European Archives of Oto-Rhino-Laryngology
Official Journal of the European Federation of Oto-Rhino-Laryngological Societies Official Jounal of the European Laryngological Society

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10.1007/s00405-002-0576-5

Laryngology

The Belgian experience with the cyranose heat moisture exchange filter. A multicentric pilot study of 12 total laryngectomees

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Received: 20 March 2002 **Accepted:** 24 October 2002 **Published online:** 31 January 2003

Abstract It is known that heat and moisture exchangers have a positive effect on the respiratory system in patients after total laryngectomy. The ATOS and INHEALTH devices are most frequently used in Belgium. However, recently a new device, the HME filter Cyranose, has become available. As a pilot study, this device has been applied to a total of 12 patients in three different centres. The temperature of the inspired air was considered as good or excellent in 90% of our patients at the 1st week and up to 100% at the 3rd month. The air humidification was considered as good or excellent in 100% of the patient population, and the HME filter positively influenced the phlegm production in 78% of our laryngectomy population. Our study stresses the benefits of a HME filter in general and seems promising for the Cyranose HME filter.

Keywords Total laryngectomy - HME filter - Respiration - Substitutional voice

Introduction

It is generally accepted that HME filters have a positive effect on the lower respiratory tract [1, 2]. The stomafilter resistance approximates the physiological airway resistance, which leads to a better ventilation/perfusion ratio and tissue oxygen saturation [3]. However, the patient's compliance is not always optimal [2, 4]. The ATOS and INHEALTH devices are the most frequently used in Belgium and the Netherlands. However, recently a new device, the HME filter Cyranose, has become available (Fig. 1, Fig. 2). This device has been developed and evaluated in France.

