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Development of a Totally Implantable Hearing Aid

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Abstract: In this paped we described briefly the activities done in the frame of development of a system for contactless detection of the vibrations of the middle ear ossicle. The system has been constructed in the form of a fiber-optic vibrometer, which can be used as the microphone of a totally implantable hearing aid. The current state of the art is described and the initial measurements are presented and commented upon.

Keywords: Micro-systems, micro-optics, fiber-optic vibrometer.

1 Introduction and Analysis of the International State of the Art

Hearing impairments are among the most common health problems, and an estimated 10% of the entire population should use some type of hearing aid. The hearing aids, which are currently common, are normally either positioned outside the ear or are partially implanted. Both types involve various disadvantages, as a result of which no more than approximately 3% of the populations of industrialized countries regularly wear such devices. The trend toward miniaturization and the intensive development work being performed in the areas of microsystem technology (MST) have led to the idea

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of developing totally implantable hearing aids (TIHA). Totally implantable means that the entire hearing aid with all its modules are positioned subcutaneously, such as near the mastoid and/or in the middle or inner ear. No components need be positioned outside the ear, and external modules are required solely for certain maintenance tasks such as switching the device on and off, making adjustments and recharging the battery. The first steps in the development of a TIHA were made in Japan 20 years ago [1]. However, solely partially implantable devices had been completed by 1999.

Even today, solely a single totally implantable device is commercially available, a product of the company Implex AG, Germany. In this system, the size of the microphone limits the device's suitability to approximately 80% of the potential users, and it is not at all suitable for implantation in children.

Development of another totally implantable middle-ear hearing aid by the US company Envoy is in phase of clinical studies. This system uses piezoelectric principle for both the reception of sound and for subsequent actuation. Mechanically, the system is highly complex and requires complicated surgery and highly precise adjustment. In addition, the chain of auditory ossicles must be broken, and this method is not popular among surgeons as it is irreversible.

In general, market studies have shown that all research institutions and companies working in this field are searching for improved solutions for totally implantable hearing aids, and solutions for implantable microphones often represent the main focus.

2 Brief Description of the IMFT's Activities

At the Institute of Micro Technique and Precision Engineering (IMFT) at Vienna Univeryity of Technology, totally implantable hearing aids were the subject of research for the first time in January 1997. Together with the Schwerpunktkrankenhaus in Wiener Neustadt, the IMFT launched a project in mid 1997 for the purpose of researching the level of global knowledge and development in the field of partially and totally implantable hearing aids (stocktaking of the state of the art and feasibility study). On the basis of this study's results, a two-year project entitled "Development of an Implantable Microphone for Total Implantation in the Middle Ear" was launched in July 1998. Development of a microphone for totally implantable hearing aids was one of the goals, which enjoyed a great deal of commercial motivation due to excellent market potential and expectations of high demand. The system concept applied to this project took the most common cause of hearing impairment into account: In most of those persons affected, the chain of auditory ossicles is intact and the impairment is caused primarily by a loss in function of the inner ear. Therefore, the project's main goal was to develop a system for contactless detection of vibrations of middle ear ossicles, which does not change or influence in any way mechanical impedance matching via the malleus, incus and stapes. The ground-breaking technologies of integrated microoptics and fiber-optic signal lines are employed, thereby making it possible to construct a miniature microphone comprising primarily a microoptic component and an optical fiber. The following advantages are provided by fiber-optic measuring techniques:

- Contactless measuring, which means there is no mechanical influence on the auditory ossicular chain.
- With special interferometric technology, amplitudes can be measured at the subnanometric range, even in the presence of relatively considerable permitted quasistatic movement.
- The entire system can consist of merely a microphone housing and a single optical fiber as a sensor. This facilitates easy implantation and the selection of suitable measuring points.
- As the optical fiber is small (0.125 mm) and elastic, it can be inserted easily and is suitable for children.
- The system is completely self-contained, and only the optical fiber and the wires for power supply and signals lead out of the module.
- No changes to the chain of auditory ossicles are necessary, and all other modifications, which are minimal, are reversible.

The principle of function can be described as follows (see Figure 1): A laser beam is directed at the tympanic membrane or one of the auditory ossicles via an optical fiber, and depending on the tympanic membrane's position, the reflected light wave undergoes a phase shift. The reflected wave interferes with the reference wave from a second fiber branch. Both signals are passed on to two photodiodes and processed by means of integrated signal processors. The result is received at the output of the decoded information signal, which can then be fed to an output stage which stimulates the area surrounding the cochlea, thereby completing the signal path.

