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Evaluation of Round Window Stimulation Using the Floating Mass Transducer by Intracochlear Sound Pressure Measurements in Human Temporal Bones

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Abstract

Hypothesis—Round window (RW) stimulation with a floating mass transducer (FMT) can be studied experimentally and optimized to enhance auditory transduction.

Background—The FMT (MED-EL Vibrant Soundbridge) has been recently implanted in patients with refractory conductive or mixed hearing loss to stimulate the RW with varying degrees of success. The mechanics of RW stimulation with the FMT have not been studied in a systematic manner.

Methods—In cadaveric human temporal bones, measurements of stapes velocity with laser vibrometry in response to FMT-RW stimulation were used to optimize FMT insertion. The effect of RW stimulation on hearing was estimated using simultaneous measurements of intracochlear pressures in both perilymphatic scalae with micro-optical pressure transducers. This enabled calculation of the differential pressure across the cochlear partition, which is directly tied to auditory transduction.

Results—The best coupling between the FMT and RW was achieved with a piece of fascia placed between the RW and the FMT, and by "bracing" the free end of the FMT against the hypotympanic wall with dental impression material. FMT-RW stimulation provided differential pressures comparable to sound-induced oval window stimulation above 1 kHz. However, below 1 kHz the FMT was less capable.

Conclusions—Measurements of stapes velocity and intracochlear sound pressures in scala vestibuli and scala tympani enabled experimental evaluation of FMT stimulation of the RW. The efficacy of FMT-RW coupling was influenced significantly by technical and surgical factors, which can be optimized. This temporal bone preparation also lays the foundation for future studies to investigate multiple issues of relevance to both basic and clinical science such as RW stimulation in

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stapes fixation, non-aerated middle-ears and third-window lesions, and to answer basic questions regarding bone conduction.

Keywords

middle ear prosthesis; cochlea; stapes velocity; round window; temporal bone; floating mass transducer; cochlear pressure

INTRODUCTION

Tympanoplasty and ossiculoplasty, which are widely used to overcome conductive hearing loss due to middle ear pathology, rely on coupling sound pressure in the ear canal to the oval window (OW) of the cochlea. The method of coupling ear canal sound to the OW can work for many middle ear pathologies, but has a significant failure rate (1,2,3), and is often not feasible for others, e.g., congenital aural atresia (4).

An alternative method of coupling sound to the cochlea is by stimulating the cochlea in a reverse manner, i.e., by round-window (RW) stimulation. In experiments in the cat, Wever and Lawrence (5) and Voss et al. (6) found that when the stapes was uncoupled from the ossicular chain and sound was presented separately to the OW and the RW, the cochlear potentials were similar for both types of stimuli. These results support the hypothesis that the cochlea responds to a difference in sound pressure between the OW and the RW, or by extension, to a differential sound pressure across the cochlear partition. Other experiments in animals using RW stimulation with a piezoelectric vibrator (7) and electromagnetic implant (8) resulted in auditory brainstem response as well as auditory-nerve potentials (7) that were similar to sound-evoked potentials. Hüttenbrink (9) reported that stimulating the RW with an electrodynamic (hydraulic) stimulator in the temporal bone resulted in stapes motion.

Recently, Colletti implanted an electromagnetic middle ear implant, the floating mass transducer (FMT: which was originally designed to mechanically stimulate the incus in patients with sensorineural hearing loss) (MED-EL Vibrant Soundbridge), into patients to stimulate the RW (10). The 7 subjects that Colletti reported on had conductive, mixed or sensorineural hearing loss; all had failed prior tympanoplasty. These patients had improvement in their speech intelligibility after FMT insertion to stimulate the RW. Other surgeons have also reported good results with this technique of stimulating the RW (e.g., 4,11,12;13). These results are also consistent with the hypothesis that RW stimulation by the FMT produces a sound-pressure difference across the cochlear partition, leading to auditory transduction.

We have recently developed techniques to measure intracochlear sound pressures simultaneously in scala vestibuli and scala tympani in human temporal bones (14). Our results (14) demonstrate that the differential pressure measurement across the cochlear partition (the complex difference between scala vestibuli and scala tympani pressures) at the base of the cochlea is a sensitive measure of the input to the cochlea.

In the present study, we used measurements of intracochlear sound pressures and stapes motion to experimentally evaluate FMT stimulation of the RW in our cadaveric temporal bone preparation. The experimental preparation also afforded us the opportunity to study various parameters influencing the coupling between the FMT and RW in order to optimize the surgical technique.

METHODS

This study was approved by the Institutional Review Board of the Massachusetts Eye and Ear Infirmary. Methods regarding the temporal bone preparation, ear-canal pressure, stapes velocity, and intracochlear pressure recordings are detailed in Nakajima et al (14). In brief, human temporal bones were prepared by shortening the bony ear canal to approximately 1 cm, and by performing a posterior tympanotomy. The stapedial tendon was severed. The bony overhang of the RW was removed to allow the surface of the FMT to be nearly flush with and in contact with the RW membrane.

