·Clinical Research·

Non-cycloplegic spherical equivalent refraction in adults: comparison of the double-pass system, retinoscopy, subjective refraction and a table-mounted autorefractor

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Abstract

• AIM: To evaluate the accuracy of spherical equivalent (SE) estimates of a double-pass system and to compare it with retinoscopy, subjective refraction and a table-mounted autorefractor.

• METHODS: Non-cycloplegic refraction was performed on 125 eyes of 65 healthy adults (age 23.5±3.0 years) from October 2010 to January 2011 using retinoscopy, subjective refraction, autorefraction (Auto kerato-refractometer TOPCON KR-8100, Japan) and a double-pass system (Optical Quality Analysis System, OQAS, Visiometrics S.L., Spain). Nine consecutive measurements with the double-pass system were performed on a subgroup of 22 eyes to assess repeatability. To evaluate the trueness of the OQAS instrument, the SE laboratory bias between the double-pass system and the other techniques was calculated.

• RESULTS: The SE mean coefficient of repeatability obtained was 0.22D. Significant correlations could be established between the OQAS and the SE obtained with retinoscopy (r=0.956, P<0.001), subjective refraction(r = 0.955, P<0.001) and autorefraction (r=0.957, P<0.001). The differences in SE between the double-pass system and the other techniques were significant (P<0.001), but lacked clinical relevance except for retinoscopy; Retinoscopy gave more hyperopic values than the double-pass system −0.51±0.50D as well as the subjective refraction −0.23±0.50D; More myopic values were achieved by means of autorefraction 0.24±0.49D.

• CONCLUSION: The double-pass system provides accurate and reliable estimates of the SE that can be used for clinical studies. This technique can determine the correct focus position to assess the ocular optical quality. However, it has a relatively small measuring range in comparison with autorefractors (−8.00 to +5.00D), and requires prior information on the refractive state of the patient.

• **KEYWORDS:** double-pass system; optical quality; retinoscopy; autorefraction; subjective refraction; accuracy; repeatability; trueness

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INTRODUCTION

Autorefractors are frequently used as a reference in subjective refractions in optometric and ophthalmological practice for spectacle prescription. Although at first autorefraction was not regarded as sufficiently accurate to substitute subjective examinations [1]. Nowadays the improvement in performance and, particularly, in accuracy has gained this technique a greater consideration [2]. The popularity of autorefractors in clinical practice lies in their ease of use, good results, and great acceptance among clinicians and patients. These instruments currently range from portable to sophisticated multifunction devices which can measure ocular parameters such as radii of curvature or aberrations. The first autorefractors were based on optical principles such as streak retinoscopy, the Scheiner method or the knife-edge principle among other [3,4]. These instruments

have evolved over 40 years until the current instruments, which incorporate new technologies such as digital cameras and computers equipped with software that processes the captured images. These improvements have produced simpler instruments that need less measurement time and achieve higher accuracy, without changing the optical principles on which they are based.

A new way of measuring the refractive state of the human eye is based on wavefront analysis with aberrometers. Aberrometers provide a detailed assessment of higher order aberrations as well as the spherical and cylindrical refraction and they use laser ray tracing or a Hartmann-Shack sensor to measure the wave aberration function and consequently the refraction[5-8].

The accuracy of autorefractors has been evaluated and compared with reference values, usually obtained by subjective refraction or retinoscopy. Similarly, the performance of autorefractors and between autorefractors and aberrometers has also been compared[9,10].

Most studies concluded that differences in accuracy between autorefractors had become very small, although a myopic shift appeared with some of them because accommodation could not be reliably relaxed. Autorefractors with a closed-view environment are usually equipped with an internal fixation test which has an automatic fogging mechanism to avoid accommodation, although they are only valid for a single distance measurement. More recently, autorefractors that allow binocular viewing of external fixation targets in open-view formats have been developed. These autorefractors avoid instrument accommodation and facilitate research on the accommodative response of the eye to real-world stimuli [2,6,11]. They also perform off-axis refraction, *i.e.* peripheral refractive error, believed to be one of the key factors of myopia progression since it might influence eye growth and refractive development[12,13].

Previous studies established that the majority of modern table-mounted autorefractors are highly accurate compared to subjective refraction in adult patients, and that handheld autorefractors showed limitations [14-18]. Other authors found that under non-cycloplegic conditions, autorefractors had a tendency towards minus overcorrection in children and that their accuracy increased under cycloplegic conditions [8,19,20]. On the other hand, aberrometers could provide refractive error measurements comparable to those of an autorefractor[10].

