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## Development and Clinical Assessment of a Heat and Moisture Exchanger with a Multi-magnet Automatic Tracheostoma Valve (Provox FreeHands HME) for Vocal and Pulmonary Rehabilitation after Total Laryngectomy

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**Hilgers FJM, Ackerstaff AH, Van As CJ, Balm AJM, Van Den Brekel MWM, Tan IB.** *Development and clinical assessment of a heat and moisture exchanger with a multi-magnet automatic tracheostoma valve (Provox FreeHands HME) for vocal and pulmonary rehabilitation after total laryngectomy.* Acta Otolaryngol 2003; 123: 91–99.

**Objective**—To develop and test the prototypes of a novel post-laryngectomy rehabilitation tool incorporating an obligatory, disposable heat and moisture exchanger (HME) and a reusable, multi-magnet automatic speaking valve (ASV).

**Material and methods**—The study subjects comprised 20 laryngectomized individuals (15 males, 5 females), 5 of whom were already using an ASV and 15 who were not. Three successive prototypes were tested. Data were collected by means of structured questionnaires, considering for example patient compliance, skin adhesion, voicing and coughing aspects, and voice and speech quality assessments, assessing for example maximum phonation time and dynamic loudness range.

**Results**—Of the 15 non-ASV users, 5 did not comply with the study due to peristomal skin adhesion problems. Of the remaining 15 patients, all 5 ASV users and 6/10 non-users were fully compliant with the new device. The cough-relief valve of the new device functions properly, as does the valve position adjustment for physical exertion. With this new device the maximum phonation time was longer than with a regular ASV (15.2 vs 11.6 s;  $p = 0.006$ ) and the dynamic range was larger (33.0 vs 24.8 dB;  $p < 0.001$ ).

**Conclusion**—The test results obtained with this new device show that its advanced features (obligatory HME and multi-magnet valve systems) offer additional benefits for further improving vocal and pulmonary rehabilitation after total laryngectomy. *Key words:* automatic speaking valve, heat and moisture exchanger, pulmonary rehabilitation, total laryngectomy, vocal rehabilitation, voice prosthesis.

### INTRODUCTION

A comprehensive rehabilitation program for laryngectomized individuals should address restoration of voice and the prevention and/or resolution of the inevitable respiratory problems resulting from this operation (1). Voice rehabilitation is increasingly achieved using a voice prosthesis placed in a surgically created tracheoesophageal (TE) fistula, either at the time of the laryngectomy [primary TE puncture (TEP)] or at a later date (secondary TEP) (2). The success rate of prosthetic voice rehabilitation is  $\approx 90\%$ , with respect to both the quality of voice and the proportion of long-term users (3). Respiratory problems after total laryngectomy are frequent and debilitating (4). Almost all patients suffer from involuntary coughing and frequent and excessive phlegm production requiring regular stoma cleaning. These pulmonary complaints show strong correlations with other physical and psychosocial problems, such as fatigue, sleeping disorders, anxiety and depression and diminished social interaction. Moreover, there is a strong correlation with voice quality, i.e. more sputum production correlates with a poorer voice. Consequently, the use of a heat and moisture exchanger (HME), which restores part of the lost/short-circuited nose functions, helps to prevent and resolve

these pulmonary problems (5–8). The decrease in pulmonary problems when using an HME has a beneficial effect on physical/psychosocial problems as well as reportedly having a significant correlation with improvement in voice quality (7).

Speaking with a voice prosthesis requires airtight occlusion of the stoma with a finger in order to divert the pulmonary air into the pharyngoesophageal segment or neoglottis, where mucosal vibrations produce the sound for speech (9). Airtight closure using a finger was sometimes difficult to achieve with the traditional HME, resulting in low compliance rates (6, 7). The development of a valved HME, which facilitates digital occlusion by means of a spring valve, led to an improved maximum phonation time and dynamic loudness range and to a higher compliance rate (9–11). However, it is still necessary to use a finger to occlude the stoma in order to produce speech. The obvious solution for obtaining “finger-free” speech is an automatic speaking valve, which stays open during normal calm breathing but can be closed by an increase in air pressure in order to produce speech. The best known of these devices are the Bivona I and II (Bivona Medical Technologies, Gary, IN), the Blom–Singer Adjustable Tracheostoma Valve (ATV) including an HME filter (Inhealth Technologies, Carpinteria, CA), the Eska–

