Review Article

Patient-specific airway stent using three-dimensional printing: a review

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Contributions: (I) Conception and design: Both authors; (II) Administrative support: Both authors; (III) Provision of study materials or patients: Both authors; (IV) Collection and assembly of data: Both authors; (V) Data analysis and interpretation: Both authors; (VI) Manuscript writing: Both authors; (VII) Final approval of manuscript: Both authors.

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Abstract: The primary function of an airway stent is to reestablish patency, impeding restenosis, supporting the tracheobronchial wall, or occluding fistulas. But stent-related complications are prevalent and can have devastating consequences. For this reason, stents are considered a last resort when there are no alternatives in treatment. Additionally, commercially available airway stents often poorly fit patients with complex airways, and they can cause various complications. At the end of the 20th century, three-dimensional (3D) printing technology was created. It has been transformative in healthcare and has been used in several applications. One of its first utilizations was the anatomical modeling of body structures that helps preoperative planning. In respiratory medicine, this technology has been essentially used in central airway diseases to produce 3D airway models and to create airway splints and prostheses. In the last decade, it has led to a transformation and allowed progress in personalized medicine, making patient-specific stents for individuals with complex airway problems. A patient-specific stent using 3D printing may minimize complications, improve quality of life, and reduce the need for repeated procedures. This review describes the recent advances in 3D printing technology, its use for developing airway prostheses to treat complex airway diseases, and the current evidence that supports its use.

Keywords: Three-dimensional printing (3D printing); airway stents; patient specific stents

Submitted Jun 01, 2022. Accepted for publication Aug 19, 2022. Published online Sep 06, 2022.
doi: 10.21037/atm-22-2878
View this article at: https://dx.doi.org/10.21037/atm-22-2878

Introduction

Numerous diseases, malignant and benign, are known to affect the airway (1). Bronchoscopy plays an essential role in diagnosing and managing these conditions (2). Bronchoscopic treatment aims to improve a patient's quality of life, alleviate symptoms, and deliver significant palliation after non-invasive treatments are deemed ineffective (1,3). Flexible or rigid bronchoscopy (RB) can provide several treatment modalities, such as laser therapy, cryotherapy, electrosurgery, argon plasma coagulation, photodynamic therapy, and stent placement (1,3-6).

The primary function of an airway stent is to reestablish patency, impeding restenosis, supporting the tracheobronchial wall, or occluding fistulas (7,8). There are various types of stents available on the market. They may consist of silicone, metallic wire mesh, or a combination of these materials (hybrid) (9). They also have different shapes (Straight, Y-shaped, or T-tubes), diameters, and

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lengths (9). Complications such as migration, granulation, infection, and mucus plugging are common (7,10-13). Therefore, stent placement should be temporary when no other techniques achieve adequate and sustained patency (5,14-16).

Benign obstructions require caution since implantation may be long-term, potentially producing a high rate of complications (14). Uncovered metallic stents are contraindicated for use in some benign diseases due to the risk of excessive granulation tissue formation that worsens airway obstruction (14). Furthermore, their adherence to the airway wall can result in significant airway damage when removed (14). As a result of complications associated with metallic stents, silicone stents are the most used for benign diseases (6,14,17). Silicone stents are made of synthetic material that elicits minimal tissue reactivity and can be easily removed (14,16).

Unfortunately, commercially available stents (CAS) only exist in limited shapes and sizes. Occasionally, it is necessary to customize them to improve fit and functionality, especially in patients with complex airway anatomy (18). This customization is usually done by cutting and sewing stents together in the procedure room and requires an experienced and highly skilled physician (18). Additionally, the procedural time needed to create the customized silicone stent may prolong a procedure, which could be detrimental to the patient (18).

The complex characteristics of tracheobronchial anatomy make the three-dimensional (3D)-printing technology ideal for developing airway prostheses to treat complex diseases. Through years of investigation and advancement, it is now feasible to manufacture a patient-specific stent using this technology (19-22). A patient-specific stent may help minimize complications, decrease procedure time, and improve patients' quality of life while reducing symptoms and the need for repeated procedures.

