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Optimum Coupling of an Active Middle Ear Actuator: Effect of Loading Forces on Actuator Output and Conductive Losses

*†Ute A. Gamm, †‡Martin Grossöhmichen, †‡Rolf B. Salcher, †‡Nils K. Prenzler, †‡Thomas Lenarz, and †‡Hannes Maier

*Cochlear Deutschland GmbH & Co. KG, Karl-Wiechert-Alee 76A; †Department of Otolaryngology and Institute of Audioneurotechnology (VIANNA), Hannover Medical School, Hannover, Germany; and ‡DFG Cluster of Excellence Hearing4all, Germany

Introduction: The desired outcome of the implantation of active middle ear implants is maximum coupling efficiency and a minimum of conductive loss. It has not been investigated yet, which loading forces are applied during the process of coupling, which forces lead to an optimum actuator performance and which forces occur when manufacturer guidelines for coupling are followed.
Methods: Actuator output was measured by laser Doppler vibrometry of stapes motion while the actuator was advanced in 20 μm steps against the incus body while monitoring static contact force. The occurrence of conductive losses was investigated by measuring changes in stapes motion in response to acoustic stimulation for each step of actuator displacement. Additionally, the electrical impedance of the actuator was measured over the whole frequency range at each actuator position.
Results: Highest coupling efficiency was achieved at forces above 10 mN. Below 1 mN no efficient coupling could be achieved. At 30 mN loading force, which is typical when coupling according to manufacturer guidelines, conductive losses of more than 5 dB were observed in one out of nine TBs. The electrical impedance of the actuator showed a prominent resonance peak which vanished after coupling.
Conclusion: A minimum coupling force of 10 mN is required for efficient coupling of the actuator to the incus. In most cases, coupling forces up to 100 mN will not result in clinically relevant conductive losses. The electrical impedance is a simple and reliable metric to indicate contact.
Key Words: Active middle ear implant—Cochlear™ Carina®—Loading forces.

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INTRODUCTION

Patients with moderate to severe sensorineural and mixed hearing loss can opt for active middle ear implants (AMEIs) when conventional (air conduction) hearing aids don't deliver sufficient amplification or cannot be worn due to medical or anatomical reasons. Currently, different middle ear implant systems are on the market that attach to the ossicular chain in various ways; e.g., a floating mass transducer (FMT) is usually clipped to the incus while other actuators are mounted to a fixation system attached to the skull and only lightly touch the incus. In the latter case of an actuator mounted in a fixation system, correct coupling of the actuator is crucial, since a weak coupling will not lead to the desired output amplitude and gain (1–3) and a very tight coupling could hinder the ossicles' mobility when the implant is turned off, and create an additional conductive hearing loss. The correlation between position of the actuator and actuator performance has been investigated previously (4). The authors found a maximum output at a displacement of 62 μm after first indicated contact and a gradual decrease in performance with further displacement to 373 μm. Their study used a coarse spacing of 62 μm and did not investigate the forces that are associated with the respective actuator positions. The present study aims to close this knowledge gap. We performed an extensive study on cadaveric temporal bones where we measured loading forces, actuator output, and ossicular vibration in response to sound (to measure conductive

Address correspondence and reprint requests to Ute A. Gamm, Ph.D., Cochlear Deutschland GmbH & Co. KG, Karl-Wiechert-Alee 76A, 30625 Hannover, Germany; E-mail: ugamm@cochlear.com

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loss) for increments of 20 μm of actuator displacement against the incus body. Also we measured actuator impedance to identify minimum loading forces necessary for optimum actuator coupling efficiency and to evaluate manufacturer guidelines using a hardware and software tool (5,6).

MATERIALS AND METHODS

Temporal Bone Preparation

Experiments were performed on 14 freshly frozen human cadaveric temporal bones (TB) that had been obtained from the Institute of Pathology of the Hannover Medical School. The experiments were approved by the ethics committee of the Hannover Medical School (No. 3452–2016). Details on the preparation of the temporal bones can be found in previously published articles (7,8). Four out of the 14 temporal bones were not compliant to the modified American Society for Testing & Materials International (ASTM) standard F2504-05 (9,10) and were therefore excluded from experiments. Another experiment was excluded due to an inconsistency in data acquisition, leaving nine TB experiments for data analysis.

