Diagnostic Capacities and Agreement of Devices in Primary Open Angle Glaucoma: Spectralis OCT, Cirrus OCT and Heidelberg Retinal Tomography 3

Primer Açık Açılı Glokomda Cihazların Tanı Kapasitesi ve Uyumu: Spectralis OCT, Cirrus OCT ve Heidelberg Retinal Tomografi 3

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ABSTRACT

Purpose: To evaluate diagnostic capacities of Spectralis Spectral Domain optical coherence tomography (OCT), Cirrus OCT and Heidelberg Retinal Tomography III (HRT) and their agreement for common parameters in primary open angle glaucoma.

Materials and Methods: 178 of 100 primary open angle glaucoma patients and 112 eyes of 60 healthy controls underwent testing with HRT III, Spectralis and Cirrus OCT. Average and quadrant retinal nerve fiber layer (RNFL) measurements in all three devices, optic nerve head parameters in HRT and Cirrus were recorded. The area under the curve (AUC) calculations of all parameters were also calculated to assess primary open angle discrimination.

Results: Spectralis OCT average RNFL measurements were higher than Cirrus OCT for both glaucoma and control groups HRT average RNFL measurements were higher than both Spectralis and Cirrus OCT devices for both glaucoma and control groups Cirrus and HRT III didn't have any agreement except cup volume in both groups and rim are in control group. Cirrus Cup/Disc ratio had the highest and HRT neuro-retinal rim area had the lowest AUC values.

Conclusions: In our study common parameters obtained from different devices had significant differences and none had a perfect AUC value.

Key Words: Primary open angle glaucoma, OCT, HRT III, Heidelberg retinal tomography, agreement.

ÖZ

Amaç: Primer açık açılı glokom tanısında Spectralis Spectral Domain optik koherens tomografi (OCT), Cirrus OCT ve Heidelberg Retinal Tomografinin tanı kapasitesinin ve ortak parametreleri için uyumunun değerlendirilmesi amaçlanmıştır

Gereç ve Yöntem: Yüz primer açık açılı glokom hastasının 178 gözü ve 60 sağlıklı kontrolün 112 gözüne HRT III, Spectralis ve Cirrus OCT ile görüntüleme uygulandı. Tüm cihazlarda ortalama ve kadran retinal sinir lifi tabakası (RSLT) ölçümleri ve HRT ve Cirrus OCT'de optik sinir başı parametreleri ölçümleri kaydedildi ve cihazlar arasındaki uyum açısından incelendi. Primer açık açılı glokom ayırım gücünü değerlendirmek amacıyla tüm parametreler için AUC (area under the curve: ROC eğrisi altı alan) değerleri de hesaplandı.

Bulgular: Hem glokom hem de kontrol grubunda Spectralis OCT'deki ortalama RNFL ölçümleri Cirrus OCT'den daha yüksekti. HRT'deki ortalama RNFL ölçümleri, Spectralis ve Cirrus OCT'nin ikisinden de belirgin olarak daha yüksekti. Cirrus OCT ve HRT arasında her iki grupta optik disk cup(çukurluk) hacmi ve kontrol grubunda rim alanı dışındaki parametrelerde uyum yoktu. Cirrus OCT'de cup/disk oranı en yüksek AUC değerine ve HRT nöro-retinal rim alanı en düşük AUC değeri olan parametreler olarak bulundu.

Sonuç: Çalışmamamızda farklı cihazlardan elde edilen ortak parametreler arasında anlamlı farklılıklar vardı ve hiç biri mükemmel AUC değerine sahip değildi.

Anahtar Kelimeler: Primer açık açılı glokom, OCT, HRT III, Heidelberg retinal tomografi, uyum.

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Geliş Tarihi - Received: 12.07.2018
Kabul Tarihi - Accepted: 09.01.2019
Glo-Kat 2019; 14: 65-71

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INTRODUCTION

Primary open angle glaucoma (POAG) is a progressive optic neuropathy with degeneration of retinal ganglion cells and their axon. As its damage is irreversible and it is treatable, early diagnosis is crucial.[1] If left untreated, POAG can lead to vision loss and even blindness.[2] Traditionally, automated perimetry, optic nerve head examination and photography are utilized for diagnosis but optic nerve damage may precede detection with these.[3] Clinically objective, efficient and quantitative tools are needed for diagnosis and current devices should be studied for this manner. The imaging tools like optical coherence tomography (OCT) devices and HRT can give quantitative measurement results and also classify results as normal, borderline and out-side the normal limits but the reliability of the devices should be studied. In this study we assessed three devices with respect to their efficiency and agreement in POAG diagnosis.

