

Surgical Pearls for Implantation of the Argus II Retinal Prosthesis

BY MARCO MURA, MD; AND GIULIO BAMONTE, MD

In this issue of Retina Today, Marco Mura, MD, and Giulio Bamonte, MD, discuss pearls for implantation of the Argus II Retinal Prosthesis System (Second Sight Medical Products).

We extend an invitation to readers to submit pearls for publication in Retina Today. Please send submissions for consideration to Dean Elliott, MD (dean_elliott@meei.harvard.edu); or Ingrid U. Scott, MD, MPH (iscott@hmc.psu.edu). We look forward to hearing from you.



— Dean Elliott, MD; and Ingrid U. Scott, MD, MPH

The first attempts to partially restore vision in blinded eyes by means of a prosthesis connected to the visual pathway date as far back as the first half of the 20th century.^{1,2} The first chronically implanted device was described by Brindley and Lewin in 1968.³ They used an array of 80 electrodes implanted in contact with the occipital pole of the right cerebral hemisphere to elicit percepts in a 52-year-old patient who was blind due to retinal detachment. However, although surface and intracortical stimulation showed promising preliminary results, significant drawbacks were encountered.

Postmortem anatomic studies of patients with retinitis pigmentosa (RP) and age-related macular degeneration have demonstrated that both inner retinal cells and ganglion cells may be preserved in these ocular conditions, even though there is considerable photoreceptor cell death. Stimulation of viable ganglion cells and cells that feed into the ganglion cell layer, therefore, may be used to elicit some form of artificial vision. Consequently, research has been redirected to find devices capable of interacting directly with the retina rather than with the brain.⁴

A number of epiretinal and subretinal implants have been developed.⁵ 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 blinded from outer retinal degenerative disease. To date, the device has been implanted in multiple patients with

profound RP as part of a worldwide clinical feasibility study (clinicaltrials.gov ID: NCT00407602).

For a detailed description of outcomes from the Argus II Retinal Stimulation System feasibility study, we refer readers to other articles in the literature.⁶⁻⁸ In brief, most patients implanted with the device showed an improvement in tasks assessing orientation and mobility, spatial-motor localization, and ability to discern the direction of motion of moving stimuli. Of 28 patients, 16 performed better with the implant on vs off, with an estimated visual field of 20°. Roughly one-third of the patients experienced a measurable improvement in visual acuity with the implant. The highest achieved visual acuity ranged from 1.6 logMAR to 2.9 logMAR, with letter reading measured at Snellen 20/1262. Some patients were capable of identifying words with high accuracy.

To date, the Argus II is the only retinal prosthesis system to receive US Food and Drug Administration approval and the Conformité Européenne Mark for sale as a medical device. This article outlines our pearls for surgical implantation of the Argus II Retinal Prosthesis System.

THE ARGUS II RETINAL PROSTHESIS SYSTEM

The Argus II epiretinal prosthesis consists of a device that is surgically implanted on and in the eye and an external unit that is worn by the user. The external unit consists of a small camera (510 x 492 pixels resolution; NTSC output) and transmitter mounted on glasses and a video processor and battery worn on a belt. The

