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ORIGINAL RESEARCH

Peripherex Home Visual Field Demonstrates High Test-Retest Reliability, Validity

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Purpose: Assessment of disease and progression is one of the greatest unmet needs in glaucoma care. Moving visual field testing into the home stands to increase access and increase testing frequency to address these unmet needs. Here, we test a novel home-based app (Peripherex Visual Field Test or PRX-VFT) that leverages eye tracking in a short, "gamified" software environment, against in-office Humphrey Field Analyzer (HFA) data.

Methods: Observational, multicenter, open-label clinical trial in patients diagnosed with glaucoma, glaucoma suspect, or ocular hypertension.

Results: A total of 190 PRX tests were performed with 97 on the left eye and 93 on the right eye, derived from 36 eyes of 19 patients who also had reliable, matched HFA data. Patients were 58% female with a mean (SD) age of 61.5 (11.9) years (range 26–78). Test-retest reliability was good, with interclass correlation coefficient of 0.7596. Detection of abnormal fields was excellent, with a sensitivity of 95.7% and a negative predictive value (NPV) of 98.27%. Detection of normal fields was very good, with a specificity of 79.26% and a positive predictive value (PPV) of 66.36%. Patients reported that compared to HFA, PRX-VFT was easier and more fun to complete.

Conclusion: In-home visual field testing using PRX-VFT on a patient's personal computer met its primary clinical trial endpoints, was feasible, and showed excellent statistical correlation to in-office HFA testing. PRX-VFT represents an opportunity for enhancing patient care at minimal additional equipment cost to the patient or healthcare system.

Plain Language Summary: The Peripherex Visual Field Test (PRX VFT) uses a patient's home computer or laptop with built-in eye tracking and patented algorithms. For this study, the PRX VFT was tested in the real-world, in-home setting, compared to in-office Humphrey visual field tests. The PRX VFT used at home showed excellent statistics against in-office testing, meeting primary endpoints in an IRB-approved multicenter clinical trial for FDA registration. These data support in-home use of the PRX VFT by the eye care provider for screening and monitoring in glaucoma, and may be extended to the screening and monitoring of other retinal, optic nerve and neurological diseases.

Keywords: visual field test, glaucoma, home healthcare, prospective clinical trial

Introduction

Glaucoma, the leading cause of irreversible blindness globally, is a chronic, progressive, and insidious optic nerve disease with characteristic visual field loss.[1] Patients with glaucoma require life-long treatment, which is often altered according to disease progression, and regular follow-up.[2] Initial glaucoma diagnosis depends on evaluation of peripheral vision, where vision loss commonly occurs in the disease. In addition, the disease causes progressive visual field loss, necessitating ongoing testing.[2]

Automated perimetry has become the mainstream assessment of glaucoma progression,[3] even as the search for alternative tests and biomarkers continues.[4,5] For the past several years, several different perimeters and test strategies have been developed, but none have had more studies and has been more used than the standard white-on-white perimetry[6–8] with the Humphrey Field Analyzer (HFA; Carl-Zeiss Meditec, Dublin, CA, USA). However, unlike solutions for home eye pressure

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testing,[9] this approach is limited to clinical office use only, requires technician or office assistant oversight, and in the context of patient access to office-sited care, does not present a viable solution for broad, community-based diagnosis of disease, nor can it be repeated frequently enough to maximize diagnostic assessment of disease progression.

The Peripherex visual field test leverages advanced algorithms and eye-tracking software to facilitate patient visual field loss testing in the office or at home, using any personal computer that has a built-in camera and connectivity to the internet, and does not require additional hardware. The user follows simple instructions built into the software to complete the test, one eye at a time. The test typically takes only a few minutes per eye. This at-home patient use provides an opportunity to quickly advance diagnostic sensitivity in glaucoma. The rationale for this study was to compare the Peripherex software visual field testing over time in a population of patients with varying degrees of glaucoma severity to in-office HFA data. Here we report high internal test-retest repeatability and reliability against Humphrey Visual Field data.

