·Clinical Research·

Evaluation of patient visual comfort and repeatability of refractive values in non-presbyopic healthy eyes

Francisco Segura[1,2], *Ana Sanchez-Cano*[2,3], *Carmen Lopez de la Fuente*[2,3], *Lorena Fuentes-Broto*[2,4], *Isabel Pinilla*[1,2,5]

[1]Department of Surgery, Gynaecology and Obstetrics, University of Zaragoza, Zaragoza 50009, Spain
[2]Aragon Health Sciences Institute, University of Zaragoza, Zaragoza 50009, Spain
[3]Department of Applied Physics, University of Zaragoza, Zaragoza 50009, Spain
[4]Department of Physiology and Pharmacology, University of Zaragoza, Zaragoza 50009, Spain
[5]Department of Ophthalmology, Lozano Blesa University Hospital, Zaragoza 50009, Spain
Correspondence to: Isabel Pinilla. Department of Ophthalmology, University of Zaragoza, C/Pedro Cerbuna, 12, Zaragoza 50009, Spain. ipinilla@unizar.es
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Abstract

• AIM: To evaluate the intra-operator repeatability in healthy subjects using the WAM-5500 auto-kerato/refractometer and the iTrace aberrometer, to compare the refractive values and the subjective refraction obtained with both devices and to determine which of these three spherocylindrical corrections allows the subject to achieve the best visual comfort.

• METHODS: Forty-two non-presbyopic healthy eyes of 42 subjects were enrolled in this prospective study. Refractive values were compared, evaluating the repeatability, the relationship between the methods and the best visual comfort obtained.

• RESULTS: Sphere, cylinder and axis results showed good intraclass correlation coefficients (ICC); the highest ICC was obtained using the spherical refraction with the autorefractometer and the aberrometer, achieving levels of 0.999 and 0.998, respectively. The power vector (PV) was calculated for each refraction method, and the results indicated that there were no statistically significant differences between them (*P*>0.05). Direct comparison of PV measurements using the three methods showed that aberrometer refraction gave the highest values, followed by the subjective values; the autorefractometer gave the lowest values. The subjective method correction was most frequently chosen as the first selection. Equal values were found for the autorefractometer and the aberrometer as the second selection.

• CONCLUSION: The iTrace aberrometer and the WAM-5500 auto-kerato/refractometer showed high levels of repeatability in healthy eyes. Refractive corrections with the aberrometer, the autorefractometer and subjective methods presented similar results, but spherocylindrical subjective correction was the most frequently selected option. These technologies can be used as complements in refractive evaluation, but they should not replace subjective refraction.

• KEYWORDS: repeatability; optical correction; aberrometer; autorefractometer; subjective refraction
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INTRODUCTION

There are many techniques for establishing the best optical correction of refraction errors. Usually, a subjective test is performed following an objective test that includes autorefractometry or retinoscopy to determine the spherocylindrical refraction with which the subject reaches his best visual quality. Currently, measurement of visual acuity (VA) is the most widespread method for measuring visual quality. Based on this statement, the refraction that allows the subject to reach his maximum VA is considered the best correction.

In recent years, advances in technology have allowed the commercialisation of sophisticated instruments to measure objective refraction in clinical use. In this study, a ray tracing aberrometer (iTrace ®, Tracey Technologies, Houston, Texas, USA) and an open view autorefractometer (WAM-5500 ® autokerato/refractometer, Grand Seiko Co. Ltd., Japan) were used. Previous studies have focused on discovering if these objective instruments can replace VA-based subjective refraction [1-8]. The patient's subjective visual achievement should be evaluated.

The aims of this study were to evaluate the intra-operator repeatability in healthy subjects using the WAM-5500 auto-kerato/refractometer and the iTrace aberrometer to compare the refractive values obtained with both devices and with subjective refraction and to determinate which of these three spherocylindrical corrections (obtained from autorefractometer, aberrometer or subjective test) allows the subject to achieve the best visual comfort.

