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A Novel Method to Improve the Accuracy and Stability of the 3D Guide Template Technique Applied in Upper Cervical Spine Surgery

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ABSTRACT

AIM: To evaluate the safety and accuracy of C1 and C2 pedicle screw placement using a three-dimensional (3D)-printed double template and compare them with those of the conventional method in a clinical study.

MATERIAL and METHODS: DICOM format data from 60 cases with C1–C2 instability were obtained after computed tomography (CT) was performed. A total of 32 cases underwent surgery via the free-hand technique, whereas 28 cases underwent surgery via a 3D-printed "pointing-drilling" guide template. The ideal trajectory of the C1 and C2 pedicle screws was designed using a baseplate as a separate complementary template for the corresponding posterior C1–C2 anatomical surface, after which the "pointing-drilling" guide template was materialized using a 3D printing machine. The 3D-printed "pointing-drilling" guide template, which was sterilized with low-temperature plasma, was used to locate the starting point and determine the drill trajectory during surgery. The positions of the screws in the axial and sagittal planes of the CT scan were observed and categorized into four grades, after which the operative time, fluoroscopy time, and intraoperative bleeding in the two groups were compared.

RESULTS: No significant difference (p>0.05) in each screw classification grade was observed between the free-hand and "pointing-drilling" template groups; however, a significant difference was observed (p=0.048) between these two groups. A significant difference (p<0.05) in fluoroscopy times was observed between the free-hand and "pointing-drilling" template groups. Conversely, no significant differences were observed in bleeding (p=0.491) and operative time (p=0.309) between the free-hand and "pointing-drilling" template groups.

CONCLUSION: The 3D-printed "pointing-drilling" guide template technique promoted more secure C1 and C2 pedicle screw placement compared with the free-hand technique in clinics.

KEYWORDS: 3D printing, Pedicle screws, Atlanto-axial, Personalized, Template

ABBREVIATIONS: 3D: 3-dimensional, **DICOM:** Digital imaging and communications in medicine

INTRODUCTION

C1–C2 pedicle screw fixation remains one of the most important methods in upper cervical spine surgery given that it improves the fusion rate and is an effective approach for the treatment of atlantoaxial instability (21). Biomechanical studies have demonstrated that pedicle screw internal fixation was better than other forms of spine instrumentation (15). However, the traditional pedicle screw technique relies on anatomical markers and has a high rate of cortical bone perforation regardless of whether assisted fluoroscopy is performed (4). The potential hazards of

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neurovascular injury have led surgeons to attempt the use of different methods to improve the accuracy of pedicle screw placement (3). At present, CT-based navigation is the most popular imaging guidance system. Compared with traditional methods, CT-based navigation promotes more accurate pedicle screw placement (1). However, this system has some shortcomings, such as a steep learning curve and excessive preoperative preparation, specific protocols, data retrieval and transmission, and information registration (23).

The application of three-dimensional (3D) printing double-guide template technology has enabled spine surgeons to design a safe surgical trajectory using the patient's own 3D images before surgery, thereby improving the accuracy of the instrument. This technology also reduces the radiation dose and prevents repetitive movement of the C-arm during surgery given that it allows for the visualization of the surgical instrument relative to the patient's anatomy over the entire desired image plane before surgery. Thus, this study aimed to evaluate the application of the 3D printing double-template technology in C1 and C2 screw placement and compare the clinical results with traditional methods.

MATERIAL and METHODS

The ethics approval number is CHEC2009-066. Dated: April 16, 2009.

Patients

The medical records and imaging data of 60 patients undergoing posterior pedicle fusion from June 2011 to July 2018 were retrospectively analyzed. A total of 32 cases underwent C1–C2 free-hand screw fixation (traditional group), whereas 28 cases underwent C1–C2 screw fixation with the assistance of the 3D printing template technique (3D printing group). The senior author placed or supervised the placement of all 240 screws. Among the included patients, 33 were male and 27 were female aged between 42 and 69 years. The most common indications for surgery were unstable C1 or C2 fracture or C1–C2 dislocation with an intact posterior element. All the included patients received C1–C2 posterior screw fixation with a total of 240 screws. However, in the traditional group, three C1 lateral mass screws were used due to failure of posterior arch screw fixation, and one C2 lamina screw was used due to the C2 pedicle being too narrow for screw fixation. The postoperative follow-up period of these patients ranged from 15 to 37 months with an average of 26 months.

