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REVIEW ARTICLE

Difficulties in the fixation of prostheses for voice rehabilitation after laryngectomy

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Abstract

In most patients with advanced or recurrent laryngeal or hypopharyngeal cancer, total laryngectomy is indicated. This means the loss of three main functions: phonation; respiration; and the prevention of aspiration during deglutition. Laryngectomy patients have various options to restore phonation: an oesophageal voice; an electrolaryngeal voice; or a tracheo-oesophageal voice. In the last case a silicone rubber shunt valve is placed in the tracheo-oesophageal wall and phonation is generated when exhaled air is forced through the oesophagus and neopharynx. This method is widely applied in Western Europe. In this paper we review the literature on fixation problems with shunt valves, tracheostoma valves and heat and moisture exchange (HME) filters. Tracheo-oesophageal speech without a valve is not considered. Despite 22 years of experience with the implantation of tracheo-esophageal shunt valves and many improvements in the design, problems still remain, such as biofilm formation with subsequent leakage through the valve, the need for frequent and inconvenient replacements, fistula enlargement leading to leakage around the device and reduced fixation, and infections. The high cost of shunt valves is a drawback to their use worldwide. To enable hands-free speech, different types of tracheostoma valve have been developed. These valves are fixed to the skin or to the tracheostoma by means of an intra-tracheal device. An HME filter is used to protect the airway and maintain physiological balance. Such devices are only suitable for a selected group of patients as fixation to the skin or trachea can be a major problem. Speaking and coughing cause pressure increases, which often result in mucous leakage and disconnection of the valve and/or HME filter. Recommendations are made for future improvements in fixation techniques.

Keywords: *Heat and moisture exchange filter, implants, leakage, prosthetic fixation, shunt valve, tissue connector, tracheostoma valve, voice prostheses*

Introduction

Total laryngectomy is indicated when cancer of the larynx or hypopharynx is locally advanced, or as salvage therapy for tumour recurrence after surgery, radiotherapy or chemo-radiation treatment [1,2]. Billroth [3,4] in 1873 was the first surgeon to perform this procedure for carcinoma recurrence. Total laryngectomy has drastic consequences on respiration, phonation and smell [5,6].

The respiratory tract is modified by the construction of a tracheostoma which bypasses the upper airway and therefore severely reduces the patient's sense of smell and his/her ability to filter, heat and humidify the inhaled air [6]. The pharynx is primarily reconstructed with remnants of pharyngeal mucosa and deglutition depends on the quality of the mucosa and the width of the neopharynx. In patients with hypopharyngeal cancer, reconstruction of the

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neopharynx with a myocutaneous flap or a free tissue transfer is often needed.

At present, the three most accepted methods of voice rehabilitation after total laryngectomy are the oesophageal voice, the electrolaryngeal voice and the tracheo-oesophageal voice by means of a shunt valve. At some specialized centres, a voice shunt is constructed surgically, which enables tracheo-pharyngeal or tracheo-oesophageal voice without the need for devices. The tracheo-oesophageal voice is well known at most clinics in the Western world and many centres consider it to be superior to the oesophageal and electrolaryngeal voices.

In this review we concentrate solely on tracheo-oesophageal voice rehabilitation using shunt valves. The principle of tracheo-oesophageal speech using a fistula to the neopharynx has been applied and described by many surgeons, such as Conley et al. [7] in 1958, Staffieri [8] in 1972 and Komorn [9] in 1974. Singer and Blom [10] introduced a shunt valve into the tracheo-esophageal fistula in 1980.

The mechanism of producing alaryngeal speech is based on insufflating air through a shunt valve seated in the tracheo-oesophageal puncture (TEP). During expiration with simultaneous closure of the tracheostoma [either manually or by means of a hands-free tracheostoma valve (TSV)], the pseudoglottis [pharyngo-oesophageal (PE) segment] starts to vibrate, creating sound that can be used for speech [11]. In many series, this method of voice rehabilitation has been successful in up to 90% of patients after laryngectomy [12–14]. However, many post-laryngectomy patients, especially those with a hypotonic PE segment and/or women, have problems accepting their low-pitched voice [15,16].

