

Laura Street

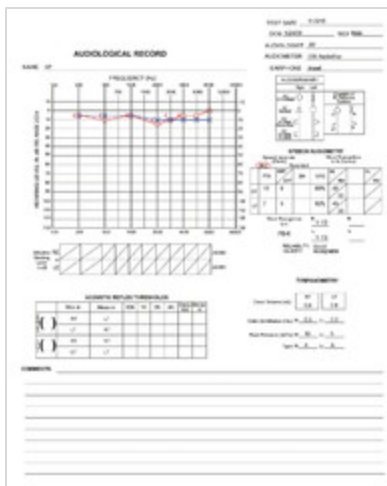
## Clinical History and Description

This case reviews test procedures and treatment options for a patient with bilateral symmetrical high-frequency sensorineural hearing loss (SNHL). Challenges that may interfere with the effective restoration of high-frequency speech cues are also discussed.

FY is a 77-year-old male who volunteered to participate in a pilot study conducted by a privately held company. The study's protocol was approved by the Western Institutional Review Board and informed consent was obtained prior to participation. At his initial visit, FY reported bilateral hearing loss for at least 20 years due to the cumulative effects of aging and noise exposure. He stated he is a retired hardware engineer with previous exposure to greater than 10 years of low- to moderate-level machine noise without the use of hearing protection. He denied otalgia, aural fullness, tinnitus, and vertigo. His medical history was negative for known familial hearing loss, rapidly progressive and/or fluctuating hearing loss, ototoxic drug exposure, frequent middle ear infections, ear surgery, head trauma, and stroke.

## Audiological Testing

After taking a case history, audiometric and immittance data were obtained ([Fig. 1](#)) to determine if FY met the inclusion criteria for the study. Pure-tone testing revealed normal hearing at 125 Hz to 500 Hz sloping to a moderate SNHL at 750 to 1,000 Hz and then sloping to a severe SNHL at 1,500 to 8,000 Hz. Speech Reception Thresholds (SRTs) revealed a bilateral mild loss in the ability to receive speech and agreed with the two-frequency pure-tone average (PTA). Word Recognition Scores (WRS) indicated slight difficulty to recognize speech in the right ear and moderate difficulty in the left ear. Tympanometry was consistent with normal middle ear function bilaterally. The absent ipsilateral Acoustic Reflex Threshold (ART) at 2,000 and 4,000 Hz agreed with the patient's magnitude of hearing loss. Neither contralateral ARTs nor acoustic reflex decay could be assessed due to limitations with the equipment.



**Fig. 1** Audiometric results. Sennheiser 200 HDA circumaural headphones were used to assess thresholds at 10,000 Hz and the thresholds at 12,000 Hz were actually thresholds obtained at 10,000 Hz.

In terms of amplification history, FY reported bilateral hearing aid use for the past four years with his current devices being a pair of basic open-fit, Receiver-In-the-Canal (RIC) hearing aids. Although FY reported overall satisfaction with his hearing aids, he wished he could follow conversations with his wife and daughter better without having to ask them to repeat themselves so often. He also reported that the clarity of soft speech was degraded. When asked about his device coupling, FY reported that his audiologist originally recommended a closed fitting, but an open-fit device was selected because he responded negatively to the occlusion associated with a closed fitting.

## Questions to the Reader

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- 1. What type of pathophysiology is generally associated with severe-to-profound SNHL and how might one better diagnose its presence in the cochlea?**
- 2. Since the most common complaint associated with SNHL is difficulty hearing in noise, what additional testing might further improve the treatment selection process?**

## Discussion of Questions

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- 1. 1. What type of pathophysiology is generally associated with severe-to-profound SNHL and how might one better diagnose its presence in the cochlea?**

Severe-to-profound SNHL is generally associated with dead regions or clusters of sensory cells that are no longer functional within the cochlea. This means that the absolute thresholds obtained for patients with one or more dead regions may not reflect the true degree of hearing loss if off-place listening is not suppressed. To review, a pure-tone elicits a response at a normal or characteristic place along the basilar membrane in a normal-hearing ear. This characteristic place then corresponds to a specific frequency response in the brain. In a severely hearing-impaired ear, a tone's place of maximal stimulation may not be situated at its normal place, but at a different place due to the presence of a dead region. Off-place listening occurs whenever the normal place for a specific tone falls within a dead region, and the tone, when made sufficiently loud, elicits a response from functional sensory cells at a different yet nearby place along the basilar membrane. By presenting a broadband masker, the responses of functional sensory cells outside of a dead region can be masked and off-place listening suppressed.<sup>1</sup> Thus, the audiogram—in combination with a test that utilizes a broadband masker—can be used to help predict which regions of the cochlea are the most amenable to amplification. The Threshold Equalization Noise (TEN) test is one test that was specifically developed for this purpose.<sup>2</sup>

The TEN test prevents off-place listening through the presentation of broadband noise that produces nearly equal masked thresholds between 250 and 10,000 Hz in listeners that, based on the findings of psychophysical tuning curves, lack dead regions. If a patient presents with a dead region, the TEN masked threshold(s) corresponding to the affected frequency range will be significantly higher than expected. As such, clinicians should consider the TEN test whenever patients present with audiometric thresholds 40 to 50 dB hearing level (HL) as this population will have dead regions at least 29% of the time, particularly if the patients exhibit a rising configuration or severe-to-profound hearing thresholds.<sup>1, 3</sup> For patients with hearing thresholds better than 40 to 50 dB HL, performing the TEN test is likely superfluous as there is generally minimal to no inner hair cell dysfunction associated with lesser degrees of SNHL. Notable exceptions to this trend include neural and central hearing losses where thresholds may be normal to profound despite the existence of healthy, functional inner hair cells.

