3D PRINTING AND ADDITIVE MANUFACTURING
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ORIGINAL ARTICLE

Not Just a Pretty Face: Three-Dimensional Printed Custom Airway Management Devices

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Abstract

Three-dimensional (3D) printing, also known as additive manufacturing, is a fascinating technology that is poised to transform the practice of medicine in the 21st century. The Society for Technology in Anesthesia hosted an engineering challenge to use a 3D printer to create a customized oral airway based on a patient's anatomy. We approached this challenge in two parts. First, we identified a model for an oral airway to base our prototype. We created a 3D rendering of the customizable oral airway and designed a user interface that would accept specific measurements to create a customized oral airway. We then rendered a 3D model of the patient's airway and surrounding structures using Mimics (Materialise, Leuven, Belgium). The model was optimized for an Object Connex (Stratasys, Eden Prairie, MN), which has the capability of printing in various materials. We specified softer materials for the flexible tissues such as the tongue, palate, vocal cords, and epiglottis; a more rigid material was utilized for the supporting structures such as the mandible, nose, and bony structures. Furthermore, we printed the model in various parts, consisting of the tongue, jaw, trachea, and head/neck, that would articulate to make up the head and neck. The head and neck was one continuous part, divided sagittally at the midline, and the trachea was divided in the coronal plane. The printing process took $\sim$30 h of printing time and resulted in an anatomically correct model that included the nasopharynx, oropharynx, and trachea with an articulating mandible. We describe the process of designing and producing anatomic models for medical device prototype design. We propose a methodology of evaluating medical device prototypes using anatomically accurate models manufactured with 3D printers.

Keywords: intubation, anesthesiology, intubating oral airway, critical care, difficult airway, airway reconstruction

Introduction

Anesthesiologists are primarily responsible for providing airway management expertise for patients in a variety of settings. Airway management devices include a range of devices from laryngoscopes to flexible fiberoptic cameras.[1] The gold standard device for intubation in most scenarios is a flexible fiberoptic bronchoscope that can be navigated into the trachea to guide the insertion of a breathing tube.[1] Adjunct devices such as intubating oral airways can be used to guide the insertion of the flexible fiberoptic bronchoscope. However, these devices come in a limited range of sizes and may not be suitable for the patients who are at the highest risk for difficulty with airway management, such as children whose anatomy does not conform to the existing devices.[2] Inability to successfully insert a breathing tube can result in catastrophic outcomes such as respiratory arrest and hypoxic brain injury.[3–5]

Three-dimensional (3D) printing, also known as additive manufacturing, is poised to transform the practice of medicine.

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3D printing is increasingly being used in medicine to enhance patient care.[6,7] Digital images from diagnostic studies such as computer tomography (CT) and magnetic resonance imaging can be converted into patient-specific 3D models for clinical applications. These models can be used to simulate and practice surgical techniques as well as to create custom prosthetics and custom medical devices.

Although the use of 3D printing is expanding in medicine in general, 3D printing applications in anesthesiology are rare. This article focuses on the use of a patient-specific anatomic model for design evaluation of a customizable device. In 2014, the Society for Technology in Anesthesia issued an engineering challenge that asked teams to design a 3D printed fully customizable oropharyngeal airway. In response to this challenge, our team created the top-award-winning design. The mannequin-specific intubating oral airway was evaluated with a patient-specific anatomic model based on a 15-year-old patient.

Materials and Methods

Airway mannequin design

A de-identified head and neck CT scan of a healthy 15-year-old patient was obtained. The images were obtained with a waiver from our Institutional Review Board. The images were acquired on a Siemens SOMATO Sensation 64 scanner running Syngo CT 2009E software. Acquisition parameters were set to: 120 kVp X-ray tube voltage, 467 mA tube current, 1.0 s rotation time, 445 μm in-plane resolution, and 3 mm slice thickness. After creating volume-rendered models in Mimics (Materialise, Leuven, Belgium), the regions of interest (ROI) were segmented by selective cropping of the volume rendering. Each unique ROI became a separate volume model. The three-matic (Materialise) software was used to subdivide volume models in the sagittal or coronal planes to create modular segments. The head and neck was divided sagittally, whereas the trachea was divided coronally to create an anterior and posterior piece (Fig. 1). To allow jaw motion, a ball-socket joint was designed to simulate the temporomandibular joint (TMJ) function using three-matic software (Materialise). The airway model was segmented in six modules, which allowed for post-print processing and disassembly for viewing and education.

