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Importance of Compliant HME Use

- Post-laryngectomy pulmonary symptoms
- Pulmonary rehabilitation with HME
- Improving compliant HME use

Preface

This document contains a bibliography and summaries of selected publications relating to the importance of compliance in HME use. The document is part of a growing, and regularly updated collection of documents, the *Atos Medical Clinical Evidence Series*, covering various clinical topics related to Atos Medical's areas of expertise. The topics are chosen based on questions that we receive from our customers.

Examples of available topics are:

- Laryngectomy and Reflux
- Primary versus Secondary TE puncture
- Primary versus Delayed Voice Prosthesis Fitting
- Early oral feeding

If you would like to receive a list of all currently available topics, if you are interested in any of the topics listed above, or if you have a suggestion for additional topics, please contact your local Atos Medical representative. Due to International Copyright law, we cannot provide full-text publications of the references. If a publication is available online via 'Open Access' the link is provided in the document.

Table of content

Total laryngectomy and pulmonary physiology

A total laryngectomy (TL) is a surgical procedure performed in advance stages of cancer in or near the voice box. During the surgery the patients' entire voice box, e.g. the larynx, is taken out. Removal of the larynx requires the airways connected to the nose and mouth to be permanently separated from the windpipe (trachea) and lungs. As a result, all breathing will have to take place through an opening in the neck – the tracheostoma. Hence, removal of the larynx will not only lead to changes related to voice and speaking, it will also have a major impact on breathing, swallowing and smelling[1, 2].

The upper airways, and particularly the nose, have many important functions that a tracheostoma will not be able to compensate for. The nose is responsible for more than olfaction – it heats, humidifies, and filters the air we breathe[1, 2]. The mucosal lining in the nose and nasopharynx is the major contributor to this conditioning process where the inspired air gain optimal levels of humidity at body temperature (core temperature [37°C] and 100% relative humidity [44 mg/L]) before reaching the lungs[1, 3]. Adequate air conditioning is mandatory not only for proper respiration and gas exchange in the lower airways, but also for mucociliary function and airway clearance[4].
The lack of proper conditioning related tracheostoma breathing have both short- and long-term negative effects on the physiology of the airways, including frequent impairment of lung functions[5]. Trying to compensate for the unconditioned (too cold and too dry) air, mucosal cells present in the windpipe and lungs will start to produce and release more mucus. Consequently, many laryngectomized patients suffer from frequent coughing and repeated daily forced expectorations in order to clear the airways[1, 2, 5]. Other factors correlating to these pulmonary problems are increased fatigue, sleep problems, psychological distress and disruption of social interactions[2, 5-7].

The publications listed below concern the publications regarding consequences of total laryngectomy on pulmonary physiology that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Scheenstra RJ, Muller SH, Vincent A, Hilgers FJ. Heat and moisture exchange capacity of the upper respiratory tract and the effect of tracheotomy breathing on endotracheal climate. Head Neck. 2011;33(1):117-24.

[2]Ackerstaff AH, Hilgers FJ, Aaronson NK, De Boer MF, Meeuwis CA, Knegt PP, Spoelstra HA, Van Zandwijk N, Balm AJ. Heat and moisture exchangers as a treatment option in the post-operative rehabilitation of laryngectomized patients. Clin Otolaryngol Allied Sci. 1995;20(6):504-9.

[3]Williams R, Rankin N, Smith T, Galler D, Seakins P. Relationship between the humidity and temperature of inspired gas and the function of the airway mucosa. Crit Care Med. 1996;24(11):1920-9.

[4]Keck T, Leiacker R, Heinrich A, Kuhnemann S, Rettinger G. Humidity and temperature profile in the nasal cavity. Rhinology. 2000;38(4):167-71.

[5]Hilgers FJ, Ackerstaff AH, Aaronson NK, Schouwenburg PF, Van ZN. Physical and psychosocial consequences of total laryngectomy. Clin Otolaryngol Allied Sci. 1990;15(5):421-5.

[6]Scheenstra RJ, Muller SH, Hilgers FJ. Endotracheal temperature and humidity measurements in laryngectomized patients: intra- and inter-patient variability. Med Biol Eng Comput. 2009;47(7):773-82.

[7]Ackerstaff AH, Hilgers FJ, Aaronson NK, Balm AJ. Communication, functional disorders and lifestyle changes after total laryngectomy. Clin Otolaryngol Allied Sci. 1994;19(4):295-300.

Scheenstra RJ et al. 2011

Title
Heat and moisture exchange capacity of the upper respiratory tract and the effect of tracheotomy breathing on endotracheal climate.

Authors
Scheenstra RJ, Muller SH, Vincent A, Hilgers FJ.

Affiliation(s)
Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands.

Journal and year of publication
Head Neck. 2011 Jan;33(1):117-24.

Type of publication
Prospective study.

Background
The aim of this study was to assess the heat and moisture exchange (HME) capacity of the upper respiratory tract and the effect of tracheotomy breathing on endotracheal climate in patients with head and neck cancer.

Subjects and Methods
We plotted the subglottic temperature and humidity measurements in 10 patients with head and neck cancer with a temporary precautionary tracheotomy during successive 10-minute periods of nose, mouth, and tracheotomy breathing in a randomized sequence.

Results
End-inspiratory temperatures of nose, mouth, and tracheotomy breathing were 31.1, 31.3, and 28.3°C, respectively. End-inspiratory humidity measurements of nose, mouth, and tracheotomy breathing were 29.3, 28.6, and 21.1 mgH_2O/L, respectively. There was a trend toward lower end-inspiratory humidity in patients with radiotherapy or with large surgery-induced oropharyngeal mucosal defects, whereas temperatures were similar.

Conclusion
This study gives objective information about the HME capacity of the upper respiratory tract in patients with head and neck cancer with precautionary tracheotomy, and thus provides target values for HMEs for laryngectomized and tracheotomized patients.

Ackerstaff et al. 1995

Title
Heat and moisture exchangers as a treatment option in the post-operative rehabilitation of laryngectomized patients.

Authors
Ackerstaff AH, Hilgers FJ, Aaronson NK, De Boer MF, Meeuwis CA, Knegt PP, Spoelstra HA, Van Zandwijk N, Balm AJ.

Affiliation(s)
Department of Otolaryngology-Head & Neck Surgery, Netherlands Cancer Institute, Amsterdam.

Journal and year of publication
Clin Otolaryngol Allied Sci. 1995;20(6):504-9.

Type of publication
Prospective study.

Introduction
A multi-institutional, prospective clinical study was undertaken to investigate whether the use of a heat and moisture exchanger (HME) in the period following total laryngectomy could prevent the development or reduce the severity of respiratory symptoms.

Subjects and Methods
Fifty-nine patients from three hospitals were provided with HMEs, either immediately post-surgery or, in the case of post-surgical radiotherapy, upon completion of the radiotherapy.

Results
For the total sample (n = 59) statistically significant improvements over time (between 3 and 6 months) could be found in forced expectoration ($P < 0.05$), in the perceived voice quality ($P < 0.001$), social anxiety ($P < 0.001$), social interactions ($P < 0.001$) and in feelings of anxiety and depression ($P < 0.05$). Repeated measures analysis of variance indicated statistically significant group differences over time in forced expectoration and stoma cleaning ($P < 0.05$).

Conclusion
No statistically significant differences over time were noted between the regular and non(regular) HME user groups in voice quality or in various aspects of daily living.

Williams et al. 1996

Title
Relationship between the humidity and temperature of inspired gas and the function of the airway mucosa.

Authors
Williams R[1], Rankin N, Smith T, Galler D, Seakins P.

Affiliation(s)
[1]Intensive Care Unit, Middlemore Hospital, Otahuhu, New Zealand.

Journal and year of publication
Crit Care Med. 1996;24(11):1920-9.

Type of publication
Review article.

Introduction
The aim of this study was to review the available literature on the relationship between the humidity and temperature of inspired gas and airway mucosal function.

Subjects and Methods
Two hundred articles/texts on respiratory tract physiology and humidification were reviewed. Seventeen articles were selected from 40 articles for inclusion in the published data verification of the model. Selection was by independent reviewers. Extraction was by consensus, and was based on finding sufficient data.

