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Orientation and Mobility Assessment in Retinal Prosthetic Clinical Trials

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As the companies developing the various types of prosthetic vision devices move towards commercialization, the importance of measuring the impact of these technologies on performance of activities of daily living (ADL) has become apparent. One of the daily activities that has been identified as potentially benefiting from prosthetic vision is orientation and mobility (O&M).

It is useful to acknowledge that vision is not required for safe and independent travel. People who are totally blind, walking with the aid of a long cane or a dog guide, travel to and from work, places of worship, grocery stores, physician's offices, and the homes of family and friends on a daily basis. They do this safely and independently. Therefore what would be the expected effect and/or benefit of the introduction of vision (for the congenitally blind) or re-introduction of vision (for the adventitiously blind) on their independent travel? One answer to this question comes from observing young children attending a residential school for the blind. You will often see groups of children walking down the hallway with one child in the lead and the other children holding hands while walking in single file. The only difference between the lead child and the followers is that the lead child has light projection or form perception – ultra low vision¹. All of the children have had O&M instruction and they are all capable of walking independently through the hallways of the school, yet their collective behavior suggests they recognize that even the limited amount of vision of the lead child makes it easier to travel. The lead child is capable of using light projection to see the lights in the ceiling and to visually trail these lights to maintain a straight line of travel in the hallway. Arriving at the intersecting corridor, the child can locate the ceiling lights for the intersecting hallway and visually trail those lights. While O&M instructors teach echolocation to listen for the walls and to hear the opening of an intersecting corridor, and O&M instruction can teach kinesthetic “muscle memory” to anticipate the length of a familiar hallway, a minimal amount of vision can enhance mobility, making it easier to travel. From this perspective can prosthetic vision improve mobility?

The purpose of this paper is to describe a study on the O&M of retinitis pigmentosa (RP) subjects in a treatment trial involving a subretinally implanted microchip, and to use the

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¹The term “ultra-low vision” is not commonly used, but is helpful when discussing the very limited levels of vision shared by many profoundly visually impaired patients. We operationally define ultra-low vision as visual impairment that impacts most daily living activities involving any visual shape recognition; in terms of visual acuity it corresponds to the inability to discern the largest ETDRS letters at 0.5 m, i.e., VA <20/1600 or 6/480.

experience to propose a research agenda for prosthetics and other experimental vision-restoring treatments in the context of O&M. The study involved patients who had an Optobionics artificial silicon retina (ASR) device implanted subretinally 15-25° temporal to the fovea in a randomly selected eye. The ASR is a 2 mm diameter, 25 µm thick, light-activated array with ~5000 microphotodiode pixels, implanted with the intention of inducing neurotrophic rescue of various aspects of vision anywhere throughout the retina, not necessarily overlying the device. Unlike candidates for most retinal prosthetic devices who have virtually no remaining functional vision, the participants in this study had a wide range of functional vision pre-operatively, and any gains in vision were hypothesized to potentially occur anywhere throughout the retina with viable, dormant photoreceptors, not necessarily over the implant as with other retinal prostheses. Our experience with mobility evaluations during this trial provides the foundation for the proposed O&M research agenda.

Methods

Instruments

Vision Tests—Best-corrected visual acuity (VA) was measured for each eye with the Early Treatment of Diabetic Retinopathy Study (ETDRS; Lighthouse International, New York) charts at 3 m, or closer (down to 0.5 m) if fewer than 10 letters were identified. The VA test procedure used during the study has been published elsewhere¹. VA was obtained with undilated pupils for half of the subjects (n=4) and with pupils dilated with 1% tropicamide for the other 4 subjects. The protocol initially specified that all VA measures should be obtained with pharmacologically dilated pupils. However, during baseline VA testing, it was noted by the investigators that a number of subjects had glare disability and decreased VA with dilated pupils. Concern was raised that the significant glare associated with dilation may increase test variability and/or may mask any treatment effects, and a change in protocol allowed subsequently enrolled subjects to complete VA testing while undilated. Within subjects, however, the same dilation status was used pre and post-implantation.

