Temporal-Bone Measurements of the Maximum Equivalent Pressure Output and Maximum Stable Gain of a Light-Driven Hearing System That Mechanically Stimulates the Umbo

*†‡Sunil Puria, †Peter Luke Santa Maria, and *†Rodney Perkins

*EarLens Corporation, Menlo Park; †Department of Otolaryngology, Head and Neck Surgery; and ‡Department of Mechanical Engineering, Stanford University, Stanford, California, U.S.A.

Hypothesis: That maximum equivalent pressure output (MEPO) and maximum stable gain (MSG) measurements demonstrate high output and high gain margins in a light-driven hearing system (Earlens).

Background: The nonsurgical Earlens consists of a light-activated balanced-armature transducer placed on the tympanic membrane (Lens) to drive the middle ear through direct umbo contact. The Lens is driven and powered by encoded pulses of light. In comparison to conventional hearing aids, the Earlens is designed to provide higher levels of output over a broader frequency range, with a significantly higher MSG. MEPO provides an important fitting guideline.

Methods: Four fresh human cadaveric temporal bones were used to measure MEPO directly. To calculate MEPO and MSG, we measured the pressure close to the eardrum and the stapes velocity, for sound drive and light drive using the Earlens.

Results: The baseline sound-driven measurements are consistent with previous reports. The average MEPO (n=4) varies from 116 to 128 dB SPL in the 0.7 to 10 kHz range, with the peak occurring at 7.6 kHz. From 0.1 to 0.7 kHz, it varies from 83 to 121 dB SPL. For the average MSG, a broad minimum of about 10 dB occurs in the 1 to 4 kHz range, above which it rises as high as 42 dB at 7.6 kHz. From 0.2 to 1 kHz, the MSG decreases linearly from approximately 40 dB to 10 dB.

Conclusion: With high output and high gain margins, the Earlens may offer broader-spectrum amplification for treatment of mild-to-severe hearing impairment. Key Words: Hearing aids—Light-driven hearing—Photonic hearing—Temporal bone measurements.

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We hypothesize that maximum equivalent pressure output (MEPO) and maximum stable gain (MSG) measurements will demonstrate high output and high gain margins in a light-driven hearing system (Earlens).

BACKGROUND

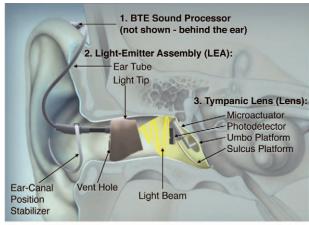
The Earlens is a nonsurgical investigational middleear hearing device consisting of the three components shown in Figure 1A: (1) a behind-the-ear unit (BTE) that processes incoming sound and transforms it into a specially encoded amplified electrical signal; (2) a Light Tip in the ear canal that receives the electrical signal and uses it to shine encoded light pulses at the tympanic membrane (TM); and (3) a Tympanic Lens (Lens) (Fig. 1B), sitting in contact with the TM, that wirelessly receives the light signal in the ear canal and uses it to power a built-in balanced-armature transducer to mechanically stimulate the umbo (1,2).

The MEPO of the Earlens provides an important guideline for setting BTE light output levels and fitting the device to a subject's hearing loss. MEPO varies across subjects, and is in part a function of the distance between the light source and the Lens. This is because the light beam spreads out over distance, such that the energy per unit area falling on the photodiode of the Lens, or the "optical efficiency," decreases as the light source moves further away from the photodiode. MEPO cannot be measured directly in subjects, since the Earlens is designed such that its equivalent output can exceed 100 dB SPL at many frequencies, and no suitable artificial middle-ear coupler exists for testing the system. For this reason, we sought to measure the performance of the Earlens using a set of fresh or frozen human cadaveric temporal bones.

Address correspondence and reprint requests to Sunil Puria, Ph.D., c/o EarLens Corporation, 4045 Campbell Avenue, Menlo Park, CA 94025, U.S.A.; E-mail: spuria@earlenscorp.com

Dr. S.P. and Dr. R.P. declare that they have a financial interest in the EarLens Corporation, which is in the process of developing the hearing system discussed in this manuscript. In addition, Dr. P.L.S.M. is a paid consultant for EarLens Corporation.

