

# Montreal's Experience with Cyranose Heat and Moisture Exchanger Use in 15 Laryngectomized Patients

Paule Dupuis, MD, Louis Guertin, MD, FRCSC, Marie-Stéphane Rainville, MOA, Dominique-Louise Prud'homme, MOA, and François Lavigne, MD, FRCSC

## ABSTRACT

**Objective:** Evaluate the effects of the improvement of filtration, heating and humidification of inspired air with Cyranose® heat and moisture exchanger (HME) on voice quality, breathing, and secretion handling in laryngectomized patients.

**Design:** Prospective study.

**Setting:** Fifteen laryngectomized patients, mean age 68, ages ranging from 50 to 91 years.

**Methods:** Information was given to patients through video and brochures. Patients were selected if they had minimal understanding, permanent decanulization, no tumour progression or bronchopulmonary infections, and received no recent radiation therapy treatment. They were given the prosthesis and a starter kit. They were then evaluated by a speech pathologist with a structured questionnaire after one week, one month, and three months.

**Main Outcome Measures:** The outcomes measured were comfort, breathing, secretions, and ease of use of the prosthesis as well as its effect on voice. Impressions of patients on humidification, filtration, and heating of inspired air were also recorded.

**Results:** At conclusion of trial, 75% of patients wore the prosthesis on a daily basis and they all found it easy to use. All patients who completed the trial found breathing and handling of secretions easier as they thought humidification and filtration of air had improved. Quality of voice improved for 50% while remaining unchanged for 37%. The positive effect of the prosthesis progressed throughout the trial. Seven patients dropped out of the trial, mainly because of adhesive-related issues.

**Conclusion:** Laryngectomized patients from the Montreal area could benefit from Cyranose® artificial nose following an adaptation period during our cold winter.

## SOMMAIRE

**Objectifs:** Évaluer les effets de l'amélioration de la filtration, du chauffage et de l'humidification de l'air inspiré avec le Cyranose®, un échangeur de chaleur et d'humidité (ECH) sur la qualité de la voix et la gestion des sécrétions chez les patients laryngectomisés.

**Devis:** Étude prospective

**Patients:** Quinze patients laryngectomisés dont les âges varient entre 50 à 91 ans pour un âge moyen de 68 ans.

**Méthodes:** L'information a été remise aux patients grâce à un vidéo et à des dépliants. Les patients ont été sélectionnés s'ils avaient une bonne compréhension, n'avaient plus de tube dans leur trachéotomie, ni de progression de la tumeur ou d'infection bronchopulmonaire et n'avaient reçu aucun traitement récent de radiothérapie. On leur a remis des prothèses et une trousse de départ. Ils ont aussi été évalués par un orthophoniste avec un questionnaire structuré une semaine, un mois et trois mois plus tard. Variables évaluées: Les résultats évalués étaient: confort, respiration, sécrétions et la facilité d'utilisation de la prothèse ainsi que son effet sur la voix. Les impressions du patient sur l'humidification, la filtration et la chaleur de l'air inspiré ont aussi été enregistrées.

**Résultats:** À la fin de l'étude, 75% des patients ont porté la prothèse à tous les jours et en ont trouvé l'utilisation facile. Tous les patients qui ont complété l'étude ont trouvé la respiration et la gestion des sécrétions plus faciles et ont trouvé que l'humidification et la filtration de l'air s'étaient améliorées. La qualité de la voix s'est améliorée chez 50% tandis qu'elle est restée inchangée chez 37% des patients. Les effets positifs de la prothèse augmentent tout au long de l'étude. Sept patients ont quitté l'étude principalement à cause de problèmes reliés aux adhésifs.

**Conclusion:** Après une période d'adaptation, les patients laryngectomisés de la région de Montréal pourraient bénéficier, en particulier durant l'hiver, du nez artificiel Cyranose®.

**Key words:** artificial nose, heat and moisture exchanger, prosthesis, total laryngectomy

Received 01/16/06. Received Revised 03/22/06. Accepted for publication 04/09/06.

