The Argus II Retinal Prosthesis: 12-Month Outcomes from a Single-Study Center

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• PURPOSE: **To study the anatomic and functional outcomes of Argus II Retinal Prosthesis System implantation in patients with retinitis pigmentosa.**
• DESIGN: **Interventional case series.**
• METHODS: **The study population included 6 patients with visual acuity no better than light perception. After the Argus II Retinal Prosthesis System was implanted, complications and anatomic and functional results were studied. The main outcome measures were mobility, square localization, direction of motion, grating visual acuity, and Goldmann visual field, all of which were assessed. Optical coherence tomography was performed.**
• RESULTS: **Implantation of the Argus II Retinal Prosthesis System was safely performed in all patients. One patient experienced postoperative elevation in intraocular pressure, which was controlled medically. In 1 patient, moderate detachment of the choroid occurred postoperatively, and it resolved spontaneously. One patient withdrew from the study. Wound dehiscence, endophthalmitis or retinal detachment was not observed. All patients were able to locate a bright light on the ceiling and a dark line on the floor after the surgery. Performance in square localization tests improved in 4 patients, and direction of motion improved in 3 patients. One patient achieved grating visual acuity. Goldmann visual field test results improved in all patients.**
• CONCLUSIONS: **The patients showed improvement in visual tasks after the surgery, and the device was well tolerated and functional over a 1-year follow-up period. A rigorous patient-selection process is necessary to maximize patient compliance with the rigorous follow-up testing schedule. Both patients and medical staff should be prepared for a lengthy, arduous rehabilitation process. (Am J Ophthalmol 2014;157:1282–1290.**

THE ARGUS II RETINAL PROSTHESIS SYSTEM (SECOND Sight Medical Products, Sylmar, California) is an epiretinal device with an array of 60 electrodes. The device was approved for marketing by the European Community in March 2011 for long-term intraocular implantation in patients with severe photoreceptor degenerations. The United States Food and Drug Administration also approved the device for marketing within the United States in February 2013.

Retinitis pigmentosa leads to photoreceptor degeneration, but the inner retinal cells (eg, bipolar, horizontal, amacrine and ganglion cells) and nerve fiber layer remain largely preserved.[1] This explains why electric stimulation of the inner retina leads to patients' perception of phosphenes.[2–4] The Argus II Retinal Prosthesis System is based on this observation and stimulates preserved inner retinal cells. Humayun and associates[5] presented the 6-month results of device use from a multicenter clinical trial involving 30 patients.

This study evaluates the safety and efficacy of Argus II Retinal Prosthesis System implantation. Anatomic and functional outcomes were examined at a single study center.

METHODS

THIS STUDY WAS AN INTERVENTIONAL CASE SERIES. THE local ethics committee of the Azienda Ospedaliero-Universitaria Pisana waived the need for ethics committee approval of this research. This was done because a postmarketing study on the Argus II Retinal Prosthesis implant had already been approved. Although our study population was different from that of the approved study, the same surgery and visual function tests were performed. Informed consent for prosthesis implant was obtained from the patients after the risks and benefits of having an Argus II Retinal Prosthesis implanted were explained. Patients were also informed that a new, higher resolution device was in development and would be available in the near future. The study adhered to the tenets of the Declaration of Helsinki and abided by all applicable Italian federal and state laws.

• **PATIENT ELIGIBILITY:** All patients recruited into this study were affected by retinitis pigmentosa (RP) and were 25 years of age or older. Subjects were required to have some visual memory, no electroretinographic response, and residual light perception. We also assessed patients' expectations following device implant, and only those with reasonable expectations that could be met within

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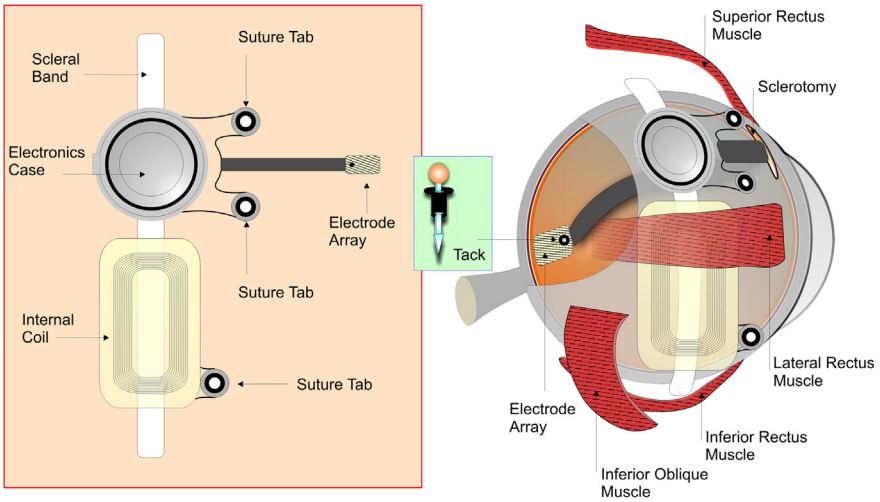

