Provox® HMEs

Literature review

Databases: PubMed Medline, Stanford Highwire Press, Atos Medical Internal ArticleBase

Search Words: HME & Laryngectomy, HMEF, Provox

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Comment

This literature review concerns the Provox Heat and Moisture Exchanger (HME Normal, HiFlow and XtraHME), Provox FreeHands HME, Provox LaryTube, Provox LaryButton and related accessories all manufactured by ATOS Medical, and devices that are similar to the new Provox Micron HME that combine the HME function with a Filter (HMEF manufactured by GE Healthcare and HUMID-VENT manufactured by Gibeck).
The searches were conducted using these product names as keywords and using their generic names as keywords in the Medline search engine and Cochrane library. Additionally, our own company database with publications on these products was screened for relevant publications.

Introduction

During a total laryngectomy, the entire larynx is removed, which leads to a permanent disconnection of the upper and lower airways and a permanent tracheostoma in the neck (see Figure 1). These anatomical changes lead, among others, to changes in voice production, breathing, and olfaction. In this review the changes in breathing after total laryngectomy and the influence of HMEs on pulmonary and psychosocial functioning are discussed.

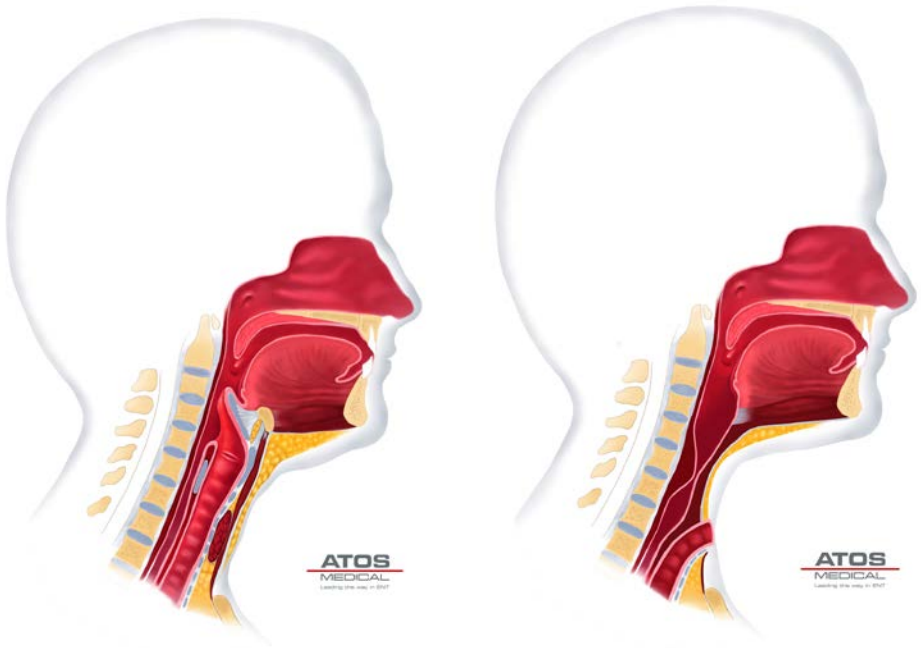

Figure 1 Schematic drawing of normal anatomical situation (A) and the anatomical situation after total laryngectomy (B). In the normal situation the patient can inhale and exhale through the nose and mouth. After total laryngectomy, the upper airways are bypassed and breathing takes place through the tracheostoma in the neck.

Post-laryngectomy pulmonary function

After a total laryngectomy, the patient breathes in and out through the tracheostoma in the neck. Therefore, the nasal functions of warming, humidifying, and filtering of the inhaled air are lost, and the upper airway resistance is lost. During normal nasal inspiration, air of 22^{o}C and 40% Relative Humidity (RH) is conditioned into air of 32^{o}C and 99% RH at the level of the trachea[1]. Due to the loss of the air-conditioning functions of the upper airways, these numbers are much lower in laryngectomized patients. Air of 22^{o}C and 40% RH is only conditioned to 27-28^{o}C and 50% RH at the level of the upper trachea. Both temperature and humidity have a significant impact on the ciliary activity in the trachea. Studies in a rabbit model have shown that at body temperature (37^{o}C) the cilia stop beating when the RH drops below 50%. If RH lowers to 60% there already is a reduction in mucociliary frequency of 30%[2, 3]. During normal nasal breathing, the inhaled air is also filtered. This filtration is important

