Ex Vivo Assessment and Validation of Water Exchange Performance of 23 Heat and Moisture Exchangers for Laryngectomized Patients

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BACKGROUND: Breathing through a tracheostoma results in insufficient warming and humidification of the inspired air. This loss of air conditioning, especially humidification, can be partially restored with the application of a heat and moisture exchanger (HME) over the tracheostoma. For medical professionals, it is not easy to judge differences in water exchange performance of various HMEs owing to the lack of universal outcome measures. This study has three aims: assessment of the water exchange performance of commercially available HMEs for laryngectomized patients, validation of these results with absolute humidity outcomes, and assessment of the role of hygroscopic salt present in some of the tested HMEs. METHODS: Measurements of weight and absolute humidity at end inspiration and end expiration at different breathing volumes of a healthy volunteer were performed using a microbalance and humidity sensor. Twenty-three HMEs from 6 different manufacturers were tested. Associations were determined between core weight, weight change, breathing volume, and absolute humidity, using both linear and nonlinear mixed effects models. RESULTS: Water exchange of the 23 HMEs at a breathing volume of 0.5 L varies between 0.5 and 3.6 mg. Both water exchange and wet core weight correlate strongly with the end-inspiratory absolute humidity values ($r^2 = 0.89/0.87$). Hygroscopic salt increases core weight. CONCLUSIONS: The 23 tested HMEs for laryngectomized patients show wide variation in water exchange performance. Water exchange correlates well with the end-inspiratory absolute humidity outcome, which validates the ex vivo weight change method. Wet core weight is a predictor of HME performance. Hygroscopic salt increases the weight of the core material. The results of this study can help medical professionals to obtain a more founded opinion about the performance of available HMEs for pulmonary rehabilitation in laryngectomized patients, and allow them to make an informed decision about which HME type to use. *Key words: total laryngectomy; heat and moisture exchanger; HME; comparison study; water exchange; humidity; weight; quality of life.* [Respir Care 2014;59(8):1161–1171. © 2014 Daedalus Enterprises]

Introduction

After total laryngectomy, breathing through the nose is inevitably replaced by breathing through the permanent tracheostoma, whereby inspired air is no longer optimally conditioned before reaching the trachea. The colder and dryer inspired air leads to pulmonary complaints such as increased mucus production and excessive coughing, and

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causes frequent airway infections.[1] For pulmonary rehabilitation after total laryngectomy, heat and moisture exchangers (HMEs) are widely used to partially restore (this lack of) air conditioning. Patients who use these devices consistently have significantly fewer complaints of sputum production and coughing and report a better quality of life.[2,3]

HMEs consist of a functional core material (usually a foam, sometimes coated with hygroscopic salt) contained in a cassette. The functional core material traps and releases a small amount of water during exhalation and inhalation, respectively. With different types of HMEs currently available, the literature is growing rapidly on the effect of HMEs on clinical complaints,[4-9] influence on respiratory function,[2,10-12] in vivo humidity measurements,[13-15] and comparison of in vitro measurements.[16,17] However, no comparative data have been published as yet on the performance of the whole range of HMEs available for laryngectomized patients today. In vivo studies are not suitable for measuring a large variety of HMEs, as the measurements are too time-consuming and burdensome for patients. Furthermore, in vivo humidity measurements are technically difficult to perform.[13,15] In vitro measurements, where either a mechanical lung model according to the ISO standards (International Standard Organization ISO 9360:2000 and 2001) or hygrometry is used, would allow the reliable assessment of a wide range of HMEs when performed in the same test rig; the heat and moisture capacity of these configurations, however, are probably not fully representative of human breathing.[18-20]

These issues were overcome with the recent development of an ex vivo method that enables measurement of water exchange performance of a variety of HMEs within a short timeframe, without the need to trouble patients, while still being universally feasible.[21] In this method, the weight of an HME is measured twice: once at the end of inspiration and once at the end of expiration. The weight difference between end inspiration and end expiration (as function of the breathing volume) represents the water exchange performance during the breathing cycle.

The present study has three aims: ex vivo assessment of the water exchange performance of commercially available HMEs for laryngectomized patients, validation of these results with absolute humidity outcomes, and assessment of the role of hygroscopic salt present in some of the HMEs tested.

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QUICK LOOK

Current knowledge

Breathing through a tracheostoma bypasses the normal heat and humidifying mechanisms of the upper airway, resulting in insufficient conditioning of the inspired air. A heat and moisture exchanger (HME) placed over the tracheostoma can increase tracheopulmonary humidity, improving patient comfort.

What this paper contributes to our knowledge

Twenty-three HMEs designed for laryngectomized patients demonstrated a wide variation in water exchange performance. The efficiency of water exchange correlated well with the end-inspiratory absolute humidity. Wet core weight proved to be a good predictor of HME performance.

Methods

The study was approved by the institutional review board of the Netherlands Cancer Institute-Antoni van Leeuwenhoek.

HME Devices

Twenty-three different commercially available HMEs intended for pulmonary rehabilitation of laryngectomized patients were ordered via local distributors. In vitro HME water loss and pressure drop values (ISO standards)[18,19] were available for HMEs produced by two manufacturers. The other manufacturers, who were all approached for sharing the ISO standard values for their various HMEs, were unwilling or unable to provide these data. The available manufacturer details of the HMEs tested are shown in Table 1.

Most HMEs consisted of a core material and a relatively simple cassette. Some HMEs had a more elaborate cassette design potentially increasing HME performance with additional water storage: the four hands-free HMEs; the Provox Micron (Atos Medical, West Allis, Wisconsin), which has an additional electrostatic filter that, although hydrophobic, influences HME performance by preheating the inhaled air[22]; the Cyranose HME (Ceredas, Antony, France), which contains a metallic grid; and the Blom-Singer humidifier holder (InHealth Technologies, Carpinteria, California), which has a considerably larger cassette.

