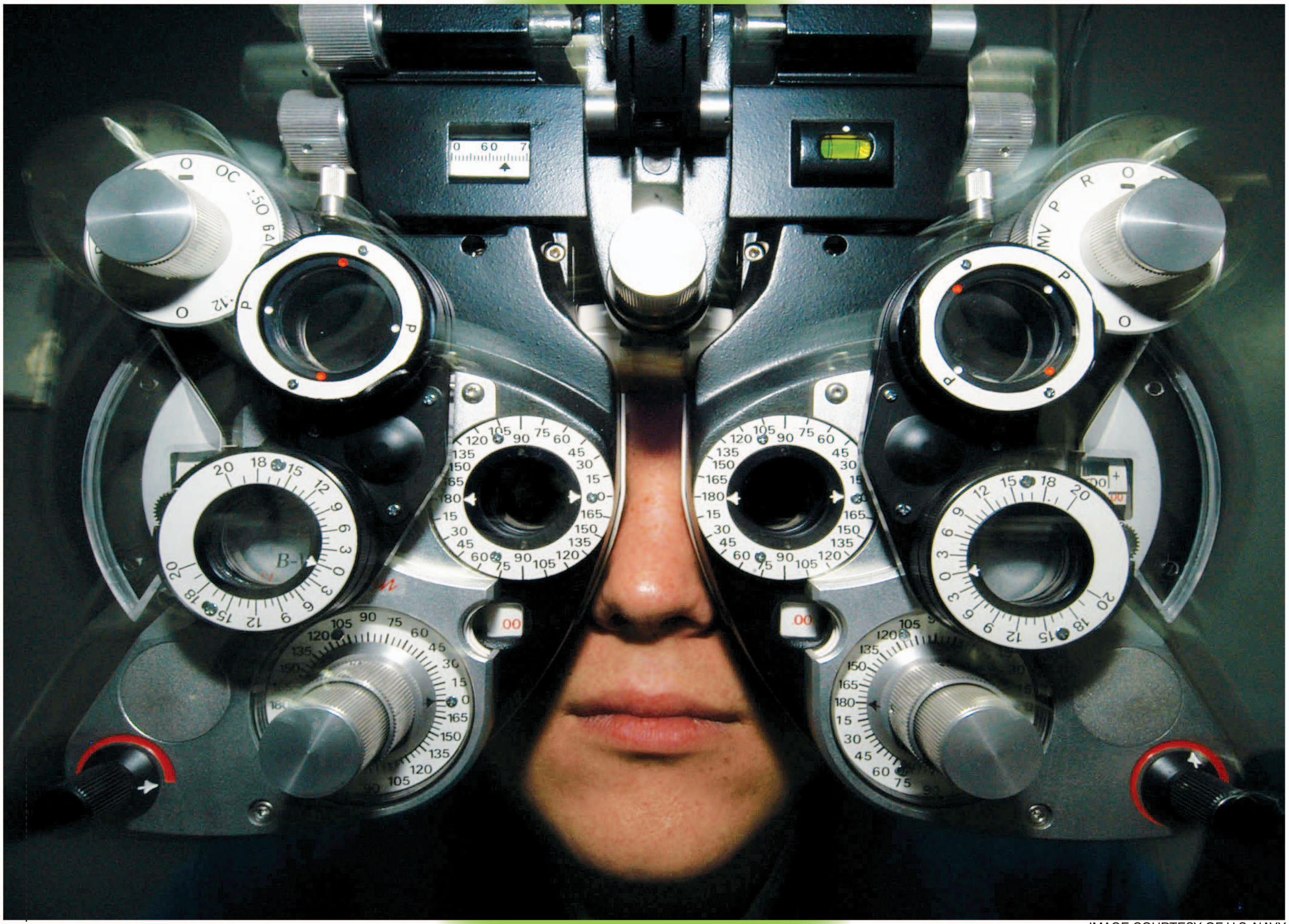

IMAGE COURTESY OF U.S. NAVY

By Leslie Mertz

Sight Restoration Comes into Focus

Versions of Visual Prostheses

The first visual prosthetic is on the commercial stage now, and a variety of new retinal and cortical implants are in the wings. When it won the European stamp of approval last year, the Argus II became the first commercially available visual prosthesis. Now Second Sight Medical Products Inc. of Sylmar, California, the company behind the Argus II, hopes to receive approval to sell the device in the United States by late 2012. As the excitement over the Argus II continues at a fever pitch, other research groups are developing their own versions of visual prostheses, working to create the potential for restoring sight.

