



Advances in Airway Stenting

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Abstract

Purpose of Review In this review, we summarize the evolution of airway stents through the decades and address the various existing stent types along with some investigational stents, and the available data supporting their use. We also briefly discuss the most common complications, the process of removal, and controversies regarding follow-up.

Recent Findings Stent technology continues to evolve in an ongoing effort to develop better stents with easier placement or removal, sustained clinical benefit, and the least number of complications. These improvements have allowed for the expansion of stent use from primarily palliation in malignant airway diseases to viable therapies for benign conditions including malacia, fistulas, and post-intubation tracheal stenosis.

Summary Airway stents can provide prompt and sustained relief of symptoms for a variety of tracheobronchial diseases. Airway stents have undergone significant advancements in the past three decades, starting with single material stents to hybrid stents and now towards more personalized stents.

Keywords Airway stents · Hybrid stents · Drug eluting stents · 3D printed stents · Biodegradable stents · Interventional Pulmonology

Introduction

Airway stenting is a procedure commonly performed by interventional pulmonologists. An airway stent (AS) or tracheobronchial endoprosthesis can be used to maintain airway patency in central airway obstruction, seal off airway fistulas, or treat malacic airways. Table 1 describes the most common indications for AS placement. Stents are made of different materials and come in different shapes and lengths. Currently available stents may be silicone, stainless steel, polymer, nitinol, tygon, tantalum, cobalt-based alloy, or hybrid of materials [1]. Despite this, preconfigured airway stents are seldom ideal due to the dynamic nature of inspiration and expiration and the distorted airway anatomy in this population of patients [2, 3]. This has led to substantial

efforts to develop custom stents for patients with complex airway diseases that may be more biocompatible and thus reduce complications [2, 4]. The advancements in computed tomography thin slicing, three-dimensional (3D) virtual airway modeling and 3D printing (3DP) technology, have enabled designing and producing intricate medical prosthetics, including airway stents a viable prospect.

The first airway stents were made of silicone, and while they were successful in maintaining airway patency, significant impairment of mucociliary clearance was noted. Over the years, metallic stents became more commonly used due to the ease of placement using a flexible bronchoscope compared to silicone stents which require rigid bronchoscopy, a competency that requires specialized expertise and a general anesthesia [5]. Tissue ingrowth and epithelialization, a major disadvantage of bare metallic stents, led to the development of second-generation self-expandable metallic stents (SEMS) that were partially covered and made from nitinol, an alloy with shape memory and super elasticity. Later, third-generation hybrid fully covered SEMS made from nitinol with a polymer covering (silicone or polyurethane) were developed [5, 6].

Conventional stents all have drawbacks that include the formation of granulation tissue, migration, and

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Table 1 Indications of airway stenting**Malignant**

- Extrinsic stenosis of central airways with or without intraluminal components due to tumor or lymphadenopathy
- Endobronchial tumor
- Malignant tracheoesophageal fistula
- Palliation of recurrent intraluminal tumor growth

Benign

- Complex, inoperable tracheobronchial stricture (post-traumatic, post-intubation, post-transplant, post-infectious)
- Tracheobronchomalacia
- Excessive dynamic airway collapse
- Benign central airway fistulae (esophagus, mediastinum, pleura)
- Pseudotumor (idiopathic, amyloid, hamartoma, broncholith)
- Tracheobronchial stenosis: idiopathic, granulomatosis with polyangiitis, relapsing polychondritis

mucostasis necessitating repeated interventions and sometimes removal or replacement of stents, with further increased risk of infection or secondary tracheobronchomalacia (TBM). Despite the availability of a wide array of stents, limitations still occur with both silicone and metallic stents. In part, this is due to the lack of conformity between the standard sized airway stent and the patient's specific airway geometry [5]. With recent advances in technology and cost reduction, it is felt that these shortcomings can be overcome by using 3-dimensional (3D) printing to produce customized airway stents.

