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ORIGINAL ARTICLE

Intra- and Intersession Repeatability of a Double-Pass Instrument

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ABSTRACT

Purpose. To evaluate the intra- and intersession repeatability of the optical quality parameters provided by the Optical Quality Analysis System (OQAS), which is based on the double-pass technique.

Methods. We performed optical quality measurements using the OQAS on 20 eyes of 10 healthy subjects who had best spectacle-corrected visual acuity of 20/20 or better. Measurements were performed by the same examiner in three different sessions that were separated by 10-min intervals. The subject's eye was realigned at the beginning of each session. During each session, three consecutive measurements were taken without realignment. The following optical quality parameters were analyzed: the modulation transfer function cutoff frequency (MTF_{cutoff}), the $Strehl^{2D}$ ratio, the OQAS values (OV) at contrasts of 100%, 20%, and 9%, and the objective scatter index (OSI).

Results. The mean coefficients of repeatability obtained for the first session were 4.51 (MTF_{cutoff}), 0.049 ($Strehl^{2D}$ ratio), 0.15 (OV 100%), 0.21 (OV 20%), 0.28 (OV 9%), and 0.11 (OSI), which were similar to those found in the second and third sessions. The confidence limits in the Bland and Altman charts when the intrasession repeatability was assessed (in a comparison of the first and second measurements of the first session) ranged from −3.16 to 3.94 (MTF_{cutoff}), −0.060 to 0.069 ($Strehl^{2D}$ ratio), −0.12 to 0.18 (OV 100%), −0.20 to 0.23 (OV 20%), −0.29 to 0.27 (OV 9%), and −0.12 to 0.13 (OSI). The same limits when the intersession repeatability was assessed (in a comparison of the first and second sessions) ranged from −5.30 to 5.49 (MTF_{cutoff}), −0.054 to 0.050 ($Strehl^{2D}$ ratio), −0.17 to 0.17 (OV 100%), −0.22 to 0.19 (OV 20%), −0.26 to 0.29 (OV 9%), and −0.12 to 0.13 (OSI).

Conclusions. Our findings showed that OQAS is a clinical instrument with a good intra- and intersession repeatability and that the realignment of the eye does not introduce any additional variability in the measurements.
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Key Words: optical quality, intraocular scattering, double-pass technique, repeatability

As the proficiency of ophthalmic surgery continues to improve, new methods to characterize and describe optical quality are needed to differentiate outcomes for these procedures. In this context, new ophthalmic instruments have become common in clinical practice, such as aberrometers and newer devices based on the double-pass technique. This technique[1] is based on recording images from a point-source object reflected from the retina after passing through the ocular media twice.

The Optical Quality Analysis System (OQAS, Visiometrics S.L., Spain)[2] is a double-pass based instrument for clinically measuring objective optical quality. The OQAS is based on the asymmetric scheme of the double-pass technique, i.e., with different entrance and exit pupil sizes, enabling the detection of both symmetric and asymmetric aberrations. Asymmetric aberrations such as coma cannot be measured by a conventional symmetric double-pass system.[3] The OQAS also incorporates features that are adapted for routine measurements in clinical practice. In addition to optical quality measurements, the system also provides an objective estimation of intraocular scattering.[4]

This system has been used to clinically evaluate pre- and postoperatively the optical quality of patients undergoing keratorefractive and phakic Intraocular Lens (IOL) surgery, as well as conventional and microincision cataract surgery.[5–7] Furthermore, this technique has been shown to be a useful tool for assessing retinal image quality in patients with keratitis[8] and nuclear cataracts,[9] evaluating presbyopia after photorefractive keratectomy,[10] examining the temporal changes in the modulation transfer function (MTF) of the eye after a blink,[11] and studying the *in vitro* optical quality of foldable monofocal intraocular lenses.[12]