Results
A relationship exists between inspired gas humidity and temperature, exposure time to a given humidity level, and mucosal function. This relationship can be modeled and represented as an inspired humidity magnitude vs. exposure time map. The model is predictive of mucosal function and can be partially verified by the available literature. It predicts that if inspired humidity deviates from an optimal level, a progressive mucosal dysfunction begins. The greater the humidity deviation, the faster the mucosal dysfunction progresses.

Conclusion
A model for the relationship between airway mucosal dysfunction and the combination of the humidity of inspired gas and the duration over which the airway mucosa is exposed to that humidity is proposed. This model suggests that there is an optimal temperature and humidity above which, and below which, there is impaired mucosal function. This optimal level of temperature and humidity is core temperature and 100% relative humidity. However, existing data are only sufficient to test this model for gas conditions below core temperature and 100% relative humidity. These data concur with the model in that region. No studies have yet looked at this relationship beyond 24 hrs. Longer exposure times to any given level of inspired humidity and inspired gas temperatures and humidities above core temperature and 100% relative humidity need to be studied to fully verify the proposed model.

Keck et al. 2000

Title
Humidity and temperature profile in the nasal cavity.

Authors
Keck T[1], Leiacker R, Heinrich A, Kühnemann S, Rettinger G.

Affiliation(s)
[1]Department of Otorhinolaryngology, University of Ulm, Ulm, Germany. tilman.keck@medizin.uni-ulm.de

Journal and year of publication
Rhinology. 2000 Dec;38(4):167-71.

Type of publication
Prospective study.

Introduction
Adequate air conditioning in the nasal airways is mandatory for respiration and gas exchange in the lower respiratory tract. The aim of the present study was to measure relative humidity and temperature in the airstream at different sites within the nasal cavity for mapping of relative humidity and temperature in the upper airways.

Subjects and Methods
Intranasal relative humidity and temperature of 23 volunteers was measured during respiration at different locations in the nasal cavity. The end-inspiratory temperature and humidity data, obtained with a miniaturized thermocouple and a capacitive humidity sensor, were determined.

Results
A high increase of humidity and temperature at the end of inspiration, in relation to the environmental conditions, was found in the anterior nasal segment. The further increase of both parameters between turbinate area and nasopharynx was less pronounced in spite of the longer distance.

Conclusion
The anterior part of the nasal cavity contributes within a short nasal passage to air conditioning of inspired air.

Hilgers et al. 1990

Title
Physical and psychosocial consequences of total laryngectomy

Authors
Hilgers FJ, Ackerstaff AH, Aaronson NK, Schouwenburg PF, Van ZN

Affiliation(s)
Department of Head and Neck Oncology and Surgery, Psychosocial Research and Pulmonology, The Netherlands Cancer Institute, and Department of Psychology, University of Amsterdam

Journal and year of publication
Clin Otolaryngol Allied Sci. 1990 Oct;15(5):421-5

Type of publication
Retrospective study.

Introduction
The aim of this study was to establish the prevalence rates of respiratory symptoms among laryngectomized patients. Additionally, data were obtained regarding fatigue and sleep problems, perceived voice quality, problems related to social contacts, and level of psychological stress.

Subjects and Methods
The incidence and severity of respiratory symptoms after total laryngectomy and their influence on daily living were studied in 59 laryngectomized patients.

Results
Daily sputum production was the principal complaint of these patients (98%), followed by coughing (64%) and the need for frequent forced expectoration (more than 5 times a day) in order to clear the airway (57%). Frequent stoma cleaning (more than 5 times a day) was required by 37% of the patients. Significant correlation was found between respiratory symptoms, voice rehabilitation and several aspects of daily living, including fatigue, sleep problems, social contacts and psychological distress

Conclusion
These findings indicate that respiratory symptoms after total laryngectomy are both frequent and troublesome. The development of effective methods for minimizing and/or preventing such respiratory problems would contribute significantly to improving the quality of life of laryngectomized patients.

Scheenstra et al. 2009

Title
Endotracheal temperature and humidity measurements in laryngectomized patients: intra- and inter-patient variability.

Authors
Scheenstra RJ, Muller SH, Hilgers FJ.

Affiliation(s)
Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands.

Journal and year of publication
Med Biol Eng Comput. 2009 Jul;47(7):773-82.

Type of publication
Prospective study.

Introduction
To date no study has investigated patient variability in endotracheal temperature and humidity. It is not known whether similar results will be obtained if measurements are repeated within a limited time-period (short-term variation), or whether temperature and humidity values fluctuate over longer time periods due to, for example, changes in the condition of the mucosa (long-term variation).

Subjects and Methods
This study assesses intra- and inter-patient variability in endotracheal climate (temperature and humidity) and effects of heat and moister exchangers (HME) in 16 laryngectomized individuals, measured repeatedly (N = 47).

Results
Inhalation Breath Length (IBL) was 1.35 s without HME and 1.05 s with HME ($P < 0.0001$). With HME, end-inspiratory (minimum) humidity values increased 5.8 mg H(2)O/L ($P < 0.0001$) and minimum temperature values decreased 1.6 degrees C ($P < 0.0001$). For the temperature and humidity minimums, the inter-patient variability was much smaller than the short- and long-term intra-patient variability. For exhalation breath length and full breath length, the opposite was the case.

Conclusion
(1) Because inter-patient variability is smaller than intra-patient variability, investigating endotracheal climate in a limited number of laryngectomized subjects is justified, provided repeated measurements per patient are accomplished; (2) main contributor to intra-patient variability is the positioning of the catheter tip in the trachea; (3) an HME leads to a shortened IBL which enhances the HME effect.

Ackerstaff et al. 1994

Title
Communication, functional disorders and lifestyle changes after total laryngectomy.

Authors
Ackerstaff AH, Hilgers FJ, Aaronson NK, Balm AJ.

Affiliation(s)
Department of Otolaryngology-Head & Neck Surgery, Netherlands Cancer Institute, Amsterdam.

Journal and year of publication
Clin Otolaryngol Allied Sci. 1994 Aug;19(4):295-300.

Type of publication
Retrospective study.

Introduction
In the current study the focus is on the non-pulmonary consequences of total laryngectomy, including results and methods for vocal rehabilitation, eructation, hyposmia and dysgeusia, swallowing, and dietary changes. Smoking habits were also evaluated. Relationships between these variables and other aspects of daily life are also reported.

Subjects and Methods
Functional changes after total laryngectomy, including voice quality, hyposmia and dysgeusia, nasal discharge, swallowing and smoking habits were studied by means of a structured interview with 63 laryngectomized patients.

Results
Eighty per cent of the patients reported that they were satisfied with the quality of their voice including speaking on the telephone. Significant correlations were found between the quality of the voice and fatigue, frequency of making telephone calls and anxiety about speaking ($P < 0.01$). Vocal rehabilitation was achieved in the majority of patients (78%) with the indwelling Provox voice prosthesis. Forty-five per cent of the patients complained about annoying eructation. Hyposmia was reported by 52% of the patients, while 15% experienced dysgeusia. A significant correlation was found between hyposmia and dysgeusia ($R = 0.43$, $P < 0.001$). All patients with a taste problem also reported a poor sense of smell. Daily nasal discharge was reported by 38% of the patients. Due to difficulties in swallowing solid food, about one quarter of the patients changed their diet. All but one patient had been heavy smokers pre-operatively. Only 9% continued to smoke post-operatively.

Conclusion
These results, along with the previously reported respiratory problems resulting from total laryngectomy, should be taken into account in counselling patients who are candidates for this surgical procedure.

Pulmonary rehabilitation with HMEs

Heat and Moisture Exchangers (HMEs) are widely used in pulmonary rehabilitation after total laryngectomy (TL) to partially restore the lost "nose" functions. The HME has a fast efficacy onset on restoring the airway climate, by utilising heat and humidity present in expired air for conditioning of the inspired air[1]. Clinical studies have confirmed the HME's ability to significantly reduce both pulmonary problems and the related psychosocial problems in laryngectomized patients[1]. Using HMEs results in fewer pulmonary infections (including tracheobronchitis and pneumonia)[2,3], less sleeping problems (less use of medication), less or no use of external humidifiers in the hospital, less hospital readmissions, and a higher quality of life and social life compared to usual care[3].

