PalmScan VF2000 vs. HFA Study Highlights

A cross-sectional, observational study comparing accuracy of diagnosis and severity of the disease in patients with glaucoma between PalmScan VF2000 virtual reality (VR) Field analyzer and Humphrey Field Analyzer.

Results:

PalmScan VF2000 vs. HFA	Sensitivity	Specificity
Non-Glaucomatous vs. Glaucomatous	100%	100%
Moderate and Severe Glaucoma vs. Mild		
Glaucoma	97.40%	97.10%
Severe Glaucoma vs. Mild and Moderate		
Glaucoma	90.60%	97.20%

		95% Confidence	
Parameter	ICC	interval	Reliability
Mean Deviation	0.96	0.939129 - 0.9669758	Excellent
Pattern standard deviation	0.94	0.91634 - 0.9546122	Excellent
Visual field indices	0.93	0.9016591 - 0.9466473	Excellent

Conclusion:

PalmScan VF2000 virtual reality (VR) visual field analyzer is an excellent tool for screening glaucomatous and non-glaucomatous patients.

Sensitivity is 97.4% and Specificity is 97.1%, when Mild versus Moderate and Severe glaucoma is assessed.

Sensitivity is 90.6% and Specificity is 97.2%, when Mild and Moderate versus Severe glaucoma is assessed.

Title of study:

A cross-sectional, observational study comparing accuracy of diagnosis and severity of the disease in patients with glaucoma between PalmScan VF2000 virtual reality (VR) visual field analyzer and Humphrey Field Analyser

Introduction:

Examining visual fields is an integral part of a full ophthalmic evaluation. Several methods for assessing visual field loss are available, and the choice of which to use depends on the patient's age, health, visual acuity, ability to concentrate, and socio-economic status. Available techniques can test the full field (including confrontation, tangent screen, Goldmannperimetry and automated perimetry), or assess just the central field of vision, such as the Amsler Grid.^[1]

Abnormalities in the visual field are a sign of damage anywhere in the visual system from the retina through to the brain's visual cortex. Visual field defects are, therefore, not limited to glaucoma. It is very important to examine the retina and optic disc carefully to assess whether or not a visual field defect matches the appearance of the disc and retina, or fits with other clinical signs. One should be very wary of the person with extensive field loss, which seems genuine, where examination of the retina and optic disc are normal. This person may have a neurological condition (e.g. a brain tumour) or they may have had a stroke and not have glaucoma at all.^[1] Research has shown that glaucomatous visual field loss is best detected and is managed with high reliability when automated perimetry is performed. Standard automated perimetry machines are highly technical and use intelligent computer software.^[2,3]



Humphrey field analyser (HFA) is an automated perimeter, which is one of the best known to ophthalmologist and optometrist around the world; it is considered to be accurate, reliable and trusted method to test the visual field defect on patients. However, HFA is not without its disadvantages, and limitations. It is big andbulky; non-portable, requires a dedicated dark room in the office, its timeconsuming and hard for patients with neck problems, elderly, pediatric, or disables to keep their head in a fixed spot so they can have a good fixation.^[4]



PalmScan VF2000 is a portable, battery operated, virtual reality based visual field analyser, developed to be able to measure the patient visual field defect accurately, and reliably. The VF2000 is composed of 3 major sections that are connected to each other wirelessly and there are no wires to deal with when using this system. The 3 major components are:^[4]

- 1. The test goggles that are worn by the patients
- 2. The controller device that is used by the health care provider to set the test parameters and to monitor the progression of the test.

3. The clicker that the patient will use to notify the system that a stimulus has been detected. The entire system can fit inside a small carrying case to make the system extremely portable.

VF2000 has additional features such as no need to occlude the fellow eye, no need for a dedicated dark room, being able to bring the device to those patients who are not able to come to the HFA device for testing such as patients with disability, in hospital patients, nursing home or bed ridden patients, and kids are able to accurately perform the exam.^[5]

The Tele- medicine capability of VF2000 gives the physician's ability to view the patients' visual field test reports and raw data through a secure web portal immediately regardless of where the

patient is located. VF2000 report is generated in PDF format and is easily imported to most EMR system. In addition to numeric map, gray scale map, total deviation, and pattern deviation maps and corresponding grayscale images, VF2000 report also provides Goldman Hemifield Test (GHT). The printout report additionally includes an easy to follow MD progression graph, so the patient's Mean Deviation can easily be followed over time. This unique telemedicine capability will allow high risk patients to remotely monitor any progression of their visual field defect at home, hence ensuring that they are optimally managed. ^[5]

VF2000 is capable of various test strategies such as full threshold, interactive threshold and fast threshold and screening. Currently 10-2, 24-1, 24-2, 30-1 and 30-2 test pattern are available on the commercial version. VF2000 has default parameters that are set to white stimulus and grey background. However, if needed different size and color variation of stimuli and background can be selected by the physician.^[5]

So aim of our study is to compare accuracy of diagnosis and severity of the disease in patients with glaucoma between PalmScan VF2000 virtual reality (VR) visual field analyzer and Humphrey Field Analyzer. As PalmScan VF2000 virtual reality (VR) visual field analyzer is a newer perimeter, its reliability is checked by comparing it with the gold standard Humphrey field Analyser

Materials and Methods:

Study Design : A cross-sectional, observational study with patients undergoing visual field testing with PalmScan VF2000 virtual reality(VR) visual field analyser and Humphrey Field Analyser

Sample size: Total 166 eyes of 98 patients were enrolled of which 86 were glaucomatous and 80 were non glaucomatous according to the Andersons criteria.