Development of the new functional system, which comprises a microphone and a signal-processing module, required taking a number of requirements into consideration and satisfying them:

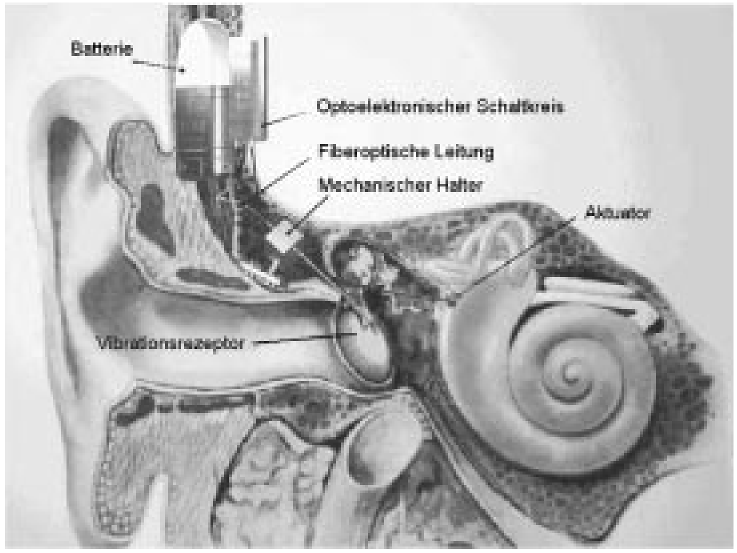
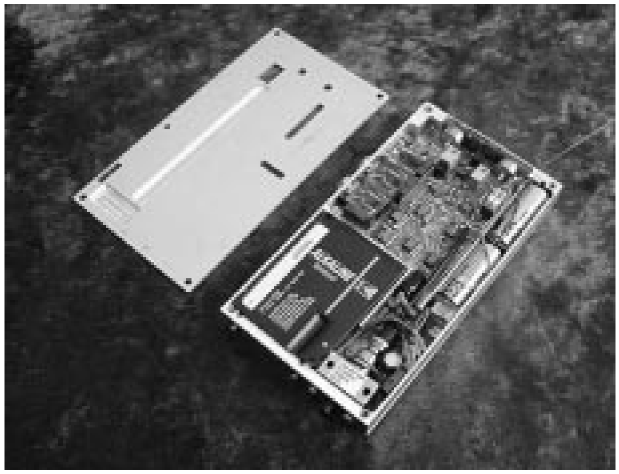


Fig. 1. Drawing of the planned microphone after implantation.

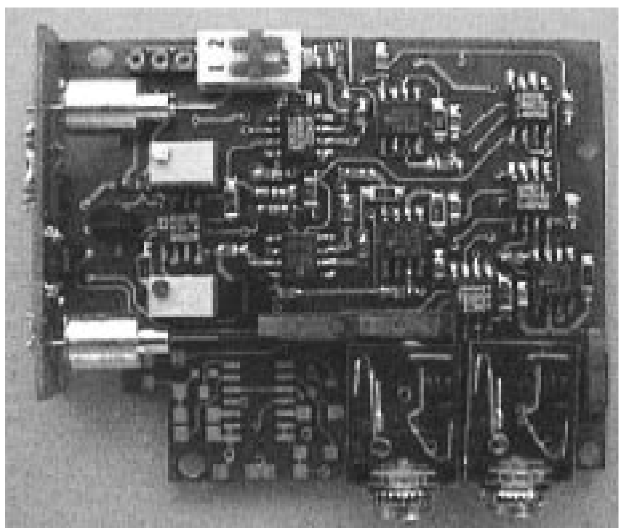
- While the dynamic vibrations at acoustic events which were to be measured lie in the nanometer range, differences in pressure can cause static shifts of the tympanic membrane by a factor of 100,000 or more. This must be taken into consideration with interferometric measuring methods which cover solely a limited range [2, 3, 4].
- Because of the goal of total implantability, low power consumption and a long service life are extremely important.
- Completely subcutaneous implantation requires the use of biocompatible materials.
- The limited amount of space available for implantation in the cranial bone requires highly integrated system construction.
- The system's frequency response must cover the range of speech, 500 Hz to 10 kHz, at least to ensure good sound quality.

3 Results of Development Work

After the preparations made during the first two years of the project, a miniaturized microphone system with integrated circuits was developed, the size of which is determined by the standard batteries it employs (Figure 2a). Signals are processed by a special electronic component (Figure 2b) produced with SMD technology.



(a)



(b)

Fig. 2. (a) First working prototype of the microphone system (b) Optoelectronic driver and data processor.