Water Exchange and Humidity Measurements

Water exchange (weight changes between inhalation and exhalation and vice versa), end-inspiratory absolute hu-

Table 1.   Manufacturer Information for the 23 Tested HMEs

Brand	HME Type	Hands-Free Speech	Core Material	Case Material	ISO Water Loss (mg/L)*†
Blom-Singer	Blom-Singer HME system	No	Foam impregnated with salt + antibacterial agent	Plastic	NA
	Blom-Singer humidifier holder‡	No	Foam impregnated with salt + antibacterial agent	Plastic	NA
	Blom-Singer hands-free valve	Yes	Foam impregnated with salt + antibacterial agent	Plastic	NA
Cyranose	Cyranose HME‡	No	Open cell polyester-based polyurethane foam	Aluminum	NA
Kapitex	Trachi-Naze Blue	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze Green	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze Orange	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze Plus Blue	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze Plus Green	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze Plus Orange	No	Pre-filter + activated carbon + HME layer	Plastic	NA
	Trachi-Naze hands-free valve type B§	Yes	Pre-filter + activated carbon + HME layer	Plastic	NA
Heimomed	Prim-Air Phon II	No	Foam impregnated with salt	Plastic	17.1–23.3†
	Prim-Air Phon II high flow	No	Foam impregnated with salt	Plastic	NA
	Prim-Air Phon I	No	Foam impregnated with salt	Plastic	23.2–24.6†
	Prim-Air Phon I high flow	No	Foam impregnated with salt	Plastic	NA
	Prim-Air hands-free	Yes	Foam impregnated with salt	Plastic	NA
Atos Medical	Provox Micron‡	No	Foam impregnated with CaCl + electrostatic filter	Plastic	26*
	Provox Normal	No	Foam impregnated with CaCl	Plastic	23.7*
	Provox HiFlow	No	Foam impregnated with CaCl	Plastic	25.4*
	Provox Xtra Moist	No	Foam impregnated with CaCl	Plastic	21.5*
	Provox Xtra Flow	No	Foam impregnated with CaCl	Plastic	24*
	Provox hands-free	Yes	Foam impregnated with CaCl	Plastic	19.1*
Servona	Servox HME	No	Foam impregnated with salt	Plastic	NA

* At tidal volume of 1.0 L according to the International Standard Organization (ISO 9360:2000 and 2001).
† At tidal volume of 0.5 L according to the International Standard Organization (ISO 9360:2000 and 2001).
‡ HMEs with a deviating cassette construction compared to other non-hands-free HMEs.
§ For the Kapitex hands-free HME, only type B was used, which differs for type A only in breathing resistance due to the silicon valve in the type A HME.
NA = not available, ie, data not provided by the manufacturer in the manual of the device, and/or on written request by the authors.

midity (AHinsp), and breathing volume were measured using ex vivo weighing as described previously.[21] In the test configuration (Fig. 1), the HME was mounted on a T-tube containing a fast heated capacitive hygrometer, absolute humidity sensor with a response time of 0.1–0.2 s,[23] and a spirometer (MLT300 Flowhead, ADInstruments, Oxfordshire, United Kingdom). A healthy volunteer (first author, CvdB) breathed through the spirometer. The maximum flow of the spirometer was 300 L/min, so the volunteer was instructed to breathe at normal speed; in case of doubt, the flow signal could be inspected. For the weight measurements, a microbalance (MC210P, Sartorius, Göttingen, Germany; accuracy within 0.1 mg) was used. Before the start of weight measurements, each HME was prepared by the volunteer breathing through the HME until equilibrium of water saturation was reached. The length of this conditioning period varied between the different HMEs and was determined for each HME separately. HME weight measurements were performed 25 times, alternating at the end of inspiration and at the end of expiration, using three different breathing patterns (tidal, shallow, and deep breathing). Between each weight measurement, at least five breathing cycles (at tidal volume) were performed to re-
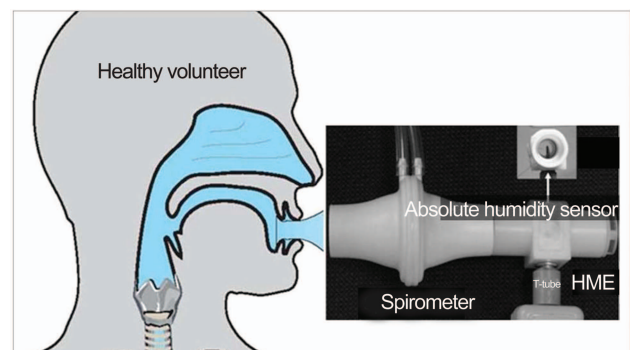

Fig. 1. Test configuration. The healthy volunteer breathes through the spirometer (dead space 70 mL), which is connected to a T-shaped tube (dead space 30 mL) containing an absolute humidity sensor. At the end of this T-tube, the heat and moisture exchanger (HME) is connected (right side). For optimal connection to the test configuration tube, a small connector tube was handmade for all different HME sizes.

condition the HME. Of each HME type, 3 different HMEs were measured on separate days. The 23 HME types were measured in a randomized order. The first weight change was discarded as a result of the differing conditioning

periods as well as the weight change between different breathing patterns, resulting in 21 weight changes for analysis per HME. Weight data points deviating > 75% from the previous and following weights in the data sequence were considered outliers and therefore excluded.

