GENERAL THORACIC SURGERY

CLINICAL AND LABORATORY EVALUATION OF A NEW THIN-WALLED SELF-EXPANDING TRACHEOBRONCHIAL SILICONE STENT: PROGRESS AND PITFALLS

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Background: Although widely established in the management of malignant airway lesions, currently available tracheobronchial prostheses made of silicone have their drawbacks resulting from rigidity and wall thickness. Therefore we present clinical follow-up data obtained with a novel thin-walled expandable prototype silicone airway stent (Polyflex stent, Willy Rüsch AG, Kernen, Germany) in 19 patients. **Methods:** Seventeen of 19 patients had tracheobronchial complications of infiltrating cancer: five had respiratory-digestive fistulas, 14 had mixed-type obstructions (mucosal infiltration plus extrinsic compression), and two had diffuse tracheal hemorrhages from the tumor surface (three patients had more than one complication). Two of 19 patients had benign postintubation stricture and malacia. Overall, 33 stents were implanted either simultaneously or in a consecutive manner. Scanning electron microscopy was performed both on prototype stents and on other available silicone stents for comparison. **Results:** The treatment improved the patients' clinical condition substantially. The mechanical properties of the new prosthesis were excellent. Important stent-associated side effects were early mucus retention ($n = 7$), infolding of the inner silicone layer ($n = 2$), and stent dislodgment ($n = 2$). As of February 1997, 10 patients have died of causes unrelated to stent placement. Seven patients with malignant airway disease are still alive from 2 weeks up to 7 months after initial treatment. Scanning electron microscopy of explanted and unused prototypes suggested that an extremely ragged luminal microstructure may contribute to the firm adhesion of secretory material and that technical smoothing of the surface avoids such complications. **Conclusions:** The novel self-expandable silicone airway stent may be a promising addition to commonly used stent types. Short-term and medium-term management of fistulas, tumor surface bleeding, and strictures (malignant and benign) is satisfactory. Scanning electron microscopy of stents provides information on peculiar features of microstructure and material that may be of use in clinical research and technical innovation. (J Thorac Cardiovasc Surg 1997;114:527-34)

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Malignant and benign stenoses of the central airways are a continuing challenge to the practicing bronchology. Newly developed cylindrical and bifurcated endoluminal silicone prostheses have passed their clinical tests. They are currently being used to restore and maintain airway patency, with negligible side effects. Long-term results are promising.¹⁻³ However, because of their unfavorably low internal/external diameter ratio and their lack of flexibility,⁴ they may impose an unwanted resistance to air flow. In addition, tracheoesophageal fistulas cannot be sealed and diffuse

Fig. 1. Polyflex prototype stents of variable lengths and diameters.

mucosal bleeding unresponsive to laser treatment cannot be appropriately stopped by those devices. Bacterial adhesion to the stents sometimes poses serious long-term problems.¹ We present preliminary clinical follow-up data obtained with a novel thin-walled (0.45 mm) self-expanding cylindrical stent made of a texture of tightly woven polyester (TREVIRA) filaments. The meshes are covered with a silicone layer. The prosthesis has an elastic recoil that enables it to regain the original shape after short-lived deforming events such as cough, forced expiration, and stent insertion itself, and to adapt smoothly to wall irregularities. Because the prosthesis is completely coated with silicone, tumor and granulation tissue should not grow through the meshes. The stent should seal the bronchial wall by intimate contact with the mucosa over its entire length (Fig. 1).

Patients and methods

Patients. From September 1995 to February 1997, 19 patients have been treated. Seventeen of 19 patients had tracheobronchial complications of infiltrating cancer: five had respiratory-enteric fistulas (primary, $n = 2$; secondary, $n = 3$), 14 had mixed-type obstructions,¹ and two had diffuse blood loss from the tumor surface. Three patients had more than one complicating condition. Two of 19 patients had benign postintubation disease: malacia below the cricoid in one and considerable tracheal restenosis caused by granulation tissue as a result of the insertion of a nitinol mesh wire stent in the other (Table I).

Eight patients had relapsing tumor (esophageal carcinoma, $n = 5$; thyroid carcinoma, $n = 1$; lung carcinoma,

$n = 2$) after resection and subsequent radiotherapy or chemotherapy or both. Three patients previously had other types of indwelling prostheses inserted into the central airways. All patients had unresectable tumors when first seen or, in the case of benign airway disease, a definitive operation was delayed. Stent placement was mandatory because of stridor or respiratory distress, hemoptysis, or clinical complaints consistent with tracheoesophageal fistula. The patients gave informed consent. They were requested to undergo regular surveillance bronchoscopic examinations in our department every 2 weeks.

