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Research paper

Controlled round-window stimulation in human temporal bones yielding reproducible and functionally relevant stapedial responses

Sebastian P. Schraven [a], Bernhard Hirt [a,b], Anthony W. Gummer [a], Hans-Peter Zenner [a], Ernst Dalhoff [a,*]

[a] *University of Tübingen, Department of Otolaryngology, Tübingen Hearing Research Centre (THRC), Section of Physiological Acoustics and Communication, Elfriede-Aulhorn-Straße 5, D-72076 Tübingen, Germany*

[b] *University of Tübingen, Institute of Anatomy, Elfriede-Aulhorn-Straße 8, D-72076 Tübingen, Germany*

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ABSTRACT

Stimulation of the round window (RW) has gained increasing clinical importance. Clinical, as well as human temporal bone and in-vivo animal studies show considerable variability. The influence of RW stimulation on the cochlea remains unclear. We designed a human temporal-bone study with controlled direct mechanical stimulation of the RW membrane to identify conditions for successful RW stimulation. Eight human temporal bones were stimulated on the RW by piezoelectric stack actuators with cylindrical aluminium rods of diameter 0.5 mm and with either flat or 30° inclined top surface. Using a dedicated two-stage positioning protocol for the actuator, we achieved highly reproducible measurements of the stimulus vibration at the RW and of the resultant vibration of the stapes footplate. The reverse transmission, characterized by the displacement ratio of the stapes-footplate relative to the actuator tip on the RW membrane, yielded an average displacement ratio of 0.089 up to 1.2 kHz when the actuator was coupled without angular misalignment to the RW membrane. The results suggest that 90-μm pretension of the RW membrane is essential for optimum and reproducible RW stimulation. The displacements are shown to be roughly consistent with the equal-volume displacement hypothesis under specific assumptions about the displacement mode of the RW membrane. It is further suggested that the large inter-patient variability in the effectiveness of RW stimulation might be due primarily to the success of coupling, rather than to the variability of functionally relevant anatomical parameters.

1. Introduction

Stimulation of the round window (RW) of the inner ear has been of interest in hearing research for decades, mainly because it turned out to be an effective experimental means for the investigation of the role of common and differential pressure variations in the cochlea for the process of hearing, and because of its role in hearing without a middle ear (see e.g. Wever and Lawrence, 1950). It is known since those times that isolated presentation of a sound signal to the RW is almost equally effective for hearing as that presented to the stapes footplate (Wever et al., 1948). On the other hand, the frequent finding that electrocochleographic measures cannot be completely cancelled by adjusting relative phase and intensity of the sound pressures presented independently to both windows (Gisselson and Richter, 2011; Tonndorf and Tabor, 1962) can be used to estimate the upper limit of the contribution of a common mode of intracochlear pressure waves relative to the physiologically dominating differential mode (Voss et al., 1996). The common-mode contribution to hearing is closely related to the hypothesis of equal-volume displacements of both windows as well as to the compressibility of the cochlear fluids. In essence, equal-volume displacement of the two cochlear windows requires that the fluid be incompressible and that there be no "third windows" to the outside. If a common mode of hearing exists, the equal-volume displacement hypothesis can no longer hold; on the other hand, if equal-volume displacement is found to be invalid, hearing must not necessarily have a common mode. These mutual dependencies have been investigated in a detailed physical treatment (Shera and Zweig, 1992): Comparisons of hearing loss for patients without tympanic membrane and ossicular chain yielded an upper limit for the compressibility of the cochlear fluid and, thereby, for the difference in volume displacement of the two windows of about 1%.

Since 2006, several clinical applications of active middle-ear implants (AMEI) to the RW have been reported. RW placement of

Abbreviations: AMEI, active middle-ear implant; CM, cochlear microphonics; FMT, floating mass transducer; LDV, laser Doppler vibrometer; MET, middle-ear tranducer; PIEZO, piezoceramic stack actuator; RW, round window; SNR, signal-to-noise ratio; TB, temporal bone; TM, tympanic membrane.

* Corresponding author. University of Tübingen, Department Otolaryngology, Section of Physiological Acoustics and Communication, Elfriede-Aulhorn-Straße 5, Tübingen, Germany. Tel.: +49 7071 2988232; fax: +49 7071 294174.

