The development of a tympanic membrane sensor for a totally implantable cochlear implant or hearing aid

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SUMMARY

We present the design and development of a tympanic membrane sensor for a totally implantable cochlear implant or hearing aid system. The sensor employs a fiber-optic lever which is hermetically sealed in a biocompatible cartridge and implanted in the middle ear cavity. The sensor prototype has been designed, constructed and tested in cats. In addition, the implantation procedure of the device has also been studied using human temporal bones.

INTRODUCTION

Cochlear implants and implantable hearing aids are partially implanted in hearing impaired patients to restore their hearing functions (Clark, 1995; Maniglia, 1996). With these hearing devices, patients have to wear a microphone/transmitter unit either in the ear canal or behind the outer ear and, in some cases, carry a bulky speech processing unit. Although the external components such as speech processor are becoming more and more miniaturised with the development of microelectronics technology, the conventional microphone is still non-implantable due to technological difficulties.

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Totally implanted hearing aids have been investigated using subcutaneous microphones implanted under the postauricular or ear canal skin (Goode, 1970; Suzuki et al., 1985), but they are suffered from feedback and sensitivity problems and so far have not been proved by FDA for clinical trials. Another more elegant approach is to implant an acoustic sensor inside the middle ear cavity to directly pick up the vibrations of the ossicular chain. Gyo et al. (1984) used a piezoelectric ceramic bimorph element (PCBE) as a sound pick-up device for a totally implantable cochlear prosthesis. The PCBE was part of an electromechanical transducer that senses vibration of the tympanic membrane by coupling it to the head of the malleus. The use of the PCBE cantilever, however, applies mechanical bias force onto the ossicular chain. Therefore, it affects the natural dynamic characteristics of the middle ear as well as the stability and robustness of the device.

In this paper, we present an acoustic sensor which employs a fiber-optic lever arrangement. The sensor is hermetically sealed in a biocompatible cartridge and surgically implanted in a patient's middle ear to directly detect the vibrations of the ossicular chain. This method not only eliminates the aforementioned problems with subcutaneous microphones, but also utilizes the sound localisation and filtering functions of patient's outer ear.

SYSTEM DESIGN AND ENGINEERING

Fig. 1 shows the overall design of the totally implantable cochlear implant and hearing aid. The system consists of a sensor implant, a main implant unit, and external equipment. The sensor is fixed on the wall of the middle ear cavity and mechanically coupled to the tympanic membrane. The main implant unit is placed in the mastoid bone and contains a speech processor, a rechargeable power supply, drive circuits for the electrode or the actuator, and the sensor circuitry. The external equipment, which communicates with the main implant unit via radio frequency (RF), is used to program the speech processor and recharge the power source. For the cochlear implant the electrode array is inserted in the cochlea and electrically stimulates the ganglion cells. In case of the hearing aid, the actuator is mechanically coupled to the stapes and vibrates the fluid in the cochlea.

The sensor implant in the middle ear consists of a coupling member, a fixation member and a bio-compatible sensor cartridge. The coupling element conducts the vibrations of the tympanic membrane to the sensor diaphragm, and the fixation shaft secures the sensor cartridge within the middle ear. As shown in Fig. 2, the acoustic sensor is hermetically sealed in a biocompatible cartridge, in which a sensitive diaphragm and an optical fiber bundle form an optical lever displacement sensor capable of detecting vibrations down to the order of nanometres (He G and Cuomo FW, 1991). The fiber-optic bundle consists of transmitting and receiving fibers, and the light guided to the photo detector is modulated by the displacement of the sensor diaphragm based on the intensity-modulation principle.

Since the sensor and main implant unit is linked via the optical fiber bundle, the light source, photo detector and receiver, and signal conditioning circuitry in the main implant unit, resulting a totally passive sensor implant in the middle ear. Therefore, the sensor is simple to construct, geometrically flexible, and immune to external electro-magnetic interferences.

The sensor cartridge, housing the distal end of the fiber bundle, has been designed as a thin disc with 1.5 mm in thickness and 3.5 mm in diameter. A back plate was added to adjust the first resonant frequency of the diaphragm. The optical fiber bundle was stranded using 250 μm multi-mode plastic fibers. Infra red light emit diode (LED) was used and modulated into a 20 kHz pulse train. To minimise the power consumption the width of the pulse was set at 2.5 μs to achieve a 5% duty cycle. The performance of the sensor prototype has been tested in-vivo using a cat model. 0 dB signal-to-noise ratio was measured at 1 kHz and 55 dB SPL.
SURGICAL PROCEDURE

The surgical procedure for the sensor implant has been proposed and evaluated with respect to the standard posterior tympanotomy on normal human temporal bones. The implantation involves the coupling of the sensor to the tympanic membrane and the fixation in the middle ear. A mastoidectomy was performed first to create a passage through the temporal bone to the middle ear cavity. The ossicular chain was then disarticulated by disconnecting the incudo-stapedial and incudo-malleal joints. Two different methods for securing the sensor cartridge were investigated. Firstly, the cartridge was fixed locally in the attic and mastoid antrum, in particular adjacent to the normal position of the head of the malleus. The sensor was then held in place using a fixation mould formed within the atrium. Alternatively, a malleable shaft member was inserted through the passage formed in the mastoid. One end of the shaft was secured on the temporal bone by means of self tapping screws, while the sensor was supported at the other end. Partial Ossicle Replacement Prosthesis (PORP) was used as the coupling member between the manubrium of the malleus and the sensor diaphragm to conduct vibrations from the tympanic membrane.

CONCLUSIONS

A tympanic membrane sensor has been developed for the totally implantable cochlear implant and hearing aid system. The novel design of using the fiber-optic displacement sensor enables sensor implant in the middle ear to be highly sensitive and totally passive. The experimental surgical studies of the sensor prototype have demonstrated the feasibility of such design concept. The development of a fully operating implant system is currently in progress.

REFERENCES

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