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A Modified Personalized Image-Based Drill Guide Template for Atlantoaxial Pedicle Screw Placement: A Clinical Study

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Manuscript Preparation E
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Background: Atlantoaxial posterior pedicle screw fixation has been widely used for treatment of atlantoaxial instability (AAI). However, precise and safe insertion of atlantoaxial pedicle screws remains challenging. This study presents a modified drill guide template based on a previous template for atlantoaxial pedicle screw placement.

Material/Methods: Our study included 54 patients (34 males and 20 females) with AAI. All the patients underwent posterior atlantoaxial pedicle screw fixation: 25 patients underwent surgery with the use of a modified drill guide template (template group) and 29 patients underwent surgery via the conventional method (conventional group). In the template group, a modified drill guide template was designed for each patient. The modified drill guide template and intraoperative fluoroscopy were used for surgery in the template group, while only intraoperative fluoroscopy was used in the conventional group.

Results: Of the 54 patients, 52 (96.3%) completed the follow-up for more than 12 months. The template group had significantly lower intraoperative fluoroscopy frequency (p<0.001) and higher accuracy of screw insertion (p=0.045) than the conventional group. There were no significant differences in surgical duration, intraoperative blood loss, or improvement of neurological function between the 2 groups (p>0.05).

Conclusions: Based on the results of this study, it is feasible to use the modified drill guide template for atlantoaxial pedicle screw placement. Using the template can significantly lower the screw malposition rate and the frequency of intraoperative fluoroscopy.

MeSH Keywords: **Atlanto-Axial Joint • Bone Screws • Computer-Aided Design • Joint Instability**

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Background

C1 posterior pedicle screw fixation was first introduced by Resnick and Benzel [1]. Since then, posterior atlantoaxial pedicle screw fixation has been popularized for the treatment of atlantoaxial instability (AAI) [2–4]. The conventional method for posterior atlantoaxial pedicle screw placement relies on careful analysis of imaging and knowledge of anatomic landmarks. Precise and safe insertion of C1–C2 pedicles remains challenging because of potential injury to the vertebral arteries [5–7] and C2 nerve roots [4] during atlantoaxial reduction and fixation.

Several methods have been explored for precise placement of screws at C1–C2, including the use of intraoperative three-dimensional (3D) navigation systems [8–10] and rapid prototyping drill guide templates [11–13]. However, intraoperative 3D navigation systems have several limitations, including the high cost of equipment and prolonged surgical duration for complicated procedures. Use of a rapid prototyping drill guide template is a relatively simple and effective method to improve the accuracy of C1–C2 screw placement. In 2009, Lu et al. [14] introduced a "template with channels," a new design of a drill guide template with 2 navigation channels for C2 laminar screw placement, which has been popularized for placement of atlantoaxial vertebral pedicle screws [11,13]. However, the use of this template with channels is limited because it is not possible to adjust the drill direction based on the template, when necessary. If the soft tissue overlying posterior vertebral surfaces is not completely removed, the good fit between posterior vertebral surfaces and the template will not be achieved. In this condition, the "template with channels" cannot help to acquire ideal screw trajectory, and surgeons cannot adjust the drill direction based on the guidance of the template. Therefore, we designed a modified drill guide template based on the "template with channels" by Lu et al. To allow for intraoperative adjustment, the modified template had 2 location holes and guide rods instead of 2 guide channels. Using this modified template, surgeons can adjust the drill direction based on guidance of the modified template, when necessary (Figure 1). The aims of this study were to investigate the feasibility of using this modified template for atlantoaxial pedicle screw placement and to compare the outcomes of atlantoaxial pedicle screw fixation via the modified template and by the conventional method.

Material and Methods

Ethics statement

The study protocol was approved by the local Medical Ethics Committee. All study participants provided written informed consent and all clinical investigations were conducted in accordance with the principles expressed in the Declaration of Helsinki.

Patients and grouping

This prospective nonrandomized controlled study was designed to compare the clinical and radiological outcomes of a modified drill guide template to those of the conventional method for atlantoaxial pedicle screw placement for treatment of AAI. Inclusion criteria were AAI due to congenital dysplasia, trauma, rheumatoid disease, and other causes. AAI patients who had undergone posterior upper cervical surgery before were excluded.

