

A Comparison Between Refraction From an Adaptive Optics Visual Simulator and Clinical Refractions

Juan Tabernero^{1,2}, Carles Otero¹, and Shahina Pardhan¹

¹ Vision and Eye Research Institute, School of Medicine, Anglia Ruskin University, Cambridge, UK

² Departamento de Electromagnetismo y Electrónica, Facultad de Química, Universidad de Murcia, Murcia, Spain

Correspondence: Juan Tabernero, Departamento de Electromagnetismo y Electrónica, Facultad de Química, Universidad de Murcia, 30100 Murcia, Spain. e-mail: juant@um.es

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Purpose: The Visual Adaptive Optics (VAO) is an adaptive optics visual simulator with an embedded Hartmann–Shack aberrometer that can give objective and subjective refraction measures. The aim of the present study was to compare the findings of the objective and subjective refractions from the VAO with a commercial autorefractometer (Topcon Corp., Tokyo, Japan) and a subjective refraction by an optometrist. The influence of age, refractive error type, and presence of ocular diseases was ascertained.

Methods: The refractive error was obtained in 469 participants using the four techniques mentioned. Data were analyzed with power vectors mean spherical equivalent, the vertical Jackson-Cross-Cylinder, and the oblique Jackson-Cross-Cylinder. Age, refractive error type (myopia, emmetropia, hyperopia) and presence of ocular diseases (yes, no) were included as covariates. Agreement was assessed using the 95% interval of agreement.

Results: The median spherical equivalent difference and the interval of agreement for all the participants with the VAO subjective, VAO objective, and autorefractometry with the clinical subjective refraction were (+0.13, 1.80 diopters [D]), (+0.38, 1.80 D), and (−0.38, 2.10 D), respectively. When considering only healthy participants, the results were (+0.06, 1.70 D), (+0.38, 1.60 D) and (−0.25, 1.80 D), respectively. When considering only those participants with any ocular condition, the results with VAO subjective, VAO objective and autorefractometry were (+0.13, 2.50 D), (+0.31, 2.70 D), and (−0.50, 4.80 D), respectively.

Conclusions: The VAO subjective refraction is more accurate than VAO objective refraction and autorefractometry, regardless of refractive error, age, or the presence of ocular conditions. The presence of ocular conditions significantly deteriorates the accuracy of all refraction methods.

Translational Relevance: Reported clinical comparisons between different types of standard refraction methods and a new adaptive optics refraction instrument (VAO) are in good agreement and support the further development of this method to increase refraction accuracy and to refract quicker than standard procedures.

Introduction

Refractive error measurement, correction and progression are all important aspects in primary vision care. According to the most recent estimates from the World Health Organization, uncorrected refractive error is the main cause of visual impairment, affecting 43% of the global population.¹

The refraction of the eye can be obtained both objectively and subjectively. Objective refraction measurements are currently determined quickly and easily with autorefractors and wavefront aberrometers, and they are often used as a starting point for clinical subjective refraction.^{2–4} Several studies have reported that most modern objective refractometers are reliable and accurate.^{5–9} However, prescribing spectacles from objective findings alone achieves limited patient

satisfaction, which is why subjective refraction is considered the gold standard of refraction.¹⁰ Clinical subjective refraction compares different dioptric lenses (i.e., spherical and cylindrical lenses) to arrive at the dioptric lens combination that produces optimal visual acuity.¹¹

Recently, new technologies have appeared with the aim of approaching the measurement of refraction in a different way.^{12–14} Most of them are objective and do not include the patient's subjective response, which limit their applicability for accurate spectacles prescription. Substantial efforts are being made in terms of miniaturizing devices, decreasing costs, and improving software accessibility to make the technology accessible to everyday clinics. Electro-optical varifocal systems, based on adaptive optics technology and used as visual simulators,^{15–17} allow one to be able to obtain certain wavefront profiles such as those experienced with multifocal intraocular lenses.^{16–18} These systems have also the potential to perform some optometric tests such as the subjective refraction since they have computer-controlled phoropter capabilities. To date, this application has not been fully explored, because adaptive optics visual simulators have been mostly confined to research laboratories and small prospective studies.¹⁹

