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Original Article

Clinical application of 3D printing in pedicle screw fixation and fusion for the treatment of old type II odontoid fractures with posterior atlantoaxial dislocation

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Abstract: Objective: To evaluate the clinical value of 3D printing in old type II odontoid fracture with posterior pedicle screw fixation and fusion of posterior atlantoaxial dislocation. Methods: From September 2014 to February 2016, a total of 19 patients with old type II odontoid fracture and with atlantoaxial dislocation were enrolled in the department of Spine Surgery, Affiliated Chenggong Hospital of Xiamen University. The patients included 10 males and 9 females, with ages ranging from 27 to 68 years old and an average of 46.9 years old. The patients were divided into two groups (experimental group of 13 cases, the control group of 6 cases) according to whether they were given 3D printing assisted surgery. The posterior pedicle screw implantation with 3D printing navigation template was performed in the experiment group and traditional X-ray-assisted posterior atlantoaxial pedicle screw fixation was carried out in the control group. The cervical spine was scanned by computed tomography (CT) after operation to evaluate the accuracy of the surgery in the two groups. The bleeding volume, wound drainage volume and operation time were also compared between the two groups. Results: 38 screws were inserted into the atlas and another 38 screws were placed in the axial of the 19 patients. According to Richter et al.'s criteria, the accuracy rate of 52 screws in the experiment group was 100%, with 51 screws (98.1%) in Grade 1 and 1 screw (1.9%) in Grade 2. The accuracy rate of 24 screws in the control group was 95.8%, with 21 screws (87.5%) in Grade 1, 2 screws (8.3%) in Grade 2 and 1 (4.2%) in Grade 3. The accuracy rate of the screws was significantly different ($P<0.05$) between the two groups. The bleeding volume in the experiment group (116 ± 37 ml) was significantly lower than that in the control group (192 ± 69 ml, $P<0.05$). The wound drainage volume in the experiment group (79 ± 32 ml) was also markedly less than that in the control group (116 ± 35 ml, $P<0.05$). The operation time in the experiment group (83 ± 20 min) was significantly shorter than that in the control group (116 ± 26 min, $P<0.05$). Conclusion: This study clearly demonstrated that 3D printing navigation template technique is an accurate, safe and rapid method with promising potential in the clinical treatment of old type II odontoid fracture with atlantoaxial dislocation.

Keywords: 3D printing, navigation template, odontoid fracture, atlantoaxial dislocation, pedicle screw

Introduction

Type II odontoid fracture with atlantoaxial dislocation is the most common cervical spine fracture. There are surgical treatment and non-surgical treatment in the clinical management. Surgical treatment is performed by anterior odontoid screw fixation or posterior pedicle screw C1-2 fusion operation. Non-surgical treatment is often conducted by traction reduction, head and neck plaster cast immobilization or Halo-vest fixed etc. Previous studies showed that conservative treatment for odontoid fracture, especially type II odontoid fracture, may cause bone non-union, which could lead to atlantoaxial instability and cause serious prob-

Table 1. General information of the patients in the two groups (mean ± standard deviation)

	Experimental Group	Control Group	*P* value
Number of patients (n)	13	6	-
Gender (M/F)	7/6	3/3	0.876
Age (years)	46.1 ± 11.1	48.7 ± 12.1	0.650

Table 2. The Preoperative and postoperative VAS score of the patients in the two groups (mean ± standard deviation)

	Experimental Group	Control Group	*P* value
Preoperative VAS score	3.1 ± 1.73	3.8 ± 1.5	0.353
Postoperative VAS score	1.0 ± 0.9	1.1 ± 1.0	0.878
P value	0.001	0.002	-

Table 3. The Preoperative and Postoperative Frankel classification of the patients in the two groups

	Experimental Group	Control Group	*P* value
Preoperative Frankel classification			
Grade C	1	0	0.756
Grade D	8	4	
Grade E	4	2	
Postoperative Frankel classification			
Grade D	3	1	0.756
Grade E	10	5	
P value	0.018	0.093	

lems [1, 2]. Therefore, surgical treatment is currently the preferred treatment for type II odontoid fracture. For the two surgical procedures, posterior pedicle screw C1-2 fusion has a significantly higher fusion rate than anterior odontoid screw fixation according to meta-analysis [3].