3D technology

Hull patented in 1986 "*an apparatus for production of three-dimensional objects by stereolithography*" this method uses a computer-aided design (CAD) and produces 3D objects formed by thin layers of a ultraviolet (UV) curable material (23). Then, in 1989, Deckard patented an "*apparatus and method for producing parts by selective laser sintering*" that uses a computer-controlled laser to direct the energy onto a powder to produce a sintered mass (24). Crump created the "*Fused deposition modeling*", which directly extrudes the supply material or filament from a heated nozzle and produces the 3D model (25). Later, Sachs and colleagues patented in 1993 "*Three-dimensional printing techniques*", coining the name for 3D printing (23,26). They, among others, made significant steps in additive manufacturing using 3D printing technology, which is a process of building a physical object using modeling data that is fast, precise, and fully customizable (26,27). The process of creating 3D objects is based on the design of a virtual 3D model, the data obtained from slicing this CAD 3D model is transferred to computer-controlled equipment that deposits material layer by layer until the item is produced. Currently, several printing technologies exist, each one offers different methods and uses various printing materials like elastomers, plastic, or metals (28). After several years of development, 3D printing was adopted in various industries, and healthcare is one important using this technology.

In the beginning, 3D printing was used exclusively for prototyping, but now it offers transformative advantages and several applications such as prostheses, implants, medical models, and medical devices. Also, this technology is rapidly evolving in biomedical engineering by creating a relatively new process called bioprinting that incorporates cells directly into a printed tissue (29). Now, healthcare 3D printing is leading a revolution in personalized medicine, making customized objects or tools that fit specific patients' needs (28).

3D printing technology and airway disease

One of the initial uses of rapid prototyping techniques in medicine was the anatomical modeling of different body structures that helps surgeons in preoperative planning (30,31).

3D printing technology has been used in respiratory medicine, especially in central airway diseases. In 2013 Tam *et al.* printed 3D models of the tracheobronchial tree of a patient with airway disease secondary to relapsing polychondritis, they used inspiratory and expiratory models and discussed the potential aid for surgical or interventional planning and education (32).

Zopf and colleagues published in 2013 a case where a bioresorbable airway splint was created using 3D printing technology and surgically tied in a malacic left main bronchus of a newborn (33).

Then, in 2015, Cheng *et al.* published the first reported case of a 3D modeled T-tube placed in the complex upper airway of a patient, this prosthesis was designed to obtain a 3D reconstruction of the trachea from a computed

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tomography (CT) scan (34).

Thomas R. Gildea, in February 2016, using CT imaging and 3D printing technology, made and implanted the first bronchial patient-specific airway stent (PSS) made out of silicone under FDA clearance for compassionate use to manage a 56-year-old male patient with airway complications of granulomatosis with polyangiitis who required multiple unsuccessful therapeutic bronchoscopies and several commercially and manually customized stents (20,22). In 2017, Gildea and colleagues reported the one-year experience of this and another patient with complex airway disease secondary to granulomatosis with polyangiitis (GPA); after insertion of PSS produced using 3D printing technology, both patients increased average time between procedures and stent life after implantation (20,22).

The same year, Guibert *et al.* published a case of a patient with an airway complication after lung transplantation, the right airway had dehiscence, a stenotic bronchus intermedius, and complex anatomy. A 3D airway was created from a CT scan, the complications were virtually resolved, a designed 3D mold was printed and used to make a custom stent that was placed successfully with RB (35). Similar efforts have been made in adult patients treating tracheobronchomalacia with 3D printing technology (36). Recently, Shan and colleagues have published their experiences treating aerodigestive fistula and malignant airway obstruction with hybrid stents customized with the assistance of 3D printing (37,38).

3D printing methods and materials in airway stents

Different 3D methods and materials have been used to create airway stents.

Cheng and colleagues used 3D slicer (a free, open-source, and multi-platform software package widely used for medical, biomedical, and related imaging research) to obtain a 3D reconstruction of the trachea using a CT scan. Then, this 3D model was imported to Solidworks® (CAD software), and a virtual T-tube was designed that matched his patient's virtual complex upper airway. After the virtual design was approved, it was sent to a manufacturer, and a silicone personalized T-tube was produced and inserted through the tracheostomy stoma under bronchoscopy guidance (19,34).