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Recently, some authors studied the repeatability of three optical quality parameters provided by OQAS measured in the same session[13]: the objective scatter index (OSI), the MTF cutoff frequency (MTF_{cutoff}), and the $Strehl^{2D}$ ratio. The authors found good intrasession repeatability limits (close to 30%) in a control group of patients, a postrefractive surgery group, and a cataract group. However, the repeatability of some other optical quality parameters provided by the OQAS system, such as the repeatability of OQAS values (OV) at contrasts of 100%, 20%, and 9%, has not been established. Furthermore, no studies have compared the within-session repeatability (with no repositioning of the subject or realignment of the eye) and between-session repeatability (which implies repositioning the subject and realigning the eye). Such studies are essential, as clinical assessments are often made in different sessions. In this study, we analyzed the variability of the parameters provided by the double-pass instrument when optical quality measurements and scattered light estimations were made in subjects with good vision. We analyzed and compared the results obtained within (intra) and between (inter) sessions.

METHODS

Subjects

This prospective study was conducted on healthy subjects recruited from the staff and students of the School of Optics and Optometry of the Universitat Politècnica de Catalunya (UPC). Subjects with best spectacle-corrected visual acuity of 20/20 or better, astigmatic cylinder correction of <0.50 D, no history of any ocular pathology, surgery and/or pharmacological treatment were invited to take part. Contact lens wearers were excluded from participating. Furthermore, only subjects with a pupil diameter of 4 mm or more in mesopic conditions were included in the study because a 4-mm artificial pupil was used in the optical quality measurements. Subjects underwent an ophthalmologic and optometric examination (without cycloplegia) to determine the following: visual acuity with a Bailey-Lovie chart; manifest refractive error; and natural pupil diameter; media opacities (e.g., corneal scar or congenital lens opacity) and tear film abnormality were analyzed at the slitlamp by the same observer. The research followed the tenets of the Declaration of Helsinki. All subjects gave their written informed consent after receiving a written and verbal explanation of the nature of the study.

Ten subjects (20 eyes), five female and five male, were enrolled in the study with a mean ± standard deviation (SD) in age of 23.1 ± 3.5 years (range: 20 to 30 years). The sample size was selected according to values used in similar studies in which the repeatability associated with measurements of optical quality of the eye was assessed.[13–15] The best spectacle-corrected visual acuity of the eyes ranged from −0.02 to −0.30 (logMAR) [−0.15 ± 0.08 (logMAR)]. The spherical manifest refractive error ranged from −0.50 to +0.75 D (+0.23 ± 0.35 D), the cylinder from −0.25 to 0.00 D (−0.10 ± 0.12 D), and the spherical equivalent from −0.63 to + 0.75 D (+0.19 ± 0.37 D). The natural pupil diameter, provided by the OQAS from an image of an additional video camera that allow pupil alignment, varied from 4.5 to 6 mm (5.3 ± 0.5 mm).

Optical Quality Parameters

Retinal image quality was measured by means of the OQAS for a 4-mm artificial pupil with the subject's retinal image optimally focused. The spherical refractive error was automatically measured and corrected by the double-pass system by means of a motorized optometer within a range of −8.00 to +6.00 D. External cylindrical lenses are required for astigmatism >0.50 D. The size of the artificial pupil is controlled by means of a diaphragm wheel located inside the double-pass system. Room illumination was kept low during testing.

The double-pass system provided the retinal image corresponding to a point-source object in near-infrared light consisting of a laser diode ($\lambda = 780$ nm) coupled to an optical fiber. From the retinal image of each analyzed eye, the monochromatic MTF was computed. The MTF represents the loss of contrast as a function of the spatial frequency. A two-dimensional radially averaged profile of the MTF is used to describe the complete eye's optical quality in the double-pass instrument. To simplify the data and facilitate the clinical comparison of retinal image quality between subjects, the system provides several parameters that are related to the MTF: the MTF_{cutoff}, the $Strehl^{2D}$ ratio, and the OVs at contrasts of 100%, 20%, and 9%.