Long-term compliant use of an HME prevents the loss of ciliated cells in the respiratory epithelium, restores ciliated cells and consequently improves mucociliary clearance[4,5]. Patients who are compliant in their HME use (day and night, 24/7) have significantly fewer complaints of coughing and excessive mucus production and report a better quality of life compared to non-compliant users[6-10]. A cost-effectiveness analysis concerning HME use reported compliant HME-users to have a better pulmonary status and lower health-care costs compared to non-compliant users[3,10].

The publications listed below concern the publications regarding clinical effects of HMEs and pulmonary rehabilitation that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Keck T, Dürr J, Leiacker R, Rettinger G, Rozsasi A. Tracheal climate in laryngectomees after use of a heat and moisture exchanger. Laryngoscope. 2005;115(3):534-7.

[2]van den Boer C, van Harten MC, van den Brekel MW, Retèl VP. Incidence of severe tracheobronchitis and pneumonia in laryngectomized patients: a retrospective clinical study and a European-wide survey among head and neck surgeons. Eur Arch Otorhinolaryngol. 2014 Dec;271(12):3297-303.

[3]Retel VP, van den Boer C, Steuten LM, Okła S, Hilgers FJ, van den Brekel MW. Cost-effectiveness of heat and moisture exchangers compared to usual care for pulmonary rehabilitation after total laryngectomy in Poland. Eur Arch Otorhinolaryngol. 2015;272(9):2381-8.

[4]van den Boer C, Muller SH, van der Noort V, Olmos RA, Minni A, Parrilla C, Hilgers FJ, van den Brekel MW, van der Baan S. Effects of heat and moisture exchangers on tracheal mucociliary clearance in laryngectomized patients: a multi-center case-control study. Eur Arch Otorhinolaryngol. 2015;272(11):3439-50.

[5]Rosso M, Prgomet D, Marjanović K, Pušeljić S, Kraljik N. Pathohistological changes of tracheal epithelium in laryngectomized patients. Eur Arch Otorhinolaryngol. 2015 Nov;272(11):3539-44.

[6]Ackerstaff AH, Souren T, van Zandwijk N, Balm AJ, Hilgers FJ. Improvements in the assessment of pulmonary function in laryngectomized patients. Laryngoscope. 1993;103(12):1391-4.

[7]Bien S, Okła S, van As-Brooks CJ, Ackerstaff AH. The effect of a Heat and Moisture Exchanger (Provox HME) on pulmonary protection after total laryngectomy: a randomized controlled study. Eur Arch Otorhinolaryngol. 2010;267(3):429-35.

[8]Parrilla C, Minni A, Bogaardt H, Macri GF, Battista M, Roukos R, Pandolfini M, Ruoppolo G, Paludetti G, D'Alatri L, de Vincentiis M. Pulmonary Rehabilitation After Total Laryngectomy: A Multicenter Time-Series Clinical Trial Evaluating the Provox XtraHME in HME-Naive Patients. Ann Otol Rhinol Laryngol. 2015;124(9):706-13.

[9]Macri GF, Bogaardt H, Parrilla C, Minni A, D'Alatri L, de Vincentiis M, Greco A1, Paludetti G. Patients' experiences with HMEs and attachments after total laryngectomy. Clin Otolaryngol. 2016;41(6):652-9.

[10]Brook I, Bogaardt H, van As-Brooks C. Long-term use of heat and moisture exchangers among laryngectomees: medical, social, and psychological patterns. Ann Otol Rhinol Laryngol. 2013;122(6):358-63.

Keck et al. 2005

Title
Tracheal climate in laryngectomees after use of a heat and moisture exchanger.

Authors
Keck T, Dürr J, Leiacker R, Rettinger G, Rozsasi A.

Affiliation(s)
ENT Department, University of Ulm, Ulm, Germany.

Journal and year of publication
Laryngoscope. 2005 Mar;115(3):534-7.

Type of publication
Prospective study.

Introduction
Heat and moisture exchangers (HME) are frequently used in the treatment and prevention of tracheobronchial dryness and infections. In this study, the short-term influence of the HME Prim-Air System (Heimomed, Kerpen, Germany) in laryngectomized patients was tested.

Subjects and Methods
After adaptation to the laboratory environment, tracheal humidity and temperature were measured before HME application, 1 minute after HME application, 10 minutes after HME application, 1 minute after removal of the HME, and 10 minutes after removal of the HME.

Results
When the HME was placed on the tracheal stoma, the end-inspiratory humidity and temperature increased significantly. Ten minutes after commencement of use of the HME, tracheal humidity further increased significantly. Ten minutes after removal of the HME, tracheal humidity and temperature decreased to values as before start of use of HME.

Conclusion
The results indicate that short-term use of the HME Prim-Air system rapidly changes the tracheal climate. The significant increase in tracheal temperature and humidity may have beneficial effects on tracheal dryness in laryngectomized patients.

van den Boer, 2014

Title
Incidence of severe tracheobronchitis and pneumonia in laryngectomized patients: a retrospective clinical study and a European-wide survey among head and neck surgeons.

Authors
van den Boer C[1], van Harten MC, Hilgers FJ, van den Brekel MW, Retèl VP.

Affiliation(s)
Department of Head and Neck Oncology and Surgery, Netherlands Cancer Institute-Antoni van Leeuwenhoek (NKI-AVL), Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands.

Journal and year of publication
Eur Arch Otorhinolaryngol. 2015 Sep;272(9):2381-8.

Type of publication
Retrospective survey.

Introduction
Laryngectomized patients, lacking conditioning of the breathing air in the upper respiratory tract, have reported considerable pulmonary complaints. It is assumed that these patients also run a higher risk of developing severe respiratory infections. Unfortunately, there is little scientific information available about the occurrence of respiratory infections and related health costs in these patients with and without the use of an HME. Therefore, the occurrence of respiratory infections in laryngectomized patients was investigated in the Netherlands Cancer Institute and by means of a survey among head and neck oncology surgeons throughout Europe

Subjects and Methods
The number of tracheobronchitis and/or pneumonia events was retrospectively scored between 1973 and 2013 in medical records of 89 laryngectomized patients treated in our institute. To assess expert experiences and opinions regarding these pulmonary problems, a study-specific survey was developed. The survey was sent by email to head and neck surgeons from ten different countries.

Results
In the medical record study, an average of 0.129 respiratory infections per patient/year was found in non-HME users and 0.092 in HME users. In the survey (response rate HN surgeons 20 %; countries 90 %) 0.285 episodes per patient/year in non-HME users was statistically higher than the 0.066 episodes per patient/year in HME users. The average mortality in the HME user group per entire career of each physician was estimated at 0.0045, and for the non-HME user group this was 0.0152.

Conclusion
There is a tendency that the number of tracheobronchitis and pneumonia episodes in non-HME users is higher than in HME users.

Retèl et al, 2015

Title
Cost-effectiveness of heat and moisture exchangers compared to usual care for pulmonary rehabilitation after total laryngectomy in Poland.

Authors
Retèl VP, van den Boer C, Steuten LM, Okła S, Hilgers FJ, van den Brekel MW.

Affiliation(s)
Department of Psychosocial Research and Epidemiology, Netherlands Cancer Institute-Antoni van Leeuwenhoek (NKI-AVL), Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands

Journal and year of publication
Eur Arch Otorhinolaryngol. 2015 Sep;272(9):2381-8.

Type of publication
Retrospective study.

Introduction
The beneficial physical and psychosocial effects of heat and moisture exchangers (HMEs) for pulmonary rehabilitation of laryngectomy patients are well evidenced. However, cost-effectiveness in terms of costs per additional quality-adjusted life years (QALYs) has not yet been investigated. Therefore, a model-based cost-effectiveness analysis of using HMEs versus usual care (UC) (including stoma covers, suction system and/or external humidifier) for patients after laryngectomy was performed.