Gildea and colleagues imported the CT scan digital imaging into a proprietary software developed for orthopedic surgery (COS Inc., Cleveland, OH, USA). A 3D virtual prototype of the airway is created. Based on this virtual model of each patient's anatomy, the desired stent dimensions were defined, including the area, diameter, angulation, branching, length, and wall thickness. The physician uses the software tools to place a series of spheres in the desired area to adjust the shapes and sizes to make a virtual representation based on clinical needs. A mold of the prescribed stent is produced with 3D printing technology, and the stent is manufactured by injecting medical-grade silicone into this mold. The stent is cleaned and finished producing a smooth surface, and external studs are added. The stent is sterilized with standard steam sterilization on site. Finally, the stent is placed with standards methods and tools using RB (20,36) (*Figures 1-3*).

Guibert used a similar workflow, designing a virtual 3D mold (VGStudio MAX software). The 3D data was imported to the 3D printing (RolandDG MDX 40A) to produce an Ertacetal POM mold. A personalized silicone stent was made from this mold. Therapeutic RB is performed, and the stent is inserted (35,39).

Shan and colleagues used data from a 64-slice multidetector spiral CT scan to reconstruct 3D images of the airway using CAD software (Vitaworks, Shanghai, China). The airway and tumor were then assigned different colors, and the image was converted into a 3D stereolithographic (STL) file. The 3D reconstruction data was added into a 3D printing (RS600, Union Tech, Shanghai, China) to create an airway mold made from photosensitive resins. The dimensions of the area of interest in the 3D printed airway mold were measured in the airway. Then, using the 3D printed airway model as a template, the covered self-expandable Y-shaped metallic airway stents (Micro-Tech, Nanjing, China) were made of temperature-memory nickel-titanium alloy. The stents were inserted using flexible bronchoscopy for evaluation and guidewires placement. Posteriorly, a stent delivery system was advanced out of the endotracheal tube, and the stent was deployed under fluoroscopy guidance (37,38).

Other materials which can be directly printed to produce an airway stent have been subject of research. In 2015, Hussain at the University of South Carolina used 3D printing technology to assess possible improvements on existing stents through designing and printing a bioresorbable tracheobronchial stent. He concluded that polycaprolactone (PCL) is fused deposition modeling printing-compatible, and thermoplastic polyurethane (TPU) is potentially viable as a biologically degradable silicone alternative (40). Wood and colleagues developed

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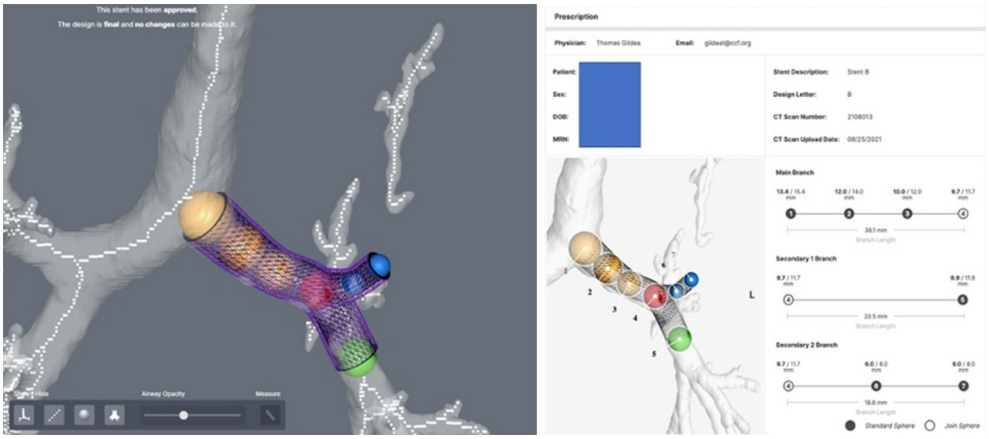

Figure 1 After a 3D virtual prototype of the airway is created. The physician uses the software tools to place a series of spheres in the desired area to adjust the shapes and sizes to make a virtual representation of the patient specific silicone stent based on clinical needs. Picture authorized by COS Inc., Cleveland, OH, USA (Visionair). 3D, three-dimensional.

