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General Introduction

The increasing use of voice prostheses has improved the prospects of vocal rehabilitation after total laryngectomy considerably. Consistently high success rates have been reported in the last 35 years, after the first description of a useful prosthetic device by Singer and Blom in 1980.1 Compared with esophageal and electrolarynx speech, a higher percentage of patients achieve an acceptable voice, enabling communication under almost all social circumstances. Success rates up to 90% are not exceptional any longer, making prosthetic voice rehabilitation the method of choice for early and reliable restoration of oral communication after total laryngectomy.2

In general, two types of voice prosthesis can be distinguished, i.e. non-indwelling and indwelling devices. The former devices can be removed and replaced by the patient. The latter stay in place permanently and have to be removed and replaced by the clinician at the end of the device life, which is determined by leakage of fluids through the prosthesis or an increased airflow resistance. Indwelling devices have the definite advantage that the patient's dexterity plays a less important role in the daily maintenance of the device, which mainly consists of cleaning with a brush and/or a flushing device without the need of regularly replacing the prosthesis. Even with increasing age and/or decreasing health a useful (prosthetic) voice can be preserved.

Based on our experiences with surgical and prosthetic voice rehabilitation (Staffieri’s procedure, and the Blom-Singer, Panje, and Groningen prostheses), acquired since 1979 in the Department of Otolaryngology-Head & Neck Surgery of the Netherlands Cancer Institute, we co-developed since 1988 a novel low-resistance, indwelling silicon voice prosthesis, Provox, in close collaboration with the medical engineering industry.3,4 It has been successfully used in our Institute since then in all laryngectomized patients. The long-term clinical results obtained with this voice prosthesis are favorable.2,5-7

Additional instruments and devices to facilitate its application have been developed as well.3 Their use, along with the surgical techniques involved and the management of many of the clinical and technical aspects, are the subject of this manual. The subsequent development of a second generation (Provox2) voice prosthesis for bidirectional, i.e. anterograde and retrograde, application is a further improvement of the Provox system.8 The anterograde replacement in the outpatient office has considerably decreased the discomfort of this procedure for the patient and the medical professionals involved.8,9 Further improvements since development of Provox2 will be discussed in the various voice rehabilitation chapters.

The problem of post-laryngectomy pulmonary function disorders has also been addressed extensively in our clinic.10-12 The relevance of simultaneous pulmonary rehabilitation for optimal voice restoration and an improved quality of life has become increasingly clear in recent years.13-15 The development of a novel, dedicated ‘valved’ Heat and Moisture Exchanger (HME, Provox HME) has added a new tool to the armamentarium of the clinicians, in this respect.16-18 Further improvements since the development of the first generation Provox HMEs will be discussed in the various pulmonary rehabilitation chapters.

Hands-free speech is the ultimate goal of postlaryngectomy voice rehabilitation, preferably taking care of pulmonary protection and rehabilitation at the same time. This is now possible with the newly developed Provox FreeHands HME.19 Further improvements since the development of FreeHands will be discussed in the chapter on hands free speech.

A further problem resulting from the permanent disconnection of the upper and lower airways is a deterioration of the sense of smell. The main cause for this disturbing side effect of total laryngectomy is the lack of a nasal airflow, which normally transports odorous substances to the olfactory epithelium high up in the nose. There are two types of smelling: ‘passive’ and ‘active’ smelling. Passive smelling continuously takes place during normal nasal breathing, whereas active smelling (‘sniffing’) is used intentionally. Research in our Institute has given more insight in the magnitude of the olfaction problem after total laryngectomy.20 Stoma breathing precludes passive smelling and only some 30% of the patients is still able to actively smell something. However, it now appears to be possible to restore olfaction in a considerable number of laryngectomized individuals.21,22 The nasal airflow-inducing maneuver (NAIM, also called ‘polite yawning’ technique, since that is what the maneuver is mimicking) enables active smelling again, will be described in detail. Further research underpinning the validity of the NAIM, since it’s conception early 2000, will be presented as well.
It should be stressed that vocal, pulmonary and olfactory rehabilitation after total laryngectomy is a multi-disciplinary team effort and that the motivation of the Otolaryngologist, the (Head Neck) oncology nurse, the speech therapist and last, but not least, of the patient is mandatory to obtain optimal results.

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References

The Provox System

1. Provox

The original Provox voice prosthesis, developed between 1988-1990, is a self-retaining, indwelling, easy to manage device for prosthetic voice rehabilitation after total laryngectomy (TL).

The prosthesis is suitable for laryngectomized patients with a tracheoesophageal puncture (TEP), also when created for several other types of voice prostheses. The Provox voice prosthesis is made of medical grade silicone rubber and is available in four lengths, i.e. the distance between the esophageal and tracheal flange is 4.5, 6, 8 or 10 mm. The other dimensions of the prosthesis are: diameter of the esophageal flange 14.5 mm, oval tracheal flange 12 x 16 mm, inner diameter of the shaft 5 mm and outer diameter 7.5 mm (i.e. 22.5 Fr.). The tracheal flange entails an introduction string.

The valve is molded in one piece with the prosthesis and is supported by a radiopaque ring (20% barium sulphate), to enhance the visibility on X-ray examination. The prosthesis is packed together with a disposable scalpel and the disposable guide wire.

The Provox voice prosthesis is inserted in the TEP tract and remains in situ without replacement by the patient. Primary introduction at the time of TL is the method of choice, but secondary introduction at a later stage is also easily accomplished. For the introduction and replacement of the prosthesis a special Guide Wire is available. This disposable instrument has a connector for easy attachment of the introduction string of the new prosthesis and an 8 mm stop for transoral removal of the remnant of the old prosthesis. It has a flexible tip, which facilitates its retrograde introduction through the esophagus and pharynx. If the guide wire becomes entrapped in the pharyngeal mucosa wall, the wire will bend near the tip and can still slide upwards through the pharynx.

2. Provox 2

In 1996-1997 a second generation Provox voice prosthesis, intended for anterograde and retrograde use, Provox2, has been developed. This adapted prosthesis can be inserted during primary TEP at the time of laryngectomy, or during a secondary procedure at a later date, in the same manner as the original Provox prosthesis, using the separately available guide wire. Replacement in the outpatients office, however, can be carried out now in an anterograde manner directly through the tracheostoma.

For this replacement a simple disposable tool, consisting of a loading tube and an inserter, is used (figure right). The Provox2 is available not only in 4.5, 6, 8, and 10 mm shaft lengths, but also in two additional lengths, i.e. 12.5 and 15 mm (figure left). The dimensions of the Provox2 prosthesis are comparable with those of the original Provox device, but the flanges have been adapted. The flanges are thinner: the esophageal flange is 1.5 mm instead of 1.6 mm to enable easier removal from the fistula tract, and the tracheal flange is 1.3 mm instead of 1.6 mm, to make the resistance towards the esophagus lower than that towards the trachea, to decrease the possibility of inadvertent dislodgment into the trachea. Furthermore, the valve construction has been improved and the tracheal flange contains the size number, allowing in vivo identification of the length of the prosthesis.

3. Provox Vega and Smart Inserter

Recently a third generation Provox voice prosthesis, Provox Vega, with a novel insertion system, called Smart Inserter, has been developed. The main advantage of this completely redesigned voice prosthesis is that its airflow characteristics have been optimized through an increase of the internal diameter without altering the external diameter of 22.5 Fr, an angled position of the valve and a valve seat that keeps the valve free of the silicone part of the prosthesis. Moreover, the valve is less prone to come into direct contact with the esophageal mucosa, because of its internalization and a 360-degree hood at the esophageal side. This decreased airflow resistance makes voicing for many patients easier, as was observed in the various studies that have been carried out in recent years. Moreover, the insertion with the Smart Inserter makes replacement of the device in many instances considerably easier. Besides a 22.5 Fr version, the real successor of Provox 2, the Provox Vega prosthesis is also available in 20 and 17 Fr versions, also with optimized airflow characteristics.


4. Provox ActiValve

Provox ActiValve is a voice prosthesis specially developed for a sub-group of patients with a much shorter than average device life (see also Troubleshooting - very frequent replacement). This short device life is not only caused by excessive and early biofilm formation, but also because of an under-pressure in the esophagus during breathing and swallowing, which opens the valve regularly.
The biofilm problem is addressed through the use of Teflon-like material for valve and valve seat (on the left the normal ingrowth of biofilm in the silicone rubber; on the right the thinner biofilm laying on top of the inert fluoroplastic).\textsuperscript{27}

The under-pressure issue is solved by incorporating magnets, which counteract this and cause an active closure of the valve (pictures below). This has resulted in a voice prosthesis, which shows a significantly longer device life than the regular Provox devices.

Below a voice prosthesis is shown that for one-year has been in situ in a patient, who required a replacement of his Provox 2 voice prosthesis every 3 weeks. Leakage occurred because the hinge has become unstable, but valve and valve seat are still clean/intact.

In a long term study, in a patient cohort with a median device life of 21 days, the ActiValve prosthesis had a median device life of 337 days, which means a 16 fold increase (p<0.001;
In a study in the USA similar median device life was found for ActiValve, making this a very cost-effective solution for patients, who require frequent replacements.


5. **Provox Vega XtraSeal**

The Provox Vega XtraSeal is a voice prosthesis with an second, extended (18mm), and thin (0.5 mm) esophageal flange for the treatment of periprosthetic leakage. The extended flange is only attached to the center portion of the standard esophageal flange and is angling downwards to enhance the contact of the esophageal mucosa and TEP tract, and thus the effectiveness of the sealing. The Vega XtraSeal can be inserted with the standard Smart Inserter, but overshooting is recommended to ensure complete extension of the extended flange in the esophageal lumen (see animations of insertion with overshooting and voice prosthesis reloading below).

Removal of the voice prosthesis is uneventful, despite its extended flange, which only slightly increases the pullout resistance, also keeping in mind that the XtraSeal is used in TEPs that show peripheral leakage and thus are not tight. An advantage of the slightly higher pullout resistance is that the risk for dislodgment towards the trachea is also low. This principle of extended esophageal flange successfully has been explored in the literature and the initial clinical experiences are favorable.


