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COATED COCHLEAR IMPLANT ELECTRODES TO SUPPRESS INTRACOCHLEAR INFLAMMATORY RESPONSE AND FIBROSIS

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Objectives. Cochlear implant (CI) research continuously strives for improving electrodes and inventing new electrode types to enable the best possible performance of CI recipients. One goal is to minimize intra-cochlear chronic inflammation and fibrosis due to foreign body reaction after implantation that leads to an increase in electrode impedance and a decrease of the dynamic fitting range of loudness levels. Additionally, chronic inflammation in the middle to long term may cause a destruction of sensorineural structures thus influencing the performance of implantees with standard indications as well as electric-acoustic stimulation (EAS) candidates due to loss of residual hearing.
While pharmacological intervention with glucocorticoids is a promising approach to dampen postoperative inflammatory reactions, prevent fibrosis, and preserve residual hearing a non-pharmacological approach was chosen, namely a passivating coating for the electrode array thereby making it less detectable by the immune system.
Methods. 20 normal hearing guinea pigs (Dunkin Hartley) were chronically implanted with custom-made electrodes (MED-EL) either coated with a highly biocompatible polymer (n=12 COATED) or common silicone arrays (n=12 NON-COATED). Impedance and ABR-measurements were performed after 1, 2, 5, 9, 12, and 16 weeks post-implantation. This was followed by histological examination of the cochleae. Evaluation included measurement of fibrosis in the cochlea, various inflammatory markers and immunohistological analysis of degeneration of spiral ganglion neurons (GAP43).
Results. Although there was no significant difference between the two groups regarding hearing thresholds animals with coated implants showed smaller shifts of postoperative hearing thresholds at higher frequencies (4 – 32 kHz). Impedance measurements revealed no statistically significant difference between the two groups. No correlation was observed between postoperative hearing loss and impedance increase. Histological analysis revealed significantly reduced chronic lymphoplasmatic inflammation ($p = 0.012$) in the basal turn of cochleae implanted with coated implants. No significant difference was observed concerning fibrosis and new bone formation. Immunohistological GAP43 staining demonstrated a significantly lower amount of degenerated spiral ganglion neurons in the basal turn of the cochleae implanted with coated electrodes ($p = 0.003$).
Conclusion. The highly biocompatible coating seems to be a promising improvement for future electrodes possibly in combination with anti-inflammatory drugs like dexamethasone.

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NANOMATERIALS-BASED STRATEGIES FOR PIEZOELECTRIC COCHLEAR IMPLANTS

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As of today, cochlear implants (CIs) represent the only option for deaf people affected by profound or severe sensorineural hearing loss (SNHL). Although conventional CIs can bring patients back to an acceptable hearing, on the other hand they suffer from some important disadvantages impacting the quality of life and hearing after implantation and for such reasons a new class of CIs is desirable. The physical properties of piezoelectric materials, which polarize in response to mechanic deformation, entitle them to replace the function of hair cells. The development of a working piezoelectric CI requires that the electric charge generated by the piezo-materials must be self-sufficient to stimulate the cochlear neurons. First studies using a basic piezoelectric polymer (polyvinylidene fluoride, PVDF) have shown the proof-of-concept, but the device sensitivity was still insufficient.
The aim of this study is to fabricate novel piezoelectric substrates based on piezo-polymers (PVDF and PVDF-TrFE) doped with ceramic nanoparticles (barium titanate nanospheres, carbon nanotubes) to obtain composite materials with enhanced performance. Several micro-fabrication strategies were investigated to produce thin piezoelectric polymer/ceramic composite scaffolds, in the form of electrospun nanofibers and micro/nano films to be placed on the basilar membrane, including spin coating, hot-press, and co-axial electrospinning. Presence of the piezoelectric crystallographic phases of the composite materials were assessed via X-ray diffraction. The piezoelectric constants were investigated with a bench set-up in which the material deformation is measured under an applied current. Finally, the substrates were cultured *in vitro* with neuronal-like cell lines and mesenchymal stem cells (MSCs) to assess their potential ability to interact with inner ear resident cells.
The fabrication parameters were tuned to optimize the piezoelectric response of the materials. Increasing barium titanate nanoparticle concentration up to 20% (w/w) in PVDF nanofiber ribbons enhanced inverse (deformation) but not direct (polarization) piezoelectric effect. Interaction with neuronal-like cells was not affected by barium titanate concentration. Differently, the presence of carbon nanotubes in PVDF-TrFE films increased performance and MSC adhesion with respect to plain PVDF-TrFE films.
Improvements in piezoelectric CIs could substantially impact the quality of life of people affected by profound SNHL and reduce the healthcare costs.