

Safety and patient satisfaction with Lyric® hearing aids

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ABSTRACT

We retrospectively studied 364 self-selected patients in a private practice with mild to moderately severe hearing loss interested in wearing a new continuous-wear hearing aid, Lyric®. Lyric hearing devices reside completely in the bony and soft tissue canal within 5 millimeters of the tympanic membrane. We endeavored to determine whether a Lyric hearing device could safely and comfortably reside completely within the bony and soft tissue canal for extended periods of time. Additionally 60 patients completed surveys exploring satisfaction with Lyric devices to determine: 1. if they preferred it to their previous hearing aid 2. How a Lyric performed when the patient was using the telephone and 3. If the patient perceived cosmetic advantages. Following a hearing evaluation a Lyric device was placed within 5 mm of the tympanic membrane and at least 3 mm medial to the lateral rim of the posterior canal wall. Devices were typically replaced every 30-120 days. Ear canals were inspected at least every 120 days and observed for infection, inflammation or tympanic membrane injury. Lyric devices were worn for 45-775 days without inflammation by 91% of regular users. The incidence of transient canal irritation was 9%. There were no cases of otitis externa, tympanic membrane injury or osteomyelitis. Patients preferred their Lyric over their prior hearing aid, when using a phone, and cosmetically, 92%, 92% and 97% of the time respectively. We concluded Lyric devices can be safely worn in the ear canal for extended time periods and satisfaction with the quality of hearing, cosmetic result and phone use is extremely high.

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INTRODUCTION

Conventional hearing aids are placed and removed from the ear on a regular daily basis. Lyric is the first continuous wear hearing aid worn 24 hours a day for up to four months. Lyric is an FDA cleared, continuous wear analog hearing aid designed by InSound Medical. In an office setting a Lyric is placed in the bony ear canal and positioned approximately 4 mm from the tympanic membrane. The Lyric devices are placed in the canal using a headlight with or without magnification by an audiologist or a physician. Until now no prosthetic device has routinely resided in the ear canal for months at a time. Foreign bodies have resided asymptotically in the ear canal for extended time periods.^[1] Hearing aids pose a unique threat considering the presence of a battery and the need to seal the ear canal to eliminate feedback without causing trauma to the canal skin. The presence of a battery in the canal or the chronic pressure of the device in the ear canal pose the potential risk of causing irritation, infection, tissue necrosis or trauma to the tympanic membrane.

METHODS AND MATERIALS

We retrospectively studied self-selected patients in a private practice with mild to moderately severe hearing loss who were interested in wearing a new continuous-wear hearing aid. Each of these patients underwent an Otolaryngology evaluation including a history, a physical examination, and a comprehensive audiometric evaluation with counseling by both the audiologist and the physician. Patients with extremely narrow or short ear canals, prominent osteomas, prior local radio-therapy or habitual swimmers were initially excluded from the study. After detailed counseling 392 qualified patients electively chose to purchase a Lyric hearing aid with a trial period. The lyric devices were placed in each ear canal and 28 patients were disqualified from wearing a Lyric when they experienced moderate initial discomfort or pain. Three-hundred and sixty-four patients who were initially comfortable with the device were included in the study. These patients were seen regularly and examined for ear canal inflammation and the ability to safely tolerate the device for extended time periods without complication. We also inquired from a subset of the 364 patients who used conventional hearing aids prior to a Lyric: 1. if they preferred a Lyric to their previous hearing aid 2. The level of satisfaction using a Lyric with the telephone compared to their prior hearing aid and 3. The extent of patient satisfaction with the cosmetic appearance of a Lyric compared with their prior conventional hearing aid. Patients responded by rating their experience on a scale of 1-5 with 1 representing inferior to their prior conventional aid, 3 representing comparable to their prior conventional aid and 5 representing superior to their conventional aid.

RESULTS

The first devices were placed in May of 2007. We placed Lyric devices in 364 patients and 644 ears. Sixty-four of the patients discontinued wearing the devices within the first month. The primary reasons for discontinuing use were persistent otalgia, canal irritation, intolerable occlusion effect or recurrent accumulation of moisture between the device and the tympanic membrane. In retrospect the majority of these patients had unfavorable canal anatomy. Unfavorable canal anatomy included a narrow anterior posterior dimension, relatively short canal (less than 23 mm), a convexity of the posterior or anterior bony canal wall or a step in the canal floor. All cases of inflammation and irritation resolved within 5 days. None of the patients were treated with a canal wick or oral antibiotics. In the remaining 300 patients and 524 ears the devices have been replaced on average every 53 days. Among these initially successful users, 21 patients (37 ears) discontinued using the devices after more than 4 weeks. Various reasons were cited by the patients. Pain was reported in 17/21 patients. Failure to provide adequate amplification was reported by 2 patients. Inability to swim was noted by one patient and intolerable occlusion effect was reported by another patient after 5 weeks. Individual devices have lasted in place as long as 127 days. The remaining group of 279 patients on average has been using devices for 189 days including replacement of devices. In this group one patient has been using devices continuously for 775 days. Seventy-two patients have been using devices for longer than 380 days. Among the 279 patients, 26 users developed transient canal irritation at some point necessitating the removal of the device for 3-14 days. All of these patients were able to resume use of the device.