6. XtraFlange

Peri-prosthetic leakage is one of the more annoying issues patients can have. This is a co-morbidity issue, with reflux and pharyngeal stenosis as the most prominent risk factors for developing TEP enlargement and thus leakage around the prosthesis. When the VP has the right length, a good solution can be to add a washer behind the tracheal flange to increase the cover of the TEP (see picture). The technique for adding a washer, either custom-made (figures left), or as the Provox XtraFlange (figure below left), by using two hemostats can be seen on the video below. A study has shown that this often can be an excellent short-term solution, which gives time for the long-term solution, i.e. proper reflux treatment and/or dilatation of the pharyngeal stenosis.

7. Provox Surgical Instruments

For the creation of the TEP tract a special Trocar and Cannula (figure left) has been developed (originally designed by Kees de Leng, former instrument maker at The Netherlands Cancer Institute), which can be used both for primary and secondary puncture (figure below left). For secondary TEP a Pharynx Protector has been designed for protection of the posterior esophageal wall and the fingers of the surgeon during primary TEP (according to an idea of I Bing Tan; figures below middle and right). The handle of this instrument can be rotated to accommodate both right and left-handed surgeons. Both instruments have been used successfully since their original description in 1990.³


8. Provox Vega Puncture Set

With the development of the Provox Vega Puncture Set,³⁴,³⁵ the original Provox Surgical Instruments and its imitations have largely become obsolete. Here are the reasons why:

1. Tracheoesophageal puncture (TEP) with primary fit of the indwelling voice prosthesis has become the standard of care both for primary and secondary procedures for voice prosthesis implantation after total laryngectomy
2. The classic TEP technique with a re-usable trocar and cannula required re-sterilization and maintenance of the instrument; regular/repeated maintenance is important since the sharp tip of the trocar is ‘vulnerable’ and often gets blunt because it ‘hits’ on the metal pharynx protector after the puncture tract is made. Thus maintenance means regular sharpening of that tip, which is the actual TEP creating part of the instrument.

3. The new PVPS system is disposable and thus the needle is always optimally sharp
4. The diameter of the classic trocar and cannula was 5 mm and that of the new PVPS needle measures only 2.5 mm, which obviously lowers the tissue trauma of the TEP procedure
5. The ‘Seldinger type’ introduction method of the new PVPS with gradually dilatation of the TEP tract in combination with a sling introducing the tracheal flange in stead of metal instruments further lowers the tissue trauma of the TEP procedure.
6. Increasingly TEP with primary fit is carried out in patients requiring total laryngectomy for chemoradiotherapy failure and in these cases lowering the trauma of the procedure is even more important.

The PVPS system consist of a puncture needle, a guide wire, a dilator with the pre-mounted Provox Vega voice prosthesis, and a pharynx protector (only to be used for primary TEP during a total laryngectomy; pharynx protection during secondary TEP should be accomplished with an intraluminal device, e.g. a rigid esophagoscope). The TEP procedure with the PVPS is simple and straightforward, as is demonstrated in the animations of primary and secondary TEP (below top left and right) and the videos of a primary and a secondary TEP (below bottom left and right).


9. Replacement accessories: Measure - Dilator

It is important to use a voice prosthesis that has the correct length. Although a slightly too long device is seldom a problem, a too short prosthesis is troublesome and might cause problems with the TEP tract. In most instances, the existing prosthesis can be used as its own measuring device. By gently pulling with a forceps at the tracheal flange, it can be determined easily, whether the device still is of the proper length. In case the length of the (already for some time established) TEP tract is not known, the Provox Measure (figure right) can be used to determine the size of the prosthesis needed. The measure has a disposable flange on its tip, which is inserted into the TEP tract. After the flange is allowed to open up in the esophagus, the sliding part of the device is gently pushed against the trachea back-wall, and the TEP length can be read on the scale (figure right). After having established the right size of the prosthesis, the measure is tilted out of the TEP tract.

Warning: the Provox measure should not be used during surgery to establish the length of a freshly created puncture tract or in a 16 Fr tract. The disposable flange has 2 different sides: a curved one for a 22.5 Fr TEP tract and a ‘hollow’ side, which allows easier removal out of a 20 Fr TEP tract.

The TEP tract of a Provox prosthesis does not need dilation during replacement of the device. However, if prostheses with a smaller diameter are replaced by one of the Provox prostheses, the procedure might be easier after some dilation of the TEP tract, using the Provox Dilator (figure). Some guidelines are: in a 16 Fr TEP tract insertion of a Provox 4.5, 6, or 8 mm can be attempted without dilation, but in most instances, especially in case a longer prosthesis is needed, the dilator should be applied first. The device can be lubricated with some gel and gently inserted in the TEP tract until a diameter of 24 Fr and left in situ for 10-15 minutes (figure). After removal of the dilator, the insertion of the Provox prosthesis should be carried out immediately, in order not to loose the dilation effect. In a 20 Fr TEP tract dilation is seldom needed, because of the retrograde insertion of the Provox (1) prosthesis and the conical end of the Provox2 insertion tube.
10. Maintenance support: Brush – Flush– Shower Aid – Plug

To facilitate the daily maintenance of the prosthesis a special Brush has been developed. This brush has a collar to preclude insertion too deep into the prosthesis and a round tip to prevent damage to the esophageal mucosa. The cleaning of the prosthesis with this brush is effective and safe. After its use the brush can be cleaned easily with water and stored dry. It can be used for several weeks until worn out. Just like a toothbrush, the brush does not and should not be sterilized or kept in any disinfectant solution.

For the longer devices (12.5 and 15 mm, an extra long brush is available (Brush XL).

Also available is a flushing device (Provox Flush), which enables easy and save flushing of the prosthesis, for instance with tap water. An additional benefit of this device is that it assists in the clearance of the pharynx from the sticky mucus, which as a result of radiotherapy many laryngectomized patients have. They often report that this flushing gives them a fresh feeling in the throat and an easier start in the morning.

An additional ‘daily maintenance’ device is the Provox Shower Aid, used in conjunction with an adhesive baseplate (figure right) or an intrastomal device (LaryTube/LaryButton), which prevents aspiration of water during showering.

Prosthesis replacement is almost always indicated because of transprosthetic leakage due to biofilm formation/candida overgrowth causing insufficient valve closure. For temporary control of transprosthetic leakage a special Plug has been developed. If thorough internal cleaning of the
prosthesis with the Provox brush or flush does not solve the leakage and the valve remains incompetent, replacement of the prosthesis is indicated. In case the patient is not able to have the prosthesis replaced at short notice, for instance during weekends or holidays, this plug can be used during the consumption of liquids (solid food only rarely causes problems). The plug can be easily placed on top of the handle of the cleaning brush and then be plugged into the tracheal opening of the voice prosthesis. The plug contains a string with a proper sized button to prevent its loss into the trachea. It is suggested that all patients are provided with this plug, especially if they are not living close to their hospital or when traveling abroad. In practice, it has been shown that, since most of the time leakage is mild, the patient does not have to bother organizing replacement of the prosthesis somewhere else, but instead with the application of this plug can postpone this procedure for several days until a visit to his/her own clinician can be arranged.

11. Heat and moisture exchangers (HMEs)

Total laryngectomy results in a short-circuiting of the upper respiratory tract, which inevitably leads to significant pulmonary problems.\textsuperscript{10} For the prevention and treatment/rehabilitation of these pulmonary problems, heat and moisture exchangers (HMEs) have proven to be very useful and effective.\textsuperscript{13-15} With the development of ‘valved’ HMEs, which have made digital closure for voicing easier and more comfortable (the first generation (Provox HMEs),\textsuperscript{16} and the second generation (Provox XtraHMEs)\textsuperscript{36}), compliance and voice quality have further improved.\textsuperscript{17,18} Not only are these devices effective to significantly reduce pulmonary and psychosocial issues, and thus quality of life, but also have been shown to improve voice rehabilitation results. Some of devices are shown in the figure below. Clinical and physiological research about HMEs will be discussed further and extensively in the chapters on pulmonary rehabilitation.


12. **Automatic Speaking Valves (FreeHands/FlexiVoice HMEs)**

A solution for the need for digital stoma occlusion in prosthetic tracheoesophageal speech is the use of an automatic speaking valve. Such a device should not only incorporate a valve mechanism that allows airtight occlusion of the stoma and, thus, diversion of pulmonary air into the pharyngoesophageal PE segment (or neoglottis) for voicing, but also should optimally integrate a heat and moisture exchanger (HME), which is indispensable for pulmonary rehabilitation.

The Provox FreeHands HME (see figure left) is an automatic speaking valve, which has the following properties:

- An HME is the basic and mandatory part of the device, situated directly in front of the stoma to keep the valve free of mucus;
- Inhalation takes place through side openings to allow breathing in pre-heated and pre-moisturized air from the body;
- Voicing is possible with low air pressures by keeping the flexible speaking valve closed with magnets;
- The speaking valve comes in three different flexibilities to accommodate individual patient needs;
- A locking position protects against involuntary closure of the speaking valve during physical exertion (walk and talk position);
• A self-centering, freely movable cough relief valve acts as cover, and the force needed for its opening is individually adjustable by means of magnets;
• Optimal cleaning and hygiene is achievable by means of a special cleaning container;
• The device is usable in combination with existing valve housings, e.g. Provox HME adhesives and/or LaryTube cannulas.

The FreeHands HME has been extensively tested and has found a widespread acceptance, provided that a complete and prolonged airtight seal can be achieved for optimal stoma occlusion.  

In order to achieve that optimal sealing, a wide variety of stoma adhesive baseplates and/or an intraluminal device (LaryButton) are available (see below).


The Provox FlexiVoice HME is a new automatic speaking valve (ASV) with integrated HME. It is the first ASV that combines automatic valve closure with the option to also manually occlude the device to speak. This is possible because the speaking valve has a front opening and an internal flexible membrane. When the patient starts to speak, the natural increase in exhalation airflow closes the membrane (Figure left). The exhaled air is thus diverted through the voice prosthesis, which allows handsfree tracheoesophageal speech.

Alternatively, the patient can choose to occlude the opening in the front with his/her finger to speak. Rotating the top of the device moves the FlexiVoice into the ‘locked mode’, or into the ‘automatic speaking mode’ (Figure above middle). In ‘locked mode’, the membrane is prevented from closing with a hook grabbing a ring at the backside of the membrane (Figure above right). Thereby, the patient is ensured of unrestricted and comfortable breathing during physical exertion, still allowing manual occlusion for speech. Three versions of the speaking valve are available, each with a different flexibility/strength of the membrane: light, medium and strong. When coughing is needed, the membrane pops out through the front opening and the patient can push the membrane back manually.

