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Progress in middle ear implants (MEls) has been systematically monitored for years by the team from the University Hospital Department of Ear, Nose, and Throat (Professor Bébéar) and the Experimental Audiology Laboratory U. M. Aran, Director) of Bordeaux. The work of Yanagihara and Suzuki and their colleagues, (19,20,23) which opened the modern era of these prostheses, showed the possibility of making such hearing aids and prompted us to launch a research program on middle car implano?ts in 1989.

The first stage consisted of the choice of the vibrator technology. The Work prior to ours implemented two vibrator technologies, piezoelectric vibrators (6,7,9, 12, 15, 16, 18, 21, 22, 24) and electromagnetic vibrators (4, 5,8, 10, 11, 13, 14, 17) Multidisciplinary consultation among physicians, researchers, and engineers failed to uncover any new technologies likely to be applied to implantable vibrators. The piezoelectric and electromagnetic technologies were considered the best. Each has its advantages and disadvantages without being clearly better than the other.

We chose the piezoelectric technology because of the structural simplicity of the vibrating component, the excellent frequency fidelity of the piezoelectric vibrators, and their low energy consumption. The characteristics sought for a piezoelectric vibrator designed for a MEI are a high vibration amplitude with low stimulation voltages and a low-frequency (under 10 kHz) linear operation. At present, the piezoelectric components best meeting these criteria are ceramics with lead, zyrcon, and titanium in a bimorph assembly. We used this type of ceramics for our research.

The second stage of the research program consisted of animal experimentation. Its aim was to confirm the validity of the auditory stimulation with an implanted piezoelectric vibrator. Using the skills and knowledge of the Experimental Audiology Laboratory, this experiment was performed on guinea pigs with both short-term and long-term implantation. At the same time as the animal experimentation, an acoustic measurement system of the in vitro performances of the vibrators was designed. Its development led us to study the characteristics of a vibrator designed for humans that could be quickly sto?udied in vitro.

A study on human petrous bones enabled us to define the shape and size of a vibrator for humans, as well as its fixing system. The surgical approach for the implantation was analyzed at the same time. The in vitro measurements of the performances of such vibrators confirmed the choice of piezoelectric ceramics and the design of the vibrator.

In designing a vibrator to be implanted in the middle ear in humans, the problem is the relationship of this vibrator with the ossicular chain. The solution adopted by the teams preceding ours requires inflicting irreversible iatrogenic damage in order to implant the vibrator. This did not appear acceptable to us, leading us to design an implantable piezoelectric vibrator that would not affect the ossicular chain's continuity.

The initial experience pertaining to the MEI in humans is discussed in this article.

ANIMAL EXPERIMENTATION

Principles

In guinea pigs, the experimentation principles were (1) to implant the piezoelectric vibrator on the membrane of the round window leaving the ossicular chain intact and (2) to compare the auditory evoked potentials by physiologic acoustic stimulation and by piezoelectric stimulation.

Materials

The animal experimentation was performed on tricolored guinea pigs. The animals were implanted when they reached a weight of 250 g, after undergoing evaluation for normality of Preyer's reflex (inclination reflex of the auditory pinnas upon auditory stimulation).

The vibrators designed for guinea pigs were 5 mm long, 0.6 mm wide, and 0.4 mm thick. For proper application on the membrane of the round window without o?contacting the osseous niche of the window, the vibrators were equipped with an extension measuring 1.5 mm and ending in a platinum ball (Fig. 1). The electrophysiologic measurement chain consisted of a stimulation chain and a recording chain for the collection of the auditory evoked potentials. The stimulation chain contained a digital sound generator run by a microcomputer, an amplifier, and an attenuator. The stimulations were transmitted either to a micro-loudspeaker, for the acoustic stimulations calibrated in decibels (dB SPL), or to the piezoelectric vibrator, for the piezoelectric stimulations calibrated in millivolts (mV). The recording chain consisted of a preamplifier, an amplifier, an averager, and a microcomputer enabling the display, analysis, and recording of the signals.

Stimulation and recording were synchronized. The stimulation signals and the evoked potentials were displayed in real time on an oscilloscope. All the measurements were performed in an electrically insulated, soundproof booth.

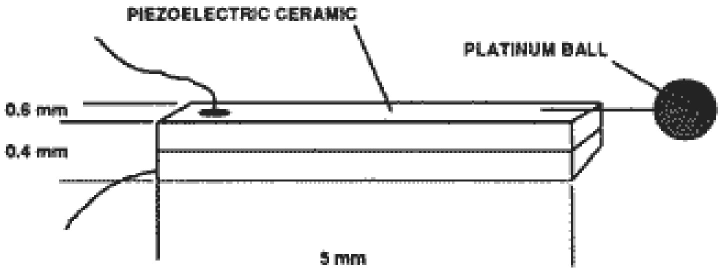

Figure 1. Piezoelectric vibrator for guinea pigs. The bimorph piezoelectric ceramic is equipped with an extension ending in a platinum ball.

