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Main Article

The Larynxane ST® intralaryngeal endoprosthesis for laryngotracheal pathologies

O Chambres, P Schultz, C Debry

Abstract

Objectives: The authors present their experience of a new intralaryngeal silicone prosthesis used to manage laryngotracheal pathologies associated with severe deglutition and respiratory disorders.

Study design: This retrospective study, conducted in the head and neck surgery department of the Strasbourg University Hospital, France, included 10 patients (12 prostheses inserted) and was conducted from November 2000 to November 2003.

Methods: A pre-operative clinical examination and a computed tomography and/or magnetic resonance scan assessed patients' laryngeal function. Two different semirigid laryngotracheal prostheses were used, inserted under general anaesthetic into the region from the supraglottic area to the first tracheal cartilages including the vocal folds and the ventricles. In group one ($n = 5$), patients presented with laryngeal stenosis with preserved deglutition function, and patent prostheses were used to restore laryngeal patency. In group two ($n = 5$), patients suffered from severe deglutition disorders and were in poor general condition and so required a cuffed tracheostomy tube, therefore obstructed prostheses were inserted to stop aspirations and to suppress the cuff of the tracheostomy tube. The study was performed under the authorization of the Biomedical Research Patients' Protection Committee of Alsace I, France.

Results: The mean implantation duration was six months. The prosthesis used in the first group restored laryngeal patency without further complications such as aspiration or prosthesis (mucous) obstruction. The prosthesis used in group two prevented aspiration and allowed to change a cuff by an uncuffed tracheostomy tube.

Conclusions: The intralaryngeal prosthesis used in group one constituted a reversible and effective method of treating laryngotracheal stenoses. The intralaryngeal prosthesis used in group two constituted an alternative to classical larynx exclusion techniques. The insertion is performed in few minutes under general anaesthetic through an endoscopic procedure. This reversible technique aimed to treat patients rapidly to reduce complications and post-operative morbidity.

Key words: Prostheses and Implants; Silicone; Larynx; Deglutition Disorders; Constriction, Pathologic

Introduction

There are many different laryngeal endoprostheses, varying in material (soft or hard, absorbable or not), form and size. Stents were originally created in order to manage laryngotracheal stenoses. In 1965, Montgomery described the use of silicone prostheses to treat tracheal stenoses.[1] Following the experience of Dumon *et al.*,[2–7] who inserted a tracheobronchial stent under endoscopic vision in the late 1980s, other head and neck surgeons developed different methods of using prostheses to treat laryngotracheal pathologies.

We present our experience with two types of endolaryngeal silicon prosthesis: a patent prosthesis, used to manage laryngeal patency disorders (e.g. stenosis, tracheomalacia); and an obstructed prosthesis, inserted to suppress aspiration in patients suffering from severe deglutition disorders. The latter might represent an alternative therapeutic solution to the traditional techniques of laryngeal exclusion.

After a preliminary study (from 1997 to 1998,[8] undertaken as part of a protocol of the Biomedical Research Patients Protection Committee, Alsace I, France), we inserted 12 laryngeal endoprostheses in 10 patients, from November 2000 to November 2003, in the head and neck surgery department of Strasbourg University Hospital, France.

Patients and methods

The concept of silicone tube was first created by Dumon (Tracheobronxane®, Novatech, La Ciotat, France) to manage tracheobronchial pathologies. The Larynxane ST® prosthesis (Novatech, La Ciotat, France) looks like a polysiloxane diabolo

From the Head and Neck Surgery Department, Strasbourg University Hospital, Strasbourg, France.
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TABLE I

PROSTHESIS TYPE, IMPLANTATION DURATION AND CHANGES

Group	Patient no.	Prosthesis		Implantation duration (days)	Prosthesis change required?
		Type	Size		
I	1	P	B	270	No
	2	P	B	150	No
	3	P	C	90	No
	4	P	A	60	No
	5	P	A	330	No
II	6	O	B	660	Yes
	7	O	C	90	No
	8	O	C	6	No
	9	O	C	60	No
	10	O	C	6	Yes

P = patent; O = obstructed; A = 14–12–14 mm; B = 16–14–16 mm; C = 18–16–18 mm

with a surface treatment to improve mucus clearance and reduce the risk of obstruction. No metallic frame is designed to keep it malleable in order to facilitate the insertion of the implant. Different standard sizes are available (18–16–18 mm, 16–14–16 mm and 14–12–14 mm), but the prosthesis can be customized as required. The surface of the prosthesis is covered with studs (1 mm in diameter) to increase stability after insertion as well as to prevent necrosis of the mucosa by limiting the fulcra with the surface of the endolarynx. The prosthesis has two different functions, determined by the design at its upper extremity: patent (used in our group one) or obstructed (used in our group two).

