Endobronchial Silicone Stents for Airway Management

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Abstract

Since 1990 and the creation of the first strictly endoluminal airway silicone stent, commercially available, by Jean-François Dumon in Marseille, it became possible to solve or palliate complex airway diseases that, previously, could either be managed by difficult surgical procedures associated with high morbidity and mortality or lead to patients' death secondary to respiratory distress. Since that time, other silicone and metallic stents have been designed, but the Dumon stent remains the gold standard in airway stenting. This chapter will describe the different silicone stents, their indications, technique of placement, advantages and drawbacks.

Keywords

Metal Stents · Stent Insertion · Metallic Stents · Central Airway · Stent Removal

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1 Introduction

The main purpose of stents designed for use in the central airways (trachea, main stem bronchi and in select cases lobar bronchi) is to restore patency of the airway to as close to normal caliber as possible. These stents may be useful in

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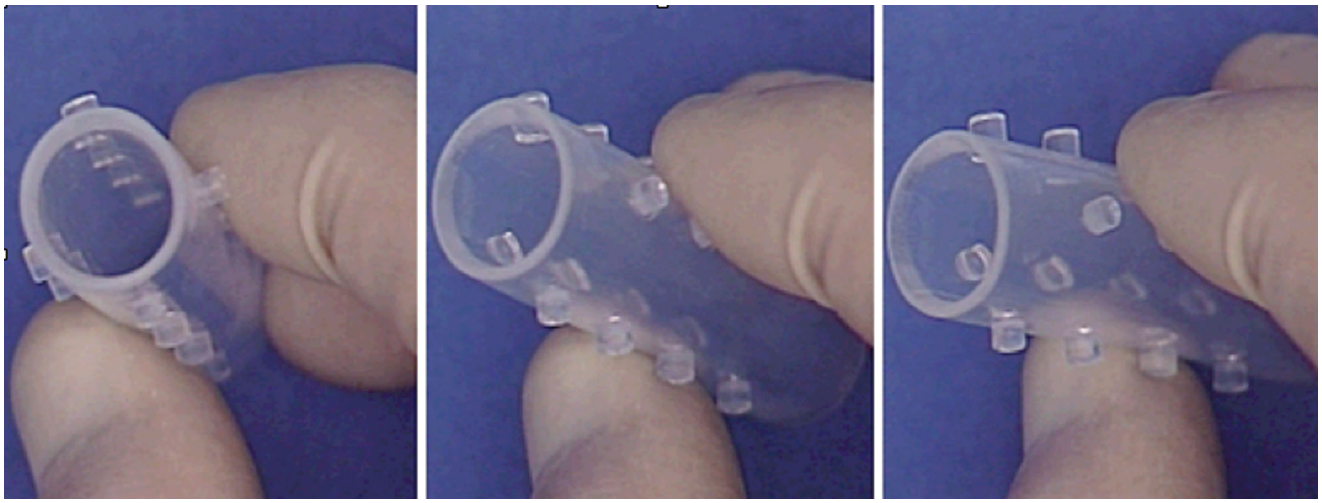

Fig. 1 The original Dumon stent. (Tracheobronxane®, Novatech, La Ciotat, France)

airway obstruction leading to the onset of debilitating symptoms such as dyspnea whether the obstruction is due to a malignant or benign process either intrinsic or extrinsic to the airway. They may also be used in order to cover fistulas between the central airways and local structures such as the mediastinum, the pleural space or the esophagus.

The Montgomery T-tube was the first silicone stent available to re-establish airway patency postoperatively for tracheal disease [1]. In the late 1980s, Dr. J.F. Dumon created the first strictly endoluminal stent specifically designed for airway use [2].

His achievements gave the discipline of interventional bronchology a very important momentum. Suddenly, pulmonologists could approach and treat central airway diseases that had formerly been considered either completely untreatable or treatable only by extensive surgical procedures. Dumon silicone stents rapidly became popular [3]. The initial airway stent had a simple design consisting of a silicone tube with small studs on the external surface to reduce migration (Fig. 1). They have become the de facto gold standard for the treatment of benign and malignant stenoses over the past 30 years.

2 Available Silicone Stents

2.1 Dumon Stent

Many silicone stents are commercially available, although the Dumon stent (Tracheobronxane®, Novatech, La Ciotat, France) remains the reference standard as it is the most commonly placed stent worldwide. There are two specific designs: straight and bifurcated [4, 5] (Fig. 2) (for disease involving the main and secondary carinas, to be treated in another chapter of this book). Stents are available in various lengths and diameters to accommodate both pediatric [6] and adult indications. The largest available external diameter is 20 mm. For irregularly shaped stenoses, i.e., those with marked reduced central airway caliber as compared to the extremities, specialized hourglass-shaped stents are available [7] (Fig. 2). These hourglass-shaped stents are particularly useful in cases of short benign tracheal disease. The currently available stents are made of silicone with radio-opaque studs both with barium sulfate and gold (Fig. 2). Soon, the new generation of transparent Dumon silicone stents (Tracheobronxane®, Novatech, La Ciotat, France) will have gold markers included in their studs to provide radio-opacity. The transparent Dumon stent offers the possibility to visualize the mucosa behind its wall.

Dumon stents have to be inserted through a dedicated rigid bronchoscope.

The commercialized introducer set includes a loading tool and a pusher (Fig. 3). A Dumon stent can be repositioned, removed and replaced at any time with ease, using standard grabbing rigid forceps. On-site modification of these stents is technically possible [8] (Fig. 4).