Supplemental digital content is available in the text.



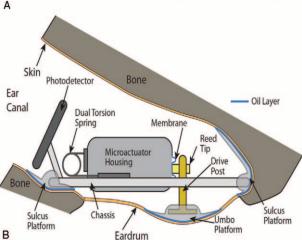


FIG. 1. (*A*) The light-driven hearing system (Earlens), a nonsurgical investigational hearing device consisting of three components: a behind-the-ear unit (BTE) that encodes amplified sound into electrical pulses that are sent to the Light Tip, which transduces them into pulses of light transmitted wirelessly to the Tympanic Lens (Lens), a light-activated balanced-armature transducer that drives the middle ear through direct contact with the umbo. (*B*) Diagram of the Lens in situ. The photodector converts light into an electrical signal, which is wired to the balanced-armature microactuator. The motor reed is attached to the drive post, which is coupled to the custom umbo platform. A pair of bias springs between the chassis and microactuator provides a static force that maintains continuous contact between the umbo platform and the eardrum.

METHODS

Temporal-Bone Materials and Preparation

Four fresh temporal bones from three donors (TB1, TB2, TB3, and TB4) were tested. A transmastoid modified facial recess approach to expose the stapes footplate was used, in which the tympanic and vertical segments of the facial nerve were removed while taking care to preserve the incus buttress, pyramidal process, stapes tendon, and ossicular chain. The middle-ear cavity was left open during measurements.

Velocity and Pressure Measurements

An ER-7C probe-tube microphone (Etymotic Research, Elk Grove Village, IL, U.S.A.) was used to measure ear-canal

pressure (P_T) within 2 to 3 mm of the TM, and a Polytec HLV-1000 laser Doppler vibrometer (LDV; Polytec, Irvine, CA, U.S.A.) was used to measure stapes velocity (V_S) .

The measurements of $V_{\rm S}$ and $P_{\rm T}$ were made with SYSid ver 7.1 (3), using the following input voltages: 1) " $E_{\rm MAX}$ ", which was 1 V_{PEAK} for sound drive and 0.126 V_{PEAK} for light drive; 2) $E_{\rm MAX}$ –10.5 dB; 3) $E_{\rm MAX}$ –21 dB; 4) $E_{\rm MAX}$ –30 dB; 5) $E_{\rm MAX}$ –40.5 dB; and 6) a nominal 10^{-7} V_{PEAK} value to measure the noise floor.

The actual voltage used for the ''noise floor'' measurements was limited by the 16-bit SYSid system to $88 \times 10^{-6} \, V_{PEAK}$, or around 59 dB higher than the nominal $10^{-7} \, V_{PEAK}$ value. Synchronous averaging reduced the measured noise floor and improved the measured dynamic range.

For sound drive, $V_{\rm S}$ and $P_{\rm T}$ were measured without the Lens in place (Fig. 2A) and with the Lens in situ on the TM. For the light-driven cases, $V_{\rm S}$ and $P_{\rm T}$ were measured using a BTE and light-emitting Light Tip to drive the Lens placed on the TM (Fig. 2B). Both the Light Tip and Lens were custom-molded to fit each temporal bone. The Light Tip was designed to be vented to the open canal (or the atmosphere in this case), although it was discovered at the end of the experiment that the TB2 vent was accidently plugged with adhesive during manufacturing.

The BTE was programmed to operate in pass-through mode, such that the stimulus signal coming from SYSid was converted into a light output without any additional processing or amplification.