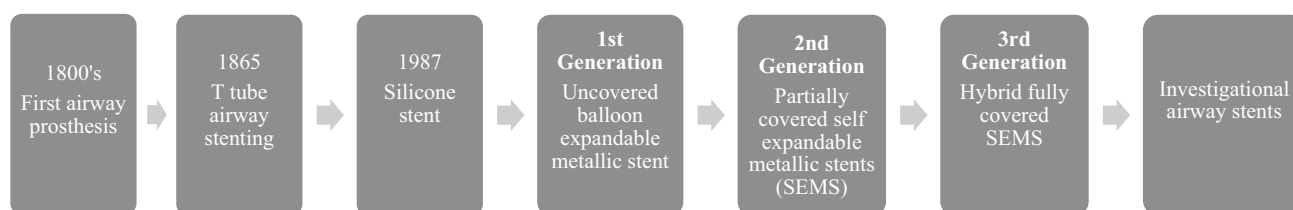
A 3D technology has rapidly entered the surgical landscape and more recently Interventional Pulmonology (IP) [7]. The 3D printing (3DP) is widely used to create custom-fitted prosthetics and is increasingly being used on smaller scales as in 3DP heart valves [8]. 3DP machines utilize computer-assisted modeling of the airway obtained from a chest CT scan and produce a piece by assembling layers of materials. This technology was adapted to 3DP an airway model with a shift toward a personalized stent development approach to improve conformity with patient airway anatomy and decrease the risk of failure due to migration or granulation tissue formation [9]. Figure 1 shows the timeline of AS development.

Silicone Stents

Silicone stents were the first ever produced and the most widely available AS. They are firm, less prone to fracture, and exhibit less expansion force thus reducing granulation tissue formation and perforation [10]. They are generally inexpensive and are easily inserted and removed; however, rigid bronchoscopy, a procedure that requires specialized training and typically a general anesthesia setting, is required [11]. They are available in straight (for tracheal or bronchial stenting) and Y-shaped (for simultaneous tracheal and main stem bronchi stenting) and are customizable by cutting down to the required length based on imaging and bronchoscopic data. Silicone stents are highly effective for benign and malignant conditions with almost immediate symptom improvement. Nonetheless, it comes with complications, including the risk of migration, typically higher with shorter stents and extrinsic stenoses, and additionally, there is an increased risk of mucostasis and infection [10].

To address these shortcomings, Jung et al. created a novel antimigration radiopaque silicone stent (GINA stent) which demonstrated better mechanical properties compared to conventional silicone stents in a porcine model. This improvement is ascribed to the transformation of the outer ring into a right-angled triangle shape and including a raised three-line arrangements for the membranous trachea. It is important to note that human-based studies are not available to confirm these findings [10].

Historically, silicone stents are primarily used for malignant central airway obstruction (CAO), and their use in benign conditions has been avoided due to the reported complication rates. However, there have been recent reports of its use in benign conditions. Ernest et al. reported the short-term use of silicone Y stents in patients with TBM and severe chronic obstructive pulmonary disease (COPD) with significant improvement in dyspnea, health-related quality of life, and functional status [12]. Ozgul et al. reported similar results with using silicone stents in seven patients with expiratory central airway collapse (ECAC) complicating COPD with significant improvement in mMRC score [13].

**Fig. 1** Timeline of airway stents innovation

Metallic Stents

Bare metallic stents have undergone a significant evolution with three generations now available. Bare metallic stents are largely limited to use in the post lung transplant population. This is due to its propensity to cause intense granulation tissue formation, which can be beneficial in a non-healing anastomosis. These can be inserted using a flexible bronchoscope by transplant pulmonologists as well as interventional pulmonologists. Recently, Jiang et al. reported the feasibility of a novel SEM through the scope delivery system in patients with CAO with shorter operation time [14]. Later, they confirmed the efficacy and no difference in short-term complications compared to the conventional over-the-wire method in a randomized control trial [15•]. Overall, these stents are fixed size and nonadjustable, and their radial force minimizes the risk of migration while increasing the risk of granulation tissue formation, mucosal incorporation, airway erosions, and perforation which makes them more challenging to remove. These stents are there for not typically used for malignant airway obstructions.

The indications for bare metallic AS has decreased, particularly in benign airway diseases after the US FDA issued a warning against their use in these conditions due to the associated complications [16]. Nevertheless, it must be noted that that was in reference to the uncovered metallic stents, the first generation of metallic stents that is rarely used now, and since then, as described below, the use of covered hybrid SEMS for benign airway diseases has been reported to be safe and effective in a long-term follow-up with no significant difference in symptom palliation, complication rates, the safety of placement, or survival between metallic and silicone AS.

