Hearing Research xxx (2016) 1–10

Contents lists available at ScienceDirect

Hearing Research

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

Research paper

Fully implantable hearing aid in the incudostapedial joint gap

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ARTICLE INFO

Article history:
Received 31 July 2015
Received in revised form
24 March 2016
Accepted 29 March 2016
Available online xxx

Keywords:
Middle ear implant
Incudostapedial joint gap
Middle ear
Fully implantable
Sensor
Actuator
Piezoelectricity

ABSTRACT

A fully implantable hearing aid is introduced which is a combined sensor-actuator-transducer designed for insertion into the incudostapedial joint gap (ISJ). The active elements each consist of a thin titanium membrane with an applied piezoelectric single crystal. The effectiveness of the operating principle is verified in a temporal bone study. We also take a closer look at the influence of an implantation-induced increase in middle ear stiffness on the transducer's output.

An assembly of the transducer with 1 mm thickness is built and inserted into six temporal bones. At this thickness, the stiffness of the annular ligament is considerably increased, which leads to a loss in functional gain for the transducer. It is assumed that a thinner transducer would reduce this effect. In order to examine the performance for a prospective reduced pretension, we increased the gap size at the ISJ by 0.5 mm by removing the capitulum of the stapes in four temporal bones. The TM is stimulated with a broadband multisine sound signal in the audiological frequency range. The movement of the stapes footplate is measured with a laser Doppler vibrometer. The sensor signal is digitally processed and the amplified signal drives the actuator. The resulting feedback is minimized by an active noise control least mean square (LMS) algorithm which is implemented on a field programmable gate array. The dynamic range and the functional gain of the transducer in the temporal bones are determined.

The results are compared to measurements from temporal bones without ISJ extension and to the results of Finite Elements Model (FE model) simulations.

In the frequency range above 2 kHz a functional gain of 30 dB and more is achieved. This proposes the transducer as a potential treatment for high frequency hearing loss, e.g. for patients with noise-induced hearing loss. The transducer offers sufficient results for a comprehensive application. Adaptations in the transducer design or surgical approach are necessary to cope with ligament stiffening issues. These cause insufficient performance for low frequencies under 1 kHz.

1. Introduction

1.1. Implantable hearing aids

Implantable hearing aids can be classified in three categories based on their working principle or medical indication: cochlea implants, bone conduction hearing aids and active middle ear implants (AMEI). Cochlea implants apply an electrical stimulus directly to the auditory nerve via electrodes, inserted into the cochlea. They are mainly used to treat severe sensorineural hearing loss. Bone conduction hearing aids like the BAHA, Bonebridge and Sophonics transfer the sound signal to the cochlea via the human skull. This approach is used mainly for cases of conductive hearing loss. AMEIs are placed in the middle ear cavity and amplify the sound transferred to the cochlea. This operating principle is similar to that of external hearing aids. They are indicated for people with sensorineural hearing loss or mixed hearing loss that is not severe enough to indicate treatment with a cochlea implant and that cannot be treated with a regular hearing aid. They often act by amplifying the ossicles' movement with an actuator attached to different parts of the ossicular chain (OC). For instance, the Vibrant Soundbridge's

Abbreviations: AI, articulation index; AMEI, active middle ear implants; dB SPL, decibel sound pressure level; FE, finite elements; ISJ, incudostapedial joint; LDV, laser Doppler vibrometry; LMS, least mean square; METF, middle ear transfer function; MSG, maximum stable gain; OC, ossicular chain; SFV, stapes footplate velocity; TB, temporal bone; TM, tympanic membrane; WR, working range

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http://dx.doi.org/10.1016/j.heares.2016.03.015
0378-5955/

(Vibrant Med-El) Floating Mass Transducer (FMT) can be clamped onto the long or short process of the incus or the stapes head (Ball et al., 1997; Beutner and Hüttenbrink, 2009), and leaves the OC intact. The Esteem's (Envoy Medical Corporation) sensor is connected to the malleus and the actuator is connected to the stapes head via a coupling element (Chen et al., 2004; Maurer and Savvas, 2010). The OC between the sensor and actuator is disconnected and partly destructed. The Carina's (Cochlear Inc.) actuator is similarly coupled to the anatomical structures (Bruschini et al., 2009; Devèze et al., 2013). The sensor is a microphone beneath the skin of the head. The Tübingen hearing system, an actuator consisting of a slotted piezo-equipped bending membrane, is designed specifically for coupling to the round window. Adaptations of the FMT and the Carina actuator for coupling to the round window also exist (Goll et al., 2013; Schraven et al., 2011). Other systems, such as the DACS or the DACS-PI, are equipped with prostheses which directly stimulate the cochlear fluid (Häusler et al., 2008; Maier et al., 2013). The existing types of implants are mostly partially implantable with the actuator inside the middle ear and the sensor (or microphone) and sound processor outside the human body. Only two approved implantable hearing aids are fully implantable (Esteem and Carina).

A good overview of implantable hearing devices is found in Green, 2011; Maurer, 2009; Beutner and Hüttenbrink, 2009; Counter, 2008; Dinces and Parikh, 2003; Luers et al., 2011 and Verhaert et al., 2013.

The implant presented in this study belongs to the third group, i.e. the active middle ear implants. The biggest challenges for middle ear implants seem to be the difficulty and complexity of the implantation, the reversibility of the surgical intervention and the bone conduction noise on the sensor.

