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The Future of Middle Ear Implants, Ear Transduction and Transducers for the Ear

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Abstract

An overview of the problems of current middle ear implants in relation to their future development is herein presented. Despite the high potential for wide application of the devices in an extensive group of patients, important hindrances have resulted in its very limited, real life application. This situation derives, in our opinion, from two main problems: the inconveniently large size of the implant's transducers and the high cost of the devices. Accordingly, research and development of new transducers focused on a smaller size and lower cost seems a must in the future development of middle ear implants. To explain this situation, the key transduction processes in the ear and the corresponding technological approaches to mimic them are herein outlined. Subsequently, the importance of recent and emerging electro mechanic technologies is stressed, providing an example from our group of the application of Micro electro mechanic system technology to the research and development of new transducers as required by the new auditory implants.

Keywords: Ear; Implant; MEMS; Transducer; Hearing loss; Otosurgery

The Problems of Mechanical Auditory Implants

Globally, the social and economic dimension of hearing loss is of considerable consequence. According to the WHO (World Health Organization), it is estimated that 360 million people worldwide suffer from disabling hearing loss (Hearing loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children (0 – 14 years), which constitutes more than 5% of the world's population. The prevalence is relatively greater in regions of South Asia, Asia Pacific and Sub-Saharan Africa, although the data are mostly incomplete, obtained from diverse sources and under different criteria [1].

According to studies from several European countries, however, these figures may be underestimated, as the real figures likely hover around 15 to 17% of the population [2]. As is the case in the United States, where, according to several sources over the years, the numbers are estimated at around 10-20% of the population [3]. Which, referring to the 2016 census, is between 32 and 64 million Americans. In Europe it is around 16% of the population. That is more than 70 million people with hearing loss of varying degree and type, of whom more than 55 million are found in the EU [3]. In the United Kingdom there are approximately 11 million (1 of 6 residents or 17.4%) according to the RNID [4]. In Germany it is roughly estimated that 13-14 million people need treatment for hearing loss [5]. In Spain, the figures are very likely underestimated (2 million people or 5.5% of the population), and the prevalent disability thereby occasioned stands at 961,348 people (26/1000 resident) according to official data [6]. In clinical practice, only one out of two of all the hearing loss cases are treated satisfactorily with ordinary means (surgery, hearing aids, etc.). The rest, however, 35 million in Europe, 27 million in the EU, 1 million in Spain, etc., represent an enormous group of patients. The economic problem derived there from is also considerable. In the EU, for instance, the annual cost of untreated hearing impairment is 168 billion Euros, and the annual cost of assistance for individuals depends on the degree of loss: mild, 2,200€; moderate, 6,600€; severe or profound, 11,000€ [2].

Faced with all this, today's mechanical auditory implants or middle ear implants (MEI) are attempting to address these problems and cover virtually all the variants of hearing loss (conductive, mixed, sensorineural, moderate and severe levels, etc.) [7]. Theoretically, every type and degree of loss is a potential candidate for one kind of MEI or another, except for that tiny group of patients who require a Cochlear Implant (Figure 1).

Consequently, hearing loss has become the object of translational research into middle-ear

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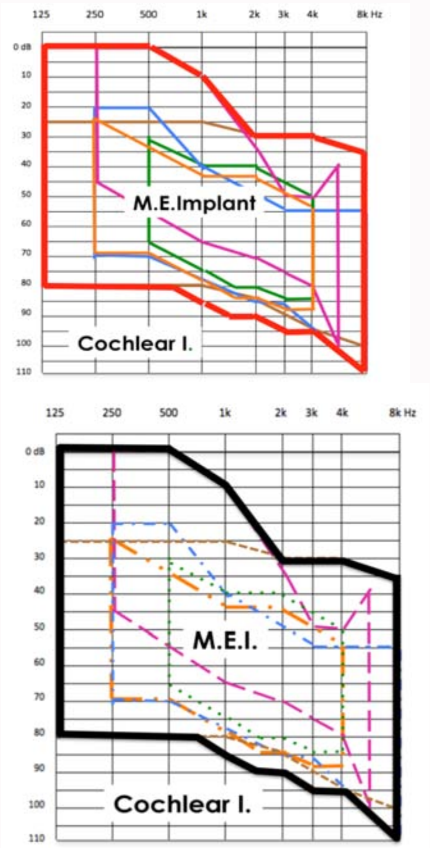

Figure 1: Indication field of the current middle ear implants according to pure tone audiometry thresholds (red line). It results from plotting the standard indication area of each type of implant (other colours) as their corresponding companies advise it.

implants and a niche market for manufacturers.

