Table C-17. Day-to-day function assessment in RPS studies

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	FLORA	Pre-implant period	Year 1 % (n=15) reporting positive or mild positive experience 80%, percentage prior positive and neutral 20% Negative 0% Year 3 (n=23) percentage reporting positive or mild positive experience 65.2%, percentage prior positive and neutral 34.8% Negative 0%	A majority of patients reported a positive experience with the device.
Ho et al. 2015 and other authors[15-26] Argus II	FLORA visual orientation (negative numbers mean System ON better)	System OFF	NR	Mean ON minus Mean OFF score Locate light: -1.69, p<0.0001 Find doorway: -1.83, p<0.0001 Window light to determine orientation: -1.38, p<0.0001 Artificial light to determine orientation: -1.52, p<0.0001 Sun to determine orientation: -0.90, p=0.06 Recognize and use shapes (e.g. stop sign): -0.75, p=0.002
Ho et al. 2015 and other authors[15-26] Argus II	FLORA mobility (negative numbers mean System ON better)	System OFF	NR	Mean ON minus Mean OFF score Independently cross street: -1.00, p=0.004 Avoid obstacles while walking: -0.67, p=0.02 Estimate size of obstacle: -0.86, p<0.001 Avoid obstacle (e.g. low hanging branch), -0.71, p=0.008 Detect curb: -1.10, p=0.0002

Table C-17. Day-to-day function assessment in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	FLORA daily life (negative numbers mean System ON better, positive numbers mean System OFF better)	System OFF	NR	Mean ON minus Mean OFF score Determine if room lights are on or off: -1.62, p<0.0001 Locate ordinary objects at various distances: -0.92, p=-0.01 Locate place setting on dining room table: -1.30, p<0.0001 Identify things in a bathroom: -0.91, p=0.03 Identify things in a bathroom (unfamiliar environment): -0.25, p=1.00 Locate dishes while washing: -1.00, p=0.02 Locate clothes: -0.83, p=0.02 Find items in a kitchen: -0.85, p=0.02 Sort light from dark laundry: -1.89, p<0.0001 Travel within home independently: 0.35, p=0.04 Identify top bottom steps: 0.76, p=0.03 Negotiate stairway: 0.45, p=0.18 Cut/chop food: 0.00, p=1.00 Identify ordinary objects at various distances: -0.83, p=0.01 Identify food on a plate: -0.15, p=1.00 Heat/reheat food: 0.29, p=0.50 Maintain safety from falls, spills, burns: 0.20, p=0.50

Table C-17. Day-to-day function assessment in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	FLORA interaction with others (negative numbers mean System ON better)	System OFF	NR	Mean ON minus Mean OFF score Locate people in a non-crowded setting: -1.15, p=0.0001 Determine when people walk by: -1.23, p<0.0001 Detect the approach of another person: -0.88, p=0.0001 Determine the direction of movement of people walking by: -0.80, p=0.001 Track another person: -0.76, p=0.0005 Visually locate people in a crowded setting: -0.33, p=0.13 Determine direction another person is facing: -0.14, p=0.50
Ho et al. 2015 and other authors[15-26] Argus II	FLORA difficulty level with 4 equal to impossible and 1 equal to easy	System OFF mean (SEM) Orientation: 3.56 (0.11) Mobility: 3.69 (0.10) Daily life: 3.05 (0.09) Interactions with others: 3.92 (0.06)	System ON mean (SEM), adjusted p value Orientation: 2.20 (0.17), p<0.0001 Mobility: 2.87 (0.18), p=0.003 Daily life: 2.47 (0.14), p=0.0001 Interactions with others: 3.13 (0.16), p<0.0001	ON minus OFF, Percent change: Orientation: -38% Mobility: -22% Daily life: -19% Interaction with others: -20%
Stingl et al. 2015, 2013[28,29] Alpha IMS	Patient reports on their visual experiences in their home and daily life. Patients used the implant usually 2–3 hours per day.	NA	13 patients described device as useful (see shapes and details), 8 as a little useful (localize objects but could not recognize shapes or details), 8 as not useful. Examples of useful vision include seeing the shape of a person's head, house outlines, pavement lines, car lights moving at night, sunflower stalk, silhouette in the mirror, picture frame on the wall.	Several patients reported a slight improvement in their remaining LP with the implant OFF but, according to study authors, "none of them could see objects without the implant power being switched ON."

Table C-17. Day-to-day function assessment in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Chow et al. 2010 and Geruschat et al. 2012[3,39] Extension study ASR	Subjective (patient) impression of visual acuity	Subjective impression preimplantation not measured, but at baseline 5 could distinguish HM and 1 patient CF.	Following implantation, through 8 years of followup, 6/6 patients reported an improvement in subjective perceptions including seeing divider line on a highway and seeing objects around the house (1), sees objects around the house, sees darkness at night instead of light gray, uses operated eye to navigate as it is now the better eye (1) sees clock on oven, can watch son play basketball, sees shapes in photos, saw color of stoplights (1), can see image of people on television, can now navigate visually through house, can locate children and pets in house, sees color of objects, at night sees darkness instead of light gray (1)	6/6 patients improved from pre- to post-operative period.

Table C-17. Day-to-day function assessment in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Chow et al. 2004[40,41] ASR	Subjective vision measured as follows: patients described their visual perceptions for 7 aspects of visual function (brightness, contrast, color, shape, resolution, movement, and visual field size). Comparison was to nonimplanted eye and that eye was given a rating of 10 (e.g., if implanted eye brightness was twice that of the left eye the patient was instructed to give it a rating of 10).	Patient 1 right/left eyes: brightness 5:10, visual field 2:10 Patient 2 right/left: no LP/LP Patient 3 right/left: HM to LP OU, brightness 7:10, shape 10:10, resolution 10:10, movement 10:10, and visual field size 10:10 Patient 4 right/left: brightness 10:10, contrast 10:10, shape 10:10, and visual field size 10:10, overall rating of visual function 10. Patient 5 right/left: 10/10 for all 7 aspects of visual function Patient6 right/left: 10:10 for all 7 aspects of visual function.	Results at 6 months for 3 patients and 18 months for the remaining 3 patients Patient 1: brightness 7:10, visual fields 15:10, visual field subjectively 750% larger than at baseline, no need to turn head to see light coming from right side. Patient 2: brightness 8:10, contrast 10:10, shape 10:10, visual field size 8:10, able to see shadows of people with right eye. Patient 3: 30:10, 35:10, 50/10, 50:10, 50:10, 50:10 (which domains these refer to not reported), patient also reported they can now use a nightlight for navigation at night and can see movement on television screen. Patient 4: brightness 15:10, contrast 17:15, shape 17:10, visual field size 13:10, movement 2:10, and reports overall visual function 25, patient can now navigate yard without a cane and can tell which lights are on at night. Patient 5: brightness 17:10, contrast 30/12, color 17:10, shape 15:10, resolution 35:10, movement 13:10, and visual field size 11:10, patient reports he can now more easily discern denominations of money, use utensils, and recognize faces. Patient 6: brightness 20:10, contrast 25:10, color 20/10, shape 20/10, resolution 20/10, movement 20/10, and visual field size 18:10, and these values are for patient on his best days. Patient reported he can now recognize denominations of money, sometimes differentiate the color of traffic lights, locate cars on street, and find cup at meals.	6/6 improved

ASR=Artificial Silicon Retina; CF=count fingers; FLORA=Functional Low-Vision Observer Rated Assessment; HM=hand motion; LP=light perception; NA=not applicable; OU=both eyes