- 1. 2. Since the most common complaint associated with SNHL is difficulty hearing in noise, what additional testing might further improve the treatment selection process?**

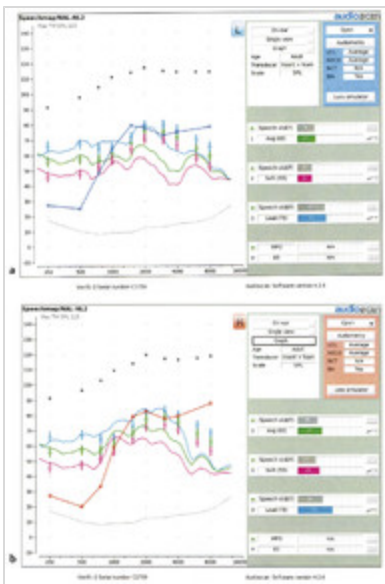
Speech-in-noise (SIN) testing addresses the most common complaint among patients with SNHL. As such, SIN testing can be used to verify difficulty hearing in noise as well as to better inform the treatment selection process. Clinically, there are several SIN tests to choose from. Some of these tests include the Bamford–Kowal–Bench (BKB) SIN test,<sup>4</sup> the Connected Speech Test (CST),<sup>5</sup> the Hearing In Noise Test (HINT),<sup>6</sup> and the QuickSIN test.<sup>7</sup> When selecting a SIN test, the clinician must consider the overall speed and ease of administering the test given few reimbursement options, the representativeness of the test compared to real-world listening situations, and the perceived difficulty of the test in relation to possible floor and ceiling effects.<sup>8</sup> In other words, the test should be sensitive enough to separate the performance of individuals with normal hearing ability in noise from those with varying degrees of

hearing difficulty in noise. The difficulty of the test should also be such that individuals cannot frequently respond with all correct or all incorrect responses. Depending on a patient's performance, the clinician may choose to give priority to devices equipped with remote microphone and/or Frequency Modulation (FM) system compatibility.

## Additional Testing

As part of the study protocol, the clinician completed the TEN test and results suggested high-frequency dead regions at 8,000 and 10,000 Hz for each ear. These results were of interest as FY was participating in a sound-quality pilot study where he would compare the performance of two pairs of devices—his current open-fit hearing aids and a new set of extended bandwidth hearing aids. If pervasive dead regions were present, FY might not have been able to effectively utilize the additional frequency components supplied by a wider bandwidth.

Next, the clinician completed real-ear measures with FY's open-fit hearing aids. [Fig. 2](#) represents the Real-Ear Aided Responses (REARs) for soft (55 dB sound pressure level [SPL]), average (65 dB SPL), and loud (75 dB SPL) speech inputs displayed as pink, green, and blue lines, respectively, with a clear roll-off in the frequency response observed beyond 4,000 Hz. When compared to NAL-NL2 (National Acoustics Laboratories' Nonlinear Fitting Procedure, version 2) targets for soft speech (pink crosses), average speech (green crosses), and loud speech (blue crosses), the targets are undershot and mostly inaudible between 2,000 and 8,000 Hz for the right ear and between 1,500 and 8,000 Hz for the left ear. Even when NAL-NL2 targets are corrected for binaural summation effects,<sup>9, 10</sup> these findings are not altogether unexpected as moderately severe to severe high-frequency SNHL cannot be optimally treated with open domes. Since FY's low-frequency thresholds are essentially normal through 500 Hz, FY's open-fit hearing aids are likely providing benefit only at 750 and 1,000 Hz. The poor speech intelligibility index (SII) values reported in [Fig. 2](#) represented by the numbers in the pink, green, and blue bars further support this conclusion. Although not displayed in [Fig. 2](#), the Maximum Power Output (MPO) of the hearing aids was also measured and found to be below the patient's predicted Uncomfortable Loudness Levels (UCLs). SIN results will be discussed later.



**Fig. 2** Real-ear aided response (REAR) measures for soft (pink; 55 dB SPL), average (green; 65 dB SPL), and loud (blue; 75 dB SPL) speech using the patient's (a) left and (b) right open-fit hearing aids.

Following completion of real-ear measures, FY's user settings were not adjusted or "optimized" for three reasons. First, the obtained measures seemed consistent with open-fit devices being used to treat moderately severe to severe high-frequency SNHL. As most hearing aid manufacturers report, the fitting range for open domes typically bottoms out between 60 and 70 dB HL. Second, patients

with steeply sloping SNHL are generally considered a difficult population to fit given the need for significant high-frequency amplification without the bothersome occlusion introduced by a closed fitting. Thus, how one defines an “optimized” fitting for this patient population is likely controversial even with additional patient counseling and changes to the hearing aid programming. Third, one goal of this pilot study was to identify which audiometric configurations and patient populations might be most well suited to receive benefit from the proposed intervention. A repeat study will likely take place in the future including a fitting optimization period with the patients’ own acoustic hearing aids prior to treatment.