Xiong et al. reported long-term (54 months) outcomes of the use of metallic stents for post-lung transplant complications in 47 patients with 60 airway complications requiring AS placement [17]. There was an impressive rate of immediate dyspnea relief with a rate of 90%. Most patients needed bronchoscopic intervention to manage stenosis from granulation tissue removal, but this was less compared to the non-transplant population possibly due to immunosuppressive medications. There were no life-threatening complications related to the stents, and the rate of stent removal was 16%. The long-term complications were low, and mortality was similar to lung transplant patients who did not require stent placement [18]. Prior to this, Gottlieb et al. reported a conflicting finding in a study published in 2009 of 111 stents, mostly uncovered AS implanted in post-transplant patients with reported 777 days follow-up showing a significantly lower survival rate in patients with SEMS compared to the total cohort (60 vs 76%; $P=0.02$). This was ascribed to the increased risk of infections and lower functional reserve in those patients [19].

Hybrid Stents

Covered metallic stents were developed to blend the advantages of both silicone and metallic stents. Despite the Food and Drug Administration (FDA) warning regarding the use of bare metal stents in benign disease, fully covered SEMS have shown promise in benign central airway obstruction (CAO) [20]. These consist of an expandable metal frame to resist compression and reduce the risk of migration and a non-porous covering material, usually, polytetrafluoroethylene, silicone, or polyurethane, which minimizes the risk of granulation tissue formation and tissue ingrowth leading to easier removal. They can be inserted using flexible or rigid bronchoscopy and are in general more expensive than single material airway stents. Currently available hybrid stents are listed in Table 2.

A few examples of hybrid airway stents include the Bonastent, which is a hybrid AS composed of a woven nitinol wire and is covered with silicone. Nitinol is known for its superior elasticity and shape memory compared to other metal alloys. These stents come in different diameters and lengths and can be implanted using a flexible or rigid bronchoscope with two delivery devices depending on the stent diameter. It was granted FDA approval in 2014. Avasarala et al. described the use of the Bonastent in 11 patients with a variety of tracheobronchial complications mostly for nonmalignant indication in transplanted patients. Ninety-one percent of the patients had bronchoscopically assessed improvement in airway patency. Described complications included a stent fracture with resultant obstruction. Interestingly, none of the transplant recipients had evidence of airway infection on a subsequent bronchoscopy [21].

Another popular covered SEMS are the Aero stents (Merit Medical Systems, South Jordan, UT) which has a larger delivery device compared to the Bonastent (12 and 22F VS 8 to 12F respectively). It is unique among airway stents in that it has a hydrophilic coating designed to prevent mucus build-up. It was approved by the FDA in 2007. It can be placed using either rigid or flexible bronchoscopy with a guidewire and fluoroscopy. It has been shown to be effective and safe in treating malignant airway stenosis or fistulas [22]. Users reported that it was easy to deploy and remove, improved luminal patency, quality of life, and dyspnea [23]. Interestingly, in a study of 172 patients with 195 stent procedures, Aero stents were associated with an increased risk of infection compared with other stent types. However, it was also observed to have a lower migration risk [24].

Investigational Stents

A. Patient-Specific 3D-Printed Stents (PS3DS)

Stent technology has rapidly progressed in the past few years. Patient-specific 3D printed stents have become more

