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New Implantable Hearing Device Based on a Micro-Actuator that is Directly Coupled to the Inner Ear Fluid

Hans Bernhard, Christof Stieger and Yves Perriard, *Senior Member, IEEE*

***Abstract*—A new hearing therapy called Direct Acoustical Cochlear Stimulation (DACS) was developed and validated in a first clinical trial with four patients. The key component of this therapy based on an implantable hearing device is a micro-actuator that is implanted in the mastoid right behind the external auditory canal of a patient. It generates vibrations that are directly coupled to the inner ear fluids and bypass therefore the outer and the middle ear. This allows treating severe to profound mixed hearing loss. The actuator transfer function has to be similar to the transfer function of a normal human middle ear to guarantee high system efficiency. A balanced armature actuator was the ideal transducer type in order to meet this requirement considering the given restrictions in size and shape.**

I. Introduction

TODAY there are many possibilities to treat the different types of hearing losses. Nevertheless, for a specific group of patients no satisfying therapy can be provided yet. These patients suffer from a so-called mixed hearing loss, which consists in a conductive (outer and middle ear) and a sensorineural (inner ear) part.

In 2002, Cochlear Ltd., Sydney, Australia and Phonak AG, Stäfa, Switzerland have decided to found the joint venture company Cochlear Acoustics Ltd., Lausanne, Switzerland with the goal to develop an efficient therapy for the patient group mentioned above based on an implantable hearing device.

Currently there is already an investigational device realized and successfully implanted in four patients. This paper will introduce this new device and its key component, which is a miniaturized electro-mechanic actuator that replaces the function of the normal middle ear.

II. Device Concept

Since the implant shall be suitable to treat conductive and sensorineural hearing loss at the same time, it was decided to develop a device that bypasses the outer and the middle ear and couples directly to the inner ear fluid. This novel approach is called Direct Acoustical Cochlear Stimulation, abbreviated by DACS.

This concept allows treating any kind of conductive hearing loss because it does not require any functional outer or middle ear. Sensorineural losses can then be compensated by amplifying the incoming acoustic signals just like a conventional hearing aid does.

The DACS device has to replace the outer and the middle ear of a hearing-impaired person. While microphones and sound processing electronics replace the outer ear functions, the functionality of the middle ear is taken over by an actuator that transforms the electrical signal provided by the electronics into a mechanical vibration.

This vibration has to be coupled to the inner ear fluids in order to create a hearing impression. A conventional stapes prosthesis serves as mechanical link between the actuator and the inner ear fluid. It is placed in the oval window of the cochlea like during a regular stapedectomy (replacement of the stapes by a stapes prosthesis), but the prosthesis is attached to the actuator instead of the incus.

The actuator itself is placed in an artificially created mastoid cavity and is firmly anchored by means of a bone plate system which is screwed to the patient's skull.

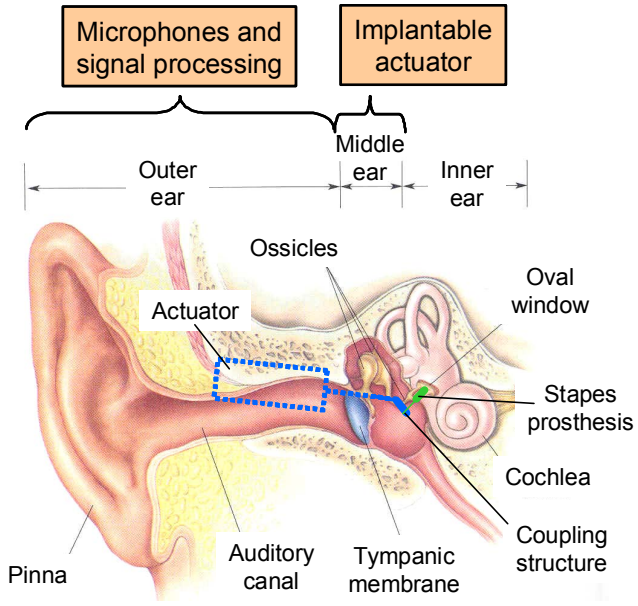

Fig. 1. Replacement of normal hearing functions by device components. The actuator is implanted behind the auditory canal and its coupling structure extends into the middle ear cavity in front of the oval window. A stapes prosthesis is attached to it and placed in the oval window.

