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## A Microcoil-Based Cortical Visual Prosthesis

**Principal Investigator:** FRIED, SHELLEY

**Institution Receiving Award:** BOSTON VA RESEARCH INSTITUTE, INC. (BVARI)

**Program:** DMRDP

**Proposal Number:** VR170089

**Award Number:** W81XWH-19-1-0057

**Funding Mechanism:** Technology/Therapeutic Development Award

**Partnering Awards:**

**Award Amount:** \$2,099,477.00

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### PUBLIC ABSTRACT

We are developing a prosthesis that can restore vision to the blind. Blindness typically results from damage or loss of function to one or more of the neural populations that mediate our sense of vision; the underlying premise of most visual prostheses is that some sense of vision can be restored by artificially stimulating neurons downstream of the non-functioning region. Thus, for example, when retinal photoreceptors are destroyed by degenerative diseases such as retinitis pigmentosa or macular degeneration, neurons downstream of photoreceptors (e.g., bipolar or ganglion cells) can be artificially (electrically) activated by the implant. The hope is that the artificially induced neural signal will be transmitted to the brain where it can be meaningfully interpreted. Proof of concept for a retinal prosthesis has been demonstrated repeatedly, and several commercial devices are now available. Unfortunately, a retinal prosthesis is of limited use if blindness originates further downstream (closer to the brain). For example, battlefield Soldiers or others that have suffered traumatic injury of the eye, have little or no surviving retinal neurons left to stimulate. In these cases, a different type of prosthesis can be used, but it must target visual neurons further downstream from the retina. Potential targets include the optic nerve, the lateral geniculate nucleus (LGN) of the thalamus, and the primary visual cortex (V1). The primary visual cortex is a particularly attractive target because it has a large surface area and is largely accessible surgically, making it relatively easy to insert a large array of electrodes. Clinical testing has demonstrated proof of principle for such an approach, but several fundamental limitations have impeded progress towards a safe, reliable, and effective device. For example, each electrode in the array should ideally create a focal region of activity that leads to a small, localized visual percept (referred to as a phosphene), but instead, a spatially expansive region of activation is created and phosphene appearance can vary significantly for different electrodes. Further, the overlap of activation that can occur between neighboring electrodes reduces the acuity that can be achieved as well as the ability for complex images to be “assembled” via simultaneous stimulation from multiple electrodes. Another significant limitation of electrode-based cortical devices arises from the foreign-body responses that get triggered by implantation into cortex. Inflammatory responses can produce a thick “scar” around the electrode that impedes the flow of current, thereby diminishing its ability to activate nearby neurons. Many additional factors also contribute to a lack of stability and the corresponding loss of effectiveness over time. Despite much effort, these problems have largely persisted. Recently, we showed that tiny magnetic coils could be used to stimulate cortical neurons. This was intriguing because the magnetic fields produced by coils can be controlled in a way that greatly improves the focality of activation, e.g., each coil in the array creates a small region of activation that does not overlap with that of other nearby coils. Further, magnetic fields are not impeded by even the strongest inflammatory (foreign-body) responses and thus contribute to better stability of coil-based implants. The demonstration of effectiveness with coils suggested that they could replace electrodes in a prosthesis and possibly overcome many of the challenges that have limited progress to date with cortical implants. Preliminary testing has been very encouraging, and our goal here is to develop a coil-based cortical visual prosthesis and then evaluate its suitability for clinical testing. Our first aim is devoted to fabrication of the device and subsequent aims evaluate safety and efficacy. Testing includes psychophysical experiments in non-human primates to see if they can detect the visual percepts created by stimulation as well as implantation into the cortex of surgical patients about to undergo resection (removal of a small part of their cortex); implantation will be limited to the cortical region about to be removed but will nevertheless provide additional confirmation of effectiveness. Successful completion of the aims proposed here will provide a strong foundation for a submission to the appropriate regulatory agencies pursuant to a clinical trial. The level of vision that will be restored remains unknown although a limited clinical trial from 20 years ago found that similar to retinal prostheses, each individual electrode from the cortical implant produced a distinct phosphene that was spatially correlated to electrode position. While it is not possible to definitively say that vision from the two approaches (retinal and cortical) are identical, the similarities are encouraging because a large portion of retinal implant users find the quality of vision provided to be useful for performing some of the activities of daily living and/or they simply enjoy the visual signal it provides. Thus, even if the performance of our new device only matches that of the previous cortical implant, it will still likely be considered useful by many blind subjects. The hope, of course, is that the enhanced features of coil-based stimulation result in much greater effectiveness of our new device. In addition to its potential as a visual prosthesis, the development and testing of the coil-based technology proposed here would also pave the way for treating many additional (nonvisual) disorders, that each affect other regions of cortex.

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