FIGURE 1. Schematic of the Argus II Retinal Prosthesis System. The diagram on the left shows the implanted part of the device with the scleral band, the internal coil and the retinal surface electrode array. The diagram on the right shows an implanted device with the scleral band positioned under the 4 recti muscles. The cable passes through the sclerotomy to the array placed over the macular region.

the device's limits were included. Additionally, the importance of study protocol compliance was emphasized during the informed-consent process, and only the patients expected to be compliant were enrolled. Patients had to be willing and able to attend all follow-up visits. Exclusion criteria included the presence of other ocular disease that might interfere with device function or inhibit postoperative device visualization; history of cystic macular edema; pregnancy or desire to become pregnant; deafness; and uncontrolled systemic disease.

We contacted by telephone 150 patients with RP who were interested in participating in the study. At that time, patients were asked about their residual visual acuity, general health, ocular health, and history of useful vision. Of the 150 initial candidates, 15 patients were invited to our clinic for further screening. The initial screening visit included a complete eye examination, retinal fundus photography, fluorescein angiography, optical coherence tomography (OCT), Goldman full-field visual field testing, and ultrasound (A-scan) axial length measurement. Patients with axial lengths between 20.5 and 26.0 mm were included. Ultimately, 6 patients were included in the study and received the Argus II Retinal Prosthesis System.

• **THE ARGUS II RETINAL PROSTHESIS SYSTEM:** The external part of the Argus II Retinal Prosthesis System consists of a glasses-mounted camera and a battery-powered video-processing unit that is worn on the patient's body. The processing unit converts the camera-captured image into an electronic signal that is transmitted by cable to a transmitting coil located on the glasses. The implanted portion of the device (Figure 1) consists of a receiving coil that wirelessly receives information from an external transmitting coil and is sutured to the sclera by an encircling scleral band. Data are sent via a small transcleral cable from the transmitting coil to the electrode array, which is firmly held to the retinal surface by a specialized tack. The array is a 6 × 10 grid of electrodes, with each electrode emitting electric pulses directly to the retinal surface. Direct retinal electric stimulation leads to a nerve response that is transmitted via the optic nerve to the visual cortex. This allows the patient to perceive spots of light. The maximum visual field obtainable with the Argus II System is approximately 20 degrees.[5]

• **PREOPERATIVE EXAMINATIONS AND VISUAL FUNCTION TESTS:** All patients had immeasurable monocular logarithm of the minimum angle of resolution (logMAR) visual acuity (worse than 2.9) before surgery. All preoperative tests were performed with both eyes open.

The square localization test, which measures a patient's ability to localize a white square on a black touch-screen monitor, was performed. The size of the square (7.3 cm) and the contrast between the square and the computer screen (100%) did not change, but the location of the square on the computer screen varied. After positioning the patient 30.5 cm away from the screen, the head was scanned to localize the square on the screen. The subject was then asked to touch the middle of the white square a total of 40 times. The average difference between the square center and the patient's touch, in centimeters, was automatically computed by the testing software.

A direction-of-motion test, which measures a patient's ability to detect motion, was also performed. A white bar moved across a black computer screen. The size (3.7 cm wide); contrast (100%); and speed (2000 ms) of the stimulus did not change, but the direction of the motion was varied. The subject was asked to indicate the stimulus

TABLE. Clinical Data of Patients After Implantation of the Argus II Retinal Prosthesis System

Patient No.	Age	Gender	Eye	Lens Status	Surgery	Complications	Number of Functioning Electrodes
1	59	m	r	Pseudophakic		Elevated intraocular pressure	57
2	30	m	r	Pseudophakic	Peeling of cellophane maculopathy	Choroidal detachment	56
3	55	f	l	Pseudophakic		None	58
4	46	m	r	Pseudophakic		Lost in follow-up	55
5	36	m	r	Phakic	Lens extraction	None	60
6	44	m	l	Pseudophakic		None	59

direction on a touch-screen. Eighty trials were performed and the average difference between the stimulus angle and the response angle was automatically computed by the testing software.

