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Five-year safety and performance results from the Argus II Retinal Prosthesis System clinical trial

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Abstract

Purpose—The Argus® II Retinal Prosthesis System (Second Sight Medical Products, Inc., Sylmar, CA) was developed to restore some vision to patients blind from retinitis pigmentosa (RP) or outer retinal degeneration. A clinical trial was initiated in 2006 to study the long-term safety

and efficacy of the Argus II System in patients with bare or no light perception due to end-stage RP.

Design—The study is a prospective, multicenter, single-arm, clinical trial. Within-patient controls included the non-implanted fellow eye and patients' native residual vision compared to their vision when using the System.

Subjects—There were 30 subjects in 10 centers in the U.S. and Europe.

Methods—The worse-seeing eye of blind patients was implanted with the Argus II System. Patients wore glasses mounted with a small camera and a video processor that converted images into stimulation patterns sent to the electrode array on the retina.

Main Outcome Measures—The primary outcome measures were safety (the number, seriousness, and relatedness of adverse events) and visual function, as measured by three computer-based, objective tests. Secondary measures included functional vision performance on objectively-scored real-world tasks.

Results—Twenty-four out of 30 patients remained implanted with functioning Argus II Systems at 5 years post-implant. Only one additional serious adverse event was experienced since the 3-year time point. Patients performed significantly better with the System ON than OFF on all visual function tests and functional vision tasks.

Conclusions—The five-year results of the Argus II trial support the long-term safety profile and benefit of the Argus II System for patients blind from RP. The Argus II is the first and only retinal implant to have market approval in the European Economic Area, the United States, and Canada.

Introduction

The last decade has seen a significant number of new retinal treatment paradigms commencing clinical trials. These have included gene therapy[1], stem cell transplantation[2], and electronic neural prostheses in different locations in the eye. [3-5] While all of these approaches hold promise, only retinal prostheses have reached the market for the restoration of some visual function in patients blind from retinitis pigmentosa. The Argus II System was the first and remains one of only two retinal prostheses to be approved for commercialization in the European Economic Area (receiving CE Mark in 2011) and the only prosthesis to date to receive FDA approval for commercialization in the USA (Humanitarian Device Exemption approval in 2013) and Health Canada approval (in 2014).

Thirty patients implanted with the Argus II Retinal Prosthesis System (Second Sight Medical Products, Inc., Sylmar, CA, USA) for the Argus II feasibility study (http://clinicaltrials.gov/show/NCT00407602) are being followed for 10 years in a long-term follow-up clinical study. All enrolled patients have now reached at least 5 years post-implantation; this report includes safety and efficacy data for all enrolled patients for that period.

Methods

The Argus II System

The Argus II Retinal Prosthesis System is a visual prosthesis with implanted and external components (Figure 1). Patients wear a pair of glasses with a small camera mounted in the frame connected via a cable to a video-processing unit (VPU) worn on the belt or shoulder strap. Implanted components include a hermetically-sealed enclosure for the electronics, which, along with a receiving antenna, is secured to the eye with a scleral band and sutures, and an array of 60 electrodes is inserted into the eye and tacked over the macula. When the system is turned ON, the visual information collected by the camera is received, processed, and converted into a brightness map in real time by the VPU. Power and data are sent via a radio-frequency telemetry link from an external antenna on the glasses to the receiving antenna on the eye. The brightness values in the video are converted into stimulation current amplitudes on each of the 60 electrodes; activated retinal neurons produce action potentials, which travel through the remaining visual system and are perceived as patterns of light by the patients.