Currently, two major approaches to visual prostheses exist, and each approach concentrates on a different point along the visual pathway. In a person who has normal sight, light travels through the eye to the retina, which is at the rear of the eyeball. There, photoreceptor cells—the rods and cones—decipher the visual input in such a

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way that nerve cells, or neurons, can transmit useful information to the optic nerve and then to the brain, where it is processed into vision.

Retinal implants, including implants that are attached to either the front surface of the retina (epiretinally) or the rear surface (subretinally), are designed to step in for nonfunctioning photoreceptor cells. People who have retinitis pigmentosa and macular degeneration have nonfunctioning photoreceptors, but the remainder of the visual pathway works. The retinal implant replaces this gap in the visual pathway to help restore vision.

Retinal implants are designed to step in for nonfunctioning photoreceptor cells.

Cortical implants are designed to bypass most of the visual pathway, so that signals go from an external camera to the implant on the visual cortex, which is the brain's visual center. Cortical implants have the potential to generate some level of sight among those who have vision loss due to any number of disorders, including glaucoma, diabetic retinopathy, severe optic atrophy, or trauma.

Argus II—On the Market

In the Argus II retinal implant system, the patient wears a pair of glasses with a very small video camera embedded in the bridge of the nosepiece (Figure 1). The camera's video signal is processed by a hip-worn computer called a visual processing unit (VPU), which allows the patient to control the signal for varying levels of contrast, brightness, and other parameters (Figure 2). The processed video data then return to the glasses, which are equipped with a little antenna so that they can send the data and power wirelessly across the skin to the implant (Figure 3). The implant consists of a receiver, a stimulator, and an array of 60 electrodes. When the video signal arrives at the receiver, it is forwarded to the stimulator. Both the receiver and stimulator sit outside of the eye under the conjuctiva, the layer of tissue that covers the white of the eye or sclera.

"The stimulator is attached to the array, which is tacked onto the front surface of the retina. The stimulator, having received instructions from the VPU, provides the appropriate electrical signals to the electrodes in the epiretinal array," explained Brian Mech, Ph.D., M.B.A., vice president of business development at Second Sight. At that point, the electrodes produce and deliver an electrical current directly to the underlying neurons of the retina. Each neuron has a long projection called an axon, or nerve fiber. The axons fire, transmitting the electrical impulse to the optic nerve that, in turn, carries the signal to the cortex, which does its own processing to produce vision.

The point of the Argus II is not to produce 20/20 eyesight but to provide sufficient vision for these patients to navigate their lives more easily. "We take patients who are blind and essentially bring them back up to low vision, so they have more independence," Mech said. "With the implant, they're much better at orientation, mobility, and some tasks of daily living. They can have a better knowledge about their environment. For instance, they can avoid obstacles, know when people are approaching or walking away, detect motion, find doors and windows, and other tasks of daily living, such as sorting laundry, that are very hard to do with a sense other than vision."

Second Sight markets the Argus II for use in patients who have severe to profound vision loss due to retinitis pigmentosa (RP), and the company anticipates running a small pilot study soon on patients who have advanced age-related macular degeneration (AMD). "The expectation of device effectiveness is similar with RP and AMD. We started testing our device with RP patients, as do all of the retinal-prosthesis research groups, because these patients are completely blind, which means there was little chance of jeopardizing any residual vision if the device wasn't perfectly safe," Mech added. In comparison, people who have macular degeneration lose vision in the center of the visual field, but usually retain their peripheral vision. "Since we're the only group out there with an approved device, and we're the only ones with long-term clinical trial data at multiple centers and in multiple countries, we're obviously the ones who are closest to being able to try it with AMD," he said.

The Argus II also has other benefits. "Because we have this external camera and processor, we can do a great deal to improve vision without ever having to put in a new implant," Mech said. "We're learning all the time about how to process video better and how to stimulate the implant better, so we've made huge progress by just changing the externals and software." The company is currently developing a new VPU to go with a smaller pair of glasses. "The new VPU will have a completely new processor, because the processors that are available now—as opposed

FIGURE 1 Shown on this mannequin, the Argus II retinal prosthesis received the CE mark in 2011, allowing it to be sold in Europe. Second Sight Medical Products Inc., the company behind the device, hopes to receive U.S. Food and Drug Administration (FDA) approval later this year. (Photo courtesy of Second Sight Medical Products Inc.)

