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Validation of a Head Mounted Virtual Reality Visual Field Screening Device

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Précis

The CFA is a moderately reliable perimeter preferred by patients to standard perimetry. While it does not approximate the gold standard, it was sensitive and specific for clinically defined glaucoma (aROC = 0.77-0.86).

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Abstract

Purpose: Testing the visual field is a vital sign for diagnosing and managing glaucoma. The current gold standard, the Humphrey visual field analyzer (HFA), is large, expensive and can be uncomfortable for some patients. The current study investigated the C3 fields analyzer (CFA), a virtual reality head mounted visual field testing device, as a possible subjective field test for glaucoma screening and eventually glaucoma monitoring.

Patients and Methods: The CFA presented stimuli in the same 54 positions as the HFA 24-2 SITA Standard test using a suprathreshold algorithm approximating an 18dB deficit. 157 patients (both controls and glaucoma patients) at the Aravind Eye Hospital, Pondicherry, India, were tested with both devices.

Results: The number of stimuli missed on the CFA correlated with HFA mean deviation ($r = 0.62$, $P < 0.001$), and with pattern standard deviation ($r = 0.36$, $P < 0.001$). The area under the receiving operator characteristic curve (AROC) was 0.77 ± 0.06 for mild glaucoma (HFA mean deviation $\geq$ -6 dB) and 0.86 ± 0.04 for moderate-advanced glaucoma (HFA mean deviation < -6 dB). Patients with an 18 dB or worse deficit at a point in the visual field on the HFA failed to see the CFA stimulus at the same position 38% of the time.

Conclusions: While the CFA did not reliably identify deficits that matched the HFA, it was moderately effective at identifying glaucoma subjects. Further refinements to the device will be required to improve point-by-point testing performance and screening performance.

Keywords: visual fields, perimetry, virtual reality, suprathreshold

Introduction

Glaucoma is the leading cause of irreversible blindness in the world, and the vast majority of cases are undetected in lower and middle income countries[1], where the undiagnosed rate often exceeds 70%[2–4]. The current gold standard for measuring the visual field is the Humphrey visual field analyzer (HFA, Carl Zeiss Meditec Inc, California, USA). Due to its size and expense, the HFA cannot be used in some resource and space limited settings. The 24-2 SITA algorithm is the most common HFA protocol, but it can be time consuming and difficult to understand or complete comfortably[5,6]. These constraints limit the use of visual field testing to detect glaucoma and in many settings visual fields are used inadequately to monitor glaucoma[7]. While some have developed portable visual field screening devices, most of these still require patients to assume a similar testing position as the HFA[8–10], which can be challenging for older, disabled or immobile patients.

Virtual reality (VR) has recently begun to be investigated as a modality for visual field testing[10,11]. Head mounted VR visual field screening devices have the potential to be affordable, user friendly and portable, widening the population that can be screened and increasing the frequency at which visual fields can be tested to monitor for worsening of glaucoma. However, specificity and sensitivity studies have been mixed[6,10,11]. To date, no VR visual field device has been tested in Asia or Africa, where the burden of glaucoma is the greatest[1,4], and where there is the most need for portable screening.

In the current study, the C3 fields visual field analyzer (CFA) was tested at a suprathreshold level and compared to the HFA 24-2 SITA procedure. Reliability, positive predictive value (PPV), approximation of the HFA and ability to identify glaucoma were

analyzed using a population of glaucoma patients and healthy controls at the Aravind Eye Hospital located in Pondicherry, India.

Patients and Methods

Subjects

The CFA was tested at the Pondicherry branch of the Aravind Eye Care system (Pondicherry, India). The study was approved by the Johns Hopkins Institutional Review Board & the Aravind Eye Hospital Institutional Review Board. Research adhered to the Declaration of Helsinki concerning research on human subjects and the Health Insurance Portability and Accountability Act (HIPAA).

