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Research Paper

The EarLens system: New sound transduction methods

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ABSTRACT

The hypothesis is tested that an open-canal hearing device, with a microphone in the ear canal, can be designed to provide amplification over a wide bandwidth and without acoustic feedback. In the design under consideration, a transducer consisting of a thin silicone platform with an embedded magnet is placed directly on the tympanic membrane. Sound picked up by a microphone in the ear canal, including sound-localization cues thought to be useful for speech perception in noisy environments, is processed and amplified, and then used to drive a coil near the tympanic-membrane transducer. The perception of sound results from the vibration of the transducer in response the electromagnetic field produced by the coil. Sixteen subjects (ranging from normal-hearing to moderately hearing-impaired) wore this transducer for up to a 10-month period, and were monitored for any adverse reactions. Three key functional characteristics were measured: (1) the maximum equivalent pressure output (MEPO) of the transducer; (2) the feedback gain margin (GM), which describes the maximum allowable gain before feedback occurs; and (3) the tympanic-membrane damping effect (D_{TM}), which describes the change in hearing level due to placement of the transducer on the eardrum. Results indicate that the tympanic-membrane transducer remains in place and is well tolerated. The system can produce sufficient output to reach threshold for those with as much as 60 dBHL of hearing impairment for up to 8 kHz in 86% of the study population, and up to 11.2 kHz in 50% of the population. The feedback gain margin is on average 30 dB except at the ear-canal resonance frequencies of 3 and 9 kHz, where the average was reduced to 12 dB and 23 dB, respectively. The average value of D_{TM} is close to 0 dB everywhere except in the 2–4 kHz range, where it peaks at 8 dB. A new alternative system that uses photonic energy to transmit both the signal and power to a photodiode and micro-actuator on an EarLens platform is also described.

1. Introduction

Hearing devices have long been the principal method of treatment for sensorineural hearing impairment. Early examples include "hearing trumpets" crafted from animal horns or sterling silver, or even the still common practice of cupping one's hands behind one's ears. Such methods are limited, but can provide some degree of benefit to the listener by producing moderate amplifications or increasing the signal-to-noise ratio of the sound originating from a particular direction. In the 20th century electronic hearing devices were introduced, which present an enhanced acoustic signal to the external auditory canal through actively amplifying and otherwise processing environmental sound. However, although these devices can provide improved hearing, their performance is still limited in one or more areas, such as for hearing in noisy environments, hearing high frequencies, preserving sound-localization cues, as well as in areas of comfort and convenience.

Hearing device manufacturers have tried various approaches to address the limitations of current devices. The open-canal-type hearing devices, first introduced in the 1990's by ReSound Corporation, address a number of these issues. They are better-accepted aesthetically, lightweight and comfortable, and by leaving the ear canal open they eliminate the undesired effects of occluding the ear canal. However, their effective frequency range is limited primarily to 1–4 kHz, and adequate amplification is problematic for those with moderate to severe hearing impairment at high frequencies.

An alternative approach is to move the transducer onto the tympanic membrane (TM) itself, and provide direct mechanical stimulation rather than stimulation with sound. Among the first reported examples of this, in which electromagnetic fields were used to generate forces on a magnet attached to the TM, thus resulting in the sensation of hearing, were those by Wilska (1959), Rutschmann (1959), Goode (1970), and Plester et al. (1978). However, none of these earlier attempts have been deemed practical, since the attachment of magnets to the eardrum was not

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well tolerated due to the migration of the eardrum epithelium (Reijnen and Kuijpers, 1971; Boedts and Kuijpers, 1978). The attachment problem was not solved until the development of the EarLens platform.

The original concepts for the EarLens platform and manufacturing methods are described in a patent (Perkins and Shennib, 1993) and in a journal publication (Perkins, 1996). In this design, a magnetic-field-generating coil would be used to drive a magnet embedded within a form-fitted silicone "lens" that rests on the tympanic membrane and is held in place by adhesion forces due to a thin layer of mineral oil between the lens and the TM. The primary coil was initially intended to be worn around the neck, much like a necklace worn under a shirt. However, because magnetic fields, and the resulting forces on the magnet, decrease in amplitude as the reciprocal of the square of the distance ($1/R^2$), this method was highly inefficient and proved to be impractical for a commercial product.

However, one important advantage of this approach was that it provided a method of directly vibrating the middle ear without requiring surgery, unlike methods involving implantable hearing aids. More recently a new effort was launched to develop an alternative implementation of the concept (Perkins et al., 2008), in which a coil wound around a ferrite core is placed within a few millimeters of the EarLens magnet, thus resulting in a significant improvement in energy efficiency. This approach incorporates three beneficial characteristics: an open canal configuration, a microphone within the ear canal to capture the natural resonances and pinna diffraction cues from the auricle, and a tympanic-membrane transducer with a wide 10 kHz bandwidth capable of transmitting important high-frequency diffraction cues (Puria and Perkins, 2005). Although different aspects of these three features were discussed in the previous effort, they were never brought to fruition. Of particular interest is that frequencies above 4–5 kHz were not part of the previous design effort, whereas they constitute a major thrust of the present effort.

Killion and Tillman (1982) made a case for the importance of increasing the bandwidth of hearing aids. However, because it was thought that speech intelligibility in quiet environments is not improved by increasing bandwidth (Fletcher, 1995), little work has since been done to increase the bandwidth of hearing devices.

It is well known among otologists, audiologists, and hearing scientists that the number one problem for those with sensorineural hearing impairment is their difficulty in understanding speech in the presence of background noise, particularly when the background noise consists of human speech. Also, poor sound quality and whistling due to feedback are common complaints. These have been corroborated by multiple surveys throughout the years (Kochkin, 2002, 2009).

Conventional strategies for improving hearing in the presence of background noise have relied on engineering principles that are only indirectly tied to functional auditory mechanisms. These approaches have included the use of directional microphones, array microphones, and noise reduction algorithms, though all have had limited success in the real world (Cord et al., 2004; Walden et al., 2004; Ricketts and Hornsby, 2005).

1.1. Speech discrimination in noise

Several recent publications in the psychoacoustic literature have shed light on potential solutions to improving speech understanding in noise. Best et al. (2005) found that increasing bandwidth increases one's ability to localize sound, while Freyman et al. (1999, 2001) and Carlile and Schonstein (2006) have reported that the ability to locate a sound improves speech understanding when multiple people are speaking. Moore et al. (2008) report that, for an overall speech level of 65 dB SPL, the 1/3-octave levels at 1 and 10 kHz center frequencies were 49 and 37 dB SPL, respectively. This suggests that there is significant energy present in speech even at 10 kHz that can be used for sound localization. Several researchers have reported that hearing-impaired subjects understand speech better in both quiet and noisy environments when the bandwidth of the speech is increased (Vickers et al., 2001; Baer et al., 2002; Preminger et al., 2005).

