Current status and future prospects in prosthetic voice rehabilitation following laryngectomy

ABSTRACT
Total laryngectomy or laryngopharyngectomy remains the procedure of choice for advanced-stage (UICC T3 and T4) laryngeal carcinoma around the world despite advances in conservative laryngeal surgery and radiotherapy. However, it has profound effects on respiration and deglutition, in addition to the most disabling effect— the loss of verbal communication. Successful voice restoration can be attained with any of three speech options, namely esophageal speech, electrolarynx, and tracheoesophageal (TO) speech using an artificial valve. Although, no single method is considered the best for every patient, the tracheoesophageal puncture has become the preferred method in the past decade. Several types of voice prostheses have been produced since the first prosthesis was introduced in 1980 by Blom and Singer. However, eventually all prostheses are confronted by the same problem, i.e., the development of a biofilm, leading to deterioration and ultimately to dysfunction of the prostheses, necessitating replacement. This article attempts to sum up the historical background as well as the current state of surgical voice rehabilitation following laryngectomy; we review the recent major advances as well as the future prospects. Data was collected by conducting a computer-aided search of the MEDLINE and PubMed databases, supplemented by hand searches of key journals. Over 50 articles published in the last three decades on the topic have been reviewed, out of which about 20 were found to be of relevance for this article.

KEY WORDS: Biofilms, olfactory rehabilitation, pulmonary rehabilitation, tracheoesophageal puncture, tracheoesophageal speech, voice prostheses

INTRODUCTION
Total laryngectomy or laryngopharyngectomy is still the treatment of choice for advanced laryngeal/hypopharyngeal carcinoma, either as a primary procedure or as salvage following irradiation alone or concurrent chemoradiation therapy. However, the procedure is associated with important consequences over and above the loss of normal voice. There is loss of nasal function, poor cough, swallowing difficulties, lung function changes, tracheostomal complications, and lifelong functional and psychological consequences. Rehabilitation of these patients has long been a major challenge, but it is only in the last three decades that the emphasis on restoration of function and quality of life has become as important as cure and survival. Over the past 25 years there has been significant improvement in the rehabilitation of these patients and different methods of speech restoration have dramatically altered and improved their quality of life. Successful voice restoration for alaryngeal speakers can be attained with any of three speech options, namely esophageal speech, electrolarynx and, most recently, tracheoesophageal (TE) speech using an artificial valve. Although, no single method is considered to be the best for every patient, the tracheoesophageal puncture has become the most preferred method in the past decade. This article attempts to sum up the historical background as well as the current state of surgical voice rehabilitation following laryngectomy and also reviews recent major advances as well as future prospects. Data was collected by conducting a computer-aided search of the MEDLINE and PubMed databases, supplemented by hand searches of key journals. Over 50 articles published in the last three decades on the topic have been reviewed, out of which about 20 were found to be of relevance for this article.

SURGICAL RESTORATION OF ALARYNGEAL SPEECH
There are two main surgical methods for surgical restoration of voice: (1) neoglottic reconstruction and (2) shunts.

Neoglottic reconstruction
Repeated attempts have been made by various surgeons all over the world to develop a...
tracheohyoidpexy technique, aiming at almost total restoration of laryngeal function. The earliest such attempt was made by Serafini in 1967. A different approach was taken by Lapidot and Ramm (1965) who described a three-stage reconstruction. Most of these techniques have generally been abandoned owing to numerous complications.

