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Main Articles

In vitro study of a multi-layer piezoelectric crystal attic hearing implant

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Abstract
We have developed a prototype middle-ear hearing implant which uses a multilayer piezoelectric actuator. In this series of experiments the actuator was attached to the medial wall of the attic so that it makes contact with the body of the incus. Initial *in vitro* evaluation has been carried out using a laser vibrometer (Polytec CLV) to measure stapes velocity. Stapes displacement is calculated by mathematical integration. The device used in this way is particularly effective at transmitting high frequency sound to the stapes. When switched off the actuator impairs the transmission of sound to the ossicular chain at low frequencies, but this effect is only 7 dB at most. The stapes displacements resulting from the action of the implant have a linear relationship with the voltages used to drive the system. The high capacitance of the present actuator means that its power requirements are higher than that of other comparable devices. An optimal method of coupling the device to the incus has yet to be identified.

Key words: Hearing Loss; Prosthesis Design; Temporal Bone; Ear, Middle; Evaluation Studies

Introduction

Attempts to develop implantable hearing aids date from the 1960s. The potential advantages of such devices are better sound quality, absence of acoustic feedback and superior cosmesis and comfort. So far the devices produced have used either electromagnetic[1–4] or piezoelectric crystal[5–9] actuators.

The semi-implantable devices developed by Yanagihara *et al.*[5] and Suzuki *et al.*[6] in Japan and Dumon[7] in France employed two layers of piezoelectric material arranged with opposite polarity so that the passage of electric current leads to bending. One end of the crystal bimorph is fixed to the wall of the middle ear while the other is attached to the stapes head. The Japanese implant can only be used in ears with erosion of the incus long process. Clinical trials have been carried out with encouraging results. Patients reported better quality with the implant as compared to their conventional hearing aids. The French device is similar in design, but can be used with an intact ossicular chain. Due to their low driving forces, the two-layer crystal design of these implants limits the stapes displacement that can be achieved.

A team based at the University of Tubingen in Germany have developed a piezoelectric device (TICA, Implex) in which the actuator consists of a disk of piezoceramic and a metal membrane.[8] Movement of the ossicular chain is achieved via a titanium rod. Short-term trials with a microphone positioned under the skin of the posterior external auditory canal wall have been carried out with encouraging results. However, feedback between the microphone and the implant is a problem in some cases and the neck of the malleus must be divided to prevent this. A second totally implantable device has been developed by St Croix Medical of Minnesota.[10] They use a piezoelectric sensor on the malleus and a piezoelectric actuator on the stapes The incus is removed.

Our middle-ear research group (UK Middle Ear Research Group, UMERG) brings together surgical and engineering expertise from the Universities of Edinburgh, Dundee and Portsmouth. We have developed a novel implant using a piezoelectric actuator which consists of multiple layers of crystal designed to be placed in the attic region of the ear (Figure 1). The crystals are arranged so that the actuator extends linearly in relation to the applied

