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CHAPTER 6

Short-term endotracheal climate changes and clinical effects of a heat and moisture exchanger with an integrated electrostatic virus and bacterial filter developed for laryngectomized patients



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Abstract

Objective

Recently an HME with an integrated antimicrobial filter (Provox® Micron HME; F-HME) has become available for use in laryngectomized patients. The purpose of this study was to assess its short-term endotracheal climate changes and feasibility in daily practice.

Methods

Endotracheal temperature and humidity were successfully measured in 13 laryngectomized patients (2652 analysed full breaths), during 10 minutes rest-breathing with the Provox® Normal HME (R-HME), with an F-HME and without HME in a randomized sequence. Additionally, a 3-week prospective clinical feasibility trial was conducted in 17 laryngectomized patients.

Results

Both R-HME and F-HME increase endotracheal minimum humidity values (5.8 and 4.7 mgH₂O/L, respectively; $p < .0001$). Compared to open stoma breathing, in contrast to the R-HME, the F-HME increases both end-inspiratory and end-expiratory temperature values (1.1 °C, and 0.6 °C, respectively). After the 3-week trial, 1 patient dropped; 11 patients (11/16 = 69%) disliked the larger design of the F-HME, and all patients reported less optimal airtight occlusion for voicing. Five patients (5/16 = 31%) reported a remarkable decrease in sputum production.

Conclusion

Both the regularly used Provox® Normal HME (R-HME) and an HME with both an antimicrobial and a hygroscopic element (Provox® Micron HME; F-HME) are effective moisture exchangers. The antimicrobial filter of the F-HME acts as a heat exchanging element and improves both the heat and the moisture exchanging capacities. The external features of the F-HME were experienced as inconvenient, but decreased sputum production was reported as well.

Introduction

In laryngectomized patients, breathing occurs through a tracheostoma. As the upper airways are bypassed, breathing resistance is reduced and inspired air is no longer conditioned and filtered. The lost conditioning function of the upper respiratory tract implicates inspiration of relatively cold and dry air in the lower respiratory tract, which leads to excessive water loss through the stoma and to an increased viscosity of the mucous layers. This in turn causes disturbed normal mucociliary function and eventually leads to a damaged mucociliary respiratory epithelium [52;54]. As a consequence, laryngectomized patients experience many chronic pulmonary complaints like frequent involuntary coughing, excessive sputum production, and repeated forced expectoration needed to clear the airways from phlegm [15]. In addition to the lost conditioning function, the lost filtration function of the upper airways makes laryngectomized patients even more susceptible for common community-acquired chest infections.

Currently, the best medical treatment option for the loss of the upper airway function is the use of passive humidifiers (i.e. heat and moisture exchangers; HMEs). It has been shown that these devices significantly increase the endotracheal water content of inspired air, considerably reduce respiratory problems and improve quality of life [33;79]. However, they do not always eliminate pulmonary complaints completely. This is due to the fact that HMEs only partially compensate for the normal air-conditioning of the upper airways and physiologic endotracheal temperature and humidity values present in normal individuals are still not achieved [56]. Additionally, a simple passive (usually hygroscopic) HME filter has to be designed with a relatively large pore size in order to provide a tolerable breathing resistance [50]. As a consequence, these HMEs are rather inefficient barriers for micro-organisms, even though some HMEs have been impregnated in a bactericide solution (such as chlorine hexidine) in an attempt to control bacterial colonization [50]. Vice versa, effective antimicrobial filters, usually constructed with a pleated hydrophobic membrane, are ineffective moisture exchangers [29;51]. In anaesthesiology, during long invasive mechanical ventilation, HME filters with both a hygroscopic element (for humidification) and a hydrophobic membrane (for filtration) are commonly used in order to reduce the risk of cross infections by ventilator circuit contamination [68]. However, the design of these HMEs would does not allow for comfortable use in laryngectomized patients, as they have quite a

large diameter and are purpose-built for a mechanical ventilation circuit. As there is unambiguous evidence for the benefit of conditioning of inspired air in laryngectomized patients exists [25-27], disposable and passive HMEs are primarily constructed as hygroscopic HMEs. As a consequence, primarily the lost conditioning function (and not the filtration function) of the upper airways is compensated for. Additionally, an HME also offers some breathing resistance.