• **POSTOPERATIVE EXAMINATIONS AND TESTING:** Follow-up visits were scheduled 1 day, 1 week, and 1, 3, 6, and 12 months after surgery. At each follow-up visit, a complete ophthalmologic examination was performed. OCT images were obtained 1 week after surgery to verify proper device positioning. Once the device was implanted, the video processing unit was individually calibrated for each patient. This was done using a special computer program that measured the perception threshold for each electrode and created a video configuration file.

Square localization and direction-of-motion testing were repeated 3, 6, and 12 months after surgery with both eyes open and the device switched on. Grating visual acuity was also tested, but only in the operated eye with the device switched on. Goldmann full-field visual field testing was performed at 12 months (last follow-up visit) in the operated eye with the device switched off. Last, patient mobility testing was conducted 1 week following device implantation. This consisted of asking the subject to locate a bright light on the corridor ceiling and to walk along a dark line (30 cm wide) on the pavement.

• **SURGICAL IMPLANTATION OF THE ARGUS II RETINAL PROSTHESIS SYSTEM:** All surgeries were performed by a single surgeon (SR). Prior to surgery, 8 mg of dexamethasone and 1000 mg of ceftriaxone were administered intravenously. Phakic patients underwent clear cornea phacoemulsification of the lens and were left aphakic. A 360-degree conjunctival peritomy was performed, and the 4 recti muscles were isolated. The prosthesis system scleral band was passed under the 4 recti muscles, and the coil was positioned in the upper temporal quadrant of the globe between the superior and the lateral rectus muscle. The coil and the scleral band were fixed to the sclera by passing a Mersilene 5-0 suture (Ethicon, Livingston, United Kingdom) through suture tabs located on the device in the temporal quadrants. In the nasal quadrants, the scleral band was fixed by 2 mattress sutures, and the scleral band was closed by a sleeve in the upper nasal quadrant.

A 25-gauge chandelier endo-illumination system was positioned in the nasal inferior quadrant to allow bimanual intraocular manipulation. A complete vitrectomy was performed using a 23-gauge valved entry system, and the posterior hyaloid was removed. Triamcinolone acetonide was used for better visualization of the vitreous, and epiretinal membranes, when present, were peeled. Customized for each patient according to the axial length, a further 5 mm wide sclerotomy parallel to the limbus was made in the upper temporal quadrant. In shorter eyes (axial length = 20.5–22.8 mm), the sclerotomy was performed 3 mm from the limbus. In average eyes (axial length =22.8–24.2 mm), the sclerotomy was performed 3.5 mm from the limbus. In longer eyes (axial length = 24.2–25.5 mm), the sclerotomy was performed 4.0 mm from the limbus. The microelectrode array and cable were passed through the sclerotomy, and the nasal sclerotomy was widened to accommodate 19-gauge tacking forceps. The array was positioned over the macular region with a silicone brush flute needle or end-gripping forceps. The surgeon ensured that the array did not cover the optic disc. Care was also taken to ensure that the cable in the vitreous cavity was neither too long nor too tight. A customized tack was placed in a ring located on the array and, in a decisive and precise maneuver perpendicular to the globe wall, the array was tacked to the posterior pole superotemporal to the macula.

Sclerotomies were closed with Vicryl 7-0 (Ethicon) thread, and a mattress suture was placed over the external part of the cable. The extraocular part of the cable was also covered with human pericardium (prepared by a tissue bank) to safely close the large sclerotomy and to prevent conjunctival erosion. The tenon and conjunctiva were sutured with Vicryl 7–0. At the end of surgery, vancomycin (1 mg) and cefazolin (2.25 mg) were injected into the vitreous cavity. Cefazolin (100 mg); dexamethasone (2 mg); and lidocaine 4% (2 mL) were injected subconjunctivally. Patients also took oral ciprofloxacin (500 mg) twice a day for 2 weeks, beginning 2 days before surgery. Postoperative topical medications were used for 2 weeks following surgery; they included moxifloxacine (1 drop, 4 times a day); dexamethasone (1 drop, 4 times a day); and atropine 1% (1 drop, twice a day). Subjects also took oral prednisolone (60 mg, once a day) for 2 weeks.

