Hearing Research 353 (2017) 97–103

Contents lists available at ScienceDirect

Hearing Research

journal homepage: www.elsevier.com/locate/heares

Research Paper

A comparative study of MED-EL FMT attachment to the long process of the incus in intact middle ears and its attachment to disarticulated stapes head

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ARTICLE INFO

Article history:
Received 10 November 2016
Received in revised form
11 June 2017
Accepted 13 June 2017
Available online 23 June 2017

Keywords:
Active middle-ear implant
Floating mass transducer
Laser Doppler vibrometer
LP coupler
CliP coupler
Bell coupler

ABSTRACT

The Vibrant Soundbridge© (VSB) active middle-ear implant provides an effective treatment for mild-to-severe sensorineural hearing loss in the case of normal middle ear anatomy and mixed hearing loss in middle ear malformation. The VSB floating mass transducer (FMT), with proper couplers, can be installed on various structures of the ossicular chain, e.g., the short and long process of the incus, the stapes head, and the stapes footplate. A long process (LP) coupler is most commonly used for FMT attachment to the long process of the incus with intact ossicular chain, while CliP and Bell couplers are two standardized and reliable methods for FMT attachment to the stapes head with missing incus and malleus. However, the difference and relationship of the vibration properties among these three FMT couplers remain unclear.

In the present study, the stapes footplate velocity responses of the LP, CliP, and Bell couplers have been investigated in eight fresh temporal bones (TBs) to evaluate the vibration properties of these three couplers. Normal and reconstructed middle ear transfer functions (METFs) were determined from laser Doppler vibrometer (LDV) measurements. A mastoidectomy and a posterior tympanotomy were performed to expose the ossicular chain. The METFs of the normal middle ear and middle ear with LP-FMT-coupler were compared under acoustic stimulation, thus the mass effect of the FMT with LP coupler was evaluated. Additional comparisons were made between the stapes footplate vibrations of the LP-FMT-coupler (with the intact ossicular chain at the long process of the incus), CliP-FMT-coupler and Bell-FMT-coupler on the stapes head (after incus and malleus removed) under active electromechanical stimulation. After the installation of CliP-FMT-coupler and Bell-FMT-coupler to the middle ear, the average velocity amplitude of the stapes footplate, comparing to the LP-FMT-coupler, was about 15 dB higher between 1 and 6 kHz, and 10 dB lower at about 0.5 kHz. Quantitatively, there was no significant difference between the CliP-FMT-coupler and Bell-FMT-coupler.

According to our study, installation of CliP-FMT-coupler or Bell-FMT-coupler on the stapes head provides considerable improvement of the middle ear mechanical and functional responses, comparing with the LP-FMT-coupler in the temporal bone experiments. Moreover, the installation of the Bell-FMT-coupler to the stapes head produces essentially the same footplate velocity responses in comparison to the CliP-FMT-coupler.

1. Introduction

Currently, treatment for patients with mixed hearing loss involves the implantation of a passive prosthesis and the use of conventional hearing aids. During the past decades, the active middle ear implant has shown safe and effective performance in

Abbreviations: FMT, Floating Mass Transducer; LDV, Laser Doppler Vibrometer; LP, Long Process; METF, Middle Ear Transfer Function; TM, Tympanic Membrane; TB, Temporal Bone; VSB, Vibrant Soundbridge©

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http://dx.doi.org/10.1016/j.heares.2017.06.006

patients with mild-to-severe hearing loss and has proven to be an alternative to conventional hearing aids (Schraven et al., 2014; Zahnert et al., 2016). Many patients suffering from congenital aural atresia and microtia have a middle ear malformation (missing incus or atrophic stapes head). These patients either cannot wear a conventional hearing aid or do not get enough benefit from it, thus active hearing aids come into play, with the semi-implantable Vibrant Soundbridge© (VSB) active middle-ear implant hearing system most commonly used.

Different attachments for the VSB floating mass transducer (FMT) have been established (Luers et al., 2013; Vyskocil et al., 2014), including total ossicular reconstruction prosthesis (TORP) vibroplasty (Beutner et al., 2011; Huber et al., 2012; Hüttenbrink et al., 2008, 2011), incus vibroplasty (Mlynski et al., 2015a,b; Schraven et al., 2014), round window vibroplasty (Rajan et al., 2011; Salcher et al., 2014), third window vibroplasty (Pau and Just, 2010), and CliP vibroplasty (Hüttenbrink et al., 2011; Park et al., 2014).

The FMT can be used together with proper titanium FMT-couplers to ease the attachment to the stapes. A Bell partial prosthesis in combination with an FMT was tested in three temporal bones (Huber et al., 2006). Although the results of laser Doppler vibrometer (LDV) measurement were encouraging, the lateral attachment of the prosthetic shaft to the FMT runs the risk of prosthesis tilting. Hüttenbrink reported his experiments on using an active middle-ear prosthesis referred to as a "CliP-Coupler" which consists of a partial ossicular replacement prosthesis (PORP) coupled with the FMT and installed on the stapes (Hüttenbrink et al., 2011).