Controlling Loading Forces

The Cochlear™ MicroDrive™ actuator (2nd generation, current model) as used in the Cochlear™ Carina® System (Cochlear Boulder LLC., Boulder, CO) was used for experimental evaluation. Seven of the experiments were performed with the same actuator which then broke and was replaced by another actuator for the last two experiments. The actuator was attached to a force sensor (LSB200, FUTEK Advanced Sensor Technology, Southern California, CA) and mounted on a three-axis micromanipulator (M3301R, World Precision Instruments Germany GmbH, Germany) to allow precise positioning relative to the incus and simultaneous force measurements. Here we used the same angle of incidence as in real surgeries where the actuator is mounted in a fixation system that is attached to the skull. A small hole was made into the incus with a surgical laser for placement of the actuator tip, which is the customary procedure at the Medical University Hannover (Fig. 1). Although the creation of a hole in the incus body was used in early procedures and is uncommon at most clinics today we used a hole for the attachment site as the clinicians think it may stabilize the actuator rod laterally. The actuator was advanced towards the incus in steps of 20 μm starting from a position without contact, and the force was recorded at each step. Contact with the incus caused an increase of measured force. We measured up to a force of 100 to 120 mN. To measure an accurate relation between actuator displacement relative to the incus and forces applied to the incus, the displacement had to be corrected for the compliance of the actuator. The compliance was measured once by advancing it against a rigid object measuring forces for each 4 μm step.

Measuring Actuator Performance at Different Loading Forces

For each displacement of the actuator against the incus, a series of single-point laser Doppler vibrometric (LDV) measurements (CLV 700, HLV 1000, HLV MM2, Polytec, Germany) at the stapes footplate (SFP) was performed. The experimental procedure as well as signal generation and acquisition have been described in detail previously (7,8). In short, during a measurement series, LDV measurements were performed during multiple forms of stimulation. First, as a reference measurement, the tympanic membrane was stimulated acoustically between 0.1 and 10 kHz with a sequence of 23 pure tones with a frequency resolution of approximately three frequencies per octave and levels of 80 to 120 dB $\mathrm{SPL_{TM}}$ (SPL at the tympanic membrane). A probe microphone (ER7C, Etymotics) placed in close proximity to the tympanic membrane was used to record the acoustic stimulus. Second, the actuator was electrically driven with the same sequence of sine wave signals previously used for the acoustical stimulation, having amplitudes of approx. -8 dB re 1 V_{rms} at each stimulation frequency. The resulting stapes footplate vibration was measured for both types of stimulation using LDV. From measurements of the sound pressure level at the tympanic membrane (p_T) and the displacement (d_u^{SEP}, unaided) of the stapes measured by LDV the normal middle ear transfer function, as defined by the ASTM standard F2504-05[10], was calculated as: $H_{TV} = d_u^{SEP} / p_T$. Similarly the electro-vibrational transfer function can be retrieved from measurements of the stapes displacement (d_a^{SEP}, aided) during stimulation with the actuator: $H_{EV} = d_a^{SEP}/E$ with E being the electrical input voltage. The equivalent sound pressure level L_E at the tympanic membrane at $E = 1\,V_{rms}$ hypothetically actuator input can be calculated using $H_{ET} = H_{EV}/H_{TV}$:

$$L_E = 20\log_{10}\left(\frac{E \cdot H_{ET}}{2 \cdot 10^{-5}\mathrm{Pa}}\right)[\mathrm{dB\,SPL}]$$

Lastly, the full spectrum of the electrical impedance of the actuator was measured for each force by recording the voltage drop across a 33 Ω resistor in series with the actuator while it was driven with white noise (12.5 Hz resolution, 1024 FFT lines between 0 and 12.8 kHz). The impedance measurements were also recorded with the experimental setup and used to gain knowledge about the behavior of the actuator under different loading forces and to be able to evaluate the performance of the transducer loading assistant (see ''Characterizing Manufacturer Guidelines for Coupling'').

