Establishing a Point-of-Care Virtual Planning and 3D Printing Program

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Abstract

Virtual surgical planning (VSP) and three-dimensional (3D) printing have become a standard of care at our institution, transforming the surgical care of complex patients. Patient-specific, anatomic models and surgical guides are clinically used to improve multidisciplinary communication, presurgical planning, intraoperative guidance, and the patient informed consent. Recent innovations have allowed both VSP and 3D printing to become more accessible to various sized hospital systems. Insourcing such work has several advantages including quicker turnaround times and increased innovation through collaborative multidisciplinary teams. Centralizing 3D printing programs at the point-of-care provides a greater cost-efficient investment for institutions. The following article will detail capital equipment needs, institutional structure, operational personnel, and other considerations necessary in the establishment of a POC manufacturing program.

Keywords
- point-of-care manufacturing
- 3D printing
- anatomic models
- surgical guides
- digital twinning

Virtual surgical planning (VSP) in plastic surgery is the digital development of a restoration, replacement, or alteration plan to either achieve cosmetic or reconstructive results to resolve medical abnormalities, diseased biologies, or enhance the patient's appearance. Many factors must be considered to plan a treatment outcome, including understanding of the complex anatomy, the extent and type of defect/abnormality, and the proximity of vital structures to the region of interest. The final treatment plan must respect all of the prior considerations while achieving functional and esthetic results. Having the ability to virtually plan such complex surgical procedures has been transforming plastic surgery and is widely used throughout the industry.[1–4] Within the last decade, technological advancements have combined VSP with three-dimensional (3D) printing to best facilitate surgical procedures. Through the development of 3D printed anatomic models and patient-specific surgical guides, this technological duo has led to more efficient and accurate surgeries improving outcomes.[5–10]

3D printing (also known as additive manufacturing or rapid prototyping) refers to a variety of technologies and processes that manufacture complex parts layer by layer from a 3D computer-aided design (CAD) model. As an additive technology, 3D printing processes build models by adding stacks of materials and fusing the layers together into a 3D object.[11,12] On the other hand, subtractive technologies (e.g., milling, drilling, laser cutting, etc.) achieves a planned part through the controlled machining and material removal, starting with solid blocks, bars, or plastic rods. Although both additive and subtractive technologies have unique benefits, 3D printing offers a wide range of material choices and high degree of complexity in the models that can be produced, making it an advantageous manufacturing method of medical models and devices.[13] During the VSP/3D printing

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process, a patient's volumetric imaging datasets are segmented, which creates a surface-based 3D model. This digital anatomic representation is then further modified in CAD software for anatomic accuracy improvements, surgical planning, and/or pre-production requirements. The devised surgical plan facilitates patient care not only through digital depictions and measurements, but also with tactile, life-sized 3D printed anatomic models and patient-specific surgical tools (e.g., cutting, drilling, contour, and template guides) to be used and referred to throughout the procedure. Due to the success and increasing use, the Food and Drug Administration (FDA) published a guidance document in December 2017 to provide some considerations and a necessary framework to safely and effectively 3D print personalized devices and anatomic models.[14]

As VSP and 3D printing rapidly influence surgical and clinical practices, it has resulted in a surge of point-of-care (POC) manufacturing within hospitals throughout the United States and internationally.[15] POC manufacturing is referred to the just-in-time creation of diagnostic models and medical devices (e.g., anatomic models, surgical tools, prosthetics, etc.) based off of patient medical imaging, occurring either at the location of patient care or at a centralized facility that is owned by the healthcare institution.[15] Because of the increased accessibility of VSP and 3D printing at the POC, it allows clinicians to bring conceptual ideas to clinical use in short turnaround times and limited costs that would not be seen from outsourcing to third party companies.

This article provides general guidance when looking to establish a POC virtual planning and 3D printing program at an institution. A common workflow used to create 3D printed, patient-specific models and devices is presented along with quality assurance steps to ensure successful production of diagnostic models and accurate devices. Based on our institution's experience of developing of our own centralized POC program, factors regarding the foundation and "bones" of the facility (e.g., personnel, software, equipment, physical space, location, etc.) are introduced to give some insight what the blueprint and planning may need to entail. Once established and fully functional, a dedicated, POC 3D printing facility will enhance patient care, improve trainee education, and encourage development of innovative solutions while remaining cost neutral or increasing financial revenue.

History of Mayo Clinic's POC Anatomic Manufacturing Program

3D printing was initially used at Mayo Clinic in 2006 to facilitate a 70-member, multi-disciplinary care team, tasked with the surgical separation of conjoined twins. Two dimensional (2D) medical illustrations were constructed to illustrate the complex anatomy obtained from disparate radiologic studies (►**Fig. 1A**). Ultimately, a 3D patient-specific, life-sized model was thought to be the best tool to demonstrate the anatomy to multiple surgical subspecialties. Mayo Clinic had a previous long-standing history of making patient-specific models through a wax moulage process (►**Fig. 2**). Due to the convergence of several technologic improvements (i.e., thin-section radiologic imaging, improved computer processing power, advances in segmentation software, and 3D printing hardware), 3D printed models were created for the planning of the 12-hour surgery (►**Fig. 1B-C**). Having a 3D model of the twin's complex anatomy helped with the successful separation and illustrated benefits of having a tactile, life-sized 3D model from volumetric imaging datasets to facilitate patient care and surgical planning. Institutional collaborations between engineering, radiology and surgery developed with time, which progressed to in-house manufacturing of 3D printed models for neurosurgery, orthopedic, and craniomaxillofacial applications. Through the multi-disciplinary collaboration, nearly 70 3D anatomic models were produced in the early years of development on existing 3D printers that were housed in the Department of Engineering.

With increasing requests due to demonstrated patient care benefits and expanding 3D printing and VSP applications, a strategic investment by the institution through the Department of Radiology was made to begin a hospital-based 3D printing program, starting with 300 square-feet of workspace. In 2013, Radiology formally established the Anatomic Modeling Unit (AMU) in the Division of Informatics as a centralized manufacturing facility. Starting off with two multi-color 3D printers, the POC program was able to hire their first full-time biomedical engineer in 2015. Less than ten years after the program's beginning, the AMU now has over 14 full time employees and has expanded to include five 3D printing technologies across 37 printers in 7,000 square feet of hospital space that is positioned five flights above the operating room. Clinical volumes have currently been exponentially growing to 800 models and 1000 guides per year.

Foundation of the POC Program: Centralization

A POC manufacturing program can either be scattered throughout the institution with each location focused on a single specialty/application or be centralized in one location, servicing multiple specialties. A centralized location includes medical imaging processing, virtual surgical planning, and 3D printing in a single hospital location where physicians and surgeons are primarily working. As opposed to a scattered POC manufacturing program, there have been several advantages illustrated at our institution to establish a centralized, collocated 3D printing program:

1. Enables cross pollination of ideas between various specialties (e.g., a surgical solution invented for an orthopedic procedure could also benefit a plastic surgical procedure)
2. Facilitates collaboration and communication within a multi-disciplinary framework, including engineers, radiologists, surgeons, computer scientists, technologists, and artists
3. Provides convenient access for physicians to participate in surgical planning sessions during their clinical workday as opposed to virtual planning sessions during defined times with medical device companies