Subjects and Methods
Primary outcomes were costs, QALYs and incremental cost-effectiveness ratio (ICER). Secondary outcomes were pulmonary infections, and sleeping problems. The analysis was performed from a health care perspective of Poland, using a time horizon of 10 years and cycle length of 1 year. Transition probabilities were derived from various sources, amongst others a Polish randomized clinical trial. Quality of life data was derived from an Italian study on similar patients. Data on frequencies and mortality-related tracheobronchitis and/or pneumonia were derived from a Europe-wide survey amongst head and neck cancer experts.

Results
Substantial differences in quality-adjusted survival between the use of HMEs (3.63 QALYs) versus UC (2.95 QALYs) were observed. Total health care costs/patient were 39,553 PLN (9465 Euro) for the HME strategy and 4889 PLN (1168 Euro) for the UC strategy. HME use resulted in fewer pulmonary infections, and less sleeping problems.

Conclusion
We could conclude that given the Polish threshold of 99,000 PLN/QALY, using HMEs is cost-effective compared to UC, resulting in 51,326 PLN/QALY (12,264 Euro/QALY) gained for patients after total laryngectomy. For the hospital period alone (2 weeks), HMEs were cost-saving: less costly and more effective.

van den Boer et al. 2015

Title
Effects of heat and moisture exchangers on tracheal mucociliary clearance in laryngectomized patients: a multi-center case-control study.

Authors
van den Boer C[1,2], Muller SH[3], van der Noort V[4], Olmos RA[5], Minni A[6], Parrilla C[7], Hilgers FJ[8,9], van den Brekel MW[10,11,12], van der Baan S[13].

Affiliation(s)
[1]Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute-Antoni van Leeuwenhoek, Amsterdam, The Netherlands.
[2]Department of Otorhinolaryngology, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands.
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[5]Department of Nuclear Medicine, The Netherlands Cancer Institute-Antoni van Leeuwenhoek, Amsterdam, The Netherlands.
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[12]Department of Oral-Maxillofacial Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands.
[13]Department of Otorhinolaryngology, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands.

Journal and year of publication
Eur Arch Otorhinolaryngol. 2015 Nov;272(11):3439-50.

Type of publication
Prospective study.

Introduction
After total laryngectomy, inspired air is no longer optimally conditioned by the upper airways. Impaired mucociliary clearance and histological changes of respiratory epithelium, such as loss of ciliated cells, have been described in laryngectomized patients. Heat and moisture exchangers (HMEs) are passive humidifiers that re-condition the inspired air. Aim of this study was to assess the effect of HMEs on tracheal epithelium and tracheal mucus transport velocity (TMV).

Subjects and Methods
Tracheal brush biopsies were collected in three groups of TLE patients: 21 long-term HME users, 10 non-HME users, and 16 non-HME users before and after 4-9 months HME use. Tracheal epithelium biopsies were assessed using a digital high-speed camera mounted onto a light microscope. TMV was determined by scintigraphy in the first two patient groups.

Results
Significantly more ciliated cells were found in HME users compared to non-HME users ($p = 0.05$). TMV was higher in HME users (median 2 mm/min; 0-7.9) compared to non-HME users (median 0.8 mm/min; 0-12.3), but this difference was not significant ($p = 0.37$). One-hour breathing without HME in long-term HME users did not measurably decrease TMV ($p = 0.13$).

Conclusion
The long-term use of an HME restores/prevents the loss of tracheal ciliated cells. A significant improvement in TMV was not found. Short-term (one hour) detachment of an HME has no measurable effect on TMV.

Rosso et al. 2015

Title
Pathohistological changes of tracheal epithelium in laryngectomized patients.

Authors
Rosso M[1], Prgomet D[2], Marjanović K[3], Pušeljić S[4], Kraljik N[5]

Affiliation(s)
[1]Department of Otorhinolaryngology and Head and Neck Surgery, University Hospital Center Osijek, J. Huttlera 4, 31 000, Osijek, Croatia. rossom@net.hr.
[2]Department of Otorhinolaryngology and Head and Neck Surgery, University Hospital Center Zagreb, Zagreb, Croatia.
[3]Institute for Pathology and Forensic Medicine, University Hospital Center Osijek, Osijek, Croatia.
[4]Clinic for Pediatrics, University Hospital Center Osijek, Osijek, Croatia.
[5]Institute of Public Health for the Osijek-Baranja County, Osijek, Croatia.

Journal and year of publication
Eur Arch Otorhinolaryngol. 2015 Nov;272(11):3539-44.

Type of publication
Prospective cross-sectional study.

Introduction
Total laryngectomy results in a permanent disconnection of the upper and lower airways. Thus, the upper airways are bypassed and can no longer condition, humidify, and filter the inhaled air, leading to damage of the tracheobronchial epithelium. There is little scientific information available about the effects of tracheostoma breathing and the degree of mucosal damage in laryngectomized patients. The aims of this study were to determine the histopathologic findings and investigate the potential impact of using a heat and moisture exchanger (HME) on the tracheal epithelium in long-term tracheostomy patients.

Subjects and Methods
Tracheal mucosal biopsies were taken from a total of 70 patients. Specimens were stained with hematoxylin and eosin and examined by a light microscope.

Results
Normal pseudostratified ciliated columnar epithelium was found in only 9 (12.9%) cases; while, 17 (24.3%) cases had some degree of basal cell hyperplasia. Squamous metaplasia was the most common finding (50%). Pre-invasive lesions (mild and moderate squamous dysplasia) were found in only one patient who used an HME, and in eight (11.4%) non-users.

Conclusion
Although the HME cannot completely restore the physiological functions of the upper respiratory track, it delivers a better quality of air to the lower airways and has a positive effect on tracheal mucosa.

Ackerstaff et al. 1993

Title
Improvements in the assessment of pulmonary function in laryngectomized patients.

Authors
Ackerstaff AH, Souren T, van Zandwijk N, Balm AJ, Hilgers FJ.

Affiliation(s)
Department of ENT-Head and Neck Surgery, The Netherlands Cancer Institute, Amsterdam.

Journal and year of publication
Laryngoscope. 1993 Dec;103(12):1391-4.

Type of publication
Prospective study.

Introduction
Traditionally, the assessment of pulmonary function has been performed by means of a cuffed trachea cannula connected to a pulmonary-function analyzer. A recently developed HME (Freevent, Pharma Systems AB, Bröksmyravägen, Söderhamn, Sweden), consisting of a baseholder (a silicone housing placed into adhesive tape) and a separated filter, enables easy connection to lung-function testing and anesthetic equipment.

Subjects and Methods
In this study, the effect of the new baseholder has been compared with that of a cuffed trachea cannula on the outcome of the pulmonary-function tests in eight laryngectomized patients.

Results
All patients and the lung-function technician preffered the use of the HME baseholder over the trachea cannula. The use of the HME baseholder resulted invariably in higher spirometric values in comparison with the use of the trachea cannula.

Conclusion
In conclusion, the results of this study indicate that the HME baseholder, used for extratracheal connection of a laryngectomized patient to a spirotachometer or pneumotachometer, is a simple and useful device for routine pulmonary-function testing. Compared to other methods commonly used, this method is more convenient for the patient and provides ease of application for the lung-function technician. Moreover, the values obtained with the HME basheolder give more valid assessment of the actual lung function of laryngectomized patients.

Bien et al. 2010

Title
The effect of a Heat and Moisture Exchanger (Provox HME) on pulmonary protection after total laryngectomy: a randomized controlled study.

Authors
Bień S, Okła S, van As-Brooks CJ, Ackerstaff AH.

Affiliation(s)
Department of Otolaryngology and Head and Neck Surgery, Regional Cancer Center, ul. Artwińskiego 3, 25-734 Kielce, Poland.

Journal and year of publication
Eur Arch Otorhinolaryngol. 2010 Mar;267(3):429-35.

Type of publication
Prospective study.

Introduction
The goal of this randomized controlled study was to investigate the effect of Heat and Moisture Exchanger use on pulmonary symptoms and quality of life aspects in laryngectomized patients.