We recruited 98 glaucoma and 101 control patients from patients and accompanying family members attending the Aravind glaucoma clinic. To qualify, patients had to have a presenting visual acuity equal to or better than 20/40, give written informed consent for the study, and take a reliable (see below) HFA 24-2 test. Control subjects could have no visible retinal disease or glaucoma, while glaucoma subjects were patients with a previous diagnosis of glaucoma. Initial classification of glaucoma and control patients was made based on clinical judgment of the diagnosing physician. Subsequently, two physicians masked to the previous classification viewed optical coherence tomography (OCT), fundus photos, and HFA printouts to make a final classification as glaucoma or not glaucoma. 42 patients were excluded who had undergone full testing owing to an ambiguous diagnosis.

Demographic information on age, gender, education level and visual acuity with presenting glasses (PVA) were collected. Education level was graded on a 0-4 scale (0 =

illiterate, 1 = primary school, 2 = secondary school, 3 = undergraduate degree, 4 = postgraduate degree).

Exams

Optical coherence tomography: A 200 x 200 cube Optic Disc Scan was taken for both eyes using the Cirrus HD-OCT (Zeiss, Oberkochen, Germany). The scan analyzed the average retinal nerve fiber layer (RNFL) thickness and RNFL thickness for the superior, inferior, temporal and nasal quadrants. RNFL defects were identified by the machine's built-in algorithm which compares thickness of the RNFL findings to those of a normative database.

Humphrey perimetry: Visual fields were measured with the Humphrey field analyzer II (Zeiss, Oberkochen, Germany), using the 24-2 SITA standard algorithm, which has been described elsewhere[5]. Eyes were measured one at a time with the fellow eye covered with a patch. HFA tests were deemed unreliable if the false positive (FP) or false negative (FN) rate was > 33%. Subjects with an unreliable HFA were given a 10-minute break and then took the HFA again. If it was still not reliable, the subject was excluded from the study. Because fixation loss (FL) cutoffs have been relaxed[12] in the past and their validity has been questioned[13], they were not used as a reliability indicator.

CFA testing: The CFA is a head-mounted virtual reality perimeter. It measures 30 degrees of the visual field. Background brightness was set at 4 cd/m^2 and stimuli brightness was set at 60 cd/m^2, using an HTC Instrument LX- 101A Light Meter Luxmeter (HTC, Taoyuan City, Taiwan) approximating an 18dB contrast on the HFA scale. This contrast level was selected based on pilot data showing that 18dB roughly captured most glaucoma visual field defects. 0.55 mm circular stimuli were placed in a 24-2 pattern identical to what is used in the 24-2 SITA

algorithm. Patients were shown an instructional video modeled after the HFA instructional video. Patients were instructed to focus on a central yellow fixation point and responded using a handheld clicker when a stimulus was shown. They were shown a short demo test to ensure understanding, and then the blind spot was found. The patient then underwent a suprathreshold test. Each point was shown twice. FL (tested 10 times) was recorded when the participant responded to a stimulus presented in the blind spot. FP (tested 10 times) was measured as a response during a trial in which no stimulus was presented during the usual trial time (200 ms for typical stimulus presentation time followed by 1300 ms of waiting time until the next stimulus). Each stimulus position was presented twice during a test. FN (tested 54 times) was recorded when one response was positive, while the other was negative at the same stimulus point. This device has not yet been approved by the FDA for the measurement of visual field. A picture of the device in use can be seen in Figure 2.

- *Intraocular pressure* (IOP): IOP was measured in both eyes with the Goldmann Applanation Tonometer (Haag-Streit, Köniz, Switzerland).

- *Slit-lamp exam*: Slit lamp exams were taken using an SL-2G (Topcon, Tokyo, Japan) lamp or a Haag-Streit, by trained physicians. Abnormal findings and the vertical cup to disc ratio (CDR) were recorded.

- *Fundus photo*: Fundus photos of both dilated eyes were taken using Fundus on Phone (Remidio Innovative Solutions Pvt. Ltd, Bengaluru, India). Photos were taken again if they were poor quality.