SUBJECTS AND METHODS

WAM−5500 Auto−kerato/refractometer The WAM-5500 auto-kerato/refractometer is an open-view instrument that uses a two-step method for calculating the refractive error[4,5]. First, three infrared light arches are projected into the retina. Second, the reflected light from the retina passes through a lens system (Badal optometer) that moves quickly to focus the image. The final position of the Badal optometer allows automatic software to determine the refraction of the examined eye. The use of three arcs allows measurements when the pupil diameter is reduced, with a minimum of 2.3 mm. This is the minimum pupil size analysed by the instrument to determine the refraction of the studied eye. This instrument has significant advantages. Its open-view condition allows more natural measurement of the refraction. It is also able to simultaneously measure the refraction (spherical equivalent) and the pupil diameter at a frequency of 5 Hz. With this function, we can know the accommodation fluctuation during a time interval, detect accommodation anomalies, and confirm cases of presbyopia or eye strain.

iTrace Aberrometer Ray tracing aberrometry is based on measuring the positions of laser beams projected into the individual retina when they pass through the observed pupil in different directions, but always parallel to the visual axis [9-11]. Each entrance point through the pupil has its own projection on the retina, and a set of entry points generates a set of projections. The analysis of retinal displacement of the projected beam allows estimation of the wavefront aberration (Zernike coefficients) of the examined eye. The instrument also provides the spherocylindrical refraction that would be able to compensate for the aberration, as well as the pupil diameter. The advantages of the device are as follows: a short measurement time of approximately 300ms (although slower than a shack hartmann-shack aberrometer) and control of the beam projection by the system, which can therefore measure pupil sizes ranging from 2 to 8 mm. The iTrace allows measurement of highly aberrated eyes and ametropias in a range of ±15 D.

Subjective Refraction A conventional phoropter and our own software for displaying optotypes on a 19" TFT screen were used for the measurement of subjective refraction [12]. The programme shows, sequentially and randomly, high-contrast and different size optotypes (VA values between 0.02 and 2.8). The programme parameters could be modified to adapt to different conditions as follows: subject distance from the screen, the number of optotypes shown for each VA value, the rate of correct answers required to pass a line of VA or the optotype we wished to show. Unlike other optotype projectors, this instrument has important advantages. The luminance values (250 cd/m^2) and contrast (550:1) of the screen are much higher than the minimum requirements. It allows much more precise adjustment of the VA and spherocylindrical refraction of the studied subject, and it allows more reliable results to be obtained because it shows random optotypes, although test time is increased.

Subjects and Experimental Procedures Forty-two non-presbyopic eyes of 42 subjects were enrolled in the study. All of the subjects gave informed consent to participate in the study. The study was conducted in accordance with the tenets of the Declaration of Helsinki, and the experimental protocol was approved by the local Ethics Committee of the Aragones Health Science Institute.

Inclusion criteria were the following: age between 18 and 35y, no presbyopia and best-corrected VA (BCVA) of 0.5 or better (according to the Snellen scale). Subjects with previous intraocular surgery, diabetes or other systemic diseases, history of ocular, congenital or neurological disease, current use of a medication that could affect visual field sensitivity or inability to perform any of the protocol tests were excluded.

All of the subjects underwent an optometric examination that included a clinical history and examination by WAM-5500 auto-kerato/refractometer, iTrace aberrometer and subjective refraction.

The measurements were monocular, under natural accommodation and pupil size, and the tests were performed under low ambient lighting conditions. The instruments (auto-kerato/refractometer and aberrometer) were calibrated using an artificial eye of known refractive error, -4.75 D for a vertex distance of 12 mm, and radius of curvature (7.62 mm) before the tests were conducted, as well as the optotype display system. Measurement conditions were maintained for the entire sample and for all instruments.

Three refractive measurements were performed with the auto-kerato/refractometer while the patient was observing a non-accommodative stimulus placed 7 m from the evaluated eye. The mean of the three measurements was calculated for far distance, resolution of 0.12 D and 12 mm of distance to vertex. Fluctuation in accommodation and pupil diameter were measured for 20 consecutive seconds.

The iTrace aberrometer was used to perform three measurements of refraction and to collect aberration data under the same conditions (stimulus, distance, number of measurements and resolution).

Table 1 ICC for three repeated measurements in healthy eyes with the WAM-5500 autorefractometer and the iTrace aberrrometer

Parameters (D)	WAM-5500			iTrace		
	ICC	Lower 95% CI	Upper 95% CI	ICC	Lower 95% CI	Upper 95% CI
Axis	0.905	0.856	0.943	0.892	0.820	0.938
Cylinder	0.937	0.904	0.962	0.939	0.898	0.965
Sphere	0.999	0.999	0.999	0.998	0.997	0.999

ICC: Intraclass correlation coefficients; CI: Confidence interval.