Between June 2012 and December 2014, a total of 54 consecutive patients (34 males and 20 females) with a mean age of 45.3 years (age range, 12–54 years) who underwent surgery for AAI were included in this study. All patients underwent posterior atlantoaxial fixation with pedicle screw placement. Of these cases, 25 underwent surgery with the assistance of the modified drill guide template and intraoperative fluoroscopy (template group), while the other 29 cases underwent surgery only using intraoperative fluoroscopy (conventional group) (Table 1).

All 54 cases presented with symptoms of craniocervical junction pain and limb anesthesia or dyskinesia to various degrees. There was no significant difference in preoperative Japanese Orthopaedic Association (JOA) score between the template and conventional groups (p=0.442), indicating similar conditions of participants between the 2 groups. Of the included study participants, 26 had congenital craniovertebral junction dysplasia or os odontoid, 22 had a traumatic atlantoaxial fracture or disruption of the transverse ligament, and 6 had a history of rheumatoid disease.

Construction of the modified drill template

For patients in the template group, preoperative computed tomography (CT) scans of the cervical spine of all patients were acquired using the LightSpeed VCT system (General Electric, Piscataway, NJ, USA) at a slice thickness of 0.625 mm and in-plane resolution of 0.35 mm. Then, CT images were stored in DICOM format and imported to Mimics® v17.0 (Materialise, Leuven, Belgium) to reconstruct a 3D model of the atlantoaxial vertebrae. Solitro and Amirouche proposed a rigorous method to create pedicle screw trajectory [15]. In this study, a cylinder (diameter, 3.5 mm) was created as a representation of a pedicle screw in the "virtual" environment of Mimics software. The ideal trajectory of a C1–C2 pedicle screw was created by direct observation of the relationship between the cylinder and pedicle cortical bone in the axial, sagittal, and coronal planes.

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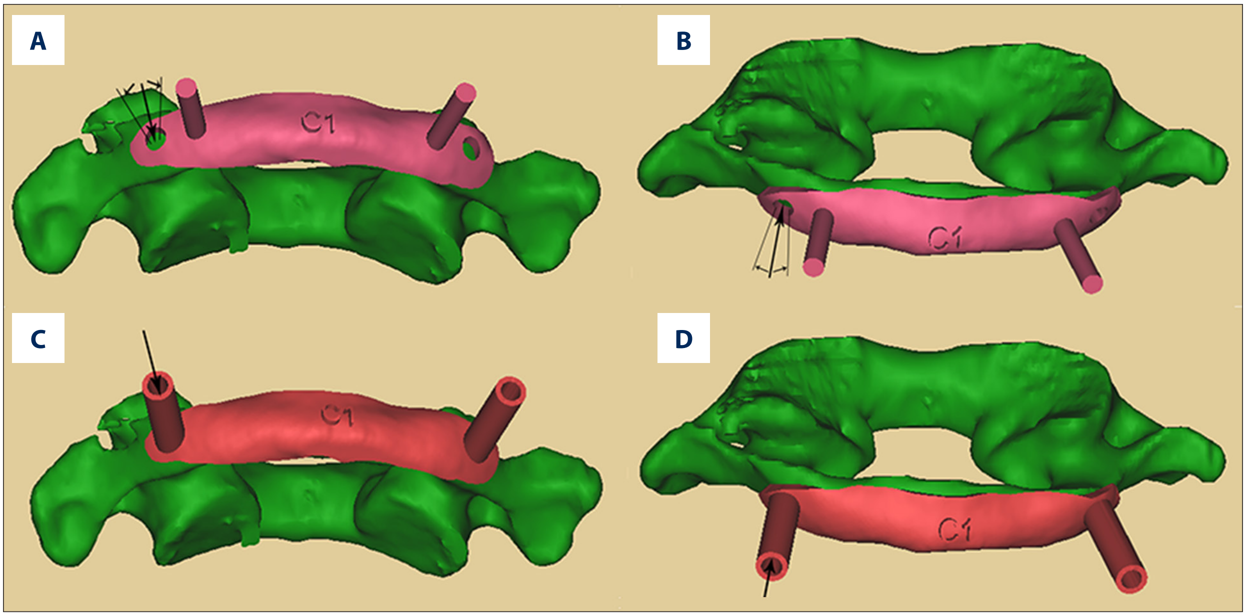

Figure 1. The modified and prior designs of drill guide templates. (**A, B**) The modified design of template has 2 location holes and guide rods. Drill direction can be easily adjusted based on guidance of the template when necessary. (**C, D**) The prior template has 2 guide channels. Drill direction cannot be adjusted based on guidance of the template.

