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3D Hybrid Electrode Structure as Implantable Interface for a Vestibular Neural Prosthesis in Humans

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***Abstract*— Implantable interfaces are essential components of vestibular neural prostheses. They interface the biological system with electrical stimulation that is used to restore transfer of vestibular information. Regarding the anatomical situation special 3D structures are required. In this paper, the design and the manufacturing process of a novel 3D hybrid microelectrode structure as interface to the human vestibular system are described. Photolithography techniques, assembling technology and rapid prototyping are used for manufacturing.**

I. Introduction

The aim of the CLONS project is the development of a closed-loop sensory neural prosthesis to restore vestibular information (i.e. angular velocity) by stimulating the semicircular canals. Specifically, the prosthesis provides sensory feedback based information from an artificial vestibular system that decodes motor activities by measurement of 3D angular head velocity as well as adaptive algorithms that optimize this feedback over time. The implantable interface consists of electronics (e.g. integrated stimulators and telemetry), circuitries, and electrode structures (see Fig. 1). The vestibular system is required for spatial orientation and maintaining equilibrium. Angular velocity is measured using the semicircular canals and then transmitted to the brain via the vestibulocochlear nerve [1].

Previous results have shown that after electrical stimulation of vestibular neurons in the semicircular canals, eye movements could be elicited in guinea pigs [2]. For this purpose, special thin-film multi-site microelectrode structures based on flexible polyimide with platinum contacts on both sides of the polyimide structure have been developed [3]. After implantation in the vicinity of neurons innervating the lateral semicircular canal, single 30µA biphasic pulses were used to evoke horizontal and vertical eye responses [4].

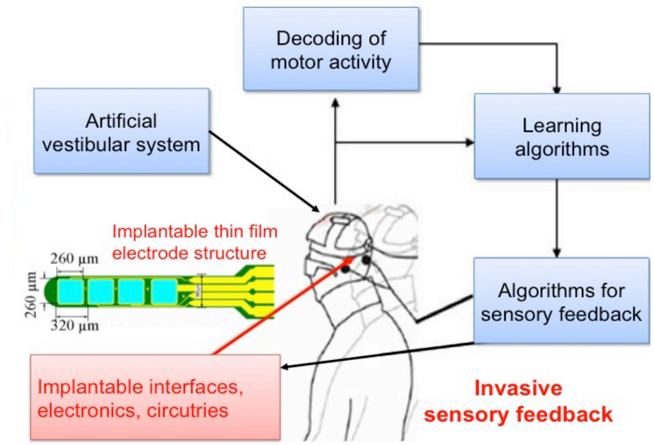

Fig. 1. Conceptual architecture of the CLONS project [1].

Moreover, in three patients with disabling Meniere´s disease, it was shown that the lateral and superior ampullary nerves could be stimulated without simultaneous stimulation of the facial nerve. The electrical stimuli with biphasic trains elicited mainly horizontal nystagmus [5]. As the surgical access to the vestibular system in humans is different to the approach during the experiments with multi-site electrodes in guinea pigs, implantable electrode structures for human application should be completely different from the animal electrodes.

This paper will present the fabrication of a polymer structure that holds the stimulating electrodes and that can be attached to the temporal bone with respect to the anatomic conditions.

II. Materials and Methods

The access to the vestibular system of humans is shown in Fig 2. After opening the attic and removing the incus and malleus head a small well was drilled above the horizontal portion of the facial nerve canal [5]. In the figure, the different nerves (posterior ampullary nerve, lateral ampullary nerve, facial nerve) are marked with colors. The superior ampullary nerve is not marked because it is not possible to distinguish it from the lateral nerve in patients.

The cavity is an area drilled out from the surgeon in order

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to expose the ampullary nerve. Using MRI and CT the surgeon should plan the surgery very carefully. Additionally a soft material like silicone should be used as electrode carrier. So it would be possible to create a resilient structure that fills out the hole.

Challenges for the development of the electrodes regarding the small area with close localization of different nerves are:

- application and fixation of electrodes
- selective reproducible stimulation of lateral and posterior ampullary nerve
- no electrical or mechanical influence on facial nerve nor on hearing

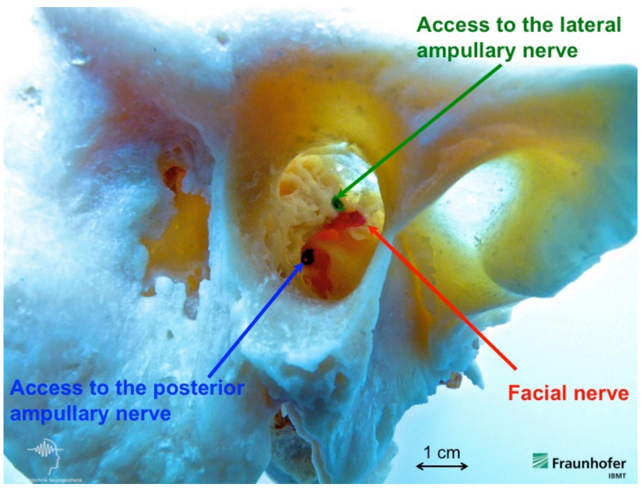

Fig. 2. Piece of skull with marked access to the lateral ampullary nerve and posterior ampullary nerve as well as the facial nerve of a human.

