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Freevent range products and TrachPhone
Literature Review

Tracheostomy HMEs and HMEFs

Freevent range products and TrachPhone

2024

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Summary

This Literature Review addresses the Heat and Moisture Exchangers (HMEs) and Heat and Moisture Exchangers with electrostatic filter (HMEFs) intended for tracheostomized patients. The products included in this review are TrachPhone, Freevent XtraCare, Freevent XtraCare Mini, Freevent DualCare, and HME DigiTop, manufactured by Atos Medical AB.

The Literature Review includes an introduction to tracheostomy, covering aspects such as clinical indications, procedure types and impact on respiratory function. It also contains an overview of the different artificial humidification methods and their clinical impact in mechanically ventilated and spontaneously breathing patients with a tracheostomy.

The introduction is followed by a technical description of the devices (TrachPhone, Freevent XtraCare, Freevent XtraCare Mini, Freevent DualCare, and HME DigiTop) and the evidence found evaluating the performance of these devices or devices with a similar design.

The searches were conducted in the PubMed search engine using search terms around "tracheostomy" and "heat and moisture exchanger" as keywords, covering a period from 1987 to 2023. Search results were screened for relevant publications and included as evidence on Freevent range products and TrachPhone. Publications included in this document were selected based on mention of TrachPhone, Freevent XtraCare, Freevent XtraCare Mini, Freevent DualCare, and HME DigiTop. Additionally, hand searches were performed for overall publications included in the introduction.

1 Introduction

1.1 Tracheostomy and its impact on respiratory function

1.1.1 Indications and procedure types

Tracheotomy is a surgical procedure that creates a permanent or temporary opening between the trachea and the anterior aspect of the neck for the purpose of ventilation. The resultant opening in the trachea is named a tracheostomy or tracheostoma. When a tracheostoma is created, the upper airway is bypassed preventing the normal air conditioning (humidification, heating and filtration) via the upper airway (Figure 1)(1, 2) .

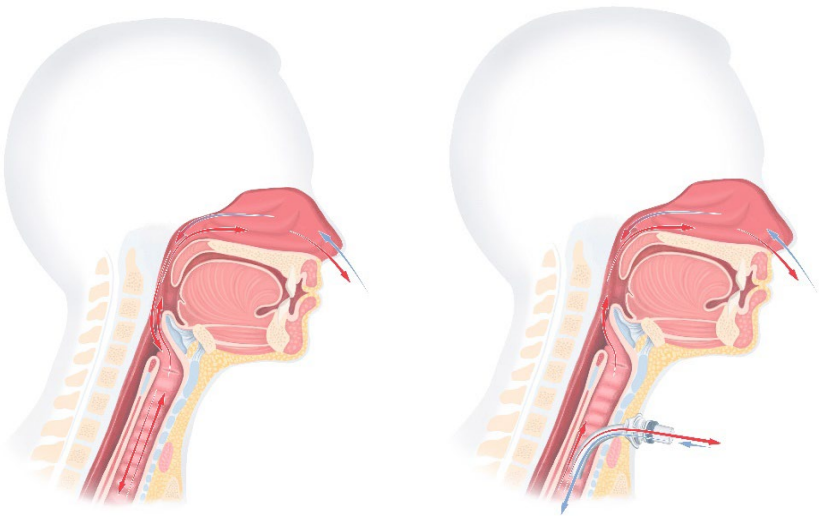

Figure 1. Schematic drawing of normal anatomical situation (left) and the anatomical situation after a tracheotomy, with a tracheostomy tube in place (right). In the normal situation the patient can inhale and exhale through the nose and mouth. After a tracheotomy, the upper airways are mostly bypassed and breathing mainly takes place through the tracheostoma in the neck.

The most prevalent indications for tracheostomy include acute respiratory failure, often necessitating prolonged mechanical ventilation, and traumatic neurologic injuries requiring airway support. Upper airway obstruction is also an indication for a tracheostomy. In cases of acute respiratory failure in critically ill patients, mechanical ventilation (MV) may be implemented (2). If MV is needed for ventilatory support for a short time, the patient may receive non-invasive MV via mask. When MV is expected to be needed for an extended period, the patient is intubated with an endotracheal tube (ETT). In cases in which the patient needs MV for a prolonged time, the ETT may be substituted by a tracheostomy tube (3).

Two different methods exist to create a tracheostoma: traditional open surgery and percutaneous dilation tracheotomies (PDT). In the traditional open surgery, the patient

will undergo a surgery in the operating theatre and be placed under general anaesthesia. In contrast, PDT is most common in an intensive care setting and can be performed at bedside using sedation and local anaesthetics (4, 5).

1.1.2 Impact of tracheostomy on respiratory function

The upper airways, and especially the nostrils located in the nasal cavities, play an important role for the conditioning of inhaled air, which involves warming, humidifying, and filtering the inspired gas (6). In patients with a tracheostomy, upper airway functions are bypassed. Therefore, the air is no longer conditioned and filtered by the upper airway before reaching the trachea (5). This may generate negative effects on pulmonary health such as higher risk for lower respiratory tract infection, increased coughing and increased tracheobronchial mucus production (5, 7-9).

