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Article

Comparison Between Aberrometry-Based Binocular Refraction and Subjective Refraction

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Purpose: We evaluate the efficacy of a new system of binocular refraction, mainly based on ocular aberrometry (EYER) and compare it with the traditional subjective refraction as gold standard.

Methods: A prospective, double blind, and transversal study was performed on 99 subjects (35 men, 64 women; mean age 37.22 ± 18.04 years; range, 7–70 years). Refractive surgery or irregular cornea were considered exclusion criteria. Subjective refraction was performed by three different optometrists and EYER by other optometrists on three different days randomly. The binocular best corrected visual acuity (BBCVA), subjective vision evaluated with visual analogue scale (VAS), refraction spent time, and mean spherical equivalent (MSE), and vertical and oblique cylindrical components (J0 and J45) were analyzed.

Results: A positive strong correlation between EYER and subjective refraction was found for MSE (Pearson, 0.984; $P < 0.001$) and J0 and J45 (Pearson, 0.837; $P < 0.001$ and Pearson, 0.852; $P < 0.001$, respectively) in the total group. There were no statistically significant differences for BBCVA ($P < 0.05$). The VAS scores were 84.29 ± 12.29 with the EYER and 86.89 ± 12.38 with subjective refraction ($P = 0.031$). The spent time to perform the refraction was statistically lower ($P < 0.05$) with the EYER compared to conventional subjective refraction for all groups.

Conclusions: The EYER system showed similar results in terms of spherical and cylindrical components, visual acuity being the spent time in the refraction lower than conventional subjective refraction.

Translational Relevance: This new objective refraction system provides less chair spent time with similar results than subjective refraction.

Introduction

Visual perception depends on optical and neural factors. Ocular wavefront aberrations are phenomena that affect the optical quality of the eye.[1] The surface of the wavefront can be decomposed mathematically in different primary coefficients that represent distortion, field curvature, tilt, defocus, astigmatism, coma, and spherical aberrations.[2] Zernike polynomials group these coefficients in low- (LOA) and high-order (HOA) aberrations. LOA analysis allows us to know the value of the spherical and cylindrical components of the eye.[3] To measure the LOA and HOA of the whole eye, commercial devices incorporate a Hartmann-Shack sensor to determine the wavefront variations induced by the ocular refractive surfaces.[4]

Due to consideration of the neural factors, subjective refraction is the gold standard method for refractive error assessment. However, different refractors provide an objective refraction as reference to facilitate subjective refraction. Conventional,[5–11] open-field,[6,8,12–17] or wavefront-based[9,10,18–21] refractors are available in the market.

In relation to efficacy comparison between refractors and subjective refraction, some studies showed that the oldest conventional refractors seem to measure more negative values of sphere and different cylindrical components than subjective refraction.[5–8] The differences in the sphere were associated with stimulation of the accommodation during the measurement process with the refractors. Others evaluated the newest conventional refractors with similar efficacy to subjective refraction in terms of sphere[9,10] and cylinder.[9] Open-field refractors showed less myopic values than conventional refractors[6] and similar spherical refraction to subjective refraction.[14–17] This suggests that the refraction measurement is not influenced by accommodation in these devices. However, Choong et al.[8] found significantly more negative values with an open-field refractor in comparison with subjective refraction under noncycloplegic conditions. On the other hand, Mallen et al.[13] even found, with an open-field refractometer, more hyperopic values than subjective refraction. Differences in the cylindrical components also were reported.[13,16,17] Concerning efficacy of the first wavefront-based refractors, Nissman et al.[18] found differences in the spherical (more negative values) and cylindrical components compared to subjective refraction. However, in the last decade, new wavefront-based refractors showed similar efficacy to subjective refraction in terms of sphere and cylinder.[19–21] As a result, and due to the possibility of analyzing the optical quality of the eye, wavefront aberrometry is being used increasingly in clinical practice.

To evaluate the objective and subjective refraction in the same device, Pujol et al.[22] designed a new system that included an open-field wavefront-based refractor. Subjective refraction was performed based on LOA in a virtual reality environment. Its efficacy was similar to the conventional subjective refraction process in all refractive parameters.

Refraction probably is the most frequent measurement in clinical practice. New wavefront-based refractors with great efficacy were developed to facilitate the refraction procedure.[19–21] However, a subjective adjustment is necessary to prescribe the final refraction. Reducing the spent time in refraction is a proper method to increase clinical efficacy.

Based on the previous idea, we evaluated the efficacy of a new open-field device, the Eye Refract (EYER) system (Visionix-Luneau Technologies, Chartres, France), which performs a wavefront-based binocular subjective refraction. Refractive parameters, visual acuity, visual satisfaction, and spent time were compared to conventional subjective refraction.