Core Weight and Water Uptake in Humid Conditions

In addition to the ex vivo weighing method, weighing of the core material of the HMEs themselves in different air humidity conditions was carried out to assess the amount of water accumulated in the devices, identical to the method described in 1988 by Ploysongsang et al.[24] The weights of the HME core material were measured after conditioning in completely dry air and at different higher air humidity conditions up until approximately 55% relative humidity (RH) at 21°C. Higher levels of humidity were not used, to avoid nonlinear behavior in the hygroscopic HMEs.[25] HMEs were kept in room conditions (between 30% and 40% RH), and long storage or storage at high humidity levels was avoided to prevent plastics of cassette and core material from slowly (time scale, days) absorbing water and getting heavier.

The HMEs were placed in each condition for approximately 4 h before being weighed. For each HME, the weight increase gradient (weight increase with increasing RH: mg/% RH) was calculated from the HME weight increase as a function of RH. Weights of the core material were obtained by dismantling the HME and subtracting cassette weight. Dry core weight is the core weight at 0% RH. Wet core weight is the core weight of HME under operating conditions (see conditioning above). The mean outcome of 3 HMEs per type was used for analysis.

Additional Equipment

HMEs were placed in an airtight box during weight measurement to prevent water evaporation. A freeze drying chamber (FDC206, SpeedVac system, Savant Instruments, Farmingdale, New York) was used to create a vacuum for 0% RH conditioning. For the wet conditions, a Plexiglas climate room containing a electromotor-driven propeller for air mixture ($26 \times 42 \times 16$ cm^2 as described previously by Zuur et al)[15] was used. Room conditions were recorded during the measurements, using a commercial calibrated humidity sensor (Testo, Almere, Netherlands) with an accuracy of $\pm 0.6°C$ and $\pm 2.5%$ RH. Calibration of the absolute humidity sensor was performed as described previously,[15] using the Testo sensor as reference humidity sensor. Calibration of the spirometer was performed according to the recommendations of the manufacturer. Spirometer data were recorded and analyzed with Powerlab software (ADInstruments), and humidity values

were registered with data acquisition software (Acquis 2.8, Anästhesie-Technik, Göttingen, Germany) and exported to a spreadsheet (Excel, Microsoft, Redmond, Washington). The body temperature of the healthy volunteer was checked at every ex vivo measurement with an electronic aural thermometer (Genius2, Kendall, Tyco Healthcare Group, Mansfield, Ohio).

Data Normalization and Statistical Analysis

Weight changes and AH_{insp} data were normalized to a reference ambient humidity of 5 mg/L as described previously.[21] A summary of the normalization formulas is given in Appendix 1 (see the supplementary materials at http://www.rcjournal.com).

Assessment of the association between water exchange and average breathing volume was determined using a linear mixed effects model for each HME type (three HMEs of one type together). The association between AH_{insp} and inspiratory breathing volume was determined using an exponential decay nonlinear least squares regression as described previously.[21]

For the core weight experiments, weighted r^2 values were calculated using weighted Pearson correlations with inverse variances as weights. Aikake information criterion was used to compare the associations between inspirational absolute humidity and both wet and dry core weights in two weighted linear regressions.

Results

The water exchange (weight change between inhalation and exhalation) as a function of the breathing volume for all HMEs is shown in Figure 2. The graphs represent the exchange of water that was condensed onto and evaporated from the HME during respiration per HME type. Of the total weight change data points (1,449), 21 (1.4%) points were excluded as outliers according to the criterion given in the methods section. The parameters of the model fits shown in Figure 2 are supplied in Appendix 2 (see the supplementary materials at http://www.rcjournal.com). Ambient absolute humidity during the measurements ranged between 7–12 mg/L, and averages and SD per HME type are given in Appendix 2 in Table 5 (see the supplementary materials).