Table 2 Commercially available hybrid airway stents

Manufacturer	Material	Shape	Size (diameter × length)	Advantage	Common Drawbacks
Ultraflex Boston Scientific, Natick, MA, USA	Nitinol with silicone or PU cover	Straight	8–20 mm × 20–80 mm	Easy placement (RB/ FB)	<ul style="list-style-type: none"> • Granuloma formation • Stent fracture
Dynamic Boston Scientific, Natick, MA, USA	Silicone with steel struts	Y	Tracheal limb: 11–15 mm × 110 mm Main bronchi limbs: 8–12 mm × 25–40 mm	Rigid structure, main- tains airway patency and reduced risk of dislodgment	<ul style="list-style-type: none"> • High contact pressure • Difficult to removal/ insertion (require laryngoscopy for placement)
Bonastent EndoChoice, Alpharetta, GA, USA	Nitinol with silicone cover	Straight	10– 30 mm × 20–80 mm	Placement with deliv- ery catheter (RB/FB)	<ul style="list-style-type: none"> • Migration • Fracture • Mucus plugging
AERO Alveolus, Inc., Charlotte, NC, USA	Nitinol with PU cover	Straight	8–20 mm × 15–80 mm	Antimigration embed into the mucosa	<ul style="list-style-type: none"> • Migration • Difficult removal
Silmet Novatech, La Ciotat, France	Nitinol with polyester cover	Straight, J, Y	10– 20 mm × 20–60 mm	Multiple shapes	<ul style="list-style-type: none"> • Migration • Fracture
Hanaro M.I.Tech Co., Ltd., Seoul, South Korea	Nitinol with silicone cover	Straight	10– 22 mm × 30–80 mm	Large flares at the end for antimigration	<ul style="list-style-type: none"> • Migration • Fracture
iCAST Atrium iCast, Maquet, Getinge, Hudson, NH, USA	Stainless steel covered with PTFE		5–10 mm × 16–38 mm	Jagged stainless-steel edges for antimigra- tion	<ul style="list-style-type: none"> • Migration
Micro-Tech Micro-Tech Co., Ltd., Nanjing, China	Nitinol with elastic cover	Straight, J, Y, TTS	Straight 12–18 mm × 40–60 m Y-shape tracheal limb: 16–20 mm × 40–50 mm Main bronchi limbs: 12–14 mm × 20/30 mm J-shape tracheal limb: 16–20 mm × 40–50 mm Main bronchi limbs: 12 mm × 30 mm	<ul style="list-style-type: none"> • Inexpensive • Easy to insert (RB/ FB) • Multiple shapes 	<ul style="list-style-type: none"> • Migration • Fracture

RB rigid bronchoscope, *FB* flexible bronchoscope, *PU* polyurethane, *TTS* through-the-scope, *PTFE* polytetrafluoroethylene

popular due to the advancement in biomedical engineering. The advantage of an airway stent designed and produced for an individual patient is that improved alignment with the airway lumen and mucosa can be achieved, presumably leading to less stent-related complications [25]. This is especially critical in patients with complex airway diseases and distorted anatomy.

Manufacturing Process. High-resolution 3D image data can be acquired with a single breath hold CT scan of the chest. Data is processed to present a virtual bronchoscopy model. Additional stent-related measurements can be either obtained from this data or via bronchoscopy. Special considerations should be accounted for. For example, if there was endoluminal

tumor, ideally it would be removed first, and any stenosis would be dilated first. Or in the case of malacia, it would be beneficial to measure the real-time diameter at different ventilation pressures. Following that, using a computer-aided design a 3D model is created which is then sliced into individual layers. The information is then transferred to a file that can be transmitted to the printer. A thermoplastic material is heated, melted, and extruded through a nozzle to form the 3D structure layer by layer. The next step is a surface treatment, depending on the material used and grinding, polishing, and dipping in solvents or liquid polymers may be used. This is followed by sterilization using plasma or ethylene oxide processes which can be

widely applied. Vapor-based sterilization techniques cannot be used since the melting temperature of most polymers is too low [4].

Experiences with 3D-Printed Airway Stents. Guibert et al. were the first to report the application of 3D printing technology in airway stents in a complex post-transplant airway after failing conventional airway stents. Immediate and significant improvements in dyspnea, quality of life, and pulmonary function were observed after the operation [26]. Miyazaki et al. reported the 3D printed Y-shaped airway stent in a post-single lung transplant stenosis of the bronchus intermedius with improvement in the patient's condition [27]. Shan et al. described the use of covered metallic Y-shaped segmented AS for the treatment of aerodigestive fistulas in 26 patients. Karnofsky's performance status (KPS) after the stenting procedure improved significantly in comparison to before stenting [28]. The same group also described the use of 3D-printed AS in malignant conditions. They successfully implanted personalized 3D-printed stents in 12 patients with inoperable malignant airway stenosis caused by lung and esophageal cancer. Dyspnea was significantly and immediately relieved in 11 patients after stent placement. There was a significant improvement in the Hugh-Jones and KPS classification after stenting compared to before stenting [29].

B. Drug-Eluting Stents (DES)

The conceptual idea of DES is not new. Several animal-based studies have been published in the past. Initially developed to inhibit granulation tissue formation by inhibiting fibroblast growth, the efficacy of DES in human remains unknown. Although endobronchial localized therapy with cytotoxic drugs is an attractive concept, largely due to avoiding systemic toxicity, studies on humans are nonexistent, and currently available animal studies are limited with small sample sizes with sparsely reported complications. It is proposed that the same inherent growth inhibitory properties of these anti-tumor agents which makes them ideal for granulation tissue prevention may be associated with local cytotoxic effects such as fistulas. There are rare reports of resistance to chemotherapeutic agents and the development of localized thrombosis [30, 31]. Currently, there is no systematic data on the transferability of animal research results to human tissue reactions. Future large human studies are needed to confirm the long-term safety and clinical utility. DES studied for the respiratory tract include cisplatin, mitomycin, sirolimus, paclitaxel, and rapamycin are detailed further.

Cisplatin. Chao et al. designed a biodegradable cisplatin eluting stent and compared it to Ultraflex

SEMS. The biodegradable stent exhibited mechanical strengths comparable to the Ultraflex SEMS. Additionally, it provided a steady release of Cisplatin for 4 weeks in vitro. In vivo studies showed sustained cisplatin levels in rabbit trachea for 5 weeks with only trace drug levels in blood [32].

Mitomycin. Zhu et al. designed a bioabsorbable tubular stent eluting mitomycin C which showed less tracheal narrowing and was found to be superior to silicone stents in animal models [33].

Sirolimus. Sigler et al. developed a Sirolimus-coated stent and reported no difference between coated and uncoated stents with regard to quality and quantity of tissue proliferation. It is speculated that the variation in results is due to the different antiproliferative drug that was used [34].

Paclitaxel. More recently, Wang et al. developed a paclitaxel-eluting stent which showed decreased granulation tissue formation compared to regular stents in animal models [31].

Rapamycin. Rapamycin eluting stents were studied in animal models with laryngotracheal stenosis with reports showing that it has more adequate mechanical stability at 4 weeks and better drug release ability at 6 weeks compared to other stents [35].

C. Biodegradable Stents (BDS)

BDS are made from knitted polymer fiber like polydioxanone which maintains its strength for six weeks and self-degrades in 3–4 months. Conceptually, BDS are novel stents that have gained more popularity as it avoids a stent removal procedure. Some reported a mean of 141 days before it degrades and other suggested restenting using BDS for conditions that need longer than the known median time [36, 37]. BDS maintains the patency of the airway for a predetermined duration and gradually degrades to a nontoxic material. It is assumed to be associated with fewer complications due to the degradable nature of the material which induce mucosal hyperplasia and contribute to the stabilization of the narrowing and decrease the total time needed for mechanical stenting [2, 6, 36].

Lischke et al. were the first to report the use of BDS in clinical application. He reported the safety and efficacy of BDS. Twenty BDS was inserted in six patients with post-transplant bronchial anastomotic stenosis. All patients reported immediate symptom relief without stent complications. One patient died one year later with pulmonary embolism, and the other five were clinically stable at a 4-year follow-up. After the 4-year follow-up, the authors reported a median time to restenting of 5 months and a median intervention free time of 24 months [38].

The indication for BDS includes conditions that require temporary airway stenting like post-intubation tracheal

stenosis (PITS), post tracheostomy tracheal stenosis (PTTS), and TBM. There are reports of its use in post-transplant airway complications or healing airway fistulas [2]. Reported risks of complications include premature stent degradation, expectoration of stent particles, exophytic granulation tissue formation, and premature failure [36]. This remains an exciting avenue for investigational studies.

D. Bioengineered Stents

Limited data exists on the use of bioengineered stents in the tracheobronchial tree. In 2018, Martinod et al. reported the feasibility of bioengineered tracheal and bronchial reconstructions using a bioengineered aortic allograft. In the study, standard airway stents were used to temporarily support the grafted matrix. In this uncontrolled study, 13 patients underwent tracheal, bronchial, or carinal transplantation. After a radical resection of a proximal lesion was performed, airway reconstruction was performed using a cryopreserved aortic allograft. The overall 90-day mortality was 5%. Ninety-day morbidity events occurred in 30.8% which included laryngeal edema, acute lung edema, acute respiratory distress syndrome, and atrial fibrillation. No adverse effect directly related to the surgical procedure. Stent removal was performed at a postoperative mean of 18.2 months. At a median follow-up of 3 years and 11 months, 10 of the 13 patients (76.9%) were alive. Of these 10 patients, 8 (80%) breathed normally through newly formed airways after stent removal [39]. Further robust research is necessary to establish true efficacy of bioengineered stents in lieu of grafted allografts.

Hybrid Y Stents

Hybrid Y-stent is a novel AS that is made of nitinol wire and silicone. The stent is Y-shaped in the likeness of a silicone Y stent. It comes tightly packed and opens in the airway when deployed. Structurally, it is a woven nitinol mesh partially covered in silicone to minimize tissue ingrowth. There are radiopaque markers at the proximal and distal ends and the bifurcation to assist with visibility under fluoroscopy during deployment. The branches have flanges to minimize migration, and it contains a retrieval loop in the proximal and distal ends that assist in positioning after deployment [40]. The sizes are predetermined by the manufacturer.

Management of the Patient with an Airway Stent

Despite the increased use of AS and the reported stent-related complications, there is no consensus on surveillance or follow-up protocol. Previously, it has been shown that stent complications happen in the first two to three months but can be seen earlier, within days, especially with stent

migration and granulation tissue formation [41–44]. In a subsequent study by Lee et al., AS-related complications were 69%, with 19% happening within the first five days of placement [45]. Given the high rate of early complications, the authors suggested routine surveillance with bronchoscopy within four to six weeks of insertion. The key questions that remain are as follows: Should there be surveillance bronchoscopies, or should bronchoscopic exam be based on clinical symptoms? What would be the best method for assessment and when would be the best time? While the development of symptoms is an accepted indication for a bronchoscopic exam, surveillance bronchoscopy in asymptomatic patients is not widely accepted. Lee recommended routine surveillance bronchoscopy regardless of symptomatic status on the grounds that it may help early detection of stent-related complications; however, the impact of this practice on mortality, morbidity, and hospitalization is not known [45]. On the other hand, Ferretti et al. reported a sensitivity of 88% of CT scans in detecting significant abnormalities and complications related to AS and suggested using CT as the first option for surveillance and to work up complications in patients who had AS placement [46]. Hence, CT scans of the chest remain the mainstay of stent evaluation in the follow-up setting based on clinical indicators before proceeding with bronchoscopic evaluation.

Following stent placement most patients are started on airway clearance regimens. A survey study was conducted by Mathew et al. to ascertain preferred practice to mitigate mucus plugging post-AS placement by interventional pulmonologists. The most common practice was using saline nebulizers with 2% hypertonic saline. While there is no existing comparison between normal and hypertonic saline, it is worth noting that normal saline is cost-effective and readily available and hypertonic saline can cause bronchospasm. Other approaches included nebulization of N-acetylcysteine, nebulization with bronchodilators, and mucolytic-containing cough syrup preparations [47••].

Guidelines on the optimal time for stent removal are not yet established. Stent removal largely depends on the development of stent-related complications, and the reason for stent placement. Overall, the shorter the duration of stent placement, the lower the degree of granulation tissue formation and the easier it is to remove it. A three-month retention time was suggested when SEMS was used for post-tracheostomy and post-intubation tracheal stenosis [48]. Even though the removal process can be challenging, the removal of silicone stents is easier than metallic which can carry a high risk of complications estimated up to 58%. Reported complications include mucosal tear, stent fracture, vocal cord spasm, severe bleeding, tension pneumothorax, re-obstruction, respiratory failure requiring mechanical ventilation, and failure to remove [49, 50].

Silicone stent removal is generally performed using rigid bronchoscopy with grasping forceps and using the twist-and-pull

technique. However, some experts employ flexible bronchoscopy for silicone stent removal. The choice of equipment used for stent removal is determined by the operator. The timing of stent removal is determined by the patient's clinical status.

Conclusion

Near the 35th anniversary of airway stents, it is worth noting that airway stenting has advanced significantly, and we are somewhat closer to finding the “perfect stent” for patients with complex and deformed airway anatomy. The rapid evolution in imaging technology has helped the development of 3D printed airway stents which are still in their early phases of use. Additionally, drug-eluting stents and biodegradable stents are innovations that may mitigate some of the more common complications of currently available stents, but these remain in infancy. The continued development of airway stents to overcome the shortcomings of classic stents and their multifaceted applications provide reasons for optimism. Hybrid airway stents are currently used most commonly in clinical practice, but studies are underway to establish best use of innovative stent technology. More research is required to establish the efficacy and feasibility of different stents in a variety of benign and malignant airway pathologies. “Which stent will best fit?” is still the key clinical question. At present, a deliberate and thorough review and thoughtful decision-making prior to stent placement followed by multidisciplinary management subsequently is the key to successfully treating airway diseases with stents.

Compliance with Ethical Standards

Conflict of interest Authors have no conflict of interest to declare.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of importance
- Of major importance

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