FIGURE 2 The external components of the Argus II include a pair of glasses with a very small video camera embedded in the bridge of the nosepiece. The camera's video signal is processed by a rectangular, hip-worn computer (shown) called a VPU. The patient can control the signal for varying levels of contrast, brightness, and other parameters. (Photo courtesy of Second Sight Medical Products Inc.)

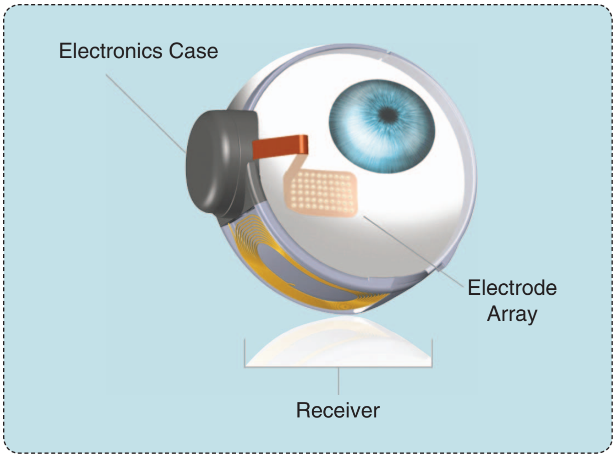

FIGURE 3 The processed video data from the Argus II's VPU returns to the glasses, which forward the signal wirelessly across the skin to the implant (shown here). From the receiver, the signal goes to a stimulator and then to a 60-electrode array that ultimately delivers current to the underlying neurons. (Illustration courtesy of Second Sight Medical Products Inc.)

to ten years ago when we originally designed that VPU—are maybe 10,000 times faster and more powerful. That means that we can do things we couldn't even consider before, such as very advanced video processing in real time," he said. "We're very excited about that."

Even so, the road to commercialization for the Argus II device has been a long and expensive one. "What people don't realize is that we're a company of more than 100 people. It's taken well over US$150 million, perhaps closer to US$200 million, to get to this point," Mech said. That includes about US$30 million in grants from the National Eye Institute. The time frame has already been about 13 years, as engineering work on the device began in 1999. Animal and eventually human studies followed, with the main, 30-patient clinical trial beginning in 2007. The CE Mark came in 2011, with U.S. FDA approval possibly coming later this year.

256-Plus Electrode Array That Lasts

A number of other research groups hope that their retinal prostheses will join the Argus II in the marketplace soon (see also "Photovoltaic Approach"). One prospect is a microelectronic retinal implant (Figure 4) under development by the Retinal Implant Research Group at the Massachusetts Institute of Technology (MIT) and the Massachusetts Eye and Ear Infirmary (MEEI). The group has now created a company, Bionic Eye Technologies, to commercialize the system.

The MIT retinal implant works on the same principle as the Argus II. "We're using an electrode array on the retina to try to stimulate the nervous system at a point downstream of the damage, but still upstream of the brain," said John L. Wyatt, Ph.D., professor of electrical engineering in MIT's Research Laboratory of Electronics. He is also a principal investigator in the Retinal Implant Research Group, which he founded with Joseph Rizzo, M.D., professor of ophthalmology at Harvard Medical School and director of the Neuro-Ophthalmology Service at MEEI (Figure 5).

The research group began its work in this field 23 years ago and has already built four generations of its implant. "We've put the first three generations into Yucatan mini-pigs for about ten months each to determine not what the animal can see with them, but how the retina responds to the chronic presence of the device," Wyatt said, noting that the group expected to begin installing its fourth-generation implant in the pigs in late summer of 2012 [1].

A fifth-generation retinal implant, which is scheduled for completion in a matter of months, is designed for human use and will be a long-term device, Wyatt said. "It will be truly hermetically sealed, so we believe that it could be perfectly usable inside a patient for 30 years."