In the tenor of the aforesaid, its application should indeed be very widespread, but if we compare the number of potential candidates for MEIs to the actual implants effectively placed, the difference is enormous. In Europe there are only a few hundred, which is approximately in the order of 1 implant for every 100,000 residents at best [7-11]. In contrast, as with the case of IC, the majority of potential candidates actually receive implants.

In other words, for any reason, MEIs are failing to give the expected response to this problem. Why is that? There are, in my opinion, several reasons.

The first has to do with the size of MEI's transducers, with respect to both sensor and actuators. In most cases, the transducers currently used for implants are too big for the middle ear cavities, where they must inevitably be placed. Various problems thus arise, such as the anatomic impossibility in certain candidates with not large enough cavities, the long and complex surgery which, given its size, would require in several implants, the need for non-standard otologic surgeons to complete it and the problems concerning the biotolerance implanting such bulky elements entails. Moreover, some sensors of full-implants are not efficient enough, or rather implied some iatrogenic damage to the Tympanic-Ossicular System (TOS) integrity.

Furthermore, the price of the devices themselves, ranging from ten to tens of thousands of euros or dollars, which far exceeds what, would be considered acceptable with regard to the sustainability of health systems and insurance companies, not mention the obvious toll it would incur on a standard patient. For both reasons, health systems, understandably, limit such devices to a reduced number of cases and to certain very specialized Hospitals, Units and therein surgeons.

The transducers' size and devices' price constitute the present hurdles but are also the keys to future development and widespread use.

The Ear Transduction

It is convenient to first have an overview of the known functional processes within the ear from the perspective of auditory implants research.

The ear is the peripheral receptor of the auditory system and, essentially, a mechanoelectrical transducer which converts sonic vibrations into an electrical signal, the receptor potential. This electrical signal is codified on the synaptic level in trains of nerve impulses that will, in turn, be decoded in the brain and converted into auditory information. This ear transducer, however, has a very particular function and specific properties in the domains of intensity and frequency, which facilitate the detection of events as befitting animals and oral communication as befitting Man.

Accordingly, its distinct parts play a different role in the process of transduction (Figure 2). On the one hand, the outer ear, middle ear and Cochlear Micromechanics (CMM) act together in quasi-real time as passive and active mechanic adaptors of the signal with regard to both intensity and frequency. To which is added, yet with a 200-300 ms latency, the action of the stapedial and malleus reflexes in cases of very intense sounds, with effects principally on the intensity (attenuation) but also on the frequency (attenuation of low frequencies).

The middle ear, in particular, has a passive adaptor function in the domains of intensity and frequency. On the one hand, it helps to compensate for the energy loss produced by the successive passage of the signal through different mediums: air (external meatus), bone (tympanic-ossicular system) and liquid (labyrinthine fluids). On the other, the acoustic properties (dimensions, arrangement and

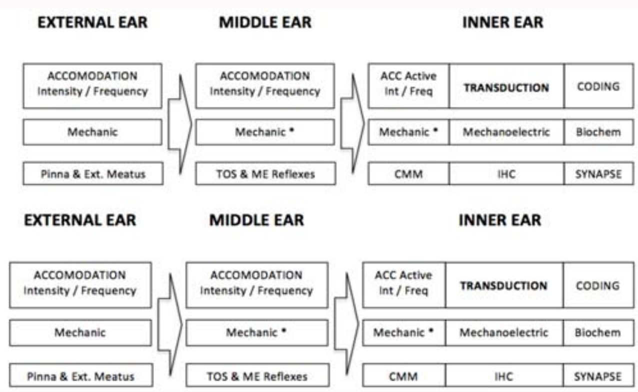

Figure 2: Scheme of the functional processes in the ear from the perspective of auditory implants requirements and the development of new transducers. The function is shown, at different levels from top to bottom, the process type and the element of the ear principally involved. TOS: Tympanic Ossicular System; ME: Middle Ear; CMM: Cochlear Micro-Mechanics; IHC: Inner Ear Cell; Biochem: Biochemically mediated process.
*Middle ear reflexes and cochlear micromechanics are neurally controlled.