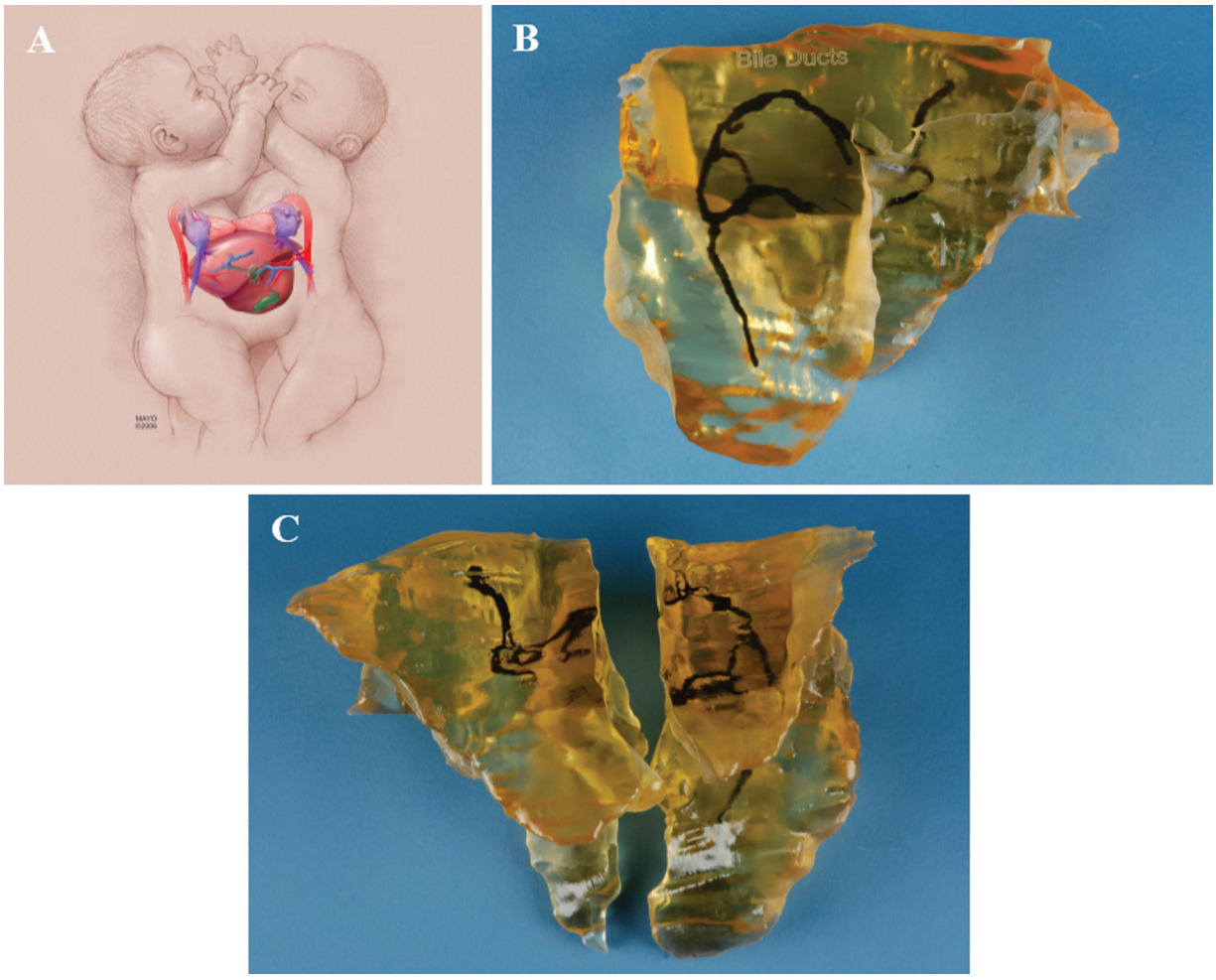

Fig. 1 Anatomical modeling was used to facilitate the surgical separation of conjoined twins at Mayo Clinic in 2006. A) 2D medical illustrations were created from radiologic studies. B-C) To better illustrate the complexity, a life-sized, 3D printed model of the twin's shared liver was fabricated from patient imaging, utilizing material jetting technology. Model was designed to have a black common bile duct for contrast and visualization. The liver was printed in two parts, displaying the surgical separation plan. (*A-B: Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved. C: From: Acre K, Morris JM, Alexander AE & Ettinger KS. Developing a Point-of-Care Manufacturing Program for Craniomaxillofacial Surgery Atlas Oral Maxillofac Surg Clin North Am. 2020 Sep;28(2):165–179, used with permission of Mayo Foundation for Medical Education and Research, all rights reserved.*)

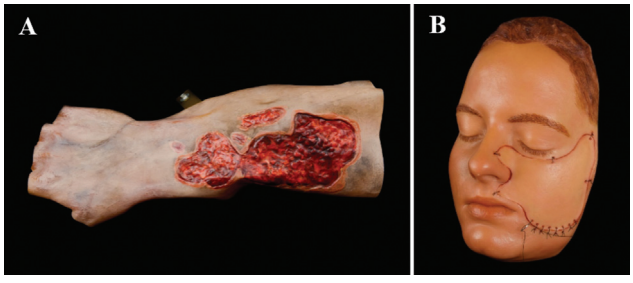

Fig. 2 Historical examples of anatomical wax moulages produced at Mayo Clinic during the 20th century. A) Model of patient's burn. B) Model of a facial reconstruction. (*Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved.*)

4. Ensures efficient and safe transport of anatomic models and surgical guides to the sterilization core, operating room (OR), or patient exam rooms
5. Enhances responses to urgent calls (e.g., ability to 3D scan patient who is receiving same-day clinical care, preparedness to scrub into the OR to assist with surgical guide placement, etc.)
6. Eliminates the barrier between the OR, surgical experts, and onsite engineers or technologists, which rapidly increases the clinical experience of the manufacturing staff (e.g., knowledge of procedures, surgical tools, etc.) and encourages innovation of novel ideas and improvements to current surgical approaches by all team members
7. Limits inefficiencies that may arise if multiple disciplines attempt to implement their own 3D printing program (e.g., centralized quality assurance, no misuse of technology, prevents underutilization of manufacturing infrastructure, and maintains clinical appropriateness of 3D printing applications)[16–18]

If the institution decides to establish a centralized POC virtual planning and 3D printing program, the facility will need to be embedded within the institutional system. In Mayo Clinic, the Department of Radiology's oversees image

protocoling, acquisition, processing, interpretation, and data storage, allowing for the best location to administer a POC manufacturing program. Centralizing manufacturing at the source data for 3D printed anatomic models and patient-specific devices has allowed for constant optimization of input data and collaboration, leading to the program's success. Imaging protocols have been created and optimized across each surgical subspecialty for both diagnostic purposes and for creating accurate 3D anatomic models. This prevents the rescanning of patients who have obtained radiologic studies that cannot be used to make diagnostic 3D printed models.

POC Manufacturing Program Workflow

The foundation to establish a hospital-based manufacturing facility is to understand the process to create patient-specific, 3D printed anatomic models and surgical guides. Critical steps include a surgical/medical order, medical image data acquisition, medical image segmentation, CAD, 3D printing, post-processing, quality assurance, delivery and sterilization, and dictation and billing as portrayed in ►**Fig. 3**. Throughout the entirety of workflow, any step is a potential source of error, which can affect the accuracy and quality of the final model or guide. The development of an in-house quality system to monitor and safeguard the fabrication process is critical to the success of a POC manufacturing program. In-depth discussions of each step are beyond the scope of this review; however, it has been addressed in previous POC manufacturing papers.[16,18–23] The following is a concise summarization of the workflow and suggested quality assurance steps that should accompany the entire process.

Surgical/Medical Order Received

To institutionalize a POC manufacturing program, a custom order set must be created by the local electric medical record