Another advancement in the fifth-generation implant is the number of electrodes in the array. Similar to how more pixels on a computer screen produce an image with higher resolution, a larger number of electrodes in the retinal array should yield vision with more detail. "The first three generations of the array had 15 or 16 electrodes. The fourth had more than 256 electrodes (the exact number is classified), but we could only drive 16 of them because of the chips that were available," Wyatt noted. The fifth-generation array will likewise have more than 256 electrodes, but the research group is building a microchip that is specifically designed to complement the array and will afford separate control of each of the 256 electrodes, which potentially will provide better vision to the patient.

Similar to the Argus II system, the MIT system incorporates a pair of glasses with a camera. The camera will connect to a smaller processor that the person will carry in a pocket. The image signal from the processor will travel to a coil that wraps around the outside of one of the lenses in the glasses. The coil will, in turn, transmit the signal as well as power to an electronics unit implanted beneath the conjuctiva, and this unit will selectively control the electrodes in the array.

One of the major differences between the MIT and Argus II systems is the placement of the array. Unlike the Argus II array, which attaches to the front surface of the retina, the MIT array attaches to the back surface of the retina. The MIT research group opted for the rear-retinal placement for several reasons. "The electrode array needs to sit smoothly against the retina over its whole area, which might be 2 × 3 mm^2 or more," Wyatt said, noting that his group found it easier to conform the array onto a convex surface than a concave one.

Photovoltaic Approach

In the search for sight, one research group at Stanford University is taking a photovoltaic approach to visual prostheses (Figure S1). The prosthesis uses a similar system: A camera is mounted on a pair of glasses, in this case video goggles, and the camera's image goes to a pocket personal computer (PC) for processing. In the Stanford system, however, the processed image returns to the video goggles where it is displayed on a liquid crystal microdisplay. The goggles then use pulsed infrared illumination in the 880–915 nm range to project the image onto a subretinally implanted photodiode array [2], explained Daniel Palanker, Ph.D., associate professor in Stanford's Hansen Experimental Physics Laboratory and the Department of Ophthalmology.

The array is made up of many tiny pixels, each of which has a disk electrode surrounded by a silicon photodiode and a return electrode. Each pixel independently converts the pulsed infrared light into electric current. As in the other retinal prostheses, this current flowing through the retina electrically stimulates the nearby retinal neurons to elicit a neural signal, which is then passed along until it eventually reaches the brain.

The photovoltaic system has several advantages, Palanker said. "Our system is wireless, it's easy to implant, and it's easy to control, because all of the electronics and image processing—and all of the associated complications—are outside the body in the pocket PC." In addition, the photovoltaic arrays are about a millimeter in length and 30 µm in thickness, making them easy to implant. Palanker added that they can scale up to a large number of pixels by inserting many arrays to tile a wide field of view.

"The main challenge in developing this implant was the fabrication of the photovoltaic arrays, which took us quite some time," Palanker said. "The system now works in vitro and in vivo. We have rats with these implants for four months already, and we have recorded in vivo visually evoked potentials, which indicate that the system works."

The next step for the Stanford group is to determine how to achieve the best resolution and sensitivity with this system. "Currently, our smallest pixels are 70 µm in size," he said. "We also are considering using three-dimensional pillar electrodes to improve proximity between the electrodes and the target neurons." Further development of the implant for human use is still in the future. "We are open for business partnership to commercialize the system, but we, as an academic group, have no plans to take it to the clinic ourselves," he added.

While Stanford's work continues, a leading developer of subretinal implants in Germany has begun conducting clinical trials of its microchip to restore sight among patients who have retinal disorders, including RP. Developed by the company Retina Implant AG, the microchip contains 1,500 independently acting microphotodiodes, each of which has an electrode. In this system, a cable leads rearward from the implanted chip and under the skin and muscle to exit behind the ear. The cable then connects with a power control unit that the patient may wear on a neckband.

According to a research paper detailing the results of the trial [3], one of the three patients in the study was able to describe and name various objects, such as silverware and fruit, to differentiate between shades of gray and to see and approach other persons in a room. The authors noted, "These results demonstrate for the first time that subretinal microelectrode arrays with 1,500 photodiodes can create detailed meaningful visual perception in previously blind individuals."

