BBC news coverage: http://www.bbc.com/news/health-33571412

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Health

Bionic eye implant world first

Fergus Walsh
Medical correspondent

21 July 2015 | Health

Fergus Walsh meets Ray Flynn and the team behind his treatment

Surgeons in Manchester have performed the first bionic eye implant in a patient with the most common cause of sight loss in the developed world.

Ray Flynn, 80, has dry age-related macular degeneration which has led to the total loss of his central vision.

He is using a retinal implant which converts video images from a miniature video camera worn on his glasses.

He can now make out the direction of white lines on a computer screen using the retinal implant.

Mr Flynn said he was "delighted" with the implant and hoped in time it would improve his vision sufficiently to help him with day-to-day tasks like gardening and shopping.

Weed or flower?

The Argus II implant, manufactured by the US firm Second Sight, has previously been used to restore some vision to patients who are blind as a result of a rare condition known as retinitis pigmentosa.

The operation, at Manchester Royal Eye Hospital, is the first time it has been implanted in a patient with age-related macular degeneration (AMD) which affects at least half a million people in the UK to some extent.

I met Ray Flynn last month, on the morning of his surgery and he explained that although his retained his peripheral vision, his central sight had disappeared.

He said: "I'm unable to put the numbers in for my card when paying in a shop or at the bank, and although I was a keen gardener, I can't tell the weeds from the flowers anymore."

The President of Second Sight is Dr. Rob Greenberg, who has provided leadership since the company was formed for the purpose of developing this technology. After medical school, Dr. Greenberg was recruited into this work by Dr. Eugene DeJuan, a retinal surgeon and my friend. The lead medical researcher, Dr. Mark Humayun, worked on this technology during and after medical school, where he worked closely with Dr. DeJuan. My contribution, from the days when the technology development began at the Eye Center at Duke University, was microelectronics engineering during my employment at the Semiconductor Research Corporation.

Howard Phillips

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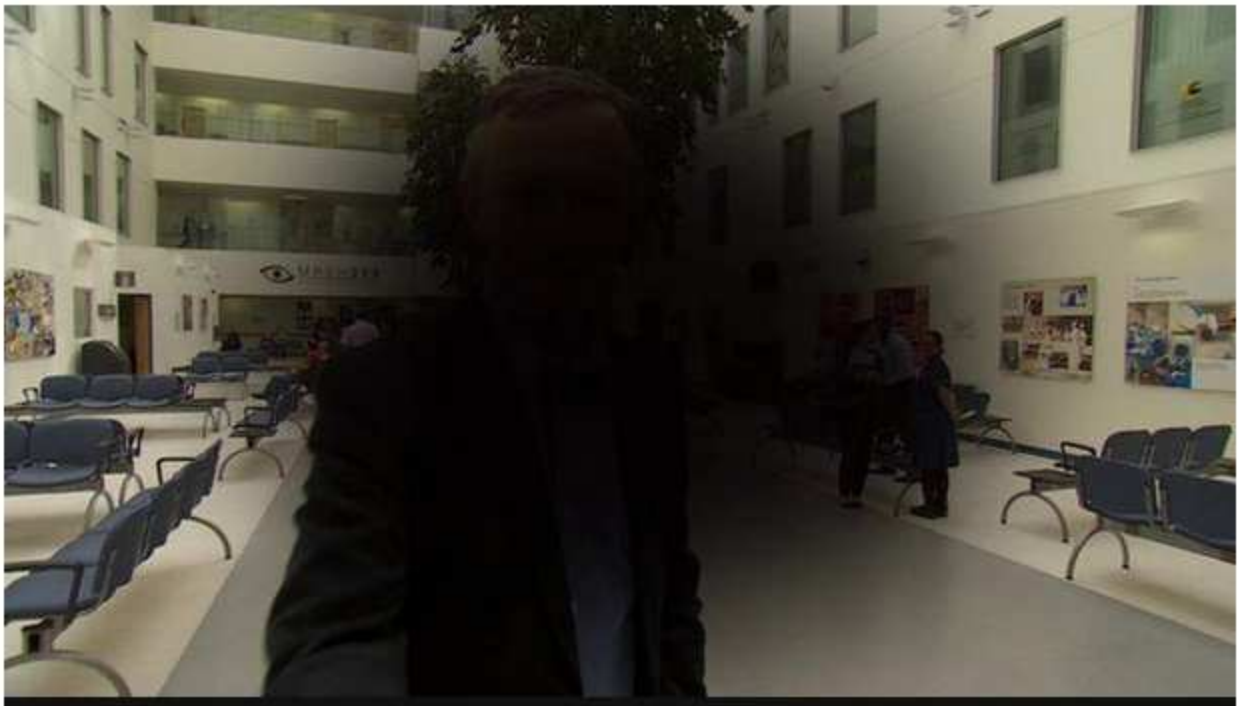


Ray Flynn's central vision has been lost due to age-related macular degeneration

Mr Flynn said he had to sit very close to the television to see anything.