There is an optional arch that can be attached on top of the device to prevent the front opening of being occluded by clothing (Figure right).

Just like with the FreeHands HME, for achieving an optimal airtight seal, a wide variety of stoma adhesive baseplates and/or an intraluminal device (LaryButton) are available (see below).

13. Peristomal adhesive baseplates

For proper application of HMEs, peristomal adhesive baseplates are indispensable. Although for esophageal speakers optimal airway humidification is also best achieved with a good seal between baseplate and peristomal skin, in order to ‘guide’ all the inspiratory and expiratory air through the HME, this seal is even more important for voice prosthesis users. For these latter patients a complete airtight seal is prerequisite for good and comfortable voicing, both with HME and ASV. Since both these devices sometimes have to be removed, e.g. for cleaning the stoma of mucus, it should be possible to leave the baseplate attached. This was not possible with the first generation HME, but since the introduction of the first Provox HMEs this has become the gold standard and a major contributor to the compliance with HME use (see Figure below left). Already with the first generation Provox HME’s, there was also the notion that different adhesives were mandatory, in order to accommodate various skin vulnerabilities. It also has become apparent that proper handling of the adhesive baseplates is imperative for the prevention of skin irritation. Skin irritation is mainly a result of the quite extensive sheer forces exerted onto the skin when removing the adhesive without using a glue dissolving solution (e.g. Remove®). Skin irritation also can be diminished/prevented with the application of hydrocolloid adhesives. In recent years, the variation in adhesive baseplates has gradually increased (e.g. the StabiliBase baseplate; Figure below right), providing further options for patients to successfully apply HMEs and/or ASVs.


For patients who need a cannula to stabilize the stoma, a special cannula system (the Provox LaryTube) is available, also enabling the use of an HME without the necessity to use an adhesive (see figure right). A very practical feature of this system is that for those patients, who only use a cannula during the night, there is a LaryTube version containing a blue ring that fits in any of the Provox Adhesives (see figure right). This enables the patient to wear the HME in the usual adhesive baseplate during the day, and at nighttime to use the cannula without the need to remove the adhesive baseplate, if this is still properly glued in place. A LaryTube with a blue ring inserted in an adhesive is also useful for combination with the Provox FreeHands HME. The cannula in the trachea stabilizes the automatic valve during voicing, which decreases the pressure on the adhesive even further, and potentially increases the time an airtight seal can be kept. Another advantage of the LaryTube cannula is that it enables the patient to use an HME during the postoperative radiation period, when the use of adhesives is often not recommended by most physicians, even not the hydrocolloid version (OptiDerm). Also in case of an irritated skin, when
the use of adhesives is (temporarily) not possible, patients can still wear an HME, by using a LaryTube cannula.

There is also a fenestrated version of the LaryTube, which is ready for use in patients with a voice prosthesis.

There is also a fenestration punch (see figures) for individualized fenestration of the standard LaryTube (with or without the blue ring).

Application of a HME and/or ASV also can be achieved with an intrastomal device, the LaryButton. It is made of a soft silicone rubber material, which can be folded inwards to ease its insertion into the stoma. The dimensions of the external retainer are optimized for the retention of the
FreeHands/FlexiVoice ASVs. The conical shield provides a proper anatomical transition between the retainer and the intratracheal part with smooth edges in the peristomal area to improve airtight sealing. The conical shield also helps to accommodate different stoma sizes, as the exact length of the button is of less importance in achieving an airtight seal, compared to a straight shield (like in the Barton-Mayo Button). The edges of the tracheal rim are smooth and it is possible to attach a neckband to improve the intrastomal retention (Figure).

To optimize retention, it would be easier if, contrary to the upward traction neckbands exert, the extrastomal fixation exerted a downward traction towards the stoma and trachea lumen. Therefore, the attachment system was renewed as well. This now consists of Velcro clips and adhesives, the LaryClips and adhesives). This novel fixation system provides safe anchoring of the button and limits its inadvertent loss, e.g. during coughing. It also diminishes intratracheal movements of the button (compare Figures below middle (no speech), and right (patient speaking)), limiting trauma to and widening of the stoma and thus reducing the need to replace the button with one of a larger diameter during the day. It has turned out to prolong ASV wearing time and comfortable hands-free speech in more patients without making the system too complicated.

1. Primary prosthetic voice rehabilitation

1.1 Total Laryngectomy

Primary prosthetic vocal rehabilitation with immediate insertion of the indwelling voice prosthesis during total laryngectomy is (our) method of choice. A rule of thumb is, that if a patient is fit enough to be submitted to this surgical procedure, he/she is fit enough for this simultaneous prosthetic voice restoration procedure. There are no obvious contraindications against this policy, except when the tissues are in a 'too poor condition', such as after exceptional high doses of radiotherapy, i.e. exceeding 70 Gy in 7 weeks, or equivalent doses, or after combined chemotherapy and radiotherapy.

Optimal results of voice rehabilitation with an indwelling Provox voice prosthesis can only be obtained if the technique of total laryngectomy meets certain requirements. Besides keeping in mind the standard oncologic principles, care should be taken to create a pharynx, which is wide and ‘flexible’ enough to enable effortless speech, without hypertonicity of the constrictor pharyngeus muscles. Furthermore, the tracheostoma should be wide enough for comfortable breathing and narrow enough to be easily occluded by the patient when speaking, although the latter 'requirement' has become less important with the availability of Provox HMEs fitted in a peristomal adhesive baseplate.

In the Netherlands Cancer Institute a standard wide field total laryngectomy is carried out with 24 hours perioperative antibiotic prophylaxis (e.g. gentamicin and clindamycin). After transoral intubation, a modified Gluck-Sorensen incision (Figure left) is utilized, extending over the lateral border of the sternocleidomastoid muscles and approximately 2 cm proximal of the sternal manubrium. Through this incision, extended to the mastoid process, the laryngectomy also can be combined with a uni- or bilateral neck dissection.

The U-shaped skin and platysma flap is then developed until the hyoid bone is reached. The cranial extension of the surgical field is the region of the submandibular glands, the lateral extension the carotid arteries and internal jugular veins. The omohyoid muscles are cut a few centimeters lateral to the thyroid cartilage, and the sternohyoid and sternothyroid muscles are undermined and severed as well. This ensures proper soft tissue coverage of the specimen. This is also realized by leaving the homolateral thyroid lobe including the isthmus attached to the specimen. The contralateral lobe of the gland is preserved with its arterial and venous blood supply. This lobe is dissected away from its attachments to the thyroid cartilage and trachea. Both superior laryngeal arteries and veins are ligated and cut, as well as the laryngeal nerves. The hyoid bone is now dissected from its attachments to the tongue musculature, starting with the greater cornu. Care should be taken at this stage to preserve the lingual arteries and the hypoglossal nerves, which is accomplished best through careful pulling out the greater cornu with a Kocher, and dissecting right onto the hyoid bone. The dissection is deepened until the pharyngeal mucosa, i.e. the vallecula is reached. The pharyngeal constrictor muscles are cut just ventral to the posterior thyroid cartilage rim.

The trachea is incised between the second and third, or the third and fourth ring, depending on the subglottic extension of the tumor. An endotracheal tube replaces the otracheal tube. The trachea is sectioned completely, while care is taken to keep the cartilage of the tracheal ‘rings’ intact. The trachea is dissected cranially from the esophagus, leaving the trachea and esophagus carefully attached to each other at the upper tracheal rim.
The pyriform sinus is opened contralateral to the tumor, and with a palpating finger inside the pharynx, the incision is extended towards the vallecula with a pair of scissors. The specimen can be rotated and the tumor can be seen directly.

Under direct vision of the tumor the dissection can be continued to the homolateral side and the larynx is pulled downwards with the postcricoid and hypopharyngeal mucosa clearly visible. Depending on the extension of the tumor more or less of the mucosa in the post-cricoid area is preserved and the specimen can be removed. In the **Figure right** the situation after removal of larynx is shown.

After careful hemostasis and rinsing with saline or distilled water, the operation field is re-draped. The trachea is sutured in position with vicryl 1-0. By suturing the caudal skin flap as far back as possible to the posterior tracheal cartilage, the tracheal lumen remains open due to the tension in the skin (**Figure right**). Another (preferred) option is to create a separate opening in the skin for the formation of the stoma. This can be done if the skin incision at the beginning of the surgical procedure is positioned more cranially (Gluck-Sörensen incision). If the sternal heads of the sternocleidomastoid muscle are protruding too much, it is advisable to incise them in order to form a flatter and easier to occlude stoma. Later, this also facilitates the application of a speech valve and/or heat and moisture exchanger.

At this stage, the tension of the cricopharyngeus muscle, also and preferably referred to as the upper esophageal sphincter, should be judged by palpation with the index finger (**Figure right**). When hypertonicity of this muscle is observed, indicated by tension of the muscle around the finger, a longitudinal myotomy should be performed. This procedure should not be confused with a (primary) myotomy of the constrictor pharyngeus muscle, which is not routinely used by us. Also primary unilateral neurectomy of the pharyngeal plexus, formerly advocated as a good method to prevent hypertonicity of this muscle group, is no longer performed, in order to avoid hypotonicity of the constrictor muscles. A good overview of total laryngectomy can be obtained from the video of Prof. R. Theo Gregor, Hamilton, New Zealand, at the end of paragraph 1.4.

### 1.2 Primary TEP and direct fit of the voice prosthesis

At this stage of the surgical procedure the primary tracheoesophageal puncture (TEP) is carried out. No temporary stenting of the TEP tract is needed with the Provox system. First, the proper size of the voice prosthesis should be selected. For this reason, the thickness of the tracheoesophageal party wall should be judged with a palpating finger. The original Provox prosthesis is available in four lengths: 4.5, 6, 8, and 10 millimeters, the Provox2 device in two
additional lengths, 12.5 and 15 mm. The Provox Vega prosthesis has 4, 6, 8, 10, 12.5, and 15 mm versions, and is not only in the 22.5 Fr version, we prefer, but also in these 6 lengths with a 20 Fr or a 17 Fr diameter. In most patients an 8 or 10-millimeter long voice prosthesis is appropriate. In case of doubt, the longer prosthesis should be used to allow for postoperative swelling and edema at the puncture site.

