Table C-16. Laboratory-based visual performance measure results in RPS studies

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	Reading Braille with the Argus II creating percepts in the form of Braille letters to be read visually rather than tactually. Single-letter tests were 8 or 9 AFC and short words were simulated 1 letter at a time in an open-choice test. Subject did not receive training before testing.	Chance level and assumption of a 100% correct identification rate for tactile Braille	Postimplantation: 1 patient who was an experienced Braille reader pre-implantation was tested and had 89% (SD:NR) correct responses for individual letters at 500 ms and 60 to 80% (SD:NR) correct responses for short words.	Single-letter recognition was significantly above chance level ($p<0.001$)
Ho et al. 2015 and other authors[15-26] Argus II	Meander Maze Tracing, or the labyrinth experiment, in which patient uses a touchscreen and tries to complete the maze without going off the path. The first test (2-AFC; n=21) involved a path with a right angle; those who passed that test or performed well with native vision (n=16) performed the mixed angle, single-turn test, and again those who did well went on to the final test, a 2-turn test. This test aimed to determine if prosthesis use could guide fine hand movements.	Stimulator OFF	Stimulator ON	Across all tests, Stimulator ON condition significantly reduced the error in tracing by 60% ($p<0.001$) and increased trace time by 211% ($p<0.001$).

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	Find the door	Stimulator OFF	Stimulator ON Month 6 (n=30) Mean percentage success: System ON 54%, (SD:NR) System OFF 27% (SD:NR) Year 1 (n=28 patients): Mean percentage success ON: 53.0% (SD 5.5%) Mean percentage success OFF 30.8% (SD 4.8%) Year 3 (n=28): Mean percentage success ON: 54.2% (SD 6.2%) Mean percentage success OFF 19.0% (SD 4.3%) Year 5 (n=20): Mean percentage success ON: 50.0% (SD 6.2%) Mean percentage success OFF 23.0% (SD 4.3%)	Performance remained better with the system ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use. Month 6: p=0.0001
Ho et al. 2015 and other authors[15-26] Argus II	Follow the line	Stimulator OFF	Stimulator ON Month 6 (n=29) mean percentage success: System ON 68% System OFF 23% Year 1 (n=28 patients) mean percentage success: System ON: 72.8% (SD 5.7%) System OFF 17.1% (SD 4.2%) Year 3 (n=28) mean percentage success System ON: 67.9% (SD 6.5%) System OFF 14.3% (SD 3.8%) Year 5 (n=20): Mean percentage success ON: 65.0% (SD 6.2%) Mean percentage success OFF 17.0% (SD 2.0%)	Performance has remained better with the system ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use. Month 6: p<0.0001

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[15-26] Argus II	Object prehension (locate, reach, and grasp) and localization in 3-dimension space completed by 5 subjects at 1 site. Patient movements were tracked with a computer system. Lights were attached to patient's finger to help them visualize their finger.	Stimulator OFF Successful prehension Finger switch ON: 0, Finger switch OFF 0	Stimulator ON Successful prehension Finger switch ON: 71.3±27.1% Finger switch OFF 77.5±24.5%	Difference between finger marker ON and OFF not significant; but for stimulator ON vs. OFF (74.4±23.4% and 0) the difference was statistically significant, p=0.04
Ho et al. 2015 and other authors[15-26] Argus II	Path reproduction in which experimenter guided person on a path through a dark room with a single illuminated landmark and then the patient had to reproduce the path as accurately as possible.	Comparison was to controls (normal vision or restricted by goggle as well as within the patient for System ON and OFF or blindfolded and landmark light OFF	System ON	1/4 patients showed improved precision when navigating with the Argus II, and 3 showed reduced precision when navigating with the Argus II
Ho et al. 2015 and other authors[15-26] Argus II	Triangle completion was similar to the Path reproduction task but the patient was asked to return directly to the start position after reaching the end of an outbound path, thereby completing a walked triangle	Comparison was to controls (normal vision or restricted by goggle as well as within the patient for System ON and OFF or blindfolded and landmark light OFF	System ON	2/4 patients showed improved precision when navigating with the Argus II, and 2/4 showed reduced precision when navigating with the Argus II
Stingl et al. 2015, 2013[28,29] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Clock task: white clock hands were placed at angles of 0 degrees, 90 degrees, or 180 degrees to each other indicating a clock time, presenting a 16 AFC test. Response rates greater than 53% were consider passing. Patents were asked to tell the time with a 2-minute timeout. This task was repeated 12 times.	Stimulator OFF Percent of patients passing the test Month1 (n=19) 0% Month 3 (n=13) 0% Month 6 NR Month 9 (n=8)13% Month 12 NR	Best achieved results: 17% passed test (4/29 but only administered to 22 patients) Percent of patients passing the test Month1 (n=19) 17% Month 3 (n=13) 25% Month 6 NR Month 9 (n=8) 11% Month 12 NR No comparisons were statistically significant	No statistically significant advantage of having the stimulator ON vs. OFF. 5 patients passed the test at least once. Only 1 participant passed this test with the stimulator OFF.