Methods

Study Design

The objective of this prospective, observational, multicenter, open-label feasibility clinical trial was to evaluate Peripherex software used to measure visual field loss over six months, and to correlate the measurements to the gold standard Zeiss Humphrey Field Analyzer (HFA) data. As a secondary measure, rate of occurrence of adverse events and usability by subjects were collected. This study was conducted at two sites in the United States. Institutional Review Board (IRB)/Ethics Committee approval was obtained from Western IRB. Informed consent was obtained from all patients before screening in accordance with the Declaration of Helsinki, and data were collected and monitored in a fashion consistent with the International Conference of Harmonization E6 Good Clinical Practice guidelines, and other applicable local regulations.

Peripherex Visual Field Test

The Peripherex visual field test was offered as a software solution delivered on the Chrome browser (Google, Inc)., agnostic to the participants' laptop or desktop computer screen size or make, although it was not made available on phone or tablet screens. Screen size and pixel density were calculated in the beginning of the first test with each screen used. Distance to the screen was calculated based on cornea/iris size in the built-in webcam used for eye tracking; the data collection was thereby corrected for screen and distance changes between participants and between tests.

The test presents the user with a large blue fixation dot, and uses eye tracking to ensure that the user is not scanning the screen. A smaller white dot of varying brightness (and therefore varying contrast against the background screen brightness) is then presented to the peripheral vision in any direction, up to the maximum distance of the screen being used (Figure 1). The user is instructed to saccade to the white dot as soon as it is recognized; the eye tracking logs appropriate direction and distance to monitor for successful saccades. This process repeats, with movement of the blue fixation dot to accommodate comprehensive testing of the visual field in all directions. The user may use their (reading) glasses during the exam and may cover one eye with a tissue or eye patch while testing the other eye.

Participants

Participants were included if they met the following inclusion criteria: able to understand, sign and complete the informed consent, able to understand the study requirements, and willing to follow study instructions. Subjects had to be over 18 years of age and could have any diagnosis of glaucoma including open-angle or closed-angle glaucoma, or ocular hypertension or glaucoma suspect. Subjects were required to have access to a personal computer with a webcam and internet connectivity, to run the Peripherex software application. Exclusion criteria included presence of any other ocular or central nervous system diseases that, in the opinion of the investigator, would contribute to visual field loss, such as macular degeneration, cataract, corneal opacification, ptosis, or dermatochalasis, or any other ocular or central nervous system diseases that, in the opinion of the investigator, would contribute to eye movement disorders, such as nystagmus, concussion, traumatic brain injury, orbital inflammatory or thyroid eye disease. Per IRB request, subjects could not be pregnant, lactating or planning to become pregnant during the study, or be concurrently participating in any other clinical trial.

