

REVIEW

# 3D Printing and Personalized Airway Stents

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## ABSTRACT

In recent years, the 3D printing industry has undergone rapid development. Clinicians and researchers have begun to apply this technology in procedural planning, tissue engineering, and device manufacturing. Rapid prototyping and additive manufacturing techniques in the healthcare field have already yielded very exciting results and point to a bright future involving these technologies. This is especially true in pulmonology. 3D printing industry

growth is accompanied by increased availability of 3D printers and printable materials, which offers exciting arrays of possible applications. In this review, we present a brief history of 3D printing and its applications in the medical field with a focus on pulmonology. Additionally, we describe a methodology on how to 3D model and print personalized airway prosthesis via 3D Slicer and a commercial 3D printer. We hope this will help to stimulate additional innovation and application of 3D printing in medicine.

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## INTRODUCTION

Airway malformations due to stenosis, malacia, traumatic injury, or external compression from cancers of the mediastinum can lead to significant dyspnea, increased work of breathing, decreased exertional tolerance. Current methodologies to address the airway malformation are limited to airway stents based on silicone, metal, or hybrid material. These stents are often plagued by a variety of issues including but not limited to the high cost of manufacturing, difficulty to place, frequently migrating in the airway, and often becoming

obstructed by granulation tissues. Development of novel approach to manufacture airway stents is urgently needed to address these issues [1].

Many consider 3D printing the third industrial revolution [2]. Unlike conventional manufacturing, 3D printing technology allows additive manufacturing, which results in less raw material waste, decreased cost of manufacturing, and increased freedom of design. The ability to alter rapidly and test new designs is often referred to as rapid prototyping. This freedom for customizing complex designs makes 3D printing an especially appealing technology to the field of medicine. 3D printing has been increasingly applied to medical disciplines where therapeutic interventions rely on defining complex anatomic structural relationships [3]. This article aims to provide a brief history of 3D printing development and medical applications in pulmonary medicine. Most importantly, we will focus on designing personalized airway stents and review the limitations that the field faces today. This article is based on previously conducted studies and does not involve any new studies of human or animal subjects performed by any of the authors.

## HISTORY OF 3D PRINTING

Conceptually, 3D printing converts a digital file into a physical model. Taking a 3D computer-aided design (CAD) model, printing software performs a virtual slice to create a stack of 2D slices that will then be fed to a 3D printer. The 3D printer will build the 3D object layer by layer using the 2D slices by joining these layers together. 3D printing has its origins in the 1980s. Charles “Chuck” Hull, co-founder of 3D Systems, is credited with the invention of the world’s first 3D printer (stereolithography, SLA) in 1983. SLA (3D systems INC, Rock Hill, SC, USA; Formlabs, Somerville, MA, USA) uses an ultraviolet laser light to trace at the surface of a pool of photosensitive resin, where the laser comes into contact with resin there is a local polymerization and crosslinking of the liquid resin [2]. The reaction platform is raised/dropped as each layer of the 2D

cross-section is created. This method offers highly accurate models, but is limited by the available photopolymer resin for use [4]. In the mid to late 1980s, there was a proliferation of 3D printing technology. In 1987, Dr. Carl Deckard, as a graduate student at the University of Texas Austin, developed the selective laser sintering (SLS) process. Selective laser sintering (3D systems INC, Rock Hill, SC) uses a carbon dioxide laser to fuse thermoplastic powder ranging from plastic, metal, to ceramic. After sintering a cross-section, the powder platform descends 1 layer thickness and a new layer of thermoplastic powder is applied. This method increases the range of materials, affords high accuracy and resolution, but at a higher cost. In 1989, Scott Crump invented fusion deposition modeling (FDM) and went on to co-found Stratasys Inc. FDM (Stratasys Inc, Eden Prairie, MN, USA) extrudes various filaments or plastic pellets, most commonly acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA), through a heated extrusion nozzle. The printer nozzle moves in an  $x$ - $y$ - $z$  plane and traces each cross-sectional layer that hardens after extrusion on a platform. FDM offers high geometric accuracy and resolution with a wide range of material. Today, these two companies, 3D systems and stratasys, are the leaders in the 3D printing industry [2]. In 1993, Emanuel Sachs of Massachusetts Institute of Technology developed three-dimensional printing (3DP) that applies a thin layer of powder substrate on a build platform, then solidifies each layers with a liquid binder that enable rapid prototype modeling. The process allows a range of material, but does not produce functional final parts.