The Visual Adaptive Optics (VAO, Voptica S.L., Murcia, Spain) is the only commercially available adaptive optics visual simulator with an embedded Hartmann–Shack aberrometer. It has different testing modalities as testing subjective responses for multifocal intraocular lens vision simulation, and it allows monocular objective (using the Hartmann–Shack aberrometer alone) and subjective refraction (subjective visual testing to refine the objective refraction) measures within a few minutes.¹⁹

The main purpose of this study was to compare the findings of both the VAO objective and subjective refractions with a commercial autorefractometer (Accuref-K 9001, Rexam Co., Osaka, Japan) and clinical subjective refraction for participants of different ages, refractive error types, and presence of ocular conditions.

Methods

Participants

This cross-sectional study was conducted on a sample of 469 adult participants (≥ 18 years old) during a period of 6 months. The study was approved by the Ethics Committee of Anglia Ruskin University (Cambridge, UK), it followed the tenets of the Decla-

ration of Helsinki and all participants gave informed written consent. In order to have a sample representative of the general and true adult population, the only inclusion criteria were to be within the visual simulation operative range of the VAO in sphere and cylinder (sphere ± 9 diopters [D] and cylinder ± 9 D).

Examination Protocol

Noncycloplegic monocular subjective refraction was obtained in all participants, in both eyes, with the VAO system (VAO subjective) and the optometrist's clinician subjective refraction procedure with a trial frame and trial ophthalmic lenses (ClinicianRefraction). The starting point of the VAO subjective refraction was obtained by means of the Hartmann–Shack wavefront sensor embedded in the instrument (VAO objective). The starting point of the conventional clinician subjective refraction was obtained by means of the Accuref-K 9001 autorefractometer (Autorefraction).

Both VAO subjective and ClinicianRefraction procedures followed a monocular refraction protocol of maximum plus power to obtain the best visual acuity. The protocol comprised four sequential steps described in detail elsewhere^{10,20}: in summary, (1) starting point of refraction, (2) spherical fogging, (3) astigmatic correction with Jackson cross-cylinders, and (4) monocular spherical endpoints. The duochrome test was not used and all refractions were performed under the same room lighting conditions. The Early Treatment Diabetic Retinopathy Study visual acuity chart and the random dot stimulus (shown for the astigmatic correction) were used in both procedures. All the VAO measurements were obtained by the same operator throughout the study (CO, optometrist, PhD). The UK-licensed optometrist who conducted all the subjective refractions had more than 30 years of working experience.

The study was conducted in a double-blind fashion, neither the VAO's operator nor could the clinician see each other results. All measurements (i.e., VAO Objective, VAO Subjective, Autorefraction and ClinicianRefraction) were obtained in one session.

Instrumentation

The VAO (Voptica S.L.)¹⁹ is the only commercially available adaptive optics visual simulator with an embedded Hartmann–Shack wavefront sensor that can perform objective and subjective refraction measures (Fig. 1). This device is the clinical version of previous prototypes developed at the University of Murcia Optics laboratory.^{15,16,19} Briefly, a Hartmann–Shack wavefront sensor (HSS in Fig. 1) embedded in

