ORIGINAL ARTICLE

Low-cost 3D Modeling Software for Generating Patient-specific Drill Guide Templates for Cervical Pedicle Screw Insertion: An In Vitro Study

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ABSTRACT

Background. Instrumented posterior cervical spine surgery (IPCSS) can be conducted using screws inserted through the pedicles of the vertebra. A safe IPCSS method uses 3D-printing to produce templates that will serve as drill guides for screw placement.

Objectives. This study describes the generation of 3D-printed drill guides using low-cost general purpose 3D modeling software and the comparison of screw insertion accuracy scores against the traditional landmark method and guides created using commercial grade software.

Methods. Twenty-five (25) subaxial pedicles of five cadaveric spines were selected and scanned using computed tomography (CT). A digital reconstruction of the five cadaveric spines were created based on the CT DICOM data. A low-cost 3D modeling software, Rhinoceros 3D, was utilized for trajectory planning and generation of a patient-specific drill template using the digital reconstruction. The templates were then fabricated in ABS plastic using a fused deposition modeling (FDM) 3D printer. Insertion of cervical pedicle screws on the cadaveric spines was done by an orthopedic resident using the 3D printed guides. Postoperative CT scans were obtained, and placement accuracy of the screws were scored by two assessors utilizing a four-point rating system. Screws in correct placement were scored Grade 0 while misplaced screws with neurovascular damage were given a score of Grade 3.

Results. Accuracy scores for the 3D-printed drill guides were 52% for assessor 1 and 44% for assessor 2. For assessor 1, screw placement in C3, C6, and C7 received the highest scores. For assessor 2, the highest scores were achieved in C3 and C7. The hybrid method of Bundoc et al. achieved scores of 94% while 3D printed guides utilizing commercial software like Materialise Mimics, Geomagic Freeform, or UG Imageware achieved scores of 80-100%. The traditional landmark method had scores ranging from 12% to 94% depending on the skill of the surgeon.

Conclusion. Commercial medical 3D image-based engineering software has high acquisition costs that might be beyond the reach of most institutions. A sub-$1000 general purpose 3D modeling software can be used to create drill templates. Several factors were identified in the design and fabrication of the template that can be addressed to increase accuracy. Trajectory planning can also be improved by automating the process. The researchers recommend further studies in these areas specially in the context of developing 3D printing as a support service for surgical operations in the Philippines.

Keywords: cervical vertebrae surgery, cervical pedicle screws, 3D printing

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INTRODUCTION

Cervical spine surgery (CSS) is used in correcting pathologies following injury, disease, or congenital defects. CSS presents many complications, as cervical spines have small dimensions and highly variable anatomic landmarks, whose proximity to delicate neurovascular structures presents a high risk of iatrogenic damage.[1,2] Literature shows that in instrumented posterior cervical spine surgeries (IPCSS), cervical pedicle screws (CPS) offer greater stability than lateral mass screws.[3-7]

Different methods are used to ensure proper CPS placement. In the free-hand technique, a long learning curve is required and the user must have expertise in analyzing preoperative images and determining anatomic landmarks.[4] In fluoroscopy, 2D X-ray images of the vertebrae are continuously taken during placement of the pedicle screw, offering high accuracy but risking exposure of the patient to high amounts of radiation.[8] Surgical navigation systems offer lower rates of screw misplacement but are still subject to errors brought by glitches in hardware and software, human error and the operator's level of experience.[5]

A recent effective CSS innovation is the creation of a patient-specific CPS template through 3D printing.[9] Preoperative thin-slice CT scans of the patient's vertebrae are loaded into a medical 3D modeling software like Mimics (Materialise, Belgium). In the software, CPS trajectory can be planned and a patient-specific drill template generated with the correct trajectory already incorporated into the template. The template can then be fabricated using 3D printing. During operation, the surgeon only needs to fit the template to the correct vertebrae and the template guides the drilling and CPS insertion. However, this process is dependent on the use of specialized medical 3D modeling software which can be cost prohibitive. In the Philippines, Bundoc et al. described a hybrid approach without the use of medical 3D modeling software.[1] In that study CT DICOM viewers were used to generate 3D models of cadaveric spines. These models were then printed whole and drill templates were manually fabricated by applying Polymethylmethacrylate (PMMA) dental acrylic over the spine models with pins inserted into the pedicles.