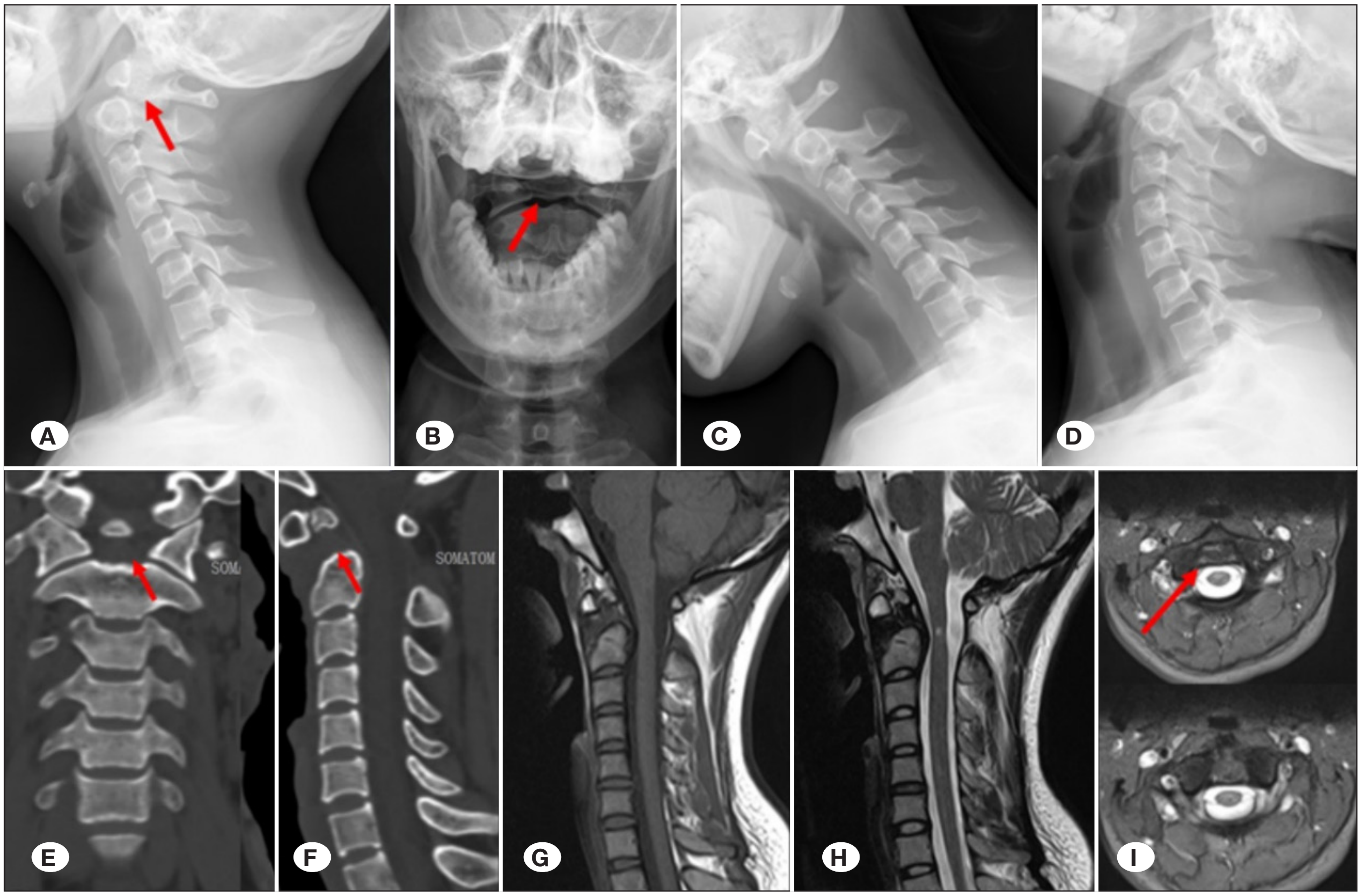

Figure 1: A 19-year-old female patient with traumatic atlantoaxial dislocation, cervical spinal cord injury at C2 and os odontoideum: **A)** Lateral, and **B)** AP X-rays of the cervical spine; the red arrows indicate the absence of middle part of odontoid process. Dynamic X-rays (**C:** flexion and **D:** extension) of the cervical spine. **E)** Coronal, and **F)** sagittal CT scans of the cervical spine. **G)** Sagittal T1W, **H)** sagittal T2W, **I)** axial T2W MRI scans of the cervical spine; the red arrow indicates the TAL is intact.

