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## Ex vivo humidifying capacity and patient acceptability of stoma cloths in laryngectomized individuals

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**ABSTRACT:** *Background.* Heat and moisture exchangers (HMEs) improve respiratory function after laryngectomy, but there is virtually no information on the benefit of traditional stoma cloths or other covers.

*Methods.* Two sequential studies were performed: (1) an ex vivo test was used to compare the humidifying capacity of stoma cloths to other coverings; and (2) a 4-week randomized trial was then performed to assess patient acceptability of cloths both alone and with an HME ( $N = 18$ ).

*Results.* The humidifying capacity of the coverings tested varied widely. For stoma cloths, a humidifying capacity of 13.7 mg/L was found to decrease to 8.5 mg/L if air-leaks around the cloth occurred. Patients

who used HMEs disliked stoma cloths because they interfered with voicing, they became soiled more easily, and were less effective at reducing coughing and mucus production.

*Conclusion.* Although less acceptable to patients who use an HME, stoma cloths do provide significant humidifying capacity and should be encouraged when HMEs are unavailable or inappropriate. © 2017 Wiley Periodicals, Inc. *Head Neck* 39: 921–931, 2017

**KEY WORDS:** stoma cloth, heat and moisture exchanger (HME), total laryngectomy, humidifying capacity, acceptability

### INTRODUCTION

Total laryngectomy has a profound impact on pulmonary physiology because of the bypassing of the upper respiratory tract.<sup>1–4</sup> The inhalation of unconditioned air through the stoma directly into the lower airways leads to excessive mucus production, involuntary coughing, and frequent forced expectoration to clear the trachea of mucus. These predictable respiratory complaints negatively impact quality of postlaryngectomy prosthetic and/or esophageal voice and speech, and quality of life.<sup>1</sup> Fortunately, heat and moisture exchangers (HMEs) have been shown to help in compensating for the changes in respiratory function and to be

clinically beneficial.<sup>5,6</sup> Since the first prospective clinical trials with such devices in the early 1990s, many studies have shown that HMEs significantly decrease coughing, phlegm production, and the need for forced stoma cleaning, whereas the reduction of these complaints also results in a decrease of tracheitis and crusting, and improvements in voice quality, pulmonary function, and quality of life.<sup>7–12</sup> Initial studies on the impact of HMEs some 25 years ago concerned patients who frequently used stoma cloths, which at that time were standard of care in most institutes.<sup>5,7</sup> In our institute, Buchanan protectors were the standard, and they were prescribed to all patients.

The relevance of postlaryngectomy humidification seems to have been intuited (even) before the first HME studies, because most institutes at that time already applied external humidification, in some cases, still with electric steam kettles, but in most already with wall-mounted, heated humidifiers.<sup>13</sup> The routine prescription of stoma cloths also attested to that. Nevertheless, the first HME studies, which essentially compared HMEs with the then standard of care stoma cloths, showed highly significant clinical improvements in respiratory problems after total laryngectomy. The observations suggested that the clinical respiratory benefits of stoma cloths in practice were limited. It has to be noted, however, that, despite significant respiratory, physical, and quality of life improvements, compliance initially was suboptimal with only about 50% of patients continuing HME use.<sup>7</sup> The reason for this was that airtight stoma occlusion, essential for prosthetic voicing, was difficult to

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Liset Lansaat and Cindy van den Boer contributed equally to this work.

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Additional Supporting Information may be found in the online version of this article.

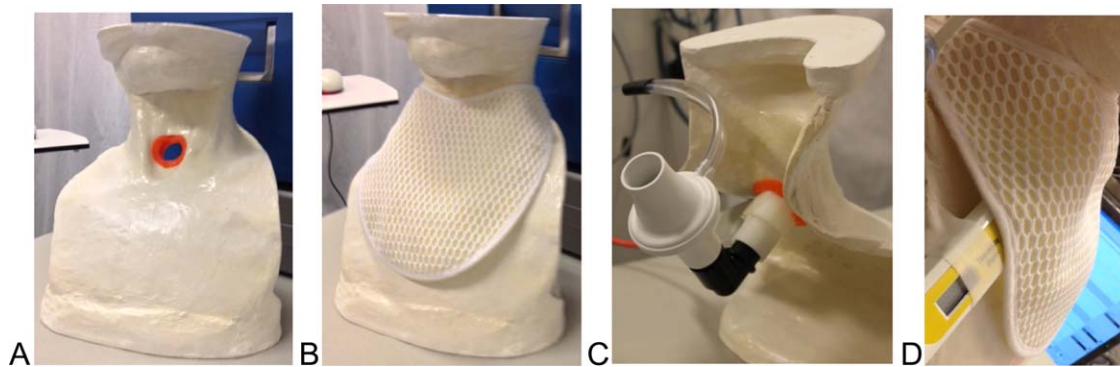


FIGURE 1. Ex vivo test configuration; (A) the laryngectomy neck and chest mannequin, made out of plaster of Paris; (B) Buchanan protector covering the tracheostoma; (C) posterior view showing the connection of the tracheostoma with the spirometer and the integrated absolute humidity sensor (mounted in the black connector); and (D) Buchanan protector lifted to create a slight air leak. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

achieve with the early HMEs. Subsequent generations of HMEs, stoma adhesives, and stoma tubes and buttons, specifically designed to be easy to use, tackled this problem.<sup>14,15</sup> The improved prosthetic voicing led to a significant improvement in compliance, as well as to a further appreciation of these medical devices in The Netherlands and elsewhere.<sup>16,17</sup>