composition) of the distinct anatomical elements, their coverings and joints, usher the frequency response to the area of maximum sensitivity that facilitates speech understanding. In fact, the external meatus has a filtering effect as its resonance frequency is in the 1.5-4 kHz band which improves the sounds that reach the eardrum by 5-6 dB in that band. The middle ear compensates for the change in air-STO impedance through three principal mechanisms of amplification: a) the ratio of surfaces between the tympanic membrane and stapedial plate (21:1 approx.) which increases the pressure therein; b) the leverage effect malleus-incus which multiplies the force by a factor of 1.2; c) the differential effect of the interfenestral phase, irrelevant under normal conditions (Ø = 180°; IΔ = 50dB), but crucial in the absence of the other mechanisms. Altogether, this provides an additional 45-60 dB (approx.) to the best sensitivity frequency area.

Yet, the real process of mechanoelectrical transduction occurs in the highly sensitive Inner Hair Cells (IHC), the generators of the receptor potential. In effect, mechanical vibrations induce motion on their hair bundle, which leads to the opening and closing of mechanically sensitive ion channels and results in the electrical response. However, the IHC have a very low threshold, (in the order of 2 x 10^{-4} din/cm^2) but a limited dynamic range of 45-60 dB (experiments with the entire CMM or with isolated hair cells) if we consider the range of audible sounds in the order of 120 dB. From here arises the need of an "tapering" of the signal received, a function the outer and middle ear carry out passively while the CMM does so actively, in quasi-real time. In the CMM, the more numerous Outer Hair Cells (OHC) play a key role, acting inversely as electromechanical transducers. Thus, the OHC bring about the necessary micromechanical changes in the organ of Corti (Tectorial Membrane, etc.) so as to taper, with precision in quasi-real time, the received signal to the limited and sensory dynamic range of its counterpart, the IHC. Added to the OHC's role of active tapering is the passive effect of the travelling-wave in the basilar membrane [12,13].

As result, a threshold stimulus of 0 dB produces a basilar-membrane oscillation near ± 0.1 nm and 120 dB moves the basilar membrane by only ± 10 nm and six orders of magnitude in sound amplitude. This represents a trillion-fold range of acoustic power that produces a variation in neural firing rate of only two orders of magnitude (from a few to a few hundred spikes per second) [14].

Likewise, frequency discrimination is also based on passive and active processes. The passive part depends on the acoustic properties of the EAC, the TOS already remarked upon and the cochlear partition via the basilar membrane tonotopic behavior. The active processes are mostly based on fine tuning and nerve firing summation. All these processes result on tonotopic coding along the cochlear turns, cochlear nuclei and primary auditory cortex. The resulting discrimination ability is very accurate and trained persons can distinguish frequency differences by only 0.1%.

Thanks to the combination of all these mechanisms, the system possesses the three required properties to appropriately adapting the signal: amplification, compressive nonlinearity and sharpened frequency selectivity. These properties, in combination, result from a critical oscillator operating near its dynamic instability; a dynamical system that follows the laws of a Hopft-bifurcation, as it was pointed out by Huspedth et al. [15].

Clinically speaking, the integrity of this active, coupled, accurate

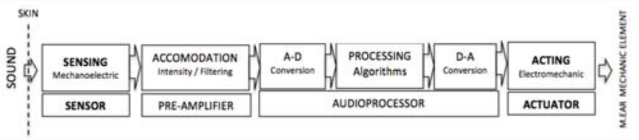

Figure 3: Structure of a fully implantable mechanical audioprosthesis or middle ear Implant with its different processes involved therein and its main functional elements. Transduction processes and elements are typed in bold.

signal-processing, which results in fine intensity and frequency discrimination, is crucial for daily activities. Consequently, patients painfully pay its alteration in pathological conditions by distinct symptoms such as hyperacusis, intolerance to noise, loss of intelligibility, etc.

This is the ear transducer and its fine and complex processes that a MEI should mimic or compensate for when the ear is damaged. Hence, the transducers and the processing algorithms represent the core of the functional properties of MEIs.