Intubating oropharyngeal airway design

A CAD intubating oropharyngeal airway model using a 9 cm Williams intubating oropharyngeal airway was designed as a reference (Fig. 2). The model featured three components that corresponded to each portion of a typical oropharyngeal airway (Fig. 2A)—the flange (Fig. 2B), the bite block (Fig. 2C), and the curved region (Fig. 2D). The CAD model was parameterized using OpenSCAD (an open-source programming-based CAD software) to allow modification without creating additional models (Open SCAD, accessed on 5/3/2016). The following modifiable parameters were created: *inner diameter* (Fig. 2B), *bite block height* (Fig. 2C), *curvature length* (Fig. 2D), *curvature bend* (Fig. 2D), and *resolution.* The *bite block height* parameter controlled the height of the bite block. The *inner diameter* defined the maximum external diameter of an endotracheal tube that could pass through the airway. The *curvature length* corresponded to the arc length of the curved portion, whereas the *curvature bend* referred to the curve angle of the oropharyngeal airway. The *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).

A web application (Tracheal Aire) was designed to allow easy modification of the oropharyngeal airway parameters (Fig. 3).[8] The application was built using OpenJSCAD, an open-source JavaScript-based CAD software program.[9] The user interface enabled the intubating oropharyngeal airway model to be exported in four different 3D printing file formats—Extensible 3D Graphics, Binary Stereolithography, ASCII Stereolithography, and Additive Manufacturing File Format.

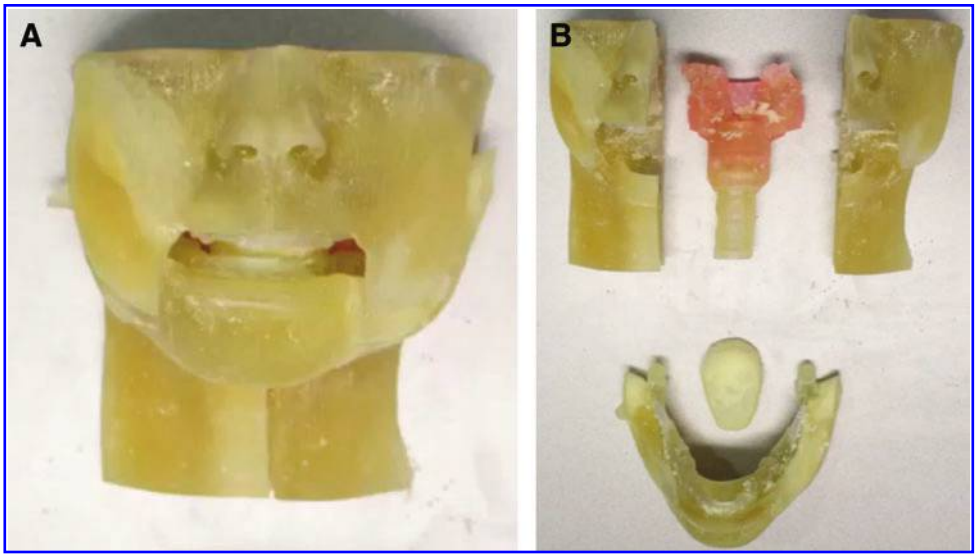

FIG. 1. **(A, B)** The airway mannequin assembled **(A)** and disassembled **(B)** into individual components. The mannequin was printed in components to facilitate exploration as well as removal of support material. Color images available online at www.liebertpub.com/3dp