The two types of shunt valve that can be distinguished are the non-indwelling type, which can be removed, cleaned and replaced by the patient, and the indwelling type, which cannot be removed by the patient for maintenance or replacement. In most cases, replacement is performed by an otorhinolaryngologist in an outpatient clinical setting [12,13].

Fixation of shunt valves, TSVs and heat and moisture exchange (HME) filters is often a major problem. In this paper we review the literature to give an overview of the fixation-related problems with the presently available devices for prosthetic voice rehabilitation after total laryngectomy. Also, new insights are put forward to improve fixation.

Tracheo-oesophageal shunt valves

Different types of shunt valve have been developed, such as the Blom–Singer® (InHealth Technologies, Carpinteria, CA), Panje prosthesis, ESKA–Herrmann® [17,18], Singh Valve—Button, duckbill Bivona®, Provox® 1, 2 and ActiValve (Atos Medical AB, Hörby, Sweden) [19], Groningen® LR and ULR (Medin, Groningen, The Netherlands) [13], Nijdam [20,21], Adeva® High Flow, VoiceMaster®, VoiceMaster® Primo (Entermed International, Woerden, The Netherlands) [22] and Staffieri [23]. Some devices are more widely applied than others after primary placement. They can be changed in a retrograde way, or in a more patient-friendly anterograde way. Table I lists the majority of shunt valves that are currently commercially available.

Fixation of shunt valves

The common fixation method for shunt valves is based on two types of form fitting: (i) a "form fit" that involves two flanges, one in the trachea and one in the oesophagus that press against the party wall; and (ii) a "force fit" in which the shaft is somewhat larger than the fistula, so that the valve is held by friction. To realize an air- and watertight fit, it is necessary to use a shunt valve whose dimensions match the size of the fistula. Good fixation cannot always be guaranteed, because the interaction between the party wall and shunt valve is a dynamic and delicate balance. Thinning of the party wall due to pressure exerted by the flanges or atrophy leads to piston movements of the shunt valve and subsequent leakage. This can also be the result of size mismatch (at the time of implantation or subsequently) or local infection. Soft tissue reactions will follow, which also result in loss of fixation. Leakage along the prosthesis was a persistent complication in up to 27% of the cases described by Laccourreye et al. [34]. For small size mismatches a shunt valve can be used with different dimensions, but the range of sizes available is limited. Another fixation strategy is employed by the Blom–Singer indwelling low-pressure shunt valve, which has an enlarged thin oesophageal flange.

Another mechanism of leakage is through the shunt valve. Nowadays, most shunt valves are made of silicone rubber, sometimes in combination with other materials, such as PTFE (Teflon) or metal. Silicone rubber is prone to biofilm adhesion and ingrowth by yeasts (e.g. Candida species) and bacteria. This leads to valve dysfunction, leakage and/or an increase in airflow resistance. These processes mean that more effort is required to speak, which results in frequent valve changes [35–37].

Different suggestions have been made to increase the survival of the shunt valves, e.g. cleaning by means of a flushing device or brush or removal of the shunt valve for inspection and cleaning on a regular basis, using probiotic strains in food supplements [35,38], using other materials, e.g. titanium and

Table I. Current commercially available shunt valves.