METHODS

This study was carried out according to Declaration of Helsinki. The study was approved by local ethical committee before patient collection. All participants were provided informed consent before enrollment.

Patient Enrollment

One hundred seventy eight eyes of 100 POAG patients patients under treatment and follow-up in glaucoma section and 112 eyes of 60 healthy controls who applied for routine eye examination in ophthalmology department were included in the study. Bilateral eyes of 78 and single eyes of 22 patients in glaucoma group; bilateral eyes of 52 and single eyes of 8 controls were included in the study. There were 48 males and 52 females in the glaucoma group and 27 males and 33 females in the control group. Mean age was 58.32 ± 7.3 years in the POAG group and 57.17 ± 8.6 years in the control group.

The individuals in the glaucoma group were follow-up patients in glaucoma section and glaucomatous perimetric defects were verified before patient enrollment by checking previous perimetries. The perimetry testing was performed with 30-2 mode (Octopus, Haag-Streit International, Koeniz, Switzerland). The patients with only reliable perimetry test results (false-positive errors <30%; false-negative errors <30%; fixation loss <30%) were included in the study. Glaucomatous visual field defect was accepted as follows: glaucoma hemi-field test outside normal limits, a cluster of <3 points in the pattern deviation plot in a single hemifield (superior or inferior) with a P value of <5%, one of which must have a P value of <1%. The optic neuropathy was defined as: diffuse thinning, focal narrowing or notching of the optic disc rim, especially at the inferior or superior poles; progression of cupping of the optic disc during follow-up visits; diffuse or localized abnormalities of the peri-papillary retinal nerve fiber layer (RNFL), especially in the inferior or superior poles; disc rim or peri-papillary RNFL hemorrhages; neural rim asymmetry between the two eyes indicating loss of neural tissue.

Inclusion criteria for the glaucoma patients were; being older than 40 years, POAG diagnosis in the glaucoma section with glaucomatous optic neuropathy and defect in perimeter testing and proven open angle with gonioscopy, IOP higher than 21 mmHg before treatment, best corrected visual acuity higher than 0.1 according to decimal Snellen chart to ensure fixation during diagnostics test in the study. Inclusion criteria for the control patients were; being older than 40 years, normal ophthalmologic examination except refraction error, normal perimetry test. Exclusion criteria for the glaucoma patients were secondary glaucoma cases, diagnosis of retinal pathology, uveitis or neuro-ophthalmologic pathologies affecting optic nerve, ocular surgery besides glaucoma surgery, media opacities that restrain imaging with devices like corneal opacities, cataracts, vitreous opacities. Exclusion criteria for the control patients were any anterior or posterior segment pathology, any ocular surgery, any defect in perimetry. For the both groups patients exceeding ±5 diopters of spherical or spherical equivalent refraction error were excluded.

Image Acquisition

Individuals who matched the above criteria for both groups underwent testing with Heidelberg Retinal Tomography (Heidelberg Engineering, Version 3, and Germany), Spectralis Optical Coherence Tomography (SD-OCT, Heidelberg Engineering, Dossenheim, Germany) and Cirrus Optical Coherence Tomography (Carl Zeiss Meditec, Dublin, CA). RNFL measurements(average, superior , inferior , nasal and temporal) in all three devices, optic nerve head parameters including optic disc area(ODA) , cup area(CA), neuroretinal rim area(RA), cup/disc ratio(CDR), cup volume(CV) in HRT and Cirrus HD OCT were recorded. For HRT III device superior RNFL was obtained by averaging superonasal and superotemporal measurements and inferior RNFL was obtained by averaging inferonasal and inferotemporal measurements to get 4 quadrant results as OCT devices. For all the participants “outside the normal limits”, “borderline” and “normal” as the own classifications of the devices according to RNFL measurements in Spectralis SD-OCT and Cirrus HD-OCT and Glaucoma Probability Score (GPS) in HRT III were recorded. Low quality images which were signal-to-noise lower (SNR) than 15 dB in Spectralis OCT, instrument quality score (IQS) lower than 6 for Cirrus OCT and topography standard deviation higher than 50 µm in HRT were excluded from the study.