Due to the complicated anatomical structure of atlantoaxial joint, which is adjacent to a large numbers of nerve fibers and blood vessels that are easily to be intraoperatively damaged, high technical requirements of atlantoaxial pedicle screw setting are needed for the surgery. It is urgent to find an adjuvant surgical method to improve the accuracy of intraoperative nail placement, and to reduce iatrogenic injury. Recently, a study of Chen et al. suggested that the use of 3D printing navigation template could significantly improve the accuracy and speed of the posterior lumbar pedicle screw fixation, as well as reduce the amount of bleeding [4]. Therefore, this study aimed to evaluate the clinical value of 3D printing in the screw fixation and fusion of posterior pedicle for the treatment of old type II odontoid fracture with atlantoaxial dislocation.

Materials and methods

General information

In this study, 19 patients of old type II odontoid fracture with atlantoaxial dislocation received posterior pedicle screw C1-2 fusions were retrospectively studied from September 2014 to February 2016 in the department of Spine Surgery, Affiliated Chenggong Hospital of Xiamen University. The patients include 10 males and 9 females, with ages ranging from 27 to 68 years old and an average age of 46.9 years old. According to the Frankel scale [5], the preoperative grades of the patients in the experiment or control group were as follows: 0 case in grade A or B, 1 case in grade C, 8 cases in grade D and 4 cases in grade E in the experiment group; and 0 case in grade A, B or C, 4 cases in grade D and 2 cases in grade E in the control group. The VAS score of the experiment and control groups were (3.1 ± 1.7) points and (3.8 ± 1.5) points respectively. The patients of experiment group were then given operation of posterior pedicle screw C1-2 fusion with the help of 3D printing navigation template, whereas those in the control group were received traditional posterior pedicle screw C1-2 fusion. There were no statistically significant differences in age, gender, number of screws, Frankel grade and VAS scores between the two groups. Which gender was analyzed by X^2 test, Frankel grade was analyzed by Mann-Whitney U test, The age, number of screws, VAS scores were analyzed by independent t-test (**Tables 1-3**).

Inclusion criteria

The inclusion criteria were as follows: (1) Patients who were diagnosed as old type II odontoid fracture accompanied by refolding or refractory atlantoaxial dislocation, and had got invalid non-surgical treatment with indications