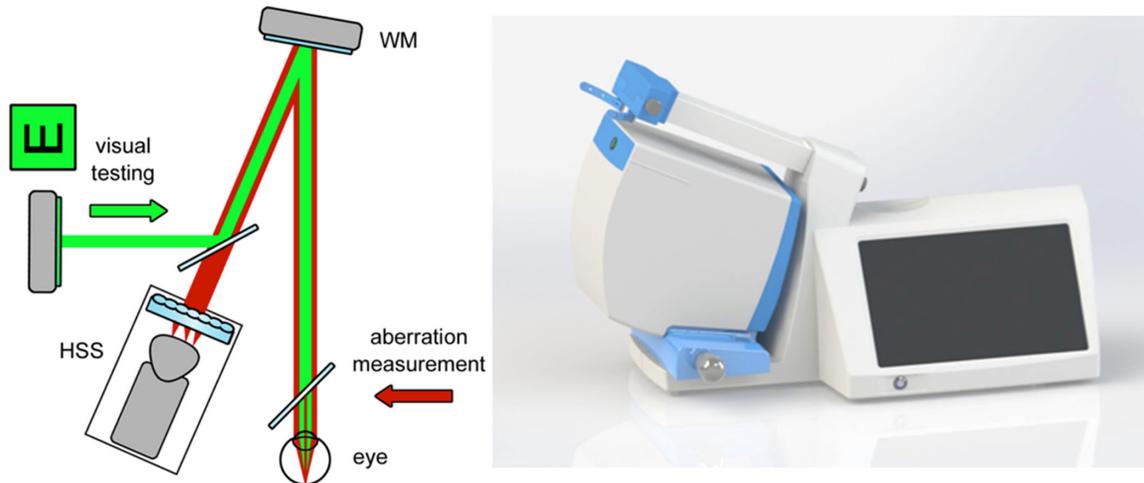


Figure 1. Schematics of an Adaptive Optics (AO) vision simulator, showing the main elements: spatial light modulator, Hartmann–Shack sensor (HSS), and microdisplay (left). Picture of the first commercially available clinical version of an AO vision simulator by Voptica (right). WM, wavefront mirror.

the instrument is used to measure ocular aberrations. This information is then relayed onto a liquid crystal setup that acts as a deformable mirror (wavefront mirror in Fig. 1). Digital images from visual tests (letter “E” in the Fig. 1 scheme) are projected to patient’s eye by reflection from the liquid crystal mirror (wavefront mirror). Operators can then perform visual testing, enabling further adding or subtracting lower and higher order aberrations onto the image. The instrument includes software to control the digital display and the liquid crystal mirror to enable replication of clinical refraction protocols which allows the addition or subtraction of spheres, cylinders and change of axis. The device can measure refraction in two ways: (i) from the objective HS wavefront sensor (VAO Objective refraction) and (ii) from a subjective visual test that uses the HS measurement as the starting point (VAO Subjective refraction).

Data Analysis

Only one eye for each participant randomly chosen was included in the data analyses. Significance was set at 0.05 and the statistical analysis was performed using MATLAB 2018 (MathWorks, Inc., Natick, MA). Normality of each variable was checked with the Shapiro–Wilk test. Agreement between the three nonclinical refractions methods relative to the gold standard (the clinician refraction) was assessed with Bland and Altman plots for each power vector component,²¹ mean spherical equivalent (M), the vertical Jackson-Cross-Cylinder (J_0), and the oblique Jackson-Cross-Cylinder (J_{45}) obtained from the sphere (S),

cylinder power (C), and cylinder axis (A):

$$M = S + \frac{C}{2}; J_0 = -\frac{C}{2} \cos(2A); J_{45} = -\frac{C}{2} \sin(2A)$$

The influence of age, refractive error, and presence of ocular conditions on the accuracy of each refractive method was conducted with Bland and Altman plots. The factor age had three levels: participants between 18 and 40 years of age, participants between 41 and 60 years of age, and participants older than 60 years of age. The factor refractive error had three levels: myopic participants, emmetropic participants, and hyperopic participants. Emmetropia was defined as the best corrected spherical equivalent between -0.25 and $+0.75$ D. The factor presence of ocular conditions was a dichotomic variable with only two levels: the presence or absence of any ocular condition.

Statistical power was assessed with the free open-source G*Power 3.0.10. A pilot study with 25 participants was conducted to calculate the sample size needed for a statistical power of 0.95 and it resulted in 40 participants for each group.