We treated 10 patients (six men and four women) between November 2000 and November 2003 in the head and neck surgical department of the Strasbourg University Hospital. The patients' mean age was 50 years (range: 34–72 years). Twelve prostheses were used in the 10 patients (Table I): five of the patent type, in five patients (group one), and seven of the obstructed type, in five patients suffering from either laryngeal obstruction or severe deglutition disorders (group two). Before the procedure, 60 per cent (6/10) of patients had required a tracheostomy tube (uncuffed in one patient in group one, and cuffed in five patients in group II), and 60 per cent of patients (6/10) had required a feeding gastrostomy tube (one patient from group one, five patients from group two). The reasons why patients required prosthesis insertion are summarized in the Table II.

All patients had a clinical examination to evaluate their laryngeal function, as follows. A neurological and cranial nerves examination was conducted. A flexible laryngeal endoscopy examination was performed to assess vocal fold mobility, laryngeal sensitivity, tongue base mobility and laryngeal elevation (assessed by the dry deglutition test). The efficiency of deglutition was evaluated with vanilla cream. Any residual food debris in the piriform fossa was noted. A pre-operative radiological examination was also conducted using computed tomography (CT) and/or magnetic resonance imaging (MRI) to determinate the aetiology as well as to assess the cricoid cartilage diameter in order to enable correct sizing of the prosthesis.

The type of implant patients received depended on their clinical symptoms. Group one patients received a patent prosthesis (Figures 1 and 2) in order to increase their endolaryngeal diameter and to relieve their dyspnoea. Group two patients received a prosthesis obstructed at the upper extremity (Figures 1 and 2), indicated for major deglutition disorders (with the risk of severe, recurrent aspiration pneumonia). In all group 2, patients had previously undergone tracheotomy and insertion of a cuffed tracheostomy tube to avoid deglutition pneumopathies.

The prosthesis was inserted under general anaesthetic. Spontaneous ventilation was required for patients without tracheotomy. Cough reflex was suppressed by spraying xylocaine 5 per cent into the upper respiratory tract. Anaesthesia was achieved with propofol and remifentanil intravenous injection, using an oxygen ratio of one. An endoscopic examination was first performed to exclude any tumour in patients with high alcohol and tobacco use. In group one, the degree of laryngeal stenosis was concurrently assessed.

The prosthesis was positioned under suspension laryngoscopy. The silicone diabolo was slipped through the larynx. Its median part was positioned at the level of the cricoid cartilage and the upper extremity positioned so as either to face the arytenoid cartilages or to be situated immediately above them (Figures 3 and 4). The placement needed to be quick and precise. A temporary

TABLE II

PATIENT DIAGNOSES

Group	Patient no.	Diagnosis	Deglutition	Airway
I	1	Thyroid papillary carcinoma	Aph	D + pre-op T
	2	Subglottic laryngectomy + ERT	N	D
	3	Supracricoidal laryngectomy + ERT	N	D + peri-op T
	4	Laryngotracheal amyloidosis	N	D
	5	Relapsing polychondritis	N	D
II	6	Locked-in syndrome	Asp	Pre-op T
	7	Locked-in syndrome	Asp	Pre-op T
	8	Cerebral anoxia	Asp	Pre-op T
	9	Cerebral anoxia	Asp	Pre-op T
	10	Cerebral vascular stroke	Asp	Pre-op T

ERT = post-operative external radiotherapy; Aph = aphagia; N = normal; Asp = aspiration; D = severe dyspnoea; T = tracheotomy; pre-op = pre-operative; peri-op = peri-operative

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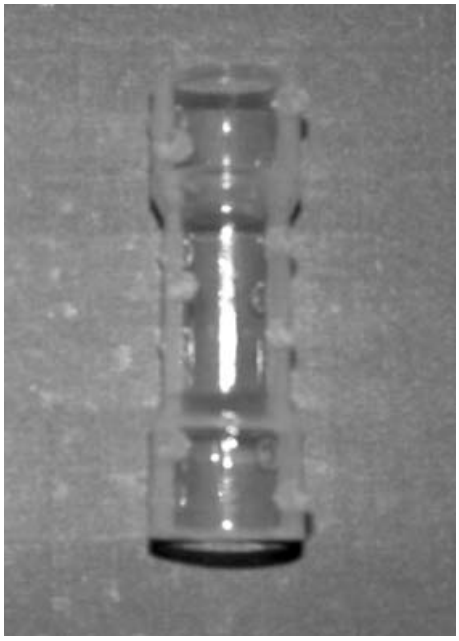