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[28,29] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Gray levels: intermediate gray level presented on half the screen and 1 of 6 different levels of gray on the other half. Each of the 6 combinations was presented 3 times in random order. Patients had to say which side of the screen was brighter. A combination distinguished correctly 2 times counted as a recognized response. A full screen of the intermediate gray served as the control. Total correct responses were tallied. There was no timeout for this test.	Stimulator OFF Percentage of patients passing test Month 1 (n=15) 37.5% Month 3 (n=10) 35% Month 6 (n=8) 27% Month 9 (n=7) 0% Month 12 (n=6) 15%	Best achieved results: 52% passed test (15/29 but only administered to 19 patients) Percentage of patients passing test Month 1 (n=15) 67.5% Month 3 (n=10) 70% Month 6 (n=8) 25% Month 9 (n=7) 30% Month 12 (n=6) 68% Months 1 and 12 were only statistically significant comparisons.	Significantly better with the stimulator ON vs. OFF for gray level recognition at months 1, 2, and 12. 15 participants recognized at least 1 gray level and up to 6 gray levels with the stimulator ON while 8 patients recognized up to 3 gray levels with the stimulator OFF.

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[28,29] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Table setup: Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. 4 dining objects were placed around a large white plate in front of the patient, who was not informed about the number of objects. Patient had to report the number, localize them, and identify them with a timeout of 4 minutes. Correct responses were tallied.	Stimulator OFF Month 1 (n=24) How many shapes 0.4 Where shapes 0.1 What shapes 0.025 Table how many 0.55 Table where 0.25 Table what 0.05 Month 3 (n=19) How many shapes 0.8 Where shapes 0.5 What shapes 0.2 Table how many 0.4 Table where 0.35 Table what 0 Month 6 ((n=15) How many shapes 1.2 Where shapes 1.1 What shapes 0.2 Table how many 0.75 Table where 0.4 Table what 0.1 Month 12: (n=8) How many shapes 0.7 Where shapes 0.2 What shapes 0 Table how many 1.2 Table where 1.0 Table what 0	Stimulator ON Month 1 (n=24) How many shapes 2.7 Where shapes 2.5 What shapes 1.1 Table how many 2.45 Table where 2.4 Table what 0.8 All comparisons statistically significant Month 3 (n=19) How many shapes 2.5 Where shapes 2.1 What shapes 0.7 Table how many 2.25 Table where 2.2 Table what 0.65 All comparisons statistically significant Month 6 (n=15) How many shapes 1.75 Where shapes 1.55 What shapes 0.3 Table how many 1.95 Table where 1.9 Table what 0.5 Table (how many and where) were the only statistically significant comparisons Month 12 (n=8) How many shapes 1.75 Where shapes 1.4 What shapes 0.4 Table how many 1.5 Table where 1.0 Table what 0 Shapes (where) were the only statistically significant comparison.	Significantly better with the implant ON vs. OFF in the first 3 months. From month 6 through 12, the statistical significance decreased (p>0.05) for most ON-OFF comparisons.

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[28,29] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Geometric shapes: 4 objects of about 5-degree visual angle each were placed in front of the patient, who was not informed about the number of objects. Patient had to report on the number of objects, point to the objects, describe, by shape description and localization, what they were with a timeout of 4 minutes. Correct responses were tallied.	Stimulator OFF	Stimulator ON	Significantly better with the implant power ON vs. OFF during the first 3 months. For month 6 through 12, the statistical significance decreased ($p>0.05$) for most ON-OFF comparisons.
Rizzo et al. 2014[31] Argus II	Patient mobility, which 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.	No comparator	All patients could locate light and walk on stripe on floor at 1 week followup	All patients could locate light and walk on stripe on floor at 1 week followup
Fujikado et al. 2011[32] STS	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were masked to stimulation because the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 4: Grasping objects A white object was set randomly either to the left or the right of the center of the board. The patient was asked to grasp the object with her right hand.	Stimulator OFF performance was less than chance level 1/1 patients	Better than chance: 1/1 patient	Only 1 patient performed this test and outperformed chance with a score of 90%.

