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ORIGINAL ARTICLE

Developing a Very Low Vision Orientation and Mobility Test Battery (O&M-VLV)

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ABSTRACT

Purpose. This study aimed to determine the feasibility of an assessment of vision-related orientation and mobility (O&M) tasks in persons with severe vision loss. These tasks may be used for future low vision rehabilitation clinical assessments or as outcome measures in vision restoration trials.

Methods. Forty legally blind persons (mean visual acuity logMAR 2.3, or hand movements) with advanced retinitis pigmentosa participated in the Orientation & Mobility—Very Low Vision (O&M-VLV) subtests from the Low Vision Assessment of Daily Activities (LoVADA) protocol. Four categories of tasks were evaluated: route travel in three indoor hospital environments, a room orientation task (the ''cafe''), a visual exploration task (the ''gallery''), and a modified version of the Timed Up and Go (TUG) test, which assesses re-orientation and route travel. Spatial cognition was assessed using the Stuart Tactile Maps test. Visual acuity and visual fields were measured.

Results. A generalized linear regression model showed that a number of measures in the O&M-VLV tasks were related to residual visual function. The percentage of preferred walking speed without an aid on three travel routes was associated with visual field ($p < 0.01$ for all routes) whereas the number of contacts with obstacles during route travel was associated with acuity ($p = 0.001$). TUG-LV task time was associated with acuity ($p = 0.003$), as was the cafe time and distance traveled ($p = 0.006$ and $p < 0.001$, respectively). The gallery score was the only measure that was significantly associated with both residual acuity and fields ($p < 0.001$ and $p = 0.001$, respectively).

Conclusions. The O&M-VLV was designed to capture key elements of O&M performance in persons with severe vision loss, which is a population not often studied previously. Performance on these tasks was associated with both binocular visual acuity and visual field. This new protocol includes assessments of orientation, which may be of benefit in vision restoration clinical trials. (Optom Vis Sci 2016;93:1127–1136)

Key Words: orientation, mobility, visual impairment, instrument development, retinitis pigmentosa, LoVADA

Promising new technologies and treatments for restoring vision are rapidly evolving, including pharmaceutical treatments, gene therapy, stem cells, and retinal visual prostheses.[1] However, testing the efficacy of these innovations is challenging. At this stage, intervention trials are limited to people who have little or no vision, and any improvements in visual function are expected to be small and unlikely to be captured in usual clinical measurements such as letter chart visual acuity or electrophysiological recordings.[1,2] Thus, researchers, funding organizations, and government regulatory agencies[3] have recognized and called for the evaluation of real-world functioning and quality of life alongside more conventional clinical measurements.[4,5]

Safe and efficient navigation—orientation and mobility (O&M)—is a vital real-world function and a principal goal of many new interventions for patients with severe vision impairment.[2] However, there are no gold standard measures of O&M,[6,7] perhaps because of the complex nature of O&M and the lack of consensus regarding what aspects of performance should be assessed and in which environments. To date, very few standardized assessments of observed O&M performance are available.[7] A basic assessment of

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vision-related mobility can be obtained using measures such as walking speed and obstacle avoidance to evaluate travel flow and efficiency.[8–11] However, the overall scope of O&M is broader than this and includes a number of other psychosocial, physical, and environmental factors.[6,12–14]

Therefore, we developed the Very Low Vision Orientation & Mobility (O&M-VLV) assessment, which includes a range of O&M tasks in an indoor setting. These tasks capture information on a person's ability to detect landmarks, self-orientation and reorientation skills, and independent navigation. These skills are important to ensure that a given mobility task could be completed safely and efficiently.

Very low vision usually necessitates the use of a primary mobility aid, such as a sighted guide, long cane, or dog guide, to support safe and purposeful O&M.[15] These aids are used to supplement other senses such as remaining vision, hearing, and touch when vision is unreliable.[7] Thus, we included the use of habitual aids (if any) in the assessment to accurately measure real-world performance.

This Orientation and Mobility—Very Low Vision (O&M-VLV) test battery formed part of the Low Vision Assessment of Daily Activities (LoVADA) protocol, developed within the Bionic Vision Australia retinal prosthesis project. We have previously reported on the Instrumental Activity of Daily Living—Very Low Vision (IADL-VLV) and Impact of Vision Impairment—Very Low Vision (IVI-VLV) tools from LoVADA,[16,17] and this is the final aspect of the protocol.

The LoVADA O&M-VLV study generated an embedded mixed methods[18] dataset about functional performance. In this report, we describe the tasks related to O&M in the protocol and compare with several measures of visual function. Future reports will provide more detailed information on the qualitative data collected from this feasibility study.

METHODS

The study was conducted at the Centre for Eye Research Australia, Royal Victorian Eye and Ear Hospital (RVEEH). Ethical approval was obtained from the Human Research and Ethics Committee at the RVEEH. All patients gave informed consent for study participation. The study adhered to the tenets of the Declaration of Helsinki.

