# ARGUS II Retinal Prosthesis System: Which patients will benefit and which will not

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A retinal prosthesis is a biomedical implant intended to restore useful vision to people who have lost their vision due to retinitis pigmentosa (RP), which severely damages the photoreceptors in the eye. In a healthy eye, the photoreceptors (rods and cones) in the retina convert light into tiny electrochemical impulses that are sent through the optic nerve and into the brain, where they are decoded into images. If the photoreceptors does not function correctly the first step in this process is disrupted, and the visual system cannot transform light into images. This lead to blindness in patients with RP.

The first effort to partially restore vision in blind eyes with the help of a prosthesis (connected to the visual pathway) was tried in the first half of the 20th century. Then in 1968, the first long-time implanted device was reported. It was a collection of 80 electrodes implanted in contact with the occipital pole of the right cerebral hemisphere to obtain perception. However, although surface and intracortical stimulation showed promising preliminary results, significant drawbacks were found later. Then the research was focused on devices capable of interacting directly with the retina rather than with the brain.

Thereafter, a number of epiretinal and subretinal implants have been developed. Among these, the Argus II Retinal Prosthesis System (Second Sight Medical Products), originally developed by Mark Humayun, MD, PhD, and colleagues at the Doheny Eye Center at the University of Southern California, aims to provide partial restoration of vision to patients who had lost vision from outer retinal degenerative disease (1). For this innovation, Dr. Mark Humayun received the prestigious National Medal of Technology and Innovation.

In a press release issued by the White House, Obama stated, "Science and technology are fundamental to solving some of our nation's biggest challenges. The knowledge produced by these Americans today will carry our country's legacy of innovation forward and continue to help countless others around the world. Their work is a testament to American ingenuity."

Humayun, who is one of nine recipients of the medal in 2016, was chosen for his lifelong dedication to bridging medical science and engineering to restore sight. He holds more than 100 issued patents and patent applications — most in the area of bioimplants for ophthalmology. His innovative work is best exemplified by the development of the Argus II, the only Food and Drug Administration-approved retinal prosthesis system that allows those with certain blinding diseases to regain some useful vision.(2)

**The ARGUS II** is a new hope for RP patients. The Argus® II Retinal Prosthesis System ("Argus II") is also known as the bionic eye or the retinal implant. The Argus II was developed by Second Sight Medical Products, Inc. of Lausanne, Switzerland and Sylmar, California, to treat adults with severe to profound RP. RP is a rare, inherited degenerative disease that damages light-sensitive cells in the retina, resulting in decreased vision at night or in low light; loss of side (peripheral) vision; and loss of central vision as the disease progresses. At present, there is no cure for RP (3).

The Argus II is intended to provide electrical stimulation of the retina to induce visual perception in blind individuals with severe to profound retinitis pigmentosa. It provides electrical stimulation of the retina to induce visual perception in blind individuals. A miniature video camera housed in the patient's glasses captures a scene. The video is sent to a small patient-worn computer where it is processed and transformed into instructions that are sent back to the glasses via a cable. These instructions are transmitted wirelessly to an antenna in the retinal implant. The signals are then sent to the electrode array, which emits small pulses of electricity. These pulses bypass the damaged photoreceptors and stimulate the retina's remaining cells, which transmit the visual information along the optic nerve to the brain, creating the perception of patterns of light. Patients need to learn to interpret these visual patterns. (4)

**Description of ARGUS II**

The Argus II System consists of an active device implanted on and in the eye and external equipment worn by the user.

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The implanted portion of the system includes a receiving antenna and an electronics case that are fixed outside the eye with sutures and a scleral band, and an intraocular 6 10 electrode array that is tacked over the macula epiretinally (i.e., on the retinal ganglion cell side). The external portion of the system includes a glasses-mounted video camera and a small video processing unit (VPU) that can be worn on a shoulder strap or belt. The camera collects visual information and sends it to the VPU, which down-samples and processes the image. Several buttons on the VPU allow user control of various image-processing algorithms, for example, enhancing contrast. Data and power are sent wirelessly from a transmitting antenna on the glasses to the internal receiving antenna. The electrodes in the array emit pulses of electricity whose amplitude corresponds to the brightness of the scene in that location. Stimulation of the remaining retinal cells induces cellular responses that travel through the proximal visual system, resulting in visual percepts that subjects learned to interpret.

**Surgical Procedure**

Subjects received the Argus II Retinal Prosthesis System in the worse-seeing eye. To implant the device, a 360-degree limbal conjunctival peritomy was performed. The rectus muscles were isolated, and the coil was inserted temporally on the globe and centered under the lateral rectus muscle. The electronics package was centered in the superotemporal quadrant. The inferior part of the scleral band was passed under the inferior and the medial rectus muscles, and the superior portion of the band under the superior rectus muscle. The implant was fixed to the eye via sutures passed through suture tabs on the implant in both temporal quadrants, and a Watzke sleeve (Labtician Ophthalmics, Inc, Oakville, Ontario, Canada) and mattress sutures or scleral tunneling were used to secure the scleral band in the nasal quadrants. A core and peripheral vitrectomy were conducted. The array was then inserted through a temporal sclerotomy. The electrode array was placed on the retina in the macular region and then tacked using a custom retinal tack (Second Sight Medical Products, Inc, Sylmar, CA). The extraocular portion of the cable was sutured to the sclera, and all sclerotomies were closed. An allograft (or suitable alternative in countries where allografts were not permitted) was fixed over the device to reduce the likelihood of conjunctival irritation. Finally, the Tenon's capsule and the conjunctiva were closed. (5)

The 5-year results of the Argus II trial support the long-term safety and benefit of the Argus II system for patients blind as a result of retinitis pigmentosa (RP).In this study (6), 30 patients at 10 centres were studied. However, performance data could be gathered only for 20 patients at 5 years. Visual function and functional vision assessments indicated continued efficacy of the Argus II up to 5 years of implantation. Patients are still able to locate objects, determine the direction of moving bar motion and perform an acuity task better with Argus II than when using only residual vision.

**Who will benefit from Argus II System?**

Argus II is currently approved and intended for use in patients with severe to profound retinitis pigmentosa (RP) who meet the following criteria:

- Adults, age 25 years or older
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful form vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

The Argus II is intended to be implanted in a single eye, typically the worse-seeing eye.

**Possible Benefits of the Argus II System:**

1. The Argus II System may help patient to do tasks visually, rather than by touch.
2. Some subjects can locate lights and windows, follow lines in a crosswalk, or avoid running into things as they walk.

3. Some patients could sort laundry or determine where other people were located in a room.
4. Some patients can read large letters or short words.
5. A few subjects were able to read smaller letters and short words. In addition, many subjects reported enjoying seeing light and motion after being blind for many years and having a greater feeling of connection to their environment and to other people.

**Limitations of Argus II System:**

1. The Argus II System provides a form of vision that differs from the vision patient used to have.
2. It does not restore normal vision. When the patient is not using the Argus II System, vision will return to its original impaired state.
3. It does not slow or reverse the progression of your disease.
4. It will not replace patient's normal visual aids. (7)

**Who will not able to benefit?**

1. Some patients who are allergic to Argus II materials
2. Currently the Argus II system is developed only for RP. Patients with other retinal diseases may not able to benefit from Argus II system.

Despite its limitations, Argus II system has brought hopes to hundreds of people living in dark and waiting for a scientific breakthrough which can possible them to see this beautiful world.

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