Best-corrected contrast sensitivity (CS) in logCS units was assessed in each eye during at least one of the post-operative test sessions at 3, 4 and 6 months. CS thresholds were measured using 4-alternative forced choice orientation discrimination of computer-generated square wave gratings projected onto a screen². Gratings were presented at a size twice as large as each subject's grating VA resolution limit. For VA and CS, we report for each eye the average across three VA charts or CS tests within a single session, in order to limit the effects of short-term variability in patients with reduced vision. The pre-operative baseline VA assessments were obtained across three visits over a period of 60 days prior to implantation (i.e., 3 VA tests per visit × 3 visits = average of 9 baseline VA tests), whereas each post-treatment time point (i.e. at 3, 4 and 6 months) only included 3 tests completed in a single visit or day.

Two 30-2, size V, Fastpac Humphrey visual field (HVF) tests for each eye were completed during each of 3 visits at baseline. We defined 5 eccentricity rings (Figure 1) and calculated the mean within-ring sensitivities and 95% confidence interval (CI) for each subject at baseline for test locations consistently detected across all 6 tests (i.e. sensitivity ≥ 0 dB). During each of the 3, 4 and 6 month follow-up visits, one test per eye was obtained.

The horizontal visual field (VF) diameter for each eye was measured using the Goldmann kinetic perimeter V4e test target at 3, 4 and/or 6 months post-implantation. We present the mean VF results for a single eye since there was a high degree of symmetry between the two eyes, as is common in RP, there was no significant difference in the VF diameter for the fellow eye (i.e. within 5 degrees). The original FDA-approved study protocol did not include

CS and Goldmann VF testing at baseline; these tests were added in a subsequent protocol modification. This O&M study was a small part of the clinical trial of the ASR. The protocol defined the vision measures that could be collected, the timing and the method of collection.

Mobility Course—There is no standardized assessment of low vision O&M³, but the O&M research literature is dominated by a few approaches, with a combination of variants of walking speed and obstacle avoidance contacts being the most common^{4,5}. It is also a common approach to seed the environment with obstacles, increasing the opportunities for detection/avoidance/contact^{6,7,8}. Using these time tested methods, we developed a controlled mobility course that each subject walked during each data collection visit.

The controlled mobility course was an indoor straight hallway, 18.29 m long and 1.4 m wide. The hallway was illuminated with ceiling mounted florescent lights with 150 fc of consistent illumination along the length of the hallway. The hallway was painted off white and the carpet was a light grey. To increase the likelihood of obstacle contact and reduce the frequency of perfect scores, a narrow hallway was selected and seeded with obstacles.

The subjects experienced two types of obstacles. The first type of obstacle was a 45 cm long section of 0.95 cm diameter dark brown foam tubing suspended by clear monofilament such that the obstacle hung from the ceiling at two heights (0.91 m or 1.5 m) above the floor 40 cm from either the left or right wall. The second type of obstacle was a segment of dark rug (20.3 cm by 45.7 cm) placed on the floor 30.5 cm from either the left or right wall. One obstacle was placed within every 1.5 m segment of the hallway alternating high to low. Each 1.5 m segment had 8 possible locations for the placement of the hanging tubes and the rugs. The placement of each element was randomized for each trial to minimize the effect of learning. With twelve 1.5 m segments and 8 options in each segment, there were 96 different obstacle course options. Avoiding the obstacles did not require sharp turns but the subject could not complete the route without touching obstacles if they walked a straight line down the hallway.

Subjects were also requested to travel independently through a second mobility course which consisted of a series of hospital corridors that involved walking on stairs, into and out of a large cafeteria. The authors felt it was important to observe subjects walking in a natural environment such as this. The cafeteria was approximately 30 × 30 meters with food lines, vending machines, cashiers, and tables/chairs. A series of tasks within the cafeteria were assigned across subjects. To minimize any learning effects, at each visit the subject was requested to complete three of the following tasks in a randomized sequence. The tasks included finding vending machines with snacks, finding vending machines with soda, locating the coffee dispenser, identifying the subway shop, finding the hot food line, locating the trash receptacles, and finding the checkout line. The sequence of control eye, treated eye and both eyes was also randomized. The corridors to the cafeteria were approximately 350 meters in length. The subject walked approximately one-third of the distance in each of three viewing conditions: using both eyes, the treated eye, or the control eye, in random sequence.