To offer additional compensation for the lost filtration function of the upper airways, the first virus and bacterial filter (for filtration) in series with a hygroscopic HME (for humidification) has recently been developed for use in laryngectomized patients (Provox® Micron HME, further referred to F-HME; see Figure 6.1a). The virus and bacterial filter in this HME is based on a matt of fibres, which contain permanent electrostatic charges. Such filters effectively trap particles (like micro organisms, pollen and water droplets) without the need for a very dense fibre-network, allowing the airflow resistance of the device to be kept at a comfort level [94]. Although microorganisms are caught, water droplets pass through as the fibres are hydrophobic. Subsequently, the inspired air passes through the hygroscopic element of the F-HME before entering the tracheostoma so that heat and moisture exchanging is achieved as well. In laboratory settings the virus and bacterial filtration function was shown to have an efficiency of > 99% (data provided by the manufacturer: report nr AM 071024). However, the effect on the occurrence of chest infections and other respiratory complains in a clinical setting is not known. Before starting a long-term clinical trial to investigate the potential additional clinical effects of the F-HME, it is important to study its basic HME capacity and the short-term effects of its different design on patient compliance.

Although the heat and moistening capacity is specified under standard physical and ambient conditions in laboratory settings (according to the ISO norm), these *in vitro* measurements do not fully represent *in vivo* behaviour [33]. Therefore, the primary aim of this study was to investigate the effects of this F-HME on endotracheal climate (temperature and humidity) in laryngectomized patients compared with those of a regularly-used HME (R-HME). Secondly, the short-term clinical and practical aspects of the F-HME were separately investigated in a prospective clinical feasibility study.

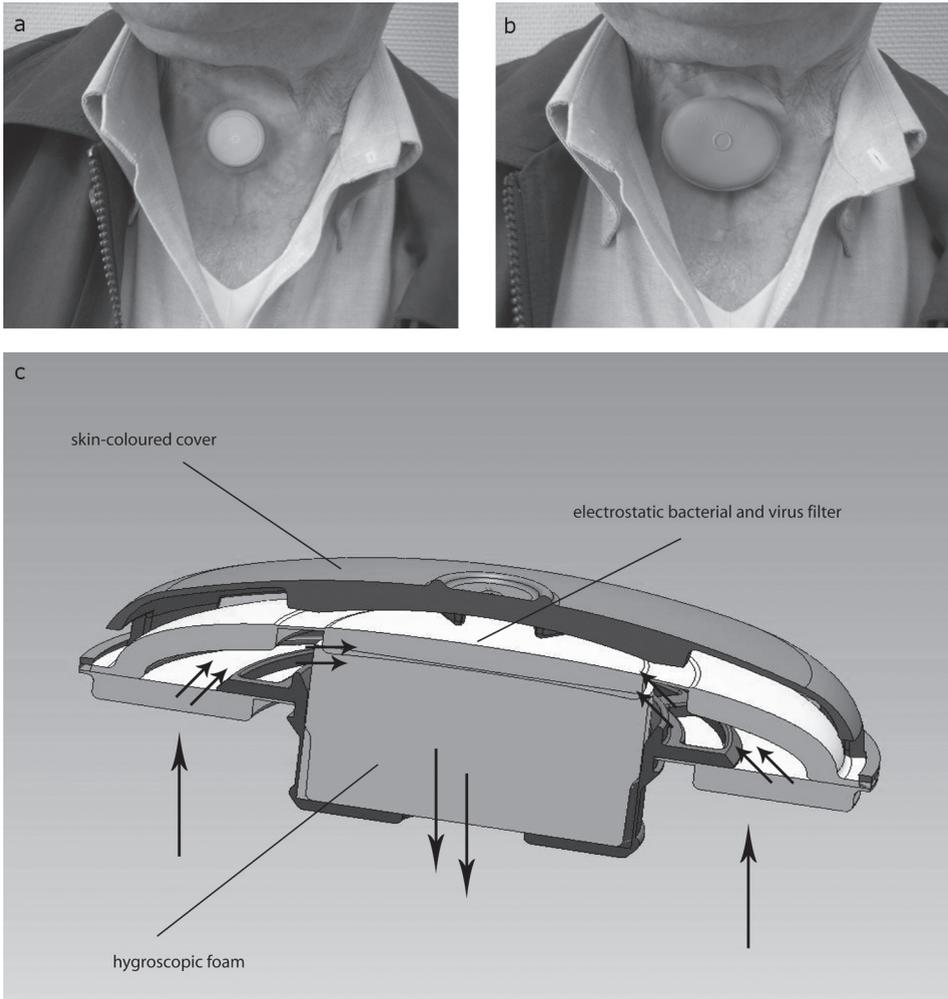


Figure 6.1 Figure 1a shows a laryngectomized patient with the regularly-used Provox® Normal HME (R-HME) (a) and the Provox® Micron HME (F-HME) (b) with electrostatic virus and bacterial filter, of which schematic drawing is shown in (c). Arrows represent airflow.

