A Comparative Study of C2 Pedicle or Pars Screw Placement with Assistance from a 3-Dimensional (3D)-Printed Navigation Template versus C-Arm Based Navigation

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Background: Since C2 is adjacent to important nerves and blood vessels, the implantation risk of C2 internal fixation in this area is high and requires high accuracy. This study mainly discussed the application value of 3-dimensional (3D)-printed navigation template in C2 screw placement.

Material/Methods: A retrospective study compared 3D-printed navigation template-assisted screw placement (group A, n=32) and the C-arm based navigation-assisted screw placement group (group B, n=32). Group A was divided into 2 sub-groups: A1 (C2 pedicle screw placement) and A2 (C2 pars screw placement); group B was divided into B1 (C2 pedicle screw placement) and B2 (C2 pars screw placement). The accuracy and safety of screw placement and clinical outcomes were evaluated.

Results: There were 64 C2 screws placed in group A, and 95.31% achieved a grade A accuracy rating, including 52 screws in group A1 (96.15% grade A) and 12 screws in group A2 (91.67% grade A). A total of 64 C2 screws were placed in group B, and 84.38% achieved a grade A accuracy rating, including 50 screws in group B1 (84.00% grade A) and 14 screws in group B2 (85.71% grade A). The accuracy of screw placement differed significantly between groups A and B (P=0.041) and between groups A1 and B1 (P=0.039) but not between groups A2 and B2 (P=0.636). The postoperative efficacy of the 2 groups was satisfactory. And there were no complications of blood vessels or nerves related to screw placement in either group.

Conclusions: Although 3D-printed navigation template-assisted and C-arm based navigation-assisted C2 pedicle and pars screw placement provided similar safety and clinical efficacy, 3D-printed navigation template technology achieved more accurate C2 pedicle screw placement.

MeSH Keywords: Imaging, Three-Dimensional • Patient Navigation • Surgical Flaps

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Background

The invention of C2 screw internal fixation technology has further advanced the operative treatment of diseases of the upper cervical spine. C2 pedicle screws and pars screws are often the preferred internal fixation methods for posterior operation of the upper cervical spine [1]. C2 pedicle screws are considered a reliable method of internal fixation because of their strong stability. However, the use of pedicle screws significantly enhances the risk of vertebral artery injury in patients with high-riding vertebral arteries (HRVAs), and par screws are another widely used, secure and useful method of screw placement [2,3]. C2 has a complex anatomical structure, with a small pedicle, and is adjacent to the vertebral artery, spinal cord, nerve root, and other important tissues. Freehand for C2 screws placement is difficult and risky, and it is easy to cause vertebral artery injury, nerve injury, or even more serious consequences [4–6]. With the development of digital orthopedic technology, computer navigation technology, and 3-dimensional (3D)-printed navigation template technology have been widely used in various types of spinal surgery, especially the application of these 2 technologies in cervical spine surgery. Both techniques can increase the accuracy of fixation with C2 pedicle screws and par screws, greatly improving the safety and effectiveness of surgery [1,7,8]. However, there has been no clear comparison of the accuracy of the 2 techniques in C2 pedicle screw and pars screw placement or related surgical complications. The aim of the present study was to compare the safety and accuracy of 3D-printed navigation template-assisted versus C-arm based navigation-assisted C2 pedicle or pars screw placement.

Material and Methods

The inclusion criteria were as follows: 1) patients who underwent placement of C2 pedicle screws or pars screws with either the 3D-printed navigation template or C-arm based navigation; 2) patients with complete preoperative and postoperative data. Exclusion criteria: 1) patients who underwent placement of C2 pedicle screws or pars screws with a freehand technique; 2) patients whose C2 screws were placed using an anterior approach; 3) patients who had a previous history of operation of the upper cervical spine; and 4) patients who had metastatic or primary cervical spine tumors.