Paule Dupuis, Louis Guertin, Marie-Stéphane Rainville, Dominique-Louise Prud'homme, and François Lavigne: Department of Orthophonie, CHUM Hôpital Notre-Dame, Montreal, QC.

Presented at the Congrès annuel de l'Association d'oto-rhino-laryngologie et de chirurgie cervico-faciale du Québec, Montréal, QC, October 23, 2005.

Address reprint requests to: Paule Dupuis, MD, 481, de la Vigne, Ile des Soeurs, QC H3E 1Y9.

DOI 10.2310/7010.2007.0036

Total laryngectomy has long been known for its adverse effects on the respiratory system, other than voice loss. This permanent bypass of the upper airway and of its protective, resistance, and humidification properties has many consequences.

The inflow of cold dry air directly in the trachea causes an augmentation of micro-organisms and dust in the lower airway, increasing the incidence of bronchopulmonary infections.<sup>1</sup> There is an excessive loss of 500 mL of water through stomal expiration<sup>2</sup> and evaporation of the mucus blanket over the ciliated cells of the respiratory tract.<sup>1</sup> Fragile ciliated cells are then directly exposed to cold air, which causes their denaturation and eventual metaplasia to stratified epidermoid cells, with its accompanying inflammation, leading to irreversible fibrosis.<sup>1</sup> The goblet cells are thus stimulated to secrete more mucus, which is difficult to evacuate given the diminution of cough efficacy postlaryngectomy.<sup>1</sup> There is a rise in the number of lower airway infections accompanied by a deterioration in pulmonary function, which, in turn, seriously affects the patient's quality of life.<sup>2,3</sup>

This accounts for the interest of the artificial nose in Quebec, which is well known for its outdoor temperature extremes, ranging from  $-30^{\circ}\text{C}$  in the winter to  $30^{\circ}\text{C}$  in summer. Winter also increases the amount of time spent inside in very dry air owing to heating.

The objectives of the Cyranose (Ceredas, France) artificial nose are to warm and humidify ambient air through recuperation of expired water vapour and heat. Filtration of inspired air and entrapment of expectorations, allowing easy cleaning, are also possible. The device was developed for ambulatory patients and is small enough not to alter the patient's external appearance.

Positive findings with a heat and moisture exchanger (HME) have already been demonstrated by McRae and colleagues relative to augmentation of tracheal temperature, relative humidity, and tissue oxygenation, as well as a reduction in excessive water loss.<sup>4</sup> The HME has been useful in pulmonary rehabilitation and psychosocial functioning postlaryngectomy.<sup>3,5,6</sup>

The device also allows comfortable use with a voice prosthesis or tracheoesophageal puncture, which increases compliance. Low compliance with the HME in patients with tracheoesophageal puncture has been observed in the past as airtight closure of the stoma using a finger was difficult to achieve with the traditional HME.<sup>3,7</sup> Negative effects on voice had repercussions on psychosocial functioning, which, in turn, decreased compliance.

The objective of the present study was to evaluate the effects of the Cyranose HME, a metallic prosthesis, in a cold climate.

## Materials and Method

The device consists of a double-sided hypoallergenic adhesive applied directly on the skin and available in six sizes to match the shape of the neck. A collar made of silicone is then applied directly on the adhesive and holds the third component, an expectoration trap. This component is a double grid of fine mesh in nickel- and chrome-plated stainless steel. An open-cell polyurethane filter covers the expectoration trap, and a nickel- or gold-plated stainless steel casing completes the prosthesis. For patients with a tracheoesophageal puncture, the casing can include a spring-operated obstruction valve, allowing airtight occlusion of the stoma for phonation.

The adhesive is the only single-use component. The casing and expectoration trap can be cleaned and reused. The filter must be changed regularly, depending on the frequency of expectoration.

Consecutive patients admitted to the CHUM-Notre-Dame Hospital otolaryngology clinic between November 2003 and January 2004 entered the study. Inclusion criteria were total laryngectomy or pharyngolaryngectomy, age over 18 years, voluntary implication, living in a nearby region, permanent decannulation, and minimal comprehension of use after the first demonstration. Patients who did not understand French or English, had active bronchopulmonary infections or tumour progression, or had undergone radiation therapy treatment within the last 3 months were excluded from the trial.