Methods

Study Design

An experimental, prospective, cross-sectional, randomized, and evaluator-masked study was conducted in compliance with good clinical practice guidelines, institutional review board regulations, and following the tenets of the Declaration of Helsinki, revised in 2008.[23] All participants were voluntarily included in the study after signing a written informed consent, where the procedure of all the trials and purpose of the study were explained. Participants were free to leave the study at any time. All trials were performed at the University Clinic of Optometry of the Faculty of Optics and Optometry (Universidad Complutense de Madrid) by four different optometrists. For each participant, three refractions were performed with the EYER by an optometrist and three subjective refractions were performed by three different optometrists. All optometrists performed the refraction on three different days (on each day, the EYER and subjective refractions were performed by a different optometrist) in random order to avoid bias. Also, the optometrists did not know the results obtained by the others at any time. All refractions were performed without cycloplegia.

Sample

We evaluated randomly 99 eyes (one per participant) of 99 healthy participants (64 women, 35 men; mean age, 37.22 ± 18.04 years; range, 7–69 years). To achieve a heterogeneous sample, we recruited the same number of participants per decade, divided into four groups (teen, adult, presbyopic, and total). Demographic characteristics are detailed in Table 1. The recruited participants had different socioeconomic status, considering students, nonstudents, workers, and nonworkers.

Inclusion criteria were age between 7 and 69, and understanding and signing the informed consent (by the legal tutors in case of subjects under 18 years old). Exclusion criteria were amblyopia; strabismus or other ocular dysfunction affecting binocular refraction; presence of any ocular disease, surgery or trauma; and use of systemic or ocular drugs that could affect the results.

EYER System

The EYER system consisted of a binocular wavefront aberrometer combined with a phoropter to

Table 1. Demographic Characteristics of Participants in the Study

Groups	Number of Eyes (Patients)	Age (Years)	Age Range (Years)	Sex (Male/Female)
Teen (7–19 y/o)				
7–12 y/o	24 (12)	9.75 ± 1.45	(8–12)	(7/5)
13–19 y/o	18 (9)	17.44 ± 2.47	(13–19)	(2/7)
Adult (20–39 y/o)				
20–29 y/o	36 (18)	25.00 ± 1.79	(22–28)	(3/15)
30–39 y/o	30 (15)	34.40 ± 2.98	(30–39)	(5/10)
Presbyopic (40 or more y/o)				
40–49 y/o	32 (16)	44.56 ± 3.31	(40–49)	(5/11)
50–59 y/o	30 (15)	55.80 ± 2.85	(50–59)	(7/8)
60 or more y/o	28 (14)	63.92 ± 2.87	(60–69)	(6/8)
Total	198 (99)	37.22 ± 18.04	(8–69)	(35/64)

y/o, years old.

perform dynamic and binocular refraction. Following the manufacturer instructions, subjects were instructed to put their chin and forehead on the chinrest and to look ahead to the test on the digital screen set at 4 m distance. Then, binocular wavefront aberrometry was performed. The wavefront metric used for objective refraction was based on the principle of equivalent quadratic, using the method of paraxial curvature matching proposed by Thibos et al.[24] This method performed by the EYER takes into account the high-order aberrations analysis up to fourth order. The EYER measures the wavefront under physiologic pupil conditions and recalculates the aberrations for 3 mm. In case of pupil size <3 mm, analysis was performed for physiologic pupil size. The Hartmann-Shack sensor used a near-infrared light of 800 nm and chromatic aberration was compensated after the measurement. The pitch of the microlens array was 0.1 mm.

After objective refraction, the optometrist asked the subjects some serial questions provided by EYER to adjust the final sphere and astigmatism with the best binocular visual acuity. The questions provided by EYER consisted of comparing two lenses (spherical or cylindrical), "lens 1 or lens 2", and the refraction was modified according to their answers. The EYER refraction was performed three times on different days by the same optometrist.

Conventional Subjective Refraction

Conventional subjective refraction was performed by three different experienced optometrists (one with 5 and the others with more than 10 years of experience) on different days, using the same digital screen that was used during EYER refraction, also placed at 4 m. All optometrists began the refraction with retinoscopy. After that, a fogging method was used for subjective refraction. The objective was to find the maximum positive sphere with the best visual acuity. The astigmatism was adjusted by the crossed cylinder technique. For comparison with EYER refraction results, the mean of each parameter evaluated from optometrists were determined.

Refraction and Visual Acuity Parameters Analysis

The refractive results were analyzed in terms of mean spherical equivalent (MSE) and vertical and oblique cylindrical components (J0 and J45) with the method proposed by Thibos et al.[25] MSE, J0, and J45 were calculated using the following equations:

$$\mathrm{MSE} = \mathrm{sphere} + \mathrm{cylinder}/2$$

$$\mathrm{J0} = -(\mathrm{cylinder}/2) \times \cos(2 \times \mathrm{axis})$$

$$\mathrm{J45} = -(\mathrm{cylinder}/2) \times \sin(2 \times \mathrm{axis})$$

The mean best binocular corrected visual acuity (BBCVA) was recorded from EYER and subjective refraction for their posterior analysis and comparison. BBCVA was assessed with trial spectacles, in the case of conventional refraction, and through the oculars of the device, in the case of EYER refraction. The high-contrast (100%) Early Treatment of Diabetic Retinopathy Study (ETDRS) chart of the digital screen was used to measure BBCVA.