Table 1. Demographics of the template and conventional groups.

	Template group	Conventional group
Patients (n)	25	29
Age (year)	43.5 (12–52)	46.9 (25–54)
Sex (Men/Women)	16/9	18/11
Causes of instability		
Congenital dysplasia	11	15
Traumatic fracture	10	7
Transverse ligament disruption	2	3
Rheumatoid disease	2	4
Follow-up time (month)	24.7 (12–39)	28.0(14–42)

The cylinder was contained entirely within the pedicel cortical bone by meticulous adjustment in different planes. The 3D atlantoaxial model and representations of the cylindrical screws were transferred to 3-matic v9.0 (Materialise) to create a modified drill guide template with rods. The surface of the template was created as the inverse of the posterior arch, lamina, and spinous process, thereby enabling a "lock-and-key" fit between the template and vertebral surfaces. Instead of creating a drill template with 2 channels, as described by Lu et al. [14], we modified the design and created a template with 2 guide rods and 2 location holes.

The 3D atlantoaxial model and its corresponding template were exported into stereolithography (STL) format. Then, the virtual 3D atlantoaxial model and drill template were converted into a physical model and template produced in acrylate resin (Somos 14120; DSM Desotech, Heerlen, The Netherlands). The template resolution was 0.1 mm, which was higher than the CT resolution. The physical model and template were produced using the STL rapid prototyping method (Form1+; Formlabs, Somerville, MA, USA).

Surgery technique

All AAI patients underwent posterior atlantoaxial fixation by the same surgeons. After induction of general anesthesia, patients were placed in prone position. A standard midline incision was made to expose the posterior bony structure of the

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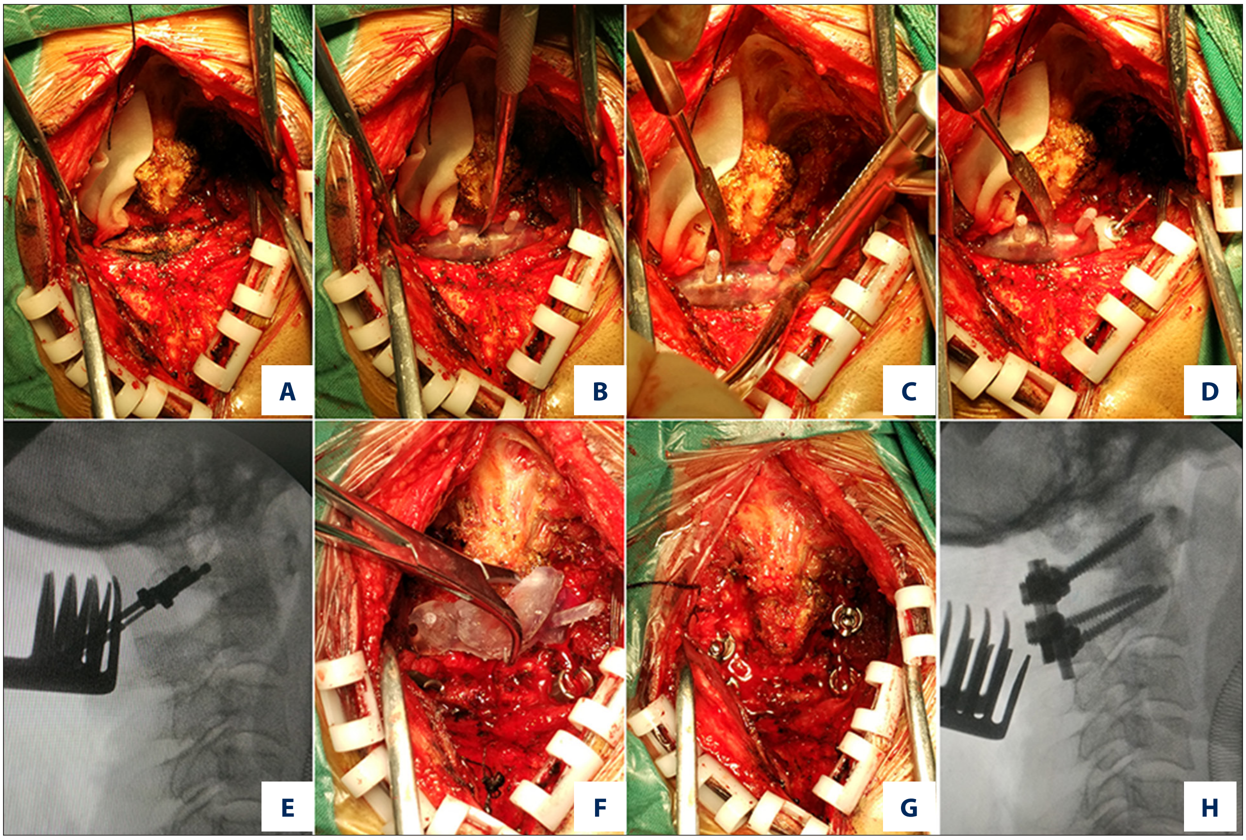