Measurement Corrections

The $V_{\rm S}$ measurements were converted from peak velocity to RMS velocity to match the calibrated $P_{\rm T}$ measurements, and a $1/\cos(55^\circ)$ adjustment factor was applied to compensate for the assumed angle of the LDV with respect to the stapes footplate (4). Additional adjustments were made to the light-driven $V_{\rm S}$ and $P_{\rm T}$ measurements to compensate for differences in the output power of the Light Tip laser diodes used for each temporal bone. The measured laser-diode output power for TBs 1 to 4 was 2.72, 2.27, 2.34, and 2.58 mW, respectively, as compared with the nominal 2.5 mW output power, thus resulting in correction factors ranging from 0.92 to 1.1.

Data Analysis

The measurements of $V_{\rm S}$ and $P_{\rm T}$ for sound and light drive were used to calculate the following quantities using custom MATLAB scripts.

Baseline Sound-Driven V_S/P_T Without the Lens on the TM

To be included in the baseline $V_{\rm S}/P_{\rm T}$ means, both $V_{\rm S}$ and $P_{\rm T}$ had to have ≥ 6 dB SNR and < 10% harmonic distortion for the second and third harmonics. These means were used in subsequent calculations to represent the baseline sound-driven $V_{\rm S}/P_{\rm T}$ response for a given temporal bone.

TM Damping Caused by Lens Placement on the Eardrum

The sound-driven $P_{\rm T}/V_{\rm S}$ response with the Tympanic Lens on the TM was divided by the mean baseline $P_{\rm T}/V_{\rm S}$ response without the Lens on the TM to compute TM Damping.

In Fay et al. (2) TM damping is defined as the change in the threshold of hearing because of the presence of the Lens on the TM, so a positive value would indicate that a larger pressure is required to elicit a given perceptual response when the Lens is in place.

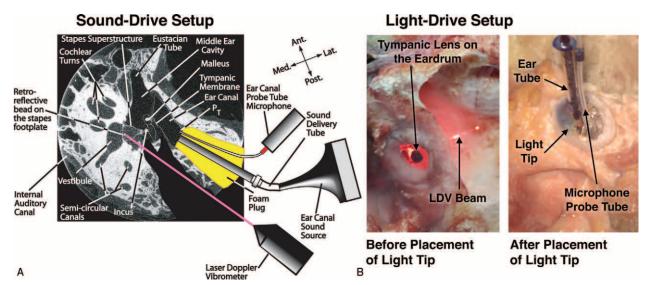


FIG. 2. Sound-driven (A) and light-driven (B) setups used for the temporal-bone experiments. A probe-tube microphone was used to measure ear-canal pressure (P_T) within 2 to 3 mm of the tympanic membrane (TM) or Lens, and a Polytec HLV-1000 laser Doppler vibrometer (LDV) was used to measure stapes velocity (V_S). (A) Setup for the baseline case of sound-driven stimulation (unaided), both without the Lens in place and with the Lens in situ on the TM (not shown). (B) Setup for light-driven cases using a custom-shaped Lens and Light Tip with the laser light source of the Light Tip within 3 mm of the Lens' photodiode.

Equivalent Pressure Output (EPO)

EPO allows the input voltages of the Earlens to be directly compared with the equivalent pressure outputs of an acoustic hearing aid, as measured near the TM. It was computed by dividing the light-driven $V_{\rm S}$ response at a given input voltage by the mean baseline sound-driven $V_{\rm S}/P_{\rm T}$ response measured on the same temporal bone.

Maximum Equivalent Pressure Output (MEPO)

MEPO is simply the EPO corresponding to the $E_{\rm MAX}$ input voltage. Estimations of MEPO using a circuit-model representation of the Lens for a range of optical-coupling efficiency values are also reported.

Maximum Stable Gain (MSG)

MSG is defined as the EPO of the Earlens divided by the corresponding feedback pressure $P_{\rm T}$ generated by the TM in response to Lens stimulation at the umbo: MSG=EPO/ $P_{\rm T}=((V_{\rm S}/P_{\rm T})|_{\rm Light})/((V_{\rm S}/P_{\rm T})|_{\rm Sound})$. For this experiment, the light-driven feedback pressure was measured at approximately 2 to 3 mm from the Lens.