Results

A total of 500 participants were enrolled in the study but only 469 participants were included in the analyses. The remaining 31 participants could not be measured with the autorefractometer and the Hartmann–Shack system owing to a very small pupil size (<2 mm) or poor vision (e.g., advanced age-related

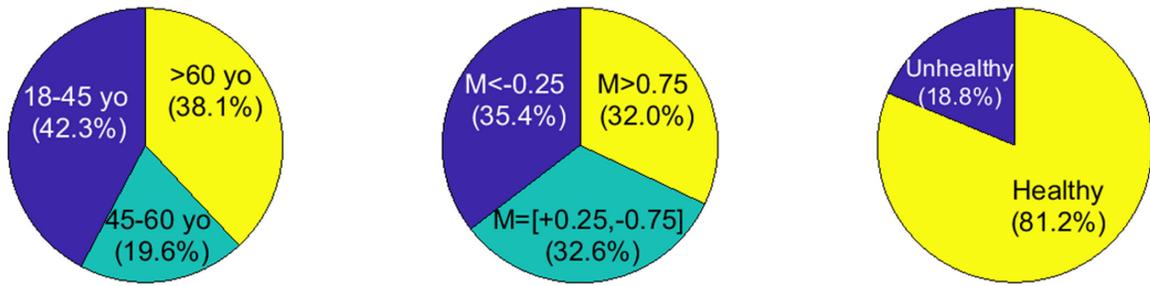


Figure 2. Proportion of participants in each age group, refractive error group, and ocular condition group.

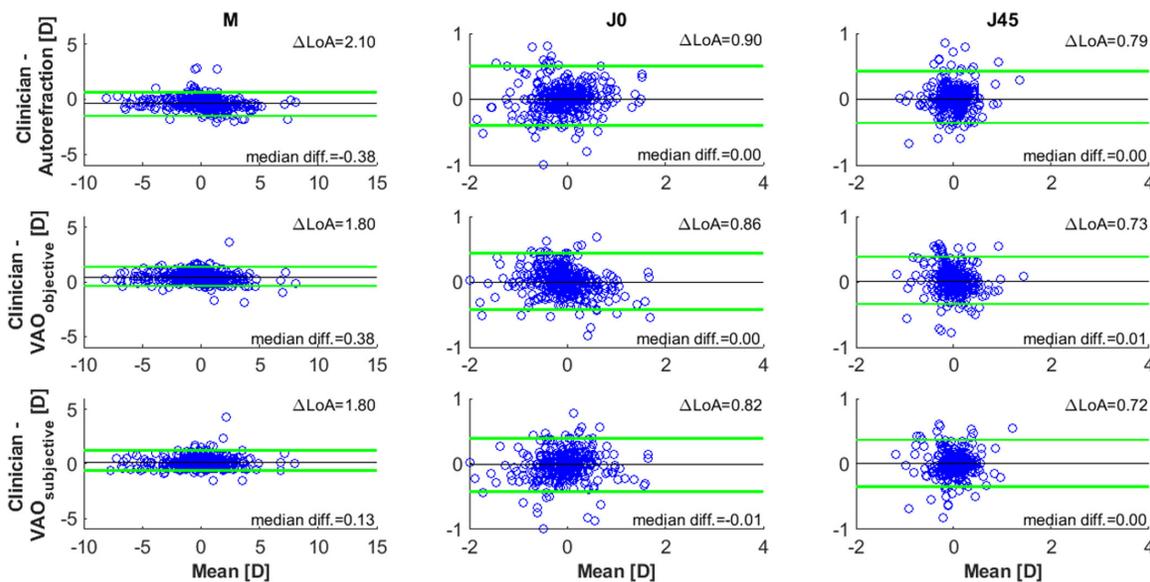


Figure 3. Nonparametric Bland and Altman plots comparing the agreement between refraction methods for each power vector component (M, J_0 , and J_{45}). Superior and inferior green lines are the percentile 97.5% and 2.5%, respectively. ΔLoA , limits of agreement percentile 97.5% - percentile 2.5%; diff., difference.

macular degeneration) and hence were excluded from the study. The frequency distribution of age and refractive error in all the sample was not normal; therefore, all the analyses that follow are described with the median for central tendency measures, interquartile range for dispersion, and nonparametric Bland and Altman plots²² for the agreement between methods. In particular, our results showed a leptokurtic frequency distribution for the spherical equivalent M with a negative skew, which matches the distribution that Lopes et al.²³ found also in a very large sample size ($N = 4,602$ participants).