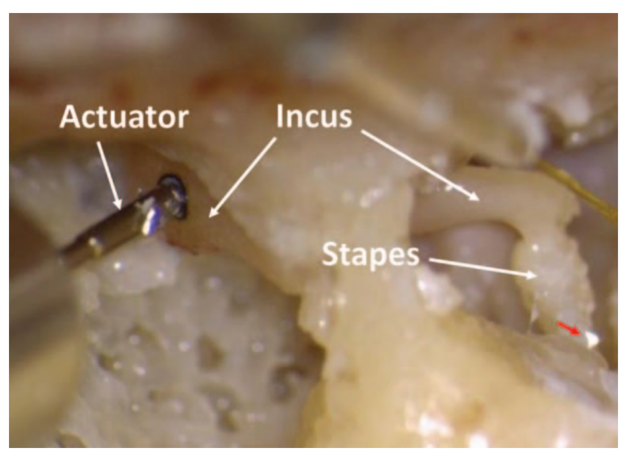

FIG. 1. View of the temporal bone during the loading experiment. The T2 actuator was coupled to a hole in the incus body created by a laser (a *black rim* of the hole is visible around the tip of the actuator). *Red arrow* points to reflector foil used for LDV measurements. Movement of the stapes was predominantly measured on the stapes footplate; in cases when the view on the stapes footplate was obscured, measurements on the posterior stapes crus were performed.

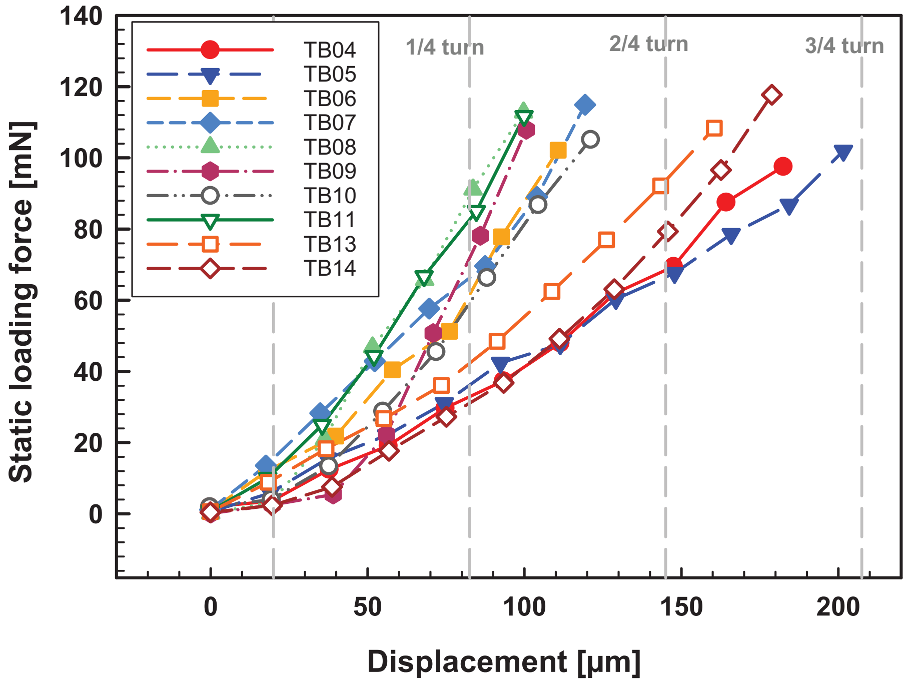

FIG. 2. Displacement of the actuator coupled to incus body versus loading forces. The displayed characteristics of the ossicles are corrected for the compliance of the actuator. Initial coupling (displacement = 0 µm) to the incus was defined by an increase in force of more than 2 mN. The vertical grey dashed lines show quarter turns of the micro-adjust screw in quarter turns.

Characterizing Manufacturer Guidelines for Coupling

The transducer loading assistant (TLA) and the Carina® test software by Cochlear Boulder LLC (Boulder , CO) are tools that measure the magnitude of the electrical impedance of the actuator at the mechanical resonance with the intention of optimizing coupling efficiency. The surgeon is advised to advance the actuator forward by turning the micro-adjust until a drop of at least 50 Ω occurs. Subsequently, they should turn the micro-adjust by another 1/4 turn (approximately 62.5 µm) to ensure stable coupling. To determine which forces exactly correspond with the drop in impedance and which forces occur after