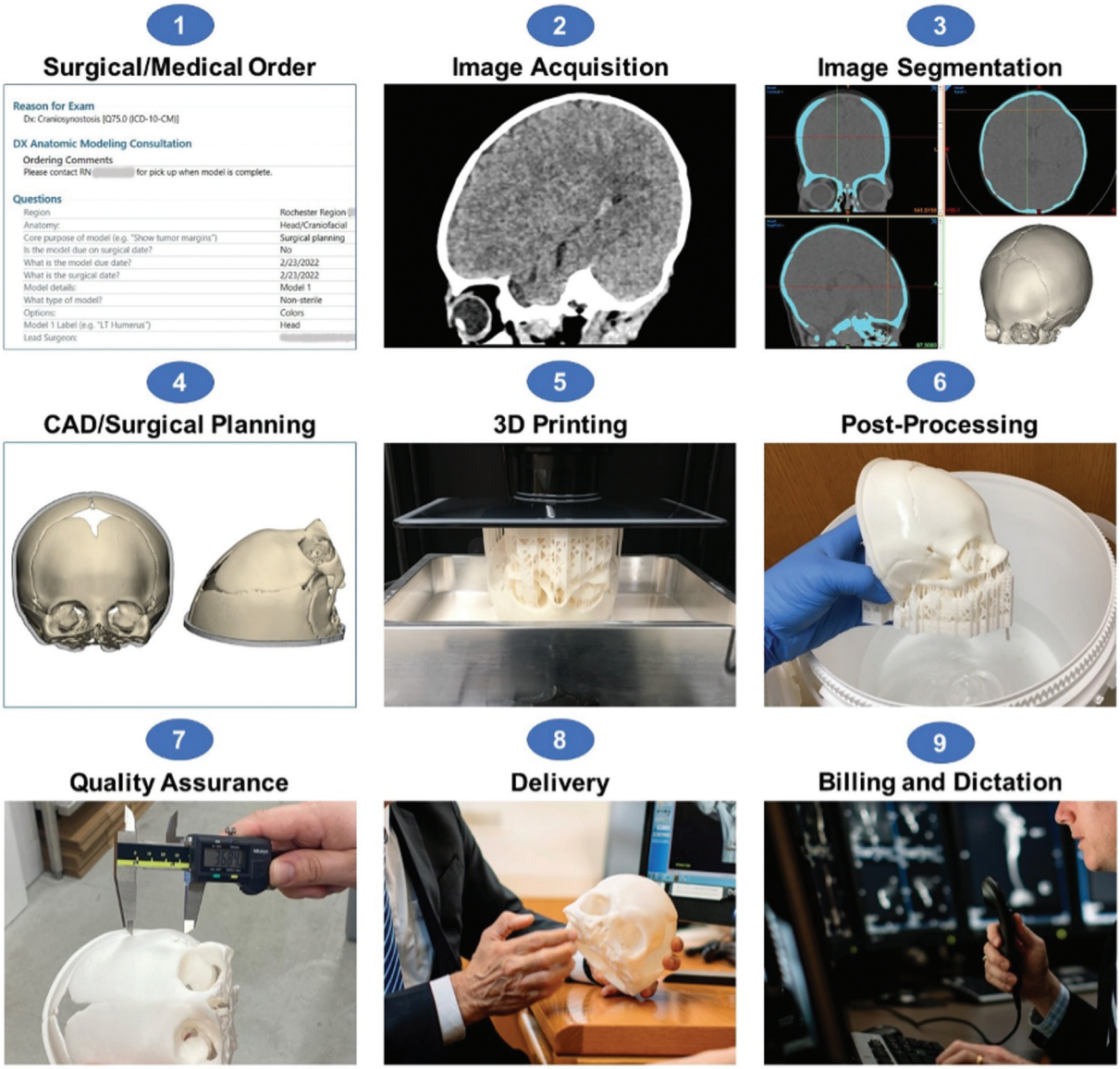

Fig. 3 Common workflow to create patient-specific, 3D printed anatomic models and surgical guides at the POC. (*Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved.*)

(EMR) team. A physician identifies the need for a 3D anatomic model, virtual surgical planning, or a patient-specific medical device, and then submits an order as part of their normal workflow. Orders specify the clinical indication and end use objective, including improved understanding of specific anatomic regions of interest (ROIs), guidance/reference during surgery, need for sterilization, bending of fixation plates, mirror imaging, or other uses to augment surgical or clinical care.

Medical Imaging Data Acquisition

Volumetric medical imaging studies provide the critical baseline data to create patient-specific anatomic models and devices. The international standard output file format for these datasets is Digital Imaging and Communications in Medicine (DICOM). For medical 3D printing, the most commonly used modality is computed tomography (CT), followed less often by magnetic resonance imaging (MRI), and even less, surface scanning with structured light and 3D/4D ultrasound.[16,20,24,25] During the time of ordering, it should be decided if the imaging study will be used for diagnostic purposes, preoperative planning, or custom device design.[26] With sufficient contrast and spatial resolution, anatomic models may be created from most volumetric medical imaging datasets; however, ordered radiographic studies need to be tailored to the desired end use with increasing resolution for each clinical application. For example, an informed patient consent model can be produced from a less detailed scan that was possibly acquired before seeing the surgical subspecialist. In contrast, patient-specific, 3D printed surgical guides require appropriate protocols for acquisition and reconstruction algorithms, such as denoising and multi-energy CT scanning with low and high KV reconstructions, to produce the most accurate medical images.[25,27–32]

In plastic surgery cases involving the head and neck as well as many other osseous applications, the CT scans often are limited by dental, orthodontic, or previous surgical metal implants, causing high attenuating beam hardening artifact.[33,34] These artifacts significantly impact the visualization of the patient's anatomy and pathology while also affecting the production of 3D models and devices. The 3D printing process becomes either impossible, the patient requires a rescan, or the process becomes more time consuming due to the additional segmentation and CAD steps required to reduce or eliminate the beam hardening artifacts. Several image acquisition techniques have been developed that can aid in metal artifact reduction and improve image quality: a jaw spacer to separate the mandible from the maxilla, gantry/head tilting, dual energy scanning, and iterative metal artifact reduction (iMAR) algorithms.[27,28,35,36]

Medical Image Segmentation

The extraction and manipulation of raw DICOM images create accurate surface-based 3D models of particular anatomy present in the scan. Within medical image post-processing software, segmentation is the process of marking an anatomic ROI or target regions of similar properties on image stacks and dividing it into anatomical structures.[20,37] A detailed discussion is beyond the scope of this article; however, segmentation can be performed manually, using automated/semi-automated rule-based techniques, machine learned algorithms, or a combination of the three.[38–47] Performing manual segmentation is very time-consuming, as the user is required to mark (with a paintbrush or a lasso) each slice of the image stack, which can contain hundreds of slices.[48] To speed up the process, various automated segmentation algorithms exist with the most common being thresholding, edge detection, and region growing.[37,49] However, when using segmentation algorithms, the presence of artifacts, congenital anomalies, previous trauma, and oncologic or infectious pathologies may cause segmentation errors and still requires expertise in manually separating the anatomic ROIs.[18,24,50] As a quality assurance step, our institution requires segmentation to be approved by either a subspecialty radiologist or the referring surgeon for all cases to ensure accuracy, especially for oncologic and congenital anatomic cases. Once the desired organs and tissues are isolated and delineated with the segmentation accuracy checked, the ROIs are interpolated from the dataset to generate a surface-based 3D model.

CAD of Anatomy, Pathology, and Planning of Surgical Intervention

Following segmentation, the surface-based 3D anatomic model is converted to a CAD file format, most commonly the stereolithography (STL) format. A STL file represents and fits the 3D surface of the model as a triangular mesh (►**Fig. 4**).[51] This allows for further manipulation and design around the 3D patient-specific anatomy and eventually facilitates exportation to a 3D printing file format. Multiple other CAD file formats, such as Virtual Reality Modeling Language (VRML/WRL), Wavefront OBJ (OBJ), Additive Manufacturing File (AMF), and 3D Manufacturing Format (3MF), can also be used throughout the 3D printing workflow, depending on the need for color and/or texture mapping.[52,53]

The three common applications for 3D printing in medicine are anatomical models, modified anatomical models, and virtual surgical planning with templates.[19] All such applications are delineated during CAD. An anatomical model represents the unaltered, as-scanned anatomy to be used for patient consent, education, and pre/intra-operative visualization, requiring very minor CAD manipulation to refine the file for 3D printing. Minor CAD includes adding connective struts to maintain anatomical accuracy, cutting the model to allow for better visualization of the ROI, smoothing the surface, hollowing various structures, and repairing the mesh from any unwanted imaging artifacts (►**Fig. 5A**). A modified anatomical model is classified as an altered version of anatomy after simple digital planning is performed to enhance surgical guidance and planning. Examples of this application include mirror imaging of the perfected anatomy, digital graft placement, and removal of an anatomical feature (e.g., tumor) to visualize the defect (►**Fig. 5B**). Lastly, virtual surgical planning is performed digitally, and from this, 3D

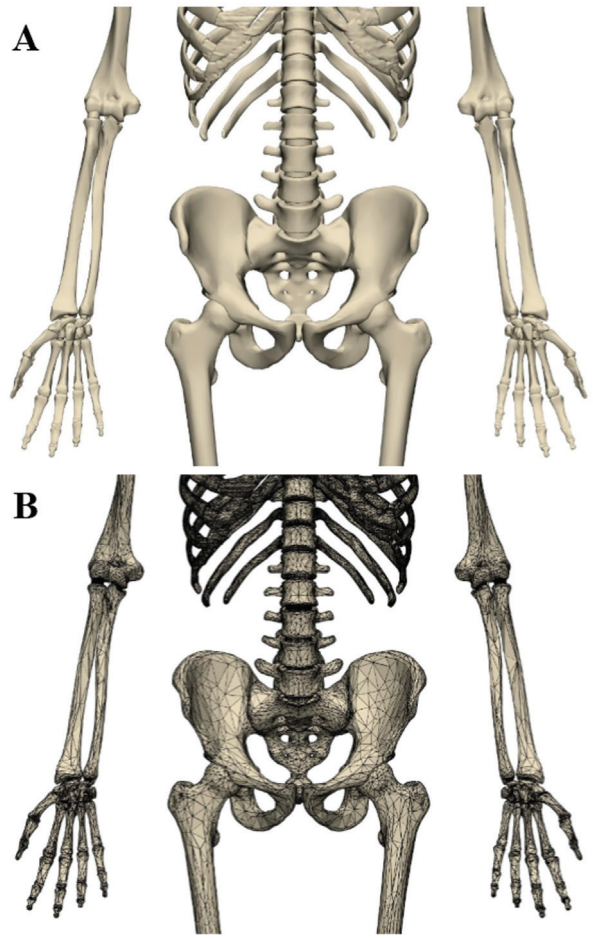

Fig. 4 A digital anatomic model within CAD software. A surface-based 3D anatomic model (A) can be represented as a stereolithography (STL) file within CAD software, which fits the 3D surface of the model as a triangular mesh (B).

