

A narrative review of progress in airway stents

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Background and Objective: Airway stents, used to restore airway patency, are mostly utilized by patients with malignant airway strictures, and are occasionally used in a range of other airway related diseases, including conditions which result in benign stenosis, malacia, and fistula. There has been an increasing number of airway stents that are being developed thanks to improvements in interventional therapy. However, the method of promoting airway stents for clinical application remains undetermined. Herein, we describe the recent advances in airway stents by reviewing the published studies, providing the reference for clinical decision-making and further research on airway stents.

Methods: Relevant articles between January 1964 and November 2021 were obtained from PubMed, Web of Science, and EMBASE databases. The terms "metallic", "silicone", "drug-eluting", "biodegradable", "radioactive", "three-dimensional (3D)", and "stents" were searched in different combinations.

Key Content and Findings: In this review, we focus on the latest evidence in terms of the application of various stents with novel materials and designs including novel metallic, novel silicone, drug-eluting, biodegradable, radioactive, and 3D stents for airway stenosis. Despite reducing the well-known complications of all current commercially available stents, novel stents are still in their infancy without a long track record of utility and safety, and remain some limitations. There are more steps to be taken before such stents enter routine clinical practice.

Conclusions: A combination of 3D-printing method and biodegradable material may present a promising avenue of solving the existing problems pertaining to "classic" stents and has potential to become the main trend in the future.

Keywords: Airway stents; silicone stents; metallic stents; airway stenosis

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Introduction

Airway stents are geometric objects fixed with biocompatible medical-grade silicone or nickel-titanium alloy. As a major component of an integrated Interventional Pulmonology service, airway stents can provide available and timely relief to patients with airway stenosis. Such stents can be metallic or silicone, based on the material. Multiple factors (i.e., indication, physician expertise, the available equipment within the endoscopy unit and specific clinical situation) should be taken into account when selecting a proper stent. Metallic stents have seen increased application in the treatment of malignant stenosis, which may be attributed to their convenience that avoids the utility of rigid bronchoscopy. Of note, uncovered metallic stents prefer the theoretical benefit of neo-epithelialization that is instrumental in normal mucociliary clearance of secretion (1,2). There was a study suggesting that even for palliative patients with malignant airway stenosis, metallic stent implantation was also a safe and effective procedure that provided rapid palliation of symptoms and improvement in patient functional status (3). However, given their significant complications and difficulties associated with removal, the United States (US) Food and Drug Administration (FDA) issued a warning against their use in patients with benign airway stenosis (4), which was validated by recent clinical field has begun to move towards greater use of silicone stents, owing to their ease of removal and more favorable complication rate compared with metallic stents.

The clinical application of silicone stents has evolved memorably over the last few decades, beginning with the silicone T-tube designed in 1965 by Montgomery (6), followed by the Dumon stent (7), which remained safe and reliable for patients with both benign and cancerrelated airway stenosis at any given moment. It should be noted that there are certain limitations with silicone stents recognized as follows: (I) insertion of silicone stents requires a rigid bronchoscopy under general anesthesia; (II) the stent-related complications, such as migration, granuloma formation, mucus plugging, infections and restenosis, must not be neglected. Hence, over the years, various novel stents have been designed to present a promising procedure of solving the limitations that "classic" silicone and metallic stents have. Table 1 shows the details of the individual stents. We present the following article in accordance with the Narrative Review reporting checklist (available at https:// jtd.amegroups.com/article/view/10.21037/jtd-21-1871/rc).

Methods

A comprehensive and systematical online literature search via PubMed, Web of Science, and EMBASE (from January 1964 to November 2021) was performed by two authors independently and the search strategy summary was shown in *Table 2* as follows.