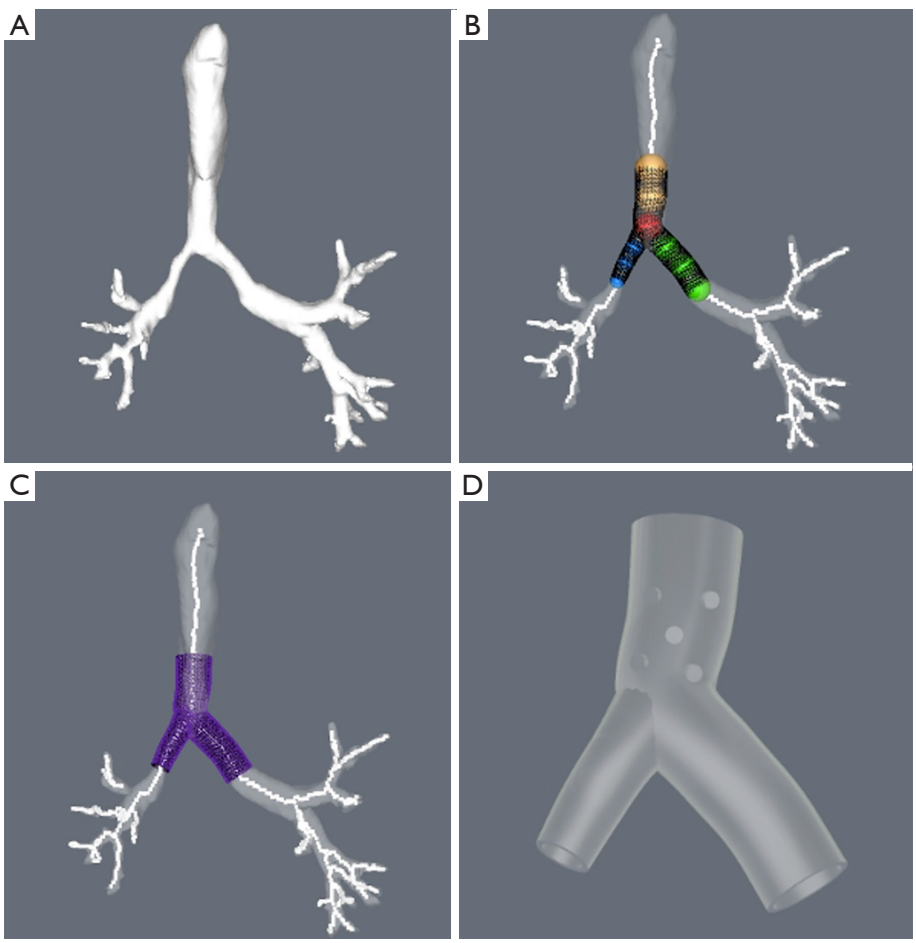

Figure 2 Patient specific silicone stent created with 3D printing technology. (A) Segmented airway. (B) Stent design with spheres. (C) Stent design. (D) Silicone stent. Picture authorized by COS Inc., Cleveland, OH, USA (Visionair). 3D, three-dimensional.

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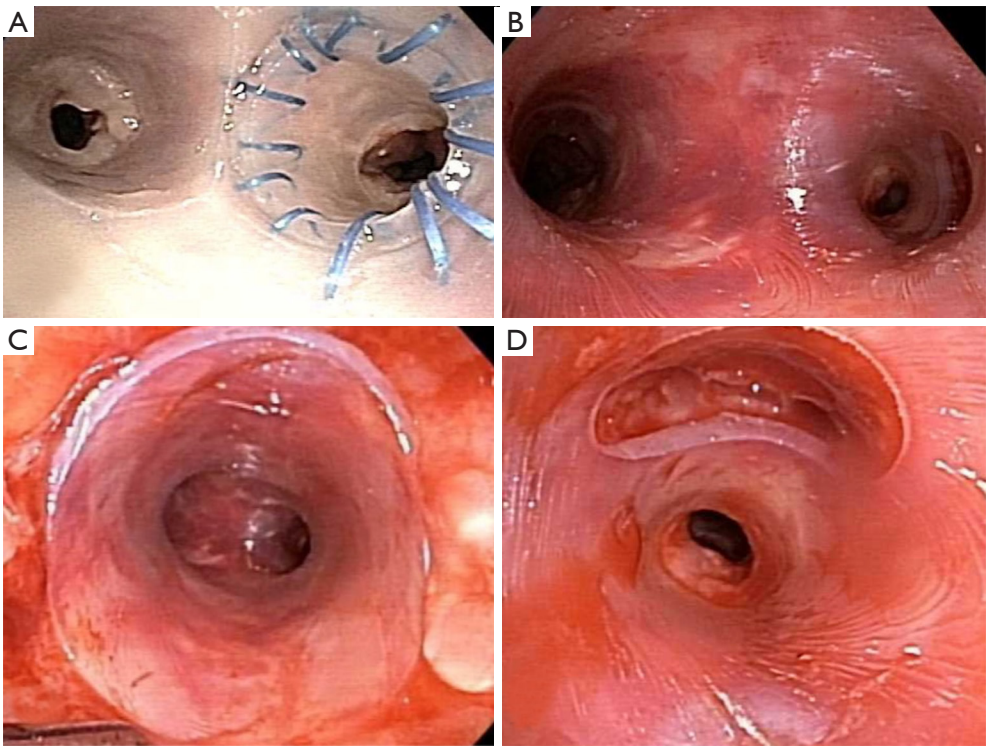

