CONTINUED FUNCTION OF AN ARGUS II RETINAL PROSTHESIS IN THE SETTING OF RETINAL DETACHMENT

Despite a complex postoperative course, a patient continues to benefit from the implant after almost 4 years.

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The Argus II Retinal Prosthesis System (Second Sight Medical Products) was approved by the US FDA in 2013 for use in patients with retinitis pigmentosa (RP) with bare light perception or no light perception vision in both eyes.[1] A metal case and receiving coil on the temporal sclera connect through a cable with an epimacular array of 60 electrodes, pinned with a tack over the central macula. Real-time video is sent from a camera located on eyeglasses to a visual processing unit worn on a belt. Interpretation of the artificial patterns of light must be learned through rehabilitation training.[1-3]

Complications remain a reality after implantation.[4] Here, we present a case of a patient who continues to experience useful visual stimulation almost 4 years after implantation despite a complex postoperative course.

CASE REPORT

A 44-year-old man with end-stage RP and bilateral bare light perception vision underwent an uncomplicated Argus II implantation in his left eye. The implant was well positioned over the macula at postoperative weeks 1 and 3 (Figure, A). At week 3, the device fitting and visual rehabilitation processes were initiated (Figure, B). At week 7, the patient presented with a tractional membrane under the electrode array with surrounding retinal detachment (Figure, C and D). This resulted in rotation of the array so that the first row of electrodes overlapped the optic disc, necessitating repair.

The patient underwent 23-gauge pars plana vitrectomy, membrane peeling, endolaser application, air-fluid exchange, and injection of 5,000 cs silicone oil. The array was rotated away from the optic nerve with a 23-gauge pick. Subretinal fluid was drained through stretch holes located immediately inferior to the macula. Endolaser was applied in the periphery, sparing the area of the stretch holes to avoid damaging the electrodes.

After 1 week of prone positioning, examination revealed proper positioning of the array over the macula. No visible residual preretinal membranes were seen. However, shallow subretinal fluid was observed inferior and temporal to the array (Figure, E and F). Over the next 3.5 years, the retina remained shallowly detached under oil with progressively increased fibrosis around the array (Figure, G). The macula was pinned flat by the array (Figure, H). The patient continued to undergo visual rehabilitation, and he developed the ability to interpret simple, high-contrast targets and to apply these skills to his daily activities.

At month 44 after implantation, the patient presented with rubeosis iridis and a 1-mm hyphema. The rubeosis was controlled with two intravitreal injections of bevacizumab (Avastin, Genentech) at 4-week intervals and then intravitreal aflibercept (Eylea, Regeneron) every 6 weeks. All injections are administered through the inferonasal quadrant to avoid implant components sutured to the sclera in the superotemporal and inferotemporal quadrants. The patient remains minimally symptomatic for artificial vision changes, reporting that the stimuli appear only 10% fainter than before the onset of the rubeosis. He continues daily use of his device.

DISCUSSION

The availability of new technologies such as Argus II for visual rehabilitation has improved quality of life for many patients living with irreversible damage due to end-stage RP.[5-7]