Patient and Methods

HME devices

The antimicrobial material (Technostat®) of the F-HME (Provox® Micron HME; Atos Medical, Hörby, Sweden, Figure 6.1a and c) is electrostatically charged. Both positive and negative charges are present on the fiber surfaces, but the overall product is electrically neutral. The *in vitro* moisture loss of the device

(including the hygroscopic HME material) is 26.0 mgH₂O/L and the pressure drop at 30 l/min is 78 Pa, according to ISO9360-2;2001. Where applicable, the purely hygroscopic R-HME (Provox® Normal HME, Atos Medical, Hörby, Sweden, Figure 6.1b) was used for comparison. Its *in vitro* moisture loss is 23.7 mgH₂O/L and the pressure drop at 30 l/min is 89 Pa, according to ISO9360-2;2001. Both the R-HME and F-HME can be placed on a peristomal adhesive or trachea cannula, and airtight occlusion for speech with a voice prosthesis is achieved by pressing down the cover with a finger.

Endotracheal temperature and humidity

Endotracheal climate was successfully assessed in 13 laryngectomized patients, 12 male and 1 female (median age 67 years; range 47–81 years, SD 10.3). All patients had been treated with radiotherapy in addition to their surgical treatment, had quit smoking and were in long-term follow-up, on average 8.0 years postoperative (median 7.0 yrs, range 0.6–19 yrs, SD 6.1).

Endotracheal temperature and humidity were measured with the Airway Climate Explorer (ACE). The development and validations have been described and published elsewhere [33]. In summary, a small diameter (5 mm) sample catheter is proximally connected to a sensor house in which a fast humidity sensor (response time < 0.7 s) is built. For the assessment of temperature a thermocouple (MLT1402 T-type Ultra Fast Thermocouple Probe (IT-23), response time 5 ms, accuracy ± 0.1 °C; ADInstruments Ltd, Oxfordshire, UK) is placed just inside the distal tip of the central, air-sampling canal of the sample catheter. The airflow during respiration is sampled with a constant rate of 0.6 L/min.

During the ACE measurements, patients were seated in a chair and were asked to breathe calmly. A small hole was punched in a peristomal HME adhesive, through which the distal tip of the sample catheter of the ACE was inserted. The catheter tip was held approximately 1 cm behind the stoma opening in the trachea. Each measurement session included three 10-minute breathing periods (observations) in a randomized sequence: one observation with open stoma breathing (without HME), one observation with the R-HME, and one observation with the F-HME. All measurements were performed in room climate condition, which was monitored with a calibrated temperature and humidity sensor (Testo BV, Almere, The Netherlands). The measurement protocol was

approved by the Protocol Review Board of the in the Netherlands Cancer Institute and written informed consent had been obtained from all patients.

End-inspiratory and end-expiratory parameters of this data set (with and accumulative number of full breaths of 2652 breaths) were analysed in conjunction to the same parameters of the more extended data set, which we used in our previous study (Chapter 3 and 4) for consistency and increased statistical power. Data processing and analysis has been described in detail in Chapter 3 and 4. In summary, from each observation, two 2-minute episodes (minutes 6,7 and 9,10) of each observation were used for analysis. The time between two end-exhalations was defined as the full breath length (FBL), and the time between end-exhalation and end-inhalation as the inhalation breath length (IBL). The midpoints of the inhalation and exhalation periods were used to approximate the IBL and FBL. We used 4 linear mixed effect models were used for the analysis of IBL, FBL, end-inspiratory temperature (T_{insp}) and end-expiratory temperature (T_{exp}). Due to the dependence of end-inspiratory humidity on IBL (A_{Hinsp}) (in contrast to T_{insp}), a non-linear exponential-decay mixed effects model was used to analyse A_{Hinsp} and A_{Hexp} simultaneously (see also Chapter 3 and 4) [84]. All three parameters were dependent on HME type (as a fixed effect), and the asymptotic humidity minima was also related linearly to room humidity H_r . The clinically relevant humidity minima (A_{Hinsp}) can be determined from the following equation:

$$A_{Hinsp} = A_1 + (\beta * H_r) + (A_2 - A_1 - (\beta * H_r)) * \exp(-IBL / A_3)$$