Participants

Forty participants were included. To be eligible for the study, participants had to be legally blind due to a rod-cone dystrophy, over the age of 18 years, and not have any physical disabilities which would mean they were unable to complete the designed O&M assessments. Legal blindness was defined according to the Australian definition, which is based on either corrected distance visual acuity (less than 20/200 in the better eye) or visual field restriction (binocular visual field constricted to 10° of arc or less around central fixation), or both.

Clinical Examination

All participants underwent a clinical examination, including visual field testing, and a battery of psychological tests that contained an assessment of cognitive function and a measure of depression. Cognitive impairment and depression have been shown to influence performance on observed as well as self-reported tasks, with increasing cognitive impairment and depression leading to worsening performance.[19,20] Thus, we decided to control for these, using an adapted Mini-Mental State Exam Second Edition Brief Version (MMSE-2 BV), which removed the visual tasks, and the Patient Health Questionnaire 9-items (PHQ-9).[21–23] For the PHQ-9, a cutoff of 10 and above to diagnose depression was used, as suggested by a large meta-analysis.[21] Using the MMSE-2 BV, participants were deemed cognitively normal if they scored 13 or above, in accordance with the user's manual.[22]

Refraction was determined first by autorefraction, followed by a monocular subjective refinement in participants with sufficient visual acuity. Habitual visual acuity and best-corrected visual acuity were both recorded monocularly and binocularly, using a standard testing protocol. All patients were first tested on a 4-meter calibrated Early Treatment of Diabetic Retinopathy Study (ETDRS) logMAR visual acuity chart at the full testing distance (4 m).[24] As almost all patients had vision of worse than logMAR 1.0 (20/200) in their better eye, the next step was to repeat the ETDRS at 1 m to expand the range of measurable acuities (using the number of letters read to determine logMAR acuity). For patients who were unable to see the chart at this distance, acuity was measured using the Berkeley Rudimentary Vision Test (BRVT).[25] The habitual binocular visual acuity was converted into logMAR units for subsequent statistical analyses.

Residual visual field (VF) was measured binocularly using manual kinetic Goldmann perimetry (Haag Streit, Switzerland), with the V4e target size. Field testing was completed by one experienced examiner, who measured each of 24 meridians (every 15°) at least twice to check for consistency. The edges of any islands or scotomas were further probed with tangential movements to accurately map the remaining field. Unreliable field tests were defined as excessive fixation losses during testing and/or unrepeatable results (i.e. where the edge of the island or scotoma was not repeatable on subsequent probing) and were excluded from analysis. Only one field (2.5%) had to be excluded from analysis as the scotoma boundaries could not be replicated within the testing session. To quantify the remaining field, the hard copy Goldmann fields were scanned into ImageJ image processing software (Research Services Branch, National Institute of Mental Health, Bethesda, MD, USA).[26] The percentage of field seen was determined by comparing the areas of combined residual binocular field to a full field of vision. For the purposes of this study, the total percentage of binocular field remaining included both central field (within 10° from fixation) and peripheral islands.

Assessment of Spatial Cognition

To assist in the interpretation of O&M performance measures, participants underwent a baseline assessment of spatial cognition using the Stuart Tactile Map (STM) test,[27] which consisted of three test plates, with patterns of increasing difficulty (A1 with 5 segments, A2 with 7 segments, and A3 with 11 segments; more detail and a figure can be found in the Appendix, available at http://links.lww.com/OPX/A242). The STM has previously been validated in congenitally blind children, but it is not commercially available; the authors were able to source this test directly from Dr. Stuart for this study.

The participant is blindfolded and the examiner guides the participant's pointer finger, from their dominant hand, over the raised wire pattern three times from start to finish. The blindfold is kept on while the participant is asked to reproduce the pattern with a pen and paper. If drawn accurately, they move on to the next level of difficulty. Accuracy refers to the correct direction and relationship of lines and angles irrespective of size of the map. A maximum of three attempts is permitted for each map. The total score (1–9) derived takes into consideration the level reached and the number of attempts, where a score of three is given for correct reproduction of the pattern with one attempt at each level.

Orientation & Mobility—Very Low Vision Tasks

All O&M tasks are described in detail in the found in the Appendix (http://links.lww.com/OPX/A242). Tasks were compiled following a review of the literature, discussion with low vision rehabilitation and O&M professionals, as well as legally blind individuals.[14] Four main tasks were completed by all participants: (1) travel through three different routes in a hospital environment, (2) room familiarization ("cafe" task), (3) an object identification task ("gallery" task), and (4) an agility, visual land marking, and re-orientation task (Timed Up And Go Low Vision (TUG-LV)). Interval measures included task time, travel distance, and percentage of preferred walking speed (PPWS: time to walk the course ÷ time to walk a level unobstructed course of the same distance with sighted guide × 100)[28,29] for route travel.[12,30,31] Measures obtained included task-specific accuracy scores for the gallery and cafe tasks, as well as time taken for all tasks. Novel performance scales (way finding, touch frequency, touch type, support, posture, and mobility aid skills) were also developed and trialed across all tasks in addition to qualitative data and participants also had the opportunity to reflect upon performance with the researchers as part of each assessment, which provided qualitative data about the task design and other factors that may have influenced participant performance; due to space restrictions, these will be detailed in subsequent publications.