FIG. 1
Larynxane ST® intralaryngeal endoprostheses. S = studs

suture was placed through the prosthesis to allow swift removal in case of complications. A temporary tracheotomy needed to be performed for one patient to facilitate insertion of the prosthesis; this tracheotomy was closed a few days later. Each patient was monitored post-operatively on the ward for 48 hours. The post-operative results are reported in Table III (see also Figure 5). Prosthesis ablation was performed under general anaesthetic by retracting its upper extremity with biopsy forceps.

Results

The mean implantation duration for prostheses was six months (range: six days to 22 months).

In group one, one patient with a history of supracricoidal laryngectomy and radiotherapy suffered from acute dyspnoea on day nine due to a partly

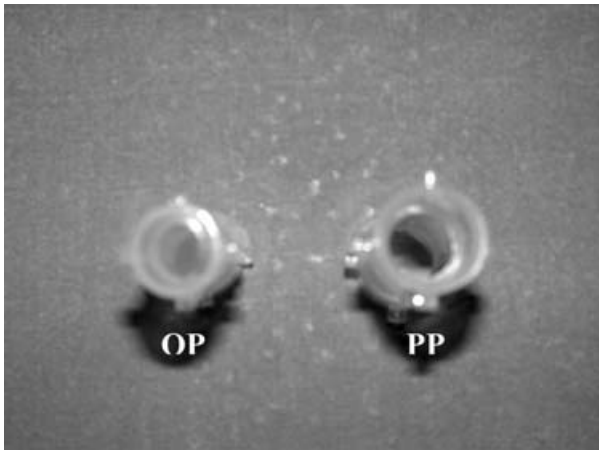

FIG. 2
Larynxane ST® intralaryngeal endoprostheses. OP = obstructed prosthesis; PP = patent prosthesis

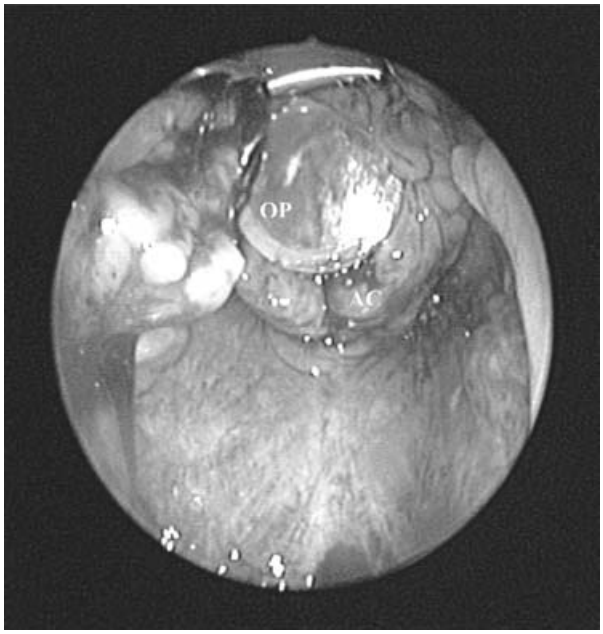

FIG. 3
Obstructed prosthesis after implantation. OP = obstructed prosthesis (above the level of the arytenoid cartilages); AC = arytenoid cartilage

obstructive granuloma. The tracheotomy was reopened as an emergency procedure. Endoscopic examination showed an arytenoidal granuloma together with epiglottic oedema that had caused mucous obstruction of the prosthesis. The removal of the prosthesis followed by granuloma laser excision created satisfactory and long-lasting laryngeal patency. In the other group one patients (4/5),

