DEVELOPMENT OF AN IMPLANTABLE

A team from the Department of Oto-Rhino-Laryngology of the University Hospital and Experimental Audiology Laboratory of Bordeaux has been developing a middle ear implant (MEI) project since 1989. The first part of this program enabled the definition and the realization of the piezoelectric vibrator, implantable in the middle ear.

DEVELOPMENT OF AN IMPLANTABLE PIEZOELECTRIC VIBRATOR FOR MIDDLE EAR IMPLANT

State of the research program

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Introduction

A team from the Department of Oto-Rhino-Laryngology of the University Hospital and Experimental Audiology Laboratory "?of Bordeaux has been developing a middle ear implant (MEI) project since 1989. The first part of this program enabled the definition and the realization of the piezoelectric vibrator, implantable in the middle ear.

The first stage consisted of the choice of piezoelectric technology, because of the structural simplicity of the vibrating comportent, the good frequency fidelity and the low energy consumption of piezoelectric ceramies (1 -5). The vibrator selected is a lead, titanate, zyrconate ceramic, in a bimorph assembly, which is the most suitable device for such application.

Animal experimentation

In guinea pigs, the experimentation principle was implantation of the piezoelectric vibrator on the round window membrane leaving the ossicular chain intact, in order to compare the auditory evoked potentials obtained by physiological acoustic stimulation and by piezoelectric stimulation (6 -10).

The vibrators were chronically implanted (longer than two months) and their tolerance studied. The evoked potentials of the auditory cortex and auditory nerve were recorded in response to clicks and short pure tones front 0.25 to 32 kHz frequencies and for acoustic stimulation level from 0 to 100 dB SPL and piezoelectric stimulation level from 250 to 1000 mV.

The piezoelectric auditory evoked potentials recorded were comparable, in appearance, latency, and amplitude to the acoustic auditory evoked potentials. The thresholds of the piezoelectric evoked potentials ranged from 40 to 100 mV, according to frequency (lower threshold for 16 kHz tone burst). Latencies were shorter than in acoustic stimulation, owing to suppression of the transfer time of the external and middle car. "?For the same relative level above threshold, the amplitude of piezoelectric evoked potentials was comparable to those of acoustic evoked potentials. These results were stable during the entire period. The optical microscopy and scanning electron microscopy examination and of the middle cars implanted three months earlier showed perfect tolerance to the vibrator, with no inflammatory reaction to the foreign body.

Acute experimentation was performed to test différent sites in the middle ear for piezoelectric stimulation. The lower threshold (3 mV) was recorded with the vibrating end of the vibrator placed on the head of the stapes. The stapes seems to bc the most efficient site for the vibrating stimulation of the inner car.

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Definition of a vibrator for human's by study on buman petrous bones

The good results of the animal experimentation led us to design a vibrator for humans and its fixing system. We chose to implant the vibrator on the stapes in humans, for three reasons: the animal experimentation showed us that the oval window seems to be the most efficient site for vibrating stimulation of the inner ear; the stapes is a more solid support than the round window membrane; and stapedial surgery is sale and reliable.

The aim of this study on human petrous bones(7- 8 -10) was to determine the surgical approach for the implantation, and the design and dimensions of the vibrator for humans and its fixing system. For this study, vibrators were implanted on the head of the stapes after disarticulation and exeresis of the incus, similar to the procedure described by Suzuki et al (11-13).

The surgical approach chosen was conservative mastoidectomy with wide posterior tympanotomy, for ears with an intact mastoid. The vibrator was positioned through the posterior tympanotomy, usually directly on the stapes' head or with an intermediate piece. It was maintained in good position by a bayonet-shaped adjustable fixing strut fastened on the posterior cortex of the mastoid. The vibrator can also be implanted on ears operated on by the radical mastoidectomy technique.

This technique enables the implantation of a vibrator with an average length of 13 mm, a width of 1.6 mm, and a thickness of 0.6 mm. This length is substantial, longer than that selected by other teams, and is favorable for the acoustic gain of future prostheses.

In vitro measurements of vibrator performance

We developed an in vitro measurement system for the acoustic performance of vibrators. The frequency spectrum and the intensity of the transmitted vibration were analyzed for continuous sinusoidal stimulations with a frequency of from 0.5 to 8 kHz and for voltages of from 0.25 to 2.5 V. We tested human-model vibrators fixed on their fixing strut (7-8-10).

Response in frequency

Analysis of the spectrum of the vibration transmitted showed a narrow peak at the same frequency as the stimul"?ation. There was no parasite frequency peak or resonance in the frequency field tested.

Analysis of the response in frequency based on the stimulation voltage shows that, for a given stimulation voltage, the intensity of the vibration transmitted is remarkably stable at all the frequencies tested (Fig. 1).

Inputloutput curves

We analyzed the intensity of the vibration transmitted according to the stimulation voltage (input/output curve) for each frequency tested. From 250 millivolts of stimulation, the sound pressures generated were over 85 dB SPL at all ficquencies. The intensity of the vibration transmitted increased with the intensity of the stimulation with a logarithmic progression. For a stimulation of 2.5 volts, the sound pressures are over 110 dB SPL (Fig. 2). These results are very encouraging for the application of such vibrators in an MEI due both to the sound intensities provided and the frequential fidelity of the vibrators.