- *Satisfaction Survey*: Patients were asked to rate the CFA and HFA on ease of use and comfort. They also chose their preferred device and whether they would use the CFA in the

home (See Fig. 1 for full survey). Literate patients were given both English and local language (Tamil) translation of the patient satisfaction survey. Researchers read Tamil translated satisfaction surveys to illiterate subjects.

Experimental procedure

Once patients were enrolled in the study, they were randomly assigned to take the HFA or the CFA first using a random number generator. Patients were given a break of at least 10 minutes between the HFA and CFA. Following perimetry, anterior segment examination and IOP testing were performed. Pupils were then dilated for OCT and fundus photography. The satisfaction survey was administered after the conclusion of both the HFA and CFA.

Statistical analysis

Sample size was determined before the study based on a power calculation to be able to detect sensitivity and specificity within a 95% confidence interval of 76.5%-91.4% assuming the test had 85% sensitivity and specificity. This resulted in a sample of 100 glaucoma subjects and 100 control subjects. All statistics were run using Stata 15.1 (StataCorp, Texas, USA). Education level was compared for glaucoma and control patients with a Wilcoxon rank sum test. Gender was compared with a chi-squared test. Age and visual acuity differences were determined with t-tests. The 0.05 α level for t-tests in Table 2 was adjusted according to the Bonferroni correction (p/# comparisons) to 0.004. Identical miss rate in Fig. 4 was found for each stimulus point with $\frac{P_b}{P_b+P_h}$ where P_b = sum of patients that showed ≤ 18 dB deficit on the HFA and did not respond to a stimulus at the same point on the CFA, and P_h = sum of patients that showed ≤ 18 dB deficit on HFA but successfully responded to stimulus at the same point on the CFA. Satisfaction survey results for ease of use and comfort were converted to a 1-5 scale, with 1 representing very

difficult/very uncomfortable and 5 representing very easy/very comfortable. Reported ease of use and comfort of the CFA and HFA were compared using a Wilcoxon rank sum test. Data is reported as mean ± SD.

Results

227 patients were enrolled in the study. 28 subjects had either unreliable HFA results, could not complete the study or did not meet other inclusion criteria on review and were excluded. The remaining 199 underwent full testing. 157 had definitive diagnoses as either case (n = 62) or controls (n = 95) and were included in the analysis. Glaucoma subjects were significantly older than controls (mean 54.2 versus mean 49.8, $p < 0.01$), and less educated ($p < 0.03$) but similarly distributed in gender ($p = 0.96$), and PVA ($p = 0.06$; Table 1). The CFA took an average of 3:29 (minutes:seconds) to complete (± 0.001).

Fixation losses and false negatives were more common with the CFA device and false positives were more common using the HFA. When comparing control and glaucoma patients, the only difference found was a higher FN rate in control patients when using the CFA (7.2% versus 4.4%, $p < 0.0001$; Table 2). When comparing CFA and HFA performance for control patients, FL rate was higher using the CFA (6.7% versus 0.1%, $p < 0.0001$; Table 2) while FP rate was higher when using the HFA (3.3% versus 1.5%, $p < 0.001$; Table 2). When comparing CFA and HFA performance for glaucoma patients, both FL (7.6% versus 0.1%, $p <0.0007$; Table 2) and FN rates (16.1% versus 6.1%, $p < 0.0001$; Table 2) were higher on the CFA.

The average proportion of instances where a subject showed ≤ 18 dB deficit on the HFA and failed to respond at that point on the CFA was 0.38 ± 0.23 and ranged from 0 to 0.9 (Figure 4).

The number of missed CFA stimuli correlated significantly with MD ($r = 0.62$, $p < 0.001$) and less strongly with PSD ($r = 0.36$, $p < 0.001$), Figure 5. After dividing glaucoma patients into early-moderate and advanced glaucoma based on the Hoddap-Parrish-Anderson criteria[14], the area under the receiving operator characteristic curve (aROC) was higher for severe glaucoma (0.87 ± 0.04; Fig. 6B) than early-moderate glaucoma (0.78 ± 0.05 SD; Figs. 6A and 6B).