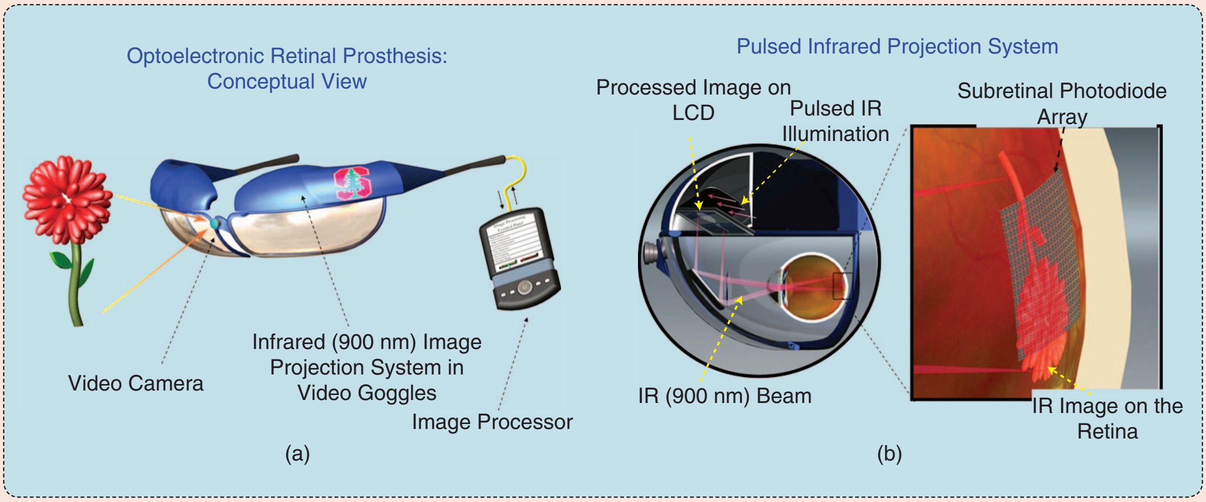

FIGURE S1 Researchers at Stanford University are taking a photovoltaic approach to visual prostheses. As shown in (a), an image from a video camera goes to a pocket PC for processing and returns to the goggles where it is displayed on a liquid crystal microdisplay. Using pulsed infrared illumination, the goggles project the image onto an implanted photodiode array as shown in (b). (Illustrations courtesy of Daniel Palanker.)

In addition, by attaching at the retina's rear surface, the MIT array avoids potential bleeding problems that can occur by attaching it inside the eye on the retina's front surface, Wyatt said. "Any bleeding inside the eye is extremely serious, because blood causes the vitreous (the gel) inside the eye to contract, and it can easily contract enough to pull the whole retina off of the eye." Finally, he said, an array implanted at the back of the retina is simply easier to replace than one inside the eye, although the newest

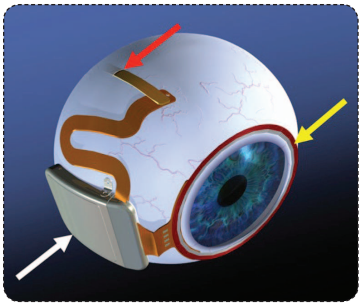

FIGURE 4 In the MIT retinal implant system, visual data are transmitted to an implanted data coil (yellow arrow) that rings the iris. Those data are sent to an electrode array (white arrow) on the retina. (Illustration courtesy of the Retinal Implant Research Group at MIT and MEEI.)

generation implant should never require replacement since it is essentially a lifetime device.

Once the fifth-generation implant is completed, the research group will begin animal trials as a first step toward receiving approval for human use. "It will take a while in the United States, because the FDA is the strictest regulatory agency in the world," Wyatt commented. "We've already raised about US$35 million over the 23 years that we've been working on it, and we'll need at least US$35 million more to get it through the FDA. And that's if we can get through the process in a few years." For that reason, the group is contemplating the option of seeking approval in another country, which will have a less expensive and much quicker approval process. "If things go well, I think it will be ready for use in people within four years," he added.

Cortical Implants

The other major area in visual prosthetics is the cortical implant, also known as the intracortical implant when it penetrates the cortex rather than lying on its surface. "In some respects the intracortical implant is not much different from the retinal approach, because both are trying to artificially communicate electronic image information to the brain," said Philip Troyk, Ph.D., director of the Laboratory of Neuroprosthetic Research and associate professor and associate dean of the Armour College of Engineering at the Illinois Institute of Technology (IIT). Like most retinal prostheses, the cortical systems typically use a pair of glasses that are equipped with a camera to gather visual data. Once that information is processed, however, it bypasses the prebrain visual pathway altogether and goes directly to the cortical implant.

