Original Article

Self-expanding stent made of polyester mesh with silicon coating (Polyflex®) in the treatment of inoperable tracheal stenoses*

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Abstract

Objective: To evaluate the Polyflex® stent in terms of its efficacy, ease of implantation, and complications in patients with tracheobronchial affections. **Methods:** This was a prospective study, in which sixteen patients with inoperable tracheal stenosis secondary to orotracheal intubation (n = 12), neoplasia (n = 3), or Wegener's granulomatosis (n = 1) were monitored. Of these patients, eleven were women, and five were men. The mean age was 42.8 years (range, 21-72 years). Patients were submitted to implantation of a total of 21 Polyflex® stents. All procedures were carried out in the operating room under general anesthesia, and the stents were implanted via suspension laryngoscopy using the stent applicator. **Results:** Stents were implanted and symptoms were resolved in all cases. The stents remained in place for a mean period of 7.45 months, ranging from 2 to 18 months. The complications observed in the immediate postoperative period were dysphonia (in two patients, 12.5%) and odynophagia (in two patients, 12.5%). Late complications were cough (in ten patients, 62.5%), migration (in seven patients, 43.75%), granuloma formation (in two patients, 12.5%), and pneumonia (in one patient, 6.25%). **Conclusion:** The Polyflex® stent is easily implanted, easily removed, well tolerated by patients and effective in resolving symptoms. However, its use is associated with a high rate of migration, especially in patients with post-orotracheal intubation stenosis.

Keywords: Tracheal stenosis; Intubation, intratracheal; Prostheses and implants; Stents.

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Submitted: 4 June 2006. Accepted, after review: 12 September 2006.

Introduction

The treatment of inoperable tracheal stenoses remains a therapeutic challenge. As the use of tracheal or bronchial substitutes does not provide good results, stents are an alternative to maintain the airway permeable in benign or malignant diseases.[1,2] To this end, various models of stents have been developed and various materials have been used to produce stents with the objective of achieving the optimal stent.[3]

Today, there are a number of models available, divided in two groups: rigid silicon stents and self-expanding metal stents.[2] The most widely used silicon stent is the Dumon stent, a cylindrical device with protuberances on the external surface that enable good fixation to the tracheal mucosa.[4-6] Its advantages are low reactivity and ease of removal.[5] However, it has certain disadvantages: it impairs mucociliary clearance; it is difficult to insert in some situations, requiring the use of apparatus especially designed to its insertion and positioning; migration of the stent is relatively common, especially in conic stenoses or those accompanied by tracheomalacia; and there is an unfavorable relationship between the internal and external diameters, which can cause unwanted airway obstruction.[5,6] Despite the disadvantages described above, these stents have been widely used and have been shown to provide satisfactory results.[5-8] The most widely used self-expanding metal stents are the Wallstent® and the Ultraflex®. These stents are easy to insert and are appropriately adjustable to the irregular surface of the stenotic trachea, although they cause a local inflammatory reaction and formation of granulation tissue that infiltrates the stent mesh and can result in obstruction.[9-11] Their removal is problematic and can cause severe complications, such as profuse bleeding.[12,13]

Considering the pros and cons of both types of stents available, the self-expanding stent made of polyester mesh with silicon coating (Polyflex® stent) as a device that is easy to insert/remove, rarely migrates, causes few granulomatous tissue reactions and presents a favorable relationship between the external and internal diameters (Figures 1 and 2). Experimental studies demonstrated that this stent is easy to insert, effective and well tolerated.[12,14]

The aim of this study was to evaluate the ease of insertion and safety of the self-expanding stents with silicon coating (Polyflex® stent) in the treatment of patients with tracheal stenoses of benign and malignant etiology who were non-candidates for definitive surgical treatment.

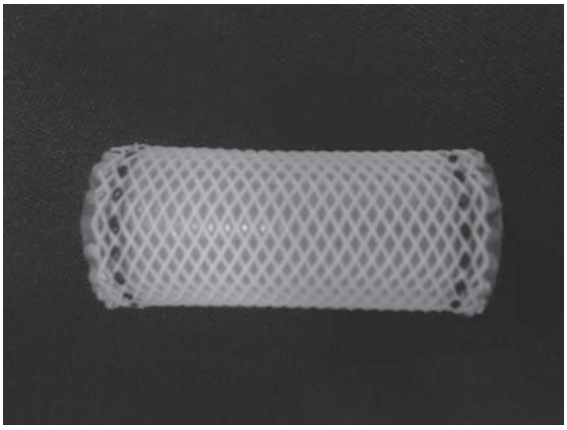

Figure 1 - Example of self-expanding stent made of polyester mesh with silicon coating (Polyflex®).

