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Clinically Relevant In Vitro Model for Chronic Electrical Stimulation and Long-Term Evaluation of Cochlear Implant Electrode Functionalization

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Abstract: Cochlear implants (CIs) electrically stimulate auditory neurons for many hours daily, exposing implant materials to chronic electrical stimulation (ES). Clinically relevant in vitro models are therefore essential for preclinical evaluation of CI electrode functionalization. We developed an in vitro set-up that simulates CI use by enabling chronic, acoustically evoked ES, impedance monitoring, microscopic inspection of electrode arrays, and ISO 10993-12–compliant supernatant sampling. CI processors were stimulated for 16 h per day, while receivers and electrodes were operated under physiological conditions in an incubator. Custom-made components allowed parallel testing of three CIs, full immersion in artificial perilymph, and in situ observation. The system was stable over several weeks and yielded clinically comparable impedance values.

I. Introduction

Cochlear implants (CIs) are the standard treatment for patients with severe sensorineural hearing loss. By bypassing damaged hair cells and directly stimulating auditory neurons, CIs restore auditory perception through electrical stimulation (ES). A CIs consist of an external sound processor, an implanted receiver and an electrode array inserted into the cochlea [1]. CI patients typically wear the processor for approximately 16 hours, during which the implant is exposed to sound-dependent, ES, followed by an unstimulated period overnight. Materials and drugs intended for electrode functionalization are therefore subjected to long-term ES under highly specific geometric and fluidic constraints. Standard in vitro test systems do not adequately reflect these conditions. In particular, ISO 10993-12–compliant extraction requires very small fluid volumes fully contacting the long and thin electrode array, approximating the natural perilymph volume of the cochlea. At the same time, microscopic observation of the electrode surface without removal is desirable to avoid surface damage, contamination, or loss of extract. To address these challenges, we developed an in vitro set-up that closely mimics CI use in patients by combining chronic, acoustically triggered ES with impedance monitoring, microscopic visualization, and ISO-compliant supernatant sampling.

II. Material and methods

II.I Custom-made components

Three custom-made components were designed to replicate the spatial and functional separation of CI components in patients and to allow parallel testing of three devices. A processor holder and a receiver box were 3D-printed from polylactic acid (PLA). The processor holder was attached to the outside of an incubator, ensuring acoustic access for stimulation. The receiver box, placed inside the incubator, contained three liquid-tight chambers to immerse the receivers while allowing magnetic coupling and signal transmission. A removable electrode compartment was manufactured from autoclavable polysulfone. It contained three narrow cavities sized according to the ISO-required extraction volume for a SlimJ electrode array. The cavities were laterally sealed with glass slides to enable microscopic observation. The compartment was fixed to the receiver box via a groove mechanism, ensuring stable positioning and reproducible alignment.

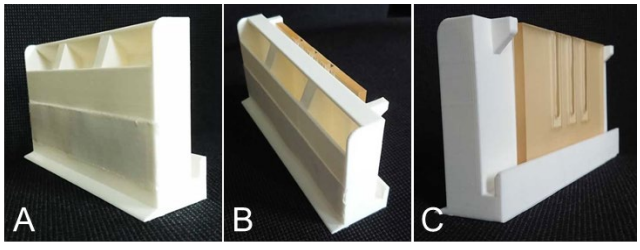

Figure 1: Images of the PLA-3D-printed receiver box: A Side view of the box with the chambers for the receivers, which are filled with saline. B Side-top view and C side view of the box with the electrode compartment (light brown) inserted in the groove at the base and fixed by the stoppers on both sides at the top.

