Table C-26. Adverse events in RPS studies

Study	Adverse Event	Result
Arevalo et al. 2015[13,14]	SAE	0/5
Arevalo et al. 2015[13,14]	Device-related AE	0/5
Arevalo et al. 2015[13,14]	Elevated IOP at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[13,14]	Pain at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[13,14]	Suture irritation at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[13,14]	Conjunctival erosion at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[13,14]	Edema at 1.3 to 2.0 year followup	2/8
Ho et al. 2015 and other authors[15-26] Argus II	SAE: death unrelated to implantation	1 year 0 patients, 3 years 0 patients, 6-year 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	SAE: Conjunctival erosion	1 year 3 patients, 3 years 4 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE: Hypotony	1 year 2 patients, 3 years 4 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE: Conjunctival dehiscence	1 year 3 patients, 3 years 3 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE: Presumed endophthalmitis	1 year 3 patients, 3 years 3 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SE: Re-tack	1 year 2 patients, 3 years 2 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Corneal opacity	1 year 1 patient, 3 years 1 patient, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE(cumulative): Retinal detachment, rhegmatogenous	1 year 1 patient, 3 years 1 patient, 5 year 1 additional patient
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Retinal detachment, tractional and serous	1 year 1 patient, 3 years 1 patient, 5-year no additional events

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[15-26] Argus II	SAE(cumulative): Retinal tear	1 year 1 patient, 3 years 1 patient, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Uveitis	1 year 1 patient, 3 years 1 patient, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Keratitis, infective	1 year 0 patients, 3 years 1 patient, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Corneal melt	1 year 0 patients, 3 years 1 patient, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	SAE (cumulative): Enucleation	1 year 0 patients, 3 years 0 patients, 5-year no additional events
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Epiretinal membrane	1 year 5 patients, 3 years 11 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Conjunctival congestion	1 year 10 patients, 3 years 10 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Ocular pain	1 year 5 patients, 3 years 9 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Hypotony	1 year 7 patients, 3 years 7 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Elective revision surgery	1 year 2 patients, 3 years 7 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Suture irritation	1 year 6 patients, 3 years 6 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Choroidal detachment	1 year 5 patients, 3 years 6 patients

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Uveitis	1 year 4 patients, 3 year 5 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative) cystoid macular edema	1 year 1 patient, 3 years 5 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Retinal thickening without cystic changes	1 year 4 patients, 3 years 4 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Ocular inflammation	1 year 3 patients, 3 years 4 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Vitreous hemorrhage	1 year 3 patients, 3 years 3 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Conjunctivitis inflammatory	1 year 2 patients, 3 year 3 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Epiphora	1 year 2 patients, 3 years 3 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Hyphema	1 year 2 patients, 3 year 3 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Headache	1 year 2 patients, 3 years 2 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Keratic precipitates	1 year 2 patients, 3 years 2 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Corneal vascularization	1 year 1 patient, 3 years 2 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): High IOP	1 year 1 patient, 3 years 2 patients

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Ptosis	1 year 1 patient, 3 years 2 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Conjunctival erosion	1 year 0 patients, 3 years 2 patients
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): 360 circumferential vitreous band traction	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Choroidal effusion	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Conjunctival dehiscence	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Corneal abrasion	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Corneal dryness	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Decrease in light perception	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Filamentary keratitis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Irregular pupil	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Nausea	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Nystagmus increase	1 year 1 patient, 3 years 1 patient

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Proliferative vitreoretinopathy	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Rubeosis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE: Scleritis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Vertigo	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Conjunctival cyst	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Corneal epithelial defect	1 year 0 patient, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Corneal fold	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Broken corneal suture	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Fibrosis around tack	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Foreign body sensation	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Ocular fibrin	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Retinal break/tear	1 year 0 patients, 3 years 1 patient