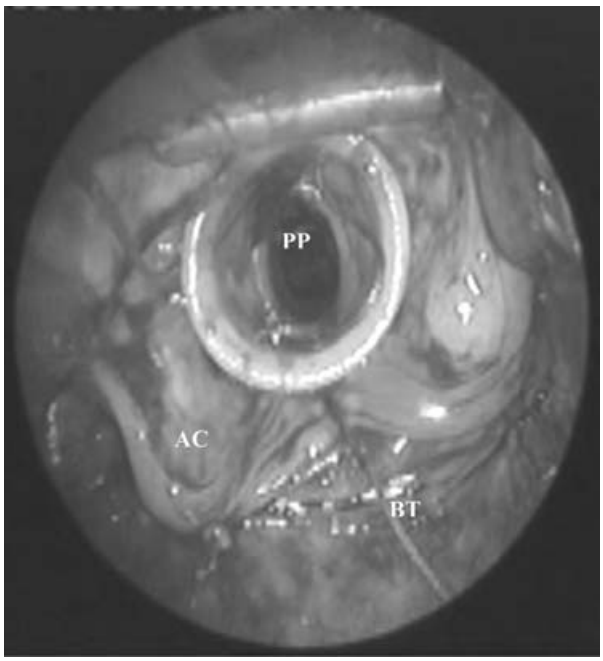

FIG. 4
Patent prosthesis after implantation. PP = patent prosthesis; AC = arytenoid cartilage; BT = bracing thread

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TABLE III

POST-OPERATIVE RESULTS

Group	Patient no.	Pain	Cough	Laryngeal sensitivity*	Airway	Deglutition
I	1	±	−	N	T −	N
	2	+	−	N	T −	N
	3	±	−	N	T −	N
	4	±	−	N	T −	N
	5	±	−	N	T −	N
II	6	±	−	I	T +	Asp −
	7	±	−	I	T +	Asp −
	8	±	−	N	T +	Asp −
	9	±	−	I	T +	Asp −
	10	±	−	I	T +	Asp −

*Before implantation. ± = painless or mild; + = pain; N = normal; I = impaired; T − = normal breathing without tracheotomy; T + = breathing with tracheotomy; Asp − = no aspiration (tested by swallowing methylene blue)

dyspnoea was reduced or alleviated immediately after the procedure. Neither mucous obstruction of the prosthesis nor post operative aspiration was reported by any group 1 patient. On post operative day 1, a flexible endoscope examination after food deglutition confirmed these findings.

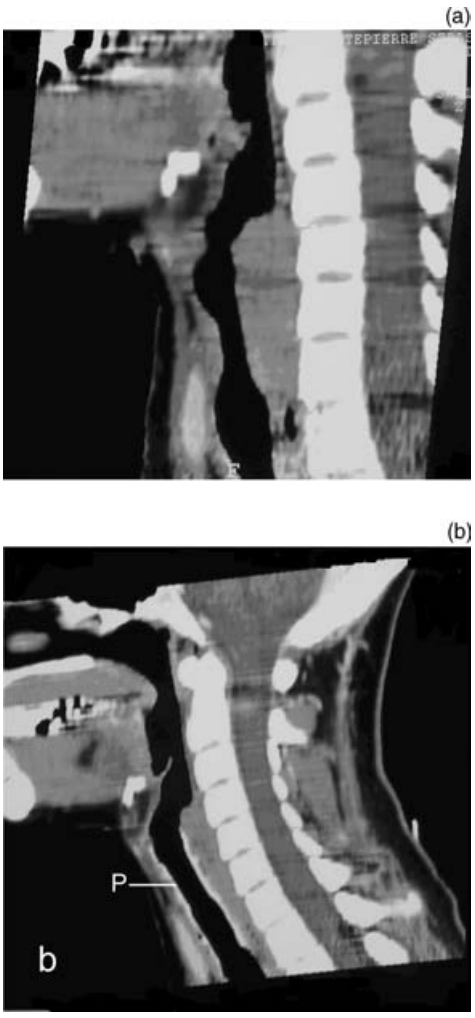

FIG. 5

(a) Pre-operative and (b) post-operative laryngotracheal computed tomography scan (relapsing polychondritis).

In group two, aspiration of food or saliva completely resolved. This was confirmed by having patients drink methylene blue in conjunction with deflation of the cuffed tracheostomy tube. Therefore, feeding could be authorized without risk of deglutition pneumopathy, and cuff complications (such as secondary stenosis or tracheomalacia) were prevented. In this group, two prostheses had to be replaced. One prosthesis (in patient number 10) was too small and resulted in a secondary mobilization. The other prosthesis (in patient number six), after a non-satisfactory voluntary ablation due to missing neurological recovered of the deglutition functions. Removal was achieved by gently retracting the upper extremity of the prosthesis.