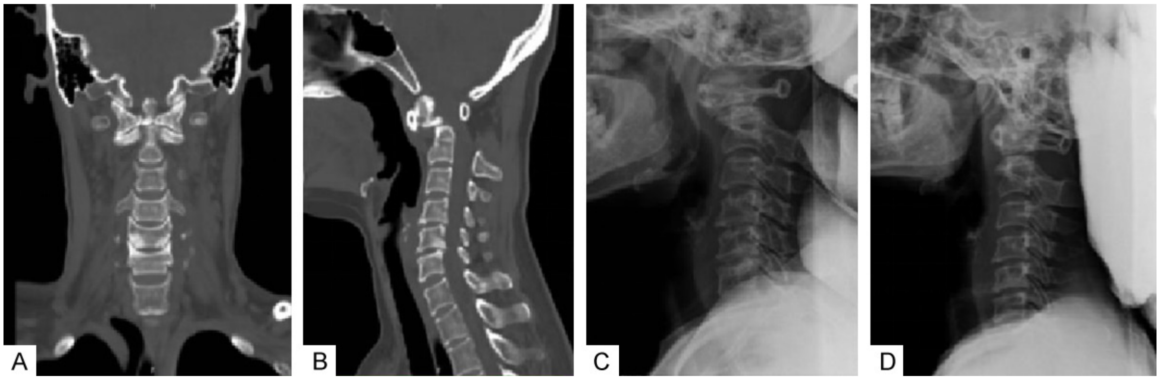

Figure 1. CT, X-ray images of cervical spine before and after skull traction. A. Anteroposterior CT film of the cervical spine showed the odontoid fracture. B. Lateral CT film of the cervical spine showed the atlantoaxial dislocation. C. Lateral X-ray image of the cervical spine showed the atlantoaxial dislocation. D. Lateral X-ray image of the cervical spine showed that atlantoaxial dislocation have completely recovered after skull traction.

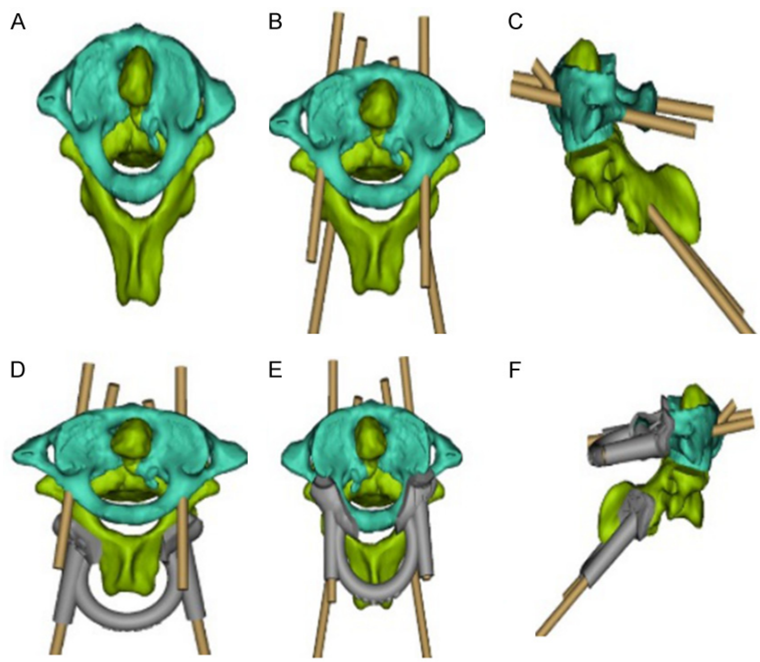

Figure 2. The atlantoaxial model was designed in Mimics 17.0 software. A. The atlantoaxial model was designed according to the CT scan data of atlantoaxial after skull traction in Mimics 17.0 software. B. Example of the Coronal screw position model of the atlantoaxial pedicle designed in Mimics 17.0 software. C. The sagittal screw position model of the atlantoaxial pedicle designed in Mimics 17.0 software. D. Example of the atlantoaxial navigation template according to the screw position designed in Mimics 17.0 software. E. Example of the coronal position of the atlantoaxial navigation template. F. Example of the sagittal position of the atlantoaxial navigation template.

for surgery; (2) Those who suffered from neck pain with or without spinal cord impairment and other clinical manifestations; (3) Those who had no lower cervical vertebral deformity; (4) Those who completely understood the treatment plan and signed the informed consent.

Exclusion criteria

Patients were excluded as one of the following criteria: (1) Patients who could not tolerate surgery due to severe liver or kidney disease, malignancy or other serious systemic diseases; (2) Those who had irreversible atlantoaxial dislocation; (3) Those patients unsuitable to screw because of less than 4 mm atlantoaxial pedicle and vertebral artery running abnormalities according to preoperative CT scan evaluation. This trial has been approved by the ethics committee of Affiliated Chenggong Hospital, Xiamen University.

Allocation concealment

The patients had no idea which group they were put. A specially assigned person was in charge of the enrollment and grouping of the patients to avoid selective bias and to ensure allocation concealment.

