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Communication and control system for a 15-channel hermetic retinal prosthesis☆

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ABSTRACT

A small, hermetic, wirelessly-controlled retinal prosthesis has been developed for pre-clinical studies in Yucatan minipigs. The device was attached conformally to the outside of the eye in the socket and received both power and data wirelessly from external sources. Based on the received image data, the prosthesis drove a subretinal thin-film polyimide array of sputtered iridium oxide stimulating electrodes. The implanted device included a hermetic titanium case containing a 15-channel stimulator and receiver chip and discrete circuit components. Feedthroughs in the hermetic case connected the chip to secondary power- and data-receiving coils, which coupled to corresponding external power and data coils driven by power amplifiers. Power was delivered by a 125 kHz carrier, and data were delivered by amplitude shift keying of a 15.5 MHz carrier at 100 kbps. Stimulation pulse strength, duration and frequency were programmed wirelessly from an external computer system. The final assembly was tested *in vitro* in physiological saline and *in vivo* in two minipigs for up to five and a half months by measuring stimulus artifacts generated by the implant's current drivers.

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1. Introduction

Vision prostheses are being developed by a number of groups worldwide [1–14]. These devices aim to restore visual function lost due to degenerative retinal diseases such as retinitis pigmentosa (RP) and age-related macular degeneration (AMD). These conditions cause a gradual loss of photoreceptors, yet a substantial fraction of the retinal ganglion cells remain forming an intact pathway to the visual cortex. The prevalence of RP is approximately 1 in every 4000 live births, and there are approximately 1,700,000 affected individuals worldwide. AMD is the leading cause of blindness in the developed world, with roughly 2 million affected patients in the United States alone. This number is expected to increase 50% by the year 2020 as the population ages [15]. The best existing treatments slow the progress of these diseases, but there is no known method to restore functional vision. While there is evidence that significant reorganization of the retina occurs after the loss of input signals from the photoreceptors [16], our group and others have nevertheless shown that focal electrical stimulation of retinal ganglion cells yields responses corresponding to the strength and location of the stimuli (e.g., [17]). Our group showed the retinal prosthesis concept in six acute human retinal stimulation trials, in which microfabricated thin-film electrode arrays were surgically inserted into the subjects' eyes, resting on or just above the epiretinal surface. An external stimulator system [18] delivered current pulses for a few hours through connections through the eye, and subjects reported their perceptions [4,5]. These experiments led us to begin development of a chronically-implantable device to fully explore the prospects of restoring useful vision.

Other groups are engaged in similar efforts (e.g., [10–14]), most developing either epiretinal [6,7] (on the front of the retina inside the eye) or subretinal [8,9] (behind the retina, between the retina and choroid) devices. Others focus on less direct stimulation of the retina using a supra-choroidal (behind the choroid, between the choroid and the sclera) or trans-scleral (outside of all or part of the sclera) approach [10–12]. Our team began with an epiretinal approach, used in the acute human surgical trials described above

Abbreviations: RP, retinitis pigmentosa; AMD, age-related macular degeneration; PXI, PCI extensions for instrumentation; ASK, amplitude shift keying; SIROF, sputtered iridium oxide film; PWM, pulse width modulation; ERG, electroretinogram; PDMS, poly(dimethylsiloxane).

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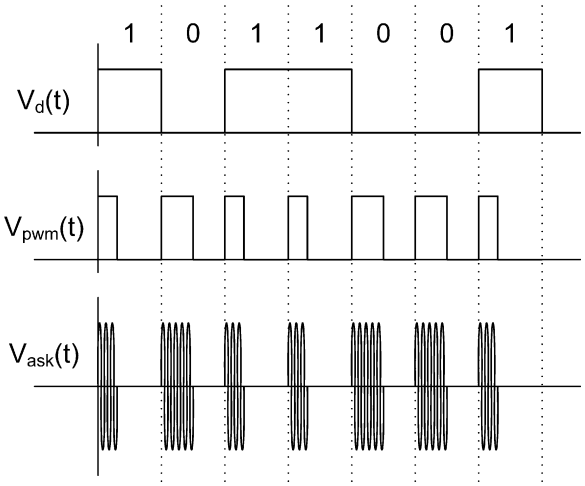

Fig. 1. Data were encoded in the carrier by amplitude shift keying (ASK), with pulse width modulation (PWM) encoding of bits. The carrier was fully modulated, with a duty cycle of 30% to represent a 1, and 50% to represent a 0.

[4,5], but has changed to an *ab externo* subretinal surgery. This approach results in improved biocompatibility and a less invasive surgery, and it leaves the bulk of the implant device outside the eye.

Our first-generation wirelessly-powered chronic retinal stimulation device [1] was implanted in Yucatan minipigs during the spring and summer of 2008. We now describe an improved version of the implant, with the circuits encased in a hermetic titanium enclosure, the coils moved to a more magnetically-favorable position, and easier surgical access for electrode array insertion. We also describe in detail our power and data telemetry systems.