Sound stimulation was presented to a sealed ear canal from a small earphone (Radio Shack 40–1377) via flexible tubing. Ear-canal sound pressure was recorded with a calibrated probe tube microphone (Etymotic ER-7C) with the tip of the flexible probe tube positioned approximately 1–3 mm from the umbo. Stapes and RW velocities were measured with a laser Doppler vibrometer (Polytec CLV700) aimed at a 0.2 mm^2 reflector (consisting of polystyrene micro beads) on the posterior crus of the stapes or on the RW membrane. Intracochlear sound pressure was measured in scala vestibuli and scala tympani simultaneously with micro-optical pressure transducers (145 μm diameter) developed by Olson (15). The calibrated accuracy of the intracochlear pressure measurements were within 2 dB. The pressure transducers were inserted approximately 200 μm deep into each scala from the cochlear surface through holes (~200 μm diameter) near the RW and OW. During transducer insertion, the temporal bone was immersed in saline. The transducers were sealed to the surrounding cochlear bone with dental alginate impression material (Jeltrate, L.D. Caulk Co., which dried to a rubbery consistency) to prevent release of fluid and pressure, and to prevent air leaking into the cochlea. To confirm that air did not leak into the cochlea, the phase between the stapes and RW was confirmed to be ½ cycle before and after pressure transducers were inserted into the scalae and sealed.

For RW stimulation, the attachment arm of the FMT (designed to clamp onto the incus) was removed and the flat end of the FMT was placed against the RW membrane. We initially studied the effects of different ways to couple the FMT to the RW. First, the FMT was placed flush against the RW. Then, one or two layers of fascia (obtained from the neck muscles) were applied between the FMT surface and the round-window membrane. To stabilize the FMT in position, Jeltrate was introduced between the free end of the FMT and the surrounding bone of the hypotympanum: this is termed “bracing” the FMT in the remainder of the paper. As discussed in Results, optimum coupling of the FMT to the RW was achieved by using fascia and bracing. Therefore, the subsequent measurements in the study were made with the FMT coupled to the RW with one layer of fascia and braced. Figure 1a illustrates the placement of the FMT for RW stimulation and shows how the pressure transducer for scala vestibuli (P_{SV}) and scala tympani (P_{ST}) were positioned near the OW and RW, respectively. We present data from six fresh and three thawed (previously frozen) temporal bones, age range 44 to 87 years, five males and four females, with postmortem time ranging from three to seven days when fresh and two to eight months if previously frozen. The fresh bones were stored in saline at 4° C prior to use; the frozen bones were stored in a −20°C freezer.

RESULTS

Coupling the FMT to the RW

Stimulation of the FMT with voltage resulted in mechanical motion of the FMT. The flat circular end of the FMT (opposite to the end that originally had the attachment arm) was used to interface with the RW (Fig. 1a). To understand how best to couple the FMT motion to the cochlea, we tried: 1) placing the FMT directly against the RW membrane, 2) placing one layer of fascia between the FMT and the RW, 3) placing two layers of fascia between the FMT and the RW, and 4) stabilizing the FMT in place by bracing its free end to the hypotympanic wall with dental impression material in addition to the two pieces of fascia at the RW (Fig. 1b). The response measured was the stapes velocity (V_{Stap}), and Fig. 1c plots the magnitude and phase frequency responses of V_{Stap} for various configurations for one temporal bone. When the FMT was placed directly against the RW membrane with "no fascia" interposed, the stapes velocity was significantly lower than with fascia between the RW and the FMT. The difference between one thin piece and two thin pieces of fascia was not large, and mainly influenced the frequency (6 kHz versus 4 kHz) where a notch occurred in the magnitude of the frequency response. When the FMT position was secured by bracing the FMT with Jeltrate placed between the free end of the FMT and the inferior hypotympanic wall, the stapes velocity frequency response was smoother across frequency, without a substantial notch. When the FMT was braced in this manner, the stability of the FMT position was greatly improved, especially for experiments where various manipulations of the middle ear were performed. All experimental results discussed subsequently were performed with one piece of fascia between the FMT and the RW, and the FMT braced.

Intracochlear Pressure Measurements

Sound pressures within scala vestibuli (P_{SV}) and scala tympani (P_{ST}) were measured simultaneously while the RW was mechanically stimulated by the FMT. The FMT was interfaced to the RW with a piece of fascia and braced on the free end by Jeltrate (as described above). We report data from six temporal bones for these experiments. Figure 2 shows a representative example of intracochlear pressure measurement with RW stimulation; P_{ST} (plotted with solid line) was higher in magnitude between 0.6 and 8 kHz, and lagged P_{SV} (plotted with dashed line) by approximately 1/4 cycle in phase between 4–9 kHz. The phase was measured with respect to input voltage to the FMT. Both P_{ST} and P_{SV} generally grew linearly with stimulus voltage, however at frequencies less than 0.7 kHz, FMT inputs greater than 0.1 $V_{p\text{-}p}$ produced considerable distortion in intracochlear sound pressure.

Differential Pressure Across the Cochlear Partition

The differential sound pressure across the cochlear partition at the base is the complex difference between P_{ST} and P_{SV}. This differential pressure is a measure of the input to the cochlea that leads to auditory transduction. Differential pressure was computed from scala tympani and scala vestibuli pressures while stimulating the RW with the FMT. Figure 3 shows results in six temporal bones; magnitude and phase of the differential pressure normalized by the input voltage to the FMT ($(P_{ST}-P_{SV})/V_{FMT}$) are plotted. The frequency response was bandpass with 60–80 dB/decade increase in magnitude slope below 1 kHz and generally a peak at 1–2 kHz. Below 0.6 kHz, the phase was between 0–150 degrees; phase became negative as frequency increased. Generally, both magnitude and phase responses were similar across temporal bones, but at frequencies above 1 kHz, the magnitude had peaks and notches that varied from bone to bone, and the phase varied at the frequencies where the magnitude fluctuations occurred.