He had given up going to see Manchester United play football as he cannot make out what is happening.

The operation took four hours and was led by Paulo Stanga, consultant ophthalmologist and vitreo-retinal surgeon at Manchester Royal Eye Hospital and professor of ophthalmology and retinal regeneration at the University of Manchester.

He said: "Mr Flynn's progress is truly remarkable, he is seeing the outline of people and objects very effectively.

"I think this could be the beginning of a new era for patients with sight loss."

How it works

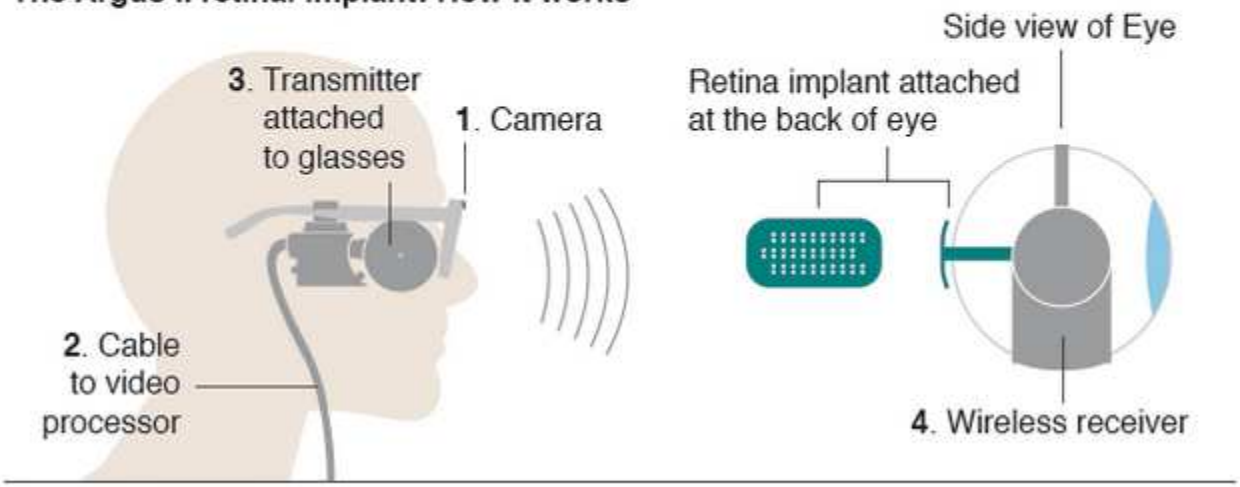
The bionic eye implant receives its visual information from a miniature camera mounted on glasses worn by the patient.

The images are converted into electrical pulses and transmitted wirelessly to an array of electrodes attached to the retina.

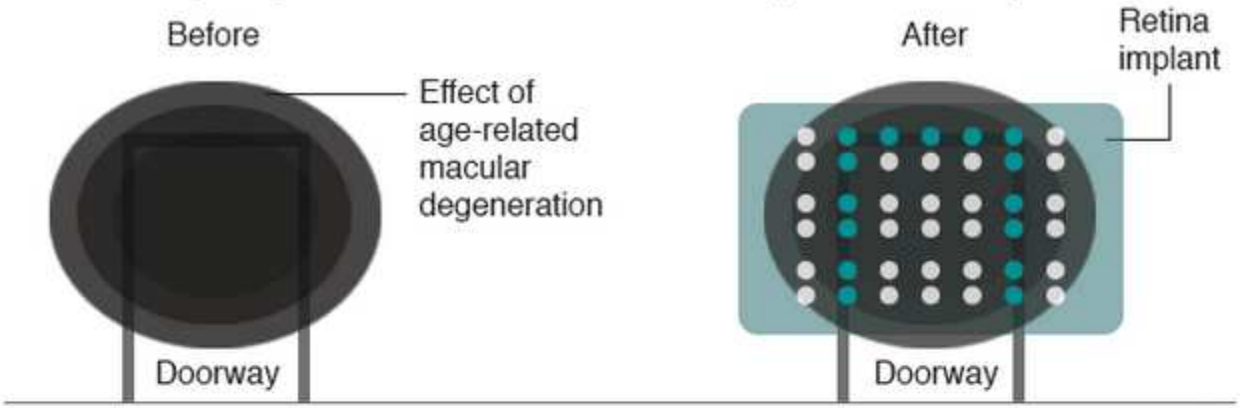
The electrodes stimulate the remaining retina's remaining cells which send the information to the brain.