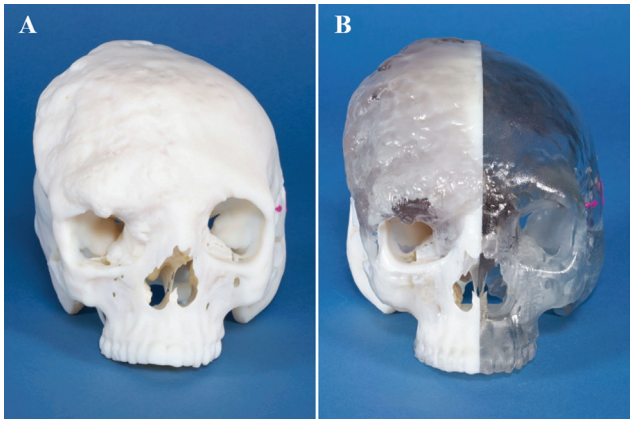

Fig. 5 Examples of an anatomic model and a modified anatomic model. A 47-year-old female presented with fibrous dysplasia. Surgical plan was to resect the abnormal fibroosseous overgrowth achieving a more normalized skull. A 3D printed model of the patient's native anatomy (A) was fabricated. To further facilitate, a modified anatomic model (B) was manufactured, combining the patient's native skull (transparent) with a "perfected" right skull printed in white to visualize the extent of the abnormality. The left, more anatomically normal side of the skull was mirrored to the right, defected side.

printed templates/guides are designed to facilitate the digital plan during the surgical procedure (►**Fig. 6**).

A handful of quality assurance steps are recommended during CAD. Initially, the contours of the final 3D model or device should be overlayed on the original imaging as a quality control step. For anatomic models, this checkpoint ensures that the model was not altered in CAD software to inaccurately represent the patient's anatomy. On the other hand, for patient-specific devices, this quality step confirms that the custom device conforms and fits to the patient's anatomic contours and that it will not inappropriately harm the patient (e.g., screw hole leading to screw placement into a major artery or vein). Further, device designs should be validated with the surgeon to ensure it fulfills its intended purpose. Lastly, as the final step of the CAD process, an anatomic model or device must be labeled. Models and devices must include an internal, unique patient identifying number stamped into the part to be used in the time-out period in the operative room and for part traceability back to the original imaging while also protecting Health Insurance Portability and Accountability Act (HIPAA) rights. As appropriate, labeling is also encouraged when it benefits communication and eliminates any confusion or potential misuse, such as indicating model sidedness (left/right), when anatomy has been mirrored or "perfected," and a scaling factor if on the rare occasion, the model will not be printed at anatomic size (1:1) (►**Fig. 7**).[16,18,19,54]

3D Printing

Beginning as one technology in the 1980s,[11,12] the International Organization for Standardization (ISO) and American Standards for Testing and Materials (ASTM) have classified 3D printing into seven distinct groups of printing processes or technologies.[55–57] Informally, 3D printing technologies can be further described by their respective raw or input materials, such as powder, resin, and solid-based.[58] When selecting a 3D printing modality for the clinical application, multiple considerations must be taken regarding color capabilities, material properties, transparency, biocompatibility, sterilization, accuracy levels, turnaround time, and cost of capital equipment/consumables.[59,60]

Once a production plan is decided upon, the CAD-modified model or patient-specific device is exported as a CAD file format compatible with the 3D printer (e.g., STL, VRML/WRL, OBJ/MTL, AMF, and 3MF). Files are then inputted into a build processing, or slicing, software. Within this program, it converts the 3D part into thin layers, and printing parameters, such as build orientation, print speed, layer height, tool path, and support material/strut location and density, are determined. The build processing software creates a build file, or machine code, that contains the manufacturing instructions tailored to a specific 3D printer.[59]

3D printers are far from operating perfectly for each use. Therefore, quality assurance steps should be taken to monitor the printers' performance and to safeguard the manufacturing of the most accurate and quality 3D prints. A detailed introduction of a recommended quality control system for 3D printers and their operation is beyond scope of

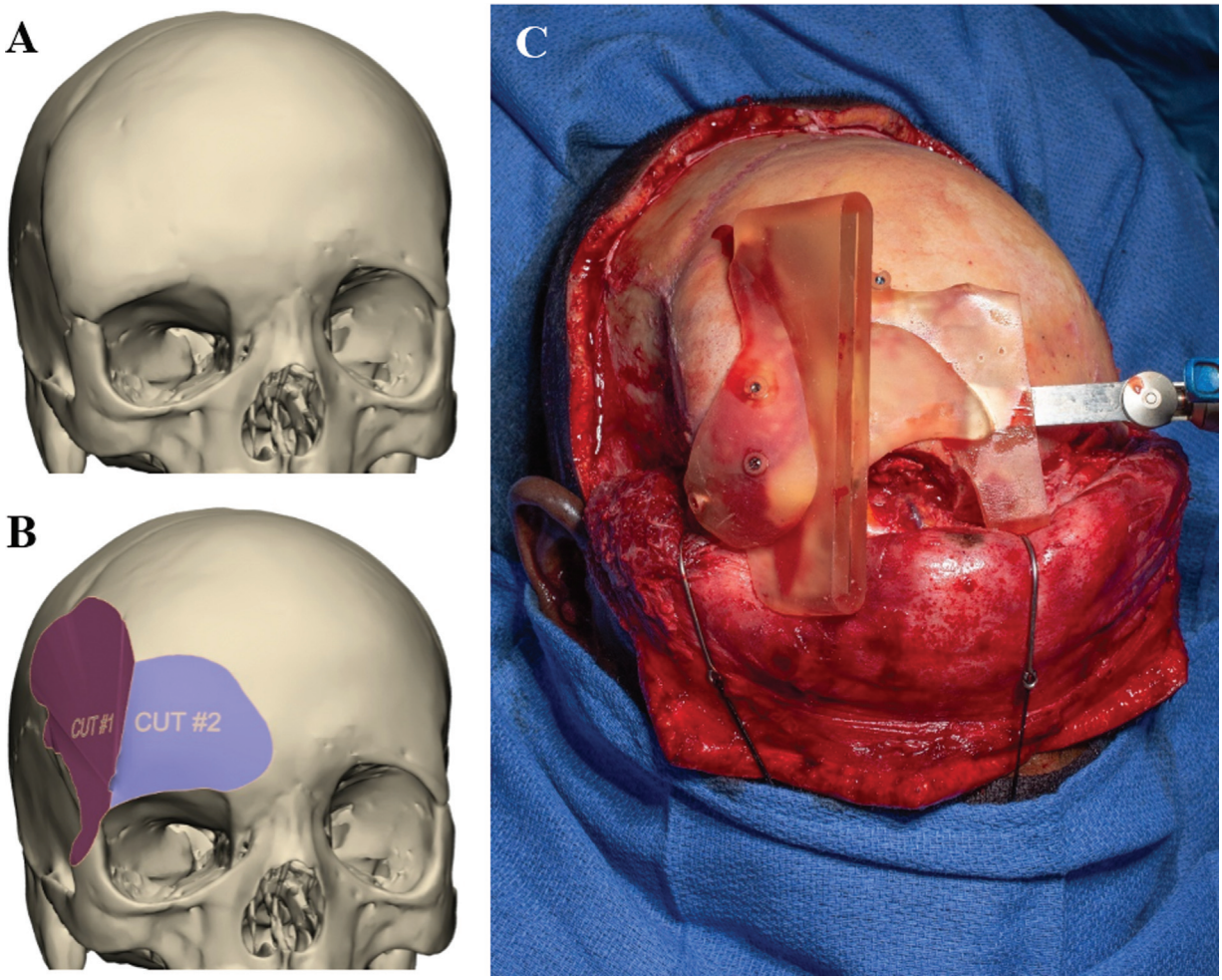

Fig. 6 Virtual surgical planning with cutting guides to facilitate craniomaxillofacial reconstruction of a patient with fibrous dysplasia. A) 3D digital model was created from the CT scans. B) A multipart guided surgical plan was created in CAD to be able to more efficiently remove large portions of the calvarium and make the patients skull more symmetric. C) A patient-specific, 3D printed cutting guide was utilized during the procedure to carry-out the virtual surgical plan.

this paper but can be found in other publications.[18,19,54] However, briefly, installation qualifications (IQ), operational qualifications (OQ), and performance qualifications (PQ) should be set in-place for 3D printer validation and to follow good manufacturing practices (GMP). Additionally, internal standard operating procedures (SOPs) should be documented and followed by team members to ensure the proper and consistent operation, cleaning, and maintenance (per build, weekly, monthly, annual) of each printer.