because the spread of viral and bacterial disease by way of the atmosphere requires, among other things, that infectious particles be inhaled by susceptible individuals and deposited at effective sites within the respiratory system for the initiation of disease[4]. The nose does not only aid in the filtration of airborne bacteria and viruses, but also other particles such as allergens, pollen, and dust. The filtration of air is a complicated subject and depends for example on tidal volume, breathing frequency, air flow velocity, and diameter of particle size[4, 5]. In laryngectomees, the filtration function of the upper airways is lost entirely due to tracheostomal breathing.

The loss of the nasal functions leads to a wide range of pulmonary complaints such as coughing, excessive sputum production, crusting, and shortness of breath[6-12]. A large number of patients (54%) complain of increased chest infections[13], which is most probably due to the loss of the nasal functions as well. Extensive post-laryngectomy histological changes (squamous metaplasia of the respiratory ciliary epithelium and chronic inflammatory changes of the lamina propria) have been observed in the trachea at the level of the carina[14, 15]. The pulmonary symptoms develop and increase during the first 6 to 12 months after the total laryngectomy and then tend to stabilize[6, 16].

Laryngectomized patients experience the physical consequences of having a stoma (frequent phlegm production from the stoma and its interference with social activities) as the most severe side effect of their surgery[17]. The respiratory symptoms significantly affect the quality of life of the patient: correlations were found between the respiratory symptoms and perceived quality of voice, aspects of daily life, anxiety and depression[11].

HMEs

An HME has three physical properties: 1) heat and moisture exchanging capacity; 2) resistance; and 3) filtering particles[18]. The basic component of a heat and moisture exchanger is foam, paper, or another substance, which acts as a condensation and absorption surface. In order to enhance the water-retaining capacity, the material is often impregnated with hygroscopic salts such as CalciumChloride[19]. The HMEs used for laryngectomees are mostly hygroscopic and might have been impregnated with a bactericide solution in order to control bacterial colonization[20]. HMEs add a variable resistance to the airway resistance, depending on the flow rate. The outcomes of studies that have measured the flow through HMEs are not consistent[20-22], but in general, the airflow resistance of an HME is lower than the airflow resistance of the nasal airway. The effect of the increased resistance (compared to stoma breathing without HME) in laryngectomees is still poorly understood[18]. With regards to the filtering function, it is believed that HMEs, due to their large pore size, filter out some particles, but not smaller microorganisms[18].

Benefits of HME use

In 1960, Toremalm described the benefits of HME use for post-tracheotomy care: in comparison to nasal breathing, a person breathing through a tracheostoma loses about 500 ml of water. By using an HME it is possible to retain 250 to 300 ml of this water loss in the respiratory system[23, 24]. In the early seventies, the use of Heat and Moisture Exchangers for condition of the inhaled air during anaesthesia is described[25, 26]. In 1990, Ackerstaff and colleagues were the first to publish results on the use of an HME in laryngectomized patients[27]. They studied the influence of an HME on respiratory symptoms in 42 laryngectomized patients. The HME (Stomvent) was found to significantly reduce sputum production, reduce forced expectoration in order to clear the airways, and reduced stoma cleaning after using the device for 6 weeks[28]. This reduction in respiratory symptoms led to an improvement in quality of life; symptoms of fatigue and malaise decreased significantly and social contacts improved[28]. Patients using a voice prosthesis benefited less from the device used in this study than patients using esophageal or artificial larynx speech since they experienced difficulties in occluding the device for speaking[28]. The HME and baseplate tested in this study could not be separated which led to a relatively large number of problems with loosening of the adhesive due to coughing [28]. Also, with this kind of HME the device will always need to be removed for stoma and prosthesis cleaning.