In stapes vibroplasty, the facial recess must be widely opened to expose the ossicular chain and to install both the FMT (length 2.3 mm, diameter 1.8 mm) and the coupler to the stapes head (with missing incus and malleus). Sufficient space in the middle ear cavity is required to ensure that FMT motion is not impeded by structures, such as the promontory, the pyramidal eminence, the handle of malleus, and the posterior canal wall. CliP and Bell couplers are standardized and reliable methods for coupling the FMT onto the stapes head. Both couplers have three shorter legs to hold the FMT. The CliP coupler has an 8-pronged clip, and the Bell coupler has 4 notched bell-like fingers, helping them to grasp the stapes head. The two couplers are similar to standard Kurz PORPs (Dresden and Tübingen types, respectively) (Beleites et al., 2011; Hüttenbrink et al., 2011).

A firm attachment of the FMT to the stapes head is crucial for proper performance of the device. The development of the coupler for standardized attachment of the FMT to the stapes led to good mechanical and functional coupling in a temporal bone preparation as well as in clinical practice (de Abajo et al., 2013). Although both the CliP and Bell couplers are commonly used for coupling the FMT to the stapes head, the usage of the CliP coupler is limited. In the case of a patient with an atrophic stapes head or a narrow relation to the promontory, the Bell coupler is an alternative option. However, quantitative comparisons of the performances of the two couplers have not been reported.

In this paper, we report our currently completed study on the vibration conduction relationship for different coupling methods of MED-El VSB FMT couplers, such as LP coupler, CliP coupler, and Bell coupler.

2. Materials and methods

2.1. Human cadaver temporal bone preparation

The measurements were performed on eight fresh human temporal bones (TBs) within 48 h postmortem. The TBs were extracted from fresh cadavers, and subsequently placed in a deep freezer at −18 °C. All TBs were carefully inspected using an operation microscope to exclude diseases. A mastoidectomy and a posterior tympanotomy were performed to expose the ossicular chain, but the external ear canal and tympanic membrane were left intact. Great care was taken not to harm the ossicular chain and its ligaments.

In our experiment, sinusoidal sounds are generated in the auditory canal by inserting an earphone (ER-4PT, Etymotic Research, USA) for stimulation. The sound pressure was simultaneously measured by a microphone probe (ER-7C, Etymotic Research, USA). For acoustic stimulation, the sound generated in the ear canal was adjusted to make sure it was neither too high (thus it would exceed the voltage allowed by the earphone or damage the tympanic membrane) nor too low (thus the measured signal was of poor quality). The measured stapes footplate vibration (displacement or velocity) was normalized to a sound pressure level (SPL) of 94 dB (or 1 Pa in sound pressure) for comparing between different groups. The distance between the speaker outlet and the tympanic membrane was estimated to be 1–2 mm. The earphone and the microphone are connected to a probe and then inserted in the external auditory canal to produce signal stimuli and monitor sound pressure. For signal generation and data acquisition, Function/Arbitrary waveform generator (Agilent 33210A 10 MHz, Agilent Technologies, USA) and Vibsoft-20 (Polytec, Germany) were used. The signal to drive either the loudspeaker or the FMT stimulation was a pure tone signal having equal amplitudes at 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 9 and 10 kHz. All measurements were averaged 30 times. The signal-to-noise-ratio (SNR) was estimated for each frequency component. Measurement response, have SNR >10 dB for stimulus frequencies below 1 kHz and >20 dB for higher frequencies.

The vibration responses of the stapes footplate were measured with LDV (CLV-2534-4, Polytec, Germany) focused on a 0.2 mm^2 reflector (consisting of 50 μm diameter polystyrene microbeads on plastic tape, 3M, USA) placed at the center of the stapes footplate. The beads should not affect the stapes footplate vibration due to the small size and mass. For each measurement, pictures were taken and great care was taken to make sure that the spatial angle between the surface normal of the stapes footplate and the LDV laser beam was approximately 60°.

The FMT stimulation was driven with the electrical input in three types of attachments, attachment of FMT to the LP of the incus using the LP coupler (LP-FMT-coupler) with intact ossicular chain, attachment of FMT to the stapes head with the CliP coupler and Bell coupler (CliP-FMT-coupler and Bell-FMT-coupler) with missing incus and malleus. The voltage stimulus was connected directly to the FMT. All results will be given for a nominal electrical input which the amplitude set to 35 mV_{rms} per spectral line, ensuring that the FMT operated within its linear range and at the same time providing sufficient SNR. The FMT was provided by MED-El (Innsbruck, Austria) for experimental use.

2.2. Measurement procedure

Firstly, the middle ear transfer function (METF) baselines of all specimens were carried out, with the ossicular chain intact. Sinusoidal sounds were generated in the auditory canal to stimulate the ossicular chain, and then the baseline vibration patterns of the normal middle ear were assessed using LDV. We applied the acceptance criteria in the normal METF standard to be allowed by Rosowski et al. (2007). Only temporal bones fulfilling this criterion were taken for further tests.

After baseline measurements, the LP-FMT-coupler (VSB model 503, MED-EL, Innsbruck, Austria) was fixed on the LP of the incus