Travel Routes

Three route travel courses were selected within an indoor setting that represented sequential increases in environmental complexity, levels 1 to 3.[13] Safety, convenience, and real-world relevance were considered in selecting courses. Route one was a straight, evenly lit corridor with no doors and no windows, and without any obstacles. On route two, the same route was used as in route one but was made more complex by the addition of randomly placed obstacles (a box, a potted tree, a chair, etc.). Route three was a complex route in a dynamic office environment with four 90° turns and one 180° turn, and pre-existing obstacles (present staff, filing cabinets, bins, etc.). All routes are described in detail in found in the Appendix (http://links.lww.com/OPX/A242). The course order, trial order, and position of obstacles were randomized. To begin, participants were asked to walk each course twice with a sighted guide to orientate them to the route. PPWS for all tasks was calculated using the second sighted guide trial from Route 1 as PWS. If the two trials of each pair were significantly different, a third was undertaken for comparison and the two trials that were most similar were taken as the pair, with the second of those used for the PWS determination. Participants were then given the opportunity to familiarize themselves with the seeded obstacles used in Route 2, which they did both visually and by touch, with the assistance of the researcher. After this, they underwent two trials unaided. If they used a mobility aid, an additional two trials were completed with their aid. Results from the second trial of each condition (aid or no aid) were analyzed to allow for a learning effect.[28,32]

PPWS was developed in the 1980s as a measure of a person's travel efficiency and is expressed as a ratio of the speed a person walks in a given environment divided by their "preferred walking speed" on a level, unobstructed route using a sighted guide.[28,33] PPWS enables participants to act as their own controls, normalizing the data for age and physical factors.[34] PPWS has been used in many studies to indicate travel efficiency in relation to novel low vision aids and[28] psychological correlates,[35] and suggest the effect of vision loss has on mobility.[29,34,36] In this study, we have used PPWS as a measure on all three route travel tasks.

Cafe Task

Room orientation is a common challenge for people with very low vision. This task required the participant to explore a room (6 × 4.5 m) containing six heterogeneously shaped tables and six chairs, and create a tactile map of the arrangement of the furniture in the room as they explored. Time and distance to complete the task were recorded along with a task accuracy score out of 35 indicating the ability to locate each item of furniture in the room, then locate and orientate the relevant furniture magnets on the magnetic map. A full score indicated accurate furniture placement on the map in relation to each other and the wall planes. Each participant's travel route was drawn on a 1:30 scale map during the task and distance measured from the map later using a Scalex Plan Wheel. Furniture placement was randomized between trials to one of six arrangements. This task was completed without a mobility aid. More detail can be found in found in the Appendix (http://links.lww.com/OPX/A242).

Gallery Task

Landmark recognition is an important part of visual orientation. Functional vision becomes evident in visual recognition and interpretation of elements of design—color, contrast, shape, letters, perspective, figure-ground detail, movement, and lighting—even if a whole object is not recognizable.[37] In the gallery task, participants were asked to walk accompanied around three walls of the room (light-colored, 16 m in total length), without a mobility aid, and attempt to visually locate and identify 15 possible "gallery" objects hung between 1.2 and 1.8 m from the ground. The targets (or objects) were chosen to reflect a range of visual stimuli of increasing complexity, including a basic light (fluorescent tube light), a complex colored light target, common company logos (such as a police logo), and common signs/symbols (such as a "No Smoking" symbol). Details of the targets and the reason for their selection are included in the Appendix (http://links.lww.com/OPX/A242).

A total task score out of 45 points was given using a 3-point scale for each target with level one indicating the target was located, level two indicating that some features were described, and level three indicating the target was correctly identified. This task was completed without a mobility aid and the emphasis was on gaining information rather than moving efficiently. Participants' need to pause between targets (for example, if they experienced any glare issues after looking at the light targets) was represented in the overall task time. The viewing time for individual targets was not measured.

Timed Up and Go—Low Vision (TUG-LV)

Timed up and go (TUG) was initially developed to assess functional stability in relation to falls prevention in elderly people.[38] Our modified version (Timed Up and Go—Low Vision, TUG-LV) increased the length of the course from 3 to 6 m to increase the chance of veering and introduced a bright light at each end of the course (one behind the chair and one at the turning point) to provide potential visual landmarks to support straight-line travel, and reorientation after turning. More details are provided in the Appendix (http://links.lww.com/OPX/A242). Each participant was familiarized with the task, and the threshold distance at which they could detect the target light was initially recorded using sighted guide before the timed trials commenced. Then the participant was asked to stand up from a chair, walk 6 m to the light target, touch the light pole, and then return to the chair and sit down again. The task was undertaken six times with no mobility aid, randomizing three trials with target lights on and three trials with target lights off. Time to complete each trial was recorded, which was measured from when the participant started to leave the seat to stand to when they were sitting back down on the seat. The average time taken across the three independent trials for each condition (target lights on versus target lights off) was used for statistical analysis.

