

Field Study News

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Healthy ears for Lyric™ wearers – the contributing key factors

This retrospective study, conducted at the Audiological Consultants of Atlanta clinic was a “slice-in-time” study to investigate the possible associations between various measurable factors and the ear health of Lyric wearers. Factors which appeared to be associated with poorer ear health were smaller devices and poor general health.

Introduction

Lyric is an FDA-approved hearing aid for individuals with mild to moderately-severe hearing loss. Since it is worn 24 hours per day for months at a time, Lyric needs to fulfill various requirements with regard to biocompatibility and pressure applied to the skin of the ear canal, as well as environmental properties such as breathability and moisture transport, in order to maintain healthy ear canals. It is known that the fitting and wearing of Lyric for months at a time may cause changes to the physiological status of the ear canal skin (Jae Hoon Sim et al., 2014). These changes do not necessarily equate to poorer ear health. However, clinicians fitting Lyric report that the amount of days a Lyric device is worn in the ear, will vary amongst individuals for a variety of reasons that include ear health.

The purpose of this study was to investigate the impact of different factors on ear health. The chosen factors that were considered to potentially impact these criteria were:

- General health
- Ear health history
- Humidity in the ear
- Microbiology of the ear
- Device size

The factors were compared to ascertain if there are any correlations or trends that can be observed that relate to ear health. If correlations or trends are seen then they could

potentially be used to predict the success of Lyric with regards to ear health when determining candidacy.

The clinic selected to participate in this study was the Audiological Consultants of Atlanta (ACA). This clinic was selected because of their robust method of ear health data collection. Before the study was conducted, data was reviewed for the total number of Lyric removals that had been collected over a period of 20 months. This was equal to 11,648 removals and five percent of the total removals was attributed to ear health conditions.

Methodology

Participants

The sample consisted of 20 existing Lyric users: Group A – ten Lyric wearers with no observed ear health conditions and Group B ten Lyric wearers with a history of observed ear health conditions. These included: non-infectious otitis externa, abrasions of the ear canal wall, hematomas or ulcers (Johnson, 2015). All participants were fit binaurally, apart from one in Group A, who was fit monaurally. The gender distribution was 40% female and 60% male. The average age was 75 years.

Ear health and general health assessment

The medical health of the subjects was assessed based on their reported

past acute medical conditions such as diabetes, auto immune disease, sinus disease, skin disease and cancer, along with a history of medication taken for these conditions. The health of the ear was ascertained, by performing otoscopy pre and post removal of the Lyric device and on past history of ear conditions, collected in the patient notes. At this stage the device size worn by the subject and the average days of wear was recorded in the notes.

Ear canal humidity measurement methodology

The humidity level of the medial ear canal is based on several factors: The surface area of the occluded medial canal, trans-epidermal water loss (TEWL), rate of the ear canal and passive moisture vapor transport rate (MVTR) through the Lyric device, which is governed by the humidity gradient between the medial and lateral region and the seal material properties.

Group A and Group B were first split by device size and percentage of measured ear canal relative humidity. An electronic sensor (Fig. 1) was created to measure temperature and moisture level in the ear canal. The sensor was embedded in a Lyric sizer and connected to a computer to record real-time measurements.

The sizer sensor was inserted into the subject's ear canal at the insertion depth of their normal Lyric device in order to mimic the occluded volume between the tympanic membrane and the device.

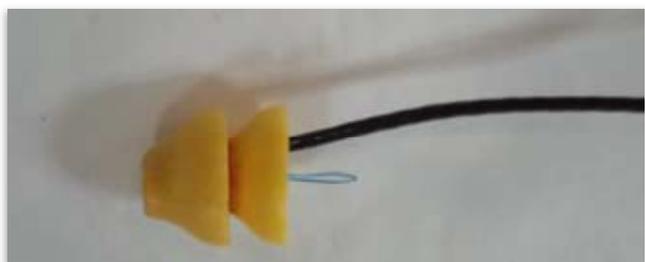


Fig. 1. Picture of the sensor embedded in a Lyric sizer

Measurements were made for an extended period of time (~15-20 minutes) to record a stable measurement (Fig. 2).