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Retinal detachment tractional	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Retinoschisis	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Non-SAE (cumulative): Scleral patch displacement	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[15-26] Argus II	Device failure (cumulative)	1 year 0 patients, 3 years 0 patients, 5 year 2 patients' devices failed at 4 years post-implantation
Ho et al. 2015 and other authors[15-26] Argus II	Safety and device functioning	6.2 years of followup: Safety remained acceptable and 24 patients still had implanted and functioning devices. 3 patients had complete or partial explantation at 14 months, 3.5 years and 4.3 years, respectively.
Ho et al. 2015 and other authors[15-26] Argus II	Retinal tack extractions (first 4 Argus II subjects requiring tack extraction for removal or repositioning of electrode array)	0/4 AEs through 18 months post-tack extraction
Ho et al. 2015 and other authors[15-26] Argus II	MRI 1.5 Tesla brain scan AEs	0/2 patients negatively affected by MRI testing 0/2 Argus II devices functioning affected 2/2 implants produced local moderate paramagnetic artifacts (50x50 mm) that precluded clear visualization of intraorbital contents causing loss of signal return and anatomical distortion but areas farther away from implant were unaffected.
Seider and Hahn 2015[27] Argus II	Intraoperative AE	Malposition of tack treated with adjusting the tack without need for its removal (1 patient)
Stingl et al. 2015, 2013[28,29] Alpha IMS	Intraoperative AE	Injury to the optic nerve with subsequent optic disc swelling (1 patient)
Stingl et al. 2015, 2013[28,29] Alpha IMS	SAEs	IOP increase to 46 mm Hg successfully treated without sequel (1 patient), retinal detachment immediately following explantation of the device treated surgically and resolved but with remaining local retinal fibrotic changes (1 patient)
Stingl et al. 2015, 2013[28,29] Alpha IMS	Postoperative adverse events	Retinal edema (1 patient)

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Stingl et al. 2015, 2013[28,29] Alpha IMS	Device malfunction	Technical failure (1 patient), retinal perfusion problem overlying device (1 patient), retinal edema leading to device not functioning (1 patient), injury to the optic nerve with subsequent optic nerve swelling leading to device malfunction (1 patient), infraorbital cable part breaks due to stress from eye movements (NR but occurred in the first few patients in the trial)
Ayton et al. 2014[30] Bionic Vision	AEs during surgery	0/3 patients
Ayton et al. 2014[30] Bionic Vision	Adverse events in immediate post-operative period	Subretinal hemorrhage on day 3 to 4 post-operatively which resolved without intervention in 55 days,101 days and 13 days respectively in the 3 study patients (3/3 patients) Pain: 3/3 with 1 patient requiring morphine Mild intraocular inflammation: 3/3 patients Intraocular pressure change: 0/3 patients Mild to moderate limitation in the abduction of implanted eye (1 patient) but improved over duration of study without lingering cosmetic or functional difficulty
Ayton et al. 2014[30] Bionic Vision	Device-related (with a direct or indirect causal link between surgery and AE); SAEs (requiring altered or increased medical management such as hospitalization or surgery)	*Staphylococcus aureus* infection at percutaneous connector on day 59 post-implantation which required a 3-day hospitalization and was determined to be device related. (1 patient) Device related SAE associated with the intraocular electrode array (0/3 patients)
Rizzo et al. 2014[31] Argus II	Elevated IOP	1 patient
Rizzo et al. 2014[31] Argus II	Choroidal detachment	1 patient
Rizzo et al. 2014[31] Argus II	Intraoperative AEs	Ciliary body touched and pulled (1 patient)
Rizzo et al. 2014[31] Argus II	Explantation	0 patients
Rizzo et al. 2014[31] Argus II	SAE	0 patients
Rizzo et al. 2014[31] Argus II	Endophthalmitis	0 patients
Rizzo et al. 2014[31] Argus II	Retinal detachment	0 patients
Rizzo et al. 2014[31] Argus II	Chronic intraocular inflammation	0 patients
Rizzo et al. 2014[31] Argus II	Proliferative vitreoretinopathy	0 patients