Interview—To capture subjects' observations of possible effects in daily life, an interview was conducted at each visit, constrained only by the stipulation that the identity of the implanted eye and the clinical test results could not be discussed. Through the entire study the O&M instructor was not provided with any information regarding the identity of the treated eye. This interview addressed the following questions: (1) Have you experienced a change in O&M since the last visit due to change of employment or residence? Have you had mobility instruction since the last visit? Has your mobility changed in any way since the last visit? Each question provided the opportunity for a free exchange of information on the

topic of mobility within the timeframe of the visit. Scoring: Each time a subject's foot touched a rug or any portion of their body touched a hanging element, thus causing movement of the element, it was scored as an obstacle contact. Time to walk the obstacle course was obtained with a commercial stopwatch.

The O&M instructor observed the walk to and through the cafeteria, monitored safety, and took notes on the travel abilities of each subject under the three vision conditions. The walk provided the O&M instructor with the opportunity to observe posture/gait, stride, ease of travel, detection of stairs and general environmental awareness for the purpose of forming impressions of the subject's overall travel ability. While non-standardized and uncontrolled, these observations are important to the development of a fuller understanding of what the subjects experienced.

Subjects: Eight subjects with reduced VA and VF due to RP participated in this study; four males and four females. The males' ages ranged from 43 – 55 (mean = 49, SD = 4.24). The females' ages ranged from 32 – 50 (mean = 43.5, SD = 8.1). All subjects self-reported independent travel: four traveling with a long cane, one with a dog guide, and three without a mobility device but relying on a sighted guide in unfamiliar or crowded areas. Two of the latter three had among the best VAs (20/125 and 20/80) and largest VFs (approximately 20° and 40°) of the group. Both reported driving to/from work on a daily basis. The third of these subjects (subject 1) restricted travel to the familiar home environment or was always accompanied by a sighted companion when away from the home. Table 1 provides details for each subject's age, gender, VA, CS, VF and mobility aid use.

All subjects completed the informed consent process which had been approved by the Johns Hopkins University Institutional Review Board.

Procedures: Subjects had their mobility evaluated within 2 weeks prior to the ASR being implanted, and at 3, 6, 9, 12 and 15 months post implant. The mobility portion of each session began with a baseline time to walk the course. The subjects were requested to walk at their normal walking speed in the hallway where the data collection was to occur but without the presence of the obstacles. The subjects were then seated out of sight of the hallway while obstacles were placed. Once the obstacles were in place, the subjects were instructed to walk down the hallway and to avoid contact with any obstacles they might see. They were not told the number, location, or type of obstacles they might encounter. Subjects were tested three times with a randomized viewing sequence: right eye, left eye, both eyes. Subjects walked without the assistance of their long cane or dog guide. Upon completion of walking the course, they were asked to turn around and reverse the route. Thus for each visual condition the subjects walked 36.6 m and experienced a total of 24 obstacles. Time to walk the route and number of objects contacted were recorded for each subject.

At the completion of the controlled mobility course the subjects participated in the walk to and from the cafeteria under the same three viewing conditions: both eyes, right eye only, and left eye only.

The session ended with the informal interview. One hour was allocated for the mobility portion of the study. All O&M data were collected by the same instructor.

Results

Due to attrition, we have the most complete O&M dataset on the pre implant and the 3 and 6 months post implant assessments. Data from these three assessment times were analyzed. Subjects one and two did not complete the entire mobility portion of the trial because they

refused to wear an eye patch, feeling anxious and unsafe about occluding an eye with the patch. They did complete the binocular portions of the study. Therefore, the sample size is 8 for the binocular condition and 6 for both monocular conditions. Descriptive statistics for time to walk the course and number of obstacle contacts are presented in Table 2. The summary data are reported for all three visual conditions (OU, treated eye and control eye). Table 2 also presents the findings of the repeated measures analysis of variance for time to walk the course and obstacle contact according to each of the three visual conditions. As is evident from the descriptive statistics in table 2, and confirmed by repeated measures analysis of variance, there were no significant differences in either obstacle detection or time to walk the course when comparing 3 and 6 month [results] to pre-treatment results.