(equation 1)

where A_1 is the asymptotic minimum, A_2 is the initial humidity value (A_{Hexp}), A_3 is the decay rate and IBL is the inhalation breath length. A_1 , A_2 , A_3 and IBL are all dependent on HME type. A_1 is linearly related to H_r with co-efficient β (= 0.94).

The difference between the model estimate of clinical temperature and humidity obtained with R-HME and F-HME was tested with t tests using the estimates of the residual standard errors at the A_{Hinsp} and the degrees of freedom estimate obtained if a standard linear mixed effects model was employed. The statistical analysis was conducted using Splus v6.2 pro.

Relative humidity (RH) values were calculated from the observed end-inspiratory and end-expiratory temperature and absolute humidity values using an approximation for the saturation humidity with an accuracy < 0.5% [33].

The median room environment temperature was 23.9 °C (range 23.0–25.0 °C; SD 0.6), the median room absolute humidity was 8.1 mgH₂O/L (range 6.1–11.0 mgH₂O/L; SD 1.9) and the median room relative humidity was 37.4% (range 26.8–57.7%; SD 9.8). For consistency with our previous work (Chapter 3 and 4) we report AH_{insp} (formula 1) with H_r = 6.4 mgH₂O/L (resulting in a difference in AH_{insp} < 0.1 mgH₂O/L).

Short-term prospective clinical feasibility study

The short-term clinical and practical aspects of the F-HME were separately investigated in a prospective feasibility study. Seventeen laryngectomized patients (14 male and 3 female; mean age 64.2 years; range 39–80 years) were included in the short-term clinical study (8 of these patients subsequently participated in the endo-tracheal temperature and humidity measurements). The time post-laryngectomy was on average 5 years (range 0.5–19 years). All patients were HME users and those laryngectomized after 1996 had started HME use immediately following surgery. Three patients daily used a low breathing-resistance HME (Provox® HiFlow HME further referred to as L-HME). Patients were instructed to use the F-HME during a 3-week testing period. Voice quality and possible difference between the R-HME and F-HME were objectified by use of voice recordings. Recordings with both the accustomed HME and the F-HME took place on the first day. With each filter, the patients had to read aloud a standard Dutch text and pronounce an /a/ three times as long as possible to assess the maximum phonation time (starting with the F-HME followed by the accustomed HME). At the end of these three weeks, data were collected by means of a study-specific questionnaire, primarily focussing on patient compliance, the ease of use and the effect on voice and breathing [95].

Due to the small sample size and the design of the short-term clinical study, the results are mainly descriptive and were analysed separately. All data obtained from the questionnaires and voice recordings, were collected in a database (SPSS v15.0). The voice recordings of 3 patients were of poor quality due to inadequate adherence of the adhesive which hampered airtight stoma occlusion during the voice recordings and therefore they were excluded from further analysis. The paired-samples *t* test was used for comparison of the

objectified voice quality between both HMEs. The level of statistical significance of 5% was used.

Results

Breath length, temperature and humidity

The model estimates of breath length, endotracheal temperature and humidity values of both HMEs and without HME are shown in Table 6.1 (see also Figure 6.2). The IBL of both R-HME and F-HME were similar (1.05 s and 1.01 s, respectively) and both significantly shorter than the IBL during open stoma breathing (1.35 s; $p < .0001$). Breathing with R-HME and F-HME increased T_{insp} with 5.8 and 4.7 mgH₂O/L ($p < .0001$), respectively, compared with open-stoma breathing (without HME). The HME effect of both HMEs is graphically shown in Figure 4.2. The end-inspiratory relative humidity (RH) values of R-HME, F-HME and without HME were 89%, 82% and 60%, respectively. End-expiratory, the RH was about 90 % in all cases (R-HME 89%, F-HME 90% and without HME 87%).