Statistical Analysis

Statistical analysis performed by SPSS 10.0 software. Mean

ages between groups compared by student t-test. Normal distribution was examined by Shapiro-Wilks test. Parameters that obtained from all devices compared between the patient groups by Mann Whitney- U test was used. As distributions of these variables were asymmetrical, they were presented as median and %25-75 percentile. Categorical results were compared by Pearson's Chi-squared test (Exact 2-sided). Ordinal association of categorical variables was analyzed by Kendal tau-b test. Agreement among devices were evaluated by Bland Altman analysis for common parameters rather than correlations as good correlation does not reflect good agreement. Area under the curve (AUC of Receiver operating curve [ROC]) calculations of all the parameters were obtained in the study to analyze their power for discrimination between glaucoma and control patients. The Area under an ROC Curve reflects the accuracy of the test depends on how well the test separates the group being tested into those with and without the disease in question. The accuracy is measured by the area under the ROC curve which is a graph between true positive and false positive rates. An area of "1" represents a perfect test; an area of "0.5" represents a worthless test. P <0.05 was accepted as statistically significant.

RESULTS

Mean age and gender was not statistical different between the glaucoma and control groups (Table 1). All the average RNFL and RNFL quadrant measurements of three devices were statistically significantly lower in the glaucoma group compared to the control group. The comparison between the groups and average RNFL and quadrant RNFL measurements can be seen in Table 2.

Bland-Altman plots for pairwise agreements between average RNFL measurements were summarized in Figure 1. When the plots evaluated, Spectralis OCT average RNFL measurements were higher than Cirrus OCT for both the glaucoma and control groups (mean difference of 5.8 µm and 6.6 µm respectively. Figure 1A-B). HRT average RNFL measurements were prominently higher than both Spectralis and Cirrus OCT devices for both glaucoma and control groups (mean difference of 129.2 µm and 135 µm for glaucoma group and 157.7 µm and 164.2 µm for control group, respectively). In addition, proportional errors were observed comparing HRT and OCT devices with increasing mean of differences with increased mean of RNFL measurements (see regression line on Figure 1 C, D, E and F). According to these results, for RNFL measurements, there was no agreement between HRT3 and OCT devices and Spectralis OCT systemically measured higher RNFL thicknesses compared to Cirrus OCT. RNFL quadrant measurements also revealed similar Bland Altman plots.

Table 1. *With respect to age and gender there was no significant difference between glaucoma and control group statistically.*

	Gender		Mean Age
	Female	Male	
Glaucoma	52	48	58.32 ± 7.3
Control	33	27	57.17 ± 8.6
P Value	P=0.749		P=0.370

Table 2. *RNFL (retinal nerve fiber layer) and RNFL quadrant measurements for all three devices for glaucoma and control group, presented as median (25%-75%).*

RNFL	Glaucoma Group Median (25%-75%) µm	Control Group Median (25%-75%) µm	P Value
Spectralis OCT			
Average	94 (80 - 101)	102.5 (96 - 107)	P<0.001
Superior	111.7 (95 - 124)	124 (113 - 135)	P<0.001
Inferior	117.7 (97 - 130)	132 (119 - 143)	P<0.001
Temporal	68 (60 - 78)	73.5(66 - 82)	P<0.001
Nasal	69.5 (57 - 79)	75 (66 - 85)	P=0.001
Cirrus OCT			
Average	87 (72 - 96)	95.5 (89 – 103)	P<0.001
Superior	108.5 (85 - 122)	121.5 (106 - 135)	P<0.001
Inferior	112(87 - 128)	128 (111 - 140)	P<0.001
Temporal	59 (51 - 70)	65 (59 - 71)	P<0.001
Nasal	65 (57 - 72)	70 (61 - 78)	P=0.001
HRT			
Average	220 (170 - 270)	250 (220 - 300)	P<0.001
Superior	272 (210 - 341)	320 (266 - 380)	P<0.001
Inferior	285(215 - 350)	310 (261 - 384)	P=0.001
Temporal	80 (60 - 90)	90 (70 - 100)	P<0.001
Nasal	250(170 - 340)	300 (240 - 350)	P<0.001

Optic disc parameters were obtained from Cirrus OCT and HRT III. Optic disc area, cup area, cup/disc ratio and cup volume were significantly higher and neuro-retinal rim was significantly lower in the glaucoma group compared to the control group for both device (Table 3).