Different kinds of thin-film electrode structures based on polyimide can be manufactured using microtechnological methods such as photolithography [6]. These structures are thin (15 µm), biocompatible, flexible, light and can be designed with multiple geometries.

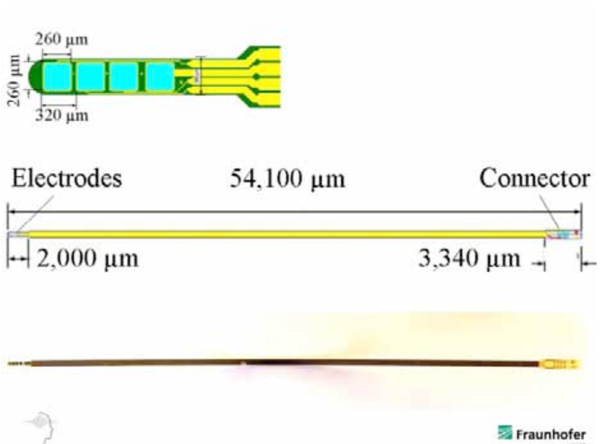

Fig. 3. Thin film polyimide structure with 4 platinum electrode contacts.

The electrode contacts and tracks are made of platinum and gold layers structured by a lift-off process. The electrical properties of electrodes depend mainly on the material and on the size of the electrode contacts. If they are coated with microrough platinum, their efficient surface is enlarged, causing a decrease in electrode impedance by two orders of magnitude. Moreover, charge injection capacity is increased by a factor of ~8 (for a pulse width of 200 µs, a value of 524 $\mu C/cm^2$ was found) [7].

The designed and manufactured polyimide electrode structure that will be used in the novel 3D hybrid electrode is shown in Fig. 3. The polyimide structure is 54.1 mm long with a 2 mm tip for four platinum electrode contacts. The square electrode contacts have an area of 67,600 μm^2 each [3].

Photolithography, assembling technology, and rapid prototyping were used for the fabrication process. After manufacturing, the electrodes were electrochemically characterized using impedance spectroscopy.

III. Results

The first step in the preparation of the 3D hybrid electrode structure was to establish a polymer model of the anatomic circumstances in the human vestibular system. For this purpose, data from a 3D scan of the original bone shown in Fig. 2 was used. Using a 3D printer, a polymer model of the bone was prepared (see Fig. 4) and was used as the basis for the following process.

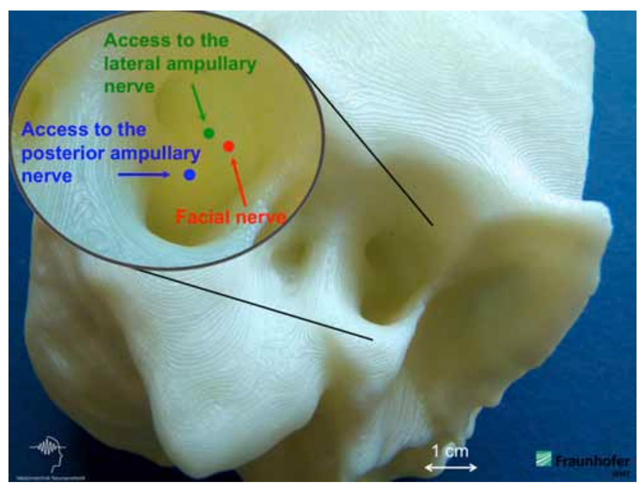

Fig. 4. Polymer model created with a 3D printer using data from the 3D scan of the original bone.

After a second rapid prototyping step a polymer model for the 3D stamp structure was created. The advantage of this second rapid prototyping step is the wide selection of different materials. This model could then be used as carrier for the polyimide electrode structures. As material for the polymer carrier, silicone or other synthetic materials can be used. There are holes (vias) in the carrier to pass the electrode structure through (see also Fig. 6).

After finishing the fabrication of the 3D polymer carrier, the thin-film polyimide microstructures were fixed. The tip of the electrode structure with the single electrode contacts is glued directly on the carrier (see Fig. 5). The four platinum electrodes contacts and the conductors can be clearly seen.

With these electrodes it is possible to create different types of electrode arrays. Multiple electrode arrays with 1x4, 2x4 or 3x4 electrodes are possible for each of the two nerves (the lateral and posterior ampullary nerve). To cover the space one electrode site is necessary at minimum.