In comparison to retinal implants, cortical implants have several advantages. Besides being able to treat forms of blindness that would not be helped by a retinal prosthesis, the cortical implant has another up side, according to Troyk. "At the cortex, you have a lot of real estate to work with. The brain is big. From a neurosurgical perspective, it is fairly easy to get at portions of the visual cortex," he explained. Because the cortex is so much larger than the retina, he said, researchers also do not have to worry about heat build-up caused by the electronics in the implant. "That can be a problem in the eye, but it's not in the brain."

On the flip side, cortical implants have one major disadvantage. "It may be technically easier to make devices to implant into the brain, but we don't know how to talk to the brain," Troyk added.

Unfortunately, vision does not work as simply as a television set with combined pixels forming a picture, Troyk said. "There are about 10 million connections that project neural information to the visual cortex, and the visual cortex then decomposes it to what are called elemental features of vision. After that, the cortex passes that information onto higher centers of the brain that then assemble the perception that we call vision." In summary, he added, "It is difficult at any level to know how to artificially insert information and manipulate it to create vision."

Mech agreed that the cortical-implant side has a way to go, noting that Second Sight has done some preliminary work in that area. "The device that we would use would not look very different from the one we're using in the retina. The harder part is the electrophysiology aspect, because we'll have lost all that preprocessing that occurs in the retina and in the optic nerve to get the signal ready to be interpreted by the cortex." With a cortical-implant system, the cortex will receive raw, unprocessed data, he said. "It will take a bit of time to learn how to do that well."

Even with those challenges, Troyk is pressing on [4]. He and his research group are developing an array of intracortical electrodes in which the electrodes poke upward off of a flat surface, rather like a hairbrush. The electrodes actually penetrate the visual cortex (Figure 6). "Now understand that the cortex is only about 2 mm deep in humans, so the insertion is not very great. The electrodes are quite small and they're very short," Troyk explained. "To provide perspective, the electrodes are like little spears that narrow down to a tiny tip. You could fit five to ten of those little tips onto the cross-section of a human hair." The electrodes are sculpted by laser and etched to an extremely fine point to minimize any damage from their insertion into the cortex, and they are made of iridium, which is an ideal medium to relay electrical current.

Troyk's group has built arrays containing 16 electrodes. Each array is an autonomous electronic module containing its own electronics that can receive power and data communication through the skin via a magnetic-link system. "Each module has a separate address, and each electrode within each module likewise has a separate address. In essence, we have a mini telephone network of electrodes in the brain, and the idea is that we can call up each electrode and

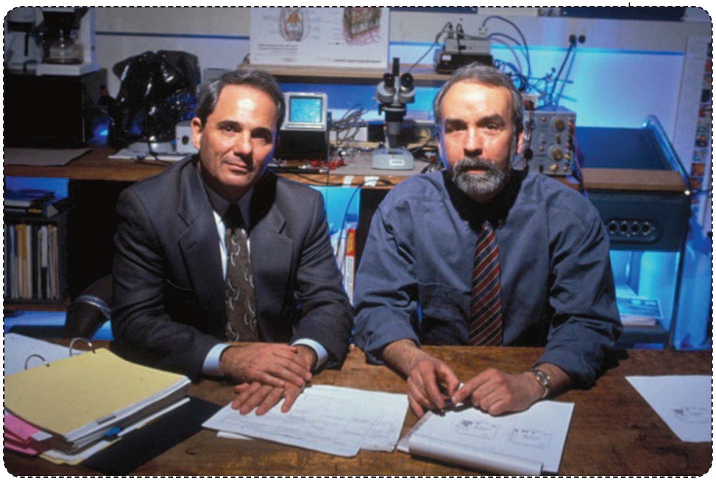

FIGURE 5 Joseph Rizzo (left) and John L. Wyatt founded the Retinal Implant Research Group at MIT and MEEI. (Photo courtesy of the Retinal Implant Research Group at MIT and MEEI.)

