

Full title: Schedule Feasibility and Workflow for Additive Manufacturing of Titanium Plates for Cranioplasty Reconstruction in Canine Skull Tumors

Short title: AM of Canine Cranial Plates

Authors: J James<sup>1</sup>, RA zur Linden<sup>1</sup>, FMK James<sup>1</sup>, J Phillips<sup>2,3</sup>, M Parkes<sup>4</sup>, ML Oblak<sup>1\*</sup>

<sup>1</sup>Department of Clinical Studies, Ontario Veterinary College, Guelph, Ontario, Canada <sup>2</sup>College of Arts, University of Guelph, Guelph, Ontario, Canada <sup>3</sup>Centre for Advanced Manufacturing and Design Technologies(CAMDT), Sheridan College, Brampton, Ontario, Canada <sup>4</sup>Additive Design in Surgical Solutions Centre (ADEISS), London, Ontario Canada

Corresponding Author: Dr. Michelle Oblak, [moblak@uoguelph.ca](mailto:moblak@uoguelph.ca)

# **Abstract:**

Additive manufacturing has allowed for the creation of a patient-specific custom solution that can resolve many of the limitations previously reported for canine cranioplasty. The purpose of this pilot study was to determine the schedule feasibility and workflow in manufacturing patient-specific titanium implants for canines undergoing cranioplasty immediately following craniectomy. Computed tomography scans from patients with tumors of the skull were considered and 3 cases were selected. Images were imported into OsiriX MD image processing software and tumor margins were determined based on agreement between a board-certified veterinary radiologist and veterinary surgical oncologist. Virtual surgical planning was performed and a 5mm bone margin was selected. A defect was created to simulate the intraoperative defect. Stereolithography format files of the skulls were imported into Renishaw Additive-manufacture for Design-led Efficient Patient Treatment (ADEPT) software. In collaboration with medical solution center, Additive Design in Surgical Solutions (ADEISS), a custom titanium plate was designed with the input of an applications engineer and veterinary surgical oncologist. Plates were printed in titanium and postprocessed at ADEISS. Total planning time was approximately 2 hours with a manufacturing time of 2 weeks. Based on the findings of this study, with access to an advanced 3D metal printing medical solution center that can provide advanced software and printing, patient-specific additive manufactured titanium implants can be planned, created, processed, shipped and sterilized for patient use within a 3-week turnaround.

## **Introduction:**

Canine cranial tumors are often challenging to treat due to complex regional anatomy and reconstruction. Historically in dogs, closure of the skull defect included a temporalis muscle or fascia flap over a polymethylmethacrylate cap.<sup>1-3</sup> More recently, the use of titanium mesh has been described. Titanium mesh for canine cranioplasty is easy to use and has a good cosmetic outcome with limited complications, but surgical time may be prolonged due to the need to contour the implant intraoperatively.<sup>1,4-5</sup> The use of additive manufacturing for preoperative printing of patient-specific titanium implants has the potential for significant impact in canine cranial reconstruction.

The emergence of additive manufacturing technology has allowed for the development of patient-specific implants and cutting guides to assist in both the pre and intraoperative phases. Patient-specific additive manufactured implants have been described for many applications in human patients including the correction of dental and maxillofacial deformities.<sup>6-7</sup> The use of this technology reduces surgery time, speeds healing, and improves clinical outcome.<sup>6,8-9</sup> In veterinary medicine, reports of additive manufacturing are limited to case reports or experimental studies, including the creation of a customized surgical plate for canine tibial plateau leveling osteotomy, correction of a persistent hard palate defect, the production of titanium mesh cages and plates (imbued with repair stimulating substances) to repair canine radial defects, and most recently a feline titanium mandibular prosthesis.<sup>9-12</sup> The timeline associated with each study were either not reported or had a greater than 4-week turnaround from diagnosis until surgery.<sup>9-12</sup>

The aim of this feasibility study was to solidify a workflow and schedule for additive manufacturing titanium implants for surgery that can be applied to various procedures involving

67 cranial surgery. To the author's knowledge, this is the first report in the scientific literature  
68 regarding the use of metallic additive manufacturing for cranioplasty in veterinary medicine.

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## **Materials & Methods**

This feasibility study was intended to investigate the workflow for the design and additive manufacturing of patient-specific titanium plates for canine cranioplasty. The process examined included computed tomography (CT) review through to implant received, no clinical patients received implants as part of this study.