Methods

Implantation of Vibrators and Collection Electrodes for Auditory Evoked Potentiais

Implantation was performed under general anesthesia. Most of the guinea pigs were implanted for long-term evaluation. Certain particular points were studied in short-term implantations.

The piezoelectric vibrators were implanted in the middle ear of the guinea pig through a posterosuperior approach under an operating microscopo?e. The end of the extension was placed in contact with the membrane of the round window under visual control. The fixed end of the vibrator was sealed in the mastoid bulla, and the ear was then closed.

Implantation of the collection electrodes for auditory evoked potentials was performed by a sagittal incision on the vertex, exposing the skull. The cortex electrode was implanted in contact with the dura mater, opposite the auditory cortex contralaterally to the stimulated ear, by a calibrated trepanation in the parieto-occipital region. Two neutral electrodes and one mass electrode were implanted in contact with the dura mater on the vertex.

The electrodes for auditory nerve evoked potentials were fitted with stereotactic positioning in relation to the cranial sutures. With the skull of the guinea pig fastened to the stereotactic framework, the vertical line of the implantation point was marked, and the skull trepanated. Two coaxial electrodes were implanted. The neutral electrode was placed in contact with the dura mater, whereas the exploring electrode was pushed in until it touched the auditory nerve, under perioperative control of the auditory evoked potentials.

The vibrator and all the electrodes were then linked to a miniature connector fastened on the guinea pig's head.

Etectrophysiologic Recordings

Stimuli. The electric signals used were either 0.1-millisecond rectangular impulses (insignificant rise and fall times), or sinusoid, diamond-shaped, or trapeziform impulses with rise and fall times not exceeding 1 millisecond. These signals were transmitted either to a loudspeaker for acoustic stimulation or to the implanted piezoelectric vibrator.

The correo?sponding acoustic stimuli were clicks for the rectangular impulses and short, pure sounds of the frequency of the sinusoid for the sinusoid impulses. The sounds were transmitted by a micro-loudspeaker placed 1 cm from the external auditory meatus. The intensity of the stimuli was calibrated in dB SPL.

For the piezoelectric stimulations, the electric signals were transmitted to the vibrator via the miniature connector fastened to the guinea pig's skull. The intensity of the stimulations was characterized by the voltage transmitted to the terminals of the vibrator in millivolts.

Evoked potentials of the cortex and the auditory nerve were recorded by averaging the response to 100 stimulations at the frequency of 10 per second.

We tested the responses to the clicks and to the short, pure sounds from 250 to 16,000 Hz. The intensities tested ranged from 0 to 100 dB SPL for acoustic stimulation and from 0 to 1 volts for piezoelectric stimulation.

Long-Terin Studies. The electrophysiologic recordings were performed on awake guinea pigs kept in a box placed in the soundproof booth. Forty-eight hours after implantation, the hearing of each guinea pig was tested by acoustic measurements. The threshold curves were recorded, as well as the input/output curves for each frequency. Only the guinea pigs with normal responses were kept for the continuation of the experiment.

Following the acoustic responses, the piezoelectric evoked potentials were studied according to the same protocols. The threshold and input/output curves were drawn. When the responses to the acoustic and piezoelectric stimulations were satisfactory, the guinea pigs were kept to study the evolution of the responses over time.
Short-Term Studies. Short-term studies were performed to check the mechanical nature of the stimulation and to test various implantation sites for the vibrator. The guinea pigs were fitted with a collection electrode for the auditory nerve evoked potentials. The piezoelectric vibrator, maintained by an autostatic arm, was then tested in various implantation positions. Recordings were thus performed with the vibrator placed at the entrance of the mastoid, on the promontorium, on the round window, and in contact with the incudostapedial joint.

Results

The hearing of the guinea pigs was checked 1 week after implantation. Only the guinea pigs for which the hearing thresholds and input-output curves were normal in acoustic stimulation were kept for the continuation of the experiment.

Cortical Evoked Potentials (1)

Ten guinea pigs were implanted on the basis of the protocol just described. With three guinea pigs, it was not possible to record any response in piezoelectric stimulation owing to failure of the implantation technique. The seven remaining guinea pigs had normal acoustic evoked potentials. The piezoelectric stimulation enabled the recording of a response of a nervous potential of the auditory cortex, comparable in shape, latency, and amplitude to the responses to acoustic stimulations. At the time of the piezoelectric stimulations, there was an electric artifact on the recording, reproducing the stimulation. These responses were called piezoelectric auditory evoked potentials.