Figure 2. Procedures of atlantoaxial pedicle screw insertion with the assistance of the modified template. (**A**) Atlas was exposed after removing the surrounding soft tissue. (**B**) Template for atlas was placed. (**C**) Hand drill was used through the location hole, parallel to the guide rod of the template, to drill the pedicle of atlas. (**D**) Locating pins were placed. (**E**) Intraoperative fluoroscopy confirmed the good position of locating pins. (**F**) Template for axis was placed. (**G**) Insertion of atlas and axis pedicle screws. (**H**) Intraoperative fluoroscopy confirmed the good position of atlantoaxial pedicle screws.

atlantoaxial vertebrae. For patients in the conventional group, posterior atlantoaxial pedicle screws were placed by careful analysis of imaging and knowledge of anatomic landmarks. The entry point of C1 pedicle screw trajectory was 18–22 mm lateral to the midline at the C1 posterior arch. The trajectory was about 10 degrees in the medial direction and 10 degrees in the cephalad direction. The C2 pedicle screw trajectory was 20–30 degrees in the medial direction and 20–30 degrees in the cephalad direction. Intraoperative fluoroscopy was used for posterior atlantoaxial pedicle screw placement.

For patients in the template group, the modified drill guide template was used for atlantoaxial pedicle screw placement. Before surgery, low-temperature sterilization was used for the template. After a standard midline incision was made, soft tissue overlying the posterior arch of C1, and spinous process, lamina, and lateral masses of C2 were removed completely to achieve a good fit between the posterior vertebral surfaces and the drill template. The drill template was press-fitted firmly onto the posterior vertebral surfaces. Good fit between posterior vertebral surfaces and the template was achieved. One surgeon held the template steady, and another surgeon started to drill the insertion hole. Piezosurgery was used to create an insertion hole through the location hole of the template. Then a hand drill was used through the location hole, parallel to the guide rod of the template, to drill the pedicle of the atlas and axis. Intraoperative fluoroscopy was used to confirm that an ideal trajectory was achieved. If the hand drill deviated from the ideal trajectory because of a poor fit between the template and posterior vertebral surfaces, the drill direction was adjusted based on guidance of the drill template. After an ideal trajectory was confirmed by intraoperative fluoroscopy, the template was taken away, and threaded 3.5-mm screws were placed (Figure 2). Preflex rods were then fixed to the screws bilaterally.

Outcome evaluation

One author (F.Y.), who did not participate in any of the surgeries, independently assessed the accuracy of screw insertion. Postoperative CT scans were acquired to measure pedicle screw angle and evaluate the accuracy of screw insertion.