In a forced choice 93% of the patients preferred the CFA to the HFA. Patients found the CFA easier to use ($p < 0.001$) and more comfortable ($P < 0.001$) than the HFA. 60% stated they would use the CFA at home if it were available.

Discussion

This prototype CFA device using suprathreshold testing was able to be used successfully in an Indian population with moderate performance in terms of sensitivity and specificity when compared with a "gold standard" clinical diagnosis based on OCT, fundus photography and HFA testing results. The CFA was better at identifying moderate/advanced glaucoma than mild disease. The CFA testing time was short, averaging under 3 ½ minutes. CFA testing was mostly reliable based on FL, FN and FP rate.

On average, just 38% of ≤ 18 dB deficits seen on the HFA were picked up by the CFA. The inferior visual field was the least concordant. The number of points missed on the CFA correlated reasonably well with MD, but less strongly with PSD, a pattern which has been observed in one other portable perimeter[8]. There are several possible reasons for this poor match up. Calibration could have been suboptimal, as a high-end photometer wasn't available and a lux meter was used instead. However, after comparing different HFA dB cutoff levels instead of 18 to CFA missed stimuli, point by point concordance did not improve (data not shown). Testing

the visual field on a flat screen could have introduced distortion and will need to be corrected for in future iterations of the device. It is possible that device alignment could have shifted during testing, though the low fixation loss rate makes this less likely.

Despite its inexact approximation of the HFA, the CFA was still able to identify glaucoma patients, as shown by the aROC, which was comparable to other portable perimeters[8,15]. The CFA appears to be a poor approximator of HFA results, but nonetheless could be used as a screening tool for glaucoma. Future work should focus on hardware and software improvements to better approximate the gold standard. The current iteration of the device could be used as a screening device, but the gold standard should still be used whenever possible for diagnosis and management.

Frequency doubling technology is another portable virtual reality based perimetry technology currently being investigated, which utilizes flicker illusions, which is hypothesized to stimulate cells most vulnerable to insult in the context of glaucoma[16]. Many of these perimeters test both eyes simultaneously, which could impair detection of single eye deficits and make testing of patients with diplopia less accurate. FDT perimeters have also been limited to 20 degrees of vision, and test fewer points compared to the CFA[15].

Patient experience with the CFA was very positive, and 93% of patients preferred the CFA over the HFA. The CFA could be used in the future for elderly, bedbound, disabled or critically ill patients that find the HFA particularly difficult to use, and for the general population to improve patient experience. The CFA will retail for $6000 USD, making it an affordable option for small clinics. It also has the potential to be used at home which could increase the frequency of visual field testing, allowing for more rapid diagnosis of worsening disease.

The current study has significant limitations. First, only the 18 dB threshold was tested, and the stimulus was uniform throughout the visual field. The use of a bright stimulus limited the ability to detect early glaucoma, and this was reflected in figure 6, as the CFA was much more sensitive detecting moderate-severe glaucoma. Further research is needed to assess the usefulness of other dB levels for suprathreshold screening by individual location. In a more mature device, the stimulus intensity should be adjusted due to the heterogeneous nature of retinal sensitivity across the visual field and changes with aging. These alterations could be informed by the development of a full threshold algorithm and the creation of a normative database for the device. Second, the diagnosis of glaucoma was based on clinical impression and available testing data which may have varied by clinician. Non-differential misclassification due to misdiagnosis would be expected to reduce the performance of the device, so our estimates may underestimate diagnostic accuracy. Third, we only included patients with reliable HFA testing. This likely overestimates the reliability of the CFA test in other populations as all included patients were good HFA test takers. Finally, we did not repeat all abnormal fields and some HFA abnormalities may not have been confirmed on repeat testing.

