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Research paper

Round window stimulation with the floating mass transducer at constant pretension

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ABSTRACT

Objective: Mechanical stimulation of the round window (RW) of the cochlea is successfully done with the Vibrant Soundbridge (Med-El), but clinical outcomes show a substantial degree of variability. One source of variability is variation in the static force applied by the stimulator to the round window (Maier et al., 2013). In this study we investigated other sources of variability by maintaining a constant pre-load testing the effect of a coupler device and the interposition of soft tissue between the stimulator and the RW.
Study design: Experimental.
Methods: The stapes footplate displacement produced by stimulation of the round window was determined in fresh human temporal bones. The response to sound and actuator stimulation was measured with a Laser Doppler Velocimeter at the stapes footplate. The RW was stimulated by a Floating Mass Transducer (FMT) with/without (1) an additional RW coupler (supplied by the manufacturer), and (2) the interposition of TUTOPATCH® between the stimulator and the RW, while maintaining a pre-load of ~1.96 mN.
Results: In 8 temporal bones with normal stapes footplate response to sound, we found an average 11.9 dB increase (500 Hz–2 kHz) under controlled conditions by using the coupler together with the interposition. The increase was statistically significant at 500 Hz ($p < 0.01$). Additionally, the coupler/interposition combination reduced the variability between experiments (FMT alone SD = 10.9 dB; FMT with TUTOPATCH® & coupler: SD = 3.4 dB @ 500 Hz) and increased the repeatability.
Conclusion: At controlled static force an improved output level, inter-subject variability and repeatability were found by using a coupler/TUTOPATCH combination in RW stimulation with the FMT. The high variability found in clinical experience is not solely due to inter-subject variability, but to coupling conditions and can be optimized further.

1. Introduction

As early as 1949, Wever and Lawrence demonstrated experimentally in cats, that direct acoustic stimulation of either the oval or the round window (RW) can be used to evoke cochlear potentials (Wever et al., 1948). In 1995 both, Dumon et al. (1995) and Spindel et al. (1995) showed in guinea pigs that efficient stimulation of the round window is possible using a middle ear implant on the round window membrane (RWM). The possibility of a RWM stimulation in human temporal bones with a middle ear implant was confirmed by LDV measurement at the stapes footplate (SFP) two years later (Hüttenbrink, 1997). It took some more years until Colletti et al. successfully implanted patients (Colletti et al., 2006) by removing the clip of the Floating Mass Transducer (FMT). He enlarged the round window niche to get visual access to the round window membrane and placed the FMT onto the round window membrane covered by artificial fascia. Since then the round window stimulation has become an established therapy in the treatment of middle ear pathologies in combination with sensorineural hearing losses (SNHL).

Despite encouraging clinical results, there is still a high variability in hearing improvement results. Sprinzl et al. (2011), who

Abbreviations: FMT, Floating mass transducer; FS, Force sensor; LDV, Laser doppler vibrometer; RW, Round window; RWC, Round window coupler; RWM, Round window membrane; SA, Sound applicator; SD, Standard deviation; SFP, Stapes footplate; SNHL, Sensorineural hearing loss; SNR, Signal-to-noise-ratio; TB, Temporal bone

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analyzed 107 patients from seven studies, determined a wide spread of hearing improvements between 30 dB and 58 dB.

Beltrame et al. (2009) determined that the achieved gain in a treated patient group is less than that predicted by the NAL-NL1 fitting rule. The high variability in provided output, independent of the degree of hearing loss indicates an underlying variability in stimulation efficiency.

To improve sound transfer to the inner ear, various procedures to position the FMT at the RW have been reported, suggesting different measures to increase maximum output and to achieve better hearing results in patients. The most commonly used methods to improve transmission across the RW, used either alone or in any combination are (1) widening the RW niche and removing the bony rim, (2) using connective tissue or artificial materials as underlay between the RW and the FMT, (3) covering the FMT with soft tissue or placing cartilage at the side of the FMT opposing the RWM.

(1) The resection of the bony rim of the RW niche enhances the exposure of the RW membrane and facilitates positioning the implant tip. Originally built for another purpose, the FMT without the clip has a diameter of 1.4 mm and complete contact between the FMT and the RW is often impossible, due to an average diameter of the RW of approx. 0.92 mm (Cervera-Paz et al., 2004). Additionally the contour of the RW margin can be irregular (Roland et al., 2007) and mucosal pseudo membranes can make it difficult to identify the RWM clearly (Kiefer et al., 2006). Experimental results in human temporal bone with a MET actuator (Otologics LLC), indicate that even a spherical prosthesis of 1.0 mm diameter may be too big (Tringali et al., 2010).