Pre-operative preparation

All Patients were routinely arranged for lateral and cervical X-ray, CT and magnetic resonance imaging (MRI) on admission (**Figure 1A-C**). Since atlantoaxial dislocation often associated

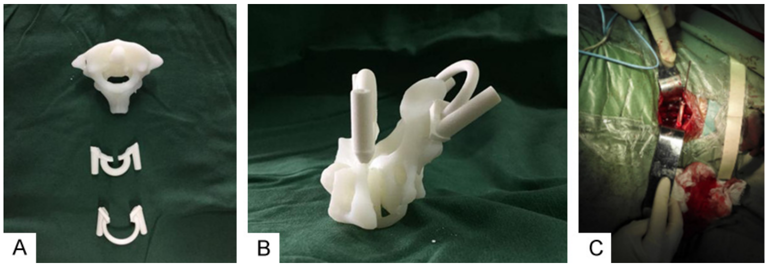

Figure 3. The atlantoaxial navigation template printed by the photosensitive 3D printer. A. An overview of the navigation template. B. Lateral position of the atlantoaxial navigation template. C. Intraoperative application of the atlantoaxial navigation template.

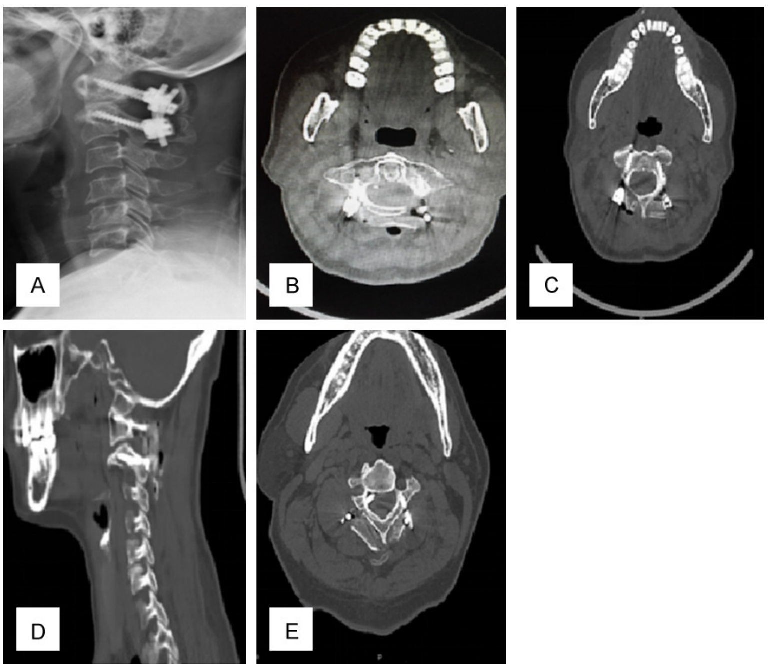

Figure 4. The pedicle screw position confirmed by intraoperative C-arm perspective or postoperative CT scan. A. The pedicle screw position was confirmed by intraoperative X-ray. B, C. The coronal pedicle screw position was confirmed by the postoperative CT image of the cervical spine in the experiment group. D. The sagittal pedicle screw position was confirmed by the postoperative CT image of the cervical spine in the experiment group. E. Example of a pedicle screw in Grade 3 in the control group according to Richter's criteria was shown in coronal CT image.