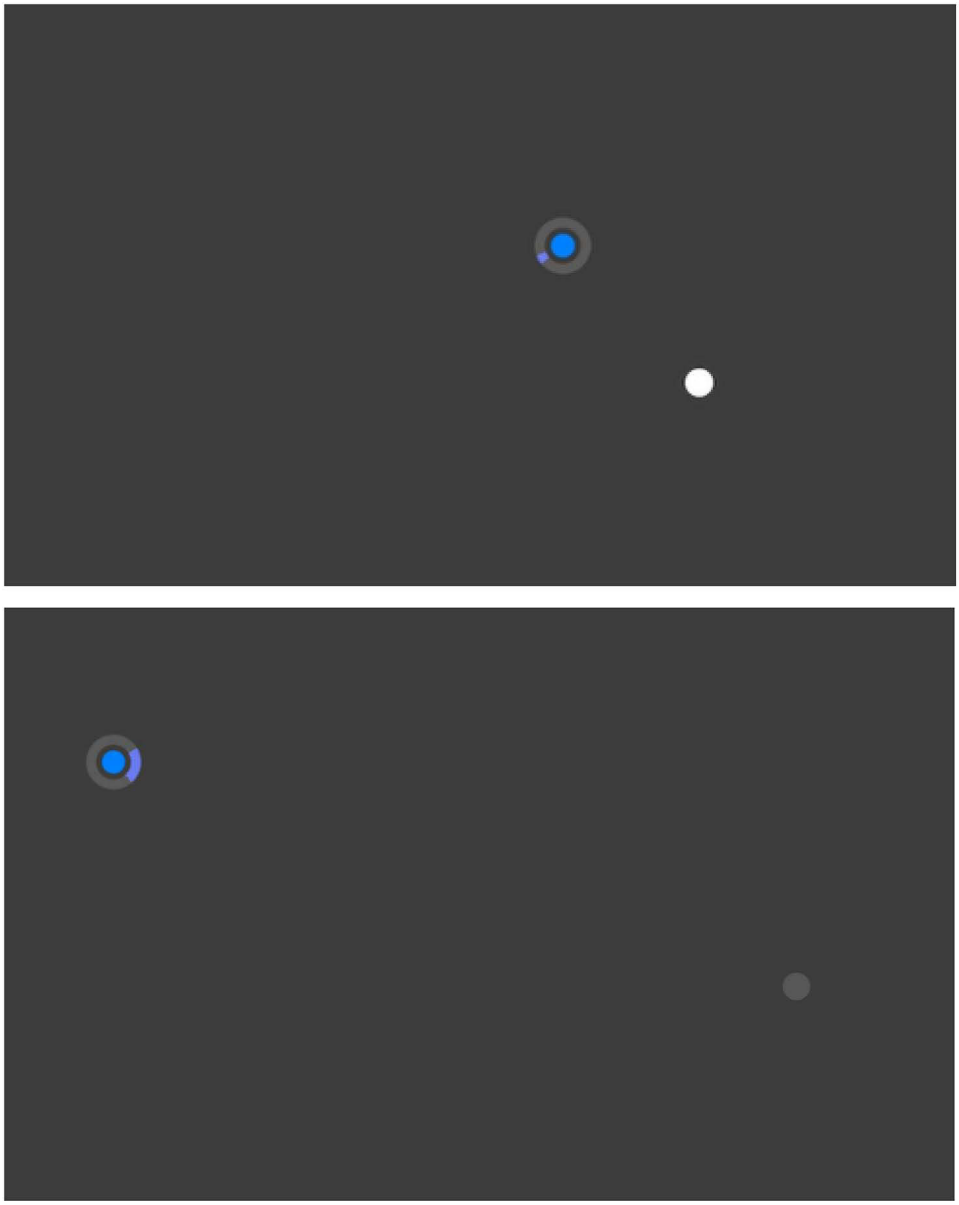

Figure 1 Example Peripherex visual field test screen showing the fixation target (blue) and a test stimulus (white) that is presented with variable brightness and contrast against a static background.

Study Protocol

Study subjects were instructed to use the Peripherex software application with advanced eye tracking to monitor their peripheral vision impairment at least once at study enrollment, and then once per week; however, they were able to run the application more or less than once a week if they chose. Each study subject was prompted by the software when finishing the testing on each eye, to rate on a 5-point scale how easy to difficult the testing process was for them (Very Easy, Easy, Neutral, Difficult, Very Difficult). A text box was available for subjects to fill in any comments regarding the testing process.

In addition, the treating physician investigator uploaded at least one Zeiss HFA 24–2 visual field test(s) performed at the clinic within 6 months of study enrollment.

Statistical Plan

Primary endpoints were pre-defined as PRX VFT test-retest correlation measured with interclass correlation coefficient (ICC), and sensitivity, specificity, and positive and negative predictive values against HFA. Data were analyzed using

JMP® 17.1.0 statistical software from SAS; GLMM models were computed using the lme4 library in R version 4.3.0.[10,11] This study is a one-arm observational proof of concept (POC) clinical trial aimed at assessing the Peripherex Software Application (PRX) in monitoring and measuring peripheral vision impairment compared to visual field measurements obtained from the Humphrey HFA. The study employed a three-factor nested design: coordinates within eye-subject, eye within subject, and subject.