Surgical Procedure

The Argus II System was implanted in the worse-seeing eye of each patient. The surgical procedure has been reported in detail elsewhere[6,7]; here, we provide a summary of the main steps. A 360-degree limbal conjunctival peritomy was performed. The receiving coil was inserted under the lateral rectus muscle and extended into the inferotemporal quadrant, while the electronics case was placed in the superotemporal quadrant. The scleral band continued under the inferior, medial, and superior rectus muscles. Suture tabs on the implant allowed fixation of the implant to the sclera, and a Watzke sleeve (Labtician Ophthalmics, Inc, Oakville, Ontario, Canada) and mattress sutures or scleral tunneling secured the scleral band in the nasal quadrants. Core and peripheral vitrectomies were performed, and a temporal sclerotomy of about 5 mm was made to allow the introduction of the 60-electrode array into the eye. The array was placed over the macula and tacked to the retina with a custom-made, spring-tension, metallic tack (Second Sight Medical Products, Inc., Sylmar, CA). The trans-scleral passage of the cable was sealed with sutures, and all other sclerotomies were closed. An allograft (Tutoplast®, aponeurosis in France) was sutured over the implant to reduce the risk of conjunctival irritation or erosion, and the Tenon's capsule and conjunctiva were closed.

Study Design

The Argus II System clinical trial was a prospective, single-arm, non-randomized study. A sample size of 30 was chosen as sufficient for an analysis of safety and efficacy, taking into account the rarity of the disease under study (retinitis pigmentosa; estimated prevalence is about 1 in 4000 people in developed countries). There were no sham surgeries and all patients were implanted with the Argus II System.

Inclusion criteria included: bare light perception or worse vision (>2.9 logMAR) in both eyes due to profound retinitis pigmentosa (in the United States) or outer retinal degeneration (in Europe); a history of useful form vision; intact and functioning optic nerve; 50 years of

age or older (later in the trial, this criterion was changed to 25 years or older in the U.S. and Switzerland and 18 or older in the U.K. and France). Exclusion criteria included: diseases or conditions that may have prevented successful implantation (e.g., axial length out of a certain range) or prevented the device from working correctly (e.g., damaged optic nerve function). The trial was and continues to be conducted in accordance with the Declaration of Helsinki and the national regulations for medical device clinical trials in the respective countries where the study is being conducted: the United States, the United Kingdom, France, and Switzerland. The study has been approved by the national ministries of health in these countries and the ethics committees or institutional review boards of participating institutions. All patients signed informed consent to participate. The clinical trial is posted on www.clinicaltrials.gov (where full inclusion and exclusion criteria can be found), under trial registration number NCT00407602.

Endpoints

The trial endpoints, summarized here, have been described in detail elsewhere. [6-9] The primary endpoint for safety was the rate, type and severity of adverse events that were related to the surgery or the device. All adverse events were collected and reported as necessary to the relevant authorities and ethics committees and received detailed review and adjudication by an independent medical safety monitor. Serious adverse events (SAEs) were distinguished as a subset of adverse events (AEs) according to the regulatory definition. In this trial, events adjudicated as serious met the criteria of “necessitated medical or surgical intervention to preclude permanent impairment or damage to a body structure” or “required hospitalization or prolonged hospitalization.” Non-serious adverse events required no treatment or only noninvasive treatment. Thus, a single type of event such as hypotony could be classified as either serious or non-serious depending on how or where it was treated.

Information about device reliability, stability, and robustness over time was gathered by tracking the number of device failures. Data on partial or complete explantation of devices were also captured. Post-explant follow-up visits were performed at 1 day, 1 week, 4 weeks, 3 months, 6 months, and 12 months post-explant except as noted below. Post-explant visits included eye exam, retinal photography, ocular coherence tomography, and Fluorescein Angiography.

The primary endpoint for efficacy was visual function, as measured by three custom-designed objective assessments. Square Localization measured the ability to locate and touch a high-contrast white square of light on a black background, on a touch screen monitor; Direction of Motion assessed patients' ability to determine and indicate the direction of a high-contrast bar that moved across the monitor; and Grating Visual Acuity measured patients' visual acuity using square-wave gratings of different spatial frequencies presented on a computer monitor. All assessments were performed with the Argus II System ON and OFF (with patients' residual vision only – binocularly for Square Localization and Direction of Motion, and monocularly for Grating Visual Acuity). Masking of patients was not possible due to the visual and auditory cues produced by the Argus II System when turned ON.

