Vision Project

Sponsor

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Website

http://rleweb.mit.edu/retina

1.0 Narrative Description of Progress to Date

The vision project seeks to develop an implantable retinal prosthesis to restore vision to blind patients. Individuals who are born with normal sight but then lose vision slowly from degeneration of their rods and cones are potential candidates. Retinitis pigmentosa and age-related macular degeneration are two important forms of blindness we hope to treat.

Our primary immediate goals have been to perform two proof-of-concept experiments: 1) human experiments (lasting two to three hours) to assess what blind patients can see when electrical current is delivered to the retina through a 10 x 10 microelectrode array, and 2) series of animal surgical trials in which a simple prototype prosthesis is surgically implanted and activated to stimulate the retina, with the induced activity being electrically recorded over the visual cortex. Success in these endeavors would demonstrate that the concept of an epiretinal prosthesis is feasible in principle. In such an optimistic outcome, the only remaining obstacle to clinical use of a retinal prosthesis in humans is demonstration of long-term biocompatibility of an implanted device, which would require major additional effort.

1.1 Human Surgical Trials

1.1A Engineering preparations

Stimulator Box

We have made several changes in the stimulator box based on the results of our first two human experiments (see below). To increase the maximum current output up to the safety limits of the electrodes, Shawn Kelly, with help from Steve Finberg at Draper Laboratory, replaced the ten original current sources with others designed at Draper for the Cochlear Implant. The new current sources supply more current and have lower offset voltage and higher output impedance

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than our original ones. The new current sources require different power supplies. Therefore several different sets of batteries are used, and the power regulators have been redesigned.

After the second human experiment we decided to increase the maximum pulse duration the box could supply. Mr. Kelly altered the digital control hardware in the box to allow more flexibility in pulse widths, pulse width ratios, stimulation frequencies, and other timing parameters. We are pleased that the stimulation box performed as expected in each of the three human trials to date.

Microelectrode Array

Based on the results of the first human surgical trial, we decided to redesign the polyimide electrode array to include monopolar electrodes that would be used in conjunction with a return electrode placed remotely on the patient's arm. Furthermore, the size of these electrodes was greatly increased, to 400 microns in diameter. The purpose was to compare our results with those obtained by the Hopkins group using similarly sized (but non-microfabricated) electrodes and to enable gross two-point discrimination experiments during surgery. Dr. Douglas Shire microfabricated these new arrays at the Cornell Nanofabrication Facility. They worked well during surgery without electrical failure or detectable damage to the patients' retinas.

While microelectrode failure had not occurred during our early human trials, we felt it prudent to conduct a series of experiments to determine any failure mechanisms of the microfabricated electrodes under conditions of current overstress and over-oxidation. We found the iridium layer on the electrode surface could be completely consumed during oxidation, leading to cracking of the oxide surface. The solution is simply to have a sufficient margin of extra iridium, so that some remains after the oxidation has been completed to the desired charge capacity. We also found that electrodes overstressed with electric current in bipolar mode gave rise to micro electroplating of the surface material to nearby return electrodes, eventually resulting in an open circuit.

The microelectrodes were overstressed by Prof. Wyatt at MIT and the materials analysis was done by Dr. Shire at Cornell. These tests gave an accurate quantitative measure of the allowable oxidation and allowable current for these electrodes and help us ensure against decomposition of the electrode arrays during or in preparation for surgical trials.

Single-Needle Electrode

For the second human surgical trial we decided to first use a narrow platinum/iridium single needle electrode to verify electrically induced perception before making a larger incision to place the microelectrode array on the retina. These needle electrodes were coated at the tip with a chromium/iridium metallization, which we subsequently oxidized to increase the charge capacity.

1.1B Human test results

Within the last year we have performed three human surgical trials in which we electrically stimulated the retina while the patients were awake but anesthetized. Our primary goals were to: 1) obtain activation thresholds with the different sized electrodes; 2) perform two-point discrimination experiments and 3) achieve visual perceptions with geometric detail. Positive outcomes in these three areas would suggest that long-term retinal stimulation might provide “useful” vision to a blind patient, perhaps by allowing them more independent mobility. All three experiments were performed without harm to the patient or a change in their visual status. All patients had end-stage retinitis pigmentosa with the ability to see only motion of a hand in the eye chosen for experimentation.