A total of 64 patients who underwent posterior internal fixation with C2 pedicle screws or C2 pars screws were included in this study. According to the method of screw placement, they were divided into the 3D-printed navigation template-assisted screw placement group (group A) and the C-arm based navigation-assisted screw placement group (group B). Group A was divided into 2 subgroups: A1 (3D-printed navigation template-assisted C2 pedicle screw placement) and A2 (3D-printed navigation template-assisted C2 pars screw placement); group B was divided into B1 (navigation-assisted C2 pedicle screw placement) and B2 (navigation-assisted C2 pars screw placement). Lee et al. [9] measured the arterial parameters of the intravascular vertebral artery (IVA), including “medial-shifting (MS)” and “high-riding (HR)” arteries. MS was divided into 3 levels: A, B and C. HR was divided into 3 levels: 0, 1 and 2. IAVA was classified into 9 types: A-0, A-1, A-2, B-0, B-1, B-2, C-0, C-1, and C-2. Among them, the C-2 category and part of the B-2 category belong to HRVAs. We analyzed the anatomical feasibility C2 pedicle screw placement by preoperative cervical computed tomography (CT) and CT angiography (CTA). C2 pars screws were selected to replace C2 pedicle screws to reduce the surgical risk for patients with vertebral artery types B-2 and C-2. Group A included 32 patients (21 males and 11 females) aged 27 to 64 years (47.2±11.1 years) who underwent C2 screw placement with 3D-printed navigation template assistance in our hospital from June 2015 to September 2018. A total of 64 C2 screws were placed, including 50 screws in group A1 and 14 screws in group B1. Disease types included fracture of the odontoid process of the axis in 15 patients, axis fracture in 8 patients, atlantoaxial dislocation in 5 patients, cervical spondylotic myelopathy in 2 patients, and basilar impression in 2 patients. Group B included 32 patients (19 males and 13 females) aged 25 to 60 years (45.6±10.4 years) who underwent C2 screw placement with computer navigation assistance in our hospital from January 2014 to September 2018. A total of 64 C2 screws were placed, including 52 screws in group B1 and 12 screws in group B2. Disease types included fracture of the odontoid process of the axis in 16 patients, axis fracture in 9 patients, atlantoaxial dislocation in 5 patients, cervical spondylotic myelopathy in 1 patient, and basilar impression in 1 patient.

Production of the 3D-printed navigation template and surgical procedures

First, plain computed tomography (CT) scanning with 1-mm slices was performed on the operative segment of the cervical spine of 32 patients. The CT images were stored in DICOM format and imported into the 3D reconstruction software MIMICS 16.0 (Materialise Company, Belgium) to create a 3D reconstruction model of C2. The 3D model was exported in STL format. Then, the optimal screw path of the C2 pedicle screws or C2 pars screws was designed after importing the model into 3-MATIC (Materialise company, Belgium) software, and the morphological anatomy of the spinous process, lamina and lateral mass of the axis were extracted after the screw placement paths were determined. A reverse template was designed in the software and fitted with the optimal screw path of the pedicle screw or pars screw to form a guide template with a positioning guide hole. The template file was sliced and input into a 3D printer. A 3D-printed navigation template (Figure 1C)
was printed with photosensitive resin material to assist placement of the C2 pedicle screws or pars screws. Finally, screw placement was simulated on the model before operation to verify the accuracy of the navigation template.

The 3D model and 3D-printed navigation template were sterilized by a plasma sterilizer before surgery. All operations were completed by the same experienced spinal surgeon. The preset placement of the screw was simulated according to the 3D-printed navigation template before operation (Figure 1A–1C). All patients were in prone position, and the head and neck maintained in the neutral position. We performed a conventional posterior incision and fully exposed the spinous process, lateral masses and lamina of the C2 vertebra. The soft tissues of C2 spinous process and lamina were completely removed, and the paravertebral muscles were fully separated by a retractor. The guide template was attached to the spinous process, vertebral lamina and articular process of C2 to tightly combine and fix them in the corresponding position. We used a high-speed drill to drill the path of the screw along the direction of the guide hole, and the probe was used to ensure the safety and accuracy of the screw trajectory. Then, we tapped and placed the appropriate screw.

C-arm based navigation

After general anesthesia, the patient was placed in the prone position. The skull was continuously maintained with appropriate traction weight. Then, we connected the navigation equipment. The navigation reference frame was fixed on the Mayfield headframe and covered completely with sterile sheets. The intraoperative cervical CT images were obtained through the navigation system combined with the self-rotating scanning of C-arm (Arcadis Orbic 3D, Siemens Healthcare GmbH Henkestr, Erlangen, Germany). Then, the images were transferred to the navigation system (Stryker Navigation), and the instruments were registered and verified for accuracy. The navigation probe guided by CT images was used to determine the entry point and the direction of the pars screws or pedicle screws, and the goal was to select the optimal screw length and avoid the neurovascular structures. The high-speed navigation drill was used to complete preparation of the screw path along the desired trajectory. The probe was then used to determine the safety of the screw path. After tapping, the appropriate length of C2 screw was placed down the desired trajectory.