The clinical case used in Figure 1 is that of a 19-year-old girl with traumatic atlantoaxial dislocation, cervical spinal cord injury at C2, and os odontoideum.

Construction of the "Pointing-Drilling" Double Template

All patients underwent preoperative CT. The cervical spine was scanned with a section thickness of 0.625 mm (Philips Brilliance 64ct, Philips Medical Systems, Netherlands) and stored in the Digital Imaging and Communications in Medicine (DICOM) format. The volume data stored in the DICOM format were imported into mimics 15.01 (Materialise, Belgium) to create a 3D model of the cervical spine. A cylinder with a diameter of 3.5–4 mm was used as a substitute for a screw to directly observe the potential perforation of the C1–C2 cortical bone on each plane in the process of 2D and 3D reconstruction (Figure 2A–G). The data for the 3D cervical spine model and cylinder were transmitted to the reverse engineering software (UG Imageware 12.0; EDS, US) in the STL format. This software can ultimately determine the optimal entry point, angle, maximum safe half diameter, and depth of the screw. This ideal trajectory was designed according to the "free-hand" technology described by Tan et al., and Resnick and Benzel (18,22). Thereafter, the transverse, sagittal, and 3D planes of the trajectories were adjusted in the Mimics software to determine the final angle and entry point of the personalized safety trajectory. The maximum depth and semi-diameter of the screw were measured using the UG Imageware, whereas the maximum safe screw depth was determined as the distance between the entry point and the junction of the distal bone cortex on the axis. At the narrowest cross-section of the pedicle, the minimum distance from the central point to the edge of the pedicle was defined as the maximum safe semi-diameter.