Patients went through a demonstration by a nurse and a video information session and were given brochures on the new device. The nurse then evaluated the patient's capacity to participate in the study, and informed consent was given. The patients answered a baseline questionnaire regarding their respiratory status (secretions, voice, respiratory comfort) before the use of the prosthesis.

Each patient received a starter kit including a complete prosthesis, 20 adhesives, two expectoration traps, and six filters. They were also given a maintenance kit including 100 adhesives and three filters. Only 3 patients required the casing with the spring-operated valve for phonation, whereas the other 12 patients used the standard casing with a fixed lid.

Evaluations during the trial were carried out by a speech pathologist with a limited structured questionnaire at the end of the first week and 1 and 3 months after the

beginning of the trial. This limited questionnaire was based on the European Organization for Research and Treatment of Cancer's more extensive and validated questionnaires on quality of life, which are already used in numerous other studies.<sup>2,3,6,7</sup>

The outcomes measured were comfort, secretion handling, cutaneous tolerance, and ease of use of the prosthesis, as well as voice quality. Modifications of humidification, filtration, and heating of inspired air noted by patients were also recorded.

## Results

Fifteen laryngectomized patients, all males, ages ranging from 50 to 91 years (mean 68 years), were included in the trial. The time since laryngectomy was between 1 and 10 years for 13 patients and over 10 years for the 2 other patients. Fourteen of the 15 patients reported excessive secretions related to either cold weather or physical effort or on awakening, which motivated them to enrol in the trial.

During the first week, two patients dropped out—one for persistent adhesive problems and the other for air leaking around the device. After the first week, 8 of 13 (62%) patients remaining in the study wore the prosthesis on a daily basis, whereas the others wore it occasionally. Six patients (46%) wore it night and day, whereas seven (54%) patients wore it only during the day.

The results regarding sensation of humidification, heating, and filtration of inspired air, as well as breathing, secretions, and voice, are reported in Table 1. One patient thought humidification of air was good outside but could not specify if it had changed, so he gave partial credit to both answers. Another patient felt that he did not wear the prosthesis enough to answer the questions; the results are therefore reported for the 12 remaining patients.

Manipulation of the device (placing the collar and the casing) was easy for 10 of 13 patients (77%) but remained

difficult for 3 patients (23%). All 13 patients (100%) who responded found removing the prosthesis easy.

The main disadvantage reported was an adhesive-related problem of the system, but 12 of 13 patients (92%) still maintained a favourable opinion of the device. Another patient decided to give up as he found the prosthesis difficult to use, wore it only occasionally, and could not report any improvements.

During the first month, three more patients gave up—two secondarily to adhesive-related problems and skin irritation and one out of fear of mucus plugging. All nine patients continuing the trial had a favourable opinion of the device at that point.

After the first month, the number of patients wearing the device on a daily basis increased to seven of nine (78%). Four patients (44%) wore it around the clock and five (56%) only during the day. The results on humidification, heating, filtration, breathing, secretions, and voice are reported in Table 2. Two patients (22%) still found the prosthesis difficult to install.

Before the end of the third month, one more patient dropped out for another surgery followed by radiation therapy.

At the conclusion of the trial (3 months), six of the eight remaining patients (75%) wore the device on a daily basis, whereas the two other patients (25%) used it occasionally. Five patients (63%) wore it night and day, and three patients (37%) wore it only in daytime. The results on humidification, heating, filtration, breathing, secretions, and voice are reported in Table 3. Installation of the device became easy for all patients (100%). All patients reported a favourable or very favourable opinion at the end of trial.