For the first two decades of its existence, 3D printing was limited to industrial purposes, which was expensive and proprietary. The introduction of 3D printing to the everyday consumer began through open source projects like RepRap (lead by Dr. Adrian Bowyer of University of Bath) and FAB@Home (lead by Dr. Hod Lipson of Cornell University). These do-it-yourself (DIY) projects coincided with several patent expirations that allowed the development of affordable desktop 3D printer systems and led to the rise of the entry-level 3D

printer industry. The adoption by both private and public sectors has resulted in rapid growth of the 3D printing industry, currently valued at five billion dollars and projected to grow to over 20 billion dollars worldwide in 2020 (Fig. 1) [5].

## 3D PRINTING AND MEDICAL APPLICATIONS

Since 1990, 3D printing has been used in oral and maxillofacial surgery [6], neurosurgery [7], and orthopedics [8]. Investigators used computerized tomography (CT) and magnetic resonance imaging (MRI) data to create anatomical models of long bones, facial bones, brain, heart, and lung. These applications of 3D printing have proved to be valuable in preoperative planning, education and training, intraoperative use of instruments, and even implantable devices [4, 9]. Perhaps the most exciting potential of the technology is the efforts in creating biological scaffolds for reseeded, which lays the foundation for the development of organ printing in the future [10–12].

## AIRWAY STENTS CONSIDERATIONS

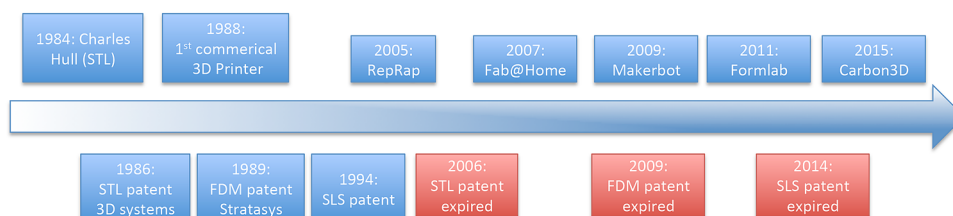
The tracheobronchial tree is well suited for 3D printing [13]. Human adult trachea spans 10–13 centimeters (cm), with 16–20 c-shaped cartilages anteriolaterally, while the posterior trachea is membranous. The right and left mainstem bronchus is ~1.5 and 4–4.5 cm in length, respectively. Internal diameter for the trachea, right and left mainstem bronchi are 16–20, 10–12, and 8–12 mm, respectively [14]. The silicone stents (Dumon stents, Novatech)

have a range of diameter (9–18 mm), thickness (1–1.5 mm), and length (20–110 mm). These stents are manufactured via conventional mold injection techniques. While customization is possible, the custom stent requires significant time and cost due to the need to create a new mold for each change in design [15]. This represents an opportunity to apply 3D printing technology to the manufacturing of airway stents.

## CURRENT DEVELOPMENTS IN PULMONOLOGY

Recently, several different groups reported different approaches of applying 3D printing to address clinical problems in pulmonology. Morrison et al. created personalized airway splints for pediatric patients with tracheobronchomalacia using MATLAB (MathWorks) and Mimics (Materialise, NV, USA) based on CT data. The airway splint was printed via Formiga P 100 System (EOS e-Manufacturing Solutions, Munich, Germany) with a blend of 96% CAPA 6501 PCL (Polysciences Inc, Warrington, PA, USA) and 4% hydroxyapatite (Plasma Biotol Ltd., Derbyshire, UK). Subsequently, the splints were treated with air blasting, sonication in 70% ethanol for 30 min, and ethylene oxide sterilization at 49 °C. The airway splints were implanted under the medical device emergency use exemption. All patients responded to treatment as expected [16]. There have been increasingly more case reports using 3D printed models in thoracic surgery planning or stent placement. Tam et al. 3D printed an airway model using a CT scan from a patient with tracheobronchial chondromalacia to

**Fig. 1** Brief historic timeline of 3D printing development



understand and characterize better the extent and location of stenosis or malacic changes. Kurenov et al. showed that it is readily feasible to 3D print pulmonary arteries from CT data, allowing for surgical planning. Finally, our group has recently reported using 3D custom designed t-tube, for a patient with recurrent medullary thyroid cancer status post resection, to bridge a segment of trachea that is fashioned from AlloDerm (LifeCell, Branchburg, NJ, USA) [13, 17, 18]. These articles, when taken together, suggest that personalized airway prosthesis via 3D design and printing is a feasible approach.