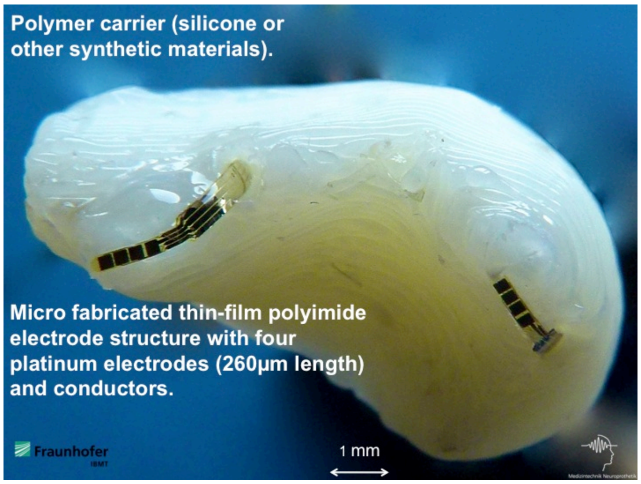

Fig. 5. 3D hybrid electrode structure for human application. There are holes (vias) in the carrier to pass the electrode connector through.

Fig. 6 shows the fixation of the 3D hybrid electrode structure in the polymer model of the human skull. After implantation the implantation tool can be removed. The carrier with the electrodes could be fixed at the stimulation site of the vestibular bone using bone cement.

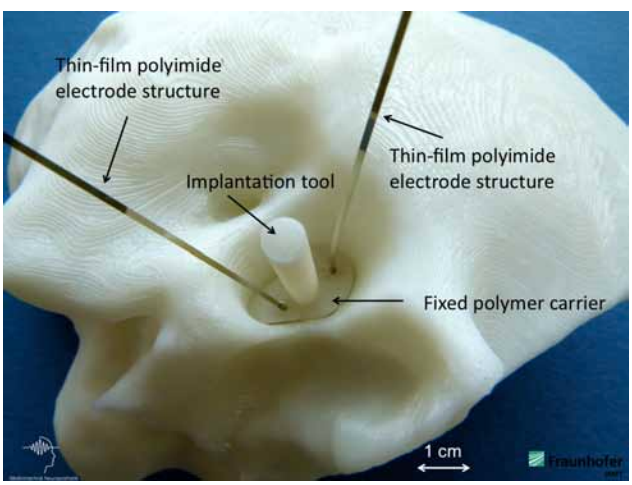

Fig. 6. Application of the 3D hybrid electrode structure.

The newly developed 3D electrodes were electrochemically characterized using impedance spectroscopy. The results are shown in Fig. 7. Using the previously determined value for charge injection capacity of microrough platinum, the maximum charge which can be reversibly injected per pulse is in the range of 0.35µC. For a pulse width of 200 µs, this corresponds to a maximum stimulation current of 1.77 mA.

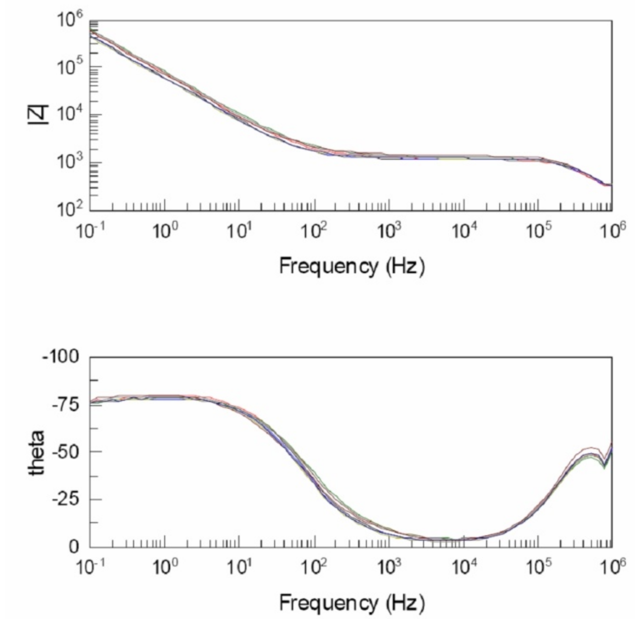

Fig. 7. Absolute impedance (in Ohms) and phase angle for the novel 3D hybrid electrode structure.

IV. Conclusion

The described process allows a fitted application of electrode structures to individual conditions. The electrode structures can be made of polymers as individually adjusted 3D hybrid electrodes. Favorable materials are polyimide and silicone. The electrode structures and tracks are made of platinum and gold. The created 3D hybrid electrode structure can be used for electrical stimulation. For such an interface integrated stimulators and telemetry subsystems are essential. The stimulator ASIC should generate biphasic current pulses with a specific amplitude, duration and pulse rate to drive the implanted electrodes [8]. Power and data transfer is provided by an inductively coupled telemetry system [9]. For patients, individual adjustment of electrodes using CT and MRI data seems feasible. With individually fitted electrode structures, stable and reproducible stimulation of the lateral ampullary nerve and posterior ampullary nerve could be arranged without any influence on the facial nerve. The electrode structure could be fixed close to the vestibular system. Specific air spaces integrated in the polymer structure could protect hearing. The next step will be a proof of concept for stimulation using the novel 3D hybrid electrodes.

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