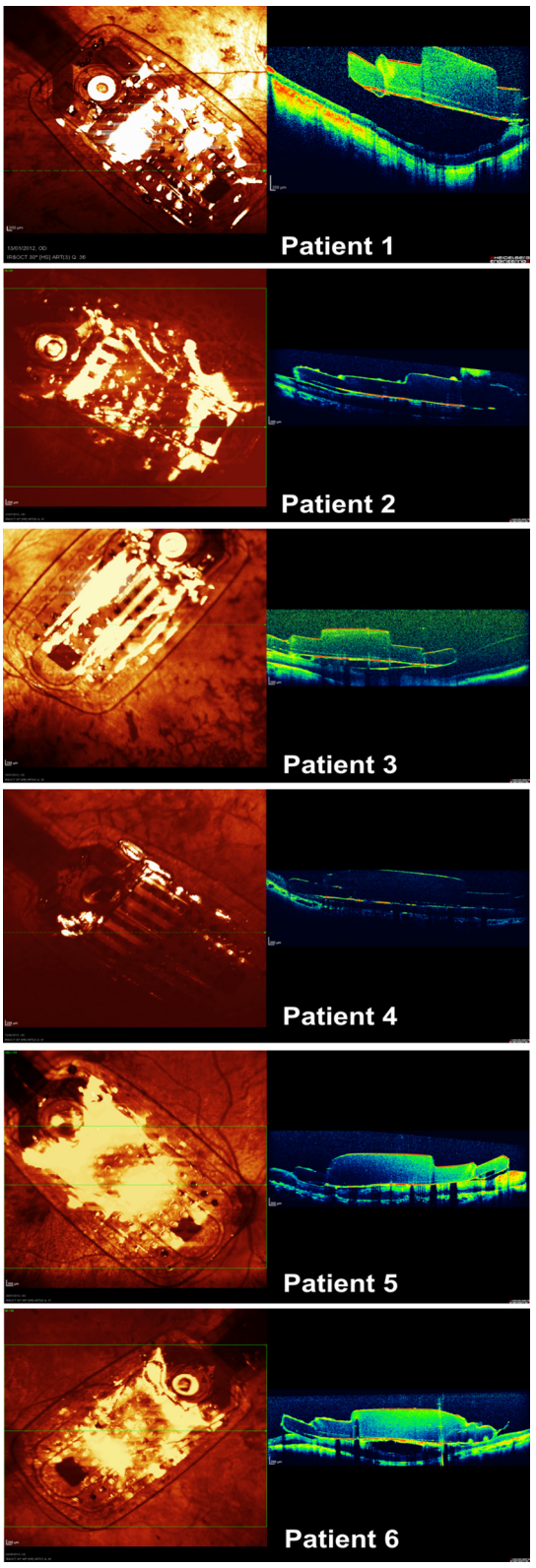

FIGURE 2. Fundus photograph (left column) and OCT-images (right column) of the 6 study eyes implanted with the Argus II Retinal Prosthesis System. With the exception of patient 1, all implants were in close contact with the internal retinal surface.

Impedance waveform measurements were obtained prior to surgery, after scleral band positioning, after retinal-array tacking, and at the end of surgery. This was done to verify that each of the 60 electrodes was properly functioning before, during and after the prosthesis implantation process.

RESULTS

• **PATIENTS:** A total of 6 patients (5 men, 1 woman) were included in this study (Table), and all surgeries were performed between October 2011 and May 2012. Subjects' ages averaged 45.0 ± 10.9 years (range, 30–59 years), and all patients had visual acuities no better than light perception. One patient was phakic and 5 patients were pseudophakic at the time of surgery. Additionally, 1 patient had cellophane maculopathy in both eyes.

• **SURGERY:** In general, surgery was uneventful. Mean operation time was 174.1 ± 36.9 min (range, 140-225 min). One phakic patient underwent lens phacoemulsification and was left aphakic (patient 5); 1 patient underwent an epiretinal macular membrane peel (Patient 2); and 1 patient had the posterior part of the ciliary body touched and pulled during array insertion. The most challenging part of surgery was correctly positioning and tacking the electrode array to the internal surface of the retina. Close contact of all 60 electrodes to the internal retinal surface is necessary for the device to function properly. After implantation, an average of 57.5 ± 1.8 (range, 56–60) of 60 electrodes in the array were functioning properly.