The MTF_{cutoff}[13] is calculated as that corresponding to a 0.01 MTF value, because there is a certain level of background noise in the MTF profile that is computed from the real recorded double-pass image. It is normally assumed that a cutoff frequency of 30 cycles per degree (c/deg) in the Contrast Sensitivity Function corresponds to a visual acuity measurement of 20/20.[16]

In the visual optics field, the Strehl ratio[17] is often computed in the frequency domain as the ratio between the volume under the MTF curve of the measured eye and that of the aberration-free eye.[18,19] This provides overall information on the eye's optical quality. The double-pass system computes the Strehl ratio in two dimensions ($Strehl^{2D}$ ratio) as the ratio between the area under the MTF curve of the measured eye and that of the aberration-free eye. This computation has a lower cost in time, which makes it more suitable for clinical practice. A Strehl ratio of 1 is related to a perfect optical system that is only limited by diffraction.

The three OVs are normalized values of three spatial frequencies, which correspond to MTF values that describe the optical quality of the eye for three contrast conditions, commonly used in ophthalmic practice[5]: 100% (OV 100%), 20% (OV 20%), and 9% (OV 9%). These values can be used to obtain more specific information on the performance of the eye's optics at different contrasts, which may remain hidden when more global parameters, such as the Strehl ratio, are considered. Specifically, OV 100% is directly related to the MTF cutoff frequency (it is the MTF cutoff frequency divided by 30 c/deg) and, therefore, to the patient's visual acuity, although it is not affected by retinal and neural factors. OV 20% and OV 9% are computed in the same way from smaller frequencies that are linked to 0.05 and 0.1 MTF values, respectively, which maintain the proportion of contrasts of 20% and 9%.

The system also quantifies intraocular scattered light from the double-pass image by means of the OSI parameter.[13,20–22] OSI is computed as the ratio of the amount of light within an annular area of 12 and 20 min arc and that recorded within 1 min arc of the central peak. Values of OSI below 1 are usually linked to eyes with low scattering.

Analysis of Repeatability

The optical quality of the 20 eyes was measured three times in three different sessions. The time between sessions was 10 min. This allowed both intra- and intersession repeatability to be assessed, as has been widely done with other ophthalmic instruments.[23,24] Moreover, the time interval between sessions, during which subjects did not perform any visual task,[25,26] ensured that there were no major changes in the optical quality of the subjects. At the beginning of each session, the subject was properly positioned and the subject's eye that was measured first (which was randomly selected) was aligned with the double-pass system. After that, three consecutive measurements (without repositioning or realignment of the eye) were made. For each measurement, six individual acquisitions from the OQAS system were used to compute the final averaged single double-pass image, as it is mandated by the software. The subject was instructed to remain stationary, to fixate on the internal fixation target, to blink just before the measurement and then to blink freely.

Study was performed in accordance with ISO 5725 standards.[27,28] The environmental temperature and relative humidity were monitored during the experimental measurements using a radio control unit (Oregon Scientific model Bar913HG). The mean temperature was 24.3 ± 0.6°C and the relative humidity was 36.6 ± 0.8%. Illuminance values at the pupil's plane measured with a conventional luxometer was of 23.3 ± 1.4 lx.

In the study, we analyzed the parameters MTF_{cutoff}, the $Strehl^{2D}$ ratio, the OV at contrasts of 100%, 20%, and 9%, and the OSI. The data from the 20 eyes were included for analysis, and the distribution analyzed with the Shapiro-Wilk test. Optical quality data were used for comparisons within the first, second, and third sessions independently (intrasession repeatability) and comparisons between sessions (intersession repeatability).

To determine whether there were intrasession differences, the consecutive measurements that were conducted first, second, and third were compared using repeated measures analysis of variance for each of the three sessions independently (intrasession repeatability). The pair of eyes was included as a factor to control for the intereye correlation. The same analysis was subsequently used to establish statistically significant differences between the averaged results obtained in different sessions, i.e., between the first and second sessions, the first and third sessions, and the second and third sessions (intersession repeatability). The statistical analysis of the data was performed using SPSS software (version 17.0, SPSS, Chicago, IL) for Windows. A p value of 0.05 was considered to be statistically significant.