First Surgery

Retinal stimulation was performed by passing electrical current through a microfabricated electrode array (100 electrodes) placed on the retinal surface. This was the first time that any research group tried to place a microfabricated device on the human retina. Our stimulating electronic system (build by Shawn Kelly, see above) worked as planned, providing accurate charge, real-time evidence that the desired charge was being delivered to the electrode array and relative ease of use. The stimulator was designed to deliver charge up to the acceptable limit for platinum electrodes, which we assumed would be used in the first test. However, in the months prior to the first experiment Doug Shire successfully built iridium electrodes on the array, which we oxidized and used for the surgery. We chose to carry out the surgery despite the fact that the stimulator could not deliver the full charge allowed for iridium primarily because we thought that available charge would be adequate (based upon animal tests and other considerations).

Outcome: Our volunteer reported seeing "faint, barely perceptible" spots of light in response to 6 of our 12 bipolar stimulations, and 1 of 12 monopolar stimulations. No geometric images were detected.

Conclusions: The following is a list of considerations that might have limited our results:
1) Retinal degeneration was too far advanced.
2) Electrical overstimulation of the retina, producing neural fatigue.
3) Larger currents are needed to get a repeatable response.
4) Anesthetic medication impaired retinal responsiveness.
5) Surgical trauma (in some non-obvious way) impaired retinal responsiveness.
6) The stimulus frequency; total length, polarity or some other parameter was inadequate.
7) Failure to preselect volunteers with extraocular electrical stimulation to determine if any perceptions would occur in advance of intraocular stimulation testing.
8). Ambient light affected the response.
9) Patient's unfamiliarity with phosphenes: exposure over hours or days might produce better results.
10) Existence of a leakage path for current, reducing current delivery to retina.

Plans for improvement: Factors that seemed most likely to have caused the sub-optimal results were modified. They included: 1) redesign and building stimulator box to provide charge up to the limit for oxidized iridium electrodes; 2) plan to begin the next experiment with a hand-held single monopolar electrode (400 μm diameter) to scan the retina for more responsive regions; 3) redesign of the microfabricated electrode array to contain two electrodes center geometries (400 μm center in addition to the 40 μm center in the original design) to permit threshold comparisons of the larger electrode size between the hand-held electrode held positioned slightly above the retina) vs. the array placed in contact with the retina (see above for additional comments about changes in the electronics and electrode array).

Second Surgery

Roughly 50 stimulation trials were conducted using a hand-held single monopolar electrode. The second-generation stimulator box was used to deliver greater charge than could be used in the first experiment (see above under "stimulator box" for details).

Outcome: The patient reported vague responses ("circle", "something real dim") to a small percentage of electrical stimulation trials. The responses occurred almost exclusively at higher currents, in the milliamp range. We performed six control trials in which electrical stimulations (17) were interwoven with negative (i.e. no electrical current) control tests (7). In one instance he reported a "light circle – real dim, dim" with a negative control test. We did not place the microfabricated electrode array into his eye because only meager perceptual responses were obtained with the large hand-held electrode, which was positioned over much of the central and peripheral retina and around the optic nerve. It was anticipated that the array would not yield

better results and attempts to insert the array would have (slightly) increased the risk of damaging the eye.

Conclusions: Primary considerations to explain the poor perception included: 1) insufficient charge delivered to retina; 2) surgical manipulation or medications might have altered retinal responsiveness; 3) retinal condition was too far advanced to respond to electrical stimulation. Most of the considerations listed in the section regarding the first surgery seemed less relevant.

Plans for improvement: 1) Pre-select next patient by performing extraocular electrical stimulation as a screening test to hopefully identify patients whose retinas might be more responsive to electrical stimulation. Subsequent extraocular stimulation testing revealed that our third patient could perceive much more detailed visual perceptions than had been obtained in our first two intraocular stimulation experiments, but only at phase durations at or greater than 4 millisec. (The longest phase duration used in the two prior experiments was 2.5 millisec.) 2) Redesign the stimulator box to deliver at least 16 millisec phase durations (which was the maximum used in the extraocular stimulation screening test; see a "stimulator box" above for more details).