Post-Processing

Following the 3D printing process, the product is cleaned of residual manufacturing materials, such as support materials or structures. The type and extent of cleaning is dependent on the 3D printing technology that was used to manufacture the model or device. Ultimately, the 3D printer's original equipment manufacturer (OEM) should have instructions for use (IFUs) for cleaning and post-processing, and these recommendations need to be followed during this step. Any such removal of struts or residual materials could cause incidental harm or damage to the final anatomical model or devices and must be performed with caution.

Similar to the quality assurance recommendations around 3D printers, post-processing for each technology and material should be internally documented in SOPs to enforce consistency and safety. Any post-processing equipment should undergo IQ, PQ, and OQ to certify their proper use.

Quality Assurance of the Final Product

Before delivery, an overall inspection is critical to identify warpages, breakages, or failures that occurred during the manufacturing life cycle or during post-processing. Discrepancies between the 3D printed model/device and the virtual CAD model must be caught before the product is delivered for clinical use. Digital and physical measurements of the final product can be taken to ensure that it has been manufactured within an acceptable tolerance. Even further, surface scanning of the 3D model can be performed to overlay the digital twin of the 3D printed product to the original CAD model and analyze any dimensional differences. A comprehensive discussion of a quality management system for 3D printed models and devices for hospital-based 3D printing programs have been published.[18,19,54]

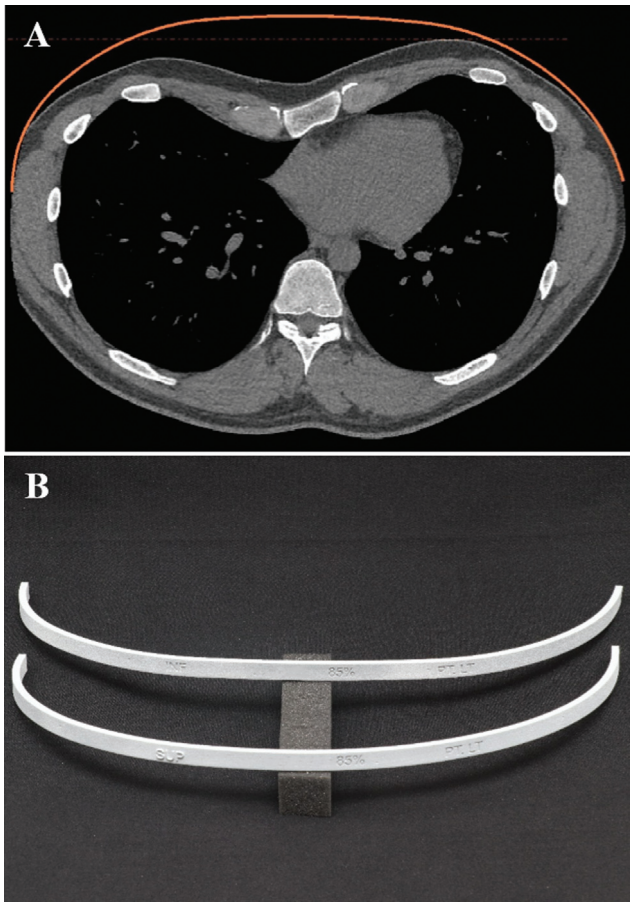

Fig. 7 Labeling 3D printed models as part of quality control. 40-year-old male patient presented with pectus excavatum and would be undergoing the Nuss procedure. A) A target surgical goal to normalize the patient's chest anatomy (denoted by orange curve) was decided upon during consultation between surgeon, radiologist, and engineer. B) From the surgical plan, 3D printed mock-ups were fabricated of what the concave, stabilizing bars should be curved to prior to surgical implantation. Bars were appropriately labeled within CAD software to avoid misuse, indicating the patient sidedness (LT), location of bar placement (inferior chest = INF, superior chest = SUP), and scaling factor (85%).

Delivery and Sterilization

A case summary is generated as one of the final steps, which includes details and images of the digital anatomy and surgical plan. This report is uploaded to the patient's EMR, allowing it to viewable by clinicians and readily accessible during the surgical procedure as reference for guide placement or tumor margins when visibility of the ROI is minimal in the OR.

Once the anatomic model or patient-specific device has passed all quality assurance steps and is properly documented, the requester and his/her team are notified. During the pick-up process, a consultation between the POC facility and the surgeon, physician, or clinical care team occurs to assure the device or anatomic model will be used appropriately. Communication includes showing any medical anomalies within the anatomic model and instructions of how the surgical guide or template was designed for use.

If the model or device is to be used in surgery, the device or model must undergo sterilization techniques, such as steam sterilization, ethylene oxide gas, and hydrogen peroxide. The most common technique used in surgical cores is steam sterilization, as it is a non-toxic method, using pressurized steam at a high temperature.[61] However, this technique is not always the best method to be used for all 3D printed parts as it can damage polymeric products that are manufactured with materials with low melting points.[62] Therefore, sterilization methods and handling instructions (e.g., time, temperature, etc.) need to be carefully deduced to avoid damage to the final device or model. During the time of delivery, sterilization IFUs are provided for the sterilization surgical core to follow. Additionally, as part of quality assurance, it is highly recommended that third party testing and validation of biocompatibility, sterilization, and cleaning methods should be performed for each 3D printing technology, material, and geometry that is intended to be used in the OR.[18,54]

Dictation and Billing

Documentation of the 3D printed model and surgical guides is essential. Similar to all other patient care information, this is stored in the EMR. Upon delivery, each case is dictated by the radiologist, including clinical indication, dates of cross-sectional imaging used to prepare the model, segmentation time, CAD time, 3D printing technology, material type, print time, and post-processing steps. At our institution, a custom dictation template was created for standardization, and the dictation is stored within the institution's RIMS, allowing recall of images and or part traceability.

Having a digital thread of the medical model/guide (starting with a medical order through the EMR ultimately ending in a dictation) triggers billing of the model and guides to third party payers. In July of 2019, Category III Current Procedural Terminology (CPT) Codes were approved and published by the American Medical Association (AMA), including patient-specific anatomic models (0559T and 0560T) and surgical guides (0561T and 0562T).[63,64] Category III codes are temporary, often assigned to emerging technologies or procedures, collecting evidence regarding the use and impact in medicine. More information regarding dictation and reimbursement of 3D printed models and devices at the POC can be found in a detailed publication.[65]

The Bones of POC Virtual Surgical Planning and 3D Printing Program

Planning for a POC planning and manufacturing facility requires an understanding of the necessary capital equipment and required operational structure. Depending on the size and scope of the operation, the necessary pieces include the multidisciplinary staff, physical space, software, 3D printer technologies, and post processing equipment, including their respective consumables and maintenance requirements.[66] While not exhaustive, some considerations involving the establishment of the program's “bones” are introduced to provide initial guidance.

Personnel

The number and breadth of employees can vary, depending on the scope and size of the POC 3D printing facility. It should be based on the anticipated case volume and range of disciplines that the program will be supporting. In general, a laboratory will start out small and expand over time. At minimum, a small surgical practice focused on one subspecialty can function with a dedicated radiologist or physician champion. However, once the volume of cases increases, it is critical to add an additional employee to aid with image segmentation, CAD, VSP, or 3D printing operations. As the POC program continues to expand, the amount and type of staff should always grow to meet the needs of the facility. In our experience, a mature, well-rounded planning and 3D printing facility at the POC should have the following personnel:

