Abstract

Three-dimensional (3D) printing, also known as additive manufacturing, is poised to transform the practice of medicine. 3D printing is increasingly being used in medicine to enhance patient care. Diagnostic imaging studies such as computer tomography (CT) and magnetic resonance imaging (MRI) can be converted into 3D models for clinical applications. These patient-specific models can be used to simulate and practice surgery, create custom prosthetics and custom medical devices.

Although 3D printing is expanding in medicine, anesthesiology applications are rare. This presentation will focus on a case study of creating customizable intubating oral airways with 3D printing technology. In 2014 the Society for Technology in Anesthesia (STA) issued an engineering challenge that required teams to design a 3D-printed fully customizable oropharyngeal airway. We will focus on:

- Basic 3D printing and design
- Creating individualized anatomic models with 3D printers
- 3D Printing techniques; pro-cons
- Discuss feasibility of using a 3D printed device for clinical care

3D Printing:

Three-dimensional (3D) printing is the process of generating physical 3D objects by sequentially placing layers of material down in different shapes. Recently it has become more accessible to the general public with the advent of low cost printers [1]. In the medical field, the prototyping capabilities of 3D printing have made it a practical tool for medical professionals to quickly fabricate customized patient implants, and models of patient anatomy for pre-surgical planning [2, 3]. However, despite its utility, 3D printing has not yet been widely adopted for general patient care. It has typically only been applied to patients who possess abnormal anatomy or are undergoing complicated surgical procedures [4].

The cost of a 3D printer usually dictates the number, type, and quality of materials it can use and size of objects it can produce. Lower cost printers such as the Makerbot Replicator 2 (Figure 2) support only a single material (usually a type of plastic) during the printing process [7]. While more expensive printers like the Object 350 Connex (Figure 3) utilize many that range from soft rubber-like materials to rigid plastics [8].

An important hurdle in creating 3D prints of actual patients is the tedious work of segmentation (carefully removing unwanted parts of the image). This step is critical in creating the ideal model and requires staff knowledgeable about the relevant anatomy.

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The most widespread application of 3D printing for patient-specific devices has focused on complex skeletal models for surgical planning including cutting guides and patient-specific implants.\(^{(2)}\) The cutting guides have the advantage of allowing the surgeons to plan ostotomies ahead of time and achieve desired results while reducing surgical time. Cutting guides have been developed for cranioplasty, mandibular reconstruction, and complex reconstructions such as joint replacements. Cardiovascular models can be generated from high-resolution CT and MRI studies and allows visual and manual inspection of complex anatomic lesions. Patient-specific hemodynamic models may be created to simulate the patient’s physiology in complex conditions such as coarctation of the aorta and to plan a therapeutic intervention.\(^{(3)}\) The HeartPrint models (Materialise, Leuven, Belgium) are patient-specific virtual and physical heart replicas that can be used for procedure planning and patient education. The HeartPrint models have been listed as class 1 medical devices in both the US and Europe, stressing the importance of patient-specific models to guide medical decision-making.\(^{(3)}\)

**Designing anatomic models:**

DICOM files are reviewed using a DICOM viewer (Figure 4). A viewer parses the files to display the biomedical image content, provide an editable list of DICOM data elements, and offer utilities for manipulating the images. These include zoom, image thresholding and filtering, brightness and contrast adjustment. Viewers also support tools for highlighting regions of interest and taking measurements relative to the dimensions of the patient. Because DICOM images maintain size and scale, image and depth data obtained through CT and MRI scans are often used to create custom medical devices and to make 3D reconstructions of patient anatomy for treatment and pre-surgical planning [2-4].

Converting DICOM images to 3D models, also referred as ‘segmentation’, requires specialized software. There are several options for segmentation software, ranging from open source platforms such as 3D Slicer\(^{E}\) to proprietary software such as Mimics (Materialise, Leuven, Belgium)\(^{F}\).

**Intubating Oropharyngeal Airway Design**

We designed A CAD intubating oropharyngeal airway model using a 9 cm Williams intubating oropharyngeal airway as a reference. The model featured three components that corresponded to each portion of a typical oropharyngeal airway -

\(^{C}\) Health C for D and R. Workshops & Conferences (Medical Devices) - Public Workshop - Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing, October 8-9, 2014.


the flange, the bite block, and the curved region. The CAD model was parameterized using OpenSCAD (an open source programming-based CAD software) to allow modification without creating additional models.\textsuperscript{G} We created the following modifiable parameters: \textit{inner diameter, bite block height, curvature length, curvature bend, and resolution}. The \textit{bite block height} parameter controlled the height of the bite block. The \textit{inner diameter} defined the maximum external diameter of an endotracheal tube that could pass through the airway. The \textit{curvature length} corresponded to the arc length of the curved portion while the \textit{curvature bend} referred to the curve angle of the oropharyngeal airway. The \textit{Resolution} parameter is a dimensionless quantity that controls the material resolution (printing quality) of the output model. All parameters except for Resolution were measured in millimeters (mm).

We designed a web application (Tracheal Aire)\textsuperscript{H} to allow easy modification of the oropharyngeal airway parameters. The application was built using OpenJSCAD, open source JavaScript-based CAD software.\textsuperscript{I} The user interface enabled the intubating oropharyngeal airway model to be exported in four different 3D printing file formats—Extensible 3D Graphics (X3D), Binary Stereolithography (STL), ASCII Stereolithography, and Additive Manufacturing File Format (AMF).