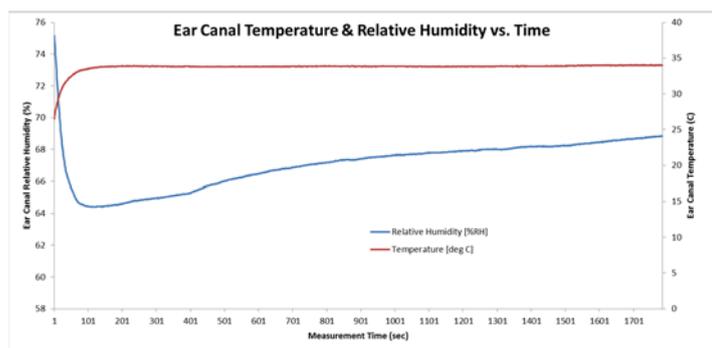


Fig. 2. Chart showing an example of collected ear humidity data

Ear canal microbiology test methodology

Upon removal of a Lyric device from the subject's ear canal, a sample of the micro-biome of the subject's medial ear canal was taken with a sterile swab. The swab was then secured in the container provided and was sent to an analysis laboratory. Aerobic bacteria and fungus culturing testing was performed at the laboratory, where a positive result indicated the presence of infectious bacteria or fungus. A negative result indicated only normal skin flora was present in the sample and no bacterial or fungal growth was present.

Results

Ear health: Patient comments and medical history results

The majority (90%) of Group A (healthy ear group) are reported as being generally healthy (Fig. 3). More than half (60%) of Group B (unhealthy ear group) are reported as being generally unhealthy (Fig. 4).

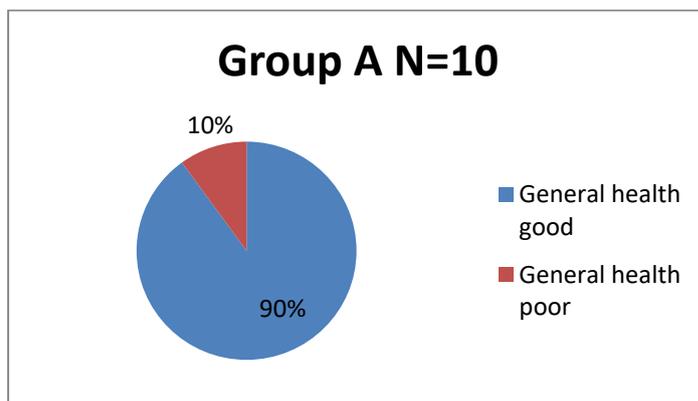


Fig. 3. Healthy ear group showing results for 10 subjects

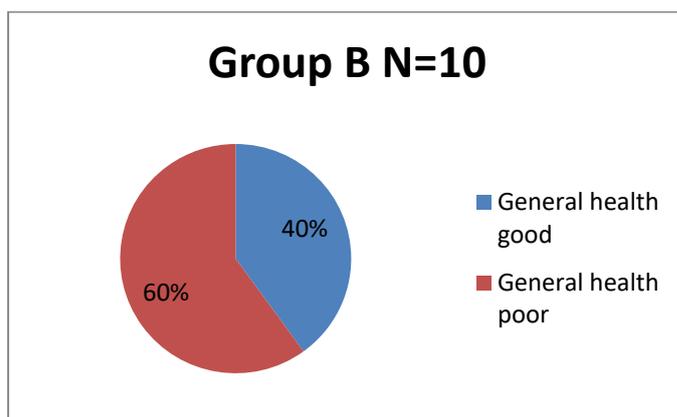


Fig. 4. Unhealthy ear group showing results for 10 subjects

Ear health versus subjects average days of wear result

The Days Of Wear (DOW) distribution was analyzed across the group. Group B participants tended to wear Lyric for fewer days than Group A participants. This suggests that a

wearer's success with Lyric may be affected by their ear health.

Ear canal humidity: Size of Lyric, relative humidity and ear health results

The ear canal humidity was measured in percentage and the range for Group A and Group B was from 55% to 94%. For each ear in Group A and Group B, the humidity level and device size were recorded. Seventy percent humidity or above is classified as a high humidity level (Fig. 5).

Device size	Measured Ear Canal Relative Humidity Range (%)							
	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94
XS		B	BBBB	BBAB	AB	B		
S	A	AA		A	B			
M	AA	A	AAA	AB	BA	A	B	A
L	B			B				B
XL		A	AB	A			B	B

Fig. 5. The table shows Group A and Group B in relation to the measured relative humidity and device size for each ear, n=39

The table shows that more of the Group B ears are fitted with the smallest device used in this study (device size XS) and Group B ears tend to have higher relative humidity measurements across all device sizes. This table also suggests an interaction between smaller device sizes and humidity ranges, with more size XS Group B ears measured with lower relative humidity ranges. This suggests that small size alone could be a factor that affects ear health.