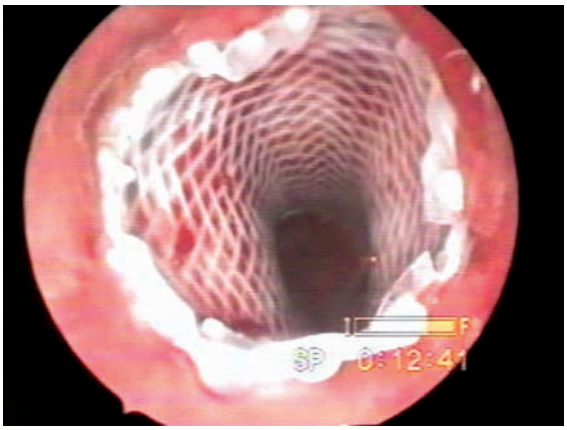

Figure 2 - Polyflex® stent within the trachea.

Methods

Between October of 2002 and December of 2004, sixteen patients treated at the Outpatient Trachea Clinic of the Department of Thoracic Surgery of the University of São Paulo School of Medicine *Hospital das Clínicas* were evaluated. All were suffering from tracheal stenosis of benign or malignant etiology and were submitted to the insertion of 21 self-expanding stents with silicon coating. The inclusion criteria for the study were as follows: having symptomatic tracheal stenosis; and having been excluded from definitive surgical treat-

ment, due to extensive tracheal disease (>50% of the extent of the trachea), due to nonresectable primary or secondary malignant mediastinal neoplasia, due to poor clinical status preventing a more radical procedure, due to previous surgical treatment failure or due to recent benign stenosis (<2 months). The exclusion criteria were being less than 16 years of age or more than 80 years of age; presenting any clinical condition that precludes sedation; requiring invasive or noninvasive ventilation; and presenting significant deglutition deficit. Of the sixteen patients studied, eleven (68.8%) were women, and five (31.2%) were men, and the mean age was 42.8 years (range, 21-72 years). The most frequent cause of stenosis was scarring resulting from orotracheal intubation or tracheostomy, totaling twelve cases (75%). Neoplasia was the second most frequent cause, observed in three patients (18.75%), of which two presented extrinsic compression caused by esophageal carcinoma, and one presented primary adenoid cystic carcinoma of the trachea. In one case (6.25%), stenosis was secondary to Wegener's granulomatosis.

After the initial evaluation, involving the assessment of clinical status, taking of a medical history, physical examination, bronchoscopy, and computed tomography of larynx/trachea, as well as after having agreed to participate in the study, all of the patients gave written informed consent. All procedures were performed in the operating room under general anesthesia, and access to the airway was gained through suspension laryngoscopy. The resolution of the airway obstruction was carried out through dilatation with metal domes or hydrostatic balloon. The selection of the size of the stent used (Polyflex®; Rusch, Int., Kernen, Germany) was based on the stenosis size, according to measurements performed using computed tomography, and the stenosis aspect after dilation. The adopted parameters complied with previous publications and the manufacturer guidelines: stent length approximately 20 mm larger than that of stenosis (in order to leave 1 cm of stent, in a normal trachea, at the proximal and distal edges); and stent diameter 4 mm larger than tracheal diameter after dilatation. A 5-mm, 0° endoscope was used to make all measurements: the distance between the stenosis and the vocal folds; the distance between the stenosis and the carina; and the length of each element. Radioscopy was used in the first two cases, after which its use was discontinued because we considered it unnecessary. Once selected, the stents were inserted using the guidewire that accompanies the kit. After the procedure, patients were evaluated in terms of their symptomatic improvement and were prospectively monitored to assess clinical status and to identify the following complications: cough; dysphonia; dysphagia; bleeding; formation of granulomatous tissue; obstruction caused by secretion plug; stent migration; lesion in the tracheal wall; subcutaneous emphysema; infection; and death. The follow-up evaluations were performed on a monthly basis or at shorter intervals, according to the symptoms. Bronchoscopies were carried out at 30 days, 3 and 6 months after insertion of the stent – or at any point if symptoms appeared.

In cases in which it was necessary to inspect, exchange or remove the stent, access to the airway was gained as described above, in the operating room using suspension laryngoscopy.

Results

A total of 33 endoscopic procedures, either for insertion, inspection or removal of the stent (Chart 1), were performed in the operating room during the follow-up period (mean, 7.45 months; range, 2-18 months), which defined the study period. There were no intra-operative complications or deaths related to the stent or the procedures. During one insertion, the patient, who suffered from severe asthma, developed bronchoconstriction and had to remain in the intensive care unit for 12 h under observation. In the other cases, patients were referred to the infirmary after being under observation for approximately 2 h.

A total of 21 stents were employed (16 insertions and 5 exchanges). On five occasions, the stent was immediately removed and replaced after insertion due to inadequate positioning. In 2 of those insertions, an error occurred during the expansion

Chart 1 - Procedures performed.