Transducers for the Ear

In accordance with its structure (Figure 3), a MEI utilizes a mechanoelectrical transducer or **sensor** to capture the acoustic signal from the surrounding environment directly or through the TOS itself (depending on its integrity or damage) while another electromechanical transducer or **actuator** releases it at a point within the ear so as to achieve mechanical stimulation. Obviously, the signal received by the sensor must be adapted by the audio processor to the needs of the patient's hearing loss before being newly converted by the actuator into a stimulatory mechanic signal. As it is shown in Figure 3, in order to emulate or compensate for the deficiencies of the ear transducer, two transducers, working inversely, are needed (sensor and actuator). In full MEIs, both must necessarily be implanted in the middle ear cavity, and it is here where the first problem arises. Presently, these transducers measure around 10-15 mm each, which makes their insertion and setting rather complicated. In fact, many potential candidates have to be turned away for purely anatomical reasons; yet, when the implant is feasible, it requires one of several lengthy and risky bone dissection techniques (mastoidectomy, atticotomy, posterior tympanotomy, etc.) enlarged up to their limits. Moreover, it is necessary to employ cements to set the implants which compromise bio-tolerability and complicate the technique.

Regarding this problem of size, if we examine the mechanical technologies available and compare their characteristics with the needs of the MEI the choice seems clear (Figure 4). For reasons of size and the cost per unit, MEMS technology seems to be the most suitable [16]. This technology stands as the counterpart to the integrated electronic circuits in micromechanical systems and thus affords the

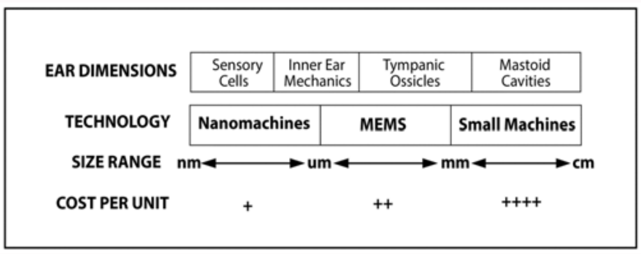

Figure 4: Current mechanical technologies related to ear dimensions and implants requirements.

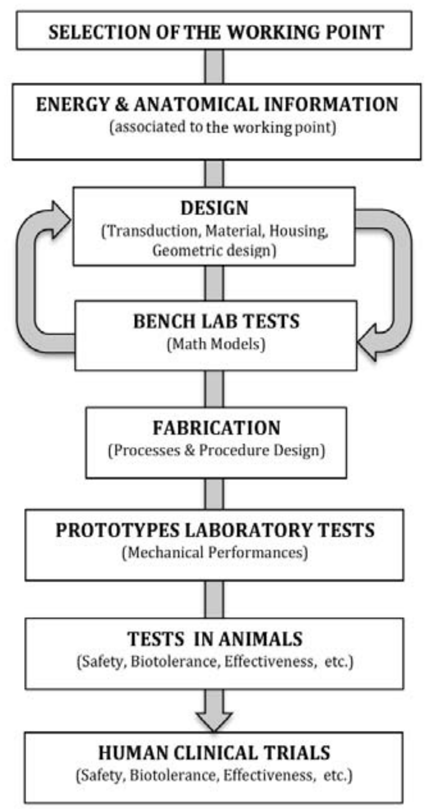

Figure 5: R&D strategy for development of new transducers for implantable audioprostheses.

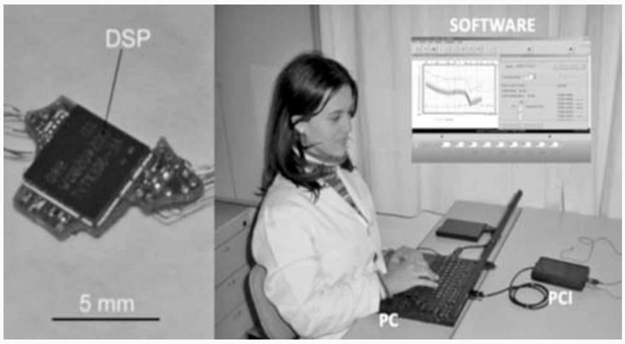

Figure 6: Developed Audioprocessor (DSP) (left) and fitting platform (right), including software and computer interface via USB (PCI).