In summary, the CFA was able to test patients with glaucoma and normal controls and was preferred over the HFA. Abnormal points did not line up between the two tests on most occasions, but those with abnormal points on the CFA were likely to have glaucoma. Further refinement is needed, but the CFA holds the promise of simplifying screening with visual fields and will allow for remote testing at many locations or even in the home.

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Figure 1. Patient satisfaction survey
English and Tamil translation of six questions grading their satisfaction with the CFA and HFA
Figure 2. C3 Fields Analyzer (CFA) The CFA device is pictured above during a trial
Figure 3. Representative C3 Fields Analyzer (CFA) and Humphrey Field Analyzer (HFA) outputs for control (A) subjects and glaucoma (B) subjects
Table 1. Age, gender and education are presented for control (left column) and glaucoma (right column) subjects
Table 2. Average fixation loss (FL), false negative (FN) and false positive (FP) rates are shown for control (left) and glaucoma (right) subjects. CFA= C3 Fields Analyzer, HFA = Humphrey Field Analyzer. Same colored pairs of asterisks indicate a significant difference between the two. Black asterisks $p < 0.0007$, colored asterisks $p < 0.0001$. Data are presented as mean % ± SD
Figure 4. Point by point agreement between HFA and CFA
Each box represents the proportion of patients that showed ≤ 18 dB deficit on the Humphrey Field Analyzer (HFA) at a stimulus position and failed to respond to that stimulus point on the C3 Fields Analyzer (CFA). The color scale ranges from dark orange (0) to dark green (1). Overall averages and standard deviations are presented at the bottom of each panel
Figure 5. Linear regression for the number of points missed on the C3 Field Analyzer (CFA) and Humphrey Field Analyzer (HFA) mean deviation (A) and pattern standard deviation (B)
Figure 6. Receiver operating characteristic curves for C3 Field Analyzer (CFA) for early-moderate glaucoma (panel A) and severe glaucoma (panel B) The area under the receiving operating characteristic curve (AROC) was 0.78 ± 0.05 for early-moderate and 0.87 ± 0.04 for severe glaucoma

Subject Descriptive Statistics			
	Control (n = 95)	**Glaucoma (n = 62)**	***P value***
Age in years (mean, SD)	49.8 ± 9.2	54.2 ± 9.3	*< 0.01
Gender (% male)	54	53	0.96
Education (count)			*<0.03
Illiterate	1	4	
Primary school	26	19	
Secondary school	26	22	
Undergraduate degree	28	12	
Postgraduate degree	14	4	
Presenting visual acuity (logMAR: mean, SD)	0.14 ± 0.2	0.19 ± 0.2	0.06

Reliability Indices for the CFA and HFA				
	Control (n = 95)		**Glaucoma (n = 62)**	
Average	**CFA**	**HFA**	**CFA**	**HFA**
FL (%)	6.74±12*	0.09±0.2*	7.58±17*	0.08±0.2*
FN (%)	7.17±7.5*	4.43±6.8	16.1±10**	6.11±6.0*
FP (%)	1.47±4.1*	3.31±3.7*	2.58±6.3	2.73±3.2

Satisfaction Survey

a. How easy was it to understand the test and use the HFA?

HFA பரிசோதனை புரிந்துகொள்வதற்கும், பயன்படுத்துவதற்கும் எந்த அளவிற்கு எளிதாக உள்ளது?

☐ Very easy ☐ மிக எளிதாக

☐ Easy ☐ எளிதாக

☐ Medium ☐ நடுநிலை

☐ Difficult ☐ கடினமாக

☐ Very difficult ☐ மிக கடினமாக

b. How easy was it to understand the test and use the CFA?

CFA பரிசோதனை புரிந்துகொள்வதற்கும், பயன்படுத்துவதற்கும் எந்த அளவிற்கு எளிதாக உள்ளது?