Third Surgery

One hundred sixteen stimulations were performed. The first 48 stimulations were delivered with a single hand-held electrode; the remaining 68 were delivered with both the larger and smaller electrodes on the microfabricated electrode array.

Outcome: Thresholds were obtained for each of the three electrode types: 1) single electrode held in the mid-vitreous cavity and near the retina; 2) large electrodes (400 μm diameter) on microfabricated electrode array positioned on the retina; 3) small (40 μm diameter) electrodes on microfabricated array positioned on the retina. Reproducible perceptions were obtained and nearly flawless performance on control testing was obtained. No clear and consistent perceptions with geometric detail were obtained. Table 1 summarizes all stimulations and responses.

Summary of human test results to date.

The third test produced the best responses by far. The two seemingly most significant considerations to explain the improved results include use of considerably longer stimulus phase durations and less advanced state of retinal degeneration. Despite similar visual acuity among the three patients, the last patient developed visual loss later in life, her progression was slower and her optic nerve was not pale (unlike the first two patients). The substantially better results obtained with the extraocular stimulation screening test in the third patient compared to the second patient (who underwent this test after his intraocular stimulation experiment) correlated with better intraocular test results. This screening test will be used to help select future volunteers for the intraocular experiment.

The inability to obtain perceptions with geometric detail (by us or the Hopkins' group) still calls into question the potential clinical value of a retinal prosthesis. The sub-optimal results could be explained by the advanced state of retinal degeneration of the patients tested to date, in which case it is possible that patients with less advanced retinal degeneration could be helped by intraocular stimulation. Hence, we plan to test patients with healthier retinas in the future. It is also possible that chronic retinal stimulation of very advanced patients might produce more detailed perceptions over time (vs. testing only during an acute surgical trial). We are therefore considering the possibility of chronically implanting a stimulating electrode array (without active electronics) as a means of testing retinal responsiveness over weeks to months to learn if perceptions improve over time.

Stimulus Strategy and Perceptual Results: Third Human Surgery

(Listed chronologically)

Electrode type	Location	Phase durations tried	Range of Current (per electrode)	Approximate Threshold Current	Example of perception
Single hand-held electrode	Mid-vitreous	16 msec (30 Hz/1.5 sec…)	49-147 μA	147 μA	Dark triangle
		8 msec	147–294 μA	250 μA	Round flash, like a pea seen at arms length.
		4 msec	245–588 μA	490 μA	Round, like a mushroom on its side, with a hard-to-see tail extending to the left.
		2 msec	784–1176 μA		No perception.
Single hand-held electrode	Retinal surface	8 msec	49-147 μA	147 μA	Dark spot
		16 msec	49-58 μA	58 μA	Butterfly; size of a quarter.
Large electrodes on array	Peripheral retinal surface	8 msec (6 Hz…)	49-9800 μA	All 8 electrodes: 196 μA. Column 1 (4 electrodes): 245 μA. 2 electrodes: 343 μA.	All 8 electrodes: broken diagonal line. Column 1 (4 electrodes): line, not broken, dark., yellow. 2 electrodes: very faint image.
Small electrodes on array	Peripheral retinal surface	8 msec	Single electrode (9,1): 74-592 μA	Single electrode: --.	No perception.
Large electrodes on array	Macular surface	8 msec	Two electrodes: 147-441 μA. Single electrode:245-441μA. All 8 electrodes: 245 μA.	Two electrodes: 441 μA. Single electrode: 392-441 μA. All 8 electrodes: 245 μA.	Two electrodes: clouds; non-descript; flashing. Single electrode: light path, 3 inches. All 8 electrodes: different sized broken spots.
Large electrodes on array	Macular surface; slightly more inferior.	8 msec	Two electrodes: 245-637 μA. Single electrode:245-637 μA.	Two electrodes: 245 μA. Single electrode (10,10):441 μA. Single electrode (1,10): 588 μA.	Two electrodes: flashing dark spots. Single electrode (10,10): dark spot; Single electrode (1,10): less distinct flash.
		8 msec (30 Hz…)	Two electrodes (1,10; 10,1): 392 μA. One electrode (1,1): 392-637 μA.	Two electrodes (1,10; 10,1): 392 μA. One electrode (1,1): 392-637 μA.	Two electrodes (1,10; 10,1): spots are dark and different sizes. One electrode (1,1): no perception.
		8 msec (6 Hz)	Single electrode (10,10): 392-588 μA.	Single electrode (10,10): 539 μA.	Single electrode (10,10): faint spot(s).
Small electrodes on array	Macular surface, inferior.	8 msec (6 Hz)	Single electrode (9,10): 148-592 μA. Column 9 (8 electrodes): 296-444 μA. Columns 8,9 (16 electrodes): 444 μA. Columns 7,8,9 (24 electrodes):444 μA. Column(s): 2; 2&3; 2,3 & 4: 444 μA. Column 7,8 & 9 (bipolar & monopolar): 444 –740 μA.	Single electrode (9,10): --. Column 9 (8 electrodes): --. Columns 8,9 (16 electrodes):444 μA. Columns 7,8,9 (24 electrodes): --. Column(s): 2; 2&3; 2, & 4: --. Column 7,8 & 9 (bipolar): 592 μA.	Single electrode (9,10): no perception. Column 9 (8 electrodes): no perception. Columns 8,9 (16 electrodes): mist. Columns 7,8,9 (24 electrodes):mist. Column(s): 2; 2&3; 2,3&4: no perception. Column 7,8 & 9 (bipolar): no perception; mist.