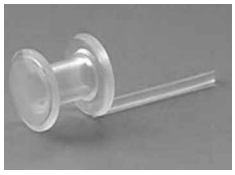
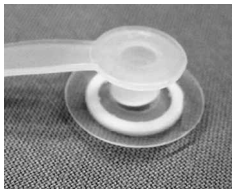
Device (type of placement)	Country of development	Photograph	Diameter (mm)	Length (mm)	Reference
Groningen LR (R)	The Netherlands		7 and 8	5, 7, 8, 9, 11, 13	24
Groningen ULR (R)	The Netherlands		7 and 8	5, 7, 8, 9, 11, 13	25
VoiceMaster (A)	The Netherlands/France		8	6, 8, 10, 12	26
VoiceMaster Primo (R)	The Netherlands/France		8	6, 8, 10, 12	26
Provox-1 (R)	The Netherlands/Sweden		7	4.5, 6, 8, 10	27
Provox-2 (A)	The Netherlands/Sweden		7	4.5, 6, 8, 10, 12.5	28
Provox Acti-Valve (Light, Strong and XtraStrong) (A)	The Netherlands/Sweden		7	4.5, 6, 8, 10, 12.5	19
ESKA–Herrmann (R)	Germany		6	Short and long with different angles	29

Table I (*Continued*)

Device (type of placement)	Country of development	Photograph	Diameter (mm)	Length (mm)	Reference
Bivona Ultra-Low resistance voice prosthesis (A)	USA		5.3 and 6.8	6, 8, 10, 12, 14, 18, 22, 25	
Bivona duckbill (A)	USA		5.3 and 6.8	6, 8, 10, 12, 14, 18, 22, 25	
Blom–Singer duckbill voice prosthesis (A)	USA		5.3 and 6.8	6, 8, 10, 12, 14, 18, 22, 25, 28	30
Blom–Singer low pressure voice prosthesis (A)	USA		5.3 and 6.8	6, 8, 10, 12, 14, 18, 22, 25, 28 (for 5.3-mm diameter only)	31
Blom-Singer indwelling voice prosthesis with or without enlarged oesophageal flange (A)	USA		6.3	4, 5, 6, 7, 9, 10, 11, 13, 14, 16, 18, 22, 25	32
Blom–Singer indwelling Advantage™ (A)	USA		6.3	4, 6, 8, 10, 12, 14, 18, 22	
Adeva high flow (A)	Germany		6	For party wall thickness 5.5–7.0, 7.0–8.5, 8.5–10	33

A = anterograde; R = retrograde.

PTFE (in the VoiceMaster) [26], fluoroplastic [19], silver oxide and thermoplastics [39], to make the shunt valves resistant to biofilm formation and prescribing antifungal agents [12,22,32,40]. Attempts have also been made to coat shunt valves with titanium and gold but it was not possible to produce a homogeneous coating [40]. In the case of the Provox ActiValve, the silicon rubber valve has been replaced by a fluoroplastic valve with magnets [19], and this has already improved device survival compared with the Provox 2. However, no long-term solution is currently available for all patients.

On average, shunt valves have to be replaced every 3–4 months [12,41]. The indications for valve replacement are mainly leakage through the prosthesis, increased pressure (device-related), leakage around the prosthesis, inaccurate size, hypertrophy or infection, and spontaneous loss (fistula-related). Op de Coul et al. [12] reported that 73% of replacements were device-related, while 13% were fistula-related. The replacement procedure is uncomfortable for the patient and can increase the risk of stoma stenosis, scar tissue formation and a dysfunctional TEP [35]. Since the introduction of a front-loading system, replacement has become less uncomfortable and damaging [12,22]. Nevertheless, this frequent need for replacement is expensive and exerts an extra burden on the healthcare system. In The Netherlands, the average annual cost of shunt valves was ≈€1200 per patient in 2004.

More serious complications include aspiration, pneumonia and ingestion followed by a mechanical ileus [42], which can be regarded as (at least partially) fixation-related. Fortunately, these complications are rare.