Figure 3 Patient specific silicone stent created with 3D printing technology. (A) Customized commercially silicone stent. (B-D) Patient specific stent created with 3D printing technology, observe how it perfectly fit in a complex airway. 3D, three-dimensional.

a platform for designing and production of 3D printing flexible airway stents with elastomeric polyurethane (EPU), after performing comparative tests with silicone stents, they concluded that 3D printed EPU stent has similar performance (41). Paunović *et al.* reported using digital light 3D printing customized bioresorbable stent in an *in-vivo* study of healthy rabbits. The stents were made of a dual polymer which was biocompatible and stayed in place for 7 weeks (42).

These 3D printing materials are promising because of the possible rapid and direct manufacturing, customization, biocompatibility, and degradability. But further research is needed before it is recommended for use in patients.

Current evidence in 3D printing PSS

Since 2015, there has been an increased number of publications on 3D printing and airway stents. We found ten studies using 3D printing and PSS in humans (22,34-39,43-45) (*Table 1*). Most studies were done on benign airway diseases such as post-surgical airway complication, post-transplant airway disease, tracheobronchomalacia, GPA airway, or post-radiotherapy airway complication. The most frequently used stent material in benign airway diseases was silicone (22,35,36,39,43,46,47).

More recent research has been done on malignant central airway obstruction or malignant aerodigestive fistula. They almost exclusively, but one, used covered metal stents (37,38,44).

Nine studies described printing out a 3D airway mold to create the PSS (there is no description in one study). And mostly, the stents were Y tracheobronchial or bronchial. Interestingly, six studies used the 3D mold to make Y-bronchial stents or a bronchial branch to the right upper lobe.

All studies showed improvement in symptoms (*Table 1*). Guibert *et al.* used 3D printing silicone PSS in 10 patients (mostly post-transplant airway complications) and described a high rate of congruence between the stent and the airway, 80% of improvement in dyspnea [>1 New York Heart Association (NYHA) point gain], quality of life [>10% VQ11 chronic obstructive pulmonary disease (COPD)-specific quality of life questionnaire score increase], and pulmonary function test [>10% forced expiratory volume

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Table 1 3D printing patients specific stent studies