Hermann device and, more recently, the Window valve (12–14). The success rate of the valves presently available is not very high, with  $\approx 30\%$  daily long-term users (15). The most frequently reported obstacle to a higher compliance rate is fixation of the tracheostoma valve to the peristomal skin (16). The airflow necessary for speech tends to lift the valve away from the stoma and consequently loosens the fixation. Other factors limiting the use of these valves include airflow resistance, inadvertent spontaneous closure of the valve during physical exertion, an inconvenient cough-relief mechanism, the motivation/dexterity required by the patient and the need for counseling by medical professionals (15). Moreover, the valves that are available either lack an HME or have a poorly integrated HME which can be abandoned by the patient without prohibiting use of the valve.

In view of all the pulmonary problems outlined above, any speech valve allowing hands-free speech should include an HME in order to be fully acceptable as a comprehensive rehabilitation tool. Therefore, an automatic speaking valve (ASV) was developed with a fully integrated, disposable HME (Provox FreeHands HME); this study describes the development and testing of this device. Results relating to short-term compliance and aspects of voice quality are presented and future indications are discussed.

## MATERIAL AND METHODS

### Patients

From a patient population of  $\approx 180$  laryngectomized patients in long-term follow-up, 20 were chosen at random and asked to participate in this prospective clinical trial. The study was approved by the Protocol Review Board of the Netherlands Cancer Institute (protocol N00VOX). All participants gave their written informed consent.

Patient characteristics are shown in Table I. There were 15 men and 5 women, with a mean age of 62 years (range 49–78 years) and a median follow-up of 4.5 years (range 5 months to 14 years). Of the total of 20 patients, 14 had undergone surgery for recurrent disease after radiotherapy, 5 had been irradiated postoperatively and 1 had not received radiotherapy. Although four patients were (partly) able to use esophageal speech, all preferred prosthetic speech. In addition, although most patients were offered the opportunity (and were trained) to use an ASV during their rehabilitation program, only five in this study group were daily ASV users (Blom–Singer ATV). With one exception, all the other patients were daily users of the Provox HME (Atos Medical, Sweden).

Table I. Characteristics of the 20 patients included in the first trial and of the 15 who continued to participate in the second phase of the trial

Characteristic	Phase 1 (n = 20)	Phase 2 (n = 15)
Gender		
Male	15	13
Female	5	2
Age (years)		
Mean	62	63
Range	49–78	49–78
Follow-up (years)		
Median	4.5	4.5
Range	0.42–14	0.75–14
Radiotherapy		
Preoperative	14	12
Postoperative	5	2
None	1	1
Preferred stoma occlusion method		
ASV	5	5
HME	14	9
Finger	1	1

Two of the five ASV users alternated between the ASV and the HME depending on the situation (ASV for social interactions, HME at home), and all patients replaced the ASV with the HME during the night.

Prior to this clinical study, technical “pre-prototype” tests were performed to evaluate the different designs of the valves and magnets. The present study consisted of three successive prototype trials which were necessary to evaluate the adjustments and improvements that had emerged from the previous trials. In the first trial episode, five patients (all non-ASV users) experienced problems unrelated to the valve, e.g. skin irritation due to the adhesive and lack of understanding of the function of an automatic valve. These 5 patients were omitted from the second trial so that 15 participants (13 men, 2 women) remained in the study. In the third and final trial, 6/15 patients were selected to assess minor technical adjustments that had no influence on the actual speaking valve and/or HME functions. Therefore, only the results of the second trial are described in this paper.