Square Localization and Direction of Motion were analyzed in terms of their mean error (the difference between the stimulus and response, in centimeters and degrees, respectively). For the analysis as a group, results from all patients were pooled at each time point, such that mean error indicated the overall performance of the group. For individual analyses, a two-tailed t-test assuming unequal variances indicated whether the mean error with the System ON was significantly different from System OFF for each patient ($p<0.05$). Grating Visual Acuity was measured on a scale of 2.9 to 1.6 logMAR. Patients who performed no better than chance at 2.9 logMAR were scored "worse than 2.9 logMAR." The percentage of patients who scored better than 2.9 logMAR was compared for the two conditions.

Secondary endpoints included the 'Door Task', a real-world assessment in which patients attempted to walk to and touch a large piece of contrasting felt (simulating a door) on a wall; the 'Line Task', in which patients followed a white line painted on black tiles; the Massof Activity Inventory, a questionnaire designed to measure changes in functional vision; the Functional Low-vision Observer Rated Assessment (FLORA), an assessment performed by trained low-vision rehabilitation specialists; and the Vision-related Quality of Life (VisQoL), a questionnaire designed to measure the quality of life of those suffering vision impairments. The FLORA and VisQoL were performed only through post-implant year 3 (as per the clinical trial protocol), and the FLORA has been described and reported elsewhere. [10,11] The Activity Inventory was not fully validated in this patient population (e.g., with very low vision patients) and as such the data are not included in this report.

The Door and Line Tasks were scored by percent success – the mean percent of correct responses (touching the door or ending at the line) for System ON and OFF was calculated over the group.

Results

Patient Demographics

Enrollment of 30 patients at 10 centers was completed in 26 months (between June 2007 and August 2009), including a pause in enrollment of about 6 months after the first 15 patients were implanted. Basic demographics are shown in Table 1.

Patients Lost to Follow-up—No patients were completely lost to follow-up as of five years post-implant. However, the number of patients included in the analysis of safety and efficacy did decline over time. Safety data were gathered to five years for 27 patients, with drop-out occurring for explanted patients at 1.2 years, 3.5 years, and 4.3 years. Performance data were gathered for N=21 or N=20 patients at five years post-implant as described below.

Safety

Previous reports presented serious adverse event (SAE) data at 1 year and 3 years post-implant. [6,7] Here, we reprint the 0-3 years cumulative SAE rates and report SAEs that occurred up to 5 years post-implant (Table 2). As of 5 years post-implant, 60% of patients (18/30) had experienced no device- or surgery-related SAEs. There were 24 SAEs among 12 patients.

All SAEs were treatable with standard ophthalmic approaches, and there were no lost eyes (enucleated) in the study. As shown in Table 2, only one additional serious adverse event had occurred up to year five since the last analysis at three years post-implant. A rhegmatogenous retinal detachment was noted in the implanted eye of one patient during a routine follow-up visit about 4.5 years post-implant. The detachment remained stable for over a year, when neovascular glaucoma associated with rubeosis was noted. Medication did not decrease the IOP. Thus, the patient underwent a pars plana vitrectomy, removal of an epiretinal membrane, fluid-air exchange, and injection of silicone oil. Two weeks postoperative, the IOP had returned to normal, and the rubeosis and retinal detachment had resolved.

One patient passed away at 6 years post-implant from natural causes unrelated to the Argus II System.

Device Reliability and Stability

As of five years post-implant, two Argus II implants had failed, both due to a progressive loss of ability to maintain radio-frequency link between the external antenna on the glasses and the receiving antenna implanted on the eye. Both devices failed around 4 years post-implant. The failures are believed to be due to a gradual exposure of a portion of the receiving antenna, possibly due to damage during surgery. The devices remained implanted to continue collecting long-term safety data for the duration of the clinical trial; thus, the root causes cannot be confirmed at this time.