### **Image Capture**

CT scans from patients with primary skull tumors were evaluated. Cases were included if the tumor was predominately mineral dense and arose from the calvarium. CT images of the cranio-maxillary field were obtained using a 16-slice detector CT scanner (GE Brightspeed CT scanner, GE Healthcare, Milwaukee, Wisconsin, United States). The raw data were acquired with a standardized protocol in helical mode, 1.0-second rotation time, 0.562:1 pitch, 120 kV and 250 mA, 25-cm collimation, 512x512 matrix size, 0.488 mm in plane resolution, 0.625 mm through plane resolution using both standard and bone algorithms.

Digital Imaging and Communications in Medicine (DICOM) format was used and the images were imported into a DICOM viewer (Osirix MD, version 8.0.2, Pixmeo SARL, Bernex, Switzerland). Tumor margins were determined based on agreement between a board-certified veterinary radiologist and board-certified veterinary surgery oncologist in Osirix MD. A bone algorithm and soft tissue algorithm were placed side by side for evaluation. A region of interest (ROI) point was placed at the most rostral extent of the tumor. ROI points were placed every 1 to 5 slices, with each slice being 0.625mm. Each ROI point was placed on the left and right aspects of the tumoral margin (Figure 1). The ROI points were placed superficially on the calvarium and point size was made based on evaluator preference. Once all points were placed, the image was converted to a 3D image using 3D volume rendering and a high contrast 3D preset to evaluate

point placement and overall margin of the tumor (Figure 1). Once an agreement was reached, the export ROI's function was selected in order to export the data as a comma-separated values (.csv) file.

### Implant Design and Fabrication

The x,y,z point data from the .csv file were extracted and converted into a text file which was imported into ANSYS SpaceClaim (version 2017, ANSYS incorporated, Canonsburg, Pennsylvania, United States). A 3D spline was generated from the x,y,z point cloud data. The spline was smoothed to ensure the whole margin was still captured in the field of view. The DICOM files for the skulls were reconstructed using Materialise Mimics (version 19, Materialise NV, Leuven, Belgium) and the stereolithography (.stl) file was exported using Materialise 3-matic.

The skull .stl and the 3D spline were imported into Geomagic Freeform (version 2017, 3D systems incorporated, Rock Hill, South Carolina, United States). The spline was given a radial thickness equal to the size of the cutting margin determined by the surgeon with the addition of the diameter of the surgical cutting burr. The thickened 3D spline was then subtracted from the skull to create the desired hole to be replicated for the craniectomy. The resulting skull model was then exported as a .stl file and sent to Additive Design in Surgical Solutions (ADEISS) where they imported the file into the cranial plate creation software Additive-manufacture for Design-led Efficient Patient Treatment (ADEPT) (version 2017, Renishaw PLC, Wotton-under-Edge, Gloucestershire, United Kingdom). The cranial plate was designed in ADEPT software, under direction of the veterinary surgical oncologist, including the margin overlap, perforations, plate thickness, slits, identifier embossing, screw hole sizing and placement over skull defect (Figure 1).

At ADEISS, the plate file was imported into Computer Aided Manufacture (CAM) software QuantAM (version 2017, Renishaw PLC, Wotton-under-Edge, Gloucestershire, United Kingdom) in order to generate the additive manufactured support structure and manufacturing instruction file. This instruction file was sent to the AM400 (Renishaw) metal selective laser melting system and the plate was printed using medical grade titanium alloy (Ti-6Al-4V) using a 40 $\mu$ m layer thickness. The completed plate was heat treated in an argon environment and then removed from the build substrate. The support structures were manually removed and the convex surface was finished to the roughness defined by the surgeon using a rotary tool. The plate was ultrasonically cleaned to remove all processing residues then shipped to the surgical facility for sterilization and surgery.

## **Results:**

Three patient CT scans were selected for inclusion in this feasibility study.

### **Patient 1:**

Two-year-old, castrated male Bichon Frise with a large bony calvarial mass present for one year and five months prior to surgery. The CT scan revealed a 28mm H x 33mm W x 51mm L expansile bony mass centered on the junction between the right frontal and parietal bones (Figure 2A). Destruction of the underlying bone was noted. This mass was smoothly margined with some lobulation and had a coarse, stippled internal architecture. The mass extended into the cranial vault by 16mm and ventrally compressed the underlying right parietal and frontal lobes with an adjacent hypodensity of the cerebral gray and matter consistent with edema and left sided shift of the falx cerebri. The mass also extended rostrally into the right frontal sinus, filling the caudal two-thirds. There was no evidence of abnormal contrast enhancement of the mass or the brain. The histologic diagnosis was an osteoma.

