Retinal Implant Project

CNF Project Number: 2504-16

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Primary CNF Tools Used: PT-72, lithography toolset/MA6, DWL2000, evaporators, AJA sputter, Gamma spray coater, SEMs, gold electro-plating, Class 2 lithography toolset, Oxford PECVD, Oxford 100 etcher, Glenn 1000, YES polyimide oven, VersaLaser

Abstract:

The purpose of the Retinal Implant Project is to restore useful vision to patients who are blind with degenerative retinal diseases. The primary illnesses we hope to treat are retinitis pigmentosa (a primary cause of inherited blindness) and age-related macular degeneration (the leading cause of blindness in the developed world). Both these diseases cause the eventual destruction of the photoreceptor cells — rods and cones — in the retina, leaving intact the ganglion cells that transmit electrical impulses (and hence visual information) to the brain. The ganglion cells may be stimulated, however, with biphasic current pulses from a microfabricated electrode array. Blind surgical volunteers have consistently described visual percepts that resulted from such stimuli, and this has led our team to develop a wireless, implantable retinal prosthesis.

Summary of Research:

The implanted portion of our device consists of power and data secondary receiving coils, and in a sealed titanium (Ti) can a small number of discrete components, and a custom designed application specific integrated circuit (ASIC) that consists of circuitry for clock and data recovery, current drivers for electrodes in a stimulating electrode array, and a programmable function generator capable of stimulating with a wide range of pulse widths and amplitudes. The current outputs drive high-charge capacity sputtered iridium oxide film (SIROF) stimulating electrodes, which in turn give rise to the visual percepts mentioned above.

CNF-fabricated components of this system have included various proof-of-concept test structures and tools used in the research effort and an integrated combination flexible circuit and stimulating electrode array. Si wafers serve as carriers for these freestanding films during processing. The electrode leads are fabricated inside of 'sandwiches' of polyimide and amorphous silicon carbide (SiC), while the SIROF electrodes are reactively sputter-deposited.

Assembly of the intraocular components of the prosthesis is accomplished by flip chip solder ball bonding of the IC and solder attachment of discrete components onto an internal flexible circuit board that is hermetically sealed into an ultraminiature Ti can. The RF coils are soldered and glued to the integrated external flex-array that is in turn thermosonically bonded to the hermetic feedthrough of the Ti can. Finally, the thermosonic bonds are protected and insulated with an over-mold. An external patient interface unit, will consist of a video camera for capturing images, a digital signal processor, and a radio frequency (RF) transmitter and coil to relay power and data to the implanted device.

Scientific challenges still remain in realizing a chronically implantable retinal prosthesis. While our first-generation device was primarily encapsulated in polymers for short term proof-of-concept implant studies, our second-generation system focused on a system that would last many years *in vivo*. Our more recent efforts have focused on developing a device with 256+ stimulation channels,

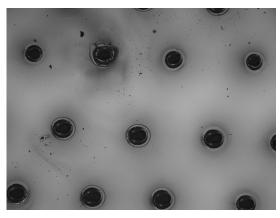


Figure 1: A image of through-wafer holes in a fused silica wafer made with the CNF VersaLaser.

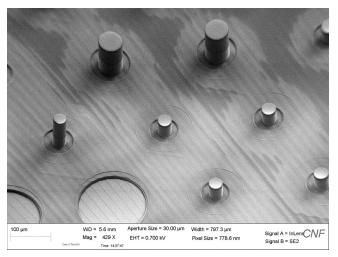


Figure 2: An SEM image of an electrode array of SU-8-based penetrating electrodes and planar electrodes fabricated on the same flexible

which is still small enough and of a configuration to be easily implanted in the ocular orbit and continue to function for many years *in vivo*. Thus, a major effort has been the development of a technological platform to build a robust, hermetically packaged, high-density subretinal visual prosthesis with a lifetime of > 10 years in biological saline that is scalable to hundreds of I/O channels.

Recent efforts in the CNF have included developing improvements to bonding of electrode arrays to Pt-pin ceramic feedthroughs by electroplating Au onto the surface of the platinum (Pt) pins. This has increased the reliability of the bonds between the electrode array and the ceramic feedthrough. Improvements in assembly techniques, underfilling, overmolding and final parylene-C protection have yielded a passive retinal implant system that has been successfully implanted in an animal model for several months with no significant adverse effects.

Other efforts in the CNF have included developing a fabrication process for indwelling electrodes for long-term implantation in brain tissue. The process currently utilizes low- stress silicon-nitride as the protective layer whereas it is expected that this will transition to silicon-carbide as the material of choice in the future. An economic means of producing a fused-silica feedthrough was also explored utilizing the VersaLaser to create through-wafer holes as shown in Figure 1, but it is not yet clear that this method is capable of producing devices with the necessary hermeticity.

The project has substantially completed implementation of a microfabrication process to incorporate SU-8-based 3D electrodes into a hybrid electrode array to achieve a more optimal interface between the electrode and the target neural cells. Fabrication work at the CNF has included process development required for such high aspect structures including the challenges of lithography with the presence of extreme topography. Many of these lithographic processes have been successfully realized using the Gamma spray coating tool. Figure 2 shows such an SEM image of an electrode array containing different geometries of SU-8-based penetrating electrodes as well as planar electrodes on the same flexible substrate. The latest microfabrication processes utilize numerous CNF tools including the Heidelberg 2000 mask writer, MA6 aligner, polyimide YES curing oven, PT72 RIE, SC4500 evaporator, Gamma Spray Coater, Au electroplating station, K & S Au ball bonder, Oxford PECVD, Oxford 100 etch tool, Parylene coater, as well as numerous metrology tools.

References:

[1] J. F. Rizzo, J. Wyatt, J. Loewenstein, S. Kelly, and D. Shire, "Methods and Perceptual Thresholds for Short-Term Electrical Stimulation of Human Retina with Microelectrode Arrays," Investigative Ophthalmology and Visual Science, vol. 44, no. 12, Dec. 2003, pp. 5355-5361.