Novel metallic stents

Uncovered stents

Restenosis is a frequent complication when implanting permanent stent into patients with benign tracheobronchial stenosis. To resolve the clinical dilemma, Li (8) designed a temporary uncovered airway stent (i.e., Chinese Li's metallic stent) that provided three options of supporting force (Figure 1) adapting to different wall thicknesses. In addition, the stent was easy to remove because of sufficient flexibility to conform to tortuous airways. In clinical practice, Li's metallic stents were successfully implanted in 4 patients with benign airway stenosis, and results showed that all patients had good symptom palliation with no severe complications after stenting. Recently, Jiang et al. (9) developed a novel through-the-scope (TTS) self-expandable metallic airway stents (SEMS) (Figure 2) delivery system that shifted an obtuse angle with over-the-wire (OTW) stent into an acute angle with TTS stent and had an outer diameter of only 2.67 mm. The aforesaid highlights made it possible for TTS SEMS to be implanted via the working channel (2.8 mm) of the flexible bronchoscope and to reduce their own shear force. It may translate to shorter placement times, greater accuracy and greater success rate when implanting stents. In their research, 36 TTS stents were placed into 25 patients with malignant central airway stenosis. 91.7% (33/36) of stents were successfully inserted and the stenosis grade of all patients improved convincingly after stent placement. It has to be mentioned that stent-related complications were common and occurred in 61.1% of patients, including mucus plugging (25%), granuloma formation (13.9%), tumor in-growth (13.9%), and hemoptysis (8.3%). Hence, larger randomized clinical trials are needed to evaluate the safety and efficacy of TTS SEMS in malignant central airway stenosis.

Covered stents

Polytetrafluoroethylene, silicone, and polyurethane, as the covering materials, endow covered stents with the additional advantages of minimizing tissue ingrowth and being deployed more easily. Currently, the structure of the tracheal bifurcation, a huge challenge for "classic" metallic stents, presents a high risk of restenosis and migration. Covered self-expanding Y-shaped stents have been introduced as a way to manage complex airway disease especially fistulization near the tracheal carina (10). Nevertheless, such stents have not been approved so far in the United States. Interestingly, in a latest retrospective analysis comparing long-term survival and complications amongst patients treated for malignant airway stenosis or tracheoesophageal fistula with Y-shaped silicon stents or covered self-expanding Y-stents, results indicated that symptom palliation, insertion safety, survival or complication rate were also found to be not different for the two types of stent (11). Fiorelli et al. (12) designed

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Table 1 The details of airway stents

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Researcher (time)	Definition	Type of stents	Manufacturer	Soft/Rigid bronchoscopy	Application
Han, <i>et al.</i> (2017)	Hinged and covered SEMS	Novel metallic stents	Nanjing Micro-Tech Medical Company, Nanjing, China	Soft	Feasible and safe for benign airway stenosis
					Avoids the use of general anesthesia, bronchoscopy and cannula
Dahlqvist, <i>et al</i> (2016)	. Micro-Tech fully covered SEMS	Novel metallic stents	Nanjing Co., Republic of Korea	Rigid	Easy to locate and to remove Complications are frequent when removing the stent but not life-threatening
Jung, <i>et al.</i> (2021)	A new silicone airway stent (GINA stent) with an anti-migration design, dynamic structure that enables the reduction of stent cross-sectional area, and radio-opacity	Novel silicon stents	Invented by Taehoon Lee	Rigid	Better mechanical properties and comparable short-term performance compared to the Dumon stent
Sigler, <i>et al.</i> (2015)	Stents have an anti-proliferative coating with sirolimus	Drug-eluting stents	Cypher Select, Johnson & Johnson, Cordis, USA	Soft	Not different from bare metal stents in an experimental environment
					Unable to inhibit the formation of granulation tissue
Fuehner, <i>et al.</i> (2013)	Stents are based on Polydioxanone	Biodegradable stents	Ella-Cs, Ltd., Hradec, Kralove, Czech Republic	Rigid	A useful and safe procedure for patients with airway stenosis after lung transplantation
Wang, <i>et at.</i> (2018)	Stents loaded with I ¹²⁵ seeds	Radioactive stents	MTN Nanjing MicroInvasive Medical (Nanjing, China)	Rigid	Less restenosis and better OS relative to bare metallic stents A safe and effective means for inoperable malignant airway stenosis
Hatachi, <i>et al.</i> (2020)	The personalized Y-shaped silicone stent using 3D printed technology	3D printed stents	3D printer (STRA-SYS; Eden Prairie, MN, USA); The Y-shaped silicone stent (Dumon; Novatech, La Ciotat, France)	Rigid	Improve the symptoms of a patient with airway stenosis caused by granulation
					Enhance the security and accuracy of stent placement