with spinal stenosis, the skull traction was performed to reduce the atlantoaxial dislocation and to avoid further damage once the type II odontoid fracture associated with atlantoaxial dislocation was confirmed in diagnosis. Xi et al. cherished the viewpoint that a heavy skull traction, at least 1/8-1/6 of the body weight for about 1-2 weeks, was needed to achieve more than 30% recovery of atlantoaxial dislocation [6]. Following the complete reduction of the atlantoaxial dislocation reviewed by cervical X-ray (**Figure 1D**), the cervical 3D model of the atlantoaxial pedicle were reconstructed by Mimics 17.0 software according to the collated CT data, which were acquired by Atlantoaxial 320-slice CT (*Japan's Toshiba Aquilion ONE*) scan with a layer of 0.625 mm. The atlantoaxial model and screw simulation of entry point were designed according to the atlantoaxial pedicle screw entry point parameters from previous studies [7, 8]. Briefly, Atlas pedicle screw was implanted into the junction of 20~22 mm next to the midline and the lower edge of the posterior arch. In addition, the screw was inclined inward with an angle of 10 to 15 degrees in the coronal plane and was tilted to rostral direction with an angle of about 5 to 10 degrees in the sagittal plane. The vertebral pedicle screw entry point was located 5 mm below the upper edge of the lamina and 7 mm from the outer edge of the vertebral canal. The screw was placed 20 degrees inwards in the horizontal plane and 30 degrees upward in the sagittal plane. The nail navigation template was then designed by the screw placement model and printed by the photosensitive 3D printer (*MEDITOOL Corp. China*) with Pangu 4.0 special 3D printing materials (*No. MDT201604014D1, SUPMED CANADA*). The navigation template was sterilized by low-temperature plasma (**Figures 2A-F**, **3A**, **3B**). Finally, the template was ready for operation.

Operational methods

The operations in both groups were performed by the same surgeon specialized in spine surgery. Briefly, each patient was placed in the prone position under general anesthesia. The situation of atlantoaxial dislocation was observed before surgery by routine lateral fluoroscopy and, if necessary, the extension or flexion of the cervical spine was adjusted to make the atlantoaxial dislocation in the reset state. A midline incision was made to expose the posterior elements of C1-C2. The medial and lateral margins of the lateral mass of the axis and the posterior surface of the posterior lamina of the atlas were then dissected for about 2 cm. After complete exposure, the 3D printing guide plate was tightly attached to the Atlas lamina, and Kirschner wire was inserted into the pinhole on the guide plate to obtain a placement angle (**Figure 3C**). Intraoperative C-arm fluoroscopy was taken to confirm the correct placement of the Kirschner. After removal of Kirschner wire and 3D navigation template, 3.5 mm universal pedicle screws provided by the US Sofamor company was then placed properly. Patients in the control group received traditional X-ray-assisted posterior Atlantoaxial pedicle screw fixation. Intraoperative C-arm perspective witnessed correct fixation of the pedicle screw (**Figure 4A**).

Postoperative management

Postoperative routine to prevent infection and rehydration, maintain the internal environment stability and other treatments were performed on the patients of each group. Drainage tube was removed within 48 hours after operation or when drainage was <50 ml. The ground activities could be permitted when the neck restraint brake protection or brace protection was performed. The accuracy of screws placement, including the intraoperative blood loss, operation time and postoperative wound drainage, in the two groups were evaluated by postoperative review of cervical X-ray, CT and Richter et al.'s criteria [9].

Evaluation of accuracy of pedicle screw implantation

According to Marcus Richter's study, the excellent rate of pedicle screw placement could be divided into three grades. The first grade was excellent, correct screw placement without pedicle perforation or with pedicle perforation <1 mm the pedicle screw is not piercing the cortex; the second grade was pedicle perforation >1 mm without the need for screw revision; the third grade was pedicle perforation >1 mm with the need for screw revision due to irritation or injury of roots or the myelon or due to reduced biomechanical stability [9].

Statistical analysis

Statistical analysis was performed with SPSS 22.0 Statistical software. Data were presented as mean ± SD (x ± s). Intergroup comparison of age, number of screws and VAS scores were done by the independent-samples *t*-test. Frankel grade was measured by Mann-Whitney U test. Gender was analyzed by X^2 test; $P<0.05$ was considered significant.

