New randomized crossover study shows significant improvements in pulmonary symptoms for patients with total laryngectomy when switching to new product range

The randomized cross-over clinical trial assessed the new Provox® Life™ System for pulmonary rehabilitation and quality of life after total laryngectomy.

A clinical study[1] funded by Atos Medical, a leading company in laryngectomy care, reveals clinical trial results that demonstrate a significant reduction in coughing, shortness of breath, and skin irritation in the patient group adhering to daily care routines with their Heat and Moisture Exchangers (HMEs). As a result of the patient's improved state, anxiety and depression were also reduced.

The newly published study is the first clinical study on Provox® Life™. It reported the following results with the patients using Provox® Life™:

- 36% reduction in forced coughing
- 26% reduction in number of days the HME had to be removed to catch their breath
- 39% reduction in average number of days with skin irritation

"Seeing the impact of the new generation HME devices on patient outcomes is encouraging, and it shows that by improving devices and supporting patients to use them in the best possible way, we can further optimize their quality of life," Dr. Claudio Parrilla and Dr. Ylenia Longobardi, the main investigators on the study state.

The objectives of the clinical study were to evaluate the effects of the use of new devices (HMEs and adhesives) on pulmonary symptoms, adherence to HME use, quality of life, dermatological symptoms, and patient satisfaction in patients with a total laryngectomy. The study took place at the Catholic University of the Sacred Heart (Gemelli Hospital) in Rome, Italy. Between December 2020 and April 2021, 40 laryngectomized patients in Italy who routinely used HMEs and adhesives were enrolled.

Patients were allocated into Group A (6 weeks use of the new devices (Provox® Life™), followed by 6 weeks use of their usual devices) or Group B (6 weeks use of their usual devices followed by 6 weeks use of the new devices (Provox® Life™)). In both groups, after 6 weeks of using the new devices, there was a significant reduction in the daily forced expectorations and (involuntary) dry coughs, a significant improvement in all domains of the Cough and Mucus Assessment questionnaire (CASA-Q), an increase in the adherence to HME use, a significant reduction in shortness of breath and skin irritation, and significantly better scores in the anxiety/depression domain of the European Quality of Life Five Dimension instrument (EQ-

[1]Longobardi Y, Galli J, Di Cesare T, et al. Optimizing Pulmonary Outcomes After Total Laryngectomy: Crossover Study on New Heat and Moisture Exchangers. *Otolaryngology–Head and Neck Surgery*. March 2022. doi:10.1177/01945998221086200

5D) were found.

"Achieving these results underscores the importance of using better performing HMEs with high humidification capacities and good breathability. Improving pulmonary health and reducing the impact on the patient's daily life has a positive effect on their quality of life. Indeed 95% of the patients in the study reported they were satisfied with the results of the Provox® Life™ system," said Corina van-As Brooks, Vice President, Medical and Scientific Affairs, Atos Medical.

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About Atos Medical

Atos Medical develops and sells medical devices that improve quality of life for people living with a neck stoma in over 90 countries. The company has a world-leading position in laryngectomy care and is a full-range global player in tracheostomy care. Atos Medical was established in 1986 and is headquartered in southern Sweden. Atos Medical is a part of Coloplast A/S. For more information, please visit atosmedical.com.