RESULTS

Baseline Sound-Driven V_S/P_T Without the In-Situ Lens

The mean baseline sound-driven $V_{\rm S}/P_{\rm T}$ responses for TB1–TB4 are shown in Figure 3A, along with an overall mean across the four bones. The overall mean of the TB1–TB4 means falls completely within the 95% confidence interval (CI) from the Rosowski et al. (5) comparison curves, as does the TB1 mean, although the other individual means stray beyond the 95% CI for some frequencies.

TM Damping

Figure 3B shows the individual means and overall mean of the TM Damping, along with the published mean

from Fay et al. (2), based on live subjects. The overall mean curve ranges from around $-9.1\,\mathrm{dB}$ ($\sim\!10\,\mathrm{kHz}$) to $+9.3\,\mathrm{dB}$ ($\sim\!1\,\mathrm{kHz}$), with a mean across the 95 plotted frequencies of 0.76 dB. The Fay et al. (2) overall mean ranges from $-0.26\,\mathrm{dB}$ ($\sim\!10\,\mathrm{kHz}$) to $+6.5\,\mathrm{dB}$ ($\sim\!1\,\mathrm{kHz}$), with a mean across the 13 plotted frequencies of 2.5 dB.

Light-Driven Stapes Velocity and Ear-Canal Feedback Pressure

The $V_{\rm S}$ responses behave linearly for the most part as the drive voltage changes, with the exception of some low and high frequencies (see Supplemental Digital Content, http://links.lww.com/MAO/A352). The $E_{\rm MAX}$ line for TB3 exhibits saturation effects above approximately 4 kHz, and the low-frequency $E_{\rm MAX}{-}30\,{\rm dB},$ $E_{\rm MAX}{-}40.5\,{\rm dB},$ and sometimes $E_{\rm MAX}{-}21\,{\rm dB}$ curves seem to be affected by the noise floor.

The feedback-pressure measurements $P_{\rm T}$ corresponding to the light-driven $V_{\rm S}$ measurements indicate the amount of pressure generated in the ear canal, around 2 to 3 mm away from the Lens, caused by the motions of the Lens as it interfaces with the umbo. $P_{\rm T}$ rises as high as 120 dB SPL in TB3 for the $E_{\rm MAX}$ voltage, and the maximums of the other three temporal bones all rise above 110 dB SPL (see Supplemental Digital Content, http://links.lww.com/MAO/A352).

Equivalent Pressure Output (EPO)

Figure 4 shows the equivalent pressure output (EPO) of the Earlens for each of the drive voltages. The EPO responses exhibit the same degree of linearity as the $V_{\rm S}$ measurements that they are based on, and range from under 50 dB SPL at the 0.5-kHz dip all the way up to 136 dB SPL in TB2 around 6 kHz. The maximum values all lie between 120 and 136 dB SPL.

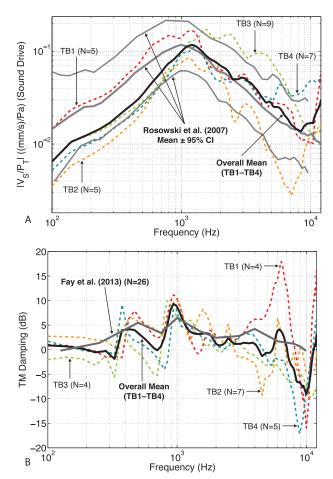


FIG. 3. (A) Mean baseline sound-driven V_S/P_T responses, without the Lens on the TM, for TB1-TB4. For the individual temporalbone means (thin dashed lines), the "N" values indicate the number of distinct measurements (i.e., both repeated measurements and measurements at different stimulus levels) used to compute each mean. The thick solid black line is the overall mean of the four individual means. The solid gray lines, from Rosowski et al. (5), represent the overall mean of the means from 13 different studies (thick solid gray line), along with the 95% confidence interval (thin solid gray lines) for those means. (B) Mean TM-Damping responses for TB1-TB4, indicating how the presence of a passive Lens on the TM dampens V_S/P_T . An overall mean of the individual means (thick solid black line), as well as an overall mean from Fay et al. (2) (thick solid gray line), are also shown. The average across frequencies of the current measurements is 0.76 dB (based on the 95 plotted points), whereas the mean from the Fay et al. (2) study is 2.5 dB (based on the 13 plotted audiometric frequencies).