Nevertheless, stoma covers too have humidifying effects, as do any other textiles or fabrics covering the nose and mouth; shawls, for instance, are used especially in the winter season to decrease uncomfortably large temperature and humidity differences between the environment and respiratory tract. Recently, Quail et al<sup>18</sup> looked into the humidifying effects of stoma cloths. The precision of their measurements, however, is unclear as they were not able to establish the proven humidifying effect of the HMEs they included in their study.<sup>19–21</sup> This is probably because of the use of nonvalidated equipment, lack of essential condensation prevention technology,<sup>22</sup> and a “humidity loading time” of only 1 minute instead of the roughly 10 minutes, which are required for HMEs.<sup>23</sup>

An essential component of the clinical benefits of HMEs and stoma cloths is patient acceptability because their pulmonary protective characteristics, as is the case with the upper respiratory tract, are dependent on continuous use of the humidifying device. A clinical study assessing patient acceptability of stoma cloths in daily life, however, has, to the best of our knowledge, never been carried out.

To address these issues, we conducted 2 sequential studies. The first was to assess the humidifying capacity of various stoma cloths with the recently developed validated ex vivo technique.<sup>23</sup> The second was to assess patient acceptability of a stoma cloth with known ex vivo humidifying capacity in a short-term prospective randomized clinical trial.

## MATERIALS AND METHODS

### Ex vivo study

**Ex vivo test setup.** In the ex vivo test, a healthy volunteer was breathing in and out through the HME mounted on a regular spirometer (MLT300 Flowhead; ADInstruments GmbH, Oxfordshire, UK), which recorded breathing

volume and frequency.<sup>23</sup> A fast absolute humidity sensor (response time, 0.1–0.2 seconds<sup>24</sup>) was integrated in the breathing circuit to monitor the humidity. A life-size mannequin of the neck and chest of a laryngectomized patient, made of plaster of Paris, was used to replicate the in vivo application of stoma cloths/HMEs as closely as possible (see Figure 1). On the back of the mannequin, the tracheostoma was connected to the spirometer, and the absolute humidity sensor was integrated in the breathing circuit as well. For optimal humidity, loading of the stoma cloths/HME before recording the data for analysis, the healthy volunteer had to breathe through the device long enough (in general at least 10 minutes) to achieve the optimal humidity loading, following the same protocol as previously described.<sup>23,25</sup> Before each test cycle, the mannequin was heated in an incubator to the level of human skin surface temperature (34°C). The temperature of the mannequin was monitored with a thermocouple (MLT1402 T-type Ultra Fast Thermocouple Probe) placed in a small hole in the mannequin near the tracheostoma.

The absolute humidity sensor and spirometer were calibrated as described previously, as was the temperature and humidity monitoring of the test room.<sup>23,25</sup> Spirometer data were recorded and analyzed using Powerlab software (ADInstruments), and humidity values were registered with data acquisition software (Acquis 2.8; Anesthésie-Technik, Göttingen, Germany). In this study, absolute humidity at end-inspiration and expiration was measured as described previously.<sup>23</sup> Unlike with HMEs in former studies, the weight difference between end-inspiration and end-expiration could not be measured for the stoma cloths, as these could not reproducibly be placed on the balance, making the margin of error too large. The black connector between the absolute humidity sensor and the spirometer (Figure 1C) added 70 mL to the dead space of the configuration used in the previous HME measurements (100 mL).<sup>23,26</sup> Therefore, in this study, the XtraMoist HME was included for comparison with the previous results.<sup>26</sup>

### Materials/devices tested for humidifying capacity

The primary purpose of this study was the performance of the large (216 × 208 mm) Buchanan protector (Kapitex Healthcare, Whetherby, UK). Three samples of the

Buchanan protectors were tested, both dry “worn” correctly and dry with an intentional small leak (Figure 1D). For comparison, a number of other materials/devices were tested once: the Tracheofix stoma cover (Servona, Troisdorf, Germany), the XtraMoist HME (HME-XM; Atos Medical, Hörby, Sweden), the Buchanan protector in combination with the HME-XM, a Buchanan protector made wet before use (2 samples), a Buchanan protector after washing, an ordinary woolen shawl, a cotton baby bib, and a standard surgical mask.

### Analysis and statistical methods

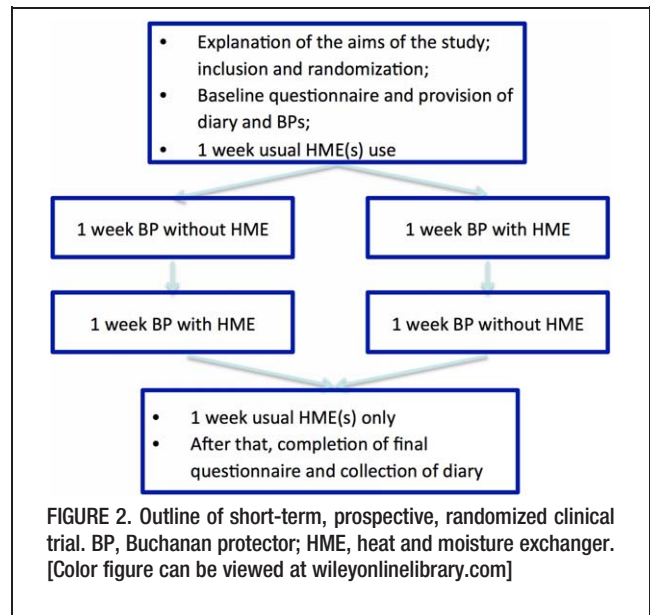
Absolute humidity data were normalized to a reference environmental humidity of 5 mg/L, as described previously.<sup>23</sup> The association between absolute humidity and inspiratory breathing volume was determined by an exponential decay:  $\text{absolute humidity} = A2 + (A2 - A1) \exp(-V \cdot \exp(A3))$ , where absolute humidity is the measured absolute humidity,  $V$  the inspired volume,  $A1$  the end-inspiratory asymptote,  $A2$  end-expiratory intercept value, and  $A3$  the log of the decay rate (see Ref.<sup>26</sup>, Appendix 2, and Ref.<sup>27</sup>). The humidifying capacity is defined as the increase of absolute humidity in the observation with the stoma covered with a device/material over the observation without cover. Using the associations between humidity and inspiratory breathing volume, the humidifying capacity was determined at the clinically relevant breathing volumes of 0.5 and 1.0 L.

