Research Article

A Novel Parsimonious Method as Accurate as Extravagant Counterparts: Streolithographically-Modeled Patient-Specific Drill Guide Template for Subaxial Cervical Pedicle Screw Insertion

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Abstract

Background: This study was conducted to develop a modified, parsimonious, faster to produce, easier to implement, and patient-specific drill guide template and also to examine if such a modification might affect the accuracy.
Methods: On two cadaveric spines, using reverse engineering, the orientation of pedicles and safe corridors for pedicle screw were determined. A drill template was designed with a surface that was the inverse of the posterior vertebral surface. The drill template was manufactured using rapid prototyping technique. To decrease the costs, the cervical spine corresponding prototypes were not manufactured. In contrary to previous studies, to preserve the stability from posterior element, the templates were designed in such a way that removing interspinous and supraspinous ligaments was not necessary. The accuracy was evaluated by computed tomography (CT) images and classified into three grades of 0: correct placement, 1: malposition by less than a half screw diameter, and 2: malposition by more than a half screw diameter.
Results: Of 20 positions available, we inserted 19 screws, because the trajectory of one of the patient-specific drill guide templates was misdirected. The overall accuracy rate for cervical pedicle screw (CPS) placement was 84.2% (16 of 19). Safely inserted screws, combining the grades 0 and 1 categories, were as high as 100%. We observed no "unsafe screw placement".
Conclusions: The total cost and the latency period before the operation was reduced and the interspinous and supraspinous ligaments were preserved. A good applicability and high accuracy was obtained for subaxial CPS (SCPS) insertion.

Keywords: Cervical Vertebra; Spine; Pedicle Screws; Instrumentation, Patient-Specific Modeling

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Background

During the last decade, we have been witnessing considerable advances in instrumentation techniques and intra-operative imaging; nevertheless, how best to implement posterior cervical instrumentation continues to be a dreaded challenge to the spine surgeons.

Screw malposition has been reported to occur in 0–4 percent in the atlas and 0–7 percent in the axis (1-3). As reported by Cheung and Luk, transarticular C1–C2 screws or Magerl screws pose an additional risk of vertebral artery injury (VAI), neurological deficit, or inadequate bony purchase (4). Screw fixation, as perilous as it is, does always carry a potential of being complicated by VAI. Incorrect cervical pedicle screw (CPS) entry is fraught with danger of VAI. The incidence of iatrogenic VAI (IVAI) has been estimated to be 1.3–4.0 percent for Magerl fixation (5). Wright and Lauryssen have estimated the risk of neurological deficit to be as low as 0.2% (6). Having appreciated the violation of the transverse foramen to be the most dreadful complication of the pedicle screw insertion, Neo et al. reported a high percent (84%) of screws showing lateral deviation (5); the finding that was reported before (7, 8). Given the possibility of catastrophic consequences that might follow VAI, the misplacement rate conferred by traditional methods relying on anatomic landmarks was judged by Neo et al. to be unacceptable, and they recommended that the technique should no longer be used. In the light of such findings, the use of computer-assisted navigation systems or other equivalent techniques are strongly recommended, especially when applied to degenerative vertebrae or when narrow pedicles have drawn plethora of attention recently (8).

The lateral mass generally opted for the treatment of cervical spine from the posterior approach entails placement of bone screws into the lateral masses of the cervical bodies that could be combined with either plates or rods. Jones et al. observed the mean load-to-failure to be 677 N for the CPS and 355 N for the lateral mass screws. The differences observed were reported to be independent of screw type, bone density, screw length, or vertebral level. They brought attention to the variability in pedicle morphometry and orientation and recommended that careful preoperative assessment be practiced in order to determine the suitability of pedicle screw insertion (9).

Despite the perception that cervical pedicle fixation would provide superior holding power, few procedures might have brought as much amount of apprehension to spine surgeons as does CPS insertion. Accurate instrumentation of pedicle screws calls for a thorough understanding of three-dimensional (3D) pedicle morphology of each individual patient in correlation with adjacent vital neurovascular structures. Additionally, accurate determination of an appropriate entry point will also help in introducing a safe and effective trajectory (8-12).