Until recently, for performing the TEP the use of the special **Provox Trocar and Cannula** (left) and **Pharynx Protector** (middle) was recommended, but since the availability of the **Provox Vega Puncture Set** (right), which enables a Seldinger dilation type of TEP and insertion procedure, this has become the preferred method/instrument.

During the original TEP technique, the **Pharynx Protector** is placed through the open pharynx into the cervical esophagus and positioned just cranially of the tracheostoma. The **Trocar and Cannula** is recommended for the actual TEP. If this instrument is not available, a non-cutting sharp trocar is preferred over any cutting device, e.g. a scalpel, because this could result in an oval shaped TEP tract prone to peripheral leakage. The Trocar is placed in the midline of the trachea back wall 5-10 mm below the upper tracheal mucosa rim. The 5 mm diameter Trocar and Cannula is directed perpendicular towards the opening of the Pharynx Protector to create a straight tract in the tracheoesophageal party wall. Next the Trocar is removed, leaving the Cannula in situ. Thereafter, a special guide wire is passed through the Cannula into the pharynx, where the voice prosthesis is attached. With the help of the guide wire, the voice prosthesis is then pulled into the TEP tract and the tracheal flange is pulled and rotated in place into the trachea with the help of two hemostats. Finally the introduction string at the tracheal flange is cut off, and the voice prosthesis is rotated in its proper position with the oval side of the flange pointing downwards. The traditional primary TEP procedure is shown in the **figures to the right** and the **video** below.
The TEP with the disposable **Provox Vega Puncture Set** (PVPS) is an even more straightforward, and potentially lower traumatic procedure, because all components are always in optimal condition (no maintenance like with the original instruments is needed) and hemostats are not required any longer. The PVPS consist of a sharp 2.5 mm diameter puncture needle, a guide wire, a dilator with the pre-mounted Provox Vega voice prosthesis, and a pharynx protector (only to be used for primary TEP during a total laryngectomy; pharynx protection during secondary TEP should be accomplished with an intraluminal device, e.g. a rigid esophagoscope). The pharynx protector and the needle are used in the same way as in the original TEP. After the puncture with the needle, the guide wire is passed through that, whereby care is taken that the wire is caught into the lumen of the pharynx protector and comes out of that into the pharynx. At this stage, first the needle is removed and then the pharynx protector, leaving the guide wire in the tiny TEP tract thus created. Next, the dilator with the pre-mounted Provox Vega (8 or 10 mm) is attached to the pharyngeal end of the guide wire, which can be secured in a second opening in the top of the dilator. After securing the guide wire to the dilator that can be advanced slowly through the TEP, gradually dilating that and under continued traction pulling the voice prosthesis through the TEP in place, whereby the loop around the voice prosthesis unfolds/delivers the tracheal flange properly into the tracheal lumen. The primary TEP procedure with the PVPS is shown in the **figures** and the **video** below.

[Images of TEP procedure with PVPS]

**Closure of the pharynx** is carried out in a T-shape. This enables a low-tension closure, tailored to the size of the defect and avoids the development of a ridge at the base of tongue i.e. the formation of a “neo-epiglottis”. Before closure of the pharynx is carried out, a nasogastric feeding tube is brought into position. The mucosa is closed with running atraumatic vicryl 3-0 sutures with a round needle starting cranially and laterally (**Figure below left**). Tissue surplus caudally is closed with a purse string suture. A second, submucosal layer is also closed with running sutures.
Finally the pharyngeal constrictor muscle is closed, running or with mattress sutures. This layer should not be closed too tightly. The Figure below right is showing the PE segment after closure of the muscle layer.

1.3 Primary tonicity control of the PE-segment

Before skin closure is completed, the final aspect of the tonicity control of the pharyngoesophageal (PE) segment should be carried out. As already mentioned, a short myotomy of the upper esophageal sphincter is performed before closing the pharyngeal mucosa (video below).

A neurectomy of the pharyngeal plexus often was added to further decrease the chance of hypertonicity. The pharyngeal plexus branches innervating the constrictor pharyngeus muscle were localized, cut and partially removed as careful as possible (figure top right). Mostly, three to five branches can be identified. This procedure was carried out unilaterally, preferably on the side of the hemi-thyroidectomy and/or neck dissection. However, this procedure has largely been abandoned, since it might increase the chance of hypotonicity and thus a poor voice. A myotomy of the constrictor pharyngeus muscle is also not recommended routinely.

After introduction of vacuum wound drains, skin closure is carried out in two layers: the subcutaneous tissue with 3-0 Vicryl interrupted and the skin with 4-0 Nylon monofilament running sutures. The end result is shown in the figure right.
1.4 Tracheostoma construction

The best results are obtained when it is possible to make the stoma in the inferior skin flap, using a separate fenestra in the skin (Figures right), at a distance of close to one centimeter to the skin incision. This may be round, but in our experience, the most effective shape is semi-circular, with the same size and orientation as the trachea. The anterior (intact cartilaginous) portion of the trachea is sutured to the circular part of the fenestra, and the posterior (membranous) portion of the trachea is sutured to the straight/horizontal part, which runs parallel to the incision of the inferior skin flap. The sutures should be placed meticulously and ensure that there is skin cover over the bare edge of the trachea, so that no cartilage is exposed (Figure right), since exposed cartilage may lead to perichondritis, infection, granulations and eventually stenosis.

In the same way, the postoperative use of a cannula, button or tracheostomy tube is to be avoided, if possible, since they cause friction to the mucocutaneous anastomosis, with the same end-result. In our experience at the Netherlands Cancer Institute it appears to be possible to have most patients leave the operating room without a cannula. A temporary cannula is only used if there is excessive edema of the skin flaps, causing obstruction, or excessive secretions, where a tube may aid in decreasing trauma to the tracheal mucosa caused by suction catheters. Once fibrosis starts to develop around a stoma, this often leads to stenosis, which process is extremely difficult to arrest, and such a patient may be condemned to the use of a cannula/button for all or much of the time. A typical example of a wide and stable stoma created in the inferior skin flap, with a Provox voice prosthesis in situ, is shown in the Figure right.

As already mentioned earlier, an additional improvement of the stoma can be obtained by cutting the sternal head of the sternocleidomastoid muscles (Video right). This causes no functional deficits, but results in a flatter peristomal area, which facilitates the use of external stoma appliances such as an HME and/or an automatic speaking valve. After wound healing is completed and possibly checked with a barium swallow (approximately 10 days post-operatively), the patient can start with vocal rehabilitation under the guidance of the speech therapist.

Video of total laryngectomy procedure with primary tracheoesophageal puncture and immediate Provox voice prosthesis insertion by Prof. R. Theo Gregor, MD PhD, Hamilton, New Zealand
2. Secondary prosthetic voice rehabilitation

2.1 Indications

Failure to obtain useful esophageal, and/or electrolarynx speech, or dissatisfaction with the results of either of the two, is the main indications for a secondary prosthetic voice rehabilitation procedure. The percentage of successful secondary prosthetic voice rehabilitations seems to be somewhat lower, compared with primary rehabilitation, probably due to the fact that the patient has not been using pulmonary driven speech for some time. Furthermore, there might be a negative selection aspect, because failed esophageal speakers might have more problems with hypertonicity of the PE-segment. Nevertheless, with proper training, and if necessary, medical or surgical treatment of hypertonicity of the PE segment, many secondary patients should be able to regain a useful prosthetic voice. In fact, we think that, as is the case for the primary prosthetic procedure, there are no real medical contraindications to this technique, with the exception of radiotherapy doses well exceeding 70 Gy in 7 weeks or the equivalent, especially when combined with chemotherapy. As a matter of caution, it should be mentioned, that secondary punctures should not be performed within 6 weeks after completion of the radiation. Severe pharyngeal or stoma stenosis form relative contraindications, but in most patients these problems should be correctable. Also in patients in whom the pharynx and/or esophagus are reconstructed with a gastric pull-up procedure, the colon, a free tubed-radial forearm flap, or a free re-vascularized jejunum graft, the method is applicable. If the patient is motivated enough, the method is worthwhile trying.

2.2 Preoperative screening

Apart from a regular ENT examination, including inspection of the pharynx for the presence of a stenosis or web formation at the base of the tongue and checking the stoma size, a barium swallow should be performed to check the size and mobility of the pharyngoesophageal (PE) segment. This is done to anticipate possible problems with the introduction of the rigid endoscope and to see whether dilation of the PE-segment is needed. Often an insufflation test is advocated in order to predict the outcome of secondary prosthetic voice rehabilitation. The test can performed through a 12-14 Fr nasogastric catheter introduced into the PE segment. Subsequently, the examiner can blow air into the pharynx to produce speech, or the catheter is connected to the stoma and the patient him/her self can try to speak by blowing air through the catheter. However, the results of this test are not very reliable and a negative result should not be interpreted as a contraindication for secondary prosthetic voice rehabilitation. A negative result could be indicative of a hypertonicity of the constrictor pharyngeus muscles, which can be corrected surgically with a myotomy or chemically with Botox.
In general, however, we are not in favor of combining secondary TEP with a myotomy of the
constrictor pharyngeus muscle. It is advisable to wait for the results of the speech therapy. Only if
hypertonicity of the constrictor pharyngeus muscle becomes apparent, and results do not improve
after proper training, a chemical neurectomy with Botox or a surgical myotomy of this muscle
could be considered. In the Netherlands Cancer Institute very few hypertonicity treatments have to
be performed, as this problem appears to be quite rare after introduction upper esophageal
sphincter myotomy. If needed, however, results of voice rehabilitation can be expected to improve
considerably. For the technique of secondary myotomy and/or chemical denervation with Botox,
see paragraph 3.2 below.