Table 6.1 Overview of the model estimates of the breath lengths, temperature and absolute humidity with R-HME and F-HME compared to open stoma breathing (without HME). Room humidity $H_r = 6.4$ mgH₂O/L.

	without HME	R-HME	F-HME	Difference R-HME minus without	Difference F-HME minus without	Difference F-HME minus R-HME
Breaths						
IBL	1.35	1.05	1.01	- 0.30*	- 0.34*	- 0.04
FBL	3.55	3.65	3.71	0.10*	0.16*	0.06
Temperature (°C)						
T_{insp}	28.5	26.9	29.6	-1.6**	1.1**	2.7**
T_{exp}	34.4	34.4	35.0	0	0.6**	0.6*
Absolute humidity (mgH₂O/L)						
asymptote (A_1)	9.7	12.6	11.8	2.9**	2.1**	-0.8**
AH _{insp}	17.0	22.8	21.7	5.8**	4.7**	-1.1**
AH _{exp} (A_2)	33.5	34.2	35.5	0.7*	2.0*	1.3**
reaction time (A_3), in seconds	0.51	0.80	0.67	0.29	0.16	-0.13

* p value $< .01$; ** p value $< .0001$

Breathing with R-HME leads to a decrease in T_{insp} compared to open stoma breathing ($-1.6\text{ }^{\circ}\text{C}$), whereas the F-HME causes T_{insp} to increase ($+1.1\text{ }^{\circ}\text{C}$). The F-HME also leads to a small but significant increase ($+0.6\text{ }^{\circ}\text{C}$) in T_{exp} .

Short-term clinical feasibility study

Of the 17 patients participating in the clinical study, 1 patient had already stopped using the F-HME already after 7 days due to health-related problems, which were neither respiratory nor device related. This patient was considered as a drop-out and therefore excluded from further analyses. Of the remaining 16 patients, 5 patients (31%) used the F-HME until about 16 days (range 14–18 days). Reasons for premature discontinuation were suboptimal voice, skin irritation (due to an irregular and deeply situated tracheostoma), shortness of breath or inconvenient use. Eleven patients (69%) used the F-HME throughout the entire 3-week observation period.

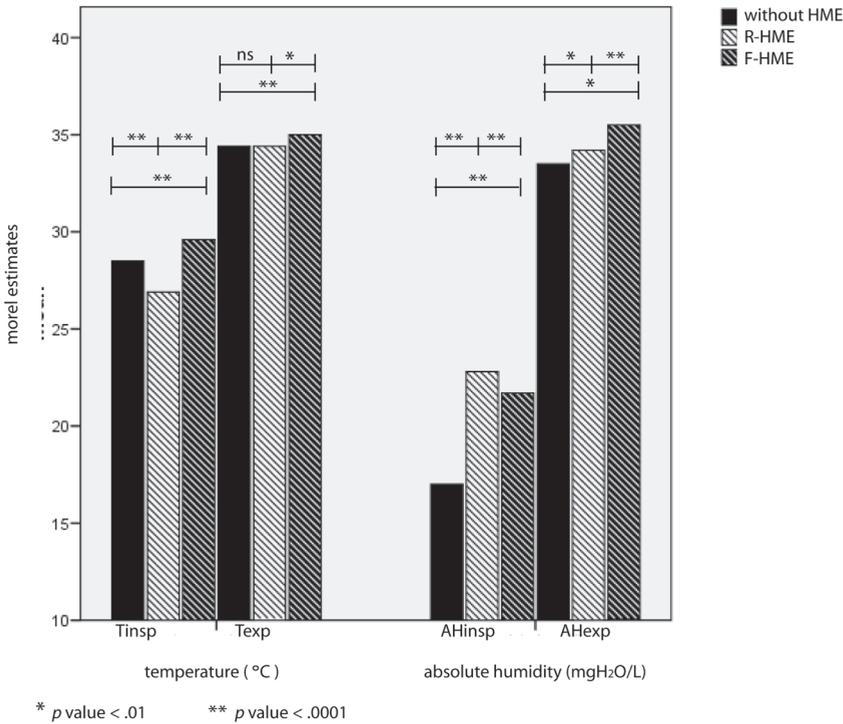


Figure 6.2 The model estimates of the end-inspiratory and end-expiratory values of temperature (T_{insp} and T_{exp} , respectively) and humidity (AH_{insp} and AH_{exp} , respectively) with R-HME, F-HME and without HME.

