Phonak
Field Study News

Lyric Ear Health and Predictive Outcome Pilot Study

This exploratory pilot study was conducted to identify predictive factors that contribute to Lyric patient outcomes and ear health, with the intention of using these learnings to optimize Lyric candidacy and fitting practice.

Grace Gardner, February 2019

Abstract

A cohort of 15 new-to-Lyric subjects completed this study (11 males, 4 females; average age = 66 years). All subjects were fit with Lyric devices using standard best practice fitting guidelines by a trained hearing care professional. Subjects were followed longitudinally over the course of approximately six months of Lyric use to monitor ear canal health, relative humidity, and microbiology, as well as general health. Subjects with less stability in longitudinal ear canal relative humidity had a greater incidence of ear health conditions as compared to those with higher longitudinal stability in ear canal relative humidity. Subjects with poorer general health, with regard to Lyric fitting contraindications and medical history review, had a greater incidence of ear health conditions when compared to subjects with fewer general health issues. No clear correlation was found between ear health conditions and positive bacterial or fungal culture results. Data collected indicate an established relationship between the stability of longitudinal ear canal relative humidity measurements and ear health. The data also indicated a relationship between subject general health and ear health. Results of ear canal microbiology samples showed no clear correlation to Lyric patient outcomes, including ear canal health. Due to the limited sample size in this study, data collection should be expanded to further explore the trends identified.

Introduction

As an extended wear hearing instrument, Lyric presents unique benefits and challenges for the end user. The Lyric user enjoys continuous auditory stimulation with minimal hassle - no need to remove the devices to sleep, shower, or change batteries. The deep and precise placement in the bony portion of the ear canal offers an exceptionally natural sound quality and an invisible hearing solution. Associated challenges include maintenance of ear health and humidity, as these factors may lead to interruptions in device use. A study was conducted in collaboration with San Francisco Audiology to examine these known challenges of Lyric use.

Objective

The aim of this study was to identify predictive factors that contribute to positive outcomes for Lyric patients and providers. Eventually, these learnings may be used to create guidelines or tools to optimize fitting candidacy and improve fitting practice. A cohort of Lyric patients was monitored longitudinally, exploring predictive factors including ear canal health, relative humidity, and microbiology, as well as general health

Methodology

A cohort of 15 binaural new-to-Lyric hearing aid users (11 male and 4 female) completed this study. The average age of the subjects was 66 years old. All subjects had bilateral mild to moderately-severe hearing loss. Lyric hearing aid programming was based on prescriptive targets from Phonak Target fitting software, combined with fine tuning adjustments secondary to subject preferences.

Subjects attended the clinic for an initial fitting appointment and one-week follow-up, as well as refitting appointments for approximately six months. Refitting intervals varied per subject based on individual needs, but were generally spaced approximately four to six weeks apart. A health history questionnaire and Lyric candidacy evaluation was completed at the initial appointment, and baseline data was collected for ear canal health, relative humidity, and microbiology. Ear canal health and relative humidity was monitored at each refitting appointment, and microbiology was monitored in the event of any ear canal health issues. Ear canal health was recorded systematically by a dedicated audiologist, including type and severity of the issue, as well as location. Ear canal relative humidity was measured with the Sensirion SEK-SHTxx/SGP30 evaluation kit, using digital sensors fit to adapted Lyric sizers to occlude the ear canal. Ear canal microbiology data was collected using dry swab cultures, and analyzed by Quest Diagnostics. All collected data were analyzed to examine trends in predictive factors contributing to successful Lyric outcomes.

Results

Ear Canal Health

The majority of ear canal conditions (e.g., redness, abrasion, hematoma) occurred in the medial region of the ear canal, with the highest percentage of conditions occurring in the medial posterior region of the ear canal (see Figure 1).