Data quality underwent rigorous evaluation, including the exclusion of certain metrics, correction of missing data, and resolution of inconsistencies, for example if participants did not complete a field. At each point in visual space, HFA sensitivity data were expressed from 0 to 33 (dB; lower numbers abnormal); at the time of this study, PRX sensitivity data were expressed from 66 to 255 (arbitrary units; higher numbers abnormal), although now PRX VFTs have been converted to a 0 to 33 scale similar to Zeiss HFA. To enable point-wise retinal threshold comparison, we reversed the x-axis coordinates for the left eyes. This ensured that all left-eye data are reflected vertically to match the right-eye fields.

The two datasets were merged using matching keys including subject, eye, and x-y coordinates. The matched coordinates are the same for both systems. Groups for analysis, including test order were created and the data were transposed to facilitate pairwise comparison analysis. When HFA data contained additional coordinates compared to PRX data (eg due to differences in computer screen size), these were excluded from statistical analysis.

The pre-specified primary study endpoint was the correlation of visual field measurements between the Peripherex software application and the Zeiss HFA visual field test(s). Basic demographics as well as adverse events in this non-significant risk trial were tabulated, and descriptive statistics were computed.

Point estimates for performance measures as well as the ICC were computed using a mixed-effects model. Having collected measurements within clusters (eg, patients, eyes, and coordinates) the study design had correlated observations. These correlations invalidated the independence assumption in commonly used univariate and multivariate statistical techniques such as *t*-tests and multiple linear regression. Therefore, we used Generalized Linear Mixed Models (GLMMs), a flexible class of models that account for correlated observations and thus are a commonly used method for cluster data analysis. This class of model does not require the normality assumption.

Results

A total of 190 Peripherex visual field tests (PRX VFTs) were performed with 97 on the left eye and 93 on the right eye, derived from 36 eyes of 19 patients who also had reliable, matched Zeiss HFA data. Patients were 58% female with a mean (SD) age of 61.5 (11.9) years (range 26–78). Initial qualitative comparison between visual fields suggested high correlation (Figure 2) that was then examined further statistically.

To evaluate the reliability (stability) of the PRX VFT light sensitivity across repeated tests (test-retest reliability), interclass correlation coefficient (ICC) was used. Using a cutoff above 110 (abnormal) on PRX light sensitivity, the ICC was 0.7596 (good test-retest reliability[12]).

To evaluate association between HFA and the Peripherex Software Application, estimated adjusted performance measures were obtained using a Generalized Linear Mixed Model (GLMM), wherein adjustments for age and gender were incorporated as fixed effects, and subject, eye, and coordinates were considered as random effects. The estimates, along with their corresponding 95% confidence intervals, are provided in Table 1.

Detection of abnormal fields was excellent. For example, sensitivity (true positive rate) showed 95.7% of the HFA-Light Sensitivity values less than 24 were correctly classified as abnormal when PRX-Avg-Light-Sensitivity was greater than 100. Using those same cutoffs, negative predictive value (NPV) showed 98.27% of the PRX-Avg-Light-Sensitivity values greater than 100 were correctly classified as abnormal when HFA-Light Sensitivity was less than 24 (abnormal). We acknowledge that the cutoff of 24 was determined empirically by the GLMM. In the Humphrey test, "abnormal" varies in Zeiss's proprietary labeling algorithm according to field location and patient age; a more nuanced deconstruction of this comparative analysis could be undertaken as a future direction.

