·Clinical Research·

Comparison of retinal nerve fiber layer and macular thickness measurements with Stratus OCT and OPKO/OTI OCT devices in healthy subjects

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Received: 2014-01-07 Accepted: 2014-04-30

Abstract

• AIM: To compare retinal nerve fiber layer (RNFL) and macular thickness measurements obtained with the Stratus optical coherence tomography (OCT) and OPKO/OTI OCT devices.

• METHODS: Included in the study were 59 eyes of 30 participants. All measurements for each eye were done on the same day with both devices. Student's paired *t*-tests were used to compare the central macular thickness and RNFL measurements of the Stratus OCT and OPKO/OTI OCT. Pearson correlation was used to assess the relationship between the devices. Coefficient of variation (COV) was calculated to assess intersession repeatability.

• RESULTS: Using both the Stratus OCT and OPKO/OTI OCT, respectively, the measured mean average RNFL thicknesses were 98.9±11.1 μm and 115.1±9.6 μm (*P*=0.001), and the measured mean central retinal thicknesses (CRT) were 196.2 ±18.8 μm and 204.5 ±21.1 μm (*P*<0.001). Measured by the two devices, the RNFL thickness values were correlated in all quadrants, as were the retinal thickness values except the inferior outer sector. COV for average RNFL and CRT thickness were 2.9% and 4.6% for Stratus OCT, and 2.1% and 4.2% for OPKO/OTI OCT, respectively.

• CONCLUSION: We found good reproducibility of RNFL and retina thickness measurements for both Stratus OCT and OPKO/OTI OCT devices. However, even though the two OCT systems provided statistically correlated results, the values for both RNFL and macular thickness were statistically different. RNFL and macular thickness measurements with the OPKO/OTI OCT were higher than that of the Stratus OCT; therefore, the two OCT systems cannot be used interchangeably for the measurements of RNFL and macular thickness.

• **KEYWORDS:** optical coherence tomography; Stratus optical coherence tomography; OPKO/OTI OCT; retinal nerve fiber layer; macular thickness
DOI:10.3980/j.issn.2222-3959.2015.01.18

Ozkok A, Akkan JCU, Tamcelik N, Erdogan M, Comlekoglu DU, Yildirim R. Comparison of retinal nerve fiber layer and macular thickness measurements with Stratus OCT and OPKO/OTI OCT devices in healthy subjects. *Int J Ophthalmol* 2015;8(1):98-103

INTRODUCTION

Optical coherence tomography (OCT) is a noninvasive imaging technique that allows high resolution *in vivo* tissue assessment. OCT applies the principle of interferometry to interpret reflectance data from a series of multiple side-by-side A-scans combined to form a cross-sectional image [1]. OCT provides objective and reproducible measurements of retinal nerve fiber layer (RNFL) thickness, macular thickness, and simulated histological examination facility. The RNFL consists largely of axonal fibers of ganglion cells and is the main anatomic structure damaged in glaucoma. OCT is a useful imaging technique to diagnose and manage glaucoma and a variety of other retinal diseases.

OCT was first described by Huang *et al* [1] in 1991. Early model OCT devices (OCT 1 and 2, Carl Zeiss Meditec, Dublin, CA, USA) produced axial resolution of 12 to 15 μm but were soon superseded by the third generation OCT, also known as time domain OCT (TD-OCT)[2]. Stratus OCT is the most widely used TD-OCT instrument. Although TD-OCTs are able to scan up to 4 times more rapidly than previous versions and produce axial resolutions of 8 to 10 μm, the speed of TD-OCT is limited by its need for a movable reference mirror. The technology of the newer spectral domain OCT (SD-OCT) provides significant advantages over TD-OCT. SD-OCT uses a Fourier domain interferometric method to provide higher resolution of up to 5 μm[3]. SD-OCT devices are able to scan approximately 60 times faster than

TD-OCT instruments, which allows for a larger number of images to be acquired per unit area in a shorter time[4].

Several companies have developed newer versions of SD-OCT, such as the OPKO/OTI OCT (Opko/OTI, Miami, FL, USA). It has an axial resolution of 5 μm and a scan speed of 27 000 A-scans per second, whereas the Stratus OCT has an axial resolution of 8 to 10 μm and a scan speed of 400 A-scans per second[5,6].