Response to OW Stimulation with Sound versus RW Stimulation with FMT

Comparison was made between the differential pressure measurement recorded with normal sound stimulation in the ear canal (n=6) (without FMT placement), and with round-window stimulation using the FMT (n=6). Of the six ears used for the acoustic stimulation experiments, three were also used in the FMT stimulation experiments. Because ear-canal sound stimulation results in larger P_{SV} compared to P_{ST} (opposite to round-window stimulation), we define the differential pressure for sound stimulation as the complex difference between P_{SV}-P_{ST} (14). Figure 4 shows the differential pressures (P_{SV}-P_{ST}) for sound-OW stimulation of 94 dB SPL (dashed line) and (P_{ST}-P_{SV}) for FMT-RW stimulation of 30 $mV_{p\text{-}p}$ (solid line). This scaling results in equivalent differential pressures at 1 kHz for OW stimulation and RW stimulation.

The scaled differential pressure responses due to the two different stimuli can be directly compared in this manner.

Above 1 kHz, the frequency dependence of the differential pressures due to constant sound pressure stimulation and RW stimulation with constant input voltage are similar. However, below 1 kHz, the differential pressure due to constant-voltage FMT stimulation decreases. This decrease cannot be readily compensated by an increase in FMT stimulus voltage because of significant distortion in the FMT response to lowfrequency, high-voltage inputs.

DISCUSSION

Our human temporal bone preparation permits evaluation of RW stimulation with a FMT in a controlled setting. In this preparation, the coupling of the FMT to the RW can be altered and various pathologies of the middle and inner ears can be simulated. We can measure the response of cochlear mechanics under various conditions by laser-Doppler measurements of stapes velocity, and the complex differential pressure across the partition (the input to the cochlea responsible for auditory transduction) with micro-optical pressure transducers. Indeed, the present set of data and our earlier work (14) are the first to report differential sound pressure across the cochlear partition in human and the first to systematically assess factors that would influence RW stimulation using the FMT.

The present study shows that optimizing the coupling between the FMT and the RW is of critical importance. A piece of fascia between the RW and FMT as well as “bracing” the free end of the FMT to the hypotympanum allows for efficient coupling between the FMT and the RW. Experimentally, we used a soft dental impression material to brace the FMT. In the clinical setting, soft tissue such as fascia would probably have a similar effect. For example, some surgeons have reported covering the FMT with fascia and/or placing fascia at the free end of the FMT (which may further encourage growth of fibrous tissue) in order to stabilize the FMT in position (12,13). Because the FMT has a diameter similar to the diameter of the round window, the coupling of the FMT’s motion to the RW can be potentially hindered by the bony overhang surrounding the RW. This bony overhang is generally partially removed to allow the FMT’s flat circular surface to abut the RW (10). It is important to avoid any trauma to the RW or cochlea while drilling away this overhang. Introducing fascia between the FMT and the RW helps to couple the FMT to the RW by introducing a compliant material to cushion any direct contact between the FMT and the surrounding bone, thereby, preventing the FMT from hitting the surrounding bone, which would impede coupling of motion to the RW. Furthermore, the placement of compliant, space-filling fascia between the FMT and the RW prevents air from being trapped between the two, thus enhancing the coupling of the FMT motion to the RW. Ideally, the contact surface of the FMT should be smaller in diameter than the RW membrane to allow the RW contact surface of the FMT freedom of movement without the possibility of hitting the RW bony perimeter. In the future, the design of the free end of the FMT could be modified to help stabilize its location.

The present study also suggests that RW stimulation with the FMT can provide differential pressure across the cochlear partition comparable to OW stimulation with sound introduced into the ear canal for frequencies higher than 1 kHz. However the FMT device has limitation in its ability to produce differential pressure for frequencies below 1 kHz. Generally, to understand speech, mid-frequency sound (above 1 kHz) is necessary, therefore it is not surprising that patients exhibited improvements in speech intelligibility with FMT insertion.

Recent publications reporting the implantation of the FMT on patients show large variations in outcome, likely due to the variety of pathologic conditions and inconsistency in the FMT-RW coupling. The FMT has been implanted against the RW on patients with conductive, sensorineural and mixed hearing loss with various ear diseases: Colletti et al. (10) used the device on 7 patients who had undergone at least one surgery in the past with a variety of pathologies including congenital aural atresia and stenosis, chronic otitis media; Kiefer et al. (4) and Wollenberg et al. (11) each reported on one patient with microtia/atresia; Beltrame et al. (12) reported on 7 patients with chronic suppurative otitis media and 5 patients with fixed stapes; and Linder et al. (13) reported on 5 patients who underwent subtotal petrosectomy requiring obliteration of the surgical cavity (including the external-ear/middle-ear/mastoid cavity) with fat. It is promising that speech discrimination generally improved for most patients.

All these publications compared pre-operative and post-operative bone conduction; the latter often varied relative to pre-operative bone-conduction results, and various explanations were offered. However, none of these reports mentioned the likely possibility that the presence of the FMT against the RW altered the freedom of motion of the RW, thereby changing the balance of impedance of the two scalae and thereby altering the effective bone conduction stimulus. Therefore, post-operative bone conduction may not be a good measure of cochlear reserve.