## Additional Questions to the Reader

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1. **What are some potential reasons why the TEN test has not been more widely adopted in the clinic?**
2. **How are the test stimuli used for many current SIN tests spectrally limited, and are there any new SIN tests that can assess the benefit of extended high-frequency hearing aids in noise?**

## Discussion of Additional Questions

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1. **1. What are some potential reasons why the TEN test has not been more widely adopted in the clinic?**

Given the potential utility of the TEN test to diagnose dead regions, one might ask why its use has not been more widely adopted in the clinic. Some of the arguments presented against using the TEN test include the following<sup>1, 11</sup>:

The original TEN test—called the TEN(SPL) test—is difficult and time consuming to administer because the test stimuli were calibrated in dB SPL rather than dB HL. This means that the clinician must first measure the patient’s audiometric thresholds in dB SPL and then administer the TEN test knowing that the presentation levels listed on the audiometer require a correction factor.

The more recent TEN(HL) test eliminates many of the calibration issues associated with the original, but uses a broadband noise that is limited between 354 and 6,000 Hz. This is useful for reducing distortion and maintaining patient comfort at elevated test levels, but limiting for identifying dead regions beyond 4,000 Hz. Given that high-frequency SNHL is the most common audiometric configuration, this change is a little counterintuitive unless one believes that providing amplification beyond 4,000 Hz is not overly beneficial (as one might argue using one or more frequency importance functions) or even realistically possible (as is generally the case with open-fit hearing aids).

A dead region cannot be confirmed diagnostically if an absolute or masked threshold is unobtainable due to the severity of the hearing loss or patient sound tolerance issues. Fortunately, if patient thresholds cannot be measured due to the former reason, the likelihood of a dead region is high given the degree of SNHL.

The validity of the TEN test has been questioned by some researchers who have assessed the agreement between the findings of psychophysical tuning curves (PTCs) and the TEN test.<sup>12</sup> Although PTCs are the current “gold standard” for diagnosing dead regions in humans, they are not without error, and false negatives resulting from beats or combination tones may account for the reported discrepancy.<sup>1</sup>

As is the case for many audiological services, reimbursement for completing the TEN test is lacking.

Finally, although the TEN test can be used to better understand the pathophysiology of high-frequency SNHL, its administration is not necessarily required to treat or counsel patients with high-frequency SNHL. Research has shown that patients with suspected dead regions have elevated pure-tone thresholds and poorer than predicted performance on speech measures in quiet and noise.<sup>3</sup> This confirms that the presence of a dead region does not alter a clinician’s decision to treat patients with high-frequency SNHL but rather perhaps how to treat patients with high-frequency SNHL.

1. **2. How are the test stimuli used for many current SIN tests spectrally limited, and are there any new SIN tests that can assess the benefit of extended high-frequency hearing aids in noise?**

One limitation of many current SIN tests is that spectral energy above 8,000 Hz is not available to the listener. This means that clinicians and researchers are restricted in their ability to verify manufacturer claims regarding extended-bandwidth hearing aid benefit in noise. Although not yet commercially available, a new version of the HINT, the hearing in speech test (HIST),<sup>13</sup> was recently developed to include high-frequency information through 20,000 Hz. Professionals interested in obtaining a copy of the HIST should contact Earlens Corporation for additional details.

The HIST employs the same adaptive test protocol as the HINT, but with re-recorded test tokens, novel masking signals, and two spatial test configurations. Rather than presenting target sentences and speech-shaped noise from 0 degrees azimuth, the HIST assesses performance either in diffuse noise (i.e., target sentences presented from 0 degrees azimuth and four maskers presented from  $\pm 45$  and  $\pm 135$  degrees azimuth) or while utilizing the head shadow effect (i.e., target sentences presented from  $-45$  degrees azimuth and two collocated maskers presented from  $+45$  degrees azimuth). Each masking signal is a recording of a different male speaker reading the Rainbow passage<sup>14</sup>, <sup>15</sup> and the Television passage.<sup>16</sup> These protocol changes to the HINT were designed to make the HIST more representative of a real-world listening environment.

The diffuse noise condition of the HIST shares some similarities with the HINT when combined with the R-SPACE simulation.<sup>17</sup>, <sup>18</sup> For those unfamiliar with the R-SPACE simulation, uncorrelated restaurant noise is produced via eight loudspeakers set 45 degrees apart in a circular array. The HINT stimuli are then presented from the front at 0 degrees azimuth with the patient seated in the middle of the array. As such, the HIST and the R-SPACE simulations are similar because they both utilize a complex array of loudspeakers as well as real speech maskers. They are different, however, because the HIST neither presents a masker from 0 degrees azimuth nor utilizes stimuli spectrally limited above 8,000 Hz. This latter characteristic is what makes the HIST especially suited to testing hearing aids with advertised bandwidths beyond 4,000 or 6,000 Hz.