We recorded cortical evoked potentials in piezoelectric stimulation at all the frequencies tested from 500 Hz to 16 kHz. Their long latency, of approximately 15 milliseconds, obviates any ho?indrance from the stimulation artifact when it is long, i.e., at low frequencies (at 500 Hz, for example, stimulation lasts 12 milliseconds). It is thus possible to record the responses at all the frequencies, whereas with the other techniques, cochlear or auditory nerve evoked potentials cannot be used at low frequencies because with their short latency, the responses are masked by the stimulation artifact.

We were able to determine the thresholds in piezoelectric stimulation for the click and for short, pure sounds from 500 Hz to 16 kHz. Depending on the frequencies, the thresholds were between 30 and 150 mV. The piezoelectric threshold curves were comparable in appearance to the acoustic threshold curves. These thresholds were constant for each guinea pig but varied considerably from one individual to another, probably because of the different positionings of the vibrator.

The amplitude of the piezoelectric evoked potentials increased with the intensity of the stimulation, but the method used did not enable the definition of the input/output function of the auditory cortex. The cortical evoked potentials are in fact ill-adapted for measuring the intensity of the auditory response. Owing to their high level of integration, their amplitude is proportional to the stimulation intensity at low levels but very rapidly reaches a maximum at high levels. The amplitude of the cortical potentials reaches a maximum, whereas that of the cochlear response continues to increase.

We repeated the measurements over a 2-month period. The individual reproducibility of the piezoelectric evoked potentials was good. The thresholds and the amplitudes were stable. We did not record more otitis media in the guinea pigs with implanted vibrators than in the o? guinea pigs with electrodes implanted on the round window as currently used in the laboratory.

We wanted to establish a cochlear input/output function for the piezoelectric stimulation. Because the evoked potentials of the auditory cortex were not suitable, the electrophysiologic technique had to be changed. Electrocochleography was eliminated because it requires the positioning of an electrode on the round window, which would have interfered with the vibrator. We decided to record the evoked potentials of the auditory nerve using an electrode permanently implanted close to the nerve.

Auditoty Nerve Evoked PotentiaiS (2,25)

Long-Term Studies. The results are based on 12 guinea pigs, each with an electrode on the auditory nerve and a vibrator implanted on the round window. Two guinea pigs with electrodes on the auditory nerve but without implanted vibrators were used as controls.

The acoustic evoked potentials were recorded first. The guinea pigs fitted with vibrators had normal thresholds identical to those of the controls. The input/output curves were recorded with clicks. They were normal, like those of the controls. The latencies were very consistent and reproducible. The amplitudes were expressed in percentage of maximal amplitude to eliminate the differences from one individual to another inherent to the positioning of the collection electrode in relation to the auditory nerve. These normal results in acoustic stimulation evidenced the harmlessness of the vibrator implantation. Its positioning does not cause any lesions to the inner ear and does not noticeably interfere with the action of the windows.

The piezoelectric evoked potentials were satisfactorily recorded for seven guineao? pigs. The threshold curves were recorded with clicks and for frequencies over 2 kHz. For frequencies under 2 kHz, the electric stimulation artifact prevented the recording of evoked potentials. At the frequencies tested, the curves are comparable in appearance to the acoustic curves (Fig. 2). The lowest thresholds were obtained at 16 kHz, around 40 mV. The click thresholds were higher.

Likewise, the input/output curves are comparable in appearance to the acoustic curves (Fig. 3). Latency decreases and amplitude increases with the rise in intensity of the stimulation. The responses were stable and reproducible. The latencies are shorter than in acoustic stimulation, owing to the absence of transfer time to the inner ear. The voltage of the stimulation could not exceed 1 volt given the experimental conditions. Compared with the logarithmic scale of decibels, and given the thresholds equal at best to 40 rnV, the dynamics of the stimulation intensity did not exceed the equivalent of 30 dB. Within this limit, the amplitudes were comparable to those obtained in acoustic stimulation for the same level above the threshold.

Experimental conduction deafness, by destruction of the tympanum, was produced in one guinea pig to study the possible role of the tympano-ossicular system at the time of the piezoelectric stimulation. In acoustic stimulation, a rise in the hearing thresholds was observed at all frequencies of 40 dB SPL. The input/output curves evidenced an increase of the latencies and a decrease in amplitudes at all intensities. In piezoelectric stimulation, the latencies and amplitudes remained the same before and after tympanic destruction. This experimentation enabled the elimination of a retrograde acoustic stimulation from the middle ear during the piezoeleo?ctric stimulation.

The auditory performances of these guinea pigs were evaluated for 7 months. The thresholds as well as the input/output curves remained remarkably stable and reproducible during this entire period.

Short-Term Studies. Short-term recordings were performed in four guinea pigs. After wide exposure of the middle ear, the thresholds at which auditory nerve evoked potentials appeared were determined in the various configurations. Clicks were used as stimuli. The vibrator was first placed in the middle ear without touching any of its structures. Up to a voltage of 1 volt, there were no electrophysiologic responses. The vibrator was then placed on the membrane of the round window, in the same manner as for long-term implantation. The thresholds were equal to 100 mV with the click and 30 mV at 16 kHz. These thresholds matched those reported in guinea pigs implanted over the long term.