The airways are lined with tracheal mucosa from nose to alveolus (10). One of the layers of the tracheal mucosa is the ciliated epithelium, responsible for many of the most important functions of the tracheal mucosa. There are at least three different cell types in the epithelium: basal cells, goblet cells and ciliated cells, with the goblet cells being the mucus-producing cells. There are 5 ciliated cells for each goblet cell. The lower the airway, the less goblet cells, and the less ciliated cells. Mucus and ciliated cells trap and expel particles and microorganisms that enter the airway (11). This mucociliary clearance depends on the quality of mucus and on ciliary function. Both factors are sensitive to changes in humidity and temperature (12, 13). After a tracheotomy, the mucociliary function may be negatively affected by the incomplete conditioning of the air. It has been demonstrated that reductions in both temperature and relative humidity of inspired gases have a direct link with the pathogenesis of ciliary damage and dysfunction (6, 14). When the mucociliary transport is optimal, it clears contaminants and excess secretions from the respiratory tract efficiently. However, the optimal mucociliary transport is achieved only if the inspired gas is conditioned to core body temperature (37 °C) and has 100% relative humidity (6, 14). When the inspired air is colder and dryer, the mucus glands and goblet cells become hyperactive, producing excessive mucus, consequently affecting the mucociliary transport (15) and thickening the airway secretions (5). The loss of the optimal mucociliary transport may predispose patients to severe airway damage (16) and pulmonary complications such as reduced clearance of secretions (16-18), excessive, and frequent airway infections (9, 19).

Additionally, when there is a partial or total disconnection with the upper airways, air filtration and respiratory resistance may be altered. The ciliated respiratory mucosa located in the internal surface of the nasal cavity participate in air filtration, preventing particulate matter contained in air from reaching the lungs. In tracheostomized patients, these contaminants may enter the trachea, producing inflammatory damage. Tissue in the nasal turbinates is capable of vascular congestion and enabling regulation of respiratory resistance. Therefore, when there is a total or partial disconnection with the upper airways, the respiratory resistance is affected (20).

Based on all the potential complications mentioned in this chapter, it is indicated that inhaled air should be filtrated, heated and humidified and so artificial humidification should be considered for patients with a tracheostomy (5).

1.2 Artificial humidification

1.2.1 Active and passive humidification

Artificial humidification systems, or humidifiers, are devices that humidify the inspired air. They are classified as active, or passive based on the presence of external sources of water. Active humidifiers can also be heated. Passive humidifiers use the heat and moisture in the patients' own expired breath to achieve humidification (21).

Humidification and heating of inspired air is a widely accepted practice for patients in intensive care units (16). Protocols for humidification may vary from hospital to hospital.

Active humidification

Active humidifiers, also known as Conventional External Humidification Systems (CEHS), act by allowing air passage through a reservoir of water (Figure 2). There are two types of CEHS, the cold-water baths, and the heated humidifiers.

In cold water baths, medical inspired gases pass through a water reservoir (at room temperature) before being delivered to the patient. This type of CEHS should not be used in combination with passive humidifiers as condensation can accumulate in the circuit, affecting their performance. They are less costly than the heated humidifiers, but they provide less humidification (16). In contrast, in heated humidifiers (HH), gases pass across a heated water chamber (Figure 2). Regular checks of temperature and water level may be required when using HH to prevent overheating as well as emptying of water condensation(22).

In both types of CEHS, after the air is loaded with water molecules, it moves along the inspiratory line to the patient's airway.