Different solutions have been put forward to correct TEP dysfunction. A small TEP diameter can be enlarged with a dilatator, whereas an enlarged TEP can be treated conservatively by removing the shunt valve temporarily. More sophisticated solutions include the injection of microspheres (made of solid silicone rubber, polymethylmethacrylate, etc.), Bioplastique® collagen solution (Bioplasty, Geleen, The Netherlands) [11,43], Hylaform®, a colourless viscoelastic gel (cross-linked hyaluronan) [44], or autogenous fat [45], suturing the surrounding soft tissue [12] or cautery with silver nitrate in the case of granulation tissue [46]. Surgical closure and a second puncture may be necessary in persistent cases. Occasionally, even interposing of the pectoralis major flap or another form of myocutaneous flap is needed to close the fistula [46]. In many cases, local infection can be treated with antibiotics or antifungal drugs.

Tracheostoma valves and filter systems

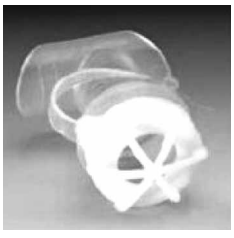
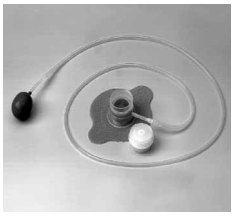
Closing the tracheostoma manually to produce tracheo-oesophageal speech is inconvenient and non-hygienic. To enable hands-free speech, a tracheostoma valve was introduced by Blom et al. [47] in 1982.

In the past, many TSVs have been produced, such as the ESKA–Herrmann® (ESKA, Lübeck, Germany) [48], Blom–Singer TSV (Bivona, Gary, IN) [5], Blom–Singer adjustable TSV (InHealth) [49,50], Adeva® Window® TSV (Adeva Medical, Lübeck, Germany) [51,52] and the Provox® Free Hands TSV (Atos Medical AB, Hörby, Sweden) [53]. Geertsema et al. [54] designed a TSV based on inhalation. An inhalation spurt sets the valve in the "speaking position", in contrast to all other TSVs. This TSV is not yet commercially available. A number of currently available TSVs are listed in Table II.

There are different options for closing the tracheostoma, namely manual, pneumatic or automatic. The pneumatic devices (e.g. the Intravent® stoma button, Intravent®-2 tracheal cannula and Extravent® speech valve) are operated by a small balloon connected to the valve by a thin tube [55,56]. The advantages are that there are no mechanical parts that make noise, the patient does not need to point to his/her handicap when he/she wants to speak and the control of the device is totally in the hands of the patient. Obvious disadvantages are that one hand is still needed to squeeze the balloon and there is a small risk of unwanted closure in certain situations, e.g. during fainting or falling, when being pushed in a crowd.

Hands-free or automatic closure of the tracheostoma can only be accomplished with a tracheostoma valve. Ideally, the TSV should have a great many features. It must close when the patient wants to speak and must be open during normal breathing or coughing and/or expectoration of phlegm. It must also have low, but not zero, airflow resistance (to allow physical exercise) [57], a low noise level (i.e. turbulence and clicking sounds) and should be small, light and easy to connect and disconnect for cleaning, maintenance or in emergency situations whilst also providing firm fixation. Many patients suffer from respiratory symptoms, such as excessive mucus production and coughing. Most of the early TSVs on the market have to be removed during coughing because they have a valve that closes on strong expiration. The Adeva Window and Provox Free Hands TSVs are exceptions due to the incorporation of a "coughing lid". Nowadays, TSVs can or must be combined with filters.

Table II. Overview of current commercially available tracheostoma valves.

Device name	Country of development	Photograph	Combination with HME filter?	Fixation	Reference
Adeva Window	The Netherlands		Optional	Cannula (Baclesse); flange and glue; intraluminal (chimney)	51
Provox Free Hands HME	The Netherlands/ Sweden		Necessary	Provox Stomafilter plaster; OptiDerm; FlexiDerm; XtraBase and Regular; Provox Lary Tube; Barton–Mayo stoma button	53
ESKA–Hermann	Germany		No	Intraluminal (chimney)	62
Blom–Singer ATSV and ATSV II	USA		Optional	Valve housing; tape discs; foam discs; true seal; Barton–Mayo stoma button; glue	47
Extravent	Germany		Optional	Provox Stomafilter plaster; OptiDerm; FlexiDerm; XtraBase and Regular; Provox Lary Tube; Blom–SingeR® base plate; Barton–Mayo stoma button	55
Intravent	Germany		No	Button	56
Intravent-2	Germany		No	Cannula with inflatable cuff between cannula and tracheal wall	56