a. *Physicians*: The POC facility serves the needs of multiple surgical and medical subspecialties. They identify the clinical indications and need for 3D printed anatomic models or surgical devices. Open access to the POC facility for the referring clinician is essential to break down barriers to use and drive innovation.
b. *Radiologist*: Serving as a medical director of the POC program, a radiologist should oversee the work produced within the facility. A radiologist enforces anatomical accuracy in the facility's final products due to his/her expertise in interpretating patient imaging. A radiologist reviews medical imaging segmentation to ensure the patient's anatomy is accurately portrayed in 3D models and future VSP steps. A dedicated radiologist also segments all tumors, critical structures not easily visible on imaging, and any abnormal, congenital anatomy that the other staff members may not be familiar with.
c. *Radiology technologists (RTs):* Due to their training and education in imaging examinations, anatomy, and equipment protocols, RTs are an integral part of a POC program and carry out the majority of segmentation They ensure that the appropriate imaging exam is ordered and performed to visualize the patient's anatomic ROI and that any relevant imaging post-processing steps are followed. This assures that the best imaging to create an accurate 3D model of the patient's anatomy is received.
d. *Engineers (clinical or biomedical):* Engineers have expertise in CAD technologies that facilitate surgeons through the digital surgical planning, design, and manufacturing process. The engineer/surgeon collaboration stimulates innovation, iterative creativity, and refinement of concepts and designs, providing a new model of what makes up a surgical team. Engineers are critical in carrying out the fabrication of anatomic guides and templates, as these require the utilization of CAD design and engineering principles beyond those needed to create anatomic models.
e. *Equipment technicians:* Regardless of the type of 3D printer (s) a POC program has, the equipment requires in-depth knowledge and hands-on interaction to run and maintain. Thus, equipment technicians assist with the operation, maintenance, and optimization of 3D printers. Technicians help facilitate the program's workflow by managing builds, handling consumables, carrying out the necessary post-processing of 3D printed parts, and keeping up with the printer's routine maintenance to ensure the most accurate and quality 3D prints. Because of the wide variety of 3D printing technologies available on the market, our facility has found it beneficial to have a technical lead to manage and upkeep printers based on the raw material types used: a resin printer lead, a filament/solid printer lead, and a powder printer lead. This has allowed the technicians to form strong relationships with the respective OEMs and to become experts in certain technologies, making troubleshooting more efficient and less time-consuming.
f. *Medical Administrative Assistant*: As the number of cases expand, there is a need to have an assistant assigned to the facility to monitor the incoming and current orders. The assistant ensures that orders have been properly submitted (e.g., medical imaging has been scheduled in time, the medical necessity has been properly identified in the order, type of model or guide has been specified, etc.), images are transferred, and that the orders are flowing through the POC program's clinical and manufacturing workflow for on-time deliveries.

As a naïve program just planting its roots within the institution, it will likely not be possible to have all the dedicated employees as indicated above. In the beginning, essential personnel can be integrated from existing work units within the hospital system as either part-time or full-time allocation. During Mayo's POC facility development, the personnel cross-assignment helped with cost containment and maintained a level of flexibility when adopting new technologies and services. If starting off with a physician/radiologist champion and a RT, the technologist can become certified in medical 3D printing through Clarkson College.[67] This program allows for imaging professionals to become proficient in the medical 3D printing process and could allow the RTs to pick-up CAD work if motivated. It is also possible for a POC program to start off with a physician/radiologist and a biomedical engineer. Depending on the engineer's drive and current knowledge of anatomy, pathology, and imaging modalities, the engineer may also pick-up some of the imaging post-processing steps (e.g., segmentation, registration, and creation of 3D meshes) in addition to their VSP and CAD work.

Regardless of the new employee, the learning curve to become proficient in imaging segmentation, anatomy, a wide array of pathologic conditions, CAD, and 3D printing can be steep. Therefore, throughout the process of expanding employees within the POC 3D printing facility, it is important to set-up an organized training program with defined and measurable objectives.

Equipment

Depending on the technology and brand, manufacturing capabilities vary between 3D printing equipment, and no

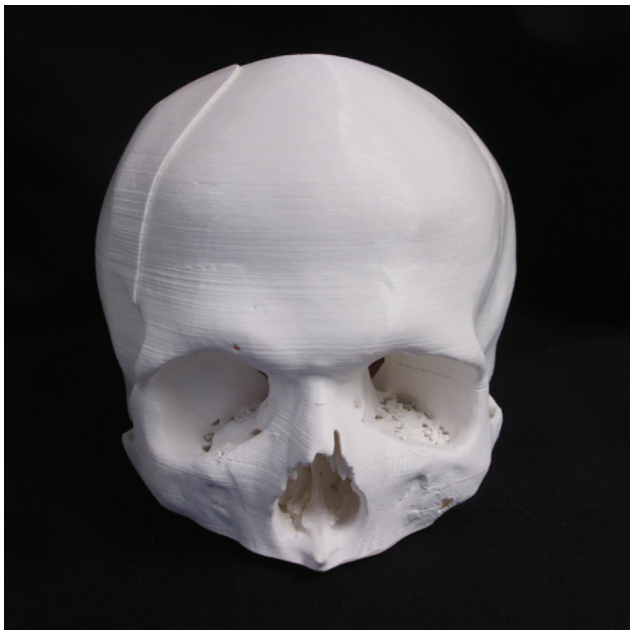

Fig. 8 Material extrusion. A patient-specific, 3D printed model was created at the POC to quickly assist with plate planning over a cranial defect, using material extrusion (S5, Ultimaker, Utrecht, Netherlands).

single 3D printer fits all needs of a POC manufacturing facility. Because each technology offers unique manufacturing benefits, having a range of 3D printers and processes can expand the facility's manufacturing capabilities. Currently, medical 3D printing uses primarily five of the seven printing technologies: material extrusion, vat photopolymerization,[68] material jetting, binder jetting, and powder bed fusion.[21,59,66] Each of these technologies are actively utilized at the POC to produce unique models or surgical guides to enhance patient care within plastic surgery (►**Figs. 8–13**).

With every 3D printer there are necessary post-processing steps and post-processing equipment, which varies between each technology. In general, post processing includes support structure removal, clean-up of excess manufacturing material (e.g., excess powder or polymeric encasement), and enhancement of the final product (e.g., smoothing, clear coating, wet sanding, photobleaching, etc.).

A detailed discussion of each 3D printing technology along with its advantages, disadvantages, and associated post-processing equipment is beyond scope of this review. However, a brief introduction into the manufacturing capabilities and common post-processing steps of the five most common 3D printing technologies in medicine have been summarized

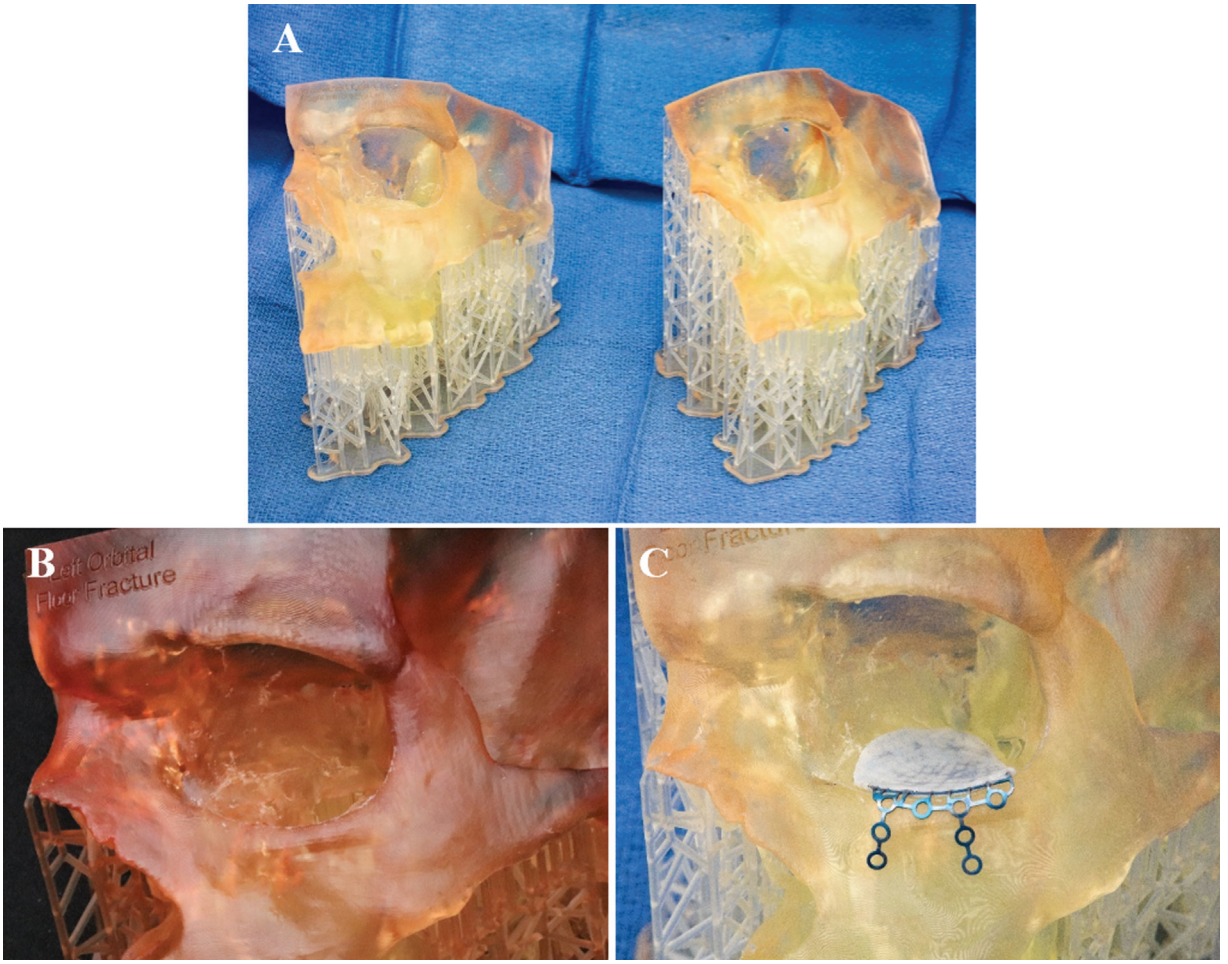

Fig. 9 Vat-photopolymerization. A) Orbital floor anatomic bending guides were 3D printed with vat photopolymerization (Form3B, Formlabs, Cambridge, MA). B) A surgical model of the patient's native left orbit/maxilla showed the extent of the orbital floor blowout. C) Orbital floor plate was pre-bent on the model of the mirrored, uninjured orbital floor prior to implantation.

