Title: **Assessment of multifocal contact lens over-refraction using an infrared, open-field autorefractor: A preliminary study**

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Abstract

Purpose: To evaluate the usefulness of an infrared open-field autorefractor as a predictor of the refractive error when fitting multifocal contact lenses (MCL).

Methods: Objective and subjective measurements of the non-cycloplegic distance refractive error were compared in patients wearing MCL. We used the Grand Seiko WAM-5500 autorefractor for the objective measurements. Three commercially available MCL were tested. Twenty-one eyes of sixteen healthy adults were included in the study. Over-refraction was evaluated in terms of spherical equivalent (SE) and astigmatic vectors (J_0 and J_{45}). The mean difference ± SD of each parameter was calculated. The Kolmogorov-Smirnov test was used to verify the normal distribution. Pearson's correlation, Bland and Altman plot and paired sample *t* test were used to compare the results obtained with both methods.

Results: The mean difference between objective and subjective results of the SE over-refraction was 0.13 ± 0.42 D; for astigmatic vectors J_0 and J_{45} were 0.03 ± 0.32 D and −0.00 ± 0.17 D, respectively. The Kolmogorov-Smirnov test showed a normal distribution for all parameters. The highest Pearson's correlation coefficients were obtained for the SE with values of 0.98 without MCL and 0.97 with MCL. The lowest were obtained for J_{45} with values of 0.65 without MCL and 0.75 with MCL. Significant correlations were obtained for each parameter. The paired sample *t* test failed to show significant differences in analyzed parameters except for J_0 without MCL.

Conclusions: The Grand Seiko WAM-5500 can be used as a screening method of over-refraction in the clinical fitting of MCL.

Key words: multifocal contact lens, simultaneous vision, over-refraction, autorefractor, refractive error.

Introduction

Presbyopia is the age-related loss of accommodation that causes blurring at near viewing distances [1]. This condition starts typically around 45 years of age [2]. Presbyopia cannot be prevented and thus eventually affects the whole population. Several methods can assist presbyopes at near viewing distances. Firstly, the use of spectacles: monofocal for near viewing or multifocal designs (including bifocals) for near and far vision. Multifocal intraocular lens (MIOL) designs have been proposed for pseudophakic patients [3] who have lost accommodation after extraction of the crystalline lens. Monovision, bifocal or MCL have been suggested for near viewing distances in presbyopic subjects [4].

Multifocal contact lens (MCL) and MIOL technologies, which are based on diffractive and refractive optical designs, emerged at the end of the 20th Century. In contrast, refractive hydrogel models with aspheric geometry are currently common. MCL are designed to provide several foci in what is known as simultaneous vision. Depending on the viewing distance, the image formed by one of the foci is focused on the retina, while the images of the other foci remain blurred. This allows clear vision for different distances but focused and unfocused images are formed simultaneously on the retina; as a result, glares and halos occur frequently [5].

A contact lens adaptation implies the proper adjustment of parameters such as the radius of curvature, material and diameter [6]. When fitting contact lenses, over-refraction [7], the residual error of refraction of the eye when the patient is wearing contact lenses, is also measured [8]. Based on this result, the refraction of the contact lens is modified to avoid any residual error. In clinical practice an autorefractor is commonly used as a screening method of over-refraction for contact lenses users [9][10]. Indeed, its suitability in monofocal contact lens over-refraction has already been demonstrated [11]. Due to the complex designs of MCL, some inaccuracies in over-refraction measurements obtained with the autorefractor can occur, similar to the inaccuracies found when performing aberrometric measurements in other multifocal systems such as MIOL [12]. However, not all authors report problems when measuring aberrations in MCL [13] and objective accommodative responses have been successfully measured using an autorefractor [14]. Moreover, autorefraction has also been used after cataract surgery in patients with MIOL [15][16]. To our knowledge, no comprehensive studies on the evaluation of autorefractors as a screening method for MCL over-refraction have been published. The purpose of this preliminary study was to evaluate the suitability of an infrared open-field autorefractor to obtain an accurate over-refraction evaluation for far viewing distances after fitting MCL in non-cycloplegic adult eyes.

Methods

Subjects

Sixteen healthy young and middle-aged adults (11 men and 5 women) from a research centre environment participated in the study. The exclusion criteria for the study were any disease or medication that caused vision problems or contraindicated the use of contact lenses. The age ranged from 26 to 48 years old (31.38 ± 7.34). The study followed the tenets of the Declaration of Helsinki and all patients signed the informed consent after they were explained the nature, procedures and aims of the study.

Multifocal contact lenses

We used three commercially available soft MCL: Air Optix Multifocal, Acuvue Oasys for presbyopia and Proclear Multifocal. Air Optix® Multifocal (Ciba Vision), used in nine eyes of the study, has a near-center aspheric refractive design [14] composed of Lotrafilcon B with a *Dk* = 110 and a water contents of 33%. Its diameter is 14.2 mm and the base curve 8.6 mm. Acuvue® Oasys™ for presbyopia (Johnson & Johnson), used in six eyes, has also a near-center aspheric refractive design [17] composed of Senafilcon A with a *Dk* = 147 and a water contents of 58%. In this case, the diameter was 14.3 mm and the base curve 8.4 mm. Proclear® Multifocal (Cooper Vision), used in six eyes of the study, has a near-center aspheric refractive design [18] composed of Omafilcon A with PC with a *Dk* = 27 and a water contents of 60%. It has a diameter of 14.4 mm and a base curve of 8.7 mm.