In a later study a device was tested in which the HME and baseplate could be separated (Freevent) [29]. Patients were randomized into a treatment (N=24) and control (N=24) group and additionally 15 patients that participated in the previous study were included to compare the two devices. The results of this study showed that the HME user group showed significant reductions in the incidence of coughing, the mean daily frequency of sputum production, forced expectoration, and stoma cleaning. Also significant improvements were found in shortness of breath, fatigue and malaise, sleeping problems, anxiety, depression, and perceived voice quality. Pulmonary function tests showed

significant improvements in inspiratory flow and volume values following the use of an HME. Despite the fact that the HME and base plate could be separated, loosening as a result of coughing still occurred frequently because the stoma was still not accessible for cleaning due to two crossed plastic bars blocking the entrance. Also, this device was still difficult to occlude for tracheoesophageal speech. In a multi-centre study in the Netherlands[30] the same HME (Freevent) was tested in 59 new patients that were enrolled in the study after postoperative or postradiotherapy wound healing was complete. Patients were interviewed at 3 months and 6 months of using the HME. The results of this study showed that significant improvements over time were found for forced expectoration, perceived voice quality, social anxiety, social interactions, and in feelings of anxiety and depression.

In a study by Keck[31], it was shown that the tracheal climate rapidly changed after application and removal of an HME. The use of an HME increased the temperature from 27-28^{o}C to 29-30^{o}C and increased the RH from 50% to 70%.

Jones[32] compared pulmonary complaints between HME-users and a placebo group. Their results showed that the subjective respiratory parameters coughing, number of chest infections, mucus production and shortness of breath at rest were all improved in the HME group.

McRae[33] reported that the use of an HME with increased breathing resistance, approximating the normal upper airway resistance, has a positive influence on tissue oxygenation. However, the validity of their measurement technique and results have been questioned, and later research showed that there is no evidence that the use of a high-resistance HME leads to increased tissue oxygenation in laryngectomees[34]. Based on their results, Zuur[34] conclude that due to the fact that high-resistance HMEs cause patient discomfort, HMEs with a convenient breathing resistance can be the first choice.

It is not expected that an HME compensates for the loss of upper airway filtration of smaller particles such as bacteria and viruses; the pores of the HME filter are larger than the diameter of the infectious particles. Only larger particles are filtered by the HME. Kramp et al.[35] conclude that the use of HME's does not endanger the exposure to pathogenic microorganisms.

Zuur et al. [18] reviewed the physiological rationale of HME use and included both in vitro and in vivo studies in this comprehensive overview. Lorenz and Maier[36] conducted a review that assessed the effects of HME cassettes on the conditioning of respiratory air, lung function and psychosocial problems.

Provox HME – Clinical Effects

The Provox HME was developed to address the issues with the early HMEs: decreased compliance due to difficulties with adherence of the base plate and troublesome combination with a voice prosthesis. Development was guided by the remarks from patients in the two previous studies. The Provox HME consists of a separate HME cassette and a self-adhesive baseplate available in two different shapes and four different materials to accommodate different skin types in stoma shapes. The Provox HME (see Figure 2) is available in Normal and HiFlow. The HiFlow cassette has a lower resistance than the Normal cassette. The HME substance that is used is a CalciumChloride impregnated foam. The HME has a spring type valve that can easily be occluded by finger for tracheoesophageal speech. The air openings are at the side of the HME such that possible occlusion by clothes or sheets is avoided. Removal and insertion of the HME from and into the base plate is easy and after removal the patient has open access to the stoma to clean the area and the voice prosthesis.

Figure 2 Provox HME with adhesive baseplates

In a first study by Hilgers et al.[37] the feasibility of the device was investigated in 19 patients. The results showed that all patients were positive about the valve closure mechanism. They reported that voicing was considerably facilitated and intelligibility improved. Also, the problems with loosening of the baseplate due to phlegm were much decreased. Balle et al.[38], in a study in Denmark in 18 patients found similar positive results as well after a trial period of 3 weeks. Most patients found stoma occlusion with the Provox HME easier and more hygienic, and 11 found that their speech ability and intelligibility had greatly improved. Five patients experienced less coughing and sputum production, while the others reported it was unchanged (12) or more (1). This was less good than the results in previous studies and the authors contribute this to the trial period of only 3 weeks. The majority of patients used one adhesive per day and 1-2 HME cassettes per day. Most patients did not experience a change in airway resistance (11) and 7 found it to be increased. Less skin irritation was reported for the OptiDerm adhesive.

In a long-term compliance study of the Provox HME in 69 patients from Ackerstaff et al.[39], 63% of the patients reported that voicing was facilitated, 55% reported that their intelligibility had improved, 65% reported that respiratory symptoms had diminished, 94% reported a considerable overall benefit of the device, 78% of the patient used the device on a regular daily basis, 6% used it irregularly and 16% did not use the device. There was an obvious relationship between the length of use of the device and pulmonary complaints. The longer the device was used, the more the pulmonary complaints (coughing, forced expectoration, sputum production) decreased.