Visual Satisfaction and Time Measurements

Subjective visual satisfaction was binocularly measured immediately after the refraction process,

Table 2. MSE Mean Values Found With Both Refraction Systems

Test	Total Group ($n = 99$)	Teen Group ($n = 21$)	Adult Group ($n = 35$)	Presbyopic Group ($n = 43$)
MSE (eye refract) mean ± SD	−0.81 ± 2.60	−0.48 ± 1.82	−2.16 ± 3.14	0.12 ± 1.93
MSE (subjective refraction) mean ± SD	−0.86 ± 2.47	−0.63 ± 1.76	−2.08 ± 3.04	0.25 ± 1.80
P value	0.304	0.112	0.340	0.131

Student's *t*-test for related samples. Eye refract vs. subjective refraction in each group studied.

without considering a standard adaptation period to the prescription. Conventional and EYER refraction satisfaction were not measured at the same time, being assessed in an unmasked situation. Visual satisfaction was evaluated with the visual analogue scale (VAS).[26] Participants were asked to mark on a 10 cm line their level of visual satisfaction from 0 to 100, with 0 being low and 100 high visual satisfaction. The mark was measured with a ruler. A 0.1 cm measurement is equivalent to a value of 1 in the VAS. Visual satisfaction was measured showing to the participants one line less of visual acuity in the digital screen than they reached with each prescription. Visual satisfaction was assessed with trial spectacles, in the case of conventional refraction, and through the oculars of the device, in the case of EYER refraction.

The spent time in the refractions was measured with a timer. In the case of EYER refraction, the time was measured from the objective refraction with the Hartmann-Shack sensors to the final binocular visual acuity measurement after subjective refraction. In conventional subjective refraction, the time was measured from the initial visual acuity measurement (after retinoscopy) to the final binocular visual acuity measurement.

Statistical Analysis

Statistical analysis was performed using the SPSS Statistics 22 software (IBM, Chicago, IL). Sample size was calculated with statistical software Granmo 6.0 (Institut Municipal d'Investigacion Medica, Barcelona, Spain). The normal distribution of the variables was assessed using the Shapiro-Wilk test. Statistical hypothesis testing was conducted to compare the results between the EYER and conventional subjective refractions. The statistical analysis variables were M, J0, J45, visual satisfaction (VAS), and time. Only one eye of each subject was randomly selected for refraction parameters. Student's *t*-test for paired samples was chosen in case of normal distributions and the Wilcoxon signed-rank test in case of non-normal distributions. Also, the degree of correlation was established between the different variables between the EYER and conventional subjective refractions with Pearson correlation test. A statistical significance of 95% was established ($P < 0.05$). Results are shown as mean ± standard deviation (SD).

Results

MSE outcomes with both methods of refraction are summarized in Table 2. There were no statistically significant differences ($P < 0.05$) for all groups. Figure 1 shows the Bland-Altman graphs for MSE. A positive strong correlation ($R^2 > 0.70$) was found for all groups.

In relation to cylindrical components, the results of J0 and J45 with both methods of refraction are summarized in Tables 3 and 4, respectively. There were statistically significant differences only between EYER and subjective refraction ($P < 0.05$) in J45 for total and presbyopic groups. Figures 2 and 3 represent the Bland-Altman graphs for J0 and J45, respectively. J0 showed a strongly positive correlation for total, adult, and presbyopic groups and a moderate correlation ($0.50 > R^2 > 0.70$) for teens. The correlation in J45 was strongly positive for total and presbyopic groups and moderate for adults, and there was no correlation ($0.00 > R^2 > 0.30$) for teens.

High-contrast BBCVA results with both methods of refraction are summarized in Table 5. There were no statistically significant differences ($P < 0.05$) for all groups. Figure 4 shows the Bland-Altman graphs for BBCVA. A positive strong correlation was found for total and presbyopic groups, while correlation was moderate for teens and adults.

The visual satisfaction was statistically lower ($P <$ 0.05, Student's *t*-test for paired samples) with the