The possibility that cochlear fluid impedance is changed, by placement of fascia and FMT at the RW, supports further investigation of this issue. Furthermore, the large variations of FMT hearing results and the wide variability in the state of the ears in the implanted patient population, reinforces the importance of studying RW stimulation experimentally. Differential pressure measurements in temporal bones can determine the details of cochlear stimulation by the RW-FMT and careful comparisons can be made with systematic simulations of various pathological conditions.

Our temporal bone preparation allowed us to estimate hearing (cochlear response due to air conduction or RW stimulation) via measurements of differential pressures across the cochlear partition, and lays the foundation for future studies to investigate multiple issues of relevance to both basic and clinical science. One can investigate the effects of changing the angle between the FMT and RW, changing the RW contact surface with various FMT adaptors, and deliberately disarticulating the ossicular chain, on the efficiency of coupling the FMT motion to the RW membrane. Also, one can investigate if RW stimulation has utility for patients with stapes fixation, non-aerated middle ears, and third window lesions of the inner ear. Our method can also be used to compare cochlear response due to FMT stimulation directly at the OW versus the RW, and to answer basic questions regarding bone conduction.

One group of patients who might benefit from RW stimulation is patients with superior semicircular canal dehiscence (SCD) or other third window lesions with conductive hearing loss as the main symptom. In ears with SCD, a conductive hearing loss can occur because air-conducted sound coming in via the OW gets shunted away from the cochlea and out through the SCD, thereby reducing the differential pressure across the cochlear partition (16). With sound stimulation via the RW, dissipation of sound energy through the SCD would be downstream from the cochlea, *after* a pressure difference has been created across the cochlear partition. However, the present FMT device would require improvement in order to produce adequate low-frequency differential pressure in a case of SCD.

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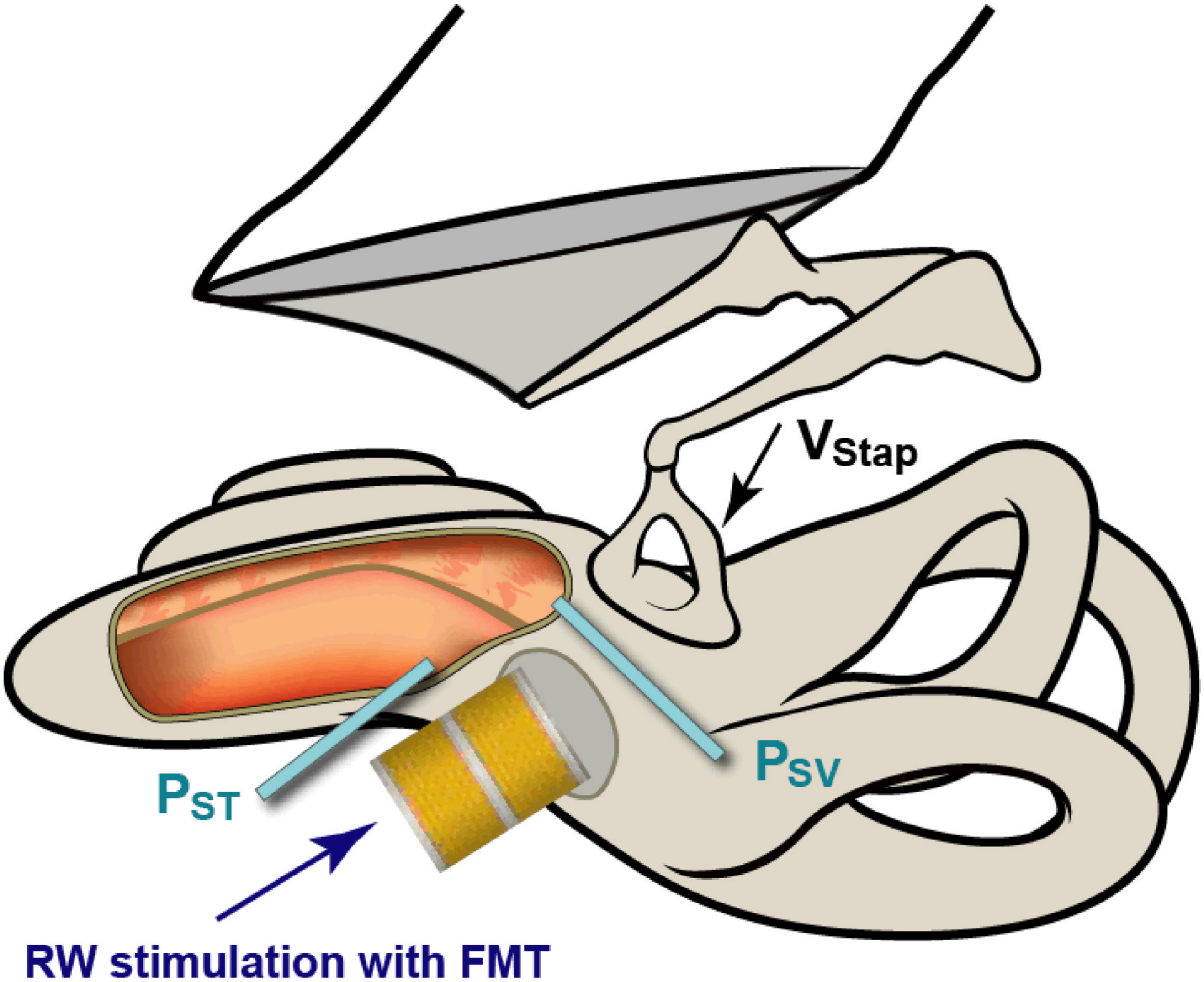