A wide-bandwidth system with a tympanic-membrane transducer and a microphone in the ear canal, which has the potential to address at least some of the complaints of acoustic hearing devices, is described in this paper.

1.2. The EarLens system

At the core of the tympanic-membrane transducer is a tiny actuator that floats on the tympanic membrane (Figs. 1 and 2), much in the way that an ophthalmic contact lens resides on the cornea of the eye. The overall system consists of three major subsystems: the tympanic-membrane transducer (*i.e.* the "EarLens"), the sound-processing unit, and the ear-canal transceiver (Fig. 1). These subsystems collectively form the EarLens system.

There are several potential techniques for wirelessly transmitting audio energy to the tympanic-membrane transducer, including electromagnetic, photonic, RF, and ultrasonic methods (Perkins and Shennib, 1993; Perkins, 1996; Pluvinage and Perkins, 2005; Puria and Perkins, 2005). In the embodiment described here, the tympanic-membrane transducer is composed of two elements: a gold-plated samarium cobalt (S_mC_o) magnet and a thin, cone-shaped, biocompatible silicone-rubber platform in which the magnet is embedded (Figs. 1 and 2).

The sound-processing unit is the control center and power source of the system. At its core are a digital signal processor (DSP) and a replaceable/rechargeable battery (Figs. 1 and 4). The sound-processing unit's main function is to apply mathematical algorithms to the input signal and modify it based on the hearing needs of the individual. The processed signal is then sent to an output stage to boost and convert it into a current, which is then passed on to the ear-canal transceiver.

The ear-canal transceiver contains an acoustic microphone and transducer driver which, in the embodiment described here, is a small electromagnetic coil with a ferrite core (Figs. 1 and 3). The microphone converts ambient sounds from within the ear canal into an electrical signal that is transmitted to the sound-processing unit. The output stage of the sound-processing unit then provides an output current that the coil and core convert into a local magnetic field whose strength varies in direct proportion to the amount of current.

In this work, four key characteristics of the electromagnetic tympanic-membrane transducer and its associated system are tested and reported. These consist of (1) the maximum equivalent pressure output (MEPO) of the EarLens system from 0.125 to 12.5 kHz, which is directly comparable to the maximum pressure output (MPO) measure used for acoustic hearing aids, and indicates the equivalent sound pressure that would be needed to match the maximum vibratory output of the EarLens system at the eardrum of a particular subject, given the maximum current that the output stage can produce and the anatomically-dependent manner in which the coil current translates into pressure at the eardrum; (2) the estimated feedback gain margin (GM), which indicates how much higher the equivalent pressure of the induced vibration at the TM is, for a given drive current, compared to the pressure at the microphone due to the backward-traveling sound wave produced by the movement of the TM itself, and which represents an upper limit to the amplification possible between the microphone and the output stage before positive feedback begins to occur; (3) the tympanic-membrane damping effect (D_{TM}), which

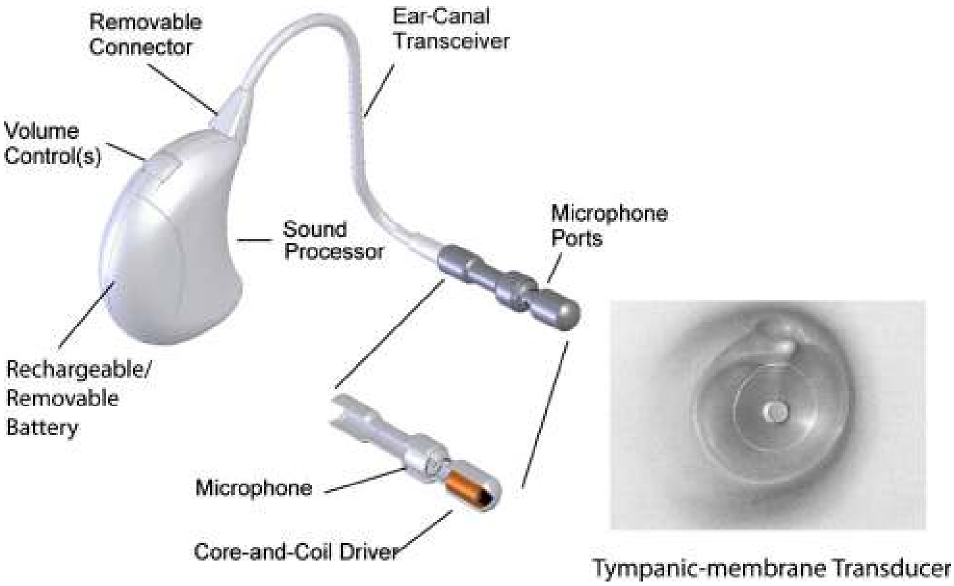

Fig. 1. Illustration of the EarLens™ electromagnetic system, with the tympanic-membrane transducer, ear-canal transceiver, and sound-processing unit subcomponents shown.

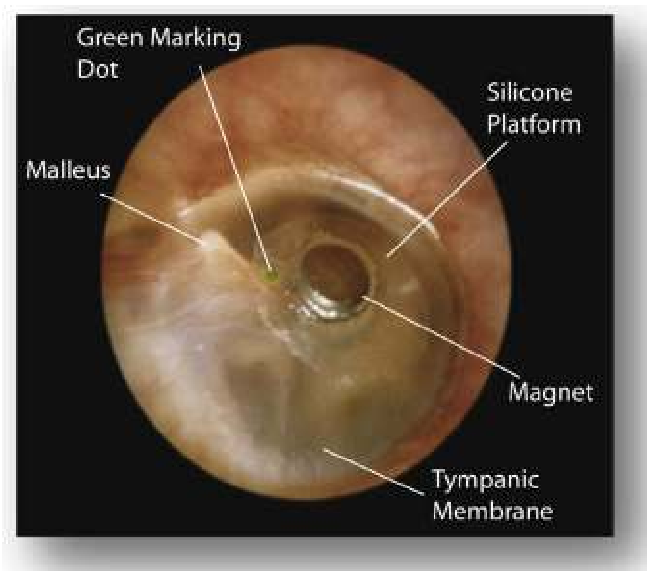

Fig. 2. Close-up view of the electromagnetic tympanic-membrane transducer *in-situ* on the tympanic membrane. The green marking dot is used to align the transducer with the malleus.

indicates how the placement of the transducer on the eardrum affects a given subject's threshold audiogram; and (4) the long-term tolerance of the eardrum to the presence of the transducer on its surface.