II.II Patient-simulating set-up and operation

The assembled set-up was operated under physiological

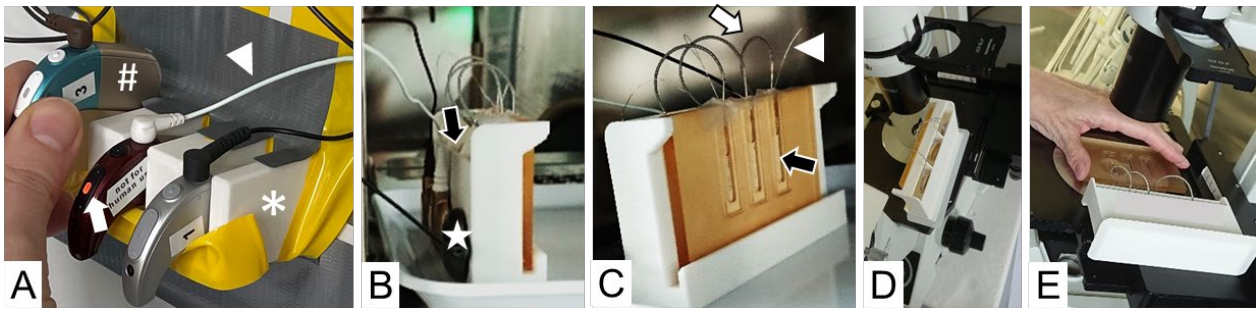

Figure 2: Set-up for CI-patient simulating ES in the incubator: The CI-processors (hash) are placed in a holder (asterisk) at the lateral wall of the incubator above the radio (not shown here) and are connected with cables (white arrow head) to the CI inside the incubator. Control light of the middle processor shows red flashing (white arrow). (A). The cables lead to the transmitters (star) (B), which are connected to the receivers placed and immersed in saline in the chambers of the box (indicated by black arrow). From the receiver, the electrodes (white arrow) lead to the other side of the box to the compartment (light brown), where the electrode arrays are immersed in the artificial perilymph filled cavities (black arrow) (C). One platin wire (white arrow head) for each CI connects the saline in the chamber with the corresponding perilymph in the cavity for current flow. D and E depict placement for microscopy.

conditions (37 °C, 5% CO_2, ~95% humidity). CI processors were acoustically stimulated by radio music for 16 h per day using a time switch, simulating daily patient use. Successful stimulation and signal transmission were monitored via processor control lights. Receivers were immersed in saline (0.9% NaCl), while electrode arrays were inserted into cavities filled with artificial perilymph. Electrical conductivity between both fluids was ensured by a platinum wire. Cavities were sealed to prevent evaporation. Long transmitter cables allowed connection between processors and receivers. Impedance measurements were performed in situ using manufacturer software. For microscopic inspection and supernatant sampling, the electrode compartment was detached and placed on a microscope stage. Artificial perilymph was removed and replenished using a syringe and fine cannula, avoiding air bubble formation and contact with the electrode array. All CI components and software were provided by Advanced Bionics.

III. Results and discussion

The set-up enabled stable, chronic ES of three CIs in parallel under conditions closely resembling clinical use. Acoustic stimulation, signal transmission, and current flow were reliably achieved. Interruptions caused by evaporation, cable defects, or battery depletion were immediately detected by control lights and resolved with minor adjustments. Battery life ranged from 19 h to more than 24 h, requiring daily replacement. Impedance measurements were successfully performed without disassembling the system. Recorded values were stable over time and within the range observed in CI patients, supporting the functional validity of the model. The electrode compartment allowed repeated microscopic inspection of electrode surfaces through the glass windows without removing the array. Supernatants could be collected and replaced in compliance with ISO 10993-12. No contamination was detected during an 8-week observation period, despite weekly handling. Careful manipulation was required to avoid mechanical stress on the relatively short electrode arrays.

The presented in vitro model addresses key limitations of standard implant testing systems by combining chronic, patient-like ES with precise fluid control and in situ observation. The narrow cavity design enables ISO-compliant extraction volumes while maintaining full contact with the electrode array. Identified limitations include mechanical stress on transmitter cables and the need for daily battery replacement, which could be mitigated by more robust cabling or alternative power supply concepts.

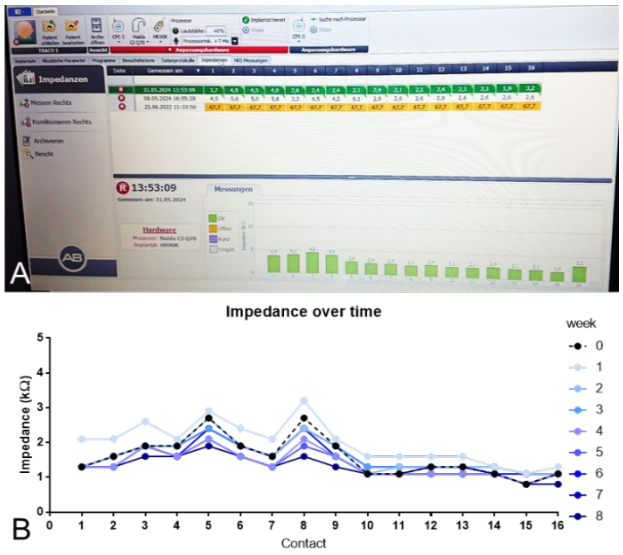

Figure 3: Impedance measurement: A: clinical sound wave software was used with the developed set-up staying in place. B: Example of weekly impedance measurement of a coated CI over 8 weeks. Slight impedance increase at week 1 was due to coating (not further described here).

IV. Conclusion

This patient-simulating set-up enables chronic electrical stimulation, impedance monitoring, visual inspection, and supernatant sampling of CI electrodes under clinically relevant conditions. It represents a valuable and versatile tool for the preclinical evaluation of CI electrode functionalization.

Author's statement

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