Extended-Wear Hearing Technology

The Nonimplantables

Neil M. Sperling, MD[a,b,*], Scott E. Yerdon, AuD[c], Marc D'Aprile, ScD, CCC-A[c]

KEYWORDS

• Lyric • Earlens • Extended-wear • Hearing aid • Nonimplantable

KEY POINTS

- A category of hearing technology has developed that consists of a deep ear canal device that remains in place for an extended period of time.
- These devices do not require a surgical event; they are inserted but not implanted.
- The ultimate goal of all hearing technologies is to improve auditory function with minimal discomfort, ease of application, and satisfactory cosmetics; a device that can meet these demands, while not requiring surgery for insertion, may be a preferred option.
- The extended-wear technologies offer distinct advantages to standard amplification.

Video content accompanies this article at http://www.oto.theclinics.com.

INTRODUCTION

As the evolution of hearing technologies simultaneously pursues improvements in sound quality and delivery method, a category of hearing technology has developed that consists of a deep ear canal device that remains in place for an extended period of time. These devices do not require a surgical event; they are inserted but not implanted. In this sense, they represent an intermediate step in the continuum from hearing aid to implantable device. The ultimate goal of all hearing technologies is to improve auditory function with minimal discomfort, ease of application, and

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[a] Department of Otolaryngology Head and Neck Surgery, New York Otolaryngology Group, Weill Cornell Medical College, 36A East 36th Street, New York, NY 10016, USA; [b] Departetnt of Otolaryngology, SUNY Downstate College of Medicine, 450 Clarkson Rd., Brooklyn, NY 11203, USA; [c] New York Otolaryngology Group, 36A East 36th Street, New York, NY 10016, USA
* Corresponding author. New York Otolaryngology Group, Weill Cornell Medical College, 36A East 36th Street, New York, NY 10016.
E-mail address: neil.sperling@nyogmd.com

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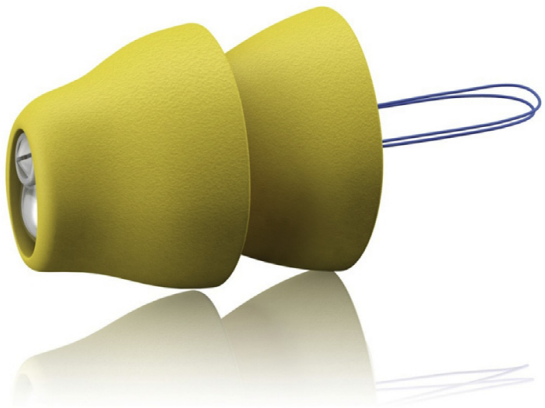

Fig. 1. Lyric device. (*Courtesy of* Sonova USA Inc, Warrenville, IL.)

satisfactory cosmetics. A device that can meet these demands, although not requiring surgery for insertion, may be a preferred option.

Over the past 2 decades, evolution in hearing aid systems sought to eliminate the recognized shortcomings of its technology. This included eliminating feedback and the occlusion effect, improving overall sound quality and hearing in noise, as well as addressing the lifestyle limitations of hearing aid use. Although many of these issues have improved with current hearing aid technology, some remain. The extended-wear technologies offer distinct advantages to standard amplification. Close proximity to the tympanic membrane (TM) and auditory anatomy appears to benefit patients using Lyric device. Earlens (Menlo Park CA, USA) has extended the audible bandwidth to 10 kHz, resulting in enhanced quality of sound significantly beyond that of standard amplification.

LYRIC

Lyric (Phonak AG, Stafa, Switzerland) was the first extended-wear hearing device, originally introduced in 2007. The device is inserted deeply into the ear canal by a hearing-instrument professional, a simple office-based nonsurgical procedure without