Agreement of Cirrus OCT and HRT for optic disc parameters were also analyzed with Bland Altman plots. Cirrus OCT measured CA slightly higher than HRT in both glaucoma and control group (mean difference of 0.06 mm^2 and 0.08 mm^2, respectively. Figure 2A-B). Cirrus OCT revealed higher cup/disc ratio compared to HRT in both groups (mean difference of 0.26 for glaucoma and 0.24 for control group. Figure 2C-D). Cirrus and HRT showed good agreement for

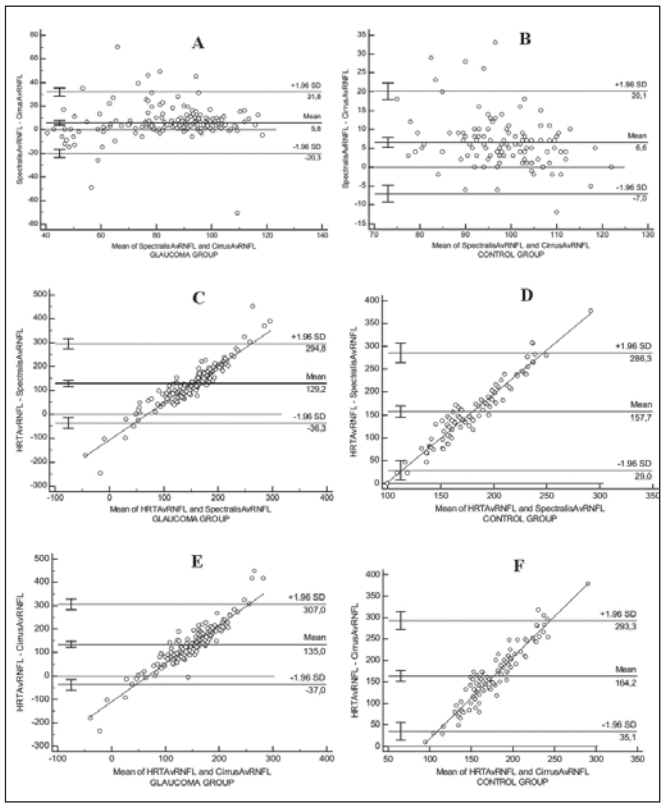

Figure 1. *Bland-Altman blots indicating agreement of devices for average RNFL thicknesses in glaucoma and control groups. (SpectralisAvRNFL = Spectralis average RNFL thickness, CirrusAvRNFL = Cirrus average RNFL thickness, HRTAvRNFL = HRT average RNFL thickness).*

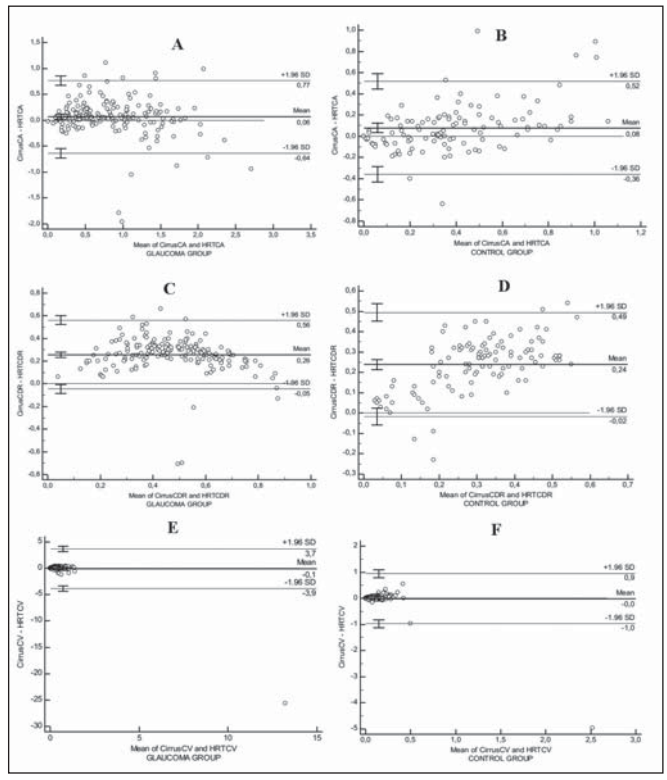

Figure 2. *Bland-Altman plots indicating agreement between Cirrus OCT and HRT III for Cup Area (CA), Cup/Disc Ratio (CDR) and Cup Volume (CV).*