A breathing volume of 0.5 L was chosen for comparison between the HMEs (vertical dashed line, Fig. 2), because this is the average tidal breathing volume previously reported for laryngectomized patients.[12] For each of the tested HMEs, the water exchange at the breathing volume of 0.5 L can be found in Table 2. The water exchange capacity ranged from 0.5 to 3.6 mg. Most HME types had a standard error of about 0.1, but the standard error of the hands-free HMEs tended to be slightly larger (up to 0.16).
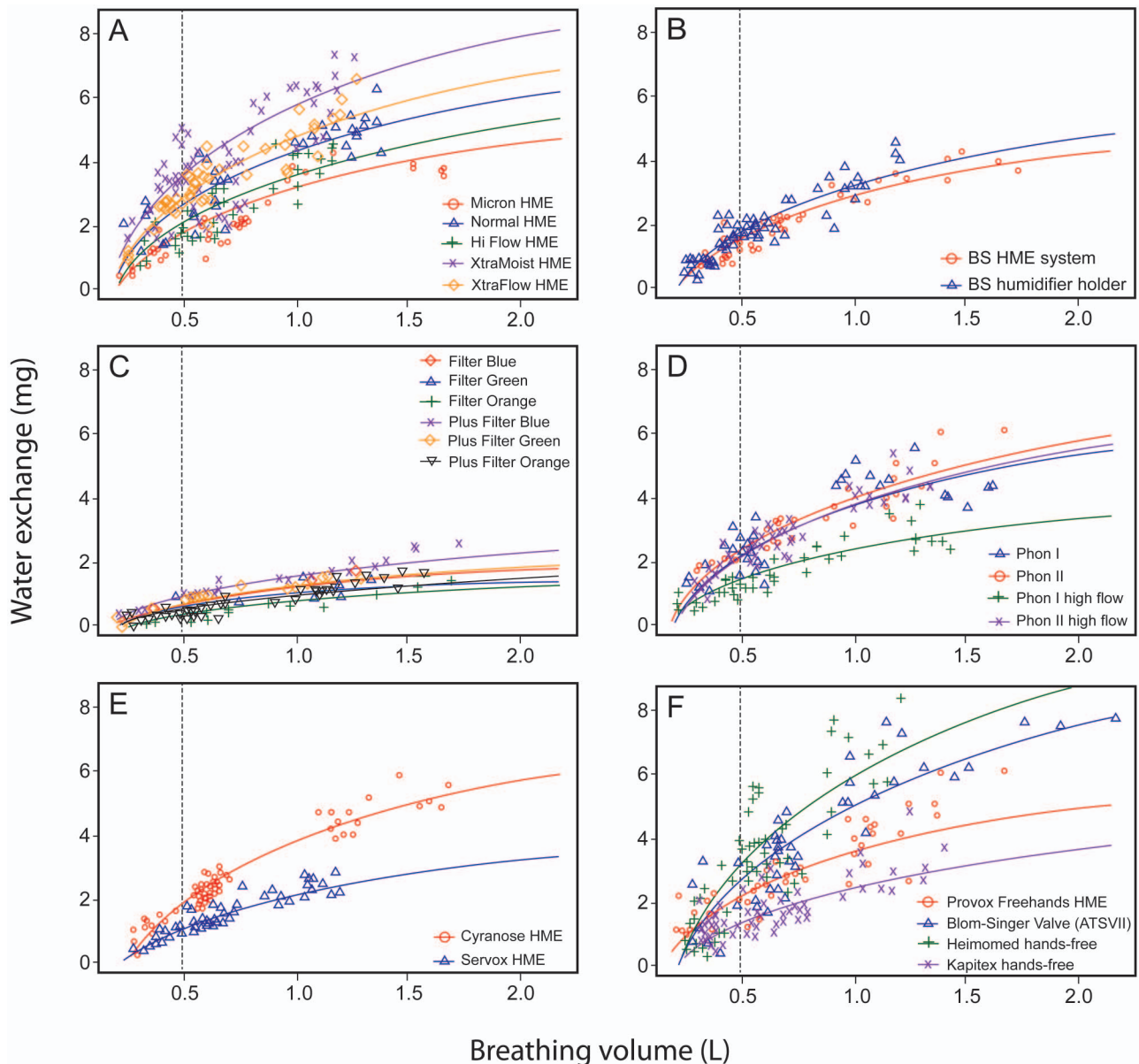
Fig. 2. The observed (points) and estimated (lines) association between breathing volume and water exchange (weight change between inspiration and expiration) for different heat and moisture exchangers (HMEs), normalized to the chosen reference ambient humidity of 5 mg/L.[21] Per HME type, 63 data points were analyzed (21 per HME). HMEs are categorized per brand, and the hands-free HMEs are plotted separately. The four HMEs with hands-free speech are placed together as a separate group (panel F) because these HMEs are only used by a selected group of laryngectomized patients, whereas the other HMEs are useful for all laryngectomized individuals irrespective of their voice rehabilitation method. Vertical dashed lines show the average tidal breathing volume for laryngectomized patients used to compare HMEs.

Figure 3A presents an overview of all HME performances from Table 2 for the water exchange including the standard errors (vertical bars) ranked from high to low performance.

In Table 2, the values of AH_{insp} at a breathing volume of 0.5 L are reported. Details of the measurements of AH_{insp} and the parameters of the exponential decay model[21] are given in Appendix 2, Table 4 (see the supplementary ma-

terials at http://www.rcjournal.com). Figure 3B shows the HME performances ranked according to AH_{insp}.

The correlation between water exchange and AH_{insp} values for each HME tested is shown in Figure 4. The calculated inverse variance weighted r^2 is 0.89. See Table 5 and Fig. 9 in the supplementary material for an in-depth analysis of the correlation shown with a Bland-Altman plot.

Table 2. Model Estimate of Water Exchange Values and AH$_{insp}$ at Volumes of 0.5 L and Standardized to a Reference Ambient Humidity of 5 mg/L