Then, the intrasession repeatability of each parameter provided by the OQAS was determined using the coefficient of repeatability (COR; 1.96 times the intrasubject SD), which represents the value below which the difference between two repeated measurements from the same session are expected to lie within a probability of 95%. The mean COR for each session was then obtained by adding the square of the individual CORs for each individual eye, and calculating the square root of the mean value.[13,14,23]

The intra- and intersession repeatability for each optical quality parameter was finally assessed by the Bland and Altman method.[29,30] This method plots the mean difference and the corresponding 95% confidence limits (CL), defined as 1.96 times the SD of the mean difference, within which 95% of the differences between measurements are expected to lie. According to this method, the charts that are obtained can be used when the true value is unknown. They can also be used to investigate any relationship in the differences between measurements from the same session or from different sessions. Specifically, to assess intrasession repeatability with this method, we used the first and second measurements and the first and third measurements of the first session. However, to establish intersession repeatability, we compared the mean values of the three consecutive measurements in each session between the first and second sessions and the first and third sessions.

RESULTS

Table 1 shows the mean and SD of the measurements made in the three sessions for each optical quality parameter provided by OQAS. The mean of the intrasubject SD (S_S) is also shown. The values for all the analyzed optical quality parameters showed a normal distribution in the study population ($p > 0.05$).

For each optical quality parameter, the intrasession repeated measures analysis of variance among measurements conducted first, second, and third, indicated that there were no statistically significant differences in any of the three sessions ($p > 0.05$).

To assess the intrasession repeatability, we calculated the mean CORs for the parameters provided by OQAS and for each of the three sessions. These values are given in Table 2. The relative

TABLE 1.
Mean and SD of the measurements performed at the three sessions for the parameters provided by OQAS

	First session		Second session		Third session	
Parameters	Mean ± SD	S_S	Mean ± SD	S_S	Mean ± SD	S_S
MTF_{cutoff} (c/deg)	46.00 ± 4.43	1.86	45.91 ± 5.51	1.78	45.98 ± 4.01	2.14
$Strehl^{2D}$ ratio	0.276 ± 0.035	0.022	0.278 ± 0.033	0.020	0.270 ± 0.035	0.019
OV 100%	1.53 ± 0.15	0.06	1.53 ± 0.18	0.05	1.53 ± 0.13	0.08
OV 20%	1.63 ± 0.20	0.10	1.64 ± 0.23	0.10	1.62 ± 0.17	0.10
OV 9%	1.71 ± 0.21	0.13	1.70 ± 0.21	0.12	1.66 ± 0.18	0.10
OSI	0.32 ± 0.13	0.05	0.32 ± 0.14	0.05	0.35 ± 0.13	0.04

The mean of the intrasubject SD (S_S) is also shown.

TABLE 2.
Mean intrasession COR for the parameters provided by OQAS (c/deg)

Parameters	First session	Second session	Third session
MTF_{cutoff} (c/deg)	4.51 (9.8%)	3.92 (8.5%)	4.78 (10.4%)
$Strehl^{2D}$ ratio	0.049 (17.8%)	0.048 (17.3%)	0.043 (15.9%)
OV 100%	0.15 (9.8%)	0.13 (8.5%)	0.16 (10.4%)
OV 20%	0.21 (12.9%)	0.21 (12.8%)	0.23 (14.2%)
OV 9%	0.28 (16.4%)	0.27 (15.9%)	0.23 (13.9%)
OSI	0.11 (34.4%)	0.13 (40.6%)	0.11 (31.4%)

TABLE 3.
Results from the Bland and Altman analysis for the first session (intrasession repeatability)