Various methods have been explored as parts of attempts for popularizing pedicle screw placement, including anatomic studies, image-guided techniques, and drill templates. Fluoroscopy-guided techniques have fallen out of favor because they expose the surgeon and patient to high levels of radiation. Furthermore, the setup has such a large equipment footprint that renders the surgeon's maneuverability hamstrung (13-15). Computer-assisted surgical navigation, while having been observed to be able to provide the ultimate accuracy in directing implant fixation, is an expensive equipment with limited availability (13-17). The 3D printing or stereolithography (STL) has recently enjoyed many refinements so as to enable us to create detailed models of the spine, based upon which we can produce patient-specific surgical templates (PSSTs). PSSTs are used to precisely insert spinal implants into the anatomy of the vertebrae (18-21).

Patient-specific drill guides, developed as low-profile templates and used as in situ with preplanned trajectories, have been shown to improve the accuracy of the screw placement and reduce radiation exposure of both the patient and the surgical staff. Moser et al. along with other investigators started to believe that the progress made in computer-aided design/computer-aided manufacturing has enabled a more sophisticated and practical application of template-guided procedures in cervical spine surgery with promising results in recent years (22-30). Burleson and DiPaola have recently noted that “there is a large amount of excitement around 3D printing in orthopedics, and only time will tell if this will be a passing fad or a major component of our operative processes in the future” (31).

Given the naivety of the technology, further refinements continue to be required to expand our understanding of what is possible and further investigations continue to be required to examine if the possibilities already reported are reproducible, before it could be widely adopted by surgeons and adapted to everyday surgical practice. The advantages have been appreciated by investigators to be largely positive. However, there are drawbacks to this new technology; the largest thereof is the surgical exposure requirement. The time needed to produce the guides has also been criticized as limiting factor with the three-guide system taking the authors an average of 3 days to produce. This limits their availability for trauma patients. As such, herein, we have attempted to:

1. Develop a more parsimonious technique, faster to produce and easier to implement.
2. Examine the hypothesis that such a modification might have not affected the accuracy.

Methods

Two cadaveric cervical spines were dissected. Volumetric computed tomography (CT) scan was performed on subaxial cervical vertebra and a 3D reconstruction model was generated from the scan data. The data were saved in format of DICOM® (Digital Imaging and Communications in Medicine). The Mimics 8.11 software (Materialise, Technologielaan 15, Leuven, Belgium) was used for 3D reconstruction from DICOM images. Using reverse engineering technique, the orientation of the pedicle and the safe corridor for pedicle screw to be placed in was determined (Figures 1-6).

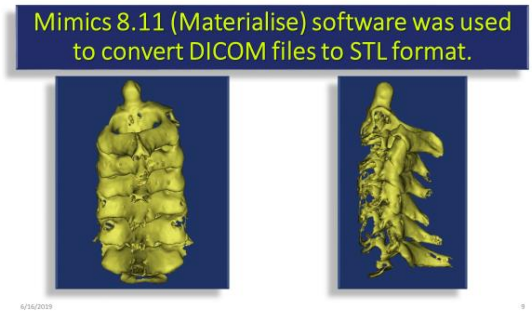

Figure 1. Digital Imaging and Communications in Medicine (DICOM) images were introduced to the software and converted to stereolithography (STL) format (sagittal and coronal view).

A drill template was designed with a surface that was the inverse of the posterior vertebral surface. The drill template (not its corresponding vertebra) was manufactured using rapid prototyping technique, prototyping from a Dimension 1200es (Stratasys, Eden Prairie, MN, USA).