The hybrid molding method was shown to have accuracy comparable to other 3D printed templates in literature. Nevertheless, it still required additional steps and had increased material costs. In this study, the researchers convert the hybrid method of Bundoc et al. into a full digital workflow through the use of a low-cost general purpose 3D modeling software.

MATERIALS AND METHODS

Twenty-five non-decaying, non-osteoporotic specimens from five cadavers were obtained from University of the Philippines College of Medicine Anatomy Laboratory. These were randomly stratified to address the covariation brought about by lateralities (right and left) and vertebral levels (C3, C4, C5, C6 and C7) of the specimens. The study was submitted to the Review Ethics Board of UP Manila and was granted exemption status.

Intervention

Each specimen was scanned using a SIEMENS Somatom Definition AS (64-slice) computed tomography (CT) machine. The resulting DICOM images were exported to 3D Slicer 4.50 (The Slicer Community, USA), a free and open source (FOSS) software used in medical image processing. Segmentation of the CT scans was done using 3D Slicer to isolate the spine from the soft tissue. From the segmentation data, a 3D model was generated for each spine and converted into stereolithography (STL) format.

Trajectory Planning and Design of Drill Templates

The spine model was loaded into Rhinoceros 5 (Robert McNeel & Associates, USA), a general purpose 3D modeling software used in product design and architecture. Using Rhinoceros 5, the posterior surface of the vertebra was extracted to serve as the mold for the drill template. A 3.00-mm thick negative mold of the extracted surface was then created. A 2.5-mm cylinder was generated to simulate the CPS and oriented such that it goes through the pedicle of the vertebra. A 6.00-mm cylinder was generated around the 2.5-mm screw simulation to serve as the drill guide. These were then repeated for the opposite pedicle. Figure 1 shows each step of the process.

Bores through the 6.00-mm cylinders and the 3.00-mm negative mold were then created. Any part of the 6.00mm cylinder projecting out of the anterior side of the negative mold was removed. A label corresponding to the spine and vertebral level (i.e. A3 for spine A, vertebral level C3) was then affixed to the left posterior surface of the negative mold. The resulting model was then exported to STL format for printing.

3D printing fabrication of the templates

The STL models of the templates were printed using acrylonitrile butadiene styrene (ABS) plastic via fused deposition modeling (FDM) process using an Afinia H-series 3D printer (Afinia 3D, USA). The ABS plastic used in this study is in the form of a filament that is loaded into the 3D printer. FDM printing melts the ABS plastic filament at temperatures above 210 ˚C and deposits the melted plastic on a build plate following the cross-sectional shape of the 3D model. The 3D printer builds the surgical template layer by layer in this manner.

CPS Insertion

Subperiosteal dissection was done to prepare for cervical screw insertion (Figure 2A). This procedure involves incision of tendinous insertions of the attached muscles, followed by blunt dissection of the muscles from the spinous process