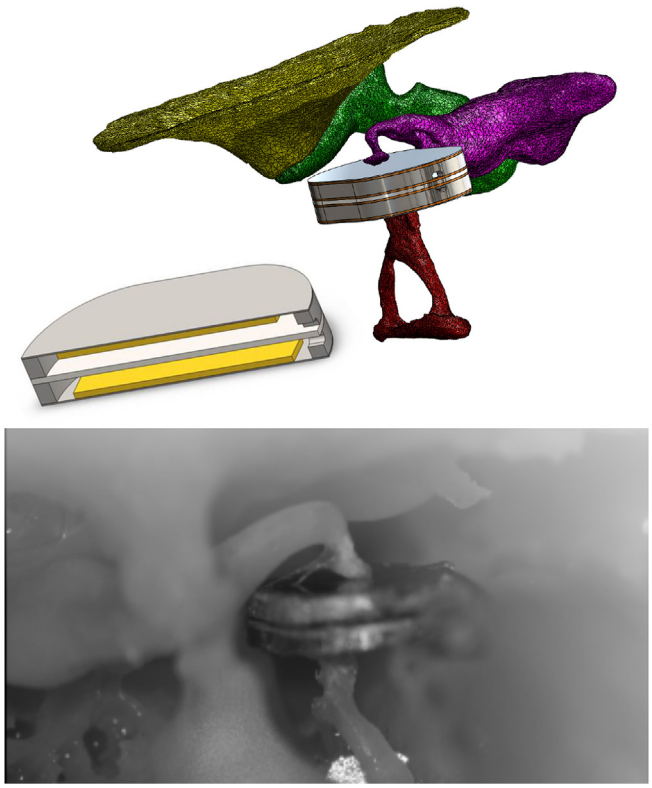

Fig. 1. Top: Transducer inside the incudostapedial joint (ISJ) gap and cross-section view of the transducer with piezoelectric single crystals (yellow) bonded onto thin titanium membranes; bottom: Transducer inside the ISJ gap of a cadaveric temporal bone sample.

1.2. Incudostapedial joint transducer

The presented transducer consists of two active elements (sensor and actuator) combined in one housing. The concept builds on the implantable sensor element introduced in Koch et al., 2013. The actuator element was added to obtain a fully implantable device. Two thin oval-shaped titanium bending membranes are attached to a titanium frame. The device is about 3 mm and 5 mm in diameter and 1 mm in height. A piezoelectric single crystal element is bonded to the inside of each membrane, one acting as a sensor and the other one driving the OC as an actuator". The sensor acts as a bending sensor with a dominating d31 (transversal) effect and a partial d33 (longitudinal) effect. The transducer is clamped inside the opened incudostapedial joint (ISJ) gap with the sensor membrane facing the long process of the incus. The sensor measures the force transmitted in the OC which correlates with the sound signal in the ear canal. The actuator element faces the stapes head and transfers the amplified signal. The transducer in the middle ear and a cross-sectional view of the transducer assembly is depicted in Fig. 1 (top). The piezo elements are wired to a preamplifier and then to a computer for data acquisition, signal conditioning, processing and amplification. The moderate complexity of these functionalities makes it feasible to implement them on a digital signal processor (DSP) that is part of a prospective implant similar in size and placement of a cochlea implant in the mastoid.

The transducer is designed to be free-floating, dispensing with the need for bone anchoring. The most obvious advantage of this approach in comparison to most others is the simplicity of the insertion and therefore the surgery. The second advantage is that it promises better reversibility of the operation than alternatives which have to remove ossicles or parts of ossicles. Fisch and May 1994 recommended opening the ISJ for inner ear protection during malleus handle manipulation with the claim of full reversibility. Recent studies like Farahmand et al. (2016) come to a less optimistic conclusion, stating that partial ossicular discontinuity can lead to a high frequency hearing loss of 20–30 dB at 4 kHz. As part of this study, we also compared the middle ear transfer function (METF) before insertion and after removal of the transducer. It must be noted that there are no in-vivo long-term studies on this topic. The transducer preserves sound transmission from the tympanic membrane (TM) to the inner ear to a good extent via the OC. Although its mass being added to the OC does have a measurable impact on the METF, the patient's natural hearing is expected to be mostly preserved. The transfer of undesirable body noise to the sensor, being an issue for subdermal microphones in the ear canal, is minimized due to the free-floating design.

The concept therefore gives hope to preserve important parts of hearing sensation, such as directional hearing, and enables natural hearing to the greatest possible extent.

The biggest drawback of the free-floating design is the missing mechanical support of the actuator element, which is braced mainly against the inertial mass of the transducer frame. Especially at lower frequencies, a great deal of the actuator's energy is lost to recoil in the incus direction of the ISJ and therefore does not contribute to the desired stapes footplate velocity (SFV) amplification. Furthermore, sensor and actuator are mechanically coupled. This suggests that feedback in this setup is more difficult to handle than in other approaches, which usually attempt to separate the sensor and actuator in order to avoid feedback.

Please cite this article in press as: Koch, M., et al., Fully implantable hearing aid in the incudostapedial joint gap, Hearing Research (2016), http://dx.doi.org/10.1016/j.heares.2016.03.015