Results

Evaluation of the accuracy rate of pedicle screws

All the 19 patients underwent posterior pedicle screw fixation with C1-2 fusion. Among all the 19 cases, 13 cases underwent posterior pedicle screw fixation with C1-2 fusion guided by 3D printing navigation template and 6 cases underwent conventional posterior pedicle screw fixation with C1-2 fusion. The 19 patients were implanted 76 pedicle screws together, of which 38 atlas pedicle screws and another 38 axial pedicle screws. Satisfactory results of pedicle screw fixation were achieved by intraoperative C-arm X ray perspective in the two groups. There was no intraoperative vertebral artery or nerve root injury. Postoperative CT was reviewed and evaluated according to Richter et al.'s criteria [9]. The accuracy rate of 52 screws in the experimental group was almost 100%, with 51 (98.1%) screws in Grade 1 and 1 screws (1.9%) in Grade 2, respectively. The accuracy rate of 24 screws in the control group was 95.8% with 21 screws (87.5%) in Grade 1, 2 screws (8.3%) in Grade 2 and 1 screw (4.2%) in Grade 3, respectively. There were three screws implanted into the spinal canal with the invasion ≤ 2 mm (**Figure 4E**). All of other screws were located in the pedicle cortical bone (**Figure 4B-D**). The accuracy rate of the screws was significantly different ($P<0.05$) between the two groups.

Evaluation of the postoperative blood loss, operation time and postoperative wound drainage

There were also significant differences in the postoperative blood loss, operation time and postoperative wound drainage between the two groups ($P<0.05$, **Table 4**). The bleeding volume in the experimental group (116 ± 37 ml) was significantly lower than that in the control group (192 ± 69 ml, $P<0.05$). The wound drain-

Table 4. General surgical information of the patients in the two groups (mean ± standard deviation)

Group	Operation time (min)	Intraoperative blood loss (ml)	Postoperative wound drainage (ml)
Experimental	83 ± 20	116 ± 37	79 ± 32
Control	116 ± 26	192 ± 69	116 ± 35
t value	-2.782	-2.721	-2.173
P value	0.015	0.017	0.047

age volume in the experimental group (79 ± 32 ml) was also markedly less than that in the control group (116 ± 35 ml, *P<0.05*). The operation time in the experimental group (83 ± 20 min) was significantly shorter than that in the control group (116 ± 26 min, *P<0.05*). There was no iatrogenic nerve injury at the final follow-up. According to the Frankel classification, there was 0 case in grade A, 0 in grade B, 0 in grade C, 3 in grade D and 10 in grade E, in the experimental group whereas there was 0 case in grade A, 0 in grade B, 0 in grade C, 1 in grade D and 5 in grade E in the control group (**Table 3**). In addition, the VAS score was (1.0 ± 0.9) in the experimental group and (1.1 ± 1.0) in the control group, there was no significantly different in the preoperative and postoperative VAS score (*P>0.05*) between the two groups (**Table 2**).

Discussion

Odontoid fracture was very common in upper cervical spine injuries, with an incidence of 9%-20% [10-12]. It is a common cause of injury in young patients, who may suffer from high-energy trauma such as car accidents and falls injury, and in the elderly, who may cause by low-energy trauma such as secondary osteoarthritis and osteoporosis [13]. According to Anderson's classification, odontoid fracture can be divided into I, II, III three types, of which the most common one was type II. The current treatment of fresh odontoid fracture includes Gallie's technology, Brooks wire fixation technology, Halifax laminectomy, Apofix lamina clamp, and Goel atlas lateral mass screws. However, the fixation was prone to loose, and even fracture and abnormal graft fusion sometimes occur in these procedures. Old type II odontoid fracture often associated with atlantoaxial instability and there were several kinds of treatments, such as occipitocervical fusion, simple posterior atlas lateral mass, axial pedicle screw reset fusion, and Magerl screw technology. But there were shortcomings of these treatments, including the impact of neck activity, low fusion rate and large angle into the nail [14]. Therefore, Tan et al. first proposed the pedicle screw technology in 2002 [15, 16]. Several studies have shown that the stability of pedicle screw system was more conducive to fracture healing, and the pedicle screw technology showed the advantages of simple operation, fewer complications and curative effect [17-19]. Furthermore, Zhai summarized the advantages of atlantoaxial pedicle screw as follows: (1) It can reduce the intraoperative operations; (2) It can keep C1-C2 joints undamaged and maintain C1-C2 joint activity even when the internal fixation is removed; (3) It can reduce surgical risk as the high entrance of the atlantoaxial pedicle screw can avoid exposure of deep structures such as the posterior arch of the C1 [20].