### The Provox FreeHands HME

This device consists of a disposable HME cassette as its obligatory core, with a reusable multi-magnet ASV on top (Fig. 1). The HME can be secured to the bottom of the speaking valve to ensure proper retention in the housing of the adhesive attached to the

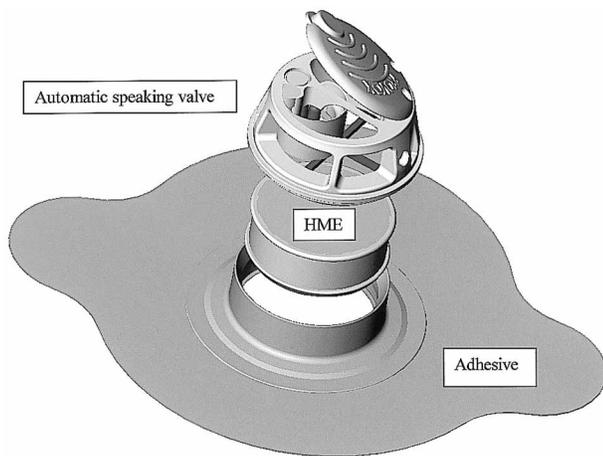


Fig. 1. Schematic illustration of the Provox FreeHands HME.

peristomal skin and is removed by “cracking” the cassette when it needs changing (at least every 24 h). The HME is deliberately placed beneath the valve to ensure protection of the valve against mucous contamination in case the patient coughs up phlegm.

The reusable ASV contains a silicone membrane, which can occlude the side opening of the device, and has a magnet at its tip. The valve has two positions: in the “standard” position the membrane can move freely; in the “activity” position (achieved by rotating the device 75° in the housing) the membrane magnet locks against an eccentrically placed pin, preventing closure of the membrane during physical exertion (Fig. 2a and b). This membrane magnet, in combination with a second magnet near the side opening, keeps the membrane closed during speech, facilitating voicing with a low trachea pressure (Fig. 2c and d). Furthermore, on the topside of the device is a cough-relief valve, which is hinged with elastic silicone bands. This valve opens during coughing so as to release the pressure built up in the trachea and to diminish the possibility of the adhesive loosening. The cough-relief valve is closed by means of magnets, which allow adjustment of its opening pressure by varying the distance between the magnets. Preferably, the speech-language pathologist (SLP) should make this adjustment for the patient (using a special screwdriver), so as to achieve a sufficiently high gradient between the pressures required for closure of the speaking valve and opening of the cough-relief valve. For adhesion to the skin, patients can use the adhesives for the Provox HME system (Fig. 3a and b) or a special cannula (LaryTube; Atos Medical AB, Sweden). Three types of easily exchangeable, color-coded membranes are

available: white (most flexible); green (least flexible); and blue (intermediate flexibility). Together with the SLP, the patient selects the most comfortable and efficient membrane for voicing. In our study group, six patients chose the white membrane, nine the blue one and no one selected the green membrane.

The airflow resistance of the HME is adapted to its combination with the automatic valve, which has some airflow resistance of its own. A special container is provided for cleaning the device (overnight) using a standard denture cleaner.

#### Structured questionnaire

Subjective responses were collected by means of a structured questionnaire, which was completed after each 2–3 week trial period. This questionnaire (interview) evaluates the patient’s experience with the Provox FreeHands HME, focusing on the efficacy of the valve, adhesion to the skin and the combination of the valve with the HME filter.

#### Voice and speech assessment

For assessment of the quality of voice and speech parameters of the Provox FreeHands HME the following data were collected. Speech recordings were obtained using the Computerized Speech Lab (CSL; Kay Elemetrics, Lincoln Park, NJ) with a sample frequency of 22,050 Hz, and stored directly on the hard disk of the computer. The data collected consisted of three repetitions of an /a/ sound sustained for as long as possible for assessment of the maximum phonation time, the highest value of which was used in the analysis; the dynamic loudness range, obtained from the Voice Range Profile program (VRP; Kay Elemetrics); and the use of read-aloud text to establish the number of pauses needed and the lag-time in seconds, and also to perform perceptual analysis to enable judgment of the overall voice quality (17). These data were collected for the three stoma-occlusion methods: the Provox HME, the Provox FreeHands HME and the Blom–Singer ATV (for those patients using this device daily or who were able to use it during the assessment session).

#### Statistical analysis

Data were entered into a specially developed database of the SPSS PC+ statistical package (version 9.0). Statistical analyses included descriptive analyses, tabulations and associations, which were measured using Pearson’s correlation coefficient. Paired Student’s *t*-tests were used to analyze differences between the three stoma occlusion methods. A two-tailed *p*-value of < 0.05 was taken to indicate statistical significance.