Detection of normal fields was very good. For example, specificity (true negative rate) showed 79.26% of the normal HFA-Light Sensitivity values greater than 28 were correctly classified as normal when PRX-Avg-Light-Sensitivity was less than 110 (normal). Using those same cutoffs, positive predictive value (PPV) showed 66.36% of the PRX-Avg-Light-Sensitivity values less than 110 were correctly classified as normal when HFA-Light Sensitivity is greater than 28 (normal).

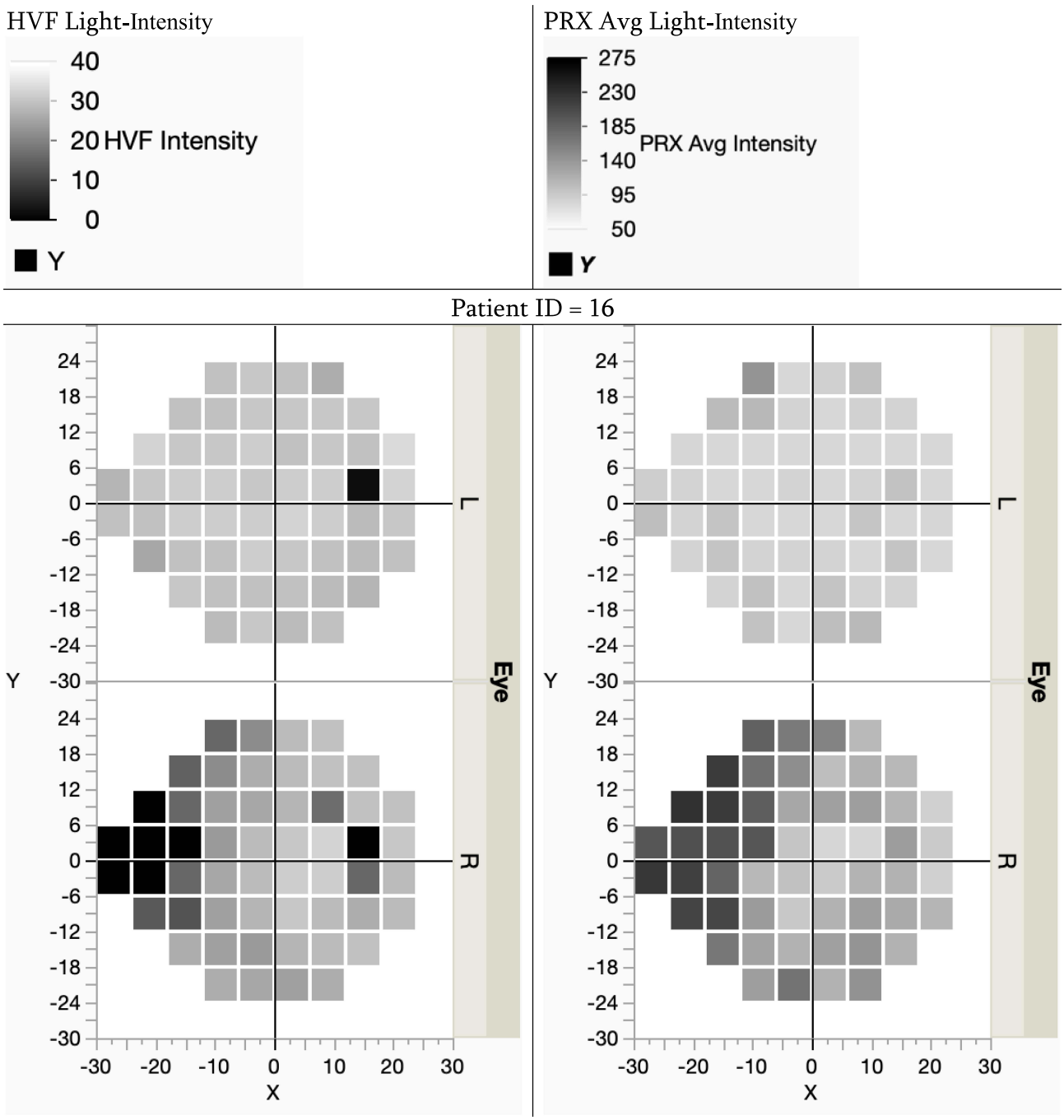

Figure 2 Example in-office Humphrey Field Analyzer visual field (HVF, left column) versus at-home Peripherex (PRX) visual field test in a patient's fairly normal left eye (L, upper diagram; note x-axis inversion to simplify statistics) and more affected right (R, lower diagram) eye.