Obviously, before a new OCT device can be accepted for use in clinical practice, it must be determined if its acquired measurements are compatible with previous OCT technologies. The goal of our present study was to compare the RNFL and macular thickness measurements using Stratus OCT and OPKO/OTI OCT in healthy volunteers in order to make such a determination.

Table 1 Demographic features of the participants

Parameters	Results
Mean age ±SD (range)	45.4±12.4 (20-65)
Intraocular pressure (mm Hg) ±SD	13.1±3.6
Sex	
F	19
M	11
Refractive error	
Mild (-1.50 to +1.50)	28 (47.4%)
Moderate myopia (-1.75 to -4.0)	21 (35.6%)
Moderate hyperopia (+1.75 to +4.0)	10 (16.9%)
Visual acuity	
20/20	39 (66.1%)
20/30	11 (18.6%)
20/40	9 (15.3%)

SUBJECTS AND METHODS

In this prospective, cross-sectional case study, the study protocol adhered to the Declaration of Helsinki and was approved by the local research ethics committee.

Subjects Healthy human subjects were recruited prospectively between January 2012 and March 2012 at two university based medical centers. Each participant signed informed consent and then underwent a complete ophthalmic evaluation including assessment of visual acuity, intraocular pressure, autorefraction, biomicroscopy, and fundoscopy.

Inclusion criteria were a best-corrected visual acuity of 20/40 or better, a spherical equivalent within the range of +4.0 to -4.0 diopters, intraocular pressure (IOP) lower than 21 mm Hg, normal appearing macula, and normal appearing optic nerves without asymmetry, cupping, notches, or hemorrhages. Exclusion criteria included intraocular eye diseases (including anterior segment diseases, glaucoma, diabetic retinopathy, age-related macular degeneration, and optic nerve pathology), a history of intraocular surgery, having significant media opacity, and poor signal strength OCT.

Methods For each study participant, all RNFL and macular thickness measurements were performed within a single day after pupil dilation with installation of Tropicamide 1% ophthalmic solution. All measurements were done twice to assess reproducibility. The technical characteristics and basic principles of the stratus OCT has been previously described[7]. The Stratus OCT (software version 4.0.1; Carl Zeiss Meditec, Inc., Dublin, CA, USA) fast RNFL (3.46 mm) protocol was used to measure RNFL thickness, and the macular thickness map scan protocol was used to obtain central macular thickness measurements. The OPKO/OTI OCT (Opko/OTI, Miami, FL, USA) is a combination of OCT and confocal scanning laser ophthalmoscopy (SLO). The OPKO/OTI OCT RNFL protocol (3.4 mm) was used to measure RNFL thickness and the macular 8×8 cubed grids over 6×6-mm^2 protocol was used to obtain central macular thickness measurement.

The OPKO/OTI OCT measurements were acquired by a well-trained operator at Center 1 and Stratus OCT measurements were obtained by another well-trained operator at Center 2. The same Stratus and OPKO/OTI OCT instruments were used for all subjects. Both OCT devices provide RNFL thickness maps with average and 4 quadrants (inferior, superior, nasal, and temporal) plus mean retinal thickness values including central foveal thickness (CFT, retinal thickness at the center of fovea) and nine sectors of the Early Treatment Diabetic Retinopathy Study (ETDRS) map containing the central retinal thickness (CRT, mean thickness in the central 1 mm diameter area).

Statistical Analysis All statistical analyses were performed using MedCalc software version 12.0 (MedCalc Software, Mariakerke, Belgium). Kolmogorov-Smirnov test was used to test wheather the data normally distributed. Student's paired *t*-test was used to compare the retinal thickness and RNFL measurements between Stratus OCT and OPKO/OTI OCT. Pearson correlation was used to assess the relationship between devices. Bland-Altman plots were graphed to assess the agreement between the two instruments for both measurements of average RNFL and CRT, which display difference against mean, and 95% limits of agreement were calculated as ±1.96 ×standard deviation (SD) of the differences. Coefficient of variation (COV) was calculated to assess intersession repeatability.

