A Novel Patient-specific Navigational Template for Cervical Pedicle Screw Placement

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Study Design. Prospective trial.

Objective. To develop and validate a novel, patient-specific navigational template for cervical pedicle placement.

Summary of Background Data. Owing to the narrow bony anatomy and the proximity to the vertebral artery and the spinal cord, cervical instrumentation procedures demand the need for a precise technique for screw placement. Patient-specific drill template with preplanned trajectory has been thought as a promising solution for cervical pedicle screw placement.

Methods. Patients with cervical spinal pathology (n=25) requiring instrumentation were recruited. Volumetric CT scan was performed on each desired cervical vertebra and a 3-D reconstruction model was generated from the scan data. Using reverse engineering technique, the optimal screw size and orientation were determined and a drill template was designed with a surface that is the inverse of the posterior vertebral surface. The drill template and its corresponding vertebra were manufactured using rapid prototyping technique and tested for violations. The navigational template was sterilized and used intraoperatively to assist with the placement of cervical screws. In total, 88 screws were inserted into levels C2–C7 with 2-6 screw in each patient. After surgery, the positions of the pedicle screws were evaluated using CT scan and graded for validation.

Results. This method showed its ability to customize the placement and the size of each screw based on the unique morphology of the cervical vertebra. In all the cases, it was relatively very easy to manually place the drill template on the lamina of the vertebral body during the surgery. The required time between fixation of the template to the lamina and insertion of the pedicle screws was about 80 seconds. 71 out of the 88 screws had no deviation and 14 screws had deviation <2mm, 1 screw had a deviation between 2 to 4 mm and there were no misplacements. Fluoroscopy was used only once for every patient after the insertion of all the pedicle screws.

Conclusions. The authors have developed a novel patient-specific navigational template for cervical pedicle screw placement with good applicability and high accuracy. This method significantly reduces the operation time and radiation exposure for the members of the surgical team. The potential use of such a navigational template to insert cervical pedicle screws is promising. This technique has been clinically validated to provide an accurate trajectory for pedicle screw placement in the cervical spine.

Key words: navigation; custom template, rapid prototyping, pedicle, cervical spine

Introduction

The use of pedicle screw based spinal instrumentation systems in the lumbar and thoracic spine has increased tremendously during the last decade because of their superior biomechanical properties and reduction possibilities. [1-2] Nevertheless, despite the perception that cervical pedicle fixation would provide superior holding strength, [3-5] cervical pedicle screws have not been implemented routinely because of large anatomic variations in the size and shape of cervical pedicles between individuals. [6-8] Moreover, the cervical region is more prone to pathologic entities such as inflammatory, neoplastic, and traumatic conditions which can distort familiar anatomy and make traditional spinal navigation more difficult and risky. [9] The small bony anatomy and the proximity to the vertebral artery and the spinal cord increase the need for very precise screw placement during cervical instrumentation procedures. [10]

Successful placement of pedicle screws in the cervical spine requires a thorough three-dimensional understanding of the pedicle morphology in order to accurately identify the ideal screw axis.[3, 11-12] Several methods have been explored for precise cervical pedicle screw placement including anatomic studies, image-guided techniques,[13] computer-assisted surgery system,[14] and drill templates.[15-20] These techniques can be broadly classified into five types: (1) techniques relying on anatomical landmarks and averaged angular dimensions; (2) techniques with direct exposure of the pedicle, e.g. by laminaminotomy; (3) CT-based computer assisted surgery (CAS), and (4) fluoroscopy-based CAS techniques. (5) Drill template techniques.