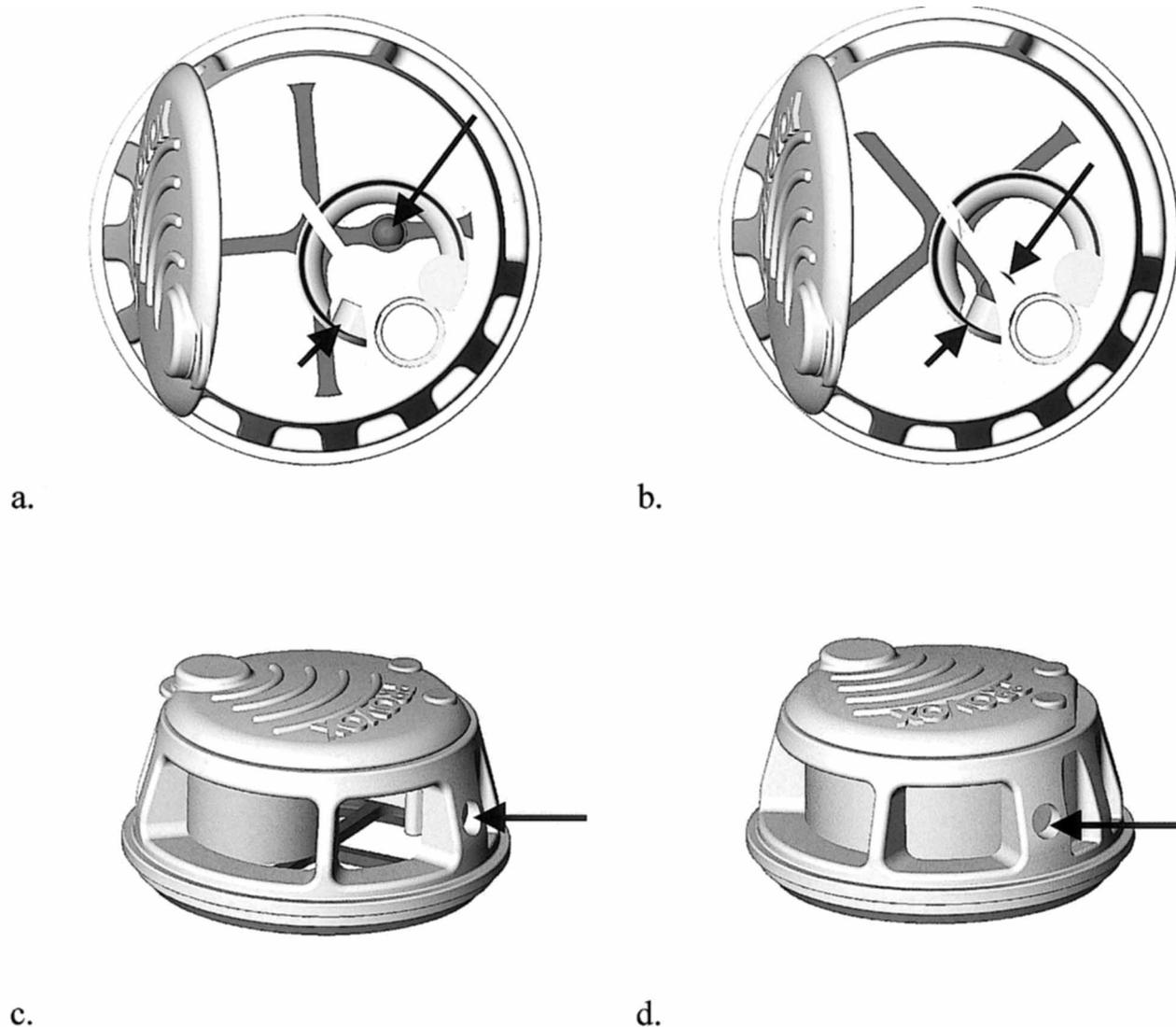


Fig. 2. (a) The sideways closing membrane of the Provox FreeHands HME has a magnet on its tip (*short arrow*), which can be trapped onto an eccentrically placed metal pin (*long arrow*), when turning the valve from the “standard” position. (b) The “activity” position, which prevents inadvertent closure of the valve during physical exertion. (c) To speak, the membrane closes off the side-opening of the device. (d) The magnet on the tip of the device is attracted by another magnet in the wall of the housing (*arrow*), which supports the membrane during speech, lowering the air pressure needed to keep the valve closed.