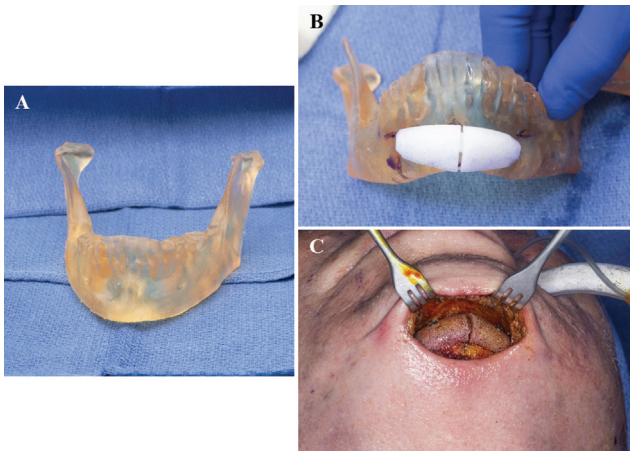

Fig. 10 Vat-photopolymerization application. A) A patient's mandible model was generated on a vat-photopolymerization printer (Form3B, Formlabs, Cambridge, MA) at the POC B) Chin implant was pre-contoured on 3D printed model and C) implanted on the patient, allowing for a minimal resection.

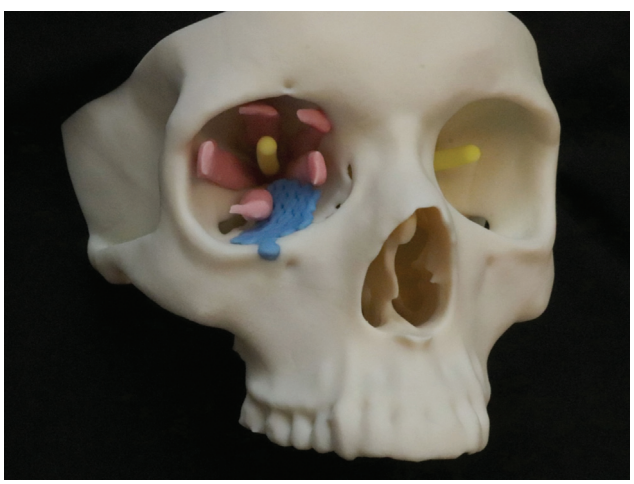

Fig. 11 Material jetting. Patient presented with a malpositioned, right orbital floor implant. A material jetting printer (J5, Stratasys, Eden Prairie, MN) was used to generate a model of the defect and surrounding anatomy. The tactile model illustrated the plate's (blue) proximity to her optic nerve (yellow) and extraocular muscles (pink). Utilizing the model, the clinician was able to further develop a surgical plan and successfully illustrate the risks and benefits of removing the malpositioned implant to the patent.

in ►**Table 1**. It is also important to remember that any machinery will come with associated power requirements and consumables to budget for. Examples of consumables would be raw input material for the 3D printers, replacement parts (e.g., printheads, resin tanks, etc.), cleaning solutions for part washing and/or machine maintenance (e.g., isopropyl alcohol), and media for any de-powdering and surface smoothing equipment.

Software

Since the workflow is highly digital, there are several unique software programs required for a POC program to optimally function. To keep track of orders and their progression through the workflow, there needs to be a case

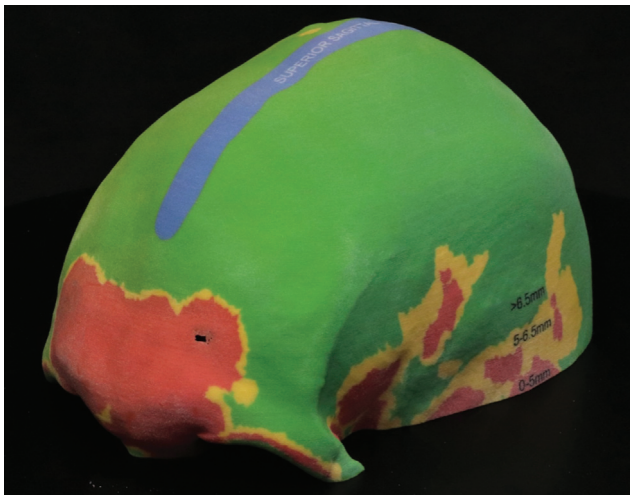

Fig. 12 Binder jetting. A bone thickness map of the patient's skull was fabricated at the POC, utilizing binder jetting (ProJet CJP 660 Pro, 3D Systems, Rock Hill, SC). Model was specifically created to assist the surgeon with identifying safe drilling locations, avoiding the patient's superior sagittal sinus and any areas that are less than 5 mm thick. Labels for color correlation and bone thickness was imprinted to enhance communication.

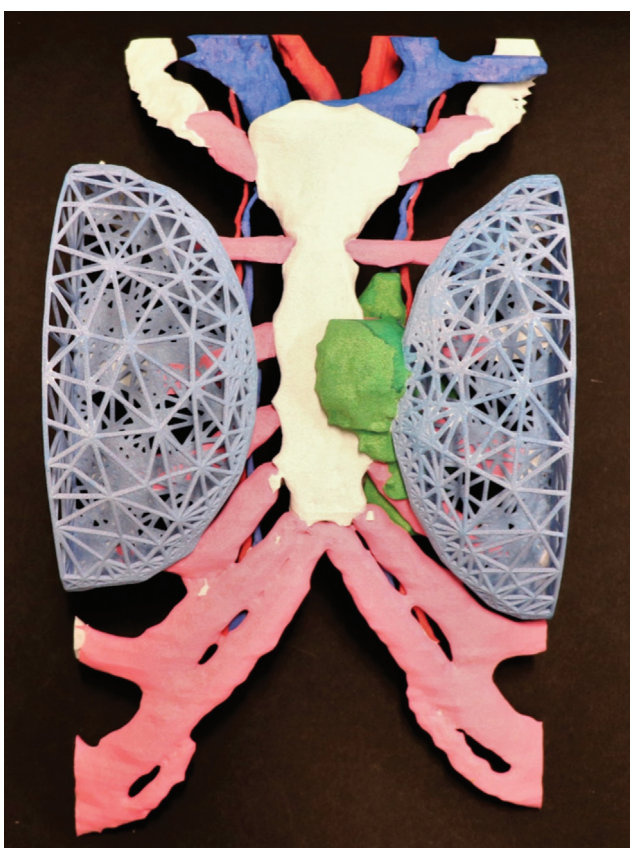

Fig. 13 Powder bed fusion. 54-year-old female underwent previous bilateral mastectomy followed by breast reconstruction with implants due to breast cancer and. She presented with a recurrent tumor invading the sternum. Colored model was 3D printed with powder bed fusion (Jet Fusion 580, HP, Palo Alto, CA) to visualize anatomy and proximity of the tumor (green) to left implant capsule (light blue). Model was utilized by clinician to decide if the implant should be removed during oncologic surgery and to review 3D model with patient to discuss implications.