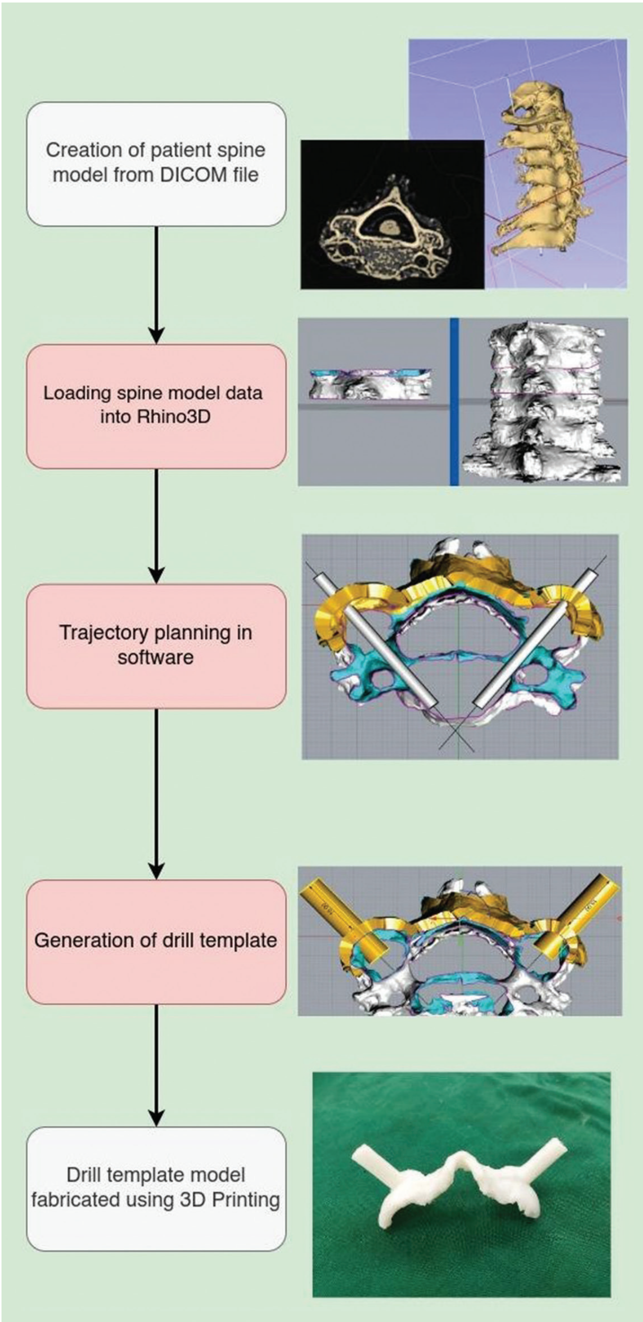

Figure 1. Step by step procedure in designing the drill templates using Rhinoceros 5.

and the lower border of the lamina.[10] This emulated the process in posterior cervical surgeries, permitting secure positioning of the drill templates on the vertebrae.

A drill template was firmly secured to the vertebra (Figure 2B). A Kirschner wire was drilled following the trajectory formed by the guide on the template. After drilling with the Kirschner wire, the template was then removed. A cervical pedicle finder and tap were used to facilitate the insertion of the CPS. This was repeated for each specimen.

Subperiosteal dissection and CPS insertion was done by an orthopedic resident (Figures 2A to 2D).

Outcome Assessment

Postoperative CT scans were obtained to determine placement accuracy of the CPS. 3D models of the CT slices were generated using the same preoperative procedure discussed above. Blind evaluation of the placement accuracy using the postoperative CT scans was done by a spine consultant and a chief resident from the Philippine General Hospital - Orthopedics Department.

The placement accuracy was given the following scores: Grade 0 for correct placement (the cervical screw is localized in the corresponding pedicle only), Grade 1 for a misplaced screw by less than half-screw diameter (1.75 mm), Grade 2 for a misplaced screw by more than half-screw diameter and Grade 3 for a misplaced screw resulting in neurovascular damage.[11]

Statistical Methods

Inter-rater reliability was calculated using Cohen's kappa, a test used to assess the agreement of ratings given by two assessors, and for qualitative ratings, such as those used in the study (Grade 0, 1, 2, or 3). Analysis was done using SPSS version 20.0 software (IBM Corporation, USA) at 5% level of significance (two-tailed). The Shapiro-Wilk test for normality was used to determine if the data were distributed normally. Independent samples t-test was done using the same SPSS software to assess for statistical significance (two-tailed, $p < 0.05$).

RESULTS

Test for Inter-rater Reliability

Cohen's κ shows only a slight agreement between the assessors' scoring, $\kappa = 0.23$ (95% CI).[12] Accuracy scores would be assessed separately for each assessor.