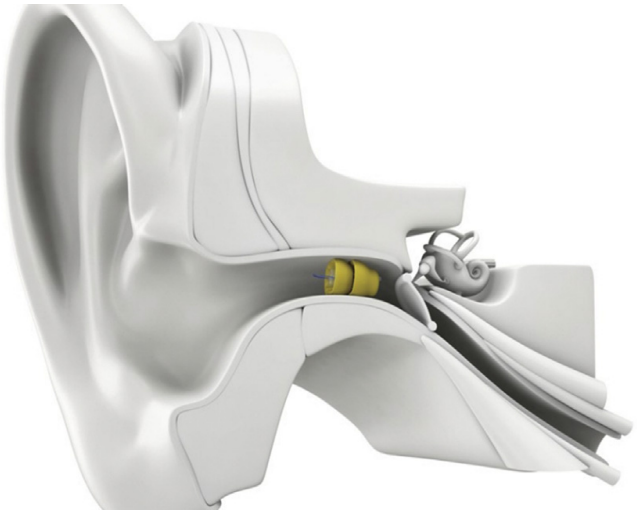

Fig. 2. Graphic of the Lyric device when deeply inserted into the ear canal. Note its proximity to the TM. Insertion and placement of Lyric should be 4 mm from the TM. (*Courtesy of* Sonova USA Inc, Warrenville, IL.)

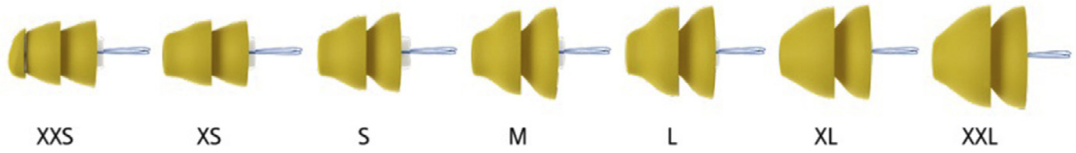

Fig. 3. Lyric devices and sizes. It is 12 mm in length. L, large; M, medium; S, small; XL, extra large; XS, extra small; XXL, extra extra large; XXS, extra extra small. (*Courtesy of* Sonova USA Inc, Warrenville, IL.)

anesthesia[1] (**Fig. 1**). The primary benefits of this device are related to its aesthetics and convenience. As such, this device appeals particularly to those concerned about wearing a visible device. In addition, it has advantages in disabled individuals or those unable to manipulate small devices.

By design, the device is placed into the bony portion of the ear canal 4 mm from the TM, minimizing the effect of cerumen and migrating exfoliated skin in the cartilaginous portion of the canal (**Fig. 2**). The device can be worn for up to 4 months, although replacement needs may vary by individual (eg, excessive cerumen production). Size is selected based on the ear canal dimensions (**Fig. 3**).

Lyric was first introduced by InSound Medical (Newark, CA, USA), which was later acquired by Sonova AG (Switzerland) in 2010. Lyric has gone through several iterations (Lyric, Lyric 2, and currently, Lyric 3), along with progressive change in its feature set. In May 2010, the Food and Drug Administration (FDA) recalled roughly 2000 Lyric 2 devices that were made in December 2009 due to a manufacturing error that could cause leakage from the battery.[2] This recall was terminated in August 2011.

Candidacy

Lyric is designed for mild to moderately severe hearing loss (**Fig. 4**). Candidacy for the Lyric device is dependent on good general health and absence of external ear disease or ongoing infectious middle ear disease. Other considerations include the size of the user's ear and the microbiology of the user's ear canal.[2] Individuals with uncontrolled diabetes, prior irradiation to the head and neck, immunodeficiency, age under 21 years, and/or those receiving anticoagulation therapy should be closely followed.[3] The Lyric is contraindicated in patients with TM perforations, chronic otorrhea, chronic ear infections, prominent osteoma or exostoses, pressure-equalizing tubes, or a history of cholesteatoma.

Design

There are 3 design aspects that enable the Lyric to be used for an extended time: (1) radial pressure on the skin of the canal, (2) breathability, and (3) placement. The device does not exceed the venous capillary pressure (20 mm Hg) by using a hydrophilic and flexible umbrella foam in order to allow for proper blood flow in the ear canal skin.[1] It uses open cell foam for moisture vapor transport as well as pressure equalization. Last, the device is ideally placed into the bony portion of the canal to prevent any effect on the sloughing of skin, to prevent irritation, and to reduce movement, all more likely in the cartilaginous portion of the canal. Of note, the device is water resistant but not waterproof, and therefore, the user is advised to avoid excessive water exposure, that is, swimming under water, but they may shower without ear protection.