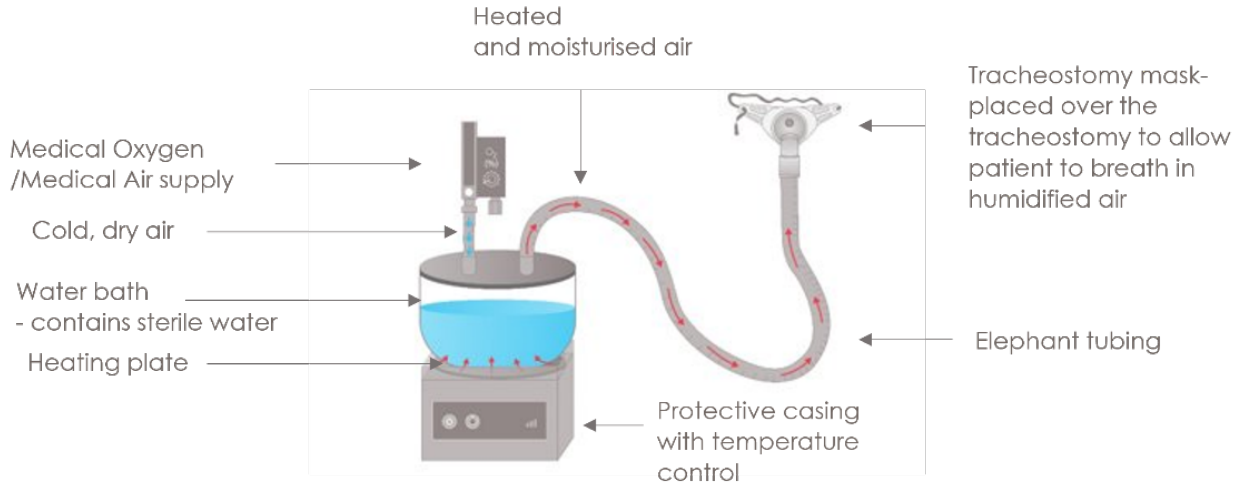

Figure 2. Heated humidifier consists of a water bath and a heating unit.

Passive humidification

Passive humidifiers are devices that aim to maintain a degree of humidity by trapping exhaled moisture and by channeling inspired gases through this humid environment. There are a variety of different passive humidifiers, including protectors (also known as 'bibs'), Heat and Moisture Exchangers (HMEs) or Heat and Moisture Exchangers with Electrostatic Filters (HMEFs) that are directly attached to tubes or buttons.

HMEs are devices intended to retain moisture and heat from the expired air and return it to the patient's respiratory tract during inspiration (Figure 3) and can be used either during mechanical ventilation or for spontaneously breathing patients. An HME can be connected between a tracheal tube connector, an angle-piece, or a catheter mount and the breathing system, or connected directly onto a tracheostomy tube connector (23, 24).

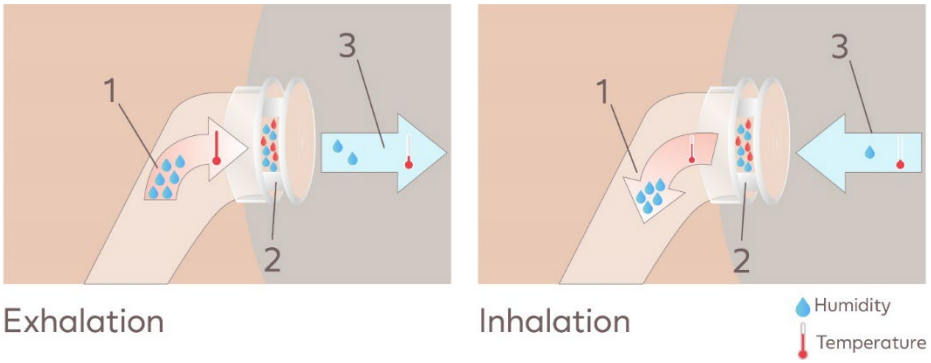

Figure 3. Working principle of an HME. The illustration on the left-hand side shows the mechanism during exhalation (breathing out): Heat and humidity from the exhaled air (1) is being collected in the HME (2). Thus, there is limited loss of heat and moisture into the environment. The illustration on the right hand side demonstrates how this heat and moisture is returned (1) to the air that passes through the HME (2) on inhalation of cold and dry air (3).

HMEs have three physical properties that help compensate for the lost functions of the upper respiratory tract: the mentioned heat and moisture exchange capacity; the HME's resistance; and filtration (25).

Generally, an HME consists of a housing that provides structural support and a core where the heat and moisture exchange takes place. To enhance the humidification of the HME, the core is typically made of materials with high thermal capacity and large surface area. Materials such as foam or paper are used to form the core and are often impregnated with a hygroscopic compound, such as calcium or lithium chloride, that have the increased ability to absorb and release moisture, and therefore improve the performance of the HME (23, 26).

The addition of an HME increases breathing resistance compared to breathing through an open stoma, however the airflow resistance of an HME is lower than the airflow resistance of the nasal airway (25). An HME that substitutes for the lost upper airway resistance creates a positive expiratory pressure, prevents alveolar collapse, and leads to increased circulating lung volume (27).

HMEs filter larger particles, but as a result of their large pore size, microorganisms, pathogens, and other small particles are not filtered to a significant degree (25). If

filtration of small particles is required, Heat and Moisture Exchangers with Filter (HMEFs) should be used. HMEFs have the humidification properties of an HME combined with the filtration properties of an electrostatic filter (> 98% bacterial and viral filtration efficiency). Electrostatic filters consist of a mat of fibers with electrostatic charges that effectively filter microorganisms, pathogens, and other small particles (28).

1.2.2 Clinical impact of using artificial humidification

Tracheostomy patients either breathe independently or need mechanical ventilation to support their breathing, either continuously or intermittently. Mechanically ventilated patients with a tracheostomy use a breathing machine called a ventilator. In contrast, self-ventilating patients with a tracheostomy can breathe on their own. They may still have a tracheostomy tube in place to support their breathing or to facilitate secretion clearance. These factors are considered when selecting the artificial humidification method.