These results are confirmed by similar studies in Spain[40] and the US[41] indicating that results can be expected to be similar across cultures and climates. For example, the study performed in the US[41] showed that compliance was 73%, and that 68% of the patients reported a decrease in coughing, 73% reported decreased sputum production, 60% reported decreased forced expectoration, and 52% reported decreased need for stoma cleaning. The daily cough-expectoration frequency decreased significantly. In this study, the patients also reported improvements in voice quality, pitch, loudness, and intelligibility. A study conducted in Poland[42] noted similar results. Compliance is crucial and pulmonary problems decrease significantly with HME use and that related aspects such as speech and sleeping tend to improve, regardless of country or climate. Masson et al.[43] concluded in their study conducted in Brazil that the use of an HME over a 6 week time period reduced cough and expectoration of patients; however the HME did not have any influence on the vocal quality of these laryngectomized patients.

Dassonville et al.[44] published the results of a randomized controlled trial including 60 patients, who were randomized between a control group that used no device of this type and a group equipped with the Provox HME. After 3 months of using the device, a notable improvement was found which was statistically significant with regard to cough and to bronchorrhoea, and very close to achieving significance with regard to breathing effort in the HME group.

Merol et al.[45] assessed the immediate postoperative airway humidification after total laryngectomy (TLE), comparing the use of an external humidifier (EH) with humidification through a Provox HME. In a randomized controlled trial 53 patients were randomized into the standard (control) EH or the experimental HME arm. Compliance, pulmonary and sleeping problems, patients' and nursing staff satisfaction, nursing time, and cost-effectiveness were assessed with trial-specific structured questionnaires and tally sheets. Compliance and patients' satisfaction were significantly better, and the number of coughing episodes, mucus expectoration for clearing the trachea, and sleeping disturbances were significantly less in the HME arm. This was also the case for nursing time and nursing staff satisfaction and preference. Authors concluded that the study shows the benefits of immediate postoperative airway humidification by means of an HME over the use of an EH after TLE and also underlines that HMEs presently can be considered the better and more cost effective option for early postoperative airway humidification after TLE.

A study comparing finger occlusion directly on the stoma and finger occlusion on top of the Provox HME (within patient comparison) has demonstrated that maximum phonation time and dynamic loudness range improved in the condition where the patient was occluding on top of the HME[46]. This can probably be attributed to better, airtight, occlusion and better distribution of occlusal forces (reducing force on the voice prosthesis and voice producing segment in the esophagus).

An Airway Climate Explorer for testing of temperature and humidity effects of HMEs in laryngectomized patients has been developed at the Netherlands Cancer Institute[47]. Assessments of the influence of the Provox HME in standard room conditions on tracheal temperature and humidity in laryngectomees shows that the HME modifies temperature and humidity[48]. Zuur et al.[48] concluded that "the presence of an HME increases the intra-tracheal humidity and decreases the intra-tracheal temperature. The calculated relative humidity suggests that not the moisture retention but the thermal

capacity is the limiting factor for the heat and moisture exchange efficiency. Therefore, an increase in the thermal capacity may result in a further improvement in the clinically beneficial effect of the tested HME". In another study Zuur et al.[49] concluded that in a cold environment, presence of an HME significantly increases both inspiratory and expiratory temperature and humidity values. In a warm environment, however, presence of an HME has a cooling effect on the temperature while it still humidifies the inspired air[50]. A further study on endotracheal temperature and humidity completed by Scheenstra et al.[51] found that an HME leads to a shortened Inhalation Breath Length which enhances the HME effect. Scheenstra et al.[52] conducted another study of endotracheal temperature and humidity and tidal volumes in 11 laryngectomized patients with Provox HME Normal, Provox HME HiFlow, and without HME. Both HMEs significantly improved tracheal climate. The Normal HME has better moistening properties and a small but significant positive effect on tidal volume. Therefore, if the higher resistance is tolerated, the Normal HME is the preferred pulmonary rehabilitation device. The HiFlow HME is indicated if lower breathing resistance is required.