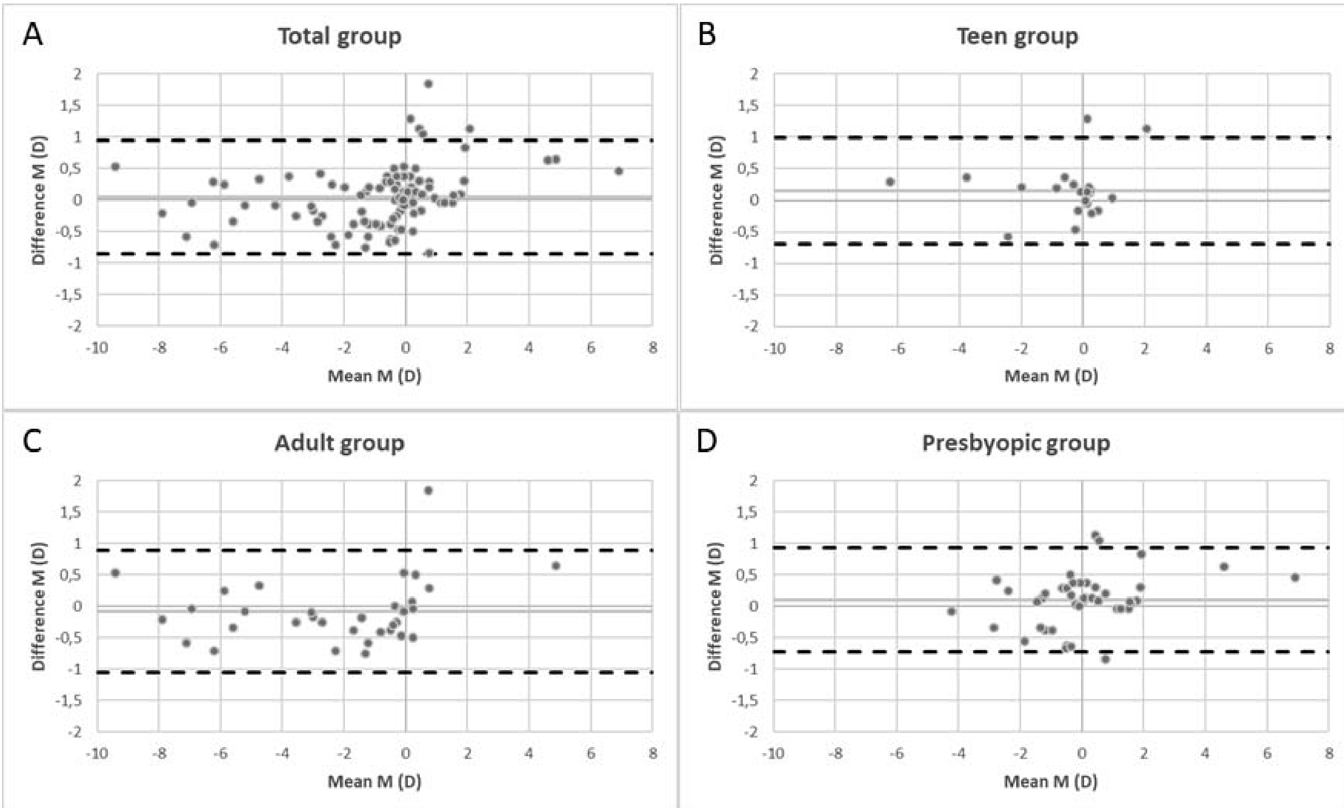

Figure 1. Bland-Altman plots between MSE of EYER and subjective refraction for total group (**A**), teenagers (**B**), adults (**C**), and presbyopic (**D**) group. The *middle line* indicates the mean difference (EYER - subjective refraction), and the *two dashed side lines* show the 95% limits of agreement.

EYER compared to conventional subjective refraction for total and presbyopic groups. No differences ($P > 0.05$, Student's *t*-test for paired samples) were found in teens and adults. The VAS scores were 84.29 ± 12.29 with EYER and 86.89 ± 12.38 with subjective refraction ($P = 0.031$) in the total group, 80.95 ± 16.32 and 79.68 ± 19.23, respectively ($P = 0.754$) in teens, 87.76 ± 9.80 and 90.30 ± 9.48, respectively ($P = 0.149$) in adults, and 83.09 ± 11.44 and 87.64 ± 8.50, respectively ($P = 0.001$) in presbyopics.

The spent time to perform the refraction was statistically lower ($P < 0.05$, Student's *t*-test for paired samples) with the EYER compared to conventional subjective refraction for all groups. The spent time was 3:25 ± 0:38 minutes (minutes:seconds) with EYER and 4:50 ± 1:17 minutes with subjective refraction ($P < 0.001$) in the total group, 3:16 ± 0:28 and 3:56 ± 1:02 minutes, respectively ($P = 0.034$) in teens, 3:15 ± 0:32 and 4:56 ± 1:15 minutes, respectively ($P < 0.001$) in adults, and 3:39 ± 0:43 and 5:12 ± 1:13 minutes, respectively ($P < 0.001$) in presbyopics.

Table 3. J0 Mean Values Found With Both Refraction Systems

Test	Total Group ($n = 99$)	Teen Group ($n = 21$)	Adult Group ($n = 35$)	Presbyopic Group ($n = 43$)
J0 (eye refract) mean ± SD	0.53 ± 0.42	0.06 ± 0.32	0.15 ± 0.40	−0.03 ± 0.46
J0 (subjective refraction) mean ± SD	0.46 ± 0.31	0.02 ± 0.23	0.12 ± 0.33	−0.01 ± 0.32
P value	0.742	0.247	0.393	0.478

Student's *t*-test for related samples. Eye refract vs. subjective refraction in each group studied.