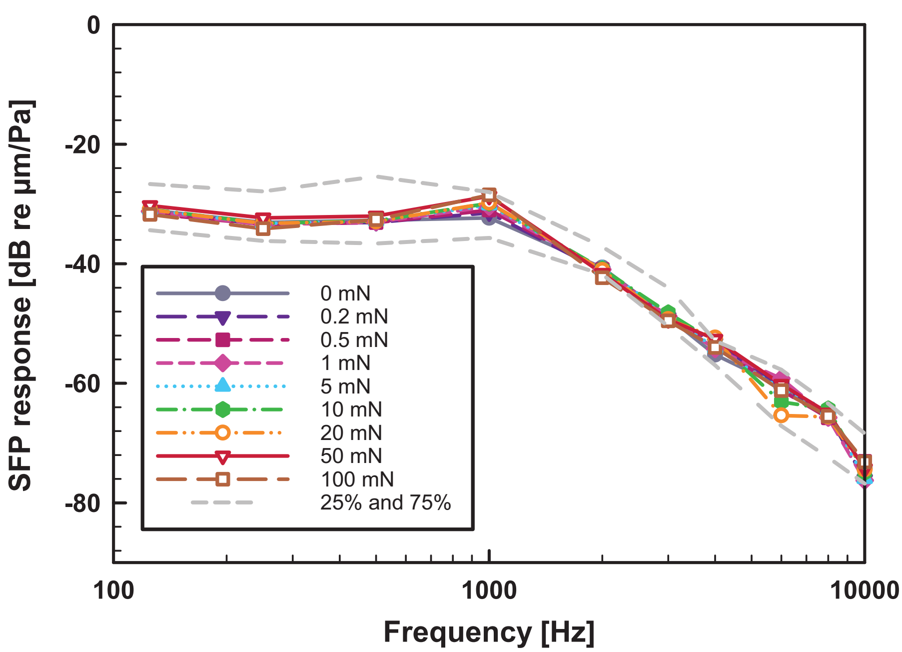

FIG. 3. Median SFP response to acoustic stimulation at the tympanic membrane. Median values of 9 TBs. Grey dashed lines display the 25 and 75% percentiles of the data points in the unloaded state. SFP indicates stapes footplate.

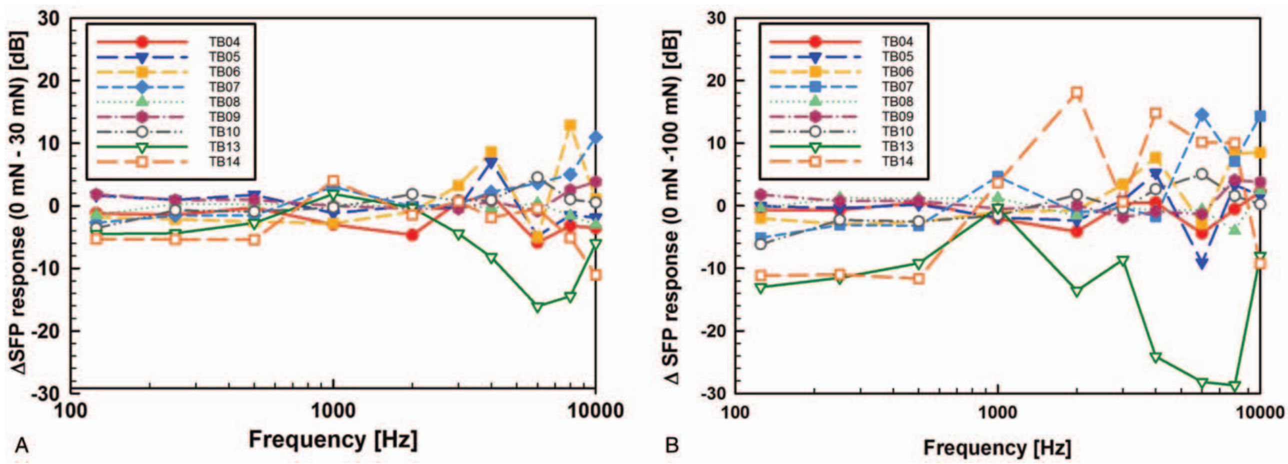

FIG. 4. Difference in SFP response to acoustic stimulation at a force of (*A*) 30 mN and (*B*) 100 mN compared with the unloaded state for individual temporal bones. N = 9. SFP indicates stapes footplate.

advancing the actuator by 62.5 μm we connected the actuator to the TLA and to the force sensor and measured the forces while we advanced the actuator forward towards a flexible rubber tube in steps of 20 μm using the micromanipulator. The stiffness of the rubber tube was 0.41 ± 0.1 mN/μm and therefore similar to one of the more flexible temporal bones (range, 0.5–1.7 mN/μm) (compare with Figs. 2 and 3). Using knowledge of this trigger point (drop >50 Ω) we then used the force and displacement data we collected from the temporal bones (Fig. 2) to estimate which forces would be applied if the actuator would be advanced by the recommended 62.5 μm; in our case 60 μm which corresponded to three steps of 20 μm from the TLA trigger point.

