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Use of Endoscopically Placed Expandable Nitinol Tracheal Stents in the Treatment of Tracheal Stenosis

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Objective: **To evaluate the potential utility of a new endoscopically placed expandable tracheal stent in the treatment of benign symptomatic stenoses of the cervical trachea.** ***Study Design:*** **Pilot study utilizing a prospectively followed case series.** ***Methods:*** **An initial group of six patients undergoing stent placement was examined with rigid and flexible endoscopy under anesthesia immediately following stent placement and at postoperative 6 to 8 weeks. Subsequently each patient was followed clinically for a minimum of 6 months.** ***Results:*** **All stents were well tolerated with no observed complications. Immediate reversal of symptomatic airway obstruction without the need for adjunctive tracheotomy was noted in every patient. At 6 weeks, endoscopic confirmation of complete intraluminal mucosalization without formation of any granulation tissue or scar bands within the stented areas was noted in each case.** ***Conclusions:*** **This preliminary pilot study supports the use of nitinol expandable tracheal stents as an alternative in the treatment of benign symptomatic tracheal stenoses.**
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INTRODUCTION

Surgical resection and anastomosis or various forms of tracheoplasty represent the standard approaches utilized in the treatment of symptomatic tracheal stenoses. The longer and more severe the area of involvement, the more difficult these reconstructive procedures will become, with an increased tendency to restenose. As a result of the tremendous advances made recently in the availability of biomaterials, endoscopic placement of tracheal stents has become an attractive alternative to open surgical approaches in a number of clinical situations.

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Stenting of the tracheobronchial tree is certainly not a new concept. In 1915, Brunings and Albrecht[1] reported on the use of bronchoscopically introduced stents. A number of devices composed of silicone or metal have been tested since that early experience. Most have been plagued with stent migration or malposition, granulation tissue formation, restenosis, or erosion into adjacent structures.[2–7]

The type of stent used most widely thus far has been the Dumon stent. This device is composed of silicone plastic and is supplied in a variety of lengths and diameters. The lack of any postplacement expansion of its outer diameter and its lack of complete luminal mucosalization leave this system prone to migration. The latter characteristic also makes clearing of secretions difficult, especially soon after stent deployment, necessitating frequent bronchoscopic debridement.[8] As the Dumon stent is a rigid tube, it does not conform well to any curves within the trachea, resulting in tilting of the stent into the tracheobronchial wall in these areas. This often gives rise to troubling retention of secretions, with subsequent potential airway obstruction. The lack of mucosalization will, however, allow for easy removal of this stent, should the need arise even years after initial placement.

In an effort to decrease migration rates, expandable stents were developed. All are introduced in a compressed form and expanded after placement in the trachea by dilatation or by inherent elasticity. The Palmaz (stainless steel) and Strecker (tantalum) stents are unfolded with balloon dilatation once they are positioned.[8] The stent becomes integrated into the trachea owing to ingrowth of tissue between the meshwork. The Gianturco and Wallstent stenting systems are similar to the Palmaz and Strecker in terms of composition and tissue ingrowth for retention. However, once released from their introducers, the former two stents expand to a preset diameter owing to the uncoiling of a geometric structure. All of these expandable metal stents elongate and compress during stent placement, causing mucosal damage.[9,10] This is especially noted at the proximal and distal ends of the stent and may lead to the formation of webs and recurrent stenosis. The Wallstent and Gianturco stents have been associated with migration, leading to airway obstruction

and brachiocephalic artery perforations.[6,8] All of the metallic mesh systems have been plagued with formation of granulation tissue due to its ingrowth between the meshwork and the often noted delayed mucosalization.

Nickel-titanium alloys (nitinol) are a superelastic biomaterial. Their unusual ability to undergo large elastic deformation arises due to the presence of a definite inflection point. Such an inflection point in the unloading of coiled nitinol implies the presence of an unloading plateau with near-constant stress. Thus, a compact (coiled) system may be delivered to a small cross-sectional area and released (unloaded). While a number of metals have been noted to exhibit this phenomenon, only nitinol alloys appear to be biologically compatible with the human body. Nitinol tracheal stents have been utilized with success in the treatment of obstructing bronchial or tracheal tumors.[10] They have been exceptionally well tolerated, with no reported adverse reaction or delays in mucosalization.

The use of nitinol expandable tracheal stents (Ultraflex System, Boston Scientific, Natick, MA) for the treatment of benign symptomatic tracheal stenoses had been previously unreported. Thus, we performed a pilot study examining in detail the potential usefulness of this device in this often difficult-to-treat patient population.