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Fujikado et al. 2011[32] STS	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation as the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 5: Touch panel A white rectangular bar was presented randomly either on the left or right of the center of a touch-panel screen that was connected to the computer. The patient was asked to touch the white bar with her right index finger. The position touched was recorded and analyzed by the computer. Depending on whether the patient touched the correct position, a different sound was emitted by the computer.	Stimulator OFF: less than chance 1/1 patient	Stimulator ON: The touch panel task was also applied to only 1 patient. The subjective phosphene was perceived shifted slightly to the right of the bar when presented on the right side and shifted to the left of the bar when presented on the left side. The success rate increased with repeated testing.	1/1 patient better with stimulator ON vs. stimulator OFF
Zrenner et al. 2011[38] Alpha IMS	Recognition of geometric of objects on a table (4 AFC)	Stimulator OFF The patient who passed with the stimulator in ON mode was tested with the stimulator OFF and failed with 0% correct responses	Stimulator ON 1 patient passed with 100% correct responses, 2 patients failed	1 patient benefited from the device in ON mode
Zrenner et al. 2011[38] Alpha IMS	Localization of dishes/flatware (3, 4, 2 AFC, respectively per patient)	Stimulator OFF The patient who passed was tested with the stimulator ON failed with 0% correct responses with stimulator OFF	Stimulator ON 3/3 patients passed	All patients benefited with the stimulator in ON mode
Zrenner et al. 2011[38] Alpha IMS	Recognition of hands on a clock (12 AFC)	Stimulator OFF The patient who passed with the stimulator in ON mode was tested with stimulator OFF and failed with 8% correct responses	Stimulator ON 1 patient passed with 92% correct responses, 2 patients not tested	1 patient benefited from the device in ON mode

Table C-16. Laboratory-based visual performance measure results in RPS studies (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Zrenner et al. 2011[38] Alpha IMS	Recognition of 9 shades of gray (2 AFC)	Stimulator OFF The patient who passed with the stimulator ON was tested with the stimulator OFF mode and failed with 40% correct responses	Stimulator ON 1 patient passed with 78% correct responses, 2 patients not tested	1 patient benefited from the device in ON mode
Chow et al. 2010, Geruschat et al[3,39] Extension study ASR	Controlled mobility course was comprised of an indoor straight hallway 18.29 m long and 1.4 m wide illuminated with 150 foot-candle, painted off white with light gray carpet and seeded with obstacles either suspended or placed on the floor. Subjects also had to navigate through the hospital cafeteria. Subjects were not permitted to use guide dogs or long canes for this assessment. Tasks were performed with the implanted eye, the nonimplanted eye, and binocularly.	Preimplantation, 6 patients completed monocular testing due to personal safety concerns and 8 completed binocular testing. Subjects were divided into worse and better vision groups. At baseline, a statistically significant (p=0.005) larger number of obstacles was found in the binocular and treated eye conditions but not in the control eye condition between subjects with worse and better visual acuity and visual fields. There were no statistically significant differences in time to complete the course in the binocular, treated, or control eye when comparing those with worse and better vision at baseline. 3/5 subjects in the worse vision group could not complete the cafeteria task at baseline or the 3- or 6-month followup. The other 2 subjects in this group could complete the task at baseline but needed to go slowly. The 2 subjects had more difficulty at the 3- and 6-month followup, corresponding to a vision reduction in the better eye (20/100 to 20/550 and 20/720 to 20/1600, respectively). Patients in the better vision group did not show a change in ability to complete the cafeteria task over time.	Monocular testing (6 patients completed this task due to safety concerns) or binocular (8 subjects completed this task) after implantation	On the controlled mobility course, no significant group differences were observed pre- vs. post-implantation for obstacle contact or time to walk the course for both eyes, or treated or control eye only conditions, suggesting the ASR device does not aid independent orientation and mobility.

AFC=alternative forced choice; cd/m^2=candela per square meter; NR=not reported; p=p-value; SD=standard deviation; STS=Suprachoroidal Transretinal Stimulation