Table 3. *Optic disc parameters obtained from Cirrus HD OCT and HRT 3 and their comparison between glaucoma and control groups. Optic disc area(ODA), cup area(CA), neuroretinal rim area(RA), cup/disc ratio(CDR), cup volume(CV).*

OD PARAMETER	GLAUCOMA Median(%25-%75)	CONTROL Median(%25-%75)	P VALUE
Cirrus OCT			
ODA	1.99 (1.78 - 2.38) mm^2	1.93 (1.72 - 2.11) mm^2	P=0.006
CA	0.81 (0.46 - 1.21) mm^2	0.37 (0.19 – 0.61) mm^2	P<0.001
RA	1.22 (0.98 – 1.43) mm^2	1.45 (1.28 – 1.69) mm^2	P<0.001
CDR	0.62 (0.49 – 0.73)	0.45 (0.31 – 0.54)	P<0.001
CV	0.24 (0.08 – 0.48) mm^3	0.06 (0.01-0.17) mm^3	P<0.001
HRT			
ODA	2.08 (1.83 – 2.48) mm^2	1.87 (1.62 – 2.04) mm^2	P<0.001
CA	0.65 (0.36 – 1.12) mm^2	0.32 (0.17 – 0.51) mm^2	P<0.001
RA	1.36 (1.17 – 1.63) mm^2	1.47 (1.32 – 1.69) mm^2	P=0.008
CDR	0.31 (0.21 – 0.48)	0.18 (0.10-0.27)	P<0.001
CV	0.15 (0.05 – 0.37) mm^3	0.05 (0.02 – 0.11) mm^3	P<0.001

CV measurements with a narrow difference interval and accumulation of plots around "0" difference line (Figure 2E-F). Cirrus OCT measured ODA slightly lower than HRT in glaucoma group and slightly higher in control group (mean difference of -0.1 mm^2 and 0.07 mm^2, respectively. Figure 3A-B). For RA measurements, Cirrus OCT had lower results compared to HRT in glaucoma group but in control group they had a good agreement (Figure 3 C-D).

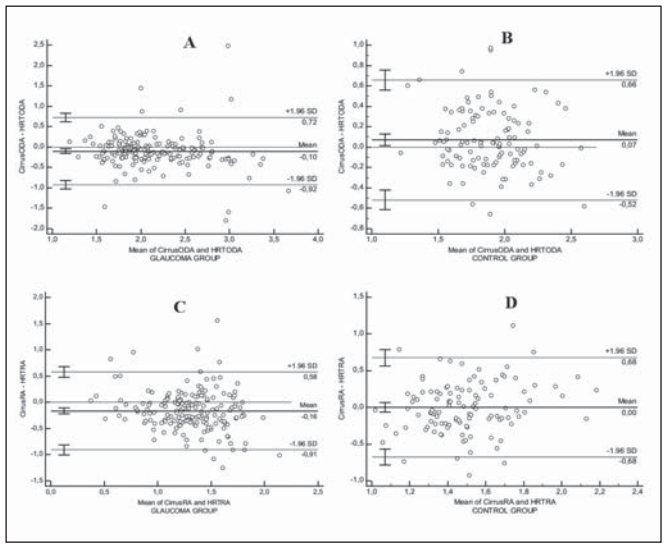

Figure 3. *Bland-Altman plots indicating agreement between Cirrus OCT and HRT III for Optic Disc Area (ODA), and Rim Area(RA).*

Patient classifications of devices were also compared and analyzed among the devices. Glaucoma Probability Score (GPS) for HRT III, RNFL quadrant analysis for Spectralis OCT and Cirrus OCT were used for this purpose (Table 4). For each device, patient classifications were significantly different between the glaucoma and control groups (Chi-square test, $p<0.05$). According to Kendall tau-b association analysis between devices with respect to patient classification, there were concordances between the devices for glaucoma group and for all cases without grouping, but there was no concordance between devices in the control group.

Area under the Curve (Receiver operating Curve) values of each parameter tested in study are shown in Table 5 by decreasing order. Values converging to "1" show good discrimination with high sensitivity and specificity, yet values converging to "0.5" show inefficiency for diagnosis.