In a test, two weeks after surgery, Mr Flynn was able to detect the pattern of horizontal, vertical and diagonal lines on a computer screen using the implant.

The Argus II retinal implant: How it works



How an image might look when viewed with the help of a retinal implant



Source: Second Sight BBC

He kept his eyes closed during the test so that the medical team could be sure that the visual information was coming via the camera on his glasses and the implant.

Mr Flynn said: "It was wonderful to be able to see the bars on the screen with my eyes closed."

The implant cannot provide any highly detailed vision - but previous studies have shown it can help patients to detect distinct patterns such as door frames and shapes.

Prof Stanga said that in time, Mr Flynn should learn how to interpret the images from the implant more effectively.

Dry AMD

- There are two forms of age-related macular degeneration - dry and wet.
- The dry form affects 85% of AMD patients and causes gradual loss of central vision, but does not affect peripheral vision.
- The Macular Society estimates that 44,000 people a year in the UK develop dry AMD.

Four more patients with dry AMD will receive the implant at Manchester Royal Eye Hospital, as part of a clinical trial.

Prof Stanga said: "We hope these patients will develop some central visual function which they can work in alongside and complement their peripheral vision."

We are very excited by this trial and hope that this technology might help people, including children with other forms of sight loss."

The Argus II costs about £150,000, including treatment costs, although all the patients on the trial will be treated free of charge.

Gregoire Cosendai of Second Sight Medical Products, described the AMD study as "totally groundbreaking research".

The trial is being held in the Manchester Clinical Research Facility - funded by the National Institute for Health Research and Wellcome Trust, which aims to bring new drugs and medical devices to patients.

Cathy Yelf, of the Macular Society, said: "This is an exciting result and we are following the progress of these trials with great interest.

"Macular degeneration can be a devastating condition and very many people are now affected as we live longer.

"These are early trials but in time this research may lead to a really useful device for people who lose their central vision."

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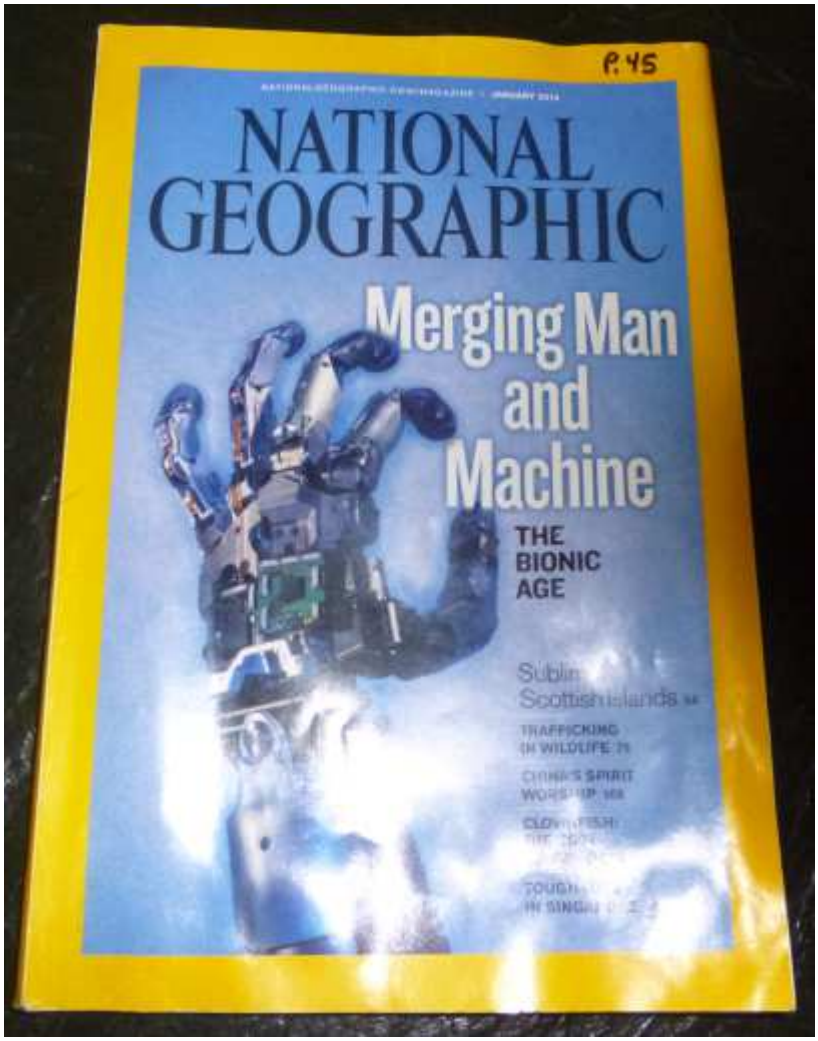
National Geographic highlighted our artificial vision technology is the issure featuring "Merging Man and Machine."