## AIRWAY MODELING

Our group has examined several software packages to aid in 3D modeling and design. In our experience, 3D Slicer (a free, open source software) offers a user-friendly approach to medical visualization and computation ([www.slicer.org](http://www.slicer.org)). Initially started as a collaborative project from MIT and surgical planning lab (SPL), the 3D Slicer prototype was built by David Gering in 1999, further developed by Steve Pieper and Ron Kikinis under the support of National Institutes of Health (NIH) [19].

3D Slicer provides an extensible platform for many automated algorithms. Nardelli et al. developed an airway segmentation algorithm as a 3D Slicer extension and validated their approach with different of CT scan parameters. Applying a region-growing approach, using a seed voxel and a threshold for separating air from tissue, the author generated a very accurate tracheobronchial tree [20]. The process to generate a physical airway model is straightforward when using this extension. (video 1).

After opening 3D Slicer, the user will need to install the airway segmentation module. After loading the CT scan, airway segmentation module can be applied to the dataset. Within the airway segmentation extension, fiducials (or seeds) are placed in the trachea, right and left bronchi, respectively. Airway modeling can begin after placement of the fiducials. After generating digital airway model, the user can save the model into .STL format, which is a

printable file in a 3D printer. The physical model can be generated from a 3D printer. (Fig. 2).

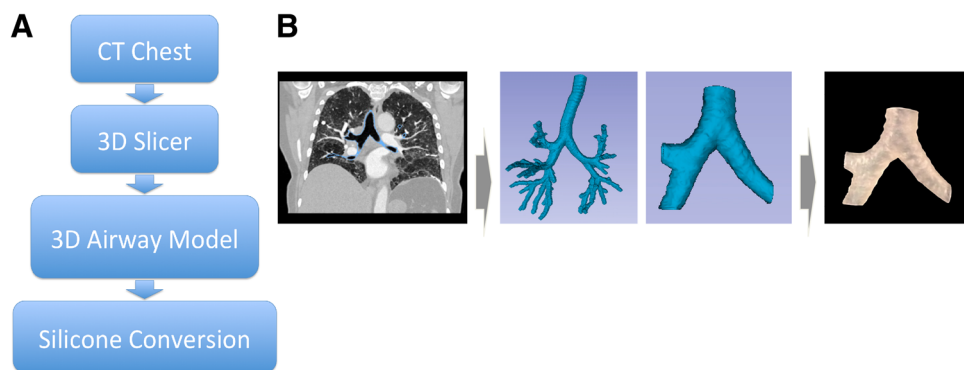
## AIRWAY INSPECTOR

Using the airway inspector extension ([www.airwayinspector.org](http://www.airwayinspector.org)), 3D Slicer has been used to perform CT-based quantification of COPD patients by extracting lung densitometry analysis such as air trapping quantification. Using 3D Slicer, COPDGene investigators evaluated over 3600 subjects' CT scans and found that airway wall thickness increased with bronchodilator responsiveness [21–25]. In a recent study of patients with NSCLC, Velazquez et al. extracted volumetric data on NSCLC size using 3D Slicer extensions [26]. The ability to provide accurate tumor growth assessment allows more precise treatment response monitoring. These approaches illustrate how 3D slicer is applied today and hints at the exciting potential in computational medical imaging.