Independent Mobility Questionnaire

The Independent Mobility Questionnaire (IMQ) was used to investigate self-reported O&M skills.[39,40] The IMQ includes 35 questions related to specific mobility situations, each rated on a 5-step scale from "no difficulty" to "extreme difficulty." Due to their very low vision, subjects who used a mobility aid reported they used it in the majority of the situations described in the IMQ, and hence after a piloting of the questionnaire (n = 5 participants with very low vision), we adapted the IMQ to gather information on performance with their aid (as compared to the original publication, which questioned patients on performance without their aid). This was done to allow comparison of our observed task results with the subjects' real-world functioning. The questionnaire has been demonstrated to be valid and reliable in detecting a decline in self-reported visual ability with retinitis pigmentosa and glaucoma in concordance with clinically measured visual function (visual acuity, contrast sensitivity, and visual field approximated by area of retina affected by RP).[39,40]

Impact of Vision Impairment Questionnaire

The IVI is an instrument for measuring the impact of vision impairment on vision-related quality of life (VRQoL). It contains 28 items with three to four active response options using Likert scaling, ranging from *not at all* to *a lot*. Items 1 to 15 have an additional response *don't do this for other reasons*. Items form three specific subscales: "reading and accessing information," "mobility and independence," and "emotional well-being."[41,42] In this study, we investigated only the mobility and independence subscale.

Statistical Analyses

The data entry and management were performed using OpenClinica open source software (version 3.1; OpenClinica LLC and collaborators, Waltham, MA). Data analysis was carried out with SPSS statistical software (version 19.0, SPSS Science, Chicago, IL).

Descriptive statistical analyses were performed to characterize the participants' sociodemographic, clinical, and performance-based O&M data. As appropriate, parametric (t-tests or ANOVA) and nonparametric (Wilcoxon, Kruskal Wallis) test were used. We used Rasch analysis to generate person measures for the IMQ and IVI mobility subscale. For both questionnaires, a high person measure (in logits) indicates that a person possesses a low level of perceived independent mobility. Evidence of construct validity was explored by evaluating associations between our O&M tests and self-reported mobility (IMQ and mobility subscale of the IVI) using Pearson's and Spearman's correlations for parametric and nonparametric variables, respectively.

We compared performance on the O&M tasks to residual vision parameters (acuity and visual fields) using descriptive statistics, correlation, and generalized linear regression models to assess the correlation of performance on different tasks with each other, as well as with measures of visual function such as binocular VA and VF. We corrected for multiple testing using a simple Bonferroni correction (i.e. accepted level of significance p = 0.05/ number of tests).

Only outcome measures which were associated with VA or VF in univariate analyses (simple correlations) were tested for an association with VA or VF through a generalized linear regression model, controlling for spatial cognition and travel preference (cane vs. human/dog guide vs. no mobility aid). A generalized linear regression model was used as it does not require a normal distribution.

RESULTS

Characteristics of the Sample

In this cohort of 40 participants, mean age was 53 years, and half of the sample was male (53%). All had rod-cone dystrophy, with the majority having autosomal recessive retinitis pigmentosa (80%). The mean visual acuity (VA) was 2.3 logMAR, which is in the range of hand movement vision, and 70% of the sample had less than 10% of visual field (VF) remaining (Table 1). We included one participant with no light perception. Participants reported a median duration of disease of 20 years (IQR: 14.75–35.75 years), and most had received O&M training from external professionals in the past. Using the MMSE, no participant was cognitively impaired. Based on the PHQ-9 scores, five participants were mildly depressed with scores $\geq$10. These patients were referred for treatment of their depression outside of the study.

TABLE 1.
Participant characteristics, n = 40

	Mean ± SD or n (%)
Age (yr)	53 ± 16
Age category (yr)	
55+	21 (52.5%)
≤55	19 (47.5%)
Sex	
Male	21 (52.5%)
Female	19 (47.5%)
Binocular VA (logMAR)	2.3 ± 1.0
% VF Remaining	11.8 ± 20.4
IMQ score (logits)	−0.19 ± 0.63
IVI mobility & independence score (logits)	−0.3 ± 1.15
Preferred mobility aid	
None	7 (17.5%)
Long cane	17 (42.5%)
Support ID cane or walking frame	4 (10.0%)
Dog guide	9 (22.5%)
Human guide	3 (7.5%)

VA = visual acuity, VF = visual field, logMAR = logarithm of the minimum angle of resolution, IMQ = Independent Mobility Questionnaire, IVI = Impact of Vision Impairment.