The articles included in section 2 of this Literature Review use the term 'spontaneously breathing patients' to refer to non-mechanically ventilated patients (as opposed to self-ventilating). Therefore, for the purpose of this Literature Review, the term 'spontaneously breathing patients' will be used to refer to non-mechanically ventilated patients.

Clinical impact of artificial humidification (active and passive) in mechanically ventilated patients

Mechanical ventilation (MV) is a life-support treatment that provides artificial ventilation using a machine that moves air into and out of the lungs for individuals that are unable to breathe adequately on their own (29). MV can be non-invasive (usually via oro-nasal mask) for shorter duration ventilation or invasive (via intubation with an endotracheal tube or tracheostomy tubes) for prolonged support (3, 30). Both, active and passive artificial humidification are used in mechanically ventilated patients (30-32). Active humidifiers involve the placement of a water reservoir in the inspiratory circuit of the ventilator, while HMEs are placed between the endotracheal tube and the ventilatory circuit, potentially increasing the resistance during inspiration and expiration (13, 21).

Several systematic reviews and meta-analysis have compared and evaluated the impact of HMEs and HHs in different clinical outcomes in mechanically ventilated patients. None of them found superiority of HMEs or heated humidifiers in terms of ventilator-associated pneumonia, mortality, length of intensive care unit stays, airway occlusion or duration of mechanical ventilation (29, 33).

An HME may be contraindicated in certain invasive mechanically ventilated patients such as patients with a low tidal volume or patients with bloody, thick, or copious secretions, and HME may not be recommended for patients undergoing non-invasive mechanical ventilation (34). HMEs are used with caution during ventilation with pressure support, for weak or fatigued patients with respiratory failure. In patients with thick or copious secretions, it may be better to use a heated humidifier instead of the HME. HMEs cannot provide an adequate degree of heat and humidity during mechanical ventilation with high flow or with low body temperature (35).

Therefore, patient candidacy becomes an essential component when choosing the appropriate artificial humidification method in mechanically ventilated patients and selection should be made according to the specific clinical context.

Clinical impact of artificial humidification (active and passive) in spontaneously breathing tracheostomy patients

In contrast to mechanically ventilated patients, humidification for spontaneously breathing patients with a tracheostomy is often poorly understood as there is no well-established standard of care regarding humidification. Both active and passive humidification methods can be used, but there is little scientific evidence comparing the performance and clinical benefits of external humidifiers (EH) and HMEs in this group of patients (36).

HMEs in spontaneously breathing tracheostomy patients have been shown to have the capacity to heat and humidify the inspired air (37, 38), similar to the capacity of the HH systems and superior to the cold humidification systems (16) as well as clinical benefits such as decreased thickness and improved coloring of secretions (39). Recently, one of the first comparative studies between HME and EH use has shown cost-effectiveness and nurse preference of HME use (40). Details about the studies on specific Atos Medical HMEs for tracheostomy patients are discussed in detail in section 2: *Evidence on Freevent Products and TrachPhone*.

Heat and moisture exchangers in patients with a total laryngectomy

More extensive research has been carried out in patients with a total laryngectomy (TL). This has helped to establish HMEs as the standard of care for humidification and pulmonary rehabilitation in laryngectomized patients. This section is relevant as TL patients also breathe through an open stoma and do not need mechanical ventilation to support their breathing. Therefore, they share characteristics with spontaneously breathing tracheostomy patients.

In the TL population, use of HMEs have shown short-term effects such as reduced dispersion of droplets, containment of secretions, decreased tracheal dryness and irritation, increased tracheostoma hygiene, easier and more hygienic stomal occlusion, and improved intelligibility of speech. Long-term effects seen, after more than 2 weeks of compliant use, were significant decreases in mucus production and plugging, coughing, forced expectorations, shortness of breath, stomal cleaning, and pulmonary infections. Significant improvements were also seen in sleep, fatigue, psychosocial aspects, and improved Quality of Life (41-49).

Several studies in the TL populations have evaluated the effectiveness of HMEs over EHs in a hospital setting, particularly focusing on mucus plugging prevention, post-operative care, cost-effectiveness, and patient and nurse satisfaction. In a randomized clinical trial, Merol et al., (46) showed that HMEs were considered the better option for airway humidification immediately postoperative. Use of HMEs compared to EHs showed a significantly higher 24/7 compliance and a significant reduction in the number of coughing episodes, sleeping disturbances, and mucus expectoration to clear the trachea. Similarly, Foreman et al., (48) found that HME use showed a reduction in episodes of mucus plugging, and in general reduced in-hospital complications and post-operative care requirements. Furthermore, in a retrospective comparative cohort study, Ebersole et al., (49) found HMEs to be superior to EHs regarding mucus plug prevention, seeing a significant decrease in the rate of mucus plugging events as well as a significant reduction in the proportion of patients with one or more mucus plug in the HME group.

For more information about the use of HMEs in patients with a total laryngectomy see the Atos Medical, Literature Review HME 2022 [1].

