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

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Abstract

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 non-surgical EarLens consists of a light-activated balanced-armature Tympanic Lens (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 and a significantly higher MSG with the MEPO providing an important fitting guideline.

Methods—Four fresh human cadaver temporal bones were used to measure MEPO directly. To calculate MEPO and MSG, we measured the pressure close to the eardrum and 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 0.1–0.7 kHz, it varies from 83 to 121 dB SPL. For the average MSG, a broad minimum of about 10 dB occurs in the 1–4 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 about 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.

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Conflicts of interest: Authors Dr. Sunil Puria and Dr. Rodney Perkins 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. Peter Santa Maria is a paid consultant for EarLens Corporation.

Hypothesis

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 non-surgical investigational middle-ear 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) (Figure 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 it 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.

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) was used to measure ear-canal pressure (P_T) within 2–3 mm of the TM, and a Polytec HLV-1000 laser Doppler vibrometer (LDV) was used to measure stapes velocity (V_S).

The measurements of V_S and P_T were made with SYSid ver 7.1 (3), using the following input voltages: 1) " E_{MAX} ", which was 1 V_{PEAK} for sound drive and 0.126 V_{PEAK} for light drive; 2) E_{MAX} –10.5 dB; 3) E_{MAX} –21 dB; 4) E_{MAX} –30 dB; 5) E_{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 $88 \times 10^{-6} V_{\text{PEAK}}$, or around 59 dB higher than the nominal $10^{-7} V_{\text{PEAK}}$ value. Synchronous averaging reduced the measured noise floor and improved the measured dynamic range.

For sound drive, V_S and P_T were measured without the Lens in place (Figure 2A) and with the Lens in situ on the TM. For the light-driven cases, V_S and P_T were measured using a BTE and light-emitting Light Tip to drive the Lens placed on the TM (Figure 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 accidentally 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_S measurements were converted from peak velocity to RMS velocity to match the calibrated P_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_S and P_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 1–4 were 2.72, 2.27, 2.34, and 2.58 mW, respectively, as compared to 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_S and P_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_S/P_T means, both V_S and P_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_S/P_T response for a given temporal bone.

TM Damping caused by Lens placement on the eardrum—The sound-driven P_T/V_S response with the Tympanic Lens on the TM was divided by the mean baseline P_T/V_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 due to 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.

Equivalent Pressure Output (EPO)—EPO allows the input voltages of the Earlens to be directly compared to the equivalent pressure outputs of an acoustic hearing aid, as measured near the TM. It was computed by dividing the light-driven V_S response at a given input voltage by the mean baseline sound-driven V_S/P_T response measured on the same temporal bone.

Maximum Equivalent Pressure Output (MEPO)—MEPO is simply the EPO corresponding to the E_{MAX} input voltage. Estimations of MEPO using a circuit-model representation of the Lens for a range of optical-coupling efficiency values is presently reported.

Maximum Stable Gain (MSG)—MSG is defined as the EPO of the Earlens divided by the corresponding feedback pressure P_T generated by the TM in response to Lens stimulation at the umbo: $MSG = EPO/P_T = ((V_S/P_T)|_{Light})/((V_S/P_T)|_{Sound})$. For this experiment, the light-drive feedback pressure was measured at approximately 2–3 mm from the Lens.

Results

Baseline Sound-Driven V_S/P_T without the in-situ Lens

The mean baseline sound-driven V_S/P_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 dB (~10 kHz) to +9.3 dB (~1 kHz), with a mean across the 95 plotted frequencies of 0.76 dB. The Fay et al. (2013) overall mean ranges from –0.26 dB (~10 kHz) to +6.5 dB (~1 kHz), with a mean across the 13 plotted frequencies of 2.5 dB.

Light-Driven Stapes Velocity and Ear-Canal Feedback Pressure

The V_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 Figure). The E_{MAX} line for TB3 exhibits saturation effects above about 4 kHz, and the low-frequency E_{MAX} –30 dB, E_{MAX} –40.5 dB, and sometimes E_{MAX} –21 dB curves appear to be affected by the noise floor.

The feedback-pressure measurements P_T corresponding to the light-driven V_S measurements indicate the amount of pressure generated in the ear canal around 2–3 mm away from the Lens by the motions caused by the Lens vibration of the umbo. P_T rises as high as 120 dB SPL in TB3 for the E_{MAX} voltage, and the maximums of the other three temporal bones all rise above 110 dB SPL (see Supplemental Digital Content Figure).