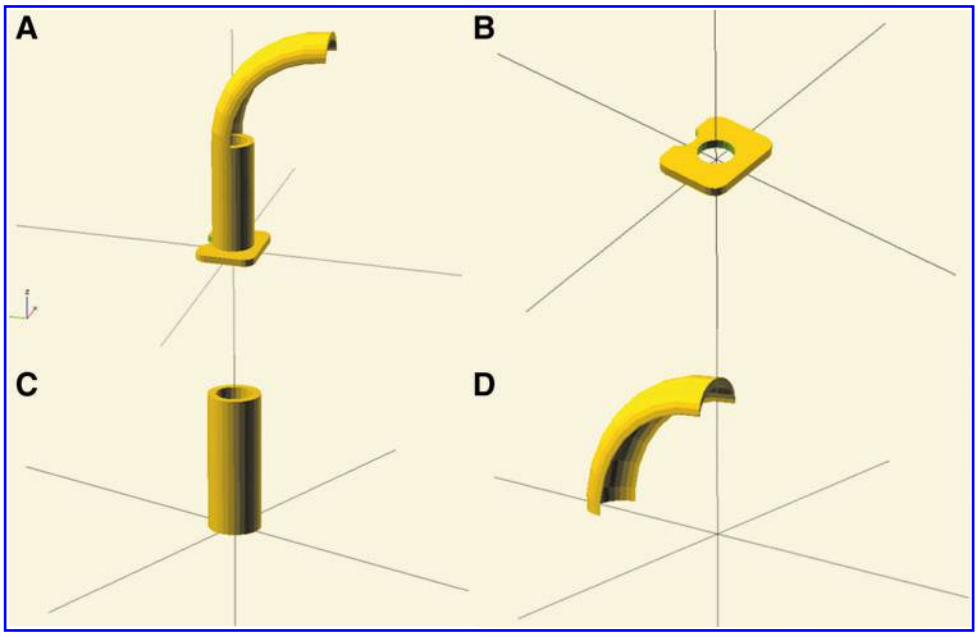

FIG. 2. **(A)** The assembled components make up the customized oral airway; **(B)** the bite-block flange; **(C)** the bite-block cylinder with adjustable length and diameter; and **(D)** the curved tip with adjustable length and curve angle. Color images available online at www.liebertpub.com/3dp

Patient-specific oral airway design

The mannequin-specific intubating oropharyngeal airways were designed using measurements from the CT scan image described earlier. The distance between the maxillary incisors and the 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) (Fig. 4) were measured. The inner diameter of the mannequin-specific oropharyngeal airway was designed to ensure adequate passage of a 7.0 cuffed endotracheal tube and pilot balloon (Mallinckrodt Hi-Lo Oral/Nasal Tracheal Tube Cuffed; Covidien, Mansfield, MA). Custom intubating oropharyngeal airways can be made to fit a range of endotracheal tubes; however, the minimum inner diameter should be wide enough to allow passage of the pilot balloon, which may vary across manufacturers.

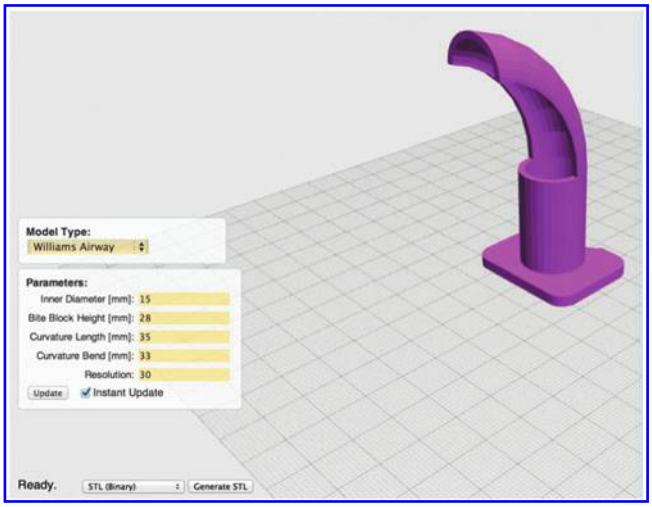

FIG. 3. The user interface to design a customized oral airway. The user enters the dimensions to adjust the bite block height, inner diameter, curvature length, curvature bend, and resolution. The resolution parameter is a dimensionless quantity that controls the material resolution (printing quality) of the output model. All parameters except for resolution are measured in millimeters (mm). Color images available online at www.liebertpub.com/3dp

3D printer methods

The anatomic airway model and the intubating oropharyngeal airway models were optimized for rapid prototyping on an Object Connex 500 (Stratasys, Edina, MN), a PolyJet™ technology capable of depositing multiple materials in a single print run. Commercially available proprietary print materials were chosen based on their respective shore durometer, or hardness, to mimic mechanical properties of airway structures. Rigid materials (shore hardness of ~85 D and Young's modulus of 2–3 GPa) were used for supporting structures, such as the mandible, nasal cavity, and skull, whereas flexible materials (shore hardness ranged from 85–50A) were used to mimic softer tissue such as the tongue, palate, vocal cords, and epiglottis. These materials were defined in the printing interfacing software, Object Studio v 9.2.8.3 (Stratasys). All model volumes were then printed in an orientation on the printer build tray to minimize material waste.