1.3 Speaking with a tracheostomy

In addition to the above-mentioned loss of conditioning of the air, patients with tracheotomies also face other post-procedure adversities such as loss of phonation. Phonation is important for the patient's quality of life, medical care, and social interactions (37, 50).

To facilitate phonation after a tracheotomy, patients need to redirect the air through the vocal cords and vocal tract by occluding the tracheostomy tube. This can be done by occluding the opening of the tube with a finger, by using a speaking valve or by pressing on an HME (Figure 4). In this way, phonation and speech are enabled and the physiological subglottic pressure is re-established (38).

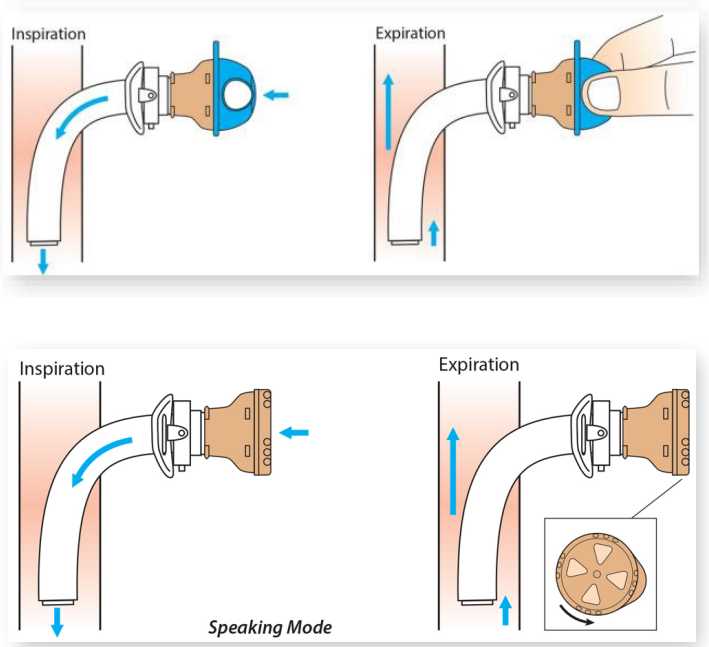

Figure 4. Inspiration and expiration airflow in tracheostomized patients with a Freevent DualCare HME DigiTop (above) and a Freevent DualCare Speaking Valve (below). During expiration, the air is redirected through the upper airways by occluding the HME DigiTop with the fingers (above) or by using the one-way valve of the speaking valve (below).

Finger occlusion, however, has several limitations. It is unsanitary and requires a level of dexterity and respiratory timing that may be difficult for some patients. Many patients dislike having to close the tracheostoma with a finger to speak as it hinders the ability to communicate through gestures or to work with both hands (8).

Tracheostomy speaking valves (TSVs) appear as an alternative to finger occlusion. Unidirectional TSVs have a displaceable element that allows air to flow through the cannula and into the lungs during inspiration. During expiration, the TSV are either bias closed (i.e., closed during rest and exhalation and open only upon inspiration) or bias open (i.e., open during rest and inhalation and closed only upon expiration) so the air cannot pass through the closed valve and is redirected through the upper airway to facilitate phonation and secretion expectoration (50).

The option to speak hands-free is important as it allows for the use of both hands during daily activities and when speaking, which in turn can facilitate non-verbal communication (8).

TSVs are often used as part of standard care with tracheostomized mechanically ventilated patients in intensive care units. TSVs are used in patients that are still on a ventilator but also while doing trails off the ventilator (51).

2 Evidence on Freevent range products and TrachPhone

Evidence on Freevent range products and TrachPhone has been searched and gathered in this section. A description of each product, the summary of the evidence available for each product, and a detailed description of each publication is included.

2.1 TrachPhone

Description of the device

The TrachPhone HME (also sold under the name Mediflux HCH F6) is a multifunctional device with a 15 mm ISO connector, intended for spontaneously breathing patients breathing through a tracheostoma. It incorporates a full-time HME, a manually operated speaking valve, a suction port to facilitate respiratory secretion management and an O_2-port. In the case of coughing or blockage, the suction port acts as a relief valve, making it possible to clean the tracheostomy tube from mucus as needed. It is a lightweight device that attaches directly to the end of a tracheostomy tube. (Figure 5).

Figure 5. TrachPhone HME.

Evidence on TrachPhone

Overall, evidence on TrachPhone comes from two studies on the actual device, and four studies on a similar device[1]. One of the two investigations involving TrachPhone was performed in a laboratory setting (52). The other was a quality improvement project showing preference for TrachPhone by nurses as well as cost saving over Conventional External Humidification Systems (CEHS)(40). Four other studies have been conducted using a similar device (17, 39, 53, 54). The four studies on similar devices have been included in this section as they show relevant results obtained when evaluating a device with similar design to TrachPhone. In vitro studies have shown that the performance of TrachPhone and the device with similar design is significantly and inversely affected by the addition of an O_2 flow. In vivo results show that the use of HME on spontaneously breathing tracheostomized patients decreases thickness and improves coloring of secretions and has no impact on respiratory mechanics and breathing patterns. In the next few paragraphs, each study is described in more detail.