Shunt techniques

Guttman was the first to try out the idea of surgically creating a tracheoesophageal fistula in 1932. Since then there have been many modifications of the basic concept. Today, tracheoesophageal shunt is the most widely used technique for surgical voice restoration. Determining the structure that can act as a sound generator depends on where the fistula enters the pharynx; different types of shunts are:

1. high tracheopharyngeal shunts (i.e., Barton, Asai, Bryce);
2. low tracheopharyngeal shunts (i.e., Staffieri, Tiwari, Algaba, Amatsu, Heerman, Conley);
3. tracheoesophageal puncture shunts (i.e., Guttman, Calcaterra, Traissac); and
4. tracheoesophageal puncture with voice prosthesis. A major disadvantage of the surgical shunt methods was the occurrence of aspiration through the fistula into the trachea and stenosis and closure of the shunt/fistula and, by the 1980s, the use of these shunt methods had diminished. However, this technique paved the way for the introduction of the one-way silicone prosthesis to keep the fistula open. After the introduction of the first useful, reliable voice prosthesis by Singer and Blom in 1980, a number of different prostheses were developed and the success rate of vocal rehabilitation after total laryngectomy improved considerably.

TRACHEOESOPHAGEAL VOICE USING VOICE PROSTHESIS

Tracheoesophageal puncture with prostheses has revolutionized the rehabilitation of the laryngectomized patient over the past two decades. This was due to a major conceptual development in the late 1970s by Eric Blom and Mark Singer. Their technique involved creating a simple tracheoesophageal puncture between the posterior wall of the tracheostome and the upper esophagus, into which was inserted a one-way silicone valve. The basis of tracheoesophageal speech is that during expiration tracheal air is shunted into the pharynx through a small, silicone-valved prosthesis in a fistulous tract. Sound is then produced by vibrating the mucosa of the PES. Speech can then be produced by articulation of this sound in the oral cavity using the remaining anatomic resonators: the tongue, teeth, and lips. The prosthesis also serves as a one-way valve to prevent salivary soiling of the airway. In the early years, the puncture technique was used as a secondary procedure in post-laryngectomy patients who failed to achieve esophageal speech. Consistently good results and the superior quality of voice with secondary puncture prompted Hamaker et al. in 1985 to incorporate the tracheoesophageal puncture at the time of laryngectomy as a primary procedure. The first voice prostheses (Blom-Singer, Panje) were designed as non-indwelling devices that had to be taken care of by the patient. In Europe, as early as the early 1980s, indwelling voice prostheses (Groningen, Traissac) were developed and found favor, as they required less dexterity on the part of the patient. A number of indwelling devices are available today, namely the Blom-Singer, Provox 1 and 2, Groningen, VoiceMaster, Nijdam, and Bordeaux voice prostheses. The Provox voice prosthesis, developed in The Netherlands Cancer Institute (1988) is currently one of the widely used devices.

The advantages of tracheoesophageal voice are many; they include:

1. Possible after a laryngectomy, neck dissection, and/or radiotherapy.
2. The fistula is a convenient route for esophagogastric feeding in the immediate postoperative period.
3. Easily reversible if so desired by the patient.
4. More quickly attained than esophageal speech.
5. High success rate for prosthetic vocal rehabilitation (close to 95% in long-term users)
6. Fair-to-excellent voice quality in close to 88%.
7. Similar to laryngeal speech on a range of voice parameters, such as fundamental frequency, jitter, shimmer, words per minute, and maximum phonation time, as compared to esophageal speech.
8. More intelligible and natural sounding, and also permits improved intensity and duration of speech.

Disadvantages of tracheoesophageal speech are:

1. Need to manually cover the stoma when voicing; although, in many cases, this has been overcome by the creation of hands-free valves.
2. Adequate pulmonary reserve is necessary.
3. Additional surgery necessary for secondary punctures
4. Violation of the posterior esophageal wall
5. Passage of the catheter through a false passage, and esophageal perforation

PRIMARY SPEECH RESTORATION

Selection of patients

Primary voice restoration is today a standard practice for patients undergoing total laryngectomy. However, there are a few contraindications to primary puncture. These are related to the increased risk of developing a postoperative fistula or wound breakdown. These contraindications to primary voice restoration are:

1. Extensive pharyngolaryngeal surgery and separation of party wall (absolute contraindication)
2. Inadequate psychological preparation of the patient
3. Doubtful ability to cope physically
4. Suspected difficulty with postoperative radiotherapy

**Insertion of voice prostheses**

Approximately a week after the primary voice restoration procedure, a voice prosthesis of the appropriate size is placed. It is generally advisable to wait a few more days before voice rehabilitation is begun in nonirradiated patients or about a week in irradiated patients. Following secondary puncture, the prosthesis may be fitted after 2–3 days unless a myotomy has been carried out, in which case the fitting is best delayed for a week.