MATERIALS AND METHODS

Stent Placement

All procedures are performed under general anesthesia utilizing orotracheal intubation with a 5.5 or a 6.0 Fr endotracheal tube. A Dedo operating laryngoscope with suspension system is then brought into position, allowing clear visualization of the endolarynx. At this point, we have utilized intermittent ventilation (with insertion and removal of the endotracheal tube guided by the patient's oxygen saturation status). Jet ventilation is also acceptable. A flexible bronchoscope is then passed into the trachea and the stenotic segment examined in detail. The bronchoscope is viewed under C-arm fluoroscopic guidance. The length of the stenotic segment is measured, allowing selection of a stent of appropriate length (Fig. 1). Also, metallic markers are placed temporarily on the neck skin, corresponding to the underlying stenotic trachea. If a rigid scar band is present, a holmium:YAG laser bronchoscopic resection of the segment is performed. Our initial settings are usually 1.5 J with a repeat of 10 pulses per second. It is important to realize that the nitinol stenting system has no significant capacity to dilate a stenosis. Thus complete laser resection is mandatory. The stenotic segment must be completely opened prior to stent deployment. The stent diameter should be 15% to 20% larger than the normal tracheal lumen. This value may be determined with the use of rigid bronchoscopes of varying sizes. Most adults require 18 to 20 mm diameter stents. Once the tracheal lumen has been opened, the stent is then inserted into the stenotic segment under fluoroscopic guidance utilizing the cutaneous markers to aid in placement (Figs. 2 and 3). Both proximal and distal release stents are available, as per surgeon preference. Adequacy of stent release and positioning is confirmed by subsequent fluoroscopy (Figs. 4 and 5) and bronchoscopy at the same surgical setting. Adjustments in stent position are possible immediately after stent placement with the use of a grasping forceps at the proximal end of the stent. We avoid much manipulation (and subsequent deformation of small areas of the stent due to the grasping forceps), as we suspect it may lead to alterations in the nitinol's ultimate three-

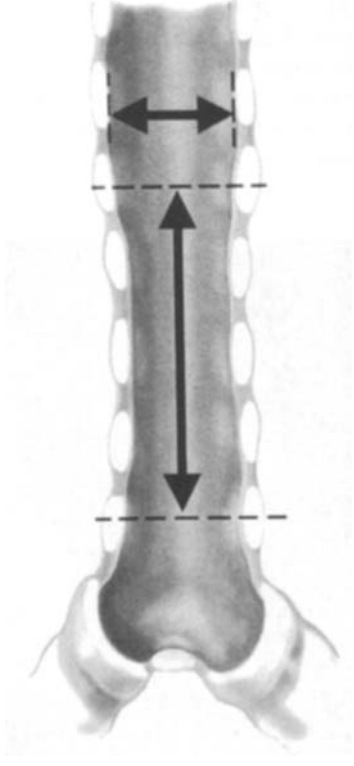

Fig. 1. Once the stenotic tracheal segment has been resected with the holmium:YAG laser or dilated, the width and length of the stent that will be required are determined.

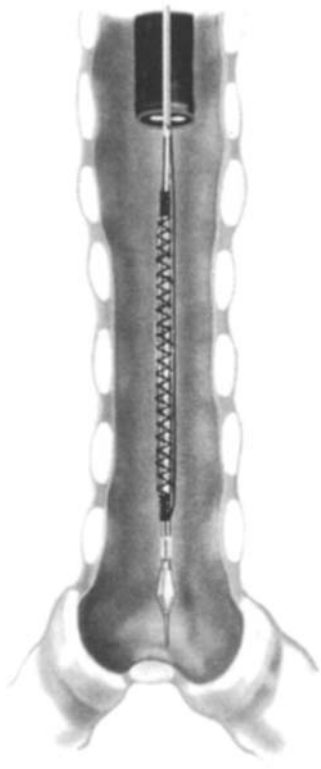

Fig. 2. Under fluoroscopic guidance, the coiled stent is brought into the determined position.

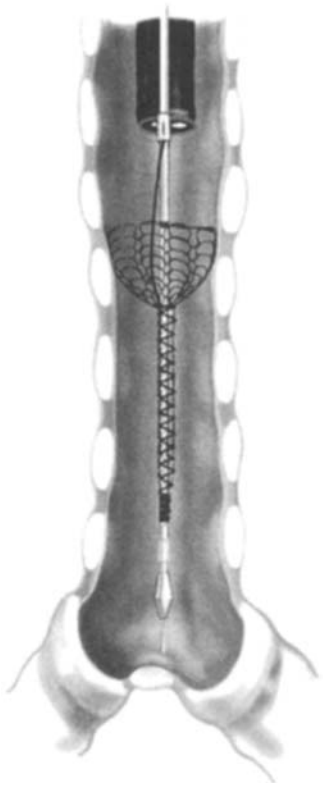

Fig. 3. The stent is next released. Both proximal and distal release systems are available. We prefer the former (as illustrated).

Fig. 4. The stent has been fully released. It will continue to expand further in the first postoperative week.

dimensional structure. Adequacy of mucosalization is confirmed at postoperative 6 to 8 weeks.

RESULTS

All stents were well tolerated with no evidence of adverse healing, scarring, or granulation tissue formation at any of the stent sites (Table I). Complete mucosalization of the intraluminal stent surface was noted in each case at the surveillance endoscopy performed at 6 to 8 weeks. All patients were noted to have marked improvement of their respiratory status following stent deployment. None required subsequent tracheostomy.