There were no adverse events recorded for any subject in the study.

Qualitative feedback was also collected and tabulated. Broadly, participants reported that the testing itself was "fun"; "getting the blue dot on the white dot was rewarding"; "it's like being at a carnival". All participants reported using one hand to cover the eye not being tested. Audio instructions were appreciated; many patients reported responding to the audio prompts aloud (although the software is not listening for any audio).

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Table 1 Performance: Sensitivity, Specificity, PPV, and NPV by HFA-Sensitivity and PRX-Avg-Sensitivity - Estimate and 95% Confidence Interval Estimated Using GLMM

Measure	Value	95% Confidence Interval
Sensitivity	0.957	[0.945, 0.967]
NPV	0.983	[0.978, 0.987]
Specificity	0.793	[0.781, 0.804]
PPV	0.664	[0.647, 0.680]

Abbreviations: NPV, negative predictive value, and sensitivity calculated using <24 (HFA) and >100 (PRX-VFT); PPV, positive predictive value, and specificity calculated using >28 (HFA) and <110 (PRX-VFT) as thresholds.

Discussion

These data represent "real-world" home-based visual field testing using a novel, eye-tracking-enabled, internet-based exam. The Peripherex VFT trial met its primary endpoints with high test-retest reliability, and using sensitivity values, excellent detection of abnormal points on the visual field (sensitivity and negative predictive value), and very good detection of normal points on the visual field (specificity and positive predictive value). We hypothesize that the slight degradation of PRX VFT-to-HFA correlation in the detection of normal points may arise from PRX's increased sensitivity to identifying abnormal points compared to the HFA. HFA data were used as the base for PRX comparison, but it is well described that HFA data themselves suffer from issues in test-retest reliability and base validity questions.[13–15] The maximum window of 6 months between HFA and Peripherex VFT may also insert some decorrelation if a subset of participants' glaucoma progressed in this time, although this would be expected to be a small subset of patients in a general glaucoma clinic.[16] Also, setting a threshold of normal vs abnormal on individual points in glaucoma patients remains a challenge, with HFA, SWAP, and other algorithms generally disagreeing on a firm threshold for "abnormal".[17,18] Here, we used below 24 on HFA as clearly abnormal and above 28 as more likely in the normal range consistent with prior studies, and do not address the inclusive area between these two values. Ultimately, with all visual field testing on any device, raw data is delivered to clinicians who interpret in the context of complete examinations for detection of disease or progression.

Enhancing screening and assessment of visual function in glaucoma patients was recently identified as the number 1 unmet need, in a joint statement of the American Glaucoma Society and the American Society of Cataract and Refractive Surgery.[19] Home visual field testing stands to greatly enhance patient care when monitoring glaucoma patients or glaucoma suspects for progression. For example, modeling the increased frequency of testing enabled by at-home devices demonstrates that progression normally detected in-office in 2–3 years can be detected with increased testing frequency in 6–12 months.[20]