Provox XtraHME – Clinical Effects

The Provox HME was developed as the new generation of HME cassettes and is designed to have improved function and characteristics when compared to the Provox HME. The Provox XtraHME was introduced to the market in February 2010 and is available in two versions: XtraMoist HME and XtraFlow HME.

Figure 3 Provox XtraHME

The XtraMoist HME was designed to have capacities close to normal nasal function. The humidification was improved compared to the Provox HME and was designed to keep good airflow for easy breathing. The XtraFlow HME was designed with focus on having superior airflow and to be use when exercising and when adapting to the breathing resistance after having been without an HME for a longer time. Compared to the Provox HME, the XtraHME has 50% more HME media (in volume), which acts as spring. The XtraHME also has a 1.4 mm lower profile than the Provox HME, and a rim on the lid to guide the correct finger position for occlusion. In Figure 4 the differences between the Provox HME and the Provox XtraHME are shown.

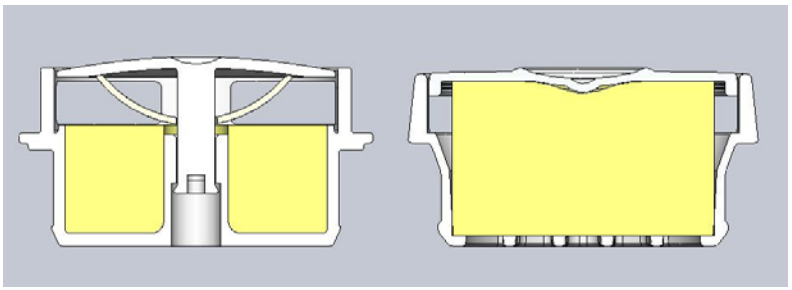

Figure 4 Schematic representation of Provox HME (left) and Provox XtraHME (right)

Scheenstra et al.[53] assessed the short-term endotracheal climate and clinical effects of two newly designed heat and moisture exchangers and compared outcomes with the regularly-used Provox HME and an older design (Stomvent). The new HMEs (Rplus with regular breathing resistance, and Lplus HME, with lowered breathing resistance) showed considerable humidification improvement over the

RHME, without the associated temperature decrease of the latter. During a 3-week observation period, 7/13 patients (54%) reported noticeable lowered mucous production with the new HME's. Authors concluded that newly designed HME's show both heating and humidification improvement compared to the R-HME. Although the appearance of the HMEs used in this study is different from the Provox XtraHMEs, the HME media used in the HMEs tested in this study is the same as the HME media used in the XtraHMEs. These newly designed HME's are nowadays marketed as the XtraHMEs (XtraMoist and XtraFlow).

Provox FreeHands HME – Clinical Effects

In addition to the Provox HME that requires finger occlusion, a device has been developed that enables hands-free speech: The Provox FreeHands HME (see Figure 5). This device combines the HME with an automatic speaking valve. Upon speech-exhalation, the membrane of the device closes off automatically, enabling the pulmonary air to be diverted through the voice prosthesis into the esophagus. This device is developed specifically for prosthetic tracheoesophageal speakers. The unique features of this device are the combination of an HME and hands-free valve (valve cannot be used without the HME), an adjustable cough relief valve that allows the air that is build up during coughing to escape, an on-off position that allows the patient to switch off the speech valve function when closing of the valve is not desired, and the availability of the speech membranes in three different strengths to accommodate different speaking pressures.