Performance

Aesthetics and convenience are the prime motives for selecting a Lyric device. Lyric not only provides an individual the ability to "forget" about the repetitive insertion and removal of hearing devices but also eliminates the need to change batteries

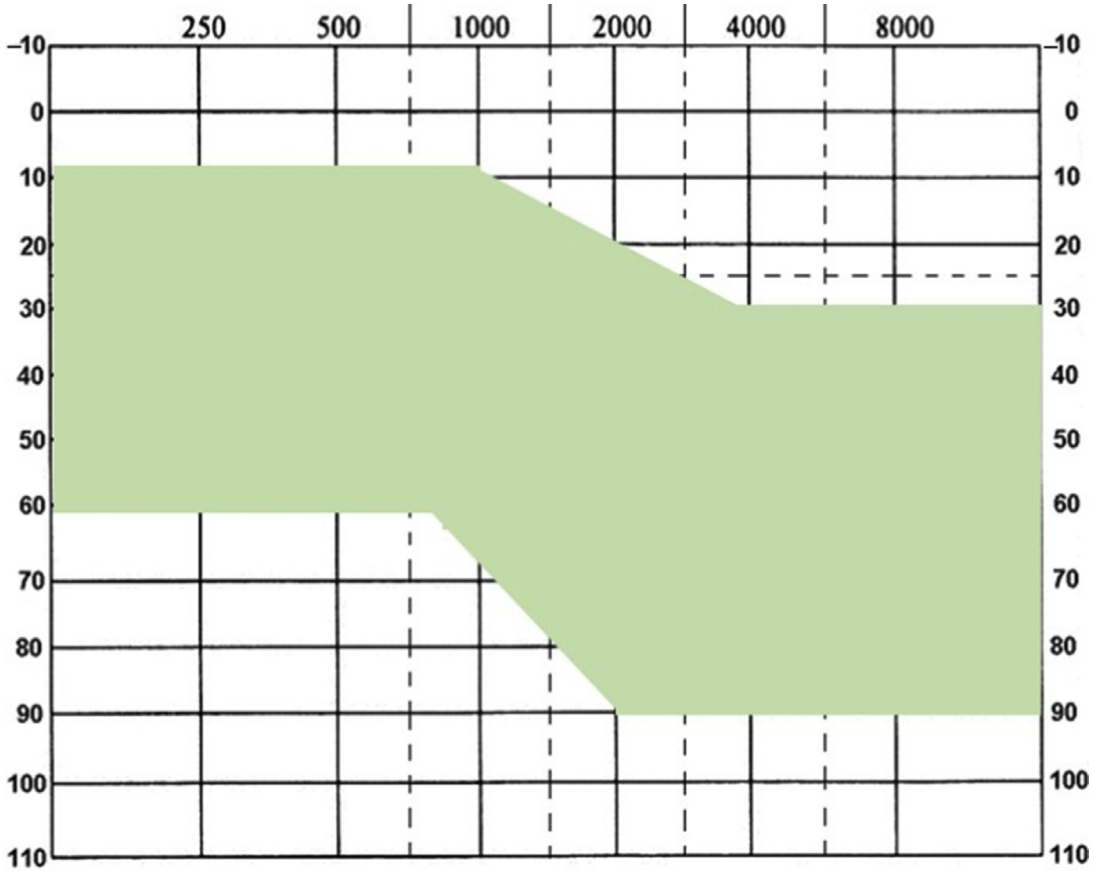

Fig. 4. Audiometric fitting range for Lyric. (*Courtesy of* Sonova USA Inc, Warrenville, IL.)

and provide wear and tear maintenance, including dehumidification, compared with conventional hearing instruments.

From an acoustical perspective, the amount of gain delivered by the Lyric device also differs from standard hearing aids. Typically, the further away from the TM the receiver is, the greater the amount of gain is required to correct an individual's hearing loss. Because the Lyric is closer to the TM, the gain required is not as great; this can reduce the risk of another common complaint of hearing aid wearers, feedback. In addition, the deep insertion of the Lyric device allows for the pinna to provide natural acoustic cues, such as aiding in localization.

Sound quality is an important aspect of all hearing devices. A field study sponsored by Phonak showed overall improvements in speech clarity, natural sound, and acceptance with Lyric 3 compared with Lyric 2.[4] These improvements in the Lyric 3 are related to the improved circuitry and phone use features.

The aesthetics of Lyric can have a positive psychosocial impact on the user. According to the manufacturer, compared with individuals who wear conventional air-conduction hearing aids, individuals wearing Lyric noted improvements in positive self-report.[5] Patient-reported improvements also included not having to worry about constant maintenance or tending to the device. In addition, the device sits securely in the ear, reducing the risk of losing the device, compared with traditional hearing aids.

