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, Oxford Cobra etcher, Glenn 1000, YES polyimide oven, Parylene-C coater, VersaLaser, numerous metrology tools

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, which 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 Ti can — a small number of discrete components, and a custom designed application specific integrated circuit (ASIC), which 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 which is hermetically sealed into an ultraminiature Ti can. The RF coils are soldered and glued to the integrated external flex-array which 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 which would last many years *in vivo*. Our more recent efforts have focused on developing a device with 256+ stimulation channels 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 > ten years in biological saline that is scalable to hundreds of I/O channels.

Recent efforts have focused on improvements in assembly techniques, under-filling, overmolding and final Parylene-C protection, using the Parylene coater, have yielded a passive retinal implant system which has been successfully implanted in an animal model for several months with no significant adverse effects. Figures 1 and 2 show an example of the implant mounted on a model eyeball.

Other efforts at the CNF have included developing a microfabrication process for penetrating electrodes for long-term implantation in brain tissue. The goal is to extend the existing retinal stimulator platform to include electrodes which can be placed at different points in the visual tract to enable the restoration of sight due to other causes of blindness. These electrodes can be placed into structures such as the lateral geniculate nucleus (LGN) to produce visual signals at that location. The LGN is a structure located deeper within the brain thus a system of implanting the electrode array into the target location has had to be developed as well. A prototype insertion device, shown in Figure 3, includes a protective split-sheath inserter, the actual electrode array/signal cable and the insertion rod. The resulting system has the potential to be utilized in other applications such as those requiring deep brain stimulation including Parkinson's disease, severe depression, morbid obesity, and obsessive-compulsive disorder, to name a few.

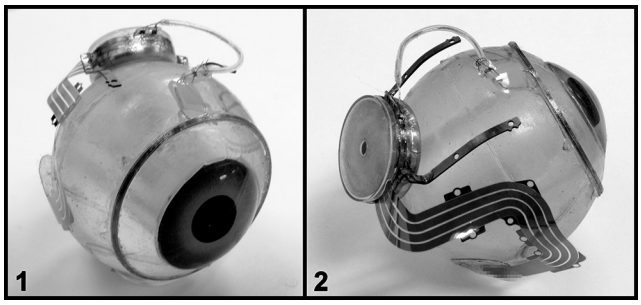

Figure 1, left: A side-frontal view of a passive retinal implant assembly is shown on an eyeball demonstrating the location of the power and data coil around the front of the eye. Figure 2, right: A side-rear view of a retinal implant assembly mounted is shown on an eyeball demonstrating the location of the hermetic titanium case and the stimulating electrode array at the back of the eye. (See pages vi-vii for full color versions of both images.)

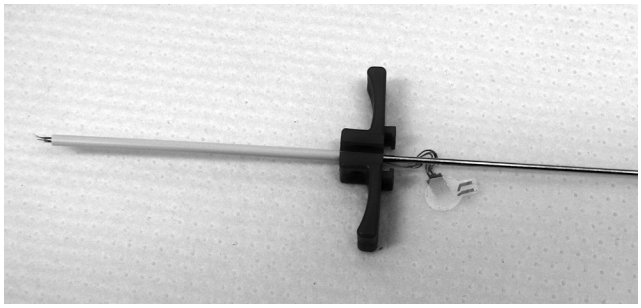

Figure 3: A prototype deep brain insertion sub-assembly is shown which includes a protective split-sheath inserter, the actual electrode array/ signal cable and the tungsten insertion rod.

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.