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Table 4. J45 Mean Values Found With Both Refraction Systems

Test	Total Group ($n = 99$)	Teen Group ($n = 21$)	Adult Group ($n = 35$)	Presbyopic Group ($n = 43$)
J45 (eye refract) mean ± SD	−0.01 ± 0.29	−0.02 ± 0.10	−0.003 ± 0.16	−0.01 ± 0.41
J45 (subjective refraction) mean ± SD	0.03 ± 0.25	0.01 ± 0.89	0.02 ± 0.17	0.04 ± 0.34
P value	0.004*	0.171	0.178	0.036*

* *P* value < 0.05; Student's *t*-test for related samples. Eye refract vs. subjective refraction in each group studied.

Discussion

We evaluated the efficacy of the EYER, a new device that incorporates an open-field aberrometer and phoropter to perform a wavefront-based binocular refraction, compared to conventional subjective refraction. The EYER had a similar efficacy to subjective refraction in terms of MSE and BBCVA. In cylindrical components compared using both methods, there were differences in J45 for presbyopics and no correlation for teens. Also, the EYER showed a lower spent time during the refraction process than did subjective refraction. To our knowledge, this is the first study to validate the EYER as a useful device to evaluate refraction in comparison with subjective refraction.

Different refractors on the market provide an objective refraction of reference to start the subjective refraction. Conventional refractors are widely used in clinical practice, but some provide more negative values of MSE than subjective refraction due to stimulation of the accommodation during the measurement process.[5–7] Wavefront-based refractors also could provide more negative values of MSE.[18] The

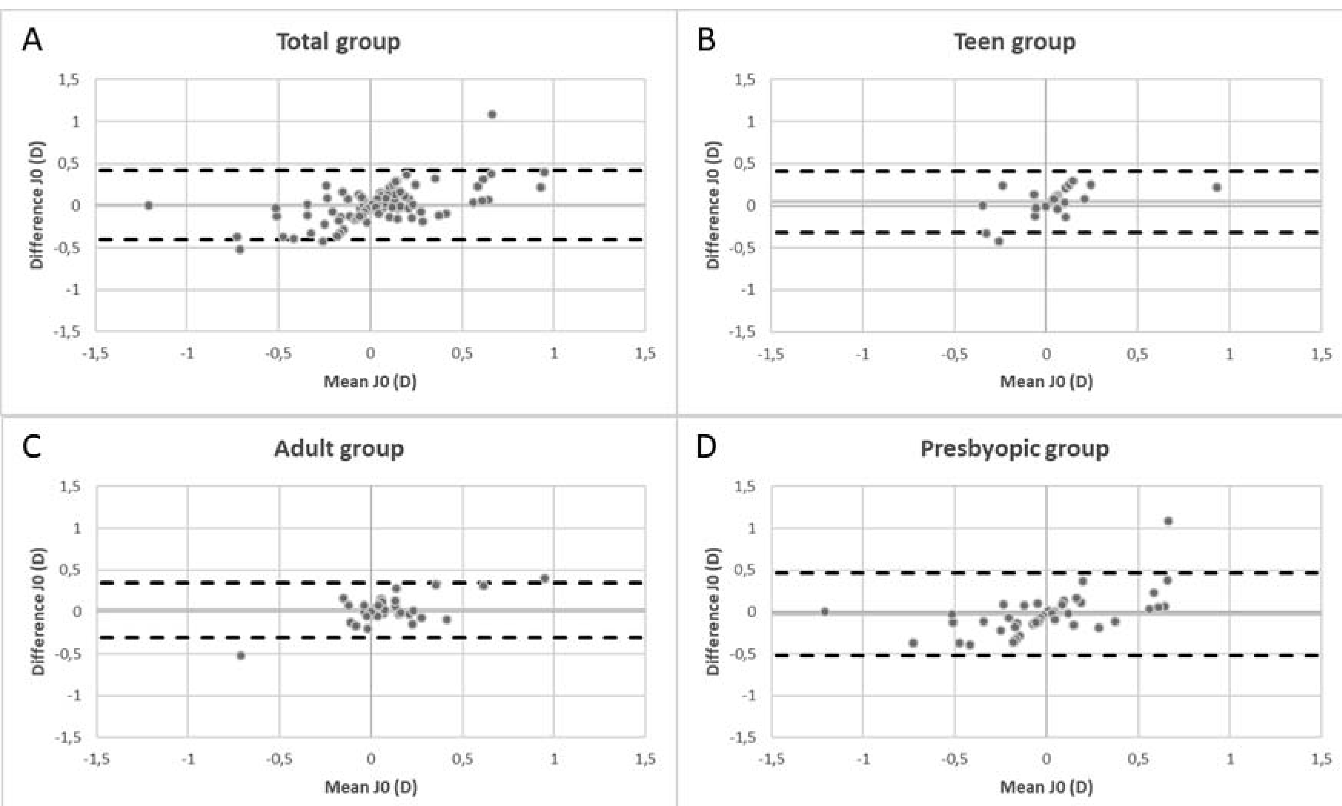

Figure 2. Bland-Altman plots between mean J0 of EYER and subjective refraction for total group (**A**), teenagers (**B**), adults (**C**), and presbyopic (**D**) group. The *middle line* indicates the mean difference (EYER - subjective refraction), and the *two dashed side lines* show the 95% limits of agreement.