2.2 Polyflex Stent

The Polyflex stent (Boston Scientific, Natick, MA, USA) (Fig. 5) is made from polyethylene threads embedded in silicone [9]. The walls of these stents are thinner than the walls of Dumon stents resulting in a better ratio of inner to outer diameter. The edges of these stents are sharper and the length of the stent changes depending on its compression state. Due to its design, a Polyflex stent can adapt slightly better to hourglass-type stenoses. The outer surface is slightly smoother, and the migration rate seems to be higher in comparison to the Dumon stent. Modified Polyflex stents with

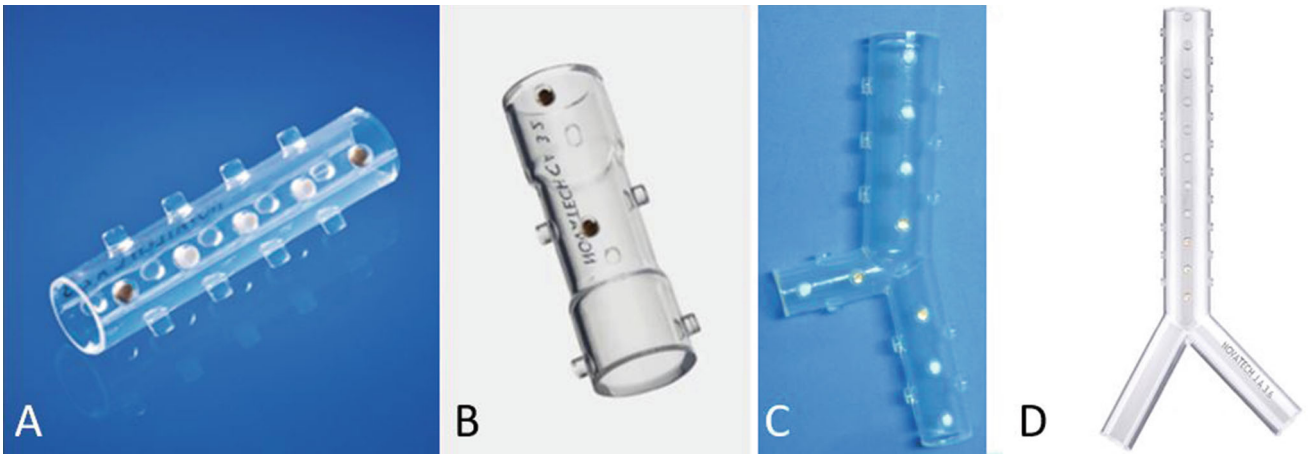

Fig. 2 The different designs of Dumon stent: (**a**) straight, (**b**) hour-glass, (**c**) Bifurcated Oki Stent, (**d**) Y Stent

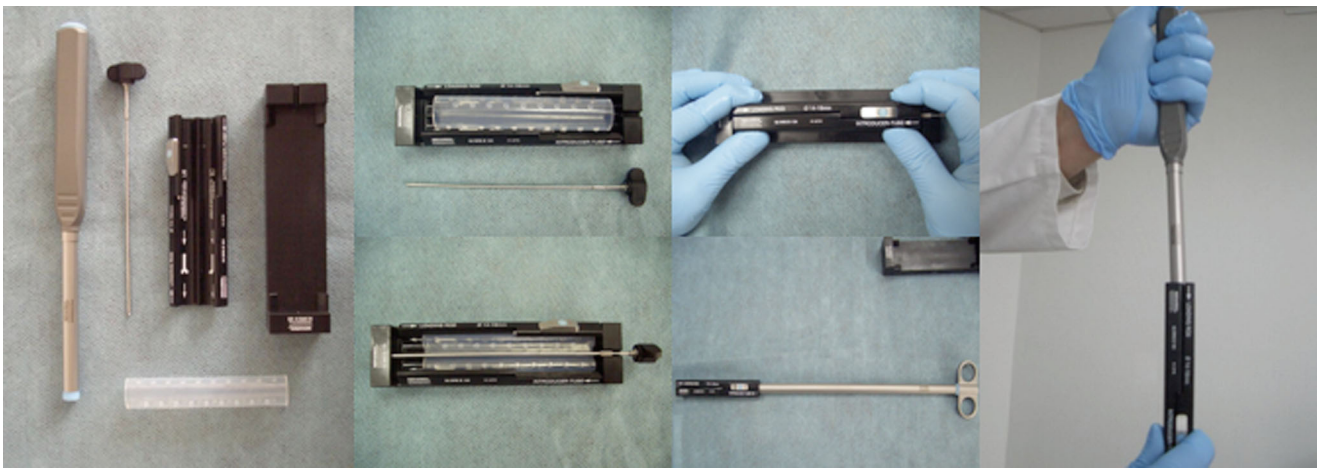

Fig. 3 Loading system for Dumon stent. (Tonn-Applicator, Novatech, La Ciotat, France)

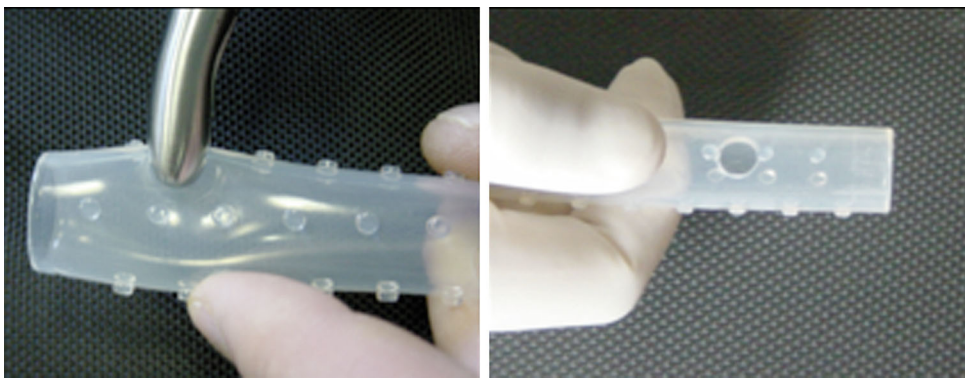

Fig. 4 On-site customization of a Dumon stent (dedicated forceps to create an orifice in order to ventilate a collateral bronchus)

outer struts have been used successfully in recent studies. Little tungsten spots in the stent wall make them visible on chest radiographs. Polyflex stents are deployed out of a semirigid tube (Fig. 4). The skill and the training that is required to place them are comparable to the competence that is needed to insert Dumon stents.