1.2 Biocompatibility Tests

The ultimate goal of this work is to become surgically capable of implanting a prototype prosthetic device in an animal eye for months without adverse ocular reaction. Drs. Rizzo, Loewenstein and Shahin have conducted experiments related to in-vivo biocompatibilty of an implanted device. These tests, which over the past nine months have been performed in 24 rabbits, 3 dogs and 12 pigs, have mostly involved surgical methods to remove cortical vitreous and to attach a stimulating electrode array to the retinal surface. Additionally, tests of biocompatibility of bulk materials of a fully microfabricated electrode array and separately of an epoxy used in the construction of our prototype prosthesis were performed over a one year long period in three animals.

Ocular examinations of the animals that underwent surgery to remove cortical vitreous or to glue an array on the retinal surface revealed in roughly 75% of cases moderate to severe intraocular inflammation. These reactions occurred despite use of ocular and systemic corticosteriods and use of two-staged surgical procedures in some animals. Use of our novel retinal glue (previously described to you) achieved retinal adhesion in only roughly 1/3 of the cases in which gluing was attempted. The major limitation seemed to be the difficulty drying the retinal field to enhance bonding of the glue. In all but one case in which gluing was successfully accomplished, subsequent follow-up revealed detachment of the array from the retina up to two months post-operatively. The reasons for such late failures are unclear. Continued difficulty in achieving complete surgical success has made it impossible to perform long-term tests of implanted prototypes, as described in our report of last year to Keck.

The bulk materials biocompatibility tests revealed no physiologic or histologic compromise of the retina.

1.3 Hermetic encapsulation testing

The implantable electronic components of a retinal prosthesis will not function if directly exposed to the fluids in the eye. A protocol was developed to determine the chronic *in vitro* electronic stability of an implant encapsulated in a transparent silicone elastomer.

Draper Laboratory, with the assistance of graduate student Joshua Moss, had designed and constructed a sensitive, automated in vitro test apparatus. The apparatus can measure sub-picoampere current leakage and support multiple test specimens in a heated saline environment indefinitely. In addition, models that reproduce the salient dimensions and material interfaces of the proposed prosthesis have been designed and fabricated. Each model contained two platinum wires, a silicone-polyimide interface and either a silicone-platinum or a silicone-Teflon^{TM} interface. The models were immersed in saline, and the platinum wires were used to detect saline leakage at any of the material interfaces. A complete electric circuit from the saline to the wires therefore represented a potential leakage path to the components of an actual implant. At 37^{o}C, one volt was applied across the saline and platinum wires. Currents between the wires and saline were measured every 10 to 15 minutes over 4 to 8 weeks.