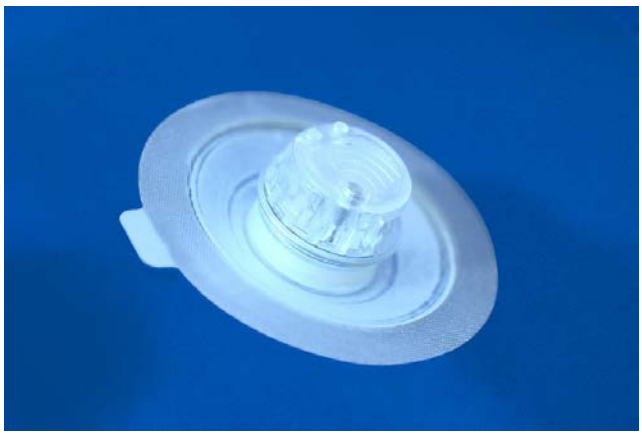

Figure 5 Provox FreeHands HME in XtraBase base plate

In a first study by Hilgers et al.[54] the feasibility of this device was investigated in 20 laryngectomized speakers of whom 5 already used an existing automatic speaking valve. Five patients discontinued using the device during the study due to problems with adherence of the base plate to the skin. Of the remaining 15 patients, 11 users used the device on a regular daily basis. The study showed that maximum phonation time and dynamic loudness range using the Provox FreeHands HME were lower than with a regular Provox HME, but higher than with another hands-free device. The finding that the use of hands-free devices results in less good phonation times can be attributed to the fact that when using a hands-free device some of the speaking air is consumed for closing the valve mechanism. The finding that the dynamic loudness range is smaller can be attributed to the fact that more air pressure is required to close the valve.

In a subsequent multi-center study 55, compliance, quality of life, and voice quality aspects of the Provox FreeHands HME were studied in 79 laryngectomized patients. Eight of them were regular users of another hands-free device, 58 had used another hands-free device unsuccessful, and 13 had never used a hands-free device. After a trial period of 6 months, 19% of the patients used the device on a daily basis (average of 5 hours), 57% used it irregularly, for example at special occasions or for a limited number of hours per day. Maximum phonation time and dynamic loudness range were found to be better than with another automatic speaking valve, but worse than with the regular Provox HME.

Tervonen et al.56 compared the Provox FreeHands HME with the regular Provox HME in 14 patients and also found that speaking characteristics were less good when using an automatic speaking valve. Compared to the Provox HME that is occluded by finger, speaking with the FreeHands HME was more difficult in 50% and easier in 21%; breathing was heavier in 64% and easier in 14%; and subjective voice quality was worse in 29% and better in 21%. Despite its limitations, 13 out of the 14 patients continued to use the device; one of them continuously and 12 of them occasionally. The

one patient that discontinued its use had difficulties with the adhesive. During this study the XtraBase adhesive was tested that was developed especially for hands-free speech. The base of this adhesive is more rigid and gives more support to the peristomal area. Both when used with a regular HME and with the FreeHands HME, on average the patients rated the skin adherence of the XtraBase as better than that of the 'conventional' (OptiDerm, Regular, FlexiDerm) adhesives.

Hamade et al.57 performed perceptual and acoustic analysis to compare speech with manual stoma occlusion and with the Provox FreeHands HME in four patients. The objective analyses showed that maximum phonation time, intensity of read speech, and percentage pause time were all significantly decreased when using the automatic speaking valve and that random noise in the speech signal increased and extraneous noise caused by the valve increased when using the hands-free device. These results were not confirmed by the perceptual evaluations. Data from a questionnaire and patient diary suggested that the main advantage of the device is the ability to speak hands-free when performing a manual task, the main disadvantage was problems with base plate seal.

Lorenz et al.58 studied the FreeHands HME in 24 laryngectomized patients. Seven discontinued its use (three due to recurrence, four due to skin adherence problems). Ten out of the remaining 17 patients used the device daily; on average 8.4 hours each day. In total, 88% of the patients considered it a great advantage to be able to speak handsfree. A long-term follow-up to this study conducted by Lorenz et al.59 found that 76% of the 17 patients considered the FreeHands to be a great advantage.

Provox Micron HME - HME and filtration

The Provox Micron HME combines a Heat and Moisture Exchanger with an electrostatic filter (see Figure 6). The electrostatic filter provides protection for the laryngectomized patient from small particles and airborne microorganisms (>99% Bacterial and Viral Filtration Efficiency).

Figure 6 Provox Micron HME

The clinical effect of the Provox Micron HME in laryngectomized patients was investigated by Scheenstra et al[60] in a short-term feasibility study. They assessed the new Provox Micron HME for short-term endotracheal climate changes in 13 patients and feasibility in daily practice in 16 patients. Compared to open stoma breathing, the Provox HME Normal increases minimum endotracheal humidity values and the Provox Micron HME also increases end-inspiratory and end-expiratory temperature values. Patients spontaneously reported a further reduction in pulmonary complaints compared to the use of the normal Provox HME.

