Letter

Single Session, Intra-observer Repeatability of an Advanced New Generation Hartmann-Shack Aberrometer in Refractive Surgery Candidates

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Sir,

Recently, a new aberrometer, the iDesign advanced Wavescan studio (Abbott Medical Optics, Santa Ana, CA, USA) has been launched for commercial use. This device is considered as a new, upgraded and more sensitive version of the Wavescan aberrometer (Abbott Medical Optics, Santa Ana, CA, USA). It has five times greater resolution, encompassing over 1,250 data points through a 7.0-mm pupil as compared to 240 points for the Wavescan.[1] However, it remains to be seen if this increase in sensitivity would hamper instrument repeatability by picking up extra signal noise, especially during testing of wavefront aberrations, which are variable to some extent.

In this consecutive case series, we measured the single user, single session repeatability of wavefront and other anterior segment measurements by iDesign in 100 refractive surgery candidates with no ocular morbidity except for refractive errors.

The study had institutional review board approval and followed all tenets of the Declaration of Helsinki. Informed consent was obtained from all candidates.

All candidates underwent a detailed evaluation and those with topographically evident keratoconus, dry eye, any previous surgical intervention in the eye or corneal scars/irregularity were excluded.

All measurements were obtained by a single experienced user (DS) on the iDesign aberrometer. The candidates waited in the dedicated examination room for 30 minutes with eyes closed and the room lights shut off. Then the tests were carried out in dark room conditions. A five-minute rest with the eyes closed was given between each measurement. The data is then analyzed by the instrument software, which looks for usable iris registration, wavefront data, and corneal topography data. The review screen shows a green icon for all these three data when measurements are practical for treatment or analysis. Three such consecutive 'good' measurements were taken. The right eyes were used for analysis. The data were noted and analyzed for a 6-mm pupil diameter. Even though the machine provides output till 6th order aberrations for individual polynomials, the analysis was limited up to the 4th order to maintain clinical relevance and ease of interpretation as beyond 4th order, most values were exceedingly low. Polar Zernike coefficients were used for the study. All data was then transferred as jpeg images and manually entered into an MS Excel (Microsoft, Richmond, VA, USA) sheet. The data was then transferred to SPSS software version 16.0 (SPSS Inc., Chicago, IL, USA) for analysis.

Mean and standard deviation of data for the three measurements (of 100 eyes) as well as the pooled data ($n = 300$) were derived. Analysis of variance was used to evaluate differences among the three measurements. The intra-subject variation was assessed by the parameters described by Altman and Bland, including intra-subject standard deviation (Sw) of the three consecutive measurements, intra-subject precision (1.96 × Sw) and intra-subject repeatability (2.77 × Sw).[2]

The means, standard deviations, 95% confidence intervals of means and the range of data are detailed in Table 1. Mean values for measurement in the three groups were comparable (ANOVA $P > 0.05$ for all measurements, Table 1). Intra-subject standard deviation (Sw), repeatability and precision values are presented in Table 2. The intraobserver Sw was 0.25 diopter (D) for sphere and 0.08 D

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Table 1. The means, standard deviation, 95% confidence interval of means and the range of data