### Patient study

**Study purpose and design.** The purpose of this segment of the study was to assess, in a prospective randomized clinical trial, the acceptability of the Buchanan protector (with now known *ex vivo* humidifying capacity) alone or in combination with the HME normally used by patients. The criterion for inclusion was that the patient should be at least 6 months post-total laryngectomy. Exclusion criteria were recurrent disease and difficulty understanding the purpose of the study. Patients in routine follow-up in The Netherlands Cancer Institute were invited to collaborate in the trial through a letter explaining the purpose of the study. In the letter, it was emphasized especially that the good HME capacities of the Buchanan protector, as established in the preceding *ex vivo* tests, made it potentially a good alternative to their regular HME. The study was approved by the protocol review board of the institute.

Ninety-one disease-free laryngectomized patients were approached by regular mail. Forty-nine patients responded (54%), 17 of whom indicated that they were not motivated for the study, 11 that they were physically and/or mentally unable to participate, and 3 that they were motivated but unable to participate because of time constraints. This left a sample of 18 motivated laryngectomized patients, who, after having given written informed consent, were enrolled in the study in April 2015.

The most important outcome measures are patient acceptability and preference for stoma cover pretrial and posttrial. Data collection consisted of study-specific structured questionnaires, patient diaries (see Appendix 1), and photographs of the stoma cover worn by the patient at baseline and after completion of the study.



At baseline, the situation with respect to HME use and voicing was assessed and patients were randomized for the order in which they were to use the Buchanan protector with and without their usual HME in weeks 2 and 3. For week 1, patients were asked to continue their usual HME use in order to collect baseline data in their diaries. For weeks 2 and 3, patients were instructed to use the Buchanan protector without the HME for 1 week and then the Buchanan protector together with their regular HME for the next week, or vice versa. In week 4, patients returned to their regular HME use. During weeks 2, 3, and 4, data were again collected in the diary. By the end of week 4, a photograph was taken once more, the diary was collected, and the final questionnaire was completed. Patients were contacted weekly by telephone for support and motivation. In Figure 2, an overview of the study design is shown.

All patients were familiar with the daily maintenance and practical issues of their regular HMEs. Because patients were mostly unfamiliar with the daily maintenance and practical issues of the Buchanan protector, they were counseled at the start of the study, in accord with the manufacturer’s recommendations. The Buchanan protector is attached by using fabric straps that are wrapped around the neck and tied in a knot; the Buchanan protector can be changed daily, or sooner if required; the Buchanan protector should be cleaned by hand in warm soapy water and rinsed thoroughly in clean water; to dry, the Buchanan protector should be kept flat by placing it between 2 clean towels, to reduce any wrinkling effect on the foam layer; the Buchanan protector should be cleaned 3 times at the most. A total of 10 Buchanan protectors, estimated to be enough for the 2-week trial period, were provided to the patients free of charge out of the department’s research budget.

### Statistical analysis

Questionnaire items regarding coughing, mucus production, skin irritation, stoma occlusion, and voicing (Table 2) asked patients to compare their experience during Buchanan