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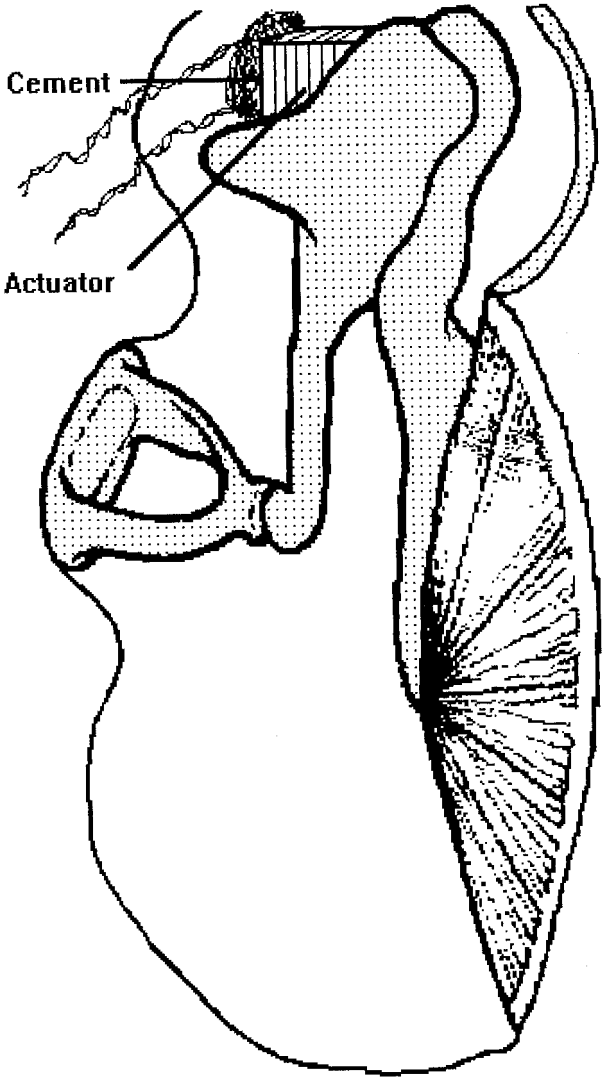

FIG. 1
In situ location of the multi-layer piezoelectric actuator.

electric voltage. So that the device can be used for patients with an intact ossicular chain, it had to be able to move the whole ossicular chain rather than just the stapes. We therefore decided to try and exploit the natural level action of the ossicular chain by placing the actuator above the axis of rotation of the malleus and stapes. Based on a study of the dimensions of 23 cadaveric incudes we calculated that any displacement achieved by the actuator would result in a stapes displacement up to 4.6 times greater (Figure 2). The high driving force that this type of actuator can generate should allow this to be achieved.

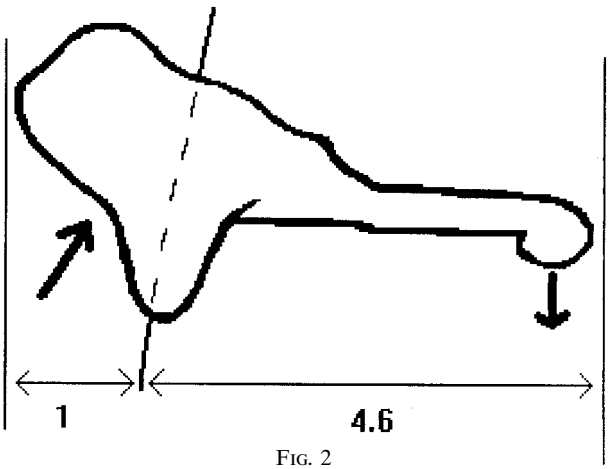

FIG. 2
Dimensions of the components of the incus lever.

This paper presents the results of our initial *in vitro* evaluation of the implant. Our aim was to investigate the effectiveness of the actuator as a means of delivering energy to the ossicular chain and its potential adverse effect on middle-ear function when not in use.

Materials and methods

A commercially available multilayer piezoelectric crystal actuator was obtained from PI (Model PL-033, Physik Instrumente, Waldbronn, Germany). The device is 2 mm long and has a cross section of 3 mm by 3 mm which contacts the incus body. Its mass is 150 mg. This was the smallest wafter that we were able to obtain, but we are advised that it would be possible to construct a smaller cross-section wafer without any loss of displacement. An electronic system to convert sound into an electrical signal to drive the actuator was constructed in our laboratory.