Eight of 15 patients (53%) completed the full 3-month trial. One patient dropped out for surgery followed by radiation therapy but was satisfied and would have continued the trial. Four had problems ranging from inadequate adhesion to cutaneous irritation, and one of these patients had cognitive and dexterity problems, which

**Table 1.** Results of the First Week (12 Patients Remaining)

Feature	Improved, n (%)	Unchanged, n (%)	Worst, n (%)
Humidification inside	10 (83)	2 (17)	0
Humidification outside	10.5 (87)	1.5 (13)	0
Heating in and out	11 (92)	1 (8)	0
Filtration in and out	12 (100)	0	0
Breathing	7 (58)	5 (42)	0
Secretions	9 (75)	3 (25)	0
Voice	3 (25)	8 (67)	1 (8)

**Table 2.** Results of the First Month (Nine Patients Remaining)

<i>Feature</i>	<i>Improved, n (%)</i>	<i>Unchanged, n (%)</i>	<i>Worst, n (%)</i>
Humidification inside	9 (78)	0	0
Humidification outside	8 (89)	1 (13)	0
Heating inside	9 (100)	0	0
Heating outside	8 (89)	1 (11)	0
Filtration in and out	9 (100)	0	0
Breathing	6 (67)	3 (33)	0
Secretions	8 (89)	1 (11)	0
Voice	3 (33)	5 (56)	1 (11)

**Table 3.** Results of the Third Month (Eight Patients Remaining)

<i>Feature</i>	<i>Improved, n (%)</i>	<i>Unchanged, n (%)</i>	<i>Worst, n (%)</i>
Humidification inside and outside	8 (100)	0	0
Heating inside	8 (100)	0	0
Heating outside	7 (87)	1 (13)	0
Filtration inside and outside	8 (100)	0	0
Breathing	8 (100)	0	0
Secretions	7 (87)	1 (13)	0
Voice	4 (50)	3 (37)	1 (13)

made manipulation of the prosthesis difficult. The two other patients gave up because of abundant secretions; one of them had a serious fear of mucus plugging, which did not allow him to pursue the trial.

## Discussion

A progressive positive effect was noted for all patients. An adaptation period was necessary to improve daytime compliance and overnight tolerance. Reintroduction of airway resistance in patients who have been laryngectomized for a long time has already been described to be troublesome.<sup>2</sup> All patients did adapt to this new resistance throughout the trial. Every patient who went through the whole trial found the prosthesis easy to install after 3 months.

The positive effects reported by patients on heating, filtration, and humidification of inspired air progressed. At the end of the trial, humidification inside and outside was good for 100% of patients, which compares with the French (94%)<sup>1</sup> and Belgian (100%)<sup>8</sup> results. Some patients were able to discontinue the use of a noisy external humidifier with deleterious effects on their environment.

Filtration of inspired air was good or excellent for 100% of our patients inside and outside, which compares

with the French results of 96% outside and 98% inside.<sup>1</sup> The Belgian patients reported better filtration inside and outside in 89% of cases.<sup>8</sup>

The heating of air improved for 100% of patients inside and 87% outside while being improved for 100% of Belgian patients inside and outside<sup>8</sup> and 94% of French patients.<sup>1</sup> The French study did not specify differences between inside and outside with regard to inspired air.<sup>1</sup> We thought the distinction was important in our climate, which is characterized by wide variations.

These results suggest that the device provides more than adequate heating of inspired air even in very cold weather as 87% of patients reported improvement. The study was done during winter months, and patients were pleasantly surprised by the fact that the prosthesis did not freeze, nor did they have cold sensation on their surrounding skin. One patient reported condensation on the filter when the weather was below  $-20^{\circ}\text{C}$ . Some patients felt better protected with the prosthesis in windy cold weather and when it rained.

A time effect was observed on patients completing the trial: after 3 months, 100% of patients found overall breathing easier, which exceeds the French results of 84%.<sup>1</sup> They reported better endurance during daily activities, which contributed to improvement in quality of life. Some

patients compared their breathing with the prosthesis with their preoperative breathing. Ackerstaff and colleagues already used objective measurements such as pulmonary function tests to show an increase in inspiratory lung function values after a short trial of the HME.<sup>3</sup>

Eighty-seven percent of patients found that handling of secretions improved, which exceeds the French and Belgian results, in which 78% and 74% of patients, respectively, found secretions reduced.<sup>1,8</sup> Patients reported less crusting and bleeding in secretions. One patient reported having less bronchitis while using the device. Patients wrote many positive comments regarding the expectoration trap, which they said was very easy to clean.