RESULTS

A total of 49 participants had volunteered for the study. Of these, 14 had images with motion artifacts, circle placement errors, or segmentation errors (defined as disparity between inner and outer boundaries detected by device and by the examiner), 3 had significant media opacity (cataract), 1 had pigment epithelium detachment, and 1 had a tilted disc. These 19 were excluded from the study. One eye of another subject, which had been enucleated because of previous trauma, was also excluded. The remaining 30 participants (59 eyes) were included in our final analysis. Demographic features of the study participants are shown in Table 1.

Table 2 Summary of OCT measurement results

Parameters	SD-OCT	TD-OCT	[a]*P*	SD-OCT/TD-OCT	[b]Correlation coefficient (significance level)
RNFL (μm)					
Average	115.1	98.9	<0.001	1.17	0.68 (*P*<0.001)
Inferior quadrant	142.2	127.1	<0.001	1.12	0.74 (*P*<0.001)
Superior quadrant	134.4	121.2	<0.001	1.11	0.73 (*P*<0.001)
Nasal quadrant	104.3	77.4	<0.001	1.35	0.57 (*P*<0.001)
Temporal quadrant	78.7	70.1	<0.001	1.16	0.60 (*P*<0.001)
Retinal thickness (μm)					
CFT	179.5	153.2	<0.001	1.17	0.42 (*P*=0.001)
Center circle (CRT)	204.5	196.7	0.003	1.04	0.67 (*P*<0.001)
Superior inner	283.5	277.9	0.002	1.02	0.76 (*P*<0.001)
Nasal inner	274.6	277.7	0.06	0.99	0.80 (*P*<0.001)
Inferior inner	282.2	276.9	<0.001	1.02	0.85 (*P*<0.001)
Temporal inner	272.5	271.9	0.57	1.00	0.74 (*P*<0.001)
Superior outer	261.9	236.8	<0.001	1.11	0.58 (*P*<0.001)
Nasal outer	278.1	248.7	<0.001	1.12	0.61 (*P*<0.001)
Inferior outer	261.5	236.7	<0.001	1.10	0.12 (*P*=0.37)
Temporal outer	251.4	228.9	<0.001	1.10	0.30 (*P*=0.02)

[a]Paired samples *t*-test; [b]Pearson correlation test. RNFL: Retinal nerve fiber layer; CRT: Central retinal thickness; CFT: Central foveal thickness.

The mean average RNFL thickness values were 98.9±11.1 μm and 115.1 ±9.6 μm with the Stratus OCT and OPKO/OTI OCT, respectively. In all quadrants, the RNFL thicknesses measured by OPKO/OTI OCT were significantly thicker than those measured by Stratus OCT, including average RNFL (Table 2). The mean central foveal thickness (CFT) values were 153.2±16.8 μm and 179.5±24.7 μm with Stratus OCT and OPKO/OTI OCT, respectively. The retinal thickness values measured by OPKO/OTI OCT were significantly thicker than those measured by Stratus OCT in all sectors, except the nasal inner and temporal inner sectors (Table 2). Figures 1 and 2 give the corresponding Bland-Altman plots comparing the average RNFL and CFT values. The average RNFL thickness measured by OPKO/OTI OCT was 16.2 ±SD μm greater than that measured by Stratus OCT, with 95% limits of agreement being -0.3 to 32.7 μm. The differences between corresponding CFT measures had a mean of 7.8±SD μm, and a 95% limits of agreement within -14.7 to 30.3 μm.

Table 3 presents the mean of the first and second measurements, as well as the coefficient of variation (COV) values. The lowest COV was for the OPKO/OTI OCT average RNFL measurement and the highest COV was for the Stratus OCT CRT measurement.

The RNFL thickness values measured by the two devices were correlated in all quadrants. The highest correlation was for inferior quadrant measurements (r=0.74, P<0.001) and the lowest correlation was for nasal quadrant measurements (r=0.57, P<0.001). The retinal thickness values measured by the two devices were correlated in all sectors except the inferior outer sector. The highest correlation was for the inferior inner sector (r=0.85, P<0.001) and the lowest correlation was for the inferior outer sector (r=0.12, P=0.37, Table 2).