RESULTS

Static Loading Forces

Loading forces were applied by advancing the actuator towards the incus in steps of 20 μm. Upon initial contact with the incus, an increase of the static loading force was recorded. We defined a threshold of 2 mN as initial contact, the position immediately before initial contact (i.e., 20 μm back) was then defined as the unloaded state and displacement 0 μm. The force curves in Figure 2 appear mainly linear at loading forces above 10 mN. Slopes of these curves vary from 0.5 to 1.7 mN/μm (0.98 ± 0.38 mN/μm [mean (MV) ± standard deviation [SD]) and indicate differences in the mechanical properties of the ossicular chain for different temporal bones. In the aforementioned bench experiments the compliance of the actuator alone was measured to be 0.18 μm/mN and was used to correct for the displacement in Figure 2.

Effect of Loading Force on Middle Ear Sound Transmission

To investigate the potential impact of coupling on passive sound transmission through the middle ear, SFP displacement in response to acoustic stimulation was measured using LDV, at different loading forces. The median stapes response normalized to 1 Pa sound pressure level at the TM upon acoustic stimulation of all TBs (n = 9) is displayed in Figure 3. A flat response of −30 dB re μm/Pa was observed up to 1000 Hz which gradually decreased by approximately 12 dB/octave down to −75 dB re μm/Pa at 10 kHz. Only small deviations from initial response occurred at high loading forces. For forces of 50 and 100 mN, a maximum decrease of 4 dB from a stapes response in the unloaded state was found at 1000 Hz. Also a deviation of approximately 5 dB re μm/Pa was found at a force of 20 mN at 8000 Hz. Additionally, we calculated the difference in SFP response in the unloaded state and at 30 mN (Fig. 4A), which is the force of recommended coupling (see section ''Transducer Loading Assistant Display Versus Coupling Force''). For frequencies up to 2 kHz the difference in SFP displacement between no contact and a force of 30 mN was less than 5 dB. Small conductive losses were found for one TB (TB 13), where the difference in SFP response was lower than −10 dB between 4 and 8 kHz with a minimum of −16 dB at 6 kHz. To investigate the influence of higher loading on sound transmission we additionally investigated the difference in SFP response between at the unloaded state and at 100 mN (Fig. 4B). Here TB 13 was losing even more transmission at 2 to 10 kHz down to almost −30 dB as well as approximately −10 dB at 100 to 500 Hz. TB 14 also lost transmission in the low frequency range (100–500 Hz; approx. 10 dB). In both Figure 4A and B, increases in sound transmission of 10 dB at 8 kHz could be observed for TB6. In Figure 4B, two additional TBs showed an increase in sound transmission of more than 10 dB (TB7 and TB14).

Effect of Loading Force on Coupling Efficiency

Equivalent Sound Pressure Levels (eq SPL) for actuator stimulation were calculated in reference to acoustical stimulation of the tympanic membrane, for loading forces from 0 to 100 mN using the stapes footplate response to sound at the unloaded state as reference (Fig. 5). For loading forces of 1 mN or less, coupling

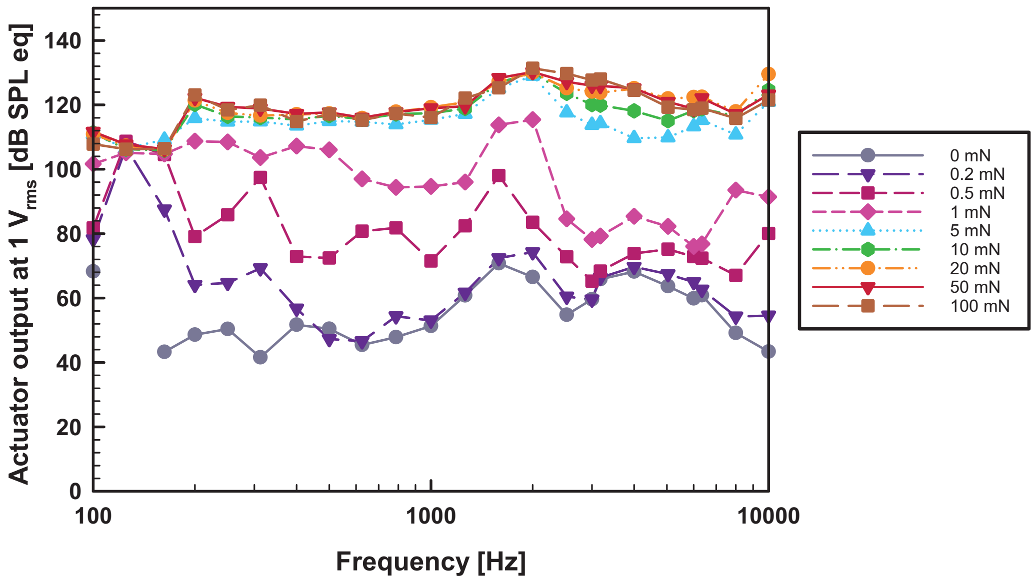

FIG. 5. Actuator output for different loading forces. Median values of 9 TBs. TBs indicates temporal bones.