## RESULTS

### Structured questionnaire

**Compliance.** Of the 5 patients who were using the ASV on a daily basis, all were able to use the FreeHands HME on a daily basis, as could 6/10 of the non-ASV users. The remaining 4 patients used the FreeHands HME irregularly (range 7–11 days) during the 2-week trial period. In this last group of patients, the reasons for irregular use were as follows: skin irritation caused by the use of extra glue ( $n = 1$ ); painful traction on the skin, which could only be relieved by finger support of the valve ( $n = 1$ ); voicing

too tiresome ( $n = 1$ ); and diminished intelligibility compared to the regularly used Provox HME ( $n = 1$ ).

**Adhesion to the skin.** This was accomplished with a Provox adhesive in all but one patient, who routinely used the baseplate of his regular ASV. With the exception of one patient, all used additional silicone glue to improve and prolong the adhesion to the skin. This use of extra glue in addition to the regular adhesive resulted in some skin irritation in three (non-ASV) users which, however, did not lead to them abandoning use of the device. Adhesion for  $\geq 24$  h was accomplished by all 5 daily ASV users and by 4 of the other patients. The remaining six

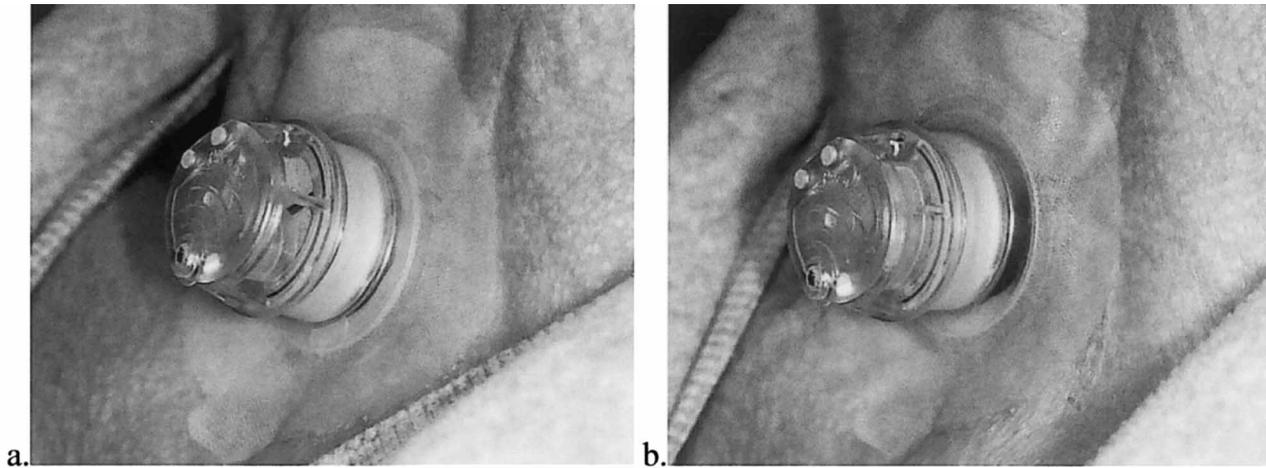


Fig. 3. The Provox FreeHands HME in front of the stoma, during (a) calm breathing and (b) speech. Note the slight change in position due to the air pressure needed for voicing. The pressure on the seal of the adhesive in this patient is relatively small, enabling use of this ASV for an entire day.

patients found it necessary to change the adhesive twice daily, or stopped using the device for the remainder of the day after the second application of adhesive resulted in loosening.