Subjects and Methods
Eighty laryngectomized patients were included and randomized into an HME and Control group. The effect of the HME was evaluated by means of Tally Sheets and Structured Questionnaires.

Results
The results showed a significant decrease in the frequency of coughing, forced expectoration, and stoma cleaning in the HME group. There were trends for the prosthetic speakers to report more fluent speech with the HME and for the HME group to report fewer sleeping problems.

Conclusion
This study, performed in Poland, confirms the results of previous studies performed in other countries, showing that pulmonary symptoms decrease significantly with HME use and that related aspects such as speech and sleeping tend to improve, regardless of country or climate.

Link to open access article

Parrilla et al. 2015

Title
Pulmonary Rehabilitation After Total Laryngectomy: A Multicenter Time-Series Clinical Trial Evaluating the Provox XtraHME in HME-Naïve Patients.

Authors
Parrilla C[1], Minni A[2], Bogaardt H[3], Macri GF[2], Battista M[1], Roukos R[2], Pandolfini M[1], Ruoppolo G[2], Paludetti G[1], D'Alatri L[1], de Vincentiis M[2].

Affiliation(s)
[1]Universita Cattolica del Sacro Cuore di Roma, Rome, Italy.
[2]Universita degli Studi La Sapienza di Roma, Rome, Italy.
[3]University of Sydney, Sydney, Australia hans.bogaardt@sydney.edu.au

Journal and year of publication
Ann Otol Rhinol Laryngol. 2015 Sep;124(9):706-13.

Type of publication
Prospective study.

Introduction
Both the immediate beneficial physiological changes in a laboratory setting and the long-term clinical outcomes of heat and moisture exchanger (HME) use are well described. So far, there has not been any research published that provides detailed insight in the pattern of changes in both respiratory function and patients' experiences with HMEs in the first weeks of use.

Subjects and Methods
A multicenter time-series study design with a 2-week double baseline period. All patients used the XtraHME for 12 weeks afterward. Data were collected 2 weeks, 6 weeks, and 12 weeks after the start of HME use. Data of 30 patients were analyzed.

Results
Pulmonary symptoms decreased significantly during the 12 weeks of HME use. After 2 weeks, a significant decrease in daily coughs and daily forced expectorations was seen. The general quality of life showed a significant increase throughout the study. More general physical complaints also significantly decreased with HME use. Patient satisfaction with the HME was high.

Conclusion
This study shows that there is a significant influence of the XtraHME on pulmonary status that can already be observed after 2 weeks of using the XtraHME and continues to improve further after 6 weeks of XtraHME use.

Macri et al. 2016

Title
Patients' experiences with HMEs and attachments after total laryngectomy.

Authors
Macri GF[1], Bogaardt H[2], Parrilla C[3], Minni A[1], D'Alatri L[3], de Vincentiis M[1], Greco A[1], Paludetti G[3].

Affiliation(s)
1 Universita degli Studi La Sapienza di Roma, Rome, Italy.
2 Speech Pathology, Faculty of Health Sciences, The University of Sydney, Sydney, Australia.
3 Universita Cattolica del Sacro Cuore di Roma, Rome, Italy.

Journal and year of publication
Clin Otolaryngol. 2016 Dec;41(6):652-659.

Type of publication
Prospective study.

Introduction
The short-term and long-term beneficial effects of HME use by laryngectomees are well described in literature. In this study, we document how laryngectomised patients, who previously did not use an HME, get accustomed to the use of HME and attachments.

Subjects and Methods
Thirty patients, who were at least 3 months post-laryngectomy and previously did not use an HME, were followed for 12 weeks and were asked to complete questionnaires about their experiences with the HME and attachments.

Results
Results show that when patients start using an HME, they report some difficulties with breathing resistance during the first 2 weeks of use. However, after 6 weeks, they have become accustomed to the breathing resistance and after 12 weeks over 96% reports that breathing was equal or less strenuous compared with breathing though an open stoma. Only a small proportion of patients experienced problems with increased coughing when starting HME use.

Conclusion
This study provides insight in the way laryngectomised patients are experiencing the use of HMEs in the first weeks. These outcomes can contribute to a better knowledge of HME use by healthcare providers and help them to manage patient expectations and improving support to patients in achieving compliant HME use.

Brook et al. 2013

Title
Long-term use of heat and moisture exchangers among laryngectomees: medical, social, and psychological patterns.

Authors
Brook I, Bogaardt H, van As-Brooks C.

Affiliation(s)
Department of Pediatric, Georgetown University School of Medicine, Washington, DC, USA.

Journal and year of publication
Ann Otol Rhinol Laryngol. 2013 Jun;122(6):358-63.

Type of publication
Retrospective study.

Introduction
After laryngectomy, pulmonary protection is mostly acquired by means of a heat and moisture exchanger (HME) that is placed on an airtight seal around the stoma. The effects of HMEs on the tracheal climate have been well described, and the filtration effect of an HME with an electrostatic filter has been described in vitro. The effects of HME use in patients have been documented in several trials in different countries. The follow-up time of the patients in these trials, however, is limited. Less is known about long-term use of HMEs, and studies describing long-term compliance with HME use are scarce. This study investigated the long-term use of HMEs in laryngectomees.

Subjects and Methods
Questionnaires were sent to 195 laryngectomees, and 75 questionnaires were returned.

Results
More than 85% of the respondents used an HME, of whom 77% were compliant users (ie, use for more than 20 hours per day). The incidence of pulmonary illnesses (either before or after surgery) was about 25%. More than 90% of the respondents were heavy smokers before laryngectomy. One third of the respondents are regularly exposed to dusty environments. Compliant HME users tend to make less use of external humidifiers and vaporizers, and have better pulmonary status and lower health-care costs. Regarding quality of life, patients who use a FreeHands device tended to have more frequent social contacts ($r = 0.251$; $p = 0.030$). The prevalence of depression is high, pointing to an urgent need to recognize and treat psychiatric problems such as depression and suicidal ideation in this patient group.

Conclusion
These findings have implications for any postlaryngectomy research that uses pulmonary parameters.

Improving compliant HME use

Despite available clinical evidence compliant HME use for optimal pulmonary rehabilitation remains an issue. In literature 48-82 % of the patients are not compliant in their HME use, consequently not using an HME day and night[1,2]. The most frequent reason for non-compliant HME use reported is dermatological problems. Patients allow their irritated skin to recover by omitting the adhesive, mostly during the night. Skin irritation is reported on average in about 20% of laryngectomized patients in the literature[1, 3-6]. In an Atos Medical survey in 2015, 47% of the patients reported to experience skin irritation. Furthermore, many patients report that they do not use adhesive and HME during nighttime due to experience of discomfort with the devices. Conventional HME devices and peristomal adhesives contain inflexible synthetic materials that are thought to influence comfort, compliance and skin irritation. As a result, compliant HME use often is not achieved, which potentially impacts the effectiveness of the pulmonary rehabilitation[1,4, 7].

Provox Luna has been developed to ameliorate these issues. It is designed to increase comfort and to address skin irritation during sleep, to increase compliant HME use. Provox Luna system consists of a soft silicon adapter and soft HME housing combined with a flexible adhesive made of hydrogel, to be comfortable and soothing for the skin. Use of hydrogel-based adhesives is commonly reported in literature for management of a wide variety of wounds, such as skin tears, pressure ulcers, burn wounds and surgical wounds[8-11]. They are water- or glycerin-based products that are thought to reduce skin irritation by adding a cooling effect to reduce pain in the wounded area[12-13].

In a recent clinical study, the effect of the use of Provox Luna, additional to a patient's usual care, on HME compliance was evaluated. Secondary outcome measures were associated changes to patient reported symptoms including pulmonary and dermatological effects. A significant increase in HME compliance was found: more compliant patients, increase in hours of HME use/day as well as total number of compliant days when using Provox Luna during the night. Additionally, a significant skin improvement overnight was observed. The authors concluded that the nighttime system Provox Luna is a useful supplement to a patient's usual care, especially in improving HME compliance and providing dermatological relief overnight[14].