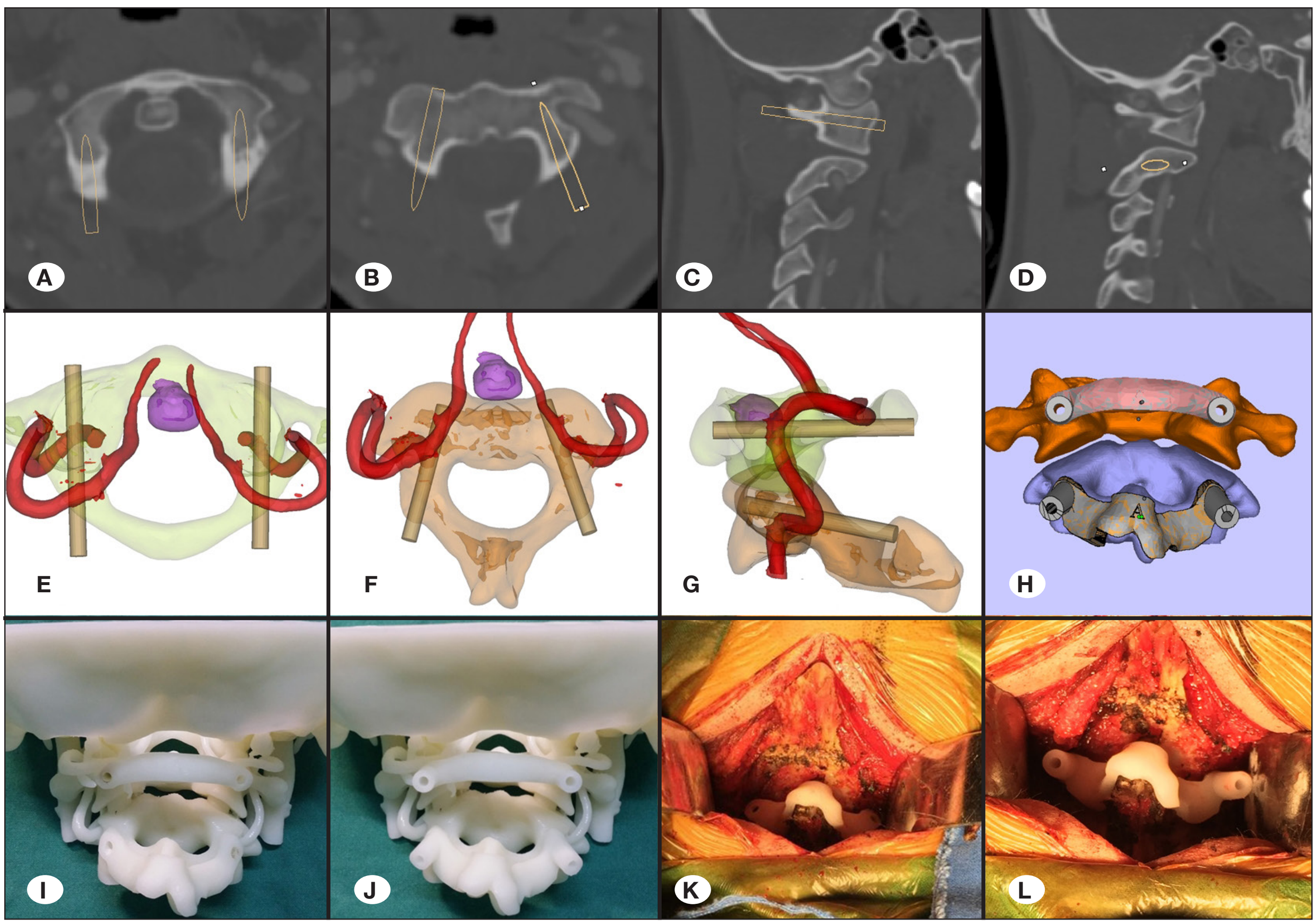

Figure 2: Atlantoaxial pedicle screw path planning, guide plate design and application: **A)** Atlas pedicle screw path planning (transverse plane); **B)** Planning of the axis pedicle screw path (transverse plane); **C)** Atlas pedicle screw path planning (sagittal plane); **D)** axial pedicle screw path planning (sagittal plane); **E)** Three-dimensional design of atlas pedicle screw (axial view); **F)** Three-dimensional design of axial pedicle screw (axial view); **G)** Atlantoaxial pedicle screw design (lateral view); **H)** Three-dimensional design of atlantoaxial pedicle screw guide template; **I)** Atlantoaxial pedicle screw pointing guide plate fixed at the corresponding position of the patient's upper cervical spine model; **J)** The atlantoaxial pedicle screw drilling guide plate was fixed at the corresponding position of the patient's upper cervical spine model; **K)** pointing guide plate fixed on the surface of the corresponding bony structure of the upper cervical spine; **L)** drilling guide plate is used to fix the surface of the corresponding bony structure to the upper cervical spine.

In the lock and key design, the drilling template was designed in a way that it approaches the surface of the C1–C2 posterior element. The thickness of the template fitted with the posterior element of C1–C2 was 2.5 mm to ensure sufficient stability of the borehole.

The guide tube was located on both sides of the guide template, with the length of the guide being 15 mm. The inner and outer diameters of the guide were 2.7 and 5.7 mm, respectively (Figure 2H). After removing the guide tube, the pointing template was completed. Thereafter, the data for the 3D model of the pointing and drilling template were transformed into a physical template made of acrylic resin using the stereolithography technology (China Hengtong Company) (Somos 14120, DSM DeSotech, Inc.) (Figure 2I, J).

Surgical Procedure

The cervical model was sterilized with high-temperature plasma, whereas the template was sterilized with low-temperature plasma. During the performance of the standard posterolateral spinal fusion dorsal approach in the trial group, the pointing–drilling double-template technique was employed to guide the screw insertion (Figure 2K, L). The pointing template was placed on the C1 posterior arch or C2 lamina and spinous process using the lock-and-key principle. After grinding the cortical bones on both sides of the approach assisted by the pointing template, the drilling template was used to screw the holes temporarily fixed with a K-wire, after which the screw was gradually replaced. The template was temporarily fixed with a K-wire, followed by screw insertion and fluoroscopy for monitoring during surgery. All screws were implanted by an experienced spine surgeon. A diagram for the application of the pointing drilling template is presented in Figure 3.

Assessment of the Drill Template Accuracy

CT scans were obtained after drilling with the 3D-printed pointing and drilling template or free-hand technique (Figure 4). An independent radiologist reviewed the pedicle screw placement. The cervical pedicle screw placement classification established by Miyamoto and Uno, and Yukawa et al. was used to assess the C1 and C2 screw positions in the sagittal and transverse planes of the CT scans (17,25). Grade 0 indicated that the screw was completely within the bone trajectory; Grade 1, the fracture of the bone trajectory with the screw was <50%; Grade 2, the fracture of the bone trajectory with the screw was >50%; and Grade 3, the screw completely deviated from the bone trajectory.