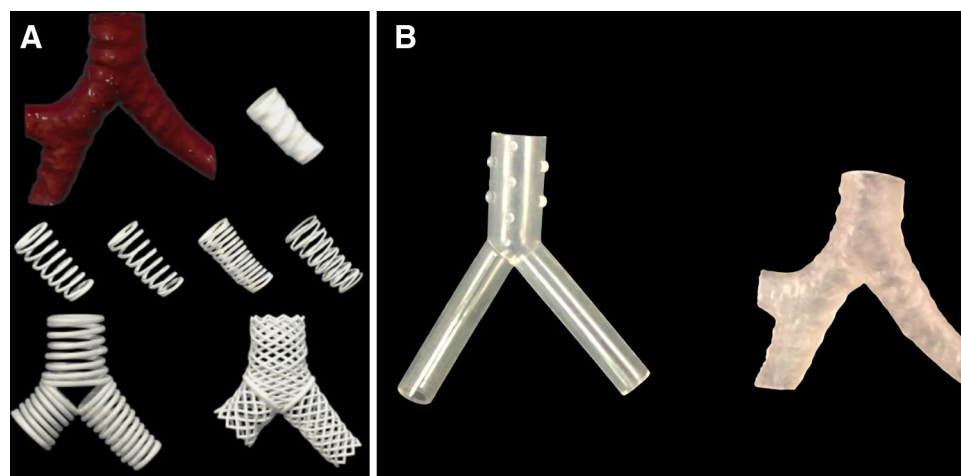
## COMBINING ART, ENGINEERING, AND MEDICINE

3D model of the airway can be easily done with 3D Slicer or an equivalent imaging software. The airway model can be further modified in commercially available digital modeling software, such as SolidWorks (DS SolidWorks Corp. Waltham, MA, USA) or Rhino (RhinoCeros; Robert McNeel & Associates, Seattle, WA, USA). Using SolidWorks, the physician can accurately design airway prosthesis based on anatomical boundaries. These designs can be rapidly altered to match clinical needs. A 3D printer can print the airway prosthesis model into a physical model for rapid prototyping. Using Rhino, the designers can create repeated patterns via a process known as tessellation. This process uses the virtual boundary from the airway walls as the surface where multiple patterns can be repeated. These processes can be used to generate a variety of stents in a matter of hours. Collaborating with engineers, the physical 3D printed model can be

**Fig. 2 a** Personalized stent project workflow schematic. **b** 3D slicer guided stent design and rapid prototyping



**Fig. 3 a** Tessellated stents. **b** Current and custom silicone stent



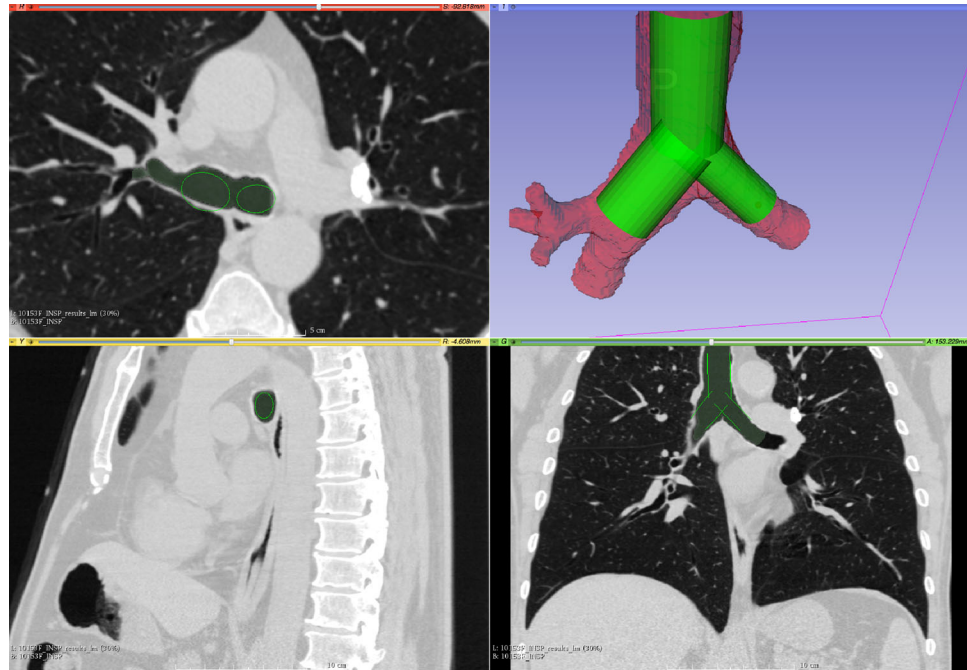
converted into silicone stent via injection molding. However, the most reliable and reproducible way to create silicone stent is to do indirect 3D printing (i.e. using the digital model of the airway to generate a digital mold for casting, which is then 3D printed). The silicone stent can then be manufactured (Fig. 3).