Device Explants

There were three complete or partial explants. In one patient, as previously reported [7], the implant was removed at 14 months to resolve recurrent conjunctival erosion. Two additional patients requested that their devices be explanted at 3.5 and 4.3 years post-implant respectively. One of these patients had experienced two conjunctival erosions, which were treated by resuturing the device and closing the conjunctiva. A third instance of conjunctival erosion occurred and the patient chose to be explanted rather than receive a third revision surgery. The entire implant was removed with no serious adverse sequelae. This patient completed post-explant follow-up through 3 months, and withdrew study consent at that point. The other patient experienced chronic hypotony and ptosis in the implanted eye, and chose explant for aesthetic reasons and to avoid additional revision surgeries. During the explant procedure, the cable was cut mid-vitreous, the sclerotomy was sutured completely closed and the extraocular portion of the device and the proximal portion of the cable were removed. The array was left tacked to the retina. No post-explant adverse events occurred.

Visual Function

Mean results over time on visual function tasks are shown in Figure 2. The number of patients included in the analysis for each time point is indicated in the axis label. Square Localization and Direction of Motion were introduced partway through the study, so baseline and year 1 follow-up results do not represent a complete data set. Later time points also include fewer patients, due to the explants and device failures described above as well as a few instances of missed protocol visits in years 4 and 5. Missed visits were due to health

reasons (1), method deviation (1), and consent to safety follow-up only after year 3 or 4 (2). One additional patient did not complete the Direction of Motion, Line Task, or Door Task at year 5 due to fatigue.

As a group, patients perform better on Square Localization with the System ON (lower mean error) than using their residual vision at all time points (Figure 2A). Direction of Motion, a more challenging assessment, also shows overall improvement (lower mean error) with the System ON at all time points (Figure 2B). Grating Visual Acuity, the most difficult assessment, also revealed better performance with the System ON – with the System OFF, all results were worse than 2.9 logMAR at yearly time points. With the System ON, 27-48% of patients scored 2.9 logMAR or better (Figure 2C), depending on the time point.

The patients' improvements when using the System compared to their residual vision can also be seen on an individual basis, in terms of the percentage of patients who perform significantly better with the System ON than OFF on each assessment. Results at 1 year and 3 years were reported previously; here, the year 3 and year 5 results are compared (Table 3).

Functional Vision

The mean percent success for the Orientation and Mobility assessments is shown in Figure 3. Performance on the Door Task was better with the System ON than OFF at all time points (Figure 3A). Similarly, patients' ability to follow a white line on the floor was much improved when using the System compared with using only their residual vision (Figure 3B).

Discussion

The Argus II System was granted regulatory approval in the European Economic Area in 2011 and the United States in 2013 on the basis of earlier results from this clinical trial. However, the original study patients will continue to be followed out to 10 years in order to collect very-long-term data on the safety and efficacy of this chronically-implanted device. Long-term data are ever more important given the device is becoming available to increasingly large numbers of patients suffering from retinitis pigmentosa and similar disorders world-wide.

The data from the original group of 30 patients – 15 of whom received an earlier design of the device before minor improvements were made[7]– continue to show clear reliability, safety, and long-term efficacy out to five years post-implant. Twenty-four devices remain implanted and functioning. The device stability remains good with only two device failures, both of which remain safely implanted but non-functional, and three explanted devices out of 30 implanted patients. Of the three explants, one was done to resolve recurrent conjunctival erosion and chronic hypotony. The other two explants were elected by the patients. While elective, these two explants were prompted by a cascade of serious adverse events in each patient that have been previously documented. [7] In these cases, the patients chose explant rather than further revision surgeries to address recurrent SAEs. One patient passed away during the trial.