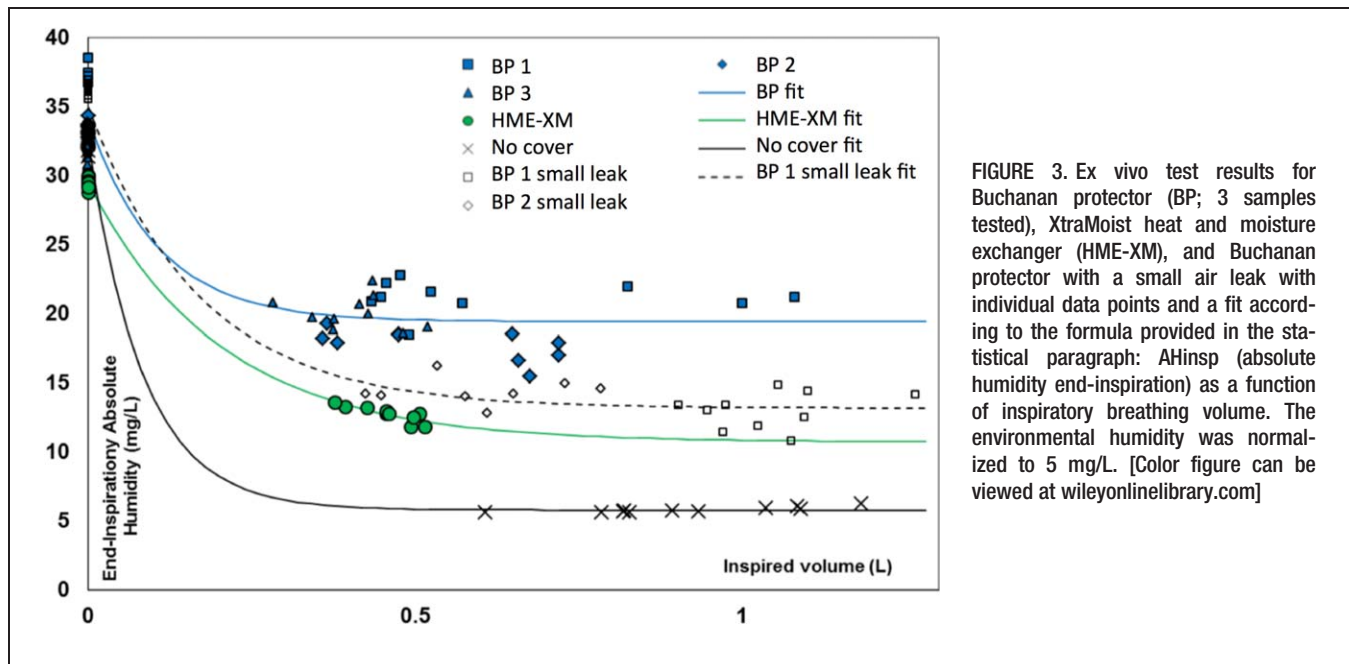


FIGURE 3. Ex vivo test results for Buchanan protector (BP; 3 samples tested), XtraMoist heat and moisture exchanger (HME-XM), and Buchanan protector with a small air leak with individual data points and a fit according to the formula provided in the statistical paragraph:  $AH_{insp}$  (absolute humidity end-inspiration) as a function of inspiratory breathing volume. The environmental humidity was normalized to 5 mg/L. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

protector use (both with and without the HME) to the situation at baseline. For these outcomes, the number of patients reporting better, similar, or worse outcomes during Buchanan protector use (as compared to baseline) were reported and tested against the null-hypothesis of no deviation from baseline in both conditions (with or without the HME) separately, using a Wilcoxon signed rank test. Questions regarding practical issues of Buchanan protector use (Table 3), on the other hand, were compared between conditions (with and without HME) again using a Wilcoxon signed rank test. All analyses were carried out in SPSS version 20.0.

## RESULTS

### Ex vivo study

Figure 3 shows the observations and fits for the main part of the ex vivo study and Table 1 shows the outcomes

for all materials and devices. The Buchanan protector added about 14 mg/L to the end-expiratory absolute humidity at a breathing frequency of 0.5 L (typical for laryngectomized patients), even when washed. Figure 3 also shows that the repeatability with the different Buchanan protector samples is consistent. A dry Buchanan protector combined with the HME-XM and, in particular, the wet Buchanan protector added even more water. Small leaks (as shown in Figure 1D) reduced the performance of the Buchanan protector from 13.7 to 8.5 mg/L; larger leaks did so even more. The HME-XM added 6.5 mg/L, comparable to the woolen shawl and cotton baby bib (when worn without leaks). Note that without the cover the humidity increased slightly, because the entrance through the mannequin already acts as an HME (although not a very effective one). The surgical mask and the Tracheofix showed the poorest performance. Table 1 also gives some data

TABLE 1. Absolute humidity effect of tested materials and devices normalized to room humidity (5 mg/L).

Values for room humidity 5 mg/L	Absolute humidity mg/L	Humidifying capacity mg/L	Absolute humidity mg/L	Humidifying capacity mg/L	A1 mg/L	A2 mg/L	A3
Breathing volume	0.5 L	0.5 L	1.0 L	1.0 L	N.A.	N.A.	N.A.
Buchanan protector wet	23.8	17.9	23.5	17.7	23.5	34.7	2.0
Buchanan protector dry + HME-XM	20.4	14.5	19.6	13.8	19.5	33.1	1.7
Buchanan protector dry ( $n = 3$ )	19.6	13.7	19.4	13.6	19.4	34.1	2.2
Buchanan protector washed	21.1	15.2	18.4	12.6	17.6	33.0	1.1
Buchanan protector cold mannequin	19.4	13.7	17.7	12.1	17.5	35.6	1.5
Shawl	16.6	10.7	15.2	9.4	15.0	31.8	1.6
Buchanan protector dry + small leak	14.4	8.5	13.2	7.4	13.2	35.0	1.8
HME-XM	12.3	6.5	10.9	5.1	10.7	29.5	1.6
Cotton baby bib	12.2	6.3	11.2	5.4	11.2	30.3	1.8
Tracheofix	9.0	3.1	7.5	1.7	7.4	29.1	1.7
Surgical mask	7.6	1.7	7.0	1.2	7.0	28.6	2.0
No cover	5.9	0.0	5.8	0.0	5.8	32.5	2.5
No cover/cold mannequin	5.6	0.0	5.6	0.0	5.6	33.2	2.9

Abbreviations: N.A., not applicable; HME-XM, XtraMoist heat and moisture exchanger.

All observations are for the warm mannequin (34°C) except where marked as cold (room temperature). Data are ordered according to asymptote A1. Humidifying capacity is the difference between the value with device/material and the value without cover at an environmental humidity of 5 mg/L.



FIGURE 4. Pictures taken at the baseline and the 4-week consultation, grouped according to patient number ( $N = 18$ ; 2 baseline and 1 end-of-study pictures are missing). [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

obtained with the mannequin at room temperature instead of  $34^{\circ}\text{C}$ , which showed that a room temperature mannequin reduced humidity only very slightly.