Theory/calculation

Mannequin and airway evaluation. The printed mannequin for anatomic accuracy was visually and manually inspected by pediatric anesthesiologists (Fig. 4). The evaluation included an attempt at direct laryngoscopy with a standard laryngoscope, Macintosh blade size 3, a video laryngoscope size 3 (Glidescope Cobalt; Verathon, Bothell, WA), and a fiberoptic bronchoscope with and without the customized intubating oropharyngeal airway in place.

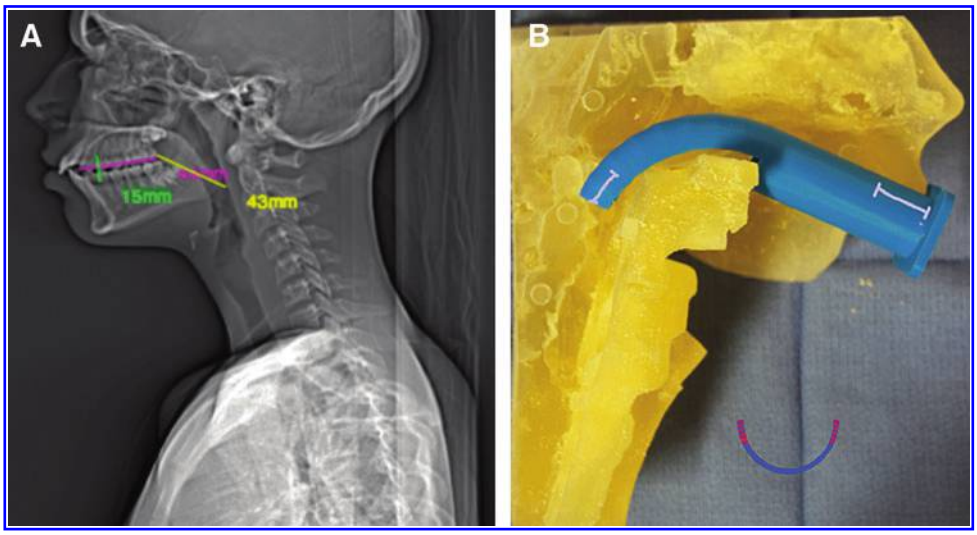

FIG. 4. **(A, B)** Lateral scout film from CT scan used to measure oropharyngeal dimensions. We measured the distance from the maxillary incisors to the base of the tongue and the distance from the base of the tongue to the epiglottis. The measurements were used to make a customized oral airway that was validated by placing the oral airway in a three-dimensional mannequin based on the CT scan. CT, computer tomography. Color images available online at www.liebertpub.com/3dp

Results

The adolescent airway mannequin was a 1:1 replica of a 15-year-old male head and neck CT scan. The model required 2.2 kg of material, 1.7 kg of support material, and a print time of 30 h. The mannequin-specific intubating oropharyngeal airway was printed to match the airway dimensions from the adolescent mannequin; required 38 g of material and 56 g of support material; and was completed in 4 h. The inner diameter, bite block height, and curvature bend were measured to be 15, 44, and 43 mm, respectively. The approximate material cost for the airway mannequin was $953 and that for the oropharyngeal airway was $17.95. This cost included the cost of raw materials and did not include any facility, labor costs, post-processing, and sterilization. The inner diameter of the oropharyngeal airway allowed passage of a 7.0 cuffed endotracheal tube with an outer diameter of 9.6 mm. The pilot balloon's widest diameter measured 0.5 cm and easily passed through the airway.

The mannequin proved to be a challenging laryngoscopy due to the limited range of motion of the TMJ and the limited ability to displace the tongue with the standard and video laryngoscopes. The epiglottis and glottis were unable to be visualized using either laryngoscope. Attempts at direct and video laryngoscopy also resulted in damage to the tongue and pharyngeal structures in the mannequin.

The fiberoptic evaluation was successful in providing an adequate view and identification of anatomic landmarks through the oral and nasal approaches. The oropharyngeal airway was positioned directly superior to the glottis and provided an adequate approach to navigate the fiberoptic bronchoscope into the trachea. The vocal cords were partially open in the mannequin. As the fiberoptic bronchoscope was advanced through the glottis, the vocal cords displaced laterally, facilitating passage of the bronchoscope. Trans-oral fiberoptic navigation into the trachea was successfully performed with and without the intubating oropharyngeal airway. The intubating oropharyngeal airway allowed direct access to the glottis and was appropriately positioned as determined by fiber optic evaluation by a pediatric anesthesiologist experienced in difficult airway management.