☐ Very easy ☐ மிக எளிதாக

☐ Easy ☐ எளிதாக

☐ Medium ☐ நடுநிலை

☐ Difficult ☐ கடினமாக

☐ Very difficult ☐ மிக கடினமாக

d. How comfortable was the HFA?

HFA கருவி மூலம் பக்க பார்வை பரிசோதனை மேற்கொள்வது உங்களுக்கு எவ்வளவு வசதியாக இருக்கிறது?

☐ Very comfortable ☐ மிகவும் வசதியாக

☐ Comfortable ☐ வசதியாக

☐ Medium ☐ நடுநிலை

☐ Uncomfortable ☐ அசௌகரியமாக

☐ Very uncomfortable ☐ மிக அசௌகரியமாக

e. How comfortable was the CFA?

CFA கருவி மூலம் பக்க பார்வை பரிசோதனை மேற்கொள்வது உங்களுக்கு எவ்வளவு வசதியாக இருக்கிறது?

☐ Very comfortable ☐ மிகவும் வசதியாக

☐ Comfortable ☐ வசதியாக

☐ Medium ☐ நடுநிலை

☐ Uncomfortable ☐ அசௌகரியமாக

☐ Very uncomfortable ☐ மிக அசௌகரியமாக

g. Which visual fields analyzer would you rather use in follow-up appointments?

நீங்கள் மறுபரிசோதனைக்கு வரும்பொழுது எந்த வகையான பரிசோதனையை பயண்படுத்த விரும்புவீர்கள்?