E-mail addresses: sebastian.schraven@med.uni-tuebingen.de (S.P. Schraven), bernhard.hirt@klinikum.uni-tuebingen.de (B. Hirt), anthony.gummer@uni-tuebingen.de (A.W. Gummer), hans-peter.zenner@med.uni-tuebingen.de (H.-P. Zenner), ernst.dalhoff@uni-tuebingen.de (E. Dalhoff).

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hearing implants is indicated in ears with a conductive or mixed hearing loss where ossicular reconstruction is not possible or unsuccessful and a conventional hearing aid cannot be used. Alternatively, it could be used in mixed hearing loss ears undergoing standard ossicular reconstruction where additional amplification after successful surgery is thought to be necessary (Baumgartner et al., 2010; Beltrame et al., 2009; Colletti et al., 2006, 2009; Cuda et al., 2009; Frenzel et al., 2009; Kiefer et al., 2006; Linder et al., 2009; Streitberger et al., 2009; Wollenberg et al., 2007). In all published RW implantations known to us, a small piece of fascia is placed between actuator and RW to protect its integrity and optimize the coupling with the actuator. There is no measurement or estimation of the necessary adjustment of pretension of the fascia or of the RW itself. The success of the implantation is not easily judged because in most publications only the postoperative threshold for the patients, but no maximum achievable equivalent sound pressure is given. The postoperative thresholds appear to be comparable to those obtained in conventional AMEI-implantations; for instance, comparison of bone conduction and postoperative threshold at frequencies of 1–4 kHz yields an improvement of 16 dB in RW stimulation (Colletti et al., 2006), as well as in forward middle-ear stimulation using AMEI attached to the ossicular chain (Boeheim et al., 2010). On the other hand, a considerable variability of RW stimulation has been noted in clinical investigations (Beltrame et al., 2009; Nakajima et al., 2010b). This discrepancy might be due to different strategies in programming the audio-processor with respect to a compromise between the goals of sufficient dynamic range and optimum threshold restoration. One point of interest is the coupling between the actuator and the RW. For instance, the floating mass transducer (FMT) has a diameter of 1.8 mm which is greater than the mean diameter of the RW. The diameter of a circle with an area equal to that of the RW according to Okuno and Sando (1988) is 1.75 mm. Therefore, a physical description of how the FMT couples to the RW membrane is not at hand or otherwise self-evident. In conclusion, the clinical experience with RW implantations makes any quantitative estimation of the coupling effects between actuator and cochlea difficult.

Investigations in coupling a middle-ear implant to the RW in human temporal bones published so far do not directly specify (measure) the vibratory input to the RW. However, using information published elsewhere, we estimate from the work of Arnold et al. (2010), Pennings et al. (2010), and that of Tringali et al. (2010) a displacement ratio of stapes vibration relative to the vibration of the stimulating actuators at the RW of 0.0021–0.0125 (−38 dB to −54 dB).[1,2]

In-vivo stimulation at the RW has presented a similarly confounding picture. Recently, cochlear microphonics, compound action potential and auditory brainstem response were measured in chinchilla in response to both normal auditory stimulation and RW stimulation by means of a middle-ear transducer (MET) from Otologics, equipped with a 1-mm diameter ball tip without intervening material (Lupo et al., 2009). Again, estimating the ratio of stapes displacement relative to actuator displacement at the RW, we obtain a value of 0.001 (−60 dB).[3]

Displacement ratios of such a small size leave us without a convincing explanation for which properties of the cochlea (e.g. third windows), the RW membrane or coupling method contribute to the exceedingly large loss, and whether this coupling loss bears any relation to the variability of clinical success with RW implants. Given that the areas of both cochlear windows are of comparable size and that their loads are not expected to be so vastly different, one might expect a displacement ratio reasonably close to unity. We therefore designed a human temporal-bone study allowing a precise displacement control of the RW membrane during mechanical stimulation, to identify conditions for successful RW stimulation and possible sources of variability.