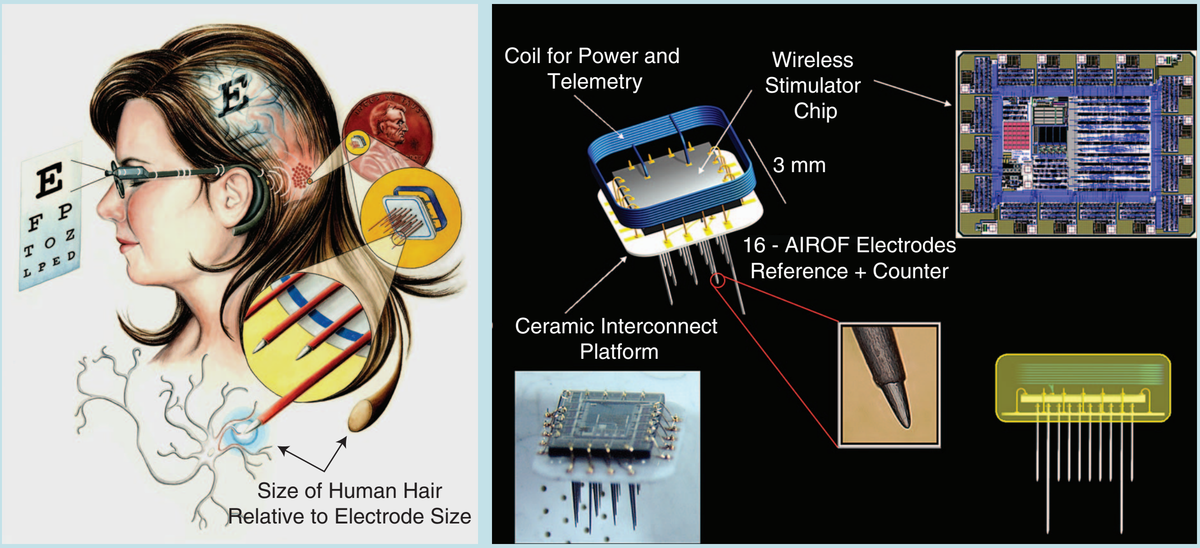

FIGURE 6 Philip Troyk and his research group at the IIT are developing an array made of 16 intracortical electrodes that penetrate the visual cortex. The electrodes are composed of activated iridium oxide film. Each array is an autonomous electronic module that contains its own electronics, which can receive power and data communication through the skin via a magnetic-link system. As shown in the idealized prosthesis design at left, the image information is communicated directly to the blind person's brain. (Illustrations courtesy of Philip Troyk.)

we can command the module by putting in certain pulses of current in certain patterns," he noted.

This work is one part of a larger project called the Intracortical Visual Prosthesis team, which Troyk leads. The team is an outgrowth of the Neural Prosthesis Project formerly run through the National Institutes of Health (NIH). According to Troyk, "for about the past ten years, the members of this team have been bringing the technology to the point where we could put enough electrodes in a human volunteer so that we can assess whether such a cortical interface is chronically viable, and whether it can actually be used to communicate any significant perceptual information."

The Intracortical Visual Prosthesis team recently received funding from the U.S. Army Medical Corps Telemedicine and Advanced Technology Research Center to prepare the technology over the next two years for a human clinical trial. "We feel we have brought the implant to the point where it is safe, it is surgically viable, and we can reasonably expect to place 600 to possibly 1,000 electrodes within the visual cortex of a human volunteer," Troyk said.

Another project that is progressing well is based on the Utah Electrode Array, which is currently undergoing animal tests. The Utah Electrode Array comes in two architectures: one has electrodes that are all of the same length, and the other has electrodes that range from short on one end to long on the other. The first is designed for applications in the brain, where it could help to restore vision; and the second is designed for implantation in peripheral nerves, where it may be useful for controlling muscle movement and potentially helping individuals who have a range of mobility limitations. With the stepped electrode lengths, electrodes could penetrate the peripheral nerves at different depths and therefore be able to pass electrical signals with great precision to the numerous layered bundles of axons (located in fascicles) within nerves.

"These two array architectures give us the ability to talk to large numbers of neurons with a selectivity that has never before been possible," said Richard Normann, distinguished professor of bioengineering and professor of ophthalmology and visual science at the University of Utah. He is leading the group that is developing the Utah Electrode Array. "The real strength of the Utah Electrode Array is that is permits unprecedented access to individual and small groups of neurons in the cortex, and to individual and small groups of nerve fibers in the peripheral nervous system."