2. Methods

2.1. Subject population

Sixteen subjects were recruited to evaluate the various functional characteristics of the EarLens tympanic-membrane transducer and its long-term wear characteristics. The study was conducted under IRB approval by Western Institutional Review Board (WIRB).

All subjects conformed with the following nine inclusion/exclusion criteria: (1) They were at least 21 years of age; (2) their PTA2 test (*i.e.* the average of pure tone audiograms for 0.5, 1, 2, and 3 kHz) was greater than 25 dBHL but less than 60 dBHL, with no threshold worse than 80 dBHL at any frequency (0.25–10 kHz); (3) they had normal tympanometry results, indicating normal mobility of the eardrum and middle-ear bones; (4) they had air-bone gaps no greater than 10 dB; (5) their speech discrimination scores were 80% or greater; (6) they exhibited no more than 10 dB of hearing asymmetry between ears; (7) they had no history of middle-ear surgery; (8) they had no chronic middle-ear disease; and (9) they did not have abnormally small ear canals.

2.2. Baseline assessments

All subjects were given an initial examination after consenting to the study, which consisted of baseline audiometric testing using a Grason-Stadler Audiometer (GSI 61) with a 2 dB step size and Sennheiser HDA 200 circumaural audiometric headphones, and medical evaluation to ensure compliance with the inclusion/exclusion criteria. A total of 3 initial audiograms were measured during 3 separate sessions for each subject, for which the average was taken after it was verified that all 3 audiograms agreed within 6 dB of one another for all frequencies. The pressure at the TM at the threshold of hearing for each subject (in Pascals), $P_{TM,Threshold}$, was also determined during each session for each audiometric frequency, using a procedure that involved measuring the eardrum sound pressure at sufficiently high signal levels to produce reliable measurements using a probe-tube microphone (www.etymotic.com, Model No. ER-10c) and SYSid version 7 (custom version running on a PC card, www.mimosaacoustics.com), and then scaling those pressures down to the equivalent threshold values (see Eq. (1)). Endoscopic photographs of each eardrum were also taken during the last of the above visits.

2.3. Eardrum impressions

An impression of each subject's tympanic membrane was made, to allow the silicone platform to be manufactured to conform exactly to the toroidal outer area and the conical umbo area of the

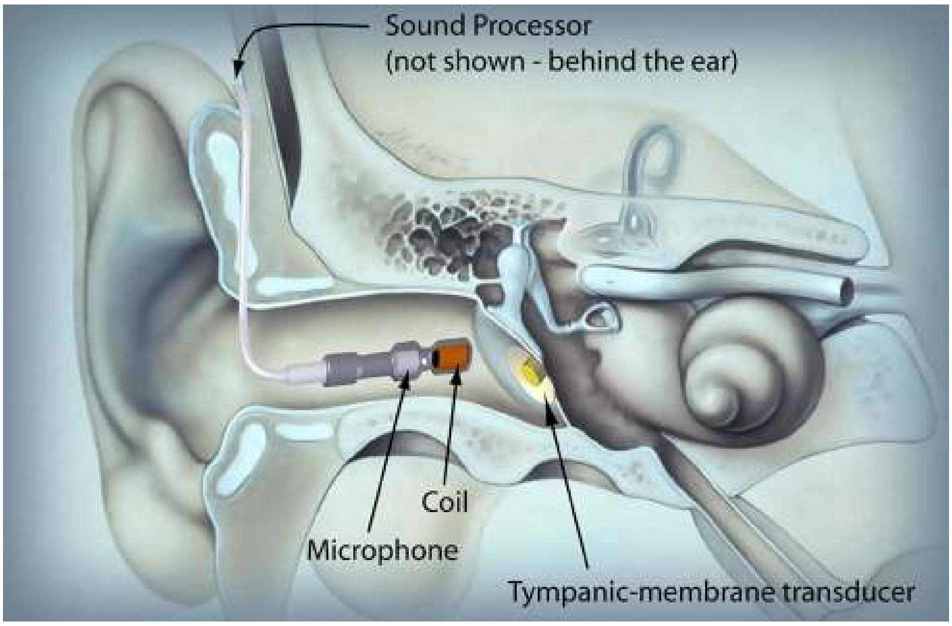

Fig. 3. Placement of the electromagnetic EarLens system in the ear. The sound-processing unit coupled to the ear-canal transceiver can be removed by the user on a daily basis while the tympanic-membrane transducer remains in place on a long-term basis.

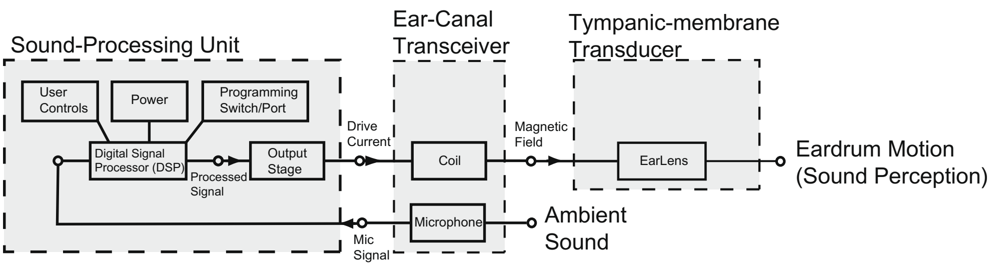

Fig. 4. System signal-flow diagram from the ambient sound input at the microphone to the eardrum motion due to the tympanic-membrane transducer, leading to the amplified perception of sound.

subject's tympanic membrane. A positive cast of the impression was used to create a replica of each individual's tympanic membrane, then this replica was used to produce the custom silicone-membrane transducer (Perkins and Shennib, 1993; Perkins, 1996).

2.4. Electromagnetic tympanic-membrane transducer and drive coil

In contrast to the previously used frustum-shaped 35 mg magnet (Perkins, 1996), the tympanic-membrane transducer described here was made from a 9 mg gold-coated disk magnet with a 0.75 length-to-radius ratio. The magnet was then embedded in a 4-mm-diameter silicone platform having a weight of 2 ± 0.5 mg. The magnetic-field-generating transducer consisted of a 400 turn coil wound around a ferrite core, with a core length of 4.5 mm and a winding length of 4 mm. The total outer diameter of the combined core and coil was 4 mm. The resistance of the coil was typically 18.5 Ohms, with an inductance of 1.2 mH. All of these parameters were based on numerous optimizations, the details of which are beyond the scope of this paper.