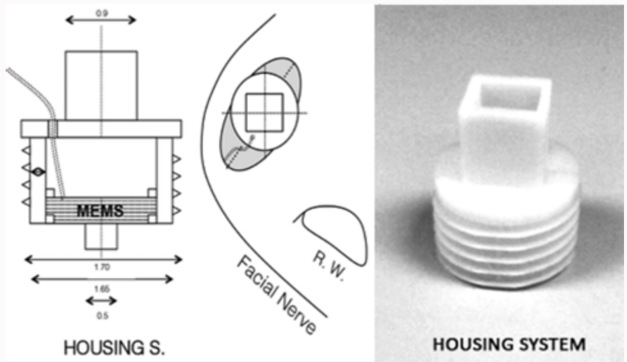

Figure 7: Scheme of a complete transducer structure for mechanical implantable audioprostheses (middle ear implants). Left: transducer element (piezoelectric) and housing system with their dimensions. Center: place of implantation of the transducer in the oval window. Right: 3D printed prototype of the housing system.

possibility of very low-cost, large-scale production of distinct models of transducers [17,18]. Furthermore, this technology is able to employ various systems of electromechanical transduction, piezoelectric, electromagnetic, capacitive, shape memory, etc. Additionally, apart from the transducer itself, the MEMS chip may also contain other micro-electronic elements. Plus, the design can be easily made and modified, adapting it to the needs of different types of patients and hypoacusis.

Furthermore, its implementation entails a very reasonable cost-benefit relationship with regard to investigative research. Although it requires a particular development strategy [19] (Figure 5) as well as a few very specific design procedures, verification, lab-testing, related software, etc., once the team is familiarized with all that it will allow for very productive laboratory work and reduce animal testing to a minimum.

Research and Development of a MEMS Actuator

As an example of practical application, presented here is a summary of the Research and Development (R & D) of a transducer actuator carried out by our team. Its development sprung from the already-existing, basic elements of the implant: the processor, the processing algorithms, the fitting software and the communication interfaces. Our team had previously developed and patented these elements for external prosthesis. For the final implant, what remains is to add the transducers (sensor and actuator) and the wireless interface. The processor corresponds with a TMS 320C5405 TI. The designed algorithms allow processing of the signal up to 128 independent bands with non-linear compression. The fitting software is Windows compatible and the communication interface between the computer and the implant is USB type (Figure 6).

The complete actuator to be developed consists of two physical elements: the Element Transducer *per se* and the Housing System which houses it and mechanically fixes it to the chosen structure of the middle ear. Both are design object, as the structure to be stimulated and the point of stimulation are key, as much with regards to their mechanical as to their anatomic-surgical requirements. In this case, it was decided to develop a transducer to functionalize old radical cavities present in some patients, but it would also be applicable to other types of problems. Hence, the oval window was chosen as the point of stimulation, just as a stapedial prosthesis stimulates (piston, etc.) (Figure 7).

However, for the design to be truly practical it is necessary to know, *in vivo* conditions, the energy requirements of stimulation at the level of the oval window. Thus, a series of experiments were conducted on various patients with non-functionalized old radical cavities who volunteered for experiments of live stimulation [20]. During these experiments, a conventional transducer was used which, once fitted to the oval window, was connected to the processor prototype and the complete system was programmed until it obtained a response subjectively acceptable. Then the functional effectiveness was tested audiologically via Tone and Speech audiometry in sound field conditions. This programmed prototype allowed for the collection of response curves. A simplified hydrodynamic model of the labyrinth (LHM) was then designed and built, which simulates the

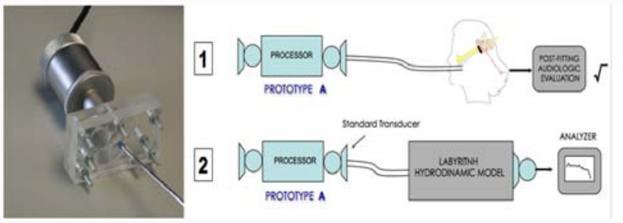

Figure 8: Developed Hydrodynamic Model of the Labyrinth (LHM) for the purposes of transducer research (left). It is employed for measuring output profile of transducers destined to stimulate at labyrinth fluids according to the experimental design (right). 1: stage of fitting the transducer to patients wearing radical cavities. 2: stage of measuring the output of the fitted prototype connected to the analyser through the LHM.