Voice quality improved for 50% of patients while remaining unchanged for 37%. In the French study, 40% of patients found their voice improved<sup>1</sup> but only 33% in the Belgian study.<sup>8</sup> Only one patient reported that the voice was more difficult with the prosthesis because he was told his esophageal voice was not as loud. One patient with a tracheoesophageal puncture, who therefore used the casing with the spring-operated valve, completed the trial and reported an improved voice with the device.

Adhesive-related problems were the main reason for dropping out of the trial. These ranged from inadequate adhesion to cutaneous irritation, preventing further use. This problem has also been reported in the French<sup>1</sup> and Belgian<sup>8</sup> studies, as well as with other HMEs.<sup>2,7</sup>

All patients kept a favourable or very favourable opinion of the prosthesis, even if some of them had to drop out of the trial. Patients also reported great satisfaction with regard to external appearance and thought the device was more hygienic as they did not have to put their fingers directly in the stoma. This also prevented stomal irritation by fingernails.

Some patients in the study also tried the Provox (Provox Heat and Moisture Exchanger, Atos Medical Inc, USA) HME. The speech pathologist and patients did not see major differences between the two devices with regard to breathing, secretions, heating, humidification, and filtration. The main difference was the cost of use over 1 year. Most of the components of the Cyranose artificial nose are reusable, except the filter and the adhesive, whereas the components of the Provox prosthesis are not reusable, which increases the yearly cost.

The end of the Cyranose trial was troublesome to most of the patients as many could not pay to replace some of the components of the artificial nose, so they had to return to their pretrial breathing state. Fifty percent of patients wanted to continue HME use, which is comparable to

other studies.<sup>2</sup> According to a study by Ackerstaff and colleagues, 69% of patients wanted to continue HME use, but only 28% wanted to continue if they received no reimbursement.<sup>2</sup> The results of our trial are therefore comparable.

## Conclusion

These results confirm that patients could benefit from this device in the Montreal area, although an adaptation period of varied length is necessary. The cold climate does not alter its function; it even highlights the benefits of the Cyranose artificial nose for laryngectomized patients. Further studies comparing the Cyranose artificial nose with other existing HME filters would be interesting, especially studies analyzing yearly maintenance costs. The modification of skin surrounding the stoma by radiation therapy causing patients to drop out of the trial for adhesive-related problems could also be studied.

## References

1. Luboinski B, Gehanno P, Traissac L. Communication sur la protection des voies respiratoires au niveau du trachéostome chez les laryngectomisés totaux- intérêt de Cyranose, nez artificiel ou ECH. *Rev Soc Fr Otorhinolaryngol* 1995;33:1-6.
2. Ackerstaff AH, Fuller D, Irvin M, et al. Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. *Otolaryngol Head Neck Surg* 2003;129:705-12.
3. Ackerstaff AH, Hilgers FJM, Aaronson NK, et al. Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger. *Ann Otol Laryngol* 1993;102:878-83.
4. McRae D, Young P, Hamilton J, et al. Raising airway resistance in laryngectomees increases tissue oxygen saturation. *Clin Otolaryngol* 1996;21:366-8.
5. Hilgers FJM, Ackerstaff AH. Comprehensive rehabilitation after total laryngectomy is more than voice alone. *Folia Phoniatri Logop* 2000; 52:65-73.
6. Hilgers FJM, Aaronson NK, Ackerstaff AH, et al. The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy. *Clin Otolaryngol* 1991;16:152-6.
7. Hilgers FJM, Ackerstaff AH, Van As CJ, et al. 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 (Stockh)* 2003;123:91-9.
8. Moerman M, Lawson G, Andry G, et al. The Belgian experience with the Cyranose heat moisture exchange filter. A multicentric pilot study of 12 total laryngectomees. *J Eur Fed Otorhinolaryngol Soc* 2003;1-7.