Subjects' results were compared between those with worse (s1,2,4,5,8) and better (s3,6,7) vision. At baseline, using a Bonferroni corrected p-value of 0.005, there was a statistically significant larger number of obstacle contacts in the binocular (mean diff=14.8; $p<0.00001$) and treated eye (mean diff=11.7; $p=0.005$) conditions but not in the control eye condition (mean diff=11.3; $p=0.03$) between subjects with worse and those with better VA and VF. These findings suggest that the number of contacts during the course may discriminate between these two visual impairment levels/groups. At baseline, there were no statistically significant differences in the time to complete the course in the binocular (mean diff=14.6; $p=0.12$), treated eye (mean diff=19.4; $p=0.17$) or for the control eye (mean diff=21.5; $p=0.10$) when comparing the subjects with the worst and best vision. There also was a statistically significant difference in a combined score ($2 \times \text{Contacts} + \text{Time}$) binocularly (mean diff=44.2; $p=0.002$), but not for the treated eyes (mean diff=42.8; $p=0.04$) and for the control eyes (mean diff=44.2; $p=0.04$) when comparing the 2 subject groups.

Walking to and through a busy cafeteria, three of the subjects with worse vision (s1,4,8) at baseline did not detect stairs and made frequent contact with tables and chairs; they were not able to complete the cafeteria tasks, requiring assistance for all three time points (baseline, 3 and 6 months post-implant). Subjects 2 and 5 walked slowly at baseline but were capable of detecting stairs. At three and six months, these subjects demonstrated decreased mobility (inability to detect stairs or complete the cafeteria tasks) compared to baseline, corresponding with a vision reduction in the better eye from 20/100 to 20/550 (subject 2) and from 20/720 to 20/1600 (subject 5). Subjects 3, 6, and 7 did not show a change in behavior for the cafeteria task.

During the interview, subject 1, who did not travel outside the home without assistance, self-reported a decrease of home mobility at the 6 month follow-up. Subjects 2 and 5 reported a decrease in mobility and increased use of the long cane at 3 and 6 months. Table 2 shows all 3 subjects losing VA over the 6-month period of our observations. Subjects 4 (dog guide user) and 8 (long cane user) reported no change during independent travel while using their primary mobility aid. The three subjects with better VA and larger visual fields (s3, 6, 7) reported subtle improvements in their mobility, but this was not observed. Each of these subjects felt they had more confidence, describing situations where they were able to anticipate and therefore avoid mobility problems. Their VA changed by <0.15 logMAR during the 6 month time period.

At baseline, the 95% CI for the thresholds of consistently detected test locations in the Humphrey Visual Field (HVF) 30-2 test ranged from 3.4 to 5.2dB across all eyes, and this was used to set our criteria for significant change. Our analysis considered five rings of increasing eccentricity within the 30 degree radius tested, as depicted in figure 1. At the 3, 4 and 6 month follow-ups, half of the subjects (s 1, 3, 5, 8) showed no statistically significant changes from baseline in either eye for over 75% of the HVF test locations. The implanted eyes of subjects 2 and 4 showed statistically significant reductions in sensitivity for a

majority (50% to 75%) of the test locations after receiving the ASR implant. The implanted eye of subject 6 developed a statistically significant increase in mean sensitivity for ring 4 ($\sim 22^\circ$) at all follow-up visits and an increase for ring 3 ($\sim 15^\circ$) at the 6 month follow-up. Subject 6's fellow eye had statistically significant increased mean sensitivity for ring 3 at all follow-ups, and ring 4 at the 3 and 4 month follow-up visits. In the implanted eye of subject 7, there was significantly improved mean sensitivity for ring 3 at the 3 month follow-up, across all 5 rings at the 4 month follow-up, and for rings 1 through 4 at the 6 month visit. Over 90% of the test locations for the fellow eye of subject 7 did not show a significant change from the baseline sensitivity. While most of these results correlate with the findings for VA changes, none of them appear to have affected performance on the obstacle course or the cafeteria walk.

Discussion

The purpose of this study was to evaluate the effect of an ASR implant on mobility. On a 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, the treated or the control eye. Notes from observations of the uncontrolled walk to and through a cafeteria found an inability to detect stairs for the subjects with the poorest vision and decreased ability in subjects who experienced reduced vision 3 to 6 months post treatment. The subjects with the best vision self-reported subtle enhancements to their travel ability, yet these were not confirmed by their performance on the controlled course or observation during the uncontrolled walk.

Unfortunately, the original study protocol failed to include measures of CS and Goldmann VF at baseline, which are stronger predictors of mobility in RP than VA^{7,9,10,11}, and therefore, we can only assess mobility changes in relation to central vision changes. Comparing pre, 3 and 6 month VA, subjects 1, 2, 4 and 5 show substantial loss of VA in the treated eye and a corresponding decrease of mobility, with subject 4's VA showing a reduction then recovery from 3 to 6 months post implant. The other subjects did not experience a significant change in VA in the treated eye or, in the case of subject 8, there was a slight improvement in VA.