The majority of participants preferred a long cane (n = 17; 42.5%), followed by a guide dog (n = 9; 22.5%), secondary mobility aid (n = 4; 10%), or a sighted guide (n = 3; 7.5%; Table 1). Seven (17.5%) participants did not use a mobility aid. Remaining VF was no different between participants who preferred no mobility aid to those who preferred a cane and those who preferred a dog or human guide (p = 0.291). Those who used no mobility aid had better binocular VA compared to those who preferred a dog or human guide (logMAR 1.5 vs. 2.7; p = 0.046), but binocular VA was no different between those who preferred a cane to no aid (logMAR 2.2 vs. 1.5; p = 0.308).

Using the Stuart Tactile Map test, 85% (n = 34) of participants could draw the most complex map A3, scoring ≥7/9. The remaining participants (15%, n = 6) could not draw A3, scoring between 0 and 6 out of 9. The mean IMQ person measures were −0.19 logits (minimum, maximum −2 to 1) and the mean IVI mobility & independence person measure was −0.3 (minimum, maximum −3 to 2; Table 1).

Performance on the O&M-VLV

All O&M tasks could be performed by all participants regardless of their level of vision, with one exception—the person with no light perception could walk the Gallery route but was unable to score on the task (i.e. could not visually locate or identify any aspects of any target).

In route travel tasks, participants' overall walking speed decreased as route and environmental complexity increased (Table 2). Body contacts with obstacles/shorelines increased from route 2 to 3 (2 to 9 without aid, p < 0.001, and 0.8 to 2.2 with aid, p = 0.04, both Wilcoxon signed rank test). In those who used a preferred aid, there was a significant difference in body contacts between those using a cane (any type) and those using a guide (any type) on route 3 (3.2 vs. 0.3, p = 0.023, Kruskal Wallis test). TUG-LV tasks were completed fastest with target lights on (Table 2). Those who did not habitually use a mobility aid scored highest on the gallery accuracy score (p = 0.023, Kruskal Wallis test).

Correlations between O&M-VLV Tasks, Visual Function, and Self-Reported Mobility

All correlations were corrected for multiple testing and correlations reaching a significance of p ≤0.0016 considered significant. Only significant correlations are reported in this section. Considering travel efficiency and environmental complexity, PPWS without an aid was correlated on all three routes (Table 3). PPWS with aid on route 1 was correlated with PPWS on route 2 (r = 0.71), which was correlated with PPWS on route 3 (r = 0.64). However, PPWS on route 1 was not correlated with PPWS on route 3 when using an aid. Both TUG-LV tasks were correlated with PPWS on routes 1 and 3 without an aid, but not on route 2.

Assessing visual function and travel efficiency in relation to environmental complexity and aid use, we found VF to be correlated with PPWS without aid on route 2 (r = 0.61) and both VA and VF correlated to PPWS without aid on route 3 (r = −0.56 and 0.71, respectively). Both TUG-LV tasks were correlated with

TABLE 2.
Performance on O&M tasks, as mean ± SD or median (range)

	Total sample n = 40
Route travel tasks	
No aid	
Route 1	
PPWS no aid, %	90.6 ± 15.3*
Route 2	
PPWS no aid, %	65.9 ± 17.9*
Obstacle contacts no aid, n	2.2 ± 1.8
Route 3	
PPWS no aid, %	58.4 ± 21.3*
Obstacle contacts no aid, n	9.1 ± 9.9
With aid	
Route 1	
PPWS with aid, %	95.6 ± 15.0*
Route 2	
PPWS with aid, %	70.1 ± 18.3*
Obstacle contacts with aid, n	0.8 ± 0.9
Route 3	
PPWS aid, %	63.3 ± 17.5*
Obstacle contacts with aid, n	2 ± 3.4
Timed Up and Go Low Vision Task	
Time TUG-LV Lights On, sec	23.8 ± 16.9*
Time TUG-LV Lights Off, sec	31.2 ± 30.2*
Cafe task	
Cafe task time, sec	448 ± 220
Cafe task map accuracy, score out of 35	30 (27)
Cafe task distance, m	44.8 ± 31.1
Gallery task	
Gallery task time, sec	393 ± 264
Gallery task accuracy, score out of 45	26 (40)

SD = standard deviation; PPWS = percentage of preferred walking speed; TUG-LV = Timed Up and Go Low Vision.

*Significant difference in paired t-tests between all three routes, with and without aid, respectively, and between times for TUG-LV.

PPWS on routes 1 (r = −0.54 and −0.58) and 3 (r = −0.66 and −0.64) without an aid. These correlations suggest that travel efficiency without an aid reduces with less vision or increasing environmental complexity, which is likely why these participants use a mobility aid. Participants indicated that although they were happy to undertake "no-aid" trials to oblige the research team, they would ordinarily use their preferred mobility aid, particularly on routes 2 and 3 where there were hazards.

We considered the impact of visual function on task achievement. Both VA (r = 0.90) and VF (r = 0.61) were correlated to the gallery score, which was designed to measure visual integration. The gallery score was correlated with PPWS on routes 2 and 3 without an aid (r = 0.57–0.67), and cafe task time and distance (r = 0.57–0.60). Visual acuity was correlated to both cafe time (r = 0.59) and cafe distance (r = 0.63). These findings indicated that participants with less vision walk more slowly on route travel tasks where there is visual challenge, and also need to walk greater distances to access the visual information they need.