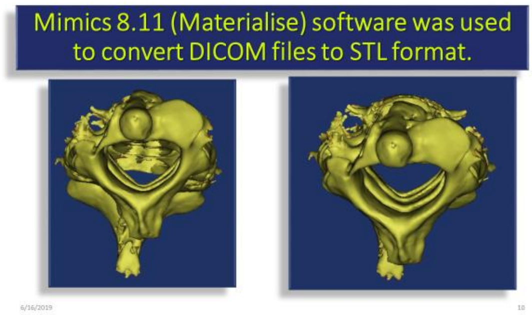

Figure 2. Digital Imaging and Communications in Medicine (DICOM) images were introduced to the software and converted to stereolithography (STL) format (axial view).

To decrease the costs, the cervical spines corresponding prototypes were not manufactured. In contrary to previous studies (22), to preserve the stability from posterior element, the templates were designed in such a way that removing interspinous and supraspinous ligaments was not necessary.

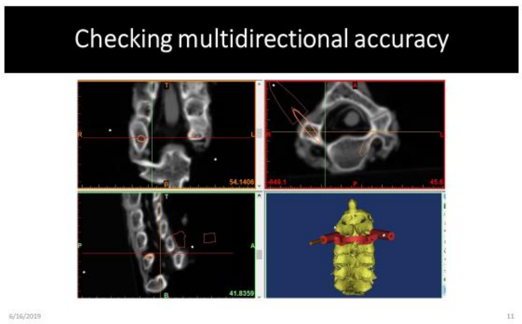

Figure 3. Multidirectional accuracy of the corridors were evaluated and adjusted to the best match.

Definitions of Terms

The placement accuracy for all 19 pedicles was evaluated in the axial, coronel, and sagittal CT images and classified into three grades as suggested by the literature (13):

- Grade 0: Correct placement
- Grade 1: Malposition by less than a half screw diameter
- Grade 2: Malposition by more than a half screw diameter

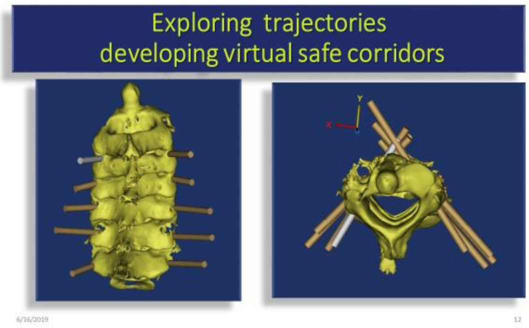

Figure 4. Trajectories were determined and scrutinized using reformatted axial, sagittal, and coronal views as well as on 3D models.

In total, 19 screws were inserted into levels C3-C7. After surgery, the positions of the pedicle screws were evaluated using CT scan and graded for validation.

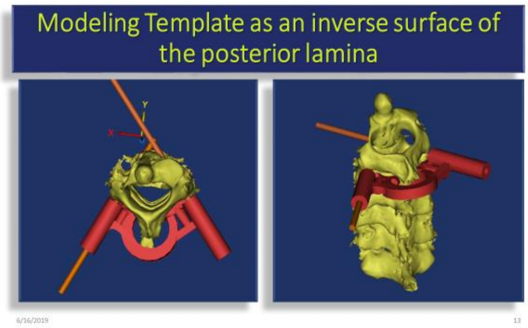

Figure 5. Templates were modeled as an inverse surface of the posterior lamina.

Results

Of 20 positions available, we inserted 19 screws, because the trajectory of one of the PSSTs was misdirected.

Figure 6. Using Drill-Guide Template for Subaxial Cervical Pedicle Screw (SCPS) Insertion

As shown in Table 1, the overall accuracy rate for CPS placement was 84.2% (16 of 19) (Figures 7 and 8).

Table 1. Accuracy of Subaxial Cervical Pedicle Screw (SCPS) Insertion Using Drill Guide Template

Vertebra	Breach/Perforation		Vertebra	Breach/Perforation	
	Major	Minor		Major	Minor
C1V3R	-	+	C2V3R	-	-
C1V3L	-	-	C2V3L	-	-
C1V4R	-	-	C2V4R	N/A	N/A
C1V4L	-	-	C2V4L	-	-
C1V5R	-	-	C2V5R	-	-
C1V5L	-	+	C2V5L	-	-
C1V6R	-	-	C2V6R	-	-
C1V6L	-	-	C2V6L	-	+
C1V7R	-	-	C2V7R	-	-
C1V7L	-	-	C2V7L	-	-

C: Cervical; L: Left; R: Right; V: Vertebral; N/A: Not available
Numbers after C identify cadaver 1 and 2
Numbers after V identify the vertebra in each cadaver specimen

Safely-inserted screws, combining the grades 0 and 1 categories, were as high as 100%.