*Use of the HME.* The HME cassette was replaced once a day by 12 patients and twice a day by 3 (with no difference between the 2 groups). Assembling and disassembling the cassette and the FreeHands HME was considered easy by all patients. The five daily ASV users had no problem with the permanent presence of the HME of the FreeHands HME. In contrast, three of them often removed the HME of their regular ASV during the day, mainly in order to readjust the blocked speaking valve protruding from the housing after coughing. The one patient who had not used an HME before the trial experienced fewer respiratory symptoms immediately after the first 3-week trial period. Coughing with the device in place sometimes led to the collection of mucous in the stoma but, in most cases, this could easily be managed by removing the device and wiping the HME without having to change the cassette.

*Voicing.* Two of the ASV users found speaking with the FreeHands HME easier, whereas the remaining three experienced no difference. Comparison between the automatic FreeHands HME and the digitally operated Provox HME showed that four patients considered speaking with the FreeHands HME easier, two found no difference and the remaining four considered speaking with the FreeHands HME more difficult. With respect to voice quality (intelligibility, loudness, fluency and intelligibility on the telephone) no differences were reported between the regularly used ASV and the FreeHands HME.

*Closing sound of the speaking valve.* This was unobtrusive in the majority of patients. Only five patients reported hearing a slight “popping” sound when they started to speak: four found this sound slightly annoying and one did not. In the remaining 10 patients, no noticeable closing sound was reported. For comparison, all five ASV users were accustomed to a “popping” sound at the onset of voicing with their regular device.

*Cough relief.* The adjustable cough-relief valve functioned properly in all patients. However, two of them experienced some disturbing side noise during coughing, probably because the magnet was not optimally attuned. The five daily ASV users reported that the FreeHands cough-relief valve functioned better because it always opened and closed correctly, even when covered with clothing.

*Breathing resistance.* Four ASV users and six of the non-users noticed no difference in breathing resistance at rest. However, one ASV user and four non-users found the breathing resistance at rest slightly higher. The “activity” position obviously decreased the inadvertent closure of the speaking valve, which was appreciated by all patients.

*Maintenance.* All patients reported that cleaning of the device in the special container was simple and effective.

*Final outcome.* The five daily ASV users were asked to compare the FreeHands device with their Blom–Singer ATV. Three patients preferred the FreeHands HME (speaking and/or coughing was easier) and continued to use it after the trial, and two preferred the Blom–Singer valve (less breathing noise and slightly easier breathing during physical exertion). Of the 10 patients who had abandoned using an ASV in

the past, 6 continued to use the new device on a daily basis after the trial period, whereas 3 used it on special occasions only and 1 patient abandoned use altogether.

#### *Voice and speech assessment*

Speech recordings could be made of all 15 patients using a Provox HME and a Provox FreeHands HME, but of only 12 patients using the Blom–Singer ATV. With the Blom–Singer ATV, in addition to the five daily ASV users, seven patients were able to speak with it, at least during the time of the recording. Of the three remaining patients, two could not produce enough trachea pressure to close the Blom–Singer valve to speak, and another needed such a high pressure to speak that this caused the valve to protrude out of the housing. The results of the objective parameters tested are given in Table II.

*Maximum phonation time.* The average maximum phonation time was 17.9 s with the Provox HME, 15.2 s with the Provox FreeHands HME and 11.6 s with the Blom–Singer ATV. Paired *t*-tests showed that the maximum phonation time with the Provox HME was significantly longer than that with the Provox FreeHands HME (15 pairs;  $p = 0.044$ ), as was the case with the Provox FreeHands HME compared to the Blom–Singer ATV (12 pairs;  $p = 0.006$ ).

#### *Dynamic loudness range*

The average dynamic loudness range was 28.2 dB with the Provox HME, 33.0 dB with the Provox FreeHands HME and 24.8 dB with the Blom–Singer ATV. The dynamic loudness range was significantly larger with the Provox FreeHands HME than with the Provox HME ( $p = 0.029$ ) or the Blom–Singer ATV ( $p < 0.001$ ).

*Number of breaths.* All patients read the same text aloud and the number of breaths needed was counted. With the Provox HME, an average of 16.4 breaths was needed, compared with 19.9 with the Provox FreeHands HME and 18.3 with the Blom–Singer ATV. The difference between the Provox FreeHands HME and the Blom–Singer ATV was not

significant, whereas the difference between the Provox HME and the Provox FreeHands HME was significant ( $p = 0.045$ ).