efficiency was suboptimal at all frequencies. For loading force of 5 to 10 mN, maximum coupling efficiency was reached at frequencies up to 1000 Hz. At 20 mN and higher, maximum coupling efficiency was achieved over the entire frequency range. Interestingly, even with very high coupling forces of 50 or 100 mN, coupling efficiency did not change.

Impedance Measurements

As a potential indicator for loading force and optimum loading position, the electrical impedance of the transducer was measured over a frequency range of 0 to 12.8 kHz. Figure 6A shows the magnitude of the electrical impedance for one representative example (TB7) at difference coupling forces. In this example, a pronounced resonance peak is visible at 1762 Hz. Increasing loading forces cause the height of the peak to drop. Small forces up to 1 mN cause only small changes in magnitude of the peak at first, but forces between 1 and 5 mN lead to a sharp drop and a complete disappearance of the peak. For all nine experiments results were similar to the displayed example. In the unloaded condition, the resonance peak was located between 1750 and 1800 Hz (average 1767 ± 21 Hz [MV ± SD]). A drop by 50 Ω or more was

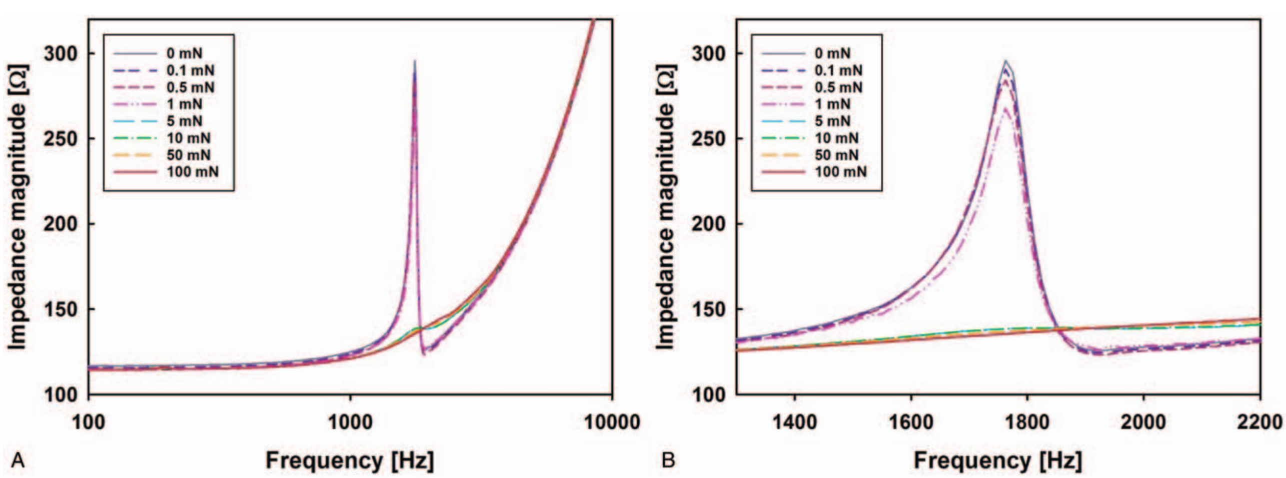

FIG. 6. (*A*) Representative display of the electrical impedance magnitude of the T2 actuator collected from one of the TBs (TB7) (*B*) magnification of the resonance peak in *A*.