Fig. 1a

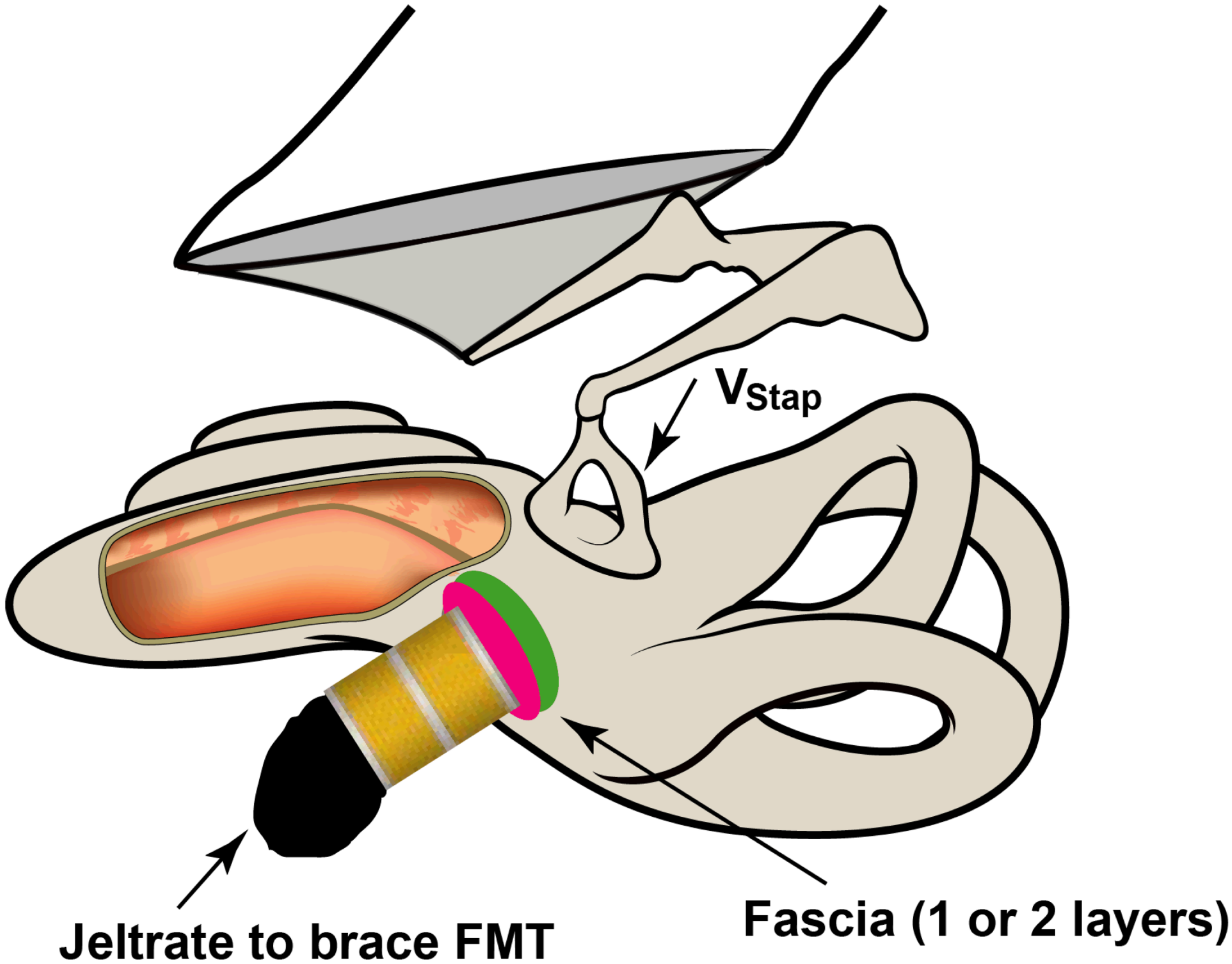

Fig. 1b

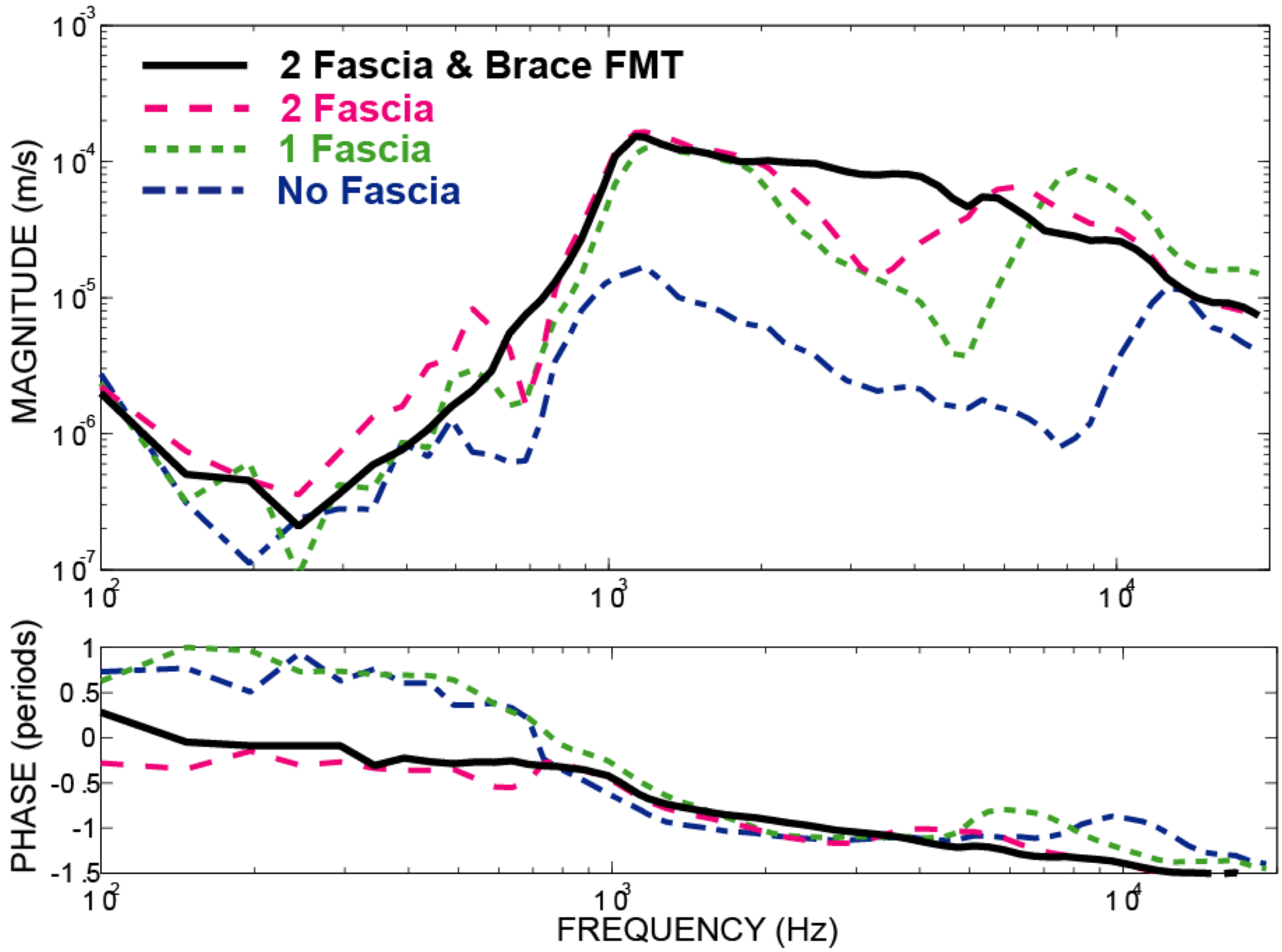

Fig. 1c

Figure 1.

a. Illustration of a left ear showing the floating mass transducer (FMT) placed against the round window (RW) membrane to mechanically stimulate the RW. Measurements include stapes velocity (V_{Stap}) measured with laser Doppler vibrometry and sound pressures in scala vestibuli (P_{SV}) and scala tympani (P_{ST}) measured simultaneously with micro-optical pressure transducers. The open area of the cochlea is only to illustrate the two scalae where the pressure transducers are inserted.

b. Illustration showing configurations for RW stimulation. The two pieces of fascia between the RW and the FMT are drawn at the round window. The dental impression material (Jeltrate) used to stabilize and “brace” the FMT is shown in solid black.

c. Stapes velocity magnitude and phase response due to FMT stimulation with 100 mV_{p-p} drive level. When the FMT was placed directly against the RW membrane "No Fascia" (dash and dot line), the stapes velocity was significantly lower than when 1 piece (dotted line) or 2 pieces (dashed line) of fascia were placed between the FMT and the RW. When the FMT was also braced with Jeltrate (solid line), the frequency response of the stapes motion was smoother across frequency.