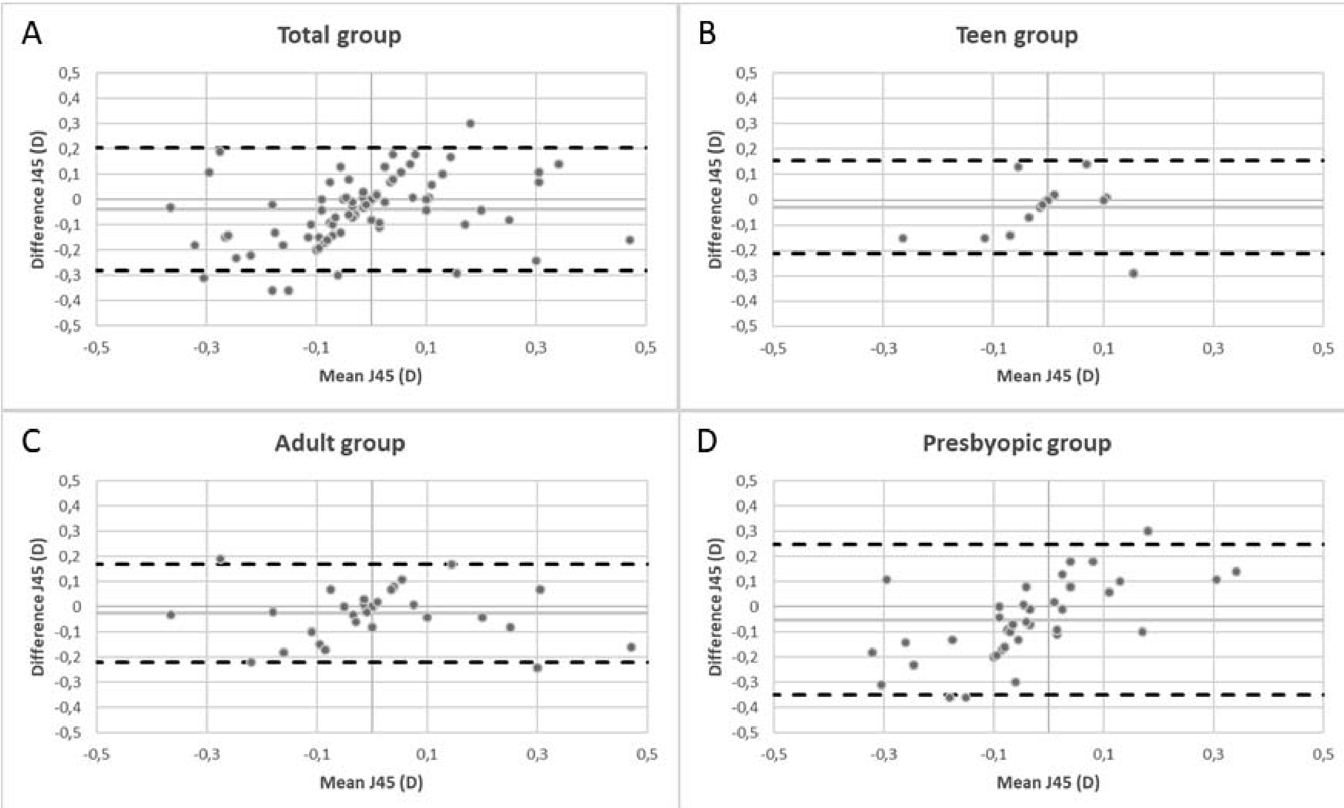

Figure 3. Bland-Altman plots between mean J45 of EYER and subjective refraction for total group (**A**), teenagers (**B**), adults (**C**), and presbyopic (**D**) group. The *middle line* indicates the mean difference (EYER - subjective refraction), and the *two dashed side lines* show the 95% limits of agreement.

accommodation stimulus does not seem to influence the refraction measurement with open-field refractors,[8,12–17] and even with some new conventional[9–11] and wavefront-based refractors.[19–21] However, none of these devices solve the subjective demands of each subject associated with their usual optical compensation. The EYER system performs an objective and subjective refraction, allowing to adjust the objective refraction obtained by the Hartmann-Shack sensors from an algorithm of subjective questions related to the visual quality during the refraction process. Through this procedure, the EYER offered similar results to conventional subjective refraction in terms of MSE (Table 2), showing a positive strong correlation ($R^2 > 0.90$) between both methods for all age groups. The final refraction of the EYER is obtained from an automatic algorithm based on the subjective answers of each subject, and this final refraction could be manually modified in the device according to the criteria of each professional. Also, the EYER refraction could be compared with the