A new instrument based on the double-pass technique (OQAS, Optical Quality Analysis System, Visiometrics S. L., Terrassa, Spain) is now available to assess the optical quality of the eye, including the effect of higher-order aberrations and intraocular scattering [21,22]. This system has already been used successfully in clinical and research applications to assess retinal image quality in healthy young patients, in patients with cataracts, keratitis and uveitis and undergoing refractive surgery, such as PRK and LASIK, and in patients with intraocular lens implants[23-30].

This instrument is not specifically designed to evaluate the patient's refractive state. However, the optical quality of the eye must be analyzed with a retinal image optimally focused so that prior to any examination the instrument must always look for the corresponding refraction. This is achieved by means of a motorized optometer that consists of an automated Badal lens system which allows the variation of the vergence of the light beam at the exit. A scanning process takes place and several double-pass images are recorded. Next, the instrument uses an algorithm that determines the best focused retinal image and where the optical quality measurements will be made. It is important to take into account that this system can neither detect nor correct astigmatism (if required it must be corrected using an external cylindrical lens), so that it allows the determination of the location of the disc of least confusion, *i.e.* the refraction in terms of spherical equivalent (SE), if a cylindrical refractive error exists.

Some authors have evaluated the repeatability of the optical quality parameters provided by the system which are related to the modulation transfer function and the intraocular scattering of the eye [31,32]. To our knowledge, the accuracy of the system measured in SE has not been investigated. We therefore studied the repeatability of the double-pass system, and compared these results with standard non-cycloplegic retinoscopy, subjective examination and autorefraction in an adult population.

SUBJECTS AND METHODS

This prospective study was conducted on 65 healthy adults recruited from the staff and students of the Faculty of Optics and Optometry of the Universitat Politècnica de Catalunya (UPC) from October 2010 to January 2011. The research was conducted according to the tenets established by the Declaration of Helsinki: all subjects gave their written informed consent after receiving a written and verbal explanation of the nature of the study, and the study was approved by the Ethics Committee.

Criteria for inclusion were as follows: best spectacle-corrected visual acuity of 0.00 or better in logMAR units; and no history of eye disease, surgery and/or pharmacological treatment. Media opacities (*e.g.* corneal scar or congenital lens opacity) and tear film abnormality were examined with the slit-lamp. Contact lens wearers were asked not to wear them for at least 24h before the measurements. Only subjects with a pupil diameter of 4mm or more in scotopic conditions were included in the study, as this was the size used in the measurements with the double-pass system. Furthermore, subjects were included in the study if their refractive error (in terms of SE) ranged from -8.00D to +5.00D, the measurement range for the OQAS instrument. Only subjects

with a cylinder below 0.75DC were included in the study since astigmatism was neither corrected by the instrument nor with an external trial lens.

Subjects underwent an optometric examination (monocular and without cycloplegia) to determine the following parameters: best spectacle-corrected visual acuity; retinoscopic refraction; manifest subjective refraction; and autorefraction by means of the table-mounted auto kerato-refractometer TOPCON KR-8100 (Japan), which enables refraction measurements with a minimum pupil size of 2mm in the range of -25 to 22D in 0.25D steps and has a closed-view environment. Moreover, the refractive error of the subjects measured in SE was also obtained with the OQAS instrument.

Measurements were performed under uniform and low illumination conditions: Illuminance values at the pupil's plane measured with a conventional luxometer (International Light, IL-1700, USA) were 23.3 ±1.4lx. All examinations were performed by the same trained optometrist. The first eye to be measured was randomly selected.

Double –pass system Figure 1 shows the diagram of the OQAS instrument. The instrument, made of a laser diode (LD) (wavelength peak=780nm) coupled to an optical fiber, records the retinal image corresponding to a point source object in near-infrared light after reflection on the retina and a double pass through the ocular media. A motorized optometer (automated Badal lens system) made of two lenses (L3, L4) and two mirrors (M2, M3), is used to measure and correct the subject's defocus. An infrared video camera (CCD1) records the double-pass images after the light is reflected on the retina and on a beam splitter (BS2). Pupil alignment is controlled with an additional camera (CCD2). A fixation test (FT) helps the patient keep the eye aligned with the system and minimizes accommodation during measurements. The entrance pupil has a fixed diameter of 2mm. The instrument has an artificial and variable exit pupil controlled by a diaphragm wheel whose image is formed on the subject's natural pupil plane. As previously mentioned, the optical quality measurements of this study were performed using a standard exit pupil diameter of 4mm.