The accuracy of computer-assisted screw insertion has been demonstrated recently: The rate of pedicle perforations was 8.6% in the conventional group and 3.0% in the computer-assisted surgery group in 52 consecutive patients who received posterior cervical or cervicothoracic instrumentations using pedicle screws.[21] Another group has also reported similar results, in which the rate of pedicle wall perforation was found to be significantly lower in the computer-assisted group (1.2%) than in the conventional group (6.7%).[22] However, despite advances in instrumentation techniques and intra-operative imaging, successful implementation of posterior cervical instrumentation still remains a challenge. As reported by Ludwig et al,[23] 18% of the pedicles (C3–C7) of human cadaveric cervical spines instrumented with computer-assisted image-guided surgical system and Abumi technique had a critical breach. Thus, there are several caveats that should be considered: (1) Mastering these techniques require a lot of time. (2) Errors may occur when adjacent segments of the spine shift intraoperatively or if the registration frame and optical array get shifted. (3) The tracking of optical array devices can be obscured by the surgeons or surgical tools. (4) High cost of the technology. (5) These techniques can lengthen the duration of surgical procedures.

Considering these difficulties, this study introduces an ingenious, custom-fit navigational template for the placement of pedicle screws in the cervical spine and further validate it in the clinical settings. Based on this technique, the trajectory of the cervical pedicle screws were first identified based on the preoperative CT scan model. The drill template was then patient-specifically designed so that it can keep in close contact with the postural surface of the cervical vertebra in order to provide the best stability for drilling. To our knowledge, current literature has not yet reported the use of navigational template for transpedicular screw placement at the cervical spine.

Materials and Methods

25 patients (14 male, 11 female, age 17–53 years) with cervical spinal pathology included 10 patients with destabilizing cervical spine injuries, 4 patients with cervical spondylotic myelopathy, and 11 patients with basilar invagination requiring instrumentation underwent cervical pedicle screw placement using a novel, patient-specific navigational template technique. According to this technique, a spiral three-dimensional (3-D) CT scan (LightSpeed VCT, GE, USA) was performed preoperatively on the cervical spine of each patient with a 0.625-mm slice thickness and 0.35-mm in-plane resolution. The images were stored in DICOM format, and transferred to a workstation running MIMICS 10.01 software (Materialise, Belgium) to generate a 3-D reconstruction model of the desired cervical vertebra (Fig. 1).

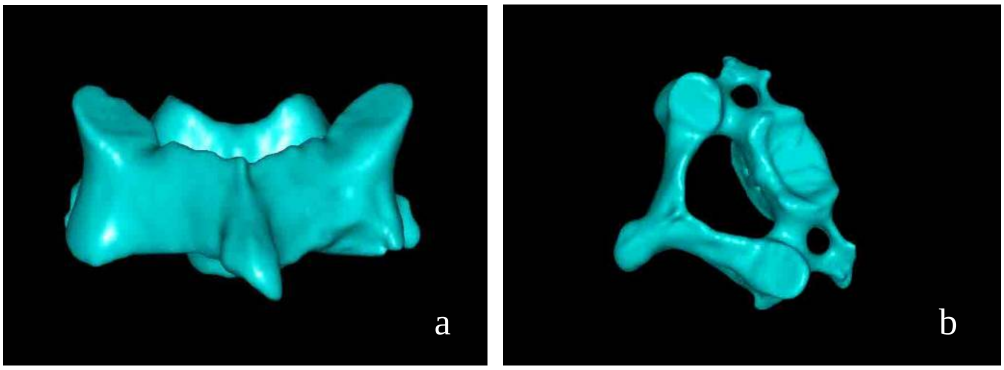


Fig.1 3-D model of the cervical vertebra (C_3).

a: posterior view ; b: lateral view

The 3-D cervical vertebral model was then exported in STL format to a workstation running Reverse Engineer software -UG imageware12.0 (EDS, US), for determining the optimal screw size and orientation. Using the UG Imageware software, the pedicles (left and right pedicle) were projected towards the vertebra and lamina (Fig.2a). As the thickness and cross section of the pedicle vary along its length, the smaller diameter of the elliptical inner boundary of the pedicle's projection was used in determining the maximum allowable dimension for screw diameter (Fig.2b). This diameter was further used to draw a circle and projected between the vertebra and the lamina to obtain the optimal pedicle screw trajectory (Fig.2c,). A 3D vertebral model was reconstructed with a virtual screw placed on both sides (Fig.2d).