SEMS, self-expandable metallic airway stents.

a fully-covered standard conical SEMS (CSEMS) as an emergency treatment for a patient with complex airway malignant stenosis, and the dyspnea immediately improved significantly after stent placement. This may be attributed to excellent conformation to the anatomy of complex and tortuous airways. In addition, it was also reported that multiple covered, bifurcated SEMS showcased high degrees of safety and efficacy for complex tracheobronchial stenosis or fistulas (13).

Apart from resulting in migration for complex airway stenosis, "classic" metallic stents can also cause certain immune rejections and poor matchings. In view of this, Table 2 The search strategy summary

Items	Specification		
Date of Search (specified to date, month and year)	From 15 February 2021 to 21 March 2021		
Databases and other sources searched	PubMed, Web of Science, and Embase		
Search terms used (including MeSH and free text search terms and filters)	Refer to Table S1		
Timeframe	From 1 January 1964 to 1 November 2021		
Inclusion and exclusion criteria (study type, language restrictions etc.)	Inclusion criteria: novel metallic stents; novel silicone stents; drug-eluting stents; biodegradable stents; radioactive stents; three-dimensional (3D) printed stents		
	Exclusion criteria: research with similar conclusions		
Selection process (who conducted the selection, whether it was conducted independently, how consensus was obtained, etc.)	Two investigators (S Tian, H Huang) performed the search strategy independently and then conducted a secondary retrieval of eligible studies. Then two independent researchers (S Tian, Z Hu) assessed potentially relevant articles, according to the above selection criteria, and the discrepancies were checked by performing a blind cross-check. If there were any disagreements, the inconsistencies were solved by another reviewer (Y Dong)		
Any additional considerations, if applicable	Apart from database retrieval, the references list of eligible literature was also manually screened to identify potentially relevant researches not included in the initial search		



Figure 1 Chinese Li's metallic stent with different supporting force.



Figure 2 The general appearance of through-the-scope (TTS) stent.

Wu et al. (14) developed an airway SEMS based on nanotechnology surface modification. A total of 42 patients with airway stenosis were randomly divided into the experimental group (SEMS based on nano-technology surface modification) and the control group (Ni-Ti memory alloy stents), with 21 patients in each group. Results revealed that in contrast to the control group, the lumen diameter of the airway stenosis, forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) levels in the experimental group was higher, and the incidence rate of complications significantly lower (9.52% vs. 19.05%, P<0.05). Furthermore, a novel fully-covered SEMS (AERO) was designed to possess the advantages of both silicone stents (i.e., ease of removal) and "classic" metallic stents (i.e., ease of placement). Ishida et al. (15) reported using the AERO stent in 36 patients with malignant airway stenosis. All patients experienced significant improvement of lung function. Migration was observed in 6 cases and no complications occurred when proceeding with stent removal.

Novel covered metallic stents are also potentially

effective in the management of benign airway diseases. Menna et al. (16) reported on a large series of 74 fullycovered SEMS placed in 68 patients with inoperable tracheobronchial stenosis or postoperative bronchopleural fistulas. Improvement in symptoms was observed in all patients and stent-related complications only occurred in 20 (29.4%) patients, which demonstrated that fully-covered SEMS were effective irrespective of airway pathology. Similarly, temporary partially-covered tracheobronchial stenting (17) and a hinged SEMS (18) were proven to be effective, safe, and easy to be performed on benign airway diseases. However, other results indicated complications were frequent during stent removal (i.e., Micro-Tech FC-SEMS and third-generation SEMS) (19,20). Hence, further research is needed to validate the safety and availability of novel covered metallic stents as well as compare the performance between novel metallic stents and silicone stents for the treatment of benign airway stenosis. Given the marked structural impact of cover configuration on stent performance, it is of great clinical attention that the loading configuration that covered stents are about to be subjected to should be considered before stent placement (21).