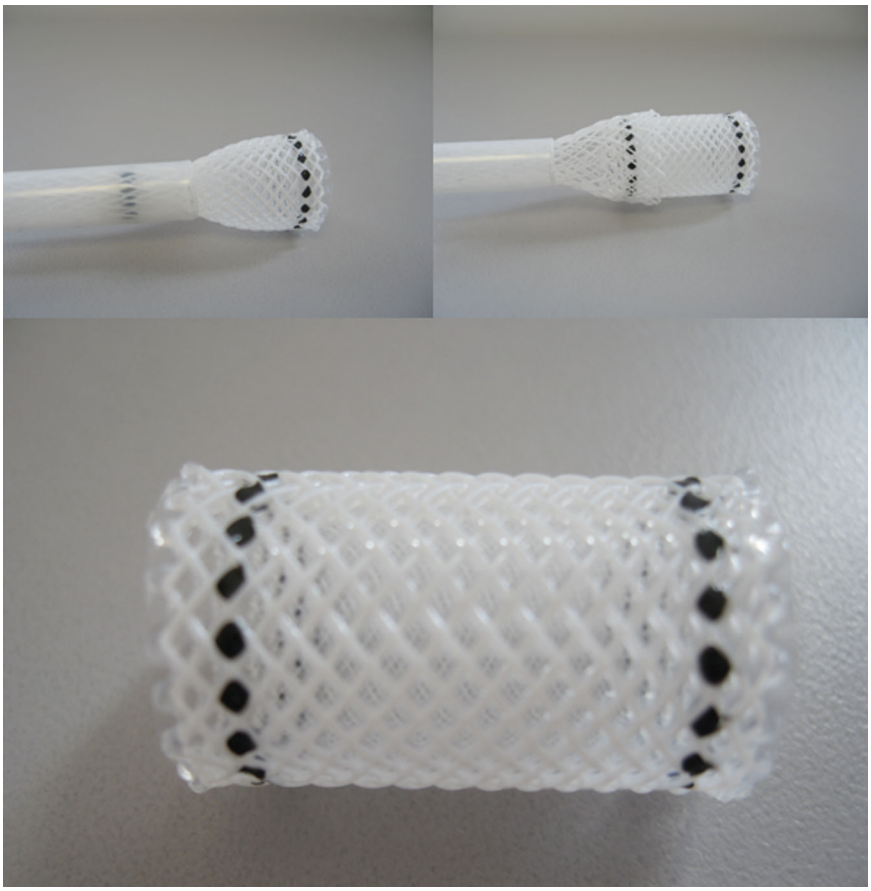

Fig. 5 Polyflex stent. (Boston Scientific, Natick, MA, USA)

2.3 Other Silicone Stents

Other CE-marked polymeric straight stents (Fig. 6) such as the Noppen stent (Reynders Medical Supply, Lennik, Belgium), which is made from Tygon [10–12], or Hood stents (Hood Laboratories, Pembroke, MA, USA), which are made from silicone, may be still available, but they are no longer advertised and have probably been replaced by the newly developed self-expanding metal stents.

As stated above, each stent has specific characteristics differing from those of the Dumon stent and therefore may provide a viable alternative depending on the indication.

Dumon silicone stents (Tracheobronxane®, Novatech, La Ciotat, France) are mainly in our institutions and are the most widely placed silicone stent, as such the remainder of the article will focus on this type of stent.

3 Indications

Any pathology leading a significant reduction in airway luminal diameter (greater than 50%) may be an indication for a silicone airway stent.

Five major indications have been established in a review by Lutz Freitag in 2010 [13]:

- Counteracting extrinsic compression from tumors or lymph nodes
- Stabilizing airway patency after endoscopic removal of intraluminally growing cancer
- Treating benign strictures
- Stabilizing collapsing airways (malacia and polychondritis)
- Sealing fistulas, e.g., stump dehiscences or fistulas between the trachea and esophagus

3.1 Malignant Airway Stenosis

The most common indication is malignant airway obstruction from a bronchogenic malignancy [14–20]. Malignant airway obstruction is often classified based on the airway involvement:

- Purely intrinsic involvement can often be managed with debulking techniques to remove the endoluminal tumor (Fig. 7). In this case, a stent may be placed as a bridge to the response to chemoradiotherapy, or alternatively it may

be considered when there is a high risk of local recurrence or as palliative after failure of the oncologic treatment**.** For patients' naïve from any oncologic treatment, placement of a stent is not recommended. The stent has proven to be well tolerated in terms of quality of life.

- The vast majority of cases present with both tumor within the airway, intrinsic and external compression of the airway, extrinsic. Treatment of mixed disease is usually multimodality with debulking and stent insertion.
- Extrinsic compression without intraluminal disease is readily treated with dilatation followed by stenting (Fig. 8).

Other malignant indications for endobronchial stenting include endobronchial metastases from sites (e.g., esophageal, thyroid, renal cell carcinoma, colon and melanoma) or alternatively low-grade tumors (e.g., cylindromas, carcinoids).

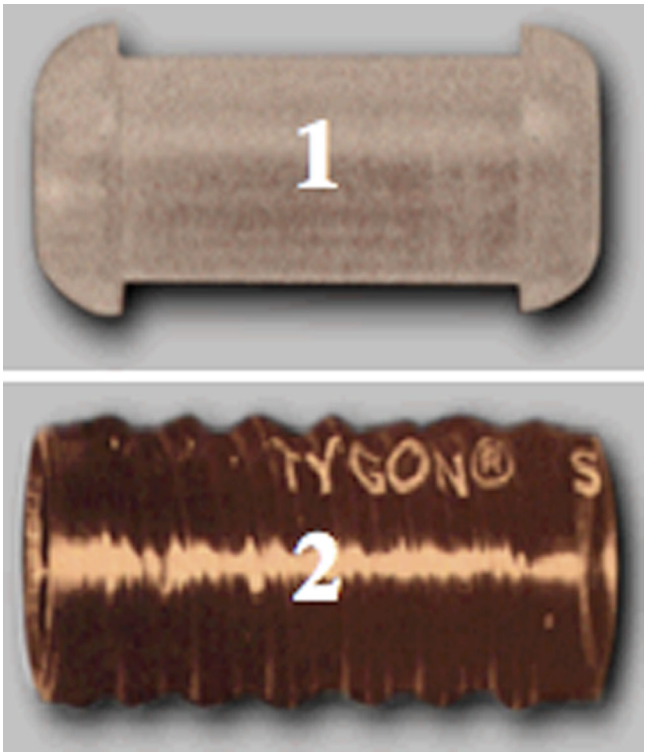

Fig. 6 Other silicone stents: (*1*) Hood stent (Hood Laboratories, Pembroke, MA, USA) and (*2*) Noppen stent. (Reynders, Medical Supply, Lennik, Belgium)

3.2 Benign Airway Stenosis

Silicone stents are also useful as treatment for benign conditions resulting in central airway obstruction. In Europe, the most common benign conditions leading to airway obstruction are postintubation or posttracheostomy stenosis, postanastomosis stenoses following sleeve resection, bronchial re-implantation, lung transplantation and tracheobronchomalacia. In Asia, posttuberculosis stenosis represents the main cause of benign central airway stenosis [21–23].