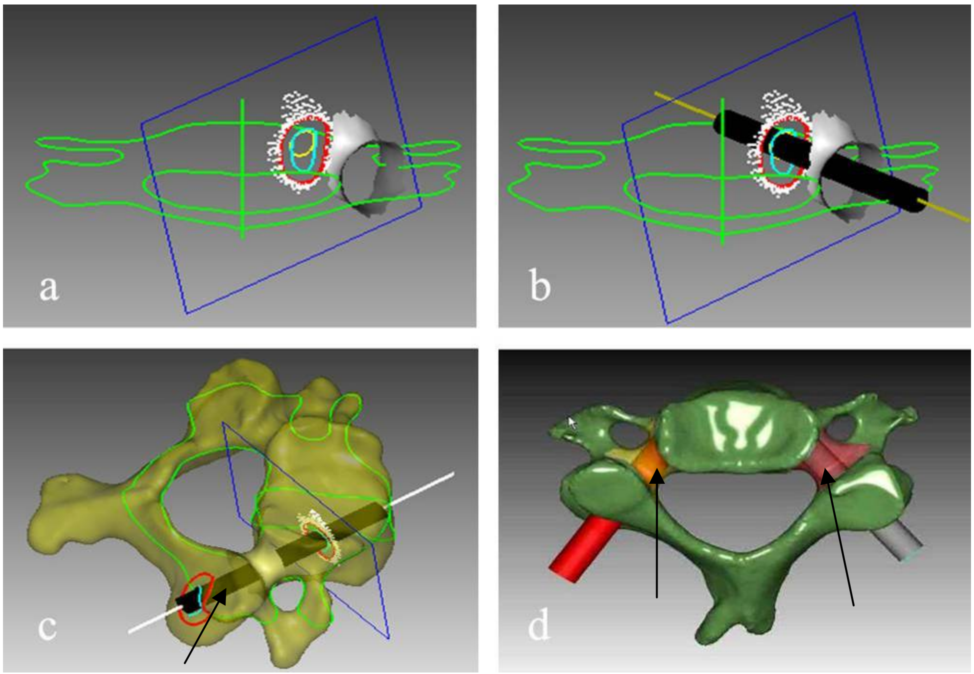


Fig.2 Analysis of cervical pedicle screw trajectory by the Reverse Engineering software

a: Pedicle and its positive projection; b: the best trajectory of pedicle screw projection;

c: Pedicle screw channel. (arrow) d: Planned screw trajectory (arrows)

Following the determination of the optimal pedicle screw trajectory, a navigational template was constructed with a drill guide on either side. The template surface was created as the inverse of the vertebral posterior surface, thus potentially enabling a near-perfect fit. It was also made sure that there was no overlapping of the template onto adjacent segments (Fig.3).

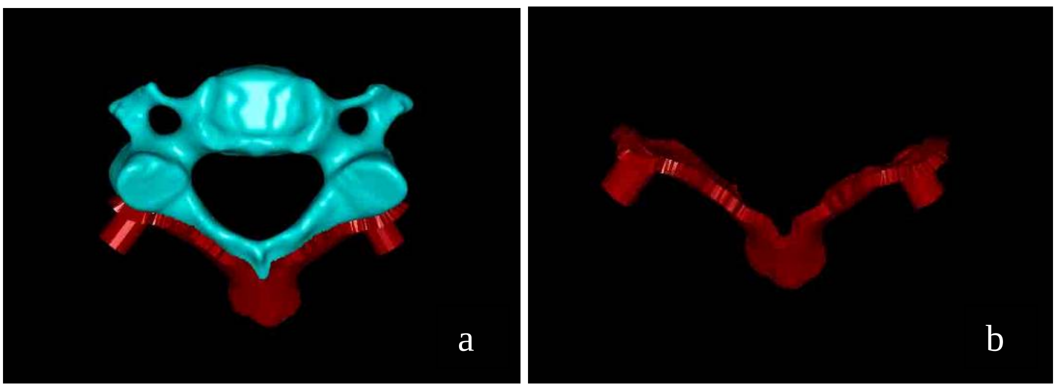


Fig.3 Design of the navigational template

a: Navigational template fits with the vertebra perfectly; b: The 3-D computer model of navigational template