Novel silicone stents

Multiple attempts have been performed to overcome the existing defects pertaining to "classic" silicone stents. The "Natural stent", a newly-developed silicone airway stent with interposing flexible outer membrane, was designed to increase fixation (22). However, the Natural stent did not present any tangible benefit over the Dumon stent for managing benign tracheobronchial stenosis patients. Given the limitations in terms of shape and mechanical features of the silicone, Vearick et al. (23) tested the reinforcement of silicone using fibers, including polypropylene (PP), polyamide (PA) and carbon fiber (CF). Tensile strength and Shore A hardness testing showed that CF exhibited the best mechanical performance, and subsequent finite element compression strength tests further confirmed this result. On the basis of the aforesaid results, the stent was produced using CF and placed in the trachea of a sheep. After 1 month of stenting, the tracheal tissue presented an inflammatory course. Longer research is clearly required to test the safety and utility of the novel stent. Recently, Jung et al. (24) created a novel silicone airway stent (GINA stent) and evaluated it using a porcine model with airway stenosis. Compared with the Dumon stent, the GINA stent presented better mechanical performance, which may be

attributed to design improvements made by transforming the outer ring into a right-angled triangle shape. However, human-based studies are required to confirm this hypothesis.

Drug-eluting stents

Drug-eluting stents might be a suitable alternative to "classic" stents. Besides the mechanical advantages of the stents themselves, sustained release of drugs would inhibit granuloma tissue formation and act as a local chemotherapy. Recently, Debiane et al. (25) randomly assigned 45 pigs to receive drug-eluting stents (DES) filled with either gendine (n=36) or standard silicone stents (n=9). Although there were no significant differences in granulation tissue volume, tracheal thickness, or tissue microbiology between DES and standard silicone, the DES stent surface exhibited antibacterial activity. Additionally, design-based stereology could quantify the tissue changes associated with airway stenting. Wang et al. (26) placed paclitaxel drug-eluting airway stents (an experimental group, n=4) and bare metal stents (a control group, n=4) into 8 beagles. It was found that the experimental group showed less granulation tissue formation than the control group, with a high concentration of the drug in the stented area and the adjacent area. Very low levels of drug were detected in the lung tissue, and side effects were not noted in the blood test. These findings were also validated in recent research (27). Similarly, rapamycin-eluting stents were studied in a mouse model of laryngotracheal stenosis; results indicated that rapamycineluting stents had more adequate mechanical stability at 4 weeks and greater drug-release ability at 6 weeks when compared with PDLGA [Poly(DL-lactide-co-glycolide)] stents (28). Surprisingly, along with drugs, genetic material can also be transferred by airway stents (29). However, it is important to remember that in the small series created by Sigler et al. (30), drug-eluting stents and bare metal stents did not differ with respect to experimental setting. As promising as these novel stents can be, this area is still in its early stages. Recently, Hohenforst-Schmidt et al. (31) critically reviewed the value of drug-eluting stents for airways.