(2) The interposition of soft tissues (e.g. fascia) between the FMT and the RW is often used with good results (Kiefer et al., 2006); (Wollenberg et al., 2007); (Colletti et al., 2009), but also a high degree of variability (Beltrame et al., 2009) is reported. Some clinical findings, analyzing audiological outcome and the position of the FMT relative to the RWM in CTs (Rajan et al., 2011) are in favor of direct coupling without interposition. Experimental findings in Thiel embalmed human temporal bones (Arnold et al., 2010a) as well as fresh preparations (Pennings et al., 2010; Nakajima et al., 2010), indicate a pronounced increase in efficiency by such interpositions, even if results can be subject to variability and low short-term reproducibility (Arnold et al., 2010b).

(3) Covering the FMT with soft tissue is described to serve the purpose of holding the FMT in place and to avoid dislocation of the FMT into the hypotympanum (Pennings et al., 2010). Later formation of scar tissue may move the FMT in an unpredictably way. Covering may keep FMT in place, preventing degradation of the coupling or dislodgement of the FMT. Furthermore, covering the FMT avoids contact to the surrounding bone that may hinder the vibration of the FMT (Colletti et al., 2009; Wollenberg et al., 2007).

To our knowledge the impact of static force in RW application of the FMT was not investigated intensively before. Earlier approaches were done with the Otologics MET transducer (Tringali et al., 2010), reporting a low variability in electro-vibrational transfer function between different preparations by using an electrical impedance based loading procedure of the actuator. Even if the forces were not explicitly determined we can assume that the pretensions produced by this approach were within a limited range.

Another alternative approach was taken by Schraven et al. who found a significant reduction in inter - individual variability by using a specific displacement of an experimental piezo-actuator relative to the RWM (Schraven et al., 2011). Although the resulting force is not directly accessed in this approach, our own experiments indicate similar mechanical properties of individual RWMs (Maier et al., 2013) and consequently the used displacement control indirectly limits the range of applied forces. Our experiments over a wide range of static forces with the DACS PI actuator (Phonak Acoustic Implants SA) also demonstrated that the applied static force is crucial for sound transmission. These findings are also supported by animal experiments in Chinchillas reporting low inter-individual variability using the Otologics MET transducer in combination with an impedance based loading procedure (Lupo et al., 2011).

The goal of the present study was to assess the contribution of different coupling mechanisms and the presence or absence of an interposed material on result variability while maintaining a constant axial static force. Using a constant static application force of ~1.96 mN of the FMT to the round window we investigated experimentally the effect of FMT RW stimulation in fresh temporal bones with and without (1) a hemispherical Round Window Coupler (RWC) that is thought to better couple the FMT to the RW, and (2) the interposition of artificial material (TUTOPATCH®).

Our focus was to investigate to what extent these manipulations, in the presence of constant pre-load, contribute to the variability of the ear's response to FMT stimulation and if controlling the static contact force can be used to provide better predictable results.

2. Material and methods

2.1. Human cadaver temporal bone preparation

For the experiments human cadaveric temporal bones were harvested <48h *post mortem* and stored for later use at −21 °C. Preparations and experiments were performed within 12 h after thawing at room temperature while preparations were periodically rinsed with saline to prevent mechanical changes by drying. A mastoidectomy was performed with a posterior tympanotomy and the facial nerve was dissected for wide access to the round window niche and stapes footplate (SFP). The round window (RW) was exposed by drilling the round niche overhang, leaving the bony rim and the round window membrane intact (Fig. 1). For experiments the temporal bone preparation was mounted in a laboratory clamp connected to a magnetic stand on a vibration isolated table (LW3048B, Newport, Germany). A closed system sound applicator with a speculum was cemented to the external ear canal (EAC) using dental cement (Paladur®). The tube of a probe microphone (Etymotics ER-7C) in the sound applicator was positioned 1–2 mm in front of the tympanic membrane. Sound was applied to the closed system with a small tube by a Beyer Dynamics DT-48 loudspeaker that was driven by a buffer amplifier (Tucker Davis Technologies SA1). For signal generation and data acquisition a commercial 16-bit, 4-input-channel Data Management System and software (DMSystem and VibSoft 4.81, both Polytec GmbH, Germany) were used. The signal to drive either the loudspeaker or the FMT actuator was a custom written multi-sine signal having equal amplitudes at 0.125, 0.25, 0.5, 1, 2, 3, 4, 6, 8 and 10 kHz generated at 25.6 kHz sample rate with the data management system. From the SFP responses to the actual input of approx. −29 dB re 1 V_{rms} at each of the frequency lines, the nominal response for 1V_{rms} was calculated. All measured response signal-spectra (800 lines FFT, 12.5 Hz resolution) were time-averaged 500 times. The signal-to-noise-ratio (SNR) of the responses was estimated for each frequency component, using the mean of three FFT lines above and three lines below each frequency as noise level estimate. Measurements of