	Between first and second measurements		Between first and third measurements	
Parameters	$Mean_d$	CL	$Mean_d$	CL
MTF_{cutoff} (c/deg)	0.39	−3.16 to 3.94	−0.30	−5.45 to 4.85
$Strehl^{2D}$ ratio	0.004	−0.060 to 0.069	−0.010	−0.080 to 0.060
OV 100%	0.03	−0.12 to 0.18	−0.01	−0.18 to 0.16
OV 20%	0.03	−0.20 to 0.23	−0.04	−0.22 to 0.19
OV 9%	−0.01	−0.29 to 0.27	−0.08	−0.34 to 0.30
OSI	−0.01	−0.12 to 0.13	0.04	−0.09 to 0.14

Mean of the differences ($mean_d$) and corresponding 95% CL for the first and second measurements. The first and third measurements are also given.

repeatability as a percentage of the mean absolute values is also reported in this Table.

Table 3 gives the mean of the differences ($mean_d$) and the corresponding 95% CL for the parameters provided by OQAS within the first session, when the first and second measurements, and the first and third measurements are compared (Bland and Altman method).

Because no statistically significant differences were observed among the three consecutive measurements performed in any of the three sessions, a repeated measures analysis of variance was performed between the sessions. We found that there were no statistically significant differences in any of the parameters when the mean results of different sessions were compared, i.e., between the first and second sessions, the first and third sessions, and the second and third sessions ($p > 0.05$).

Finally, Table 4 shows the results obtained for each parameter when the Bland and Altman method was used to compare different sessions. In this case, we took into account the mean values of the three consecutive measurements in each session. Specifically, this method was used to compare the first and second sessions and the first and third sessions.

As an example of the methodology used in this study and the results, Fig. 1 illustrates the Bland and Altman plots for the parameters provided by OQAS when the first and second sessions are compared.

TABLE 4.
Results from the Bland and Altman analysis between sessions (intersession repeatability)

	Between first and second sessions		Between first and third sessions	
Parameters	$Mean_d$	CL	$Mean_d$	CL
MTF_{cutoff} (c/deg)	0.09	−5.30 to 5.49	0.02	−4.52 to 4.57
$Strehl^{2D}$ ratio	−0.002	−0.054 to 0.050	0.006	−0.070 to 0.082
OV 100%	0.00	−0.17 to 0.17	0.00	−0.14 to 0.14
OV 20%	−0.02	−0.22 to 0.19	0.01	−0.20 to 0.22
OV 9%	0.01	−0.26 to 0.29	0.05	−0.30 to 0.34
OSI	0.00	−0.12 to 0.13	−0.02	−0.15 to 0.10

Mean of the differences ($mean_d$) and the corresponding 95% CL for the first and second sessions, and for the first and third sessions are given.

DISCUSSION

Objective optical quality measurements performed with a double-pass system have been demonstrated to be useful in several clinical applications. Therefore, the repeatability of these measurements, specifically those made by means of the OQAS instrument, becomes a fundamental issue. In this study, we analyzed the intra- and intersession repeatability of this instrument, and highlighted the influence on the results of repositioning the patient and realigning the eye.

The mean values found for the parameters provided by the OQAS related to optical quality and intraocular scattering, i.e., the MTF_{cutoff} (45.96 c/deg), the $Strehl^{2D}$ ratio (0.275), the OV 100% (1.53), OV 20% (1.63), and OV 9% (1.69), and the OSI (0.33), suggested that there was a good optical quality in all the eyes, as expected considering the characteristics of the population included in the study. These results are slightly better than those found by Saad et al.[13] for a control group of eight subjects aged <30 years [MTF_{cutoff} (39.44 c/deg), $Strehl^{2D}$ ratio (0.234), and OSI (0.47)]. Moreover, the mean values obtained for the parameters in each of the three sessions are close to each other, which demonstrates a high degree of repeatability of the instrument.

Regarding intrasession repeatability, the results for all parameters showed no within-session statistically significant differences in any of the three sessions, when we compared the variance in the measurements performed first, second, and third. This suggests that repetitions of the measurements do not affect the final results, and that the variability of the instrument is kept constant over time.