All surgeries were performed under neuroelectrophysiological monitoring, and group A and B were performed by 2 experienced spinal surgeons, respectively. The surgeon in group A preferred 3D-printed navigation templates technology and mastered 3D-printed templates technology, while the surgeon in group B preferred navigation technology and mastered navigation technology. All patients in this study voluntarily chose the surgical method after being informed of the technologies of navigation assistance and guide plate assistance and the possibility of related complications. All patients signed informed consent forms for the operation before surgery.

Evaluation methods

The time of placement of each C2 screw, the amount of bleeding during the operation, and the frequency of fluoroscopy during operation were recorded. The VAS (visual analogue scale) and JOA (Japanese Orthopedic Association) scores were recorded preoperatively and at 3 and 6 months postoperatively. All patients underwent postoperative plain CT scans of the cervical spine. The accuracy of screw placement and the incidence of related complications in the 2 groups were compared. The accuracy of C2 pedicle screw and pars screw placement was divided into 5 grades according to the new C2 screw grading...
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system proposed by Hlubek et al. [1] as follows: grade A, screw was completely confined within the cortical surfaces; grade B, transverse foramen breach with the screw obstructing 1–25% of the foramen; grade C, transverse foramen breach with the screw obstructing 26–50% of the foramen; grade D, transverse foramen breach with the screw obstructing 51–75% of the foramen; grade E, transverse foramen breach with the screw obstructing 76–100% of the foramen; grade M, medial breach into the spinal canal. Grade A was defined as accurate screw placement, grade B as acceptable screw placement, and grades C, D, E, and M as poor screw placement, and screw placement with intraoperative vertebral artery or nerve injury was directly defined as grade M. The rate of screw placement of grade A accuracy in each group was calculated, and the differences between groups A and B, A1 and B1, and A2 and B2 were compared.

Statistical analysis

SPSS 19.0 software was used for statistical analysis. Measurement data are presented as the mean±standard deviation (SD). The independent t-tests were used to compare the clinical data of the 2 groups, and differences in clinical data before and after the operations were compared by paired t-tests. The chi-square test was used to analyze the difference in the accuracy of achieving a grade A screw rating between the 2 groups. In all analyses, a P-value <0.05 was considered statistically significant.

Results

Clinical outcomes

The time required for screw placement, fluoroscopy frequency and intraoperative blood loss of the 2 groups are shown in Table 1. In the 2 groups, the time of screw placement, intraoperative fluoroscopy frequency and technology costs were significantly better in group A than in group B (P<0.05), while the difference in intraoperative blood loss was not statistically significant (P>0.05). Preoperative VAS or JOA scores did not differ significantly between the two groups (P>0.05), and the VAS and JOA scores at 3 and 6 months postoperatively were significantly improved compared with the preoperative scores (P<0.05) but did not differ significantly between the 2 groups (P>0.05) (Table 2). There was no screw loosening, broken screw or broken rod in the 2 groups, and all the patients were completely fused after surgery.

Accuracy evaluation

A total of 64 C2 screws were placed in group A with the following ratings: 61 grade A screws, 2 grade B screws, and 1 poor
grade M screw, but there were no poor screw placement grades of C, D, or E. A total of 52 C2 screws were placed in group A1 with the following ratings: 50 grade A screws (Figure 2A–2C), 1 grade B screw, and 1 poor grade M screw, but there were no poor screw placement grades of C, D, or E. A total of 12 C2 screws were placed in group A2 with the following ratings: 11 grade A screws and 1 grade B screw (Figure 3A–3C), and there were no poor screw placement grades of C, D, E, or M. A total of 64 C2 screws were placed in group B with the following ratings: 54 grade A screws, 6 grade B screws, and 4 poor grade M screws, but there were no poor screw placement grades of C, D, or E. A total of 50 C2 screws were placed in group B1 with the following ratings: 42 grade A screws (Figure 4A, 4B), 4 grade B screws (Figure 5A–5C), and 4 poor grade M screws, but there were no poor screw placement grades of C, D, or E. A total of 14 C2 screws were placed in group B2 with the
following ratings: 12 grade A screws and 2 grade B screws, with no poor screw placement of C, D, E, or M. The accuracy of achieving grade A screw placement in group A and B was 95.31% and 84.38%, respectively (P=0.041). The accuracy of achieving grade A screw placement in groups A1 and B1 was 96.15% and 84.00%, respectively (P=0.039). The accuracy of achieving grade A screw placement in the groups A2 and B2 was 91.67% and 85.71%, respectively (P=0.636) (Table 3). There were no complications of blood vessel or nerve injury related to screw placement in either group.
Discussion