HME Type	Water Exchange (mg)*	AH$_{insp}$ (mg/L)*	Weight Increase Gradient (mg/% RH)	Dry Core Weight (mg)†	Wet Core Weight (mg)†	Water Uptake mg ± SD
Blom-Singer HME system	1.54 ± 0.10	7.59 ± 0.19	0.25	56.6 ± 3.8	73.8 ± 5.3	17.3 ± 1.9
Blom-Singer humidifier holder‡	1.65 ± 0.10	7.78 ± 0.16	0.71	126.8 ± 2.3	191.8 ± 4.4	65.0 ± 0.8
Blom-Singer hands-free valve‡	2.48 ± 0.16	10.87 ± 0.22	0.71	126.8 ± 2.3	191.8 ± 4.4	65.0 ± 0.8
Cyranose HME	1.94 ± 0.10	8.30 ± 0.31	0.02	137.2 ± 6.0	138.7 ± 5.4	1.5 ± 0.1
Trachi-Naze Filter Blue§	0.78 ± 0.09	5.93 ± 0.22	0.08	44.4 ± 3.4	50.5 ± 5.0	6.1 ± 4.7
Trachi-Naze Filter Green	0.63 ± 0.09	5.80 ± 0.17	0.14	45.9 ± 3.8	55.2 ± 4.4	9.3 ± 0.6
Trachi-Naze Filter Orange	0.45 ± 0.09	5.45 ± 0.23	0.10	50.5 ± 3.8	57.1 ± 4.2	6.6 ± 0.8
Trachi-Naze Plus Blue	0.92 ± 0.09	6.02 ± 0.22	0.12	46.4 ± 4.9	54.4 ± 6.3	8.0 ± 1.7
Trachi-Naze Plus Green	0.68 ± 0.09	6.01 ± 0.24	0.07	43.9 ± 4.1	49.0 ± 2.5	5.1 ± 1.7
Trachi-Naze Plus Orange	0.56 ± 0.09	5.83 ± 0.17	0.08	55.2 ± 4.4	60.5 ± 4.7	5.3 ± 0.3
Trachi-Naze hands-free§	1.29 ± 0.11	6.68 ± 0.12	0.08	44.4 ± 3.4	50.5 ± 5.0	6.1 ± 4.7
Prim-Air Phon II	2.09 ± 0.11	8.78 ± 0.20	0.16	143.6 ± 2.7	160.0 ± 5.9	16.4 ± 4.6
Prim-Air Phon II high flow	2.03 ± 0.12	10.45 ± 0.14	0.34	179.5 ± 10.0	213.2 ± 16.9	33.8 ± 7.1
Prim-Air Phon I	2.16 ± 0.10	7.33 ± 0.22	0.20	97.5 ± 2.8	117.7 ± 5.6	20.2 ± 2.8
Prim-Air Phon I high flow	1.36 ± 0.09	6.28 ± 0.27	0.06	71.0 ± 15.3	75.3 ± 11.5	4.4 ± 5.5
Prim-Air hands-free	2.98 ± 0.16	13.35 ± 0.22	0.51	166.3 ± 16.2	215.0 ± 20.8	48.7 ± 6.3
Provox Micron HME	1.86 ± 0.11	7.56 ± 0.27	0.25	86.6 ± 6.3	106.6 ± 7.4	19.9 ± 3.0
Provox Normal HME	2.66 ± 0.13	8.53 ± 0.13	0.62	88.8 ± 6.5	141.9 ± 11.3	53.1 ± 8.4
Provox HiFlow HME	2.04 ± 0.11	7.91 ± 0.19	0.60	89.4 ± 5.3	137.1 ± 9.7	47.7 ± 4.5
Provox XtraMoist HME	3.61 ± 0.13	11.91 ± 0.22	1.72	173.4 ± 5.5	345.9 ± 33.2	172.5 ± 28.5
Provox XtraFlow HME	2.89 ± 0.11	10.21 ± 0.16	0.99	159.8 ± 4.7	249.0 ± 15.4	89.2 ± 11.0
Provox hands-free HME	2.15 ± 0.12	8.08 ± 0.22	0.37	103.3 ± 15.8	134.6 ± 18.0	31.3 ± 0.9
Servox HME	1.14 ± 0.10	7.14 ± 0.13	0.07	91.3 ± 1.5	95.9 ± 1.7	4.6 ± 0.2

* Mean ± SE.
† Mean ± SD.
‡ Core material identical, so weight increase gradient and other values were only measured once.
§ Core material identical, so weight increase gradient and other values were only measured once.
AH$_{insp}$ = end-inspiratory absolute humidity
RH = relative humidity
HME = heat and moisture exchanger

The last 4 columns of Table 2 list the results for the weight measurements of the HMEs in different humidities: the weight increase gradient (weight increase per % RH), dry core weight, wet core weight, and water uptake (the difference between wet and dry core weight). The correlations between AH$_{insp}$ and wet core weight are shown in Figure 5 for all HMEs, as well as for a selection of HMEs with relatively simple cassettes that are likely to have no relevant HME effect of their own (see selected HMEs in methods section). The overall weighted variance r^2 was 0.79, and 0.87 for the simple cassette HMEs. The correlations between AH$_{insp}$ and dry core weights for all HMEs and the simple cassette HMEs were 0.69 and 0.85, respectively. The Aikake information criterion of the weighted linear regressions of AH$_{insp}$ as predicted by wet core weight was 29.9, whereas the Aikake information criterion when using dry core weight was 38.0, suggesting that wet weight is a better predictor of AH$_{insp}$. Water exchange also correlates with core weight (see Table 2), but the r^2 values are lower because of the larger standard error of the water exchange values.

The relation between HME water uptake and water exchange values is illustrated in Figure 6 for the simple cassette HMEs. The data points for the HMEs with a hygroscopic (salt-containing) core material and the types specified by the manufacturer as not containing such material are marked differently (see Table 1 for details). It is clear that, for hygroscopic HMEs, the water exchange improves when more water is absorbed onto the HME.

Discussion

In this study, the ex vivo water exchange performance of 23 presently obtainable HMEs was assessed, the results of which were then validated with absolute humidity measurements at the end of inspiration (AH$_{insp}$).