If performance on the obstacle course was sensitive to patients with varying degrees of vision loss, we would expect to see a difference in the number of obstacle contacts between the subjects with the worst and best VA and VF. At baseline, there was a significantly larger number of contacts when comparing the subjects with worse vision (s1,2,4,5,8) to those with better VA and VF (s3,6,7), but no statistically significant differences in the time to complete the course for these 2 subject groups. This indicates that the number of contacts is a more sensitive measure than time to distinguish between patients with remaining functional vision for mobility and those with ultra-low vision. Subjects 1, 2, 4 and 5 experienced a loss of VA over the duration of the study but their performance for obstacle avoidance did not deteriorate further, suggesting their relatively stable, severely constricted VFs $<5^\circ$ played a larger role in the detection of narrow hanging and floor level obstacles, rather than the further decrease in VA that was already poor at baseline. On the other hand, the drop in VA may explain why subjects 2, 4, and 5 were observed to have, and self-reported, an increase in mobility problems during the walk in the complex environment of the cafeteria, suggesting the complex environment may be more sensitive to VA changes than the obstacle course.

The uncontrolled walk to and through the cafeteria without mobility devices demonstrated the importance of a mobility device for the ultra-low vision subjects. Four of the eight subjects (s2, 4, 5, 8) all legally blind by VA and/or VF, reported using a mobility aid (long

cane or dog guide). These subjects were unable to identify the location of stairs, requiring intervention (verbal command of “stop” or touching the arm) by the examiner at baseline, three and six months and under all three conditions (OU, tx, control eye). From the point of view of O&M, this is not surprising given the severity of the dual loss of VA and VF. By comparison, subject 3 met the VF criteria for legal blindness but had moderate loss of VA, while subjects 6 and 7 did not meet the criteria for legal blindness by VA or VF. They did not require an intervention during the uncontrolled walk.

While there were no group effects, the two subjects (s6 and 7) with the best VA and VF reported subtle benefits from the ASR. Both subjects had very few obstacle contacts at baseline, the 3- and 6-month follow-ups, making only 1,0,0 and 2,1,1 contacts respectively. For these subjects, there may have been a ceiling effect. Both reported examples of mobility tasks that they thought had become easier. Subject 6 reported better awareness of the location of objects in her large open-floor-plan office. Subject 7 said he was less likely to walk into half-opened kitchen cabinet doors and less likely to step on the dog. These observations suggest improved anticipation of obstacles, but there could be a placebo effect. It is also possible that the self-reported improvement of these two subjects was due to the use of far-peripheral visual function that was not consistently tested pre-operatively under this study’s protocol. Future trials in RP patients should include VF testing in the far periphery (e.g., Goldmann perimetry) rather than relying on Humphrey perimetry.

This study allows us to draw some general conclusions regarding the role of ultra-low vision – be it the individual’s remaining vision or vision regained through an experimental treatment such as a retinal prosthesis – in O&M. Much of the work on retinal prostheses has been with completely functionally blind subjects with light perception/projection only. It may be that subjects with better VA and larger VFs can experience more benefit from a small improvement in vision than subjects who are severely visually impaired or totally blind. This is an issue that requires further exploration and that will benefit from a program of systematic study. The major challenge will be to find a metric that is sensitive to actually capture changes in mobility when these are infrequent and subtle.

The findings of this study demonstrate that the ASR implant was an underpowered approach with insufficient stimulation and any resulting neurotrophic effects on the retina may not have provided enough improvements in vision to cause significant, observable changes in mobility. Developers of visual prostheses should consider how much vision (VA and VF) their implant is expected to offer. From the point of view of the O&M specialist, subjects will need to use their mobility aids for the detection of obstacles and drop offs until new treatments are able to provide visual previewing that is as reliable as the tactile warnings provided by the long cane or the guidance of the dog guide.

While there did not appear to be a benefit to mobility as we measured it, there may be an application in the area of orientation. Combining the use of the long cane for mobility with ultra-low vision for orientation may be of practical benefit. Examples would be to detect the location of windows in a room, or to visually follow the lights in the ceiling, both common orientation techniques for travelers with severe low vision. Veering while crossing the street is a common problem for the blind and severely visually impaired^{12,13}. Detecting contrast from pedestrian crosswalk lines could enable the traveler with ultra low vision to stay in the crosswalk (orientation), while using the long cane for detection of the curb and to clear the walking path (mobility).