Before assessing the optical quality of the eye, the instrument performs a scanning process above and below a starting point of spherical correction by means of the optometer (±3.00D with a 0.25D step) which the user must introduce into the software of the instrument. Consequently, the starting point must be just approximate, *i.e.* within a range of ±3.00D from the true SE refraction. If the subject was not wearing spectacles, the starting point selected was 0D. On the other hand, if the subject wore spectacles, the prescription measured by means of an auto lensmeter Tomey Corporation TL-3000B (Japan) was used. After this scan, the software of the instrument uses an algorithm based on the analysis of the

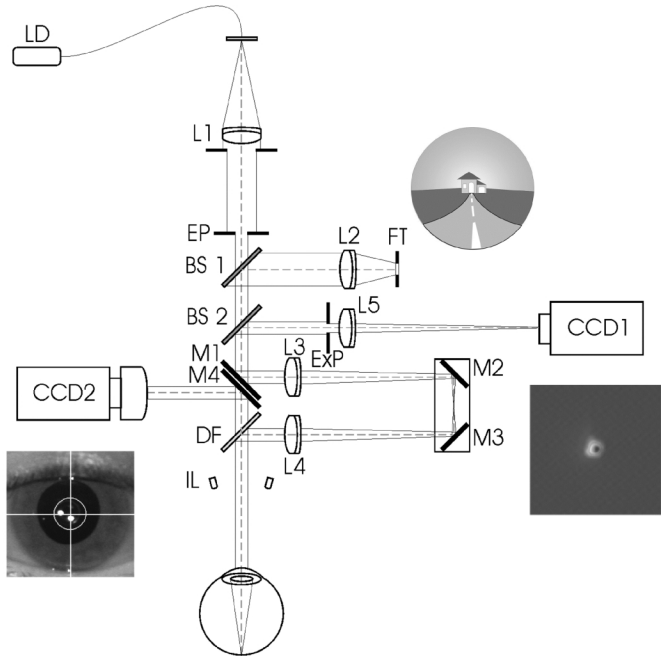

Figure 1 Diagram of the double–pass system LD=Laser diode; L1, L2, L3, L4, and L5=Lenses; EP=Entrance pupil; ExP=Exit pupil; BS1and BS2=Beam splitter 1 and 2; FT=Fixation test; CCD1 and CCD2=CCD cameras 1 and 2; M1, M2, M3, and M4=Mirrors; DF=Dichroic filter; IL=Infrared LEDs. The fixation test used by the instrument and examples of images acquired by the cameras of the system are also shown.

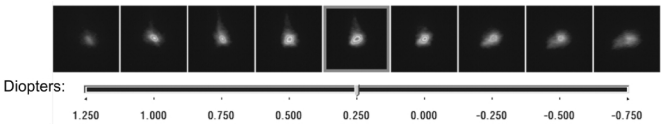

Figure 2 Double–pass images acquired during the scanning process performed with the Badal lens system, which allows the variation of the vergence of the light beam. The image optimally focused, automatically selected by the instrument, is shown in green.

intensity of the recorded double-pass images to automatically assign a SE value that corresponds to the image optimally focused, where the optical quality measurements will then be taken (Figure 2). Specifically, the algorithm looks for the image with the maximum peak intensity and afterwards it introduces a correction that takes into account the intensity fluctuations in the neighboring images due to noise sources of the camera.

Analysis of Accuracy According to the International Organization for Standardization, the investigation of accuracy involves the assessment of two factors: precision and trueness [33,34]. Precision is defined as the closeness of agreement between independent test results. The two extremes of precision are defined as repeatability and reproducibility. Repeatability is the minimum variability between test results and is calculated when independent test results are obtained with the same method, in one laboratory, with one piece of equipment, in the same subject by the same operator with the shortest possible time between successive

readings. In contrast, reproducibility is the maximum variability of a test method and is determined when test results have been obtained with the same method on identical test material in different laboratories, using different equipment and operators. Trueness is defined as the closeness of agreement between the average value of a large series of results and an accepted reference value. The following estimates can be determined: laboratory bias and bias of the measurement method. The first one refers to the difference between the results of a particular laboratory and the accepted reference value. The second refers to the difference from a reference value expected to apply to all measurements made by that method. To obtain accurate estimates of the bias of the measurement method a multicenter study using the same group of subjects with a large number of measurements per subject is recommended. In this study we performed a clinical evaluation of the OQAS instrument to objectively assess the SE, and we analyzed its repeatability and trueness in terms of laboratory bias. Other analyses were beyond the scope of this study.