Statistical Analysis

The SPSS software version 21.0 (IBM Corp. USA) was used for statistical analysis. The chi-squared test was employed to assess all data for the free-hand and double-template groups. The chi-squared correction test and Fisher's exact probability test was used when the data was not suitable for the chi-squared test. The operative time, fluoroscopy time, and intraoperative bleeding in both groups were assessed using the two-sample *t*-test for independent samples. A *P*-value of 0.05 indicated statistical significance.

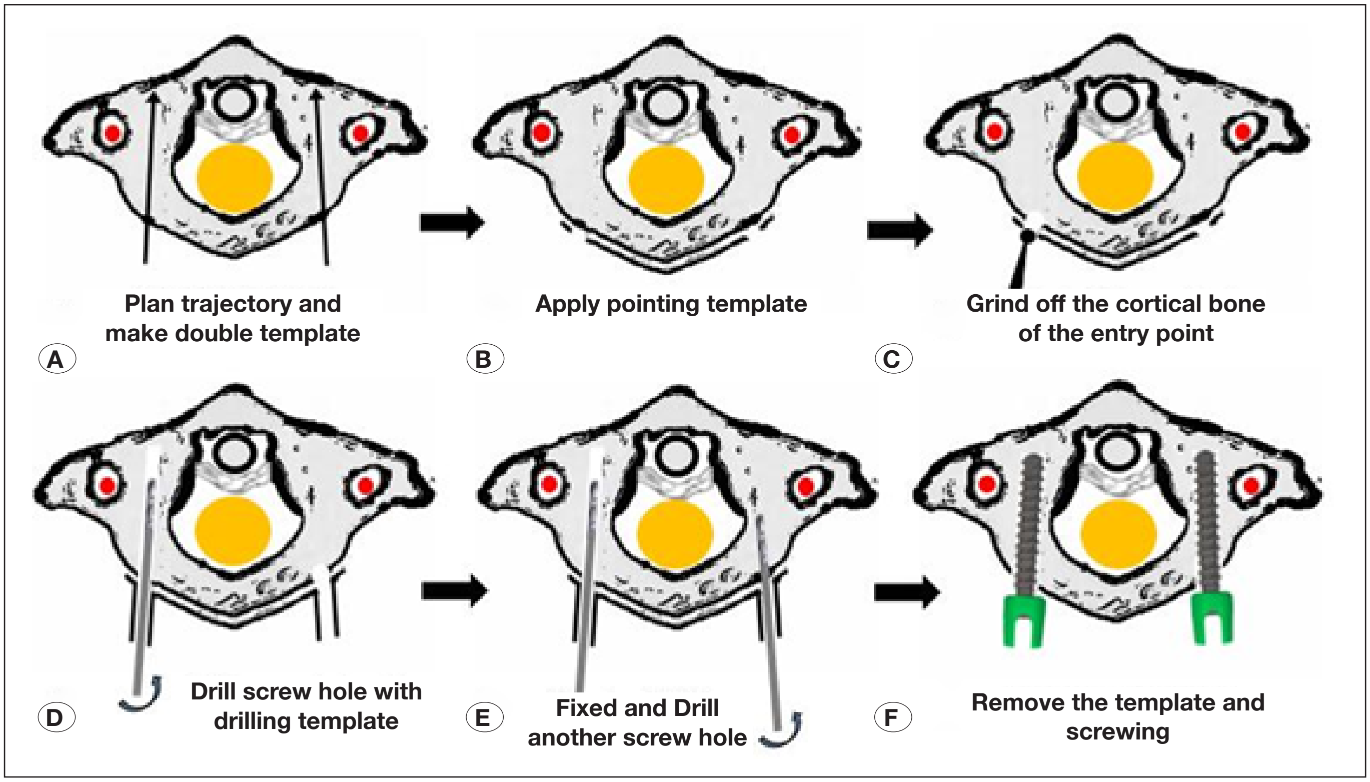

Figure 3: The schematic diagram of pointing and drilling template application.