### **Patient 2:**

Three-year-old, spayed female shih tzu/poodle cross that presented with a quickly growing bony mass that was present for two years and one month prior to removal. The CT scan revealed a 35mm H x 25mm W x 32mm L, round, smoothly margined, mildly lobulated, mineral dense, expansile mass arising from the calvarium, centered at the junction between the right parietal and frontal bones (Figure 3A). The mass was non-homogenous with a coarsely granular and stippled appearance. The mass expanded into the right calvarium causing compression of the right parietal and frontal lobe, with no evidence of cerebral edema, and resulted in a mild left sided shift of the falx cerebri. The histological diagnosis was an osteoma.

149 Patient 3:

150 Seven-year-old, spayed female Nova Scotia duck tolling retriever that presented with a  
151 firm mass on the skull that was first noted 14 days before surgery. The CT scan revealed a large  
152 soft tissue dense mass arising from the left frontal bone overlying the left frontal sinus. The mass  
153 mildly contrast enhanced and invaded the left frontal bone, resulting in bone lysis and expansion  
154 of the bone, with mild smoothly margined periosteal new bone formation, and a focal 2.5 mm  
155 defect between the lytic frontal bone and the brain (Figure 4A). The mass extended into the  
156 dorsolateral aspect of the left frontal sinus. The diploe of the caudodorsal aspect of the frontal  
157 bone had an increased mineral density compared to the right side, that extended just to the right  
158 of midline. The mass (and mineral dense diploe) was 40mm L, 28mm W, x 29mm H. The  
159 histologic diagnosis was a squamous cell carcinoma that invaded the calvarium and surrounding  
160 tissues.

161 All scans were imported and tumors confirmed to affect the skull based on the CT  
162 imaging. The veterinary radiologist and surgical oncologist collaborated to identify the tumor  
163 margins in all cases using OsirixMD and the studies were exported for processing as .csv files as  
164 described (Figure 2A-B, Figure 3A-B, Figure 3A-B). The tumor evaluation process from start to  
165 file export was performed with a mean time of 642s (240- 912s), or just under 11 minutes.  
166 Modifying and importing the .csv file into the design software required a mean of 300s. A 5mm  
167 surgical margin was set and a virtual defect created, as described, in all cases prior to plate  
168 creation (Figure 2C, Figure 3C, Figure 4C). The mean time to create the 3D spline and smooth  
169 the .csv contour was 300s along with an additional 300s to create the tube for the margin cut  
170 from the spline. The plate was then designed in consultation with ADEISS using the software  
171 ADEPT, as described, with the engineer and surgical oncologist (Figure 2D, Figure 3D, Figure

4D). The mean time to create the cranial plate in ADEPT using the reconstructed skull with the craniectomy was 900s, or 15 minutes. In all cases, margin identification, creation and plate design were completed within 2 hours. ADEISS then 3D printed and post-processed the cranial plate with a turnaround time of 2 weeks. In all cases, planning, printing, post-processing and shipping was completed within 3-weeks of CT scan image availability.

## **Discussion:**

This study demonstrates that with access to advanced expertise and a medical 3D printing solution center, such as ADEISS, patient-specific additive manufactured titanium implants for cranioplasty are feasible and can be manufactured for patient use within a 3-week turnaround from diagnosis to surgery. In 3 dogs, a patient-specific implant was created from CT images that were preoperatively planned, computer-designed and manufactured using the workflow outlined in this study.