Most strikingly, the performance of the various devices proved to be highly heterogeneous. The HME water ex-
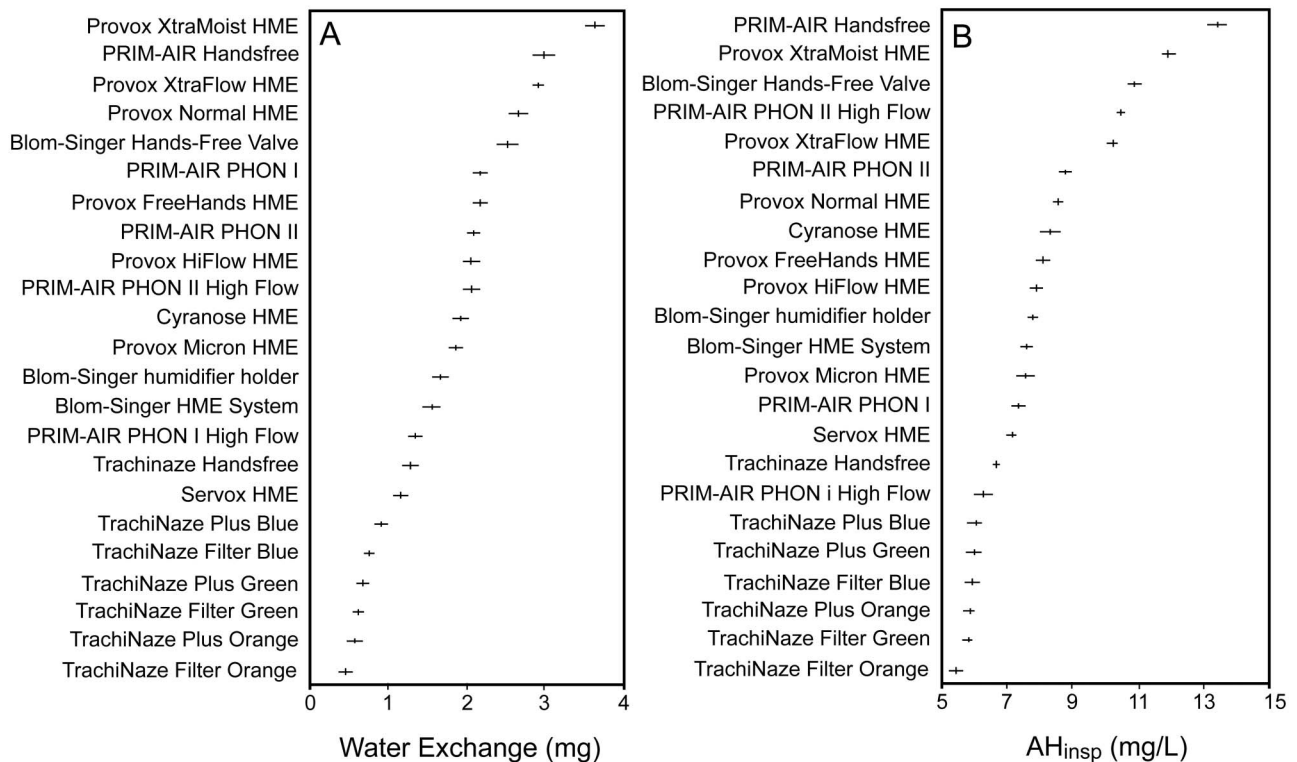
Fig. 3. Mean water exchange values (A) and end-inspiratory humidity (AH$_{insp}$) values (B) ranked at performance from high to low at a breathing volume 0.5 L and normalized to a reference ambient humidity of 5 mg/L (data shown in Table 2). Horizontal lines through each point represent the standard error. HME = heat and moisture exchanger.
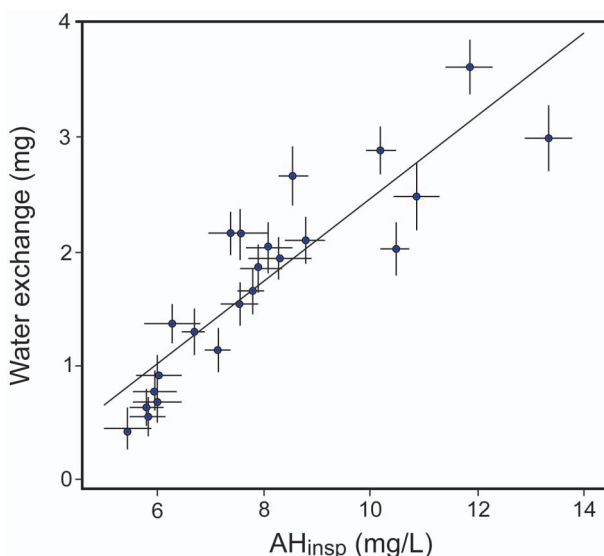

Fig. 4. Correlation between the water exchange and end-inspiratory absolute humidity (AH$_{insp}$) at a breathing volume of 0.5 L and normalized to the chosen reference ambient humidity of 5 mg/L. The inverse variance weighted r^2 is 0.89. Vertical and horizontal bars represent the standard error per data point.
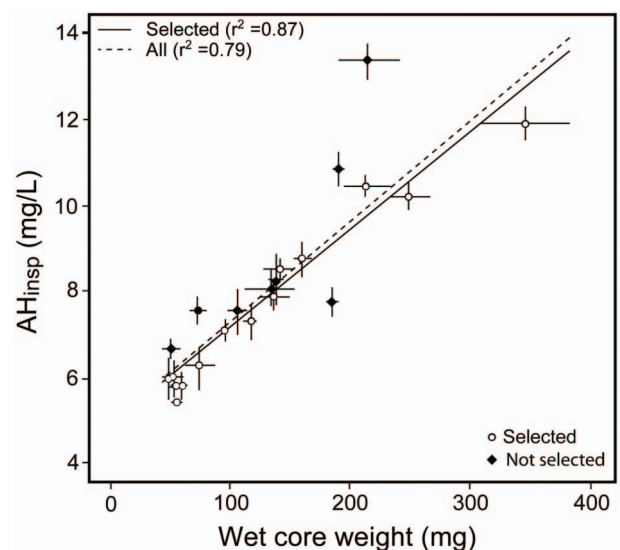

Fig. 5. Relation between wet core weight of the heat and moisture exchanger (HME) and end-inspiratory absolute humidity (AH$_{insp}$) for all HMEs and for HMEs with a simple cassette (see methods section and Table 1, selected HMEs). The horizontal and vertical bars represent the standard errors of each data point.