Only one new serious adverse event developed between 3 and 5 years post-implant, a rhegmatogenous retinal detachment that was successfully treated and resolved. There were no lost eyes and there was no damaged residual vision in the study. However, it is clear that any chronic implant in the eye carries a continual risk of serious adverse events. While outside the scope of this paper, additional instances of SAEs were found in four patients after the 5-year time point. In two patients, these represented recurrences or worsening of previous SAEs; in two, they were new events (conjunctival erosion and subsequent endophthalmitis in one patient, and a rhegmatogenous retinal detachment in another). These will be reported in a future paper when the dataset is complete and events have been adjudicated. It is therefore critical for any patient considering being implanted with the Argus II System to understand the long-term and ongoing risks; both the patient and his or her ophthalmologist must commit to at least a yearly evaluation of eye health for as long as the System remains implanted.

Results on a battery of visual function and functional vision assessments indicate continued efficacy of the Argus II System out to five years post-implant. Patients are still able to locate objects, determine the direction of motion of a moving bar, and perform an acuity task better with their Systems on than when using only their residual vision. The five-year visual function results are similar to those seen at three years, particularly when considering the individual analysis data (e.g., 33% of patients performed Grating Acuity better with the System ON than OFF at three years, and 38% did so at five years). Functional vision performance likewise showed sustained improvement with the System ON out to five years post-implant. It should be noted that 9-10 patients did not participate in efficacy testing during the five year follow-up period as discussed above. The resulting smaller Ns may have led to bias in the results at later time points. This potential bias will be evaluated in future reports, such as those on the post-approval studies currently in progress.

Conclusions

As of October 15, 2015, over 200 patient-years of data had been collected on the 30 patients implanted with the Argus II Retinal Prosthesis System. The longest implant duration to date is 8.4 years – and this device, as well as 23 others, continues to function, reliably enhancing basic visual function for these patients who otherwise can see almost nothing. The outcome of the functional tests described in this report and the acceptable safety profile of the Argus II System in this clinical trial led to its regulatory approval in EU, the USA, and in Canada. The device has gone on to be implanted in many patients and, in many countries, remains the only currently available treatment for profound vision loss in RP and outer retinal dystrophy. These new long-term data from the original study continue to demonstrate that this therapy remains an option for patients with retinitis pigmentosa and may allow for stable and reliable restoration of some basic visual function.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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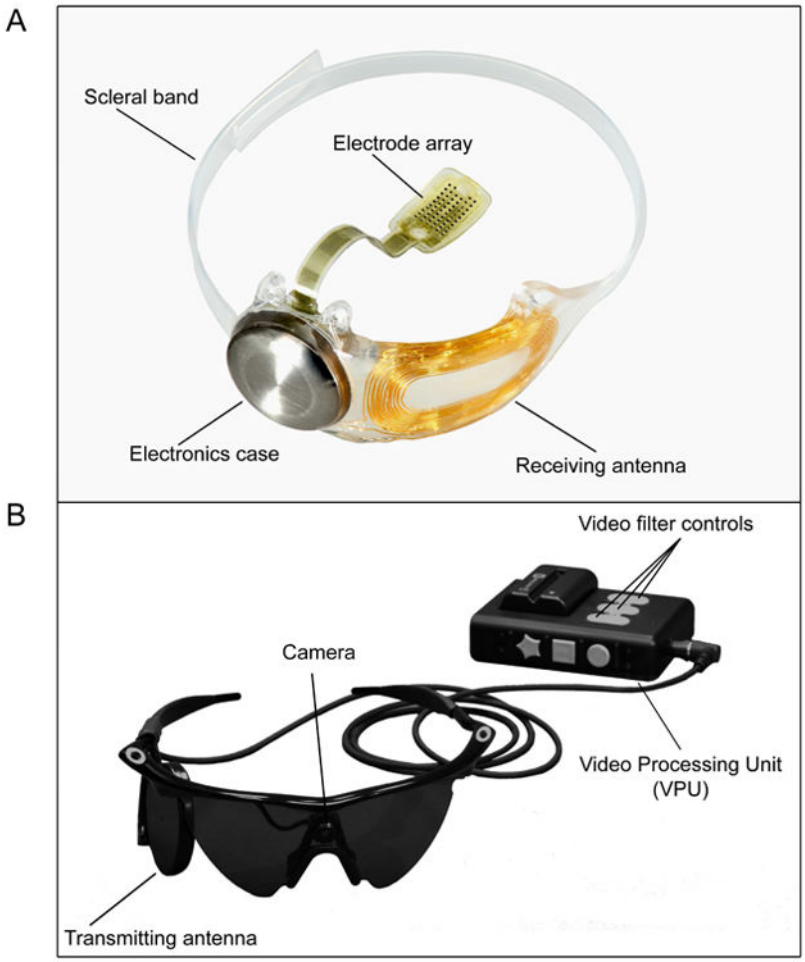