Previous methods of cranioplasty in dogs are not ideal and recently the use of titanium mesh has been described in a small subset of dogs with good outcomes.<sup>1</sup> In humans it has been shown that titanium mesh can provide a safe and reliable implant that allows for postoperative CT and magnetic resonance imaging.<sup>13</sup> Despite this benefit, it does not always provide a cosmetic solution or one that reduces surgery time, speeds healing, or improves clinical outcome.<sup>6,8-9</sup> While none of these claims can be currently made for additive manufactured titanium plates, it can be hypothesized that some of these limitations may be eliminated with the use of this advanced technology. Access to patient-specific additive manufacturing for canine cranioplasty may allow for replacement of the previously preferred titanium mesh reconstruction in cases where complex contouring and reconstruction is necessary.<sup>1,4</sup>

This study relied on several different software programs and modalities for planning. Preoperative CT imaging is an important part of presurgical planning in patients with primary cranial tumors. The characteristics of the tumor on advanced imaging allow for determination of the invasiveness of the tumor and whether a patient is a surgical candidate or not.<sup>14</sup> The tumor margins were identified based on the CT scan in Osirix MD prior to transfer to Freeform for creation of the virtual defect. To identify the tumor margins, ROI points were marked on the CT

in Osirix MD with the radiologist and surgical oncologist and this method was the most easily translatable for communicating the exact location and extent of the tumor. This step was also important because the surgical oncologist and radiologist were the ones identifying the margins, as would occur in clinical practice. Creation and export of the tumor ROI allowed the design engineer to accurately create a defect with surgical margins that mimicked the surgical procedure and allowed for design of the implant. The surgical margin communicated to the design engineer directly related to the invasiveness of the tumor and extent of bone affected as seen in previous cases.<sup>16</sup>

The use of the Renishaw ADEPT software allowed for a seamless transition from the imported skull files to plate design. This software was designed for use in human skulls but was able to adapt to the many variations of the canine anatomy. By using this software, the team was able to design the plate in an efficient manner, allowing complete plate design and exportation for printing to occur in under 15 minutes. Alternatively, if the ADEPT software was not available this whole process would have to be performed in a CAD software such as Geomagic Freeform which, in the authors experience, would typically add approximately 2.5 hours to the design process. In addition, it has been noted in additive manufacturing application reviews that the skill and expertise needed to operate CAD software is a limitation of this technology.<sup>17</sup>

Accurate CT representation of the tumor was important in this study as planning of the anticipated surgical defect was necessary to design the plate. Single-staged surgical planning and reconstruction is often necessary in veterinary medicine as a second surgical procedure may be cost prohibitive or unpalatable to owners. If a single-stage procedure is performed, careful planning is required to ensure that the previously designed implant will fit into the planned defect. As a result, various methods need to be considered in order to standardize the surgical

approach. In human medicine, typically this procedure is performed in 2 stages. When a single stage procedure is elected, intraoperative molding or patient-specific cutting guides have been used to aid in improving intraoperative accuracy.<sup>7,18-22</sup> In veterinary medicine, there have been very few known uses of cutting guides and most of them are for orthopedic procedures. The use of patient-specific cutting guides in veterinary medicine has been sparsely reported but likely represent the future of surgical planning for advanced procedures and may aid in the accuracy of bone cuts and more accurate plate placement.<sup>10,23-24</sup>

The creation of a custom implant for patients in veterinary medicine with the use of additive manufacturing technologies has both benefits and pitfalls. Having access to a medical solution center, such as ADEISS, allows individuals to access this advanced expertise and service in a single location. A recent review of additive manufacturing in human medicine determined that the planning time costs for these types of surgeries is well worth the benefit, stating that an hour spent in production of an additive manufactured implant is equivalent in cost to 10 minutes saved in the surgical suite.<sup>25</sup> The use of patient-specific modelling has been proven in multiple studies to reduce surgical hemorrhage as well as reduce surgical time, which in effect decreases general anesthesia time and wound exposure.<sup>26</sup> The increased procedure time in human cranioplasty directly correlates with increased risk of surgical site infections which makes the importance of patient-specific implants that fit perfectly over the craniectomy site necessary.<sup>27</sup> Costs and cost savings for this procedure are unknown at this time but it is likely that this would result in a decrease in surgical and anesthesia times, and therefore costs may be similar to the current standard of care. Overall there are many potential benefits although the cost-benefit ratio has yet to be proven in veterinary medicine. While this model allows for access to this technology, there will be a lag of approximately 2 weeks from case submission to printed plate

availability. In most cases, this planning time will not affect outcomes but may not be favorable to all owners. In addition, due to the highly specialized nature of these procedures, cost to the owner for the preoperative planning, surgery and postoperative recovery will still be a significant consideration. Despite these potential limitations, many patients that are already undergoing this complex and expensive procedure would ultimately choose to provide the best standard of care for the greatest outcome.