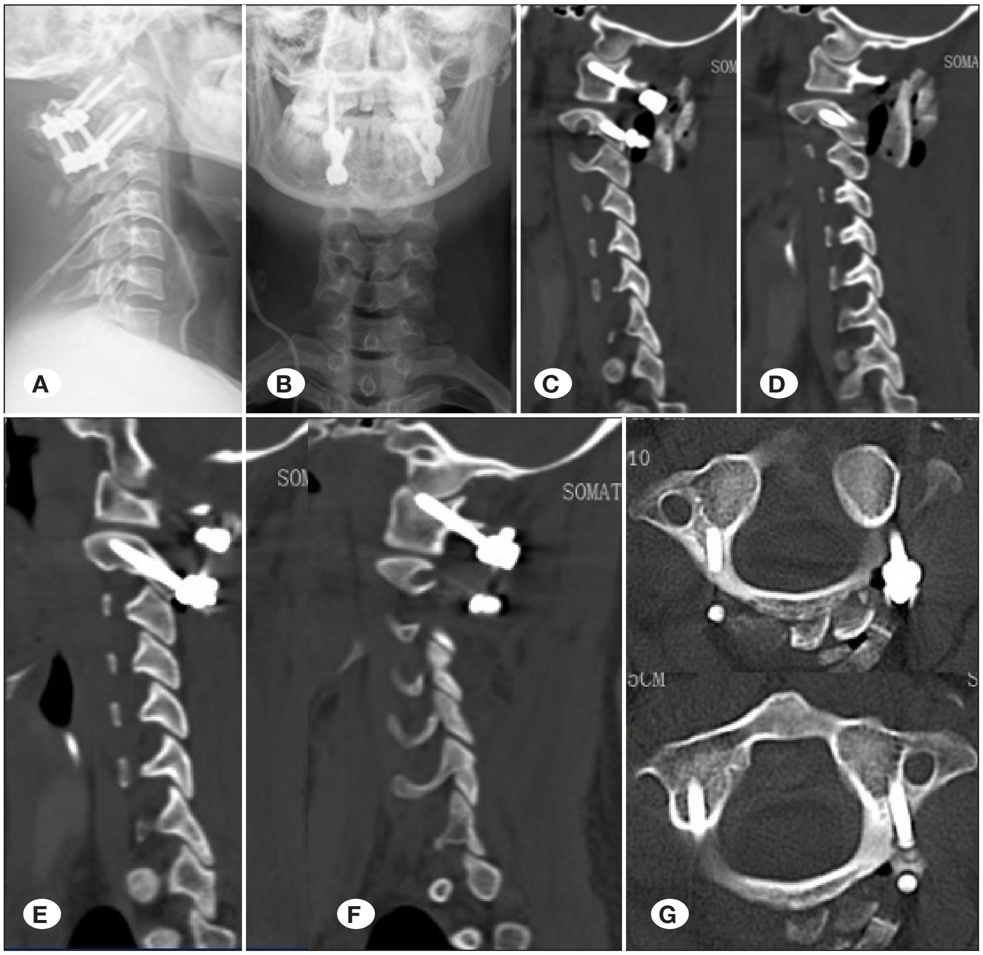

Figure 4: The postoperative X-rays **(A, B)** and CT scans **(C-G)** show safely placed C1 and C2 pedicle screws.

RESULTS

A total of 64 screws were implanted at the C1 level using the free-hand technique, among which 56 were positioned in the C1 pedicle, 5 were re-adjusted for the pedicle screw position, and 3 were implanted using the C1 lateral mass screw technique after the pedicle screw failed. A total of 64 screws were implanted at the C2 level using the free-hand technique, among which 60 were positioned at the C2 pedicle and 4 were re-adjusted for the pedicle screw position. A total of 56 screws were implanted at the C1 level using the double-template technique, among which 53 were positioned at the C1 pedicle and 3 were re-adjusted for the pedicle screw position. A total of 56 screws were implanted at the C2 level using the double-template technique, among which 55 were positioned at the C2 pedicle and 1 used the C2 translaminar screw technique after the pedicle screw failed. The screw position classification of the C1 pedicle screw in the free-hand group was as follows: 47 screws (Grade 0), 6 screws (Grade 1), 2 screws (Grade 2), and 1 screw (Grade 3). The screw position classification of the C1 pedicle screw in the double-template group was as follows: 50 screws (Grade 0), 2 screws (Grade 1), 1 screw (Grade 2), and 0 screws (Grade 3). No significant difference was observed between both groups for each grade (Table I). The screw position classification of the C2 pedicle screw in the free-hand group was as follows: 54 screws (Grade 0), 5 screws (Grade 1), 1 screw (Grade 2), and 0 screws (Grade 3). The screw position classification of the C2 pedicle screw in the double-template group was as follows: 52 screws (Grade 0), 3 screws (Grade 1), 0 screws (Grade 2), and 0 screws (Grade 3). No significant difference was observed between both groups for each grade (Table II).

