"A Cochlear Nucleus Auditory prosthesis based on microstimulation"

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Progress Report #5

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ABSTRACT

The objective of this project is to develop a central auditory prosthesis based on an array of microelectrodes implanted into the ventral cochlear nucleus, in order to restore hearing to patients in whom the auditory nerve has been destroyed bilaterally. The microelectrode arrays for the first human implantations are being assembled in Sydney, Australia by Cochlear Ltd using discrete iridium microelectrodes fabricated at HMRI. At HMRI, we fabricate the electrodes, insulate the shafts, and expose and activate the electrode tips. During the past year, 155 microelectrodes electrodes have been shipped to Sydney. In Sydney, they are incorporating these into arrays, using the specifications developed at HMRI and HEI. Cochlear Ltd. expects to deliver implantable devices by December of this year.

The array of microelectrodes is implanted into the patient's brainstem with the aid of an inserter tool. In association with Altair Instruments, Inc, we have modified the tool to facilitate sterilization. In preparation for the first human implantations, we have conduced three training session in the use of the array inserter tool, with neurosurgeon Dr. William Hitzelberger.

Our contract's work scope includes the development of a 16-site microstimulation array based on silicon substrate probes. The large number of electrode sites offer increased flexibility in conveying signals into the cochlear nucleus. These probes are fabricated at the University of Michigan, using photolithographic technology. Probes with shanks of two different lengths have been designed by engineer Jamile Hetke, from specifications provide by HMRI. They are now ready for delivery to HMRI, where they will be incorporated into arrays using procedures described previously.

In preparation for chronically implanting the silicone substrate arrays into the cochlear nuclei of cats we have expanded the capacity of our telemetry-stimulator to 16 channels.

The silicon probes and may fracture if they are over-stressed. We have been investigating procedures for tethering the shanks of the silicon substrate probes so that if they do fracture from the superstructure, the detached shanks or fragment do not migrate down into the brain. This is an important consideration if such electrode array are to be used in human patients. Our efforts to stabilize the shanks by encapsulating them in organic polymer (Parylene-C) have not been promising, since the encapsulant has shown a tendency to tear in response to lateral strain, at the point when the underlying silicone substrate is fractured. During the past quarter, we have evaluated the tensile properties of a film of flexible silicone-elastomer (NewSil Med A) applied to the silicon substrate. Silicone elastomers are capable of bonding covalently to the rigid silicon substrate, so the attachment between this film and the substrate coating should be very stable during prolonged soaking in vivo. When the silicon probes were intentionally fractured, the adherent film of silicone elastomer formed a durable hinge, with sufficient tensile strength to prevent a fractured probe from detaching completely from the array superstructure.

Microstimulation array for human use.

At HMRI, iridium microelectrodes are fabricated, coated with Parylene-C, their tips exposed, and the iridium metal is activated. At Cochlear Ltd. (Sydney, Australia), the microelectrodes are incorporated into arrays. These are integrated with the surface electrode array used in the current auditory brainstem implant and with the Nucleus 24 receiver. During the past year, HMRI has shipped 155 microelectrodes to Cochlear, and the group of implanted are now completed and undergoing sterilization. Cochlear expects to deliver the devices to the House Ear clinic by the first of December.

In preparation for the human implants, the Principal Investigator (DBM) has been instructing neurosurgeon William Hitzelberger in the loading and handling of the array inserter tool. Implantation of the array using the tool is not difficult, but the array must be loaded into the tool on the sterile operative field using a technique designed to minimize the chance of damaged to the Parylene-coated iridium microelectrodes. Dr. Hitzelberger has participated in 3 sessions, and has implanted the arrays into the feline spinal cord. Also, an inserter tool dedicated to the human project is now available, and Dr. Hitzelberger has been practicing accessing the human cochlear nucleus in patients undergoing removal of unilateral acoustic Schwannomas. Of course, no microelectrode arrays have been implanted into these patients.

On October 5, a description of the procedure and an informed consent form was submitted to the Institutional Review Board of St. Vincent's Hospital where the implant surgeries will take place. The protocol was approved by the IRB, pending some minor revisions of the informed consent form.

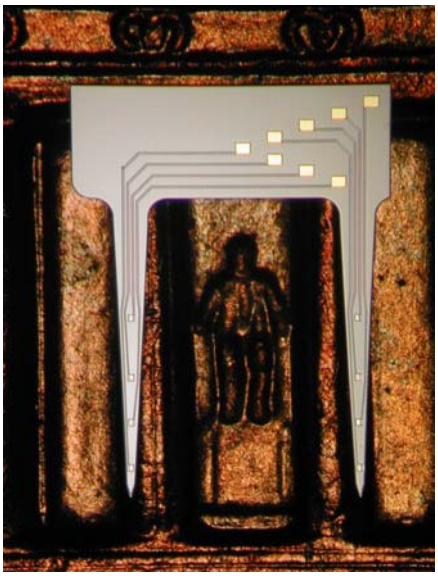

Figure 1

II. Development of a silicon substrate array.

Our contract's work scope includes the development of a 16-site microstimulating array using silicon substrate probes fabricated at the University of Michigan. Two probes with 2 shanks and 8 active electrode sites were designed by engineering Jamille Hetke. One probes has shanks 2 mm in length for implantation into the feline cochlear nucleus, and one has 3 mm shanks, which has been designed to span the full dorso-ventral extent of the human cochlear nucleus. It will be evaluated in the feline lumbar spinal cord. The probes have now been fabricated at the University of Michigan, and a 2-mm probe is shown in Figure 1. We will now incorporate the probes into arrays for implantation into the feline ventral cochlear nucleus employing the procedure developed using probes designed for the feline spinal cord (Quarterly Progress Reports #1, 3 & 4).