Repeatability was assessed with the measurements of the first 22 eyes, corresponding to 11 subjects. The head of the subjects was properly positioned on the chinrest, and the optometrist manually aligned the pupil with the optical axis of the double-pass system. Next, nine consecutive measurements of the SE were taken. The pupil was realigned between each measurement. 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. The repeatability was then determined by means of the coefficient of repeatability [COR; 1.96 times intrasubject standard deviation (SD)], the value below which the difference between two repeated measurements is expected to lie with a probability of 95%. The mean COR was obtained by adding the square of the individual CORs for each individual eye and calculating the square root of the mean value[31,32].

Once the repeatability of the system was ensured, the analysis of trueness was carried out. A total of 125 eyes of 65 subjects were considered in this case, and only one measurement per technique was made. In the case of the first 22 eyes used in the assessment of repeatability, only the first reading was selected to perform this analysis. To assess the laboratory bias of the OQAS instrument we compared its readings with those found by retinoscopy, manifest subjective refraction and autorefraction, with the aim of obtaining a wide and complete comparison. All refractive errors obtained by means of retinoscopy, subjective refraction and autorefraction were converted into SE values(SE=sphere+half negative cylinder).

The trueness of the OQAS readings was tested from different points of view. Firstly, Pearson correlation coefficients (r) were used to compare the OQAS SE values with those obtained by retinoscopy, subjective refraction and autorefraction. The use of correlation coefficients is a useful statistical method for the comparison of two data sets and has been extensively used by other authors [9]. However, it must be taken into account that this analysis can produce some inaccuracies due to the fact that it measures the strength of a relation between two variables but not agreement between them. A perfect agreement is obtained if the readings of the two variables lie along the line of equality, but a perfect correlation is also obtained if the points lie along any straight line. For this reason, agreement between data was also evaluated by calculating the mean of the differences (*i.e.* the bias) between the SE provided by the OQAS and that of retinoscopy, subjective refraction, and autorefraction, according to the Bland and Altman analysis [35]. 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. These charts can be used to investigate any relationship in the differences in SE between the measurements performed by means of two techniques since they are plotted against the average value. Finally, an analysis of variance (ANOVA) test was used to compare the means of the differences, with the two eyes of each subject considered as dependent variables. A Kolmogorov-Smirnov (K-S) test was used to test for normality of the SE values, and also of the differences between OQAS and retinoscopy, subjective refraction and autorefraction.

Statistacal Analysis Data analysis was performed using SPSS software (version 17.0, SPSS, Chicago, IL, USA) for Windows. A P value of 0.05 was considered significant.

RESULTS

Measurements of 125 eyes of 65 subjects were finally included in the study. Five eyes were excluded for having a cylinder larger than 0.50DC. Twenty-three subjects (35.4%) were male and 42 (64.6%) were female. The mean age of the population studied was 23.5±3.0 years (range: 18 to 49 years). Their best-spectacle corrected visual acuity was -0.03±0.04 (range: -0.18 to 0.00) in logMAR units. Table 1 shows the mean refractive error in terms of SE (±SD) and the corresponding ranges (minimum, maximum) obtained by retinoscopy, subjective refraction, autorefraction, and OQAS.

Figure 3 shows the distribution of SE values among the 125 eyes refracted with the different techniques. The plots illustrate the asymmetrical distribution of the refractive errors with a tail in the myopic direction in all cases. The distribution of all variables included in the study were non-normal (P<0.05).