Limitations

Subjects in this study were required to walk without their usual mobility aid (long cane or dog guide). Allowing the use of these aids would have eliminated the possibility of

observing/scoring the effects of any vision changes on mobility, unless the improvements in vision were quite substantial. For future studies, if the primary outcome measure is mobility, then the investigator must take away the mobility device. However, if it is concluded as we suggest here, that the most observable effect from prosthetic vision devices will be on subjects' orientation skills, then it would be appropriate to allow them to use their primary mobility aids while performing tasks developed to measure orientation.

Two subjects with advanced RP chose to not participate in trials with their better eye patched and without access to mobility aids. While comparing performance between the treated and control eye was considered important for this study, these two subjects exercised their right as a human subject to refuse participation in some of the planned procedures. This is something to consider when designing O&M evaluations for ultra-low vision subjects.

Another possible limitation was the design of the obstacle course. The course was seeded with obstacles that were inconsequential: They were so lightweight and yielding as to not noticeably impede the subject's movements. The course did not involve changes in elevation and it involved walking down a straight hallway without sharp turns. Future studies may try to offer a more complex and realistic obstacle course if mobility is considered an outcome measure.

Lastly the limited number of participants and their individual differences make it difficult to offer general projections or predictions about what might happen with a diverse population of patients with implants. Samples of subjects with similar visual status could increase our understanding of the impact of the implant.

Research agenda for O&M in an ultra-low vision population

The development of a research agenda for O&M begins by defining terms. For the O&M instructor, orientation (i.e., a mental process) is distinct and separate from mobility (i.e., physical movement). Orientation is "knowledge of one's distance and direction relative to things observed or remembered in the surroundings and keeping track of these spatial relationships as they change during locomotion"^{14,15}. Mobility, as the term is commonly used within the field of O&M, is "the act of moving safely and effectively from one's present position to a desired position in another part of the environment"^{14,15}. Various cane or dog guide techniques provide the competent user the ability to detect obstacles and changes in elevation. Essentially the mobility problems created by blindness or severe low vision are greatly diminished. Blindness has its greatest impact on independent travel by limiting orientation abilities and O&M instructors have relatively limited resources for instruction to enhance orientation skills. Until the visual skills provided by any kind of vision restoration technology enable better or equally effective mobility skills as the long cane or dog guide, consumers should continue to use these traditional tools. Thus a research agenda that addresses the needs of the consumer should emphasize the impact of the technology on orientation.

The advantage of emphasizing research in orientation is two-fold: Very little vision is required to improve orientation and it addresses unmet needs of the visually impaired consumers. The value of light projection is illustrated by the story of Michael May who experienced a restoration of vision in adult life. In a book written about his life¹⁶ he had serious concerns that if the experimental procedure was unsuccessful he might lose his light projection and the benefits it provided for orientation.

Based on these considerations, our suggested research agenda for O&M with ultra-low vision has three main themes: assessment, instruction, and sensory integration. There is a

need to develop methods for identifying and quantifying orientation abilities and providing immediate and sensitive assessment of the functional impact of regained vision. Acknowledging the difficulty to identify a list of items that can only be accomplished visually¹⁷, we can increase our understanding of the impact of an implant by choosing activities that can only be accomplished with vision in the context of orientation. Subject interviews are a valuable source of information. They document individual experiences and should allow us to construct an assessment in which subjects can demonstrate the enhancement in orientation skills they express in self-reports.

Future systematic research should explore whether subjects will benefit from a structured rehabilitation curriculum. Many technologies for the blind and/or low vision offer a brief instructional program. It is currently unknown whether subjects naturally adapt to prosthetic vision or if they may benefit from instruction.