Although Lyric is digitally programmable, it is an analog hearing aid. As such, there are limitations in terms of the digital signal processing that can be had. The analog components limit some of the desirable features found in other digital hearing aids,

such as ear-to-ear communication, which enhances localization ability, along with more technologically savvy perks, such as Bluetooth and other connectivity capabilities.

Safety

A small percentage of Lyric users present with ear complications in which the device should be removed to allow for healing and on occasion referral for otolaryngology evaluation and treatment. Most commonly seen are abrasions, bleeding, ulcers, and otitis externa. The complications tend to occur in the first 2 weeks of placement and are a result of traumatic insertion, sizing error, poor placement, or patient manipulation of the device. In addition, the patient is counseled by the dispensing audiologist that if the device "dies" in their ear canal, they are to use the provided extraction tool and remove the device immediately. A retained Lyric in the ear canal for a prolonged time may lead to infection. An article published by Phonak indicated there have not been any incidents reported to the Lyric Quality Systems team of more serious complications, such as persistent TM perforation, osteomyelitis, or stenosis.[1] A publication by Thompson and colleagues[3] reports a rare case of benign necrotizing otitis externa/external ear canal cholesteatoma that was seen after Lyric placement.

Summary

Considering the aesthetic advantage and reduced care routine, Lyric devices may be advantageous for specific populations. Individuals with mild to moderately severe hearing loss who have normal ear anatomy and no ear/general health contraindications could be considered for this device. The proximity to the TM enhances reported sound quality, makes use of the external ear anatomy for localization, and reduces the likelihood of acoustic feedback.

Despite the ease of use of Lyric, this device has some detriments that the practitioner and user should take into consideration before proceeding. Some areas not widely discussed in the literature include limitations related to analog signal processing, restricting certain activities while wearing Lyric (eg, underwater swimming is not recommended), and lack of access to connectivity solutions. Last, because it is removed and replaced at 3- to 4-month intervals or sooner, the long-term cost of this device may be greater than most conventional air-conduction hearing aids.

EARLENS

In 1996, Dr Rodney Perkins[6] introduced the Earlens as a new method of transmitting sound to the human ear. This original report introduced several new concepts, including the feasibility of placing a transducer directly on the TM for an extended period of time. It also addressed several of the recognized shortcomings of standard amplification, including feedback, occlusion effect, and sound quality. The initial system involved an electromagnetic "collar" worn around the neck. A commercially available, solely ear-based, FDA-approved device was introduced in 2016.

The system uses a light-activated microactuator in contact with the umbo portion of the TM (**Fig. 5**). The microactuator is supported in place by a ring-shaped platform that includes a light detector and sits in the annular sulcus of the TM. An open-fit ear canal light tip is connected to a behind-the-ear (BTE) photon processor. Sound is processed and communicated to the light tip, which converts it to an invisible light emission. The emitted light is detected by the photo detector on the TM lens, which converts it to mechanical movement of the actuator on the umbo, augmenting the natural auditory physiology. Direct umbo stimulation produces less acoustic feedback than traditional

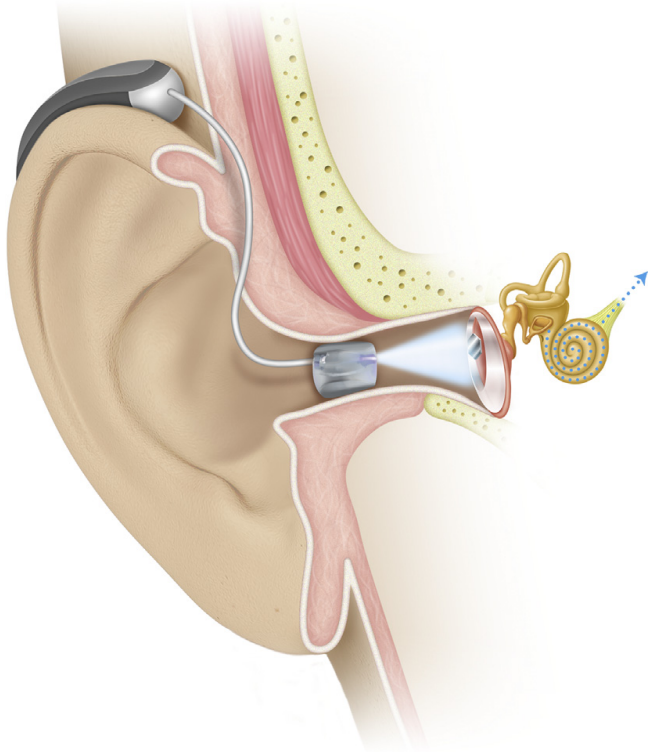

Fig. 5. Graphic of Earlens system in place. (*Courtesy of* Earlens Co, Menlo Park, CA.)