A subgroup of 22 eyes corresponding to 11 subjects were used for the analysis of repeatability. Five of the subjects (45.5%) were male and 6 (54.5%) were female. The mean

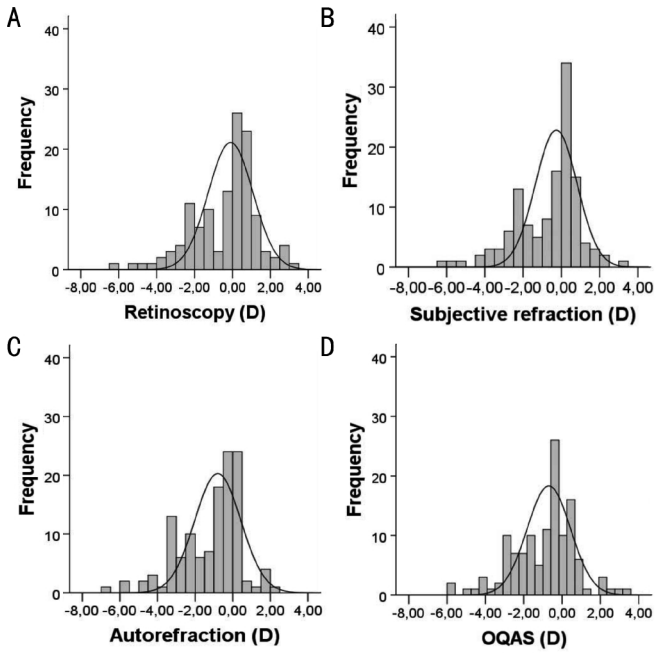

Figure 3 Distribution of the refractive error values in terms of spherical equivalent obtained with the different refraction techniques. The normal distribution curve is also plotted in each graph All variables showed a non-normal distribution: A: Retinoscopy (P=0.008); B: Subjective refraction (P=0.002); C: Autorefraction (P=0.001); D: OQAS (P=0.032) (n=125; D: diopters).

Table 1 Mean refractive error measured in spherical equivalents (±standard deviation, SD), and its range obtained by retinoscopy, subjective refraction, autorefraction and the OQAS

(n=125; D: diopters)

	Spherical equivalent (D)		
	Mean±SD	Range	
		Min	Max
Retinoscopy	-0.45±1.69	-6.13	3.13
Subjective refraction	-0.73±1.67	-6.38	3.00
Autorefraction	-1.20±1.67	-6.75	2.00
OQAS	-0.96±1.67	-6.00	3.50

age was 23.1±3.5 years (range: 20 to 33 years). Their best spectacle-corrected visual acuity was -0.10±0.06 (range: -0.18 to 0.00). The mean refractive error obtained with the OQAS in the analysis of repeatability in terms of SE (±SD) was 0.25±0.41 (range: -0.50 to 1.00), the mean of the intrasubject SD was 0.10, and the calculated mean COR was 0.22.

Correlations between groups of data were performed firstly for the analysis of trueness. As shown in Figure 4, significant correlations could be established between the OQAS SE and the SE obtained with the other three techniques (P<0.001). Secondly, the biases [the mean difference (±SD) and the corresponding 95% CL] between measures were calculated (Table 2). Figure 5 shows the corresponding Bland and Altman plots, where when comparing the OQAS SE with that of retinoscopy and subjective evaluation, some outliers in the data sets can be observed, mainly for emmetropes and

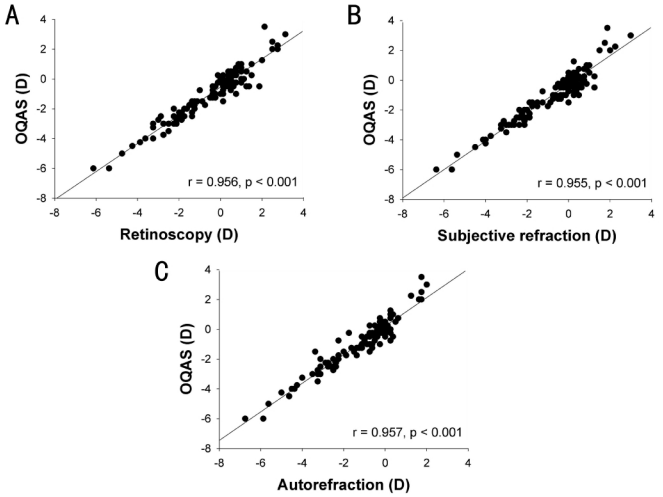

Figure 4 Correlation of the refractive error values in terms of spherical equivalent between the OQAS and A: Retinoscopy; B: Subjective refraction; C: Autorefraction (r: Pearson correlation coefficient, P: statistical significance) (n=125; D: diopters).