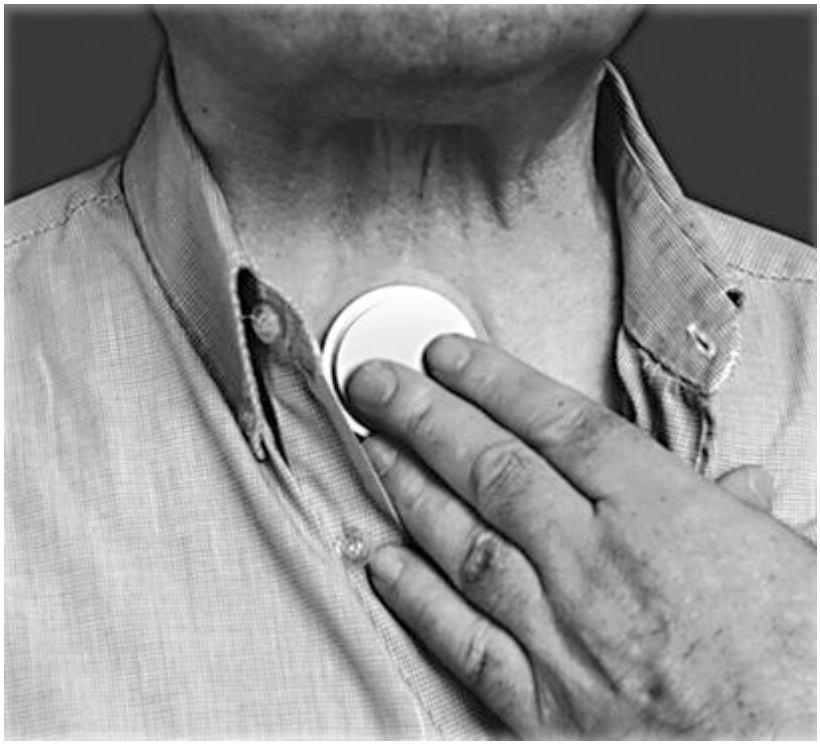

Fig. 1. The Cyranose device. The frontal view, on a patient

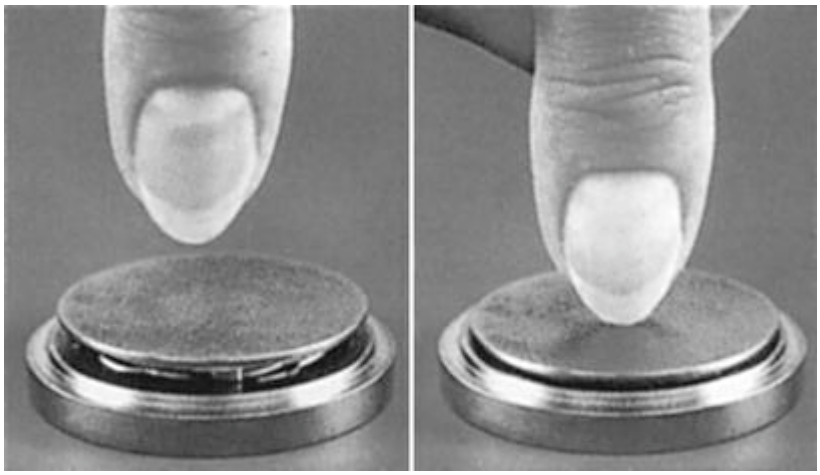

Fig. 2. Side view of the Cyranose device

Luboinski et al. claim that a HME filter must meet the needs of filtration, heating and moisturising the inhaled air [5]. The Cyranose device approximates the efficiency of physiological filtration and augments the water content in the intratracheal air with 6 15 mg/l of air. The intratracheal temperature is raised by 12°C. In their clinical studies, Luboinski et al. conclude that after an adaptation period the majority of patients are satisfied. The device is easy to apply, filtration is judged improved by 96 98% of the patients, heating by 94% and moisturising by 94%, and respiration is judged as more comfortable in 84%. Forty percent of the patients estimated their oesophageal speech as better, and secretions had diminished in 78%.

As these results are very attractive, we decided to perform a pilot study in our population. For this, a multicentric study was designed.

Subjects and methods

Patients

The study concerned patients who had undergone a total laryngectomy or laryngo-pharyngectomy and who volunteered to enter the study protocol. Individuals with active bronchopulmonary infections, tumor progression or who had undergone radiotherapy less than 3 months before were excluded. The first centre (Ghent University Hospital) supplied three patients, the second centre (University Hospital of Louvain at Mont Godinne) supplied five patients and the third centre (Institute Bordet) supplied four patients (12 patients in total).

Study design

Patients matching the inclusion criteria were selected chronologically, according to the timing of their follow-up examination (Table 1). At the moment they entered the study, the use of the device was well explained, and the device was applied. A questionnaire was taken at the end of the 1st week and at the end of the 1st and 3rd months. At the end of the 3rd month, a clinical examination completed the evaluation.

Table 1. Summary of the patient's characteristics. Patient: *G* Ghent University Hospital, *M* Mont-Godinne, *B* Institute Bordet. For the date of surgery, when the exact date is unknown, the year and month of surgery are mentioned. Voice rehabilitation (speech therapy for tracheo-oesophageal and/or oesophageal speech): *Y* yes, *N* no. For pulmonary distress, the patients were interrogated for allergic bronchitis, spasm and inhalation. Therapy: *Y* positive history or clinical examination, *N* negative history or clinical examination

Patient	Date of surgery	Voice rehabilitation	Pulmonary distress (questionnaire)
G/1	29/08/97	Y	Y
G/2	24/03/97	Y	Y
G/3	12/09/96	Y	N
M/1	24/01/92	N	Y
M/2	../12/90	N	Y
M/3	../08/91	N	Y
M/4	1987	Y	N
M/5	09/12/96	N	N
B/1	13/02/90	Y	N
B/2	03/07/96	Y	N
B/3	02/02/00	Y	N
B/4	../06/85	Y	Y

Functional outcome assessment

The questionnaire aimed for (1) detecting changes in the respiratory effort (the patient's perception of air quality, which means filtration of dust, air humidity and air temperature), (2) evaluating phlegm production, (3) evaluating general satisfaction, (4) evaluating the ease of application and (5) evaluating voicing.