acoustic amplification at equivalent frequency amplitudes and leads to enhanced high-frequency gains (125–10,000 Hz) without feedback.[7]

Candidacy

Individuals with mild to severe hearing loss can be considered for Earlens fitting (**Fig. 6**). The ear canal must accommodate lens insertion, eliminating individuals with narrow canals or exostoses. An intact TM is required. This device has not been used in individuals who have a history of middle ear disease or prior ear surgery.

Design

Earlens consists of 3 main components: the *BTE Photon Processor*, which is connected to the ear canal; the *Light Tip*, which communicates wirelessly with the *Tympanic Lens* (**Fig. 7**). The lens is custom made according to the patient's anatomy, based on deep ear canal impressions. The lens consists of a platform that conforms to the patient's tympanic sulcus. A coating of mineral oil and the lens' customized shape keep it in position. Its open design and layer of oil allow for natural egress of epithelium and keratin.

The lens is constructed of a form-fitting perimeter platform that conforms to the annular sulcus. It also supports the moving parts that transmit the signal at the umbo platform.

Impressions

Deep ear canal impressions required for Earlens fitting may be new to the dispensing audiologist or hearing instrument specialist, because there is no foam otoblock between the impression mold and the TM. Given that the impression includes the TM surface, it is the otolaryngologist who is appropriately equipped for this procedure. Microscopic and endoscopic views of the medial ear canal and annular sulcus are