Subjects had a median age and an interquartile range of 54 and 22 years, respectively. Analogously, participants had a median subjective spherical equivalent of 0.25 and an interquartile range of 1.88 D. The proportion of participants in each sample grouped

according to age, refractive error type and presence of ocular conditions is shown in Figure 2. The group with ocular conditions comprised 64 eyes with cataracts, five amblyopes, seven eyes with maculopathy, and 12 participants with glaucoma ($n = 5$), Rod dystrophy ($n = 4$), Sjogren’s syndrome ($n = 1$), or corneal scarring ($n = 2$).

Overall Analysis

The Bland and Altman plots comparing autorefractive, wavefront refraction and adaptive optics subjective refraction with the clinician subjective refraction for each power vector component are shown in Figure 3. All groups have the same sample size ($N = 469$ participants).

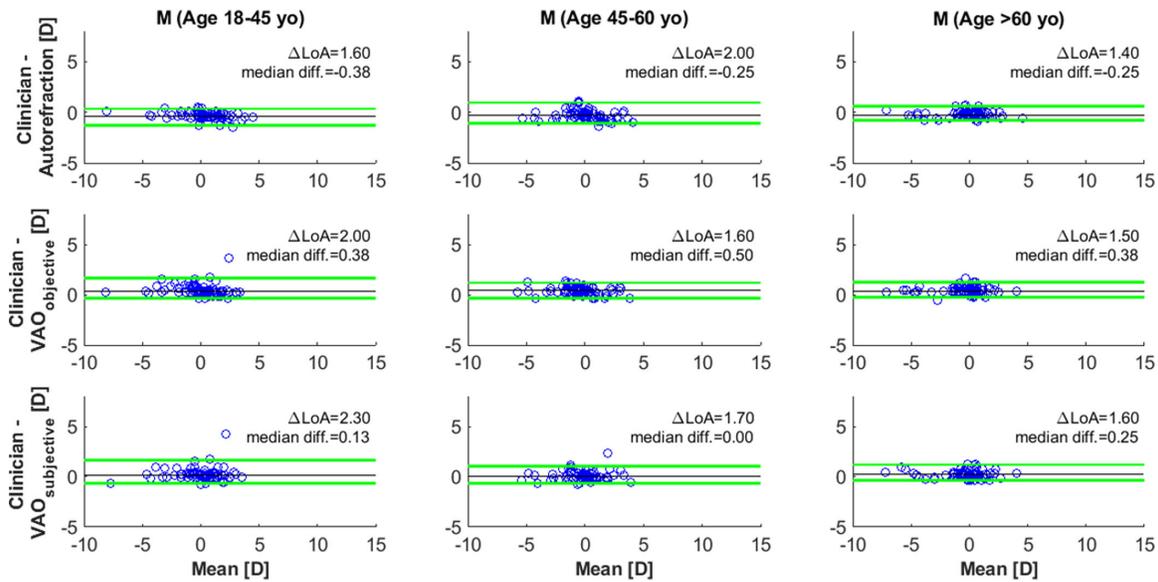


Figure 4. Nonparametric Bland and Altman plots comparing the agreement between refraction methods for the spherical equivalent M in three different age groups. Superior and inferior green lines are the percentile 97.5% and 2.5%, respectively. Δ LoA, limits of agreement percentile 97.5% – percentile 2.5%; diff., difference.

Grouped by Age

The Bland and Altman plots comparing the spherical equivalent measured with autorefraction, wavefront refraction and adaptive optics subjective refraction with the clinician subjective refraction for each age group are shown in Figure 4. All groups are randomly matched in sample size ($n = 122$ participants).

Grouped by Refractive Error Type

The Bland and Altman plots comparing the spherical equivalent measured with autorefraction, wavefront refraction, and adaptive optics subjective refraction with the clinician subjective refraction for each refractive error group are shown in Figure 5. All groups are randomly matched in sample size ($n = 75$ participants).