We then compared the security rate and general situation between the two groups (a screw of grade 0 indicated safety, whereas a grade of 1–3 indicated hazard) (Table III). The chi-squared test suggested a significant difference in security rate and general situation between the free-hand and double-template groups ($p=0.048$). The average operative time in the free-hand and double-template groups was 126.3 min (range, 100–160 min) and 121 min (range, 90–156 min), respectively, with the two-sample t-test suggesting no significant difference ($p=0.309$). The average fluoroscopy time in the free-hand and double-template groups was 10.8 (range, 8–15) and 5.7 (range, 3–11), respectively, with the two-sample t-test suggesting no significant difference ($p<0.0001$). The average blood loss during surgery in the free-hand and double-template groups was 276.6 mL (range, 100–530 mL) and 235.4 mL (range, 90–650 mL), respectively, with the two-sample t-test suggesting no significant difference ($p=0.491$).

Table I: Free-Hand Group vs. Double Template Group in C1 Pedicle Screws

Screw	Free-hand group (n=56)		Double template group (n=53)		p-value
Deviation	**Number**	**Percent**	**Number**	**Percent**	
Grade 0	47	83.9	50	94.3	0.382
Grade 1	6	10.7	2	3.8	
Grade 2	2	3.6	1	1.9	
Grade 3	1	1.8	0	0	

Table II: Free-Hand Group vs. Double Template Group in C2 Pedicle Screws

Screw	Free-hand group (n=60)		Double template group (n=55)		p-value
Deviation	**Number**	**Percent**	**Number**	**Percent**	
Grade 0	54	90	52	94.5	0.719
Grade 1	5	8.3	3	5.5	
Grade 2	1	1.7	0	0	
Grade 3	0	0	0	0	

Table III: General Information

	Free-hand group (n=116)	Double template group (n=108)	p-value
Grade 0	101	102	**0.048***
Grade 1-3	15	6	
Intraoperative adjustment	9	3	
Accuracy rate	87.1%	94.4%	
Operation time (min)	126.3 (100-160)	121 (90-156)	0.309
X-ray times	10.8 (8-15)	5.7 (3-11)	**0.000***
Blood loss (ml)	276.6 (100-530)	235.4 (90-650)	0.491

**Statistical significance.*

DISCUSSION

The technique for the C1–C2 pedicle screw fixation using landmarks had been first introduced by Resnick and Benzel in 2002 (18). The main factors affecting the accuracy of the C1–C2 pedicle screw fixation include minimal risk of variations in individual atlantoaxial anatomy and screw misplacement from inherent defects. The midline of the C1 and C2 shifts during the screwing procedure due to the drilling pressure (14), which affects the planned screw trajectory. The traditional method for the C1–C2 pedicle screw fixation relies on preoperative imaging and knowledge of anatomic landmarks to avoid screw misplacement (19). However, several studies have demonstrated varying rates of errant placement, with the C1–C2 posterior instrumentation having the highest rates (6,14,20,24).

The application of intraoperative CT (ICT) and 3D C-arm navigation technology has also been rapidly increasing. Some studies investigating the accuracy and safety of the pedicle screw fixation have found slight variations therein. A study analyzing 260 cases of ICT with 1219 pedicle screws, and 3D C-arm with 308 pedicle screws demonstrated that the final accuracy rates were 99.5% and 88.9% for ICT and 3D C-arm, respectively in cervical regions (11). Although the perforation rates of the navigation techniques have remained low, some shortcomings exist, such as excessive time consumption, expensive equipment, complexity of instrument manipulation, and inconvenient disinfection. Accordingly, 39 of the screws fixed *via* 3D C-arm navigation could not be clearly evaluated in the cervical-thoracic spine. Contrarily, the 3D-printed template technique does not have the aforementioned shortcomings and can improve the accuracy of screw placement.