2.3 Secondary TEP and direct fit of the voice prosthesis

The instruments needed for this procedure were besides the
contents of the original Provox (1) package, i.e. the voice
prosthesis (of a proper length), the guide wire and the scalpel, or
in case the Provox2 device is used, a prosthesis with the proper
length and a separately packed guide wire, a short rigid
esophagoscope with a light source, the Provox trocar and
cannula and 2 curved non-toothed hemostats (Figure right).
Since the introduction of the fully disposable Provox Vega
Puncture Set (PVPS; right), this Seldinger type instrument set
has largely replaced the traditional Provox instruments, guide
wire and hemostats. It should be kept in mind, though, that the
pharynx protector in the PVPS is NOT used during secondary
TEP, and can be discarded right away. Pharynx protection with
the PVPS should be accomplished with the rigid esophagoscope,
or another intraluminal tube/instrument. All secondary TEPs
should be performed under peri-operative 24-hours broad-
spectrum antibiotic prophylaxis.

If carried out under general anesthesia, the laryngectomized
patient is intubated. The short rigid esophagoscope is introduced
and moved towards the tracheostoma (Figures right). In case of
a stenosis, it might be helpful to introduce a thin nasogastric tube
first, to facilitate the introduction of the scope and to guide the
dilatation, which should be carried out first. When the tip of the
esophagoscope reaches the tracheostoma, the scope is
swiveled 180°, turning the oblique open side of the
esophagoscope upwards. After proper oxygenation, often the
ventilation tube can be removed for several minutes by the
anesthetist, which gives a clear view into and open access to the
tracheostoma. It also makes it somewhat easier to palpate the
proper position of the scope with a finger.

At this stage, selection of the proper size of the prosthesis should
be made. The thickness of the tracheoesophageal party wall can
also judged with the palpating finger on top of the
esophagoscope or another intraluminal protection device. Four
lengths of the Provox voice prostheses are available: 4.5, 6, 8
and 10 millimeters, with two additional lengths (12.5 and 15 mm)
in case of Provox2. The Provox Vega prosthesis has 4, 6, 8, 10,
12.5, and 15 mm versions, and is not only in the 22.5 Fr version,
we prefer, but also in these 6 lengths with a 20 Fr or a 17 Fr
diameter. In most patients an 8 or 10-millimeter long voice
prosthesis is appropriate. In case of doubt, the longer prosthesis
should be used to allow for postoperative swelling and edema at
the puncture site.
In case the traditional Provox instruments are used, the trocar and cannula is then placed in the midline of the tracheoesophageal wall, 5-10 mm below the muco-cutaneous junction, and a TEP is created through a perpendicular puncture towards the lumen of the scope. The sharp tip of the trocar is caught in the esophagoscope under visual guidance of the assistant. With the **PVPS**, the sharp needle in the package is used for the TEP. Since this needle is considerably thinner than the Trocar and Cannula, and very much sharper, the puncture is much easier than with the latter instrument, especially in fibrosis at the puncture site, as will be noticed immediately by clinicians familiar with the traditional TEP procedure.

In case of the traditional TEP, the trocar is removed and the flexible guide wire introduced through the cannula. With PVPS, the guide wire can be introduced directly into the lumen of the needle. In both methods, the guide wire will appear in the esophagoscope and can be pushed upwards.

The esophagoscope is now removed and the Provox voice prosthesis is attached to the connector head of the guide wire (**Figures below**). By pulling the guide wire inwards, the introduction string of the prosthesis is introduced into the TE fistula. During this stage of the procedure the ventilation tube of the anesthetist can be re-introduced for a few minutes. Finally, after removing the ventilation tube once more, the prosthesis can be pulled and rotated into the TE fistula with the help of two curved non-toothed hemostats.

In case of the **PVPS**, the dilator with the pre-mounted Vega prosthesis is attached and secured to the guide wire (**Figures below left**). Next the prosthesis can be pulled in place by advancing the dilator, which gradually widens the TEP tract, and by the unfolding of the tracheal flange with the loop around the voice prosthesis (**Figures below right**).
Finally, the introduction string is cut off, and the prosthesis can be turned in its proper position with the oval side of the flange pointing downwards in the trachea (Figure right).

After the patient is awake, the impermeability for liquids of the prosthesis and the TE fistula is checked, by letting the patient drink some water. If there is no leakage, oral feeding can be resumed right away. Speech therapy usually also can start the same day.

Reminder: It is important to place the Provox voice prosthesis at the correct position in the tracheal back-wall, i.e. the puncture should be carried out in the midline 5-10 mm below the upper tracheal rim, causing the upper border of the tracheal flange of the prosthesis almost to reach the muco-cutaneous junction. A too low position of the prosthesis leads more easily to leakage, makes cleaning and replacement more difficult, and might result in less optimal speech.

Below a video of the traditional secondary TEP with Trocar and Cannula, and an animation and a video of the PVPS secondary TEP.

2.4 Alternative technique secondary TEP

Sometimes the introduction of a rigid esophagoscope can be difficult, making the standard secondary puncture technique too cumbersome, for instance in case of trismus or severe scarring of the neck. A good option then is the alternative procedure, described here. This procedure can
also quite easily be performed under local anesthesia. Besides the instruments, used in the standard technique, a bendable uterine probe (Simm’s Uterine Probe EO 12, 330 mm (13 inch), with a 4 mm blunt tip, Aesculap, Tüttlingen, Germany) is needed. The curvature of this probe can be adjusted easily. Figure end of page right shows the bent probe and the trocar and cannula, from which the cannula part is used in this procedure.

The probe is passed gently by feel through the mouth, pharynx and cervical esophagus towards the stoma. If needed, the curvature of the probe is adjusted according to the anatomical situation. The tip can be easily seen protruding (Figure below left) and palpated in the posterior tracheal wall. With the disposable scalpel of the original Provox package or any other scalpel with a sharp curved tip, the TEP tract is created by puncturing towards the tip of the probe at a distance of 5-10 mm from the muco-cutaneous juncture (Figure middle). The tip of the probe then can slide outwards through the TEP tract (Figure right).

Next, the cannula is placed on top of the tip and with gentile pressure onto the probe passed into the esophagus (Figure below left). After removal of the probe, the remainder of the procedure is identical the standard secondary puncture technique, described earlier. The guide wire is passed through the cannula out of the mouth and the Provox prosthesis is attached (Figure middle). The guide wire is pulled back into the TEP and the prosthesis is rotated into the TEP tract by pulling onto the tracheal flange with two non-toothed hemostats. The last Figure right shows the prosthesis in its proper place, high up in the stoma. The video below shows the alternative method.
In case of the PVPS, the procedure is similar, but care should be taken that, when advancing the guide wire through the needle and further upward through the pharynx and oral cavity, it is not caught into the mucosa, because the tip of the PVPS guide wire is not blunt like that of the original Provox guide wire. With the PVPS, the procedure is also increasingly carried out under local anesthesia and direct flexible endoscopic view, which allows checking correct passage of the guide wire, which is important when the clinician decides not to use pharynx protection.

3. Secondary treatment PE segment hypertonicity

3.1 Introduction

Hypertonicity and/or spasm of the constrictor pharyngeus muscles in the pharyngoesophageal (PE) segment are the main causes for failure to acquire fluent tracheoesophageal speech. If patients seem to be troubled by hypertonicity, it is important to confirm this diagnosis. Insufflation through the voice prosthesis into the PE segment using a catheter can give the clinician already a good idea whether the resistance of the PE segment is too high. Insufflation could also be done directly through the TEP after removal of the prosthesis to make sure that the problem is not related to the voice prosthesis itself. Too high resistance can be further objectified through trachea pressure measurement during voicing at a comfortable loudness level. A pressure above 0.4 kPa at that loudness level (approximately 65 dB at 30 cm mouth to microphone distance) indicates hypertonicity. The next diagnostic procedure should be videofluoroscopy (see chapter on videofluoroscopy), which can differentiate between hypertonicity, stricture, and recurrence.1

Finally, a diagnostic plexus pharyngeus blockade with 1% lidocaine can be carried out, to establish whether a short-term pharmacological relaxation of the constrictor pharyngeus muscles solves the problem temporarily. Literature shows that in some cases, the temporary relaxation helps also long-term to acquire fluent speech.42

The primary mode of treatment of hypertonicity of the PE segment is intensified speech therapy (see chapter on speech therapy), where the addition of relaxation exercises sometimes can be helpful. Once patients get the feeling for fluency of the air and realize that they should press less strong instead of harder during voicing, conservative speech therapy training might overcome this problem. We reserve the invasive methods, i.e. chemical denervation with Botulinum toxin as the first choice and constrictor pharyngeus myotomy as the second choice, for failures of speech therapy only.

3.2 Chemical denervation constrictor musculature with Botulinum toxin

3.2.1 Introduction and physiologic effects:

Botulinum toxin is an endotoxin produced by the microorganism clostridium botulinum. The disease Botulism is known since the 18th century and the bacteria causing it is isolated in the beginning of the 20th century.

The endotoxin blocks the acetylcholine release at the neuromuscular junction and is rapidly (in 30-60 minutes) taken up by contracting muscles. Clinical onset of the symptoms begins in 24-48 hours. The endotoxin causes a permanent denervation of the muscles with atrophy starting after 2 weeks. The nerve endings, however, always regenerate, a process that takes several months. Therefore, the duration of the effect is mostly not more than 3-6 months.

Botulinum toxin has a wide range of clinical applications in the head and neck region, such as blepharospasm, cervical and laryngeal dystonia, hemifacial spasm, strabismus, and more recently also for hypertonicity/spasm of the PE segment. Botulinum toxin is commercially available in 2 products: Botox (Allergan) and Dysport (Speywood) (the latter is 4 times less active). The effect is measured in MU (mouse units), where 1 MU = LD50 for Swiss Webster female mice. The LD50 for humans is approximately 2500-3000 MU. The single dose limit is 400 MU, and no serious reactions or adverse events are reported with this dose, but in clinical practice much lower doses are applied. Contraindications are: pregnancy, lactation, pre-existing neuromuscular diseases
(myasthenia gravis, Easton-Lambert syndrome, ALS), and simultaneous use of drugs, affecting neuromuscular junctions, such as amino-glycosides.

### 3.2.2 Application in PE segment hypertonicity

The dose of Botox advised mostly is 50-100 MU (4 times as much in case Dysport is used), which is considerably higher than in most other indications in the head and neck region. The toxin is easily inactivated, which means that the vial, which contains 100 MU, should be kept in the refrigerator until use. The toxin is reconstituted in 2 to 4 cc normal saline and should be used within 6 hours after reconstitution.