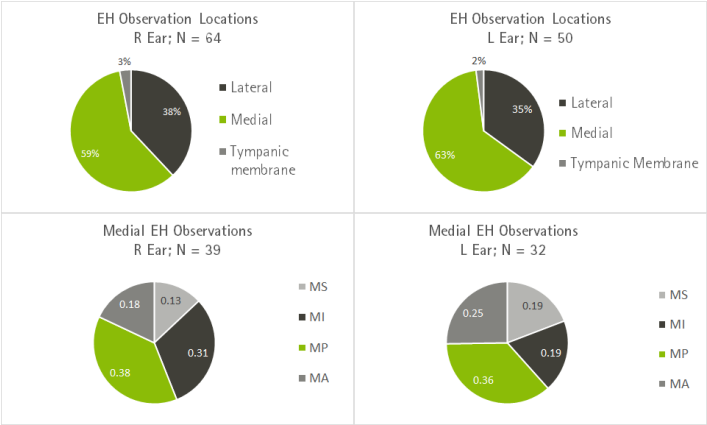

Figure 1. Ear Canal Observations by Location.

MS = medial superior, MI = medial inferior, MP = medial posterior, MA = medial anterior

Ear Canal Health vs. General Health

Subject ears were classified into one of two groups based on ear canal health issue presentation: Group A (No observed Ear conditions) and Group B (Observed Ear conditions). Group A ears were able to sustain continuous Lyric use for the duration of the study, while Group B ears required rest (a break from Lyric use) at some point during the course of the study secondary to an ear canal condition. Subjects were then classified as generally healthy or unhealthy based on review of health history questionnaires, Lyric contraindications, and Otolaryngologist and Audiologist clinical observations. Co-morbidities of particular interest were allergies and skin sensitivities, chronic health conditions requiring medication, and combinations of health concerns. Group B ears had a higher concentration of generally unhealthy subjects, when compared to Group A ears. These data suggest that there may be a correlation between subject general health and ear canal conditions (see Figure 2).

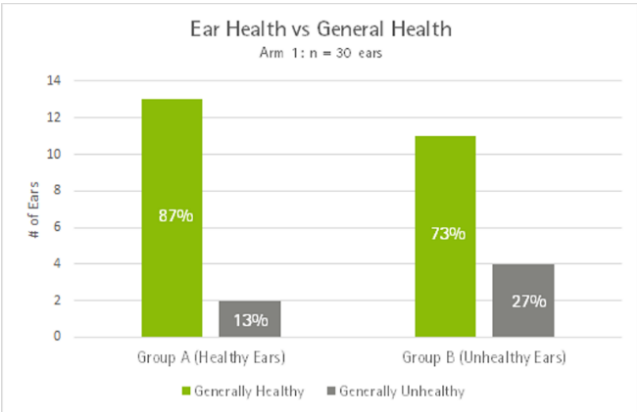

Figure 2. Observed ear condition vs general health

Ear Health vs. Relative Humidity

Relative humidity measurements taken in the baseline condition were predictive in some cases, but they were not

necessarily a good predictor of long term ear health for all Lyric users. Some ears with observed ear conditions had low baseline relative humidity and some ears with no observed ear conditions had high baseline relative humidity (see Figure 3).

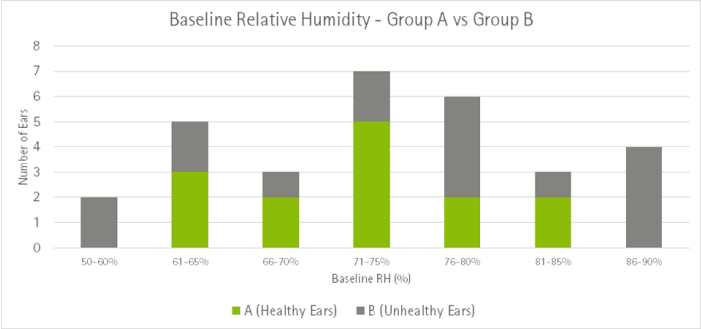

Figure 3. Baseline Relative Humidity and observed ear conditions

In the ears where n ear condition was observed, relative humidity generally showed an initial increase after Lyric fitting, which then stabilized over time. Therefore, relative humidity stability was determined by taking the average of the first two measurements, and determining the largest change from that measurement over the course of refitting appointments (see Figure 4).