2. Implant design methods

2.1. System description

Our retinal prosthesis system includes an external PXI computer-based controller with a user interface for selecting which electrodes to drive and with what level of current. Data from the computer system were sent to a power amplifier, which then transmitted wirelessly to the implant by near-field inductive coupling. Data at 100 kbps were encoded by amplitude shift keying (ASK) on a 15.5 MHz carrier. Power was also wirelessly transmitted to the implant using a 125 kHz carrier, and was rectified by the implant to create ±2.5 V power supplies.

A custom integrated circuit [19], shown in Fig. 2 and fabricated in 0.5 μm CMOS, received and decoded the incoming data and delivered stimulating current to the appropriate electrodes based on the timing of transmitted commands. The chip was capable of delivering up to 930 μA of current per channel at steps of 30 μA. This circuit was designed to be an extremely flexible research tool, and was capable of delivering more current than was needed for this animal work. Currents typically delivered to electrodes ranged from 30 to 240 μA. The chip consumes 1.3 mW, excluding current sources. In typical stimulation modes (180 μA, 1 ms per phase biphasic pulses, repeated every 20 ms), the total implant power consumption is approximately 2 mW.

The package containing the chip was attached to the outside of the eye, and its electrical stimulation current was delivered to the retinal nerve cells via a thin-film microfabricated array of sputtered iridium oxide film (SIROF) electrodes, which was surgically inserted into the subretinal space through a flap in the sclera.

In a future clinical implant, patients will wear a camera mounted on glasses, and will carry a small battery-powered controller which will perform the required image signal processing, intelligently extracting features from a megapixel image and re-creating that image with dozens or hundreds of electrodes.

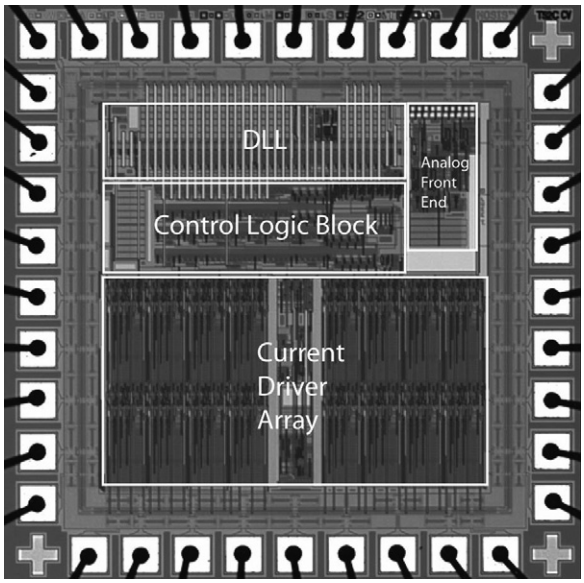

Fig. 2. Custom integrated circuit for the retinal prosthesis. This 0.5 μm CMOS (3M2P) chip with 30,000 transistors received incoming stimulation data, decoded it with an envelope detector and a delay locked loop, and delivered the appropriate stimulation currents to electrodes with 15 current sources.

2.2. Differences from first-generation device

Our first-generation implant [1] was assembled on a flexible substrate that wrapped around the eye inside the socket, attaching to the sclera of the eye (Fig. 3). This device had three significant design drawbacks: (1) small receiver coils limited power and data telemetry effectiveness due to poor coupling; (2) the silicone coating held up well in studies of up to 10 months, but did not appear to be viable for chronic trials of 5–10 years; and (3) the required surgical approach for electrode array insertion was very challenging, due to the need to insert the array through the coils. In addition, the power and data telemetry amplifiers used with the first-generation device had limited range and reliability. The class E amplifier used for power transmission used a startup circuit which did not always start reliably, and the class A amplifier used for data transmission

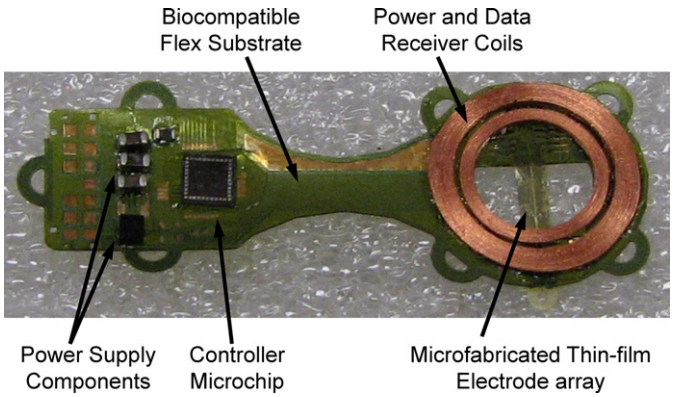

Fig. 3. First-generation retinal prosthesis. The flexible implant wrapped around the eye, with coils and 15-electrode array in the superior-temporal quadrant and circuitry in the superior-nasal quadrant. The prosthesis received power and data by inductive coupling on separate telemetry channels, and the electrode array accessed the subretinal space via an incision through the sclera of the eye.