Parameter	Measurments*	Mean	SD	ANOVA (*P*)	95% CI for mean		Range	
					Lower bound	Upper bound	Minimum	Maximum
Sphere	Number 1	−3.75	2.94	0.9	−4.31	−3.19	−11.01	1.97
	Number 2	−3.78	2.95		−4.34	−3.23	−11.08	2
	Number 3	−3.76	2.93		−4.32	−3.21	−11	2.08
	Pooled	−3.77	2.94		−4.08	−3.45	−11.08	2.08
Cylinder	Number 1	−0.99	1.04	0.9	−1.19	−0.8	−5.3	−0.08
	Number 2	−1	1.03		−1.2	−0.81	−5.14	−0.04
	Number 3	−0.99	1.01		−1.19	−0.8	−5.01	0.04
	Pooled	−1	1.02		−1.11	−0.89	−5.3	0.04
Refraction axis	Number 1	85.91	66.87	0.9	73.27	98.56	0	179
	Number 2	85.9	66.74		73.29	98.52	0	180
	Number 3	86.05	67.59		73.45	98.62	1	179
	Pooled	85.95	66.13		78.74	93.16	0	180
White to white measurement	Number 1	12.06	0.36	0.9	11.99	12.12	11.3	13.1
	Number 2	12.05	0.35		11.98	12.12	11.4	13
	Number 3	12.06	0.35		12	12.13	11.2	13.1
	Pooled	12.06	0.35		12.02	12.09	11.2	13.1
Scotopic pupil diameter	Number 1	6.47	0.94	0.8	6.3	6.65	4.2	8.9
	Number 2	6.52	0.93		6.34	6.69	4.1	8.9
	Number 3	6.53	0.89		6.36	6.69	4.3	8.9
	Pooled	6.51	0.92		6.41	6.6	4.1	8.9
Total (lower + higher order) RMS	Number 1	4.81	3.09	0.9	4.23	5.39	0.4	13.2
	Number 2	4.87	3.11		4.28	5.46	0.27	13.4
	Number 3	4.91	3.1		4.33	5.5	0.26	13.2
	Pooled	4.86	3.09		4.53	5.2	0.26	13.4
Higher order RMS	Number 1	0.38	0.17	0.4	0.35	0.41	0.08	1.05
	Number 2	0.37	0.16		0.34	0.4	0.14	0.99
	Number 3	0.35	0.15		0.33	0.38	0.12	1.03
	Pooled	0.37	0.16		0.35	0.38	0.08	1.05
Defocus (Z02)	Number 1	4.61	3.23	0.9	4	5.22	−1.54	13.19
	Number 2	4.66	3.25		4.05	5.28	−1.61	13.23
	Number 3	4.7	3.25		4.09	5.31	−1.58	13.19
	Pooled	4.66	3.23		4.31	5.01	−1.61	13.23
Astigmatism (Z±22)	Number 1	0.71	0.7	0.9	0.57	0.84	0.06	3.16
	Number 2	0.72	0.72		0.59	0.86	0.03	3.41
	Number 3	0.69	0.68		0.57	0.82	0.01	3.27
	Pooled	0.71	0.7		0.63	0.78	0.01	3.41
Coma (Z±13)	Number 1	0.19	0.09	0.8	0.17	0.2	0.02	0.43
	Number 2	0.19	0.09		0.17	0.21	0.01	0.42
	Number 3	0.18	0.09		0.16	0.2	0.02	0.39
	Pooled	0.19	0.09		0.18	0.2	0.01	0.43
Trefoil (Z±33)	Number 1	0.15	0.08	0.9	0.13	0.16	0.01	0.37
	Number 2	0.15	0.08		0.13	0.16	0.02	0.39
	Number 3	0.14	0.08		0.13	0.16	0.02	0.41
	Pooled	0.15	0.08		0.14	0.15	0.01	0.41
Spherical aberration (Z04)	Number 1	0.03	0.11	0.9	0.01	0.05	−0.14	0.43
	Number 2	0.04	0.11		0.02	0.06	−0.16	0.47
	Number 3	0.04	0.1		0.02	0.06	−0.18	0.53
	Pooled	0.04	0.11		0.02	0.05	−0.18	0.53

Contd...

Table 1. Contd...

Parameter	Measurments*	Mean	SD	ANOVA (*P*)	95% CI for mean		Range	
					Lower bound	Upper bound	Minimum	Maximum
Second order astigmatism (Z±24)	Number 1	0.06	0.04	0.6	0.06	0.07	0	0.18
	Number 2	0.06	0.04		0.05	0.07	0	0.16
	Number 3	0.06	0.04		0.05	0.07	0.01	0.17
	Pooled	0.06	0.04		0.06	0.07	0	0.18
Tetrafoil (Z±44)	Number 1	0.06	0.04	0.6	0.05	0.06	0.01	0.15
	Number 2	0.06	0.04		0.05	0.07	0	0.17
	Number 3	0.06	0.04		0.05	0.06	0.01	0.18
	Pooled	0.06	0.04		0.05	0.06	0	0.18

*For measurements Number 1, Number 2, Number 3 n=100 each, for pooled n=300. RMS; Measurements, number 1, number 2, number 3 for the first, second and third measurements respectively and pooled for the overall data. K1, flatter meridian; K2, steeper meridian; CI, confidence interval; SD, standard deviation; RMS, root mean square; ANOVA, analysis of variance

Table 2. Measures of repeatability for all the parameters analyzed for the new aberrometer

