates	5	
Fabrication	DT guide plate fabrication by using 3D printer	180	91.5%
	Post-processing for SLA printed part	15	

Result and Discussion

According to the design method for DT guide plates proposed in this paper, the mesh models of DT guide plates for L1-L5 (Fig. 4a-e) were produced based on an artificial lumbar vertebral model. Despite slight differences in each lumbar vertebra, the proposed method produced the appropriate guide plates. Figure 4f shows five DT guide plates produced by the SLA 3D printer that mount onto each section of the artificial lumbar vertebral model.

From software simulations (Fig. 5), the two TT screws had a minimal external distance of 3.45 mm and 2.97 mm to the vertebral body and an internal minimum distance of 4.88 mm and 3.92 mm, respectively. Regarding the two CBT screws, the minimum external distance from the vertebral body was 7.15 mm and 5.72 mm, and the internal minimum distance was 2.69 mm and 4.94 mm, respectively. Neither of the two screw types interfered with each other, nor did they penetrate the vertebra itself.

Next, screw implantation was simulated. The L1 guide plate was installed on the L1 vertebral AM model. Then the preplanned locations of the screws were drilled. The L1 guide plate was stably attached to the L1 model, as shown in Figure 6a. A small probe was inserted into the guide hole to investigate the vertebra internally. Finally, a TT screw (diameter, 7.0 mm; length, 40 mm) and CBT screw (diameter, 5.5 mm; length, 40 mm) were selected for implantation. Figure 6b shows that the L1 model was not penetrated by the screws.

Figure 5. Gap between the pedicle and (a) TT and (b) CBT screws in the L1 model.

The average processing time to generate a physical L1 DT guide plate was 3.55 h, with 8.5% and 91.5% of the time respectively used in the design and fabrication stages, though design time will fall with technician experience. In addition, the manufacturing parameters and direction of the DT guide plate can be adjusted to improve 3D printing efficiency.

In this study, tough resin, a cheaper and non-biocompatible resin, was selected to print the DT guide plates. To improve the application of our proposed

method, Dental SG Resin, which is a more expensive Class 1 biocompatible resin provided by the vender, will be used in future work involving animal models.

Figure 6. Simulation of screw implantation. The L1 model with (a) the DT guide plate attached and (b) two TT screws and two CBT screws implanted.

Conclusion

DT is a novel spinal fixation method for patients with osteoporosis. This paper describes the development of a DT guide plate design method based on CAD and AM techniques. In addition, to simulate screw implantation, a 3D printed model of the L1 vertebra was fabricated with physiological properties from cortical and cancellous bone data of patients with osteoporosis. The initial software simulation and actual screw implantation tests prove that DT guide plates created by the proposed method can be implanted correctly in the vertebral body.

Acknowledgment

This research is supported by Ministry of Science and Technology, Taiwan under Grant no. NSC 106-2218-E-008-002.

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