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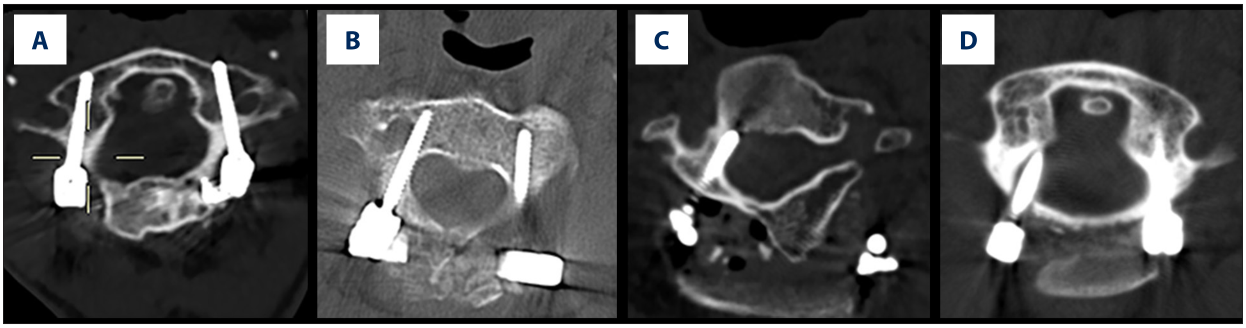

Figure 3. Accuracy of atlantoaxial screw insertion was evaluated according to the grading system. (**A**) 0 – no deviation (the screw was contained entirely within the cortex). (**B**) 1 – deviation of ≤2 mm or less than half the diameter of the screw. (**C**) 2 – deviation of >2 mm and <4 mm, or more than half the diameter of the screw. (**D**) 3 – deviation of >4 mm or complete deviation.

Furthermore, in the template group, transverse and sagittal angles of pre- and postoperative atlantoaxial pedicle screw trajectories were measured. In both template and conventional groups, axial view CT of the entire length of each pedicle screw was used to evaluate the medial and lateral deviations of the pedicle screws according to the grading system reported by Lu et al. [16] as follows: 0 – no deviation (the screw was contained entirely within the cortex); 1 – deviation of ≤2 mm, or less than half the diameter of the screw; 2 – deviation of >2 mm and <4 mm, or more than half the diameter of the screw; and 3 – deviation of >4 mm or complete deviation (Figure 3).

All patients were followed up at 3, 6, 12, and 24 months postoperatively. At each follow-up, JOA and visual analogue scale (VAS) of neck and arm assessments were made. Plain radiograph, dynamic plain radiograph, and multidetector CT were performed during each follow-up visit to evaluate bone fusion and detect fixation failure.

Statistical analysis

Data were analyzed by the 2-tailed *t* test and rank-sum test using SPSS 19.0 statistical software (IBM-SPSS, Inc., Chicago, IL, USA). Data are presented as the mean ± standard deviation. A probability (*p*) value of <0.05 was considered statistically significant.

Results

Surgery was successful for all 54 AAI patients, with no incidence of intraoperative spinal cord injury or VA injury. Nine patients with traumatic atlantoaxial fractures, but no disruption of the transverse ligament, underwent posterior atlantoaxial pedicle screw fixation without fusion, while the other 45 patients underwent posterior fixation with atlantoaxial fusion. Bleeding in the venous plexus occurred in 6 patients (1 in the template group and 5 in the conventional group) when drilling the atlantoaxial pedicle. Postoperative complications included 2 cases of occipital neuralgia in the conventional group resulting from irritation of the C2 nerve roots, which was alleviated after conservative treatment. There were no significant differences in surgical duration (p=0.127) or intraoperative blood loss (p=0.121) between the template and conventional groups. The use of intraoperative fluoroscopy was significantly decreased in the template group (p<0.001).