3.2.1 Postintubation or Posttracheostomy Tracheal Stenoses (PITTS)

PITTS are classified between simple (web-like) and complex (involving the deterioration of the cartilaginous rings) (Fig. 9). Simple PITTS are generally not amenable to stent insertion unlike the complex PITTS which recur in about 70% after dilatation alone. Dumon stents are suitable for this indication as they are removable and do not jeopardize a possible postponed surgery unlike metallic stents [24–27]. This prompted the FDA to published recommendations for

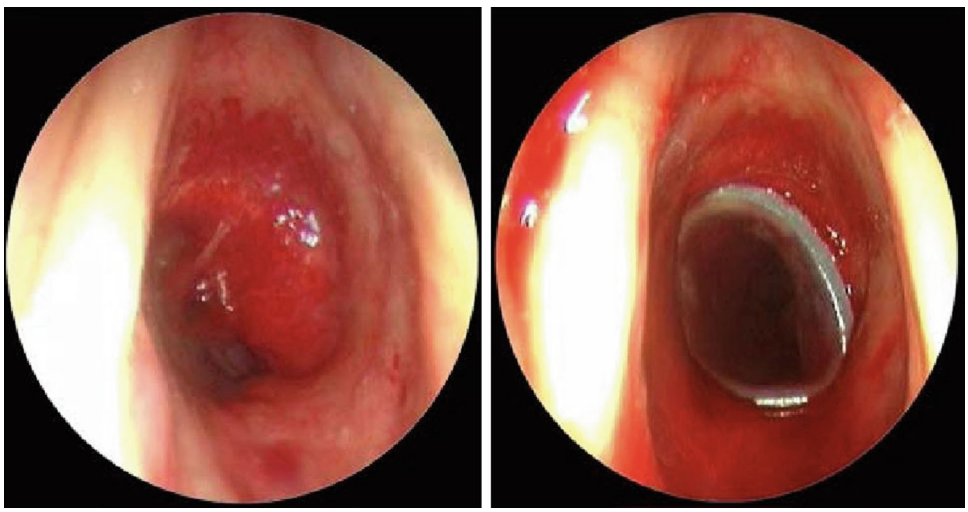

Fig. 7 Malignant obstruction of the trachea before and after placement of a silicone stent

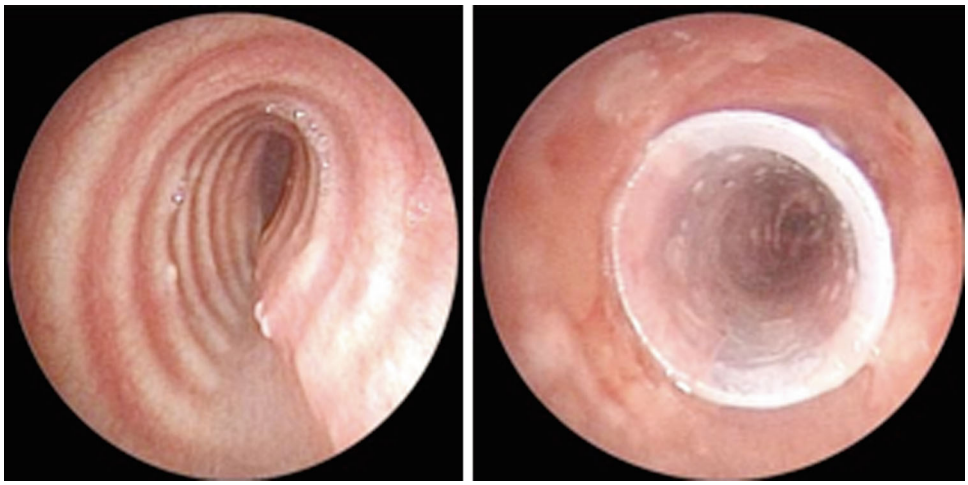

Fig. 8 External compression of the trachea before and after silicone stent placement

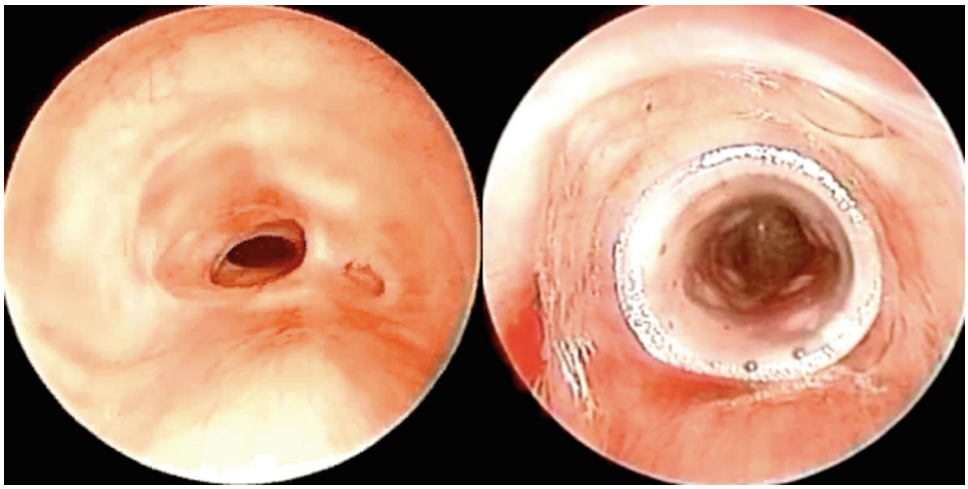

Fig. 9 Complex tracheal stenosis before and after silicone stent placement

the use of nonfully covered metallic stents in this indication [28].

Migration is probably the most challenging complication in this indication; its rate ranges from 11% to 17.5%, especially when the stenosis is very close to the vocal cords. This can be reduced by the use of a dedicated hourglass silicone stent or by external fixation. Long-term results (no recurrence after stent removal at 1 year) vary from 40%, when the stent is placed for 6 months, to more than 60%, when the stent remains in place for 18 months [27].