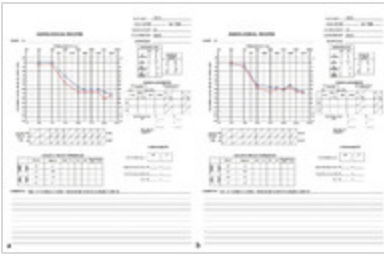
The HIST is completed in approximately 10 to 15 minutes and then a reception threshold for sentences (RTS in dB) is calculated for each spatial condition. These values represent the speech-in-noise ratios (SNRs) required to repeat 50% of the target sentences correctly in noise. More negative RTS values represent better performance in noise; more positive RTS values represent poorer performance in noise. To assist the clinician to interpret the test data, normative values have been developed and the test has been validated against the HINT using 24 normal-hearing listeners. When the HIST was completed on 25 participants with mild-to-severe SNHL, the participants' average RTS value improved significantly by 1.3 dB when a simulated hearing aid bandwidth was extended to 10,000 Hz and the participants were permitted to utilize the head shadow effect. This finding suggested that the participants could experience as much as an 11.6% ( $1.3 \text{ dB} \times 8.9\% \text{ per dB}^{19}$ ) improvement in sentence recognition under these conditions. A nonsignificant SNR improvement of 0.5 dB was then observed for the diffuse condition when extending the simulated hearing aid bandwidth.

## Additional Testing

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The clinician performed HIST testing after verifying that FY's hearing aids had a directional response in the Audioscan Verifit 2. Upon completing the HIST, the computer produced an RTS value of  $+3.0$  dB for FY. This finding indicated that FY needed the speech signal to be 3.0 dB louder than the noise for FY to correctly repeat 50% of the sentences while wearing his directional hearing aids and utilizing the head shadow effect. Under the same conditions, 24 normal-hearing listeners without hearing aids achieved a mean RTS value and standard deviation of  $-4.9 \pm 1.26$  dB. As such, FY's performance with open-fit hearing aids was significantly poorer than that of normal-hearing listeners. Lack of audibility above 1,000 Hz, a reduced directional response with open-fit hearing aids,<sup>20</sup> and an impaired ability to differentiate between speech and noise due to hearing loss likely contributed to FY's performance.

While somewhat unconventional for verifying hearing aid fittings today, functional gain (FG) was assessed by measuring FY's unaided and aided sound-field thresholds. These data are presented in [Fig. 3](#), with "O" symbols representing the unaided responses and "X" symbols representing the aided responses for each ear. Sound-field threshold testing was completed with the non-test ear plugged and a loudspeaker positioned at 0 degrees azimuth 1 m from the patient at ear level in a sound booth. When comparing unaided and aided sound-field thresholds, an improvement of 15 dB HL was noted for FY at 1,000 Hz for the right ear only. This finding agreed with the real-ear measures obtained earlier.



**Fig. 3 (a)** Right ear. **(b)** Left ear. Unaided and aided sound-field thresholds indicating little to no significant benefit in the high frequencies with FY's acoustic hearing aids. Thresholds at 750 and 1,500 Hz were not measured because testing at these frequencies was not part of the study protocol despite the patient's sloping configuration. A standing wave may have affected the right unaided threshold at 8,000 Hz. The 12,000 Hz thresholds were actually thresholds measured at 10,000 Hz. O, unaided sound-field threshold; X, aided sound-field threshold.

FG is the difference between a patient's unaided and aided sound-field thresholds. Many clinicians use FG measures to help verify cochlear implants, middle ear implants, and bone-anchored hearing aids (i.e., devices that cannot be verified via real-ear measures). FG measures are less likely to be used today to verify hearing aid performance because the validity and reliability of FG measures can be compromised more easily than real-ear measures. Some of the ways in which the data from sound-field threshold testing, and therefore FG measures, can be contaminated include the following<sup>21, 22, 23, 24, 25</sup>:

- Incorrectly assuming that unaided thresholds obtained under headphones are equivalent to those obtained by various loudspeaker arrays in the sound field.

- Conducting testing in a sound booth that has not been acoustically treated in the proper manner (i.e., not all sound booth surfaces were acoustically treated with sound absorbing tile, foam, and/or carpeting, and unnecessary equipment was kept in the test booth).

- Using test stimuli more susceptible to standing waves particularly in the reverberant field where both direct and reflected sound sources exist (e.g., using pure tones instead of frequency-modulated (FM) tones or warble tones).

- Presenting test stimuli at high intensity levels without proper ipsilateral or contralateral masking can cause:

- The test loudspeaker or hearing aid transducer to saturate and produce distortion.

- The plugged non-test ear to respond in patients with asymmetrical hearing loss.

- Off-place listening to occur in patients with dead regions.

- Using a test loudspeaker other than the one utilized for calibration via the substitution method (e.g., using of the 90 degree azimuth loudspeaker rather than 0 degree azimuth loudspeaker as was previously calibrated).

- Allowing the patient to adjust the hearing aid settings or move away from the precalibrated test position in the reverberant field (i.e., changing the distance, height, or angle of the patient's ear in relation to the designated test position).

- Failing to eliminate the presence of low-level noise from the hearing aid circuit or in the test environment that can mask the stimuli for listeners with normal hearing or mild low-frequency hearing loss.

- Ignoring the effects that hearing aid compression characteristics can have on stimulus presentation levels (e.g., nonlinear hearing aids generally provide more gain to soft-level inputs and less gain to high-level inputs albeit differently across manufacturers relative to their time constants and compression thresholds).