A total of 216 pedicle screws (100 in the template group and 116 in the conventional group) were placed. In the template group, 26 of the 100 screws were inserted after the adjustment of drill direction. The adjustment of drill direction was caused by the poor fit between posterior vertebral surfaces and the template. There were no significant differences in transverse or sagittal angles between pre- and postoperative atlantoaxial pedicle screws (p>0.05) (Table 2). Of the 100 screws in the template group, 96 (96.0%) were rated as grade 0, 4 (4.0%) as grade 1, and none as grade 2 or 3. Of the 116 screws in the conventional group, 103 (88.8%) were rated as grade 0, 8 (6.9%) as grade 1, 4 (3.4%) as grade 2, and 1 (0.9%) as grade 3. The accuracy rate of screw insertion was significantly greater in the template group than in the conventional group (p=0.045). The 4 screws rated as grade 2 (2 in atlas and 2 in axis) and the 1 screw rated as grade 3 in the atlas deviated medially from the cortex and entered the spinal canal. Fortunately, malposition of these screw did not induce neurological damage (Figure 4).

Of the 54 patients, 52 (96.3%) completed the follow-up for more than 12 months. The average follow-up period was 26.4 months (range, 12–42 months). Two patients (3.7%) in the conventional group were lost to follow-up after 6 months. Preoperative JOA (p=0.442) and VAS (neck, p=0.809; arm, p=0.408) scores were similar between groups. At the last follow-up, all patients showed significant improvements in postoperative JOA score (p<0.001), while the postoperative VAS score significantly decreased (neck, p<0.001; arm, p<0.001). There were no significant differences in postoperative JOA score (p=0.782), improvement rate of JOA score (p=0.921), and postoperative VAS score

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Table 2. Comparisons of transverse and sagittal angles between pre- and postoperative atlantoaxial pedicle screw trajectories.

Screw trajectory	Transverse angle (°)		Sagittal angle (°)	
	Left	Right	Left	Right
C1 preoperative	7.87±1.36	8.70±1.84	7.87±1.80	7.98±1.85
C1 postoperative	7.25±2.18	8.29±1.03	7.47±2.03	8.56±1.75
P	0.219	0.400	0.406	0.232
C2 preoperative	22.43±3.46	22.28±3.40	26.32±3.40	24.85±2.77
C2 postoperative	23.53±2.63	22.38±2.17	24.52±3.16	25.65±2.78
P	0.161	0.892	0.079	0.298