The three mean intrasession COR values obtained for each of the three sessions (Table 2) were similar and good for all the optical quality parameters. In the context of measuring individual eyes, a repeatability of 50% is often selected as the highest acceptable value for metrological purposes in biology.[14] The best CORs were obtained for the parameters MTF_{cutoff} and OV 100%, which are directly related to each other. In contrast, slightly higher percentages of repeatability were linked to OVs with smaller contrasts (20 and 9%). All OV parameters are computed from the MTF profile provided by the OQAS system at different normalized frequencies

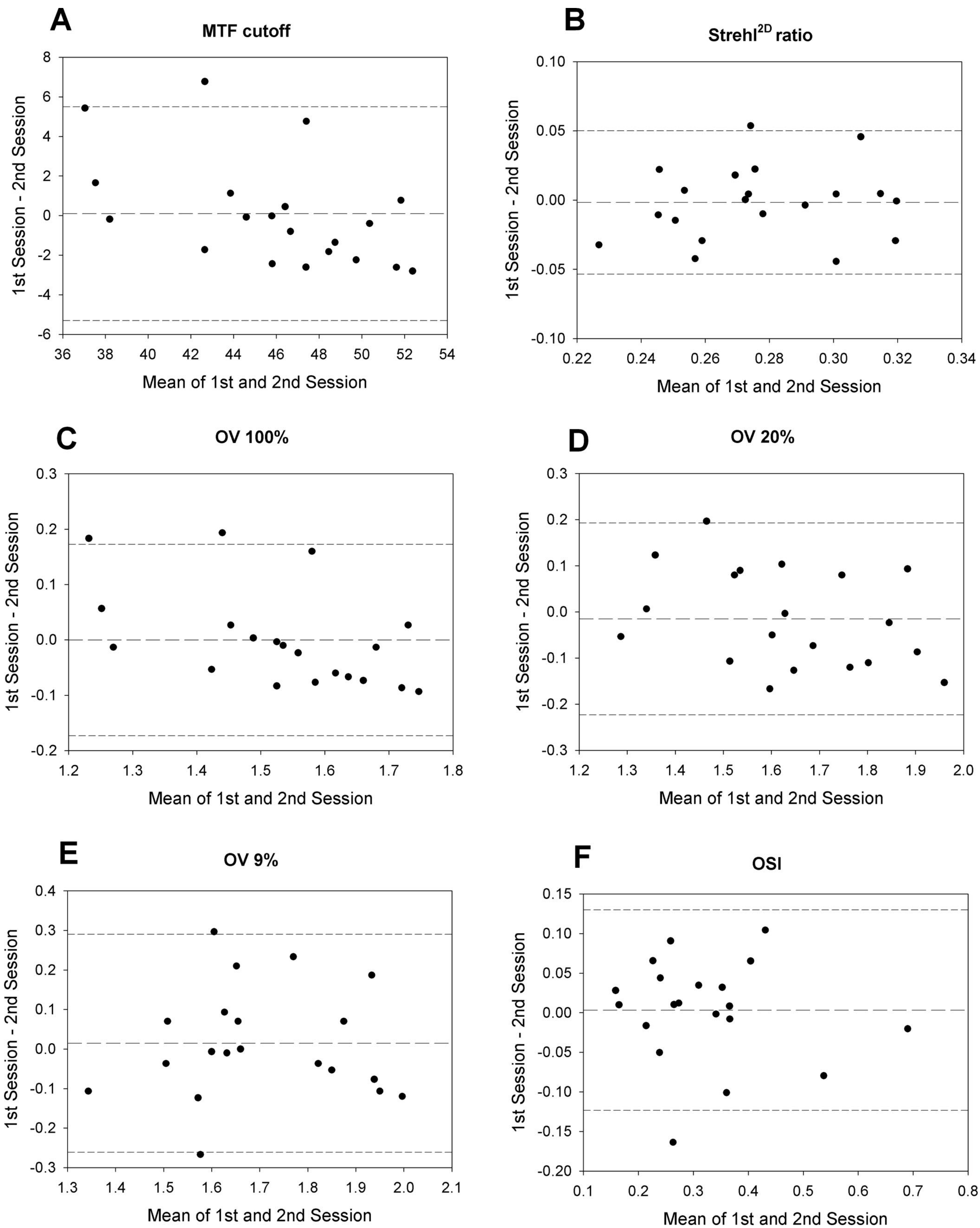

FIGURE 1.