A limitation of the methods described in this paper is that CT imaging does not always accurately represent the full soft-tissue extent of the tumor making surgical margins more difficult to determine. The use of magnetic resonance imaging may be helpful for evaluation of soft tissue components but was not considered in this study.<sup>28</sup> The plates created in this study were designed to cover the bony defect that would be created by surgical excision. In cases where intraoperative modification may be necessary based on the characteristics of the tumor, a staged procedure or creation of several plates may be necessary to allow more accurate planning of the implant after the defect is made.

This study demonstrated that a patient-specific additive manufactured implant may be created using this workflow and can be produced within a timeframe that is reasonable to ensure patient outcomes are not compromised. Having a patient-specific implant that reconstructs the defect created following a craniectomy procedure may reduce surgery time, speed healing, and improve clinical outcomes for patients in the future. The ability to provide this type of care to patients undergoing a craniectomy has now been realized. Since this study was completed, the authors have successfully utilized the workflow and techniques in a clinical patient.

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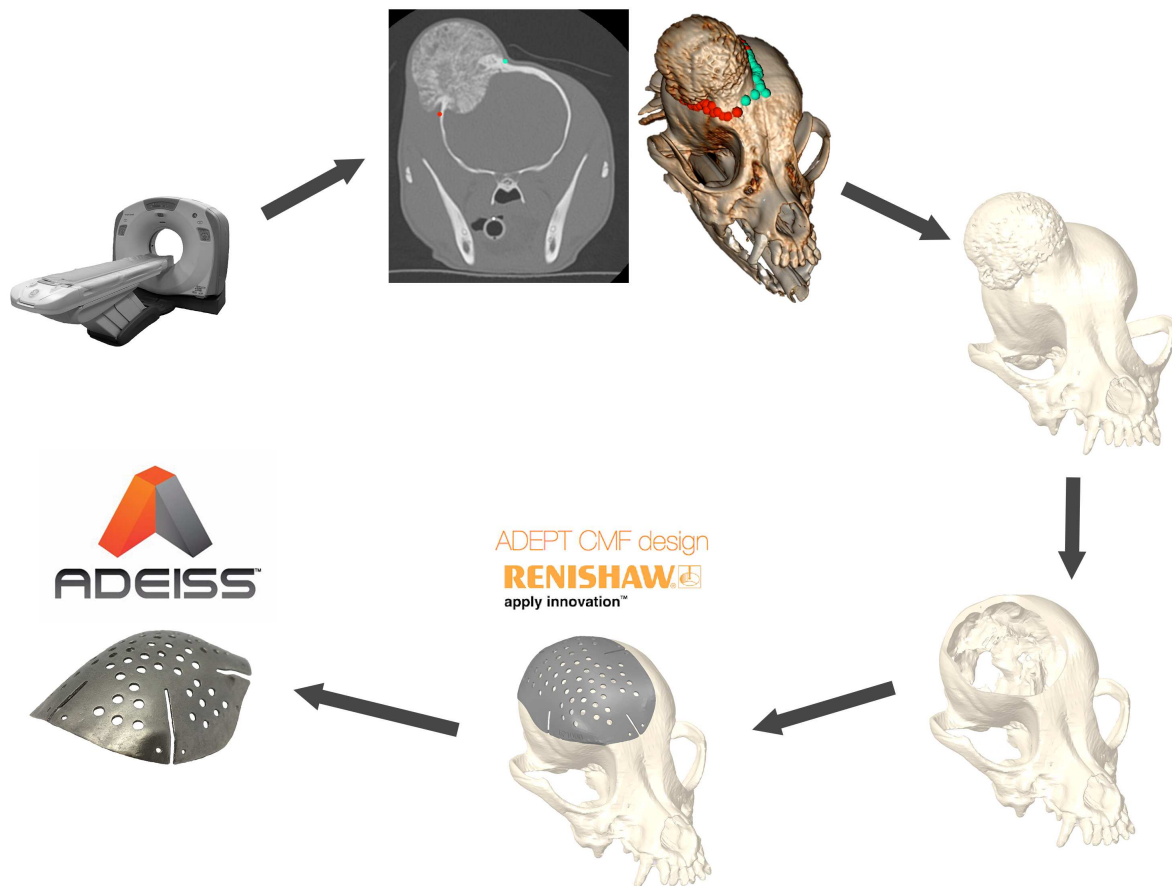
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346 **Figures & Figure Legends**