Analysis of the voice recordings showed that with the accustomed HME patients had to take on average 23.9 breaths to complete reading the standard text, which was increased with the F-HME to 27.8 breaths ($p < .01$). Also the duration of reading the complete text was prolonged with the F-HME (89.4 s vs 81.9 s; $p < .01$). In the questionnaire, all patients reported problems with the airtight closure required for trachea-esophageal speech. Eight patients indicated that it was difficult to find the exact point for closing, which reportedly was mostly due to the relatively large and oval shape of the F-HME. The size of the F-HME was perceived as rather large in 11 patients (69%), 1 patient thought the size was acceptable, and 4 patients had no opinion. The colored cover of the F-HME was well accepted in 8 patients (56%), 5 patients (31%) did not appreciate the color and 3 patients had no opinion.

If prescribed, 9 patients (63%) would have liked to continue the use of the F-HME (of whom 4 patients on daily basis and 5 patients during specific situations like in quiet moments on their own, during long conversations or during flu epidemics), 4 patients (35%) do not know and 3 patients (19%) would use it not at all. No difference in preference was seen between accustomed R-HME and F-HME users.

Although a short-term positive clinical effect in this patient cohort was not expected since all were daily HME users, and thus was not specifically addressed in the questionnaire, it is noteworthy that at the end of the 3-week trial period 5 patients (31%) spontaneously reported a noticeable decrease in pulmonary secretions, particularly when waking up in the morning. All of them also indicated to prefer to continue the use of the F-HME.

Discussion

Endotracheal temperature and humidity

Both the regularly-used hygroscopic HME (R-HME) and the HME with an electrostatic virus and bacterial filter in series with a hygroscopic element (F-HME) achieved a significant increase in exhalation breath length (EBL; 0.4 and 0.5 s, respectively) and end-inspiratory endotracheal humidity (5.8 and 4.7 mgH₂O/L, respectively). The prolongation of EBL is probably due to the increased breathing resistance of both HMEs and, analogous to the effect of pursed lip breathing, has been shown to be accompanied by an increase in tidal volume (70 ml). However, this effect is small and its clinical relevance is uncertain.

The R-HME provides a better moistening capacity, which was anticipated as the hygroscopic element of the F-HME is more porous to compensate for the additional air resistance of the filter. Consequently, less water vapour can be adsorbed during expiration and, thus, less retained humidity is available for evaporation during the subsequent inspiration. However, it has to be kept in mind that the amount of water that evaporates into the inspired air not only depends on the quantity of hygroscopic material, but also on the temperature of the inspired air [29;96]. In contrast to the R-HME, which in room temperature conditions slightly cools the inspired air (-1.6 °C) due to the heat-consuming evaporation process, breathing through the F-HME increases temperature in a significant degree with 1.1 °C. Compared to the R-HME, this increase in temperature is 2.7 °C. This means that fully saturated inspired air through the F-HME (at 29.6 °C) would hold about 4 mgH₂O/L more water vapour than air inspired through the R-HME (at 26.9 °C).

The better heat-capacity of the F-HME can be explained by the heating of the air in the bacterial filter. Due to its hydrophobic properties this filter only acts as a heat exchanger and inspired air entering the F-HME will be first warmed up in the antibacterial filter before passing the hygroscopic part of the HME. As a result, the F-HME is both an efficient *heat* and moisture exchanger, whereas the R-HME is primarily a moisture exchanger (except in a cold room environment of 4–5 °C, where also the R-HME increases endotracheal temperature) [36]. Keck et al [79] had also found an increase (of about 1.5 °C) in endotracheal end-inspiratory temperature of a (different) passive hygroscopic HME device, but they measured deeper inside the trachea (about 3 cm behind the HME) [79], which is probably too deep to measure only the evaporative and cooling effect of the HME itself and also measures the heat and moistening capacity of the trachea mucosa.

The decrease in temperature caused by the R-HME in room environment has been reported previously and it was hypothesized that the heat capacity is the limiting factor for the moistening capacities of a (hygroscopic) HME [33]. It was suggested that, in the development of new HMEs, the heat capacity should be increased since improved heat capacity allows for improved humidification. However, this is technically a challenging proposal as the choice of hygroscopic filter materials is limited. The serendipitous finding that a hydrophobic antiviral and antibacterial filter acts as an effective heat exchanger and even improves the humidity exchange of the combined filter offers an interesting alternative to improve future HME design.