Microbiology: Bacterial culture results

Regardless of the ear health group (A or B) the majority of microbiology cultures produced negative test results meaning normal skin flora was detected almost exclusively.

In Group (A), 89% of the subject's ears tested, showed normal skin flora for bacterial growth (Fig. 6).

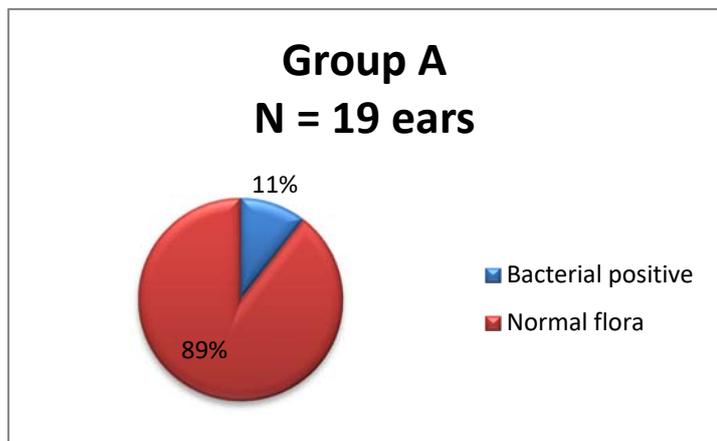


Fig. 6. Healthy ear group showing results for 19 ears

In Group (B) 79% of subject ears tested showed normal skin flora (Fig. 7).

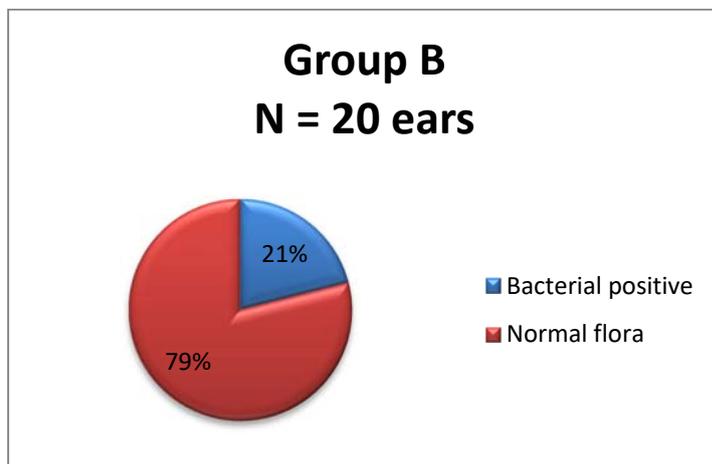


Fig. 7. Unhealthy ear group showing results for 19 ears

These results do not show a clear correlation between ear health and bacterial culture results.

Discussion and conclusion

This retrospective study indicates that for the relatively few Lyric users (5%) who have poorer ear health, smaller device size appears to be a risk factor, even when the relative ear canal humidity is lower. The amount of days the Lyric device is worn can be affected by the ear health of the individual, with poorer ear health leading to fewer days of device use. There is also a possible correlation between an individual's ear health and their general health, in that healthier people tend to have healthier ears. Reassuringly, there is no clear correlation between ear health of Lyric users and bacterial culture results. This study has identified the parameters that potentially impact days of wear and a longitudinal study investigating these in more detail is currently underway.

The results of this study suggest that, to minimize ear health issues associated with Lyric, Lyric providers should continue to monitor the Lyric user's overall general health with regards to contraindications that could potentially arise. They should also manage expectations of patients with smaller ear canals being fitted with smaller sized Lyric hearing aids at the time of fitting.

References

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Authors and investigators

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Anna is currently working as the global clinical development and training manager for the In-the-Ear team with a focus on Lyric. Anna joined Phonak headquarters in Switzerland in August 2008 and during this time has worked on many key projects representing audiology from the perspective of the hearing care professional and the end user. She has worked in the field of audiology and hearing aids for 25 years .

Principal investigator



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In 1983 Dr Solodar founded the Audiological Consultants of Atlanta, the first private Audiology and Speech pathology practice in Georgia which currently operates with six office locations, ten licensed audiologists, and eight audiology assistants. Dr. Solodar is licensed by the state of Georgia as an Audiologist. She has worked in the field of audiology and hearing aids for 42 years.