Perhaps more exciting, the next generation airway inspector is being developed. The chest imaging platform ([www.chestimagingplatform.org](http://www.chestimagingplatform.org)) aims to facilitate chest CT imaging computational analysis. When complete, CIP will provide physicians with a portfolio of analytic tools for CT imaging analysis that includes lung density, airway wall thickness, airway size, vascular distribution, and vascular size. Additionally, using the information gathered, one may perform disease-specific quantification tasks such as digital modeling of airway, automatic sizing of stents, and even guidance of stent placement (Fig. 4) [27].

## BARRIERS IN 3D MEDICAL PRINTING

Despite the exciting developments in healthcare 3D printing, we are faced with several challenges. While 3D printable materials are increasing, there is still a lack of FDA approved, 3D printable, flexible, implantable grade material that is suited for manufacturing endobronchial stents. Furthermore, the lack of clear FDA guidance on cleansing and material testing protocols for 3D printed products makes it hard for designers and manufacturers. Four sterilization techniques are commonly used to sterilize medical equipment. Autoclaves with steam at high temperature (121 or 132 °C) and pressure is commonly used for equipment cleansing; however, most materials from 3D printers cannot tolerate these conditions. Low

**Fig. 4** 3D Slicer stent modeling as part of the CIP package for stent modeling. Stent model is based on CT dataset. The coronal, sagittal, axial views of CT scan and model stent based on the 3D reconstruction of the airway are presented



temperature ( $>60^{\circ}\text{C}$ ) approaches, such as ethylene oxide, hydrogen peroxide, and gamma radiation, are more suitable for sterilize 3D printed material [28]. Typically, several FDA pathways can bring a product to market. Premarket approval (PMA), 510(k), and humanitarian use device (HUD) are the most common [29]. Medical devices are classified into class I, II, and III, with increasing risk associated with higher the class, which require a very rigorous evaluation process [30]. 510(k) approval requires a new product to demonstrate equivalence to a prior marketed device, which requires a less stringent review process [31]. Humanitarian use device (HUD) pertains to devices targeting rare disease ( $<4000$  patients per year) that can get to market without effectiveness guarantee [32]. Currently, the majority of 3D printed devices received FDA approval via 510(k) [33, 34]. Similarly, the European commission also has regulatory framework for medical devices, which falls under council directive 90/385/EEC, 93/42/EEC, and 98/79/EEC that applies to active implantable medical devices (AIMDD), medical devices (MDD), and in vitro diagnostic medical devices (IVDMD), respectively. 3D printed devices that are implantable and based

on morphological features specific of each patient are classified as custom-made devices according to the directive 93/42/EEC.

## EXCITING FUTURE DIRECTIONS

As the field of 3D printing expands into healthcare, it is only a matter of time to personalized medical devices that can be manufactured onsite (i.e. in the hospital). This development will bring customization of medical prosthesis to address each patient's specific needs. Airway stents are a perfect example. Given individual anatomy and needs differ (i.e. central airway stenosis with anatomical distortion), airway stents should be manufactured with those personalized criteria in mind. Currently, airway prosthesis such as airway stents is mass-produced without significant consideration to the individual airway parameters. This often results in stent migration due to poor sizing and fit of the stent. Additionally, granulation tissue formation can occur at the end of the stents due to constant mechanical irritation resulting from a stent digging into the airway tissue. These limitations of the current airway stents can be

reduced with a 3D printed personalized airway stent that is a perfect match to the patient's airway. While this is an exciting possibility, the full potential of 3D printed airway stents remains to be evaluated through future clinical trials. Current limitation for the realization of 3D printed airway stent is the lack of a suitable 3D printable flexible, biocompatible material. However, with the expansion of 3D printing involve drug-eluting, biodegradable stents or grafts, which are already being explored in the cardiovascular arena, we are hopeful that a suitable material will be available in the near future [35]. Personalized airway prosthesis will be a reality in the foreseeable future.

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**Compliance with Ethics Guidelines.** This article is based on previously conducted studies and does not involve any new studies of human or animal subjects performed by any of the authors.

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