Visual field testing in the home may be provided by virtual reality (VR) headset goggle-based systems[21–23] or by computer or tablet-based testing,[24–29] of which some use eye-tracking to assist with reliability. These PRX VFT data compare favorably to other computer-, tablet-, or VR goggle-based visual field tests. For example, in one computer-based test using additional peripheral equipment for eye tracking performed in the research setting in Denmark and compared to Octopus Perimetry, using up to 150 test points achieved a sensitivity of 100% and specificity of 78%, although subsequent testing in real-world office settings showed worse reliability for screening.[30] The Melbourne Field Test (MFT) implemented on Apple iPads compared to Zeiss HFA 24–2 testing detected 39 of 54 abnormal hemifields and showed sensitivity on global indices (mean deviation, visual field index and pattern standard deviation) ranging from 0.77 to 0.85.[31] The authors of that paper characterized the overall performance as "good" and called specifically for improved fixation monitoring. Another online VFT, Peristat was compared against HFA 24–2 SITA standard testing and found that abnormal points showed Spearman rank correlations ranging from 0.55 to 0.77.[32] Limitations in all of these studies include comparison against a single adjacent Zeiss HFA test, which as noted above suffers from its own modest

test-retest reliability, but taken together, these data suggest that PRX's use of eye-tracking enhances its algorithm and provides improved testing reliability indices.

Demonstrating strong data in the real-world, home-use setting also supports the premise of greatly increasing patient access to high-quality care. Selling every patient a visual field testing device, whether VR goggle-based or otherwise, raises a barrier to accessing this care pathway that a software-based app like the PRX VFT overcomes. As a majority of patients are likely to have a computer with a webcam in the home environment already, this can greatly increase access to care, efficiency, and convenience, improving patient outcomes and eye care provider effectiveness. The same software solution can be set up in the office or in centralized community spaces, such as libraries or drugstores, for screening or monitoring of glaucoma. The PRX VFT should also be immediately applicable to visual field screening and monitoring in other diseases in eye and vision care including other optic neuropathies, macular conditions such as age-related macular degeneration and chloroquine screening, and neurological conditions including stroke, as examples.

The current work raises important questions to be addressed in future studies, including assessment with larger sample sizes, differential performance across stages of glaucoma severity (the current study was not powered for such an analysis), and longitudinal studies to assess for detection of progression in cohorts of active patients. Algorithm improvements are also expected when increasing dataset size and implementing artificial intelligence/machine learning tools, especially when inclusion of advanced eye tracking parameters can be used to enhance detection of disease or progression.

Taken together, these data support a firm threshold on the PRX VFT that clinicians can use with high confidence to diagnose abnormal points in the patient's visual field (based on high sensitivity and NPVs) and good confidence to diagnose normal points (based on specificity and PPV); retesting either population with higher frequency will allow the clinician greater confidence in assessing visual function as part of their comprehensive exam.

Disclosure

Dr Mitch Ibach reports personal fees from Zeiss and Glaukos, outside the submitted work. Dr John Berdahl reports personal fees from AbbVie, Aerpio, ALJ Health, Alcon, Aldeyra, Aquea Health, Aurion Biotech, Avelino, Balance Opthalmics, Bausch & Lomb, Belkin, CorneaGen, Dakota Lions Eye Bank, Elios Vision Inc, Expert Opinion, Glaukos, Gore, Greenman, Horizon Surgical, Iacta Pharmaceuticals, Imprimis, iRenix, IVERIC Bio, Inc, J&J, Kala, LayerBio, MELT Pharmaceuticals, MicroOptx, New World Medical, Ocular Surgical Data, Ocular Therapeutix, Omega Opthalmic, Orasis, Oyster Point, RXSight, Santen, Sight Sciences, Surface Inc, Tarsus, TavoBio, Tear Clear, Tissue Gen, True North CRO, Vance Thompson Vision, Verana Health, Versea Biologics, Vertex Ventures, and ViaLase, outside the submitted work. Mr Yitzi Kempinski reports personal fees from Peripherex, Inc, outside the submitted work; In addition, Mr Yitzi Kempinski has a patent EP4504031A1 pending to Peripherex Inc, patents US9746918B2, US10254831B2 and US9911037B2 issued to Umoove Services Ltd. Dr Jeffrey Goldberg reports a patent 16/087,327 licensed to Peripherex, a patent 63/327,388 pending to Peripherex, and shares in Peripherex. The authors report no other conflicts of interest in this work.

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