Vibrator for humans preserving the ossieular chain

At the time of our study, the vibrator designed for implantation in humans required the exeresis of the incus or its long process to bc implanted on the head of the stapes. This exeresis causes serious iatrogenic damage, which is not acceptable froin an ethical point of view in a patient whose ossicular chain was previously normal. This is particularly important in the case of sensorineural

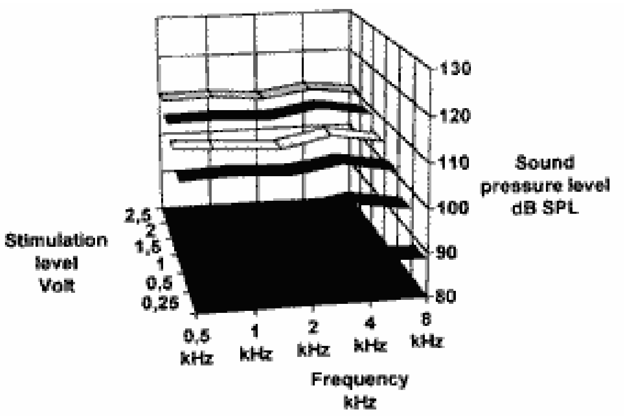

Fig. 1. Frequency response of a human-type vibrator. The sound pressure level of the output vibration is described as a function of frequenc"?y, for a steady stimulation level. For a given stimulation tension, the intensity of the output vibration was very stable at all frequencies tested.

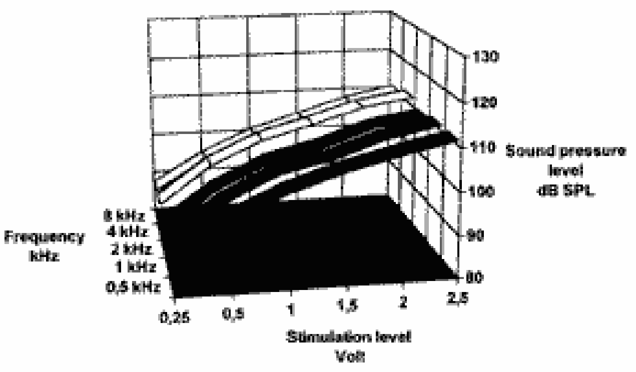

Fig. 2. Input-output fonction of a human-type vibrator measured in vitro. The sound pressure level of the output vibration is described as a

fonction of the tension of stimulation of the vibrator. For each frequency tested, minimal output level was over 85 dB SPL, and in creased over 110 dB SPL.

hearing loss, which should constitute, in the long run, an important indication for an MEL We therefore developed a piezoelectric vibrator for humans, implantable on the stapes' head without removing the incus [10].

The vibrator used was a bimorph ceramic of the same size as that described above, equipped with a plate-shaped extension fixed to its vibrating end. The principle is to implant the vibrator in such a way that the extension is inserted between the end of the long process of the incus and the head of the stapes, in place of the lemicular bone of the incudostapedial joint (Fig. 3). The mens and the stapes are preserved. The dissection of the incudostapedial joint and the exeresis of the lenticular bone only involve minor iatrogenic damage, which can be repaired if the vibrator has to be removed. This point is important in the future application of MEls in the rehabilitation of sensorineural hearing loss.

We perform the experimental analysis of the performance of these vibrators by in vitro aconstic measures, using the previously described method. Moreover, we are currently developing a method to measure intracochl"?ear sound pressures on human petrous bories, to evaluate the performance of vibrators once implanted.

Parallel to these experimental measurements, we have developed a mathematical model of the working of the vibrator, attached to ils fixing strut. This is realized through a tridimensionally finished elements code, which takes into account the physical characteristics of the materials and their assembly, and enables différent fittings to be studied and optimized.

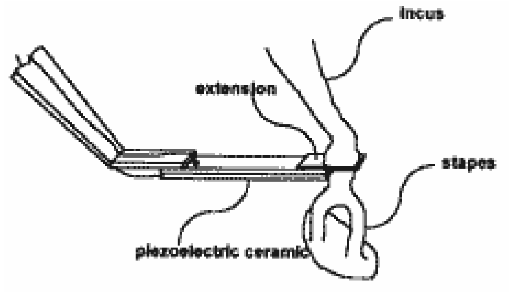

Fig. 3. Vibrator enabling preservation of the ossicular chain. The vibrator is fixed to the fixing strut. The piezoelectric ceramic is equipped with a plate-shaped extension. The vibrator is implamed in such a way that the extension is inserted between the end of the long process of the incus and the head of the stapes, in place of the lenticular bone of the incudostapedial joint.

Conclusions

The development of our research program on MEls is being pursued. The realization of the implantable vibrator has nearly been achieved. The design of an implamable piezoelectric vibrator preserving the ossicular chain is an important point in the future device. Once the vibrator has been achieved, we hope to realize a partially implantable MEl, for reasons of battery limitations, material reliability, and evolution of the prosthesis. A percutaneous connection between the external and implantable parts of the prosthesis is being considered for good energy output.

The aim and end purpose of MEls is a totally implantable MEl, for severe and average sensorineural deafness. When the implantation of such prostheses becomes commo"?nplace, deafness should lose the character of an infirmity that il still represents in the eyes of many.

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