2.5. Placement and maintenance

Prior to placement of the transducer, a droplet of mineral oil was placed on the eardrum. Once placed on the eardrum, the EarLens maintains its position by floating on a thin layer of mineral oil film. The concave shape and the adhesive forces provided by the mineral oil are similar to those conferred by the convex shape of the cornea and the surface tension characteristics of the lacrimal fluid, which provide positional stability for ophthalmic contact lenses. Periodically, the patient atomizes a small amount of mineral oil into the ear canal to replenish the oil lost by slow skin migration (Reijnen and Kuijpers, 1971; Boedts and Kuijpers, 1978).

After positioning the tympanic-membrane transducer on the center of the eardrum, a photograph was taken using a 4-mm-diameter, 0-degree-angle, rigid endoscope (www.karlstorz.com). Subjects then returned to the clinic for weekly follow-up visits with the otologist and audiologist for the clinical measurements described below. Between clinical measurements, the ear-canal transceiver was removed while the tympanic-membrane transducer stayed on the TM.

2.6. Clinical and electro-acoustic measurements

The signal flow of the complete system is illustrated in Fig. 4. With the exception of the maximum system current, $I_{Coil,Maximum}$ (see 2.7.e), all of the measurements reported here were made without the sound-processing unit. The coil was otherwise driven by an external amplifier, and the coil current of the ear-canal transceiver and the probe-tube microphone signal were measured through an optical isolation box (not shown). The audiometer was set to use a

2 dB step size and warble tones (FM) at standard audiometric frequencies between 0.125 and 12.5 kHz. Four electro-acoustic and functional measurements of clinical significance (1–4 below) were sought.

2.7. Maximum equivalent pressure output (MEPO)

A primary outcome measure of interest is an estimate of the *in-situ* maximum equivalent pressure output (MEPO) of the EarLens system, which represents the sound pressure level that would have to be applied at the eardrum to produce the same degree of TM vibration that the EarLens system produces with the coil current set to its maximum value, and given the anatomical constraints on the coupling between the coil and magnet for a given subject. Because the tympanic-membrane transducer operates by directly vibrating the eardrum rather than by subjecting it to a sound field, the MEPO could not be measured using a microphone, but instead had to be determined indirectly by the steps described in a–f below.

a. As the first step, the eardrum pressure at the threshold of hearing for a given subject (in Pascals), $P_{\mathrm{TM,Threshold}}$, was determined for each audiometric frequency. Because the signal-to-noise ratio was often too low to directly measure the TM pressure with a probe-tube microphone at the threshold of hearing during an audiometric test, the audiometer and probe-tube microphone were instead used to first measure the pressure using an audiometer setting that was sufficiently high to yield a reliable pressure measurement. Then the measured pressure was scaled by an appropriate factor to yield the equivalent TM pressure at the threshold of hearing. This procedure is summarized by the equation

$$P_{\mathrm{TM,Threshold}} = P_{\mathrm{TM,High}} 10^{\left((HL_{\mathrm{Threshold}} - HL_{\mathrm{High}})/20\right)}, \tag{1}$$

in which $P_{\mathrm{TM,High}}$ (in Pascals) is the average of 3 TM pressure measurements that were made using a probe-tube microphone during the subject's 3 initial testing sessions, for which a sufficiently high output from the audiometer's headphone was used to provide an adequate signal-to-noise ratio; $\mathrm{HL}_{\mathrm{Threshold}}$ is the average of the 3 audiometer settings (in dBHL) that were determined to correspond to the subject's threshold of hearing during the 3 initial testing sessions; and $\mathrm{HL}_{\mathrm{High}}$ is the setting on the audiometer (in dBHL) that was used to produce the audiometer headphone output that was used to measure $P_{\mathrm{TM,High}}$, such that the conversion of the dB difference $\mathrm{HL}_{\mathrm{Threshold}}$–$\mathrm{HL}_{\mathrm{High}}$ to a linear scale in the equation yields a scale factor that converts $P_{\mathrm{TM,High}}$ to $P_{\mathrm{TM,Threshold}}$.

b. After $P_{\mathrm{TM,Threshold}}$ was determined, the subject was fitted with the tympanic-membrane transducer.

c. On the following visit, the tympanic-membrane transducer was inspected to ensure that it was still in position. The ear-canal transceiver was then placed in the ear canal and configured to be driven by the output of the audiometer, after which the coil current needed to reach the threshold of hearing, $I_{\mathrm{Coil,Threshold}}$, was then determined for each audiometric frequency, using the following equation:

$$I_{\mathrm{Coil,Threshold}} = I_{\mathrm{Coil,High}} 10^{\left((HL_{\mathrm{Threshold}} - HL_{\mathrm{High}})/20\right)}. \tag{2}$$

Here, $I_{\mathrm{Coil,High}}$ is the measured coil current corresponding to a sufficiently high audiometer setting for achieving an adequate signal-to-noise ratio; $\mathrm{HL}_{\mathrm{Threshold}}$ in this case is the audiometer setting corresponding to the subject's threshold of hearing using the tympanic-membrane transducer; and $\mathrm{HL}_{\mathrm{High}}$ represents the audiometer setting that was used to generate $I_{\mathrm{Coil,High}}$.

d. Since $P_{\mathrm{TM,Threshold}}$ and $I_{\mathrm{Coil,Threshold}}$ were both determined for a common reference point, namely the subject's threshold of hearing, their ratio can be used to represent the relationship between the coil current for the tympanic-membrane transducer and the TM pressure that would be needed to produce the equivalent vibration of the TM (assuming the latter varies linearly with the former). This ratio is referred to as the transducer response, $T_{\mathrm{Transducer}}$:

$$T_{\mathrm{Transducer}} = \frac{P_{\mathrm{TM,Threshold}}}{I_{\mathrm{Coil,Threshold}}}. \tag{3}$$

e. The maximum output current from the sound-processing unit with the coil attached, $I_{\mathrm{Coil,Maximum}}$, was then approximated by measuring the voltage across a 1-ohm resistor placed in series with the approximately 18.5-ohm coil, while ensuring that the total harmonic distortion plus noise (THD+N) was less than 2%.

f. Finally, the MEPO was calculated as:

$$\mathrm{MEPO} = I_{\mathrm{Coil,Maximum}} T_{\mathrm{Transducer}}. \tag{4}$$

2.8. Feedback pressure ($P_{Mic,Feedback}$)

To measure the feedback pressure near the ear-canal transceiver microphone location, $P_{\mathrm{Mic,Feedback}}$, which is due to backward-traveling sound waves generated by the vibration of the tympanic-membrane transducer, a constant-voltage tone was played through the coil for each audiometric frequency, and the resulting acoustic pressure at the probe-tube microphone within 4–5 mm of the ear-canal entrance was then measured. The coil current, I_{Coil}, was calculated by measuring the voltage across a 1-ohm resistor placed in series with the coil. The transducer feedback response, T_{Feedback}, was then calculated as follows:

$$T_{\mathrm{Feedback}} = \frac{P_{\mathrm{Mic,Feedback}}}{I_{\mathrm{Coil}}}. \tag{5}$$