2. Material and methods

2.1. Measurement setup

A cylindrical aluminium rod (Fig. 1; item 1), of diameter 0.5 mm and length 7 mm, with 0° (Fig. 2A, B) or 30° inclined top surface (Fig. 2C), was glued onto a 2 × 2 × 2 mm^3 piezoelectric stack actuator (PIEZO; Model PL022.30, Physik Instrumente GmbH, Karlsruhe, Germany, Fig. 1; item 2). Instead of a straight rod, some of the preliminary experiments used a cranked rod (Fig. 2D), having a cylindrical pin of 0.5 mm diameter shifted by 2.4 mm with respect to its base. To accurately position the actuator tip on the RW, the actuator was fixed to a micromanipulator (Model MM3A-LS, Kleindiek Nanotechnik GmbH, Reutlingen, Germany, Fig. 1; item 3). The stick-slip effect based manipulator uses one linear and two rotary axes to travel a working distance of 12 mm in the translational direction and ±20 mm in the lateral directions, as measured at the tip of the actuators. The manipulator has a magnetic base with which it can be easily positioned on an iron base plate (Fig. 1; item 4). The manipulator can be moved in fine steps of 0.25 nm without inducing the stick-slip effect, or in a coarse mode using the stick-slip effect. When near the RW, a coarse mode was used ("S5"), where a single command produced a step of 5 μm. Commands were given by a Sony-Play Station© joypad which allowed easy control of the manipulator.

A laser Doppler vibrometer (LDV) system (Model OFV 302, Polytec GmbH, Waldbronn, Germany; Fig. 1; item 5 symbolizes its object beam), focused on a single reflective glass microbead (P-Retro, Polytec GmbH, Waldbronn, Germany) of diameter 45–63 μm placed on the RW or stapes footplate, was used for velocity

[1] In Arnold et al. (2010), direct coupling of an FMT to the RW without intervening material, called "standard coupling", led to 5.6 nm displacement amplitude at the stapes, coupling underlaid with subcutaneous tissue to 18 nm. Using as reference, the displacement amplitude of the FMT for the standard-coupling situation (0.32 μm, with all measurements in response to 0.1-V_{rms} drive voltage), the RW-induced stapes displacement relative to FMT displacement was 0.0175 (−35 dB) for direct coupling and 0.056 (−25 dB) for coupling underlaid with subcutaneous tissue, respectively. In Pennings et al. (2010), velocity amplitude at the stapes for 1-V_{rms} drive voltage and 1 kHz was −103 dB re. 1 m/s for direct coupling and −92 dB re. 1 m/s for coupling with fascia, respectively (their Fig. 2). This corresponds to displacement amplitudes of 1.2 nm and 4.0 nm, respectively. If, as a reference, we were allowed to take the same actuator vibration as in the former investigation, we compute a ratio of 0.0038 (−49 dB) and 0. 0125 (−38 dB), respectively. These numbers indicate an unexplained variability in those experiments and, generally, to a rather high inefficiency of RW stimulation.

[2] In Tringali et al. (2010), the RW was stimulated without intervening material, such as fascia or silicone, using a MET (Otologics, Boulder, CO, USA). The MET was equipped with ball tips of either 0.5-mm or 1-mm diameter, and the output signal was stapes velocity induced by the transducer drive voltage. We observe 0.13 mm/(sV) at 1 kHz from their mean-value curve, giving the highest value of the transfer function (0.5-mm ball diameter, resection of the RW niche – their Fig. 4D). This corresponds to a relative displacement amplitude of 20.7 nm/V. Because the MET is expected to deliver 1 μm/V at 1 kHz (see Fig. 6, 90° preloading, in Rodriguez et al., 2006), the ratio of vibration amplitude for RW stimulation compared with stapes stimulation is 0.0021 or −54 dB.

[3] Fig. 3 from Lupo et al. (2009) shows that cochlear microphonics (CM) input–output functions were almost identical for all frequencies, when CM amplitude is plotted versus ear-canal sound pressure in dB SPL and versus actuator input voltage in dB re. 1 mV for the RW stimulation. For instance, at 1 kHz and 8 kHz, the displacement amplitude at the stapes driven by sound pressure in the ear canal is expected to be 0.64–1.1 nm and 0.04–0.08 nm at 60 dB SPL, respectively (Ruggero et al., 1990; Songer and Rosowski, 2007). 60 dB re. 1 mV, on the other hand, equating to 1-V_{rms} input voltage to the Otologics transducer, which typically induces a displacement amplitude of at least 1 μm/V at 1 kHz and 0.04 μm/V at 8 kHz, respectively (see Fig. 6, 90° preloading, Rodriguez et al., 2006). Therefore, the ratio of stimulus amplitudes needed at the stapes compared with the RW is 0.0006–0.001 and 0.001 to 0.002, respectively, corresponding to a huge disadvantage of approximately 60 dB for RW stimulation.