Operative techniques. With the patients under general anesthesia, orolaryngeal intubation was performed with the use of an operative laryngoscope attached to a chest support (Karl Storz, Tuttlingen, Germany). The tip of the laryngoscope had an internal diameter of 20 mm. It was positioned to expose the entire circumference of the vocal cords. Ventilation was sustained by a low-frequency oxygen jet through a nozzle fixed at the proximal orifice of the instrument. The laryngoscope thus served as an access for necessary manipulations within the tracheobronchial tree, and at the same time it allowed continuous administration of oxygen. Before stent placement in patients with central obstruction, a set of semirigid plastic applicator tubes of increasing diameter were used to dilate the stenosis. In five of them, mechanical debulking with a rigid forceps preceded the bougie maneuver. During dilation, the jet was attached to the tube so that efficient ventilation could be maintained. The distal end of the applicator tube was extended just beyond the aboral edge of the stenosis. For verification of the tube's correct position, which has to be marked at the outside, bronchoscopic examination through the tube is indispensable. For insertion of the stent into the applicator, an open-ended flexible basket attached to the opposite tip of the pusher entraps the prosthesis, compressing it on its way into the narrow

Table 1. Patient characteristics and management (February 20, 1997)

Patient (sex/age)	Nature of lesion	Site	Reason for stenting	Total No. of prototype stents	Observations, side effects, complications	Follow-up
1 (M/56)	Esophageal Ca	Trachea	Tumor bleeding	2	Retained secretions, bacterial adhesions	2 mo, death
2 (M/63)	Esophageal Ca	Trachea	Obstruction, secondary fistula	6	Retained secretions, bacterial adhesions, tumor overgrowth, infolding of silicone layer	10 mo, died of fatal hemorrhage
3 (M/57)	Esophageal Ca	Trachea	Obstruction, secondary fistula	2	Retained secretions, bacterial adhesions, tumor overgrowth	11 mo, died of pneumonia
4 (M/50)	SCLC	Trachea	Obstruction	1	Retained secretions	2 mo, died of metastatic disease
5 (F/75)	Thyroid Ca	Trachea	Obstruction	3	Retained secretions, tumor overgrowth	1.5 mo, died of SVC compression
6 (M/45)	Esophageal Ca	Trachea	Obstruction, secondary fistula	1		9 mo,* died of fatal hemorrhage
7 (F/64)	Esophageal Ca	Trachea	Primary fistula	2	Bacterial adhesions	1 mo, died of hepatic coma
8 (M/71)	NSCLC	Trachea	Obstruction	1		1.5 mo, alive
9 (F/74)	NSCLC	Trachea	Obstruction	1		2 mo, alive
10 (M/53)	Esophageal Ca	Trachea	Obstruction	1	Minor granulation tissue	1 mo, alive
11 (F/53)	Esophageal Ca	Trachea	Obstruction	1		2 wk, alive
12 (M/51)	NSCLC	Left MB	Obstruction	1		7 mo, alive
13 (M/75)	NSCLC	Right MB	Obstruction	1		3 mo, alive
14 (M/51)	Esophageal Ca	Right MB	Primary fistula	1	Bacterial adhesions	2 mo, died of pneumonia
15 (M/75)	NSCLC	Right MB	Obstruction	1		4 mo, alive
16 (F/68)	NSCLC	Right MB	Obstruction	1	No complete reopening	1 mo, died of pneumonia
17 (F/57)	NSCLC	Right MB	Obstruction	2		1.5 mo, died of fatal hemorrhage
18 (F/72)	Benign	Trachea	Malacia	2	Retained secretions, stent dislodgment, bacterial adhesions, minor granulation tissue	Alive
19 (M/37)	Benign	Trachea	Stricture	3	Retained secretions, stent dislodgment, minor granulation tissue, bacterial adhesions, infolding of silicone layer	Alive

Ca, Carcinoma; SCLC, small-cell lung cancer; NSCLC, non-small-cell lung cancer; MB, main-stem bronchus; SVC, superior vena cava.