Although issues related to calibration and data contamination are potentially significant, careful measures can yield useful results. For example, in FY's case, FG measures supported conclusions drawn from real-ear measures.

## Diagnosis and Treatment

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Pure-tone testing and immittance findings for FY were consistent with bilateral symmetrical high-frequency SNHL likely related to the cumulative effects of aging and noise exposure. Real-ear measures and HIST results further suggested that FY could receive additional benefit from hearing aids if he could tolerate the high-frequency amplification. The TEN test indicated that FY could likely use high-frequency speech cues at least through 6,000 Hz. Since FY was previously unsuccessful with closed-fit air conduction hearing aids and since he met the inclusion criteria for a paired-comparison pilot study, FY was fitted with Earlens hearing aids bilaterally.

## Additional Questions to the Reader

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1. **What treatment options are available for patients with high-frequency SNHL and what are some of the advantages and disadvantages of each option?**
2. **What are the major components and features of the Earlens hearing aid?**
3. **What are the advantages and disadvantages of the Earlens?**
4. **How does a clinician verify the performance of the Earlens without using real-ear probe tube microphone measures?**

## Discussion of Additional Questions

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1. **1. What treatment options are available for patients with high-frequency SNHL and what are some of the advantages and disadvantages of each option?**

Closed-fit hearing aids, open-fit hearing aids, frequency-lowering technology, hybrid cochlear implants, and hearing assistive technology (HAT) have all been proposed as possible treatment options for high-frequency SNHL. The advantages and disadvantages of each of these options are briefly summarized below:

Hearing aids with a custom earmold or custom shell are closed-fit devices if the vent is sufficiently narrow. RIC and slim-tube hearing aids with closed or double domes can also be viewed as closed-fit devices, but domes are generally more comfortable, less capable of providing retention in the ear canal, less suitable for providing high-frequency gain, and less successful at preventing feedback oscillation compared to custom earmolds. Regardless of the coupling, the greatest disadvantage of a closed fitting is the potential for patient discomfort. For example, custom earmolds and shells can cause discomfort particularly if they are seated deeply in the ear canal. Also, closed-fit hearing aids can result in bothersome occlusion particularly if the patient has normal or near-normal low-frequency thresholds. While custom earmolds or shells can be modified or remade until a comfortable fit is achieved, occlusion can only be “solved” by counseling the patient or compromising the fit by resorting to a more open vent or ordering a new earmold or shell that resides deeper in the ear canal.

Open-fit devices are those employing an earmold, a custom shell, or a dome with the maximum vent size possible. The advantages and disadvantages of an open fitting are essentially the reverse of those for a closed fitting. Open-fit devices generally are more comfortable and provide less occlusion at the cost of significant gain and acoustic feedback prevention. As such, digital feedback cancellation will likely need to be enabled for almost any open-fit acoustic hearing aid. Additional drawbacks to open-fit devices include a reduced directional response<sup>20</sup> and poorer streaming performance due to increased leakage of amplified low-frequency signals out of the ear canal.

Hearing aids with frequency-lowering technology are sometimes recommended for patients when high-frequency information is unavailable due to the existence of cochlear dead regions, a hearing aid’s inability to restore high-frequency audibility, or a patient’s intolerance of high-frequency amplification. To overcome one or more of these issues, frequency-lowering technology alters the spectral content of the input signal so that all or part of the output signal is presented to a lower frequency region in the cochlea. In short, the potential advantage of frequency lowering is the ability to “extend” a patient’s usable bandwidth by exploiting his or her residual low-frequency hearing. Hearing aids with frequency-lowering technology typically use one of two approaches: frequency transposition or frequency compression. Devices with frequency transposition present high-frequency information as though it is lower in frequency by a fixed amount. For example, if frequencies above 3,000 Hz are shifted down by 1,000 Hz, a 4,000 Hz signal would be presented as a 3,000 Hz signal, a 6,000 Hz signal would be presented as a 5,000 Hz signal, etc. While this is one way to ensure that patients have access to high-frequency speech cues, sound quality and speech clarity are negatively affected when the high frequencies are transposed into mid-frequency bands that are already occupied by other frequencies. For instance, vowel formants and nasal antiformants may be masked by transposed high-frequency information. In the above example, overlapping frequency components could theoretically occur between 2,000 and 3,000 Hz. Frequency compression is related to frequency transposition in that frequencies are transposed not by a fixed amount, but by a fixed ratio. For instance, if frequencies above 3,000 Hz are compressed at a ratio of 2:1, a 4,000 Hz signal would be presented as a 3,500 Hz signal, a 6,000 Hz signal would be presented as a 4,500 Hz signal, etc. Frequency compression is advantageous in that high-frequency information is made accessible without the need to overlap frequency bands. Undesirable effects can occur, however, if a large frequency compression ratio is selected or if frequency compression is applied below 1,500 Hz where pitch cues reside. At present, evidence-based recommendations for how and when to utilize frequency-lowering technology (if at all) are lacking as each manufacturer uses its own method, and research examining the effects of various frequency-lowering parameters (e.g., the frequency at which frequency lowering should start, the compression ratio, etc.) is sparse. Of the studies that have been conducted thus far, frequency lowering appears to be advantageous for some patients in quiet so long as frequency lowering is not applied below 1,500 Hz, the transposition shift or compression ratio is not overly large, and/or the hearing loss is not steeply sloping. While many clinicians verify that the phonemes /s/ and // are audible with frequency lowering, it is important to ensure that other phonemes are not negatively impacted at the same time.<sup>26, 27</sup>