The EPO responses typically rise up to $0.4\,\mathrm{kHz}$, dip around $0.5\,\mathrm{kHz}$, and rise again up to around $0.8\,\mathrm{kHz}$ before becoming relatively flat with various moderate peaks and dips up to $10\,\mathrm{kHz}$. All of the lines for a given TB are generally linearly related to drive voltage, except for E_{MAX} in TB3, where the output saturates above $5\,\mathrm{kHz}$. The dip around $0.5\,\mathrm{kHz}$ has been identified as an antiresonance caused by the pair of bias-force torsion springs in the Lens. The addition of damping to the springs in future designs could reduce the depth of this dip.

Maximum Equivalent Pressure Output (MEPO)

Figure 5A presents the MEPO curves corresponding to the $E_{\rm MAX}$ drive voltage for each temporal bone, along with an overall mean of those curves. For comparison, the overall mean of MEPO measurements from the Fay et al. (2) study, extrapolated based on the hearing thresholds of 26 ears using live subjects, is shown, along with one standard deviation above and below. The minimum audible pressure (MAP) from Killion (6) is also shown.

The overall mean of the current MEPO results lies above the Fay et al. (2) mean by at least 10 dB for most frequencies, and sometimes by more than 20 dB. One exception to this is at 0.5 kHz, where the characteristic dip of the current measurements brings the mean slightly below the Fay et al. (2) mean. In the clinical study with the Alpha version of the Lens (2), the antiresonance occurred slightly below 0.5 kHz because of softer bias springs and that the 12 measurement frequencies in that study (compared with 95 for the current study) were too widely spaced to capture this local minimum.

The Fay et al. (2) results also seem to be smoother than the current results because their mean was based on 26 ears rather than only 4 for the current study. The current overall mean MEPO lies between 60 and 110 dB above the MAP curve, which is up from around 50 to 97 dB for the in-vivo study (2).

Maximum Stable Gain (MSG)

Figure 6 shows the mean maximum stable gain (MSG) for each temporal bone, plus an overall mean across the four temporal-bone means. Mean and standard deviation responses from Fay et al. (2) are shown for comparison, but these responses are based on a microphone location within the BTE above the pinna, such that a much smaller feedback-pressure reading, and consequently much higher MSG, is to be expected compared with the current study.

For TB2, the MSG below 0.8 kHz is typically lower by about 5 to 10 dB than for the other ears. This is likely because the TB2 Light Tip was accidently blocked during manufacturing.

Even with the microphone placed so close to the TM, the mean MSG for the current study still indicates that the Earlens is capable of providing from 5 to more than 40 dB of stable gain. In comparison, the MSG for an acoustic hearing aid, with the "feedback" and output pressures measured at the same point close to the TM, would be 0 dB since the output and feedback pressures should be the same under these conditions.

DISCUSSION

Advantages of the Earlens Over Acoustic Hearing Aids

For open-canal acoustic hearing aids, the options for microphone placement and the amount of available amplification are limited by how much sound from the speaker gets fed back into the microphone (7). The TM does not function as a very efficient loudspeaker, particularly at higher frequencies when its surface breaks up into