### Patient study

**Baseline data.** The study included 17 men and 1 woman. The mean age was 67.9 years ( $\text{SD} \pm 10.4$ ). The average age at total laryngectomy was 58.9 years ( $\text{SD} \pm 11.0$ ). The median follow-up since total laryngectomy was 107.9 months ( $\text{SD} \pm 84.1$ ). Two patients underwent total laryngectomy with postoperative radiotherapy (RT), and 16 patients underwent salvage total laryngectomy for an RT failure, with 3 of them also receiving additional postoperative RT. All patients used prosthetic tracheoesophageal speech. Seventeen patients continuously used a regular HME, and 1 patient used an automatic speaking valve (ASV). Four of the regular HME users frequently switched to an ASV. The median ASV use per day was 16 hours (range, 1–24 hours). Median HME use per day was 22.0 hours (range, 10–24 hours). All but 3 patients used their HME(s) 24/7: 1 patient regularly (4/7 days) used a Tracheofix stoma cover, and 3 patients sometimes (1 day per 2 weeks) used a Buchanan protector to recover

from skin irritation caused by the HME adhesive. Figure 4 shows the stoma cover situation at baseline and at the end of the 4-week trial for all patients.

### Baseline use of heat and moisture exchanger stoma attachments and additional stoma covers

Twelve patients used a stoma adhesive all day, 4 alternated between adhesive and a LaryTube or LaryButton, whereas 2 patients used a LaryTube or LaryButton all day. Eight patients reported the additional use of a scarf, and 3 the use of their regular clothes (for example, a turtle neck), whereas 7 reported to never use anything else to cover the HME/stoma. Regarding the duration of additional stoma cover use, 5 patients reported to always using a stoma cover, all for cosmetic reasons and, in 2 cases, also for increased comfort (“less cold”), and 6 patients reported occasionally using additional cover, mostly for cosmetic reasons as well, but sometimes for extra protection in wintertime. Reasons for the 13 patients to only occasionally (6 patients) or never (7 patients) use an additional stoma cover were (more options per patient possible): cover have feeling of dyspnea ( $n = 4$ ), cover got wet (1), cover did not look good (1), unnecessary (6),

**TABLE 2. Practical aspects and symptoms reported for the 2 Buchanan protector combinations “Buchanan protector + heat and moisture exchanger” and “Buchanan protector only.”**

Aspect/symptom (no. of patients answering the questions)	Buchanan protector + HME No. of patients	<i>p</i> value Buchanan protector + HME vs HME	Buchanan protector only No. of patients	<i>p</i> value Buchanan protector only vs HME
Coughing (increased compared to regular HME use) (Questions 3–6; <i>N</i> = 17)	0	1.000	4	.046*
Mucus production (increased compared to regular HME use) (Questions 7–10; <i>N</i> = 17)	1	.317	5	.025*
Skin irritation (less compared to regular HME use) (Questions 19–22; <i>N</i> = 16)	0	1.000	5	.025*
Stoma occlusion (more difficult compared to regular HME use) (Questions 23–24; <i>N</i> = 15)	3	.083	14	.000*
Voicing (more difficult compared to regular HME use) (Questions 25–26; <i>N</i> = 15)	2	.157	13	.000*

Abbreviation: HME, heat and moisture exchanger.

Questions allowing comparison between all 3 stoma cover conditions (including HME only). Although the questions allowed for patients to report less coughing, decreased mucus, etc., compared to regular HME use, these outcomes did not occur and are subsequently not represented in the table.

\* One-Sample Wilcoxon signed rank test.

too hot (2), made stoma cleaning more difficult (1), and string around neck irritated (1).

### Adherence to protocol

At 4 weeks follow-up, all patients came in for their final assessment. Thirteen patients (72%) completed the study as intended. Of the remaining 5 patients, 2 used the Buchanan protector in combination with the HME for 2 weeks, because they did not want to discontinue ASV use, and 2 patients used the Buchanan protector without the HME for 2 weeks, because they misunderstood the assignment, and the fifth patient stopped after a couple of days of Buchanan protector use, because he needed a LaryTube to prevent his stoma from shrinking. This last patient also did not answer all the follow-up questions (data reported missing when applicable).

### Preference and practical aspects

The practical aspects reported in relation to stoma cover use are summarized in Tables 2 and 3. As can be seen, significantly more problems were reported in the Buchanan protector-only week. An unpleasantly wet and dirty Buchanan protector and problematic stoma occlusion, voicing, and speaking were reported by 12 to 14 patients

in the Buchanan protector only week and by 3 patients or fewer in the Buchanan protector + HME week. Increased coughing and mucus occurred in 7 patients in the Buchanan protector-only week, and only 1 patient in the Buchanan protector + HME week. Buchanan protector washing was needed considerably more frequent in the Buchanan protector-only period, with a median of every 24 hours as compared to 60 hours in the Buchanan protector + HME week. The only positive aspect for Buchanan protector-only was the level of skin irritation with 5 patients reporting less skin irritation. More details can be found in the Appendices.

### Future preferences

Patient's future preferences were addressed in the final 3 questions (question 29–31) of the study-specific questionnaire. For question 29 (“Which type of stoma cover do you intend to use in the future?”), 9 patients reported that they would keep using an HME only, whereas 9 patients indicated they would use an additional stoma cover alongside the HME. Patient's reasons for this (question 30) can be found in Table 4. The answers showed a negative attitude toward the Buchanan protector-only use and were quite similar to the answers given at baseline to questions 1 and 2 (data not shown for brevity). Nighttime

**TABLE 3. Buchanan protector specific questions compared between the 2 Buchanan protector combinations.**

Aspect/symptom (no. of patients answering the questions)	Buchanan protector + HME No. of patients	Buchanan protector only No. of patients	<i>p</i> value
Buchanan protector getting wet (Questions 11–14; <i>N</i> = 16)	0	12	.001*
Buchanan protector getting dirty (Questions 15–18; <i>N</i> = 16)	2	12	.002*
Buchanan protector washing needed, median hours (Question 27; <i>N</i> = 16)	60 h	24 h	.028*
Buchanan protector washing problematic (Question 28; <i>N</i> = 15)		6	

Abbreviation: HME, heat and moisture exchanger.