• **POSTOPERATIVE COMPLICATIONS AND ANATOMIC OUTCOME:** None of the patients had any serious adverse events that required further surgery or required device explantation during the 12-month follow-up period. One patient had elevated intraocular pressure the day after implant surgery, and it was controlled medically. A moderate choroidal detachment occurred in 1 patient the day after implant surgery, and it was probably caused by the accidental pulling of the ciliary body during array insertion. The choroidal detachment spontaneously resolved and did not require medical or surgical treatment. No cases of endophthalmitis or retinal detachment were observed. The implant displayed good biocompatibility over the 12-month follow-up period, and no signs of chronic intraocular inflammation, proliferative vitreoretinopathy or epiretinal membrane formation were observed. The microelectrode array remained well positioned, and all electrodes that were functioning immediately after surgery continued to work properly during the 12-month study period. One patient withdrew from the study 1 month after surgery and was lost to follow-up.

• **POSTOPERATIVE TESTING RESULTS:** Postoperative OCT imaging showed that the array was well positioned

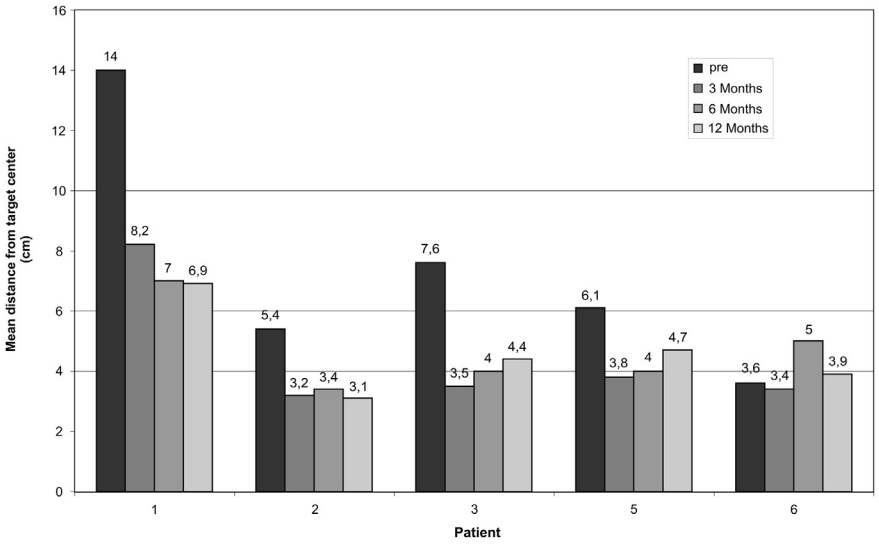

FIGURE 3. Square localization testing results before and after Argus II Retinal Prosthesis System implantation. This test measures a patient's ability to localize a white square (7.3 cm in size) on a black touch-screen monitor. The size (7.3 cm) and contrast (100%) of the square did not change, but its location was varied. After the patient was properly positioned 30.5 cm away from the screen front, and the head was scanned, the patient was asked to touch the middle of the square. The computer then calculated the average distance, in centimeters, between the touch and the square's center for 40 trials. The test was performed with both eyes open, and the device was switched on during postoperative testing sessions.

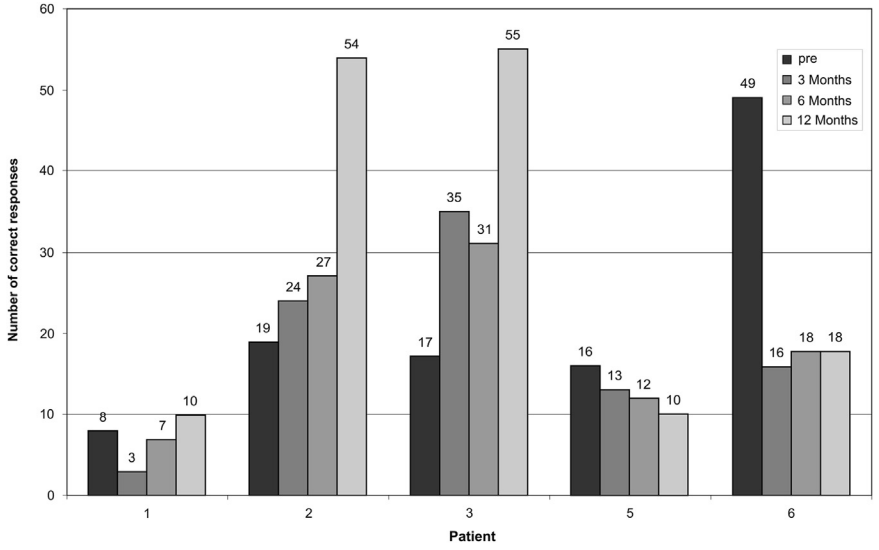

FIGURE 4. Direction-of-motion testing results before and after Argus II Retinal Prosthesis System implantation. This test measures a patient's ability to detect the direction of a white bar moving across a black computer screen. The size (3.7 cm wide), speed (2000 ms) and contrast (100%) of the bar did not change, but the direction of travel varied. Once the patient was properly positioned, she or he was asked to indicate the direction of travel on a touch-screen. The computer then calculated the average difference between the stimulus angle and the response angle for 80 trials. The test was performed with both eyes open, and the device was switched on during postoperative testing sessions.

in all patients. Patient 1 had a posterior pole staphyloma and, consequently, some of the array was not in close contact with the retinal surface (Figure 2).