*Voice quality.* According to the perceptual assessment of voice quality by the SLP (17), there were 10 good, 2 reasonable and 3 poor voices among the 15 patients available for studying the Provox HME and the Provox FreeHands HME, and there was no difference between both stoma occlusion methods. Voice quality was good in 11 patients and reasonable in 1 in the group in which the difference between the Blom–Singer ATV and the Provox FreeHands HME could be studied; no difference was found between both stoma occlusion methods.

*Availability of the voice.* With both the Provox HME and the Provox FreeHands HME the availability of the voice was always immediate, with no time lag noted. With the Blom–Singer ATV, in 3/12 patients there was a time lag of 1–2 s, caused by a difficulty in closing the valve to speak.

## DISCUSSION

Airtight stoma occlusion is important in tracheoesophageal speech. Stoma occlusion can be accomplished by means of digital occlusion, by placing a finger directly onto the tracheostoma or on top of an HME with speech valve (Provox HME), or by use of an ASV enabling hands-free speech (9). The latter method has the advantage of being more natural and allows the patient to use both hands for other activities (18).

Renewed interest in this area has been stimulated by the innovative work of Verkerke and colleagues, but long-term results of their new tracheostoma valve are not yet available (14). The success rate of older devices (e.g. the Bivona and Blom–Singer valves) is not very high, with only  $\approx 30\%$  daily users (15). In the present study, only 25% of the randomly selected patients were long-term ASV users, which is a disappointingly low rate. There are several reasons for this low compliance rate, the main one being the fixation

Table II. Data on the different objective parameters determined using the three stoma occlusion methods. The values in parentheses indicate the number of patients in the test group of 15 patients who could be assessed with the specified device

Parameter	Provox HME (15)	Blom–Singer ATV (12)	Provox FreeHands HME (15)
Maximum phonation time (s)	17.9	11.6	15.2
Dynamic loudness range (dB)	28.2	24.8	33.0
Number of breaths	16.4	18.3	19.9
No. of patients with a time lag of 1–2 s at the onset of voicing	0	3	0

of the tracheostoma valve to the peristomal skin (16). The airflow used for speech tends to lift the valve away from the stoma and consequently loosens the fixation. Moreover, the need to exert constant pressure to keep the valve closed creates a continuous pressure on the seal of the adhesive. Obviously, this pressure is highly dependent on the “back-pressure” in the neoglottis: patients with a hypertonic neoglottis will exert more pressure on the seal than those with a normo- or hypotonic neoglottis (who are able to keep the adhesive in place for a prolonged period of time). On the other hand, because of the rapid pressure drop during speech, patients with a hypotonic neoglottis have more difficulty keeping the valve closed and ensuring a sufficiently long phonation time. In addition, there are pulmonary/respiratory and physical/psychosocial factors which also contribute to the limited use of the hands-free tracheostoma valve in laryngectomized individuals (5–8, 11, 19).

With the newly developed Provox FreeHands HME, several of the problems discussed above have been addressed and solved. The use of different sets of magnets to support diverse functions is an important advantage in this respect. The magnet on the tip of the membrane diminishes the pressure needed to keep the valve closed during speech and also prevents inadvertent closure during physical exertion. The cough-relief valve (also supported by magnets) works independently of the speaking valve mechanism, and can be adjusted to the individual. This solution, first used by Verkerke et al. (14), also diminishes the pressure on the seal of the adhesive and, more importantly, does not interfere with voicing, as is the case with the older ASVs. These solutions may account for the suggestion of improved compliance: in this pilot study, in addition to the 5 daily ASV users, 6 of the remaining 10 patients were able to use the Provox FreeHands HME on a daily basis. Of the remaining four patients, three now use the Provox FreeHands HME for special occasions, and only one patient discontinued its use. Moreover, three of the daily ASV users switched to the Provox FreeHands HME thanks to the easier voicing and more optimal cough relief. None of the patients had any problem with the permanent presence of the HME, which was easy to handle and did not inadvertently separate from the reusable valve. It is noteworthy that after the first 3-week trial period the only patient not regularly using an HME reported a clear improvement in pulmonary problems.