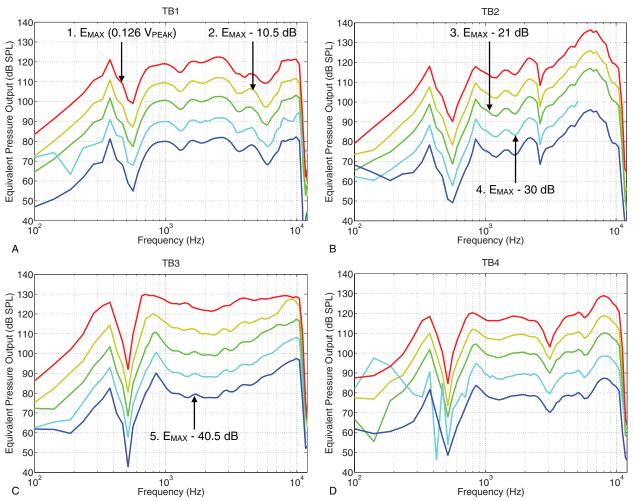


FIG. 4. Equivalent pressure output (EPO) responses at various stimulus levels, for TB1–TB4 (A-D). EPO is calculated as the light-driven $V_{\rm S}$ measurements (Fig. S1) normalized by the mean sound-driven $V_{\rm S}/P_{\rm T}$ transfer function for the corresponding temporal bone (Fig. 3A). Responses to the following five drive voltages are shown: $E_{\rm MAX}$ (0.126 $V_{\rm PEAK}$), $E_{\rm MAX}$ –10.5 dB (3.76 \times 10⁻² $V_{\rm PEAK}$), $E_{\rm MAX}$ –21 dB (1.12 \times 10⁻² $V_{\rm PEAK}$), $E_{\rm MAX}$ –30 dB (4.00 \times 10⁻³ $V_{\rm PEAK}$), and $E_{\rm MAX}$ –40.5 dB (1.20 \times 10⁻³ $V_{\rm PEAK}$).

modes and it generates evanescent sound waves in the ear canal that become attenuated in the far field (3). Because of this, the MSG of the Earlens can be increased beyond what would be possible for an acoustic hearing aid with a microphone placed at the same location.

The First Measurements of a Newly Designed Tympanic Lens

The baseline sound-driven measurements of the newly designed Lens (Fig. 3A) are consistent with previous reports (5), suggesting that the temporal bones used have normal middle ears. Because the 95% CI represents the spread of the means from various studies, rather than the spread of all the individual temporal-bone responses from those studies, the TB2–TB4 responses shown here are most likely not unusual.

MEPO Comparisons to Model Predictions

In addition to the temporal-bone measurements of MEPO, we have also developed a way to calculate

MEPO based on a mechanical circuit-model representation of the Lens in situ in the ear canal (Fig. 5B, inset). The model incorporates some of the key elements of the output transducer and its coupling to the effective impedance of the ossicular chain, as depicted in Figure 1B, and has been used as a design tool to predict the average behavior of the Lens and its sensitivity to parameter variations. Its parameters (see Fig. 5, legend) were derived from values in the literature (3) and bench testing.

Figure 5B shows model MEPO calculations, for optical efficiency values ranging from 40 to 100%, which capture the general trends of the mean Lens output. The MEPO Specification was chosen to ensure that the output would be sufficient to fit subjects having a hearing loss up to 60 dB HL below 0.5 kHz and up to 80 dB HL above 4 kHz (2).

The minimum near 0.5 kHz, due to the antiresonance mode caused by the two bias springs, is generally captured by the model. These springs provide coupling