The BCVA of the patient was determined by spherocylindrical subjective refraction.

To compare the spherocylindrical corrections provided by the three methods, the power vector (PV) parameter was used [13,14]:

$$M=S+\frac{C}{2}$$

$$J_0=-(\frac{C}{2})\cdot\cos 2\alpha$$

$$J_{45}=-(\frac{C}{2})\cdot\sin 2\alpha$$

$$PV=\sqrt{M^2+J_0^2+J_{45}^2}$$

where S is the value of the sphere, C is the value of the cylinder and α is the angle of the cylinder.

Spherocylindrical corrections obtained from the three different methods were mounted in three trial frames. An optotype (with a VA value less than the maximum in each case) was projected on the screen. Subjects compared their perceived visual quality of the optotype projection with the three different prescriptions (each one was presented in a random fashion during ten seconds). The individuals were asked to choose among the three refractions, giving a numeric value of "1" to the one with which they felt most comfortable, a value of "2" to the next, and a value of "3" to the one with which they felt least comfortable.

Statistical Analysis Statistical analyses were carried out with the Statistical Package for the Social Sciences (SPSS 17.0, SPSS Inc., Chicago, IL, USA). To assess the reliability of the repeated measurements with both instruments, intraclass correlation coefficients (ICC) were used. This is defined as the ratio of the between-subjects variance to the sum of the pooled within-subjects variance and the between-subjects variance. Interpretation of the ICC considered slight reliability for values between 0 and 0.2, fair reliability for values between 0.21 and 0.4, moderate reliability for values between 0.41 and 0.6, substantial reliability for values between 0.61 and 0.8 and almost perfect reliability for ICC values greater than 0.81.

For the inter-refraction study, the values of each PV obtained from the autorefractometer, the aberrometer and subjective refraction were compared by a non-parametric paired Wilcoxon test. Bland and Altman[15] plots were used to assess agreement; the three procedures were compared by displaying the differences between measurements by two methods against the mean of the two measurements. The comfort levels among the three refractions and their classification were compared.

RESULTS

Table 1 shows the repeatability findings, and no statistically significant differences were found among repeated measurements (P>0.05). All measured parameters showed good ICCs, and all of them were highly repeatable with ICCs higher than 0.88. The highest ICC was obtained using the spherical refraction with the autorefractometer and the aberrometer, achieving levels of 0.999 and 0.998, respectively.

The PV (mean±standard deviation) was calculated for each refraction method, PVsub (subjective PV), PVauto (autorefractometer PV), and PVabe (aberrometer PV): PVsub 1.341±1.560 D, PVauto 1.334±1.452 D and PVabe 1.374±1.675 D. The results (mean±standard deviation) indicated that there were no statistically significant differences between PVsub and PVauto (P=0.985), PVsub and PVabe (P=0.480) or between PVauto and PVabe (P=0.587).

Figures 1, 2 and 3 show the Bland-Altman plots of PV reproducibility between the methods. The figures illustrate the agreement between the PVsub, PVauto and PVabe values, and the scatterplots demonstrate the agreement among the measurements; more than 90% of the measurements were within ±0.5 D. These differences were related to the PV values and were higher in those with higher total refractions. In some cases, direct comparison of PV values from the three methods showed that aberrometer refraction gave the highest values, followed by subjective refraction; autorefractometer refraction gave the lowest values.

Lastly, the subjects were asked for their preferred choice of spherocylindrical correction on a trial frame. The preference percentages of spherocylindrical correction are presented in Figure 4. The mean AVmax reached with the preferred correction was 1.28±0.23. The subjective method was the most valued correction as the first selection (62%), and the autorefractometer was the third (19%). Equal values (43%) were found for the autorefractometer and aberrometer as the second selection (Figure 4).