3.2.2 Bronchial Stenosis Following Lung Transplantation

Stent placement could potentially deteriorate mucosal ischemia, and restenosis is a common finding. While the overall results (survival and clinical outcome) favor stent placement, a high rate of stent-related problems such as scarring, mucus plugging, bacterial colonization and migration have to be accepted with currently available stents. It is advisable to select a stent that can be removed if necessary without causing further tissue damage. Recently, our group has published a retrospective study on Dumon stent placement in anastomotic stenosis after lung transplantation [30]. The stents have been removed definitely in 70% of the patients without further recurrence. The new surgical technique for bronchial anastomosis (one cartilaginous ring of the donor bronchus is conserved) implies an anastomosis very close to the secondary carinas on both sides, this indicates bifurcated stents when a complication occurs [31–33].

3.2.3 Tracheobronchomalacia

During recent years, various stents have been used for these indications, but several unanticipated problems have been encountered. Therefore, most endoscopists have become reluctant about the use of permanent stent placement for malacias [34, 35]. The choke region can be identified with

new techniques but any procedure may simply shift the choke region toward the periphery and there are no clear predictors whether a patient will benefit from a stabilizing procedure. Therefore, in a trial and error approach, it can be considered to temporarily place a stent and test whether the patient improves clinically from this internal splinting. If they do, they are sent to the surgeon for external stenting techniques. If not, the stent is removed and physiotherapy and CPAP is recommended. The straight Dumon stent cannot be recommended for malacic stenoses as it is held in place by contact pressure between the airway wall and the studs. In flexible dyskinetic tracheas and gradually opening benign stenoses, it is prone to migration.

3.3 Airway Fistulas

3.3.1 Tracheoesophageal or Bronchoesophageal Fistulas

Tracheoesophageal or bronchoesophageal fistulas are most often secondary to malignancy [36, 37]. Esophageal carcinomas show airway infiltration in up to 30% of cases. Fewer than half of these patients are operable. If an esophago-airway fistula develops, a rapid decline of the overall condition with distressing cough and aspiration pneumonia is usually observed. In rare cases, primary bronchogenic carcinomas invade the esophagus causing similar problems. Insertion of an esophageal tube improves the quality of life but usually fails to seal the fistula. Furthermore, the esophageal tube can protrude into the lumen of the airway and compromise ventilation. Placement of an airway stent can prevent obstruction from the esophageal tube and can help in sealing the fistula (Fig. 10).

3.3.2 Bronchopleural Fistulas

Postpneumonectomy or lobectomy stump fistula is a severe complication of thoracic surgery. Its incidence ranges from 4.5% to 20%. The incidence is lower for benign conditions compared to patients with a known malignancy. Surgery is the treatment of choice of this condition but endoscopic techniques have been advocated as an option when surgery is not possible or has to be postponed. Among them, placement of silicone stents is an option. Watanabe et al. [38] reported successful sealing of a postlobectomy fistula using a Dumon silicone stent, but long-term outcome was not described. Similar results were obtained in two clinical reports using Dumon silicone stents [39, 40].

4 Contraindication

In life-threatening situations, there are hardly any contraindications. However, other techniques should be used first before a stent is placed. Intraluminally growing tumors should be removed first by laser resection, for example, and then a larger stent should be placed if it is still necessary. Treating benign lesions requires particular caution as a stent might be harmful in the long run, even if the patient has an early benefit. In general, only removable stents should be used for these indications until a multidisciplinary team has determined inoperability. Instability of the airways is not a contraindication but hardly ever a good indication for permanent stent placement.

5 Silicone Stent Deployment

In our opinion, the deployment of a silicone stent must be performed using rigid bronchoscopy under general anesthesia. In addition to stent deployment, the rigid bronchoscope