Figure 4. Determining Relative Humidity Stability (ΔRH)

Subjects presenting with less stability in ear canal relative humidity over time had a greater incidence of observed ear conditions than those with more stable longitudinal relative humidity (see Figure 5).

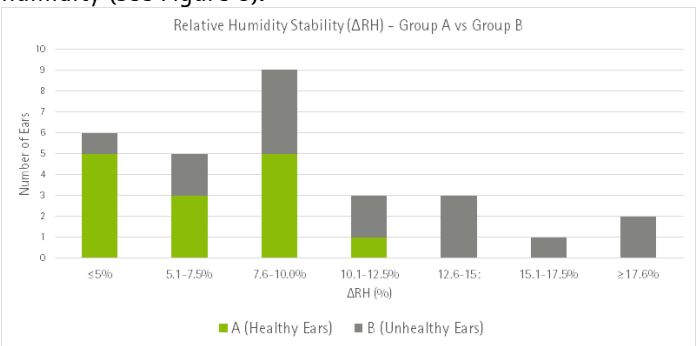

Figure 5. Relative Humidity Stability vs. Observed Ear Conditions

Ear canal relative humidity stability values were analyzed for a correlation between right and left ears of each subject, and with subject age. There was no correlation between relative humidity stability from the right to left ear for each subject (R^2 = .0008, see Figure 6). Similarly, there was no correlation seen with relative humidity stability and subject age (see Figure 7). Due to ear conditions, three subjects had insufficient relative humidity data to establish bilateral relative humidity stability for these ear-to-ear comparisons.

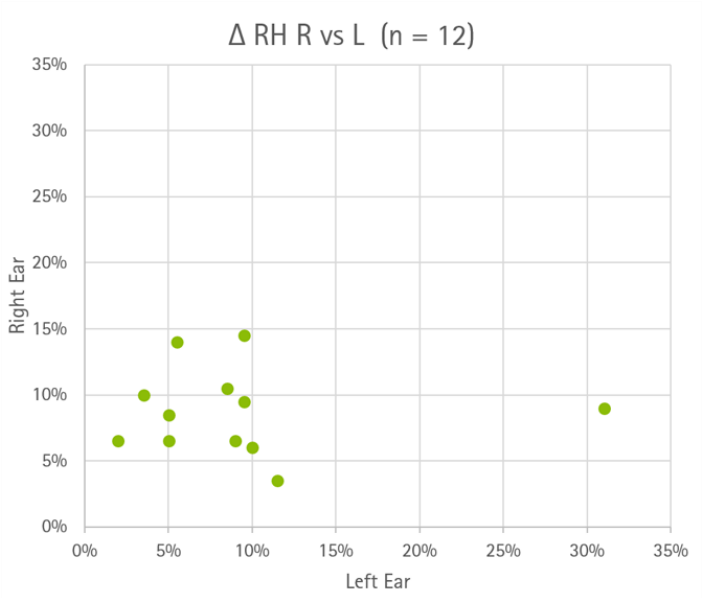

Figure 6. Ear Canal Relative Humidity Stability Between Right and Left Ears

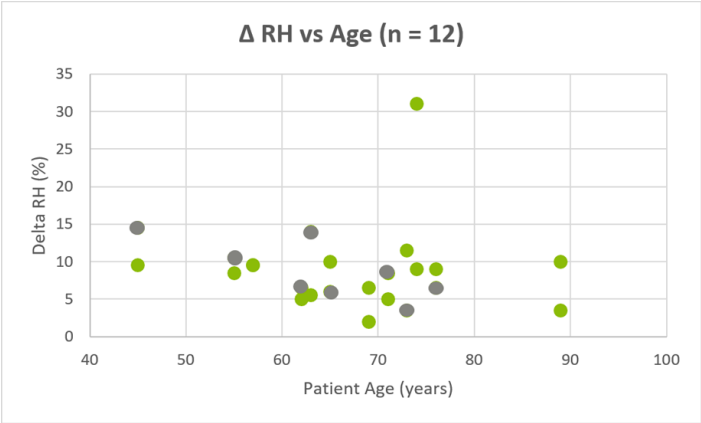

Figure 7. Ear Canal Relative Humidity Stability (ΔRH) and Subject Age

Ear Canal Health vs. Ear Canal Microbiology

Baseline bacterial and fungal culture results were measured for study subjects at the beginning of the study, and again at re-fitting appointments.