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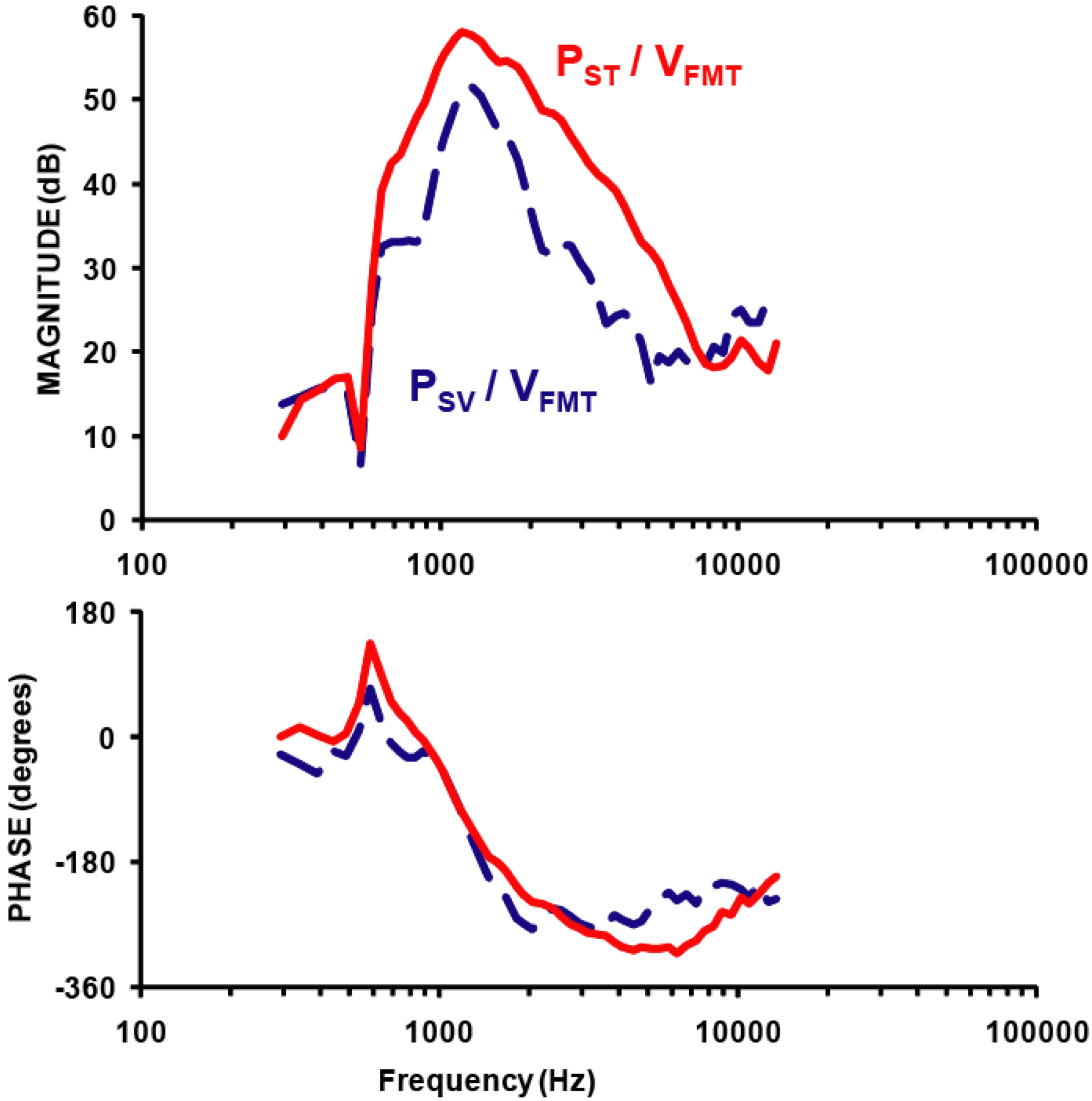

Figure 2.

Scala tympani pressure (P_{ST}, solid line) and scala vestibuli pressure (P_{SV}, dashed line) relative to the FMT input voltage (V_{FMT}) in units of dB re Pascal/Volt. The phase is referenced to the voltage input stimuli.

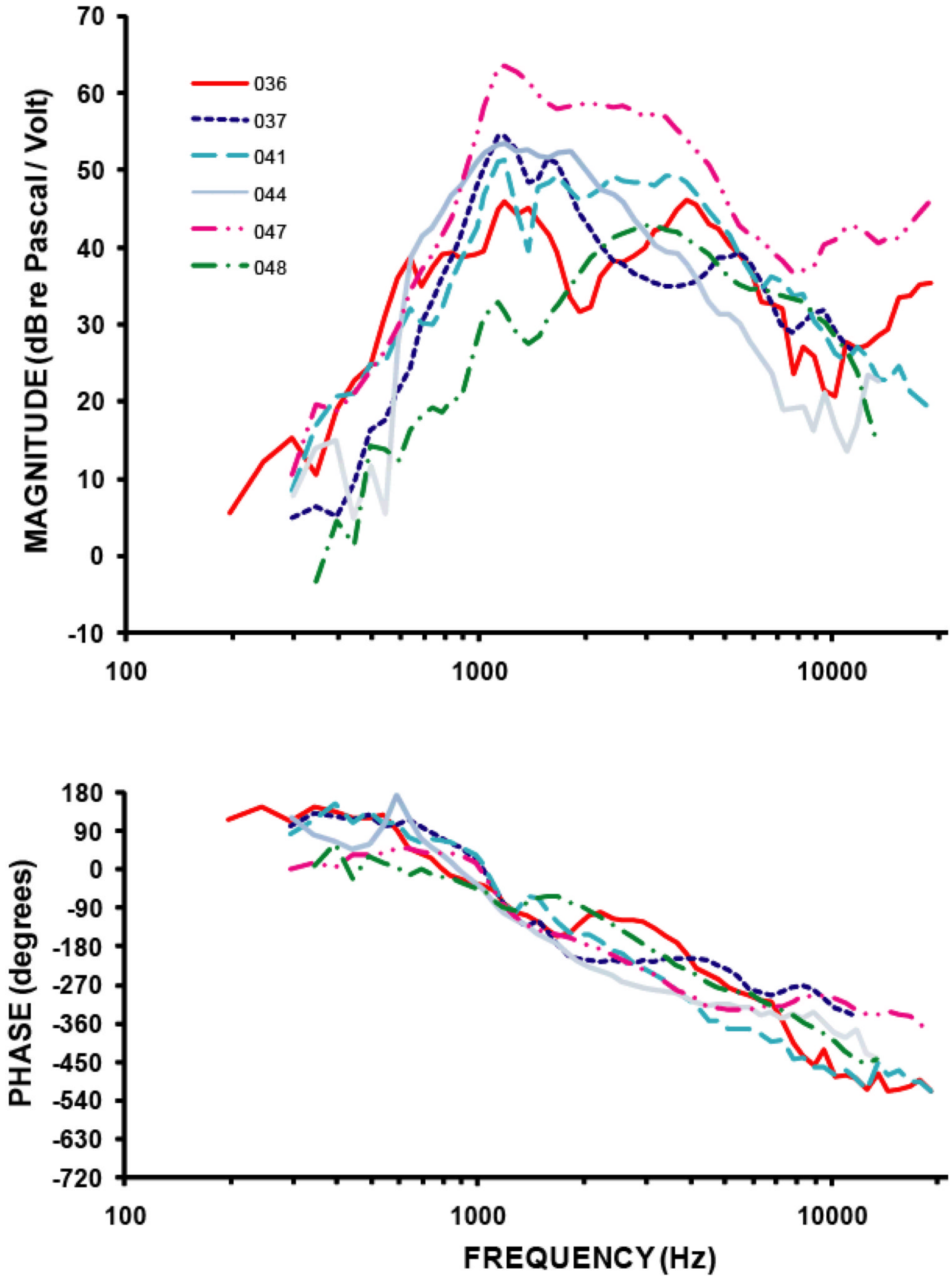

Figure 3.