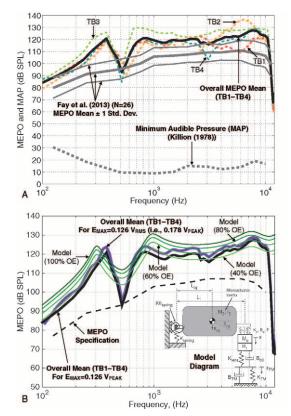


FIG. 5. (A) Maximum equivalent pressure output (MEPO) responses for TB1-TB4, which are simply the EPO responses at the $E_{\rm MAX}$ stimulus level. Individual measurements from each temporal bone are shown (thin dashed lines) along with the mean curve (thick solid black line). Mean (thick solid gray) and standard deviation (thin solid gray) results from Fay et al. (2), based on extrapolations from hearing thresholds of live subjects and the peak output voltage of the sound processor, are also shown. The minimum audible pressure (MAP) curve from Killion (6) is shown for comparison. (B) Comparison of measured and model-predicted MEPO responses. Measured MEPO means are shown for both the normal case with $E_{\text{MAX}} = 0.126 \, \text{V}_{\text{PEAK}}$ (thick solid black line), and for a scaled case (thick solid purple line) that indicates how the MEPO mean would change (accounting for device saturation) if E_{MAX} were set to 0.126 V_{RMS} (i.e., 0.178 V_{PEAK}) instead. Modeled MEPO responses (thin solid lines) are shown for optical-efficiency values ranging from 40 to 100%, corresponding to different spacings between the photodiode and the light source. The MEPO Specification curve (thin dashed line) indicates the minimum output requirement needed to treat patients within the inclusion criteria of the Fay et al. (2) clinical study. (B, inset) The lumped-element mechanical circuit model of the Lens in situ in the ear canal used for calculating MEPO. The linear (K_{spring}) and torsional (K_{θ}) spring constants for the bias springs are shown, as well as the mass (M_2) and moment of inertia (I_2) of the microactuator, with the distance from the spring rotational axis to the center of gravity shown as L_{CG} and the length of the drive post shown as L_1 . The coupling stiffness (K_0) and damping (B_0) of the balanced actuator reed are shown, with a force F delivered to the drive post with mass M_0 . The umbo platform has mass M_1 , stiffness $K_{\rm lens}$, and damping because of oil B_{oil} . The umbo platform sees a load impedance consisting of the middle-ear stiffness K_{TM} and damping B_{TM} . The umbo moves a distance of X_{TM} when driven by the microactuator. The depicted model parameters are as follows: $K_{\rm spring} = 167 \, \text{N/m}$; $K\theta_{\rm spring} = 2e-5 \, \text{N-m/rad}$; $L_1 = 5 \, \text{mm}$; $M_2 = 110 \, \text{mg}$; $L_2 = 9.5e-11 \, \text{kg-m}^2$; $L_{\rm cg} = 2.3 \, \text{mm}$; $K_{\rm o} = 430 \, \text{N/m}$; $B_{\rm o} = 0.0033 \, \text{N-s/m}$; $M_{\rm o} = 0.62 \, \text{mg}$; $M_1 = 0.62 \, \text{mg}$; $M_2 = 0.62 \, \text{mg}$; $M_3 = 0.62 \, \text{mg}$; $M_4 =$ 0.7 mg; $K_{lens} = 3000 \text{ N/m}$; $B_{oil} = 0.02 \text{ N-s/m}$; $K_{TM} = 1300 \text{ N/m}$; $B_{TM} = 1300 \text{ N/m}$ 0.23 N-s/m.

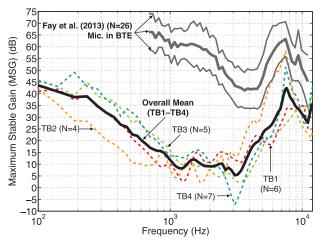


FIG. 6. Maximum stable gain (MSG) responses for TB1–TB4. The MSG is the EPO divided by the feedback pressure, P_{T} , which for this study is measured at a point 2 to 3 mm from the Lens. Individual temporal-bone means are shown (thin dashed lines), along with an overall mean (thick solid black line). Values >0 dB for the temporal-bone measurements indicate that the Earlens can produce a higher gain without producing unstable feedback than an acoustic hearing aid measured with the same microphone location. Fay et al. (2) mean and standard deviation results are shown for comparison (solid gray lines), although these results were measured with the feedback pressure measured outside of the ear canal in a BTE above the pinna where it should be much lower (making the MSG much higher) than at a point close to the eardrum.

between the motor and the chassis and provide a bias force that allows the umbo platform to maintain contact with the TM despite changes such as body position, middle-ear-cavity pressure, and environmental pressure. The model responses are somewhat damped in comparison to the measurements, which seem sharper with their higher peaks and lower dip. Improvements to the model are needed to better capture the dip and surrounding peaks, as simple parameter variations could not achieve a better fit to the data. Work is ongoing to reduce the depth of the dip by adding damping to the spring. It is expected that this fixed narrow dip in the frequency spectrum will not have perceptual consequences, but this needs to be evaluated more carefully.