\* One-Sample Wilcoxon signed rank test.

TABLE 4. Reasons for not wanting to use a Buchanan protector in the future, including "other reason(s)."

Reason not wearing Buchanan protector in future	No. of patients
Buchanan protector causes feeling of dyspnea	9
Buchanan protector is getting wet	6
Buchanan protector does not look good	11
Speaking/occlusion stoma more difficult	14
Less easy in everyday use	14
Other reason	13
Fabric straps are not easy to wrap around the neck/uncomfortable	4
Buchanan protector is turning around while sleeping	2
Dry cough	1
More viscous mucus	1
What to do when taking a shower?	1
More coughing	1
More mucus	1
To prevent air leak, Buchanan protector has to be wrapped uncomfortably tight around neck	1
Unhygienic	1
Scarf is lighter	1
Buchanan protector is too warm	1

Note: Question 30 of the study-specific questionnaire; for questions 29 and 31 see text; more options per patient is possible.

Buchanan protector use especially was considered dispreferable and several patients reported that, when they woke up, the Buchanan protector was often out of place. Because none of the patients had a preference for Buchanan protector-only, question 31 was not answered by any of them. Finally, comparison with baseline preference shows that 9 of the 11 patients who used an additional stoma cover beforehand (5 always, and 6 sometimes), indicated they would continue to do so in the future, whereas 2 indicated that they would only use an HME. The photographs taken at baseline and at 4 weeks were in line with the preferences expressed.

## DISCUSSION

For a long time, stoma cloths were standard of care for postlaryngectomy stoma and airway protection in most countries. Undoubtedly, substitution of lost upper respiratory tract air conditioning was already considered necessary several decades ago, as postoperative humidification would be applied and stoma covers would be routinely prescribed. Patient acceptability of those measures was, although, never studied. With the arrival of HMEs for laryngectomized patients in the early 1990s, the lack of evidence for the standard of care was deemed unimportant, because of the highly significant positive effects HME devices were found to have, even in patients who already use standard of care stoma cloths.<sup>5,7-11</sup> With additional technical improvements, patient acceptability and compliance of the HMEs increased further,<sup>16,17</sup> reducing stoma cloths as a means to provide humidification to second choice in many countries. Currently, stoma cloths are used for cosmetic reasons or to recover from skin irritations that can be caused by stoma adhesives.

Because of the technical difficulty in developing validated test equipment, the basic physics of humidity and

temperature exchange in HMEs could only be established in the past few years.<sup>22,23,27</sup> One of the main early findings was that, although the HMEs tested generated a significant increase in humidity, there would at the same time be a slight but significant decrease in temperature right behind the HME at the end of inspiration because of evaporative cooling.<sup>28,29</sup> This finding pointed to an insufficient thermal capacity, which in the subsequent generations of HMEs was addressed by incorporating additional material and hygroscopic salt. This resulted in increased water entrapment, improving both the thermal and humidifying capacity of the HME, and diminishing the issue of temperature drop under room temperature conditions.<sup>30</sup> Thus, interestingly enough, the clinical evidence for the beneficial effects of HMEs preceded the physical<sup>26,27</sup> and physiological<sup>31,32</sup> evidence for those effects considerably.

Thermal capacity is presently the main limiting factor for humidifying capacity while keeping the HME small enough to be cosmetically acceptable.<sup>33</sup> Stoma cloths are much larger and, therefore, potentially have a good HME effect. Indeed the study by Quail et al<sup>18</sup> showed a large humidifying effect of several stoma cloths tested, but the validity of the results may be questioned, because they failed to measure the proven humidifying capacity of the tested HMEs.<sup>19,20</sup> Our study confirms that stoma cloths (and shawls etc.) can have a substantial humidifying effect. The humidifying capacity of a dry Buchanan protector without leaks is even larger than the capacity found by Quail et al<sup>18</sup>: the 13.7 mg/L in our study against about 8.3 mg/L for Quail et al<sup>18</sup> (this value had to be calculated as it is not given in the article, see Appendix 2). In our study, a wet stoma cloth, which is heavier and, thus, has a larger thermal capacity, was (not unexpectedly) found to have an even larger humidifying effect, which was not observed by Quail et al.<sup>18</sup> The lower values in their study may have been due to small leaks around the cloths and/or to humidity loss because of condensation in the nonheated suction tube. The values in our study are probably slightly underestimated as well, due to the somewhat larger dead space behind the HME in the mannequin ex vivo setup. Indeed, the humidifying capacity of the HME-XM was slightly lower than previously found (6.5 instead of 6.9 mg/L).<sup>7,25</sup>

The question remains, however, whether the measured humidifying capacity of stoma cloths really is at the patient's full disposal in clinical practice. In view of the significant clinical benefit earlier established for HMEs in populations routinely using stoma covers,<sup>5,7</sup> this is quite doubtful. Both the ex vivo and the clinical study offer likely explanations.

The ex vivo study shows the impact of leakages, which enable unconditioned air to bypass the cloth. A slight lifting of the stoma cover leads to an immediate drop (from 13.7 to 8.5 mg/L at 0.5 L tidal volume) of the humidifying capacity, as shown in Figure 3 and Table 1. The leak in Figure 1D is probably small compared with the leaks that will occur in everyday life as a patient moves (and certainly during sleep). The clinical study shows a rather low patient acceptance of stoma cloths if worn without an HME, because of a variety of disadvantages reported (see Tables 2, 3, and 4), making it likely that patients will take off the stoma cloth too often. These 2 drawbacks are plausible explanations for studies on HMEs showing a clinical improvement over stoma cloths.