behaviour of the labyrinthine fluids and the conditions of stimulation in the oval window. This model was connected to the programmed prototype according to each patient in order to procure the individual measures [21] (Figure 8). With this response information in intensity and frequency from real cases, we proceeded to the design of the transducer element with MEMS technology. We decided to use the piezoelectric transduction type and the design was accomplished by utilizing a specific software (Coventor Ware®) and carrying out simulated measurements in the laboratory using ANSYS® software and finite element models of the ear. These measurements with distinct geometric configurations were repeated cyclically in each one, modifying the design until able to procure and select the most apt configurations [22,23] (Figure 9).

Finally, after the thorough examination of very specific aspects related to the process of their production, several distinct prototypes were manufactured in a clean room. The manufacturing process required as well its own research. With this technology, various models can be produced on a single wafer simultaneously, and even up to hundreds of units [24,25] (Figure 10). Once manufactured, their isolated response (without Housing) was analyzed in the laboratory under highly precise Atomic-Force Microscopy (AFM) [26]. This technique brought to bear that the displacement measurements of piezoelectric material were within the expected and necessary range to stimulate the fluids, in other words, displacements in the order of 50 nm (Figure 11). If necessary, these displacements can be augmented by activating other layers of the transducer element. Following up on these measurements with AFM, once the complete MEMS-Housing is implemented, the measurements with the coupled LHM will be taken. After the development of the remaining parts of the final implant (communication RF, etc.), what will follow will be experiments on the mechanical effectiveness via Laser Doppler Vibrometry with the system implanted in human temporal bones and in live animals, including the corresponding tests of bio-tolerance. Because the possibility of eventual vestibular damage, these tests will include vestibular function assessment pre/post implantation. Consequently, this aspect will be specifically mentioned in the Informed Consent of future clinical trials, similarly to our preclinical experiments [20].

In short, this actuator is of such small dimensions that it is easily implantable in any normal temporal bone. Moreover, the cost per unit of the commercial version will be considerably low. All of this should resolve the current problems surrounding the implantability of actuators and significantly reduce its cost. Additionally, by employing a specifically designed housing system, it could also be implemented at other points of the mechanical portion of the ear as well as applied