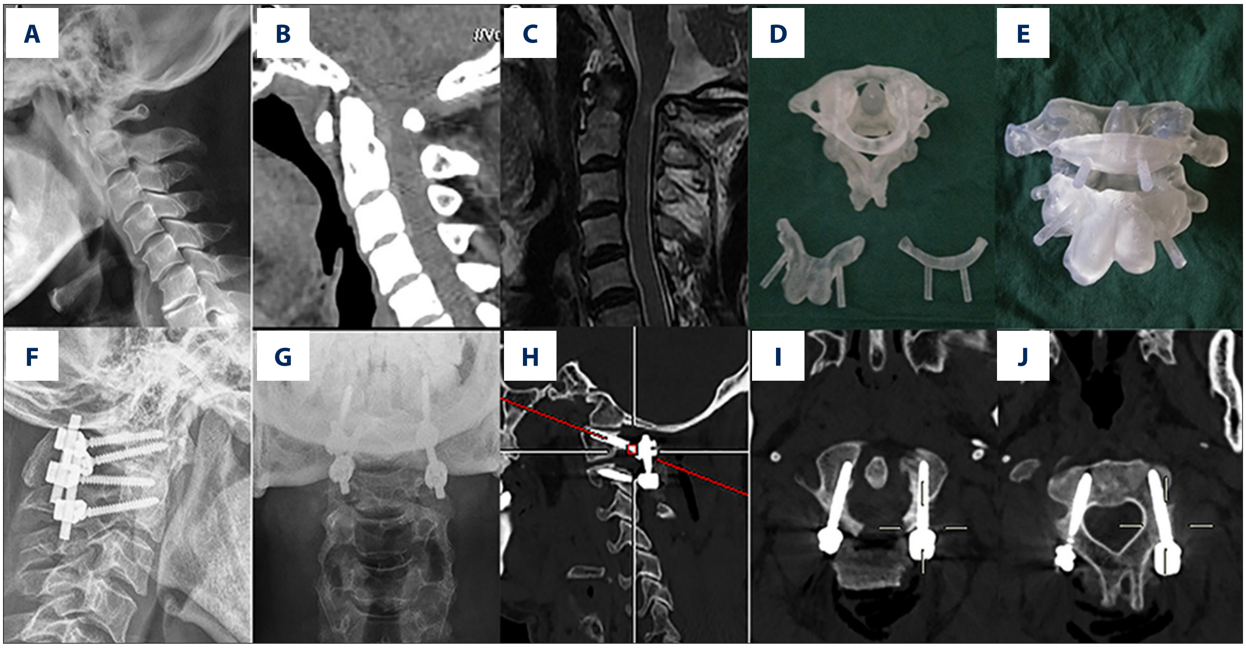

Figure 4. Representative images of a 53-year-old man with traumatic atlantoaxial dislocation and transverse ligament disruption. Posterior reduction and atlantoaxial pedicle screw fixation with fusion was performed. (**A–C**) Preoperative lateral radiograph, sagittal CT scan, and sagittal MRI showed evidence of atlantoaxial dislocation and compression of the cervicomedullary junction. (**D, E**) Atlantoaxial model and corresponding templates produced by the rapid prototyping technique. (**F, G**) Postoperative anteroposterior and lateral radiographs showed good positioning of the pedicle screws. (**H–J**) Postoperative sagittal and axial CT scans showed good positioning of the atlantoaxial pedicle screws.

(neck, p=0.172; arm, p=0.405) between the 2 groups at the last follow-up. Radiological outcomes were evaluated based on postoperative radiographs and CT scans. At the last follow-up, the postoperative fusion rate was 100%. There was no incidence of fixation failure or atlantoaxial redislocation (Table 3).

Discussion

Posterior C1–C2 pedicle screw fixation has been demonstrated to be rigid and stable for treatment of AAI. Several strategies of C1 pedicle screw placement have been introduced [1,2,17]. However, none of these strategies is universally safe because of significant anatomic variability among vertebrae [18]. The procedures for C1–C2 pedicle screw insertion are technically demanding and increase the risk of iatrogenic injury to the cervical spinal cord and vertebral arteries, which can be fatal [19,20].

Several reports have described the efficacy of intraoperative 3D navigation systems to aid in the placement of cervical pedicle screws [21–23]. A clinical study by Richter et al. [21] noted that the prevalence of pedicle perforations was 8.6% in a conventional treatment group and 3.0% in a 3D navigation group. However, intraoperative 3D navigation systems have several

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Table 3. Comparison of outcomes between the template and conventional groups.

	Template group	Conventional group	P
Intraoperative fluoroscopy (times)	2.76±0.72	3.97±0.94	0.000
Operation time (minutes)	171.84±22.46	182.76±28.40	0.127
Blood loss (ml)	309.20±33.41	322.07±26.51	0.121
Accuracy of screw insertion			0.045
0	96	103	
1	4	8	
2	0	4	
3	0	1	
Preoperative JOA	11.16±1.82	11.55±1.88	0.442
Postoperative JOA	14.16±1.40	14.28±1.62	0.782
Improvement rate of JOA (%)	53±15	54±16	0.921
Preoperative VAS			
Neck	5.28±0.98	5.34±0.97	0.809
Arm	5.16±0.99	5.38±0.94	0.408
Postoperative VAS			
Neck	2.60±0.866	2.93±0.884	0.172
Arm	2.68±0.900	2.86±0.693	0.405

Improvement rate of JOA = (Preoperative JOA – Preoperative JOA)/(17 – Preoperative JOA) ×100%.

limitations, including high cost of equipment and prolonged surgical duration for complicated procedures. Besides, as intraoperative 3D navigation requires configuration of reference points, any changes in spinal alignment will induce registration or probing errors.