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Hans Bernhard, Helbling Technik Bern AG, Stationstrasse 12, CH-3097 Liebefeld, Switzerland (phone: +41 31 979 1635; fax: +41 31 979 1610; e-mail: hans.bernhard@helbling.ch)

Christof Stieger, Department of ENT, Head, Neck Surgery, Inselspital University of Berne, CH-3010 Berne, Switzerland

Yves Perriard, Senior Member IEEE, Integrated Actuators Laboratory (LAI), Ecole Polytechnique Fédérale de Lausanne (EPFL), CH-1015 Lausanne, Switzerland

III. Device Requirements

There are several main user requirements that have to be considered:

- High maximal power output of at least 125 dB SPL (sound pressure level) over the whole specified frequency range from 100 Hz to 10 kHz
- Long device autonomy
- Biocompatibility what implies a hermetic titanium housing in order to prevent any body reaction
- Device dimensions that allow implantation in most of the anatomical cases

The first two requirements listed above can be directly transformed into performance requirements of the actuator. Knowing the transfer function of the middle ear, it is possible to asses the volume of displaced inner ear fluid that corresponds to a given sound pressure level in front of the tympanic membrane (Fig. 2). Since the device has to displace the same amount of liquid in order to generate the same sound intensity, the required deflections (Fig. 3) can be calculated by considering the cross-sectional area of the stapes prosthesis that acts like a piston.

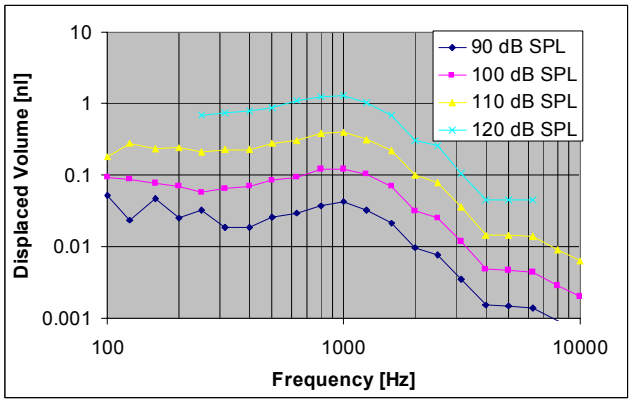

Fig. 2. Middle ear transfer function assessed on a fresh human temporal bone [1]. Different sound pressure levels were applied in front of the tympanic membrane and the displacement of the stapes was measured with a laser Doppler vibrometer. The displacement was converted into displaced volume by multiplication with oval window area of 3.2 mm^2.

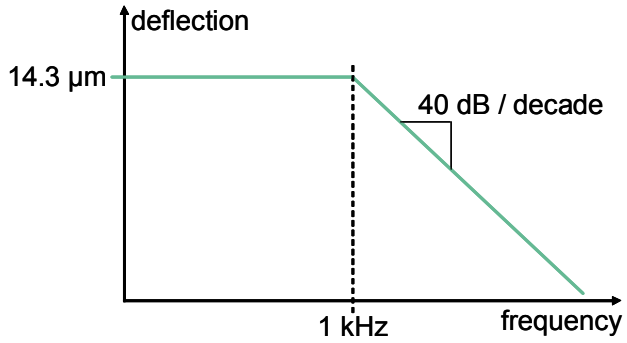

Fig. 3. Simplified deflection characteristic that corresponds to an equivalent sound pressure of 125 dB SPL if a stapes prosthesis with a diameter of 0.4 mm is used.

To meet the required device autonomy, the actuator power consumption to reach the specified maximal deflections is limited to 1 mW (given by the implemented electronics and power source). Therefore the actuator transfer function has to follow as close as possible the deflection characteristic of the middle ear in order to maximize the system efficiency and autonomy.

Table I summarizes the main actuator requirements. The preferred actuator shape and dimensions were assessed by analyzing the size of the mastoid cavity in human temporal bones [2].

TABLE I
Main Actuator Requirements

Requirement	Specified Value
Resonance frequency	1 kHz
Maximal deflection below resonance	14.3 µm
Deflection drop above resonance	40 dB per decade
Maximal power consumption	1 mW
Actuator shape	cylindrical
Maximal diameter	3.6 mm
Maximal length (without coupling structure)	14 mm

IV. Actuator Development

A. Actuator Principle

The piezo-electric and the electro-mechanic principle were considered for the design of the actuator. A first rough evaluation showed that piezo-electric actuators with the required dimensions are not able to generate the specified deflections. Therefore it was decided to develop an electro-mechanic actuator.

The electro-mechanical principle again provides several basic designs like electro-dynamic, electro-magnetic or balanced armature actuators. The following paragraph explains why the balanced armature actuator was the best choice for this application.