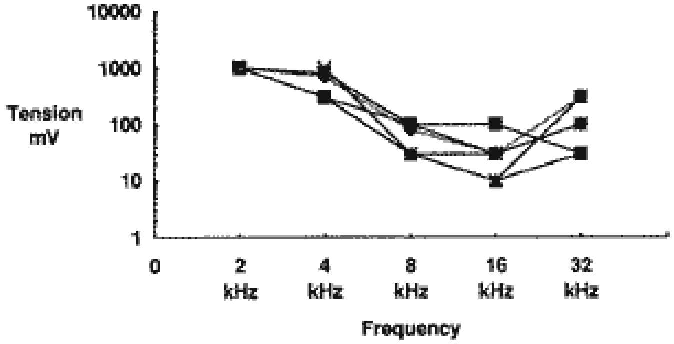

Figure 2. Thresholds of piezoelectric-evoked auditory potentials in seven guinea pigs. The piezoelectric vibrator is implanted on the round

window membrane. Auditory evoked potentials are recorded by an electrode in contact with the seventh nerve.

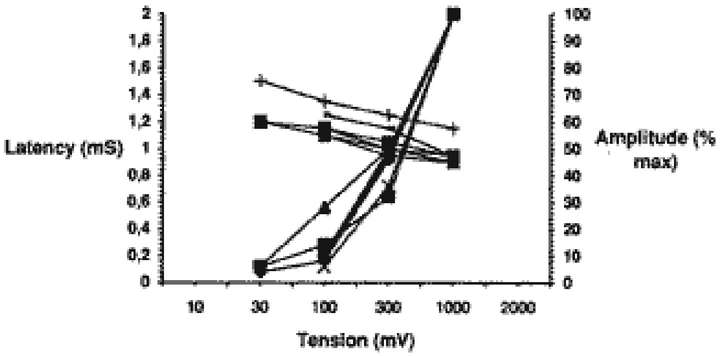

Figure 3. Input-output function of piezoelectric-evoked auditory potentials in seven guinea pigs. The piezoelectric vibrator is implanted on the round window membrane. Auditoryevoked potentials are recorded by an electrode in contact with the seventh nerve. Amplitudes are described as percentage of the maximum amplitude of each guinea pig.

o? In two guinea pigs, the vibrator was placed in contact with the incudostapedial joint. This manipulation was especially difficult owing to the narrowness of the guinea pig's middle ear. In both cases, the thresholds were 3 mV, which was clearly better than in all the other locations.

Vibrator Tolerance

The tolerance of the middle ear to the vibrators was assessed by optical microscopy and electron microscopy examination of the middle ear in certain guinea pigs.

Using optical microscopy, we examined the middle ear of two guinea pigs implanted 2 months earlier. In both cases, the appearance of the ear was excellent. The vibrator and its extension were covered by a normal mucosa, with normal vascularization. No signs of chronic inflammation were visible. The contact surface between the end ball of the extension and the membrane of the round window did not display any anomalies.

Examination using scanning electron microscopy of the middle ear in two other guinea pigs, implanted 3 months previously, confirmed these data. Nevertheless, cracks were evident in the insulating varnish covering the vibrator (Fig. 4).

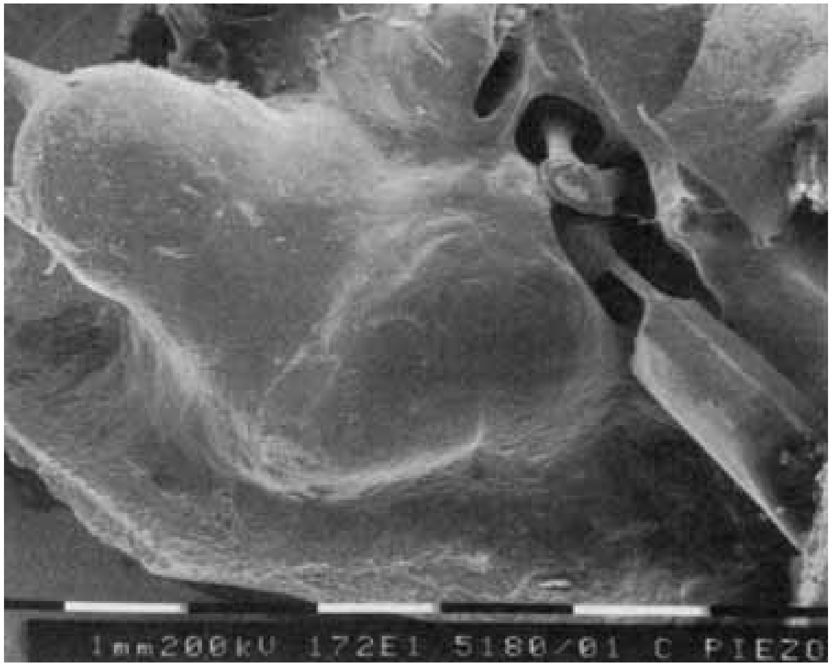

Figure 4. Scanning electron microscopy of the middle ear of a guinea pig implanted 3 months previously. The platinum ball ending the extension of the vibrator lies on the round window membrane. A normal mucosa covers the vibrator. No sign of chronic inflammation is visible.