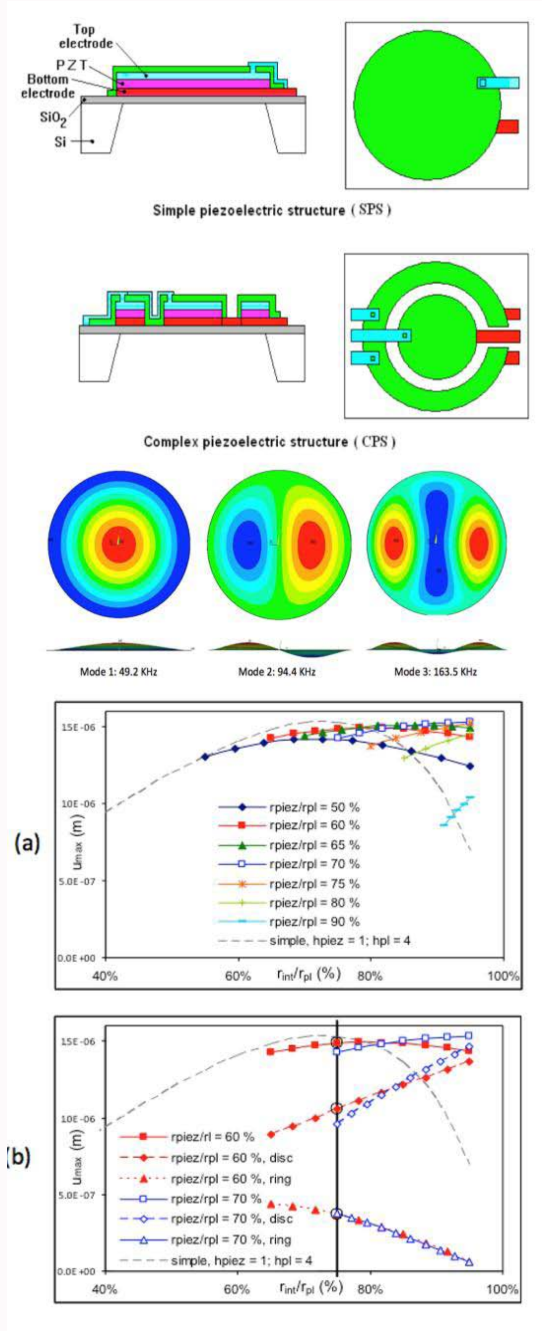

Figure 9: Examples of evaluation in the lab of expected mechanical behaviour of different designs and functional options of a transducer element by using computational simulation before the manufacturing the prototype. Top: Simple (SPS) and Complex (CPS) structure configuration of the piezoelectric transducer element. Middle: Resonance frequencies of the SPS 3D model (plate of Si, rpl = 0.5 mm, rpiez/rpl = 80 %, hpiez = 1 mm, hpl = 2 mm). Bottom: evaluation of the trend of the first natural frequency with different design parameters in CPS configuration (material PZT, plate of SiO2, rpl = 0.5 mm), static analysis, (a) umax in terms of rint and (b) behaviour with only one actuator).

to other pathological conditions (malformations, etc.).

Conclusion

At present, mechanical auditory implants are directed towards a broad set of potential patients, but they have trouble meeting the expectations they engender. In fact, among the millions of possible

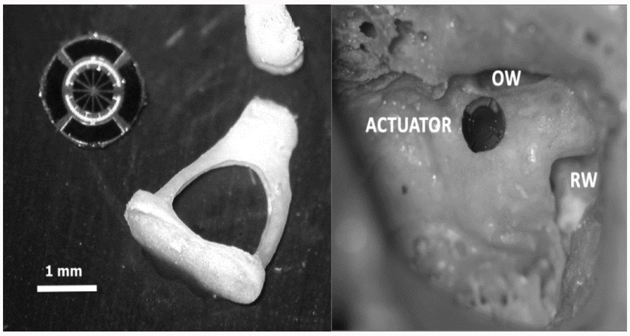

Figure 10: Actuator manufactured by MEMS technology showing its relative size to middle ear anatomic elements (stapes footplate in the left; oval and round windows in the right). (Modified from Urquiza R et al. [16], Campanella H et al. [25], with permission).

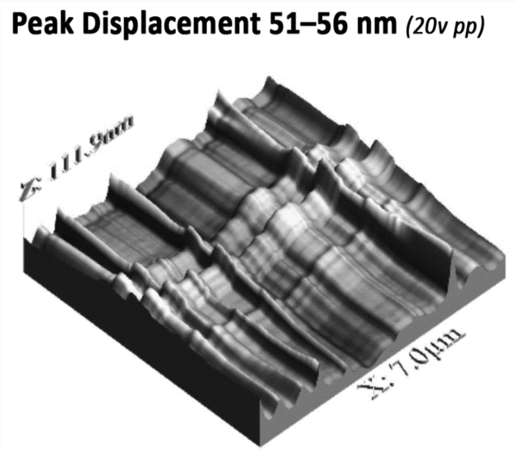

Figure 11: Displacement 3D chart obtained by Atomic Force Microscopy of the manufactured MEMS actuator as a response to electric pulses. Displacement corresponds to the height difference between the base level and the peaks. (modified from López García J et al. [24] with permission).

candidates in Europe only a few hundred actually receive the implants. Following an analysis of the clinical and technological problems, as well as the ear's role as a transducer, we have concluded that these problems stem from the excessive size of the transducer implants and the price of the devices. Consequently, we believe that the future of these implants must undergo a miniaturization and reduction of cost, objectives which are achievable today with the existent mechanical technologies. Among them, MEMS technology is extremely suitable and its high potential may resolve not only this fundamental problem but also other particular setbacks, such as the design of the sensory method and of the sensor itself, which is currently a weak point of full implants.

In general, the key within this field of translational research is in adapting the incredible potential of different available technologies to the complexity of auditory problems. But this is only possible when it is guided by trans-disciplinary research teams, and its creation, while indeed a complex and lengthy task, is an ineluctable one.

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