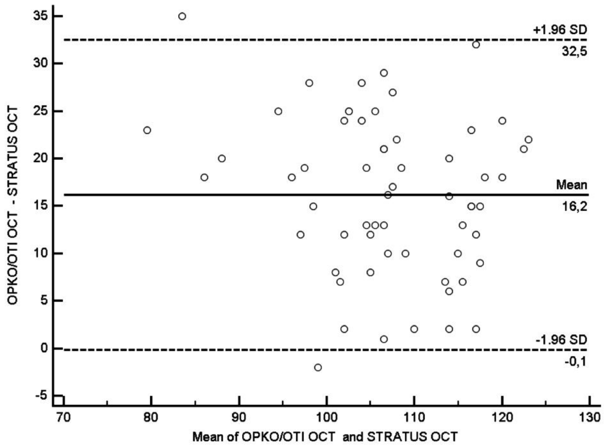

Figure 1 Bland –Altman plots of RNFL thickness measurements with OPKO/OTI OCT and Stratus OCT devices.

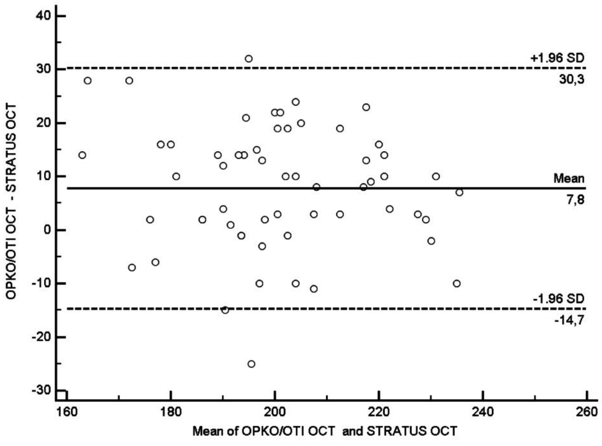

Figure 2 Bland –Altman plots of CRT measurements with OPKO/OTI OCT and Stratus OCT devices.

Table 3 Mean of first and second measurements and intersession repeatability

Parameters	Mean of repeated measurements	COV (%)
Stratus		
RNFL average	98.9±11.1	2.9
RNFL inferior	127.1±15.7	3.4
RNFL superior	121.2±16.7	4.1
RNFL nasal	77.4±17.5	3.7
RNFL temporal	70.1±14.4	3.3
CRT	196.7±16.8	4.6
OPKO/OTI OCT		
RNFL average	115.1±9.6	2.1
RNFL inferior	142.2±16.3	3.6
RNFL superior	134.4±14.2	4.2
RNFL nasal	104.3±14.7	2.9
RNFL temporal	78.7±15.5	3.4
CRT	204.5±17.7	4.2

RNFL: Retinal nerve fiber layer; CRT: Central retinal thickness.

DISCUSSION

In this study, we compared the RNFL and macular thickness measurements by using Stratus OCT and Spectral SLO/OCT devices on healthy volunteers. We observed that RNFL and macular thickness measurements obtained by Stratus OCT correlate well with those from OPKO/OTI OCT. However, there were statistically significant differences between the devices in terms of both RNFL and macular thickness measurements. In all individual quadrants and on average of all quadrants, the RNFL thickness measurements by OPKO/OTI OCT were thicker than those by Stratus OCT. To our knowledge, only one published study compares measurements of RNFL thickness scanned with both Stratus OCT and OPKO/OTI OCT. Pierro *et al* [8] reported higher RNFL thickness measurements with OPKO/OTI OCT compared to Stratus OCT in healthy subjects. Their SD-OCT/TD-OCT ratio was 1.04; the ratio in this study was 1.17. Other studies also compare RNFL thickness measurements between Stratus OCT and other SD-OCTs in healthy subjects[9-14]. In order to be more descriptive, we have summarized reported average RNFL and mean SD-OCT/mean TD-OCT values of those studies in Table 4. Average RNFL thickness measurements with Cirrus HD-OCT, Spectralis, and Topcon 3D OCT 1000 devices in healthy subjects was reported to be less than those obtained from Stratus OCT (SD-OCT/TD-OCT ranges 0.88-0.98). Conversely, RNFL thickness measurements with RTVue, Topcon 3D OCT 2000, NIDEK RS-3000, and OPKO/OTI OCT devices in healthy subjects have been reported to be greater than those obtained by Stratus OCT (SD-OCT/TD-OCT ranges 1.02-1.07).