Study site: Laxmi Eye Institute, Panvel

Study population: Patients undergoing visual field testing with PalmScan VF2000 virtual reality (VR) visual field analyzer and Humphrey Field Analyser.

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Inclusion criteria:

- 1. Ability to understand and willingly provide informed consent for study participation.
- All patients diagnosed to have Glaucoma (primary open angle, angle closure glaucoma and secondary glaucoma) qualifying ANDERSON'S CRITERIA^[6] between 20-65 yrs of age. ANDERSONS CRITERIA include:
 - Three non edge points depressed to an extent found in less than 5% of the population, one of which is depressed to an extent found in less than 1% of the population
 - In the global indices we see that pattern standard deviation is depressed and has a value expected in less than 5% in the population
 - The Glaucoma Hemifield Test is abnormal
- 3. Normal patients with no ocular diseases between the age of 20-65 yrs were are also included.
- 4. Patients with Spherical correction of 0 to -6 diopters and astigmatism range for study eyes 0 to 1.5 dioptors
- 5. Proper instructions must be given to patients so they can produce high reliability results. Only tests with high reliability will beused in the study. A high reliability test is defined to be one with less that 25% error for False Positive, False Negative and Blind spot errors.

According to Hodapp classification^[7], mild, moderate and severe glaucoma was classified based on Mean deviation.

Mean deviation	Classification
<6	Mild
<12	Moderate
>12	Severe

Exclusion criteria:

- 1. Patients having any preexisting corneal pathology
- 2. Patients with any preexisting macular pathology that is likely to affect the test

3. Any other co-existing ocular co morbidities that are likely to affect the test

Endpoints:

- 1. Diagnosis based on perimeter
- 2. Mean deviation
- 3. Pattern standard deviation
- 4. Visual field index

Data Analysis:

We will calculate the means and standard deviation for continuous variables and proportions for categorical variables. The means will be compared using t- tests and proportions will be measured using chi-square tests or Fischer's exact. We also propose to use regression methods to adjust for confounders

To test the interrator reliability Kappa statistic will be used. Sensitivity and Specificity will be derived. For the three global indices: Mean deviation, pattern standard deviation and visual field indices, Bland-Altman Plot will be constructed and Intraclass Correlation Coefficient (ICC) which is a measure of the reliability will be used.

Results:

Total 166 eyes of 98 patients were enrolled of which 86 were glaucomatous and 80 were non glaucomatous according to the Andersons criteria.

Kappa^[8] statistic can be interpretated as follows:

Values	Agreement
≤ 0	No agreement
0.01–0.20	None to slight agreement
0.21–0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61–0.80	Substantial agreement
0.81–1.00	Almost perfect agreement

According to our study:

Kappa (95% CI)	Comparison between Humphrey field analyzer and PalmScan VF2000 VR perimetry	Agreement
0.819 (0.784 - 0.872)	both the groups (glaucomatous and non-glaucomatous)	Almost perfect agreement
0.626 (0.536 - 0.767)	Only glaucomatous group	Substantial agreement

	VR perimetry					
	Humphrey field analyser		Glaucomatous			
		Non-	Mild	Moderate	Severe	Total
	Groups	glaucomatous				
		80	0	0	0	80
	Non-					
	glaucomatous					
	Mild	0	19	2	1	22
Glaucomatous		0	5	10	3	18
	Moderate					
		0	0	9	37	46
	Severe					
		80	24	21	41	166
	Total					

According to hodapp classification:

Thus, Non glaucomatous is perfectly shown by both the perimeters.

Humphrey field analyzer	VR perimetry		Total
	Non- Glaucomatous Glaucomatous		
Non- Glaucomatous	86	0	86
Glaucomatous	0 80		80
Total	86 80		166

Hence, Sensitivity = 100% Specificity = 100%

Humphrey field analyzer	VR perimetry		Total
	Moderate and severe glaucoma	ε	
Moderate and severe glaucoma	59	5	64
Mild glaucoma	3	19	22
Total	62	62 24	

Mild Versus Moderate and Severe glaucoma

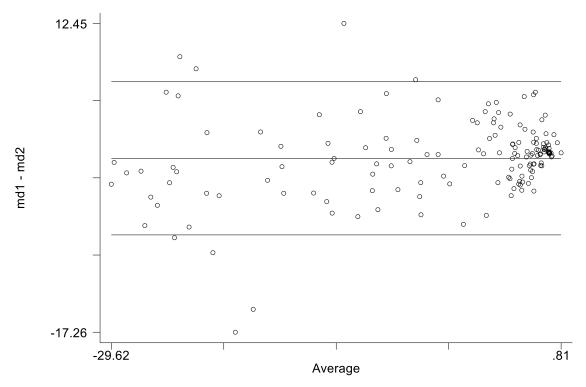
Hence, Sensitivity = 97.4% Specificity = 97.1%