*This patient was part of a previous study on the long-term effect of other common silicone stents. His death was probably due to endoscopic manipulation within a region of previous brachytherapy.¹

sheath (Fig. 2, A). After the stent has been inserted into the distal end of the tube, the basket is torn off with the stent in place. The applicator set plus indwelling pusher and stent is then guided to its premarked intratracheal or intrabronchial position. After that, the tube is drawn back over the pusher, releasing the stent into the airway (Fig. 2, B). Bronchoscopic examination then confirms the correct position of the prosthesis. In cases of improper positioning, the stent can be repositioned with the use of a rigid optical forceps. If necessary, atraumatic extraction through the relaxed vocal cords is performed with ease.

Scanning electron microscopy (SEM). Five freshly explanted Polyflex stents (Willy Rsch AG, Kernen, Germany) that had been in place 0.5, 1, 2, 3, and 10 months were placed in fixative (3% glutaraldehyde) overnight.

Both the inner and outer surfaces were gently rinsed with phosphate-buffered saline solution (pH 7.4). Subsequently, 1 cm² pieces were cut out and dehydrated through a series of ethanol dippings. Specimens were subjected to critical-point drying (Balzers CPD 020; Technotrade International, Inc. [Bal-Tec], Balzers, Liechtenstein) with carbon dioxide as the transitional fluid, mounted on scanning electron microscopy (SEM) stubs, gold coated (15 nm) in argon (Edwards Sputter Coater S 150 B; Baxter Healthcare Corp., Edwards Division, Santa Ana, Calif.), and examined with a Nanolab 2000 SEM (Bausch & Lomb, Rochester, N.Y.). Samples of hitherto unused stents (Polyflex stent, *n* = 4; Dynamic stent, *n* = 2 [Willy Rsch], and Dumon, *n* = 2 [Bess Medizintechnik GmbH, Berlin, Germany]) were gold coated at once.

Fig. 2. A, *Top*, Stent, basket, and applicator sheath. *Bottom*, Introduction of stent into applicator by means of a basket. B, *Top to bottom*, Release of the stent into an obstructed airway segment. The tip of the operative laryngoscope is located at the vocal cord level. *Inset*, Details of stent release. See text for further information.

Results

Clinical results. To date we have implanted 33 prototype stents of variable diameters and lengths into 19 patients (see Table I). The predominant location was the trachea. Two patients were provided with two serial overlapping Polyflex stents each during the first intervention to seal a large bleeding tumor area or to reopen an unexpectedly long stenotic segment of the right main-stem and

intermediate bronchi. In another two patients, indwelling Dumon prostheses were replaced by Polyflex stents. In one the stent was used to decrease air flow resistance by a more favorable inner/outer diameter ratio; in the other it was used to seal a tracheoesophageal fistula underneath the Dumon stent and at the same time bridge an obstruction located at the interface with an adjacent distal Dynamic stent. A rigid tracheal restenosis produced

Table II. Reasons for reintervention

	No. of events
Reasons for stent exchange/extraction	
Dislodgment	3
Tumor overgrowth	2
Infolding of interior membrane	2
Reasons for additional stent insertion	
Tumor overgrowth	3
Fistula extension or insufficient seal	2
Reasons for transient stenting	
Decompression by radiotherapy	1
Stent-induced widening of benign stricture	1

by granulation tissue that developed as a reaction to a nitinol mesh stent, inserted because of postintubation stricture, was dilated cautiously, and a Polyflex stent was inserted to entirely cover the nitinol prosthesis (Fig. 3, *A* and *B*).

An additional left-sided cordectomy was performed in a patient who had high-grade mixed obstruction of the proximal trachea and complete bilateral vocal cord palsy. In another patient the right vocal cord was resected 5 months later, because of stridor, along with an intact functioning tracheal stent.

Primary endoscopic treatment improved the patients' clinical condition substantially. Tumor bleeding and hemoptysis were suppressed, fistulas were efficiently sealed for a certain time (14 days, 1, 1, 3, and 6 months), and satisfying tracheobronchial patency could be achieved in all patients with benign disease and in all but one patients with malignant obstruction (see Table I).