Table 1. Technical Considerations with 3D Printing Applications for Prototype or Device Design

Pre-printing	*Printing*	*Post-printing*
Material chemistry	Printing process characterization	Cleaning/excess material removal
Physical properties	Software	Effect of complexity on sterilization and biocompatibility
Recyclability	Post-processing steps	Final device mechanics
Part reproducibility	Additional machining	Design envelope
Process validation		Verification

Source: Federal Register Online.[14]

Discussion

We have presented a technical description of a unique application of 3D printing in anesthesiology. Customized patient devices may enhance patient care and allow focused safe practice of various procedures. Customizable intubating oropharyngeal airways may be particularly useful to pediatric anesthesiologists, because there is no equivalent product available for clinical use in the world. One challenge specific to pediatrics is that smaller patients require small endotracheal tubes, which may have a smaller outer diameter than the pilot balloon attachment. The endotracheal tubes described here have pilot balloons that measure 0.5 cm at the widest point. In some cases, the pilot balloon tube must be severed and then repaired to introduce the endotracheal tube through a device such as an oropharyngeal airway or a laryngeal mask.[10]

The 3D printed patient model was anatomically accurate and enabled the design of a customized oropharyngeal intubating airway for the patient. Although direct laryngoscopy was technically challenging because of poor tissue compliance, fiberoptic intubation was readily performed in the mannequin with the intubating airway *in situ*. As newer materials become available, 3D printed materials will more closely mimic human tissue compliance and perform better as training and simulation tools.[11]

An important hurdle in creating 3D prints of actual patients is the tedious work of segmentation (i.e., carefully removing unwanted parts of the image). This step is critical in creating the ideal model and requires staff who know the relevant anatomy. TMJ articulation in the 3D printed models may prove to be challenging. Because the joint is in a static location when the CT scan is obtained, it is difficult to create its full range of motion by simply printing the image. Reproducing its complicated functions (hinging and sliding) requires a unique design that is separate from the 3D print. This is the most challenging aspect of recreating the natural craniofacial mechanics of the head and neck in a 3D printed model. Although our printed TMJ allowed opening of the model's mouth, we were unable to simulate the anterior sliding motion that occurs with a jaw thrust or direct laryngoscopy. This likely contributed to the difficulty with performing direct laryngoscopy and will need to be addressed in future designs and prints.

The FDA continues to demonstrate 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.[12] In 2016, the FDA published a draft guidance document on the technical considerations for additive manufacturing for medical devices.[13] In addition to requirements for 510k submissions for medical devices, the FDA outlines additional considerations that are specific to devices produced via additive manufacturing. Key elements to consider include material control, build considerations, post-processing, and testing the final device. The build considerations, such as the orientation of the device on the building surface, are important, because they can affect the quality of the print as well as its structural integrity. In the case of the oral airway, printing the airway with the cylinder in a vertical or a horizontal position would affect the directionality of the layers. This variation can introduce different weak points that are unique to each version of the device. The FDA encourages inclusion of these printing variations in post-processing and testing steps. In addition, the biocompatibility of the final device after post-processing and sterilization should be established, if appropriate. The biocompatibility tests should demonstrate (i) adequate penetration of all exposed surfaces; (ii) that no microbial or hazardous substances remain on the device after the sterilization process; and (iii) that the structure and composition of the device is not altered during the sterilization process.

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 less demand than equivalent adult devices, thus limiting the range of options available in the market.

There are alternatives to the FDA's 510k submission process, such as the humanitarian device exemption (21 CRF 814 Subpart H) and the investigational device exemption (21 CFR 812.1). To use this customizable intubating oropharyngeal airway in a clinical setting, the device would have to be reviewed and approved locally by the institutional review board, which would have the discretion of enforcing requirements such as sterilization, biocompatibility, and quality assurance testing for the materials and production processes. These steps may be cost prohibitive for individual institutions to pursue production of low-volume customizable medical devices via additive manufacturing.

As described earlier, 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 evaluation before ever testing them on humans or animals. In this context, the cost of maintaining and operating a printer may be lower than that of 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.

Conclusions

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 to find applications for 3D models to improve patient care in the operating room and beyond.

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Authors' Contribution

J.A.G., Y.D., K.G., M.L.R., H.K., and J.E.F. designed and conducted the study, analyzed the data, and wrote the article; A.F.S., M.A.R. designed the study and wrote the article; N.H.M. designed and conducted the study, analyzed the data; N.D. designed and conducted the study.

Author Disclosure Statement

No competing financial interests exist.

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