The cafe task, TUG-LV and route 3 were the only tasks which included orientation challenges involving finding direction, making turns and reorientating. Both the TUG-LV and the cafe task are correlated to spatial cognition as measured by the STM (all $r > 0.60$, $p < 0.0016$; Table 3). Both TUG-LV tasks (lights on and lights off) were correlated with the cafe map accuracy score (r = 0.53–0.60, Table 3) and route 3 speed was associated with both TUG-LV tasks and cafe time.

None of the O&M-VLV tasks were significantly correlated with either IMQ or IVI mobility & independence scores. This might be because the questions were examining different elements of O&M than the performance-based tasks, or that they were not sensitive enough to capture subtle differences in performance with very low vision.

Relationship of Visual Function to O&M-VLV Performance

Remaining VF was associated with PPWS on route 1 to 3 without aid (Table 4). Binocular VA was associated with obstacle contacts on route 3 without an aid, the TUG-LV task time, with lights on and off, and cafe time and distance (Table 4). Both VA and VF were associated with the gallery score.

DISCUSSION

In this study, we tested a battery of tasks related to O&M consisting of route travel as well as visual exploration, orientation, and reorientation. We found that a number of measures in the O&M-VLV protocol were associated with poorer visual acuity and/or fields in this cohort, namely PPWS without an aid on three travel routes, the number of contacts with obstacles, the time taken to complete the TUG-LV task, the time taken and distance traveled on the cafe task, and the score for the gallery task. Conversely, self-reported ability for independent mobility (IMQ and IVI Mobility scale) was not associated with any of the tasks in our assessment. This highlights the necessity of assessing O&M

TABLE 3.

Correlations between O&M-VLV tasks, IMQ and IVI mobility& independence subscale person measures, and binocular BCVA and VF, Pearson or Spearman correlations coefficients, and significance

	IVI M&I PM	IMQ PM	PPWS R1 no aid	PPWS R1 aid	PPWS R2 no aid	PPWS R2 aid	PPWS R3 no aid	PPWS R3 aid	TUG-LV Time Light On	TUG-LV Time Light Off	Cafe time	Cafe score	Cafe distance	Gallery time	Gallery score
IVI M&I scores (logits)	1														
IMQ scores (logits)	**0.60***	1													
PPWS R1 no aid	−0.01	0.07	1												
PPWS R1 aid	−0.27	−0.21	0.40	1											
PPWS R2 no aid	−0.17	−0.07	**0.63***	0.25	1										
PPWS R2 aid	−0.42	−0.41	0.20	**0.71***	0.40	1									
PPWS R3 no aid	−0.16	0.03	**0.70***	0.22	**0.80***	0.22	1								
PPWS R3 aid	−0.14	−0.04	−0.03	0.35	0.23	**0.64****	0.29	1							
TUG-LV Time Light On	0.18	0.22	**−0.54***	−0.34	−0.48	−0.30	**−0.66***	0.01	1						
TUG-LV Time Light Off	0.21	0.23	**−0.58***	−0.27	−0.52	−0.26	**−0.64***	0.18	**0.92***	1					
Cafe time	0.14	0.01	−0.31	0.12	−0.456	−0.09	**−0.63***	−0.19	0.33	0.34	1				
Cafe score	−0.06	−0.18	0.32	−0.07	0.34	0.09	0.28	0.09	**−0.60***	**−0.53***	−0.19	1			
Cafe distance	−0.00	−0.14	−0.19	0.08	−0.27	−0.08	−0.49	−0.23	0.13	0.12	**0.88***	0.02	1		
Gallery time	0.19	0.15	−0.18	−0.05	−0.27	−0.15	−0.34	−0.18	−0.06	−0.02	0.11	0.04	−0.04	1	
Gallery score	0.13	0.13	0.47	0.07	**0.57***	0.10	**0.67***	0.19	−0.53	−0.50	**−0.60***	0.29	**−0.57***	0.23	1
Binocular VA	−0.38	−0.76	−0.30	−0.01	−0.47	−0.10	**−0.56***	−0.12	0.49	0.44	**0.59***	−0.20	**0.63***	−0.23	**−0.90***
Binocular VF	0.06	−0.71	0.45	0.17	**0.61***	0.16	**0.71***	0.30	−0.36	−0.34	−0.46	0.22	−0.31	−0.21	**0.61***
STM score	−0.08	−0.25	0.14	0.18	0.04	0.19	−0.14	−0.01	**−0.61***	**−0.61***	0.05	**0.70***	0.20	0.12	0.08

Bold font indicates statistical significance.

IVI = Impact of Vision Impairment questionnaire; M&I = Mobility & Independence subscale; PM = person measure; R1 = route 1; IMQ = Independent Mobility Questionnaire; IVI = Impact of Vision Impairment; PPWS = percentage of preferred walking speed; TUG-LV = Timed Up and Go Low Vision; STM = Stuart Tactile Map.

