Hearing Research xxx (2016) 1–6

Contents lists available at ScienceDirect

Hearing Research

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

Research paper

Coupling of an active middle-ear implant to the long process of the incus using an elastic clip attachment

Sebastian P. Schraven [a], Robert Mlynski [b,*], Ernst Dalhoff [c], Andreas Heyd [c], Daniela Wildenstein [c], Kristen Rak [a], Andreas Radeloff [a], Rudolf Hagen [a], Anthony W. Gummer [c]

[a] Department of Oto-Rhino-Laryngology, Plastic, Aesthetic and Reconstructive Head and Neck Surgery, Comprehensive Hearing Center, University of Würzburg, Josef-Schneider-Straße 11, D-97080 Würzburg, Germany
[b] Department of Otorhinolaryngology, Head and Neck Surgery "Otto Körner", University Medical Center Rostock, Doberaner Straße 137–139, D-18057 Rostock, Germany
[c] Department of Otolaryngology, Section of Physiological Acoustics and Communication, University of Tübingen, Elfriede-Aulhorn-Straße 5, D-72076 Tübingen, Germany

A R T I C L E I N F O

Article history:
Received 18 March 2016
Accepted 23 March 2016
Available online xxx

Keywords:
Middle-ear surgery
Active middle-ear implant
Incus vibroplasty
FMT
Incus
Laser Doppler vibrometer
LP-coupler

A B S T R A C T

The active middle-ear implant Vibrant Soundbridge© (VSB) is used to treat mild-to-severe sensorineural hearing losses. The standard surgical approach for incus vibroplasty is a mastoidectomy and a posterior tympanotomy, crimping the Floating Mass Transducer (FMT) to the long process of the incus (LPI) (standard crimped application). However, tight crimping increases the risk of necrosis of the LPI, resulting in reduction of energy transfer and loss of amplification.

The aim of this study was to develop a new coupling device for the LPI, that does not require crimping, and to test its vibrational transfer properties in temporal-bone preparations.

An extended antrotomy and a posterior tympanotomy were performed in ten fresh human temporal bones. As a control for normal middle-ear function, the tympanic membrane was stimulated acoustically and the vibration of the stapes footplate was measured by laser Doppler vibrometry (LDV). FMT-induced vibration responses of the stapes were then measured for the standard crimped application at the LPI and for the newly designed elastic long process coupler (LP coupler). For the LP coupler, velocity-amplitude responses in temporal-bone preparations showed increased mean amplitudes at around 1 kHz (~10 dB) and a reduction between 1.8 and 6 kHz (13 dB on average for $2 \leq f \leq 5$ kHz).

In conclusion, attachment of the FMT to the LPI with the LP coupler leads to generally good mechanical and functional coupling in temporal-bone preparations with a notable disadvantage between 1.8 and 6 kHz. Due to its elastic clip attachment it is expected that the LP coupler will reduce the risk of necrosis of the incus long process, which has to been shown in further studies. Clinical results of the LP coupler are pending.

1. Introduction

The active middle-ear implant Vibrant Soundbridge© (VSB), originally developed to restore moderate-to-severe sensorineural hearing loss by Geoffrey Ball, is in reliable use since 1996 (Fischer et al., 2001). The implanted part of the VSB, the vibrating ossicular replacement prosthesis (VORP), has been composed of a receiver/stimulator, a conductor link, and the floating-mass transducer (FMT), which converts the electrical signal into mechanical vibrations. The VSB, characterized by safe and effective performance in patients with moderate-to-severe sensorineural hearing loss, is an alternative to conventional hearing aids in selected cases such as external otitis (Mosnier et al., 2008; Snik and Cremers, 2004; Todt et al., 2002; Zwartenkot et al., 2013). In incus vibroplasty, the surgical approach consists of a mastoidectomy and a

Abbreviations: FMT, floating mass transducer; LDV, Laser Doppler vibrometer; RW, round window; LP, long process; LPI, long process of the incus; SNR, signal-to-noise ratio; SP, short process; TM, tympanic membrane; TB, temporal bone; VSB, Vibrant Soundbridge©

* Corresponding author.
E-mail address: robert.mlynski@med.uni-rostock.de (R. Mlynski).

http://dx.doi.org/10.1016/j.heares.2016.03.012

posterior tympanotomy to expose the ossicular chain and to insert both the FMT (length 2.3 mm, diameter 1.8 mm) and the opened crimping forceps. The FMT is fixed at the long process of the incus (LPI), in such a manner that the axis of the FMT is perpendicular to the stapedial footplate. Sufficient space in the middle ear is required to avoid FMT motion from being impeded by structures such as the promontory, the pyramidal eminence or the tympanic membrane.

The preload on the electrical cable (Stieger et al., 2007) and a firm attachment of the FMT to the LPI are crucial for proper performance of the device (Fisch et al., 2001). Crimping the FMT with the crimping forceps to the LPI does not always result in optimal coupling and is a potential factor of the variability of clinical results (Snik et al., 2001). The use of bone cement to optimize FMT attachment in cases of unsuccessful fixation has been described (Lenarz et al., 2001; Snik and Cremers, 2004). Beside Lenarz' results of improved functional gain which could have been confounded by the gain-setting of the FMT, there is no data available showing a surgical or functional improvement and long-term stability for reinforced attachment at the long incus process by the use of bone cement. However, these reports as well as congress communication indicate that there exist sporadically difficulties in FMT attachment with the standard crimp coupler at the long incus process.