Conclusions

Experimentation on guinea pigs made it possible to obtain piezoelectric auditory evoked potentials, by stimulation of the round window, comparable o? to acoustic auditory evoked potentials. The range of frequency covered by the piezoelectric vibrator is excellent and responses were obtained from 250 Hz to 16 kHz. The intensity dynamics of the piezoelectric stimulation was limited by the experimental conditions. The short-term experimentations showed that the most effective stimulation site appears to be the stapes. The discrepancy between the response thresholds to the piezoelectric stimulation on the round window and the stapes may be due to a wider dispersion of the energy transm-itted by the vibrator on the flexible membrane of the round window than on the oval window-stapedial joint. Tolerance to the vibrators was excellent, both morphologically and functionally, but should be more thoroughly documented.

STUDY OF A VIBRATOR ON HUMAN PETROUS BONES

The good results of the animal experimentation led us to design a vibrator for humans as well as its fixing system (3). We chose to implant the vibrator on the stapes in humans. This choice was determined by three factors: (1) the animal experimentation showed us that the oval window seems to be the most effective application site of vibrations to the liquids of the inner ear, (2) the stapes is a solid support, less fragile than the membrane of the round window, and (3) stapedial surgery is a reliable, proven surgical procedure.

This first study on human petrous bones had as its goals determining choice of the surgical approach for implanting the vibrators and design of the sizes of vibrators for humans and of their fixing system. For this study, vibrators were implanted on the stapes after disarticulation and exeresis of the incus, similar to the procedure described by Suzuki.(18)

The surgical approach determines o?the length of the vibrator. The best approach is that enabling implantation of a vibrator of maximal length. With a bimorph-type vibrator, the amplitude of the vibrations generated, and thus the gain of a future prosthesis, is proportional to the length of the vibrator. The study on human petrous bones (12 petrous bones) showed us that for ears with intact mastoids, the best surgical approach for implanting the vibrator is a conservative mastoidectomy with a wide posterior tympanotomy. The vibrator is positioned through the posterior tympanotomy, most often directly on the head of the stapes or with an intermediate part. The vibrator can also be implanted on ears operated with radical mastoidectomy technique.

The vibrator is maintained in an implantation position by a bayonet-shaped, pliable fixing strut that is fastened to the posterior cortex of the mastoid. A window for the adjustment of the anchorage point on the mastoid cortex and the plasticity of the fixing strut enable precise adjustment of the vibrator on the head of the stapes (Fig. 5). This technique enables the implantation of vibrators with an average length of 13 rnm, a width of 1.6 mrn, and a thickness of 0.6 mm. This length is substantial, longer than that of the piezoelectric vibrators used by other research teams.

IN VITRO MEASUREMENTS OF VIBRATOR PERFORMANCE

Materials and Methods (3)

We developed an in vitro measurement system to analyze vibrator performance before implantation and to compare various vibrators. This is an acoustic measurement system of the vibrations transmitted by the vibrator. The measurements were performed in a liquid medium, using a hydrophone. The measurement chain made it possible to analyze the frequency rangeo? and to measure the intensity of the vibration transmitted (Fig. 6).

We tested human-model vibrators attached to their fixing struts. They were stimulated by a sinusoid electric current with calibrated voltage and frequency. We recorded the performances of the vibrators, for stimuli from 0.5 to 8 kHz, which is the frequency range of interest for humans, and for voltages from 250 mV to 2.5 V, compatible with biomedical use. The output voltage of the hydrophone was converted into dB SPL by the calibration function of the hydrophone.

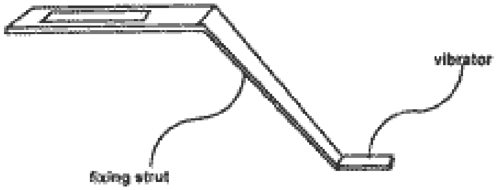

Figure 5. Human-type piezoelectric vibrator and its fixing strut. The bayonet-shaped fixing strut is placed in the mastoid and fixed on its posterior cortex. The vibrator is implanted on the stapes through the posterior tympanotomy.