Immediate insertion of the indwelling voice prostheses: The indwelling voice prosthesis is inserted immediately at the time of primary TEP, with no need for temporary stenting of the fistula tract with a feeding tube.[8–11] Numerous advantages with this technique have been claimed, provided a device of sufficient length is used. The advantages include:

1. Diminished risk of separation of the tracheoesophageal wall due to the retrograde insertion technique using a special trocar and cannula for the TEP and a disposable guidewire (Provox).
2. The tracheoesophageal wall is stabilized by the voice prosthesis to some degree.
3. The flanges of the prosthesis give optimal protection against leakage of saliva and gastric reflux.
4. Less irritation of the stoma and the fistula tract than with a feeding tube
5. No postoperative interference with a cannula or a HME is needed.
6. Patients become familiar with the maintenance of the voice prosthesis soon after operation.
7. No need for early postoperative prosthesis fitting at a time when the stoma is not yet completely healed and when the patient's mental and physical status is not yet optimal.
8. Postoperative radiotherapy is not a contraindication.
9. The first replacement is usually some months later, by which time wound healing is completed.

The disadvantages are the presence of a feeding tube in the nose and throat for 10 days and temporary deterioration of the voice during postoperative radiotherapy. Reassurance is important during this period as most patients can expect to regain a useful voice.

**SECONDARY SPEECH RESTORATION**

**Assessment and selection criteria**

The first and the most important step is an assessment of PE segment tonicity. The most reliable and accurate way of assessing PE segment physiology is video fluoroscopy, which has three important components: a modified barium swallow, attempted phonation, and an esophageal insufflation test (Taub test).

Selection criteria for patients for secondary voice restoration are:

1. Good motivation
2. Mental stability of patient
3. Adequate understanding of postsurgical anatomy and of the tracheoesophageal punctures voice prosthesis by the patient
4. No alcohol or other substance dependency
5. Adequate manual dexterity
6. Adequate visual acuity
7. Positive esophageal air insufflation test
8. No significant pharyngeal stenosis or stricture
9. Adequate pulmonary reserve
10. Stoma of adequate depth and diameter
11. Intact TO party wall

**PE segment tonicity**

The PE segment needs to be tonic to allow a steady stream of air through the segment in order to produce a good voice. Hypertonicity or spasm has been considered to be the cause of failure in 10–12% of patients. Treatment options for pharyngoesophageal spasm include pharyngeal constrictor myotomy, unilateral pharyngeal plexus neurectomy and, more recently, chemical denervation of the pharyngoesophageal segment through the use of Clostridium botulinum toxin.

**Replacement technique**

Indwelling voice prosthesis replacement is carried out by either a speech therapist, nurse, or an otolaryngologist in an outpatient clinical setting. The technique of insertion varies with the type of prosthesis. The original Provox device is replaced in a retrograde manner with a special disposable guidewire, but this technique is somewhat uncomfortable for the patient and the pharyngeal route can be difficult if there is a stenosis of the PE segment.[13] The Provox 2 voice prosthesis was therefore developed, which can be easily inserted with a simple loading tube in an anterograde fashion, with the retrograde method still available as a backup procedure.[13] The Blom-Singer voice prostheses also has a similar anterograde method of insertion using the dissolvable gel cap.