The biomodel of the desired vertbera as well as its corresponding navigational template were produced in acrylate resin (Somos 14120, DSM Desotech Inc, USA) using stereolithography – a rapid prototyping (RP) technique (Hen Tong company, China). The accuracy of the navigational template was examined by visual inspection before surgery. The biomodel of the vertebra and its corresponding template were placed together, and a standard electric power-drill was used to drill the screw trajectory into the biomodel of the vertebra through the template navigation holes. Visual inspection was performed for identifying any violation (Fig.4)

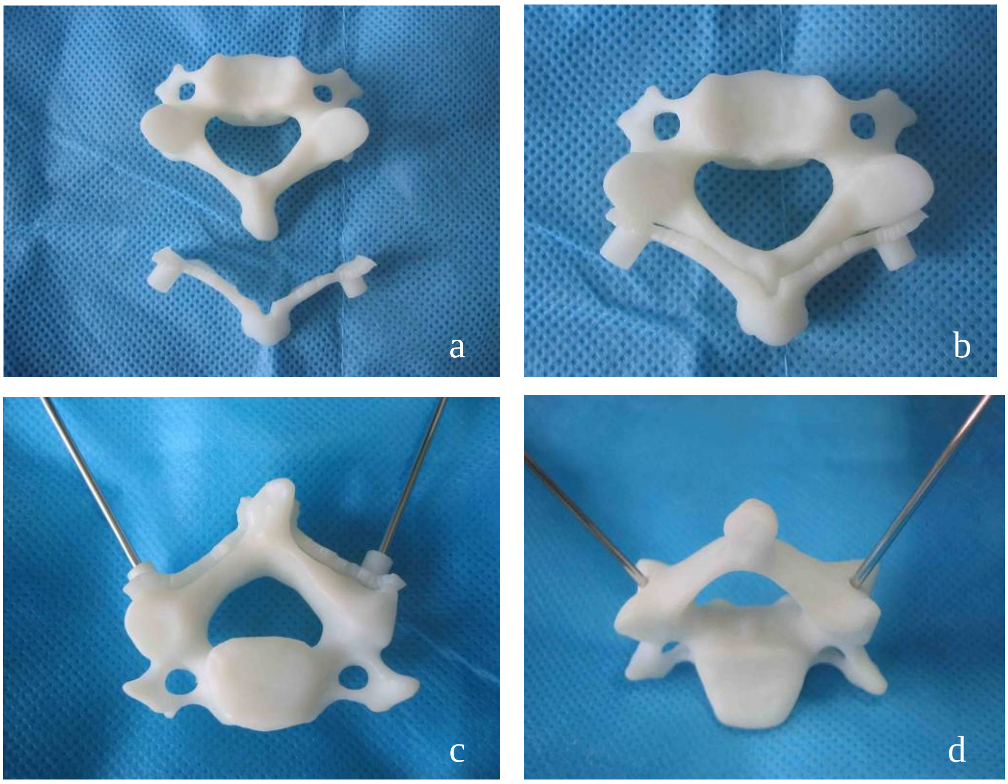


Fig.4 The accuracy of the navigational template was examined by visual inspection
a: RP model of vertebra and navigational template; b: navigational template fits RP model of vertebra perfectly; c: K wires inserted through navigational template into the pedicles; d: accuracy of the navigational template examined by visual inspection.