change capacity (of the 23 HMEs tested) ranged between 0.5 and 3.6 mg at a tidal volume of 0.5 L. Comparison

studies of other HME types (for temporarily tracheostomized patients and in mechanical ventilation settings)
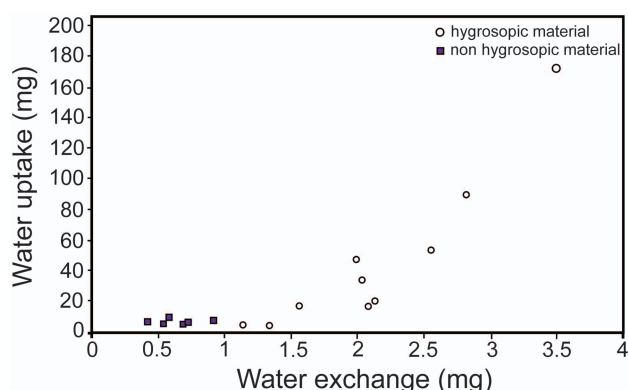
Fig. 6. Water uptake (weight increase between dry and wet heat and moisture exchanger [HME] core material) as function of HME water exchange performance. Not shown are the results from HMEs with a potentially substantial HME effect from the cassette (see methods section and Table 1).

also showed a considerable variability in the performance of HME values.[20,26,27]

The high correlation (Fig. 5, $r^2 = 0.89$) between water exchange and AH_{insp} confirms our previous results based on only 6 different HMEs from one manufacturer, which shows that water exchange is a valid measure for HME performance and means a further and broader validation of the ex vivo weighing method.[21] The present study might have revealed even more interesting results if the manufacturers' ISO specifications for all tested HMEs had been available for comparison with the ex vivo results. Unfortunately, such a comparison was not possible, because the manufacturers approached were unable or unwilling to provide these data, and because the data that were available were measured under different ISO conditions (see Table 1). We have therefore used the AH_{insp} as the accepted standard for validation, as this quantity has been validated using in vivo studies against ISO observations, but it is possible that the water exchange actually is a better quantity because it measures the average performance over the full inspiration and expiration, whereas the AH_{insp} is only measured at end inspiration (see also Table 5 and Fig. 9 in Appendix 2, available in supplementary materials at http://www.rcjournal.com). In particular, for the best performing HMEs, the ranking according to the water exchange outcome differs from the ranking according to AH_{insp}. This might be due to technical difficulties with either of the methods, but it might also be a true result because the water exchange measures the averaged performance over a breathing cycle and AH_{insp} is an instantaneous observation.

For 2 Atos Medical HMEs, we found slightly different water exchange values from those reported previously, with notably slightly higher values for the Provox Normal and XtraFlow, resulting in a better correlation with the AH_{nsp} (see Table 2).[21,28] The present results are indeed probably more reliable as a result of a learning curve effect associated with the application of any new technique and, in particular, because we were more careful in this study not to exceed the flow limitation of our spirometer.

The current study has been performed with a mouth-breathing healthy volunteer instead of stoma breathing of a laryngectomized subject. In both situations, the expired air is almost completely saturated with water, but the saturation is more complete in the volunteer (99% RH vs 92% RH).[29,30] The use of a laryngectomized patient might have slightly influenced the absolute results, but the relative ordering of the HMEs would not be different, as can also been seen in Figure 7, where the results of this study are compared with actual in vivo observations.

This ex vivo method enables an HME comparison study without performing measurements clinically in laryngectomized patients, which with 23 different HMEs would be a near impossible undertaking. As mentioned in our previous papers, an advantage of the ex vivo HME-weighing method is that it can be carried out by a single volunteer. The reason for this is that the spirometer included in the test configuration registers all breathing variations of the volunteer, so that the inhaled volume—the primary confounder when comparing HMEs—can be taken into account properly and will not be unintentionally influenced by the volunteer. Moreover, in a previous study with 6 different volunteers, the intervolunteer variation was negligible.[21]