In early tests, six models exhibited no deleterious leakage at the silicone-polyimide interface for at least four weeks, indicating that silicone elastomer is an effective encapsulant at the silicone-polyimide interface. Also, a silicone-platinum interface showed no leakage while a silicone-Teflon interface was predictably unsuccessful. However, the models are becoming increasingly sophisticated and more representative of an actual implant, and three of three of the most recent models have shown leakage at almost all interfaces. We are now researching existing techniques for encapsulating implantable electronics with appropriate feed-through and evaluating them for applicability to this project. An encapsulation technique combining silicone and epoxy will be tested with new models in the coming months.

1.4 Mechanical design of second-generation retinal prosthesis

The “next generation” design moves the majority of the implant off of the sensitive retina and places the power/drive electronics onto an intraocular support structure positioned in the plane of the normal lens of the eye. The only required part of the implant in contact with the retina is the electrode array that is light, flexible, and significantly less damaging to the eye. The primary objective was to minimize contact with the retina and improve the design of our retinal prosthesis to enhance its long-term biocompatibility.

The mechanical design of the retinal implant prosthesis has evolved to take advantage of lessons learned from previous configurations and implant methodologies. In support of the new configuration, Draper has prototyped a platform structure intended to be an inexpensive custom-designed component. Prototypes were created using the StereoLithography (SL) process available at Draper. During the period of performance, five new units were created.

Prototype “dummy” implants were prepared and delivered to Dr. Rizzo for animal testing. Iterative designs were made based upon results at animal surgery. Surgical implantation of the most recent version of the prototype with dummy electronics, which we suspect will be acceptable for long-term testing in rabbits will be performed within the next two weeks.

Draper has continued to develop the IOL design and has fabricated prototypes of the support structure using StereoLithography. As has been noted in the past this process is being utilized for design development only. The photopolymer material is not considered to be a biocompatible material and will not be used as such for chronic testing. The objective has

1.5 In-vitro retinal stimulation studies in rabbit

In the past year doctoral student Andrew Grumet has made significant progress investigating retinal responses to microelectrode array stimulation. Refinements in experimental methods permitted Andrew to characterize thresholds for generating single spikes in optic nerve fibers on the surface of the rabbit retina.

Initial measurements of this type will be presented in a poster session at this year's ARVO meeting in May. These experiments employed an electrode array of 61 hexagonally-arranged, ten-micron diameter disks on 70 μm centers, fabricated by Dr. Shire. Each electrode can be used for either stimulation or recording. Stimuli were delivered to locations roughly along a line joining the recording electrode and optic disk, about 100-500 μm away from the recording electrode. Electrically evoked responses exhibited classic properties of action potentials, such as all-or-none and strength-duration behavior. Responses also appeared to be the result of direct (rather than trans-synaptic) stimulation, arriving less than 1ms after the end of the pulse and robust at repetition rates up to 540 Hz. The orientation (relative to the optic disk) and large separation distances of the stimulating and recording electrodes implied retrograde, or axonal, stimulation. The stimulation thresholds (about 0.25μA, or 100pC, for a 400μs pulse) were much lower than most reports in the literature. Possible explanations for the difference could be the small stimulating electrodes and the current confinement resulting from the insulating backplane on which the electrodes were patterned. We were encouraged to find that the threshold charge densities were at least five times below currently accepted limits for safe stimulation (1mC/cm^2 for activated iridium oxide) for pulses less than 600 μs in duration, despite the use of such small stimulating electrodes.

Mr. Grumet has designed and Dr. Shire has fabricated a new electrode array pattern for experiments conducted this spring. Half of the available electrodes are aligned in a rectangular grid and spaced at twenty-five micron intervals. These electrodes were used exclusively for stimulation, permitting detailed mapping of stimulation thresholds as a function of electrode position. Threshold maps of nine fibers were made by sequentially driving a number of these electrodes monopolarly (with distant return) and monitoring the responses at a recording

electrode. Minima ranged from 0.1 to 0.2 μamps (for a 400 μsec pulse) and increased by approximately tenfold at a distance of 40 μm. Additional measurements were made with the stimulator connected across pairs of these electrodes (bipolar stimulation) to investigate thresholds as a function of field orientation relative to the fiber direction. Thresholds for perpendicular fields were found to be two to three times higher than for parallel fields, provided the fiber was far enough away from the stimulating electrodes (25 μm for 50 μm dipole spacing) that longitudinal fringing fields were minimal. This last result is qualitatively consistent with theoretical models developed in Mr. Grumet's M.S. thesis and may form the basis for a strategy to minimize fiber stimulation. This should allow an epi-retinal prosthesis to generate a much better quality of visual perceptions.