*Correlation is significant at the 0.0016 level (2-tailed).

outcomes using performance-based tasks and not simply relying on patient reported outcomes.

The presented O&M tasks have been designed to be conducted in various locations using commonly available apparatus and hence could potentially be used in multisite clinical trials assessing sight restoration and low vision rehabilitation. However, this is known to be a challenge in O&M research, as it is near impossible to set up identical courses in different locations. As such, we are working to identify the important factors in such mobility courses, so that they may be replicated between sites, rather than needing an identical setup. In addition, further testing of these complex tasks is needed to ascertain efficacy and to facilitate development of a shorter O&M testing protocol. The whole O&M protocol could take up to four hours of testing, depending on the number of breaks a subject had, which would not be feasible for repeated measures during a time-restricted trial. Removing the route 1 task and the trials of all routes with the habitual aid would reduce the overall time needed in a trial setting. Here, researchers need to be clear about whether their purpose is to show clinical difference or functional relevance. Removing route 1 and trials with habitual aid would mean forfeiting data with functional relevance—route 1 gives baseline data about the participants' travel style in easy environments which is useful in demonstrating concurrent validity with other route travel tasks; trials with habitual aid give data which are more relevant to participants' real-world travel choices, increasing the generalizability of findings in relation to everyday functional performance. Although this task set is correlated with the levels of remaining binocular VA and VF in cross-sectional data, the ability of this task set to detect a longitudinal change in visual function needs further investigation.

We employed multiple measures for all tested tasks (i.e. PPWS and obstacle contacts for route travel, or time and accuracy for the cafe and gallery tasks) to allow for the best chance to capture relevant O&M performance in this exploratory study. This range of measures enabled us to capture differences in participants' priorities on different tasks. For example, participants could walk slower to avoid obstacle contacts. In a pre-post trial setting, multiple

TABLE 4.

Generalized linear regression model of factors associated with O&M task performance, controlling for STMS and mobility aid preference

	B	Std. error	p-value	95% CI Lower	95% CI Upper
PPWS L1 no aid					
VA	0.58	2.60	0.822	−4.51	5.68
VF	0.31	0.12	0.010	0.07	0.54
PPWS L2 no aid					
VA	−1.64	2.66	0.537	−6.85	3.57
VF	0.48	0.12	<0.001	0.24	0.72
Obstacle contacts L2 no aid					
VA	0.38	0.32	0.236	−0.25	1.02
VF	−0.02	0.01	0.080	−0.05	0.00
PPWS L3 no aid					
VA	−5.23	2.78	0.060	−10.67	0.21
VF	0.58	0.13	<0.001	0.33	0.83
Obstacle contacts L3 no aid					
VA	7.37	2.15	0.001	3.16	11.57
VF	−0.05	0.06	0.388	−0.18	0.07
TUG-LV time light on					
VA	7.67	3.15	0.015	1.50	13.84
VF	−0.19	0.14	0.193	−0.47	0.09
TUG-LV time light off					
VA	12.76	4.29	0.003	4.36	21.17
VF	−0.20	0.20	0.319	−0.58	0.19
Cafe time					
VA	120.41	43.48	0.006	35.19	205.62
VF	−3.38	1.99	0.090	−7.28	0.53
Cafe distance					
VA	23.28	5.21	<0.001	33.49	19.99
VF	0.00	0.24	0.974	0.46	0.00
Gallery score					
VA	−10.23	1.13	<0.001	−8.02	82.20
VF	0.18	0.05	0.001	0.28	12.02

Shaded areas indicated statistical significance.

VA = visual acuity; VF = visual field; TUG-LV = Timed Up and Go—Low Vision; PPWS = percentage of preferred walking speed; STMS = Stuart tactile map score.

measures are appropriate as they will increase the chance to capture even a small difference, i.e. someone may not walk faster after the intervention, but may have fewer obstacle contacts, or perform a task not faster but with higher accuracy. Thus, multiple measures should be retained for this purpose.

In line with a number of other studies, we found an association between route travel performance and remaining VA and VF.[12,43–45] In participants with moderate vision loss, route travel performance tends to correlate more highly with VF than with VA,[46] and certain types of VF loss are more important for route travel than others (central and mid-peripheral damage, in particular in the inferior VF).[45,47]

In a previous study of 10 participants with severe vision loss, travel time and contact with obstacles were measured in four different mazes in which participants were tested repeatedly.[11] The authors reported statistically significant differences between three different levels of residual visual function based on VA and VF.[11] The maze used in this previous study better reflects our routes 2 and 3, and thus supports our findings of an association of VF with performance on these tasks.

