Lyric: Research Studies and Medical Information
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Jacob Johnson, MD

Medical Director, Lyric

• Managing Partner, San Francisco Otolaryngology Medical Group (7 Otolaryngologists)
• Associate Clinical Professor, UCSF Department of Otolaryngology and Head & Neck Surgery
• President, San Francisco Audiology (4 Audiologists)
• Board Member & Chair of Quality, Brown and Toland Medical Group (1500+ physicians)
• Otolaryngology Representative & Past President, UCSF Association of Clinical Faculty (3000+ physicians)

• 2001-2007: Lyric Development & Clinical Studies
• 1/2007: First Lyric commercial sale
• 2006-2007: Initial training of ENT-Audiology teams
• 2007-present: Lyric Medical Monitoring & Support, Clinical Research Support
• 2012, 2013: Phonak U
• 2013: International Lyric ENT support
Objective: Create a Framework for Understanding and Promoting Lyric

1. Lyric Medical: Development, Candidacy, Clinical Monitoring
2. Lyric Research Studies
Lyric Medical: Development, Candidacy, Clinical Monitoring

- First and only Invisible, *Extended Wear* Hearing Device
- Today, over 20,000 patients are wearing Lyric Hearing!
- Over 13 years of clinical data monitoring
Ear Canal – Bioengineering Perspective- Skin/ Seal Interaction

3 Principles Followed to Achieve 24/7 use:
Avoid excessive pressure- below venous capillary pressure
Provide adequate moisture vapor transfer rate (MVTR)
Device designed to reside in bony portion of ear
Rational Design - Materials and Design for Safety, Comfort, and Longevity

Lyric 1 & 2 Module

Lyric 1 & 2 CT Scan
Lyric candidacy – Primary criteria (ENT- Audiology relationship) a partnership is needed for optimum management

Patients are evaluated for Lyric candidacy using four primary criteria:

- Fitting Range- mild to severe hearing loss
- Lifestyle
- Ear Canal Anatomy & Skin Quality
- Medical History
Prior to Lyric use, medical clearance is recommended for patients with the following conditions:

- Prescription anticoagulation therapy
- Non-medically managed diabetes
- Implantable medical device
- Patients under age 21
- Compromised immune system
  - Chemotherapy within the last 6 months

Lyric Candidacy has simplified over time with 6 years of post release monitoring.
Lyric use is contraindicated for patients with the following conditions:

Middle Ear Conditions
- Chronic or acute drainage
- TM Perforation
- PE Tubes
- Cholesteatoma

Skin Conditions
- Chronic external otitis

Other Conditions
- Radiation to the head or neck ever
- Cognitive ability (insufficient to understand device use)
- Chronic ear pain
- Bleeding disorder
Lyric Ear Status: ENT-Audiology relationship: a partnership is needed for optimum management

- Placing Lyric may lead to Ear Canal Skin Issues with 2 Distinct Presentations
  - The skin issues will in nearly all cases resolve by removing the Lyric and resting the ear for 3-14 days

- Type 1
  - Discomfort/pain for the patient – usually within first 1-2 weeks of placement in new users
    - Hematoma
    - Abrasion

- Type 2
  - Weak or malfunctioning device usually within 2-4 weeks of placement in experienced users
    - Non-infectious Otitis Externa (Moisture with Keratin- usually painless differentiating from infectious otitis externa)
    - Ulcer (Rare cases but will heal with office care and does not create restrictions.)
      Avoid layering cerumen accumulation in one persistent area
Type 1 Ear Canal Hematomas- may result in discomfort in the first 7-14 days or seen on aggressive removals. Deep Cerumen (important to have a clean ear).
Type 1. Ear Canal Abrasion- may result in discomfort in the first 7-14 days or with aggressive removals.
Type 1. Hematoma/ Bruise (likely patient manipulation of device) - may result in discomfort in the first 7-14 days. Important to council patients to not touch device.
Type 2. Non-infectious Otitis Externa (moisture with keratin)- often not painful and presents with device malfunction. Removal of the device leads to resolution in 3-14 days without aggressive treatment.
Safety Study: Michael Scherl, MD