Positive bacterial culture results did not correlate with observed ear conditions (see figure 9). In subject right ears, 18 bacterial cultures were positive, and 79% of those samples did not coincide with any observed ear conditions. In subject left ears, 10 bacterial cultures were positive, none of which coincided with observed ear conditions.

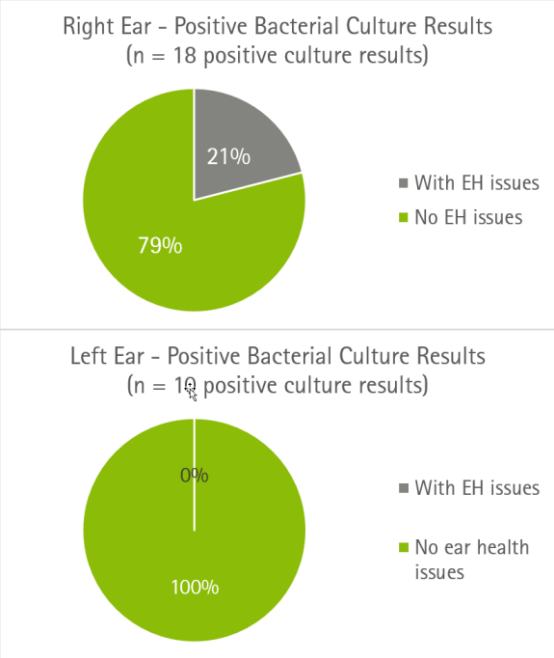

Figure 9: Positive Bacterial Culture Results and observed Ear conditions Right Ear vs. Left Ear

Discussion and Conclusion

As a pilot study, this investigation explored a wide variety of factors that may contribute to Lyric patient outcomes, which led to the discovery of the following potential emerging trends.

- Ear conditions are observed most in the medial region of the ear canal. The posterior region was most commonly affected by ear health issues.
- Subjects with poorer general health, with regard to Lyric fitting contraindications and medical history review, have a greater incidence of observed ear conditions when compared with subjects with fewer general health concerns.
- Baseline measurements for ear canal relative humidity do not necessarily predict future ear health outcomes; longitudinal stability of relative humidity is a better predictor of ear health outcomes. Subjects with higher longitudinal stability in ear canal relative humidity exhibited fewer ear conditions when compared with subjects with less stable ear canal relative humidity. Ear canal relative humidity measurements cannot be generalized to the contralateral ear when measured unilaterally. Ear canal relative humidity measurements cannot be generalized based on age.
- No clear correlation exists between ear health issues and positive bacterial or fungal culture results.

The collected data set may be improved by a more focused exploration of these emerging trends with an increased patient population with greater geographic diversity. Additional data is currently being collected and analyzed to examine the nature of these trends and practical application of these findings in clinical practice.

References

Brook, I., & Coolbaugh, J. C. (1984). Changes in the bacterial flora of the external ear canal from the wearing of occlusive equipment. Laryngoscope, 97, 963–965.

Johnson, J. (2015). Lyric: Clinical and Medical Review. Phonak Insight, retrieved from https://www.phonakpro.com/evidence., accessed on 6th March, 2019.

Karaca, Ç. T., Akçay, S. Ş., Toros, S. Z., Oysu, Ç., Verim, A., Çelebi, Ş., & Aksaray, S. (2013). External auditory canal microbiology and hearing aid use. American Journal of Otolaryngology, 34, 278–281.

Sim, J. H. (2014). Clinical and Microbiological Evaluation of an Extended-Wear Hearing Instrument. Audiology Neurotology Extra, 4, 32-45.

Authors

Grace Gardner is a Research and Development Audiologist with the Sonova USA team located in Fremont, California, where she focuses on hearing instrument clinical research. She has a Doctor of Audiology degree from Pacific University in Oregon, as well as a background in language studies, linguistics, and speech and hearing science.