Test for Normality of Data

Shapiro-Wilk Test was run to determine if the assessors' scoring of insertion accuracy followed a normal distribution for the 3D printed drill templates. For the first assessor's assessment, the accuracy rate assumed a normal distribution, $p > 0.05$ ($p = 0.814$). For the second assessor, the accuracy rate assumed a normal distribution, $p > 0.05$ ($p = 0.314$).

Overall Accuracy Rates

Figure 3 shows CT scans of specific cervical vertebrae after CPS placement, displaying the appearances of inserted CPS according to their respective placement accuracy grades. Figure 4 summarizes the accuracy rates of CPS insertion using the 3D printed template.

The overall accuracy rate given by the first assessor is 52% wherein 13 out of 25 CPS insertions were given a rating of Grade 0. Six CPS placements were rated Grade 1, three

CPS placements were rated Grade 2, and another three were rated Grade 3 by the first assessor. On the other hand, the overall accuracy rate given by the second assessor is 44% wherein 11 out of 25 CPS placements had Grade 0 rating. Six CPS placements were rated Grade 1, four were rated Grade 2, and another four were rated Grade 3.

DISCUSSION

Internal fixation of the cervical spine is considered the gold standard in correcting degenerative, oncologic, and traumatic spine pathologies.[3-7] It provides superior biomechanical stabilization over non-pedicular techniques such as lateral mass screws.[6,7]

The use of template guides presents certain challenges in CSS. Improper anchorage of the templates on the lamina or wrong sizing of the guide tubes can result in deviations from the planned screw trajectory.[13] In addition, some removal of soft tissue is required in order to maximize the

Figure 2. Steps in CPS Placement: **(A)** Subperiosteal dissection, **(B)** Placement of the 3D printed template on the target spine level, **(C)** Drilling using the 3D printed template, **(D)** Insertion of the CPS after drilling.

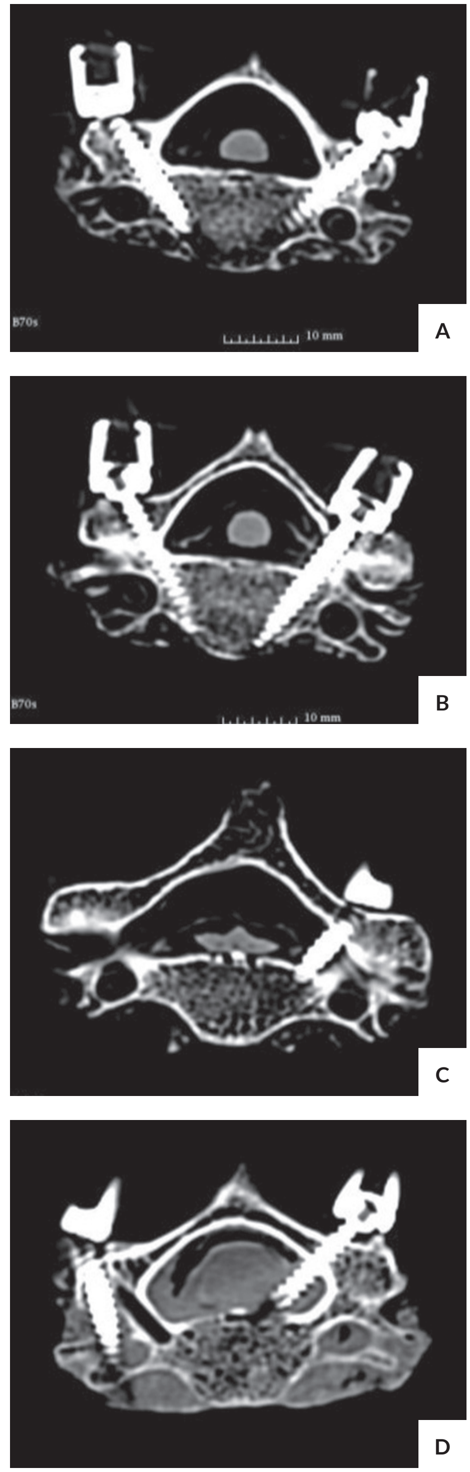

Figure 3. Post-instrumentation CT scans showing accuracy of CPS insertions: **(A)** Grade 0 for Spine A, level C4, both sides; **(B)** Grade 1 for Spine A, level C5, right side; **(C)** Grade 2 for Spine B, level C5, left side; **(D)** Grade 3 for Spine C, level C4, both sides.