Goel et al. [10] first reported the use of C2 pedicle screws. The entry point of the screw was located in the middle of the upper and lower articular processes of C2. The head inclination was 20–25°, and the inclination was 15–30°. A biomechanical study by Su et al. [3] found that the pull-out strength of the C2 pedicle screw was almost double that of the C2 pars screw. The internal fixation system consisting of a C2 pedicle screw has ideal strength of fixation. Previous biomechanical studies [11–13] showed that pedicle screws had greater insertional torque and peak pullout strength than pars screws. However, in some patients, when the vertebral artery passes through the C2 transverse foramen, flexion, and high arch deformity are observed, which makes the pedicle screw placement difficult and risky. Incidence of HRVAs at C2 of 14.5% and 16.5% have been reported [14,15]. This anatomical variation significantly increases the risk of vertebral artery injury when C2 pedicle screws are placed [14]. Others have shown that C2 pars screw placement is a safe alternative [16,17]. Although the stability of C2 pars screw is weaker than that of pedicle screw, C2 pars screw is safer in patients with HRVAs. And Elliott et al. [16] considered that C2 pars screw has good biomechanical properties. In the C2 vertebral body, the vertebral artery in the C2 transverse foramen is close to the C2 pedicle and lateral mass, and imprecise screw placement will lead to serious blood vessel damage, especially main vertebral artery damage. Hlubek et al. [1] placed 426 C2 pedicle or pars screws in 220 patients, and 2 patients suffered from vertebral artery damage. Therefore, accurate placement of C2 pedicle and pars screws is very important. With the rapid development of computer technology, navigation-assisted pedicle screw placement and 3D-printed navigation template-assisted pedicle screw placement have achieved satisfactory clinical results [18–20]. However, the accuracy and security of these 2 techniques for C2 screw placement remain controversial.

This study retrospectively compared the accuracy and safety of C2 pedicle and pars screw placement with assistance from a 3D-printed navigation template or C-arm based navigation. For patients with HRVAs, the relatively safe C2 pars screw placement was used as an alternative to reduce the risk and difficulty of C2 pedicle screw placement and improve the success rate of surgery. The accuracy of grade A screw placement in groups A and B was 95.31% and 84.38%, respectively (P=0.041). The results indicated that the accuracy of 3D-printed navigation template-assisted C2 pedicle or pars screw placement was better than that of C-arm based navigation-assisted screw placement. Among the 2 groups, the accuracy of grade A screw placement in groups A1 and B1 was 96.15% and 84.00%, respectively. In 2 previous studies [4,6], the accuracy of C2 pedicle screw placement via the freehand technique was 82.7% and 82.5%. Therefore, compared with traditional C2 pedicle screw placement, the 2 methods can accurately set the placement point and direction of the C2 pedicle screw and effectively increase the accuracy of C2 pedicle screw placement. Yu et al. [21] proved the safety and effectiveness of 3D-printed navigation templates based on 3D models of the cervical spine through cadaver studies, and this technology can achieve accurate C2 pedicle screw placement. Singh et al. [22] showed that intraoperative navigation significantly improved the accuracy of C2 pedicle screw placement. Our results are consistent with previous literature reports. But we found a significant difference (P<0.05) in accuracy between the 2 groups, indicating that screw placement by a 3D-printed navigation template was more accurate than navigation-assisted screw placement. Hlubek et al. [1] compared the accuracy of C2 pedicle screw placement between the freehand and navigation techniques and noted that displaced reference frames in the cervical region, displacement of C2 and registration inaccuracies in the navigation were the main factors affecting the accuracy of navigation-assisted screw placement of the C2 pedicle screw. In this study, there were 4 grade B screw ratings and 4 grade M screw ratings in group B1. We suggest that the main factor affecting the accuracy of screw placement might be the change in the navigation image.