Supplemental overlapping stents were needed in four patients who had tumor overgrowth or extension of fistula after 2 weeks ($n = 2$) and 1 month ($n = 2$). In three patients, two of whom had additional indwelling esophageal stents, secondary fistulas developed either spontaneously or after radiotherapy of infiltrating esophageal tumor underneath a tracheal prosthesis 4 and 4.5 months after the initial intervention. Overgrowing tumor necessitated stent exchange in another patient after 2 months. Continuing tumor growth and compression beyond the tracheal carina plus ostium of the main-stem bronchi in one patient required substitution of tracheal Polyflex stents by a bifurcated prosthesis (Dynamic stent)^{1,2} after 10 months. In two patients, the inner silicone layer of the prosthesis became detached from the filament meshwork and folded inside 1 and 3 months after initial treatment. These stents were replaced by new ones to prevent further luminal narrowing. Stent dislodgment occurred only

Fig. 3. *A*, Patient 19. Tracheal stent covering granulation-induced stenosis. The passage from the proximal nonstented portion of the tracheal segment to the distal portion is step-shaped. The stent adapts smoothly to the narrowing airway lumen. *B*, Patient 3. Two overlapping serial stents in the trachea.

in the benign cases and was the reason for three exchanges within 1 day to 1 month from previous treatment (Table II).

A salient feature at follow-up bronchoscopic studies was a glue-like sticky mucus inside the tracheal stents early in the postoperative course. It could be

Fig. 4. SEM. **A**, Prototype stent, outer surface. (Magnification 24.9 $\times$.) **B**, Piece of a torn and infolded membrane, outside. Rupture lines at the top of empty fiber channels (*arrowheads*). (Magnification 10.1 $\times$.) **C**, Early prototype stent, inner (luminal) surface, bird's eye view. (Magnification 249 $\times$.) **D**, Latest prototype stent, luminal surface. (Magnification 501 $\times$.)

removed after being rinsed with saline solution and secretolytic agents using a bronchoscope with an extralarge working channel. Frequent inhalation of hypertonic saline solution did not entirely prevent the adhesion of slime within the stents, but it was easier to remove. However, mucus problems were encountered only in the early prototype tracheal stents. Such problems never occurred in the bronchial prostheses that were derived from the same series or in any of the latest prototypes. Twelve of these prostheses were inserted into 11 patients since September 1996. *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Escherichia coli* were repeatedly isolated from the lavage specimens of seven patients. As of February 1997, 10 patients have died. Causes of death were acute hemorrhage ($n = 3$), pneumonia ($n = 3$), hepatic coma ($n = 1$), respiratory failure resulting from disseminated pulmonary

metastases ($n = 1$), superior vena cava syndrome ($n = 1$), and unknown ($n = 1$). Seven patients with malignant tracheal obstruction are still alive from 2 weeks up to 7 months after initial endoscopic treatment. Of the two patients with benign disease, one no longer has a stent. After removal of the prototype, he had residual low-grade obstruction without clinical significance as evidenced by a minor decrease of peak expiratory flow compared with the best flow rate before extraction (6.8 vs 7.3 L/sec). The other underwent tracheotomy and replacement of the frequently dislodged Polyflex stent by a Montgomery stent.

SEM studies. Low-magnification SEM studies of the outside wall suggest that the typical weaving texture of the polyester fibers makes the stents anchor on the mucosal surface (Fig. 4, *A*). Thin strata (4 to 10 μm) of the otherwise large silicone

layer (450 μm) span the outer vertex of the filaments, thus fixing the entire layer to the frame. Interestingly, it is through these strata that rupture lines of torn and infolded membranes run (Fig. 4, B). The inner surface of the early prototypes at low magnification (100 to 500 $\times$) and high magnification (1000 $\times$ to 2000 $\times$) has an extremely ragged appearance (Fig. 4, C). A dense agglomeration of irregular lines, frequent jagged spikes about 50 μm high, and sudden sharp brinks can be seen, as well as quite a few pores with orifices of up to 20 μm in diameter. Cells and secretory material are occasionally found submerged in these pores. The respective features can be observed both in explanted and in hitherto unused stents. The improved latest prototypes show a flat, smooth inner surface (Fig. 4, D). Dumon and Dynamic stents¹ were scanned for comparison. At low and high magnifications their luminal surfaces appear smooth and evenly structured by a delicate pattern of wavelike folds distributed in regular intervals over the whole area. No crude irregularities or micropores can be observed.

Discussion

Although biomechanical studies are still unpublished, endoscopic evidence suggests that the currently presented prototype is as resistant to extrinsic stress as are conventional silicone stents. The occurrence of membrane infolding does not argue against these properties, because the supporting fiber frame remains stable. Kinking resulting from excessive compliance or even stent fracture was never observed.