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Rizzo et al. 2014[31] Argus II	Epiretinal membrane formation	0 patients
Rizzo et al. 2014[31] Argus II	Device malfunction	0 patients
Fujikado et al. 2011[32] STS	Any AE in the 5- to 7-week period after implantation	Retinal detachment 0/2 patients Retinal/vitreous hemorrhage 0/2 patients Eye-movement restriction in all directions: 2/2 patients
Fujikado et al. 2011[32] STS	Any adverse event during or following explanation	VA: 0/2 patients maintained LP VA Eye restriction in all directions: 2/2 patients experienced recovered ability to move eyes in all directions
Klauke et al. 2011 and other authors[33-37] EPIRET3	Implant intraoperative AEs	None
Klauke et al. 2011 and other authors[33-37] EPIRET3	Post-operative implantation AEs	Mild transient inflammatory response (2), significant inflammatory reaction with a 1.5 mm painless hypotony without chemosis (1), hypotony due to permanent finger manipulations by the patient and a flat anterior chamber, inflammation and an epiretinal proliferation at the central tack (1)
Klauke et al. 2011 and other authors[33-37] EPIRET3	Intraoperative explantation AEs	Tacks removed because they were found to be loose (1), removal of a loose tack led to a central retinal defect (1)
Klauke et al. 2011 and other authors[33-37] EPIRET3	AEs during the 6-month followup period	Mild epiretinal gliosis formation at the tack fixation site (4), VA dropped from HM to LP in the patient with the central retinal defect but returned to HM at the 3-month followup (1), retinal detachments (0), choroidal neovascularization (0), new cystoid macular edema after 4 weeks (0)
Klauke et al. 2011 and other authors[33-37] EPIRET3	AEs during 2-year followup period	Conjunctivitis >1 year after implantation successfully treated with medication (1) Inflammatory reaction due to corneal sutures successfully treated with medication (1) Patient reported slight decline in residual visual perception in both eyes and a minor choroidal atrophy in the area where the retinal tacks were placed as well as some atrophy resulting from the laser photocoagulation at the posterior pole in the study eye was noted (1) Slight decline in visual perception following retinal defect repair in study eye due to tack removal (1) Posterior segments stable without clinically relevant progression of gliosis, no vascular abnormalities or leakages seen, and no intraretinal fluid around remaining tacks, all patients had clear corneas and were aphakic Nonprogressive gliosis present in study eye at 2-year followup (4 patients)

Table C-26. Adverse events in RPS studies (continued)

Study	Adverse Event	Result
Zrenner et al. 2011[38] Alpha IMS	Serious adverse events Preretinal bleeding Persistent IOP increase Intraocular inflammation Retinal detachment Retinal neovascularization	0/3 patients
Zrenner et al. 2011[38] Alpha IMS	Intraoperative complication	Small circumscribed area of subretinal bleeding at the posterior pole with complete reabsorption by day 10 (1)
Zrenner et al. 2011[38] Alpha IMS	Explantation	Mild skin infection of the retroauricular cable exit with restitutio ad integrum after a few days (1)
Chow et al. 2004[40,41] ASR	AEs in the immediate postoperative requiring intervention	IOP elevation to >25 mm Hg which required IOP lowering medication and steroid taper (3)
Chow et al. 2004[40,41] ASR	Scratchiness in the eye	Resolved after 6 weeks once external absorbable sutures dissolved (several patients, N not specified)
Chow et al. 2004[40,41] ASR	Aniseikonia between his aphakic ASR implanted eye and unoperated eye when using glasses	Anterior chamber intraocular lens relieved symptoms (1)
Chow et al. 2004[40,41] ASR	Syneresis of images seen in the implanted eye believed to be related to syneresis of a previously implanted posterior chamber intraocular lens	Symptoms substantially improved after replacement of the syneretic posterior chamber intraocular lens with a stable anterior chamber intraocular lens (1)
Chow et al. 2004[40,41] ASR	Final followup Infection Prolonged inflammation or discomfort Neovascularization Implant rejection Implant migration Implant erosion through the retina Retinal detachment	0 patients
Chow et al. 2004[40,41] ASR	10-year followup visit (n=1) Encapsulation Neovascularization Inflammatory response	0/1 patient

AE=adverse event; ASR=Artificial Silicon Retina; HM=hand motion; IOP=intraocular pressure; LP=light perception; MRI=magnetic resonance imaging; SAE=serious adverse event; STS=Suprachoroidal Transretinal Stimulation; VA=visual acuity