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Laryngectomy Clinical Summaries

Post-laryngectomy pulmonary and related symptom changes following adoption of an optimal Day-and-Night Heat and Moisture Exchanger (HME) regimen

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Background

- Total laryngectomy (TL) has negative consequences for pulmonary health. Post-surgery, the lower respiratory tract is exposed to unfiltered, colder and drier air. This leads to an increase of mucus production that causes involuntary coughing and forced mucus expectorations.
- The use of Heat and Moisture Exchangers (HMEs) can partially compensate for the humidification deficit, and therefore contributes to improving pulmonary health post-surgery.
- Benefits on pulmonary health can be observed by consistently using HMEs throughout the day and night.
- However, patients can be sensitive to breathing resistance when using HMEs and this hinders the adherence.
- A new generation range of HMEs (Provox® Life™) has been developed to offer optimized humidification and different devices with distinct levels of breathing resistance to facilitate device use throughout the day and night.
- The different breathability levels offered by the new generation HME range facilitate device adherence 24/7, since it addresses participants' specific needs and individual breathing requirements[1].

Objective

To evaluate the effect of the use of new generation devices (Provox Life™) and the establishment of an "optimal Day & Night regimen" on pulmonary health, HME adherence and use, sleep, skin irritation, quality of life and participants' overall satisfaction.

Design and methods

- The clinical study was designed as a multi-center, prospective, two-phase study.
- The study was conducted in 3 different centers in Australia, between August 2021 and April 2022.
- 48 participants were initially recruited. The average age of the participants was 70.4 years. 6 participants later withdrew. 2 device related, 4 non-device related. 42 remained as participants in the study.
- Participants were total laryngectomized patients and had routinely used HMEs and attachments prior to the study.

Objective

To evaluate the effect of the use of new generation devices (Provox® Life™) and the establishment of an optimal Day & Night regimen on device adherence and use, pulmonary health, shortness of breath, sleep, skin irritation, quality of life and participants' overall satisfaction.

Study design

- Multi-center, prospective, two-phase clinical study
- Phase 1: "like-for-like" transition to Provox Life™ (6 weeks)
- Phase 2: optimal Day & Night regimen using the full range of Provox Life™ HMEs (6 weeks)
- Each participant acted as their own control
- 48 laryngectomized participants initially recruited, 42 of them included in the study (6 withdrew for varied reasons)

Outcome parameters

- HME adherence and use
- Pulmonary health (cough symptoms, cough impact, sputum symptoms and sputum impact)
- Shortness of breath
- Sleep
- Attachments and skin irritation
- Quality of life
- Participants' perception and overall satisfaction

Key points

- Transition from the participants' usual care (Provox® HMEs) to the new range of optimized performance devices (Provox Life™ HMEs) improves pulmonary health.
- Implementing an optimal Day & Night regimen further improves pulmonary health.
- Adopting an optimal Day & Night regimen improves sleep
- The new generation range of HMEs facilitates adherence to an optimal Day & Night regimen, offering options for specific needs. This leads to an increase in duration and types of HMEs used across the study phases.

Reference

Ward, EC, Hancock, K, Boxall, J, et al. Post-laryngectomy pulmonary and related symptom changes following adoption of an optimal day-and-night heat and moisture exchanger (HME) regimen. Head & Neck. 2023; 1- 13. https://doi.org/10.1002/hed.27323

- Participants were excluded if they already had a Day & Night routine using Provox Luna HME in the night or daily use of Provox Micron HME (HME with electrostatic filter for protection against airbone particles).
- Each phase had a duration of 6 weeks with a flexible adjustment period before the start of each phase.
- Phase 1 ("like-for-like" transition to Provox Life™): participants were provided with a comparable set and number of Provox Life HMEs to their Provox usual care; either Go HME (if they were using XtraFlow HME before the study) or Home HME (if they were using XtraMoist HME before the study). This phase explored the benefits participants achieved from the optimized humidification properties of the new generation devices.
- Phase 2 (optimal Day & Night regimen with Provox Life™): participants were asked to use the full range of Provox Life™ products, including HMEs and attachments. They were encouraged to achieve an optimal Day & Night regimen to reach the highest humidification level possible. The optimal Day & Night regimen implied the use of primarily Home HME during the day and Night HME when sleeping. Go HME, Energy HME and Protect HME to be used dependent on the situation or activity level.
- Data were collected at baseline, and at the end of phase 1 and 2, respectively. These data were collected by means of the Cough and Sputum Assessment Questionnaire[2] (CASA-Q), the Jenkins Sleep Evaluation Questionnaire[3] (JSEQ) to assess sleep, the EQ-5D-5L[4] to evaluate quality of life, questions about skin integrity, a tally sheet on coughing, a diary on HME hours of use, and study specific questions around use of HMEs, shortness of breath and reimbursement options.

Results

Pulmonary health

- Analysis from CASA-Q showed a significant improvement for all 4 domains between baseline and phase 2. Significant improvements were also observed for all domains except Sputum impact between baseline and phase 1 (figure 1).