Differential pressure normalized to FMT input voltage $(P_{ST}-P_{SV})/V_{FMT}$ (the pressures that are normalized to the input voltage are subtracted in the complex domain). Each curve represents data from a different temporal bone.

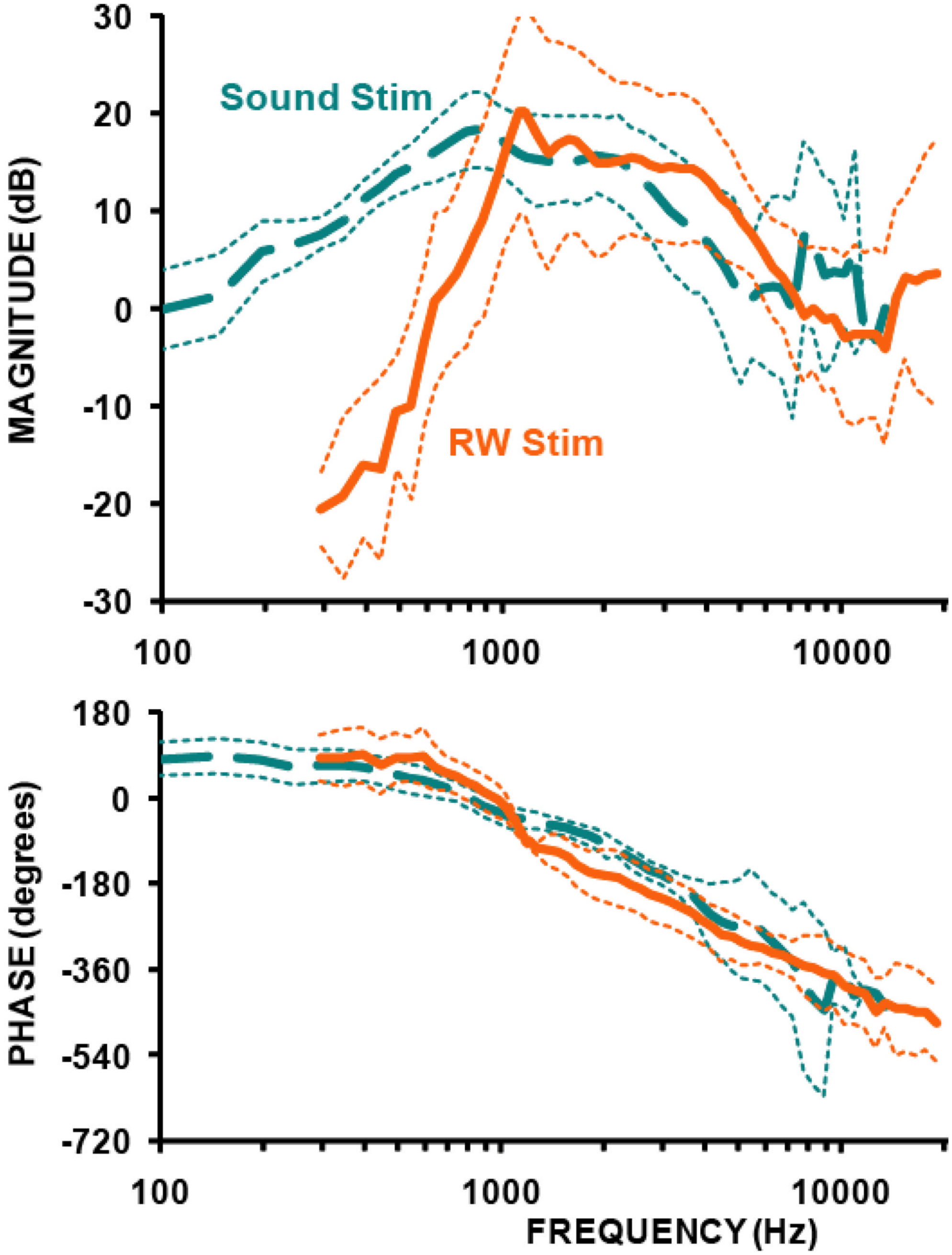

Figure 4.

Comparison of differential pressure responses due to OW stimulation with sound (via the ear canal, tympanic membrane and ossicles; n=6; thick dashed line) and RW stimulation using the FMT (n=6; thick solid line). The pressures that are normalized to the input pressure or voltage are subtracted in the complex domain. The magnitude of the sound-stimulated differential pressure $(P_{SV}-P_{ST})/P_{EC}$ is in units of dB re Pascal/Pascal. The magnitude of the RW-stimulated differential pressure $(P_{ST}-P_{SV})/V_{FMT}$ is in units of dB re Pascal/30mV$_{p\text{-}p}$. The thin dotted lines represent one standard deviation.