The template was sterilized and used intraoperatively for navigation and for confirming anatomic relationships. For safety reasons, fluoroscopy was performed intraoperatively during drilling and insertion of the pedicle screw on the first 3 patients. For the remaining cases, fluoroscopy was performed only after the insertion of all the pedicle screws, thus considerably reducing the exposure time to radiation. After surgery, the positions of the pedicle screws were evaluated using X-ray and CT scan. An axial image, including the whole length of each screw, was obtained, and the medial and lateral deviation of the screw was classified into 4 grades [6]. Grade 0, no deviation; the screw was contained in the pedicle. Grade 1, deviation less than 2 mm or less than half of the screw diameter. Grade 2, deviation more than 2 mm and less than 4 mm, or half to one screw diameter. Grade 3, deviation more than 4 mm, or complete deviation. The screw positions were independently evaluated by two surgeons (Dr Guo P. Chen and Yu B. Chen) with regard to the extent of pedicle wall violation.

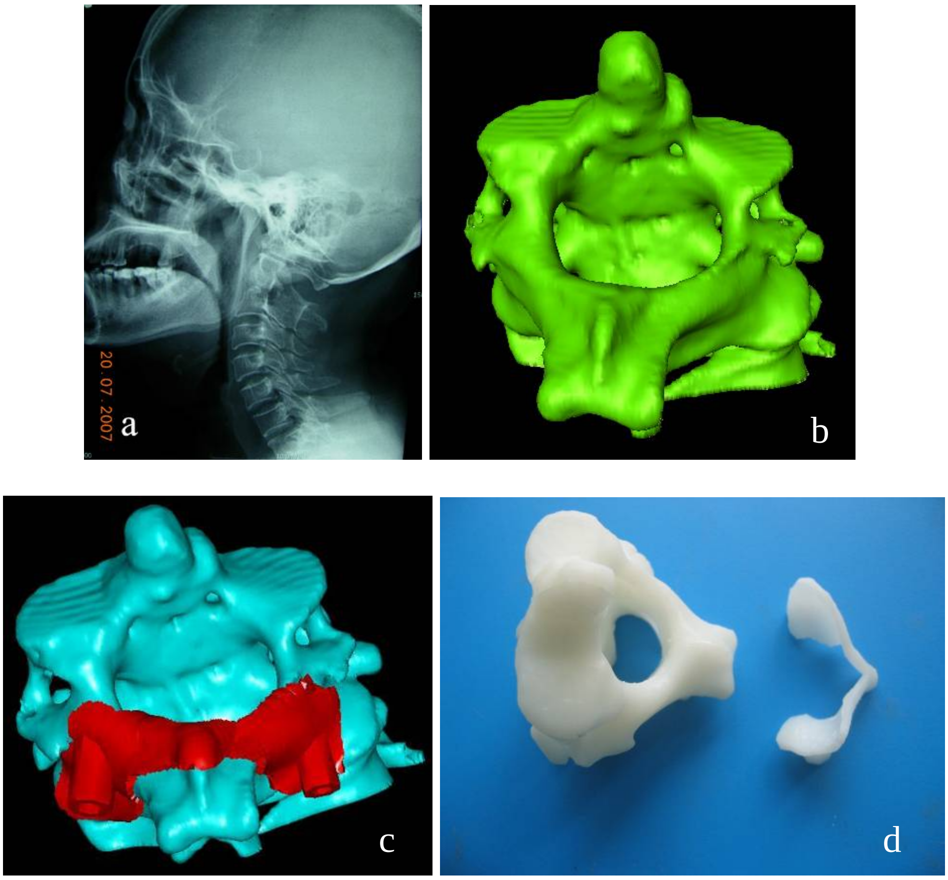
Results

The accuracy of the navigational template was examined before operation by drilling the screw trajectories into the vertebral biomodels. Each navigational template was found to be fitting to its corresponding vertebral biomodel appropriately without any free movement, and the K wires were found to be inserted through the drill hole through the pedicle and into the desired vertebra without any violation as found by visual inspection.

During the operation, it was easy to find the best fit for positioning the template manually, as there was no significant free motion of the template when it was placed in position and pressed slightly against the vertebral body. As such, the navigational template fulfilled its purpose for use as *in situ* drill guide.