The measurements made of the combined optical and electronic system included two elements, which are important for checking and characterizing the system:

- Measurement of the acoustic reproduction as a function of frequency and amplitude of the vibrating surface.
- Determination of the range for possible static movement compared to

the potential frequency behaviour.

The vibrations of the human auditory ossicles were simulated by mounting a miniature mirror on a piezoelectric actuator (PI P-244.10). The position of the sensor fiber in relation to the mirror can be altered by means of an adjustable fiber holder. Figure 3 shows the sensor fiber and the miniature mirror, which has been mounted on the piezoelectric actuator.

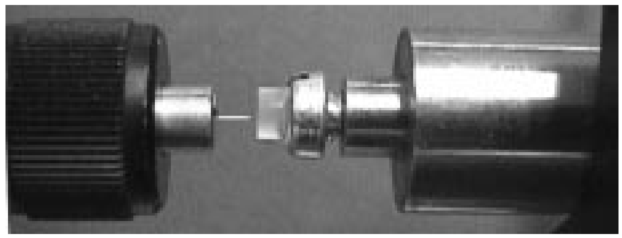


Fig. 3. Vibrating micromirror with sensor fiber in position.

The amplitude and quality of the reproduced signal was determined through application of a sine-wave sound to the actuator and then operation at various amplitudes and frequencies. This method enabled precise classification of the amplitudes and the resulting distortion. The piezoelectric actuator's calibration curves were applied to the frequency responses which were measured because the actuator was unable to supply a linear amplitude curve when the frequency was varied.

This system was used to determine the influence of quasistatic changes by shifting the vibrating mirror along the axis of movement. The results of the measurements are shown in Figure 4. (They are based on a frequency of 5 kHz and an actuator voltage of 2.5 volts, which corresponds to 5 nm p-p movement of actuator.) A frequency of 5 kHz was chosen in order to avoid the generation of actuator resonance while remaining within the medium frequency range of human speech. Figure 4 shows a plateau, which is the range in which interferometric fading compensation is effective. The results show that movement with an amplitude of up to one nanometer can be measured; at the same time, static variation of 30 to 85 m is permissible, depending on laser output and the required minimum intensity. This range is correlated with the coherence length of the light being used. The length of this plateau can be increased-thereby increasing the effective range of fading compensation and with that permitting greater static pressure changes-by employing a source with greater coherence length. Even the present system is able to process static changes such as those which occur in the course of normal life; signal fading can occur, though solely in individual cases. This would be reflected in decreased volume of the sound pattern which is reproduced.

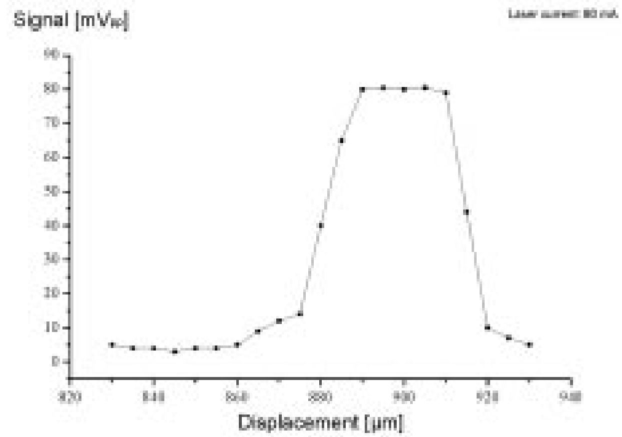


Fig. 4. System behaviour at static shift in the vibrating surface. Laser current of 80 mA, actuator voltage of 2.5 Vpp.

4 Summary

The integrated version based on a macroscopic laboratory-built system has proven in practical tests that its optical and electronic components function satisfactorily. The frequency behaviour satisfies the requirements for good speech quality and medium music quality. The static deviation of the vibrating object which was determined to be permissible guarantees that the movement which would occur in normal daily life will always supply a signal of sufficient strength to the detectors. Solely unusually extreme changes in pressure could result in a weakening or temporary loss of the signal. This could be prevented through careful selection of stronger light sources with greater coherency.

5 Future Work

Plans have been made on the basis of this project's results to further miniaturize developed fiber-optic vibrometer, at the same time reducing its power consumption. Examination of the system's long-term behaviour after implantation will be of considerable importance in doing so. Measures for preventing the implant from being covered by biological matter are being examined and tested. The ultimate goal is producing a prototype for a miniaturized microphone, which can be used with both totally implantable middle-ear hearing aids and totally implantable cochlea hearing aids.

Expression of Thanks

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