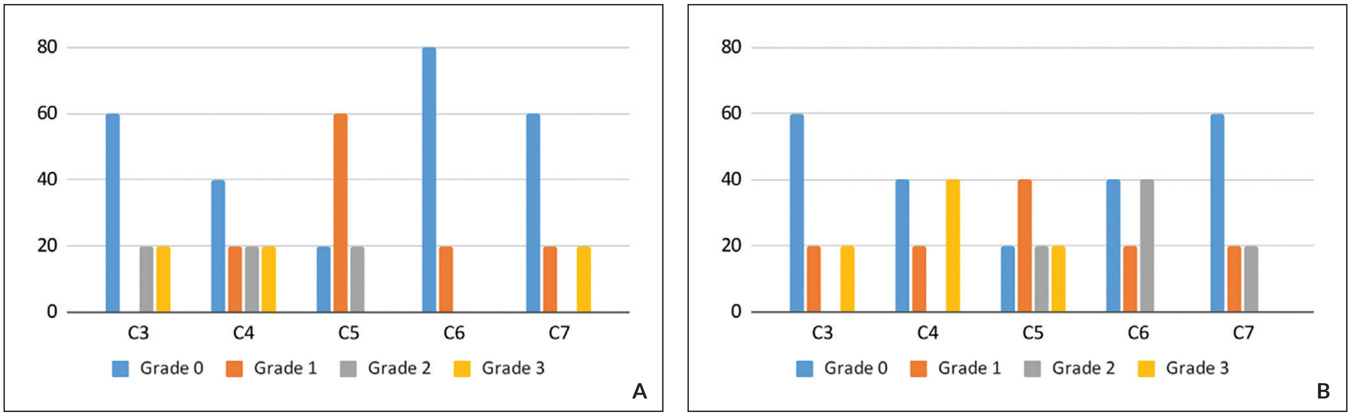

Figure 4. Accuracy rates per cervical level for pedicle screw insertion using the 3D printed template for **(A)** Assessor 1 and **(B)** Assessor 2.

contact area between the template and cervical bone.[14] The method of Bundoc et al. which combined both 3D printing and manual molding achieved accuracy scores of 94%.[1] However, the hybrid method requires additional steps and material costs compared to a full digital workflow. Similar high accuracy was also seen for 3D printed screw templates in literature. Kaneyama et al. created a multi-stage 3D printed screw guide for the midcervical spine using the software Geomagic Freeform (Data Design, Japan) which achieved an accuracy score of 100%.[2] A similar study by Lu et al. for the cervical spine was able to incur high accuracy rates of 80.6% contributed by the use of a high-resolution CT scanner and advanced fabrication methods.[9] In addition, Lu et al. utilized the commercial Mimics (Materialise, Belgium) and UG Imageware (EDS, USA). This setup provided rapid and easy preparation and manipulation of the vertebral model. Fabrication was done using the Stereolithography (SLA) process which has superior accuracy and resolution compared to the FDM process used in this study.

In the current study, the accuracy rates given by the assessors, as compared to the aforementioned literature on CPS guides, may have been caused by multiple factors that transpired during design and fabrication.

First, problems arose with the vertebral segmentation process. Several of the cadavers have already hardened by the time that the cervical spines were harvested, and this probably led to the Hounsfield value of soft tissue becoming very close to that of cortical bone. This would have affected the segmentation of the CT scan with the possibility of some soft tissue being mistaken for cortical bone. Hence, the accuracy of the resulting spine model is affected. Fortunately, this is not the case in living patients, where it is easier to delineate soft tissue and bone during the segmentation process.