A total of 88 screws were inserted into levels C2–C7 with 2-6 screws on each patient. Of these pedicle screws, 71 were in Grade-0, 14 in Grade-1, 3 in Grade-2, and no screw was in Grade-3. None of the cases had complications caused by pedicle perforation and especially there were no injury to the vertebral artery or to the spinal cord, nor was there a need for revision of pedicle perforation in any of the cases.

In this study, cervical pedicle abnormality existed in five patients. The pedicles (four C_2 and one C_7) of these patients were very narrow with a minimum diameter of 3.5mm. Screws of relatively smaller diameter (3-mm) were chosen for these patients accordingly, and were placed inside pedicles accurately using navigational templates. (Fig.5)



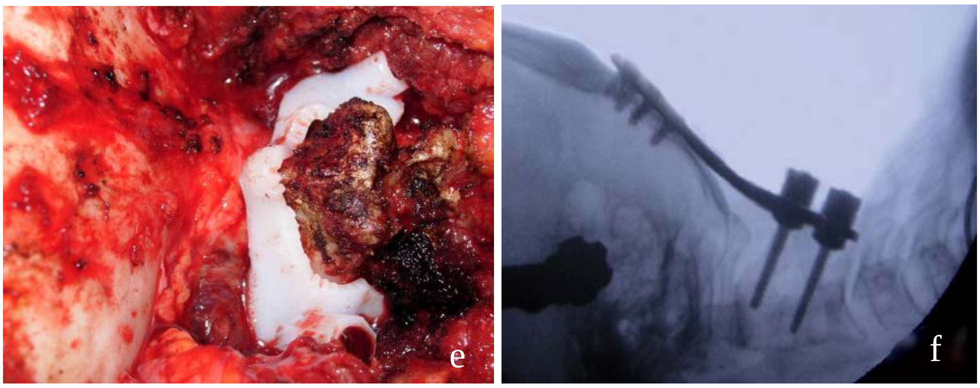


Fig.5 A female patient was diagnosised of basilar invagination, trans-C_2 Pedicle screw Occipto-Cervical Fusion was done; In this case the $C_{2,3}$ fusion was observed and the diameter of left C_2 pedicle was only 3.5mm, the C_2 pedicle screw was inserted using the navigational template; a: the X-ray shows atlantoaxial dislocation; d: 3-D model of $C_{2,3}$; b,c: Pedicle screw trajectory and design of the C_2 navigational template; d: RP model of $C_{2,3}$ and navigational template, e: the navigational template fit the posterior part of C_2 perfectly; f: fluoroscopy show good positioning of pedicle screw;

In another case, the pedicle was extremely narrow in level C2 with a minimum diameter of only 1.5-mm and therefore the C2 cervical fixation was not performed. The CT data showed congenital fusion between C2 - C3 and therefore pedicle screw fixation was successfully performed on level C3 using the drill template.

By using this novel, custom-fit navigational template, the operation time has been considerably reduced. On an average, each vertebral pedicle screw insertion took about 80 seconds. Fluoroscopy was required only once after the insertion of the entire pedicle screws, which has considerably reduced the duration of radiation exposure to the members of the surgical team. Currently the production time for RP model is about 2 days and the cost is about $50 per vertebral level. The production time can be brought down to 1 day and the cost can be reduced to $20 if the RP model of the vertebra is not needed.

Discussion

The use of drill templates were initially demonstrated in hip and knee.[19] Several studies have also described their use in spine surgeries including the cervical spine.[15-18] Berry et al.[15] used a three V-shaped knife design to support the drill template. Goffin et al.[16] designed a template with clamps to interface with the posterior course of the cervical vertebra. More recently, Owen et al.[17] introduced a drill template which was designed to match the posterior surface of the cervical vertebra around the entry point, providing a greater contact area with the vertebra and thus offering better stability, however, the surgeons were not confident of the screw positioning in the cervical spine. When compared with other template designs, this study has successfully introduced a novel, custom-fit navigational template for the placement of pedicle screws in the cervical spine and has further validated the technique in clinical settings by applying it to 25 patients requiring cervical pedicle screw insertion. The clinical application of this technique has demonstrated the high accuracy of this technique. In this study, a preoperative CT scan was obtained to customize the placement of each screw based on the unique morphology of the patient's cervical vertebra. The availability of high resolution CT scanner and advanced technologies used in the present study provide possibility for high geometric accuracy of the drill template. The Mimics software used in this study to reconstruct the 3-D model of the vertebra from the CT scan data is capable of providing fast, easy and powerful 3D image processing and editing. Besides, the rapid prototyping technology, which is based on building the model by stacking thin layers, has been used in this study[17-20, 24] instead of milling.[16] Rapid prototyping can reproduce more complex designs because of its high accuracy and versatility. The resolution of the rapid prototyping machine is well above the 0.35-mm resolution of the template model and thus the accuracy of reproduction is not a limiting factor.[17]