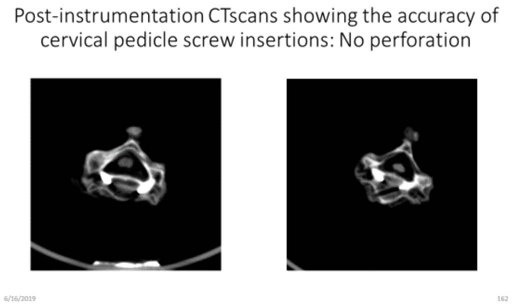

Figure 7. Post-Operation Computed Tomography (CT) Scan for Evaluating the Accuracy of the Subaxial Cervical Pedicle Screw (SCPS) Insertion: No Perforation

We observed no "unsafe screw placement".

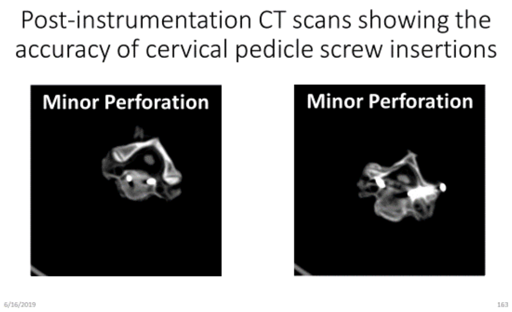

Figure 8. Post-Operation Computed Tomography (CT) Scan for Evaluating the Accuracy of the Subaxial Cervical Pedicle Screw (SCPS) Insertion: Minor Perforation

Discussion

Major Findings

Herein, we are introducing and reporting on the accuracy of a more parsimonious version of a patient-specific surgical drill guide template. The currently available techniques include producing PSST constructed from 3D-printed plastic models based on DICOM images of cadaveric specimen. The modification examined in the current study had two aspects. First, spine biomodel was not produced and, as such, the PSSTs were not tested before surgery. Second, during skeletonization of the cervical vertebrae, interspinous and supraspinous ligaments did not need to be sacrificed. The technique was observed to have a convincing accuracy of 100% for safe placement. The screw placement had an accuracy of 85%. The perforations observed were grade 1 perforations. Both lateral and medial pedicle wall breaches were observed. The screws, however, were accurately directed to the intended trajectories from predetermined entry points. Because the vertebral foramen had not been breached, this placement was considered to be a "safe placement" (32).

Instrumentation of the cervical spine can be fraught with potential complications. The anatomic sizes and dimensions are smaller than those of other regions of the spine, and neurovascular structures are in the close vicinity of the ideal screw trajectories (31). Kaneyama et al. introduced a three-step technique to guide subaxial CPS (SCPS) insertion (27). Sugawara et al. originally described this technique for thoracic pedicle screws (29, 30). Utilizing a similar method, 98% (47/48) of the screws were found to have been placed with acceptable parameters.