First, the position of the hypertonic bar of the PE segment should be determined. This can be achieved best with videofluoroscopy, which should be carried out in the same body posture wherein the injection will be performed afterwards. The upper and lower border of the hypertonic bar of the PE segment is marked in a resting position, using lead beads, taped on the skin.

Next, the Botox solution can be injected unilaterally at the upper and lower marking site and halfway. We use 100 MU in a tuberculin syringe, injecting carefully between the carotid artery and the pharyngeal wall (it should be kept in mind that the carotid artery often is displaced medially after total laryngectomy). The needle is advanced onto the prevertebral fascia and then withdrawn 0.5-1 cm and Botox is injected at the upper border, lower border and midway those two. The procedure is best carried out under EMG guidance, using a hollow 27 gauge EMG needle. However, it is advisable also in this case to mark the hypertonic bar of the PE segment in order to be surer of the correct injection site.

The effect of the Botox treatment can be noticed in 24 hours, and, interestingly enough, if a positive effect is obtained, it can last much longer than the normal physiologic effect, which persists, as already mentioned, between 3 and 6 months. It is not unusual that a single injection is sufficient to achieve a permanent effect. The video below shows an example of pre and post Botox treatment voicing.

### 3.2.3 References


3.3 Surgical constrictor pharyngeus myotomy

The surgical technique is as follows: a vertical paramedian skin incision is made on the side of the hemi-thyroidectomy and or neck dissection (Figure left). Care is taken not to damage the carotid artery, which in most patients is displaced medially. The pharynx is dissected free carefully (Figure right). If nerve branches of the plexus pharyngeus are seen, they should be severed. A meticulous paramedian myotomy is then performed, cutting the last muscle fiber, without entering the pharyngeal lumen.

This is greatly facilitated by the introduction of a cuffed anesthesia tube into the pharynx, prior to the surgical procedure. By inflating the balloon of this tube and moving the tube slightly up and down, it can be easily seen whether the last muscle fibers have been cut. The figure left is showing the inflated balloon after the complete myotomy and the figure right the situation with the deflated balloon. The full length of the constrictor pharyngeus muscle should be myotomized. Especially high up at the base of tongue no muscle fibers should be forgotten. The wound is closed in layers, after leaving a small diameter suction drain behind. The result of this procedure can be judged usually already on the first postoperative day.

4. TEP tract closure
4.1 Indications

Closure of the TEP tract can be indicated when there are problems such as widening of the tract causing periprosthetic leakage, not responding to conservative measures (e.g. use of a voice prosthesis with an extended esophageal flange, such as the Provox Vega XtraSeal, and/or use of an additional flange at the tracheal side, such as the Provox XtraFlange, or temporary removal of the device). Also a prolapse and/or infection of the TEP tract, spontaneous extrusion of the prosthesis, postoperative wound infection problems around the stoma, severe hypopharyngeal stenosis or a too low or high position of the TEP can be indications for TEP tract closure.

If the TEP tract exists longer than 6 months surgical closure is mostly needed. If the TEP is present less than 6 months or in patients with spontaneous extrusion of the prosthesis or infection of the tract, spontaneous closure can be expected.

4.2 Surgical technique

The aim of the surgical procedure is to close the TEP tract in layers and to strengthen the posterior tracheal party wall. If the stoma needs revision, this can be accomplished at the same time (see the following chapter on stoma revision).

The figure right is showing a case of a hypertrophic, too low situated TEP tract, which caused persistent leakage around the prosthesis. An incision is made horizontally on either side of the stoma, and curved posterior to encompass the posterior line of the stoma and a superiorly based skin and platysma flap is created (figure below left). The figure below right shows the posterior tracheal wall is dissected away from the esophagus, revealing the TEP tract.

The TEP tract is then completely dissected free to enable a hemostat being passed underneath (figure below left). The tract is opened and cut completely (figure below right).
The esophageal opening is closed with inverting vicryl sutures (figure right). A second muscular layer is sutured to reinforce the esophageal wall. If needed, the sternal head of the sternocleidomastoid muscle can be dissected from the sternum to create a superiorly based tendon/muscle flap, which can be easily interposed between the esophagus and the trachea. Even if this additional layer is not needed, it is advisable to take this opportunity to cut the sternal heads of the sternocleidomastoid muscles, if this has not been done at the time of laryngectomy. This has the advantage that the stoma area will be flatter after this procedure, which makes the use of stoma appliances, such as an HME or automatic stoma valve, easier, as already described earlier in the chapters on total laryngectomy and tracheostoma construction.

![Image](image.jpg)

Next the tracheal wall is sutured in one layer (figures below).

![Image](image2.jpg)

Finally, the skin is closed in one layer (figure below). Wound drains or dressings are generally not required. The figure below right shows the final situation at the completion of the procedure. A secondary TEP can be carried out after complete healing of the stoma, mostly after 6 weeks.

![Image](image3.jpg)
5. Stoma revision

5.1 Introduction

The construction of a stable tracheostoma during laryngectomy is essential for successful prosthetic voice rehabilitation. A tracheostoma should be large enough to make the use of a cannula not necessary, and small enough to be easily occluded with a patient's finger for speech production. In addition, the stoma should possess several other 'qualities' to facilitate speech rehabilitation. This chapter addresses the major surgical considerations for constructing, maintaining or reconstructing an optimal stoma.

Stenosis of the tracheostoma after laryngectomy can be a frustrating complication, which may occur shortly after the operation or after several months. Stoma stenosis has no accepted definition, but the incidence in the literature varies between 4% and 41%. Montgomery has classified stenosis into three types: vertical-slit, concentric and inferior-shelf type. This may have some merit, although most of the cases of stenosis cannot be classified strictly into one type or another. Some authors consider a stoma stenotic when a cannula is needed. There is some rationale for the concept that a stoma with a cross-sectional area less than that of the glottis at rest may be considered too narrow. Severe stenosis may not only interfere with the clearing of secretions or crusts from the trachea leading to airway obstruction, but is also troublesome in relation to prosthetic voice rehabilitation. The effects of stenosis may be aggravated by the use of non-indwelling prostheses, since they protrude from the TEP tract through the stoma. This problem can be avoided with the application of indwelling voice prostheses. The effectiveness of these prostheses has improved considerably over the last decades due to new designs and materials. Nevertheless, these prostheses still have to be replaced regularly.

Generally, the voice prosthesis replacement procedure can be accomplished safely and simply in an outpatient clinic setting. However, stoma stenosis may complicate this so that general anesthesia may be required. In addition, if a cannula has to be worn, it can be more difficult or sometimes impossible to achieve an airtight seal over the stoma, resulting in escape of air and suboptimal or no voice at all. Also the use of external speech valves and the use of heat moisture exchangers may be more complicated, or impossible. Reconstruction of a stenotic stoma is therefore a procedure, which might be necessary even if the patient has no complaints of retention of secretions or breathing problems, but desires prosthetic voice rehabilitation.

5.2 Surgical techniques for stoma reconstruction

The simplest method of widening the stoma is the dilatation of the stenosis with a cannula or button. However, often this is only a temporary solution as it does not remove the stenotic scar tissue and even may aggravate that.

5.2.1 General principles

Various more or less elaborate techniques have been described to reconstruct a stenotic tracheostoma. Previous radiotherapy does not preclude reconstruction, but can make surgery more difficult. Excision of the stenotic scar tissue is the first step, which has to be performed to prevent recurrent stenosis. Excess subcutaneous tissue and fat have to be excised as well as overhanging skin flaps. If necessary, the remaining thyroid lobe has to be lateralized if it is bulging into the stoma borders.

Sometimes it is also necessary to resect the sternal heads of the sternocleidomastoid (SCM) muscles if they deepen the lateral walls of the tracheostoma, and when one SCM head has already been removed as part of a neck dissection, the opposite SCM should be cut to obtain a more symmetrical surface. Apart from these common steps, the reconstructions can be classified into three categories. In each category minor variations have been described, but the principles are essentially the same within each group.

5.2.2 Category 1
The first technique consists of removing the stenotic part of the stoma with about a centimeter of skin and simple suture of the skin to the tracheal wall. This so-called ‘doughnut method’ is probably the oldest method. It has the disadvantage that it does not interrupt the line of circular wound healing which is prone to recurrent stenosis. Most of the variations of this technique consist of the creation of lateral traction of the walls in an attempt to prevent a new stenosis. Some also advocate the use of radial incisions with subsequent dilatation with cannulas. We believe this latter method to be more likely to cause recurrent stenosis, since lack of primary wound healing may lead to more fibrosis.

5.2.3 Category 2

The second group of reconstructions consists of inserting a cutaneous flap in the dorsal part of the upper trachea. Not only does this result in widening of the diameter of the stoma but it also causes an interruption of the circle of scar tissue, thereby decreasing the risk of a new stenosis (figures below). Several modifications have been described but they all have in common the use of a posterior skin flap.

This technique usually succeeds in increasing the diameter of the stoma, but it can interfere with prosthetic voice rehabilitation, since the dorsal part of the tracheostoma becomes covered with skin. That part of the tracheostoma is the location of the TEP tract and thus the voice prosthesis. Therefore, if a prosthesis is already in situ, it may have to be removed and reinserted at a later date. Consequently, the patient loses his voice for at least several weeks. Furthermore, the thickness of the skin might complicate the insertion of a new prosthesis. The common wall of trachea and esophagus may become too thick for the current types of prostheses.

5.2.4 Category 3

The last technique, which we call the lateral flap technique, also consists in interrupting the line of circular scar contracture by inserting two cutaneous flaps in the lateral walls of the stoma, by using a double Z-plasty (figures left and below).
Category 3 techniques involving two lateral plasties: in the posterior tracheal wall a Provox voice prosthesis is shown. **Figure top right:** incision for lateral Z-plasty; **figure left:** Interposition of the flaps; **figure right:** after suturing.

A modification consists of a superiorly based, bilateral skin flap, which is rotated into the lateral walls of the trachea. Another modification, which we prefer, is the so-called “fish-mouth” technique. It consists in the splitting of the first two tracheal rings at 3- and 9-o’clock positions, where after two laterally-based V-Y flaps are inserted into the split tracheal walls (figures below). Essentially these methods are based on the same principles as the dorsal flap, i.e. interruption of the line of a circular scarring. However, they do not have the potential disadvantage of interfering with the location of the voice prosthesis.