	Pooled mean	Pooled SD	Sw	CoVar (Sw/mean)	Intra subject precision 1.96×Sw	Intra subject repeatability 2.77×Sw	ICC	ICC 95% limits (lower-upper)
Sphere	−3.77	2.94	0.25	0.07	0.49	0.7	0.999	0.998–0.999
Cylinder	−1	1.02	0.08	0.08	0.15	0.21	0.995	0.994–0.997
Axis	85.95	66.53	1.66	0.02	3.25	4.60	0.998	0.998–0.999
White to white	12.06	0.35	0.11	0.01	0.21	0.3	0.956	0.940–0.969
Scotopic pupil diameter	6.51	0.92	0.43	0.07	0.85	1.19	0.972	0.962–0.980
Total RMS	4.86	3.09	0.76	0.16	1.49	2.11	0.995	0.993–0.997
HOA-RMS	0.37	0.16	0.18	0.49	0.35	0.49	0.919	0.889–0.942
Defocus (Z20)	4.66	3.23	0.7	0.15	1.36	1.93	0.996	0.995–0.997
Astigmatism (Z22)	0.71	0.7	0.22	0.31	0.43	0.61	0.979	0.972–0.985
Coma (Z31)	0.19	0.09	0.05	0.26	0.11	0.15	0.936	0.912–0.954
Trefoil (Z32)	0.15	0.08	0.06	0.40	0.12	0.18	0.893	0.853–0.924
Spherical aberration (Z40)	0.04	0.11	0.06	1.50	0.12	0.18	0.97	0.958–0.978
Second order astigmatism (Z42)	0.06	0.04	0.03	0.50	0.06	0.09	0.823	0.758–0.874
Tetrafoil (Z44)	0.06	0.04	0.03	0.50	0.06	0.09	0.776	0.693–0.840

Pooled standard deviation, measure for the overall spread in data. Sw, measure for the spread in the same parameter in the same eye measured by the device. RMS; Measurements, number 1, number 2, number 3 for the first, second and third measurements respectively and pooled for the overall data. K1, flatter meridian; K2, steeper meridian; Sw, intrasubject standard deviation; ICC, intraclass correlation; CoVar, coefficients of intra-subject variation; SD, standard deviation; HOA, higher order aberration; RMS, root mean square

for cylinder. The intraobserver Sw was less than 0.07 for all higher order aberration (HOA) terms. Intrasubject variation in the precision and repeatability were dependent on Sw and therefore showed similar trends [Table 2]. Coefficients of intra-subject variation (CoVar) were worst for spherical aberration [Table 2]. Sphere and cylinder had good, low CoVar values [Table 2].

Wavefront aberrometry is a sensitive tool and intra-user repeatability is an important step in the assessment of the device. Intra-subject standard deviation was low for lower order terms and 95% of the data was computed to be within 0.5 D for sphere, 0.15 D for cylinder and 3.25 degrees of each other. Wang et al also noted that the standard deviation for Wavescan was 0.29 D for sphere and 0.16D for cylinder.[3] Mean spherical equivalent (SEQ) in their study was lower (-2.86 D for virgin corneas and -0.27 D for post excimer laser corneas) as compared to our mean SEQ(-4.2 D). However, the intraclass correlations in our study were better for iDesign as compared to the Wavescan data from the previous study. For iDesign, sphere and cylinder were 0.999 and 0.995 D, as compared to 0.992 and 0.902 D, respectively, by Wavescan. This is perhaps on expected lines, as iDesign is claimed to be a more advanced version of the Wavescan.[1]

López-Miguel et al evaluated the repeatability of Topcon KR-1W for 75 eyes.[4] The 95% data for Sw was 0.40 D for spherical error and 0.26 D for astigmatism in their study. The intraclass correlation coefficients (ICCs) for auto-refraction limits of agreement (LOA) terms were not provided in the study. For wavefront data, the ICC for total ocular HOA root mean square (HOARMS) was 0.902 at 6.0 mm pupil with Topcon KR-1W.[4] In another study, López-Miguel et al evaluated the Zywave aberrometer (Bausch and Lomb, Rochester, NY, USA).[5] The ICC for total HOA and HOARMS was 0.99 and 0.96, respectively, for Zywave at 6.0 mm pupil.

Compared to the aforesaid studies, our findings revealed an ICC of 0.995 for total ocular RMS and 0.919 for ocular HOARMS at 6.0 mm pupil for the iDesign. Even though these studies were performed on different populations, the ICC values being tighter for iDesign provide a perspective towards good repeatability with iDesign.

There are certain shortcomings in the present study. The non-comparative nature of the study, and the fact that we have not compared our data to Wavescan limit interpretation of our results. However, on its own, this study establishes that the iDesign demonstrates good performance in terms of single session, intra user repeatability for anatomical, refractive and wavefront parameters and seems to be better in some aspects as compared to its predecessor, the Wavescan. A future study comparing Wavescan and iDesign head to head will be advantageous.

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Nil.

Conflicts of Interest

There are no conflicts of interest.

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