In our study group, macular thickness measured by OPKO/OTI OCT was thicker than that measured by Stratus OCT. Two previous studies have compared macular thickness scanned with Stratus OCT and OPKO/OTI OCT and both of them reported higher CRT values with OPKO/OTI OCT compared to Stratus OCT in healthy subjects [5,15]. Their SD-OCT/TD-OCT ratio were 1.14 and 1.13; the ratio in the current study was 1.04. Other studies compare Stratus OCT with other spectral domain OCT macular thickness measurements [13,16-18]. Table 5 summarize previously reported central macular thickness measurements and mean SD-OCT/mean TD-OCT values. Similar to our findings, in all reported studies, SD-OCT measured central macular thickness values were greater than those of TD-OCT (SD-OCT/TD-OCT ranges 1.08-1.34).

The Stratus OCT and OPKO/OTI OCT devices differ as to measurement modalities. The OPKO/OTI OCT measures RNFL thickness within a 3.46 mm diameter at the center of the optic disc, whereas the Stratus OCT measures within a diameter of 3.40 mm. Because RNFL thickness decreases the further away it is from the optic disc margin, that difference could not explain the discrepancy.

The segmentation software is different between the Stratus OCT and OPKO/OTI OCT devices. Each device uses the internal limiting membrane (ILM) as the inner boundary for both RNFL and retinal thickness measurements. To obtain an RNFL layer thickness measurement, the Stratus OCT uses the top of the ganglion cell layer as the outer boundary whereas the OPKO/OTI OCT uses the bottom of the fiber layer as the outer boundary. To obtain a retinal thickness measurement, the Stratus OCT uses the inner segment/outer segment junction (IS/OS) as the outer boundary whereas the OPKO/OTI OCT uses the outer retina pigment epithelium (RPE) layer as the outer boundary [15]. The segmentation border difference may be a reason for the discrepancy in macular thickness measurements, but cannot explain the discrepancy in RNFL measurements. We don't have a satisfactory explanation for the fact that some spectral domain devices show higher RNFL thickness than Stratus device whereas some other spectral domain devices show lower RNFL thickness than Stratus device

In this study, we also measured and compared the repeatability indices of the Stratus OCT and the OPKO/OTI OCT devices. We found good repeatability of RNFL and macular thickness measurements for both. The repeatability of both devices' RNFL thickness measurements was observed to be higher than that of macula thickness measurements. Several studies on the repeatability of the Stratus OCT system have been published. Regarding the repeatability of measurements by the Stratus, Paunescu *et al* [7] reported a mean RNFL intraclass correlation coefficients (ICC) of 0.79 and a CMT ICC of 0.88. Budenz *et al* [20] studied 88 normal participants using the Stratus OCT and reported an ICC of 0.98 for repeated mean RNFL measurements. Gurses-Ozden *et al* [21] reported acceptable reproducibility of macular thickness measurements in healthy subjects. Limited data are available on reproducibility of the OPKO/OTI OCT device, but Lee *et al* [22] reported excellent repeatability of the

Table 4 Summary of previous studies comparing SD-OCT and TD-OCT (Stratus) RNFL measurements in healthy subjects