The term *hybrid cochlear implant* is used to describe a configuration where a cochlear implant (CI, hereafter) and a hearing aid are worn on the same ear. The CI provides high-frequency information via electrical stimulation, and the hearing aid provides low-frequency information via acoustic stimulation. At present, the crossover frequency (or frequencies) where it is best to transition from acoustic to electrical stimulation has not been well defined, but it may be worthwhile to begin providing electrical stimulation to frequencies presenting with dead regions. Given the method of signal transmission, a hybrid fitting is generally recommended for patients with steeply sloping high-frequency SNHL (i.e., patients with several “unaidable” high-frequency thresholds). The benefit of utilizing a hybrid system is that the CI and the hearing aid can provide more information together than would be possible with each device alone. For instance, studies evaluating speech perception in quiet and noise have



found that a patient will oftentimes perform significantly better with a hybrid system than a CI or a hearing aid individually. In this way, a hybrid system can be thought of as a device providing the “best of both worlds” for patients with steeply sloping hearing loss—the CI provides the “unaidable” high-frequency information and a hearing aid provides the aidable low-frequency information.

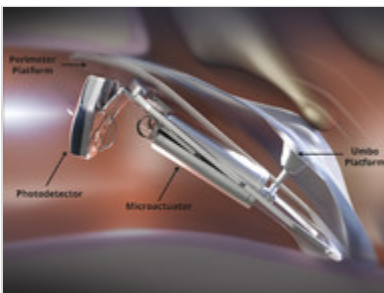
As one might expect, the drawback to utilizing a hybrid system is that it requires an invasive surgery that carries its own risks. For example, low-frequency hearing may not be preserved postoperatively due to cochlear trauma. Low-frequency hearing may also degrade gradually or even spontaneously years later. According to a recent review article, 24 dB HL was the mean low-frequency PTA shift for 26 patients 6 months after implantation with a short electrode array.<sup>28</sup> When low-frequency hearing is reduced following cochlear implantation, it can have important implications for the hearing aid benefit achieved in the implanted ear. Once again, as is the case for many audiological services, insurance coverage and payment options for fitting hybrid devices and providing aural rehabilitation are limited.

Finally, since patients with high-frequency SNHL oftentimes present with difficulties hearing in noise, FM systems or remote microphones using the 2.4-GHz wireless band may prove helpful. FM systems and remote microphones are advantageous in that they improve the SNR by effectively reducing the distance that exists between the speaker and the hearing aid user. Although an FM system can improve the SNR by as much as 25 dB,<sup>29</sup> patients may find hearing aid accessories aesthetically unappealing and/or cumbersome to use in addition to their hearing aids.

## 1. 2. What are the major components and features of the Earlens?

The Earlens hearing aid<sup>30</sup> is a new device for treating mild-to-severe SNHL and has received approval from the FDA (Food and Drug Administration) in 2015 and experienced a limited commercial release in 2016. It is priced competitively with high-end acoustic hearing aids and is composed of a peritympanic transducer, a behind-the-ear (BTE) hearing aid, a laser diode, and a battery charging station. The Earlens is a novel device that mechanically drives the tympanic membrane via a transducer placed deeply in the ear canal by an otologist or otolaryngologist.

The *tympanic lens* or the *tympanic membrane transducer (TMT)* consists of a tiny circular surface that contacts the umbo of the tympanic membrane, a microactuator that drives the system, and a photodetector that collects light to power the system. [Fig. 4](#) illustrates the major components of the lens. To prevent lens extrusion with long-term wear, a parylene-coated perimeter platform and a small chassis with compression springs are customized to fit each patient’s anatomy and to allow the tympanic membrane to move normally with breathing, swallowing, coughing, etc. Epithelial migration is also permitted through the maintenance of a thin layer of mineral oil between the lens’ surfaces and the external auditory meatus.



**Fig. 4** Lens component of the Earlens. Refer to the text for additional details.

The BTE component of the Earlens, called the *photon processor*, functions similarly to other devices on the market. It includes a digital signal processor (DSP) with 20 channels; a rechargeable battery providing at least 16 hours of battery life per 4-hour charging session; two configurable buttons that can be programmed to turn the devices on and off, change programs, or make volume adjustments; and automatic adaptive directional microphones that produce omnidirectional, bidirectional, hypercardioid, and cardioid patterns. While the Earlens processor does not presently include a telecoil, it does have a Bluetooth antenna that can be enabled for made-for-iPhone (MFi) compatibility. Since the company’s value proposition is to make a broader bandwidth audible to the patient, the Earlens processor does not presently make use of frequency-lowering technology. Finally, the Earlens fitting (ELF) software permits the

creation of as many as four programs and the adjustment of as many as nine gain handles. The noise reduction, feedback cancellation, and acclimatization features can all be modified in ELF as well. For instance, the clinician can choose to acclimatize the high frequencies above 4,000 Hz for an experienced hearing aid user or the full bandwidth between 125 and 10,000 Hz for new users.