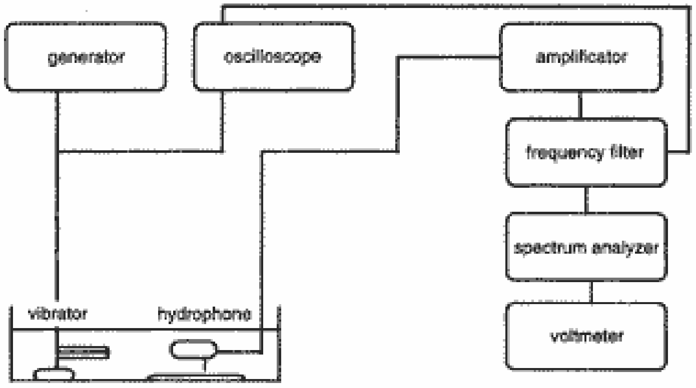

Figure 6. Measurement chain of the acoustic performances of the vibrators. The vibrator is stimulated by a sinusoid electric current, calibrated in tension and frequency. The frequency spectrum and intensity level of the output vibration are analyzed.

Results (3)

The measured environmental and electronic background noise corresponded to 5 mV at the output of the hydrophone. For the minimal stimulation voltage used (250 mV), the output levels were between 40 and 50 mV. The noise-to-signal ratio was therefore at a minimum of 8. The background noise therefore had no adverse effect on our measurements.

Response in Frequency

The analysis of the spectrum of the vibration transmitted so?hows a narrow peak of the same frequency as the stimulation. There was no artifact or resonance frequency in the range tested (0.25 to 8 kHz) although a resonance peak appeared around 10 kHz (Fig. 7). Analysis of the response frequency based on the stimulation voltage shows that for a given stimulatiori voltage, the intensity of the vibration transmitted is remarkably stable at all the frequencies tested. There was a decrease in the intensity of the vibration around 2 kHz, but only by approximately 3 dB SPL, which was insignificant with respect to the intensities reached (Fig. 8).

Lnput/Output Curves

We analyzed the intensity of the vibration transmitted according to the stimulation voltage (input/output curve) for each frequency tested.

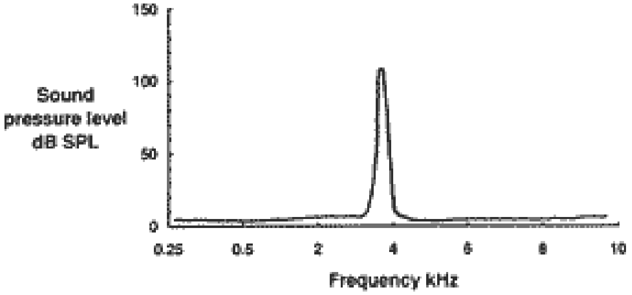

Figure 7. Frequency spectrum of the output vibration. Analysis of the spectrum of the transmitted vibration shows a narrow peak of the same frequency as the stimulation.

From 250 mV of stimulation, the sound pressures generated are over 85 dB SPL at all frequencies. The intensity of the vibration transmitted increases with the intensity of the stimulation. For a stimulation of 2.5 V the sound pressures are over 110 dB SPL (Fig. 9). The increase in sound pressure in relation to the voltage is remarkably linear, when expressed in millivolts, or logarithmic, when expressed in dB SPL.

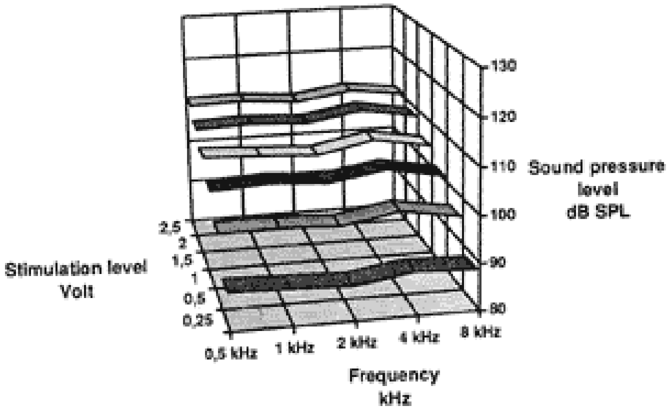

Figure 8. Frequency response of a human-type vibrator. The sound pressure level of the output vibration is described as a function of frequency for a steady stimulation leo?vel. For a given stimulation tension, the intensity of the output vibration is very stable at all frequencies tested.