Skin-related problems (e.g. allergic reactions, vulnerability due to previous radiotherapy, shear forces, etc.) or problems related to the patient’s motivation and/or “mental dexterity” have remained unsolved.

In our study, this was reflected by the group of patients (25%) who were necessarily excluded from the second trial episode. One suggested solution for skin problems is the use of a special cannula (e.g. the Barton–Mayo button). However, in our small population 9/10 laryngectomized individuals (who had abandoned use of an ASV in the past) had no skin problems and continued to use the new device. This suggests that patient compliance may increase in future. However, this study did not aim to assess compliance, and this factor will be addressed in a prospective clinical multicenter trial.

Studies investigating the effect of an ASV on tracheoesophageal speech have yielded contradictory results. Some have reported no speech differences between digital occlusion directly on the tracheostoma and occlusion by means of an ASV (15, 20, 21). Williams et al. (22) found that the total pause time and the percentage of total reading time occupied by pauses were longer, and that the maximum phonation time was longer in the case of occlusion by an ASV. Blakely and Podraza (23) reported that tracheoesophageal speech produced with occlusion by an ASV was associated with more extraneous sound energy than tracheoesophageal speech produced with direct digital occlusion. Williams et al. (18) found the same effect regarding extraneous speaking voice, but noted that the visual presentation of a patient during speech was better with the use of an ASV. Fujimoto et al. (24) suggested that an ASV adversely affects the conversational intelligibility of tracheoesophageal speech, a result most likely caused by valve noise.

Van As et al. (9) studied the role of stoma occlusion (comparing direct digital occlusion of the stoma with digital occlusion on top of the valved Provox HME in the same patient) by means of acoustic analysis, maximum phonation time and dynamic loudness range. In their study, acoustic analyses (only possible in 13/20 voices) showed no significant differences between the two occlusion methods. However, the study showed a positive influence on the maximum phonation time and dynamic range. The average maximum phonation time was 12.65 s in the digital occlusion group and 16 s in the HME occlusion group, compared with 17.9 s for HME occlusion in the present study. The average dynamic loudness range was 23.2 dB in the digital occlusion group and 26.5 dB in the HME occlusion group, compared with 28.2 dB for HME occlusion in the present study. It appeared that 75% of the patient group benefited from 1 or both of these improvements. In the present study, the maximum phonation time with the Provox HME (mean 17.9 s) was significantly longer than that with the Provox FreeHands HME (mean 15.2 s) and the Blom–Singer ATV (mean 11.6 s). Thus, although

some phonation time is still “sacrificed” for the benefits of hands-free speech, this is significantly less than with the formerly used ASV, which is undoubtedly due to the application of magnets. With respect to the apparent discrepancy between the maximum phonation time and the number of breaths needed to intone a standard text, it should be kept in mind that the number of breaths is merely determined by natural pauses in a sentence. When phonation time is longer, the natural pauses can be reached more comfortably, thus reducing the number of breaths between these pauses. With the Provox HME the maximum phonation time is obviously closer to normal.

A somewhat unexpected finding is that the dynamic loudness range of the Provox FreeHands HME is even larger than that of digital occlusion with the Provox HME. This advantage may be due to the membrane magnet, which allows the valve to stay closed even at very low airflows, or to the digital pressure exerted on the stoma region changing the neoglottic area, thus influencing its modulation characteristics. This aspect requires longer-term investigation in a larger study population. The magnet also allows (almost soundless) closing of the membrane and no time lag at the onset of voicing. The prolonged maximum phonation time, larger dynamic range and absence of a time lag are important factors in enabling the voice to sound more similar to a normal laryngeal voice (25). That there was no difference in voice quality for the three stoma-occlusion methods, as judged on a fairly crude perceptual scale (good, reasonable and poor) is not unexpected; potential differences may well emerge when using specific perceptual scales (e.g. judging fluency or extraneous speaking noise) (17).

In conclusion, we have described the development of a novel post-laryngectomy rehabilitation tool, i.e. a combination of an obligatory, disposable HME for pulmonary protection and rehabilitation and a reusable multi-magnet ASV enabling hands-free speech. Extensive prototype testing has resulted in a comprehensive device incorporating several beneficial features aimed at further improving vocal and pulmonary rehabilitation in laryngectomized individuals.

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