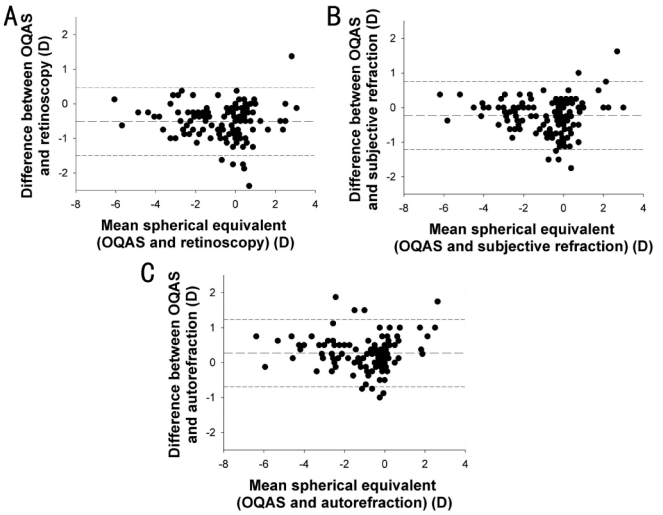

Figure 5 Bland and Altman plots showing the mean of the differences ($mean_d$) and the corresponding 95% confidence limits (CL) in terms of spherical equivalent when the OQAS was compared with A: Retinoscopy; B: Subjective refraction; C: Autorefraction (n=125; D: diopters).

Table 2 Mean differences ($Mean_d$) measured in spherical equivalents (±standard deviation, SD), and corresponding 95% confidence limits (CL) when the OQAS is compared with retinoscopy, subjective refraction and autorefraction

(n=125; D: diopters)

Difference between OQAS and	Spherical equivalent (D)	
	$Mean_d$±SD	95%CL
Retinoscopy	-0.51±0.50	-1.49 to 0.47
Subjective refraction	-0.23±0.50	-1.21 to 0.75
Autorefraction	0.24±0.49	-0.71 to 1.25

hyperopes. In the case of the autorefractor, the outliers were found along the positive and also part of the negative range. If the differences depend on the mean, *i.e.* they have a significant correlation coefficient at the 5% significance level, conclusions about the mean difference should be

cautiously drawn (Bland, Altman, 1986)[35]. The correlation coefficients corresponding to the Bland and Altman plots can be observed in Table 3. All correlations had *P* values above 0.05, therefore they were not statistically significant and the differences did not vary in any systematic manner across the range of measurements.

Furthermore, in terms of differences the assumption of normality was valid in all comparisons. As shown in Figure 6, this was investigated using normal probability plots and the K-S test, now with a $P>0.05$ in all cases. We found that the differences in SE between the OQAS and the other analyzed techniques were significantly different ($P<0.001$).

DISCUSSION

Before relying on measurements obtained with a new diagnostic device, it is crucial to guarantee that it provides accurate results. The analysis of parameter variability due to random errors associated with routine use of the instrument is therefore essential and leads to the identification of instrument measurement repeatability. In this study, the repeatability of the OQAS SE was found to be as good as other available autorefractors (COR: 0.22D), which suggests that this new instrument is more repeatable than subjective refraction [1,36-38]. Although subjective refraction is generally considered the gold standard for determining refractive error measurement, repeatability limits of up to 0.78D have been reported. Furthermore, the calculated COR was smaller than 0.25D, the value generally used in prescribing spectacles and therefore of no clinical significance.

On the other hand, systematic errors produce biases between the SE provided by the double-pass system and the other tested techniques, *i.e.* retinoscopy, subjective refraction, and autorefraction. In this context, significant correlations ($P<0.001$) could be established between the OQAS SE and that obtained with any of the other three techniques for refraction, with correlation coefficients (r) above 0.955 in all cases (Figure 4). The correlation coefficients (r) have been used already by some authors to compare autorefractor measurements with subjective refraction [9]. However, the calculation of these coefficients may have some limitations since they measure the strength of an association between two variables but not agreement between them. A perfect agreement is achieved only if the readings for the two variables lie along the line of equality but a perfect correlation is also found when points lie along any straight line. We reported these results because they offer a straightforward and preliminary idea of the comparison.

Moreover, small mean differences between the OQAS SE and those measured by the other tested techniques were generally obtained in all comparisons (Table 2). The differences between every pair of techniques compared plotted as a function of their mean SE (Table 3 and Figure 5) did not show any recognizable pattern. Consequently, it could be concluded that differences did not vary in any systematic manner over the range of measurements, and that a good agreement between techniques existed.