Sensory integration is another topic that would benefit from a structured program of research. The ASR subjects appeared to attend almost exclusively to visual input, perhaps sacrificing the information that was available through their other senses. Subjects may not be capable of integrating new information from prosthetic vision, if it is too different in nature from their previous native vision, and may end up with problems analogous to those experienced with the use of electronic travel aids (ETAs). ETAs were designed to provide continuous output of auditory or tactile information for processing and interpretation by the blind user. The sonic guide and the sonic pathfinder are two devices which provide a continuous and rich source of auditory information, however, users complain that there is too much information which interferes with their ability to process the naturally occurring sensory information they use during travel. They use the technology only in specific situations and turn it off when it is not being used. It may be that for some users, prosthetic vision will be similar in only offering situational benefits. Studies exploring the situational use of prosthetic vision compared to full time use should be considered. Learning to integrate prosthetic vision may be a challenge. Two potentially important research activities are measuring attentional demand and developing instructional programs to improve sensory integration. Attentional demand in mobility has been studied using a divided attention paradigm and this might serve as a starting point^{18,19}.

In summary, the results of this study did not find any objective difference in mobility following improvements or decreases in vision among subjects who received the ASR implant. A few subjects reported that the implant enhanced their mobility, but there was no complementary evidence from our controlled course tests or uncontrolled O&M performance. Based on this study, we propose a research agenda that emphasizes orientation when evaluating the impact of regained vision. Individualized assessment of mobility skills should account for the needs and abilities of the subject, instructional methods should be developed and evaluated, consideration should be given to whether the restorative technologies would be best applied constantly or situationally, and training individuals to use these new technologies should consider how the information they provide will be integrated with other sensory information.

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Figure one.

Grouping of the Humphrey 30-2 target locations into five concentric rings of equal width, aimed at reducing test-retest variability while assessing the concentric visual field loss common in retinal degenerations

Table one

Mean vision data for each subject, pre-implant and at 3 and 6 months post-implant

ID	Age	Sex	VA Pre Op Tx Eye	VA Pre Op Control eye	VA 3 – 4 month post op Tx	VA 3 – 4 month control	VA 6 month post op Tx	VA 6 month post op control	CS 3 – 6 months post op Tx	CS 3 – 6 months post op control	3-6 month VF diameter	Mode of Travel
1	32	F	20/500	20/500	20/550	20/500	20/800	20/500	0.38	0.3	<5°	NA
2	49	M	20/110	20/160	20/550	20/160	20/1280	20/160	0.38	0.08	<5°	Cane
3	55	M	20/460	20/125	20/500	20/100	20/640	20/110	0.98	1.13	20° §	NA
4*	50	F	20/950	20/1280	20/1600	20/1000	20/800	20/1280	0.45	0.45	<5°	Dog
5	49	M	20/720	20/240	<20/1600	20/200	20/1600	20/240	0.9	0.98	<5°	Cane
6*	44	F	20/80	20/60	20/80	20/70	20/80	20/60	1.2	1.28	30° §	Cane
7*	43	M	20/160	20/80	20/160	20/100	20/160	20/80	0.83	0.83	40° §	NA
8*	48	F	20/500	20/600	20/400	20/640	20/320	20/600	0.68	0.53	**	Cane

NA: Do not use a mobility device

§ Developed increased sensitivity in far periphery (70-90°) outside of central VF diameter post implant

* Undilated VA measures

** Subject 8 had no measurable central visual field; only far peripheral islands

Table two

Descriptive statistics for time to walk the course and obstacle contacts

Time to Walk Course						
	OU Mean *	OU SD	Tx eye Mean	Tx eye SD	Control eye Mean	Control eye SD
Pre-surgery	38.5	14.7	40.4	16.1	42.0	16.1
3 month	36.9	10.9	39.1	10.7	34.4	9.4
6 month	41.6	13.6	43.5	14.7	40.4	13.5
RM ANOVA §	F(2,7)=1.23, p=0.32		F(2,5)=0.63, p=0.56		F(2,5)=1.23, p=0.36	

Obstacle Contacts						
	OU Mean *	OU SD	Tx eye Mean	Tx eye SD	Control eye Mean	Control eye SD
Pre-surgery	10.9	8.4	8.5	6.7	9.7	7.0
3 month	7.6	5.5	9.3	5.3	10.0	6.8
6 month	11.3	6.5	8.8	5.0	7.8	7.1
RM ANOVA §	F(2,7)=2.0, p=0.20		F(2,5)=1.06, p=0.19		F(2,5)=8.17, p=0.47	

* sample size for the condition of both eyes is 8. Sample size for the treated and control eyes is 6 due to two subjects refusal to wear an eye patch.

§ RM ANOVA = repeated measures analysis of variance comparing results at 3 and 6 months to pre-surgery