Figure 1.

Argus II System. A. Photograph of the implanted components of the Argus II System. B. The external (body-worn) components of the System.

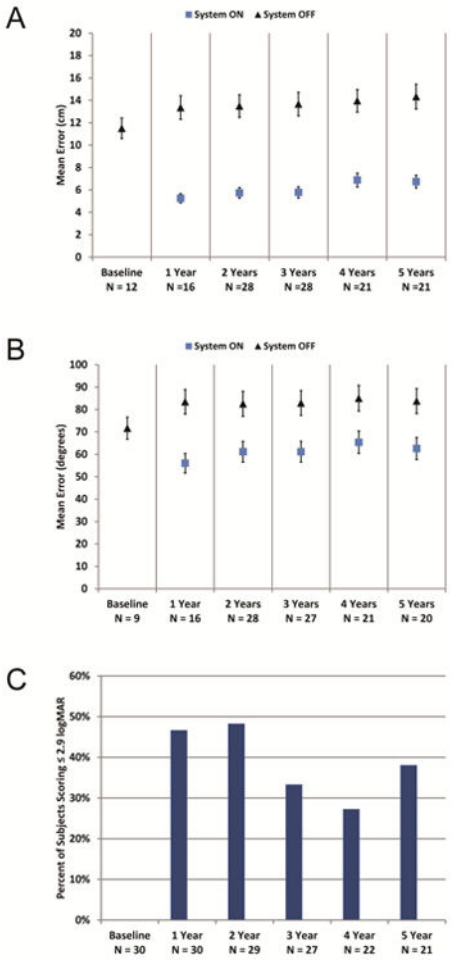

Figure 2.

Results for A. Square Localization, and B. Direction of Motion, and C. Grating Visual Acuity at yearly time points. A and B: Mean error with the System ON is shown as blue squares; mean error with the System OFF (with residual vision only) is shown as black diamonds. Error bars indicate standard error. C: The percent of patients scoring 2.9 logMAR or better on Grating Visual Acuity with the System ON (in the implanted eye) are shown at each time point. There were no patients who scored 2.9 logMAR or better with the System OFF in the implanted eye.