Mobility tests were performed once the fitting process was completed, generally 1 week after surgery. All patients were able to use the device in everyday conditions and to locate a bright light on the ceiling and a 30 cm wide dark stripe on the floor.

Square localization-testing results improved in 4 (80%) of 5 patients after surgery, compared to preoperative results

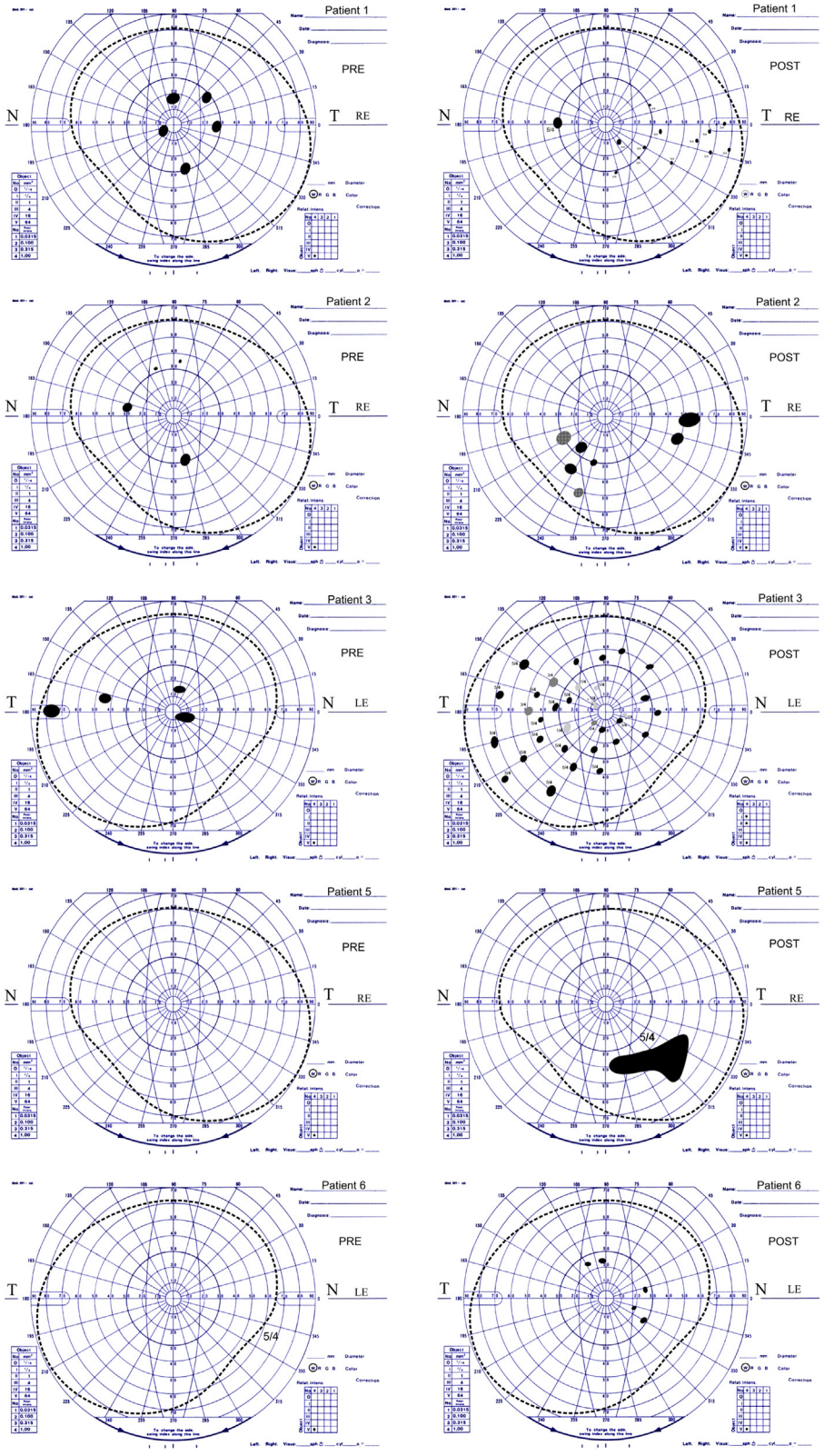

FIGURE 5. Pre- (left) and postoperative (right) Goldman visual field testing results for each patient implanted with the Argus II Retinal Prosthesis System (right). Testing results are presented in numeric order, with Patient 1's results in the top row and Patient 6's results in the bottom row. The dotted line indicates the boundary of a normal visual field; black areas indicate where patients were able to perceive target V4. Postoperative testing was performed with the device switched off.

(Figure 3). Additionally, 3 (60%) of 5 patients performed better in direction-of-motion testing 12 months after surgery than before surgery (Figure 4). Goldmann visual field results improved in all patients in the operative eye (Figure 5). Additionally, Patient 2 was able to identify gratings (grating visual acuity = 2.2 logMAR) in the operative eye when the device was switched on.

DISCUSSION

SURGERY WAS SAFELY PERFORMED IN ALL PATIENTS. ONLY minor surgical complications occurred and no patient required additional surgery. Of the 6 patients, 5 (83%) were followed for the full 12 months, with 1 patient lost to follow-up 1 month after surgery. Using a sutureless 23-gauge vitrectomy system did not complicate surgery. Because the insertion of the electrode array required a large sclerotomy, this wound was covered with human pericardium that had been prepared by a tissue bank. This was done to prevent conjunctival erosion and hypotony from wound dehiscence.[5] We did not observe these complications.

As noted above, 1 of our patients was lost to follow-up. The subject withdrew his consent to participate in the study shortly after surgery, and he could not be convinced to return to our clinic for further training in how to use the device on his own, independent of the study. Losing a patient to follow-up is not a trivial matter because the device is an intraocular foreign body, and long-term adverse effects related to the device are not well known. It is likely that the patient withdrew from the study because his expectations of the device were not fulfilled, despite multiple preoperative patient interviews and a rigorous subject selection process. Implanting physicians must keep in mind that RP patients can be psychologically fragile and are subject to neuropsychiatric disorders.[6] In addition, patients with low vision are often affected by visual hallucinations.[7] Therefore, we recommend that recipients of retinal prostheses be followed-up by a psychologist, in addition to an ophthalmologist, retinal surgeon and rehabilitation specialist, to help close the gap between reality and unreasonable expectations. Future studies of retinal prostheses should include psychological evaluation results in enrollment criteria. Subject retention is imperative to achieving optimum device function. A precise and customized device fitting is required, as is patient training in using the device. This is time consuming and tiring for the patient, who has already had to attend lengthy clinical visits.