This study also provides some additional insight into how HMEs function. Although clinicians might consider it to be a rather simple device (just a piece of foam), the theory of HME performance is actually quite a complicated combination of thermodynamics and flow mechanics. An HME must be able to store (and release) a considerable amount of heat, required to condense and evaporate the water in the expired/inspired air. If the HME is unable to do this, the temperature increase/decrease inside the HME will slow the condensation/evaporation process.[31,32] The most important parameters of the HME core material are therefore probably heat capacity (to store evaporative heat), its structure (to ensure sufficient contact with the air flowing through the device), and heat conductivity. Heat capacity is determined by the heat capacity index of the chosen material and its quantity. Figure 5 (see also Table 2) shows that the amount of core material predicts HME performance very well for HMEs that do not have an additional HME effect from the cassette (point above the fit line in Fig. 5). Points below the line show core materials that do not participate in the HME effect (dead weight). However, most points are on the fit line, which suggests that all core material participates in the absorption of evaporative heat. The observed ex vivo variations therefore are likely a result of other parameters, such as differences in the heat capacity index of the core material and/or to HME
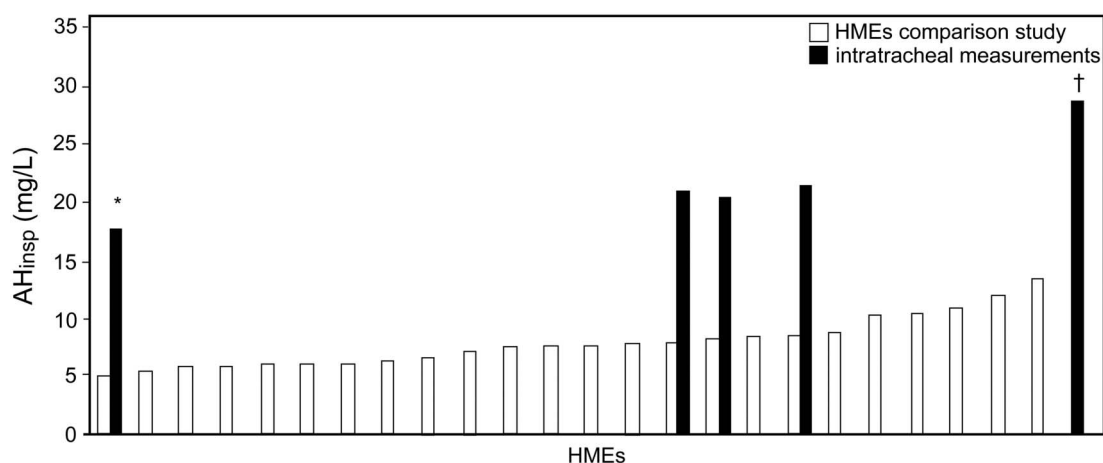
Fig. 7. End-inspiratory absolute humidity (AH$_{insp}$) of heat and moisture exchangers (HMEs). Filled bars represent the AH$_{insp}$ values of HMEs tested in this study; black bars represent the AH$_{insp}$ values of HMEs measured 1 cm intratracheal in laryngectomized patients for 3 corresponding HMEs and nose breathing. All values are standardized to a reference ambient humidity of 5 mg/L. The intrapatient variability in the intratracheal AH$_{insp}$ measurements was large (2.04 mg/L), due to some variety of the absolute humidity sensor probe in the trachea.[14] * without HME, † nose breathing.

effects of the cassette. This correlation points toward total heat capacity, determined by the amount of core material, as the most important HME design parameter. HME optimization requires that as much (thin) core material as possible is stored in the limited available space (the HME should stay cosmetically acceptable) without an unacceptable increase in breathing resistance.

This draws attention to the role of hygroscopic salts that are used to improve the performance of some HMEs. The best performing HMEs in this test are hygroscopic HMEs. Two of the HMEs that are supposed to be hygroscopic according to manufacturers' specifications (Servox and Prim-Air Phon I high flow, Table 1) had only an average performance and a weight increase gradient close to zero (Table 2), while showing no water uptake (Fig. 6); these HMEs behave as if they do not contain any hygroscopic salts in/on the core material. The fact that the performance of hygroscopic and nonhygroscopic HMEs with the same wet core weight is comparable also refutes the common notion that hygroscopic salt plays a part in or is required for the quick storage and release of water during breathing. Figure 6 shows the true explanation for the function of hygroscopic salt. It increases the weight of the HME by attracting a layer of water, and, because water has a high heat capacity, the performance of the HME improves. The amount of water can be large; for the Provox XtraMoist HME, for instance, water constitutes 50% of the total wet core weight.

It is important to note that, although a large water uptake enhances the HME performance, it can also have undesirable side effects. Breathing resistance may increase if the pores in the foam become too small, and, in extreme cases (such as entering very cold outside air from a warm room), excessive water might condense in the HME and may start dripping into the trachea or on the clothes/skin.

To understand the meaning of these ex vivo results for clinical practice, the issue is to what extent these HMEs can bridge the physiological humidity gap between nose and stoma breathing.[13,30,33-35] The physiological tracheal climate during nose breathing is known for healthy volunteers and for head and neck cancer patients with a temporary tracheotomy.[29,30] As laryngectomized patients are head and neck cancer patients, the subglottic humidity value during nose breathing in this patient group (29.3 mg/L at 1 cm behind the temporary tracheostoma)[30] can be considered the target humidity value in the upper trachea of laryngectomized patients. In Figure 8 (available in the supplementary materials at http://www.rcjournal.com), the HMEs tested are placed in order of their AH$_{insp}$ values next to the target AH$_{insp}$ value of nose breathing (all values are standardized to a reference ambient humidity of 5 mg/L). Also included in the figure are the considerably higher in vivo values of three HMEs published previously.[12,22] These are due to the fact that the trachea itself has a considerable HME effect too, which influences the in vivo measurements where the humidity is measured in the stoma/trachea approximately 1 cm behind the HME. This effect is absent in the ex vivo setup, where the absolute humidity sensor was placed downstream of the HME outside the body. Extrapolating the trend of the in vivo values to those of the ex vivo measurements, as shown in Figure 7, one can see that the best performing HMEs come closer to the target value for optimal physiological climate conditions in the trachea. However, there is clearly still some room for improvement of the water exchange capacity even with the best performing HMEs.

The better understanding of HME performance achieved in the present study should help professionals in choosing the right HME for their patients. It might furthermore trigger the development of new HMEs for laryngectomized patients with performance that restores the physiological situation in the trachea even more, leading to an even greater reduction of clinical complaints and improvement of laryngectomized patients' quality of life.

Conclusions

The 23 HMEs for laryngectomized patients tested show wide variation in water exchange performance. Water exchange correlates well with the end-inspiratory absolute humidity outcome, which validates the ex vivo weight change method. In addition, (wet) core weight is a good predictor of HME performance for HMEs with a simple cassette. Hygroscopic salt increases the weight of the core material and therefore the performance of the HME. The results of this study can help medical professionals to obtain a more founded opinion about the performance of available HMEs for pulmonary rehabilitation in laryngectomized patients, and allow them to make an informed decision on which HME type to use.

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