In addition to the overall MEPO mean from Figure 5A, which was measured using a drive voltage of 0.126 $V_{\rm PEAK}$, another version is also shown to indicate how the MEPO could change if the drive voltage were 0.126 $V_{\rm RMS}$ instead (i.e., 0.178 $V_{\rm PEAK}$). This correction factor was measured on the bench, and shows how the Earlens could be expected to behave if the input voltage were moderately boosted beyond $E_{\rm MAX}$, in a way that accounts for the frequency-dependent saturation of the device. These nonlinear saturation effects are not well described in the model.

MEPO Comparisons Between Two Generations of the Tympanic Lens

For the current Lens, the overall mean (n = 4) MEPO varies from 116 to 128 dB SPL in the 0.7 to 10-kHz range,

with the peak occurring at 7.6 kHz, whereas the MEPO for the Alpha transducer was 111 dB SPL. This increase in MEPO by 17 or more dB (more than a factor of 7) is in part because of an improved balanced armature motor design and a more efficient emitter and photodiode combination. These improvements will allow for some combination of increased battery life, reduced BTE size, and increased MEPO.

MSG Comparisons

The overall mean MSG for this study, with the microphone 2 to 3 mm from the Lens, has a broad minimum of about 10 dB in the 1 to 4 kHz range (Fig. 6), whereas in that range the MSG from the previous Alpha study, with the microphone in the BTE above the pinna, nearly 30 to 40 mm lateral to the TM, was 40 to 60 dB (referred to as "Gain Before Feedback" in that study). The average MSG for this study peaks at about 42 dB near 7.5 kHz, whereas in the Alpha study the peak was about 62 dB, also near 7.5 kHz. Both studies had their ear canals widely vented (except, accidentally, for TB2 in the present study).

The difference in microphone location is thought to account for most of the measured difference in MSG between the two studies. In practice, the measured feedback pressure will vary depending on the measurement location, with measurements at points closer to the open end of the ear canal (or outside of the ear canal altogether) generally expected to be lower in magnitude than at a point close to the TM. This is largely because the radiation impedance looking outward from the ear canal is expected to decrease as one moves laterally, such that the measured feedback pressure decreases (8,9). This reduced feedback pressure, in turn, should result in an increase in MSG. Therefore, the reported MSG values for this temporal-bone experiment are considerably lower than the MSG values one would expect for an Earlens microphone placed more laterally in the ear canal or outside of the ear canal within the concha or above the pinna in the BTE, for example.

The origin of the measured feedback pressure is the vibrating TM surface. When driven by sound in the forward direction, the TM surface moves up to 30 times more than the umbo (10,11). However, the TM surface breaks up into more and more modes as the frequency increases (11,12), such that the sound pressure radiation because of these modes tends to cancel in the far field and thereby produce lower feedback pressure at frequencies around 3 to 4 kHz than at lower frequencies (3). This is also likely to be the case when the umbo is mechanically driven (13,14). The motion of the motor surface itself is likely to contribute little to this feedback pressure.

In acoustic hearing aids, a feedback canceller is used to improve the gain margin and expand the range of hearing-level criteria for fitting the device. This improvement varies from 0 dB (no benefit) to 18 dB (significant benefit) depending on the algorithm used and the acoustic

conditions (15). Another approach to improve feedback is the use of occluding domes that close the ear canal, but this leads to unwanted occlusion effects. The Earlens is unique in that MSGs of more than 40 dB can be achieved at high frequencies with an open ear canal and no feedback cancellation. It is possible to use feedback-cancellation algorithms with the Earlens to reduce feedback in the mid frequency range where the MSG is lower.

CONCLUSIONS

The maximum equivalent pressure output (MEPO) and maximum stable gain (MSG) characteristics of the light-driven hearing system (Earlens) offer a feasible way of providing broad-spectrum amplification appropriate to treat listeners with mild-to-severe hearing impairment, while at the same time maintaining a widely vented ear canal.

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