An additional way in which Earlens is unique is that it does not utilize a receiver in the ear canal such as an RIC hearing aid. Instead, the Earlens employs a laser diode embedded in an open earmold called a *Light Tip* to convey information. The frequency response of the hearing aid is, thus, presented by an invisible laser light in two ways: (1) the frequency components of the signal are represented by the on/off pattern of the emitted light and (2) the intensity of the signal is represented by the power of the emitted light. Upon leaving the Light Tip, the infrared light is converted back into mechanical energy at the level of the tympanic membrane by the peritympanic transducer vibrating the umbo. Videos that depict how the Earlens works and how a lens is nonsurgically placed into the ear canal are included with the electronic version of the Adult Audiology Casebook (2nd edition) at <https://ecomsci.thieme.com/>. These videos can also be accessed online at <https://youtu.be/O554HdSZhKk> and <https://youtu.be/2BqXM G2wDBI>.

### 1. 3. What are the advantages and disadvantages of the Earlens?

By driving the tympanic membrane via a peritympanic transducer and by presenting a light stimulus rather than an auditory stimulus, the Earlens can provide more stable gain over a wider frequency bandwidth than is presently possible with an open-fit acoustic hearing aid. According to a study by the manufacturer, the Earlens can produce an average of 40 dB of stable gain between 670 and 10,000 Hz using an open earmold and no active feedback suppression.<sup>31</sup> Although the Earlens can occasionally be driven to feedback at high intensities, feedback is far less likely to occur and far easier to manage given the device's unique method of sound transmission. Other benefits of the Earlens include improved performance in noise compared to an unaided condition on the HINT and the HIST as well as an ability to nonsurgically remove the lens at the patient's request, at the physician's discretion, or prior to magnetic resonance imaging (MRI). Statistically significant data from the manufacturer also indicate that no change in residual hearing occurs following removal of the lens.<sup>32</sup>

One potential disadvantage for patients wearing the Earlens is an increased likelihood of experiencing generally mild perceptual effects (e.g., autophony and/or damped hearing) caused by mass loading the tympanic membrane with the lens. According to the manufacturer, approximately 62% of participants ( $N=13$ ) reported a noticeable damping effect (measured as 0–7 dB on average across all frequencies) to which they acclimatized following a few weeks of lens wear.<sup>31</sup> Another potential disadvantage of the Earlens is the need for a deeply seated, yet still open, earmold to ensure proper alignment of the laser light and the photodetector. Although occlusion is not an issue, earmold modifications and/or remakes may be required to achieve a more comfortable fit.

### 1. 4. How does a clinician verify the performance of the Earlens without using real-ear probe tube microphone measures?

For clinicians who routinely perform hearing aid verification measures, another possible disadvantage to Earlens is that it is not compatible with probe tube microphone measures due to the lack of acoustic output. Instead, the clinician must calibrate the device using an in situ test called *Light Calibration*. During light calibration, the clinician measures patient thresholds between 125 and 10,000 Hz using tones generated by the hearing aid on the ear. The hearing aid software then uses the data to generate transfer functions characterizing the amount of light energy required to produce each in situ threshold. These transfer functions—combined with the patient's audiometric thresholds and the Cambridge Method for Loudness Equalization 2 - High-Frequency (CAM2) fitting formula<sup>33</sup>—are used to generate the input–output characteristics of the Earlens hearing aid.

In addition to the required in situ calibration step, the clinician may measure the patient's unaided and aided sound-field thresholds to determine the FG provided by the Earlens. During testing, aided sound-field thresholds can be measured either with the patient's user settings or with a special test mode called *FG mode*. When the device is set to FG mode, the hearing aid provides linear insertion gain and all advanced features are disabled except for feedback cancellation. The gain prescribed during FG mode is equal to the user's prescribed insertion gain at the compression threshold and is, thus, comparable to the CAM2 prescribed gain for soft speech.<sup>34</sup>

FG mode allows for assessment of the insertion gain provided for soft, average, and loud inputs as long as the MPO is not reached. In this way, testing with FG mode can serve as verification that the device is meeting some target (e.g., aided sound-field thresholds of ~20 dB HL for hearing losses 40 dB HL or at least 50% improvement in aided sound-field thresholds for hearing losses 45 dB HL)<sup>24, 35</sup> and that the Light Calibration data were recorded accurately.

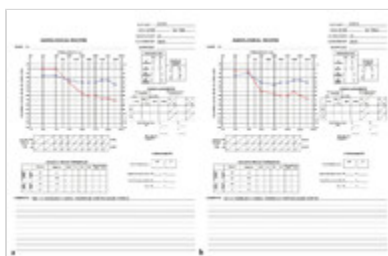
Although sound-field threshold testing cannot measure the response of nonlinear hearing aids to different input levels, unaided and aided sound-field thresholds are useful because they can account for middle ear impedance variability across patients as well as verify that the prescribed gain levels are adequate for reaching threshold.<sup>36</sup> In a study conducted by the manufacturer, mean FG for 39 subjects fitted with the Earlens was 31 dB between 2,000 and 10,000 Hz and 39 dB between 9,000 and 10,000 Hz.<sup>32</sup> This is significant as current acoustic hearing aids can neither provide broadband amplification of this magnitude nor restore high-frequency audibility above 4,000 and 6,000 Hz where hearing is most commonly impacted by SNHL.