**COMMON PROBLEMS**

**Leakage through the prostheses**

Leakage of fluids through the valve is the most common problem related to maintenance of the tracheoesophageal puncture and is also the commonest indication for replacing any voice prostheses. There are several causes of leakage through the prostheses. Careful observation of the prostheses in situ and after removal should be done to determine the cause of the leakage. The condition and positioning of the flap valve in situ should be checked for the following:

1. Presence of deformities that may have occurred during the insertion process, including inversion of the flap valve
2. The presence of a partial remnant of the gel cap, which interferes with proper closure of the flap valve
3. Movement of the flap valve in conjunction with the...
A prosthesis that is too old may have a curled or deformed appearance of the valves and should be replaced. After removal, attention should be paid to the color and overall condition of the device. The presence of microbial colonization of the valve mechanism commonly interferes with proper seating of the valve, causing leakage through the device and consequent shortened prosthesis life. Valve incompetence is generally caused by *Candida* deposits on the silicon material and is the most important factor determining the life of the voice prostheses.

**Leakage around the prostheses**

Leakage around the prostheses is the second commonest reason for replacement and is most commonly caused by a too-long prosthesis causing pistoning in the TE fistula. This is solved easily in most cases by downsizing the device. If this does not help, a possible solution is temporary removal of the prostheses to allow the fistula to shrink. Other causes can be lack of wound healing due to tissue necrosis caused by radiation and hypothyroidism. Assessment for recurrent cancer or metastatic disease must also be performed. If the leakage occurs around a 16F-diameter prosthesis, then a solution would be to have a 20F-diameter prosthesis of the same length inserted. Another option is to first remove the prosthesis and then to insert a smaller diameter rubber catheter (e.g., an 18F for a 20F prosthesis and 14F for a 16F prosthesis) in an attempt to systematically reduce the diameter of the puncture; later, a new prosthesis of the original diameter and length can be reinserted. Long-term success with type I collagen injections into/around the posterior tracheal wall at the puncture site has been reported by Remacle and Declaye.\(^{(15)}\) More recently, success was reported by Luff et al. with Hylaform (Collagen (UK) Ltd., Thame, Oxon, United Kingdom) and Perie et al. with autologous fat injection in the management of intractable leakage around the TEP site.\(^{(16,17)}\) Surgical closure of the TE fistula is rarely performed nowadays. Other common associated problems are immediate aphony or dysphonia, PES hypertonicity problems, delayed aphony or dysphonia, puncture tract problems, small or large tracheostoma, granuloma, excessive tracheostoma mucous discharge, and hypotonic voice.

**INDWELLING VS NONINDWELLING VOICE PROSTHESSES**

Brown et al. have demonstrated that on acoustic analysis of the voice produced there is no significant difference in frequency range or maximal phonation time between indwelling and nonindwelling devices. Using a patient satisfaction survey, they also found that the quality of voice was perceived to be the same, or slightly better, with the indwelling prosthesis and that maintenance of the indwelling prosthesis was considered easier.\(^{(11)}\)

**PRIMARY VS SECONDARY POSTLARYNGECTOMY VOICE RESTORATION WITH TRACHEOESOPHAGEAL PUNCTURE**

Brown et al. demonstrated that there is apparently no significant difference in patient satisfaction on subjective and objective assessments of voice quality in patients undergoing primary or secondary TEP.\(^{(11)}\)

**HANDS-FREE SPEECH**

Excellent results have been reported with the use of voice prostheses for the rehabilitation of laryngectomees. Many patients consider it a disadvantage that the tracheostoma must be closed manually for speech production, since this makes it difficult or impossible for them to simultaneously communicate through gestures or to work with both hands. An automatic tracheostoma valve helps patients overcome this problem. Different types of tracheostoma valves have been developed in recent years and allow ‘hands-free speech.’ The Blom-Singer tracheostoma valve and the Provox FreeHands Heat and Moisture Exchanger are common examples. The majority of patients have no major difficulties in producing hands-free speech with these valves. Little has appeared in the literature concerning automatic speaking valves. In the published studies the results are similar and suggest that the greatest problem is fixation of the valve to the peristomal skin. Overproduction of mucus, excessive coughing, or a high speaking pressure can be additional problems. Breathing is described as being harder with an automatic speaking valve than with a digital system. Automatic speaking valves are useful, easy-to-use devices in speech rehabilitation and attempts should be made to solve the problems associated with their use, especially for better securing the valve to the tracheostoma. All options for attaching the speaking valve securely to the tracheostoma must be considered, including the use of different types of adhesives and base plates, cannulas, and/or tracheostoma buttons (Barton-Mayo or LaryButton).

