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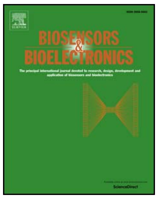

# *In-vitro* and *in-vivo* measurement of the animal's middle ear acoustical response by partially implantable fiber-optic sensing system

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## ABSTRACT

The main obstacle in realization of a totally implantable hearing aid is a lack of reliable implantable microphone. In this paper we have described a potentially miniature fiber-optic vibrometer based on a modified Michelson interferometer, designed to serve as a middle-ear microphone for totally implantable cochlear- or middle-ear hearing aids. A model of the sensing system was used for *in-vitro* and *in-vivo* investigation of acoustical response of sheep's middle-ear ossicles. Surgical and implantation procedure of introducing the sensing optical fiber into the middle-ear and its aiming at the incus was investigated and described here in detail. The frequency responses of the incus was measured while a cadaver and living sheep was exposed to the sinusoidal acoustical excitation of 40–90 dB SPL, in the frequency range from 100 Hz to 10 kHz. The amplitude of the incus vibration was found to be in the range between 10 pm to 100 nm, strongly depending on the frequency, with a lot of resonant peaks, corresponding mainly to the natural outer ear canal gain. The noise floor in the experiments was about 2 pm/Hz$^{1/2}$, but recently we have decreased it to < 0.5 pm/Hz$^{1/2}$, which corresponds to a minimal detectable sound level of 31–35 dB(A) SPL for humans. The histological examination of temporal bones of cadaver animals and the intensity of *in-vivo* optical signal demonstrated that the aiming of the sensing fiber to the target has been preserved for five months after the implantation.

## 1. Introduction

Millions of people all around the world suffer from some kind of hearing impairment that cause a number of difficulties not only for the stroked persons but also for the whole society. The situation is going to be even worse, especially in the developed countries, due to the urban noise pollution (Hammer et al., 2014; Goines and Hagler, 2007) caused by industrialization and transportation. The most sensitive population are children, which are additionally exposed to the recreational noise by loud headphones music. Because of that they may have educational and/or behavioral problems leading to speech-language and educational consequences (Lieu, 2004). In addition, many different middle- and inner-ear related pathologies and development of abnormalities can also induce different types of hearing loss, including conductive and sensorineural, depending on the etiology.

Some of the hearing troubles can be successfully managed by conventional hearing aids (CHA), which are typically worn externally, behind-the-ear or in-the-canal. However, a number of disadvantages and limitations are encountered, including stigmatization, chronic otitis and distortion of the patient's own voice, feedback noise, limited speech comprehension and normal daily activities (Zwartenkot, 2017). A totally implantable hearing aid (TIHA) can be a suitable solution and there is a permanent effort to figure out the complex hearing mechanism (De Paolis et al., 2017) and to find a practical solution for TIHA (Gérard et al., 2017; Lefèbvre et al., 2016).

An implantable hearing aid typically consists of a microphone, signal processing unit, transducer and battery. The most challenging issue is the microphone, because it has to provide a long-term reliability and safe operation inside the human body. The main drawback of the current implantable microphones is the lack of reliability due to different effects caused after implantation. There are just a few commercially available TIHA devices (Pulcherio et al., 2014), which contain an

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implantable microphone. Although some clinical trials have demonstrated 10–20 dB better functional gain than the semi-implantable devices, a degradation of the initial sensitivity of the microphone has been recognized, mainly due to the skin effect on the membrane (Calero et al., 2016).

To overcome the above mentioned issues, we propose here a contactless sound sensing technique, based on detection of vibration of ossicles inside the middle-ear by fiber-optic interferometry. Unlike other solutions, the entirely ossicular chain, including the outer-ear canal and its resonant amplification effect, will be preserved. A permanent operation of the system in case of atmospheric pressure changes (Didyk, 2006) will be assured, because of a rather large separation between the sensing fiber and incus. Therefore, it is supposed the system to function also during the growth period of skull in children. We tested the technique during the *in-vitro* and *in-vivo* experiments on animals, by measuring the frequency response of incus in the sheep middle-ear. Technical and medical aspects of the future implantable microphone, including the system noise, surgical and implantation procedure of the sensing optical fiber were also investigated.

Our measurements show that the amplitudes of the sheep's ossicle vibrations are in the range from several picometers to hundreds of nanometers, when exposed to the sound pressure levels (SPL) between 40 and 90 dB re 20 μPa. These results are in accordance with earlier results, obtained by Laser Doppler Vibrometer measurements (Whittemore et al., 2004; Voss et al., 2000; Willi, 2003). To our knowledge, this is the first time that these measurements are done *in-vivo,* by a sensing probe implanted inside the middle-ear of an animal. A very small amplitude of vibrations were accurately measured using a specific algorithm for demodulation of the quasi-quadrature signals, which is described in our earlier paper (Tomic et al., 2017). The quasi-quadrature signals were obtained using a fiber-optic configuration based on a 3 × 3 single-mode fiber-optic coupler (Koo et al., 1982), which is very suitable for the implantation, because has no any active or bulky components. The histological examination of the temporal bones of the animal cadaver demonstrates that the target-sensing fiber axis was preserved after 5 months of implantation (see Fig. 6).

