There are revolutionary advances in surgery — radical shifts that change the trajectory of a field — and evolutionary changes, or more incremental advances. The introduction of the Argus II retinal prosthesis was clearly a revolutionary change and earned its primary inventor, Mark S. Humayun, MD, PhD, of USC, the United States National Medal of Technology and Innovation in 2016.

The Argus II, named after Argus Panoptes, the all-seeing giant with 100 eyes from Greek mythology, has been termed the “bionic retina” by the lay press. The Argus II received U.S. Food and Drug Administration approval as a humanitarian use device for patients who have bare light perception or no light perception vision secondary to retinitis pigmentosa.

In this installment of Practical Retina, Paul Hahn, MD, PhD, from NJ Retina shares his significant experience in implanting the Argus II. He explains the importance of careful patient selection, setting appropriate patient expectations, and the rehabilitative process required postoperatively. Dr. Hahn provides surgical pearls for the various steps of the implantation procedure.

Artificial vision will hopefully become a burgeoning field, and the Argus II represents an early milestone in this effort. A number of other devices are in various stages of development. Although there are likely to remain a limited number of centers and surgeons who perform this specialized procedure throughout the world, readers are sure to find Dr. Hahn’s insights on the Argus II Retinal Prosthesis enlightening.

Science fiction has long predicted the development of artificial vision to restore sight to the blind. In 2013, the Argus II retinal prosthesis (Second Sight Medical Products, Sylmar, CA) was approved by the U.S. Food and Drug Administration (FDA), having received the Conformité Européenne (CE) mark 2 years prior in 2011 and approval by Health Canada in 2015. This device provides artificial visual stimulation otherwise permanently lost and consists of an external (wearable) and internal (surgically implanted) component. The external equipment includes custom glasses that house a video micro-camera connected by a wired cable to a video processing unit (VPU) (Figure 1A). The VPU transforms video from the micro-camera to data that are then transmitted wirelessly to the surgically placed internal implant, which receives power wirelessly via induction from the external hardware.

The implanted component consists of a receiving coil and electronics case secured to the eye in a scleral buckle fashion and a 60-electrode array that is fixed to the inner surface of the retina with a retinal tack (Figure 1B). Wireless communication from the external VPU stimulates electrodes within the array to emit small electrical pulses that excite remaining viable inner retina cells, including ganglion cells. These artificially stimulated retinal ganglion cells transmit signals through the visual pathway to elicit patterns of light.

INDICATIONS

Although retina specialists may not routinely encounter the Argus II, most eye care providers will likely be asked about this technology by patients, including those who may be eligible for this device. The Argus II is currently FDA-approved in the U.S. for a well-defined subset of patients: adults (age 25 years or older) with a diagnosis of retinitis pigmentosa (RP) and a history of prior useful vision who have progressed to bare light perception or no light perception vision in both eyes. Contraindications include comorbidities that would prevent the implant from functioning properly (eg, optic nerve disease, cortical blindness, history of retinal detachment, retinal vascular occlusion, trauma, and severe strabismus). Other contraindications include conditions that would prevent adequate implantation of the Argus II.

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Practical Concepts
With the Argus II Retinal Prosthesis

by Paul Hahn, MD, PhD
such as conjunctival thinning, axial length less than 20.5 mm or greater than 26 mm (given the fixed intraocular cable length), and conditions that prevent implant visualization such as corneal opacities. Phakic patients will also require removal of the lens prior to or during Argus II implantation. Finally, the implant is not recommended in patients with a tendency to eye rubbing or with a metallic or active implantable device in the head such as a cochlear implant.

Beyond these technical eligibility criteria, an ideal candidate for this technology must have appropriate expectations. As with any prosthesis, the Argus II requires significant rehabilitation to maximize its utility, and patients should understand that this is not a “plug-and-play” device. The surgery is outpatient, typically 3 to 5 hours in length, and performed under general anesthesia. The postoperative recovery is similar to a combined scleral buckling and vitrectomy procedure. Complications are rare, but particular attention should be directed toward potential hypotony, conjunctival erosion, and endophthalmitis. A few weeks following the surgery, the device is programmed during the course of several days and then turned on for the first time. Although patients will start to experience flashes of lights immediately at the time the device is first turned on, they will undergo subsequent low vision rehabilitation and occupational therapy to learn how to best use the device, interpret these flashing lights, and maximize its utility in their own environment.