**BIOFILMS ON VOICE PROSTHESSES**

Microbial colonization of voice prostheses has been a major factor limiting the life of all voice prostheses. Antimicrobials have been used with success to solve this problem. However, long-term medication carries with it the risk of development of resistant strains. Therefore, recent research has focused on development of other means of preventing biofilm formation on voice prostheses. Numerous techniques have been devised with varied results. Approaches that have been tried include modification of the physicochemical properties of the biomaterial surface, achieving an antifouling improvement for the silicone rubber material by the development of new biomaterials, and development of alternative prophylactic and...
therapeutic agents, including probiotics and biosurfactants. As antimicrobial resistance is a matter of growing concern, the development of novel alternative prophylactic and therapeutic agents, including probiotics and other surface-active compounds such as biosurfactants, are expected to gain prominence in the future as antifouling strategies.

**PULMONARY REHABILITATION**

Pulmonary rehabilitation is of vital importance to every patient undergoing voice rehabilitation. Some of the lost nasal functions of normal conditioning, i.e., heating, moisturizing, filtering of the air, etc., can be restored by application of a heat and moisture exchanger (HME). During expiration HMEs collect heat and moisture and use this to ensure that the inhaled air is filtered, warmed, and humidified during subsequent inspiration. HMEs also increase the airflow resistance of the stoma, so pulmonary physiology is improved as well. Their consistent use appears to have a positive effect on pulmonary function and problems and on the related quality-of-life issues, including voice quality—not only of tracheoesophageal but of esophageal speech as well.\[19,20\]

**OLFACTORY REHABILITATION**

Total laryngectomy results in a permanent disconnection of the upper and lower airways and leads to a wide range of adverse effects. This change in anatomy also leads to loss of the smell, the nasal airflow-inducing maneuver (NAIM), or ‘polite yawning technique,’ was developed by Hilgers et al.\[24\]

**‘POLITE YAWNING TECHNIQUE’ OR NAIM**

The oral cavity is enlarged a couple of times (as during yawning) by lowering the mandible, floor of mouth, and tongue. With the lips securely closed (polite yawning), an underpressure is created in the oral cavity and, consequently, air is drawn into the nose, resulting in orthonasal airflow. The orthonasal airflow carries the odor molecules to the olfactory epithelium and thus results in olfaction.

The NAIM method is easy to learn and rapidly improves the capacity to smell and taste. It is recommended that olfactory and gustatory rehabilitation should be incorporated into routine rehabilitation program for patients undergoing laryngectomy.

**CONCLUSION**

Tracheoesophageal speech using voice prostheses has revolutionized vocal rehabilitation following total laryngectomy and, in many centers, it has replaced esophageal speech as the gold standard for voice rehabilitation. The advantages of these devices are numerous and include immediate voice production, high success rates compared to esophageal speech, relatively low complication rates, and possibility of sustained speech, with a more fluent quality than with esophageal speech. TEP speech has clearly improved the quality of life of laryngectomized patients. But it is not without its associated problems, such as obstruction of the prostheses and leakage through the devices, and troubleshooting of these problems should be anticipated. With the development of automatic tracheostome valves, even hands-free speech is now possible. Today, rehabilitation focuses not only on optimal voice rehabilitation but also on adequate pulmonary and olfactory rehabilitation.

Biofilm formation on voice prostheses has been a major problem, limiting the lifetime of all voice prostheses, and the development of novel alternative prophylactic and therapeutic agents, including probiotics and other surface-active compounds such as biosurfactants, are expected to gain prominence in the future for preventing biofilm formation.

**REFERENCES**


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