- 279 patients wore Lyric1 for 45-775 days
  - average use was 189 days
- 91% of the patients wore Lyric successfully without inflammation
- 9% developed transient canal skin irritation that resolved within 3-14 days and the patients were able to continue wearing Lyric

There were no cases of:
- Otitis externa (infectious)
- Tympanic membrane injury
- Osteomyelitis
- Tissue necrosis
- Sudden SNHL

Scherl, 2004
Lyric: Clinical Monitoring

Comparison of microbial growth from Lyric2 group

- Pre-Lyric
- Lyric Wear
- Post-Lyric

- Staphylococcus
- Turicella ototodis
- Coryneform Bacterium
- Others

Cultures negative
No medicinal treatment
Clear keratin as needed
Ear micro-biome
Lyric: Learning Curve/ Opportunity - Requires Fitter Commitment

Ear Status Variables
- Ear
- Fitter
- Device

Type 1:
- Ear + Fitter

Type 2:
- Ear + Device
• >200,000 Lyric fittings in 2013
• Majority of patients wore Lyric successfully without any ear issues
• Ear Issues - transient canal skin irritation (sometimes looks worrisome) resolved within 3-14 days and the patients were able to continue wearing Lyric
• Repeat skin irritations then consider another hearing solution
• 12 years of Lyric Research Subjects- none have needed any antibiotic/steroid ear drops, oral antibiotics, surgery
• No serious complications in 13 years of clinical monitoring
Lyric Research Studies

24/7 Hearing Research:
Neuroscience Perspective – Continuous Auditory Stimulation
Deep in Canal Perspective – Auditory Performance
Studies:

- Bay Area Lyric and Tinnitus Study  
  - Eunice Fu, Christine Sanford, SFA and CSG Better Hearing  
  
- Teenager Study  
  - Jace Wolfe, Hearts of Hearing, OK  
  
- Lyric and Asymmetric Hearing Loss  
  - Jolie Chang, Steven Cheung, Jennifer Henderson-Sabes, UCSF  
  
- VA Portland Tinnitus Study  
  - Jim Henry, VA Portland  
  
- Psychological Impact Study  
  - Helena Solodar, Audiological Consultants of Atlanta  
  
- Lyric 3  
  - Michelle Griffin, John Pumford, Lyric Research Clinic  
  
November 2012

September 2013

August 2013

January 2014
Effectiveness of continuous wear, in-canal hearing amplification devices for Tinnitus
Objective and Study Population

- This pilot study aims to assess the effectiveness of continuous wear hearing aids for chronic tinnitus with the Tinnitus Functional Index (TFI).
- Specifically, this study examines the tinnitus changes in patients treated with Lyric hearing aids, an in-canal device that can be worn 24/7.

26 adults reporting both hearing loss and chronic subjective tinnitus

- Age
  - Average: 64.6
  - Median: 66
  - Range: 53-77
- Gender
  - Male: 20
  - Female: 6
60% of all patients showed *meaningful* reduction in TFI scores at 3 months. 21 patients (80%) report *meaningful* reduction in TFI scores in at least one measure over the course of the study.
VA Portland and Phonak Tinnitus Study

- Protocol similar to Bay Area Study
- Will wear hearing devices 4 months
- Three evenly matched groups
  - 25 wear Lyric
  - 25 wear Audeo
  - 25 wear Audeo with Tinnitus Balancer
Effectiveness of continuous wear, in-canal hearing amplification devices for Teenagers
Objectives

- Evaluate potential benefits and limitations of the Lyric extended wear hearing device in school-aged children
  - Evaluate usability of the Lyric in children
  - Compare speech recognition in quiet and in noise between the Lyric and daily wear devices
  - Compare audibility between the Lyric and daily wear devices
    - Real ear probe microphone measures
    - Aided sound field thresholds
  - Compare subjective impressions between the Lyric and daily wear devices
Subjects

• 18 children were enrolled into the study
  – 11-17 years-old

• 16 of 18 children were successfully fitted with Lyric devices
  – 1 rejected the device for insufficient output
  – 1 rejected the device because he did not like the way it felt while in his ear → “It doesn’t hurt. It’s just different.”
Lyric: Real Ear Measurements
Real ear measures- Developed a Lyric verification protocol

» Real ear measures will be used with Lyric 3 and most external studies.
Real ear measures

VOILA! Evidence for Audibility!
Aided Thresholds

No statistically significant differences except for aided thresholds at 6000 Hz.

n = 16
Real Ear Probe Microphone Measures

Jayden, with mild to moderate hearing loss, who reluctantly wore an open-fit device.