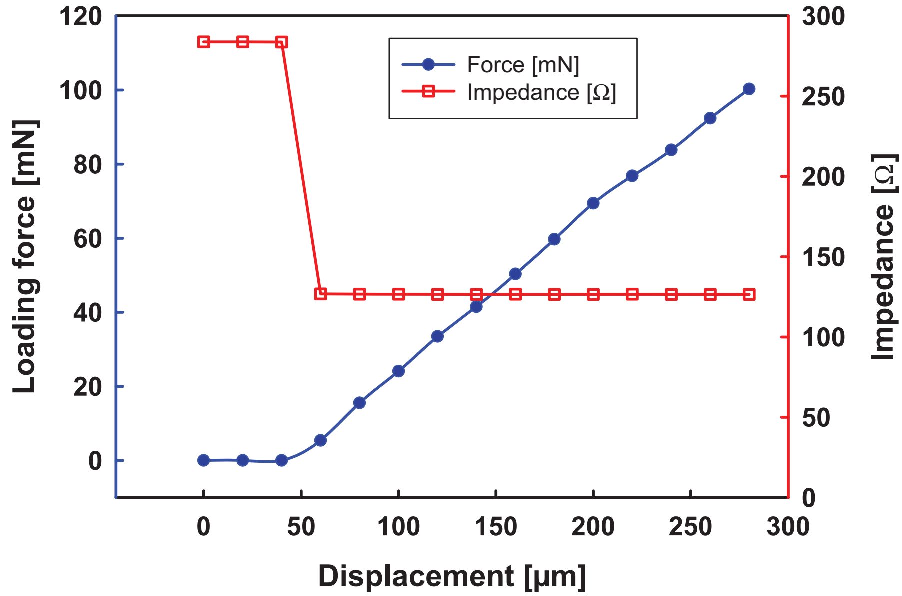

FIG. 7. Exemplary contact force versus displacement displayed in combination with the impedance indication of the TLA when pushed against ossicle simulation. TLA indicates transducer loading assistant.

recorded at an average force of 1.1 ± 1 mN (MV ± SD). In some of the temporal bones we also noted a shift of the resonance with increased force in some of the experiments but this shift was not consistent throughout all experiments (data not shown).

Transducer Loading Assistant Display Versus Coupling Force

To investigate how the values displayed by the TLA correlate with actual loading forces, we pushed the transducer against a flexible piece of rubber tube and measured loading force, displacement, and the response of the TLA simultaneously. In Figure 7 we plotted displacement versus force in combination with the TLA response for one of the experiments. The TLA indication changed abruptly at a force of approximately 3 mN. In total we repeated the bench test eight times with two different transducers and found this TLA trigger point between 1 and 7 mN (average 2.8 ± 2.5 mN [MV ± SD]). Using the average trigger force we estimated the forces when following the suggested procedure (1/4 turn forward) from the experimental temporal bone data by reading the corresponding force 60 μm forward to a displacement that correlated with the average trigger force of approximately 2.8 mN. By this we estimated the loading forces between 12 and 65 mN; in average 28 ± 17 mN (MV ± SD) when the standard intraoperative procedure with the TLA according to the manufacturer guideline is applied.

DISCUSSION

This study investigated how middle ear implant actuator output and the occurrence of conductive losses depend on loading force. The findings were additionally put in context with current recommendations by the manufacturer to use the transducer loading assistant tool.

This study investigated coupling to the incus body only. Conclusions drawn from this study are therefore exclusively valid for this type of incus coupling which currently accounts for the largest fraction of implantations in clinical practice. However, alternative ways of coupling using coupling elements that either clip to the long process of the incus or the stapes head, as well as round window are also important ways to couple the actuator as they bypass the middle ear partially or completely and should be investigated in the future. A need for more detailed literature is highlighted be the fact that previous studies on alternative coupling investigated actuator performance in general but did not investigate loading forces (11). Other studies that did investigated loading forces (e.g., on the round window (12)) however used a different actuator.

The setup used in the study, with both the laser hole in the incus body, and the use of a very stiff micromanipulator, should prevent any lateral movement of the actuator tip. If an actuator was used in real surgery at an oblique angle of incidence to the incus, without a laser hole, then lateral motion of the actuator tip along the surface of the incus could be possible, and result in different displacement-vs-efficiency characteristics.

Actuator Efficiency

As displayed in Figure 5, measurements of actuator output (expressed as eq SPL) at various coupling forces showed that a force of minimally 10 mN or higher, should be applied to achieve optimal coupling. Forces below, which correspond with forces at initial contact, lead to suboptimal coupling. Coupling with 5 mN lead to an actuator output that is equivalent to the output at

10 mN throughout the spectrum with the exception of 3 to 6 Hz where the output was about 10 dB lower. A recently published study compared actuator output measured in temporal bones with clinical data from implant recipients (8), and found that clinical outcomes in those patients matched experimental results in temporal bones with very high accuracy at a loading force of 5 mN. This indicates that loading forces during clinical application might have been suboptimal in that case, and a 10 dB increase in actuator efficiency at 3 to 6 kHz could have been achieved by applying higher loading forces to the actuator. It is important to note that higher loading forces, up to 100 mN, did not lead to a decrease in average actuator efficiency, underlining the robustness of the T2 actuator.