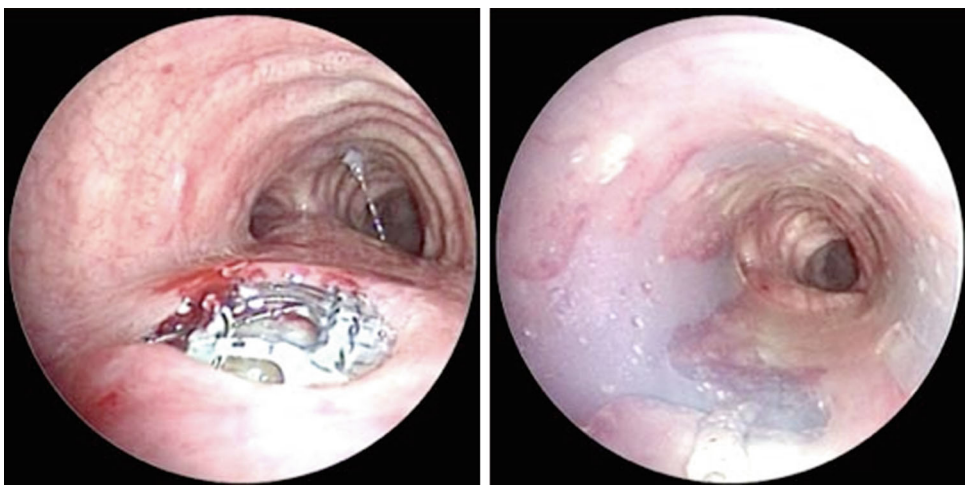

Fig. 10 Tracheoesophageal fistula before and after silicone stent placement

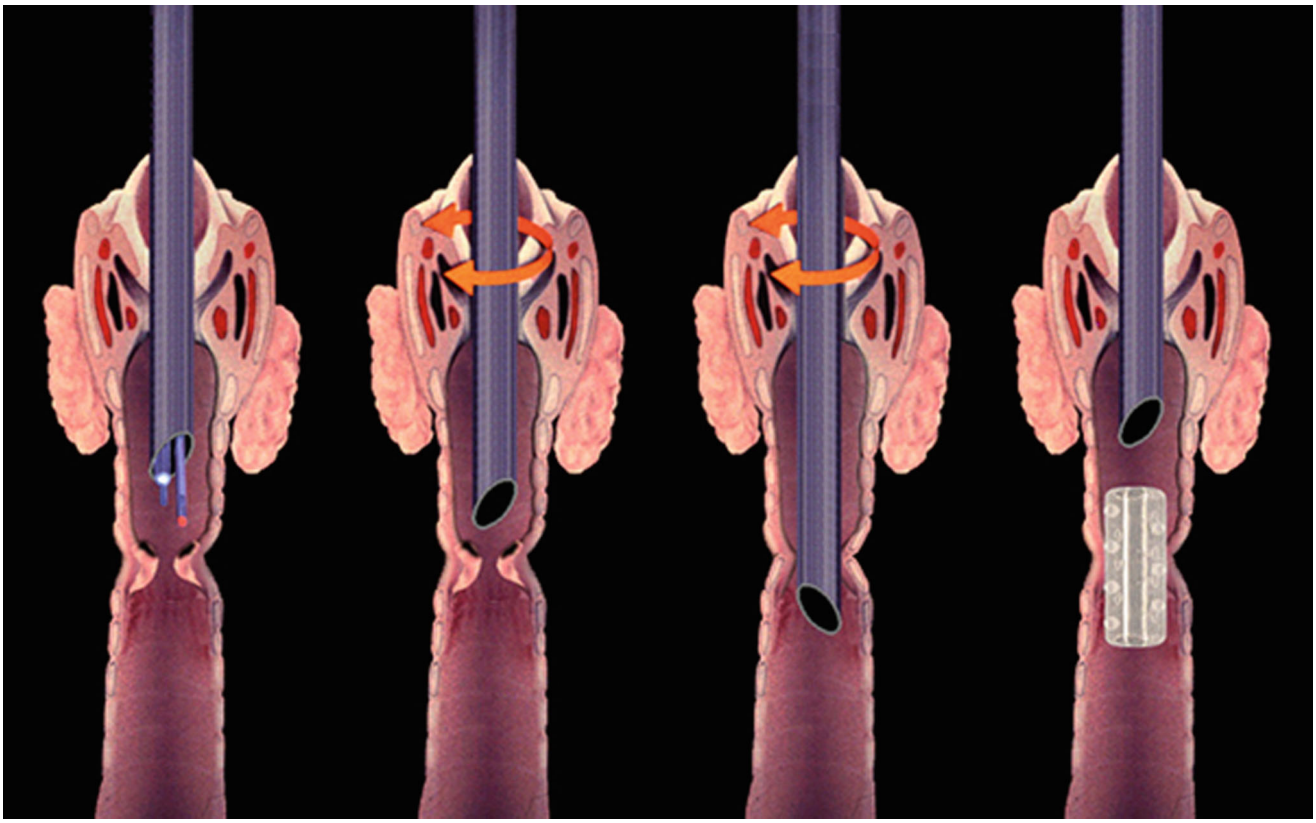

Fig. 11 Mechanical dilation using a rigid bronchoscope before stent insertion

serves as a useful tool both for mechanical tumor debulking and airway dilation prior to stent insertion (Fig. 11). Rigid bronchoscopy is essential for the insertion of Dumon stents as they are not auto-expandable.

The appropriate length of the stent is determined intraoperatively by using either the rigid optic or a flexible bronchoscope to measure the length of the lesion to be covered (Fig. 12). Preoperatively preliminary measurements can be estimated from the CT images and then confirmed endoscopically. Ideally, the stent should extend 5 mm above and below the abnormality.

With respect to the selection of the most appropriate stent diameter, this is based on the largest diameter rigid bronchoscope barrel utilized to maximally mechanically dilate the airway (Fig. 12). Stent diameter is decided upon on a case-by-case basis; however, some general guidelines will follow. In stenotic lesions of the trachea, 14–16-mm stents are often selected. The 12- to 13-mm and 10- to 11-mm stents are usually appropriate for stenoses involving the main stem bronchi and bronchus intermedius, respectively. The sizing for fistulas and tracheobronchomalacia differs as there is no lesion to which the stent may anchor; therefore, in order to avoid migration, it is important to oversize the stent slightly.

The stent is loaded into the dedicated stent deployment device and then positioned just distal to the lesion. The stent is subsequently moved more proximally into an ideal position with the rigid bronchoscopy forceps (Fig. 13). Pushing the stent more distally is rarely advised due to the risk of perforation at the level of the pathologic airway.

Upon deployment, the stent may not completely open, and a balloon catheter or one of the rigid instruments (rigid scope itself or the forceps) may be used to complete the expansion of the stent (Fig. 13).

No matter the indication for the airway stent, we recommend annual reassessment and replacement of the stent until such a time the stent is no longer indicated.

Stent removal is generally easy (Fig. 14). Using a rigid bronchoscope, rigid dedicated forceps are inserted alongside the optic. The proximal edge of the stent is grabbed and the stent is turned 360 ° on its position. Then the stent is pulled proximally, and its first 2 or 3 mm is inserted in the bevel of the rigid bronchoscope. This way, when the rigid bronchoscope and the stent will be pulled back in one block, the proximal edge of the stent will not damage the larynx and the vocal cords. The stent should not be pulled back on the entire length of the rigid bronchoscope. In some cases, when a

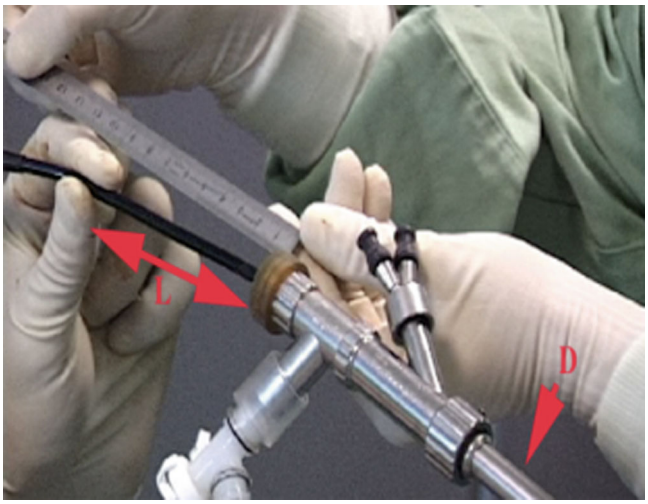

Fig. 12 Technique of length and diameter measurements

silicone stent has remained in place for more than 2 years, its structure modifies and, during its removal, it can break in pieces of different sizes. All the pieces have to be removed one by one.