Category 3 techniques involving lateral V-Y plasties; in the posterior tracheal wall a Provox voice prosthesis is shown. **Figure left:** the incision, which is also extended along the posterior border of the stoma; **figure right:** the insertion of the lateral V-Y flaps into the “fish-mouth created by making incisions at 3- and 9- o’clock in the trachea

These techniques can also be used when combining the reconstruction of the stoma with a closure of a TEP tract. In this case, after removal of the voice prosthesis and closure of the tract, the posterior tracheal wall may be strengthened through interposing other tissue, usually muscle, between the trachea and esophagus. The aim of such a procedure is to achieve a stoma with a proper diameter with a strengthened posterior tracheal wall (figure above). A secondary TEP can be performed after complete healing of the reconstructed stoma, mostly at approximately six weeks.

### 5.3 Comments and Conclusions

The etiology of tracheostoma stenosis may be related to one or more of the following factors:

1. Incorrect stoma construction at the time of laryngectomy.
2. Excessive scar tissue due to infection or fistula near the stoma or repeated trauma by cannulas.
3. Absent or defective tracheal rings at the stoma. (Stoma recurrence of carcinoma is regarded as having a totally different etiology and therefore is not discussed here)

The first reason is probably the most important. Preventive measures at the time of the surgery and in the direct postoperative period are the most valuable tools in the maintenance of a tracheostoma with an appropriate size and can avoid multiple reconstruction procedures. In our experience the best results are obtained when it is possible to create the stoma in the inferior skin flap, using a separate fenestra in the skin as described in the chapter on primary puncture (see chapter on Tracheostoma construction).

Once a stoma has started to form fibrous tissue leading to stenosis, it is extremely difficult to arrest this process, and such a patient may be condemned to the use of a stoma button or cannula for all or much of the time. A reconstruction of the tracheostoma should then be considered. As mentioned above, stoma revision may also be a part of a TEP closure after which a stable tract can be created after secondary TEP. The same procedure might be considered in certain patients, who have recurrent problems with granulation tissue, thickening of the wall, and resultant inward displacement and even “disappearance” of the prosthesis as well as chronic widening of the TEP tract.

Well healed, wide stoma, one-year after the procedure. The scar of the V-Y flap still can be seen to the right of the stoma.

Conclusions

In the light of the current widespread use of voice prostheses after laryngectomy, we believe that tracheostoma construction and reconstruction should be planned in consideration with prosthetic voice rehabilitation. If the voice prosthesis is successful, we advocate the use of the lateral flap techniques in the reconstruction of tracheostoma stenosis. In that way the prosthetic speech production is uninterrupted. If the stoma stenosis occurs together with TEP tract problems, temporary closure of the TEP could be considered in the same procedure.

5.4 References

6. Pharynx reconstruction and prosthetic voice rehabilitation

Voice rehabilitation after (sub)total laryngopharyngectomy with or without esophagus resection traditionally only has been possible with an electrolarynx. Reconstruction of the pharyngeal defect after subtotal pharyngectomy, with only a small strip of mucosa left, can best be achieved with a pectoralis major myocutaneous (PM) flap (figure left). The barium swallow of this reconstruction is shown in the figure right.

We have the experience that primary insertion of a indwelling Provox (Provox, Provox2, Provox Vega) voice prosthesis after the application of a PM-flap results in a relatively good voice which is comparable to that after a standard operation.\textsuperscript{60,61} We, therefore, prefer this method of reconstruction over the removal of the remaining mucosa strip and reconstruction of the pharynx with a free revascularized flap. The advantages of the PM-flap over any other free flap are obvious: the PM-flap is readily available, is easily harvested, and requires little extra operation time; if constructed properly, there is little chance of stenosis; no abdominal surgery (in case of jejunum or gastric omentum flap) and no special microsurgical expertise are needed.
If, however, a total pharyngectomy has to be performed, the **free revascularized jejunum** reconstruction appears to be very reliable, and combined with a primary insertion of a voice prosthesis results in a fair voice in all patients, in whom we have used this type of reconstruction. The **figure left** shows the jejunum flap after microvascular anastomosis; the **middle figure** shows the barium swallow, 12 days postoperatively; the **figure right** shows a voice prosthesis in the esophagus, just below the jejunum segment. The voice, however, is sometimes blocked by the autonomous peristalsis of the jejunum segment and sounds “wet” due to the continuous production of secretions. From a prosthetic voice rehabilitation point of view, the jejunum cannot be considered the ideal reconstruction method anymore.

Compared to a gastric pull-up operation (if a total esophagectomy is not indicated) the jejunum flap has some advantages: no need for esophagectomy, less abdominal trauma, no intra-thoracic trauma, no postoperative dumping syndrome, and primary prosthetic voice rehabilitation is possible.

Alternatives are the use of a revascularized tubed radial fore arm flap. Another alternative is the free greater curvature gastro-omentum flap (figures below left and right).

If the total laryngopharyngectomy has to be combined with total esophagectomy, reconstruction with a gastric pull-up procedure is our method of choice. A relevant observation in this respect is the improved vocalization by using a greater curvature tube instead of the complete stomach. The **figure below left** shows an intra-operative picture of the tubed stomach pull-up in the neck and the **figure below right** the postoperative barium swallow; note the excellent diameter of the tube, which is comparable to the normal esophageal diameter.
The **figure below right** shows a Provox 2 voice prosthesis in situ in the lumen of a tubed stomach, and the **figure below left** a Provox voice prosthesis in a full gastric pull-up. The much larger diameter of the latter explains lower (amphoral) voice quality, with the full gastric reconstruction. The voice obtained with the tubed stomach clearly has a better intelligibility and loudness. Other advantages of a greater curvature tube over a complete gastric pull-up are: the transposition through the esophageal bed is less difficult, and there is less intra-thoracic cardio-pulmonary compression, and dumping.

It is our experience that prosthetic vocal rehabilitation after extensive pharyngeal reconstruction is possible in virtually all patients and should be aimed for. It can be concluded that in pharyngeal reconstruction, besides oncological and technical arguments, the possibility of applying primary instead of secondary prosthetic voice rehabilitation and the quality of the resulting voice should also play a role in the choice of the reconstruction method.

### 6.1 References pharynx reconstruction:


Voice prosthesis replacement

1. Indications for replacement

Voice prosthesis are not permanent implants, and require periodic replacement. Indications for replacement can be divided in prosthesis-related and fistula-related indications.2

1.1 Prosthesis related indications

Prosthesis-related indications are leakage through or obstruction of the valve. The most common indication (74%) for replacement of the Provox and Provox2 voice prostheses is prosthesis-related, i.e. incompetence of the valve due to candida overgrowth, causing leakage of fluids through the valve. And for the Provox ActiValve and Vega that is not different. Obstruction of the prosthesis, leading to total blockage of the prosthesis and/or excessive pressure to obtain adequate speech, is a rare prosthesis-related indication for replacement (3%). If obstruction occurs, cleaning of the prosthesis by suction, preferably under endoscopic control, can be tried before replacement is undertaken. Inspection of the prosthesis can easily be carried out with a rigid 30° nasopharyngoscope or a flexible laryngoscope. This enables easy inspection of the valve and also makes cleaning of distinct areas of the prosthesis possible. The latter might solve the leakage problem without the need for replacement.

1.2 Fistula-related/TEP tract related indications

Fistula-related (now mostly referred to as TEP tract-related) indications for replacement comprise of peripheral leakage (leakage around the prosthesis), infection of the TEP tract, hypertrophy and/or granulation, or spontaneous loss of the device, because the TEP tract has become too wide. These indications form less than a quarter of the reasons for replacement. The majority of these indications are formed by peripheral leakage, where a too long prosthesis causes a pistoning effect, by which fluids are squeezed around the device during drinking. In most cases, downsizing the prosthesis by inserting a shorter device solves this problem.

It should be realized, that subsiding of surgical edema and tissue reaction is a natural course of events, especially with indwelling prostheses, which are not handled by the patients themselves (less trauma to the fistula); this means that during follow-up often a shorter prosthesis is needed and is sufficient to solve the peripheral leakage. This phenomenon is not considered to be an adverse event, in contrast to all other TEP tract-related indications, which will be discussed in the Troubleshoot section.

The mean device life of the Provox and Provox2 voice prostheses in the Netherlands is approximately 5 months, but individual variations can be considerable. Shorter (4-6 weeks) and much longer durations of use (up to 10 years) have been observed. This has resulted in the Netherlands Cancer Institute in a median device life of 3 months, which is the more important figure to know/publish. The 3rd generation Provox Vega voice prosthesis has been reported to have a longer device life than the Provox265

For a complete overview of the long-term aspects of prosthetic vocal rehabilitation using the Provox System, we refer to Op de Coul et al. (2000).2


2. Replacement procedures

Replacement of any of the indwelling Provox voice prostheses should be carried out by a medical professional trained in the procedure. A good view on the tracheostoma using a headlight is mandatory and a suction system is very helpful. Use good metal suction tube. One or two curved non-toothed hemostats should be at hand.

With the original Provox prosthesis good assistance during its retrograde replacement in the outpatient office, preferably by a trained nurse, was recommended. The anterograde replacement of the Provox2, Provox ActiValve, and more recently the Provox Vega voice prostheses has made the procedure considerably easier and can be carried out without assistance.

2.1 Choosing the right length

Care should be taken to replace the prosthesis with one of the correct length, in order to ensure proper function and to avoid undesirable side effects. The voice prosthesis always should be slightly too long, because an exact fitting device might cause edema, which makes the prosthesis rapidly being ‘too short’. During follow-up, the thickness of the trachea wall might change, due to subsiding of surgical or radiation edema, or due to infection, making the fistula tract shorter or longer, respectively. Therefore, never replace the prosthesis automatically with one of the same size. Always check first if the length is still correct by grasping the flange of the prosthesis with a hemostat and slightly pulling it outward (figure below left and middle). Judge the distance between the flange and the tracheal mucosa, and if this is less than 2-3 mm, the same length can be chosen. In case of a greater distance, the prosthesis length should be chosen accordingly, but it has to be kept in mind that only rarely more than one size shorter should be used.