In an investigation that was conducted in a laboratory setting, the authors examine how spontaneous breathing parameters and oxygen flow affect the humidification performance of 11 HMEs designed for tracheostomized patients (TrachPhone included). Spontaneous breathing was simulated with a mechanical ventilator, lung model and a heated humidifier. For the 8 HMEs with O_2 ports, the researchers recorded measurements while administering both 0 and 3 L/min of dry oxygen. Once the system reached a steady state, the team used a hygrometer to measure the absolute humidity (AH) of the inspired gas. The results revealed that there were variations in AH among the different HMEs. When oxygen was supplied, the AH dropped below 30 mg/L for all HMEs. These findings indicated that none of the HMEs were able to supply sufficient humidification when supplemental oxygen was introduced (52).

In a quality improvement project carried out at Stanford University School of Medicine, researchers evaluated the feasibility and effectiveness of using TrachPhone HMEs by patients who underwent a tracheotomy in a hospital setting. They compared this approach to the CEHS. The efficacy of TrachPhone HMEs was assessed by monitoring patient's tolerance to the HME (assessed by respiratory status and suction needs) reviewing nursing notes and conducting questionnaires. The results revealed that immediately after surgery, 69 out of 71 patients (97%) were able to tolerate HME use. Additionally, 24 out of 27 nurses (89%) preferred the HME over the traditional CEHS. Some reasons for the nurses' preference included a reduction in maintenance efforts (50%, n= 12), improved patient communication (50%, n=12), less need for extensive training of patients and caregivers (46%, n = 11), and decreased suction requirements (42%, n=10). Some nurses cited occasional mucus obstruction that required replacement (55%, n=15). Nevertheless, the authors conclude that TrachPhone is safe and offers numerous advantages to both patients and nurses compared to the traditional CEHS (40).

As mentioned above, there are 4 additional publications on a similar device. Below, each of these publications are described in more detail.

In a study with 40 spontaneously breathing chronically tracheostomized patients, two groups were formed. Group 1, with 20 patients, received an HME (Mediflux HCH-6V) with similar design to TrachPhone connected to the tracheostomy cannula 24 h/day for 10

[1] The similar devices included in these publications as Mediflux were not produced by Atos Medical but are of similar design as TrachPhone.

days. The HME was changed every 24 hours. Group 2, with 20 patients, continued to breathe through their tracheostomy with no HME. The results of this study show that the use of HME decreases thickness and improves coloring of secretions over a period of 10 days (39).

In an investigation with 9 patients breathing spontaneously through an external humidification system, data on respiratory patterns and mechanics were collected. Two of the patients had a nasotracheal tube and seven were tracheostomized. In the study, two different HMEs were used, both with similar designs to TrachPhone. One was the Icor Mediflux 1 (M1) and the other was the Icor Mediflux 2 (M2). Both HMEs had the same chemical composition but different internal volumes. M1 has 40 mL and M2 has 20 mL. Results show that M2 did not impose a significant ventilatory load. M1 was clinically tolerated but imposed significant effort for the patients. The authors conclude that an HME with smaller internal volume is preferable for clinical use in this group of patients (54).

In a different study, 21 spontaneously breathing chronically tracheostomized patients were enrolled. The patients had never used HME during spontaneous breathing before the study. The study started after two days of acclimatation to the HME (Mediflux HCH-6V). The patients breathed through a fenestrated cuffed cannula. During the study, the cannula was cuffed, and the inner cannula inserted to ensure that the patients breathed only through their tracheostomy. The results of this study showed that the use of HME did not cause significant changes in respiratory mechanics and breathing patterns. Thus, demonstrating that HME may be used in chronically tracheostomized stable COPD patients breathing spontaneously (53).

In an in vitro evaluation, different Heat and Moisture Exchangers (HMEs) designed for spontaneously breathing tracheostomized patients were evaluated. Two of the evaluated HMEs were the Mediflux HCH 6F and Mediflux HCH 6V, with a similar design to TrachPhone. Investigators used an experimental lung model connected to a breathing circuit to simulate the conditions of a spontaneously breathing patient. The study aimed to evaluate the impact of O_2 flow on the HMEs' performance, specifically on temperature and absolute humidity. Seven HMEs were tested under 2 different minute ventilations (V_E), and 4 different O_2 flows. One of the HMEs tested in this study has a similar design to TrachPhone. Evaluation showed that absolute humidity and temperature were significantly and inversely affected by the addition of O_2. Additionally, the HMEs were tested over a 24-h period with a fixed V_E. Temperature, resistance, and weight measurements were recorded. Results showed that no significant changes in absolute humidity, flow resistance or pressure drop were observed after 24 h (17).