The array was well-positioned over the macular region and did not cover the optic nerve head. On OCT imaging in 1 patient, we observed that the array was not attached to the internal retinal surface because of a posterior pole staphyloma (Patient 1). To minimize the effect of this separation between the macular surface and the device, intraoperative, microscope-mounted OCT imaging would be helpful. It is also possible that the array position differs in the intraoperative prone position and the standing or sitting position. Intraoperative OCT imaging would allow this to be determined by comparing intraoperative and postoperative scans. Preoperative A-scan ultrasound axial length measurements on this patient averaged 23.41 mm and did not exclude him from surgery. However, the patient was pseudophakic, had nystagmus and could not fixate, so preoperative measurements were difficult to obtain and were imprecise. A B-scan ultrasound should also be performed in such patients to rule out staphyloma before surgery. In this case, 1 week after surgery, the nystagmus diminished and the patient demonstrated better ocular motility control. In fact, preoperative eye movement control difficulties improved in all patients with the condition after device implant. Therefore, it was easier to obtain high-quality OCT images after surgery than before surgery in several patients.

When the microelectrode array is not in close contact with the internal retinal surface, a higher threshold current is needed to elicit visual perception.[8,9] Humayun and associates[10] also found that the macular and the extramacular regions have markedly different excitation thresholds. However, following accurate postoperative device calibration in the patient with staphyloma, the problem of imperfect electrode array attachment to the internal retinal surface was overcome. During the calibration process, the lowest current level needed for phosphene perception is determined for each of the 60 electrodes. This is done by the rehabilitation specialist, who sends electrical signals, in increasing current levels, to each electrode until the patient perceives a phosphene. As mentioned above, this process is time consuming and requires a cooperative patient. Additionally, it is often difficult for a patient to distinguish between artificial retinal stimulations and naturally occurring, spontaneous phosphenes. Therefore, after a patient becomes familiar with the device, stimulation thresholds can change. This is generally seen as a positive sign because it may indicate retinal and visual system reactivation. Thus, the fitting process must be repeated, and the custom device settings specific to the patient must be adjusted at each visit.