Biodegradable stents

The concept of biodegradable stents has gained much attention, owing to the fact that they will disintegrate gradually as time passes. It is theoretically-presumed that

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biodegradable stents can reduce the rate of stent-related complications (e.g., migration, granuloma formation). Recently, a survey study has showed that amongst all available airway stents in medical applications, 7.5% of them are biodegradable stents (32). There have been several studies reporting the use of these novel stents in the management of airway stenosis. Rodriguez-Zapater et al. evaluated airway reaction caused by a biodegradable polydioxanone airway stent (i.e., ELLA stent) in a rabbit model. The stent only produced a mild reaction that recovered with tracheal degeneration (33). A landmark study was done by Lischke et al. (34), who first reported the application of biodegradable stents in the clinical field. A total of 20 biodegradable stents were inserted endoscopically in six patients with post-transplant bronchial anastomotic stenosis. All patients had immediate symptomatic relief without complications after stenting. One patient suddenly died of pulmonary embolism 1 year post-implantation; the other five remained clinically-well during a 4-year followup period. Further research has confirmed this as well (35). Furthermore, Stehlik et al. (36) reported on the safety and efficacy of biodegradable stents in the treatment of benign airway stenosis. All of the aforesaid stents are made of bioabsorbable polydioxanone, and recent study showed that high-purity zinc and magnesium are possibly ideal materials for biodegradable stents due to satisfactory biocompatibility and appropriate corrosion (37). However, the literature mainly focused on animal trials and the sample size of related studies is small, and thus the significance of the results in clinical setting remains to be determined.

Radioactive stents

Radioactive stents have been successfully utilized in patients with malignant biliary obstruction or esophageal cancer. The deployment of radioactive stents in the management of malignant airway stenosis appears to be an attractive prospect. A prospective randomized controlled study was conducted by Wang *et al.* (38), who randomly assigned 66 patients with inoperable malignant airway stenosis to receive a novel bare metal stent loaded with either I¹²⁵ seeds (RBMS, n=33) or a "classic" bare metal stent (CBMS, n=33). Stents were successfully implanted in all patients and the stenosis immediately improved in both groups after stent implantation. The incidence of complications after stenting was found to be equal in both groups, while the RBMS group had a longer median survival compared with the CBMS group, with statistical significance (170 *vs.* 123 days, P<0.05). Recently, a meta-analysis indicated that radioactive stents placement had a lower stent restenosis rate (13.7% vs. 37.8%, P<0.00001), higher 3-month survival rate (71.9% vs. 52.7%, P=0.03), and increased overall survival (OS) (P<0.0001) in comparison with normal stents placement when used to treat malignant airway stenosis, and the difference was statistically-significant (39).

Three-dimensional (3D) printed stents

The advent of 3D-printed stents can be attributed to advances in biomedical engineering. It is common knowledge that personalized management to the anatomy of complex and tortuous airways is a main clinical dilemma faced by interventional pulmonologists. 3D printing technology enables stents to be personally-tailored to patient-specific airway anatomy and all anatomical shapes, diameters, and lengths can be provided to allow rapid prototyping and onsite customization (40): first, the shape of a stent can be designed regarding the computed tomography (CT) and bronchoscopy measures; second, a computeraided design program is employed to construct 3D model; then a construction file containing the information of this model is generated that can be transferred to the printer; in the next step, an original customized stent is produced with the stereolithography printers; following various surface treatments including grinding, polishing, dipping in solvents or liquid polymers, and sterilization, a ultimate 3D-engineered personalized airway stent is manufactured and can be applied rapidly in clinical work (41). In theory, 3D-printed stents meet all the requirements of ideal stents.

An increasing number of studies evaluated the value of 3D-printed stents in the management of airway stenosis. Guibert and colleagues (42) reported the first 3D-printed application in airway stenting for a complex post-transplant airway that could not be managed by a conventional airway stent. Immediate and significant improvements in dyspnea, quality of life and pulmonary function were observed after the operation. They then expanded the utilization of computer-aided design in other highly complex situations and obtained promising proof-of-concept outcomes that would contribute to further research on this new technique (43,44). Miyazaki et al. (45) described their experience with a 3D printed airway model in a stenosis of the intermediate bronchus after right single-lung transplantation. A Y-shaped airway stent with the fabricated orifice to ventilate the upper lobe was accurately modified on the basis of 3D-printed technology. After the easy and successful