HME filters perform three important functions of the nose that are bypassed after laryngectomy: the inhaled air is warmed, moisturized and filtered. Tracheostoma filters can reduce tracheal irritation and phlegm production and, if they are used starting on the first postoperative day, patients can become accustomed to breathing with the increased airflow resistance at an early stage and there is an increased chance of success [54,58,59]. Filters with different airflow resistance, such as the Aqua+® T Trachinaze®, Bivona, Provox®, Tracoe® humid assist, Portex®, Stom-Vent®, Trachemex®, Humidus Type 301, Humidifilter Blom–Singer®, Humidotrach®, Trachvent, Thermovent T, Tracheolife, Tracheofix® tracheostoma cover, Stom-Vent® HME filter, Stom-Vent® 2 [57], Provox® HME cassette HiFlow™ [60] and Cyranose® [61] with speech button, are now available so that patients can switch devices depending on their activity level [6]. Several filters have been studied in terms of moisture output, pressure drop, voicing and intelligibility (using questionnaires).

Whether a patient can or will use the TSV and/or filter depends on many factors, such as the size (not too much protrusion) and weight of the device, stoma shape, phonation pressure, noise level, ease of connection, phlegm production, physical activity, agility and comorbidity. The Provox Free Hands cannot be used without attaching an HME filter to the back of the valve. This has the advantage that the delicate mechanism of the valve is not hampered by mucus. However, mucus easily collects at the back of the valve or in the filter, which increases the airflow resistance and means that the filter has to be replaced. The Adeva Window can be used with and without an HME filter. The filter can be placed on the front of the coughing lid of the valve. During coughing, the mucus passes the valve and does not become trapped in the HME filter.

Increased airflow resistance makes it impossible for some patients with a TSV to perform strenuous physical activities.

Fixation of tracheostoma valves and HME filters

There are two common fixation methods for TSVs and/or HME filters. Firstly, the device can be attached to the skin by means of self-adhesive strips or tape, sticking plaster (such as FlexiDerm™, OptiDerm™, tape disc, foam disc) [53] and/or glue, and secondly by intra-luminal devices, such as a cannula, stoma button or housing with flanges (ESKA–Herrmann and option for Adeva Window) [6,48–52,59,63]. Fixation of the cannula is accomplished by means of a piece of string around the neck, a pneumatically controlled cuff or adhesive discs (Lary Tube™). Silicon rubber devices with flanges are fixed by the form of the housing.

Fixation of the Intravent-2 is different as it has an inflatable cuff just dorsal to the cannula flange in the opening of the tracheostoma. Fixation is enhanced when strong fixation is needed (during speech), and thus it would seem to be superior to other cannulas.

The most common fixation-related problems are leakage of air and mucus. The size and shape of the stoma and the peristomal skin play an important role. Other disadvantages of the current fixation methods are painful skin irritation or even skin and/or soft tissue infection caused by skin maceration and traction, tracheal irritation, time-consuming cleaning and re-attaching, noise, dislodgment and high cost.

Many patients find it difficult to achieve airtight, firm fixation of TSVs and HME filters and therefore need to be instructed carefully by stoma care practitioners. For example, to fix the ESKA–Herrmann TSV and the Adeva Window fitted with the intra-tracheal T-type silicone rubber, a surgically formed envelope (chimney procedure) is required. This technique to create a tracheostoma is rather uncommon in some countries. However, if the patient can become accustomed to this intra-tracheal device, it can lead to satisfactory long-term airtight fixation [64]. To install most other types of extra-tracheal device, the patients need a flat, thoroughly cleaned area of skin around the tracheostoma [48,59,65]. Sometimes an incision in the front border of the sternocleidomastoid muscles helps to flatten peristomal contours [1,50]. Giacomarra et al. [66] described a promising new solution for tracheostoma stenosis. This so called star plastic, consists of a surgical technique that combines radial incisions, V-shaped and interposing flaps. In this way a circumferential strip of peri-stomal cutis and subcutis is removed and when the margins are sutured together with little traction, the storma is widened.