Due to the complicated anatomical structure of the atlantoaxial joint, which is adjacent to a large number of nerve fibers and blood vessels and other important structures, such as spinal cord, C2 nerve root, venous plexus and vertebral artery etc., it put forward higher requirements for the atlantoaxial pedicle screw setting to avoid intraoperative damage to nerves and blood vessels in the posterior cervical pedicle screw C1-2 fusion surgery. He et al. have shown that the minimum height of male and female atlas pedicle were (4.4 ± 1.2) and (3.8 ± 0.8) mm respectively and that even a tiny mistake of pedicle screw placement resulted in the spinal cord and nerve root injury or the surrounding blood vessels damage, such as the vertebral artery, which then accordingly increased the risk of surgery and postoperative complications [21]. Accumulative studies have shown that about 3.6%-27.27% of postoperative complications were caused by the carelessness in posterior atlantoaxial pedicle screw fixation [15, 22, 23]. Qin et al. believed that the key factors for the successful atlantoaxial pedicle screw placement were as follows: fully exposure of the operative field, accurate localization of the entry point and the correct direction of screw placement [24]. Therefore, it's urgent to explore an effective technique to improve the accuracy of posterior pedicle screw fixation in C1-2 fusion surgery, and to improve the surgical safety.

Currently, the popular auxiliary techniques include digital navigation template, CT three-dimensional (3D) navigation system, 3D printing navigation template, and so on. Numerous literatures have shown that the accuracy rate of pedicle screws placement with the aid of digital navigation templates and computer based navigation system was 92.6% and 97.5%-97.9%, respectively. Surgery assisted by digital navigation template need to peel more soft tissues, which not only increases the intraoperative risk of iatrogenic injury, but also extends the operation time. In the cases of a computerized three-dimensional navigation system, it cannot be used any more when the intraoperative system fails. It can also lead to more placement errors due to the mobility of the cervical spine during surgery. In addition, the price of this navigation device is relatively higher than others [25-27].

3D printing, also known as the additive manufacturing, refers to processes used to synthesize a three-dimensional object in which successive layers of adhesive material, such as a liquid or powdery metal plastic, are formed under computer control to create the object. As a newly developed technique, the application of 3D printing in medical field is a great innovation and will promote the development of medical surgery. It has been demonstrated that the use of 3D printing navigation template improved the accuracy and speed of the posterior lumbar pedicle screw fixation. At the same time, the amount of intraoperative blood loss was significantly reduced [4]. The advantages of 3D printing in atlantoaxial pedicle screw placement have also been reported in several other studies [28-30]. In addition, compared to the latest computer navigation nail technology, the 3D printing was easier to be learned and to be manipulated in more extensive applications [31]. Therefore, here we aimed to explore whether the 3D post-navigation template assisted posterior pedicle screw C1-2 fusion can improve the accuracy and safety of operation placement and shorten the operation time, as well as reduce the intraoperative blood loss.