In case the tracheal flange shows some deformation, this might indicate that the prosthesis is too short and a longer version should be used. Use of a prosthesis with a longer shaft should also be considered if the tracheal mucosa shows a tendency to become hypertrophic and to bulge over the tracheal flange.

In case of doubt, the Provox measure can be used to establish the actual length of the TEP tract (in case of a 20-23 Fr. diameter prosthesis; figure below right).

2.2 Provox

Although rarely used at present, for completion the original retrograde Provox replacement\(^3\) is described here. The video shows an animation of this procedure.
1) Obtain satisfactory local anesthesia of the trachea and oropharynx with lidocaine 10% spray. Some experienced patients might prefer replacement of the prosthesis without local anesthesia, since the lidocaine spray causes the same or sometimes even more irritation than a rapid replacement procedure itself. Introduce the guide-wire through the old prosthesis and push it upward through the pharynx and out of the mouth. Often it is easy to grab the guide-wire in the pharynx with a finger. Sometimes the introduction of the guide-wire needs special attention. This is particularly true for the low positioned prosthesis. Grasping the tracheal flange with a non-toothed hemostat and changing the position of the prosthesis in a more upright direction, can facilitate the proper movement of the wire into the pharynx. In the rare event that the wire is trapped at the base of the tongue or tonsil, a tongue depressor and hemostat are useful in freeing the guide-wire.

2) Grasp the tracheal flange of the prosthesis with a curved non-toothed hemostat, cut this off from the prosthesis with the disposable scalpel, included in the package, and remove it over the guide-wire.

3) Remove the esophageal remnant of the prosthesis transorally with a push and pull action of the disposable guide wire that has a 8 mm halfway stop for this purpose.

4) Attach the new Provox voice prosthesis to the connector of the guide-wire and secure it in its slid with a gentle pull of the introduction string of the prosthesis (figure right). Pull the wire the prosthesis towards the existing TEP tract and ask the patient to swallow the new prosthesis.

5) Introduce the prosthesis into the TEP tract. Because of the oval shape and flexibility of the tracheal flange the prosthesis can be introduced easily into the tract, mostly with the help of the curved non-toothed hemostat. Finally, the introduction string is cut off with the disposable scalpel.

6) The prosthesis in situ after removal of the introduction string, ready for speech. Preferably, the long end of the tracheal flange points downward in the trachea.

2.3 Provox 2 and Provox ActiValve

The anterograde replacement of the Provox\textsuperscript{2} and ActiValve\textsuperscript{2} voice prostheses is carried out with a disposable insertion tool for insertion of the voice prosthesis directly through the stoma into an established TEP tract. The 'second generation' Provox2 has been adapted for anterograde insertion by having softer flanges (the esophageal flange being the more rigid one), and more curved junctions between the flanges and the shaft. This allows easier insertion in the loading tube and facilitates removal out of the TEP tract with a hemostat. The diameter of the shaft is similar to that of the original Provox prosthesis, but the thickness of the esophageal flange is decreased from 1.6 mm to 1.5 mm, and of the tracheal flange from 1.6 mm to 1.3 mm. The size of the prosthesis (the spacing between the flanges) is marked on the tracheal flange, to facilitate identification of the length of the prosthesis in situ. The available sizes are 4.5, 6, 8, 10, 12.5 and 15 mm. The Provox ActiValve, the special problem solving voice prosthesis, has the same dimensions and sizes, but the valve seat of this prosthesis is slightly longer/bulkier than that of the Provox2.

**Loading of the Provox2 and ActiValve voice prosthesis into the insertion tool (see also the video at end of this section):** the insertion tool consists of a loading tube and an inserter pin. This inserter pin has 2 mark-lines: number 1 is the line indicating the correct position of the prosthesis in the loading tube; number 2 is the line indicating that the esophageal flange is unfolded just outside the tip of the loading tube. The safety string of the voice prosthesis is guided through the center of the opening of the inserter pin, and locked in the top slit of the opening. Thereafter, the prosthesis is placed on top of the inserter (figure below left).

Next, the esophageal flange of the voice prosthesis is squeezed between thumb and index finger and hooked into the loading tube ensuring that the esophageal flange is folded forward (figure below middle). The thumb of the other hand should push down and forward the flange, which is still protruding from the slit of the loading tube (figure below right). This flange has to be kept down firmly within the tube, while pushing the inserter pin forward until mark-line 1 is reached.

Now the prosthesis is in the correct position for insertion (figure below left). The only difference with the Provox ActiValve is that, because of its slightly longer/bulkier valve seat, there is a little
more resistance felt during its insertion into the loading tube, especially when holding the thumb down to squeeze the esophageal flange into the tube and when pushing the inserter pin forward.

To prevent accidental loss during its insertion, both the Provox2 and the ActiValve have a security string that extends in the axis of the flange and also can serve as the introduction string, if the voice prosthesis is inserted in the traditional retrograde manner through the pharynx (see animation above right). The possibility to replace these devices both in an anterograde and in a retrograde manner makes the Provox prostheses the most versatile prosthetic devices presently available.

The anterograde replacement procedure can be accomplished easily by any trained clinician (Otolaryngologist/resident, Speech Language Pathologist, and Oncology Nurse). Local anesthesia is seldom needed. In some patients, the procedure may exert some coughing that can be suppressed with 10% lidocaine spray into the trachea. Local anesthesia in the pharynx is not needed.

Replacement of the Provox2 and ActiValve prosthesis: the old prosthesis is removed by pulling it out from the TEP tract with a non-toothed hemostat (see video next page). Alternatively, up to the clinician's discretion, the tracheal flange can be grabbed with a hemostat and cut off, and the remainder of the device is then pushed into the esophagus, allowing for natural passage through the intestinal tract. The patient's clinical history of abdominal diseases should hereby be taken into account.

The loading tube is inserted into the TEP tract (figure below left) until the back wall of the esophagus is slightly touched. Then, with the loading tube kept in this position with one hand, the inserter pin, held between thumb and index finger of the other hand, is pushed forward until marker line 2 is reached. The thumb should be used as stopper, to avoid the tracheal flange to prematurely slide out of the loading tube. In this position the forward folded esophageal flange has been unfolded in the lumen of the esophagus.

Next, the complete insertion tool, thus loading tube and inserter pin together, is pulled backwards, anchoring the unfolded esophageal flange on the anterior esophageal wall. Then, the loading tube can be slid backwards, keeping the inserter pin in place, allowing the tracheal flange of the voice prosthesis to unfold properly in the trachea (figure below middle). Most of the times this happens
immediately. Sometimes, the tracheal flange has to be unfolded intentionally, either by turning the inserter with the prosthesis around its axis, or by turning and pulling this flange into position with a non-toothed hemostat.

The proper position of the voice prosthesis can be checked easily by rotating and exerting slight traction on the tracheal flange, after which the safety string of the prosthesis can be cut off with a small pair of scissors, or a scalpel (figure above right). The Provox2/ActiValve voice prosthesis is then ready for use.

Video left: Provox2 loading insertion device  Video middle: Provox2 removal of old prosthesis  Video right: Provox2 immediate insertion and overshooting examples


2.4 Provox Vega and Vega XtraSeal

The successor of Provox2, the 3rd generation Provox Vega voice prosthesis, is inserted with the Smart Inserter. This has been adapted from the original Provox2 anterograde system to facilitate all steps of the loading and insertion procedure (see Figures below). The main adaptation is that the voice prosthesis is stored in a retainer at the base of the loading tube. Loading of the prosthesis itself into the loading tube is controlled manually by forwarding the inserter stick, and proper forward folding of the esophageal flange into the loading tube is ‘automatically’ accomplished by an integrated folding mechanism.
Another adaptation was that the tip of the loading tube - the part that enters the TEP tract - was smoother and had integrated webs, as was described in the original phase-I and -II Vega publications.\textsuperscript{23,24} This construction decreased the distention of the tip and allowed better retention of the prosthesis within the tube during the final stage of the insertion procedure, which was intended to prevent inadvertent, accidental overshooting of the voice prosthesis. However, in daily practice, this somewhat softer and smoother tip of the loading tube turned out to be slightly less controllable/steerable than that of the original Provox2 loading tube. Therefore, in the present version of the Smart Inserter the originally described loading tube was replaced with the original Provox2 tube (see figures below for comparison). This tube is also somewhat longer, which results in a better view on the stoma during the replacement procedure.

There is also an overshooting mechanism: if clinically needed, the folding device can be advanced into the container, which enables pushing the complete prosthesis into the esophagus. The unfolding of the tracheal flange is then accomplished with two hemostats, similar as described for Provox 2 and ActiValve. If the insertion fails and needs to be repeated, the prosthesis easily can be reloaded into the insertion system.

The Provox Vega XtraSeal is inserted with the same Smart Inserter as the standard Vega prosthesis (see videos next page left). The only difference is that the thin extended esophageal flange, which is integrated underneath the standard esophageal flange, has to be folded downwards in order to achieve proper and comfortable loading of the voice prosthesis. This is especially important when the first attempt has failed and the voice prosthesis has to be reloaded. Deliberate downward folding of the thin extended esophageal flange is a must (see figure right).
Moreover, it is advisable to always use the overshoot mechanism in order to ensure complete unfolding of the esophageal flanges in the lumen of the esophagus. (see videos below) This unfolding the tracheal flange mostly has to be accomplished with the help of two hemostats.


3. Additional remarks in conjunction with prosthesis replacement

- Patients should be advised not to eat shortly before replacement of the prosthesis. Replacement on an empty stomach prevents vomiting during the procedure.

- Patients should be instructed to clean the prosthesis with the special Provox cleaning brush and/or the Provox Flush. Because of the almost unobstructed and stable lumen of the prosthesis, patients are often also able to clean the device by forced expectoration with the stoma closed. It's worthwhile to explain this to the patients and to instruct them how to do this. Especially when voicing is blocked, they might be able to rapidly regain that in this way, and to avoid the unease of having to use the brush in public.

- The oval shape of the tracheal flange is helpful in determining the optimal position of the prosthesis. The oval end should point downwards, in which position the oblique esophageal 'chimney' is cranial and 'protecting' the valve.
- Occasionally, mild leakage through or around the prosthesis may occur in the first weeks after introduction of a new prosthesis. This is often temporarily and no reason for immediate replacement of the prosthesis.
Accumulative reference list