Plots showing the mean of the differences ($mean_d$) and the corresponding 95% CL when the first and second sessions were compared for each parameter provided by (A) OQAS: MTF_{cutoff}, (B) the $Strehl^{2D}$ ratio, (C) OV 100%, (D) OV 20%, (E) OV 9%, and (F) OSI.

(smaller contrasts are related to lower frequencies). Hence, it can be concluded from the results that the variability of this function in the double-pass system is greater at lower frequencies. The $Strehl^{2D}$ ratio and the OSI parameter in particular are associated with larger COR percentages, as both parameters have mean absolute values closer to 0. The repeatability error is not as large for the $Strehl^{2D}$ ratio as it is in the case of OSI. The first parameter is calculated from the integration of the whole MTF profile divided by the area under the MTF curve of the aberration-free eye. The OSI is computed from the ratio between the light recorded inside an external annular region of the double-pass image and that recorded closer to the peak. Consequently, $Strehl^{2D}$ ratio is less affected by local variations of the MTF curve at specific spatial frequencies. However, variations of the amount of light in the double-pass image, especially in external regions of the image, could probably have a great impact on the OSI. The results are slightly better than those previously found by Saad et al.,[13] who performed 20 consecutive measurements with realignment of the eye between each measurement to assess the repeatability of the double-pass system [MTF_{cutoff} (24.2%), $Strehl^{2D}$ ratio (22.6%), and OSI (56.1%)].

According to the Bland and Altman method, the mean differences in comparisons (Table 3) within the first session, i.e., using the first and second measurements and the first and third measurements, are close to 0. Relatively small 95% CL were found for all parameters, which suggest that the instrument is repeatable over time when consecutive measurements are taken, if the subject is not repositioned and the eye is not realigned. However, when the first and third measurements were compared, some of the optical quality parameters showed slightly larger 95% CL than when the first and second measurements were considered.

The small variability between measurements in the same session, which mainly occurred when they were more distant in time, can be attributed not only to the instrument but also to small misalignments of the instrument and the eye, and to changes that occur in the eye during the measurements. Microfluctuations of accommodation, instability of the tear film, or small fixational eye movements can directly affect the short-term variability of ocular aberrations.[31] With the OQAS, any final single optical quality measurement is obtained from the averaging of six independent consecutive measurements, each of which takes about 240 ms because the instrument waits until a good image is acquired. Furthermore, the subjects blink freely during the measurements. Therefore, the noise sources can be mainly attributed to microfluctuations of accommodation and fixation movements, rather than to the tear film.

Moreover, it can be seen that larger 95% CL are related to OV 20% and OV 9% parameters when they are compared with the same parameter analyzed at 100% of contrast. This agrees with previous COR results obtained for these optical quality parameters.

However, no statistically significant differences were observed when different sessions were compared. Therefore, the measurements taken with the instrument are rather constant over time, even if the patient is repositioned and the eye realigned.

The Bland and Altman analysis performed between different sessions (Table 4, Fig. 1), specifically when the first and second sessions and the first and third sessions were compared, reported mean differences that were similar to 0 and relatively small 95% CL. Moreover, the mean differences and the 95% CL obtained between different sessions and within the first session are comparable. This suggests that the intra- and intersession repeatability of the instrument is similar, and that the repositioning of the subject and the realignment of the eye between sessions do not introduce any additional variability in the measurements.

The results found in this study suggest that OQAS is a clinical double-pass instrument with good intra- and intersession repeatability over time. Further studies are required to analyze repeatability of this instrument in eyes with worse optical quality such as with substantial refractive errors, keratoconus, or a history of corneal refractive surgery.

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