There are also some similar devices on the market that are used in ventilator dependent patients and during anesthesia that have both Heat and Moisture Exchanging and Filtration capacities (HUMIDVENT, Gibeck; HMEF, GE Healthcare). The use of an HME with Filter has been found to decrease the incidence of Ventilator Associated Pneumonias (VAPs) in ventilated patients on the intensive care unit (ICU) in comparison with Heated Humidifiers[61, 62]. A review in 1988 by Subayi et al.[63] showed that HMEFs decrease the rate of nosocomial pneumonias in comparison with heated humidifiers. In a study that was carried out in guinea pigs, a bacterial and viral filter was found to successfully protect the pigs from sensitization to aerosolized Natural Rubber Latex[64]. Also, the use of HMEFs during anesthesia prevents bacterial migration from the patient to anesthesia circle systems[65, 66].

Attachment of HME, FreeHands HME and Provox Micron HME

The HME devices can be attached to the tracheostoma in two different ways: peristomally (base plate) or intraluminally (laryngectomy tube or stoma button).

For peristomal attachment the Provox HME can be attached into a variety of available Provox adhesives (Provox OptiDerm, Regular, FlexiDerm, XtraBase or StabiliBase). Additionally, some patients may require the use of Provox Silicone Glue to improve the seal of the adhesive to the skin. Other products that are recommended for proper application of the adhesive are Remove (to remove glue from the skin) and SkinPrep (to protect the skin against adhesive and glue and prevent skin irritation). Tervonen et al.[56] reported that skin adherence with the XtraBase adhesive was perceived as better. Dirven et al.[67] reported that the combination of FlexiDerm, and extracted base from an XtraBase adhesive and the external neckbrace demonstrated to have the smallest outward neck movement during handsfree speech.

Van der Houwen[68] et al. studied in detail (peri)stoma geometry data of a diverse population of laryngectomized patients in relation to adhesive use. The study revealed a mismatch between patients and adhesives. Authors conclude that based on their data new adhesives can be developed that could help improve rehabilitation after laryngectomy.

For intraluminal attachment the HME device can be attached into a LaryTube or a LaryButton. The primary goal of using a LaryTube or LaryButton is usually to maintain stoma patency, although more recently a LaryButton has also shown to be beneficial in combination with a hands-free speaking valve.

The Provox LaryTube is a so-called laryngectomy tube or tracheostoma tube (see Figure 7). Many laryngectomized patients require a laryngectomy tube to maintain stoma patency, especially in the early postsurgical days and during postoperative radiotherapy[69]. Some patients experience permanent problems with stoma patency, requiring permanent use of a laryngectomy tube[69]. The unique feature of the Provox LaryTube is that it is the only laryngectomy tube available that holds an HME. The LaryTube can hold a Provox HME or Provox Freehands HME. The LaryTube is held in place with a tubeholder (necktie) or it can be clicked into a baseplate (model with Blue Ring). For patients using a voice prosthesis, a fenestrated LaryTube is available.

Figure 7 Three different types of LaryTubes. Left: with blue ring; Middle: regular; Right: fenestrated.

Laryngectomy tubes are considered a necessary part of laryngectomy care. A stoma that is too small causes difficulties in breathing and changing the voice prosthesis. There are no studies available on LaryTube or laryngectomy tubes in general.

The Provox LaryButton is a so-called laryngectomy button or stoma button (see Figure 8). A stoma button is primarily used in stoma's that are shrinking and that have a tight 'lip' or 'rim' that holds the button in place[69] . The LaryButton can hold an HME or FreeHands HME. Studies have shown that the use of a stoma button increases successful use of a hands-free speaking valve[70]. The unique features of the LaryButton are that it, in contrast to other available models, is more stoma and patient friendly in design (rounder edges, softer materials) and that it can be held in place by using an additional neck tie or LaryClips (small adhesives combined with Velcro-attached hooks). These

additional features enlarge the number of patients that is able to use the device. The need for a tight 'lip' or 'rim' to hold the button in place is less important.

Figure 8 LaryButton with LaryClips

A study on the use of the LaryButton and LaryClips[71] demonstrated that the system was appreciated by the majority of the patients and that its use led to increased success with usage of hands free speaking valves. Lewin et al.[72] describe how the LaryButton and other trachea buttons with the intraluminal attachment have become a preferred method for securing hands-free speaking valves to the stoma. These are effective because they eliminate the need for adhesives and glues that are often ineffective in sustaining a peristomal seal during hands-free TE speech production.

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