For the adequate fixation of HME filters and TSVs, other solutions have been suggested. For example, the low success rates achieved with the Barton stoma button (Bivona) are due to the lack of a circumferential stoma lip, an irregular stoma contour or inappropriate device size. Success rates can be increased, for example by having a maxillofacial prosthodontist modify the button to the geometry of the tracheostoma [49,50]. A technique was also published [67] to adapt the standard housing device of the Blom–Singer TSV: polyvinysiloxane impression material was used to make a tight fit. Despite these solutions, long-term fixation of a TSV or an HME filter is still a problem in a large number of patients. Consequently, only

≈25–30% of patients use TSV devices on a regular basis [53].

Discussion

After total laryngectomy, the fixation of prosthetic devices to enable speech is a problem for many patients. In recent years, many prostheses and fixation aids have been developed. For most patients in developed countries, the shunt valve is available as a tool for successful voice rehabilitation. Patients who use this device are bothered by leakage through and around the valve due to material and fixation discrepancies, respectively. Sooner or later these problems will necessitate valve replacement. The malfunctioning device can be replaced relatively easily, but correction of the TEP generally involves various risks to the patient. These vary from administration of antifungal drugs and injections in the party wall to rigorous surgical corrections.

In contrast to the shunt valve, long-term use of the tracheostoma valve is only feasible in a minority of patients. Many factors, such as pre- and post-laryngectomy treatments, comorbidity, motivation, ability/skills and cooperation of the patient, determine success. Also, higher success rates can be expected when more attention is paid to the shape of the tracheostoma during the surgical procedure itself [2].

HME filters equipped with a manual speech valve stay attached more easily. Every time the patient talks, the housing/adhesive base plate is pressed against the peristomal skin again.

Two of the goals of the new Eureka-funded research project "Newvoice" (www.eureka.be) are to develop improved fixation techniques for the TSV and shunt valve and to develop an improved voice-producing shunt valve. Improvements in the fixation of these prostheses imply better chances of successful speech rehabilitation.

A deep lying stoma complicates proper attachment of tracheostoma valves (and/or HME filters). A possible solution to improve the shape of the stoma and peristomal skin, besides incision of the front borders of the sternocleidomastoid muscles, is to use a circle shaped silicone rubber implant for tissue augmentation. This may help to create a large flat area for device attachment. Another approach, analogous to the success of the percutaneous bone-anchored hearing aid (BAHA) [68,69], is the tracheostoma tissue connector [70], which may offer a solution for long-term attachment of the TSV. In contrast to the BAHA, this is a soft tissue-anchored device. A titanium ring will be used as a bone substitute because subcutaneous anchoring is necessary.

Concerning the shunt valve, the tracheo-oesophageal tissue connector will have to bridge the gap between the two mucosal tracts of the trachea and oesophagus. This tissue connector is not based on bone anchoring but has to attach the device to the walls and surrounding fibrous tissue of the dorsal trachea and anterior oesophagus.

With both concepts, the mesh is the most important structure for soft tissue fixation because it allows ingrowth of capillaries and fibrous tissue for firm implant fixation. At present, these two prototypes are being designed and tested in animals [71].

Conclusions

Fixation problems frequently occur with shunt valves and cause device malfunction. As fixation of TSVs is difficult, only a minority of patients use the devices and benefit from hands-free speech. HME filters are easier to attach than TSVs and are acceptable to the majority of patients.

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