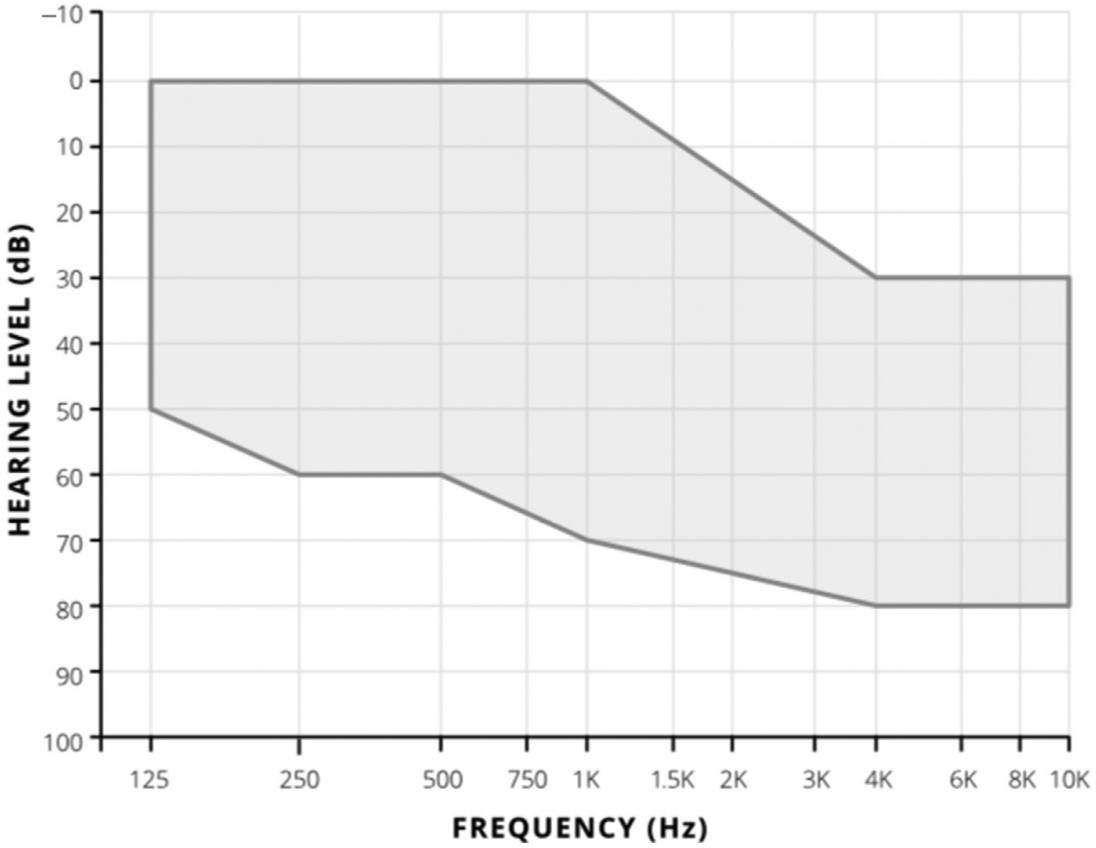

Fig. 6. Audiometric fitting range for Earlens. (*Courtesy of* Earlens Co, Menlo Park, CA.)

important to obtaining the optimal fit. Under microscopic guidance, and with familiar instrumentation, the otolaryngologist can comfortably work at the TM surface without adverse event.

The impression procedure uses 2 impression materials separated in time and patient position. A low-viscosity deep impression of the TM and bony ear canal is completed as the patient is in the supine position. A successive higher-viscosity impression of the lateral ear canal and conchal area is done in the sitting position. After the cure time is completed, the composite impression is mobilized and removed by hand. No anesthesia is required. At the moment that the impression breaks its seal with the TM/ear canal, there may be brief discomfort. This procedure takes approximately 15 minutes for each ear and generally is tolerated well.

Impressions are used to build a custom-fit lens and light tip and to assure proper alignment of the 2.

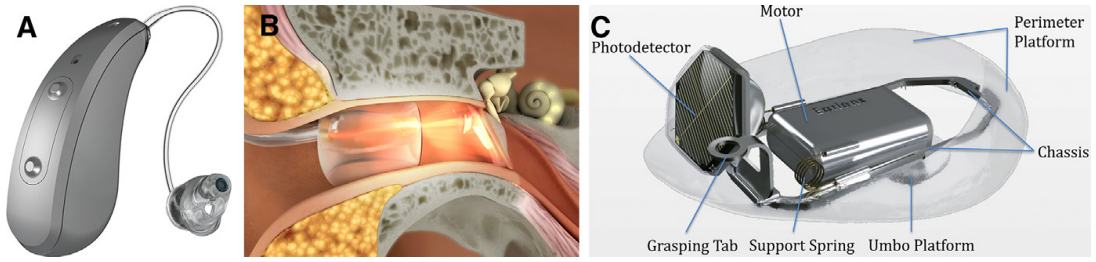

Fig. 7. Components of Earlens system: (*A*) photon processor, (*B*) light tip in the ear canal, (*C*) lens. (*Courtesy of* EarLens Corporation, Menlo Park, CA.)

Insertion

Once the customized lens and light tip/processor are available, the otolaryngologist places the lens onto the TM (**Fig. 8**, Video 1). Thorough ear canal cleaning and application of a thin layer of mineral oil must be completed before lens placement. Lens placement is a brief office-based procedure that is followed immediately by audiologic programming to provide same-day fitting and initial use.

Programming

Initial programming

In general, Earlens programming is similar in workflow to that of a traditional hearing aid. The first step in programming an Earlens device is entering the audiogram into "ELF," the proprietary software. Step 2 requires connection of the photon processor to a wired programming bridge called "HI-PRO 2." Step 3 is detection of the device followed by a light calibration and feedback test. Light calibration is similar to an audiogram (patient responds to the softest audible pure tone) from 0.125 to 10 kHz. After light calibration, the feedback test eliminates any possibility of acoustic feedback. In the final step, step 4, the data are saved to the photon processor and the aids are disconnected from the HI-PRO 2 cables.

There are exceptions to the rules above. After step 3, if a patient is uncomfortable with the sound quality, the audiologist may adjust multiple parameters (including but not limited to pitch, maximum equivalent pressure output [MEPO], expansion, manual volume control, and listening algorithms). After all sound quality–related concerns are addressed, the devices are paired via low-energy Bluetooth with the patient's cell phone (currently only available on Apple products). This pairing allows for the patient to customize their listening experience while seamlessly streaming phone calls, music, and other audio.

First follow-up

The patient returns 1 week after their initial fitting. During this appointment, the audiologist addresses any patient questions or concerns. Otoscopy is completed to verify proper lens position. Last, the patient is tested functionally in a sound-treated booth with narrowband noise from 125 Hz to 10 kHz in the sound field. If any frequency response is more than 25 dB HL (hearing level), the devices are reprogrammed to be slightly louder at those specific frequencies.