Initial insertions	16
Repositioning for migration	5
Permanent removal	7
Exchange due to migration	2
Exchange due to deterioration	2
Exchange due to inappropriate size	1

of the stent. However, in the 3 remaining insertions, we considered the complication to be the result of unfavorable anatomical conditions and a particularly challenging insertion: stenosis in tortuous tracheas (since the guidewire is rigid); stenosis too near the vocal fold; and an extremely long stenosis. In all 5 insertions/re-insertions, the stent was easily removed with two pairs of forceps and was repositioned without complications.

The reasons to exchange the stent were as follows: deterioration of the stent silicon (in two cases, at 8 and 14 months after insertion); fracture of the stent (in two cases, during repositioning for migration); and exchange for another stent of a more appropriate size (in one case).

In three cases, the stent migrated distally and was repositioned using traction with forceps, whereas the migration was proximal in two cases, in which the stent was removed and repositioned.

During the follow-up period, seven patients were submitted to definitive removal of the stent, either because they were submitted to surgery (two cases), because the stenosis remained stable and asymptomatic (four cases), or because an infection developed and tracheostomy was required (one case). The four patients in whom the stenoses remained stable and asymptomatic presented minimal residual stenosis that had a fibrotic aspect on the bronchoscopy. Among these four cases, the longest follow-up period after the removal of stent was 6 months. In all procedures, the stent was removed without difficulties by traction with two pairs of endoscopic forceps. One patient with an esophageal neoplasm died 3 months after the insertion of the stent, due to complications related to the underlying disease (Table 1).

The immediate postoperative complications were dysphonia in two patients (12.5%) and odynophagia in two patients (12.5%). These complications occurred in patients with stenoses located near the glottis. In three patients, the symptoms regressed in the first month after surgery. Only one patient with dysphonia remained symptomatic for a prolonged period – approximately 6 months (Table 2).

In the follow-up evaluations, we observed the following complications: cough in ten patients (62.5%); migration in seven patients (43.75%); formation of granulomas in two patients; and pneumonia in one patient (6.25%). Cough was the marker of complications. Of the ten patients who developed this symptom during the follow-up, seven had other complications, such as stent migration, tracheal granulomas and deterioration of the stent silicon (Table 2).

Stent migration was the most serious complication observed. In four cases, the migration was early (after less than 30 days). We attributed these migrations to technical problems. In a subsequent analysis of these four patients, we determined that, in two cases, the stent size selected was inappropriate, and that, in the other two cases, the stent positioning was incorrect, since one of those two stenoses was near the glottis, and the other was near the carina. In three patients, we observed late migration, occurring from 3 to 6 months into the follow-up period. Table 3 summarizes the characteristics of patients who experienced stent migration and of those who did not. It is interesting to observe that, although the follow-up period was short, none of the patients whose stenosis was neoplastic in origin experienced migration.

Discussion

One group of authors used the Polyflex® silicon stent in an experimental model of induced tracheal

Table 1 - Patients in whom the stent was removed prior to the study endpoint.

Patient	Etiology	Follow-up (months)	Reason for stent removal
3	OTI	2	Submitted to surgery
5	OTI	2	Submitted to surgery
11	Wegener	2	Residual stenosis/asymptomatic
6	Esophageal SCC	3	Death
4	OTI	5	Residual stenosis/asymptomatic
10	OTI	8	Residual stenosis/asymptomatic
2	OTI	9	Residual stenosis/asymptomatic
7	OTI	12	Pneumonia

OTI: orotracheal intubation; SCC: spinocellular carcinoma; Wegener: Wegener's granulomatosis.

Table 2 - Postoperative complications.

Complication	Frequency (%)
Precocious	
Dysphonia	12.50
Odynophagia	12.50
Late	
Cough	62.50
Migration	43.75
Granuloma formation	12.50
Pneumonia	6.25

stenosis in pigs.[12] The tracheal stenosis was induced according to technique developed by another group of authors,[7] who evaluated the aspects related to the application of stents and their short-term results. They concluded that the stent, from a technical point of view, is easy to insert and remove. All of the animals presented clinical improvement, although the stent migration rate was quite high.

In another experimental study,[14] long-term results were evaluated in 12 sheep that received Polyflex®, Dumon or Gianturco stents. The variables analyzed were the complications and the histological aspect of the tracheal surface one year after the stent insertion. The authors concluded that the Polyflex® stent causes low tissue reaction but has a high migration rate. The same authors considered the Gianturco stent inappropriate for long-term use, since they observed complete perforation of the tracheal wall in later follow-up evaluations.