Grouped by the Presence or Absence of Ocular Conditions

The Bland and Altman plots comparing the spherical equivalent measured with autorefraction, wavefront refraction, and adaptive optics subjective refraction with the clinician subjective refraction for both the group with and without ocular conditions are shown in Figure 6. Both groups are randomly matched in sample size ($n = 88$ participants).

Discussion

A new refraction system based on Adaptive Optics technology was investigated in a large sample for different age groups, refractive error types, and presence of ocular conditions. Agreement of this new method in relation to the conventional clinical procedure was assessed in 469 participants. A total of three variables were analyzed: the power vectors components (M, J_0 , and J_{45}).

To study the agreement of a new refraction method with the gold standard, it is important to analyze the precision (i.e., repeatability and reproducibility) of the gold standard, because it provides an estimate threshold at which perfect agreement can be considered, that is, if the 95% limits of agreement between a new method and the gold standard are similar to the precision of the gold standard method, we can consider both methods to be equivalent. The repeatability of subjective refraction has been studied in the past in many studies, 95% Limits of Agreement between ± 0.29 D and ± 1.16 D in healthy adult eyes (without cycloplegia) for the spherical equivalent M has been reported considering different sample sizes and number of repetitions.^{14,24–29} Analogously, the reproducibility of subjective refraction has been shown between ± 0.39 D and ± 0.55 D for the spherical equivalent.^{19,25,27,30–32} Rosenfield and Chiu²⁶ suggested a limit of 0.50 D as a minimum significant shift in refractive status, which is

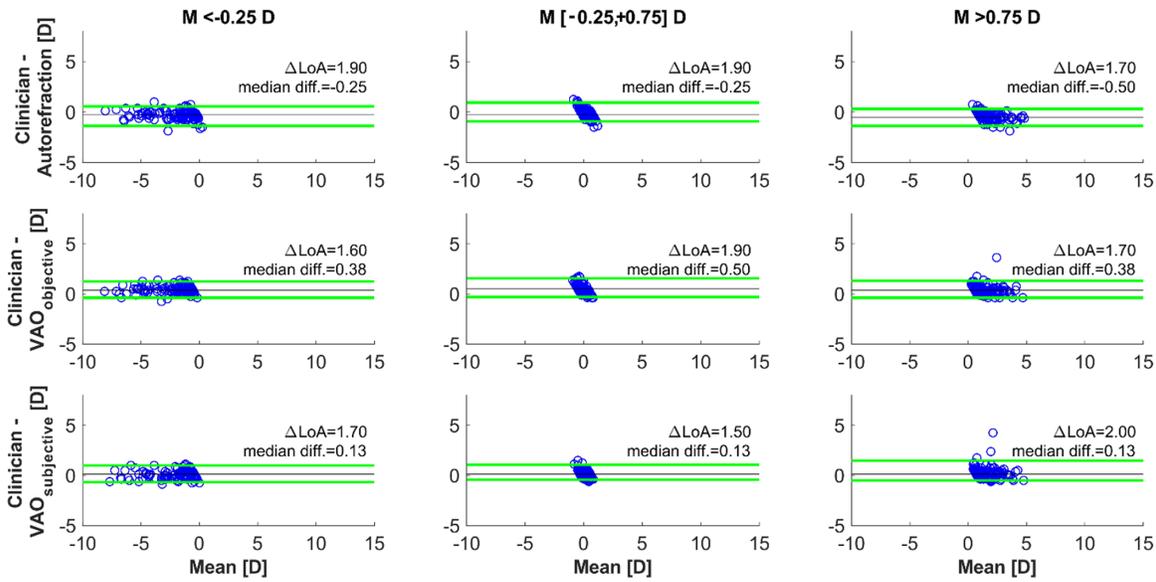


Figure 5. Nonparametric Bland and Altman plots comparing the agreement between refraction methods for the spherical equivalent M in three different refractive error groups. Superior and inferior green lines are the percentile 97.5% and 2.5%, respectively. Δ LoA, limits of agreement percentile 97.5% – percentile 2.5%; diff., difference.