Currently, a University of Utah research team under the leadership of Bradley Greger, Ph.D., assistant professor in bioengineering, is conducting tests of the cortical version of the Utah Electrode Array [5]. For this work, monkeys are trained to fixate on a small illuminated spot in the middle of a computer screen, and indicate when they notice a second small point of light elsewhere on the screen. "Once the animal learns this task, we can make the dot dimmer and dimmer until it becomes so faint that the animal can't see it. This allows us to figure out how bright the spot has to be for him to see it," Normann explained. Graduate students, who were similarly tested, showed comparable visual capabilities.

Once the monkeys are implanted with a cortical array, the researchers repeat the test, except substituting the second light stimulus with a perceived spot of light, known as a phosphene, which results from an electrical current that is passed through one of the electrodes in the cortical array. "With this study, we can figure out how much of an electrical current is required for the animal to indicate that it sees something," Normann said. "After two years of experimentation, we have learned both that these electrodes will remain functional for at least that length of time, and that stimulation of the electrodes also continues to produce these phosphenes, the presumed visual percepts, for at least that period."

The primate experiments are mainly being used as an index of safety and efficacy, and to set the stage for human experimentation, Normann said. Those human studies are necessary to help guide the development of cortical implants. "We want to get these arrays into the human visual cortex so we can ask more sophisticated questions, and can begin to understand the nature of the percepts that are produced by stimulating different groups of electrodes, such as a row of electrodes versus a column of electrodes. We hope to learn whether there is some simple linear mapping between electrodes stimulated and the nature of the percepts produced, or whether it is a complicated, complex interaction that makes this whole process much more difficult."

He added, "These are basic questions that will have to be answered so that we can come up with design specifications for an optimized visual prosthesis using cortical electrical stimulation."

> **Engineers think they know how their technology will be used and vision specialists think they know what blind patients would find useful, "but the reality is that we don't know."**

Still Learning

IIT's Troyk concurred with Normann's assessment: Many fundamental questions still need answers. He and a team of researchers, including two psychologists at IIT, are mounting an ambitious study of visual perception that tracks down and interviews blind individuals who participated in long-ago experiments that implanted electrodes into their brains. "They were very controversial experiments, especially those of William Dobelle," Troyk said, noting that the private researcher charged his subjects for the privilege of participating in his experiments, which began in the late 1970s. (Dobelle, who died in 2004, was a conominee in 2003 for the Nobel Prize in Physiology or Medicine for his work on artificial organs.)

By the end of the year, the IIT team plans to have spoken to all 14 of the still-living individuals who received one of Dobelle's implants, as well as many of their family members. During that time, the team will also interview the family members of the other two now-deceased Dobelle patients, and additional patients who received optic nerve implants in Belgium at about the same time. "This landmark study will help us develop an understanding of how people respond to receiving vision prostheses, what their experiences have been, and what functionality has returned," he said. "For the very first time, we're developing a basis for why an individual might participate to get a vision prosthesis, what their expectations are, how we can involve them in the work, and how we can assure that they are well-informed and certainly not exploited in any way."

Engineers think they know how their technology will be used and vision specialists think they know what blind patients would find useful, Troyk said, "but the reality is that we don't know." While the goal of both retinal and cortical implants is to produce the points of light known as phosphenes as a means to create visual capability, researchers and engineers are still unclear how exactly patients can and will make use of them.

As an example, Troyk described a patient who received one of Dobelle's implants and had only nine useful phosphenes. Most researchers would not consider that a success, he said, "but with those nine phosphenes, that patient could see to the curb on the street better, and therefore was able to navigate to a job that was much farther than he would have ordinarily felt comfortable traveling."

The IIT study has turned up similar stories from other patients. Troyk said, "Even though the patients know that they were inappropriately charged money and were abandoned by Dobelle before they could make optimal use of their implants, some of them said that they would actually do it again for the simple reason that they did gain useful visual perception and it did make a difference in their lives." He added, "The field of visual prostheses is not about whether we can get patients to see the giant 'E' on an eye chart. Trying to boil it down to a simplistic notion of optical acuity says nothing about how the visual perception can be used by the person to improve their quality of life."

The IIT study is one of many under way that will contribute to the overall understanding of the visual system and how best to design prostheses that will help people with vision impairments. These studies, which are coming at a fast and furious pace now that retinal and cortical implants are on the market or in clinical trials, or are in the research pipeline, will shape the future of visual prostheses.

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