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_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.

The EPO responses typically rise up to 0.4 kHz, dip around 0.5 kHz, and rise again up to around 0.8 kHz before becoming relatively flat with various moderate peaks and dips up to 10 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 kHz. The dip around 0.5 kHz has been identified as an antiresonance due to the bias-force springs in the Lens. The addition of damping to the spring 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_{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, are shown, along with 1 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 Fay, et al. (2), the anti-resonance occurred slightly below 0.5 kHz due to a softer bias spring and the 12 measurement frequencies in that study (compared to 95 for the current study) were too widely spaced to capture this local minimum.

The Fay, et al. (2) results also appear 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 50–97 dB for the *in-vivo* study.

Maximum Stable Gain (MSG)

Figure 6 shows the mean maximum stable gain (MSG) for each temporal bone, plus an overall mean across the 4 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 to the current study.

For TB2, the MSG below 0.8 kHz is typically lower by about 5–10 dB than for the other ears. This is likely because the TB2 Light Tip was accidentally 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 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 new Lens

The baseline sound-driven measurements 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 (Figure 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 Figure 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 percent, 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 anti-resonance mode of the two bias springs is generally captured by the model. These springs provide coupling between the motor and the chassis and provide a bias force that allows the umbo platform to maintain contact with the TM in spite of changes such as body position, middle-ear-cavity pressure, and environmental pressure. The model response is somewhat damped in comparison to the measurements, which appear sharper with higher peaks and lower dips. Improvements to the model are needed to better capture the dip and surrounding peak responses, 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 $0.126 V_{PEAK}$, another version is also shown to indicate how the MEPO could change if the drive voltage were $0.126 V_{RMS}$ instead (i.e., $0.178 V_{PEAK}$). 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_{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 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 $7\times$) is due in part to 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 2–3 mm from the Lens, has a broad minimum of about 10 dB in the 1–4 kHz range (Figure 6), whereas in that range the MSG from the previous Alpha study, with the microphone in the BTE above the pinna, nearly 30–40 mm lateral to the TM, was 40–60 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, while 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 due to these modes tends to cancel

in the far field and thereby produce lower feedback pressure at frequencies around 3–4 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. 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.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

(A) The light driven hearing system (Earlens), a non-surgical 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 photodetector 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 provide a static force that maintains continuous contact between the umbo platform and the eardrum.

Figure 2.

Sound-drive (A) and light-drive (B) setups used for the temporal-bone experiments. A probe-tube microphone was used to measure ear-canal pressure (P_T) within 2–3 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.

Figure 3.

(A) Mean baseline sound-driven V_S/P_T responses, without the Lens on the TM, for TB1–TB4. For the individual temporal-bone 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 grey lines, from Rosowski, et al. (5), represent the overall mean of the means from 13 different studies (thick solid grey line), along with the 95% confidence interval (thin solid grey lines) for those means. (B) Mean

TM-Damping responses for TB1–TB4, indicating how the presence of a passive Lens on the TM affects 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 grey line) are also shown. The average across frequencies of the current measurements is 0.76 dB (based on the 95 plotted points), while the mean from the Fay, et al. (2) study is 2.5 dB (based on the 13 plotted audiometric frequencies).

Figure 4.

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

Figure 5.

(A) Maximum Equivalent Pressure Output (MEPO) responses for TB1–TB4, which are simply the EPO responses at the E_{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 grey) and standard deviation (thin solid grey) 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 Killian (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 $E_{MAX}=0.126 V_{PEAK}$ (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 micro-actuator, 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_o) and damping (B_o) of the balanced actuator reed are shown, with a force F delivered to the drive post with mass M_o . The umbo platform has mass M_1 , stiffness K_{lens} , and damping due to 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: $K_{spring}=167$ N/m; $K_{\theta spring}=2e-5$ N-m/rad; $L_1=5$ mm; $M_2=110$ mg; $I_2=9.5e-11$ kg-m²; $L_{cg}=2.3$ mm; $K_o=541$ N/m; $B_o=0.0037$ N-s/m; $M_o=0.62$ mg; $M_1=0.7$ mg; $K_{lens}=3000$ N/m; $B_{oil}=0.02$ N-s/m; $K_{TM}=1300$ N/m; $B_{TM}=0.23$ N-s/m.

Figure 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 2–3 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 grey 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.