☐ HFA ☐ எச் எப் ஏ

☐ CFA ☐ சி எப் ஏ

☐ Neither ☐ இவ்விரண்டும் இல்லை

Why? _____

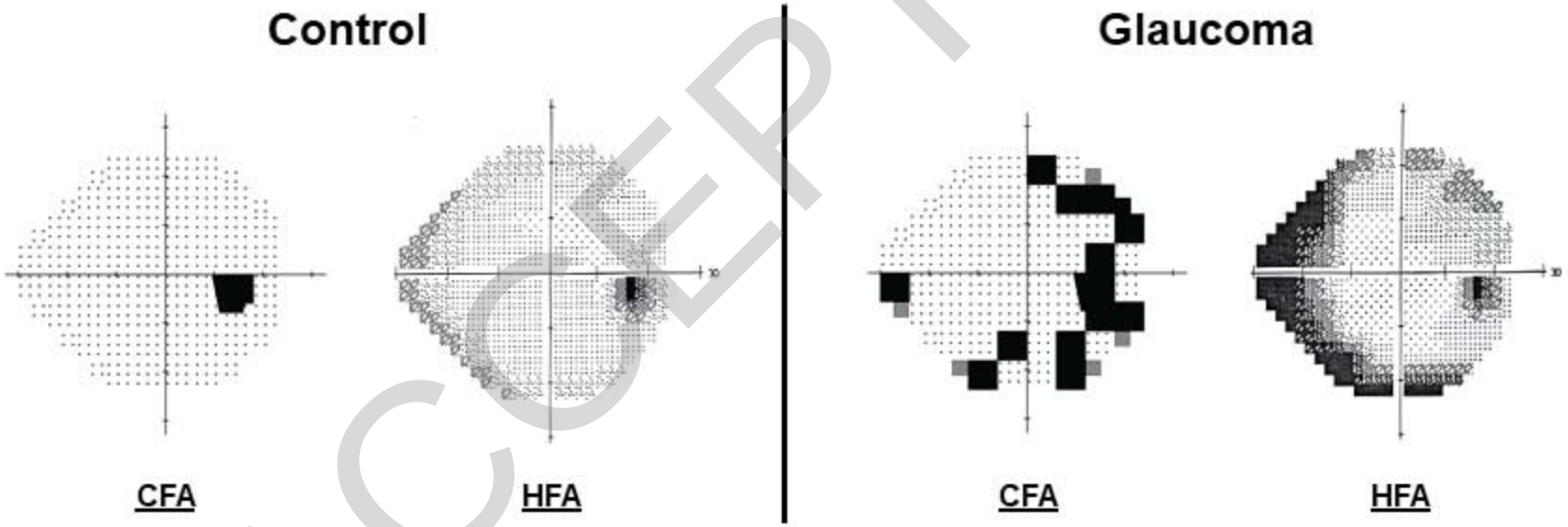
ஏதனால்? _____

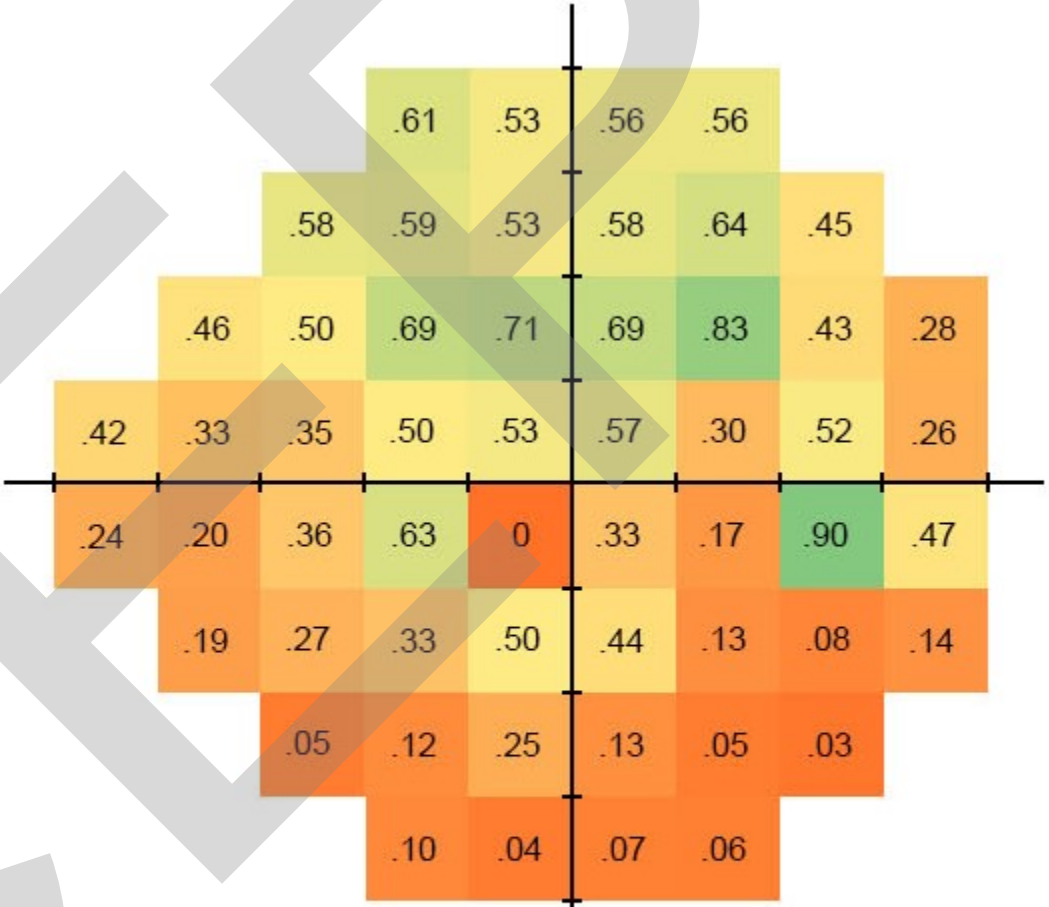
h. If the CFA was available for home use, would you use it?

CFA கருவி கொண்டு வீட்டிலேயே பரிசோதனை மேற்கொள்ளும் வசதி இருந்தால் நீங்கள் அதை பயன்படுத்தி பரிசோதனை செய்துகொள்வீர்களா?

☐ Yes ☐ ஆம்

☐ No ☐ இல்லை





Average: 0.38

SD: 0.23