insertion, the patient's status improved. Gildea et al. (46) used a similar method (application of a patient-specific silicone airway stent designed from a 3D printed mold) to cope with complex airway stenosis caused by granulomatosis polvangiitis in two patients, bringing about a durable improvement of symptoms over 1-year follow-up. Shan et al. (47) reported a small series of 12 patients with malignant airway stenosis caused by lung cancer and esophageal cancer. All patients underwent successful implantation of personalized 3D-printed stents, and dyspnea was significantly and immediately relieved in 11 patients after stent placement. There was significant improvement in the Hugh-Jones and Karnofsky performance status classification of patients after stenting relative to those before stenting, with statistical significance. Morrison et al. (48) placed patient-specific airway stents using 3D-printed technology into three infants with severe tracheobronchomalacia. Lifethreatening airway diseases did not occur in all infants and two out of the three infants could be completely free from mechanical ventilation. Hatachi et al. (49) performed successful placement of a patient-specific Y-shaped silicone stent created from a 3D-printed airway model in a patient with airway stenosis caused by granulation. The patient's symptoms improved after stenting and post-operative bronchoscopy and CT scan indicated that all main airways were open. Similarly, Cheng et al. (50) developed and implanted a personalized 3D-printed Montgomery T-tube into a patient with a tracheal anastomotic dehiscence. Follow-up bronchoscopy and CT imaging revealed no granulation tissue at 4 weeks. The patient was capable of phonating when discharging himself from hospital.

Other relatively recent studies showed that personalized 3D-printed stents were a safe and effective alternative to classic stents in the treatment of patients with tracheobronchomalacia (51) and inoperable malignant airway stenosis (52). Additionally, a 3D-printed personalized airway stent that integrated the above-mentioned new-designed GINA stent with a flexible structure and an easy positioning was also developed by the research group of Kim. As a proof of concept, they implanted this 3D-engineered personalized GINA stent into two pigs of which the tracheal stenosis was at least 50%. Three weeks after stenting, the stent remained in situ, and at both ends of which, neither overgrowth of granulation tissue nor mucus plugging was seen (53).

As prospective as this technique may be, 3D-printed stents 3% were seldom deployed all over the world (32), which might be interpreted by the high costs involved and the limited clinical experience. Thus, a randomized study with a larger patient cohort and a combination of 3D-printed stents and conventional devices is needed to better confirm aforementioned findings.

Conclusions

Progress in airway stents over the years have mainly been in offering more choice for patients with airway stenosis, especially complex and benign airway lesions. However, very few of the novel stents entered routine medical environment and ideal stents have, regretfully, not yet been designed. For the time being, among commercially available stents, Ultraflex (covered SEMS) and Dumon (silicone stent) remain the commonest type of stent used all over the world (32,54). 3D-printed airway stents, as the vertex of scientific and technological progress, open up a new way to resolve the therapeutic impasses. Regardless of how perfect 3D-printed stent is, it is still a foreign body and side effects seem inevitable. Therefore, a combination of 3D-printing method and biodegradable material may present a promising avenue for future treatments of airway stenosis. It is important to note that stent implantation is only a component of an integrated treatment, and the multidisciplinary management strategy using both airway stents and the standard treatment of primary disease should be the preferred procedure.

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Supplementary

Table S1 The detailed search strategy PubMed #1 silicone [Title/Abstract] #2 metallic [Title/Abstract] #3 metal [Title/Abstract] #4 "drug eluting" [Title/Abstract] #5 biodegradable [Title/Abstract] #6 radioactive [Title/Abstract] #7 "three dimensional" [Title/Abstract] #8 OR/ (#1-7) #9 tracheobronchial [Title/Abstract] #10 tracheal [Title/Abstract] #11 airway [Title/Abstract] #12 bronchial [Title/Abstract] #13 OR/ (#9-12) #14 stent [Title/Abstract] #15 stents [MeSH Terms] #16 OR/ (#14-15) #17 #8 AND #13 AND #16