Table 5. BBCVA Mean Values Found With Both Refraction Systems

Test	Total Group (n = 99)	Teen Group (n = 21)	Adult Group (n = 35)	Presbyopic Group (n = 43)
BBCVA (eye refract) mean ± SD	−0.12 ± 0.09	−0.08 ± 0.09	−0.16 ± 0.06	−0.11 ± 0.09
BBCVA (subjective refraction) mean ± SD	−0.12 ± 0.08	−0.10 ± 0.05	−0.15 ± 0.06	−0.10 ± 0.09
P value	0.623	0.183	0.570	0.913

Student's *t*-test for related samples. Eye refract vs. subjective refraction in each group studied.

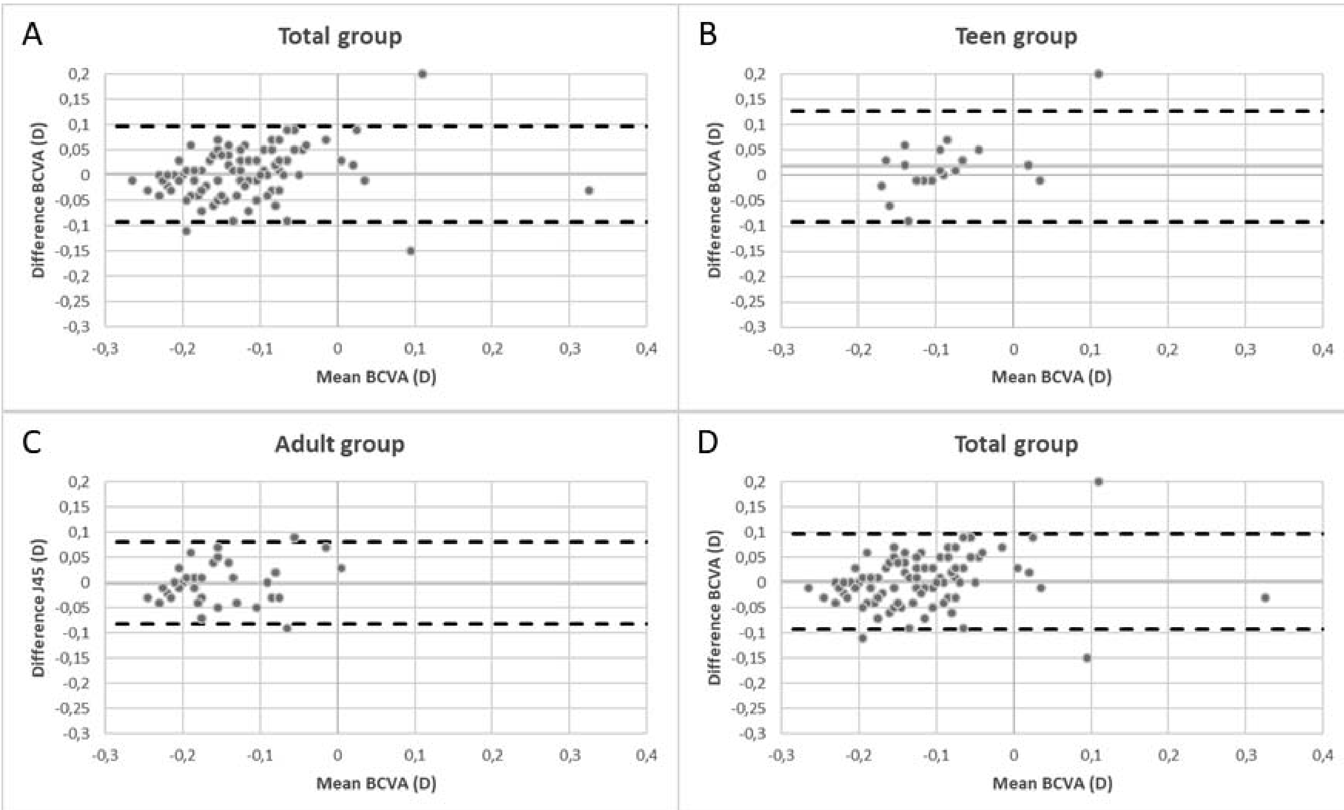

Figure 4. Bland-Altman plots between mean BBCVA of EYER and subjective refraction for total group (**A**), teenagers (**B**), adults (**C**), and presbyopic (**D**) group. The *middle line* indicates the mean difference (EYER - subjective refraction), and the *two dashed side lines* show the 95% limits of agreement.

usual optical compensation or any other manually chosen method.

Some subjects showed higher MSE-positive values, more than 1 diopter (D), with the EYER compared to subjective refraction. This was attributed to the algorithm of the EYER to perform its subjective refraction. Also, these differences were not related with the differences superior to 0.10 logMAR found in the BBCVA. High differences in BBCVA could be attributed to the fact that subjective BBCVA was measured with a trial lens and EYER BBCVA through the oculars of the device. However, the number of positive and negative differences seems to be similar.