Stable fixation requires tight crimping with probably increased risk of incus necrosis. Verhaegen et al. (2012) reported at least three cases of incus necrosis several years after VSB implantation. At the Department of Otorhinolaryngology, Plastic, Aesthetic and Reconstructive Head and Neck Surgery of the University of Würzburg incus erosion and necrosis was detected in 35% of vibroplasty revision surgery patients (4/11patients with incus vibroplasty; 2/6 patients with incus vibroplasty combined with stapesplasty, see Schraven et al., 2016). The necrosis of the LPI is a well-known concern in stapes surgery. Anatomical and histological studies indicate that the necrosis of the LPI is not caused by occlusion of blood supply due to crimping (Chien et al., 2009), but is probably due to mechanical trauma during the process of crimping or, alternatively, due to excessive motions in cases where crimping was too loose (Gerlinger et al., 2009). Moreover, anatomical variation of the cross-sectional shape of the LPI (Tóth et al., 2013) is problematic for a form-closed crimping of the FMT, because the crimping forceps may be closed to a fixed minimum diameter instead of closing at a well-defined, limited force.

We started to investigate the possible influence of imperfect crimping by reinforcing the former standard attachment of the FMT to the LPI with an additional reinforcing spring-like structure derived from a Soft CliP® stapes prosthesis (Mlynski et al., 2015a). The reinforcement of the FMT attachment led to significant improvement in the averaged electrovibrational transfer function measured at the stapes footplate and round-window membrane in 10 temporal bones, and also to lower vibroplasty thresholds in 9 patients as compared to 11 patients without reinforcement. Moreover, detailed analysis of the temporal-bone data showed that those FMT attachments which showed comparably weak performance in the standard attachment condition profited most from the reinforcement – a fact corroborating our hypothesis on problems of the standard crimp attachment.

After investigating the alternative fixation of a standard FMT with crimp attachment to the short process of the incus (SPI) (Schraven et al., 2014), a coupler for standardized attachment of the FMT to the SPI (SP-coupler) was developed, which led to good mechanical and functional coupling in a temporal-bone preparation as well as in clinical practice (Mlynski et al., 2015b). The development of the new SP-coupler was done considering the experience with the crimped coupler with and without reinforcement, and was therefore based on an elastic clip design. This avoids the disadvantage of the crimp method which by principle has to be bent shortly on site to a diameter considerably narrower than in its final state.

As in some patients the attachment to the SPI is not possible due to anatomical limitations, it was decided to design a coupler for attachment at the LPI based on the same design principle. We call the new coupler throughout the present paper LP-coupler in line with the naming of the SP-coupler. The aim of the present study is to perform a functional evaluation of the LP-coupler in human temporal bones.

2. Material and methods

2.1. Temporal bones

The temporal bones used in this study were also part of our previous reports "SP-coupler" (Mlynski et al., 2015b) and "vibro-EAS" (Schraven et al., 2015). In short, ten left human temporal bones were extracted from human cadavers at the time of autopsy, within 48 h post mortem, using an oscillating bone saw, and subsequently placed in a deep freezer at −18 °C. The temporal-bone specimens were obtained from the Department of Pathology, University of Würzburg, following appropriate guidelines and procedures for obtaining and using human tissue. On the day of the experiment, the temporal bone was allowed to thaw at room temperature, and was then immersed in saline solution (0.9%) for about 3 h before beginning the experiments. Experiments were performed within 3 months post mortem.

After removal of connective tissue, a subtotal mastoidectomy, an extended antrotomy and a posterior tympanotomy were performed. The RW niche was exposed by drilling promontory overhangs until the RW membrane was identified in its full circumference. Middle-ear ligaments and muscles were not sectioned. Specimens were firmly mounted in a holding block. The prepared bones were kept moist by repeated flushing with saline solution (0.9%) to prevent dehydration. Experiments were performed in a temperature-controlled laboratory (21 ± 1 °C).

Dissections were performed by experienced otosurgeons (SPS and RM). All ears appeared anatomically normal, as ascertained with light-microscopic examination.

2.2. Vibration measurement set-up, stimulus generation and acquisition

The vibration measurement setup, signal generation and data acquisition have been described in detail elsewhere (Schraven et al., 2011, 2012, 2014, 2015; Mlynski et al., 2015a,b). Vibration responses were measured with a laser Doppler vibrometer (LDV) system (Model OFV 302, Polytec GmbH, Waldbronn, Germany) focussed on a 45- to 63-μm-diameter reflective glass micro bead (P-Retro, Polytec GmbH) placed near the centre of the footplate; this was the only bead on the footplate.

2.3. Vibration-measurement procedure

A series of six vibration measurements at the stapes footplate was performed in each temporal bone.

First, acoustic baseline vibration measurements of the middle ear were obtained. The external auditory canal was occluded by an otoacoustic emission insert probe (ER-10C, Etymotics Research, Elk Grove, USA) and left unchanged in the ear canal until all vibration measurements were completed. The vibration of the stapes footplate in response to the acoustic stimulus was then measured.

Second, the FMT of a VSB (MED-EL, Innsbruck, Austria) was firmly crimped to the long incus process (standard crimped