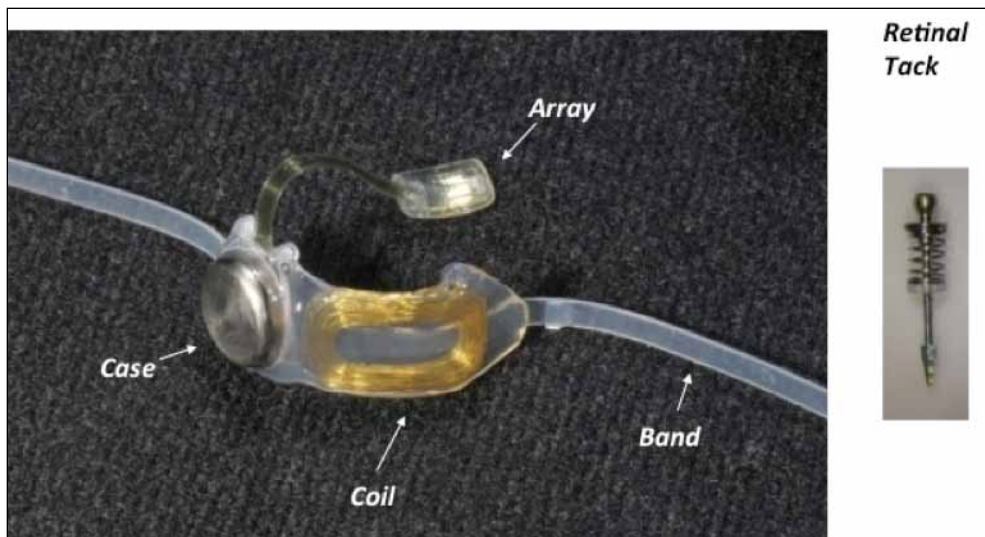


Figure 1. The implanted portion of the Argus II consists of a receiving and transmitting coil, a case housing electronics needed for stimulation, and a multielectrode array that is secured to the vitreoretinal surface with a retinal tack.

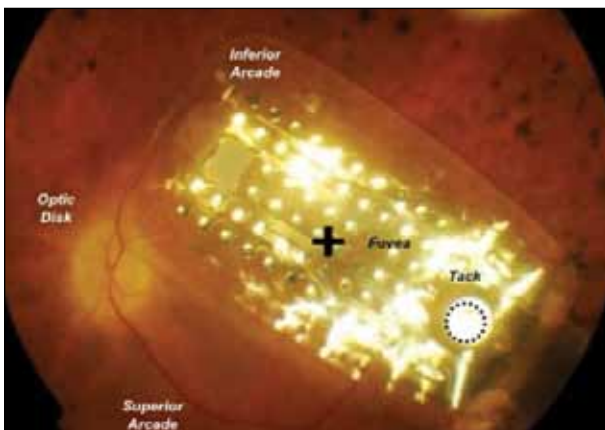


Figure 2. The array position and tacking location.

implanted portion (Figure 1) consists of a receiving and transmitting coil, a case housing electronics needed for stimulation that is fixed to the scleral surface, and a multielectrode array (60 electrodes; 200- μ m diameter each) that is secured to the intraocular vitreoretinal surface with a retinal tack (Figure 2).

The multielectrode array is connected to the case by a metalized polymer cable that penetrates the sclera in the location of the pars plana incision made during implantation. The camera captures video and sends the information to the video processing unit, which converts the image to electronic signals that are then sent to the transmitter on the glasses. The implanted receiver receives these data wirelessly and sends electrical stimulus pulses to the multielectrode array via the polymerized cable. Controlled electrical stimulation depolarizes remaining retinal neurons. Evoked

action potentials travel through the optic nerve and up to higher visual centers, such as the lateral geniculate nucleus, resulting in phosphenes by exciting areas in visual cortex.⁴

SURGICAL TECHNIQUE

A 360° conjunctival peritomy is performed in a standard fashion. To avoid dehiscence of the conjunctival wound in the proximity of the implant case, only 1 radial incision is made, in

the inferonasal quadrant. The 4 recti muscles are isolated with 2-0 silk. The episcleral portion of the implant is now ready to be inserted under the recti muscles and secured onto the sclera with sutures.

First, the receiving coil is inserted under the lateral rectus muscle while the electronic case rests in the superotemporal quadrant. Then the medial portion of the encircling band is passed under the superior rectus muscle. The lateral portion of the encircling band, connected to the receiving coil, is passed under the inferior and medial recti muscles and secured with a Watzke sleeve to the medial extremity in the superonasal quadrant. Every maneuver must be performed with care not to pinch the silicone shell of the implant or any electronic component, including the multielectrode array, which, at this stage, is hanging outside the eye. To avoid causing damage, the array may be inserted in a small bag created from a cut finger of a surgical glove.