Unlike the other silicone-based prostheses that are inflexible because of massive circular coating, the new prototype readily adapts to uneven bronchial contours such as conical or step-shaped strictures. Thus stenting of complex obstructive processes is possible without excess luminal decrease or subsequent dislodgment. In addition, overlapping of sequential prototypes to extend the supported tracheobronchial segment without spatial interruption elegantly avoids exchange maneuvers that may end in fatal hemorrhage, as was reported after previous brachytherapy.¹

Benign obstruction, in particular that resulting from malacia, certainly is difficult to stent with a cylindrical prosthesis. Dislodgment may occur either because of the stent's incomplete anchoring on a normal noninfiltrated mucosa or because of large differences in tracheal cross-sectional area during inspiration and expiration associated with a low

grade of radial expandability of the stent itself. Some authors have, however, documented restoration of long-standing patency in benign stenoses with the help of mesh wire wall stents.⁵

Airway stenting in tracheoesophageal or bronchoesophageal fistulas is not a common practice. However, given that esophageal stents fail to obliterate fistulas in 33% to 70% of cases owing to the absence of tumor-associated stenosis,^{6,7} a different approach may be necessary. Indeed, airway prostheses of the currently presented type are capable of sealing connections to the digestive tract on their own, as was the case in three of five patients. The remaining two patients had additional esophageal stents. Sufficient, albeit transient, closure of tracheoesophageal or bronchoesophageal fistulas was achieved for a median of 1 month before recurrence of symptoms. This compares favorably with the 33.5 ± 25.8 days (mean $\pm$ standard deviation) during which lone esophageal stents sustain intact function in patients who have a fistula.⁸ Presumably, neither treatment will prolong mean survival over mere supportive care.⁶

For several reasons, the SEM technique was a valuable investigative tool to reveal biomaterial flaws underlying adverse clinical effects:

1. The entire membrane is suspended on the meshwork by a thin, narrow layer of silicone spanning the filaments. Dissection occurs exclusively within this layer, and infolding ensues. In other words, the most important area of the silicone stent would seem to be the weakest and most susceptible to shearing stress. Therefore a more intimate weld of filament and silicone or else a thicker outside layer should prevent its being torn off.

2. The observed features of the internal surface may have precipitated frequent episodes of mucus plugging. In view of the ragged appearance, it is conceivable that slime and cellular debris were caught in place mechanically. Additional factors may have been both a decrease in humidity in holes and pits, with secondary rapid drying out, and cellular adherence to the biomaterial.⁹

We therefore hypothesize that properties of the surface microstructure may lead to rapid adhesion of secretory particles and that, on the other hand, modification of the surface might substantially improve the issue. We scanned Dumon and Dynamic stents in parallel and found only smooth surfaces, with a delicate texture of regular wrinkles at comparable magnifications. The fact that mucus impaction in these two types of stents is reportedly^{1,3} rare

is indirect evidence in favor of our hypothesis. In addition, we did not observe problems with retained mucus with the latest improved stent types.

3. Given the frequent and repetitive culture of *Staphylococcus aureus* and *Pseudomonas aeruginosa*, as well as other gram negative strains, from respiratory secretions of patients with stents, concern has been raised over the clinical impact of chronic purulent bronchitis associated with silicone airway prostheses.¹ It was speculated that microbes might be able to damage and colonize the plastic substance, thus facilitating bacterial adhesion and subsequent chronic inflammation.¹ However, no signs suggestive of "biodegradation"¹⁰ could be found on SEM scrutiny, because the observed features were invariably present in explanted and unused stents alike. It is therefore possible that bacteria adhere to the devices, using the preformed irregular landscape. In vitro studies to quantify bacterial adherence on different stent types and materials are ongoing.

In conclusion, the mechanical properties of the new self-expandable silicone stent make it a future candidate to restore and sustain patency in malignant central airway stenoses. The spectrum of indications for silicone stents may be enlarged to involve the transient seal of respiratory-enteric fistulas and diffuse mucosal bleeding.

However, drawbacks remain: Occasional infolding of the interior membrane may lead to secondary obstruction. Owing to its peculiar microstructure, the new prototype tends to retain mucus early after implantation. Bacterial adhesion is a property shared by the other commonly available silicone stents. Frequent dislodgment in benign stenosis as a result of malacia appears to disqualify the stent for this indication.

The SEM technique provides useful information

on surface profiles, flaws, and potential changes of stent material before placement and after long-standing tissue exposure. SEM follow-up as a basis for eventual technical improvements should help to prevent untoward effects of indwelling prostheses. Before final recommendations can be given, long-term observations are warranted.

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