Second, the trajectory planning was done by medical students and the lack of specialist knowledge might have contributed to the errors in spite of the fact that the software used provided multiple views (coronal, sagittal, and cross-sectional) to evaluate the screw trajectory.

Third, the spinous processes were removed from the spine specimens which further reduced the surface that the template can be anchored on. This could have contributed to the low accuracy rates.

Fourth, CPS insertion can be thought of as a three-step process: locating the entry point, screw hole drilling, and finally screw insertion. This study utilized a template for only one step of the process - screw hole drilling. In contrast, Kaneyama et al. created templates for each stage of the process and they attributed this design decision as a contributing factor to their high accuracy rates.[2]

Fifth, during fabrication, no draft shield was used. A draft shield is a thin perimeter wall that is printed together with the model that reduces temperature fluctuations in the space around the model. ABS plastic is prone to warping due to minute changes in temperature. This might have affected fidelity of the contact surface of the template.

Lastly, during CPS insertion itself, spinal alignment might be altered due to torsion from drilling or screwing and this was cited as contributing factor to an 11.1% screw malposition rate seen in CPS insertion guided by image navigation systems.[15] This particular factor can be remedied in 3D printed templates by increasing the surface area of contact between the template and the spine, and increasing the thickness of the bore guide (in this study, it was only 1.5 mm), and adding reinforcing ribs around the cylinder. In a related note, for this study, the insertion of the CPS into the cadaver models was carried out by a resident who had no experience in spine surgery. This might explain the significant difference in accuracy with the hybrid method of Bundoc et al. In that study, CPS insertion was done by a spine fellow with high technical competence in the insertion technique.[1]

In spite of low accuracy scores compared to other 3D printed templates, the template in this study is still an improvement over the traditional topographic method, and comparable to the combination of topographic method and laminoforaminotomy. The traditional topographic method has a reported accuracy of 12% and improves moderately to

45% when combined with laminoforaminotomy to provide additional visual and tactile cues to the surgeon.[3]

Accessibility for the local setting is another advantage. The acquisition cost of specialist medical 3D modeling software can be prohibitive. The researchers have interviewed some colleagues who have been quoted as much as $100,000 for a user license. In contrast, general purpose 3D modeling software like the one used in this study, can be acquired for less than $1,000. There are also free and open source alternatives like Blender (Blender Foundation, Netherland). There was also the added benefit of an easier learning curve as evidenced by the fact that the entire design process was done by medical students.

Trajectory planning can be improved by making the process objective – a software algorithm can be used to determine optimal screw trajectory. Newer additive manufacturing technologies like selective laser sintering (SLS) are also becoming more accessible. These newer methods allow printed models with superior resolution, accuracy, and structural strength to SLA and FDM. The methods discussed in this paper can also be applied to other surgical treatments like knee arthroplasty where a template may help decrease operation time. The capabilities of other general purpose 3D modeling software should also be explored.

Further work is needed to improve the accuracy of the 3D printed templates fabricated using this methodology and make it competitive with those created with more expensive software. The researchers recommend further studies in these areas specially in the context of developing 3D printing as a support service for surgical operations in the Philippines.

CONCLUSION

Accuracy scores for CPS insertion of the 3D printed drill templates were 52% for assessor 1 and 44% for assessor 2. Several factors were identified during the fabrication process that contributed to the accuracy scores. The researchers believe that the accuracy of the 3D printed templates can be greatly improved by addressing issues in segmentation, design, and fabrication.

Statement of Authorship

MSOA contributed in the conceptualization of work, acquisition and analysis of data, and drafting and revising of manuscript; RCB contributed in the conceptualization of work, and drafting and revising of manuscript; RLCA, JALA, CGA, ADGA, PGIA, ABLA, SPHA, FSA and KSA contributed in the acquisition and analysis of data; ACTA and JRTA contributed in the acquisition and analysis of data, and drafting of manuscript.

Author Disclosure

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