Figure 1. Lyric in a canal

	Inferior	Slightly inferior	Comparable	Slightly superior	Superior
Overall	0	0	2	21	37
Phone Use	0	1	1	7	51
Cosmetic	0	0	1	5	54

Table 1. Lyric devices compared with prior conventional hearing aid

RESULTS

Ear canals were carefully inspected in patients with complaints of pain and device failure. Additionally all ear canals were inspected at the time of device replacement. There were no episodes of otitis externa, osteomyelitis, tympanic membrane perforation or sudden sensory-neural hearing loss. There were 2 patients who developed serous otitis media requiring placement of a ventilation tube in the tympanic membrane and were subsequently able to continue using the Lyric. Each had a history of serous otitis media episodes prior to using a Lyric. There was also one patient who has developed 2 episodes of vertigo while using a Lyric. Patients on all forms of anti-coagulation were included in the study and did not experience any history of bleeding problems in the ear canal. There were 12 patients in the group of 300 users with diabetes and they did not experience any unusual canal inflammation. We randomly selected 60 of the 279 to complete a simple questionnaire. Patients rated Lyric hearing aids superior to their prior hearing aid 92% of the time. They also rate Lyric superior to their hearing aid when using a phone and cosmetically; 92% and 97% of the time respectively.

DISCUSSION

Lyric hearing aids were cleared by the FDA in 2002. Lyric hearing aids represent a significant change in the pattern of hearing aid utilization. Because they represent the first continuous wear hearing aid and are worn for months at a time the possibility of canal, tympanic membrane and middle ear injury would be a cause for concern. Most canal, tympanic membrane and middle ear injuries associated with hearing aids have been associated with the process of making a mold.^[2] These complications are related to retained molding material.^[3] The most severe complications are associated with a retained battery in the ear canal resulting in tissue necrosis.^{[4][5]} Additionally hearing aids in patients with a history of radiation can result in osteoradionecrosis.^[6] We refrained from fitting any patients who had a history of any prior local radiation. Diabetic and immunocompromised patients are at risk for malignant otitis media. In our surveillance of a Lyric wearing population we did not find any otitis externa, malignant otitis externa or injury to the tympanic membrane. We did not have any cases of profuse bleeding even in our patients on anti-coagulation medications. We did not have any patients with an exposed battery in the ear canal and also did not find any patients with tissue necrosis.

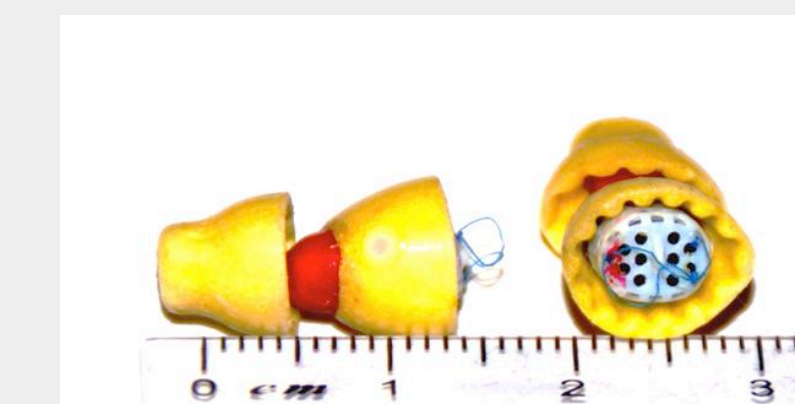


Figure 2. Lyric devices.

In the group of 64 patients who failed within the first 4 weeks most had progressive otalgia. Their canals demonstrated evidence of focal irritation and occasionally diffuse inflammation. The pain abated with removal of the device generally within an hour. All canals healed spontaneously within 5 days. There were no cases of diffuse canal circumferential edema and erythema as seen with otitis externa. Rarely fluid would develop medial to the device and lateral to the tympanic membrane causing the device to fail but not causing any patient morbidity. Similarly in the patients who developed pain after 4 weeks, the pain abated quickly after removal of the device and the skin healed within a few days. Lyric patients consistently rated Lyric hearing devices as superior to their prior hearing aid. In separate questions they specifically rated their Lyric superior to their prior conventional hearing with regard to phone use and cosmetic appearance. The continued follow-up for device replacement is further evidence of the patient preference.

CONCLUSIONS

Lyric hearing aids are safe and can be worn continuously without serious complication for extended periods. Lyric users prefer the Lyric hearing aid to their prior conventional hearing aid. Users should be followed carefully over the next years to confirm the safety of long term use. Additional outcomes studies to confirm the value of this product should be performed.

REFERENCES

- [1] [Schulze SL, Kerschner J, Beste D.](#) Pediatric external auditory canal foreign bodies: a review of 698 cases. Otolaryngology Head Neck Surg. 2002 Jul;127(1):73-8
- [2] [Wynne MK, Kahn JM, Abel DJ, Allen RL.](#) External and middle ear trauma resulting from ear impressions. J Am Acad Audio. 2000 Jul-Aug;11(7):351-60.
- [3] [Kohan D, Sorin A, Marra S, Gottlieb M, Hoffman R.](#) Surgical management of complications after hearing aid fitting. Laryngoscope. 2004 Feb;114(2):317-22.
- [4] [Kavanagh KT, Litovitz T.](#) Miniature battery foreign bodies in auditory and nasal cavities. JAMA. 1986 Mar 21;255(11):1470-2.
- [5] [Premachandra DJ, McRae D.](#) Severe tissue destruction in the ear caused by alkaline button batteries. Post grad Med J. 1990 Jan;66(771):52-3.
- [6] [Chang Gung.](#) Osteoradionecrosis of external auditory canal in nasopharyngeal carcinoma Med J 2007 Mar-Apr;30(2):116-21.