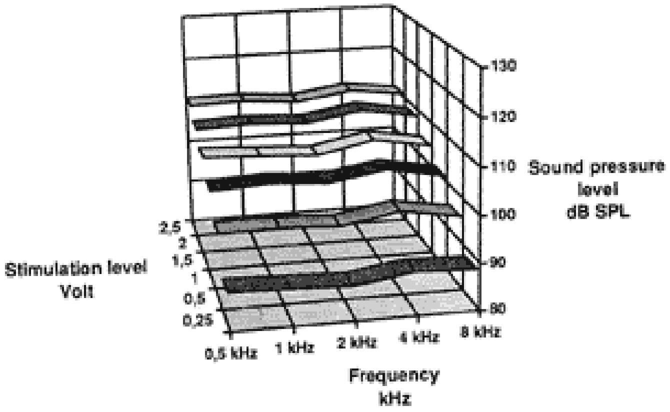

Figure 9. Input-output function of a human-type vibrator, measured in vitro. The sound pressure level of the output vibration is described as a function of the tension of stimulation of the vibrator, For each frequency tested, minimal output level is over 85 dB SPL, and increases over 110 dB SPL.

The vibrators tested were used outside their resonance frequency. This made it possible to take as much advantage as possible of the linearity of their input/output curve and of their frequency fidelity, which are thus excellent. On the other hand, their output is lower than at the resonance frequency.

These results are very encouraging for the application of such vibrators in a ME1 because of both the sound intensities provided and the frequency fidelity of the vibrators.

VIBRATOR ENABLING THE PRESERVATION OF THE OSSICULAR CHAIN

At the time of our in vitro study of human mode 1 vibrators, we used basic vibrators requiring the disarticulation and exeresis of the incus, for implantation on the stapes, as described by Suzuki .17 The need for disarticulation and removal of the incus is justifiably considered a major obstacle in the wider use of this implantation technique. The exeresis of the incus, or of its long process, causes serious iatrogenic damage, wh1à is not acceptable from an ethical point of view in a patient whose ossicular chain was previously normal. This is perfectly illustrated in the case of subjects sufferio?ng from presbycusis, which should constitute, in the long run, an important indication for MEI. A technique had to be found that would enable the implantation of a piezoelectric vibrator without irreversibly interrupting the ossicular chain.

Resuming our study of human petrous bones, we found a technical solution enabling the implantation of the vibrator on the head of the stapes without removing the incus. The vibrator used is a bimorph ceramic of the same size as that described earlier, 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 lenticular bone of the incudostapedial joint (Fig. 10). The incus and the stapes are preserved. The dissection of the incudostapedial joint and the exeresis of the lenticular bone involve only minor iatrogenic damage, which can be repaired if the vibrator has to be removed.

These vibrators were implanted on 12 petrous bones in our study. It appears likely, however, that the anatomy of some ears will not enable the implantation of such vibrators. A radiologic analysis for screening such cases should be performed.

The performance of these vibrators should be studied in vitro with the method described previously. Moreover, we are currently developing a method to measure intracochlear sound pressures on human petrous bones to evaluate the performance of these vibrators in implantation positions.

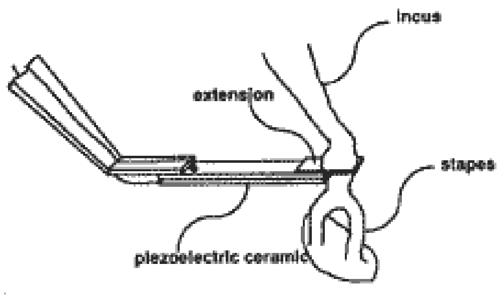

Figure 10. Vibrator enabling the preservation of the ossicular chain. The vibrator is fixed to the so?ame fixing strut as described in Figure 5. The piezoelectric ceramic is equipped with a plate-shaped extension. The vibrator is implanted in such a way that the extension is inserted between the end of the long process of the incus and the head of the stapes, in place of the lenticular bone of the incudostapedial joint.

CONCLUSION

The development of our research program on MEls is being pursued. The first part of this program confirmed our choice of the piezoelectric technology. Experimentation on guinea pigs showed the validity of piezoelectric auditory stimulation and the excellent tolerance of the middle ear to the vibrators. The study on human petrous bones led us to design a vibrator the dimensions of which provide high performance.

The in vitro study of the performance of these vibrators demonstrated their excellent frequency fidelity and their satisfactory output, promising a wide application in deafness. We found a technical solution to the problem of the relation between the vibrator and the ossicular chain. The vibrator that we describe can be implanted on the head of the stapes while preserving the ossicular chain. This point is important from the point of view of future application of MEls in the rehabilitation of sensorineural hearing loss.

Development of a MEI for humans has begun. For reasons of battery limitations, material reliability, and evolution of the prosthesis, we are planning the production of a partially implantable middle ear implant (P-MEI). We are considering a percutaneous connection between the extemal and implanted parts of the prosthesis for good energy output. We hope to produce this implant soon. We are currently experiencing the beginning of a new era of otorhinolaro?yngology: that of implanted auditory prostheses. The first fruits of this era were cochlear implants and direct bone conduction prostheses, but the latter applies to only a limited number of patients. With middle ear implants, the field of implantable prostheses will be extended to numerous cases of deafness, notably those related to sensorineural senescence. Their field of application is therefore enormous. Technical shortcomings currently limit their indications but should be overcome rapidly.