DISCUSSION

Traditional surgical resection of stenotic segments or various forms of tracheoplasty may be associated with a number of serious complications, not the least of which is recurrent stenosis. Granulation tissue is the most common cause of anastomotic obstruction, often clinically apparent at 1 week after surgery. It occurs in approximately 7% of anastomoses.[11,12] Other potential complications include airway obstruction, wound infection, swallowing dysfunction, tracheoesophageal fistula, and a mortality rate of 2.5%.[11,12] These factors, as well as the frequent need for long-term stenting of the anastomosis following open repair of long segment stenoses, with subsequent aphonia and need for a tracheotomy, led us to investigate any viable alternatives. The retention of these stents appears to be excellent thus far. The presence of complete mucosalization at 6 weeks in each patient, we believe, has prevented granulation tissue formation and subsequent recurrence of scarring and stenosis. Based on our preliminary experience, endoscopically assisted insertion of nitinol expandable stents appears at this time to represent an effective alternative to traditional surgical techniques. Our tracheal stent patients are routinely being discharged on the first postoperative day.

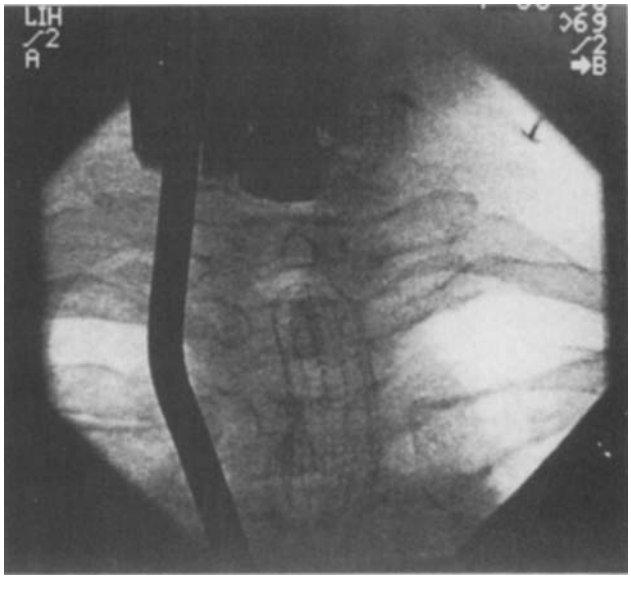

Fig. 5. Intraoperative fluoroscopic view of completely released stent.

TABLE I.
Patient Series.

Patient No.	Sex	Age (y)	Etiology	Preop Exercise Tolerance	Preop % Stenosis	Length (cm)	Postop Exercise Tolerance	Complications
1	F	51	Laryngotracheal fracture 20 y ago with 3 previous laryngotracheoplasties	1 block, no stairs	90	4	Normal	None
2	F	41	Traumatic tracheal transection with subsequent progressive stenosis	1 block, 1 set of stairs	90	3	Normal	None
3	F	54	Invasive B-cell lymphoma of thyroid with subsequent tracheomalacia	2 blocks, 1 set of stairs	80	5	Normal	None
4	F	27	Severe laryngotracheal fracture with severe subglottic stenosis	N/A (permanent tracheostomy)	80	4	Normal	None
5	M	41	Subglottic stenosis secondary to prolonged intubation	1 block, no stairs	100*	1.5	Normal	None
6	F	55	Subglottic stenosis secondary to repeated cautery excision of granulation tissue; dislodged T tube	0.5 blocks, no stairs	90	3	Normal	None

*Patient needed preoperative emergent tracheostomy.

Furthermore, the ability of these stents to be used in conjunction with open techniques, obviating the need for occlusive stenting of the anastomosis, may represent a potential advancement in the treatment of this patient population, allowing them to return to full vocal and respiratory functioning in a shorter period of time.

Although our results are quite positive, with no adverse healing, stent migration, granulation tissue, or restenosis at any of the stent sites identified to date, further follow-up of this patient population is required and will be reported in the future. No adverse consequences of this stenting system have been reported in the literature to date, other than for relatively minor granulation tissue formation in a small percentage of patients, but the potential certainly exists, as with any implantable device.[8] In the treatment of malignant strictures, it has been noted that the nitinol stenting system has been uniformly well tolerated, with none of the adverse effects listed. A coated stent is available that may decrease the ability of malignant tissue to grow into the stent prior to completion of mucosalization. It should be noted that, although all of our patients were significantly improved from a respiratory standpoint immediately after the procedure, each of them continued to improve even further over the first postoperative week. This arises secondary to the further uncoiling of the nitinol system that occurs over this period. No further changes are to be expected after this first week.

CONCLUSION

In this article we present our initial experience with the use of the Ultraflex endoscopically placed expandable nitinol stent for the treatment of benign tracheal stenoses. To our knowledge, this is the first report of the use of this stenting system for this purpose. Our experience has been quite favorable, with no adverse effects identified. All patients continue to have no significant airway compromise or any apparent tendency to restenosis at the stent sites. Further follow-up of this patient population is required before it can be recommended as the treatment of choice for this patient population.

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