2.9. Feedback gain margin (GM)

The feedback gain margin (GM), an important measure of hearing-aid performance, is the maximum amount of gain (in dB) that can be applied to the microphone input signal before positive feedback begins to occur. It can be calculated as

$$\mathrm{GM} = 20\log_{10}\left(\left|\frac{T_{\mathrm{Transducer}}}{T_{\mathrm{Feedback}}}\right|\right). \tag{6}$$

2.10. Tympanic-membrane damping effect (D_{TM})

The tympanic-membrane damping effect, D_{TM}, signifies the extent (in dB) by which the subject's threshold of hearing is made worse by the placement of the tympanic-membrane transducer on the eardrum. It is calculated as

$$D_{\mathrm{TM}} = HL_{\mathrm{Threshold,After}} - HL_{\mathrm{Threshold,Before}}, \tag{7}$$

where $\mathrm{HL}_{\mathrm{Threshold,Before}}$ and $\mathrm{HL}_{\mathrm{Threshold,After}}$ are the thresholds of hearing (in dBHL) that were respectively determined before and after the transducer was placed on the eardrum, using the same standard audiometric techniques in both cases.

2.11. Long-term wear

The long-term safety of the tympanic-membrane transducer was documented in seven of the 16 subjects (13 ears total) by photographic evidence obtained during weekly visits, in which the otologist inspected the ear canal and tympanic membrane, and documented the status of the tympanic membrane with a video endoscope. Audiometric follow-up testing was done within 1 week of removing the transducer, to document any changes relative to pre-placement thresholds of hearing.

3. Results

3.1. Maximum output

The mean and standard error (STE) of the audiograms measured for the 16 subjects are shown in Fig. 5. The hearing levels of subjects were generally expected to be better than the plotted "inclusion guideline" in order to qualify for the study, although the guideline was not treated as a strict limit above 6 kHz. The maximum equivalent pressure output (MEPO) from the EarLens system is shown in Fig. 6, in terms of a line representing the mean across subjects, as well as lines representing one standard deviation (STD) above and below the mean. For the lower STD curve, 86% of subjects had higher MEPO values at a given frequency, whereas for the mean and upper STD curve, 50% and 14% of subjects had higher values, respectively. To produce the dB-SPL version of the inclusion guideline seen in Fig. 6, the hearing-level version of the guideline from Fig. 5 was added to the Killion (1978) minimum audible pressure curve shown in Fig. 6. For the frequencies where a subject's MEPO curve lies above this inclusion guideline, it can be said that the EarLens device would be capable of producing an audible sound pressure for that subject, provided that his or her threshold of hearing were at least as good as this inclusion guideline. Note that the MEPO itself is independent of a subject's hearing level, and that the MEPO varies across subjects as a result of the influence that differences in anatomy have on the coupling between the coil and the tympanic-membrane transducer.

If the MEPO variability reported here, which again is due to anatomical differences between the subjects, can be said to be representative of the variability in the general population, then the tympanic-membrane transducer design could be said to have sufficient output to reach threshold for up to 60 dBHL of hearing impairment all the way up to 8 kHz in approximately 86% of the population (lower STD line) with less than 2% THD + N. Furthermore, the system could be said have sufficient output to reach threshold for up to 60 dBHL of hearing impairment up to at least 11.2 kHz in 50% of the population (mean line). This demonstrates that the EarLens system is capable of reaching threshold and provide some functional gain at relatively high frequencies in a large number of subjects, but not in all subjects.

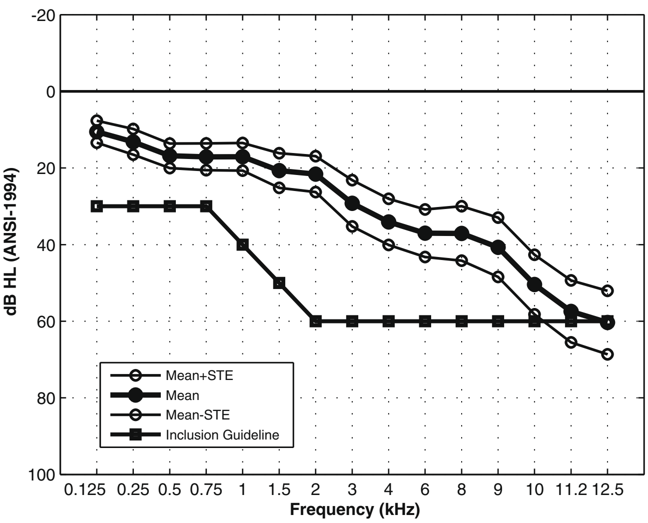

Fig. 5. Mean and mean ± 1 standard error (STE) of the initial audiograms for the sixteen subjects participating in the present study, at standard audiometric frequencies. To qualify for the study, each subject's audiogram was generally expected to lie above the "inclusion guideline", although this was not strictly enforced above 6 kHz.

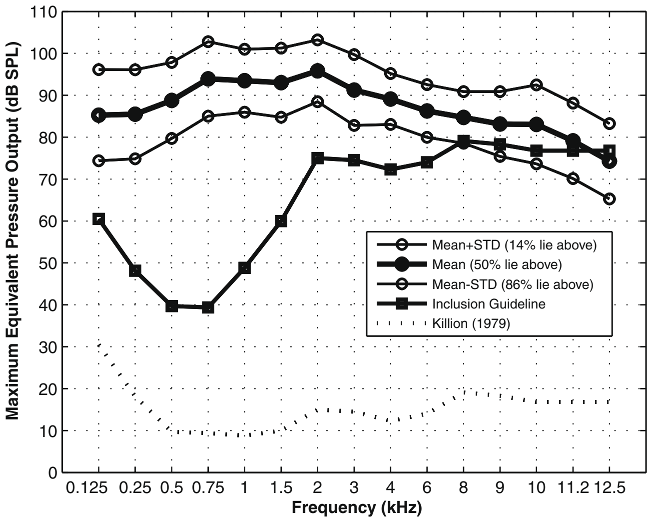

Fig. 6. Mean and mean ± 1 standard deviation (STD) curves of the maximum equivalent pressure output (MEPO) for the electromagnetic EarLens system, across sixteen subjects. Also shown is a dB-SPL version of the "inclusion guideline" from Fig. 5, which was calculated by adding that curve to the Killion (1978) minimum audible pressure curve, which is also shown. Note that the MEPO varies across subjects due to the way that anatomical differences affect the coupling between the coil and the magnet, and that it does not depend on a subject's hearing level. If a subject's anatomy were such that their MEPO curve lies above the inclusion guideline, then the EarLens system would be capable of generating audible sounds for that subject as long as their threshold of hearing were at least as good as the inclusion guideline. For the population used, 86% of the subjects have a MEPO that lies above the lower curve labeled 'mean-STD'. Because the inclusion guideline is below the 'mean-STD' curve for frequencies at and below 8 kHz, amplification can be given at those frequencies. Similarly, for 50% and 14% of the population, amplification can be given for frequencies up to 11.2 kHz and 12.5 kHz, respectively.