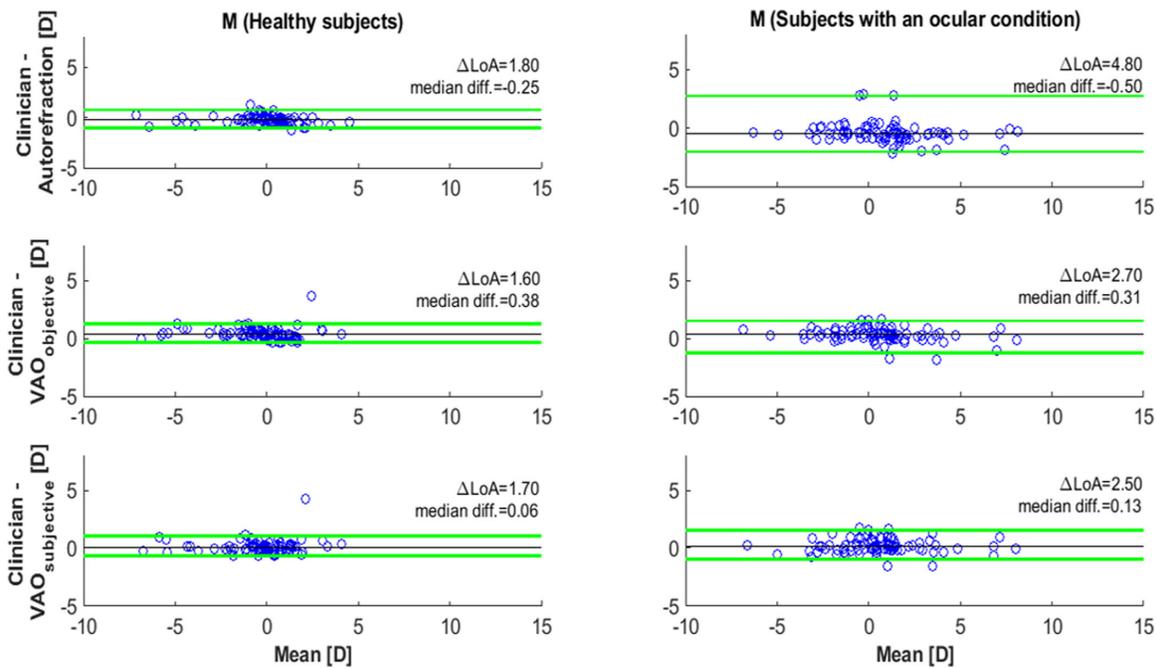


Figure 6. Nonparametric Bland and Altman plots comparing the agreement between refraction methods for the spherical equivalent M in two groups: healthy participants and participants with an ocular condition. Superior and inferior green lines are the percentile 97.5% and 2.5%, respectively. Δ LoA, limits of agreement percentile 97.5% – percentile 2.5%; diff., difference.

reasonable considering the results from all the previous studies of precision in subjective refraction.

Having all these factors in mind, the VAO subjective refractions shows overall better limits of agreement in most of the cases and shows a much better

central tendency in all cases (median difference with respect the gold standard is close to zero) than autorefraction and VAO objective refraction. These findings are expected; the subjective refraction of VAO mimics the gold standard method and includes visual acuity

measurements. It is not surprising that VAO subjective refractions were on average left slightly myopic compared with the gold standard measurements as instrument accommodation artefacts could have been induced,³³ owing to the closed and small field of view of the VAO system; however, if VAO subjective refractions had used the same starting point of refraction as the clinician refraction (i.e., autorefractometer instead of Hartmann–Shack measures), the agreement between both methods would have likely been better as the autorefractometer provided—on average—overplus refractions, whereas the Hartmann–Shack overminused them.