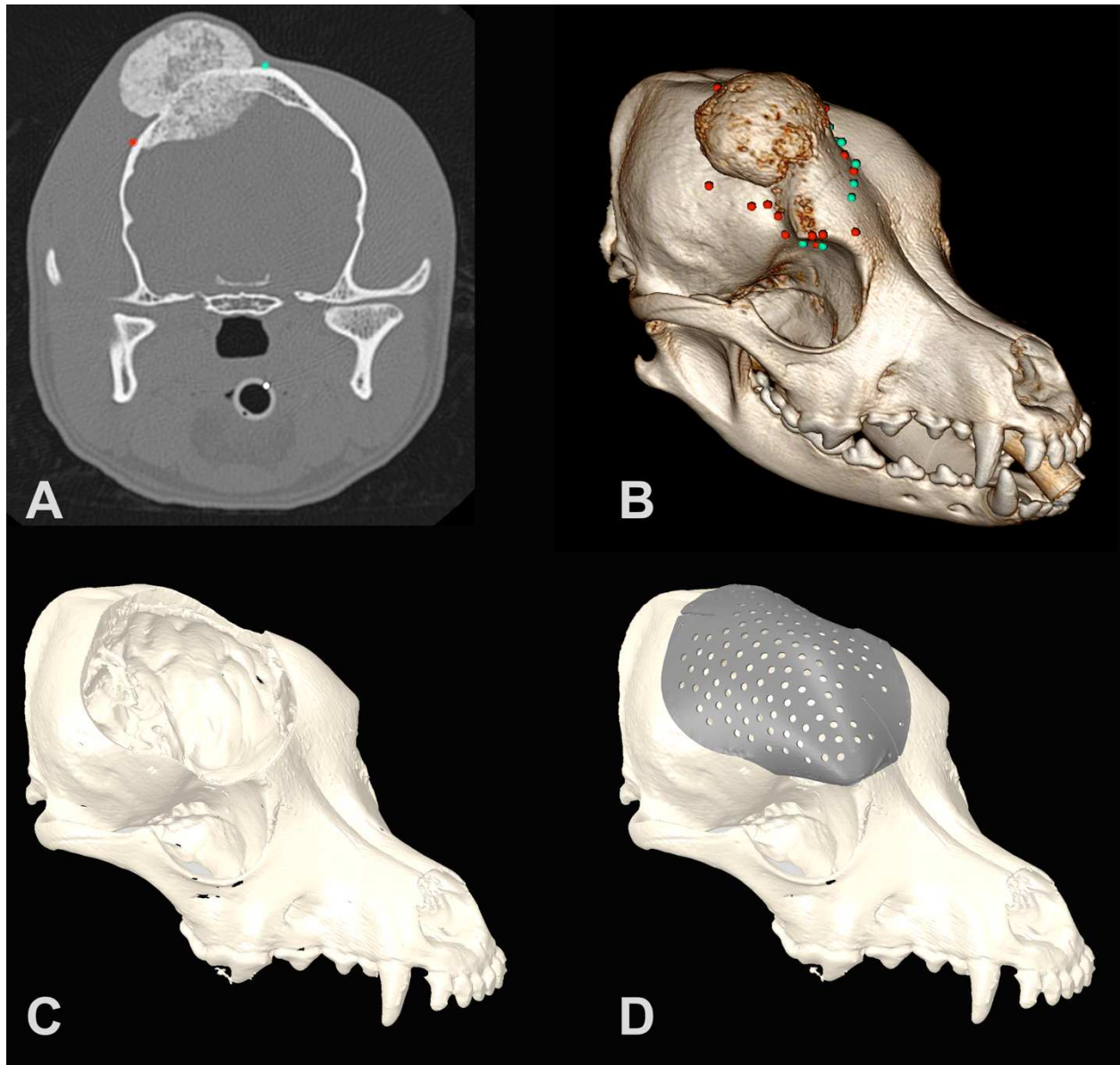


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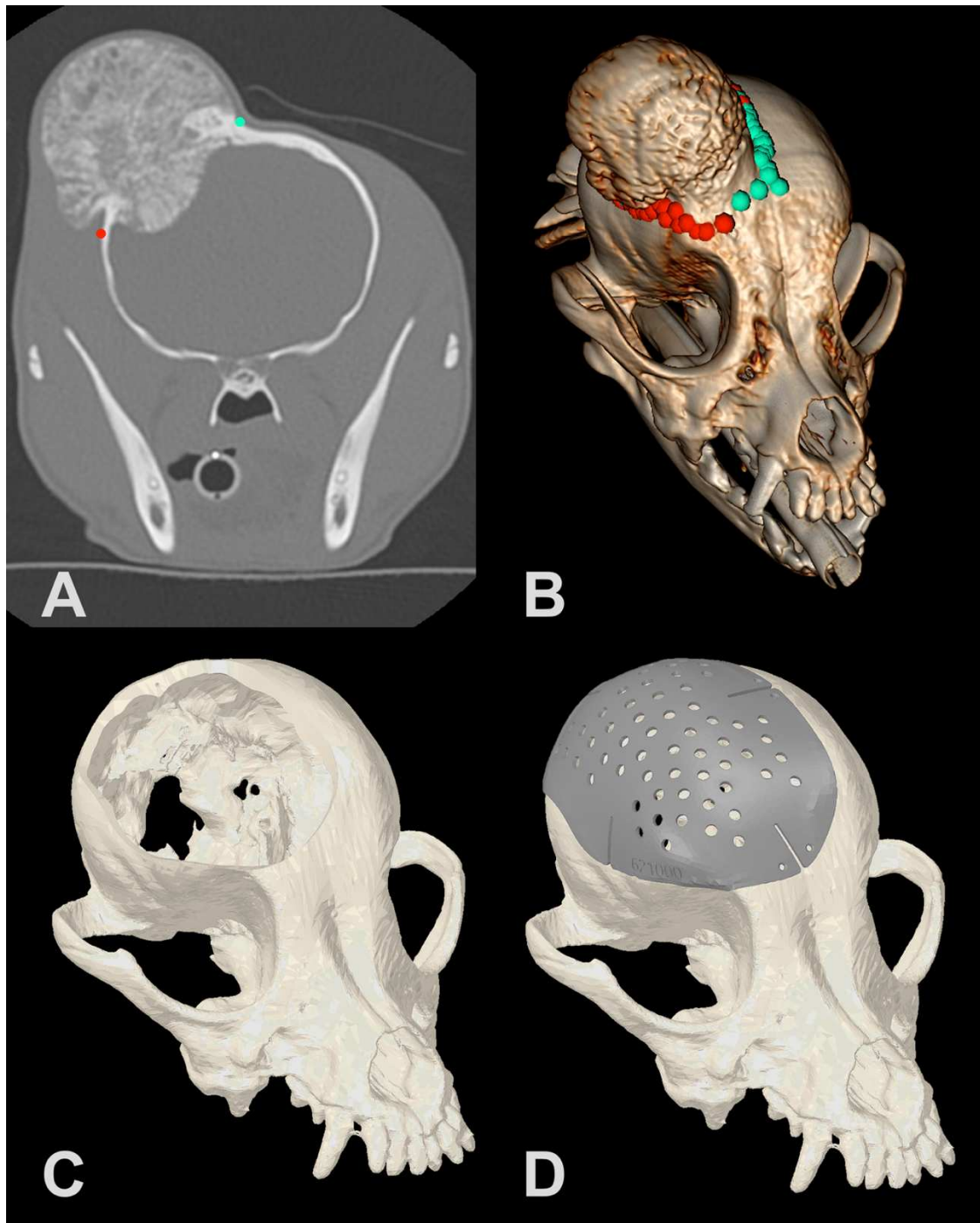
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348 **Figure 1** Proposed workflow from CT scan to printed plate.