Based on our review of postoperative CT scans and measurement of the entry point and angulation, the placement of 116 consecutive free-hand pedicle screws in the C1–C2 vertebrae resulted in a cortical breach rate of 12.9% (15 screws misplaced), with 9 screws having been adjusted during surgery. The placement of 108 consecutive pedicle screws *via* the double-template technique in the C1–C2 vertebrae resulted in a cortical breach rate of 5.6% (6 screws misplaced), with 3 misplaced screws having been readjusted to the safety trajectory after the template was reseated. The current study suggested that the 3D printing group had higher intraoperative time than the traditional group, albeit not significantly. However, the 3D printing group spent much more time on preoperative preparation than the traditional group. Thus, the 3D-printed template technique was not suitable for emergency operations. To stabilize the template, the surgeon needed to completely remove the soft tissue on the corresponding surface of the bone structures. Although this may increase blood loss in the 3D printing group, no significant difference was observed in the estimated blood loss between the two groups. The C-arm fluoroscopy times were longer in the traditional group than in the 3D printing group given the need for repeated confirmation of the security of screw trajectory when using the C1–C2 free-hand pedicle screw technique. Although the surgeon had rich experience in C1–C2 pedicle screw fixation, a significant difference between grade 0 and grades 1–3 screws was observed between these two groups. This may demonstrate greater accuracy in the 3D printing group than in the traditional group.

Despite the known reliability of C1–C2 free-hand pedicle screw fixation for the reconstruction of C1–C2 stability, neurovascular injury may occur during the C1–C2 joint rotation under the pressure of the drilling force (16). Cervical pedicle screw fixation performed with the assistance of a 3D-printed drill guide has been comprehensively described in the literature (2,5,13). When the drill template is used in clinics, the surgeon can only establish the channel according to the direction of the tube. Once the guide template is unstable, an error will appear in the channel. To address this problem, Jiang et al. designed a drill guide template with holes located in two areas and guide rods that can be easily adjusted with the drill direction when necessary (12). Theoretically, however, the drill cannot completely pass through the ideal trajectory. Hu et al. indicated that the instability of the drill guide template was caused by the drilling force when grinding the bone cortex of the entry point (7–9). This difficulty stems from the susceptibility of the drilling template to wiggle caused by the drilling force before removing the cortical bone of the entry point. Compared with a single-drill guide system, the “pointing-drilling” guide template system has many more advantages. To optimize the surgical procedure, the entry point was created by the power drill using the pointing template, which improved stability when using the drilling guide template. Hence, the C1–C2 pedicle screw fixation technique performed with the assistance of the double guide system could reduce the radiation exposure to surgeons and patients. Surgeons in the early stage of learning or those handling complicated cases are advised to confirm the position of the K-wire and screws *via* C-arm fluoroscopy. Finally, this technique does not require expensive equipment unlike the navigation system and intraoperative CT.

Clinical disinfection methods mainly include high-temperature disinfection, low-temperature plasma disinfection, and ethylene oxide disinfection. The cervical spine model with a short curing time (photosensitive resin material) is not suitable for low-temperature plasma and ethylene oxide sterilization. Due to the large size of the cervical spine model, the unsolidified liquid material inside the model will eventually appear on the surface of the model, which will affect the safety of model disinfection. However, an excessively long curing time will affect the timeliness for the creation of the preoperative model. Smaller guides minimize the use of high-temperature disinfection. Excessively high temperatures may cause deformation of the guide plate, affecting its accuracy. In addition, given that the light curing time of the guide plate is relatively short, low-temperature plasma or ethylene oxide disinfection is recommended. Moreover, if the curing time of the larger model is relatively short, high-temperature disinfection is recommended given that moderate deformation of the model does not affect its guidance and use during surgery. Only Hu et al. reported three cases of infection during the clinical application of the guide plate-assisted screw placement; however, it could not be ruled out whether they were associated with the use of the guide plate (10). Surgeons should attach importance to the disinfection of guides in subsequent use.

CONCLUSION

The 3D printing “pointing-drilling” guide template technique is more secure than the free-hand technique in the placement of C1 and C2 pedicle screws in clinics.

AUTHORSHIP CONTRIBUTION

Study conception and design: YH, ZSY
Data collection: WXD, JZ
Analysis and interpretation of results: BZ, XYS
Draft manuscript preparation: ZSY
Critical revision of the article: YH, ZSY
All authors (ZSY, YH, WXD, JZ, BZ, XYS) reviewed the results and approved the final version of the manuscript.

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