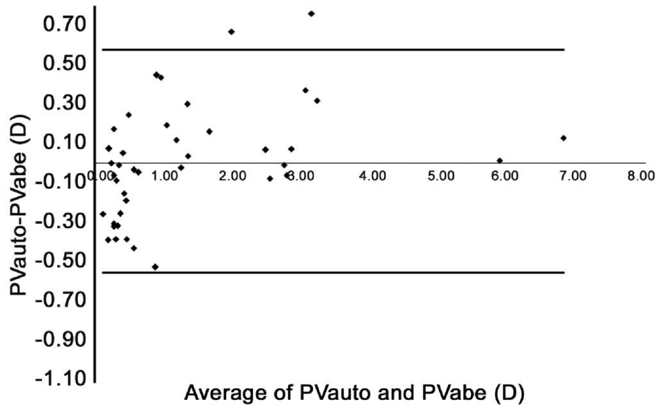

Figure 1 Bland−Altman analysis showing the distribution of PV differences (PVsub−PVauto) on the y−axis and the average of the instrument readings PVsub+PVauto)/2 on the x−axis The overall agreement is low (mean ±1.96 SD: +0.0073±0.2898 D, with 95% limits of agreement between -0.5636 and +0.5782).

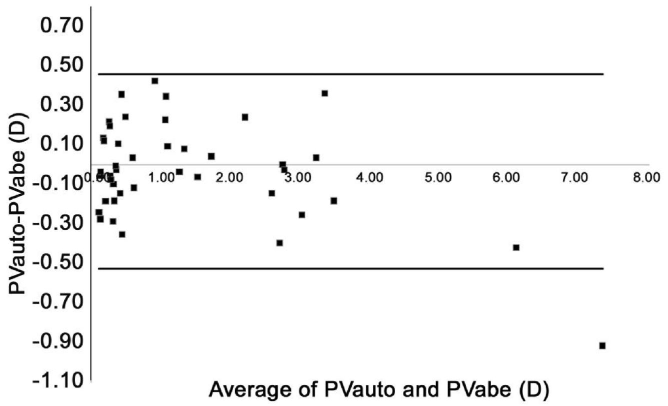

Figure 2 Bland−Altman analysis showing the distribution of PV differences (PVsub−PVabe) on the y−axis and the average of the instrument readings PVsub+PVabe)/2 on the x−axis The overall agreement is low (mean±1.96 SD: -0.0331±0.2514 D, with 95% limits of agreement between -0.5258 and +0.4590).

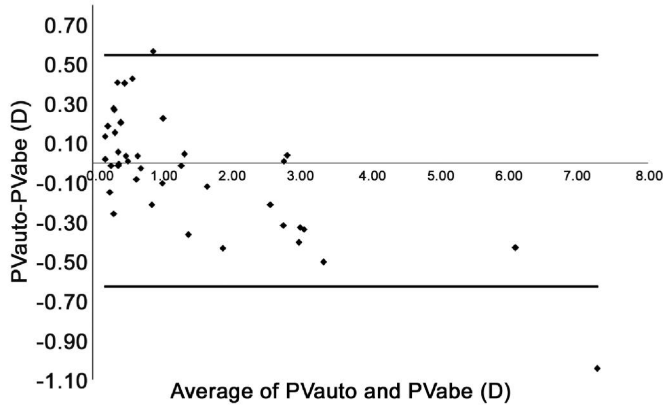

Figure 3 Bland−Altman analysis showing the distribution of PV differences (PVauto−Pvabe) on the y−axis and the average of the instrument readings PVauto+PVabe)/2 on the x−axis The overall agreement is low (mean±1.96 SD: -0.0404±0.3002D, with 95% limits of agreement between -0.6288 and +0.5480).

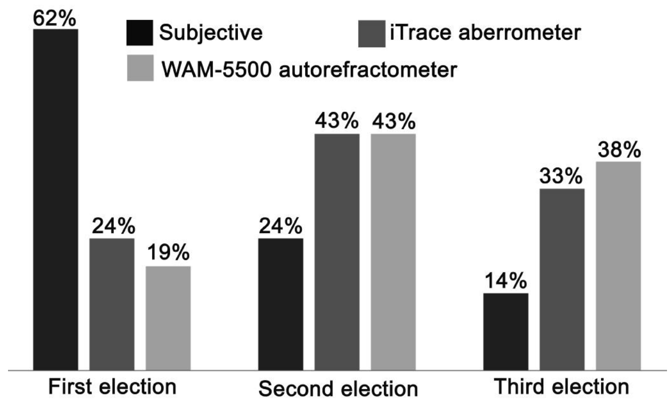

Figure 4 Preference percentage of spherocylindrical correction for the three methods (subjective, aberrometer and autorefractometer), after subjects compared their perceived visual quality of the optotype projection with the three different prescriptions (presented in a random fashion), taking into account the responses of all of the eyes.

