IMPROVED COCHLEAR IMPLANT BIOMATERIALS THROUGH PHOTOPOLYMERIZATION

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Cochlear implants (CIs) help restore basic auditory function in patients who are deaf or have profound hearing loss. CI electrode arrays are made of platinum wires and contacts encased in a silastic housing. These materials provide mechanical stability and flexibility critical to the long-term function of the CI. However, they also induce local tissue reactions that can have detrimental effects. For example, trauma from insertion of the CI can damage cochlear health and any residual acoustic hearing. Further, the fibrotic capsule that encases CI electrode arrays leads to increased impedances and decreased signal resolution which reduce CI effectiveness. Intracochlear fibrosis is also implicated in the loss of acoustic hearing that can occur months to years after implantation. Thus, developing materials that mitigate insertion trauma and the inflammatory, fibrous response to CI materials could significantly improve device function and safety. Ultra-low fouling zwitterionic polymers are a class of materials that show significant promise to reduce fibrosis. However as bulk materials they lack mechanical properties and long-term durability suitable for use in CIs.

To leverage the ultra-low fouling surface properties of zwitterionic polymers while maintaining the proven mechanical properties of current CI materials, we have developed a photochemical process for simultaneous polymerization, grafting and cross-linking of zwitterionic thin films on relevant CI materials. Photopolymerization has been used to covalently graft hydrogels of sulfobetaine methacrylate (SBMA) and carboxybetaine methacrylate (CBMA), two zwitterionic monomers, to PDMS surfaces. To produce the photografted hydrogels, the balance between crosslinker, photoinitiator and zwitterionic monomer is critical to impart sufficient mechanical stability and anti-fouling capacity. With a lower (5-30 wt%) range of crosslinker, films induce a greater than 90% decrease in cell and protein attachment. Incorporating appropriate amounts of crosslinker, zwitterionic monomer, and photoinitiator enables the hydrated coating to remain attached and viable under significant normal forces and bending. Failure due to bending or normal force only initiates after drying in ambient conditions for 60 minutes, demonstrating sufficient durability under typical handling conditions.

These zwitterionic coatings also produce a much more lubricious surface which leads to a reduction of up to 95% in the coefficient of friction relative to uncoated PDMS, thereby dramatically reducing the required insertion force for implantation. The effect of thin film photografted zwitterionic coatings on fibrosis reduction has also been demonstrated *in vivo* using model implants and human cochlear implant electrode arrays, exhibiting a fibrotic capsule thickness reduction of at least 50% regardless of surface geometry, duration of implant (up to one year), or the material coated. Additionally, coatings on CI arrays have shown up to a 50% decrease in impedance for systems implanted in sheep which demonstrates the potential of these photografted and photopolymerized materials in improving CI effectiveness. These results demonstrate that grafted zwitterionic thin films could lead to significantly reduced scarring and fibrosis for a variety of different biomaterials.