Daily Wear: Oticon Delta 6000

Phonak Lyric Extended Wear

Jayden reports that the Lyric provides better speech recognition for all situations, and she also reports better spatial awareness.
Speech recognition in noise is significantly better with the Lyric ($p < .05$)
Lyric 2.3 Max Output Pressure -- Measurement Setup

- **Stainless steel mounting disk**
- **Lyric 2.3 device**
- **IEC hard-shell SLA ear model**
- **Device distance from TM**

Ranges from 4 mm to 1 mm

- **Input SPL**
  - Ranges from 105 to 116 dB

- **Measured SPL close to TM**

→ Device programmed to max gain without feedback, high frequency boost = ON
Results: Lyric 2.3 Size XS, in IEC-XS1
Effectiveness of continuous wear, in-canal hearing amplification devices for Self Perception
Purpose

- Pilot study to assess psychosocial benefit / self perception impact of Lyric devices
  - Do subjects report a positive impact of wearing Lyric on their self-esteem, competence and adaptability?
Objective & Design

- Pilot study to assess psychosocial benefit / self perception impact of Lyric devices
  - Do subjects report a positive impact of wearing Lyric on their self-esteem, competence and adaptability?

- Up to 32 subjects (no fewer than 16 subjects at conclusion of study)
- Eligibility criteria includes:
  - Candidate for Lyric (audiometric, lifestyle, health)
  - First time adult users of amplification (21 – 80 years old)
  - Mild to moderately-severe sensorineural hearing loss bilaterally with WRS > 20% bilaterally
  - English speakers
  - No history of ear disease or surgery
- Subjects wear devices for 8 weeks, complete various objective and subjective measures
Combination of various objective and subjective measures including:

- **Primary Measure:**
  - Psychosocial Impact of Assistive Devices Scale (PIADS)

- **Secondary Measures:**
  - Real-Ear Measurements
  - QuickSIN
  - Hearing Handicap Inventory for Adults (HHIA)
  - Speech, Spatial and Qualities of Hearing Scale (SSQ)
  - Expected Consequences of Hearing Aid Ownership (ECHO)
  - Satisfaction with Amplification in Daily Life (SADL) questionnaire
  - International Outcome Inventory for Hearing Aids (IOI-HA)
  - Attitudes Towards Loss of Hearing Questionnaire (ALHQ)
  - Fear of Aging questionnaire
  - Functional Social Support Questionnaire (FSSQ)
Effectiveness of continuous wear, in-canal hearing amplification for Asymmetric Hearing Loss
Background

- Work done at UCSF has demonstrated changes in the auditory cortex with asymmetric hearing function.
- Electrophysiology measurements in monkeys with moderate asymmetric hearing loss showed asymmetric reorganization of the auditory cortex with misalignment in the cortex on one side.
- Preliminary work with MEG imaging in patients with asymmetric hearing loss shows similar unequal auditory cortex reorganization between the hemispheres.
- Asymmetric reorganization may impair binaural integration and may be rehabilitated with hearing amplification. However, rehabilitation has not been prospectively studied with neuroimaging.

Study Question and Design

- Does amplification in asymmetric hearing loss restore binaural integration? Can we measure changes in the auditory cortex using auditory and Neuroimaging measures?

- Prospective one year study in subjects with asymmetric sensori-neural hearing loss.
  - The poorer ear will be aided with a
  - Lyric® hearing aid.
  - Measurements taken at intervals over
    - 1 year.

- Lyric® use:
  - Worn continuously allowing for potential
  - constant auditory stimulation
  - Amplification without signal processing delay
Patients and Fitters

- Patients love Lyric
- Attracts new, loyal patients
- No inventory cost
- No internet or low-cost competition
- Sell & fit the same day

Why Lyric?

- Lyric is an out-of-the-box product that has rejuvenated our interest in amplification
- Dramatically helped bring new patients into the practice
- Dramatically helped people hear who would not have worn any other device
Jayden - Why Lyric?