Table 3. Comparison of the accuracy rate between the 3-dimensional (3D) printed navigation template group and the c-arm based navigation group.

| Group | Screws | Grade A | Grade B | Grade C | Grade D | Grade E | Grade M | Accuracy rate (%) |
|-------|--------|---------|---------|---------|---------|---------|---------|-------------------|
| A1    | 52     | 50      | 1       | 0       | 0       | 0       | 1       | 96.15             |
| B1    | 50     | 42      | 4       | 0       | 0       | 0       | 4       | 84.00             |
| A2    | 12     | 11      | 1       | 0       | 0       | 0       | 0       | 95.31             |
| B2    | 14     | 12      | 2       | 0       | 0       | 0       | 0       | 85.71             |
| A (total) | 64 | 61 | 2 | 0 | 0 | 0 | 1 | 91.67 |
| B (total) | 64 | 54 | 6 | 0 | 0 | 0 | 4 | 84.38 |

The accuracy rate of grade A in A1 and B1 groups (P=0.039), the accuracy rate of grade A in A2 and B2 groups (P=0.636), and the accuracy rate of grade A in A and B groups (P=0.041).
caused by the mobility of C2 during the operation. Although we tried to reduce atlantoaxial mobility via continuous traction during surgery, we could not avoid it completely. The relevant literature [7,23,24] has also reported that navigation technology relies on the registration procedure for matching preoperative or intraoperative CT images with the patient’s actual vertebral anatomy. Vertebral displacement will lead to mismatching between the registered image and real-time spinal alignment during the operation, resulting in screw dislocation. By contrast, we used guide plate technology to design a 3D model by preoperative plain CT scanning of C2 and then made a 3D-printed navigation template with a positioning guide hole according to the anatomical shape of C2 to complete the planning of the screw trajectory. During the operation, the guide plate was directly adjusted and fixed to the C2 vertebral plate, spinous process and articular process. The C2 pedicle and pars screws were accurately placed through the guide holes, and the registration error caused by C2 displacement during the operation was successfully avoided. Our 3D-printed navigation template was a single vertebral guide plate, not a continuous guide plate, and each 3D-printed template matched the corresponding vertebral body. The intraoperative template of C1 was attached to C1 (if we use it), and the template of C2 was attached to C2. Therefore, when the patient was in prone position, the shape and arrangement of C1-C2 would not affect the intraoperative screw placement. Using the 3D-printed navigation template for screw placement, Zhang et al. [25] found that guide plate technology was not affected by adjacent vertebral bodies, the position of the patients or changes in respiratory movement. This technology can achieve accurate image registration based on the 3D model and help avoid errors caused by intraoperative vertebral displacement. Lu et al. [23] found that the guide plate clearly provided the surgeon with the best entry point and angle, making the operation safer and simpler. Unlike computer navigation, the position relationship between 3D-printed navigation template and the corresponding vertebral body was fixed, which can provide real-time navigation. Therefore, we conclude that the unique feature of the guide plate is that it is created based on the theory of reverse operation and can perfectly match the posterior surface of C2, especially for patients with anatomical variation and spinal deformity, and the 3D-printed navigation template can be used to place pedicle screws more safely, accurately, and quickly. Although there was also 1 grade B and 1 grade M screw ratings in group A1, our analysis showed that the incomplete removal of soft tissue led to a decrease in the accuracy rating of screw placement. The relevant literature [26,27] has also reported that soft tissue on the bony surface might affect the accuracy rating of screw placement when using 3D-printed navigation templates, leading to deviation of the entry point and angle of screw placement. However, we found that this limitation of navigation template technology is easier to control and avoid compared with the uncontrollable drawbacks of computer navigation, such as image drift. If the surgeon is more thorough in removing the soft tissue on the surface of C2 during the surgery, the accuracy of screw placement can be further improved, and accurate matching can be achieved. Taller et al. [28] found that the method of intraoperative CT-guided screw placement has the advantages of high accuracy, low risk and effective restoration in treating C2 vertebral fracture. We found that although CT-guided screw placement can determine the intraoperative position of the screw, this method can prolong the operation time, increase intraoperative blood loss, increase radiation exposure of operators and patients, and possibly cause intraoperative contamination. Therefore, we do not routinely use CT to determine the screw position during the operation. And we recommend using the assistive devices (navigation or 3D-printed templates technology) during screw placement to reduce the incidence of injury.