The encirclement band is then sutured with polyester 5-0 suture in all quadrants. The electronic case and the coil are sutured to the sclera with mersilene 6-0, using the special tab holes carved on the silicone shell. The placement of the sutures and, therefore, the positioning of the electronic case on the sclera are performed according to special axial length-related tables, developed to result in correct placement of the multielectrode array on the retinal surface, above the macula.

A 3-port pars plana vitrectomy is then performed with the aid of a chandelier light. We use the Alcon Constellation vitrectomy system, using 25-gauge (25+ Series) instruments and valved trocars. The BIOM system (Oculus) is used to visualize the retina. After core vitrectomy is performed,

triamcinolone acetonide is injected into the vitreous cavity. A posterior vitreous detachment is induced, avoiding excessive traction on the retina. The vitreous cortex is usually very adherent in eyes with RP and normally does not detach further than the midperiphery. If macular epiretinal membrane is present, it is peeled away from the macula; however, to avoid macular tear, we do not recommend peeling the internal limiting membrane.

Vitreous base shaving is then performed, with particular attention directed to the superotemporal quadrant. A 5-mm straight sclerotomy in the superotemporal quadrant is now performed (we use a 15° blade or a 5.1-mm premeasured slit knife). The distance of this sclerotomy from the limbus is calculated according to the axial length-related tables mentioned above. The array is then introduced into the eye with silicone-tipped forceps (avoid toothed instruments), grabbed at the level of a special handle located on the distal end of the array. The valved trocars avoid turbulence in the eye and unwanted movements of the array, greatly facilitating this maneuver.

If all previous steps have been performed correctly, the array is now precisely above the macula. A uniform stimulation of the macular ganglion cells can be elicited. If the array is out of position or twisted, a higher threshold is needed to stimulate the ganglion cells, with consequent potential underperformance of the system.

We proceed to tack the array to the retina with a bimanual technique. Another 20-gauge sclerotomy is created in the inferotemporal quadrant to introduce the tack tool. The array is held in the desired position (via the little handle) with end-gripping forceps while, with the other hand (using special forceps via the 20-gauge sclerotomy), we proceed to insert the tack in the dedicated hole located at the root of the array. During this maneuver, the intraocular pressure must be set at 60 mm Hg. An indirect sign of a successful tacking is a slight whitening of the retinal surface while pushing on the tack.

The 20-gauge and 5-mm sclerotomies are now carefully sutured with 7-0 vicryl, avoiding damage to the transparent cable connected to the intraocular array. The 25-gauge trocars are removed, and the sclerotomies are sutured. The array cable is secured with a mattress suture (passing above it) to avoid movement and extrusion. Processed pericardium is applied on top of the array cable and the anterior edge of the electronic case. The conjunctiva is closed in a standard fashion, and steroids are injected subconjunctivally. Last, intravitreal injection of 0.1 mL ceftazidime (2.25 mg/0.1 mL) and vancomycin (1 mg/0.1 mL) is performed. For a video demonstration of this procedure, visit eyetube.net/?v=lebek/.



CONCLUSION

The following pearls will promote success in the challenging case of Argus II Retinal Prosthesis implantation:

- Perform careful calculation of the distance from the limbus to where the sutures are placed and the 5-mm-long sclerotomy is created.
- Ensure proper instrumentation is used; avoid toothed instruments and use valved trocars.
- Avoid traction on the retina while inducing posterior vitreous detachment.
- Avoid internal limiting membrane peeling.
- Perform careful vitreous removal in the quadrant where the array is to be inserted (superotemporal).
- Set intraocular pressure to 60 mm Hg while inserting the tack.
- Perform careful sclerotomy suturing, avoiding hypotony and endophthalmitis. ■

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