The publications listed below concern the publications regarding compliant HME use that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Herranz J, Espiño MA, Morado CO. Pulmonary rehabilitation after total laryngectomy: a randomized cross-over clinical trial comparing two different heat and moisture exchangers (HMEs). Eur Arch Otorhinolaryngol. 2013;270(9):2479-84.

[2]Ackerstaff AH, Fuller D, Irvin M, Maccracken E, Gaziano J, Stachowiak L. Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. Otolaryngol Head Neck Surg. 2003;129(6):705-12.

[3]Ackerstaff AH, Hilgers FJ, Balm AJ, Tan IB. Long-term compliance of laryngectomized patients with a specialized pulmonary rehabilitation device: Provox Stomafilter. Laryngoscope. 1998;108(2):257-60.

[4]Op de Coul BM, Ackerstaff AH, van As-Brooks CJ, van den Hoogen FJ, Meeuwis CA, Manni JJ, Hilgers FJ. Compliance, quality of life and quantitative voice quality aspects of hands-free speech. Acta Otolaryngol. 2005;125(6):629-37.

[5]Pedemonte-Sarrias G, Villatoro-Sologaistoa JC, Ale-Inostroza P, López-Vilas M, León-Vintró X, Quer-Agustí M. Chronic adherence to heat and moisture exchanger use in laryngectomized patients. Acta Otorrinolaringol Esp. 2013.

[6]Hilgers FJ, Ackerstaff AH, Balm AJ, Gregor RT. A new heat and moisture exchanger with speech valve (Provox stomafilter). Clin Otolaryngol Allied Sci. 1996;21(5):414-8.

[7]Hilgers FJ, Ackerstaff AH. Comprehensive rehabilitation after total laryngectomy is more than voice alone. Folia Phoniatr Logop. 2000;52(1-3):65-73.

[8]Willams C. Hydrogel dressings: their role in dry and sloughy wounds. Community Nurse. 1998;4(9):42-4.

[9]Sood A, Granick MS, Tomaselli NL. Wound Dressings and Comparative Effectiveness Data. Adv Wound Care (New Rochelle). 2014;3(8):511-29.

[10]Hampton S. A focus on ActiFormCool in the reduction of pain in wounds. Br J Community Nurs. 2007;12(9):S37-S42.

[11]Blumenstein I, Borger D, Loitsch S, Bott C, Tessmer A, Hartmann F, Stein J. A glycerin hydrogel-based wound dressing prevents peristomal infections after percutaneous endoscopic gastrostomy (PEG): a prospective, randomized study. Nutr Clin Pract. 2012;27(3):422-5.

[12]Hess CT. When to use hydrogel dressings. Adv Skin Wound Care. 2000;13(1):42.

[13]Sarabahi S. Recent advances in topical wound care. Indian J Plast Surg. 2012;45(2):379-87.

[14]Ratnayake CBB, Fles R, Tan IB, Baaijens LWJ, Pilz W, Meeuwis C, Janssen-van Det PHE, van Son R, van den Brekel M. Multicenter randomized crossover trial evaluating the Provox® Luna™ in laryngectomized subjects. The Laryngoscope. 2019 Feb 20. [Epub ahead of print]

Herranz et al. 2013

Title
Pulmonary rehabilitation after total laryngectomy: a randomized cross-over clinical trial comparing two different heat and moisture exchangers (HMEs).

Authors
Herranz J, Espiño MA, Morado CO.

Affiliation(s)
Complexo Hospitalario Universitario A Coruña, Lugar Xubias De Arriba 84, 15006 La Coruña, Spain.

Journal and year of publication
Eur Arch Otorhinolaryngol. 2013 Sep;270(9):2479-84

Type of publication
Prospective randomized cross-over study.

Introduction
Post-laryngectomy heat and moisture exchanger (HME) use is known to have a beneficial effect on tracheal climate, pulmonary symptoms and related aspects. This study aims to investigate differences in clinical effects between the first and second generation Provox HMEs. The second generation (Provox XtraHME) has better humidification properties than the first generation (Provox HME), and has been shown to further improve tracheal climate.

Subjects and Methods
Forty-five laryngectomized patients, who were already using an HME, participated in a prospective, randomized cross-over clinical study in which each HME was used for 6 weeks.

Results
Results showed that for most parameters studied, the second generation HME performed equally well or better than the first generation HME. The improvement in tracheal climate translated into patients reporting significantly less tracheal dryness with the second generation than with the first generation ($p = 0.039$).

Conclusion
Using an HME with better humidification properties is related to a reduction in tracheal dryness in our study population.

Ackerstaff et al. 2003

Title
Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals.

Authors
Ackerstaff AH, Fuller D, Irvin M, Maccracken E, Gaziano J, Stachowiak L

Affiliation(s)
The Netherlands Cancer Institute, Amsterdam, The Netherlands.

Journal and year of publication
Otolaryngol Head Neck Surg. 2003 Dec;129(6):705-12.

Type of publication
Prospective study.

Introduction
A multicenter study based in the United States assessed the heat-moisture exchanger effect on respiratory symptoms and "voice quality" of laryngectomees.

Subjects and Methods
The study group consisted of 81 consecutive laryngectomees (62 men and 19 women; mean age, 66 years; age range, 45 to 89 years), with a median follow-up of 3.5 years (range, 0.5 to 24 years). A structured questionnaire was used to assess 3-month results, and tally sheets recorded the frequency of cough-expectoration during first and last trial weeks.

Results
Compliance was 73% (n = 59); decrease in coughing, 68%; sputum production, 73%; forced expectoration, 60%; and need for stoma cleaning, 52% of these 59 patients. Regarding daily cough-expectoration frequency, a statistically significant decrease ($P < 0.0001$) was found between the first and last trial weeks. Regarding influence on voice quality, 46% of regular users reported improvement in intelligibility, 30% in loudness, 37% in fluency, and 40% in telephone intelligibility. Fourteen patients (19%) reported skin irritation, with discontinuation of 7 patients.

Conclusion
The observed decrease in pulmonary symptoms and improvement in voice quality confirm earlier reports from the Netherlands, United Kingdom, and Spain indicating improvement in postlaryngectomy quality of life.

Ackerstaff et al. 1998

Title
Long-term compliance of laryngectomized patients with a specialized pulmonary rehabilitation device: Provox Stomafilter.

Authors
Ackerstaff AH, Hilgers FJ, Balm AJ, Tan IB.

Affiliation(s)
Department of Otolaryngology-Head & Neck Surgery, Netherlands Cancer Institute, Amsterdam, The Netherlands

Journal and year of publication
Laryngoscope. 1998 Feb;108(2):257-60.

Type of publication
Prospective study.

Introduction
Previous studies have demonstrated the positive effect of a heat and moisture exchanger (HME) on the respiratory system in patients after laryngectomy. However, patient compliance with these devices was reduced by device-related problems and troublesome combination with a voice prosthesis. Recently a more specialized device has become available. This is an HME combined with a valve for easy digital occlusion of the stoma (Provox Stomafilter; Hörby, Sweden). In the authors' initial study of this revised device, a clear improvement in short-term compliance was demonstrated.

Subjects and Methods
To investigate long-term compliance, 69 consecutive patients were interviewed by means of a structured questionnaire.

Results
The results show that all patients expressed their satisfaction with the valve used for digital occlusion of the stoma. Sixty-three percent of the patients reported that voicing was facilitated. Subjective intelligibility improved in 55% of the patients. Previous problems with other devices (e.g., plaster adherence, skin irritation, and handling) were clearly diminished, increasing the long-term compliance of the patients to 78%.

Conclusion
This new HME can be considered as a beneficial pulmonary rehabilitation tool for laryngectomized patients.

Op de Coul et al. 2005

Title
Compliance, quality of life and quantitative voice quality aspects of hands-free speech.

Authors
Op de Coul BM, Ackerstaff AH, van As-Brooks CJ, van den Hoogen FJ, Meeuwis CA, Manni JJ, Hilgers FJ.

Affiliation(s)
Department of Otolaryngology, Head and Neck Surgery, University Medical Centre St Radboud, Nijmegen, The Netherlands.