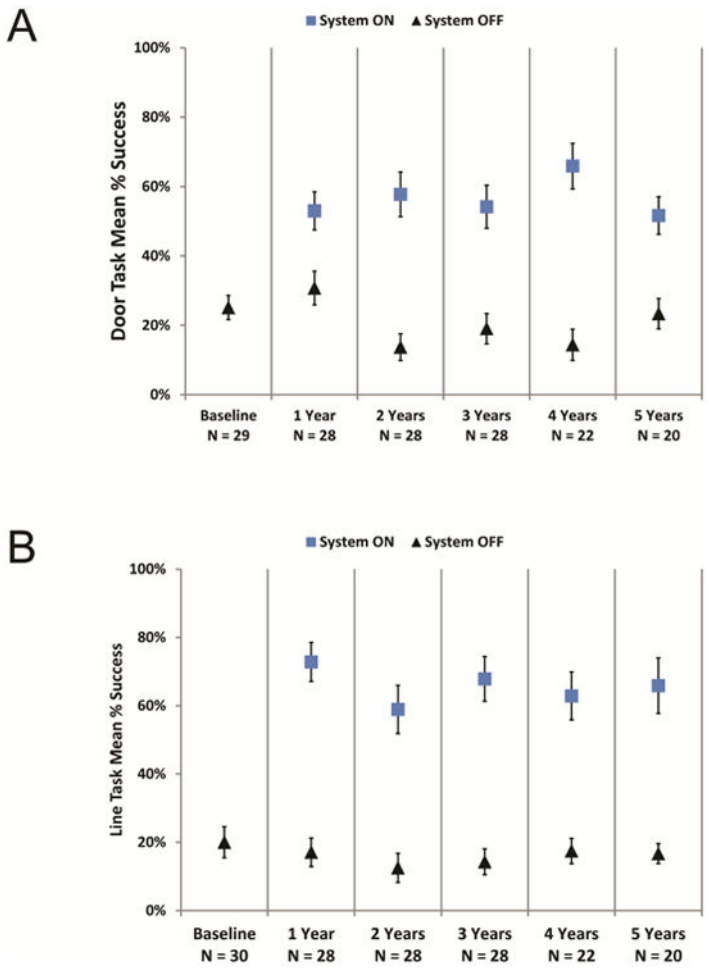

Figure 3.

Mean Percent Success on the Door Task (A) and Line Task (B) with the System ON (blue squares) and System OFF (residual vision only, black triangles). Error bars indicate standard error of the mean.

Table 1

demographics of enrolled subjects

N	**30**
Retinitis pigmentosa	29 (including 1 LCA)
Choroideremia	1
Bare light perception (BLP)	29
No light perception (NLP)	1
Female	9
Male	21
Age at time of implant (mean ± SD)	58 ± 10 years
Age at time of implant (range)	28 – 77 years
Years since diagnosis at time of implant (mean ± SD)	35.2 ± 11.7
Years BLP at time of implant (mean ± SD; N = 15)	15.9 ± 7.9

Table 2

Serious Adverse Event rates (cumulative) to 3 and 5 years post-implant

	Year 3			Year 5		
Serious Adverse Event Type	**N subjects with SAE**	**% subjects with SAE**	**95% CI**	**N subjects with SAE**	**% subjects with SAE**	**95% CI**
Conjunctival erosion	4	13.3%	3.1 - 30.7%	4	13.3%	3.1 - 30.7%
Hypotony	4	13.3%	3.1 - 30.7%	4	13.3%	3.1 - 30.7%
Conjunctival dehiscence	3	10.0%	2.1 - 26.5%	3	10.0%	2.1 - 26.5%
Presumed endophthalmitis	3	10.0%	2.1 - 26.5%	3	10.0%	2.1 - 26.5%
Re-tack	2	6.7%	0.8 - 22.1%	2	6.7%	0.8 - 22.1%
Retinal Detachment - Rhegmatogenous	1	3.3%	0.1 - 17.2%	2	6.7%	0.8 - 22.1%
Retinal detachment - tractional and serous	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Retinal Tear	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Uveitis	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Keratitis - infective	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Corneal Melt	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Corneal Opacity	1	3.3%	0.1 - 17.2%	1	3.3%	0.1 - 17.2%
Total	**23**			**24**		

CI = confidence interval. SAE = serious adverse event

Table 3
Individual Visual Function Assessment Results

	Year 3		Year 5	
Visual Function Assessment	**N**	**% subjects significantly better ON than OFF**	**N**	**% subjects significantly better ON than OFF**
Square Localization	28	89.3%	21	80.9%
Direction of Motion	27	55.6%	20	50%
Grating Visual Acuity	27	33.3%	21	38.1%