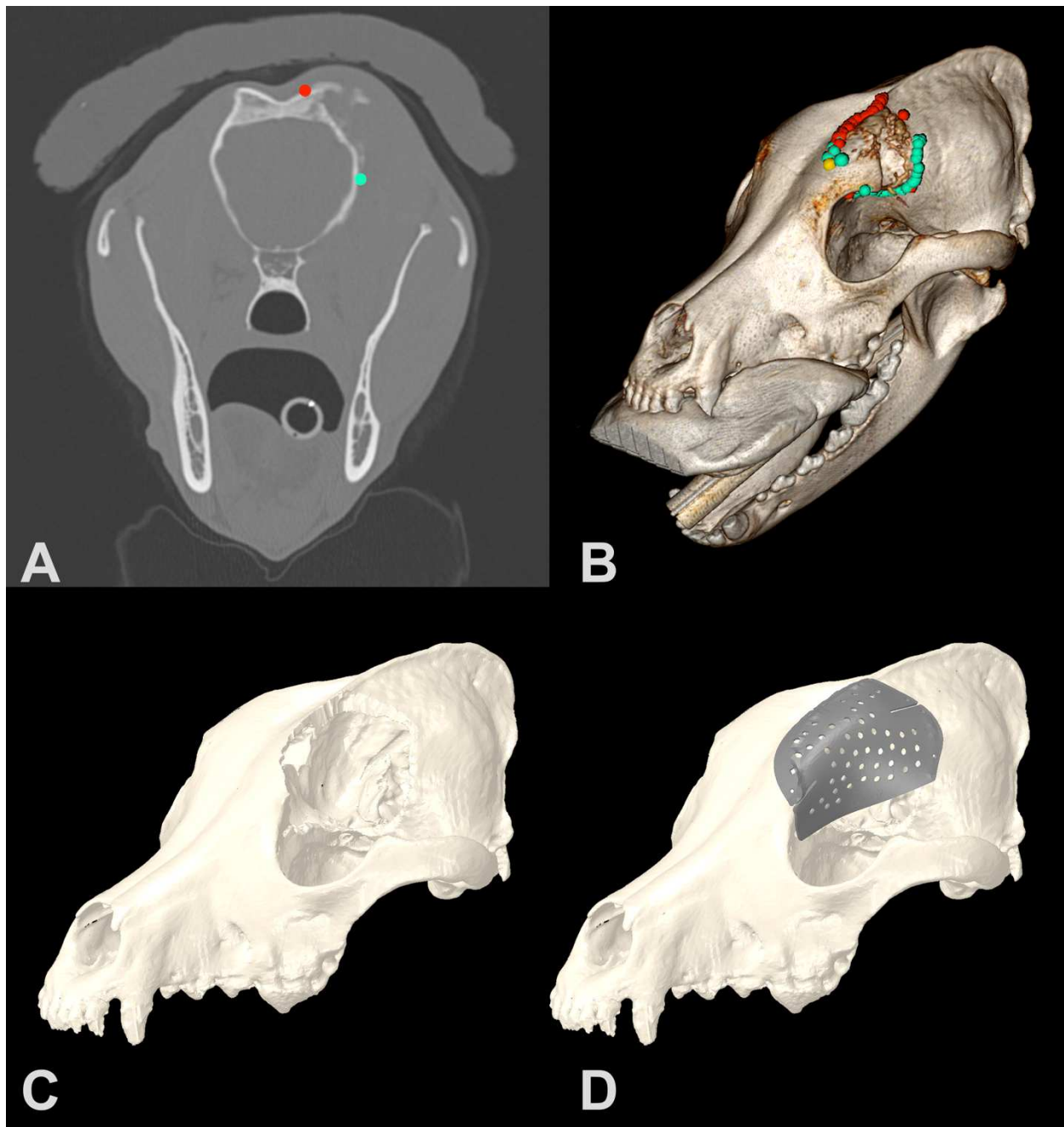
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**Figure 2** Workflow for Patient 1. **A.** CT image with Region of Interest (ROI) points for in  
**B.** Three-dimensional reconstruction with ROI points in OsiriX  
**C.** Three-dimensional spline in Geomagic Freeform software with tumor removed based on  
**D.** Titanium plate designed in ADEPT software.



**Figure 3** Workflow for Patient 2. **A.** CT image with Region of Interest (ROI) points for in OsiriX MD imaging software. **B.** Three-dimensional reconstruction with ROI points in OsiriX MD. **C.** Three-dimensional spline in Geomagic Freeform software with tumor removed based on surgical cutting margins. **D.** Titanium plate designed in ADEPT software.



**Figure 4** Workflow for Patient 3. **A.** CT image with Region of Interest (ROI) points in OsiriX MD imaging software. **B.** Three-dimensional reconstruction with ROI points in OsiriX MD. **C.** Three-dimensional spline in Geomagic Freeform software with tumor removed based on surgical cutting margins. **D.** Titanium plate designed in ADEPT software.