Journal and year of publication
Acta Otolaryngol. 2005 Jun;125(6):629-37

Type of publication
Prospective clinical multicenter trial.

Introduction
To make a long-term (6 months) assessment of compliance and aspects of voice, breathing and quality of life using a new ASV: the Provox FreeHands heat and moisture exchanger (HME).

Subjects and Methods
This was a prospective clinical multicentre trial in 79 laryngectomized patients (8 regular ASV users, 58 previously unsuccessful users and 13 new users). Data were collected at baseline and after 1 and 6 months by means of European Organization for Research and Treatment of Cancer Quality of Life questionnaires and specific structured questionnaires concerning compliance, skin adhesion, voicing and pulmonary aspects. An objective assessment of voice parameters (maximum phonation time, maximum phonation time while counting, dynamic loudness range and number of pauses in a standard read-aloud text) was made for comparison of different stoma occlusion methods (digital occlusion via an HME and two different ASVs). A subjective assessment of overall voice quality was made.

Results
After 6 months, 19% of patients used the new ASV on a daily basis (mean 5 h/day), while 57% used it on an irregular basis as an additional rehabilitation tool for special occasions. Two-thirds of the study group indicated that they would continue to use the new ASV after the study period. With respect to the objective parameters, statistically significantly better maximum phonation times and dynamic loudness ranges were observed with the new ASV compared to the Blom-Singer ASV. However, the best results for all the objective parameters were obtained with digital occlusion via the Provox HME.

Conclusion
With the use of a new automatic stoma valve (ASV) it appears possible to rehabilitate patients who have previously been unsuccessful in acquiring hands-free speech. As well as making daily ASV use possible for an additional group of patients, this new device was also appreciated by

many patients as an additional rehabilitation tool for specific occasions. Despite statistically significant improvements in aspects of voice and breathing using this novel ASV, improvement of peristomal adhesion is probably the main factor needed to further increase success rates. Nevertheless, our results show that it makes sense to keep trying to achieve hands-free speech, even if previous attempts have failed.

Pedemonte-Sarrias et al. 2013

Title
Chronic adherence to heat and moisture exchanger use in laryngectomized patients.

Authors
Pedemonte-Sarrias G, Villatoro-Sologaistoa JC, Ale-Inostroza P, López-Vilas M, León-Vintró X, Quer-Agustí M.

Affiliation(s)
Servicio de Otorrinolaringología, Hospital de Sant Pau, Barcelona, Spain

Journal and year of publication
Acta Otorrinolaringol Esp. 2013 Jul-Aug;64(4):247-52.

Type of publication
Prospective study.

Introduction
Total laryngectomy leads to pulmonary problems such as excessive sputum production, forced expectoration and increased coughing. The use of a heat and moisture reduces these symptoms. The aim of this study was to quantify chronic adherence to HME use in laryngectomized patients

Subjects and Methods
115 patients were questioned about the use of HMEs.

Results
Of the 115 patients, 90 (78.2%) used the HME consistently and 25 (21.8%) abandoned its use. The most common causes of desertion were adhesion problems due to mucus and skin irritation. Of the 30 patients with voice prostheses, 90% of them used the HME system regularly. Voice prosthesis use (P=.05) and early indication in postoperative laryngectomy (p=.001) were factors significantly associated with chronic HME use.

Conclusion
There is high adherence (78.2%) to heat and moisture exchanger (Provox HME) use in laryngectomized patients. Chronic HME use was higher in patients with voice prosthesis and the ones with early indication in postoperative period. The major causes of abandonment were related to problems with the adhesive.

Hilgers et al. 1996

Title
A new heat and moisture exchanger with speech valve (Provox stomafilter).

Authors
Hilgers FJ, Ackerstaff AH, Balm AJ, Gregor RT.

Affiliation(s)
Department of Head and Neck Oncology and Surgery, Psychosocial Research and Pulmonology, The Netherlands Cancer Institute, and Department of Psychology, University of Amsterdam

Journal and year of publication
Clin Otolaryngol Allied Sci. 1996 Oct;21(5):414-8.

Type of publication
Prospective study.

Introduction
In previous studies investigating the influence of a heat and moisture exchanger on the respiratory and psychosocial problems of laryngectomized patients, the value of regular use of such a device could clearly be established. However, the compliance with the use of these devices was not optimal, mainly due to problems related to the plaster and to the often troublesome combination of these HMEs with a voice prosthesis. Therefore, a prospective, clinical trial was undertaken to investigate whether the use of a newly developed heat and moisture exchanger (HME, Provox stomafilter) could improve the acceptibility of such a device.

Subjects and Methods
In total, 19 patients participated in this study, 13 men and six women. Vocal rehabilitation was achieved with a Provox voice prosthesis in all patients. Each of the patients was provided with a supply of HMEs for a 3-week trial period.

Results
The results showed that all patients were clearly positive about the valve used for digital occlusion of the stoma. Voicing was considerably facilitated and the intelligibility improved.

Conclusion
Problems experienced in previous studies related to the adhesive tape, such as skin irritation, inadequate adherence and loosening of the plaster by coughing or forced expectoration, could be solved by the availability of the different adhesives included in this system.

Hilgers et al. 2000

Title
Comprehensive rehabilitation after total laryngectomy is more than voice alone.

Authors
Hilgers FJ, Ackerstaff AH.

Affiliation(s)
Department of Otolaryngology, Head and Neck Surgery, The Netherlands Cancer Institute, Amsterdam, The Netherlands

Journal and year of publication
Folia Phoniatr Logop. 2000 Jan-Jun;52(1-3):65-73.

Type of publication
Retrospective randomized control study.

Introduction
The goal of this randomized controlled study was to investigate the effect of Heat and Moisture Exchanger use on pulmonary symptoms and quality of life aspects in laryngectomized patients.

Subjects and Methods
Eighty laryngectomized patients were included and randomized into an HME and Control group. The effect of the HME was evaluated by means of Tally Sheets and Structured Questionnaires.

Results
The results showed a significant decrease in the frequency of coughing, forced expectoration, and stoma cleaning in the HME group. There were trends for the prosthetic speakers to report more fluent speech with the HME and for the HME group to report fewer sleeping problems.

Conclusion
In conclusion, this study, performed in Poland, confirms the results of previous studies performed in other countries, showing that pulmonary symptoms decrease significantly with HME use and that related aspects such as speech and sleeping tend to improve, regardless of country or climate.

Williams C. 1998

Title
Hydrogel dressings: their role in dry and sloughy wounds.

Authors
Williams C.

Affiliation(s)
Wrexham Maelor Hospital, North Wales.

Journal and year of publication
Community Nurse. 1998 Oct;4(9):42-4.

Type of publication
Review article.

Introduction
Hydrogels have been thought to be only suitable for the treatment of sloughly and necrotic wounds, but can be used during all stages of wound healing.

Subjects and Methods
Description on available types of hydrogel dressings including: Intrasite gel, Nu-Gel, Purilon gel, Granugel, Aquaform gel, Sterigel, Geliperm and Sheet hydrogels.

Conclusion
Hydrogels are cost-effective, safe and easy to use, causing no pain or trauma on application and removal.

Sood et al. 2014

Title
Wound Dressings and Comparative Effectiveness Data.

Authors
Sood A[1], Granick MS[1], Tomaselli NL[2].

Affiliation(s)
[1] Department of Surgery, Division of Plastic Surgery, University of Medicine and Dentistry in New Jersey (UMDNJ)-New Jersey Medical School , Newark, New Jersey.
[2] Premier Health Solutions , LLC, Cherry Hill, New Jersey.

Journal and year of publication
Adv Wound Care (New Rochelle). 2014 Aug 1;3(8):511-529.

Type of publication
Comprehensive Invited Review.

Introduction
Injury to the skin provides a unique challenge, as wound healing is a complex and intricate process. Acute wounds have the potential to move from the acute wound to chronic wounds, requiring the physician to have a thorough understanding of outside interventions to bring these wounds back into the healing cascade. The development of new and effective interventions in wound care remains an area of intense research. Negative pressure wound therapy has undoubtedly changed wound care from this point forward and has proven beneficial for a variety of wounds. Hydroconductive dressings are another category that is emerging with studies underway. Other modalities such as hyperbaric oxygen, growth factors, biologic dressings, skin substitutes, and regenerative materials have also proven efficacious in advancing the wound-healing process through a variety of mechanisms.