Not only the end-inspiratory temperature (T_{insp}), but also the end-expiratory temperature (T_{exp}) and humidity (AH_{exp}) increased significantly during breathing with the F-HME (0.6 °C and 2.0 mgH₂O/L, respectively), whereas the R-HME had hardly any influence on the end-expiratory values. The higher temperature of the inspired air caused by the preheating by the antibacterial filter probably underlies the increase in expiratory absolute humidity. The maximum amount of water that can be contained in air depends strongly on air temperature. Warming of inspired air along the respiratory tract causes the point of 100% saturation with water vapour (44 mgH₂O/L, referred to as the Isothermal Saturation Boundary; ISB) to be more cranially located [20]. Because the trachea stays warmer with the F-HME, the exhaled air thus can contain more moisture. The higher inspiratory and expiratory temperature of the F-HME will lead to a longer distance along the respiratory tract (caudal from the ISB) with optimal temperature and humidity. This in turn leads to less hyperactive mucous and goblet cells, resulting in a net reduction in mucous production. Clinically, the extent of mucous production is best noticed in the morning, when an accumulation of mucous has occurred during sleep, when there is little coughing or forced expectoration in order to clear the airways. The better heat-exchange properties of the F-HME in comparison with the R-HME might explain why almost one third of the patients spontaneously reported a reduced mucous production, particularly when waking up in the morning. This is particularly striking, since the observation period was only 3 weeks. All of these patients were relieved in such way that they continue to use the F-HME at least during the night. Although not seen in all patients, reduction of sputum production is an important finding which may improve quality of life for it also implicates less stoma cleaning, less forced expectoration in order to clear the airway and a reduction in the number of HME devices used per day. Although the reduced sputum production may seem obviously to be due to the beneficial effects of the improved heat capacity of the F-HME, this hypothesis cannot be fully evidenced based on the results of the present study, as no control group was included and the clinical study was purely observational. Additionally, no conclusions can be proposed (yet) about the effect of the F-HME on the incidence and occurrence of chest infections, coughing and other pulmonary problems since the antimicrobial effect of the F-HME was not the purpose of this study due to its short-term observation period.

As the clinical feasibility part of the study was purely observational due to the inclusion of a limited number of patients ($n = 19$). The number of included

patients in the *in vivo* tracheal climate assessment part of this study ($n = 13$) may also seem too limited for a clinical study. However, it should be realized that the analysis is based on the accumulative number of 2652 full breaths, which allows for valid statistical conclusions about the short-term climate effects of HMEs. Moreover, we learned from previous studies that the variability between patients (inter-patient variation) is much smaller than the intra-patient variability. Inclusion of more patients is therefore not expected to lead to significant different results (see Chapter 2).

When considering a long-term clinical study to investigate the additional filtration effect of the F-HME, one must bear in mind that improved heating (and simultaneously improved moistening) of the respiratory tract also improves mucociliary activity [52-54], which may also lead to a reduction of chest infections irrespective of the beneficial effect due to the improved filtration of the antimicrobial filter of the F-HME. In addition, clinicians must be aware of possible reduced patient compliance when prescribing the F-HME, as about one third of the subjects did not complete even a short-term observation period of 3 weeks due to practical and external features and even more patients perceived the device as (too) large and aesthetically inconvenient. Based on the present clinical and *in vivo* endotracheal climate assessment evidence, prescription of the F-HME, therefore, mainly is indicated in situations in which theoretically a beneficial clinical effect can be expected, for example in laryngectomized patients with a high risk on common community-acquired respiratory infections (during flu epidemics), or in patients working in a very dusty/polluted environment. The use of the F-HME, at least during the night, could also be trialled in patients suffering from continued excessive sputum production despite the regular use of one of the standard HMEs.

Conclusions

Both the R-HME and the F-HME have been shown to be effective moisture exchangers. Although the R-HME achieves better moistening of inspired air, the F-HME provides a better heating capacity. The additional heating is a favorable side effect of the hydrophobic virus and bacterial filter, which functions as an additional heat exchanger. The associated increase in end-expiratory humidity (AH_{insp}) of the F-HME may contribute to the beneficial clinical effects like an additional reduction in sputum production.