While the Earlens is designed to be a light-driven device, the processor can be coupled to an RIC for some device verification purposes. For instance, some investigators at Earlens can verify the functionality of the directional microphones and/or the noise reduction feature using a coupler. Gain and output characteristics, however, are not assessed using an RIC because coupler measures would not reflect the true performance of the Earlens when coupled to a Light Tip. At present, Earlens RICs are unavailable, but may be offered in the future for ear canal and tympanic membranes that cannot accommodate the Lens.

## Outcome

FY completed a 2-month fitting optimization period that provided him the opportunity to adjust to the increased high-frequency amplification he was receiving from his Earlens. At FY's initial fitting, gain was provided over the full bandwidth between 125 and 10,000 Hz, but with the acclimatization feature active for frequencies above 4,000 Hz. The acclimatization period was then completed in 1 month's time. Gain was provided over the full range of frequencies despite the possibility that high-frequency dead regions could negatively impact FY's word recognition performance and/or sound quality ratings. This decision was made as recent research has suggested that patients typically perform better (or at least not poorer) on speech perception tasks when high-frequency amplification is provided even in the presence of dead regions.<sup>1, 3, 37, 38</sup> FY's experience was consistent with these findings as he reported significant benefit and a general appreciation for the extended bandwidth and additional high-frequency gain provided by his Earlens. He also denied autophony and a noticeable damping effect on his hearing following Lens placement.

At the end of FY's fitting optimization period, aided sound-field threshold testing and the HIST were repeated with the Earlens. [Fig. 5](#) displays FY's hearing aids and Earlens aided sound-field thresholds. When the results for FY's original open-fit devices were compared to those for his Earlens, improvements of 25 to 40 dB HL were noted between 2,000 and 10,000 Hz for the right ear and 20 to 35 dB HL were noted between 1,000 and 10,000 Hz for the left ear. These findings suggest significant improvement in terms of FY's access to high-frequency speech information. The slightly reduced low-frequency sound-field thresholds obtained with the Earlens were likely due to the noise floor of the hearing aids at that time.



**Fig. 5 (a)** Right ear. **(b)** Left ear. Aided sound-field thresholds indicating significant benefit in the high frequencies with Earlens. There was no significant difference between the Earlens-aided sound-field thresholds obtained with the patient's user settings versus the *Functional Gain Mode* settings. Thresholds at 750 and 1,500 Hz were not measured because testing at these frequencies was not part of the study protocol. The 12,000-Hz thresholds were actually measured at 10,000 Hz. O, hearing aid-aided sound-field threshold; X, Earlens-aided sound-field threshold.

FY's HIST results indicated that the signal needed to be  $-2.8$  dB softer than the noise for FY to correctly repeat 50% of the target sentences. When compared to the HIST result for FY's open-fit hearing aids, the SNR improvement achieved with Earlens was 5.8 dB, suggesting up to 51.62% ( $5.8 \text{ dB} \times 8.9\% \text{ per dB}$ ) improvement in sentence recognition in noise when listening with Earlens and taking advantage of the head shadow effect. Collectively, the aided sound-field threshold and HIST data suggested that the audible extended bandwidth delivered by Earlens was providing FY with significant objective benefit in both quiet and noisy listening situations under laboratory conditions.

After completing his Earlens trial, FY agreed to have the lenses removed so he could return to wearing his acoustic hearing aids for a period of 2 weeks. After wearing his acoustic hearing aids for 2 weeks, FY returned and completed a manufacturer-developed questionnaire whereby he indicated that speech and music sounded clearer and more natural with his Earlens when compared to his acoustical devices. At the end of the pilot study, FY had the opportunity to either continue with his acoustic hearing aids or return to his Earlens devices at no cost. FY elected to return to his Earlens devices and he has continued to volunteer for additional studies at Earlens, having acquired an appreciation for hearing aid research and the quality of life improvements his new devices have afforded him.

## Key Points

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When testing patients with high-frequency SNHL, clinicians should be conscientious of the possibility of cochlear dead regions.

Although confirming the existence of cochlear dead regions with the TEN test does not alter the clinician's decision to treat patients with high-frequency SNHL, it may impact how the clinician chooses to treat patients with high-frequency SNHL.

Unlike other SIN tests, the HIST can be used to assess the benefit of extended bandwidth hearing aids in noise.

Closed-fit hearing aids, open-fit hearing aids, frequency-lowering technology, hybrid CI, HAT, and the new Earlens are all options for treating patients with SNHL.

The Earlens provides gain between 125 and 10,000 Hz because it directly drives the tympanic membrane via a transducer placed deeply in the ear canal. It can only be verified with sound-field threshold testing as it utilizes a laser diode rather than a receiver to present the signal.

## Acknowledgments

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The author would like to thank Suzanne Levy, PhD, Director of Clinical Research at Earlens Corporation, for providing constructive comments on earlier versions of this case study. Her feedback, along with those of the editors, significantly improved the depth and quality of the information discussed. Sincere appreciation is also given to FY who has continued to exhibit curiosity and enthusiasm for hearing aid research.

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