There were 1 and 2 grade B screw placement ratings in groups A2 and B2, respectively. The accuracy of grade A screw placement in groups A2 and B2 was 91.67% and 85.71%, respectively, (P<0.05). In C2 pars screw placement, the screw is located in the C2 lateral mass and does not enter the pedicle. Although the length of the pars screw is short, the strength of the resistance to pullout, rotation and flexion is less than that of the pedicle screw. The pars screw can significantly reduce the risk of vascular and nerve injury and increase the safety of screw placement in patients with HRVAs. On this basis, the guide template and navigation technologies can provide the optimal entry point and direction, so there was little difference between the two technologies in increasing the accuracy of C2 pars screw placement.

The VAS and JOA scores at 3 days and 6 months postoperatively were significantly improved compared with the preoperative VAS and JOA scores (P<0.05), and there was no significant difference between the 2 groups (P>0.05). This finding indicated that patients who underwent 3D-printed navigation template and navigation-assisted screw placement achieved better clinical efficacy postoperatively. In addition, there were no vascular or neurological complications related to screw placement in either group, indicating that both techniques can provide greater safety of screw placement. Kaneyama et al. [8] demonstrated the validity of 3D-printed navigation template-assisted screw placement, which can significantly improve the safety and accuracy of C2 pedicle and pars screw placement. Similarly, Yang et al. [29] used navigation to place upper cervical screws without vertebral artery injury or spinal cord injury, proving that this technique can improve the safety of screw placement.

We found that navigation technology not only requires complicated and expensive equipment but also has a rather steep learning curve. Once there are errors in the selection and
operation of reference points during navigation, repeated registration is required, which prolongs the operation time and fluoroscopy frequency and reduces the accuracy of computer navigation. However, the surgeon and equipment requirements for using a 3D-printed navigation template are low. The guide hole on the template can help to place pedicle and pars screws, which not only shortens the surgical time but also reduces the frequency of fluoroscopy use and the radiation exposure of surgeons and patients during the operation.

We summarized our experience using a 3D-printed navigation template for C2 pedicle and pars screw placement. 1) The attachment of the guide plate without soft tissue obstruction is key to screw placement. When we peel soft tissue from the bony surface, we must do so more thoroughly for 3D-printed navigation template-assisted screw placement than for traditional operation. The guide plate should be closely combined with the vertebral body to improve the stability of the guide plate, and the guide plate should be fixed by assistants to avoid intraoperative displacement. 2) We should design a guide hole of suitable length and drill to a certain depth when using a high-speed bit to prevent the screw from deviating from the track. 3) First, in vitro experiments were performed based on the preoperative model to determine the safety of the screw track. 4) The template design should not exceed the interval of a single vertebral body. It should be noted that the design and printing of 3D-printed navigation templates requires some time, the production cost of the guide template is generally 1100 CNY, and the production time is 1 day, so the guide template cannot be used in emergency surgery, and the direction of future research should focus on how to shorten the manufacturing time of guide templates and how to produce 3D-printed navigation templates more efficiently.

Limitations of this study include the following. 1) This study was a single-center retrospective study with a small sample size, and large samples and multi-center studies are required to verify the results. 2) There are many types of navigation systems, but only one type of navigation system was included in this study. However, there has been no study of the differences in C2 screw placement assisted using different navigation systems, and the incorporation of a single system has a greater impact on the results of this study.

Conclusions

Although 3D-printed navigation template-assisted and C-arm based navigation-assisted C2 pedicle and pars screw placement can provide similar safety and clinical efficacy, 3D-printed navigation template technology is superior to navigation technology in achieving accurate C2 pedicle screw placement. Moreover, 3D-printed navigation template-assisted screw placement does not require special equipment and high technology costs, thus significantly reducing the difficulty of the operation, simplifying the process of screw placement, and reducing radiation exposure. Therefore, this technique is suitable for wide application in hospitals at all levels.

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