The aim and end purpose of middle ear implant research is the totally

implantable MEI, for severe and average sensorineural deafness. When the implantation of such prostheses becomes commonplace, deafness should lose the character of infirmity that it still represents in the eyes of many.

References

1. Bébéar JP, Dumon T, Zennaro 0, et al: implants d'oreille moyenne: Actualité sur notre recherche. In Arnette (ed): Proceedings of the 24th French National Congress of Otorhinolaryngology, Paris, September 1991

2. Dumon T, Aran JM, Bébéar JP. Protheses auditives implantables: Développement d'un vibrateur piézo-électrique implantable dans l'oreille moyenne. Résultats expérimentaux. In Arnette (ed) : Proceedings of the 26th French National Congress of Otorhinolaryngology, Paris, September 1993

3. Dumon T, Zennaro 0, Charlet de Sauvage R, et al: Implants d'oreille moyenne : Développement d'un prototype humain. Rev Laryngol Otol Rhinol (Bord) 114:147,1993

4. Glorig A, Moushegian G, Bringewald PR, et al: Magnetically coupied stimulation of the ossicular chain: Measures in kangaroo rat and man. o? J Acoust Soc Am 52:694-695, 1972

5. Goode RL: Electromagnetic implantable hearing aids. Adv Audiol 4:22-31, 1988

6. Gyo K, Coode RL: Mesurement of stapes vibration driven by the ceramic vibrator of a middle ear implant: Human temporal bone experiments. Adv Audiol 4:107-116, 1988

7. Gyo K, Yanagihara N, Saiki T, et al: Present status and outlook of the implantable hearing aid. Am J Otol 11:250-253, 1990

8. Heide J, Tatge 1, Sander T, et al: Development of a semi-implantable hearing device. Adv Audiol 4:32-43, 1988

9. Hiki S, Takahashi N: Audiological evaluation of the middle ear implant. Adv Audiol 4:134-148,1988

10. Hough J, Vemon J, Meikel M, et al: A middle ear implantable hearing device for controlled amplification of sound in the human. Laryngoscope 97:141-151, 1987

ll. Hough J, et al: Experiences with implantable hearing devices and presentation of a new device. A-nn Otol Rhinol L"gol 95-60, 1986

12. Kodera K, Yamane H, Suzuki K, et al: Evaluation of the cerarnic vibrator in the cat. Adv Audiol 4:117-123,1988

13. Maniglia AJ: Implantable hearing devices: State of the art. Otolaryngol Clin North Am 22:175-200, 1989

14. McGee TM, Kartush JM, Heide JC, et al: Electromagnetic sendimplantable hearing device: Phase l clinical trials. Laryngoscope 101:355-360, 1991

15. Ohno T, Kajiya T: Performances of the middle ear implants. Adv Audiol 4:85-96, 1988 16. Ohno T, Kajiya T, Miura H: Structure and performance of the main components. Adv Audiol 4:51-72, 1988

17. Spindel JH, Corwin JT, Ruth RA, et al: The basis for a round window electromagnetic implantable hearo?ing aid. In Proceedings of the 13th Annual International Conference of IEEE Engineering in Medicine Biology Society, Orlando, October 1991

18. Suzuki JI, Kodera K, Ashikawa H, et al: Implantation of partially implantable middle ear implant and the indication. Adv Audiol 4:160-165, 1988

19. Suzuki JI, Yanagihara N, Toriyama M, et al: Principle, construction and indication of the middle ear implant. Adv Audiol 4:15-21, 1988

20. Yanagihara N, Aritomo H, Yamanaka E, et al: Implantable hearing aid: Report of the first human applications. Arch Otolaryngol Head Neck Surg 113:869-872, 1987

21. Yanagihara N, Arimoto H, Yamanaka E, et al: Intraoperative assessment of vibrator induced hearing. Adv Audiol 4:124-133, 1988

22. Yanagihara N, Gyo K, Sato H, et al: Implantable hearing aid in fourteen patients with mixed deafness. Acta Otolaryngol [Suppll (Stockh) 458:90-94, 1988

23. Yanagihara N, Suzuki JI, Cyo K, et al: Development of an implantable hearing aid using a piezoelectric vibrator of bimorph design: State of the àrt. Otolaryngol Head Neek Surg 92:706-712, 1984

24. Yanagihara N, Yamanaka E, Sato H, et al: Efficacy of the partially implantable Middle ear implant in middle and inner ear disorders. Adv Audiol 4:149-159, 1988

25. Zennaro 0, Dumon T, Erre JP, et al: Piezo-electric middle ear implant hearing aid experimental model in guinea pig. In Moricci JP, Plonsey R, Coatrieux JL, et al (eds): Proceedings of the 14th Annual Intemational Conference of the IEEE Engineering in Medicine and Biology Society, Paris, October-November, 1992

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