At the end of the 3rd month these items were linked with a clinical examination.

Results

During the 1st week, one patient (M1) was withdrawn from the study. The reason for this was poor stomal skin quality, which resulted in an inconsequent application of the filter. Patient M3 had some filter application difficulties at the start, but entered the study protocol at the end of the 1st week (Table 2). Although he evaluated the filter as very positive, patient G2 left the study at the 3rd month because of periods of heavy perspiring and loosening of the housing.

Table 2. Functional outcome at the end of the 1st week. The subjective ratings for filtration (outdoor/indoor), humidity (outdoor/indoor) and temperature: *g* good, *exc* excellent, *nd* not different (in comparison with the situation without HME). For phlegm production, the ratings of not different or better are in comparison with the situation without HME. Application of the cyranose device was rated: *ve* very easy, *e* easy, *diff* difficulty subjectively rating the handling of the HME. The subjective interpretation of the patient's satisfaction with their own voice (voice quality) was rated for overall contentment as excellent, good or bad

Features	End of 1st week	End of 1st month	End of 3rd month
Filtration outdoor	80% g/exc	90% g/exc	89% g/exc
	20% nd	10% nd	11% nd
Filtration indoor	80% g/exc	9 0% g/exc	89% g/exc
	20% nd	10% nd	11% nd
Humidity outdoor	40% g/exc	100% g/exc	100% g/exc
	60% nd		
Humidity indoor	90% g/exc	100% g/exc	100% g/exc
	10% nd		
Temperature outdoor	90% g/exc	100% g/exc	100% g/exc
	10% nd		
Temperature indoor	90% g/exc	81% g/exc	100% g/exc
	10% nd	19% nd	
Phlegm	70% better	50% better	78% better
	30% nd	50% nd	22% nd
Application	60% easy	91% e/ev	89% e/ev
	40% diff	9% diff	11% diff
Voice	20% better	30% better	33% better
	80% nd	70% nd	67% nd
Satisfaction	70% exc, 30% good	73% exc, 27% good	78% exc
			11% good
			11% bad

Overall, there were three drop outs: (1) patient G 2 because of occasional loosening of the housing, (2) patient M1 because of poor skin quality and (3) patient M3 because of sudden death.

The "overall satisfaction" developed from 70% "excellent" and 30% "good" at the end of the 1st month to 78% excellent, 11% good and 11% bad. The changes in respiratory effort, meaning dust perception, air humidity and air temperature, confirm the positive evolution over time.

Discussion

Luboinski et al. reported a benefit in outdoor filtration in 96% of the patients and indoor in 98% of the patients. Comparing our results to Luboinski's data, the overall benefit is less. However, there was an increase from the start towards the 3rd month (80% over 90% to 89%). Contrary to Luboinski et al., the temperature of the inspired air was considered as good or excellent in 90% of our patients at the 1st week and up to 100% at the 3rd month. These results exceed the French results. Although only 40% of our population had a better feeling of humidification outdoors at the end of the 1st week, at the end of the 3rd month this parameter scored better in our pilot study group compared to the French population (100% in our population versus 94% in the French population). The effect of the HME filter on phlegm production is comparable in the French and Belgian populations (78%).

Regarding the results over time, we established an increase in percentage in all items. This confirms the statement of several authors that an adaptation period of 3 months at least is mandatory [*4*, *5*]. Nevertheless, the surplus value of the HME is established even by this short follow-up period.

Overall, we can state that patients benefit from their HME device, which agrees with former manuscripts [*1*, *2*, *3*, *5*]. It is difficult to compare our data with the other types of HMEs in the literature because of different methods and data. It certainly would be most interesting to exactly compare the different HME types in functional outcome and costs in order to select the most profitable type. This could be a subject for further study.

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