3.2. Feedback gain margin (GM)

An important advantage of the tympanic-membrane transducer is that it generates less feedback pressure in the ear canal than acoustic devices. The motion of the eardrum due to the tympanic-membrane transducer is expected to produce retrograde sound waves that propagate out through the ear canal and can be picked up by the transceiver microphone. However, due to the inefficiency of the eardrum as a loudspeaker, particularly above 1 kHz, these retrograde waves are normally expected to have relatively low amplitudes (Puria, 2003) compared to the incident sound waves picked up by the microphone as they enter the ear canal. The feedback gain margin indicates how much gain can be applied between the microphone input and the coil before the retrograde waves become large enough to cause positive feedback.

Fig. 7 shows, as a function of frequency, the mean feedback gain margin across subjects. The overall STD, represented by error bars, is approximately 7 dB. On the whole, the gain margin is typically greater than 30 dB, though in the limited 3 (±1) kHz and 9 (±1) kHz regions, the mean gain margins dip down to 12 dB and 23 dB, respectively. The reduced gain margins in these regions are the result of increases in the ear canal pressure near the microphone due to resonances of the ear canal. It is in these limited frequency ranges that the system is most likely to produce positive feedback, which is perceived as a whistling sound. The use of a feedback-cancellation algorithm as a way of compensating for this is described in the discussion section.

3.3. Tympanic-membrane damping effect (D_{TM})

Placing additional mass on the eardrum, in the form of the tympanic-membrane transducer, has the effect of dampening the sound vibrations entering the middle ear in a frequency-dependent manner. We refer to the resulting shift in the threshold of hearing due to placement of the transducer on the eardrum as the tympanic-membrane damping effect (Fig. 8), which can be compared to the "insertion loss" concept from the hearing device vernacular. On average, placing the transducer on the eardrum has a damping effect of less than 2 dB for frequencies below 1.5 kHz and above 6 kHz. At the 2 kHz, 3 kHz, and 4 kHz points, the average damping effects are 5 dB, 8 dB, and 7 dB, respectively. The STD (represented by error bars) reaches its maximum of 6 dB at 4 kHz.

The tympanic-membrane damping for the presently-described device is much smaller than for the earlier-generation device, which had a magnet mass of 35 mg (compared to the present 9 mg) and a larger platform diameter. In general, the tympanic-membrane damping losses of the presently-described transducer are much smaller and in much narrower frequency ranges than the insertion losses experienced by wearers of conventional closed-canal hearing devices, which are typically more than 20 dB above 1 kHz.

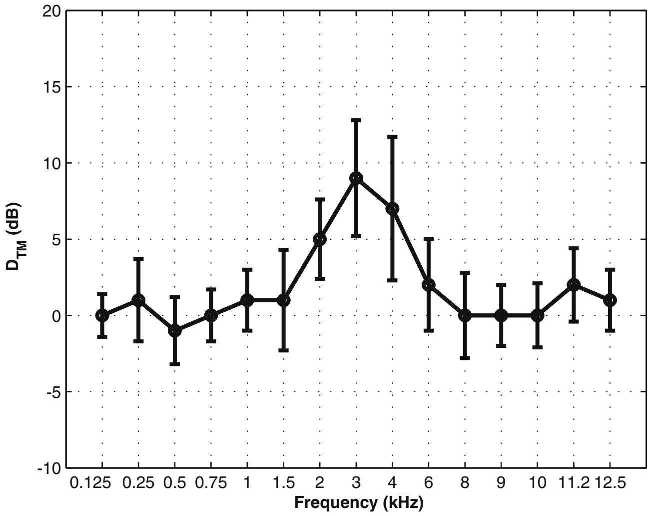

Fig. 8. The tympanic-membrane damping effect (D_{TM}), which represents the extent by which a subject's threshold of hearing is made worse by the placement of the tympanic-membrane transducer on the eardrum. The mean and mean ± 1 STD are shown.

3.4. Long-term wear

A subset of seven subjects (13 ears) was selected for participation in the long-term wear safety study. The seven subjects wore the tympanic-membrane transducer platform for a total of 1062 days, ranging from 4 to 10 months for any given ear. Considering the number of ears studied, a total of 1771 "ear-days" were observed. During this period, no complications were observed. Fig. 9 shows endoscopic images collected for the left and right ears of three representative subjects. The average differences in study exit and study entrance audiograms were within the previously-stated test/re-test variability criterion (*i.e.* within 6 dB for all frequencies). The photographic documentation obtained from the video endoscope, as well as the clinical audiograms, support the conclusion that all of the ears studied remained unchanged over the course of the study period, and thus that there were no adverse effects observed due to long-term wear of the tympanic-membrane transducer on the tympanic membrane.

When additional oil (0.25–1.0 μL) was added at a frequency of once every 1–3 weeks, the tympanic-membrane transducers remained in place. In a few subjects that did not follow the oil replacement regimen, some of the transducers displaced from the center of the eardrum.

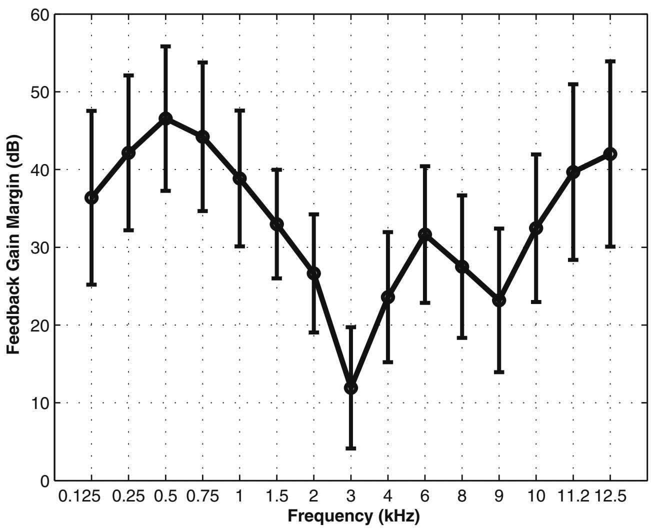

Fig. 7. The feedback gain margin (GM) of the electromagnetic EarLens system, which indicates the maximum amount of gain that can be applied to the signal between the microphone and the coil before positive feedback begins to occur. The mean and mean ± 1 STD are shown.