The performance of the device was studied using fresh human temporal bones. Stapes velocity was measured using a laser Doppler vibrometer (Polytec CVL) and stapes displacements were calculated by mathematical integration. A cortical mastoidectomy was carried out and extended to expose the ossicular chain in the attic. The actuator was placed against the upper part of the body of the incus and cemented to the medial wall of the attic with epoxy resin. The medial aspect of the stapes footplate was exposed via the internal auditory meatus and a small spot of retro-reflective paint was applied to the footplate to ensure a satisfactory reflective signal from the laser vibrometer. Acoustic stimulation was delivered from a digital sound waveform generator via a length of wide bore acoustic tubing cemented into the external auditory meatus with epoxy resin. Fine bore tubing was cemented into a hole in the posterior wall of the external auditory meatus and a probe microphone was attached so that the sound pressure level delivered to the tympanic membrane during acoustic stimulation could be monitored. The temporal bone was placed in a specially designed holder that allows precise positioning of the specimen. The holder and the laser vibrometer were mounted on a platform designed to exclude external vibration. This experimental method was developed by members of our group to study ossicular reconstructions *in vitro* and has been reported previously.[9]

At the start of the experiment stapes displacements were recorded under acoustic stimulation of 90 dB SPL at frequencies from 125 Hz and 8000 Hz. The actuator was then cemented into place and acoustic stimulation was applied as before. Electrical stimulation was applied at 10 Vp-p (3.5 Vrms) using

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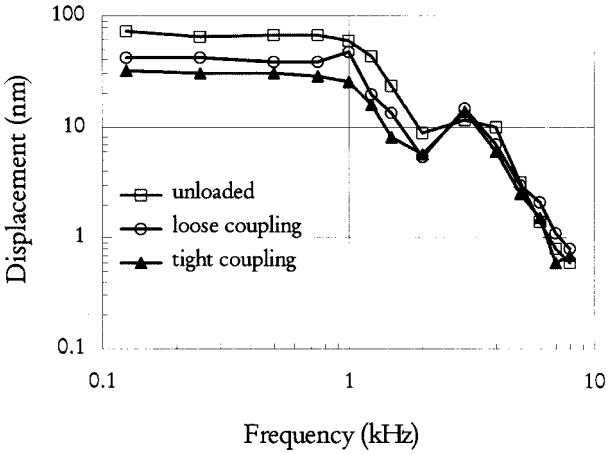

FIG. 3

Stapes displacement for acoustic stimulation with the ossicular chain unloaded and with the implant *in situ,* for loose and tight coupling.

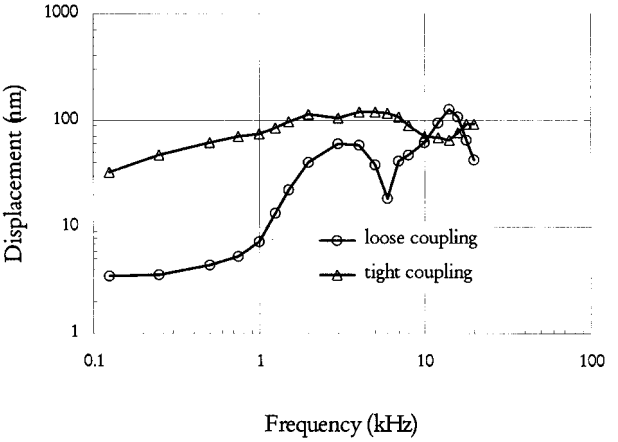

FIG. 5

The effect of stimulation of the ossicular chain by the implant with loose coupling and tight coupling.

frequencies from 125 Hz and 20 000 Hz. This was repeated using 1 V, 3 V, 5 V and 10 V at the frequencies 1000 Hz, 5000 Hz and 10 000 Hz. In order to investigate the efficiency of transmission by this method, the actuator was then cemented to the incus and further acoustic and electrical stimulation was applied. This experiment has been carried out on three separate temporal bone preparations.

Results

The results for acoustic stimulation, under normal (unloaded) chain, the actuator cemented to the medial attic wall only (loose coupling), and the actuator cemented both to the medial attic wall at one end and to the incus at the other end (tight coupling), are presented in Figure 3. Loading of the ossicular chain with the implant does reduce the stapes displacements for the same level of sound input and this effect is more marked at low frequencies. Above 2000 Hz no such loading effect is evident. The effect of loading expressed as change in displacement in dB is presented in Figure 4. Unless the actuator is cemented to the incus, the maximum attentuation is less than 7 dB.