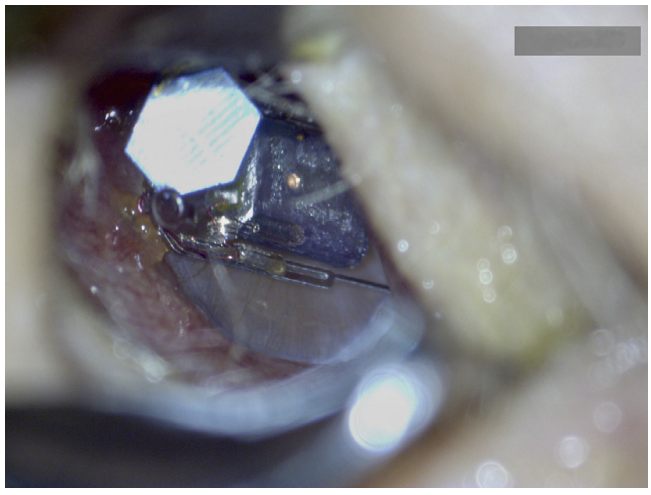

Fig. 8. Lens in situ on the TM. (*Courtesy of* Neil M. Sperling, MD, New York, NY.)

Subsequent follow-up

When all patient concerns have been addressed and hearing thresholds have been verified to be 25 dB or better from 0.125 to 10 kHz, the patient returns to clinic every 3 months (4 times per year) for verification of lens placement and professional cleaning of the light tip. The visit generally includes evaluation by the audiologist and otolaryngologist. The patient is encouraged to return if there are any issues between this time interval.

Performance

Data from the preliminary studies of Earlens revealed favorable safety measures and outcomes. Outcome measures included maximum outputs of 90 to 110 dB for frequencies up to 10 kHz, and maximal stable gain before feedback of more than 40 dB even at higher frequencies with a widely vented ear canal.[8,9] In general, studies on feedback of traditional amplification indicate the presence of feedback at far lower inputs.

Earlens delivers output to much higher frequencies than current hearing aids. At lower frequencies, Earlens MEPO would be comparable to traditional amplification less than 5500 Hz except that Earlens also adds an extension of low-frequency amplification to 125 Hz, whereas traditional amplification does not typically go below 500 Hz.

TM damping was the measured effect of the lens on hearing without amplification. The mean overall TM damping across all frequencies was 4.1 dB. A slight fullness in the ear is commonly reported with the lens in place but is not noticed when the device is active.

MEPO is a measure of output at the point of contact with the TM that corresponds to the maximum pressure outputs of an acoustic hearing aid. MEPO is used as a measure of maximal output of an Earlens device. Maximum outputs for Earlens, as measured in a 2016 temporal bone study, were 120 to 136 dB sound pressure level.[9]

From the clinical study published in 2017, impressive outcome measures include average word recognition improvement of 33% compared with unaided condition, an average functional gain of 30 dB from 2 to 10 Hz, and maximal functional gain of 68 dB at 9 and 10 kHz.[7]

These findings imply significant benefit to patients with hearing loss, including those who would otherwise be considered poor traditional hearing aid candidates.

As noted in Gantz and colleagues,[7] the functional gains achieved with Earlens compares favorably with some implanted devices and exceeds them at high frequencies.

Maintenance

The Earlens system requires patient maintenance, including instillation of oil in the ear several times per week. The oil maintains a layer between the lens and TM, allowing epithelial migration to continue uninterrupted. The lens is designed to remain in place for months to years.

Safety

Only mild temporary adverse effects from this system have been reported and included ear canal discomfort, abrasion, or swelling. In the safety study published in 2017, all such effects resolved except for ear fullness that was reported in 1 of 41 patients.[7] TM injury has not been reported. None of the reported adverse events were considered serious.

Summary

Earlens appears to be a significant advance in hearing technology. The physics of light energy in the ear canal avoids some of the limitations of acoustically based

amplification. The extension of functional gain to low and high frequencies enhances subjective sound quality. This extension of audible frequencies is likely to add clarity and enhance hearing in noise. The available data are promising. Long-term data are not yet available.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at https://doi.org/10.1016/j.otc.2018.11.003.

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