Author	Reference no.	Year	Type of study	No. of patients	No. of stents	Type of airway disease	Airway mold	Stent material	Type stent	F/U in months	Comparation with CAS	Results	AEs	Processing time in days
Cheng *et al.*	34	2015	Case study	1	1	Benign	Yes (virtual)	Silicone	T-Tube	4	No	Improvement in phonation, no granulation tissue after 4 months	N/D	N/D
Guibert *et al.*	35	2017	Case study	1	1	Benign	Yes	Silicone	Right bronchial stent branched to the RUL	2.5	No	Improvement of symptoms, PEF	N/D	N/D
Gildea *et al.*	22	2018	Case study	2	2	Benign	Yes	Silicone	Y-stent for LMB	12	No	Increase time between procedures. Increase stent life. Decrease procedure time	N/D	7
Schweiger *et al.*	36	2018	Case study	2	2	Benign	Yes	Silicone	Y tracheobronchial	5 and 8	No	Symptoms improvement	N/D	7
Guibert *et al.*	39	2019	Prospective	10	10	Benign	Yes	Silicone	Y bronchial and tracheobronchial stent	4	No	90% congruence, 80% improvement in dyspnea, quality of life and FEV1 or PEF	3 months complication rate 40%	50
Aravena Leon *et al.*	43	2019	Retrospective	4	13	Benign	Yes	Silicone	Y bronchial and tracheobronchial stent	21.6	Yes	No difference compared to commercial stents in RB loading, placement, removal. Increase time between procedures. Increase stent life	PSS experienced a lower severity of migration. All other AEs were not statistically different between the two groups	7
Duong *et al.*	44	2020	Case study	1	2	Malignant	N/D	Polyurethane	Right bronchial stent branched to the RUL	2	No	Symptoms improvement	PSS replacement at 2 months and migration and removal of the 2nd PSS	N/D
Huang *et al.*	45	2021	Retrospective	6	7	Benign (post esophagectomy)	Yes	Hybrid (nitinol, silicone, and PTFE)	Y tracheobronchial	16.7	No	All fistulas sealed. Leaking control in 6 patients. KPS improvement	2 had mucus retention, 1 had excessive granulation tissue and stent removal	N/D
Shan *et al.*	37	2021	Retrospective	12	13	Malignant	Yes	Hybrid (nitinol, silicone, and PTFE)	Y stent (1 bronchial, rest tracheobronchial)	5.6	No	1 patient had 2 stents; 11 had significant symptoms improvement, KPS improvement	4 had mucus retention, 2 excessive granulation tissue, 0 migration, 0 removal	4
Shan *et al.*	38	2021	Retrospective	26	26	Malignant ADF and post esophagectomy	Yes	Hybrid (nitinol, silicone, and PTFE)	Y stent (1 bronchial, rest tracheobronchial)	5	No	Clinical success rate 80%. Resolution ADF post-esophagectomy (9/16). Resolution malignant ADF (0/10). KPS improvement	2 (7.69%) granulation tissue treated cryotherapy and stent removal; 5 (19.23%) sputum retention, treated w/suction; 1 (3.84%) had stent migration underwent a second stent; 1 (3.84%) not tolerate the stent and was removed	N/D

3D, three-dimensional; F/U, follow-up; CAS, commercially available stents; AEs, adverse events; N/D, not described; RUL, right upper lobe; PEF, peak expiratory flow; LMB, left main bronchus; FEV1, forced expiratory volume in the first second; RB, rigid bronchoscopy; PSS, patient-specific airway stent; PTFE, polytetrafluoroethylene; KPS, Karnofsky Performance Scale; ADF, aerodigestive fistula.

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in the first second (FEV1) or peak expiratory flow (PEF) increase] (39). Aravena Leon *et al.* presented a retrospective study of patients who received 3D printing silicone PSS at the Cleveland Clinic. Interventional pulmonologists involved in the procedures completed a survey, and two physicians graded stent-related adverse events (AEs) based on the Common Terminology Criteria for Adverse Events Scoring System. A total of 13 PSSs were placed in 4 patients. Compared to the CAS, no difference was described to load, place, or remove the PSS (P>0.05). Bronchoscopists noted a significant clinical improvement after the PSS was placed (P=0.03). The average lifespan of the PSS was significantly higher than the CAS (300.2 *vs.* 124.0 days, P<0.001). The average duration between bronchoscopies was substantially longer with PSS than CAS (65.6 *vs.* 36.6 days, P=0.004) (43,47).

Shan *et al.* published a study of 12 patients with malignant airway obstruction secondary to lung or esophageal cancer, 13 covered metal PSS were placed. They described an improvement in the Hugh-Jones dyspnea scale (P=0.003) and Karnofsky Performance Scale (KPS) (P=0.006) (37).

Concerning to the AEs depicted in the different trials. Guibert and colleagues described a 40% complication rate at 3 months, one patient had a mucus plug, two stent migrations, and one untreatable cough. Three of them required stent removal. At four months of follow-up, an additional mucus plug event occurred, and one patient developed distal stenosis at a lobar level that required balloon dilation. Non-life-threatening complications were observed (39). Aravena Leon and colleagues demonstrated that silicone PSS experienced a lower migration severity than CAS (P=0.0225). All other AEs were not statistically different between the two groups (43,47). Shan *et al.* showed in covered metal PSS a complication rate of 50% (6/12) in 5.6 months of follow-up. Four patients experienced mucus plugging, two had excessive granulation tissue formation and none had migration or required stent removal (37).

Discussion

The use of any stent in complex benign or malignant airway disease is always an option of last resort. Stent-related complications are prevalent and can have catastrophic consequences. The three most common adverse events related to silicone stenting are migration, stent occlusion (by either granulation tissue or mucus), and infection. These three conditions can also be significantly intertwined, as others have shown the association between stent granulation and infection (6). The complication rate described in the literature is variable and has been communicated between 21.5% to 65% (5,6,14-18). Many patients experience long-term palliation despite these risks, even with non-malignant conditions.