Other authors used the Polyflex® stent in a clinical study of nineteen patients suffering from tracheobronchial complications resulting from advanced neoplasia, with stenosis or tracheoesophageal fistula.[15] All of the patients presented clinical improvement after surgery, and the complication rate was low. Of those nineteen patients, seven evolved to mucus accumulation and two to stent migration. In two patients, the stent curved during insertion. Therefore, the authors considered the stent a good alternative for the treatment of neoplasia-related stenoses and fistula. The results of this series of cases comply with those of the experimental studies in terms of the ease of insertion, tolerability and efficacy. However, the migration rate in the present study was low in comparison with that observed in animal studies. It is important to observe that only neoplasia-related stenoses were evaluated in this study, as well as only the short-term results.

Similarly to the experimental studies and the series of cases mentioned above, we observed, in our study, that the stent is easy to insert and remove. Although we removed and repositioned the stent

Table 3 - Characteristics of the patients according to the occurrence of stent migration and the length of the follow-up period.

Patient	Gender	Age	Etiology	Follow-up (months)	Stent size (mm)	Migration
3	M	23	OTI	2	20 × 50	N
5	M	46	OTI	2	20 × 50	N
1	F	28	Tracheal tumor	3	22 × 50	N
6	M	72	Esophageal SCC	3	22 × 50	N
13	F	26	OTI	3	18 × 50	N
16	F	47	Esophageal SCC	3	18 × 50	N
12	F	53	OTI	12	18 × 40	N
8	M	21	OTI	15	20 × 70	N
15	F	39	OTI	18	18 × 40	N
11	F	55	Wegener	2	16 × 40	Y
14	F	45	OTI	3	18 × 50	Y
4	F	27	OTI	5	18 × 50	Y
10	F	59	OTI	8	18 × 40	Y
2	M	41	OTI	9	18 × 50	Y
7	F	21	OTI	12	18 × 60	Y
9	F	47	OTI	14	18 × 70	Y

OTI: orotracheal intubation; SCC: spinocellular carcinoma; Wegener: Wegener's granulomatosis; N: no; Y: yes.

immediately after its expansion on five occasions, four were in the first half of the cases, which corresponds to the learning curve. When we decided that the trigger point would be 1 cm caudal from the distal edge of the stenosis, according to the measurement taken using the rigid endoscope, we had no difficulties in positioning the stent. The situations in which the stent insertion was particularly difficult were: 1) stenoses too near the glottis and carina, because there is little space to anchor the stent in these situations, and special care must be taken in order not to select a mainstem bronchus or leave the stent transglottic; 2) stenoses in tortuous tracheas, because the rigid guidewire makes it difficult to advance the stent through the trachea and the stenosis. In cases in which the stent had to be removed, the procedure was easily performed with two pairs of forceps, without the bleeding observed upon the removal of other kinds of self-expanding stents. It was possible to remove, reposition and reinsert the same stent. There were only two cases in which the stent was cracked by the traction during removal.

None of the patients in our study sample presented severe complications. However, stent migration occurred at some point during the follow-up in 43.7% of the cases (0.06 migrations/month). This migration rate was high if compared to that of three other studies,[15-17] in which the reported migration rates were 10.5, 7.1 and 6%. It is important to mention that, in those studies, the use of stents was indicated due to tracheobronchial or esophageal complications related to neoplasia. Our migration rate is more comparable to that observed in experimental studies and studies in which stents were used for treatment of benign esophageal diseases. We believe that the high migration rate observed in our study is attributable to two factors: First, the majority of the stenoses were of inflammatory etiology. In the literature, lower migration rates have been reported in studies employing Polyflex® stents. However, the patients involved were suffering from malignant stenoses. It is notable that, although we had only three cases of malignant stenosis, and the follow-up of those cases was short, none of them presented stent migration. Second, the learning curve effect probably influenced the stent migration rate. There were four cases of early migration, which we attributed to technical problems, such as the selection of an inappropriate stent size or incorrect positioning. Despite tomographic and endoscopic criteria, the selection of the appropriate stent was problematic. As previously mentioned, stent insertion was particularly difficult when the stenosis was near the carina or the glottis, as well as when the stenosis was long or was in a tortuous trachea.

As part of the follow-up evaluation, we performed bronchoscopy on postoperative days 7, 30 and 90 – or at any point if there was suspicion of complications related to the stent. In the absence of such suspicion, bronchoscopy provided a low yield, since only one case of stent migration was identified in a patient who was completely asymptomatic. In the other cases, significant complications identified through bronchoscopy were already suspected due to symptoms such as cough or dyspnea. Therefore, routine bronchoscopies are unnecessary. Bronchoscopy should be performed only in the presence of suspicious symptoms.

In conclusion, the self-expanding Polyflex® stent proved easy to insert/remove and was well tolerated over the long term. The main complications were cough and stent migration. Therefore, there is a need for additional studies assessing stent performance in patients with malignant neoplastic processes and in those with benign processes are needed, as well as for comparative studies evaluating different types and models of stents.

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