'VISION'

Perhaps most important to patients and physicians is understanding what recipients will see with this device. Patients should understand up front that they will not be able to read, to drive, or even to recognize faces, which are often what patients would most like to recover. The Argus II provides a new type of visual stimulation that is different than what normally sighted people see. It provides flashes of light that can allow patients to localize objects and identify movements. Patients report being able to determine where surrounding people are standing relative to their own location, which improves their sense of social connectedness, one of the most important benefits of this device. They may be able to localize their dinner plate or a glass of water, sort clothes by light or dark, follow a sidewalk or the straight lines of a crosswalk, determine the direction of moving people in front of them, “see” the location of a loved one’s face, and identify doorways and windows. Although in isolation, many of these percepts may be difficult to interpret, Argus II users learn to place these visual stimuli in the context of stimuli from their other senses to provide an additional dimension to orient themselves.

SURGICAL PEARLS

Most vitreoretinal surgeons may not be involved with surgical implantation of the Argus II, but the device was engineered to accommodate surgical tech-
niques familiar to trained surgeons. The implant is secured to the sclera in a scleral buckle-style fashion. A thorough vitrectomy is indicated. The array is inserted into the vitreous cavity through a 5.2-mm sclerotomy and then tacked to the retinal surface. Incisions must be carefully closed.

Perhaps the most critical part of the case is centration of the array, which is directly influenced by positioning of the extraocular components. The Argus II consists of a fixed cable that links the extraocular components to the internal array. The position of the array, which must be centered over the macula, is predetermined by the orientation of the extraocular components. The electronics case has two tabs that are sutured to the scleral wall at predefined distances from the limbus – if the electronics case is sutured obliquely, the cable will enter obliquely and force the array to an eccentric position away from the macula center. Careful measurements should be performed to confirm that the external hardware is secured in a perfectly circumferential orientation to allow the cable to enter the eye radially centered. Perfect placement should be confirmed prior to inserting the cable and array into the vitreous cavity (Figure 2). The carpentry proverb to “measure twice and cut once” applies well here.

The step unfamiliar to most is tacking, which involves use of a specialized tack forceps to secure the array with a tack that passes through an anchoring ring on the array and penetrates the choroid and sclera (Figure 3). First-time surgeons typically focus their preparation on the tacking step, and surgeons should certainly practice this in a model eye prior to their first case.

Surgical implantation of the Argus II is still in relative infancy, and techniques are continually being refined. Each surgical step has many nuances, and every surgeon will have their own perspective and

Figure 2. Positioning of the extraocular Argus components. (A) Calipers are used to measure a predefined radial distance from the limbus. (B) A suture is passed to exit precisely at this predefined distance and will anchor one of the electronics case tabs. (C) Both tabs are sutured, securing the electronics case in a circumferential fashion. (D) Appropriate positioning is confirmed by passing the intraocular cable and array over the cornea and visualizing that the array naturally passes in a direction centered over the cornea.
approach. As before any first-time procedure, prior discussion with experienced surgeons is invaluable, and Second Sight has facilitated proctoring of all first-time cases by an experienced surgeon.

CONCLUSION

The Argus II marks the onset of an exciting era of artificial vision to restore vision previously considered permanently lost. Until now, this device has only been formally evaluated in patients with end-stage RP, which is its current indication. A pilot study evaluating its use in advanced dry age-related macular degeneration is currently underway, and this device may also prove to benefit other retinal degenerations. Beyond the Argus II, another retinal prosthesis — the Alpha IMS (Retinal Implant AG, Re-
utlingen, Germany), a light-sensitive subretinal implant — has received the European CE mark in 2013 for end-stage RP patients. More recently in 2016, the Iris II (Pixium Vision, Paris France), a 150-electrode epiretinal implant, received the CE mark for outer retinal degenerations and has been approved in 2018 to begin human trials in the U.S. There are also other retinal-based implants and alternative approaches for artificial vision that are in early phases of development. There have not yet been any studies comparing outcomes with these different devices. Although the technology is early and still far from natural vision, initial experiences and successes with the Argus II and other artificial vision devices should encourage ongoing development of future technologies and provide meaningful hope for all patients with vision loss.

REFERENCES


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Disclosures: Dr. Hahn has served as a consultant for Second Sight Medical Products and as a consultant and speaker for Genentech. Dr. Fine is a consultant and/or speaker for Allimera, Allergan, Genentech, Regeneron, and Spark Therapeutics and has equity/patent interests in Auris Surgical Robotics.