B. Actuator Design

The actuator transfer function has to follow as close as possible the deflection curve in Fig. 3 which represents the frequency characteristic of a simple mechanical system with one mass suspended by a spring. The resonance frequency f_{res} of such a system is calculated by the following equation:

$$f_{res} = \frac{1}{2\pi}\sqrt{\frac{k}{m}} \quad (1)$$

where k is the rigidity of the spring and m the mobile mass.

The parameters that mainly influence the amplitude of the deflection d are the mobile mass m and the force F which is generated by the actuator:

$$d \propto \frac{F}{m} \quad (2)$$

With this information it is possible to define the basic mechanical structure of the actuator. The mobile mass

should be as small as possible in order to maximize the generated deflections. At the same time the resonance frequency f_{res} has to be kept at 1 kHz what means that a low mass requires a low rigidity of the spring.

At this point, the concrete mechanical implementation of the spring has to be considered: The cylindrical housing of the actuator has to be hermetic. The only way to get the generated movement out of this completely closed case is to make one of the face sides compliant. In this case one of the two face sides of the cylindrical housing was made of a flexible diaphragm which acts as spring. The dimensions of this diaphragm are limited by the maximal actuator diameter of 3.6 mm and its minimal thickness which is limited to 25 µm due to the employed laser welding process.

By calculating the rigidity k_D of such a diaphragm, using an adequate model from [3], it can be shown that the necessary force F to reach the required deflection d of 14.3 µm cannot be generated with the given limitations in size and input power. Hence a possibility had to be found that allows reducing the rigidity of the diaphragm. The proposed solution makes use of an inherent property of a balanced armature actuator:

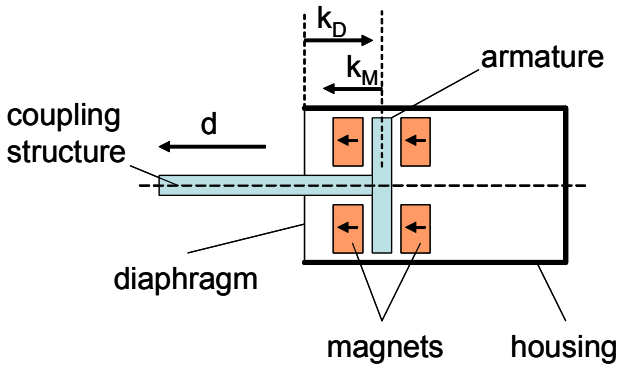

Fig. 4. Main elements of a balanced armature actuator. The armature is positioned between two magnets. A spring (the diaphragm) provides a restoring force that keeps the armature in the center of the two magnets. If the armature moves in direction d, the rigidity of the diaphragm k_D exerts a force in the opposite direction, the magnet on the other hand attracts the armature and creates a force in the direction of the movement represented by k_M.

The attraction force of the magnets can be interpreted as a "negative rigidity" k_M that reduces the overall rigidity k:

$$k = k_D + k_M \tag{3}$$

This allows adjusting the rigidity k to an appropriate value by varying the strength of the magnets. Therefore the resonance frequency f_{res} can be kept at 1 kHz without increasing the mobile mass m.

An analytical model was used to describe the electro-mechanical part of the actuator. The electro-magnetic part was simulated with a finite element model. By using those models it was possible to optimize the values of the parameters step by step in order to maximize the deflection d while keeping the required frequency characteristic unchanged.

V. Results

A. Actuator

Actuator prototypes were fabricated and characterized in order to compare their performance with the requirements. Fig. 5 shows a cross-section of the actuator indicating its main elements.

The frequency characteristic of the actuator was measured using laser Doppler vibrometry. The measured transfer function of the actuator meets the requirement as shown in Fig. 6.

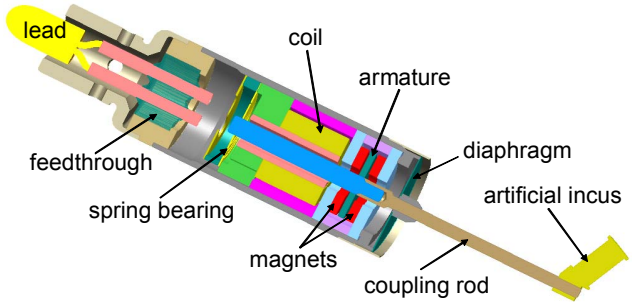

Fig. 5. Longitudinal section though the actuator.