Another previous study of O&M performance of eight participants undergoing implantation of an ''artificial silicone retina'' found that travel speed and contacts did not improve with the device on.[12] The authors hypothesized that retinal implants would be unlikely to affect overall mobility performance due to potentially very small gains in VA or VF, and may only have a measurable impact on obstacle avoidance when not allowing participants to use their habitual mobility aid. However, retinal implants were thought to most likely improve orientation skills even if gains in VA or VF were small.[12] This is reflected in our results, where differences in VA and VF were only reflected in route travel without an aid. Against this background, object recognition or visual exploration tasks such as the gallery task tested in this assessment may provide the best chance to capture a change in visual function, as it was associated with both VA and VF.

One of the main differences between this study and previous work is that we chose to allow the participants to preview the tasks and the environment before each task. Participants were allowed to explore the environment in any way they wished (tactile as well as visual). We made this decision after consultation with O&M instructors and patients who expressed their views that if a person feels safe in the test environment, they are more likely to perform at their optimal level. The advantage of allowing a preview is that it reduced the effect of learning on subsequent trials. However, this does mean that our results are not directly comparable to studies where the participant is in an unknown environment.

Another key difference with previous O&M studies is that our participants were asked to complete a number of trials with their habitual mobility aid. This was done to investigate the optimal performance of that individual on the task using the aids that they would normally use in a given situation. Completing mobility tasks unaided gives an indication of the direct influence of vision parameters on performance (as noted by the results of this study) but does not reflect the true ability of a person in a real-world situation. As such, we elected to measure tasks both with and without aids, to compare the efficacy of these measures. Although measurements with an aid give a good indication of a person's real-world function, we believe that measures without aid are more sensitive to changes in measures of visual function. We believe there is the need for both sets of information in studies of O&M, vision rehabilitation, and vision restoration trials, depending on the aim of the specific study.

Self-reported ability for independent travel as measured by the IMQ and the IVI mobility and independence subscale did not correlate with any of our O&M tasks. This likely reflects the variability between participants' own perception of O&M ability in real life and what was tested under laboratory conditions in this study. We recently assessed the measurement properties of the IMQ using Rasch analysis and found it to be valid for use in participants with severe visual loss after minor amendments to optimize psychometric properties.[48] In the current study, we were then able to use the Rasch-transformed person measures to confirm the lack of correlation between the IMQ and our O&M measures. This finding may be due to the IMQ having been developed with a group of RP patients who had a broad range in remaining visual function, with a considerable number of them still seeing well.[39] The IMQ captures different aspects of peoples' difficulty with independent mobility than to what was tested in this laboratory environment, with several of our tasks focusing on orientation and visual exploration rather than mobility. The IVI was designed to measure overall VRQoL with a subscale relating to mobility and independence, rather than O&M ability more broadly, which may explain its lack of association with any of the O&M tasks. However, future studies in a larger sample are needed to replicate these findings. Self-reported outcomes commonly have a high variability, which may obscure identification of associations in small studies.

Strengths of this study include the incorporation of input from people who were legally blind, O&M professionals, occupational therapists, and low vision professionals. Lack of such collaboration can be a shortcoming in the design of other existing O&M assessments, as noted in a previous Cochrane review.[7] In the O&M-VLV tool, we included a broad set of tasks related to travel, visual exploration, and orientation. Performance was timed and scored in a range of ways to capture important aspects relevant to overall O&M performance.

A full ophthalmic eye examination (including retinal imaging) was completed to confirm ophthalmic diagnosis. Characterization of the sample also included a psychological assessment, unlike many other studies, which allowed us to control for cognitive function, including spatial cognition. We used Goldmann VFs to maximize the sensitivity of field measurement,[12,45] but it should be noted that due to the very low vision of our patients, field results will be more variable than in a normally sighted population due to fixation issues.

As a clinical investigation, our study is limited by its relatively small sample size, and further studies are needed to evaluate the assessment in more detail, ascertain its sensitivity to changes in vision, and determine its reliability and validity in other samples as well as its association with real-world O&M performance. In future studies, we will aim to evaluate a reduced number of tasks to develop a protocol that could be used in a clinical trial environment. We also wish to investigate the correlation with these tasks with contrast sensitivity (CS) in subjects with slightly more residual vision, as CS has been shown to be significantly associated with mobility performance.[29] This was not possible in the current study due to the very poor acuity of the majority of our participants, with a lack of suitably validated tests for this level of vision.

Questions have been raised in the literature about the best way to measure preferred walking speed which is used as a baseline for PPWS calculations.[32] Two sighted guide trials of preferred walking speed enabled us to be confident of the repeatability of this measure.

Although it is hoped that these tests may be of use in outcome evaluation of patients with vision restoration interventions in the future, they will need to be trialed with those treatments to establish feasibility. In particular, visual prostheses currently provide patients with limited numbers of phosphenes,[49,50] and studies with prosthetic vision are needed to determine whether or not these assessments can detect small changes provided by prosthetic vision.

In conclusion, in this study, we found that tasks assessing route travel without an aid, an orientation/reorientation task, and a visual exploration task were correlated with residual vision measures in this sample of participants with severe vision loss due to retinitis pigmentosa. Future studies will investigate the feasibility and efficacy of these tasks in vision restoration trials to further evaluate their validity.

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