In both groups, patients did not complain of laryngeal pain (9/10) but did report mild discomfort for up to eight days post-operatively (mean 48 hours). Analgesia (paracetamol) was administrated to only one patient (1/10, patient number two in group one). Some patients experienced temporary coughing.

Discussion

The laryngeal pathologies encountered in this study involved either airway patency or airway protection.

Laryngeal airway protection requires complex mechanisms involving both elevation and closure of the larynx. A non-functional larynx can cause deglutition disorders. Neurologic and muscular pathologies account for the main aetiologies (e.g. cerebrovascular occlusion and degenerative pathologies). These swallowing disorders can also occur as a result of partial laryngopharyngeal surgery, especially after: excision of more than 2 cm of the tongue base,[10] removal of arytenoid cartilage[11] or hyoid bone; and damage to the superior laryngeal nerve.[12] Some deglutition disorders may develop several months or years after radiotherapy of the upper airways (up to 40 per cent in the study by Lazarus *et al.*).[13,14] Classical consequences of radiotherapy include failure of laryngeal elevation, tongue base impaction deficiency, delayed pharyngeal passage time and loss of pharyngeal sensitivity[15] leading to coordination impairment.[13]

Different treatments have been proposed to manage these pathologies. Guatterrie and Lozano found that physical therapy or speech therapy could reduce deglutition difficulties from 90 to 50 per cent.[16] Medical treatment is necessary in certain conditions (e.g. myaesthenia). Surgical treatment may be suitable for a functional larynx. Myotomy of the upper oesophageal sphincter is indicated in cases of dysfunction (e.g. achalasia, Zenker's diverticulum and occulopharyngeal muscular dystrophy) or in cases of pharyngeal transit perturbation (e.g. myopathies and neurogenic causes).[17] Unfortunately, these treatments are not always possible and a tracheotomy is often performed as an initial procedure to manage severe swallowing disorders. The respiratory tract is protected by a cuffed tracheostomy tube to prevent saliva aspiration (which may cause life-threatening complications); however, this procedure

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has serious complications, including tracheal stenosis and tracheomalacia caused by trauma from the cuff or cannula.[8] Furthermore, the cannula hampers deglutition by disturbing laryngeal elevation and by reducing laryngeal sensitivity through ventilation exclusion.[18] Morbidity is thus frequent, and the treatment is difficult, expensive and has social drawbacks for the patient (e.g. regular aspirations, cannula removal, infections treated by antibiotic therapy, hospitalizations).

Swallowing disorders may also require placement of a nasogastric tube when deglutition disorders are fluctuating (e.g. myopathies). However, a nasogastric tube does not protect from inhalation risks and may even increase them by inducing interarytenoid oedema.[8,19] Gastrostomy is another solution, enabling adequate nutrition while awaiting improvement in the underlying condition,[8,20,21] but it does not offer adequate protection against the risk of pneumopathies caused by saliva aspiration or gastroesophageal reflux aspiration.

Surgical laryngeal exclusion procedures are recommended as the definitive treatment for iterative pneumopathy inhalations. They comprise partial larynx closure, but offer little reversibility. Many techniques have been described and their results are variable. Tracheoesophageal anastomosis does not avoid tracheotomy and may possibly lead to formation of a cutaneous fistula. Although the reversibility of this technique is subject to discussion, the results when used for deglutition disorders are satisfying.[22–24] Laryngotracheal separation techniques[25–27] create a subglottic bag, but cutaneous fistulas are a frequent complication.[25] According to Eibling *et al.*[26] and McIlwain *et al.*,[27] the results regarding aspiration management are satisfactory. Tucker's technique[28] is also interesting; this involves creating a double stoma and thus avoiding the need for a subglottic bag. For the management of deglutition, the results of this technique are satisfying. Nevertheless, these techniques cause nerve trauma and secondary reconstruction is difficult. The risk of fistula formation is high and tracheotomy is usually definitive. Closure of the glottis[29–31] raises the problem of stenosis, and one wonders at the acceptability of these techniques. However, aspirations are controlled and deglutition is restored. Supraglottic closure is the least aggressive and surely the most reversible procedure. Laryngeal closure at the level of the ventricular folds[32] is a simple and reliable technique for managing aspiration; its reversibility under endoscopy is satisfactory, but it does not guarantee phonation recovery and the sutures sometimes break. In cases of epiglottic flaps, according to Castellanos,[33] a cervicotomy is preferable to a endoscopic procedure, the latter being more difficult. Aryepiglottopexies[34–36] and epiglottopexies[37] are complicated by suture breakdown (the best series reported a 50 per cent success rate) but phonation is preserved, at the expense of a whispered voice. These procedures were attempted in our surgical department from 1992 to 1997, but because of bad results[8] we decided to use intralaryngeal endoprostheses instead.