The cylinder is a susceptible parameter to be corrected according to the criteria of the professional. Low astigmatism could not be prescribed and high astigmatism could not be fully compensated in the subjects who were not previously corrected, due to their previous neural adaptation. This could be the reason why different conventional,[5,7,8,11] open-field,[8,13,16,17] and wavefront-based[18] refractors showed differences in respect to subjective refraction in terms of cylindrical components. In our study, statistical differences were found only in the oblique component (J45) for presbyopic and total groups (Table 4). Despite these differences being statistically significant with a high sample size, they could not be considered clinically relevant due to the low differences (<0.25 D). Also, it should be noted that the correlation between EYER and subjective refraction in both cylindrical components was not as high as the MSE correlation. This was associated with the fact that subjective refractions tended to avoid the cylinders compensation lower than 0.25 D. Subjective refraction was Plano in 27.1% of subjects compared to 7.3% of subjects with EYER. On the other hand, there was no correlation in J45 for the teen group, which was in accordance with a higher standard deviation with the subjective refraction (Table 4).

In relation to BBCVA, the EYER showed similar results to subjective refraction (Table 5). Despite this similarity, differences in visual satisfaction were found between both methods. The EYER showed a statistically lower visual satisfaction than subjective refraction for total and presbyopic groups (see Results). This reduction could be explained considering that the VAS was measured through the EYER oculars and, in the case of subjective refraction, with trial spectacles. However, this could not be considered clinically relevant because the differences in VAS scores were approximately 3% to 4%. In addition, Pujol et al.,[22] who designed an instrument to perform objective and subjective refraction, did not report visual acuity results. No studies evaluating visual satisfaction with refractors in a quantitative manner were found in the scientific literature. In a qualitative manner, Strang et al.[27] evaluated the preference between two prescriptions, comparing conventional and subjective refraction, and 51.1% of the participants preferred the optometrist's prescription against 19.1% who preferred the refractor prescription, while 29.8% found both equally good. Also, Gajwani et al.[28] performed a satisfaction survey of a refractor-based prescription for 2 weeks, and found that 92% of the participants were satisfied with the prescription. However, they did not compare it to a subjective refraction prescription.

The time of the EYER refraction was lower than that of subjective refraction for all age groups (see Results). It should be considered that the spent time for subjective refraction did not include the previous objective refraction (retinoscopy) and measurement of the BBCVA. Therefore, the benefit of the EYER in terms of time is greater than what the results showed. Reducing the spent time for refraction would imply reducing the chair time for refraction and increasing the spent time for other specialized optometric practices. No studies evaluating the spent time for subjective refraction were found in the scientific literature. This measurement was made to know if the spent time by each optometrist for subjective refraction was or was not too long than that for EYER. Mean spent times by each optometrist were: 5:37 ± 1:47, 4:15 ± 1:39, and 4:47 ± 2:05 minutes, with the maximum difference between optometrists being 1:22 minutes. Considering that the three optometrists are experienced, this range of time could be considered normal.

The wavefront aberrometry allows a precise objective analysis of the refractive error considering the physiologic pupil size.[1–3] Sometimes, subjects with an irregular cornea or multifocal intraocular lenses could be difficult to refract due to their high values of coma and spherical aberration, respectively,[29,30] which influence visual quality during the refraction process. By this, it would be interesting to test if the EYER system is a reliable device to evaluate refraction in these subjects. In our knowledge, there are no studies evaluating the efficacy of wavefront-based refraction in subjects with irregular cornea or implanted with multifocal intraocular lenses. The EYER system also could be used to automatically assess the accommodation and binocularity after the refraction, reducing the time of the complete visual examination.

There are some limitations that could be improved in future studies. On one hand, visual satisfaction and BBCVA should have been assessed with trial spectacles in both methods of refraction to compare them under the same experimental conditions. The EYER measurements were taken through the oculars of the device, which could be affecting visual perception and VAS measurement. Also, conventional and EYER visual satisfaction could have been taken under masked conditions. On the other hand, the refraction should have been done under cycloplegic conditions in the teen group to eliminate the influence of the accommodation stimulus. Despite this, there is scientific evidence supporting that open-field refractors could provide similar results in children with and without cycloplegia.[12] Against this argument, Choong et al.[8] found more negative values in terms of sphere with an open-field refractor in children without cycloplegia. However, these differences were inferior to 0.25 D in comparison with binocular subjective refraction.

In conclusion, the EYER system showed similar results to conventional subjective refraction in terms of spherical (MSE) and cylindrical (J0 and J45) components, visual acuity (BBCVA), and visual satisfaction (VAS). The spent time for refraction also was lower with the EYER system. Therefore, the EYER system seems to be a useful device to evaluate refraction in all age groups, reducing the chair time.

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