The results for electrical stimulation with the actuator cemented to the medial attic wall only (loose coupling) and to the incus as well (tight coupling) are presented in Figure 5. With loose coupling the transmission of frequencies above 1000 Hz is considerably better than that of lower frequencies, both in terms of the magnitude of stapes displacements achieved and the quality of the wave form recorded (Figure 6). When the voltage is varied a linear change in response is evident with both loose

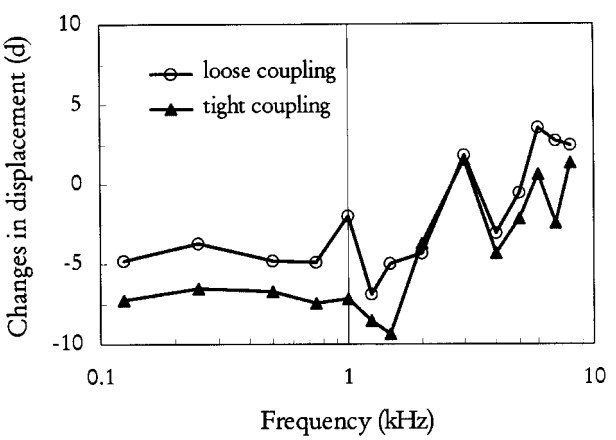

FIG. 4

The effect of loading the ossicular chain with the implant expressed as change in displacement in dB in relation to the normal chain.

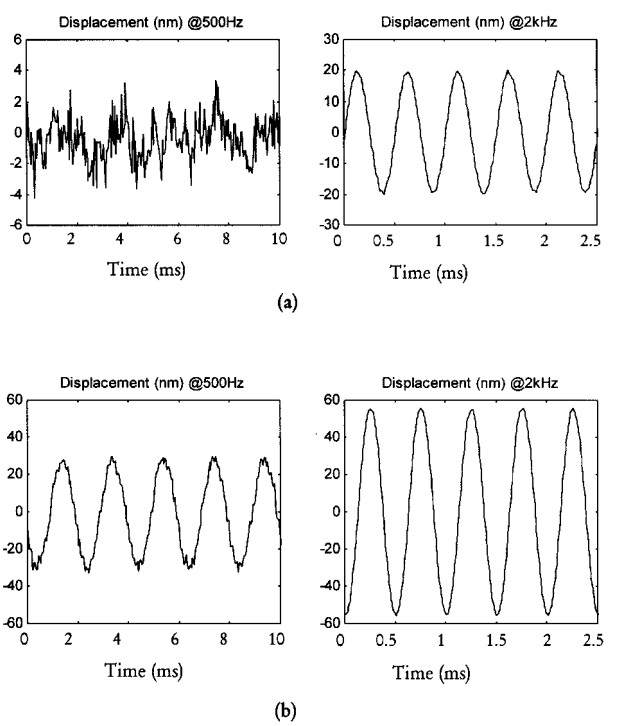

FIG. 6

Displacement waveforms at 500 Hz and 2 kHz using the implant under (a) loose and (b) tight coupling conditions.

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and tight coupling at all the frequencies tested. There was also a linear relationship between power consumption and frequency. At 500 Hz this was only 3.5 mW, while at 10 000 Hz it was 70 mW. The power requirements of the device are significantly higher than those of the disk type actuators such as the TICA implant,[8] because of the high capacitance of our actuator and its higher driving voltage (3.5 Vrms) currently applied.

Discussion

The results of this preliminary study are encouraging, but a number of significant problems must be overcome if this type of actuator is to be applied clinically. The loading effect of the implant is not as great as we had feared it might be, but it could still be significant, especially at low frequencies. Our original concept of an implant attached to the attic wall and resting against the incus does allow sound transmission to occur but the arrangement is inefficient, especially at low frequencies. The interface between the implant and the incus has not, however, been optimized so improvements in this area might overcome this difficulty.