3.5. Maintenance of transducer position

The positional stability of the tympanic-membrane transducer was excellent. Only minor rotations of the transducer were thought to have occurred in one or two patients, and for all 16 subjects good contact was maintained between the device and the central tympanic membrane throughout the study. This is particularly interesting because we know that conventional ventilation tubes passing through the tympanic membrane are often forced out, probably as a result of forces exerted on them by the migrating squamous epithelial surface. Also, we know from other experiments (not shown) that magnets glued onto the umbo area are not maintained in this position for any extended period. This likely results from the glue bond failing and/or from migration of the epithelium carrying the magnet away from the placement site and/or the desquamating epithelium pushing the transducer of the tympanic membrane. In the case of the tympanic-membrane transducer, it is theorized that the extended positional stability is a result of several factors. The concave shape of the umbo area confers some degree of stability, especially in combination with the molecular adhesive and surface tension characteristics of the mineral oil. As noted above, these factors are similar to those operative in ophthalmic contact lenses. In addition, however, it is believed that the migrating squamous epithelium is able to migrate normally and slide beneath the mineral oil layer, leaving the tympanic-membrane transducer in its original position.

4. Discussion

4.1. Acoustic contribution of the auricle and external ear canal

In the visual system, locations of objects are directly mapped onto the retinas. In the auditory system, however, there is no such

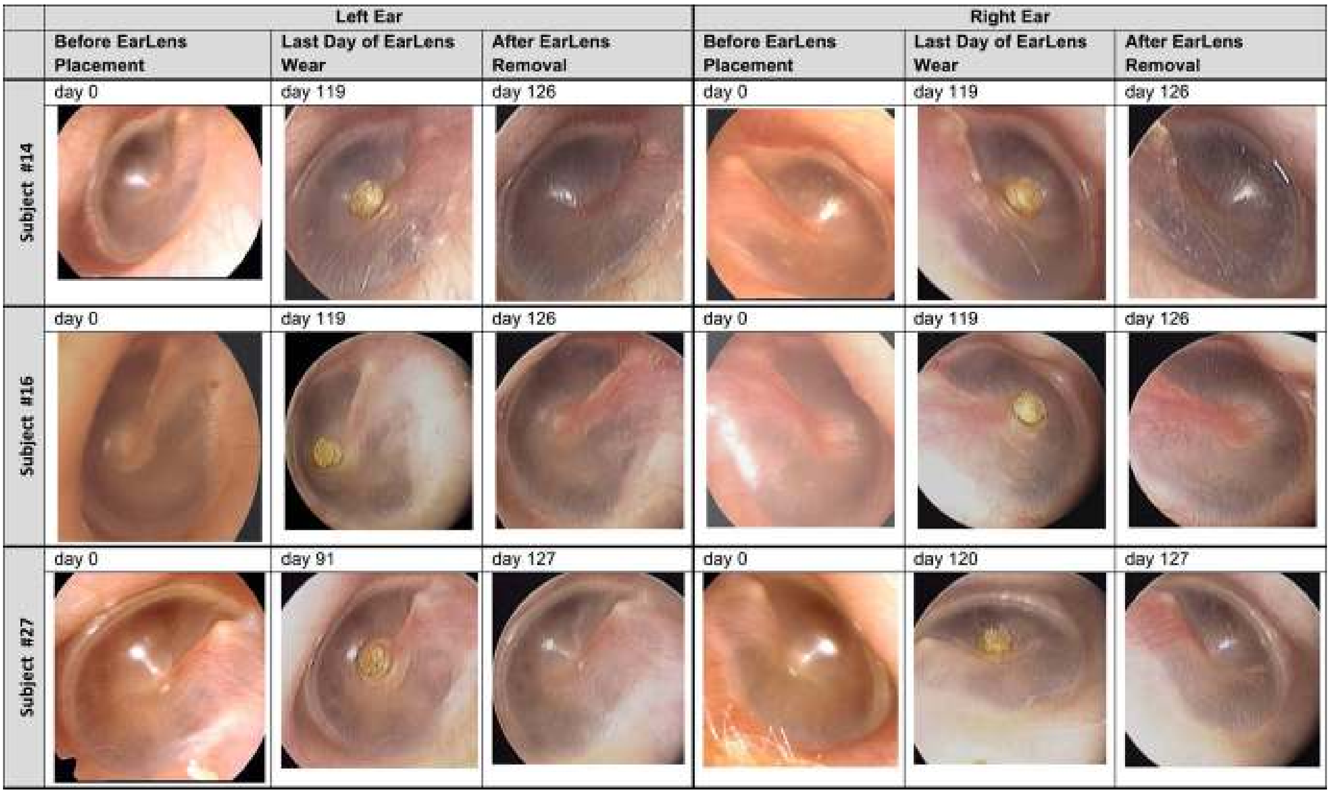

Fig. 9. Long-term wear results for tympanic-membrane transducers. Photographic documentation is shown from three representative subjects (rows), for the both the left ear (left three columns) and the right ear (right three columns). For each ear, a photograph was taken at the start of the study (day 0), on the day the EarLens transducer was removed (up to 120 days later for the three subjects shown), and around 1 week after transducers were removed.

spatial mapping of sound-source locations onto the sensory epithelium. Rather, the brain uses acoustical cues present at both ears to compute the source locations of sounds. These cues are created in part by the interaction of the sound waves with the torso, head, and external ears, and include both interaural time differences (ITD) and interaural level differences (ILD) between the ears, which vary with sound-source location (reviewed by Middlebrooks et al. (1989)). The ITD cues are salient at low frequencies, and represent differences in a sound's time of arrival at the two ears in the horizontal plane (e.g., Blauert, 1997).

Numerous studies, both in humans (Shaw and Teranishi, 1968; Shaw, 1969; Musicant and Butler, 1984; Middlebrooks et al., 1989) and in cats (Musicant et al., 1990; Rice et al., 1992), have shown that sound pressure at the ear-canal entrance varies with the location of the sound source for frequencies above 5 kHz. This spatial filtering is due to the diffraction of the incoming sound wave by the pinna. It is well established that these diffraction cues help in spatial localization, especially monaurally or at high frequencies. For conventional hearing aids, due to their limited bandwidth and microphone locations, the high frequency spatial-localization cues are not presented to the listener.

4.2. Potential benefits of the proposed system

The design of the EarLens System is intended to achieve three major advantages over conventional hearing device transducers.