## 2. Principle of operation

The measurement of very small amplitude of vibrations of the middle-ear ossicles was based on a Michelson interferometric configuration (Fig. 1), realized by a 3 × 3 single mode fiber-optic coupler (FOC 3 × 3). The two output arms of the coupler are the sensing (SA) and reference arm (RA) of the interferometer while the third, needless one, is cleaved at 8° to suppress the back reflections. The central input arm is connected to the laser diode (LD) *via* an optical isolator (OI). A red laser diode (RLD) is simultaneously connected to facilitate the aiming of the probe beam to the target. The other input arms are connected to InGaAs photodiodes (PD-X,Y), which provide the two quasi-quadrature interferometric signals (Koo et al., 1982).

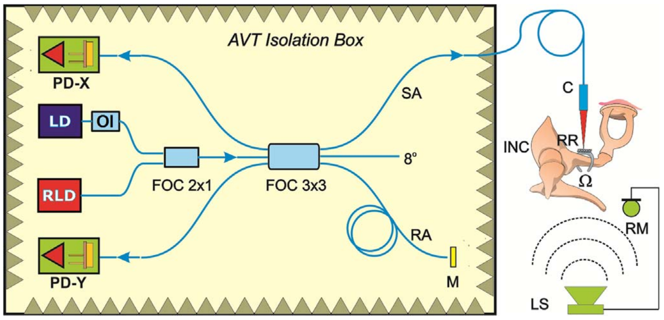

**Fig. 1.** Schematic of fiber optic sensing configuration: AVT – acoustical, vibrational and thermal isolation box, FOC 3 × 3–single-mode fiber-optic 3 × 3 coupler, LD–laser diode, RLD – red laser diode, OI – optical isolator, PD-X and PD-Y– InGaAs photodiodes and transimpedance amplifiers, SA – sensing arm, RA – reference arm, M – mirror at the fiber end, 8° – cleaved fiber end, C – collimator, INC – incus in the middle ear, Ω – ring, RR – retro-reflecting tape, LS – loudspeaker, RM – reference microphone.

The probe beam was emitting from the SA, collimated by a miniature GRIN lens (C) and directed towards the vibrating target. The target was incus (INC) in the sheep's middle-ear, equipped with a small piece of the retro-reflecting tape (RR) and attached to the bone by a specially designed omega-ring (Ω). The use of the RR has been necessary to provide sufficiently amount of the reflected radiation (Koch et al., 2016) regardless of a small alternation of the incus position and orientation. The RA, being approximately equal in the optical length to the sensing one, was terminated by a silvered surface layer (M). The whole set-up was placed into an isolation box (AVT) to suppress the environmental influences.

A vibration of the target changes the length of the optical path in the SA and, consequently, the optical phase difference (OPD) between the two coupler arms. This OPD's changes generate the raw interferometric signals in both photodetectors, which can be represented by:

$$\begin{aligned} V_{PDX}(t) &= X_{DC} + X_A \cos(k \cdot V \sin \omega t + L(t)) \\ V_{PDY}(t) &= Y_{DC} + Y_A \cos(k \cdot V \sin \omega t + L(t) + \Psi) \end{aligned} \tag{1}$$

where $V$ and $\omega$ are the amplitude and frequency of the target vibration; $\Psi$ is the phase shift ($\sim 120^\circ$) introduced by the 3 × 3 coupler; $X_{DC}$ and $Y_{DC}$ are DC signal levels; $X_A$ and $Y_A$ are interferometric term amplitudes, which depend on the target reflection, the coherence degree between the beams and the alignment and state of polarization of the probing beam. *L(t)* is a quasi-random motion of incus, mainly caused by the atmospheric pressure changes, environmental infrasound and the host man/sheep dynamism. This motion causes the signal instability and neither photodetector signal alone can provide a stable sound detection. However, the constant phase shift $\Psi$, generating the additional signal in the quasi-quadrature relationship, allows elimination the influence of *L(t)* by the suitable signal processing algorithm (Tomic et al., 2017). In the phase recovery process, the influence of variable amplitudes $X_A$ and $Y_A$ is also removed.

## 3. Experiment

The experiments on eight sheep were performed. Two subjected animals were expelled from the *in-vivo* investigation because the skin of the ear canal was too much damaged and bled and a complete obstruction of the canal was found. The third animal experienced hard respiratory problems after the anesthesia and died 3 h after the operation. The remaining 5 animals recovered well from the surgery and lived until the final experiment. We measured the post-implantation acoustic response for all of them, but only the frequency response of the sheep denoted as #5 is presented here as a typical result.

A full control of the *in-vitro* and *in-vivo* experiments have been assured by performing all investigations under the same conditions in the operating/surgical room of the Institute of Biomedical Research (IBR) of the Medical University of Vienna, at the General Hospital of Vienna. Acoustic measurements were made using a calibrated reference microphone and the Affinity audiometric system, produced by Interacoustics, under the same testing protocol.

The histological preparation and microscopic examination of the temporal bones were made at the Medical University of Vienna, Institute for Histology and Embryology II, Department for Biomaterial and Skeleton Research by coauthors H.P. and R.P. The ethic commission of the University of Vienna gave permission to this project under the Number BMWF-66.009/0084-CGT/2007.

### 3.1. Sensing system

Sensing system (Fig. 1) consists of implantable (the sensing fiber and associated holder) and non-implantable (the optoelectronic