6 Complications

The major complications related to silicone stents include migration (9.5%), formation of granuloma (7.9%), obstruction secondary to secretions (3.6%) and bacterial overgrowth [41, 42].

Migration is most frequently the result of under-sizing the stent diameter or alternatively due to tumor involution secondary to treatment. This complication is rarely fatal and most often presents clinically as cough or dyspnea. It is managed simply by extraction of the migrated stent under

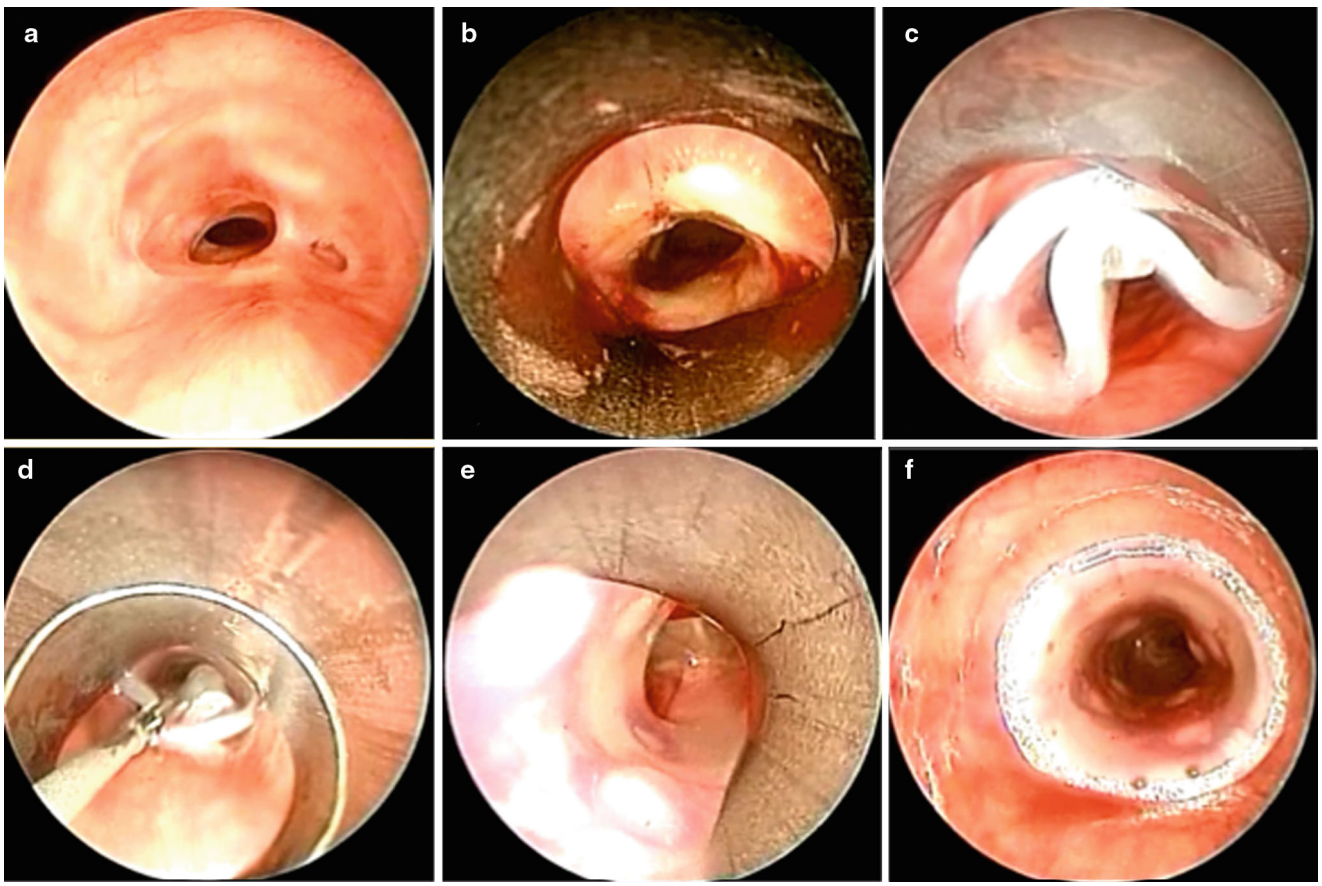

Fig. 13 Technique of silicone stent placement: (**a**) Tracheal stenosis. (**b**) Preliminary dilation using a rigid bronchoscope. (**c**) The stent is inserted at the level of the stenosis. (**d**) Rigid forceps unfold the proximal edge of the stent. (**e**) The rigid tube unfolds the body of the stent. (**f**) Final result after complete opening