The use of PSSTs to place pedicle screws in the subaxial cervical spine has been studied by many investigators. The pedicles of C3-C7 generally miniature the thoracic and lumbar pedicles anatomy. Furthermore, their anterolateral borders lie within the close vicinity of the vertebral foramen, making screw placement such perilous an adventure that many surgeons might opt not to embark upon (31). Burleson and DiPaola have argued that attempting SCPS insertion can lead to error in screw positioning, which is frequently unacceptable given the small window between the central canal and vertebral foramen. Insertion of SCPS is rarely performed and not often biomechanically necessary. Risk of injury to the vertebral artery imposed by SCPS insertion may not worth the reward of increased biomechanical strength, which some authors have found not to be clinically relevant. Many surgeons use lateral mass screws for fixation of the subaxial cervical spine as a remedy to this apprehension. Navigation has frequently been reported as a useful guide to the insertion of SCPSs; however, this method is flawed by the fact that the surgeon may face a failure when the patient's position is altered in any way (31). However, spatial position of the patient might not affect the techniques using PSSTs. PSSTs were used by Moser et al. for placement of 3.5mm SCPSs in 4 cadaveric specimens. Randomization of the template-guided instrumentation was performed for each cervical level and side. The contralateral side was then instrumented with the freehand technique. In total, 48 screws were inserted in this study with 66.7% (n = 16) of template-guided versus 20.8% (n = 5) of freehand CPS being fully contained within the pedicle. Meanwhile, 91.7% (n = 22) versus 50.0% (n = 12) were within the < 2 mm "safe" zone. They have opted to use 3.5mm screws and avoid any pedicle with diameters < 3.5 mm, whereas other articles preferred to instrument pedicles of smaller sizes with 2.7mm screws (9). Bundoc et al. developed a different technique to increase the accuracy. Under direct visualization before the surgery, they inserted K-wires into the pedicles of each vertebral model and applied cement to the lamina, engulfing the base of the K-wire to create a guide. They removed the K-wire after that the cement hardened and placed the guide onto the actual cadaveric spine and attempted drilling K-wires through the guide. A 94% success rate with 3 of 50 screws perforating was obtained by this investigators (32).

Having found that the production of spine biomodel is dollar and time-consuming, in the current study we attempted to omit this step only to observe that the accuracy did not yield to this economic pressure.

Given the variation in cervical anatomy, it might be prudent to screen each patient individually for their eligibility regarding CPS insertion. If the surgeon opts for performing SCPS insertion, patient-specific surgical guide might improve accuracy.

Strengths and Limitations

Our findings need to be interpreted in the light of strengths and limitations. The CT scan used herein is not state of the art. The vertebrae available were not fresh cadaveric samples and as such, the anatomical details might have not been exquisitely captured on the CT. We were running short of budget and, therefore, the cervical spines corresponding prototypes were not manufactured. We did not have a spine surgical armamentarium. Despite the aforementioned limitations, the conjecture that the current method confers a high accuracy still holds in the light of the fact that all the limitations, if any, might have biased the estimate of the accuracy toward the null. As such, a logical case could be built and hypothesizing that the limitations had been removed, a higher accuracy could have been obtained.

The strength of the current study lies in two points. First, parsimonious approach omitted the stage of producing biomodel of the vertebrae and as such, the total cost and the latency period before the operation decreased. The time needed to produce the guides is a limiting factor that has hampered the technique from becoming popular since the very beginning of its commencement, because this limits their availability for trauma patients. The three-guide system has been reported to take the authors an average of 3 days to be produced (32). Second, more stability is preserved by not sacrificing the interspinous and supraspinous ligaments. The largest drawback to the implementation of the PSSTs has been reported to be the surgical exposure requirement. For the guides to fit properly, all muscle must be removed from the lamina under the PSST. The ultimate goal of the posterior cervical instrumentation is to obtain stability. Interspinous and supraspinous ligaments are major contributors to the cervical stability (33). There is no need to say that extensive skeletonization by sacrificing interspinous and supraspinous ligaments goes contradictory to the stability and defeats the very purpose of instrumentation.

Conclusion

A novel parsimonious technique using a patient-specific surgical drill guide template was developed for SCPS insertion. The stage of producing biomodel of the vertebrae was omitted; nevertheless, a good applicability and high accuracy was obtained for SCPS insertion. In this way, we were able to considerably reduce the total cost and the latency period before the operation. Furthermore, herein, we demonstrated that more stability could be preserved by not sacrificing the interspinous and supraspinous ligaments. We feel that use of such templates to instrument cervical vertebral pedicles could be promising.

Conflict of Interest

The authors declare no conflict of interest in this study.

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