DISCUSSION

Our study followed procedures similar to those previously described for assessing correlated refractive measurements obtained by aberrometer, autorefractometer and subjective refraction [1,2,6-8,16]. This study suggests that both the iTrace and the WAM-5500 have satisfactory intraobserver reproducibility for measuring ocular refraction in non-presbyopic healthy subjects; the repeatability, with an ICC over 0.9, was excellent. Different data on the repeatability of refraction measurements in healthy subjects have been previously reported, but, to our knowledge, there have been no previous studies investigating the tolerance and the selection of the subjects' prescriptions using our study conditions. The iTrace aberrometer used in the present study recorded more positive PV results than did subjective refraction, and at the same time, more positive values than the refractometer; however, there was no significant difference between them.

On the trial frame, spherocylindrical corrections obtained from the three different methods were mounted in three trial frames. Subjects compared simultaneously their perceived visual quality with the three different prescriptions during a few seconds. The subjective refraction prescription was chosen most often, by 26 subjects; the second most frequently chosen was the aberrometric prescription, by 10 subjects; and the least frequently chosen was the autorefractometric prescription, by 8 subjects. Similar percentages (43%) were found between aberrometer and autorefractometer as second election; the autorefractometric prescription was chosen most often as third election, by 16 subjects. Different selections can be due to low levels of accommodation while objective measurements were taken. Slight changes in visual comfort can affect the final refraction, but open-field instruments can improve the results of refraction compared to closed-field ones because they produce less instrumental myopia [17]. This does not occur in the subjective methods because the accommodative state is better controlled. Preference percentage of subjective method was particularly high in hyperopic eyes. Despite this fact, and referring to the characterisation of the sample, the subjects had normal fluctuation in accommodation values. Some peaks of fluctuation in accommodation were observed in the range of 0.5 D, but most of these were under 0.2 D. The minimum values were in the range of 0.075 D, which is the average value attributed to microfluctuations of accommodation [18]. The averages of high-order Zernike aberration coefficients were also calculated and achieved values close to zero except for a normal spherical value of 0.11 m, and root-mean-square values were similar to previously reported results [19,20]. Therefore, the final selection cannot be attributed to intrinsic characteristics of the sample.

The repeatability of the iTrace aberrometer has been previously evaluated by Wang *et al* [21], who reported results consistent with our data: ICCs of 0.992 and 0.764 for the sphere and astigmatism, respectively; and by Pinero *et al*[22] who found excellent repeatability with within-subject standard deviations for the sphere equal to 0.18 D and 0.15 D for the cylinder.

Previous versions of the iTrace system have been studied, and good repeatability was also found with standard deviations for an equivalent sphere of ±0.14 D and ±0.10 D[23,24]. The repeatability of the WAM-5500 has been evaluated by Sheppard and Davies [25] with mean intrasession repeatability of 0.14 D for the cylindrical component and 0.09 D for the spherical one. The results of the present study are comparable to these other studies because the obtained ICCs were excellent in both cases: 0.937 and 0.999, respectively. Other open-field autorefractometers have been previously evaluated; the standard deviation of the results was 0.16 D or better for the Shin-Nippon SRW-5000 and 0.13 D or better for the Shin-Nippon NVision-K 5001, both of which were highly repeatable[4,5].

Sheppard and Davies [25] evaluated the WAM-5500 to find prescriptions similar to subjective refraction. The mean spherical component (*P*=0.77), spherical component (*P*=0.21) and J45 cylindrical vector (*P*=0.92) showed significant differences, but the J0 cylindrical vector (*P*=0.01) did not, although it had no clinical implications. Our results are consistent with their findings because they did not show differences between PVsub and PVauto (*P* =0.871). However, differences were found when hyperopic and myopic eyes were studied separately. Subjective refraction provided lower sphere and cylinder values in hyperopic eyes. In myopic eyes, the autorefractometer obtained sphere values that were more positive than did other methods.

In terms of measurements and in agreement with previous studies, the iTrace aberrometer and the WAM-5500 autorefractometer showed high levels of repeatability in healthy eyes. Refractive corrections from the aberrometer, the autorefractometer and subjective refraction presented similar results, but spherocylindrical subjective correction was the most selected option. In conclusion, these technologies can be used as complements to refractive evaluation but should not replace subjective refraction.

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