Table 4. *Patient classification according to device classification. Based on glaucoma Probability Score (GPS) for HRT 3, RNFL quadrant analysis for Spectralis OCT and Cirrus OCT.*

	GLAUCOMA				CONTROL			
	Normal	**Borderline**	**OTNL***	**Total**	**Normal**	**Borderline**	**OTNL***	**Total**
HRT III	54(30.3%)	35 (19.6%)	89 (50%)	178(100%)	91 (81.2%)	11 (9.8%)	10(8.9%)	112(100%)
Spectralis	107(60.1%)	24(13.5%)	47(26.4%)	178(100%)	104(%92.8)	7(6.2%)	1(0.9%)	112(100%)
Cirrus	105(58.9%)	13(7.3%)	60(33.7%)	178(100%)	95 (84.8%)	5(4.4%)	12(10.7%)	112(100%)

*OTNL=Outside the normal limits.

Table 5. *Area under the curve (Receiver Operating Curve) values and 95% confidence interval of each parameters included in the study. Values converging to "1" show good discrimination whereas values converging to "0.5" show inefficiency for the diagnosis (decreasing order).*

PARAMETER	**AUC VALUE (95% Confidence Interval)**	**PARAMETER**	**AUC VALUE (95% Confidence Interval)**
Cirrus cup/disc ratio	0.769 (0.715 – 0.823)	*Cirrus Superior RNFL*	0.683 (0.621 - 0.745)
Cirrus cup area	0.761 (0.707 - 0.816)	*HRT global RNFL*	0.64 (0.577 - 0.703)
HRT cup area	0.759 (0 .705 - 0.812)	*Cirrus Temporal RNFL*	0.639 (0.576 - 0.702)
Cirrus cup volume	0.750 (0.695 – 0.805)	*HRT Superior RNFL*	0.635 (0 .571 - 0.699)
HRT cup/disc ratio	0.749 (0.694 - 0.804)	*Spectralis Temporal RNFL*	0.624 (0.560 - 0.688)
Cirrus neuro-retinal rim area	0.73 (0.672 - 0.787)	*HRT Temporal RNFL*	0.622 (0.557 - 0.687)
Spectralis global RNFL	0.728 (0.670 - 0.785)	*HRT Nasal RNFL*	0.622 (0.558 - 0.686)
HRT cup volume	0.727 (0.670 - 0.785)	*Spectralis Nasal RNFL*	0.620 (0.555 – 0.684)
Spectralis Inferior RNFL	0.715 (0 .656 - 0.774)	*Cirrus Nasal RNFL*	0.613 (0.546 - 0.681)
Spectralis Superior RNFL	0.71 (0.652 - 0.769)	*HRT Inferior RNFL*	0.612 (0.548 - 0.677)
Cirrus Global RNFL	0.709 (0.650 - 0.768)	*Cirrus optic disc area*	0.596 (0.532 - 0.661)
Cirrus Inferior RNFL	0.707 (0.648 - 0.766)	*HRT neuro-retinal rim area*	0.592 (0.527 – 0.657)
HRT optic disc area	0.693 (0.633 - 0.753)		

According to results, CDR in Cirrus OCT had the highest and HRT RA had the lowest AUC value (Table 5).

DISCUSSION

In open angle glaucoma, significant RNFL thinning or structural damage were reported to occur before detectable visual field defects.[4] Ghasia et al.[5] evaluated Spectralis OCT in pediatric and adult glaucoma/glaucoma suspect patients and concluded that the reproducibility of RNFL measurements were very good. Spectralis and Cirrus OCT for RNFL measurements were reported to have excellent repeatability although there were differences in quadrant RNFL measurements.[6] Leite et al.[7] compared RNFL measurements among three OCT devices (Spectralis, Cirrus and RTVue) and reported that measurements between devices were not compatible even they were correlated. In another study, same authors stated that their diagnostic accuracy for glaucoma was similar according to AUC values.[8] In our study, according to Bland Altman analysis average and quadrant RNFL measurements in Spectralis OCT tended to be slightly higher (4-9 µm) than Cirrus OCT (Figure 1A -1B and Supplementary material). In addition, Spectralis OCT global, superior and inferior quadrant RNFL measurements had higher AUC values than all Cirrus RNFL measurements (Table 5).

