

New clinical study demonstrates significant improvement in pulmonary health and related symptoms when using Provox® Life™

A new multi-center, prospective, two-phase clinical trial¹ supported by Atos Medical, a leading company in laryngectomy care, demonstrates a significant improvement in cough and sputum symptoms, leading to improved sleep, with Provox Life.

In 2020, Atos Medical launched a new range of heat and moisture exchangers (HMEs) and adhesives, aimed at improving pulmonary health and quality of life for people living with a laryngectomy. A growing body of evidence has shown that the superior humidification and breathability of Provox Life HMEs lead to improved clinical outcomes.

People who have undergone a total laryngectomy rely on HMEs to compensate for the lack of upper airway humidification and filtration. With legacy HMEs, many laryngectomized patients use only one type of HME throughout the day irrespective of activity levels. The objectives of the new clinical study were to examine changes in pulmonary and related symptoms using the new generation of Provox Life HMEs.

The study was a two-phase clinical trial starting with the transition to comparable Provox Life HMEs and usage patterns (stage one). In the second stage, patients used different types of HMEs based on the activity, aiming for the highest possible humidification day and night. The following results were reported:

1. During stage one, transitioning to the higher performing Provox Life HMEs significantly improved overall pulmonary health
2. During stage two, using the highest humidification HMEs optimally during the day and night further improved pulmonary health
3. Quality of sleep only improved significantly when Provox Life HMEs were used throughout the day and night
4. Using the new generation of Provox Life HMEs enhanced HME adherence and facilitated the use of an optimal day and night regimen

The research confirms the potential to improve pulmonary health and related symptoms for laryngectomized patients by using better performing HMEs. There is also a potential to increase the number of hours HMEs are used per day when using a range of devices with different breathing resistance levels that suit the activity.

"Using the Provox Life range improved cough and sputum symptoms and led to

¹ Elizabeth C Ward, Kelli Hancock, Jenni Boxall, Clare L. Burns, Ann-Louise Spurgin, Belinda Lehn,⁴ Juliet Hoey,⁴ Rachelle Robinson,⁵ and Adele Coleman: *Post-laryngectomy pulmonary and related symptom changes following the adoption of an optimal Day-and-Night Heat and Moisture Exchange (HME) regimen*. First published on 20 February 2023, <https://doi.org/10.1002/hed.27323>

associated benefits including improved sleep. These changes can be attributed to both the enhanced humidification properties of the devices and an increased duration of HME use supported by using devices with different breathing resistance for situational use," said Ph. D. Elizabeth Ward, lead investigator of the clinical study.

"We're thrilled to see the benefits that this clinical study will bring to the laryngectomy patient community. Data from the study confirms recent research and shows that transitioning to better HMEs has a positive impact on pulmonary health. Improving pulmonary health and related symptoms such as sleep can also have long term benefits to patient well-being and quality of life. The study underlines the importance of optimizing HME usage patterns and marks another milestone for Provox Life," said Allana Kelley, Vice President, Medical and Scientific Affairs, Atos Medical.

Contacts

Peter Mønster
Sr. Media Relations Manager
Tel: +45 4911 2623
E-mail: dkpete@coloplast.com

Aleksandra Dimovska
Director, Investor Relations
+45 4911 2458
E-mail: dkadim@coloplast.com

About Atos Medical

Acquired by Coloplast in 2021, Atos Medical is the Voice and Respiratory division of Coloplast. The global leader in laryngectomy care, Atos Medical is also a leading developer and manufacturer of tracheostomy products. Atos is passionate about making life easier for people living with a neck stoma around the world by providing personalized care and innovative solutions, while clinical research and education of both healthcare professionals and patients are integral parts of the business. For more [information](#), please visit atosmedical.com.