There are several advantages in using such patient-specific drill template design: firstly, the surgeon can decide location, orientation and the size of each screw based on the unique morphology of the cervical vertebrae even before going to the operation table. The observations in this study have demonstrated that the pedicle may differ widely from patient to patient.[25] Therefore, preoperative CT evaluation is suggested as a mandatory step for precise planning of the surgical procedure. The diameter of the screw should be appropriately selected for the individual pedicle. During the course of this study, we have come across abnormal cervical pedicles in five cases. The use of patient specific drill templates has given us the ability to successfully handle even such abnormal cases by helping us choose the right screws and decide on the best orientation of screw insertion for each pedicle. The second advantage of this technique is its simplicity of application as this technique does not require much expertise on the surgeon's part and the preoperatively prepared drill template can be used intraoperatively to assist with surgical navigation and precise placement of instrumentation. Third, in contrast to the image-guided technique, this technique eliminates the need for complex equipment and time-consuming procedures in the operation theatre, thus this technique reduces the duration of the surgical procedure. Fourth advantage is the accuracy of screw placement without perforating the spinal canal or the blood vessels. In abnormal cases with very narrow pedicles, this technique also gives the flexibility to examine the accuracy of the drill templates by inserting the screws into the biomodel of the vertebra. Thus this technique has a potential role to play in spinal revision surgeries and spinal deformity surgery where the radiographic landmarks can look distorted and obscured. Lastly, the need for fluoroscopy during screw insertion is eliminated, which as a result considerably reduces the radiation exposure to the members of the surgical team.

Nevertheless, there are also some potential sources of errors in this technique. This technique requires clean preparation of the bone surface, including thorough removal of the attached muscle and fat tissue without causing damage to the bony surface structure in order to ensure proper fit of the drill template on the lamina. Even with this limitation considered, our technique proves to be better that the techniques reported in literature so far. For example, the use of V-shaped knifes to support the drill template as done by Berry et al. [15] did not require excessive soft-tissue dissection from the vertebra. However, the surgeons were not confident of the screw positioning in the cervical spine. Another issue is that, in the clinical setting, a template should be capable of being used as an *in situ* drill guide, any movement between the bone and the template due to vibration while drilling will affect the accuracy greatly. Therefore, the template has to be firmly placed in position by the surgeon while drilling. Based on the findings from D'Urso et al., [26] the use of this technique in the thoracic and lumbar regions of the spine is not recommended due to the presence of excessive soft tissue.

This template design is unique in that it is created based on reverse engineering principle, and therefore can match the postural surface of the cervical vertebra perfectly. after the preparation of the bone surface with thorough removal of the attached muscle and fat tissue without damaging the bony surface structure, all our templates can be easily and securely held in place by the surgeons' free hands.

Conclusion

This study has introduced a novel navigational template for use in cervical pedicle screw placement, and has clinically validated its viability in 25 patients. The preliminary clinical trials have demonstrated that this design can improve the accuracy and safety of pedicle screw placement in the cervical spine. The uniqueness in this design is that the template is created as the inverse of the posterior vertebral surface, thus enabling a near-perfect fit in a lock-and-key fashion and thus providing better stability in the clinical setting. With its wide applicability, high accuracy and cost-effectiveness, this design will likely enjoy widespread use in the future.

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