2.2 Freevent XtraCare and XtraCare Mini

Description of the devices

Freevent XtraCare and Freevent XtraCare Mini are Heat and Moisture Exchangers combined with an electrostatic filter (HMEFs). The HME is impregnated with a hygroscopic salt and conditions the inhaled air. Freevent XtraCare and Freevent XtraCare Mini devices with 15 mm ISO connector are intended for tracheotomized patients spontaneously breathing through a tracheostoma.

The electrostatic filter provides patients with a tracheostoma with protection from small airborne particles, such as dust, pollen, bacteria (99% bacterial filtration for both Freevent XtraCare and Freevent XtraCare Mini) and viruses (99% viral filtration for Freevent XtraCare and 98% for Freevent XtraCare Mini)[2].

Figure 6. Freevent XtraCare HMEF (left) and Freevent XtraCare Mini HMEF (right).

The device helps to compensate for the lost heating, humidification, and filtration functions of the upper airway. Freevent XtraCare and Freevent XtraCare Mini have an optional O_2-adaptor, which can be fitted over the device, after which O_2 can be administered through the HMEF[3].

Evidence on Freevent XtraCare and XtraCare Mini HMEs

The use of Freevent XtraCare HME and XtraCare Mini has been recommended by several guidelines and protocols for safe tracheostomy care, especially during the COVID-19 pandemic (55-58). In the next few paragraphs, each of the guidelines and protocols are described in more detail.

During the COVID-19 outbreak, professional organizations offered guidance for managing tracheostomized patients and minimizing aerosol risk. Combining the Freevent XtraCare HME with a closed-circuit suction system (Figure 7), as demonstrated by the Kelley Circuit, provides humidification and filtration for self-ventilating patients. As it is a Closed-circuit system, it protects both patients and healthcare professionals. The circuit provides humidification and filtration also upon expiration. To test this closed system in one study, the authors selected 4 tracheostomized patients that had not tested positive for COVID-19 and were able to self-ventilate requiring various levels of O_2. Results showed no significant respiratory rate change, reduced sputum, unchanged secretion viscosity, and positive clinician experience. After the mentioned clinical experience, the authors found it beneficial to exchange the ProTrach (now Freevent) XtraCare every 12 hours,

[2] Since pathogens can enter and leave the human body in other ways (such as the mouth, nose, and eyes), Freevent XtraCare and Freevent XtraCare Mini can never guarantee complete protection. Please read the instructions for use for guidance. Viral Filtration Efficiency and Bacterial Filtration Efficiency at an increased Challenge Level Test procedure adapted from ASTM F2101, was performed for Freevent XtraCare and Freevent XtraCare Mini at Nelson Laboratories (US) in accordance with USFDA (21 CFR Parts 58, 210, 211 and 820) regulations. Mean VFE and BFE was >99%. Data on file.

[3] Flow rates of up to 15 L/min can be used. However, the HME effect will be reduced as the oxygen flow increases. At a typical flow of 3-4 L/min, the HME performance is minimally affected but at 15 L/min HME cannot completely compensate for the extra drying caused by supplementary oxygen.

when breathing difficulty arises, at regular intervals, and at least once every 24 hours (55).

The Kelley Circuit has been included in guidelines for safe tracheostomy care during the COVID-19 pandemic. In these guidelines they propose to change from open suction to a modified closed-circuit suction system, such as the Kelley circuit, to reduce the exposure of staff and patients to aerosol generating procedures (59).

The use of Freevent XtraCare HME has also been recommended in individuals with a tracheostomy to protect themselves and others during the COVID-19 pandemic. In these protocols, it is recommended to place a Freevent XtraCare HMEF on the cannula in patients with a tracheotomy (57, 58).

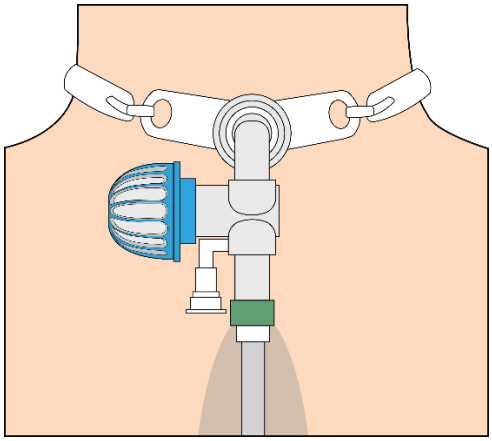

Figure 7. The Kelley Circuit with a closed-circuit suction system attached to the ISO 15 hub of the tracheostomy tube and the ProTrach (now Freevent) XtraCare attached to the ventilator hub on the other side.

Freevent O_2 Adaptors are accessories that fit Freevent XtraCare and Freevent XtraCare Mini. They are clipped over the base of the HMEF, and the combined device is attached to the tracheostomy tube, or similar device. Additional oxygen can then be supplied via the oxygen port of the O_2 Adaptor (Figure 8).