Fanihagh et al.[9] compared OCT devices including Cirrus OCT and HRT III in glaucoma patients with respect to RNFL measurements and they concluded that HRT III was poorly correlated with OCT devices. In this study, HRT III did not have any agreement with OCT devices and had remarkable higher measurements (Figure 1 C,D,E,F). The reason could be that RNFL thickness was calculated between imaginary reference plane that was 50 micron posterior to temporal optic disc margin and retinal surface rather than anatomical true layers in HRT whereas RNFL thickness was measured by automatic layer segmentation in OCT devices.[10-12]

Spectralis OCT and HRT III were previously compared in pre-perimetric glaucoma patients and it's shown that Spectralis OCT performed better diagnostic capability than HRT III.[13] Leung et al.[14] compared Spectralis OCT and HRT and reported that their diagnostic classification didn't have agreement and Spectralis OCT RNFL measurements was shown to have better sensitivity than HRT III optic disc measurements. In another study analyzing multiple glaucoma diagnostic devices including Spectralis RNFL measurement and HRT scores, AUC values of Spectralis was the highest although it was not statistically significant.[15] Conversely, in our study as single parameters, AUC values of HRT CA and HRT CDR were higher than all RNFL parameters obtained from both OCT devices, although HRT RA area had the lowest AUC value. Furthermore, HRT III classification had higher prediction ratio in the glaucoma patients than other devices (Table 4). This might be resulted from different patient recruitment methods. In one of the studies mentioned above patients were pre-perimetric[13], the other only used perimetry to diagnose glaucoma,[14] whereas in our study combination of clinical examination and perimetry were utilized

Sung et al.[16] compared RNFL thickness and optic nerve head parameters in Cirrus OCT for glaucoma diagnosis and concluded that RNFL was better than optic nerve head parameters for glaucoma discrimination. On the contrary, in our study we found that cup/disc ratio, cup area, cup volume and neuro-retinal rim area had higher AUC values than all RNFL measurements in Cirrus OCT. In addition, according to AUC values, 6 optic nerve head parameters obtained from Cirrus OCT and HRT III (Cirrus CDR, Cirrus CA, HRT CA, Cirrus CV, HRT CDR, Cirrus RA) performed better than all RNFL measurements of all devices (Table 5).

For the Area under the ROC Curve we accept a method as a gold standard to get true positive and false positive results. Some studies used only perimetry, some studies used combination of clinical examination and perimetry.[13, 14, 15] So they might not be comparable and we did not compared AUC result numbers with other studies. Instead we presented device comparisons within the cited studies.

Sato et al.[17] compared optic nerve head parameters between Cirrus OCT and HRT and concluded that although high correlation was founded, parameters were not comparable except cup/disc ratio. Other studies also compared optic disc parameters between these instruments reporting significant differences for parameters and they pointed the differences between devices according to measurement, reference plane and algorithms.[18,19] In our study, when Bland Altman plots analyzed Cirrus and HRT didn't have agreement except CV in both groups and RA in control group. Cirrus CDR, Cirrus CA had the highest AUC values among the optic nerve head parameters (Table 5).

Banister et al.[15] reported that diagnostic tools including Spectralis OCT and HRT III missed severe glaucoma cases and they could not replace clinical evaluation. In our study, for the patient classification of the devices in glaucoma group, significant number of the patients were classified as normal (Table 4). Ethnical differences in measurements were reported before,[20-22] so this may be resulted from ethnical/regional differences between our study population and the normal databases of the devices. Modifying the databases for different region for normal population could result in different findings in further studies.

There were several limitations of this study. Pre-treatment IOP data was not available for all the glaucoma patients (lost

first examination file, referred under treatment patients from other clinics, etc). The glaucoma patients were included in the study with previous perimetries performed in glaucoma section and recent perimetries were not obtained, therefore perimetric PSD (pattern standard deviation) and MD (mean deviation) data were not recorded in the study and the glaucoma patients were not staged accordingly. As there is not any "gold-standard" test, clinical examination and additional tests were used to diagnose glaucoma patients in the glaucoma section by specialists and the diagnostic devices in the study were evaluated in this basis. This subjective assumption may not be as powerful as an objective test.

CONCLUSION

In this study the common parameters obtained from the devices had significant differences. Thus, in clinical practice they should not be used interchangeably as that may lead misinterpretation. None of the parameters in our study had an AUC value very close to 1 implying perfect diagnosis. Therefore, the primary open angle glaucoma should still be diagnosed with combination of clinical examination, perimeters and diagnostic devices rather than an isolated test or a parameter.

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