The use of customized drill guide templates, which were first introduced by Radermacher et al. [24] for surgeries of the hip and knee, can also help to improve the accuracy of spinal screw insertion. A series of drill guide templates have been designed. Goffin et al. [25] introduced a template with clamps to interface with the posterior structures of the vertebrae. Berry et al. [26] adopted a 3 V-shaped knife design to support the drill guide template. More recently, Lu et al. designed a template with 2 guide channels by reverse engineering for screw insertion of the lumbar [27], cervical [16], and thoracic [28] vertebrae. This template design with 2 channels has been popularized for insertion of spinal screws [11,12,29–32]. Compared with intraoperative 3D navigation methods, guide templates eliminate the need for complex equipment and complicated intraoperative procedures, thereby reducing the surgical duration. When compared with the conventional method, a guide template can result in greater accuracy of screw insertion. In a laboratory study, Lu et al. [16] placed 84 cervical pedicle screws into 6 specimens, which resulted in the placement of 82 (97.6%) screws entirely within the pedicle, although 2 (2.4%) screws slightly perforated the pedicle. A clinical study by Sugawara et al. [31] reported that none of 58 thoracic pedicle screws violated the cortices of the pedicles.

However, the template with 2 channels proposed by Lu et al. [14] has a major limitation, as the drill direction cannot be intraoperatively adjusted based on the template, when necessary, without removing the template. To solve this problem, we designed the modified drill guide template with 2 location holes and 2 guide rods. The advantage of the modified template is that surgeons can adjust the drill direction easily based on the template guidance, which is difficult when using the "template with channels". If intraoperative fluoroscopy shows that the actual trajectory deviates from the ideal trajectory, the drill direction can then be adjusted based on guidance of the template.

In the current study, the template group had significantly lower intraoperative fluoroscopy frequency ($p<0.001$), which was in accordance with the findings of a prior study [13]. Postoperative CT scans showed that the template group had higher accuracy of screw insertion ($p=0.045$) than the conventional group. In the conventional group, there was even 1 screw rated as

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grade 3 in the atlas deviated medially from the cortex and entered the spinal canal, which posed danger to the patient. Fortunately, malposition of the screw did not induce neurological damage. These results demonstrate the advantages of using the modified drill guide template for atlantoaxial pedicle screw placement. In the template group, there were no significant differences in transverse or sagittal angles between pre- and postoperative atlantoaxial pedicle screw trajectories, which proves the reliability of the modified template.

There are some differences in results between our study and prior studies using drill guide templates. In our study, of 100 screws in the template group, 96 (96.0%) were rated as grade 0, 4 (4.0%) as grade 1, and none as grade 2 or 3. However, in a cadaver study, Hu et al. [11] placed 64 C1 and 64 C2 pedicle screws with the assistance of a drill guide template, which resulted in no violation of the pedicle cortex. This screw malposition rate was lower than that in our template group, likely because it is clearly easier to insert screws in cadavers. Moreover, our study showed that the template group had higher accuracy of screw insertion (p=0.045) than the conventional group. But a study by Yang et al. [13] showed no significant difference in screw malposition rate between the template and conventional groups. This difference can be explained by the following reasons. Firstly, the design of the guide templates used in the 2 studies was different, and our template had the advantage of intraoperative drill direction adjustment. Secondly, the sample sizes for posterior atlantoaxial screw fixation were different between this study and the prior study (54 *vs.* 25 patients, respectively). Thirdly, the evaluation methods of screw malposition rate were also different between the 2 studies, and we applied a rigid 4-level category instead of a 2-level category. This study did not involve direct comparison between "template with channels" and the modified template. Further study is needed for comparison of the 2 templates in the future.

Using the modified drill guide template can minimize, but not completely eliminate, screw malposition. There are potential sources of error in this modified template design. If clean preparation of posterior vertebral bony surfaces is not accomplished, then a good fit between the template and bony surfaces will not be ensured. In addition, any movement between the template and bony surface due to vibration or other causes while drilling can induce considerable deviation from the ideal screw trajectory. Therefore, the template should be placed firmly in position while drilling.

The design of the modified template has several limitations in common with that of the template with channels. First, complete removal of soft tissue on bony surfaces is required, which is key to accurate screw insertion. Second, even though production of each template costs only ~ US $30, it takes 2–3 days from image transfer to final production [11], so the use of the proposed template is not suitable for emergency surgery.

Conclusions

The results of this study suggest that the use of this modified drill guide template for atlantoaxial pedicle screw placement is feasible and can significantly lower the screw malposition rate and the frequency of intraoperative fluoroscopy, with similar clinical outcomes as the conventional method. Application of this modified drill guide template provides an alternative for atlantoaxial pedicle screw insertion.

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