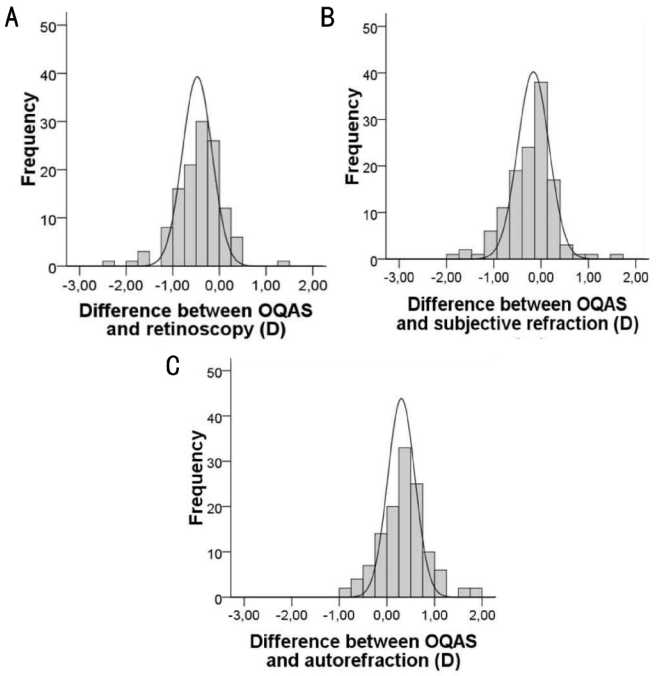

Figure 6 Distribution of the differences of refractive error values in terms of spherical equivalent obtained when the OQAS was compared with the different techniques for refraction. The normal distribution curve is also plotted in each graph All variables showed a normal distribution: A: Differences between OQAS and retinoscopy ($P=0.090$); B: Differences between OQAS and subjective refraction ($P=0.216$); C: Differences between OQAS and autorefraction ($P=0.088$) ($n=125$; D: diopters).

Table 3 Correlation coefficients (*r*) and significance (*P*) of the differences of two measures plotted against the mean, *i.e.* the Bland and Altman plots shown in Figure 5 ($n=125$; D: diopters)

Difference between OQAS and	*r*	*P*
Retinoscopy	0.039	0.667
Subjective refraction	0.001	0.994
Autorefraction	0.004	0.969

The differences in SE between the double-pass system and the other analyzed techniques were significant ($P<0.001$). The readings from OQAS were on average slightly more negative than those found by retinoscopy -0.51±0.50D and subjective refraction -0.23±0.50D, whereas a small positive bias 0.24±0.49D was obtained when compared to values provided by the autorefractor (Table 2). Therefore, OQAS readings could be less influenced by proximal accommodation than the autorefractor used, although a similar degree was initially expected since both devices have a similar closed-view environment. These kinds of autorefractors generally produce results that are over myopic, mainly in young subjects, due to the fact that their accommodation is not fully relaxed[39,40]. This is being partially

improved by the use of binocular, open-view designs which allow movement of a real visual target in free space along the subject's line of sight, thus stimulating or relaxing accommodation and avoiding induced artifacts from convergence[2,6,11].

The largest differences were found between the OQAS and retinoscopy, while the other two procedures (subjective refraction and autorefractor) provided similar values although with opposite sign. Although these biases are statistically significant, they are not clinically significant except for retinoscopy, since they are smaller than 0.25D. Figure 6 shows that 35.2% of the OQAS readings were within ±0.25D of the retinoscopic SE, 60% within ±0.50D, and 76.8% within ± 0.75D. When comparing the OQAS and subjective evaluation, 56.0% of the OQAS values were within ±0.25D of the SE measured by subjective refraction, 74.4% within ± 0.50D, and 86.4% within ±0.75D. Finally, when comparing the OQAS and the autorefractor, 53.6% of the OQAS readings were within ±0.25D of the SE measured by autorefraction, 79.2% within ±0.50D, and 90.4% within ± 0.75D. The SE values measured by OQAS had good and similar percentages of agreement when compared with subjective refraction and autorefraction, although more discrepancy was found comparing with retinoscopy. Similar differences have been reported in autorefractors, whose readings were compared with subjective refractive errors [17-19,41].

In conclusion, the OQAS instrument provides accurate SE estimates and can therefore be used in the optometric and ophthalmological practice as part of the refractive routine to obtain an objective, repeatable and valid result as close as possible to the eventual prescribed refractive error. However, the double-pass system has a relatively small measuring range in comparison with autorefractors and needs a priori information of the approximate refractive state of the patient.

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