New Vision
Power and data processing provided by belt computer

Our artificial vision invention was featured in the AARP bulletin.

I was pleased to have been a co-inventor that had the priviledge of contributing to this research program. Please see the patent info later in this document.

Howard Phillips

FDA panel recommends approval for Second Sight's 'bionic eye'

https://www.massdevice.com/news/fda-panel-recommends-approval-second-sights-bionic-eye

September 28, 2012 by *MassDevice staff*

And FDA advisory panel recommends that the federal watchdog agency approve a humanitarian device exemption for Second Sight's Argus II "bionic eye" retinal implant.

An FDA advisory panel recommended approval for a "bionic eye" designed to restore sight for the blind.

The FDA's Ophthalmic Devices Panel voted 17-2 that the Argus II device's benefits outweigh any potential risks; 18-1 that a clinical trial demonstrated "a reasonable assurance of safety;" and was unanimously agreed that the proposed minimum age requirement of 25 years is appropriate.

The "bionic eye," which uses a head-worn camera to capture a scene and process it into electrical signals that are then sent to the cells in the eye, may pose long-term risks that increase over time, according to panel documents released ahead of the meeting. Nevertheless, the panel agreed that the federal watchdog agency ought to grant a humanitarian device exemption for the Argus II retinal prosthesis.

The FDA is not obliged to abide by the panel's ruling, but usually follows its advisory boards' recommendations.

In a small study conducted in support of the FDA application, 30% of Argus II recipients required multiple revision surgeries to manage adverse events more than 2.5 years after the procedure. More than 40% experienced non-serious "fibrotic events," which include retinal detachment and retinal tears, and 10% suffered serious fibrotic events.

Online videos, showing human testing of the artificial vision system:

http://www.nytimes.com/video/2013/02/14/science/100000002039719/the-fda-approves-a-bionic-eye.html?smid=pl-share&WT.mc_id=VI-D-E-TAB-AD-VAR-VIDEO-ROS-0412-NA&WT.mc_ev=click#100000002039719

US005109844A

United States Patent [19]

de Juan, Jr. et al.

[11] **Patent Number: 5,109,844**

[45] **Date of Patent: May 5, 1992**

[54] **RETINAL MICROSTIMULATION**

[75] Inventors: **Eugene de Juan, Jr.; Mark S. Humayun; D. Howard Phillips**, all of Durham, N.C.

4,832,051	5/1989	Jarvik et al.	128/784

FOREIGN PATENT DOCUMENTS

0329112	2/1988	European Pat. Off. .
1943956	5/1971	Fed. Rep. of Germany .

Acknowledgment

Many physicians and engineers have contributed to the development of this technology, and I enjoyed working with them. The original work began at the Duke Eye Center at Duke University in North Carolina under the direction of Dr. deJuan; and at The University of North Carolina under the direction of Dr. Propst.

Patent number: 5109844

A method for stimulating a retinal ganglion cell in a retina without penetrating the retinal basement membrane at the surface of the retina comprises: (a) positioning a ganglion cell stimulating electrode on or above the retinal basement membrane; (b) providing a ground electrode in operative association with the ganglion cell stimulating electrode, with the ground electrode positioned on or above the retinal basement membrane and positioned for capturing electric current produced by the stimulating electrode; and (c) applying a voltage to said stimulating electrode sufficient to produce an electric current which penetrates the retina and produces an action potential in a retinal ganglion cell. Apparatus for practicing the foregoing method is also disclosed.