2.0 Problems encountered or unexpected developments

Human surgery

The first two patients showed substantially poorer results than hoped for. We made five changes in procedure (longer pulse durations, larger available currents, inclusion of large as well as small electrodes on the array, the single-needle electrode and the presurgical extraocular stimulation test as part of screening) and selected a patient who appeared to have a less severely degenerated retina. These differences likely helped in yielding much better results in the third patient. All procedural changes will continue to be incorporated in future experiments. The changes in the stimulation box have required a major increase in circuit size and complexity that make the entire system somewhat unwieldy.

Biocompatibility

It continues to be difficult to reliably remove cortical vitreous from young animal eyes despite use of all methods suggested in the literature. We also continue to experience unacceptable post-operative inflammation in a large percentage of animals. The explanations for the animal-to-animal variation in the tendency to inflammation are unclear. We have not been able to identify a vendor to supply us with older adult animals that might have less adherent cortical viteous (as is true for humans) and possibly be less prone to severe inflammation.

In-vitro retinal stimulation studies in rabbit

Andy Grumet has found it difficult to record from a single axon with a microelectrode array when the stimulus is electrical. Electrical stimulation causes a number of axons to fire simultaneously, and microfabricated electrodes are not sufficiently selective to isolate a single fiber. He has circumvented this problem for his doctoral work by recording ganglion cell body responses due to retrograde stimulation.

Encapsulation of a retinal implant

The sensitive test system developed by Josh Moss has detected saline leakage in all his more recent tests. Improved methods of bonding to polyimide must be explored. We will also test bonding of the silicone encapsulant to silicon, which could be used rather than polyimide to microfabricate our electrode array.

3.0 Further progress expected within the next six months

We expect to continue human stimulation tests. We will attempt to identify patients with slightly better retinal function, within criteria established by the human studies committee at the Massachusetts Eye and Ear Infirmary and the Massachusetts Institute of Technology.

Shawn Kelly has begun preliminary literature research on magnetically coupled transmission and low-power circuits in preparation for advanced circuit design work for his doctorate. He should have a clear plan of attack in place by the end of October.

Josh Moss will begin testing new encapsulation techniques with new models over the next few months, while training a new student who will take his place when Josh leaves for medical school. He and his successor will determine if silicone will bond better to a silicon electrode array than to polyimide, or whether epoxy is a better encapsulant.

Andrew Grumet will complete his doctoral dissertation describing his multielectrode in vitro stimulation apparatus and his results to date. He will continue his work as a postdoctoral fellow, altering the system to allow for conventional single-electrode recording from axons while stimulating with the microelectrode array.

Scientific Publications

J.F. Rizzo and J.L. Wyatt, Retinal Prosthesis, Age-Related Macular Degeneration, Mosby, Inc: 412-432, (1999).

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A.E. Grumet and J.L. Wyatt, Jr., "Multi-electrode stimulation and recording in the isolated retina," submitted to *Jour. Neuroscience Methods.*

Presentations

A.E. Grumet, J.F. Rizzo, J.L. Wyatt, Ten Micron Diameter Electrodes Directly Stimulate Rabbit Retinal Ganglion Cell Axons, *Association for Research in Vision and Ophthalmology,* Ft. Lauderdale, FL, May 9-14, 1999.

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J.F. Rizzo, J. Loewenstein, S. Kelly, D. Shire, T. Herndon, J.L. Wyatt, Electrical Stimulation of Human Retina with a Micro-fabricated Electrode Array, *Association for Research in Vision and Ophthalmology,* Ft. Lauderdale, FL, May 9-14, 1999.