We also found that the square localization test and the direction-of-motion test, the most common visual function tests used in RP and retinal prosthesis patients, did not always correspond to actual visual performance. In the square localization test, the patient is more likely to indicate a margin of the square than the square's center. This is because it corresponds to the region with the greatest contrast, where perception would be more likely. Moreover, the patient has to learn to interpret visual information coming from the residual functioning retina and the information coming from the cyclopic eye (camera) positioned on the forehead. Both tests also require good hand-eye coordination, a skill that most patients had not used for many years because of blindness. Therefore, the

absolute number of correct answers (ie, correctly indicated squares) was not considered; rather, the mean distance, in centimeters, between the touch and the actual square center was measured. As with the fitting process, performing these tests is time consuming and requires large amounts of patience by both the subject and the examiner. Indeed, in similar studies, not all patients were motivated to participate in the required testing.[11] Because of this, several attempts have been made to develop instrumentation for easier and faster low-vision testing in RP patients that are also reproducible.[12–14] Tools that measure visual acuity accurately in these patients are also needed.

Goldmann visual field testing results also improved in these patients after the Argus II Retinal Prosthesis System was implanted. In agreement, visual field improvements in both the retinal regions covered by the implant and in more distant retinal areas were previously observed by Chow and coworkers.[15] This visual function improvement may be due to the effects of electric stimulation.[16] Pardue and associates[17] observed that the number of photoreceptors located directly over or around the implant increased with both active and inactive device implantation in Royal College of Surgeons (RCS) rats. In addition, Ciavatta and associates[18] observed retinal expression of basic fibroblast growth factor (Fgf2) in RCS rats with implanted subretinal microphotodiode arrays. It is also known that the perception of vision in RP patients is dependent on daily general health and subjective mood.[19–21] We believe that visual improvements perceived by patients are similar to those that occur in amblyopic patients who have lost the dominant eye.[22–24]

In conclusion, our 12-month single-center results show that a visual prosthesis can be safely implanted and well tolerated and can functional over a period of 1 year. A rigorous patient-selection process is necessary to maximize patient compliance with the rigorous follow-up testing schedule. Both patients and medical staff should be prepared for lengthy and arduous rehabilitation processes.

ALL AUTHORS HAVE COMPLETED AND SUBMITTED THE ICMJE FORM FOR DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST, and none were reported. Design of study (S.R., C.B., L.C., L.A., F.G.E., F.B., E.D.B.); Collection, management, analysis, and interpretation of data (C.B., L.C., L.A.); Preparation, review, and/or approval of the manuscript (S.R., C.B., L.C., L.A., F.G.E., F.B., E.D.B.).

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REPORTING VISUAL ACUITIES

The AJO encourages authors to report the visual acuity in the manuscript using the same nomenclature that was used in gathering the data provided they were recorded in one of the methods listed here. This table of equivalent visual acuities is provided to the readers as an aid to interpret visual acuity findings in familiar units.

Table of Equivalent Visual Acuity Measurements

Snellen Visual Acuities				
4 Meters	6 Meters	20 Feet	Decimal Fraction	LogMAR
4/40	6/60	20/200	0.10	+1.0
4/32	6/48	20/160	0.125	+0.9
4/25	6/38	20/125	0.16	+0.8
4/20	6/30	20/100	0.20	+0.7
4/16	6/24	20/80	0.25	+0.6
4/12.6	6/20	20/63	0.32	+0.5
4/10	6/15	20/50	0.40	+0.4
4/8	6/12	20/40	0.50	+0.3
4/6.3	6/10	20/32	0.63	+0.2
4/5	6/7.5	20/25	0.80	+0.1
4/4	6/6	20/20	1.00	0.0
4/3.2	6/5	20/16	1.25	−0.1
4/2.5	6/3.75	20/12.5	1.60	−0.2
4/2	6/3	20/10	2.00	−0.3

From Ferris FL III, Kassoff A, Bresnick GH, Bailey I. New visual acuity charts for clinical research. Am J Ophthalmol 1982;94:91–96.