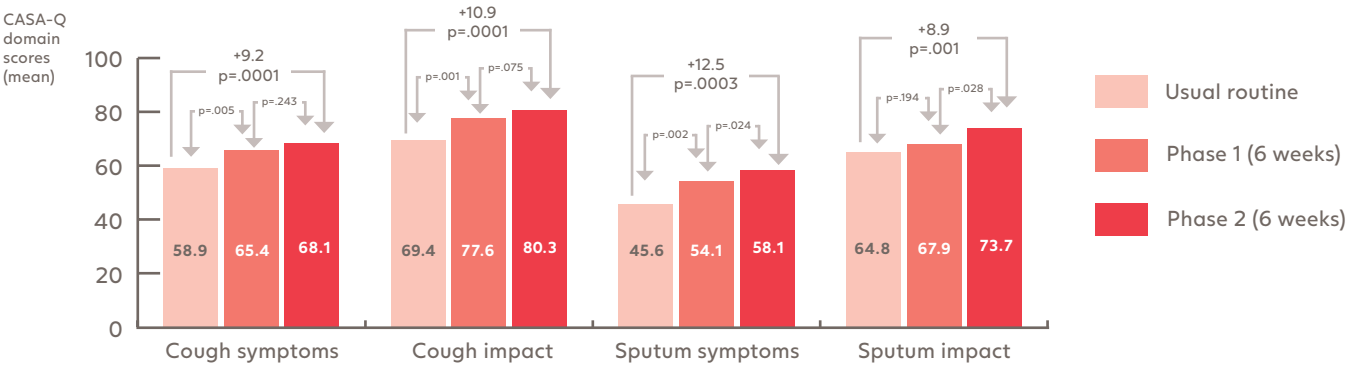

Figure 1 CASA-Q domain scores
The graph shows CASA-Q domain scores (from left to right: Cough symptoms, Cough impact, Sputum symptoms, Sputum impact) as reported by participants for usual routine, phase 1 and phase 2. Lower score values indicate higher pulmonary symptoms/impact level. A significant improvement was observed for all domains between baseline and phase 2, and for all domains except Sputum impact between baseline and phase 1.

- An additional analysis was performed across all CASA-Q domains for the subgroup of 26 participants that were already 24/7 HME adherent at baseline. Cough symptoms, cough impact and sputum symptoms showed significant improvements across all the phases. No significant changes were observed for sputum impact.
- Shortness of breath significantly improved when walking. No changes were reported when resting or climbing stairs.

HME adherence and use

- A significant increase in hours of HME use was observed across the phases. Participants went from using HMEs an average of 21.6 hours at baseline to 23.1 hours at the end of phase 2.
- The number of participants that reported achieving an optimal Day & Night HME routine increased from 62% at baseline to 76% in phase 1 and 90% by the end of phase 2.

- The number of HMEs used per day went from 1.5 in baseline to 2.4 in phase 2. This was primarily driven by the fact that the participants used different types of HMEs.

Sleep

- Significant improvements were observed in total sleep score between baseline and phase 2. The Jenkins sleep questionnaire also showed significant improvements from phase 1 to phase 2 (figure 2).
- The greatest improvements are for waking up several times at night, having trouble staying asleep, tired, and worn out).

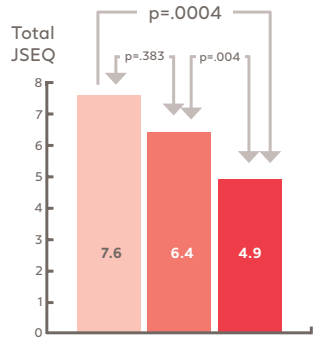

Figure 2 JSEQ score values
No significant improvement was observed when participants changed their usual routine for a "like-to-like" routine. Significant improvement was observed from baseline (usual routine) to phase 2 and from phase 1 to phase 2. High score values indicate lower sleep quality.

Usual routine Phase 1 (6 weeks) Phase 2 (6 weeks)

Quality of life, attachments and skin irritation

- No significant changes in the EQ-5D-5L index score or VAS scale were observed.
- Mean duration of adhesive life (hours) did not change across the phases.
- Skin status, skin irritation and impact on skin irritation was unchanged.

Participants perceptions and satisfaction

- More than 70% of the participants reported positive advantages including reduced pulmonary complaints, improved breathability, improved voice, better adhesive seal (phase 1) and improved sleep (phase 1 and 2).
- 79% of the patients got used to the new range in less than 1 week.
- 90% found it easy or very easy to choose among the different new generation HMEs.
- 95% would like to continue using Provox Life™ range in the future.
- At the end of phase 2, 95% of the participants stated that they would continue using the Day & Night range if reimbursement would allow it.
- 41% would pay out-of-pocket to continue using the Day & Night range.

Conclusions

- The transition from using Provox HMEs to Provox Life™ HMEs improved pulmonary health, owing to the optimized humidification properties of the new generation devices.
- Better breathability of the new generation Provox Life™ HMEs and ability to change devices to suit the activity level, improved HME adherence in established HME users.
- Implementing an optimal Day & Night regimen (using the highest humidification HME for the situation) further improves pulmonary health and sleep quality.

Suggestions and requests to: clinicalaffairs@atosmedical.com.

[1]Longobardi Y, Galli J, Di Cesare T, D'Alatri L, Settimi S, Mele D, et al. Optimizing Pulmonary Outcomes After Total Laryngectomy: Crossover Study on New Heat and Moisture Exchangers. Otolaryngol Head Neck Surg. 2022.
[2]Cough and Sputum Assessment Questionnaire. A 20-item questionnaire, used to assess the frequency and severity of cough and sputum and their impact on daily activity (validated for Chronic Obstructive Pulmonary Disease-COPD).
[3]Jenkins Sleep Evaluation Questionnaire, used to assess sleep by recording scores on 4 different sleep items
[4]European Quality of Life 5 Dimensions, used to self-assess QoL by recording scores on five health care dimensions (mobility, self-care, daily activities, pain/discomfort, and anguish/depression).