An interesting observation is that, although none of the patients preferred stoma cloths only, half of them still prefer covering the HME (eg, with a turtle neck or their clothes for aesthetic reasons). Again, the combination of the ex vivo study and the clinical study offers an explanation for this apparent paradox. The clinical study showed (see Table 2, 3, and 4) that with the Buchanan protector alone the vast majority of patients complained about wetting of the cloth. This complaint was completely absent in the combination with the HME. At first sight, one might conclude from the ex vivo study that (Table 1) the HME hardly has any function in the combination, because the Buchanan protector + HME combination is only slightly better than the Buchanan protector-only (humidification 14.5 vs 13.7 mg/L). However, the HME has an additional relevant effect in this combination: it prevents loss of water,<sup>34,35</sup> and keeps that water inside the confines of the trachea. Therefore, with the Buchanan protector + HME combination, the stoma cloth and the patient's clothes in daily practice remain dryer and the cloth requires less frequent cleaning. In addition, the combination allows for better humidifying capacity than the HME only (assuming the Buchanan protector is worn without leaks).

Adding a stoma cloth may also be beneficial during extreme situations, such as dry and cold winter conditions, as the combination has a considerably higher performance than the HME only (humidification 14.5 vs 6.5 mg/L), provided that the breathing resistance does not become too high. Furthermore, a scarf or shawl makes sense considering the performance of the woolen shawl only (10.7 mg/L). Scarfs or shawls made from natural materials are probably to be recommended because natural materials in general have a good moisture affinity. This is also seen in our study: baby bib (cotton) and shawl (wool) perform much better than the surgical mask or Tracheofix.

Patient recruitment for the study was a challenge, with only 18 of 91 patients (20%) who received an invitation letter being willing or able to participate. The fact that all were using an HME might have biased their willingness to change their daily routines. However, all patients were highly motivated to try something new for potential further improvement of their pulmonary status, which might have compensated (partly) for potential bias in this respect.

Nevertheless, limitations of the clinical study obviously were the relatively low number of patients, and that the study population (by necessity restricted to voice prosthesis and HME/ASV users), probably has a lowered acceptability for stoma cloths, factors that have negatively skewed the results against the cloths. This possibly underestimates their value, and makes the results not fully applicable for esophageal and electrolaryngeal speakers, because some of the issues patients had concerned ease of voicing. However, the issues with the Buchanan protector becoming uncomfortably wet and soiled, and the increase in mucus would still apply to esophageal and electrolaryngeal speakers as well. It seems worthwhile, therefore, to address these aspects in a larger cohort, also including nonvoice prosthesis and non-HME users. Stoma cloths might be more acceptable to patients not yet habituated to an HME, and/or not applying tracheoesophageal prosthesis voicing. It has to be stressed that the stoma cloth used in this clinical trial provides more than just a cosmetic

cover and protection against foreign bodies: it potentially has a good humidifying capacity. If patients without access to HMEs are able to wear the stoma cloth properly and accept the wet cloth against the skin, they very likely will experience better pulmonary health than without such a stoma cover at all. With respect to further technical developments, it has to be kept in mind that the solution for the main Buchanan protector issues in such patients (air leakages and wetting of the skin), likely the reasons for the limited effect of stoma cloths in the clinical studies in the past,<sup>5,7</sup> will probably lead to the "reinvention" of the HME, which completely eliminates these 2 issues. Maybe the use of different materials and designs (for instance, a stoma cloth with an inner water repellent layer and a fitting design) might further improve cloth-like stoma protection, but then costs might become an issue again.

In conclusion, this study shows that HMEs are the preferred choice of patients. Although a well-worn stoma cloth has a good humidifying capacity, patient acceptability in the present patient cohort seems to be low. A stoma cloth in addition to an HME can offer additional humidification in extreme conditions and aesthetic benefits for some patients. If an HME is not an option, for instance (temporarily) because of skin irritation, a stoma cloth is a valuable alternative provided air leaks are avoided. If HMEs or commercial stoma cloths are too expensive, a simple alternative, such as a shawl or baby bib (again, worn properly without leaks), offers some protection and is better than no HME/stoma cover.

## Appendix 1 . Study-specific structured questionnaires, and diary (translated from Dutch).

I. Baseline measurement (+ picture of neck to document "stoma-cover habit" of patient):

Date: dd – mm – year Patient number:

Age: dd – mm – year In years:

Sex: male – female total laryngectomy date: dd – mm – year

RT pre or post-total laryngectomy:pre – post Voice prosthesis type and size

Stoma cover (circle what is applicable): HME XtraMoist – XtraFlow – Normal – HiFlow – Micron – FreeHands (+ hours per day: ..... ) – other .....; HME day and night – only daytime – only nighttime; number of HMEs per day: .....; Adhesive preference: .....; number of adhesives per day: .....; Lary-Tube; LaryButton.

1. Besides your HME, do you use other means of covering your stoma?

- Yes
- Occasionally
- No, continue to question 4

2. If yes, how do you cover your stoma?

- With Buchanan bib
- With turtle neck
- With shawl
- With cloths
- Otherwise .....

3. If yes, why (more answers possible)?

- a. Provides extra comfort
- b. Breathing air less dry
- c. Breathing air less cold
- d. Cosmetically better
- e. Other reason . . . . .

If yes: questionnaire is completed.

4. If no or occasionally, why not or not always (more answers possible)?

- a. Causes feeling of dyspnea
- b. Gets wet
- c. Wet cloths are uncomfortable
- d. Irritating skin
- e. Does not look good
- f. Other reason . . . . .