Table 1 Brief overview of the five common 3D printing technologies in medicine

3D Printing Technology	Available Options	Materials	Post-Processing	Applications
Material Extrusion (FFF, FDM)	Desktop	– Solid – Multi-material – Color – Opaque – Rigid and flexible – Limited resolution	– Support strut removal – Surface finishing (e.g., smoothing)	– Prototyping[b] – Simple anatomical modeling – Molds – Implants (PEEK, PEKK)
Vat-photopolymerization (SLA, DLP, CDLP, CLIP)	Desktop or Industrial	– Resin – Single material – Monotone – Opaque and transparent – Rigid and flexible	– Excess resin removal – Support strut removal – UV cure – Surface finishing (e.g., smoothing, clear coating)	– Prototyping[b] – Simple anatomical modeling – Surgical guides – Dental applications (e.g., implant guides, dentures)
Material Jetting	Industrial	– Resin – Multi-material – Color – Opaque and transparent – Rigid and flexible	– Support encasement removal – Surface finishing (e.g., clear coating)	– Complex anatomical modeling
Binder Jetting	Industrial	– Powder – Single material – Color – Opaque – Rigid	– Excess powder removal – Infiltration with compounds (e.g., wax or cyanoacrylate)	– Complex anatomical modeling
Powder Bed Fusion (SLS, SLM, EBM, DMLS, DMLM)	Desktop or Industrial	– Powder – Single material – Monotone[a] – Opaque – Rigid and flexible – Durable	– Excess powder removal – Surface finishing (e.g., smoothing, dyeing)	– Prototyping[b] – Complex anatomical modeling – Surgical guides – Orthoses – Molds – Implants (metal, PEEK, PEKK)

Abbreviations: CDLP, continuous digital light projection; CLIP, continuous liquid interface production; DLP, digital light processing; DMLM, direct metal laser melting; DMLS, direct metal laser sintering; EBM, electron beam melting; FDM, fused deposition modeling; FFF, filament fabrication; SLA, stereolithography; SLM, selective laser melting; SLS, selective laser sintering.
[a]Exception: One multi-color powder bed fusion printer (Jet Fusion 580, HP, Palo Alto, CA) exists on the market.
[b]All technologies can be utilized for prototyping, but technologies that are more cost-efficient for prototyping are listed.

management system. In the initial start of the program, the laboratory may find it best to track their cases with weekly meetings, lists, or an excel tracking sheet. However, once the volume of cases and surgical disciplines expand, a more robust solution will be needed. In our experience, a customizable manufacturing execution system (MES) has allowed us to keep track of relevant clinical information, adhere to due dates, and record 3D printing details and quality assurance measurements, making each case auditable with part traceability.

Software for advanced medical 3D visualization and 3D printing is considered a Class II medical device. Therefore, when models are being created for diagnostic use, software should be regulated through the 510(k) process. There exist three categories of medical visualization software, ranging from most expensive to least: 1) software with FDA clearance to produce diagnostic use 3D printed models, 2) software with FDA clearance to produce digital 3D visualizations of medical images without 3D printing (e.g., Siemens SyngoVia, Terarecon, GE AW, Phillips Intellispace portal, Circle 42, etc.), and 3) software with no FDA clearance.[37] Currently, it is recommended per the FDA guidance document that clinical use of 3D printing should utilize 510(k) approved software.[14] Examples of such include DICOM 2 Print (D2P, 3D Systems, Rock Hill, SC) and Mimics Innovation Suite (Materialise, Leuven, Belgium). A POC manufacturing program will need at least a segmentation and CAD software. Depending on the clinical applications that the POC laboratory will be focusing on, there are also available surgical planning software specific to subspecialities that facilitate VSP sessions with surgeons (e.g., ProPlan CMF 3.0 (Materialise, Leuven, Belgium) for craniomaxillofacial applications).

As for manufacturing, build processing software is a requirement to load any model/device onto a 3D printer for production. Within this software, printing parameters and orientations are decided for each part being manufactured. Slicing/build processing programs can be propriety to the 3D printer and its OEM (e.g., PreForm for Formlabs printers). However, there also are a few universal industrial-grade or open-source software on the market (e.g., Magics

(Materialise, Leuven, Belgium) for industrial printers, Sli3er as an open-source option, etc.).

Physical Space and Layout

The blueprint of the 3D printing laboratory will need to account for several attributes. Most critically and often overlooked, workstations for staff performing digital work are necessary and should include computers powerful enough to run the image processing, surgical planning, and CAD software. Because multidisciplinary collaboration is critical to success, it is recommended to plan for a consultation area with a whiteboard to meet with clinicians to brainstorm and discuss active clinical cases or projects. Within this environment, it is also advantageous to consider a model display area to promote discussion and innovation with any visitors to the laboratory.

The manufacturing area is recommended to be in a separate room from the personnel workstations. 3D printers and post-processing equipment can be noisy and expel unwanted heat and volatile, noxious compounds, making for an unacceptable work environment. It is recommended to keep the powder-based printers in a separate room from the resin-based printers as the powder-particles can permeate the liquid resin, detrimentally impacting the 3D printers and their products. Any piece of equipment (printer or post-processing) will also require a bigger footprint than the machine's dimensions to allow for operational access and clearance for maintenance access. If affordable or as a long-term goal, an uninterruptible power supply (UPS) is highly recommended for each printer to ensure consistent power supply, resulting in high quality products and less interrupted builds. Because 3D printing requires consumables for manufacturing, cleaning, and maintenance, it is important to map out as much storage as possible to keep a safe amount of back-up materials and parts to keep the laboratory functioning without supply interruptions. Rooms with 3D printers and their consumables should be a dry, ventilated environment with the ability to control temperature and humidity with no direct sunlight. Since the manufacturing facility is housed within the hospital, special positive pressure airflow systems, high air turnover rates in industrial 3D printer rooms, and ventilation to the outside all needed to be designed in accordance with hospital facilities.

Although equipment exists to assist with post-processing, most 3D printed parts still require manual post-processing to fully clean-up and perfect the final product. Workbenches and sinks need to be installed for manual model clean-up as these steps are messy. An additional workbench should be planned specifically for model/guide quality assurance steps, where measurements, inspection, and possibly 3D scanning of the final product can take place in a clean, dedicated area.

As for the facility's elements, certain 3D printers and post-processing machines may require an extra level of safety to be implemented in the space to ensure no incidental harm to patients or hospital staff. Some additional safety elements to include within the physical manufacturing space are appropriate ventilation with consistent purging of the room air, electrostatic discharge (ESD) flooring, an eye wash station, and a fume hood for any chemical uses, such as lye baths, during post-processing. Consultation with local fire departments to assure local and state regulations are being followed is a consideration as the facility grows in size and scope.

Financial Planning

The initial capital investment and appropriate budgeting for a POC planning and 3D printing program is challenging. The extent of the initial funding varies depending on need. A small practice to support a single surgical discipline would only need one to two staff members with a single, desktop 3D printer. On the other hand, a centralized, collocated POC facility would need multiple employees and a wide range of 3D printers (desktop and industrial grade). In the beginning, it is anticipated that the POC program will not generate significant revenue, and unfortunately, there is a significant up-front cost to fund the facility (e.g., staff, software, hardware, and physical hospital footprint). The benefits of improved patient care and indirect benefits to the institutions such as decreased overall cost for the entire care encounter outweigh these initial investment costs. Applying for small grants (internal or external) is recommended to provide the beginning capital investment for the POC manufacturing facility. With time, the cost of 3D printing at the POC will be more cost-efficient than outsourcing to vendors once cost justifications are fully highlighted within the institution. Such cost justifications include reduced surgical time at an average rate of $80.00 -$100.00 per minute, less reoperations and need for revisions, enhanced outcomes, reduced cost of surgical guides and virtual surgical planning, improved patient consent, reduced length of stay, and patient and physician satisfaction.[1–10,69–74]

As alluded to in the workflow section, the category III CPT codes can assist with cost justifications. Even though they are temporary codes and do not guarantee reimbursement, it is highly encouraged to use these codes. A permanent reimbursement solution for patient-specific 3D printed models and surgical guides is critical to the longevity and growth of a POC program. POC medical 3D printing needs to have established Category I CPT codes for models and guides, which can be achieved with increasing utilization and proven value to patient care across the United States. A national ACR registry to collect all necessary data from academic institutions utilizing this technology is in the second year of operation at the time of writing this article.[75]

Conclusion

A POC surgical planning and 3D printing program allows for a cost-effective method to produce just-in-time and customizable anatomic models and surgical instruments, utilizing the patient's medical imaging data. During establishment, the extent of the facility should fit the institution's resources and needs, which can then further deem the extent of personnel, equipment, software, and physical space required for the program to begin and steadily grow. The workflow required to 3D print patient-specific models/devices is complex with a high

level of precision performed throughout every step. To safeguard the process all the way to the final product, a robust, internal quality control system is critical to establish within the facility to ensure patient safety. As opposed to third party medical device companies, a POC, centralized surgical planning and manufacturing laboratory provides convenient access for surgeons to digitally plan cases within their busy clinical schedule and encourages innovation due to the constant collaboration between multidisciplinary teams. Even further, the onsite location allows for a quicker turnaround time and extra level of safety on delivery than outsourcing for anatomic models or guides. The future of 3D printed anatomic models and devices becoming a standard at the POC remains bright and enthusiastic, especially as it begins to integrate with other advanced image visualization techniques, such as augmented and virtual reality.[73,76,77] The technological combination at the POC will ultimately enhance best practices, leading to better patient care, less institutional costs, and improved patient satisfaction.

Conflict of Interest
None declared.

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