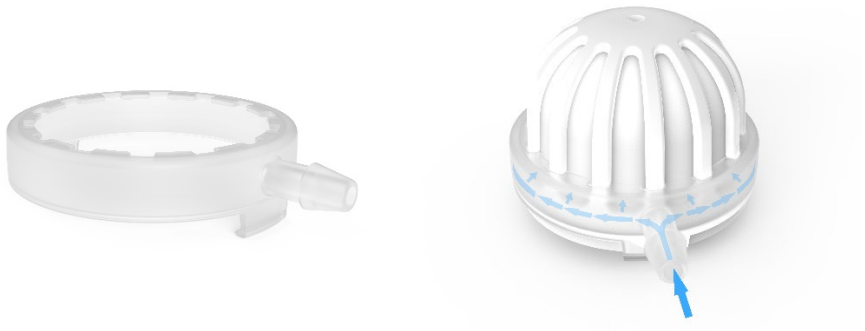

Figure 8. Freevent O_2 adaptor (left) and the same adaptor attached to Frevent XtraCare HMEF (right). The blue lines indicate the path that the O_2 follows when being delivered.

2.3 Freevent DualCare Speaking Valve, HME DigiTop and HME DigiTop O_2

Description of the devices

Freevent DualCare (Figure 9) is a speaking valve that enables hands-free speech. Freevent DualCare combines a speaking valve with an HME, and in this way, enables hands-free speech and supports the patients' lungs with humidifying of the inspired air. The system to switch between the speaking mode and HME mode consists of a lid that can be twisted. In speaking mode, a flexible membrane acts as a one-way valve. This membrane opens during inhalation and remains closed during exhalation, allowing the air to travel through the vocal folds. In this way, the patient can speak during exhalation. In HME mode, the membrane is moved out of the airway opening so the valve becomes a two-way valve, and the patients can inhale and exhale through the device.

Figure 9. Freevent DualCare HME.

Freevent HME DigiTop and HME DigiTop O_2 allow the patients to use the HME without the speaking valve and can manually be occluded to enable speaking. The HME DigiTop O_2 enables the option to connect oxygen tubing to the oxygen port connector for patients requiring additional oxygen.

Evidence on Freevent DualCare Speaking Valve

Freevent DualCare has been evaluated in one *in-vivo* clinical study and one *ex-vivo* clinical study. They showed that Freevent DualCare speaking valve offers humidification when used in HME mode (37, 38). Both studies are described in more detail in the next two paragraphs.

In a single-center feasibility study, 16 adult patients with tracheostomies were enrolled in a non-randomized prospective trial. Over a two-week period, participants tested the Freevent DualCare speaking valve while maintaining their daily routines. Following this, they had the option to continue into a long-term evaluation. Assessments involved the Euro QoL-5D, Borg scale, and various questionnaires evaluating speech, pulmonary function, and patient preferences. A minor redesign was implemented and the participants were asked to test the updated device for a week. In all, 11 participants agreed to continue. The device was well-tolerated, decreasing speaking noise and enhancing the natural voice sound, as preceived by the patients. Additionally, the study showed two significant results regarding coughing and mucus. Patients reported significantly less discomfort breathing dry air and less dry coughs during the night with

Freevent DualCare HME compared with the devices that they were using prior to the study. Overall, 11 out of 16 preferred the DualCare over their regular devices. No significant adverse events took place. The DualCare allowed hands-free speech with benefits similar to an HME, demonstrating its clinical feasibility and potential to improve the lives of tracheostomy patients (37).

An ex vivo investigation evaluated the humidifying function of tracheostomy speaking valves. The study examined water exchange and storage of three tracheotomy speaking valves. ProTrach (now Freevent) DualCare was tested during the study with two different HMEs. For all three valves, water storage was absent while speaking. The study concluded that tracheostomy valves with integrated HMEs lack humidification capacity in speaking mode. DualCare speaking valve allowed switching between speaking mode and HME mode. Water storage was negligible in speaking mode, but in HME mode DualCare XtraMoist reached a higher value than DualCare Regular. HME mode appears to offer the highest degree of humidification in all the cases (38).

3 Conclusions

This Literature Review highlights the importance of the upper airway in conditioning inhaled air (humidification and warming) and how the lack thereof has a direct impact on pulmonary health for patients with a tracheostomy. Extensive research is published on the benefits of using HMEs as a method of humidification in laryngectomized patients. In those patients, the use of HME is a well-established standard of care that has been shown to improve pulmonary health and quality of life. However, the evidence supporting the establishment of a standard of care that ensures conditioning of air in spontaneously breathing patients with a tracheostomy is limited. HME use in tracheostomized patients has been shown to offer advantages compared with external humidifiers, such as improved patient compliance, less need for extensive training of patients and caregivers, less maintenance, and lower costs. Additionally, devices such as Freevent DualCare offer the possibility to switch from HME mode to speaking mode, allowing the patients with a tracheostomy to speak hands-free. Future research in this field can help to determine the best pathway of care for these patients.

4 Internal References

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