Complications such as retinal detachment, vitreous hemorrhage, tack

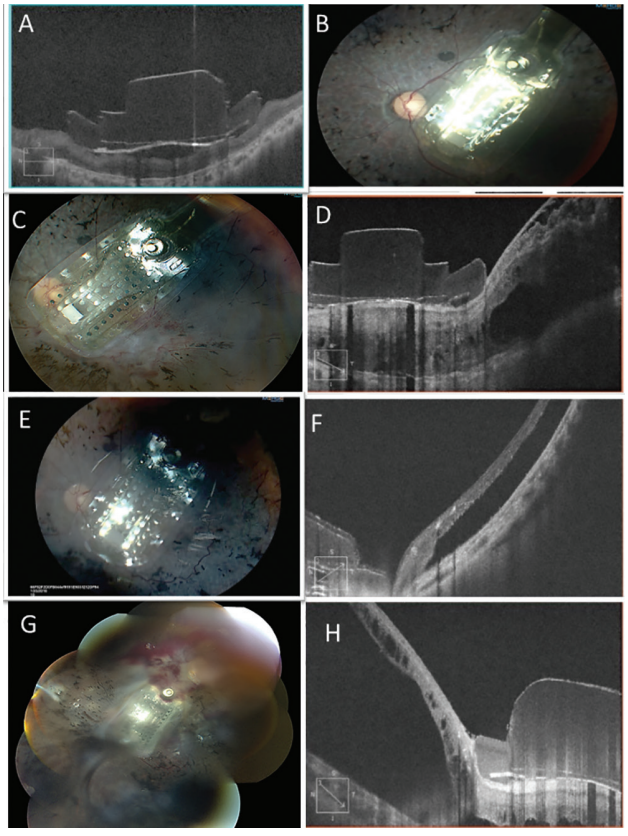

Figure. OCT through the fovea at postoperative day 4 after Argus II implantation shows a well-positioned electrode array over the inner retina (A). Fundus photograph at postoperative week 3 shows that the Argus II array is well-centered over the macula without electrodes overlapping the optic nerve (B). At this visit, adjustment of the electrodes' settings (fitting of the prosthesis) and rehabilitation were initiated. Fundus photograph at week 7 shows a preretinal fibrotic membrane temporal to the electrode array causing rotation of the array toward the optic nerve (C). OCT B-scan shows a preretinal membrane with traction on the underlying retina and macular edema (D). Fundus photograph at 1 week after vitrectomy, membrane peeling, and silicone oil injection shows rotation of the electrodes away from the optic nerve (E). OCT B-scan temporal to the array shows a shallow retinal detachment at 1 week after silicone oil injection (F). Fundus photograph montage at 3.5 years after implantation demonstrates an intraretinal hemorrhage and significant fibrosis around the array and the cable (G). OCT B-scan through the nasal portion of the electrode array shows a retinal detachment but complete apposition of the array to the macula at 3.5 years after implantation (H).

loosening, sterile anterior or posterior uveitis, endophthalmitis, and macular edema have been reported after Argus II implantation. Chronic hypotony and conjunctival erosion occur in approximately 13% of cases by 5 years.[1-4]

The longest prospective cohort, by da Cruz and colleagues, reported 5-year efficacy and safety data from 30 patients treated across 10 centers. The authors reported a total of 24 serious adverse events among 12 patients, most of which occurred within the first year after implantation. By 3 years, there was one rhegmatogenous retinal detachment and one tractional retinal detachment. By 4.5 years, another patient developed a rhegmatogenous retinal detachment followed by neovascular glaucoma the following year, treated by vitrectomy and silicone oil. Two device failures due to loss of signal transmission were identified by 4 years.[4]

When complications arise, patients are eager to hear about their artificial vision prognosis, and surgeons seek guidance on how to surgically manage these patients, avoid damage to the implant, and manage patients' expectations. The case presented here illustrates several important points.

First, the electrode array can continue to function in silicone oil and after laser application to the peripheral retina. Second, because it is not recommended to apply laser close to the array—laser may damage electrodes—and the retina is significantly degenerated in eyes with advanced RP, retinal detachment repair may be challenging in these cases. Retinal breaks may have to be left untreated. Third, rubeosis in the setting of chronic retinal detachment may be managed with anti-VEGF injections given via the nasal scleral quadrants. It is recommended to avoid passing needles in the temporal quadrants where the external components of the implant are located.

Familiarity with the Argus II device and the location of the implant components around the eye is essential for safe management of complications that may arise after implantation. We stress the importance of providing long-term follow-up, visual rehabilitation, and emotional support to the patients to encourage continued use of the prosthesis and a sense of psychological wellbeing. ■

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