First, the tympanic-membrane transducer is capable of operating over a wider frequency range, with a bandwidth exceeding 11.2 kHz for about 50% of the population and up to 8 kHz in 86% of the population (Fig. 6). Moore and Tan (2003) have reported that the perceived naturalness of speech and music is improved by increasing both the low-frequency and high-frequency responses.

Second, the amount of acoustic feedback is greatly reduced, even with an open ear canal and the microphone placed within the ear canal. Measurements indicate a gain margin of typically more than 30 dB (Fig. 7), which means that the signal picked up by the microphone could be amplified by as much as 30 dB before positive feedback would begin to occur. The exceptions are in the 3 (±1) kHz and 9 (±1) kHz ranges, where the mean gain margin is reduced to about 12 dB and 23 dB, respectively. The fact that the gain margin is low only for limited frequency regions is important, since feedback-cancellation algorithms can be more effective if the cancellation is only required for a limited range of frequencies (Chi et al., 2003). Typical gain improvements due to feedback cancellation are on the order of 8–20 dB. This would make it possible to place the microphone in an open-ear-canal configuration while at the same time providing much more gain than is available with current open-canal hearing devices.

Third, by placing the microphone within the ear canal, the normal acoustic advantages provided by the pinna and ear-canal resonances are preserved, thus eliminating the need for directional microphones.

The most significant potential benefit of the EarLens system, however, is that the combination of the above three advantages may enable improvements to speech discrimination in noisy environments. Providing important sound-localization cues and a wider bandwidth can allow the brain to better segregate sounds originating from different locations, and this is thought to enhance our ability to understand desired target speech in the presence of interfering speech (Puria and Perkins, 2005). This notion has been corroborated by recent psychoacoustic experiments which demonstrate that, by increasing the bandwidth from 4 kHz to 10 kHz of both target speech sentences and symmetrically-placed masking speech (originating from 30° to each side of the target speech), an approximately 2.5 dB improvement in the detectability of the target speech is achieved, which is significant (Puria et al., 2008). In the context of an implantable hearing aid with an ear-canal microphone, Zenner et al. (2004) also demonstrated improvements in speech recognition when masking noise came from a different location than the target speech.

There are several areas where the electromagnetic tympanic-membrane transducer can be improved. These include using a smaller coil size for greater user comfort, reducing the sensitivity to the distance and orientation between the magnet and coil, improving battery life, and improving the feedback gain margin in the ear-canal resonance region(s). Another area for improvement is that for frequencies above 8 kHz, the MEPO needs to be higher than the subject's threshold because peak values of speech are higher than average spectral levels of speech (Moore et al., 2008). These constitute significant engineering challenges for the future.

4.3. A better approach: the EarLens photonic system

One way to solve a number of the electromagnetic system's present shortcomings is to use a light beam as the means of transmitting energy wirelessly to the tympanic-membrane transducer. To motivate the feasibility of using the energy contained in light to stimulate the auditory system, consider that a cone cell in the eye needs approximately as much energy, in the form of visible light, as a hair cell in the cochlea needs, in the form of audible sound, to trigger a perception at the threshold of detection.[1]

Pluvinage and Perkins (2005) proposed a photonic system to activate a tympanic-membrane contact transducer. Subsequently, there have been several applications that describe the use of photonic methods to produce eardrum vibrations using piezoelectric and electromagnetic transducers on the eardrum (Perkins et al., 2005; Fay et al., 2008; Puria and Perkins, 2005). More recently, Lee et al. (2008) proposed an actuator consisting of dual photodiodes, two oppositely wound coils, and two magnets on a platform coupled to the tympanic membrane. A more invasive implantable hearing aid approach was proposed by Wang et al. (2005) and Abel et al. (2007), where light is transmitted through the eardrum to a photodetector inside the middle-ear cavity. The voltage from the photodetector then drives a piezoelectric transducer attached to one of the middle-ear bones.

After studying the feasibility of a light-driven tympanic-membrane contact transducer and concluding that such a system was technically feasible, we are now developing a photonic EarLens system. In this system, the audio signal is encoded into one or more wavelengths of light using a laser diode housed in the sound-processing unit. The diode output is transported to the ear canal via nearly invisible sub-millimeter-diameter optical fibers. A tympanic-membrane transducer containing a photodiode then converts their emitted light energy into an electrical voltage, which after demodulation powers a miniature electromagnetic actuator that vibrates the umbo.

The much thinner energy-carrying fiber(s) are significantly more comfortable to wear than the coil in the ear canal. Moreover, while in the electromagnetic system changes in the coil position relative to the magnet would affect the sensitivity of the system, in the optical system such positional effects are believed to be significantly smaller.

[1] As shown previously in Puria and Steele (2008), the work performed at the absolute threshold of hearing is estimated to be 3×10^{-18} J. For comparison, a dark-adapted eye requires 90 photons to perceive a flash. Of these 90 photons, only about 10 photons reach the sensory cones needed for perception of the flash. The energy of 10 photons in the visible spectrum is calculated to be approximately 4×10^{-18} J, which is close to the estimated absolute threshold of hearing.

In our current development of the photonic EarLens system, we have observed outputs of 90–115 dB SPL in the frequency range between 200 Hz and 10 kHz in a limited number of ears. We are encouraged by these preliminary studies.

The vast improvements that have been made in laser diodes, optical fibers, optoelectronics, and battery technology are what make the photonic EarLens now feasible and, potentially, could pave the way for a new generation of hearing devices.

5. Conclusions

In the 0.125–11.2 kHz frequency range, the electromagnetic EarLens System has an average maximum equivalent pressure output (MEPO) that ranges from 80 to 96 dB SPL. These effective output pressures, which were achievable in 50% of subjects all the way up to 11.2 kHz, and in 86% of subjects up to 8 kHz, are sufficient to reach threshold for hearing impairment of up to 60 dBHL. The maximum amount of amplification that can be applied to the microphone input signal before positive feedback occurs, the feedback gain margin (GM), is generally at least 30 dB for the system, except in the 3 and 9 kHz regions where resonances in the ear canal cause it to be lower. The reduced feedback gain margins in the canal-resonance regions indicate that the use of a feedback-cancellation algorithm could prove necessary. The increase in hearing thresholds due to placement of the EarLens transducer on the tympanic membrane, referred to as the tympanic-membrane damping (D_{TM}), does not exceed 8 dB on average, and is limited to the region around 3 kHz. The tympanic-membrane transducer was found to be stable and safe for long-term wear, was comfortable, and was easily tolerated by subjects. No structural changes to the tympanic membrane or to the auditory thresholds were observed for any of the subjects over a maximum study period of 10 months. This study supports the idea that the enhanced capabilities of the EarLens System may enable improvements to a patient's ability to understand speech in noisy environments.

Our current work in developing the optical transmission of sound to a tympanic-membrane contact transducer appears promising.

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