Inventors: Eugene de Juan, Jr., Mark S. Humayun, D. Howard Phillips

Original Assignee: Duke University
Current U.S. Classification: 607/53; 623/6.63
International Classification: A61N 105

Original patent for this technology

U.S. Patent number 5,109,844, issued May 5, 1992, entitled Intraocular Visual Prosthesis and Retinal Microstimulation. This patent covers a method for using a microcircuit, similar to a computer microchip, implanted in a blind eye to restore vision to humans. Research associated with this project led to successful animal trials and successful human surgical trials.

I am pleased to have been part of the original R&D team; and to have been a co-author of the original patent that was granted for this technology. Other authors and co-authors of the original patent were Eugene de Juan, M.D., and Mark S. Humayun.

When the patent was issued (1992), I was a member of the faculty at The University of North Carolina at Charlotte.

General Manager, Phillips Company
www.phillipscompany.4t.com

For more information about the final FDA approval, please request a copy of BiomedCV.pdf

All good inventions spawn ideas that spread

Our original invention has spawned similar efforts around the world. Below is a story based on the use of bionic eye technology in England and Germany.

https://www.buzzfeed.com/fionarutherford/blind-woman-fitted-with-a-bionic-eye-sees-for-the-first-time?bffbscience&utm_term=.tcVDz7xq7q#.qaNybX5qXq

Rhian Lewis, who has retinitis pigmentosa, after she received a retinal implant at the Oxford Eye Hospital at the John Radcliffe Hospital, Oxford. *BBC / Press Association Images*

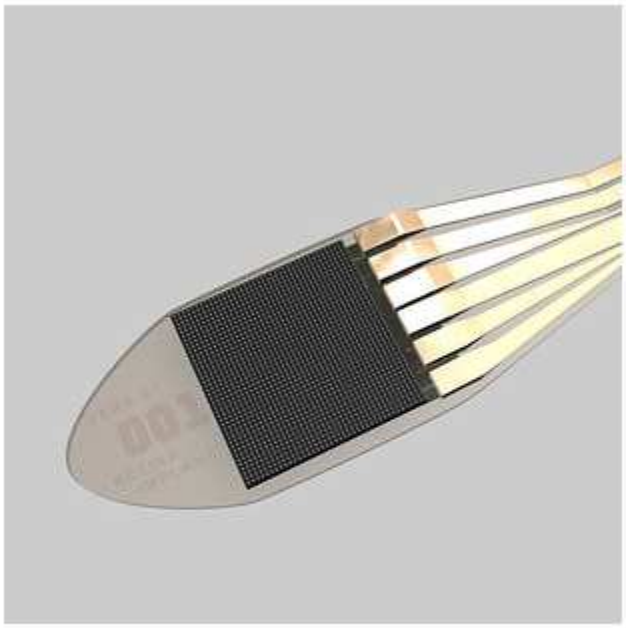
A blind British woman has spoken of her joy at having her sight partially restored after being fitted with a bionic eye.
A blind British woman has spoken of her joy at having her sight partially restored after being fitted with a bionic eye.

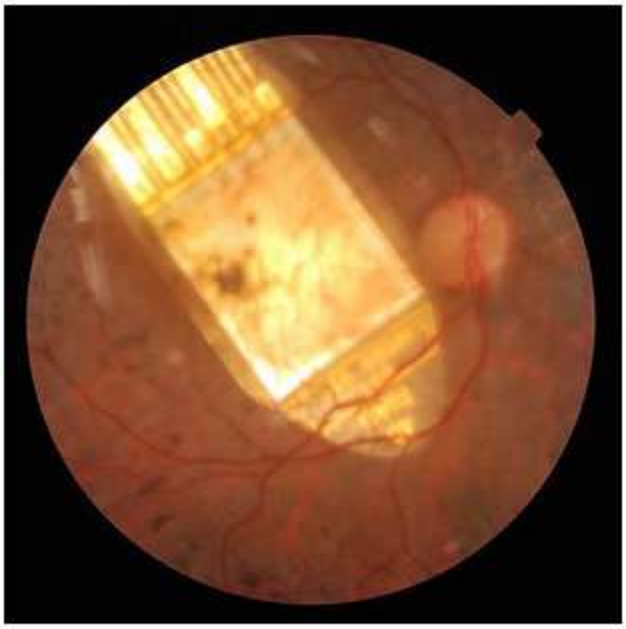
Rhian Lewis, who has retinitis pigmentosa, after she received a retinal implant at the Oxford Eye Hospital at the John Radcliffe Hospital, Oxford. BBC / Press Association Images

Rhian Lewis had a tiny 3×3mm electronic chip implanted at the back of her right eye's retina in order to help her see, the Press Association reported. She is the first patient outside Germany to be fitted with such a device.