In preparation for evaluating these arrays in the feline cochlear nucleus, we have expanded the capacity of our backpack-telemetry controlled stimulator, from 4 to 16 channels. In order to avoid a complete redesign of the uplink decoder in the backpack, the 16 channels are partitioned into 4 groups of 4, and all members of a particular group will inject the same

current simultaneously. However, all of the electrodes can be selected or deselected, all have individual control current drivers, and the electrode voltage across any electrode can be monitored.

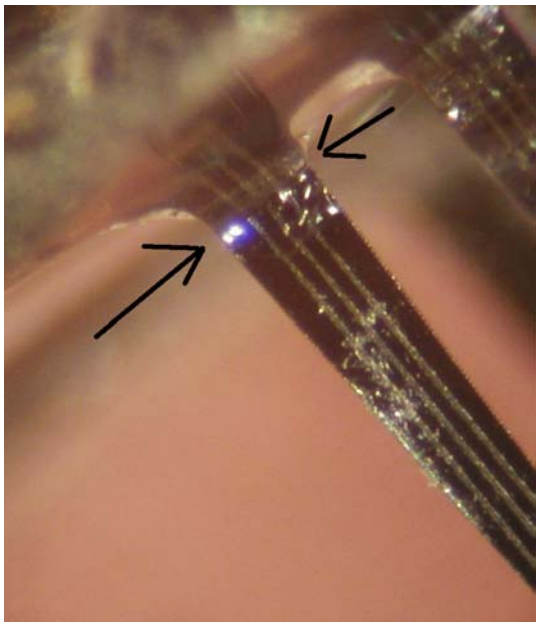

Figure 2

The shanks of the silicon probes have been

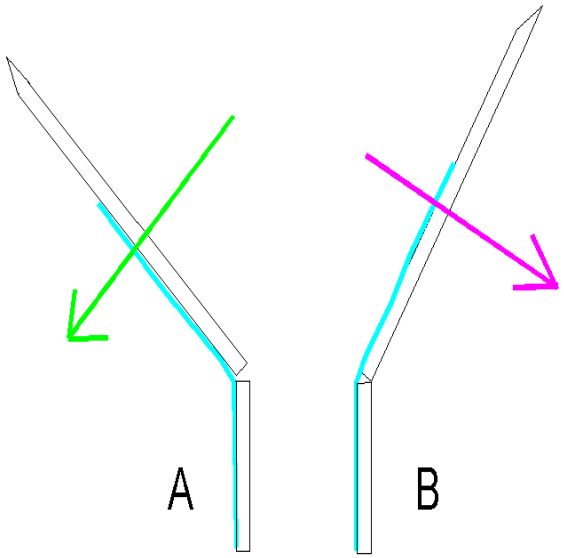

Figure 3

designed with a relatively low aspect ratio in order to reduce the chance that they may fracture during handling or implantation. As reported previously, we have developed a procedure for strengthening the junction between the shanks and the superstructure where the probes are most likely to fracture. However, our objective is to develop the silicon substrate array for human use, and therefore, we have been investigating procedures for tethering the shanks so that if they do fracture, the detached shank or fragment does not have the opportunity to migrate down into the brain. Our efforts to stabilize the shanks
by encapsulating them in 3 : m of Parylene-C have not been promising since the hinge formed by the encapsulant at the point of fracture has shown a tendency to tear in response to lateral strain (Quarterly Progress Report #4). During the past quarter, we have evaluated the tensile properties of a film of flexible silicone elastomer (Nusil Med A) applied to the unfeatured side of the shanks. Since silicone elastomer will bind strongly to the silicone and shanks, such a coating should be very stable *in vivo.* Unlike Parylene, the elastomer cannot be removed from the electrode sites using an excimer laser, and therefore, the elastomer can be applied only to the rear surface of the shanks. Three probes were fractured by bending them toward the elastomeric film and 3 others by bending them away from the film. Figure 2 shows a coated probe shank which was intentionally fractured. The hinge formed by the elastomer film is indicated by the arrows. When the shanks were fractured toward the film (Figure 3A), the resulting hinge exhibited a tensile strength of at least 1 gram, which should be more than adequate to prevent the probes from migrating from the site of implantation, and should be adequate to allow extraction of a fractured probe. When the shanks were stressed and

fractured in the direction away from the film (Figure 3B), the hinges were weaker, possibly due to damage to the film inflicted by the sharp edge of the fractured probe. However, the tensile strength of the hinge still appeared to be adequate to anchor a fractured probe, although it is questionable that the strength would be adequate to allow extraction of the fractured probe. However, our primary consideration is to permanently anchor the fractured shank to the array's superstructure.