In this study, the accuracy of the 3D navigation template-assisted placement of nail reaches 98.1%, which was consistent with previously reported results [28, 32]. In both the experiment and control groups: (1) Compared with preoperative stage, the Frankel and neck pain VAS scores at the final follow-up were significantly improved; (2) Imaging examination showed atlantoaxial dislocation and bony fusion; (3) There were no complications such as nerve root or vascular injury, internal fixation device rupture or loose. These results suggested that there were clear therapeutic effects in both groups. However, by comparing with control group, we found the operation time, intraoperative blood loss and postoperative drainage were all significantly reduced in the experimental group. Numerous researches in the traditional X-ray-assisted posterior Atlantoaxial pedicle screw fixation for odontoid fracture with atlantoaxial dislocation have shown that the average amount of intraoperative blood loss was about 250-300 ml and the average operation time was about 1.5-2.8 hours [18, 33]. However, the mean blood loss was (116 ± 37) ml and the average operation time was (83 ± 20) min in this study, which were significantly reduced. These results clearly indicate that the 3D printing navigation template was a rapid, safe and low-injury auxiliary technique in operation.

Before surgery, we performed a 320-slice CT scan for the patients who suffered cervical spine injury. The accuracy of the CT scan (0.625 mm layer thickness) has been improved greatly compared to other commonly used ones with 1 mm layer thickness. The higher accuracy of CT scan provided the realistic simulation of the cervical vertebra model and reduced the error of the entry point. Moreover, there are some other advantages of 3D printing navigation template: (1) It reduced the radiation damages in patients due to the short-term imaging during the surgery. (2) The template material used in 3D printing navigation template was medical resin, which was harmless to the patients. (3) It was easily to be sterilized by low-temperature plasma disinfection. (4) Before surgery, the surgical needle point can also be simulated by the navigation template and the atlantoaxial model. It is a good teaching example for the surgeon in understanding the possible iatrogenic complications and the anatomical structure around the atlantoaxial. (5) 3D navigation template was cheap and acceptable for the patient. (6) 3D printer was affordable for most hospitals.

In the design of 3D navigation template, the following issues should be paid attention to: (1) The data of CT scan can only be collected after the skull traction reduction of the atlantoaxial dislocation. (2) The possible misplacement between the navigation template and the atlantoaxial caused by the insufficient dissection of atlantoaxial surrounding tissues should be comprehensively considered. (3) The size of the navigation template should not be too large because large guide plate is not easy to be placed and is not conducive to postoperative rehabilitation.

Postoperative complications in patients may also result in surgical failure. Yin et al.'s study showed that the short-term complications of posterior cervical pedicle screw of C1-2 fusion include wound infection, internal fixation device loosening or fracture [34]. And the long-term complication usually is the recrudescent atlantoaxial dislocation. Studies have shown that odontoid fracture associated with atlantoaxial dislocation was positively related to the mortality in elderly patients [13, 35]. Therefore, the odontoid fracture associated with atlantoaxial dislocation, especially in elderly patients should be closely monitored to prevent the occurrence of complications.

Taking together, the 3D printing navigation template assisted posterior pedicle screw of C1-2 fusion surgery was a fast and safe surgical approach, which could improve the accuracy of nail placement, significantly shorten operation time, reduce blood loss and be conducive to postoperative rehabilitation for patients.

However, there were still some shortcomings in this study: (1) The number of surgical cases received surgical operation with 3D printing templates was relatively small. (2) Some patients could not completely understand the advantages of 3D printing in intraoperative applications. (3) It took about 3-4 hr for the photosensitive 3D printer to print out the guide plate model. (4) Sometimes there was artificial error in importing the CT data designing and printing the template with Mimics 17.0 software. (5) As this study was a retrospective study, the cases could not be randomly grouped. (6) The cases in this study were limited to patients without anatomical deformity in the atlantoaxial and vertebral artery. According to the limitations mentioned above, not only the problems need to be solved, but also further study need to be done to explore the application of the 3D printing template in patients with anatomical deformity in the atlantoaxial and vertebral artery.

We believe in the near future, with the development in 3D printing navigation template and the thoroughly acquaintances of the 3D printing for patients, as well as the improvement of equipment, the application of 3D printing navigation template technology in the upper cervical spine will be widely accepted.

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Disclosure of conflict of interest

None.

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