The procedure, which can take up to eight hours, was conducted in June by surgeons at Oxford's John Radcliffe Hospital.

The surgery was part of an ongoing trial that could help thousands of people suffering from sight loss.





The small electronic chip implanted at the back of the retina to replace damaged photoreceptors.
University Of Oxford / Press Association Images

University Of Oxford / Press Association Images

Lewis, 49, has suffered from retinitis pigmentosa – an inherited condition that causes gradual deterioration of the light-detecting cells in the retina and can eventually lead to blindness – since she was 5 years old.

Around 16 years ago she lost most of the vision in her left eye, and became completely blind in her right eye.

Her condition affects 1 in 3–4,000 people in the UK, and scientists have not yet found a cure.

The small electronic chip is implanted at the back of the retina to replace damaged photoreceptors.The implant placed in Lewis's eye was made by German firm Retina Implant AG. It works by replacing the light-sensitive retinal cells in the eye. The device is connected to a tiny computer kept underneath the skin behind the ear that looks similar to a hearing aid.

A magnetic coil is applied to the skin to switch the device on, allowing signals to travel to the optic nerve and brain.

Since Lewis's optic nerve and the brain wiring needed for vision were still intact, once the device was turned on, her brain just needed time to adjust to the signals it was receiving.

Rhian Lewis takes part in a test to read a clock face. BBC / Press Association Images

"It was a bit nerve-wracking," Lewis, who lives in Cardiff, told the BBC. "I didn't know what to expect.

"They sort of put the magnet to the little receiver there on my head and switched the receiver on.

"They said I might not get any sensation… and then all of a sudden within seconds there was like this flashing in my eye, which has seen nothing for over 16 years, so it was like, 'Oh my God, wow!'"

She added: "It was just amazing to feel that something was happening in that eye, that there was some sort of signal."

If the trial continues to be successful, it's possible the implant could be made available on the NHS, the BBC reported.

The surgical team also hope that one day the technology could be applied to other eye diseases.

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Excerpt from article

The Bionic Eye

A Quarter Century of Retinal Prosthesis Research and Development

Mark S. Humayun, MD, PhD,[1] Eugene de Juan, Jr., MD,[2] Gislin Dagnelie, PhD[3]

This article describes the history of visual prostheses, with emphasis on the development of the Argus II retinal prosthesis system (Second Sight Medical Products, Inc., Sylmar, CA). A brief overview of cortical electrical stimulation in the blind is provided, followed by an account of the design and development of retinal stimulation equipment at the Duke Eye Center in the late 1980s; the first human intraoperative tests there and the subsequent 8 years of tests at the Wilmer Eye Institute; the transfer of the project to the Doheny Eye Institute at the University of Southern California and the founding of Second Sight Medical Products; and the development and clinical trials of the Argus I and Argus II systems. In a series of vignettes, we pay tribute to the many colleagues and patient volunteers without whose help the work would not have been possible. *Ophthalmology 2016;■:1–10 © 2016 by the American Academy of Ophthalmology.*

Creating the Concept. Diagram showing Research Triangle, North Carolina, where the concept was created. In 1987, 3 individuals came together and launched research into the development of a retinal prosthesis that eventually led to the current Argus II implant: Mark Humayun, who as a Duke medical student was struggling with his grandmother's vision loss resulting from diabetic retinopathy; Eugene de Juan, Jr., who at the Duke Eye Center had reassured the mother of a young girl losing her vision that "something is being done"; and **Howard Phillips, a nuclear and electrical engineer who was Vice President of SRC**, an advocacy group for the United States microelectronics industry. Their patent application in 1990 marks the formal start of the epiretinal prosthesis project. Initial animal studies at Duke were made possible by 2 experts who helped Humayun design a stimulator: Roy Propst, a biomedical and electrical engineering professor at the University of North Carolina, Chapel Hill, and Humayun's PhD advisor, and Wentai Lu, an electronics and computer engineering professor at North Carolina State University (Raleigh); other experts who helped were Ralph Cavin at SRC and Eric Javel, a cochlear implant researcher at Duke University.

And, a nice thing is....
every so often, I get a royalty check

Dear Dr. Phillips,

The Duke Office of Licensing & Ventures is happy to inform you that you will be receiving a royalty payment within the next 4-5 weeks of **$8,703.75** in regards to the **Second Sight, JHU License Agreement**.
If you have any questions or do not receive your payment, please contact me.

Best Regards,

Deborah

****

Deborah Gornto
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