An earlier study using an earlier generation actuator, manufactured by Otologics (13) also describes robust performance up to 3/4 turns of the (same) micro-adjust past initial contact. Another study using the same, earlier generation actuator (14) reports reduced performance starting at 1/2 turn of the micro-adjust, but their definition of ''initial contact'' is different.

Previous to our study, Tringali et al. (4) measured actuator output at different positions of the actuator against the incus. They found the actuator to be performing best at 62 μm from initial contact as indicated by the TLA which correlates with manufacturer guidelines. In the experiments by Tringali et al. (4), the actuator was moved forward up to 373 μm, which is considerably further than we did. They found a decrease in actuator output of up to 37 dB at largest displacements. We did not observe a decrease in actuator efficiency but, since we defined 100 mN as maximum force applied to the incus. In only four out of 10 temporal bones we displaced the actuator by more than 150 μm with a maximum of 200 μm. We therefore cannot draw any conclusions on actuator performance beyond 200 μm displacement.

Conductive Losses

To evaluate the occurrence of conductive losses due to stiffening of the ossicular chain we stimulated the tympanic membrane acoustically during each step of actuator displacement and measured stapes vibration. In their previous study, Tringali et al. (4) investigated only the loss of sound transmission for initial loading. They reported that no losses occurred in five temporal bones for three different actuators. When following the suggested procedure of the manufacturer leading to more realistic loading forces of 30 mN we observed in one of the nine temporal bones a clinically relevant reduction in stapes displacement (conductive loss) at high frequencies when loaded with 30 mN compared with the unloaded state (Fig. 4). In the case of overloading (Fig. 4B) with 100 mN conductive losses were found in 2 TBs. Several TBs in Figure 4A and B showed apparent increases in stapes displacement at high frequencies with loading, which we explain with rocking-like motion of the stapes that could alter the LDV signal and is known to occur at high frequencies (15–17).

Impedance Measurements for Coupling Guidance

The magnitude of the electrical impedance of the actuator at its resonance frequency dropped drastically even with very small coupling forces. It is therefore a very sensitive indicator of whether the actuator is in contact with the incus, but it cannot be used to measure forces in the clinically interesting range of 5 to 30 mN. In a few of the experiments we additionally found that the reduced resonance peak shifted towards higher frequencies with higher forces (data not shown). We explored the option to use the shift of the resonance peak as measure of force but found this phenomenon only in a few experiments and could not identify a systematic change in resonance frequency with loading forces.

Coupling According to Manufacturer Guidelines

The manufacturer recommends using a hardware and software tool as guide for coupling. Using a force sensor coupled to the actuator we identified the average trigger point of the TLA to be 2.8 ± 2.5 mN. Furthermore it is recommended to advance the actuator by a 1/4 turn of the microadjust screw (62.5 μm) after indicated initial contact. We determined the forces corresponding with a 60 μm displacement to lie at 28 ± 17 mN. Regarding actuator output, this force lies within the range of most efficient coupling that we described in Sections Effect of Loading Force on Coupling Efficiency and Actuator efficiency. Since we did not see a decrease in actuator efficiency up to forces of 100 mN, we can conclude that a turn of the micro-adjust screw by 1/2 or even 3/4 during implantation would not lead to a decrease in actuator output. However, this information has to be considered carefully, since we saw the occurrence of an air-bone gap in one out of nine temporal bones already at coupling with 30 mN and at forces of 100 mN we found the creation of an air-bone gap of more than 10 dB in two temporal bones (Fig. 4B).

CONCLUSION

In this study we investigated the effect of static loading forces on actuator output, conductive losses, and actuator electrical impedance. Efficient coupling could be achieved by applying loading forces of at least 10 mN. When the actuator is coupled according to manufacturer recommendation using the TLA, optimum transmission will be achieved, and the probability for implantation-related additional conductive losses are low, and exist only at higher frequencies (16 dB, 6–8 kHz). Additionally we confirmed that the electrical impedance of the actuator is a reliable indication for contact but is not useable as a force sensor for forces more than 10 mN.

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