Mild and Moderate Versus Severe glaucoma

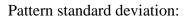
Humphrey field analyzer	VR	Total	
	Severe glaucoma Mild and Moderate glaucoma		
Severe glaucoma	37	9	46
Mild and Moderate glaucoma	4	36	40
Total	41	45	86

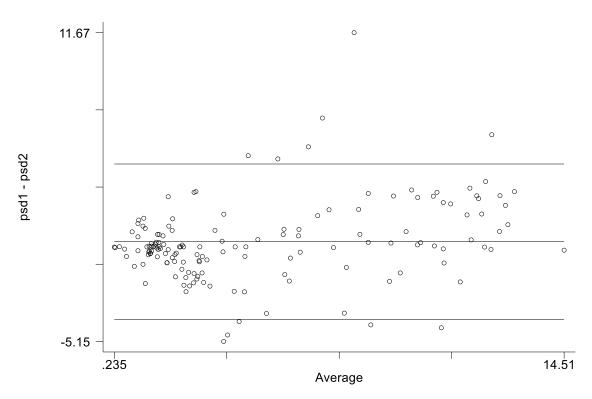
Hence, Sensitivity = 90.6% Specificity = 97.2% Bland-Altman Plot was constructed for three global indices: Mean deviation, pattern standard deviation and visual field indices.

Mean deviation:

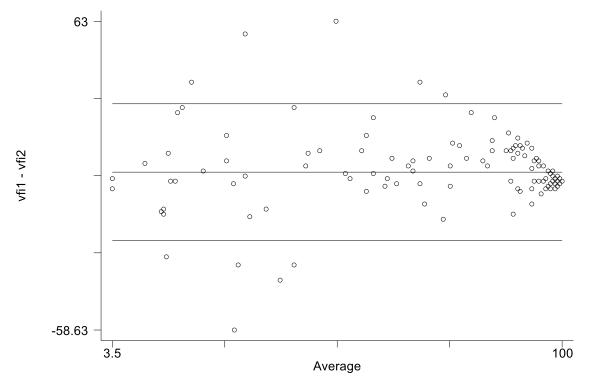


Limits of agreement (Reference Range for difference): -7.897 to 6.839 Mean difference: -0.529 (CI -1.093 to 0.036) Range : -29.620 to 0.810 Pitman's Test of difference in variance: r = 0.253, n = 166, P = 0.001





Limits of agreement (Reference Range for difference): -3.943 to 4.515 Mean difference: 0.286 (CI -0.038 to 0.610) Range : 0.235 to 14.510 Pitman's Test of difference in variance: r = 0.317, n = 166, P = 0.000



Visual field indices:

Limits of agreement (Reference Range for difference): -23.369 to 30.484 Mean difference: 3.558 (CI 1.494 to 5.621) Range : 3.500 to 100.000 Pitman's Test of difference in variance: r = 0.002, n = 166, P = 0.984 Intraclass correlation coefficient:

The Intraclass Correlation Coefficient (ICC)^[9] is a measure of the reliability of measurements or ratings

ICC	Reliability
<0.5	Poor
0.5 – 0.75	Moderate
0.75 – 0.9	Good
> 0.9	Excellent

In this study:

Parameter	ICC	95% Confidence interval	Reliablity
Mean Deviation	0.9551613	0.939129 - 0.9669758	Excellent
Pattern standard deviation	0.9383746	0.91634 - 0.9546122	Excellent
Visual field indices	0.9275604	0.9016591 - 0.9466473	Excellent

Discussion:

Thus , Kappa statistic shows that Humphrey field analyzer and PalmScan VF2000 virtual reality(VR) visual field analyser has perfect agreement when non glaucomatous as well as glaucomatous were compared. Hence it is an excellent tool for screening glaucoma and non-glaucoma. Sensitivity and Specificity being 100% . It is even better than optical coherence tomography(OCT) for glaucoma . Sensitivity and specificity in discriminating between healthy and glaucomatous eyes were 95.2 and 91.9%, respectively^[10]

When Mild versus Moderate and Severe glaucoma is assessed, Sensitivity is 97.4% and Specificity is 97.1%

When Mild and Moderate versus Severe glaucoma was assessed, Sensitivity is 90.6% and Specificity is 97.2%

Bland Altman plot used for measuring the agreement between the two perimeters, interpreted that there is statistically significant difference between the two perimeters when mean deviation and pattern standard deviation were compared. However, Visual field indices did not show any statistically significant difference.

Intraclass Correlation Coefficient which is a measure of reliability was also derived, both the perimeters show excellent reliability for all the three global indices.

Conclusion:

PalmScan VF2000 virtual reality (VR) visual field analyzer is an excellent tool for screening glaucomatous and non-glaucomatous patients.

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