Results
There is an overwhelming amount of wound dressings available in the market. This implies the lack of full understanding of wound care and management. The point of using advanced dressings is to improve upon specific wound characteristics to bring it as close to "ideal" as possible. It is only after properly assessing the wound characteristics and obtaining knowledge about available products that the "ideal" dressing may be chosen.

Conclusion
The future of wound healing at this point remains unknown. Few high-quality, randomized controlled trials evaluating wound dressings exist and do not clearly demonstrate superiority of many materials or categories. Comparative effectiveness research can be used as a tool to evaluate topical therapy for wound care moving into the future. Until further data emerge, education on the available products and logical clinical thought must prevail.

Link to open access article

Hampton S. 2007

Title
A focus on ActiFormCool in the reduction of pain in wounds.

Authors
Hampton S.

Affiliation(s)
Eastbourne Wound Healing Centre. sylvie@tissueviability.org

Journal and year of publication
Br J Community Nurs. 2007 Sep;12(9):S37-42.

Type of publication
Product focus review article.

Abstract
Pain is as very common problem in wound management and is one that is often neglected. This has an impact on both healing rates and patient quality of life. Pain is an indication that something is wrong and acts as one of the body's most important protective mechanisms and as such, should never be ignored. A comprehensive assessment of pain is vital and a plan of care formed that considers the type of pain that is being experienced and what interventions should be used. ActiFormCool is an ionic hydrogel dressing that has the ability to reduce pain in painful wounds, and this natural type of intervention should be the first consideration in reducing pain.

Conclusion
When pain is reduced, quality of life increases for the patient and the practitioner can be reassured that the simplest, most effective pain relief has been offered to their patients.

Blumenstein et al. 2012

Title
A glycerin hydrogel-based wound dressing prevents peristomal infections after percutaneous endoscopic gastrostomy (PEG): a prospective, randomized study.

Authors
Blumenstein I, Borger D, Loitsch S, Bott C, Tessmer A, Hartmann F, Stein J.

Affiliation(s)
First Medical Department, Johann Wolfgang Goethe-University Hospital, Frankfurt/Main, Germany.

Journal and year of publication
Nutr Clin Pract. 2012 Jun;27(3):422-5. doi: 10.1177/0884533612444536. Epub 2012 Apr 20.

Type of publication
Prospective randomized study.

Introduction
Despite the use of prophylactic antibiotics, peristomal infection is the most common complication of percutaneous endoscopic gastrostomy (PEG). A new glycerin hydrogel (GHG) wound dressing has been proposed to possess more effective antimicrobial properties but has not been tested in a larger trial. The aim of the study was therefore to assess the superiority of GHG regarding the incidence of peristomal wound infections during a 30-day postprocedure follow-up.

Subjects and Methods
Sixty-eight patients with cancer undergoing PEG were recruited from 1 university and 2 general hospitals between January 2007 and December 2008. Patients were randomized to group 1 (34 patients), which received GHG, or group 2 (34 patients), which received a traditional wound dressing. Dressing changes were done at day 1 and weeks 1, 2, and 4 (group 1) vs daily changes during week 1 and at weeks 2 and 4 (group 2). The PEG site was assessed by using 2 different infection scores.

Results
At the end of the first and second weeks, a statistically significant reduction of the mean infection scores was seen in patients with GHG wound dressings (first week: 1.64 ± 1.6 vs 3.12 ± 2.69, $P < .008$; second week: 1.37 ± 1.11 vs 2.53 ± 2.37, $P < .02$). After 7 days, wound reactions occurred in 14.7% in the GHG group vs 47.05% in the traditional group ($p < 0.005$). The GHG wound dressing required 5 times less frequent dressing changes.

Conclusion
The GHG wound dressing significantly reduces peristomal wound infections and is a convenient, cost-effective alternative for wound management following PEG.

Hess CT. 2000

Title
When to use hydrogel dressings.

Authors
Hess CT.

Affiliation(s)
Wound Care Strategies, Inc., Harrisburg, PA, USA.

Journal and year of publication
Adv Skin Wound Care. 2000 Jan-Feb;13(1):42.

Type of publication
Review of wound-care products.

Summary
Hess reviews categories of wound-care products and discuss what they can and can't do, and what to consider when developing a wound-care plan. Products discussed are: hydrogel dressings, amorphous hydrogels, impregnated-gauze hydrogel and sheet hydrogels.

Sarabahi et al. 2012

Title
Recent advances in topical wound care.

Authors
Sarabahi S.

Affiliation(s)
Department of Burns and Plastic Surgery, VMMC and Safdarjung Hospital, New Delhi, India.

Journal and year of publication
Indian J Plast Surg. 2012 May;45(2):379-87. doi: 10.4103/0970-0358.101321.

Type of publication
Review article.

Introduction
There are a wide variety of dressing techniques and materials available for management of both acute wounds and chronic non-healing wounds. The primary objective in both the cases is to achieve a healed closed wound. However, in a chronic wound the dressing may be required for preparing the wound bed for further operative procedures such as skin grafting. An ideal dressing material should not only accelerate wound healing but also reduce loss of protein, electrolytes and fluid from the wound, and help to minimize pain and infection. The present dictum is to promote the concept of moist wound healing. This is in sharp contrast to the earlier practice of exposure method of wound management wherein the wound was allowed to dry. It can be quite a challenge for any physician to choose an appropriate dressingmaterial when faced with a wound. Since wound care is undergoing a constant change and new products are being introduced into the market frequently, one needs to keep abreast of their effect on wound healing.

Conclusion
This article emphasizes on the importance of assessment of the wound bed, the amount of drainage, depth of damage, presence of infection and location of wound. These characteristics will help any clinician decide on which product to use and where, in order to get optimal wound healing. However, there are no 'magical dressings'. Dressings are one important aspect that promotes wound healing apart from treating the underlying cause and other supportive measures like nutrition and systemic antibiotics need to be given equal attention.

Link to open access article

Ratnayake et al. 2019

Title
Multicenter randomized crossover trial evaluating the Provox® Luna™ in laryngectomized subjects.

Authors
Ratnayake CBB[1,2], Fles R[2], Tan IB[2,3], Baijens LWJ[3,4], Pilz W[3,4], Meeuwis CA[5], Janssen-van Det PHE[5], van Son R[2], Van den Brekel MWM[2].

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[5]Erasmus Medical Center, Rotterdam, The Netherlands.

Journal and year of publication
The Laryngoscope. 2019 Feb 20. [Epub ahead of print].

Type of publication
Prospective randomized study.

Introduction
The aim of this study was to compare the relative compliance, and the dermatological and pulmonary outcomes when the Provox® Luna™ system is added during the night to the usual tracheastoma care of laryngectomised subjects.

Subjects and Methods
This was a multicenter randomised crossover trial conducted in the Netherlands Cancer Institute, Erasmus Medical Center and Maastricht University Medical Center. The study included 46 laryngectomised subjects with prior HME and adhesive experience.

Results
A significant improvement in the number of compliant individuals was found: Luna: n=43/45 (96%), UC: n=35/46 (76%), P=0.02. The Luna period was associated with longer intervals of daily HME use (Luna 23.2 hours (range: 15.6-24.0 hours), Usual care: 21.5 hours (range: 6.0-24.0 hours), P=0.003) and an increased frequency of skin improvement overnight (Luna 3.9 days (SD: 7.0 days), Usual care: 8.1 days (SD: 10.8 days), P=0.008). Fifty six percent (n=26) of participants wanted to continue using the Provox® Luna™ system at the conclusion of the study.

Conclusions
An improvement in compliance and skin recovery overnight was observed when the Provox® LunaTM was added to the usual adhesive and HME use. Therefore, there is utility in supplementing the usual post-total laryngectomy care with the Provox® Luna™ system at night,

particularly in the setting of compliance concerns and in subjects who desire dermatological relief overnight.

Link to open access article