\textit{Airway Mannequin Design}

We obtained a de-identified head and neck CT scan of a healthy 15-year-old patient. After creating volume rendered models in Mimics we segmented the regions of interest (ROI) by selective cropping of the volume rendering. The head and neck was divided sagittally while the trachea was divided coronally in order to create an anterior and posterior piece. In order to allow jaw motion we designed a ball-socket joint to simulate the temporomandibular joint (TMJ) function using 3-matic software. The airway model was segmented in 6 modules, which allowed for post-print processing and disassembly for viewing and education.

\textit{Patient-Specific Oral Airway Design}

We designed the intubating oropharyngeal airways using measurements from the CT scan image described above. We measured the distance between the maxillary incisors and base of the tongue (corresponded to airway bite block height) and the distance between the base of the tongue and the epiglottis (corresponded to airway curvature length). The inner diameter of the oropharyngeal airway was designed to ensure adequate passage of an endotracheal tube and pilot balloon with a 1cm tolerance.

\textsuperscript{H} http://nmcgill.com/ta.html Accessed 5/7/2016
Medical devices produced with 3D printers must be reliable and durable and not contribute to patient harm due to malfunction. Regulatory and quality assurance requirements may vary depending on the proposed production plan. For individual applications such as production and use by an individual or medical institution, government regulatory agencies may not have to be involved (depending on the country). However, human subjects research oversight groups such as the Institutional Review Board should provide input on the process at the institution. If the plan were to produce and distribute the device, government regulatory agencies such as the FDA (USA) would be responsible to regulate the device.

Device manufacturers, whether it is an individual hospital or a device corporation, need to ensure that the supply chain of materials is reliable and safe. Process control and material traceability must be ensured throughout the manufacturing process. The materials must be free of contaminants and impurities. Storage and expiration dates must be tracked and accounted for. Governing and regulatory agencies may require certificates of conformance to demonstrate compliance with the materials acquisition, storage and handling.

In order to ensure reliability and safety, the device should be tested for biocompatibility after it has been processed. For example, following the 3D print and removal of the support material, the device would undergo sterilization or decontamination. Subsequently the device would undergo biocompatibility testing to evaluate whether residual biologic organisms are detected. Lastly, the device would also undergo structural testing to ensure that it was not altered during the sterilization or cleaning processes.

3D Printing for medical devices – bench to bedside:

The Food and Drug Administration (FDA) has demonstrated interest in the potential applications of additive manufacturing in the medical device industry. An FDA public hearing held in the fall of 2014 provided a forum for industry, academics and regulatory agencies to discuss the current and future applications for additive manufacturing. Several questions were raised throughout the session, ranging from ensuring adequate manufacturing control standards to ensure the manufactured devices, whether 3D printed or not, meet biocompatibility and safety standards set forth by the FDA. From a biocompatibility standpoint, the FDA requires that the devices are thoroughly evaluated to ensure that the sterilization or cleaning processes achieve the following 1) adequate penetration of all exposed surfaces; 2) no microbial or hazardous substances remain on the device after the

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sterilization process; and 3) that the structure and composition of the device is not altered during the sterilization process. The FDA 510(k) application requires that the final products meet the biocompatibility testing. Therefore, it may not be sufficient to prove biocompatibility of a material in its raw form such that various devices could be produced with the specific material.

The FDA 510(k) process also requires quality control systems for manufacturing devices, which ensures the integrity of the materials, the integrity of the device and the reliability of the printing process to produce the expected device within acceptable ranges. In the end, the medical device produced should prove to be reliable and safe to use, no matter how it was manufactured. Additive manufacturing requires adequate planning for all phases of manufacturing such as pre-printing, printing and post-printing considerations as described in Table 1.

From a practical standpoint, the cost of printers and materials for producing 3D models continue to decrease, therefore we may be approaching a tipping point for device prototyping and manufacturing. In general, the amount of material and time required to print a model increases exponentially as the model size increases. This may be advantageous to pediatric medical devices, since they are generally smaller. Furthermore, pediatric medical devices are often in lower demand than equivalent adult devices, thus limiting the range of options available in the market.

As described above, anatomically accurate models may be used for various applications in healthcare, including planning therapeutic interventions and designing medical device prototypes. The anatomic models may be used in pre-clinical device design and validation before ever testing on humans or animals. In this context, the cost of maintaining and operating a printer may be lower than maintaining a facility for animal or human clinical trials. Custom medical devices such as the intubating oropharyngeal airway may only truly benefit a small number of patients with complex anatomy. Traditional manufacturing methods are not cost-effective to make custom devices in small quantities. To this end, 3D printed custom medical devices may become more common in healthcare.

Summary

The 3D printing industry is positioned to make a disruptive impact in surgical planning, medical education, medical device manufacturing, and eventually tissue engineering and regeneration. 3D printers are becoming increasingly accessible and affordable and may shepherd a wave of innovation. Anesthesiologists have a unique opportunity to think outside the box and find applications for 3D models to improve patient care in the operating room and beyond.

References: