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Review Article

A Review of Tracheal Stent in Clinical Application and Future Development

Katherine Wang[1], Yiqing Tang[2] and Peng Ding[3,*]

[1] *Case Western Reserve University, Cleveland, USA*

[2] *Ohio State University, Columbus, USA*

[3] *Otolaryngology-Head and Neck Surgery, Cleveland Clinic, Cleveland, USA*

***Corresponding authors:** Peng Ding, Otolaryngology-Head and Neck Surgery, Cleveland Clinic, Cleveland, Ohio, USA

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Abstract

Tracheal stents have the potential to revolutionize respiratory care by providing crucial relief and support for patients grappling with tracheal disorders. This literature review is structured to encompass fundamental concepts, recent advancements, surgical considerations, complication solutions, and the ongoing development of tracheal stents. Stent design has undergone notable evolution over time with various materials such as drug-eluting and biodegradable stents improving effectiveness and contributing to complication reduction. Despite these advancements, challenges persist within the realm of tracheal stents, including complications such as stent migration, granulation tissue formation, and tissue erosion. However, with modern technology and new arising inventions today, many methodologies like diverse imaging techniques and computer-based modeling have enhanced the precision of stent placement, facilitating the creation of personalized stents tailored to individual patient needs. This in turn, manages to alleviate many of the complications described above.

Keywords: Tracheal stent; Respiratory care; Complication solutions

Introduction

Stents were initially introduced to address aortic conditions, such as aortic aneurysms and cardiac diseases, during the 1980s. Prior to the advent of modern technological advancements, the management of these conditions posed significant challenges. Substantial progress was achieved through the development of contemporary surgical techniques, establishing open surgical repair as the gold standard. A seminal moment in this field was the pioneering work of Charles Dotter, who introduced endovascular therapy and conceptualized the use of stents as supportive devices. Dotter's innovative idea of coronary angioplasty in 1964 paved the way for the first implantation of a coronary stent by Jacques Puel in 1986. The initial safe implantation of an airway stent was documented in 1990 [1]. Dotter's contributions remain integral to current medical practices, with stents predominantly utilized in cardiac and pulmonary applications.

The trachea, a fibrocartilaginous structure located in the lower respiratory tract beneath the larynx, constitutes the primary component of the tracheobronchial tree, facilitating air movement into and out of the lungs [2]. Tracheal stenosis, characterized by the narrowing of the trachea due to factors such as trauma, congenital anomalies, or tumors, frequently necessitates the use of tracheal stents for therapeutic intervention. Tracheal stents play a pivotal role in managing tracheal stenosis by maintaining tracheal patency, thereby alleviating respiratory distress, reducing hospital readmission rates, and contributing to a more efficient and sustainable healthcare approach.

Stent Materials

There are three primary types of stents: uncovered, fully covered, and partially covered. Stents can also be further classified based on various material combinations. Initially, the esophageal stents were fully uncovered, bare metal. However, to prevent migration and granuloma formation, a multitude of materials have been employed to cover the metal mesh [3]. Stents comprise a varied range of materials, traditionally categorized into two main groups: metal and polymer. Recent advancements in material innovation have expanded the options to include silicone, drug-eluting compounds, and biodegradable materials [4]. Each material comes with its distinct advantages and drawbacks, as detailed in **Table 1** [5].

Bare metal stents, drug-eluting stents, and biodegradable stents are primarily applied in coronary or carotid artery interventions, whereas silicone stents are primarily used in airway interventions, often in conjunction with metal stents. Additionally, while the fundamental tube shape is shared between the cardiovascular and airway stents, airway stents may employ T-tube or Y-shaped tube designs [6]. In airway stents, the primary structure is composed of a bare metal mesh overlaid

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Table 1. Summary of stent materials.

Material	Description	Pros	Cons	Place
Metal	Simple tubes that are made of metal mesh. These stents are typically covered with another material like silicone.	• Only require topical anesthesia • Can be inserted via flexible bronchoscopy • Easy to remove • Covered metal stents minimizes tissue ingrowth • Better internal to external diameter ratio than silicone stents which leads to larger airway lumen • Easier to spot on film • Lower rates of migration	• Expensive • High risk of restenosis and migration • Difficult to remove • Tumor and/or granulation tissue may grow through the mesh/stent • Serious complications have been reported	Cardio- vascular and airway stents
Silicone	These stents are made up of a material that can be easily molded into a specific shape. These are used more often if the stent is temporary.	• Molds easily • Good for short term use • Can be easily repositioned	• Higher risk of migration • Repeated bronchoscopy may be needed for repositioning. • Obstruction from accumulated secretions may occur from granulation/ tissue growth	Utilized in airway stents
Drug Eluting	Stents that are coated with medicine that is released into the artery over time to prevent the artery from narrowing again.	• Mechanical advantage • Act as a local chemotherapy • Able to inhibit granuloma tissue formation	• Similar to bare metal stents when applied clinically.	Used in cardio-vascular field
Bio-degradable	These stents dissolve after a few months. Is useful in the temporary sense as there is not another procedure required to remove them.	• No takeout procedure is needed • Reduce the rate of stent related complications	• Small sample size of related studies done • Significance of results in the clinical setting remains to be determined	Mainly used in cardio-vascular field

with a silicone-like material such as polyurethane or nitinol. This combination offers the advantage of both flexibility and moldability, as the silicone component allows the stent to be shaped according to specific requirements and metal provides structural stability. Silicone stents are also particularly favored for temporary use, due to their ease of insertion and removal, safety record, and cost-effectiveness [7-9]. These qualities also lend short-term stenting to typically be employed to provide stability post-surgery, allowing for easy removal once the area has fully healed. In contrast, long-term stents implanting in the trachea commonly prioritize using stronger materials for prolonged use such as metal, hybrid compositions, and various polymers in order to prevent collapse or stenosis [3].

The choice of stent material should be determined by a comprehensive assessment of various factors. Indications, physician expertise, and the specific clinical situation all play crucial roles in selecting the most suitable stent. Each material comes with its own set of indications and guidelines, aiding in the decision-making process for optimal stent selection in specific scenarios [10]. For instance, certain stents necessitate rigid bronchoscopy and general anesthesia for implantation. Some offer less invasive options with local anesthesia. Others, such as metallic stents, can be inserted using flexible bronchoscopy under topical anesthesia [11]. Patient preferences can significantly impact the ultimate choice of stent material.

Tracheal Stent Structures and Functions

Commonly used tracheal stents include the Montgomery T-tube and the Aboulker stent. The Montgomery stent, made of silicone, features an elongated central lumen and a shorter one projecting at a 75- or 90-degree angle from the side. The Aboulker stent is a prolonged prosthetic attached to a metal tracheostomy tube wired into the trachea, often applied in pediatric cases following laryngotracheal reconstruction surgery. Recognized by their cigar-shaped design with variable diameters, Aboulker stents prove highly effective in addressing scar formation and preventing lumen collapse after reconstructive surgery [12].

Many conditions can cause airway stenosis, including malignant and benign tumors, congenital abnormalities, airway injury, endotracheal intubation, tracheostomy, autoimmune diseases, tracheomalacia, and bronchomalacia. For instance, approximately 20-30% of patients with tracheostomy develop tracheal stenosis to varying degrees, with 1-7% requiring invasive procedures and recurrent emergency department visits [13]. To address this, tracheal stents are utilized to help prevent lumen collapse and stabilize surgical reconstruction of the trachea. Different stents are used for various indications. Some short-term stents that are used to stabilize the trachea after surgery include Montgomery laryngeal stents, Aboulker stents, endotracheal tubes, and laryngeal keels, which are all

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made of silicone. Some long-term stents include the Montgomery T-tube and the long Albouker stent. Additionally, there are multiple contraindications for airway stents. Some absolute contraindications for tracheal stents include patients who are medically unstable for general anesthesia, patients who are allergic to the stent material, and absence of expandable lung distal to the obstruction. Some relative contraindications include high chances of poor outcome despite stenting and increased risk of complications [12].

Tracheal Stent Procedure

Tracheal Stent Placement:

In the context of tracheal stent placement, careful consideration and precautions must precede the procedure. Anatomical factors, such as the location of the vocal cords, airway bifurcation, and potential encroachments on nearby structures like the esophagus or major blood vessels in the thoracic cavity, necessitate thorough assessment [14]. Thus, a CT scan of the neck and chest is necessary to fully assess the anatomy before tracheal stent placement.

For placement of Montgomery T-tube, a tracheostomy tube should be inserted to ensure an open airway. After inserting a rigid bronchoscope under general anesthesia, a high frequency jet ventilator is connected. Some patients may have partial obstructions in their airway, which must be resolved before inserting the stent. Such procedures include balloon dilatation and granulation tissue resection. The classical insertion technique of a T-tube involves initially inserting the distal end of the T-tube into the trachea using a hemostat. The proximal end of the T-tube is then aligned with the trachea until the entire internal branch of the tube is inside the trachea. The position is subsequently adjusted using a rigid bronchoscope. It is important to note that ventilation cannot be maintained during insertion, so completing the procedure in a timely manner is crucial, as prolonged duration can be potentially dangerous [15].

Insertion of metallic stents in the trachea typically involves general anesthesia and a rigid or flexible bronchoscopy to provide direct endoscopic visualization. The airway is dilated as needed and then a guidewire is inserted followed by the stent delivery device. The process is verified by bronchoscopy or sometimes fluoroscopy. Finally, a chest radiograph is done to verify that the location is satisfactory [12].

There is still some debate as to which specialty of surgeon should be allowed to perform the stent implant procedure, and it varies in hospitals [16]. For example, in Cleveland Clinic mostly interventional pulmonologists implant tracheal stents, whereas in other hospitals thoracic surgeons or otolaryngologists might perform this procedure. Although these surgeons work in different departments, they are all well trained in this type of procedure.

2 Tracheal Stent Removal

Essentially every type of airway stent would need removal except for biodegradable stents. Two common methods of stent removal are flexible bronchoscopy and rigid bronchoscopy. A flexible bronchoscopy includes the usage of a light source, fiber optics, and a camera providing increased visual range of the airway including the lower and smaller airways [17]. A rigid bronchoscopy is most used to manage trachea or a proximal bronchus [18]. The procedures for removing tracheal stents vary considerably, influenced by factors such as the stent material, the surgeon's preference, and the resources available. Across different regions, the lack of clear training and standardization presents opportunities for new innovations and designs aimed at enhancing the efficiency of tracheal stent removal in the future [19].

Tracheal Stent Complications

Short-term vs Long-term Complications

Common complications include post-operative infection, stent migration, granulation tissue formation, and mucus plugging [20]. Short-term complications encompass post-operative fever, bleeding, mucus secretion, irritating coughing, and dyspnea, while long-term complications involve granulation, stent migrations, stent fractures, stent-associated infections, in-stent restenosis, and hoarseness. Granulation tissue formation arises due to repetitive motion trauma and infection. Both granulation tissue formation and stent migration can occur as early as 5 days post-operation but typically manifest around 2-3 months after stent placement. It is recommended to conduct surveillance bronchoscopy within 4-6 weeks post-stent placement to detect complications early [21].

Complication Factors

The complication rate varies depending on the type and material of the stent. For instance, the complication rate for silicone stents ranges from 9.5% for stent migration to 3.6% for stent restenosis. Hybrid stents, however, have a higher migration rate compared to silicone stents, with each material presenting its own strengths and weaknesses [11]. The bronchoscopy procedure itself carries potential complications, including mechanical injury such as bleeding, issues related to medication administration (primarily sedation), or patient comorbidities. However, these complications are generally uncommon and not severe, making bronchoscopy a safe and routine procedure today [22].

Complication Solutions

Stent migrations can be commonly prevented by selecting a better fitting stent, such as an hourglass-shaped stent, or by incorporating studs into the stent design. Additionally, the development of biodegradable stents has emerged as a recent solution to mitigate both stent migration and hyperplastic tissue growth, consequently reducing the necessity for early stent removal. However, hybrid stents, while offering flexibility, are more susceptible to stent migration. Lastly, the hitch stitch method, which involves fixing the stent cannula to the tracheal wall, has demonstrated effectiveness in preventing stent migration [23]. Solutions for other complications, such as granulation tissue formation and in-stent restenosis, will be discussed in the next section.

Limitations of Tracheal Stents in Clinical Application

Though the idea of airway stents may seem like a brilliant solution to many problems, there are a few limitations to its clinical application. Firstly, implanting the stent requires surgical procedures under bronchoscopy with general anesthesia. These components come with small, but potentially serious risks to the patient if done improperly. Additionally, the stent related complications pose a severe limitation to the stent's clinical application. This includes stent migration, granuloma formation, mucus plugin, infections, and restenosis from granulation formation.

Future Development of Tracheal Stents

3D Printed Stents

A promising development is the 3D printing of customizable stents. It has been used in the treatment of lung disease and the production of smaller scale utilities such as heart valves. As for their application in the airway, patient-specific airway stents developed by Cleveland Clinic physician Tom Gildea have been recently cleared by U.S. Food and Drug Administration (FDA). These patient-specific stents, designed via CT scans and proprietary 3D visualization software, are printed using a 3D printer and injected with medical-grade silicone. This process allows the physician and their team to customize the stent to perfectly fit the patient's anatomy. This type of stent has a plethora of positive advantages over universal airway stents. First, they have the potential to be more tolerable than traditional airway stents, as universal airway stents must be frequently changed or cleaned due to problems stemming from a poor fit. Moreover, the patient-specific stents harbored shorter procedure times and improved patient-reported symptoms, ultimately reducing the need for stent changes and modifications [24, 25].

Another example of current progress being made in this field can be found at The Radiological Society of North America (RSNA), where preoperative planning and tracheal stent design in thoracic surgery are offered, providing clinical examples that demonstrate basic techniques involved in 3D printing. These techniques include image segmentation and computer-aided design, accomplished by utilizing a software already cleared by the FDA. Segmentation, the process of separating relevant anatomy to be included in the 3D printed model, is particularly helpful in enhancing surgical intervention. It aids in the creation of airway models by visualizing the amount of air in the trachea and the lungs, as well as in the identification of bones and tumors. This leads to a more accurate definition of the intratracheal configuration, increasing the quality of specialized tracheal 3D stent designs [26].

Self-Expandable Metallic Stents (SEMS)

SEMS can be customized for each patient and configured into various shapes. These stents were implanted via fluoroscopic guidance under sedation. Patients were followed postoperatively with monthly CT scans and/or bronchoscopy. The technique demonstrated a success rate of 96.6%, with adequate stent placement and immediate cessation of air leaks in 148 bronchopleural fistula patients [24]. SEMS is also a valid solution for patients with comorbid diseases or for those who are not candidates for rigid bronchoscopy or general anesthesia. These stents can be successfully implanted using flexible bronchoscopy under topical anesthesia [9]. Additionally, SEMS have been proven to be very effective to improve airway obstruction for the palliation of malignant structures with better conformation to irregular airways and a greater ease of placement compared to silicone stents [27]. They have been widely used in treating malignant central airway obstruction, successfully alleviating complications such as stent migration and granulation tissue formation [28]. In a study with 131 stents deployed in 116 patients, 98 patients showed clinical improvement after stent insertion, demonstrating that SEMS placement achieved significant clinical benefits [29].

Drug Eluting Stents

Drug-eluting stents may serve as a viable alternative to classic stents. In addition to providing the mechanical benefits of traditional stents, they offer sustained drug release. This can inhibit granuloma tissue formation and potentially serve as localized chemotherapy for malignant airway structures [30]. In related animal studies, subjects with these stents exhibited less granulation tissue formation compared to the control group. Despite their promise, research on drug-eluting stents is still in its early stages [3].

Biodegradable Stents

The concept of biodegradable stents has gained traction over the past couple of years. These stents can be made from bioabsorbable polydioxanone, high-purity zinc, and magnesium, all of which are considered ideal materials for biodegradable stents due to their satisfactory biocompatibility and appropriate corrosion rates. These stents are unique because they gradually disintegrate over time, theoretically reducing the incidence of stent-related complications such as migration and granulation formation. Their temporary nature also lowers the risks associated with bronchoscopies and general anesthesia, as additional stent extraction procedures would not be necessary. Studies on biodegradable stents have demonstrated that most patients experience immediate symptomatic relief without complications post-stenting. Another study reported safe and reliable outcomes in the treatment of benign airway stenosis [31]. However, most published studies have either been conducted on animals or involved small sample sizes. Consequently, the clinical significance of these results remains to be determined.
Smart Stents

In-stent restenosis remains a significant risk despite the widespread use of stents globally. A "smart" stent with microscale sensors and wireless capabilities has been developed to continuously monitor restenosis by tracking local hemodynamic changes. This electrically active stent functions as a radiofrequency wireless pressure transducer, compatible with standard angioplasty procedures. In a swine model, the smart stent successfully detected blood clot formation and real-time local blood pressure changes over a range of 108 mmHg, applicable to human conditions [32]. In another study, the smart stent, fabricated using MEMS-based micromachining technology, can wirelessly transmit signals without additional power. Cytocompatibility is confirmed via cytotoxicity tests on cultured cardiomyocytes. The stent shows high sensitivity, structural integrity, and durability, with phantom studies indicating its potential for real-time heart monitoring [33].

In contrast to cardiovascular stents, airway stents have not started any research in the field of smart stents yet. More research is guaranteed in airway stent advancement.

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