The studies reported in this review showed that the 3D printing PSS is at least as safe as the CAS. The rate of complications is similar, and no threatened-life complications were described. The production of 3D printing PSS in the shape of Y-bronchial and Y-tracheobronchial stent that are congruent and fit the complex airways of those patients probably helped to decrease the migration rate compared to CAS (43,47).

The technical success of the PSS congruence to the complex airway is high in several of the studies presented here. It potentially means a decrease in AEs. Many of the complications associated with stents are directly related to fit problems. A stent that is too loose or too tight has a higher migration rate. A stent that puts too much pressure on the airway may lead to tissue necrosis and perforation. A stent that does not sit properly may incite granulation at the ends or cause impaired secretion clearance. A stent that is too long may create increased resistance and a barrier to clear secretions. Multiple methods and applications of stent shape and sizing are possible choosing size is now an interesting challenge. Further, material properties may have clinical implications. Even in silicone stents, there are stents with variable durometer and modulus that can impact entirely new considerations of wall stress.

The PSS could be loaded and deployed with existing standard techniques, similar to conventional stents (43,47). This is an understated but essential finding, as some complex stent designs, like the dynamic Y-stent, require special equipment for placement.

The benefits could be broad. There is a consistent improvement in symptoms through all the studies described. One trial showed an increase in quality of life and pulmonary function test (39). Only one study compared the PSS to CAS. This demonstrated an increase in stent life and time between procedures, it might be correlated to an improvement in the quality of life of patients with complex benign airway diseases who ordinarily require several and consecutive bronchoscopies in an attempt to achieve palliation (43,47).

Related to malignant disease, an essential additional finding is associated with the increase in the KPS (37,38,44).

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It could be linked with the resolution of the obstruction, the augmented congruence, and the decrease of AEs, which could improve symptoms and the ability to receive additional oncologic therapy.

The studies described in this review are not large enough to draw broad conclusions about the use of patient-specific stenting. Most of them are studies of cases or retrospective cohorts which are also subject to significant bias and should only be viewed as hypothesis-generating. They merely represent an initial, conservative user for a proof-of-concept. Despite their small sample size, the initial experience has shown that patient-specific stents are very effective and safe in the palliative treatment of extraordinary complex airway disease, beyond all the best available care to date. Designing outcomes trials with a wide variety of diseases and no standard stent design features can be quite challenging.

Other advances are a matter of ongoing research. New materials that might be directly printed and could be biodegradable when temporal stents are desirable (42). 3D printing drug-eluting stents that could be a potential treatment strategy to avoid excessive granulation tissue, prevent infections, and control airway-related malignancy (48).

Conclusions

3D printing technology has advanced important steps in the last decades. Healthcare has used this technology for education, preoperative planning, medical devices, prostheses, implants, and medical models. Respiratory medicine is leading a revolution in personalized medicine, making customized airway stents that fit the specific needs of patients with complex malignant or benign airway disease. These PSSs created using 3D printing technology have shown the potential to improve symptoms, quality of life, performance status, stent life and decrease the time between procedures and AEs. Randomized control trials with a large number of patients comparing PSS against CAS will be needed but challenging to determine the real impact that this technology will have on this group of patients. The ability to design many more variables into the process adds further complexity.

Acknowledgments

The authors of this review wish to thank to Adrianna Baiera and Keith Grafmeyer for assisting in previous research on which the work was based.
Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editor (Calvin S. H. Ng) for the series "Lung Cancer Management—The Next Decade" published in *Annals of Translational Medicine*. The article has undergone external peer review.

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2878/coif). The series "Lung Cancer Management—The Next Decade" was commissioned by the editorial office without any funding or sponsorship. TRG reports that Cleveland Clinic and Cleveland Clinic Institutional Officials/Leaders have an equity interest in Visionair and are entitled to royalty payments from the company for technology developed at Cleveland Clinic. Visionair is the manufacturer of the stents. TRG is the inventor and may be entitled to royalty payments from the company in accordance with Cleveland Clinic policy. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Cite this article as: Aravena C, Gildea TR. Patient-specific airway stent using three-dimensional printing: a review. Ann Transl Med 2023;11(10):360. doi: 10.21037/atm-22-2878

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