Laryngeal stenosis causes progressive narrowing of the larynx lumen followed by organic alteration of the airway walls due to tissue proliferation. Causes include: external trauma; laryngeal surgery; resuscitation; burns; and laryngeal infiltration due to such disorders as tuberculosis, Wegener's granulomatosis, amyloidosis, relapsing polychondritis[38] or, rarely, secondary to diphtheria. Laryngeal stenoses may cause dyspnoea, dysphonia and, infrequently, deglutition impairment (the latter occurring in 6 per cent in the study by Chabolle).[39]

Treatment of laryngeal stenosis is based on enlarging techniques: endoscopic dilatation; microsurgery with laser; laryngotracheoplasty via external approach;[40,41] endoluminal stenting by Aboulker's tube;[42] and use of Montgomery's T-tube[1] or other metallic and silicone stents.[43–45] Tracheal end-to-end anastomosis, the association of a surgical procedure on the glottic area together with a silicone stent insertion, has been described for some indications.[46,47]

We consider intralaryngeal endoprosthesis to be a real alternative to the above surgical techniques, which are much debated and sometimes irreversible. Endoscopic insertion under general anaesthesia is simple. The equipment needs to be improved however to compare to Dumon's prosthesis which is inserted with the help of a push prothesis. In order to avoid granuloma formation, the prosthesis must be placed above or facing the arytenoid cartilages, especially for long term placement. In addition the Larynxane ST® prosthesis do not traumatize the mucosa and is easily removed under local anaesthetic (in contrast to metallic stents).

From our experience, patent intralaryngeal prostheses prevent aspiration as long as the function of the tongue base is preserved. Use of this prosthesis requires consideration of the neurological integrity of hypopharyngeal peristalsis as well as exclusion of most central neurological diseases and surgical injuries. In our study, patients managed with this type of prosthesis (i.e. group one) did not present with aspiration. Obstructed intralaryngeal prostheses, like uncuffed tracheotomy tubes, facilitate feeding rehabilitation by suppressing aspiration.[8,48] After insertion, patients complained of dysphonia caused by impairment of vocal fold movement and also by the modification of the glottic area caused by the prosthesis. Patients must be informed prior to insertion of the likelihood that they will develop a whispered voice. However, following ablation and speech therapy, there was no vocal dysfunction and no cricothyroid ankylosis. This vocal reversibility is very important. Compared to the other prostheses in use (Aboulker and Montgomery's T-tube), the Larynxane ST® prosthesis offers a low risk of granuloma formation; nevertheless, the risk rises if the prosthesis is situated under the arytenoid cartilages.

It should be noted that an intralaryngeal prosthesis represents a foreign body which may move during resuscitation procedures (during tracheal intubation, for example). The patient must therefore be clearly informed of the implications of their prosthesis.

Conclusion

The Larynxane ST® intralaryngeal endoprosthesis represents a real alternative to classical laryngeal exclusion techniques in the management of severe deglutition disorders. Some indications extend to laryngotracheal stenosis with preserved deglutition. Insertion and withdrawal are simple and the device aims to treat rapidly patients in poor general condition by reducing operative and post-operative morbidity. The reversibility of this technique is also an advantage, especially in acute laryngeal disorders in which potential recovery is possible. The results of our study will encourage us to continue using intralaryngeal endoprostheses.

- **This paper describes the authors' experience with the use of a semi-rigid laryngotracheal prosthesis for the management of upper airway pathology**
- **The prosthesis was used in two groups of patients. In the first group, a hollow prosthesis was used to restore laryngeal patency in patients with stenotic airways. In the second group, a solid prosthesis was use to prevent laryngeal aspiration in patients with tracheostomy and severe deglutition disorders**
- **The technique of insertion and the surgical results are described in detail**

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Address for correspondence:
Dr Olivier Chambres,
Service de Chirurgie ORL et Cervico-faciale,
Hôpital de Hautepierre,
Avenue Molière,
67098 Strasbourg cedex, France.

Fax: (+33) 388127646
E-mail: olivier.chambres@chru-strasbourg.fr

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