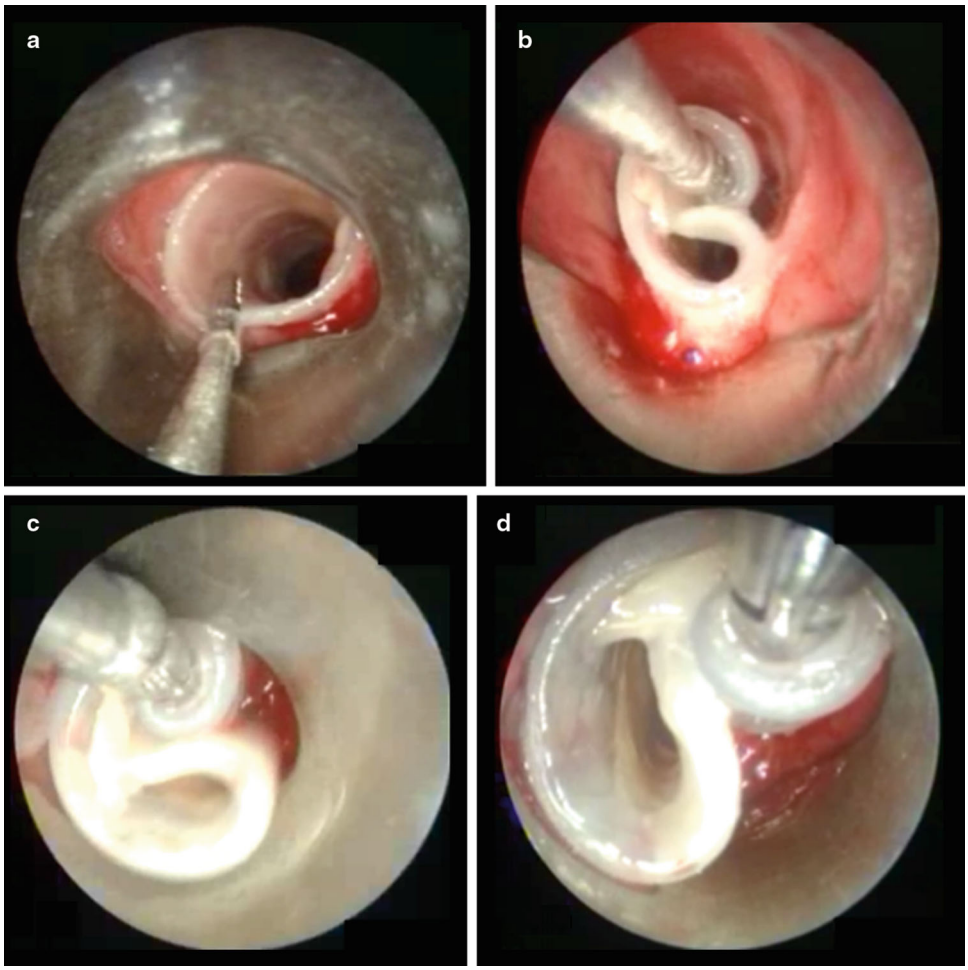

Fig. 14 Technique of stent removal (**a**) The rigid forceps grab the proximal edge of the stent. (**b**) The stent is turned 360° on its position. (**c**) The first millimeters of the stent are introduced in the rigid tube. (**d**) The rigid tube and the stent are removed in one block

rigid bronchoscopy and eventual replacement with a more appropriate sized stent. Percutaneous external fixation has been proposed to reduce the risk of migration.

Granulation tissue has a tendency to form at the proximal and distal margins of the stent and is related to chronic inflammation. They can lead to obstruction of the stent, and therefore, mechanical or thermal (laser, cautery, cryotherapy) means should be considered. Replacement of the stent may also be necessary.

Mucoid impaction of the stent leading to obstruction may be quite serious and even lethal. The risk may be reduced by maintaining humidification of the stent via nebulization of sterile normal saline 2–3 times daily while the stent is in place.

Stents that become impacted with secretions most often associated with bacterial overgrowth should generally be removed and replaced.

7 Discussion

7.1 Advantages

Silicone stents are indicated for the vast majority of clinical indications whether malignant or benign, in contrast to metal stents that should for the most part be avoided in benign disease. Metal stents that are completely covered with silicone may be exception.

Although complications do occur with these stents, they are very rarely fatal and usually readily reversible. In point of fact, silicone stent removal is quite easy. They have a radial force sufficient to render them quite effective in extrinsic airway compression. In addition, they can readily be manipulated and moved within the airway without concern.

Techniques do exist to preserve ventilation to lobes that may be covered by an endobronchial stent, most commonly the right upper lobe with Y stents. These include fenestrations or addition of stents to the distal limbs, Borgne Y.

It is important to note that the cost of a silicone stent is significantly less than a metal auto-expandable stent in the order of 1.5–2 times.

7.2 Disadvantages

The necessity for rigid bronchoscopy and general anesthesia for the placement of a silicone stent is considered by some as a disadvantage; however, in our opinion, this is not the case. These same skills/resources are essential for the management of potential complications that may result from the insertion of metal stents.

Due to pliability properties of the silicone stent, curvilinear conformations are not the ideal indication for silicone stents. In these situations, the stent may either involute centrally resulting in obstruction or even migrate due to the tendency to maintain its straight tubular conformation.

Conditions such as tracheobronchomalacia where there is a variable dimension of the airway may not always be ideally served by a silicone stent with a fixed diameter. Unfortunately, few other viable options exist for these conditions as metal stents, particularly those that are not fully covered with silicone are considered at least relatively contraindicated due to the difficulty with removal and high risk of fracture.

The tubular structure with the external studs of the Dumon stent may limit its ability to attain a complete seal between the stent and the airway wall. This may be important in the case of fistulas as there is potential for a small residual leak around the stent.

Finally, due to the greater thickness of the silicone stent compared to its metal counterpart, there is consequently a reduction in flow rate.

8 Conclusion

The ideal airway, according to Artificial Intelligence, should possess several key characteristics to ensure optimal patient outcomes.

1. **Biocompatibility**: The stent should be made from materials that are well-tolerated by the body and do not induce significant inflammatory or immune responses.
2. **Flexibility and Radial Force**: The stent needs to be flexible enough to conform to the natural anatomy of the airway but also provide sufficient radial force to keep the airway open.
3. **Ease of Placement and Removal**: The stent should be easy to deploy and remove using bronchoscopic techniques. This involves having a delivery system that allows precise placement without causing trauma to the airway.
4. **Nonmigratory**: The stent should stay in place once deployed. Migration of the stent can cause significant complications and negate its therapeutic effects.
5. **Minimal Side Effects**: The ideal stent should minimize the risk of granulation tissue formation, infections and other complications such as erosion or perforation of the airway.
6. **Radiopacity**: Being radiopaque is important for the stent to be visible on imaging studies, allowing for precise placement and monitoring postprocedure.
7. **Customizability**: The ability to customize the stent in terms of size and shape to fit the specific needs of the patient's airway anatomy can be highly beneficial.

This ideal stent has yet to be developed but, in our opinion, the Dumon stent® gathers most of the characteristics listed above: biocompatibility, radial force, easy removal, radio-opacity and customizability. It has proven its efficacy in nearly all indications for endobronchial stenting expect in expiratory collapse of the airway. Complications with this type of stent are infrequent and rarely life-threatening. More importantly, the potential complications are readily manageable, which is not necessarily the case with their metal counterparts. The ease of removal renders them the best available option for benign disease and also in malignancy when there is an expectation of tumor response to chemoradiotherapy. In most centers, budgetary constraints must also be considered, and from this standpoint, silicone is by far superior to the much more costly option of a metal stent. Overall, it is our opinion that these airway stents are a safe, cost-effective and valuable tool in the management of all causes of airway obstruction and fistula.

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