In the presence of ocular conditions, the limits of agreement significantly increased for all refraction methods, which suggests that in those cases the conventional subjective refraction procedure is necessary. It is possible that some ocular diseases may show a big variation than others, and this possibility is currently being explored. However, when comparing how agreement is affected by different refractive error groups or age groups, our results do not show an effect of age or refractive error type on the agreement between methods, except for the emmetropic group (M between -0.25 and $+0.75$ D) in which there is a similar systematic bias in all refraction systems. This bias shows an overminus for slight myopic errors and an overplus for slight hyperopic refractive errors. It seems likely that a combination of factors such as the uncertainty of the best focal plane given by the depth of focus of the eye³⁴ and a somewhat unconscious decision of the clinician to leave the participants with neutral refractions (because a prescription is not usually given for such small errors)¹⁰ masks these differences.

In comparison with other studies, most of them have considered only healthy (and most likely young) adults. This study is the first to our knowledge that compares different refraction methods in a large sample and clusters the analysis in different age groups, refractive error groups, and whether there is an ocular condition or not. A recent pilot study analyzed agreement of the VAO subjective refraction procedure in a sample of 38 normal participants,¹⁹ and reported 95% limits of agreement of ± 0.67 D, ± 0.16 D, ± 0.17 D, for the M, J_0 , and J_{45} , respectively. These values cover an interval of 1.34 D, 0.32 D, and 0.34 D, respectively, showing smaller values than ours (Fig. 3): 1.80 D, 0.72 D, and 0.82 D, respectively. The fact that we considered not only healthy participants but participants with different eye conditions (e.g., cataracts) and a sample size that is more than 12 times larger could possibly explain these differences.

Other refraction systems such as retinoscopy, autorefractometer, wavefront refraction, and automated

subjective refraction have also been previously compared with the gold standard refraction. For noncycloplegic retinoscopy, Jorge et al.³⁵ found 95% limits of agreement of ± 0.65 D (interval of 1.30 D) in a sample of 192 healthy adults; similarly, Ciuffreda and Rosenfield¹⁴ obtained 95% limits of agreement of ± 0.84 D (interval of 1.64 D) in a sample of 50 participants. For autorefractometer, there exist many comparison studies^{3,7,12,14,25–27,29,31,35–37} because there are many different commercial autorefractometers. The 95% limits of agreement ranged from ± 0.31 D (interval of 0.62 D)²⁵ to ± 1.47 D (interval of 2.94 D).¹⁴ The wide range of limits of agreement found in all these studies can be explained because of the differences in optical principles (e.g., Scheiner, retinoscopy, image size, and best focus, among others¹⁰) as well as the differences in study design (e.g., an average of three consecutive readings or just one reading) and sample sizes (from 12 up to 192 participants). Analogously to autorefractometer, for wavefront sensor refractometers there are many validation studies^{7,12,14,37,38} and the 95% limits of agreement ranged from ± 0.56 D (interval of 1.12 D)¹⁴ to ± 1.04 D (interval of 2.08 D).¹² Finally, automated subjective refraction is not as popular as objective refraction systems; however, there exist a few studies,^{25,27,29,36,38,39} each with a completely different automated algorithm, that found 95% limits of agreement between ± 0.52 D (interval of 1.04 D)³⁸ to ± 1.20 D (interval of 2.40 D).³⁹ Our results (and others) indicate that automated refraction techniques with devices such as the VAO are promising areas for applying artificial intelligence and algorithms for improving prediction of visual outcomes.

An accurate refraction device/method should not only have a small mean bias (<0.25 D), but also small limits of agreement ($<\pm 0.50$ D). Our data demonstrate that the VAO subjective refraction system is well able to correct the mean bias. However, caution is still required because the VAO showed some discrepancy with clinical subjective refraction and hence a complete replication was not obtained. Whether the limits of agreement are acceptable in a clinical situation is to be determined in a further study.

Conclusions

The VAO subjective refraction system has shown to be clinically more accurate than objective refraction. Age or refractive error type do not affect the agreement between method. However, the presence of ocular conditions can dramatically decrease accuracy of refraction with all refraction methods.

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