Epoxy resin was chosen for the fixation of the implant during the early experiments because it is inexpensive and bonds both to bone and the piezoelectric ceramic. In the clinical setting an alternative fixation method would be required. We have also used a biocompatible cement, Biocem (Corinthian Medical). This fixation method is adequate in the short-term, but it may be that it would not be viable in the long-term. The cement might not be able to withstand the vibrations to which it would inevitably be subjected. Other methods of fixation are therefore being explored.

The current actuator performs better at high frequencies than at low frequencies and this could be a valuable aspect of its performance, given that the most commonly encountered pattern of sensorineural hearing loss affects the high frequencies more than the low frequencies. There must be some concern that it would impair low frequency hearing and this potential problem would need to be addressed to make an implant of this sort available.

In order to assess stapes movement under acoustic stimulation with a laser vibrometer, a relatively high level of stimulation was used (90 dB SPL). Equivalent displacements can be produced with the piezoelectric actuator. In the clinical context lower stimulation levels would be required. Because of the linear relationship between applied voltage and stapes displacement lower voltages than those used in this experiment would be adequate.

Comparison of our data with that reported by the Tubingen Group suggests comparable performance in terms of potential sound level input and frequency response. However, the power requirements of the TICA device appear to be significantly lower. This is because the multi-layered device is a heavy capacitance load for the driving circuitry. There is also considerable variation in power requirements in relation to frequency.

Most middle-ear hearing implants have been designed to move the ossicular chain in a physiological manner. However, the Vibrant Soundbridge (Corporation) employs an alternative approach. This electromagnetic implant is attached to the incus long process and contains a magnet which vibrates within the electrical field generated by a coil around it. The arrangement can be likened to a loud speaker placed close to the stapes. Energy will reach the cochlea via the incus and stapes and by acoustic coupling across the middle-ear space.

Acknowledgement

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References

1 McGee TM, Kartush JM, Heide JC, Bojrab DI, Clemis JD, Kulick KC. Electro-magnetic semi-implantable hearing device: Phase I clinical trials. *Laryngoscope* 1991;**101**:355–60
2 Maniglia AJ, Ko WH, Rosenbaum M, Falk T, Zhu WL, Frenz NW, *et al.* Contactless semi-implantable electromagnetic middle ear device for treatment of sensorineural hearing loss. *Otolaryngol Clin North Am* 1995;**28**:121–40
3 Fredrickson JM, Coticchia JN, Khosla S. Ongoing investigations into an implantable electromagnetic hearing aid for moderate to severe sensorineural hearing loss. *Otolaryngol Clin North Am* 1995;**28**:107–20
4 Baker RS, Wood MW, Hough JV. The implantable hearing device for sensorineural hearing impairment. The Hough Ear Institute experience. *Otolaryngol Clin North Am* 1995;**28**:147–53
5 Yanagihara N, Gyo K, Suzuki K, Araki H. Perception of sound through direct oscillation of the stapes using a piezoelectric ceramic bimorph. *Ann Otol Rhinol Laryngol* 1983;**92**:223–7
6 Suzuki J, Kodera K, Yanagihara N. Middle ear implants for humans. *Acta Otolaryngol* 1985;**99**:3–4, 313–7
7 Dumon T, Zennaro O, Aran JM, Bébéar JP. Piezoelectric middle ear implant preserving the ossicular chain. *Otolaryngol Clin North Am* 1995;**28**:173–87
8 Leysieffer H, Baumann JW, Müller G, Zenner HP. An implantable piezoelectric hearing aid transducer for inner ear deafness. II: Clinical implant. *HNO* 1997;**45**:801–15
9 Abel EW, Lord R, Mills RP. Methodology for laser vibrometer studies of stapes footplate displacement. *Proceedings of the Second International Symposium on Middle Ear Mechanics in Research and Otosurgery* 2000;89–97
10 M Schröder. Envoy™ totally implantable hearing restoration system. The 3rd International Symposium on Electronic Implants in Otology and Conventional Hearing Aids. Birmingham, UK 31 May–2 June 2000, Final Programme and Abstract Book, Session 3.3. p11

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