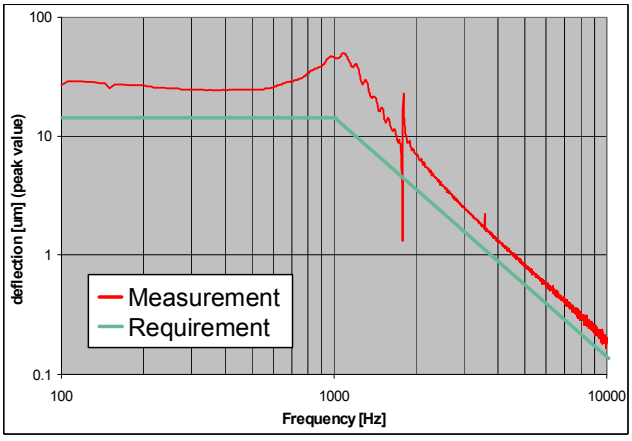

Fig. 6. Comparison between the required and the measured frequency characteristic. Input power of the actuator is 1mW.

TABLE II
Main Actuator Characteristics

Characteristic	Typical Value
Frequency range	0.1 – 10 kHz
Maximal deflection (below resonance)	25 µm
Equivalent sound pressure	130 dB SPL
Maximal power consumption	1 mW
Diameter	3.6 mm
Length (without coupling structure)	14 mm
Weight	0.4 g
Coil resistance	12 Ω
Coil inductance	7.5 mH
Magnet material	SmCo

B. *Investigational Device*

A full hearing system was implemented based on the newly developed actuator and already existing components in order to prove the DACS concept in human patients. It consists in an external part that is connected through a precutaneous connector to the implant. Fig. 7 shows a device overview.

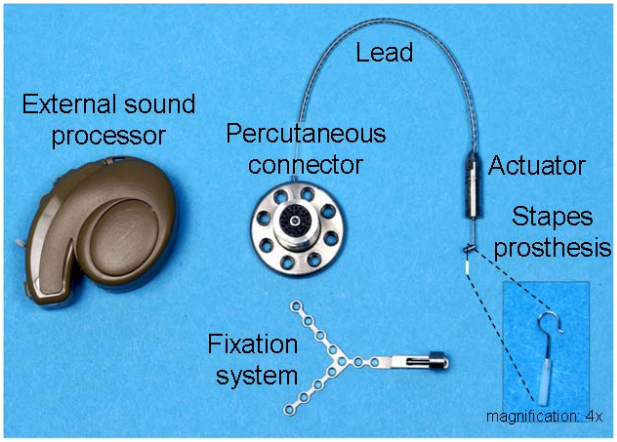

Fig. 7. First DACS device for clinical evaluation.

C. *Clinical Results*

Fig. 8 shows a representative example of the hearing gain that can be achieved with the DACS device [4]. Before the implantation, this patient had air conduction thresholds of up to 100 dB HL. With the device, the thresholds could be improved by 45 dB to 65 dB what leads to impressive improvements of speech recognition thresholds (SRT) and speech discrimination scores (SDS) as shown in Table III.

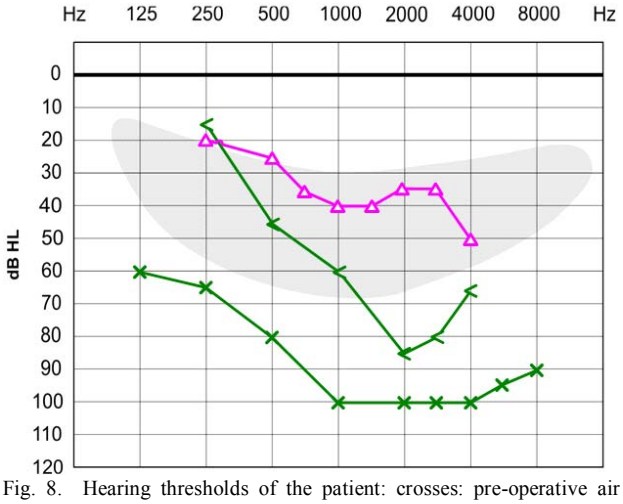

Fig. 8. Hearing thresholds of the patient: crosses: pre-operative air conduction thresholds, arrows: pre-operative bone conduction thresholds and triangles: post-operative air conduction thresholds with the DACS investigational device.

TABLE III
IMPROVEMENTS OF SPEECH RECOGNITION AND DISCRIMINATION

	SRT	SDS		
		60 dB	75 dB	90 dB
pre-operative	77.5 dB HL	0%	0%	0%
with DACS	27.5 dB HL	80%	85%	90%

VI. CONCLUSIONS

It was possible to design the actuator in way to meet the imposed requirements. The frequency characteristic measured on realized device fits well to the required curve. This means that the device is able to provide a constant equivalent sound pressure level of more than 125 dB from 0.1 to 10 kHz if the actuator input power is kept constant at 1 mW.

Four successful implantations have proven that the device works within the specified limits and is able to successfully treat patients with severe to profound mixed hearing loss.

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