II. End of study (+ picture of neck to document “stoma-cover habit” of patient).

Date: dd – mm – year Patient number:

1. Which stoma cover method during these 2-week trials do you prefer?

- a. HME only, like before
- b. HME and Buchanan protector together
- c. Buchanan protector-only
- d. Other . . . . .
- e. No preference

2. Can you indicate why? . . . . .

3. Did you notice any difference in coughing in the past weeks?

- a. Yes
- b. No, continue to question 7

4. If yes, how

- a. More coughing
- b. Less coughing

5. If more coughing, during which period?

- a. HME only
- b. HME and Buchanan protector together
- c. Buchanan protector only

6. If less coughing, during which period?

- a. HME only
- b. HME and Buchanan protector together
- c. Buchanan protector only

7. Did you notice any difference in mucus production in the past weeks?

- a. Yes
- b. No, continue to question 11

8. If yes, how

- a. More mucus production
- b. Less mucus production

9. If more mucus production, during which period?

- a. HME only
- b. HME and Buchanan protector together
- c. Buchanan protector only

10. If less mucus production, during which period?

- a. HME only
- b. HME and Buchanan protector together
- c. Buchanan protector only

11. Does the Buchanan protector become wet during use?

- a. Yes
- b. No; continue to question 14

12. If yes

- a. With combination of HME and Buchanan protector
- b. With Buchanan protector only
- c. With both

13. If with both

- a. More with combination of HME and Buchanan protector
- b. More with Buchanan protector only

14. Is the Buchanan protector getting wet unpleasant for you?

- a. Very unpleasant
- b. Rather unpleasant
- c. A little unpleasant
- d. Not unpleasant

15. Is the Buchanan protector getting dirty during use?

- a. Yes
- b. No, continue to question 19

16. If yes

- a. With combination of HME and Buchanan protector
- b. With Buchanan protector only
- c. With both

17. If with both

- a. More with combination of HME and Buchanan protector
- b. More with Buchanan protector only

18. Is the Buchanan protector getting dirty unpleasant for you?

- a. Very unpleasant
- b. Rather unpleasant
- c. A little unpleasant
- d. Not unpleasant

19. Is the skin more or less irritated by wearing the Buchanan protector?

- a. More
- b. Less
- c. No effect; continue to question 23

20. If more or less

- a. More with combination of HME and Buchanan protector
- b. Less with combination of HME and Buchanan protector
- c. More with Buchanan protector only
- d. Less with Buchanan protector only

21. If with both
  - a. More with combination of HME and Buchanan protector
  - b. More with Buchanan protector only
22. Is this irritation unpleasant for you
  - a. Very unpleasant
  - b. Rather unpleasant
  - c. A little unpleasant
  - d. Not unpleasant
23. How does stoma closure work with the Buchanan protector covering the HME?
  - a. Stoma closure is more difficult
  - b. Stoma closure is easier
  - c. Stoma closure is not more difficult nor easier
24. How does stoma closure work with the Buchanan protector without HME?
  - a. Stoma closure is more difficult
  - b. Stoma closure is easier
  - c. Stoma closure is not more difficult nor easier
25. How does voicing work with the Buchanan protector covering the HME?
  - a. Voicing is more difficult
  - b. Voicing is easier
  - c. Voicing is not more difficult nor easier
26. How does voicing work with the Buchanan protector without HME?
  - a. Voicing is more difficult
  - b. Voicing is easier
  - c. Voicing is not more difficult nor easier
27. How long can you wear the Buchanan protector before it needs to be washed?
  - a. In combination with HME: . . . . . hours
  - b. Without the HME also covering the stoma: . . . . . hours
28. What do you think about having to wash the Buchanan protector?
  - a. Not a problem
  - b. A little bit of a problem
  - c. Very problematic
  - d. Too problematic
29. Which type of stoma cover do you intend to use in the future?
  - a. HME only, like now
  - b. HME in combination with Buchanan protector
  - c. Buchanan protector only
  - d. HME in combination with other stoma cover
  - e. Do not know yet

30. If you do not want to use a Buchanan protector, what is/are the reason(s) for that (more answers possible)?
  - a. Uncomfortable/too obstructive
  - b. Uncomfortable/too wet
  - c. Does not look good
  - d. Voicing/stoma closure too difficult
  - e. Daily use more cumbersome
  - f. Other reason(s) . . . . .
  - g. Not applicable
31. If you do want to use a Buchanan protector, what is/are the reason(s) for that (more answers possible)?
  - a. Breathing air feels warmer
  - b. Breathing air feels more moistened
  - c. Does look better
  - d. Voicing/stoma closure easier
  - e. Daily use easier
  - f. Other reason(s) . . . . .
  - g. Not applicable

Thank you very much for your participation/cooperation. Compressed dairy and tally sheath to record stoma cover method, frequency of spontaneous coughing and deliberate mucus production, and to document any unusual events (eg, whether you have a cold or discoloration of your mucus), or any other peculiarities with respect to the use of the HME and/or Buchanan protector (\* circle what is applicable).

Week 1/2/3/4* Date	Stoma cover (HME-only, Buchanan protector + HME, Buchanan protector only*		Spontaneous coughing	Deliberate mucus expectoration	Remarks
Day 1					
Day 2					
Day 3					
Day 4					
Day 5					
Day 6					
Day 7					

**Appendix 2 . Estimation of environmental corrected humidity values in Quail et al.<sup>18</sup>**

Quail et al<sup>18</sup> do not provide values normalized to 5 mg/L, but clinical observations taken at different environmental humidities. The value of 8.3 mg/L at 5 mg environmental humidity was obtained from Figure 3 in their article, using the average value for the Buchanan protector/stoma cloth and the average value “without,” as an estimate for the average environmental humidity. The formula used for normalization can be found in Appendix 1 of Ref. <sup>23</sup> of the present article.

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