SD-OCT device	Study	Average RNFL thickness (μm)		SD-OCT/TD-OCT (Average RNFL thickness)	*P*
		SD-OCT	TD-OCT		
Cirrus	Sung *et al*[9]	97.30	110.60	0.88	<0.001
Cirrus	Pinilla *et al*[10]	95.50	97.85	0.98	0.003
Cirrus	Knight *et al*[11]	92.00	99.40	0.93	<0.001
Cirrus	Seibold *et al*[12]	98.68	110.10	0.90	<0.001
Cirrus	Pierro *et al*[8]	90.08	99.63	0.90	<0.005
Cirrus	Huang *et al*[13]	101.47	110.74	0.92	<0.001
Spectralis	Shin and Cho[14]	106.38	110.88	0.96	<0.001
Spectralis	Seibold *et al*[12]	106.59	110.10	0.97	<0.001
Spectralis	Pierro *et al*[8]	93.30	99.63	0.94	<0.005
RTVue	Pierro *et al*[8]	103.90	99.63	1.04	<0.005
RTVue	Seibold *et al*[12]	112.78	110.10	1.02	<0.001
Topcon 3-D OCT 1000	Huang *et al*[13]	106.75	110.74	0.96	<0.001
Topcon 3-D OCT 2000	Pierro *et al*[8]	106.51	99.63	1.07	<0.005
NIDEK RS-3000	Pierro *et al*[8]	102.43	99.63	1.03	<0.005
OPKO/OTI OCT	Pierro *et al*[8]	103.58	99.63	1.04	<0.005
OPKO/OTI OCT	Current study	115.30	98.70	1.17	<0.001

Table 5 Summary of previous studies comparing SD-OCT and TD-OCT (Stratus) macular thickness measurements in healthy subjects

SD-OCT device	Study	Average CRT (μm)		SD-OCT/TD-OCT	*P*
		SD-OCT	TD-OCT		
Cirrus	Kakinoki *et al*[17]	258	197	1.31	<0.001
Cirrus	Sull *et al*[18]	262	203	1.29	<0.001
RTVue MM6	Sull *et al*[18]	256	203	1.26	<0.001
Topcon 3-D OCT 1000	Sull *et al*[18]	231	203	1.14	<0.001
OPKO/OTI OCT	Forte *et al*[5]	281	256	1.10	0.003
Cirrus	Huang *et al*[13]	244	191	1.28	<0.001
Topcon 3-D OCT 1000	Huang *et al*[13]	222	191	1.16	<0.001
Spectralis	Wolf-Schnurrbusch *et al*[15]	288	213	1.35	<0.01
OPKO/OTI OCT	Wolf-Schnurrbusch *et al*[15]	243	213	1.14	<0.01
Cirrus HD-OCT	Wolf-Schnurrbusch *et al*[15]	276	213	1.30	<0.01
SOCT Copernicus	Wolf-Schnurrbusch *et al*[15]	246	213	1.16	<0.01
RTVue-100	Wolf-Schnurrbusch *et al*[15]	245	213	1.15	<0.01
RTVue-100	Huang *et al*[16]	209	194	1.08	<0.001
Spectralis	Grover *et al*[19]	271	202	1.34	<0.001
OPKO/OTI OCT	Current study	204	196	1.04	0.003

CRT: Central retinal thickness.

OPKO/OTI OCT RNFL thickness measurements (a CV of 1.9% for average RNFL thickness measurements), and Wolf-Schnurrbusch *et al* [15] found good repeatability of the OPKO/OTI OCT RNFL measurements (a CV of 2.23% for central retinal thickness measurements) [19]. These reported data on repeatability of both devices were comparable with our findings.

The current study has several limitations. First, our study involves a relatively low number of participants. Second, the measurements, although all completed on the same day, were taken at two geographically close but different medical centers. However, in clinical practice, measurements in different centers may need to be assessed together. Third, two different well trained operators were employed in the operation of OCTs, one at each clinic. Nevertheless, image quality and circle placement assessment was carefully performed and those images with quality or circle placement problems were excluded. Fourth, because the study involved only Caucasian subjects with healthy eyes, the results cannot be extrapolated to those of other ethnic backgrounds or to patients with retinal diseases or glaucoma.

In summary, we found good reproducibility of RNFL and retina thickness measurements for both Stratus OCT and OPKO/OTI OCT devices. However, even though the two OCT systems provided statistically correlated results, the values for both RNFL and macular thickness were statistically different: RNFL and macular thickness measurements with the OPKO/OTI OCT were higher than that of the Stratus OCT. These findings prove that the two OCT systems cannot be used interchangeably for the measurements of RNFL and macular thickness.

ACKNOWLEDGEMENTS

The authors appreciate the contributions and editorial assistance made by S. Delacroix.

Conflicts of Interest: Ozkok A, None; **Akkan JCU,** None; **Tamcelik N,** None; **Erdogan M,** None; **Comlekoglu DU,** None; **Yildirim R,** None.

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