WAM-5500

The Grand Seiko AutoRef/Keratometer WAM-5500 (Grand Seiko Co. Ltd., Hiroshima, Japan) employed in this study is a binocular open-field autorefractor and keratometer. The basic principle of refractive power measurement consists of capturing the image of a ring target of infrared light after reflection on the retina. The size of the pattern formed at the eye-ground varies in relation to the refractive power. This pattern is then detected by a CCD sensor and analyzed by image processing to calculate the refractive data. The instrument can measure refraction in the range of ±22 D sphere and ±10 D cylinder in increments of 0.01, 0.12 or 0.25 D for power, and 1° for cylinder axis. The vertex distance can be adjusted (to 0, 10, 12, 13.5 or 15 mm); the minimum pupil size for measurement is 2.3 mm [19]. In this study the selected vertex distance was 12 mm. The measurements were performed in illuminance conditions low enough to obtain pupil diameters above 2.3 mm ($Mean_{PupilDiameter}$ = 6.27 mm [from 5.6 to 6.8 mm]). The Grand Seiko AutoRef/Keratometer WAM-5500 (Grand Seiko Co. Ltd., Hiroshima, Japan) had been previously validated for all these functions [20].

Measurement Protocol

The measurements were obtained in two different sessions per person; only one eye was fitted with a MCL per session.

The first session started with a medical history, followed by a complete optometric exam without MCL, which included keratometry, distance subjective refraction (Jackson crossed cylinder, maximum plus for best visual acuity) and objective refraction (Grand Seiko AutoRef/Keratometer WAM-5500). The visual acuity (VA) was evaluated with a Bailey & Lovie Chart 5 with the participant at a distance of 6 m (20 ft) [21]; observation through a slit-lamp ruled out any exclusion criteria conditions. Three subjective and objective refraction measurements were performed consecutively.

Once the initial exam was completed, one eye was selected and fitted with a MCL. The dioptric power of the contact lens was chosen randomly, without taking into account the subjective refraction of the patient. This procedure had been used in similar studies that fitted all lenses to ensure good movement and centration on the eye without controlling the power of the lens, thus enabling the evaluation of the autorefractor in a wide range of spherical powers [11]. As a result, in most cases the power of the MCL did not agree with the refraction distance of the patient.

After fitting the MCL, the patient spent one hour with it to achieve a correct adaptation, checked with the observation of the centration by means of a slit-lamp. Next, three consecutive repetitions of objective over-refraction with the autorefractor and three subjective distance over-refractions were performed to obtain the spherical and astigmatic components of the residual refraction.

In the second session the same procedure was used to fit the MCL on the eye not measured in the previous session.

All measurements were performed by the same optometrist.

Data analysis

Subjective and objective over-refraction results were entered into a spreadsheet in negative cylindrical form and the mean spherical equivalent (SE; equation 1) and astigmatic refraction were determined. Power Vector analysis [22] was used for astigmatic data at axis 0 (J_0; equation 2) and at axis 45 (J_{45}; equation 3).

$$SE = \text{sphere} + (\text{cylinder}/2) \quad (1)$$

$$J_0 = -(\text{cylinder}/2)\cos(2*\text{axis}) \quad (2)$$

$$J_{45} = -(\text{cylinder}/2)\sin(2*\text{axis}) \quad (3)$$

Statistical analysis

Statistical analysis was performed with SPSS for Windows [23]. The Kolmogorov-Smirnov test was used to verify the normal distribution of the spherical equivalent (SE), J_0 and J_{45} for objective and subjective over-refraction with and without MCL. The pair of eyes was included as a factor to control for the intereye correlation. In those cases where correlation between eyes was confirmed, one of them was excluded from the study.

Agreement between the objective and subjective over-refraction was evaluated for each measured component with the mean differences ± SD and the 95% confidence limits, as suggested by Bland and Altman [24]. Pearson's correlation coefficient was also calculated to compare both techniques. To evaluate if there was any tendency in the differences to systematically vary over the range of measurements, the Pearson correlation coefficient and its significance were also used in the Bland and Altman plots. Finally, a paired sample *t* test was carried out to analyze if there were significant differences between measurement methods for each parameter obtained in the study. A p value ≤ 0.05 was considered significant.

Results

Finally, twenty-one eyes were included in the study. The mean best corrected visual acuity without MCL was −0.13 ± 0.10 logMAR (range: −0.28 to +0.02 logMAR) and with MCL −0.07 ± 0.08 logMAR (range: −0.22 to +0.18 logMAR). The results with and without MCL were analyzed to determine if the WAM-5500 is a valid screening method for over-refraction in MCL wearers. A Kolmogorov-Smirnov analysis indicated that all parameters had a normal distribution ($p > 0.05$).

Table 1 shows the refractions' data and table 2 the mean of the differences ± SD between Pearson's correlation coefficients and their significance, and the paired sample *t* test significance.

	Refraction data			
	Without MCL		With MCL	
	Mean subjective refraction ± SD (Range)	Mean objective refraction ± SD (Range)	Mean subjective refraction ± SD (Range)	Mean objective refraction ± SD (Range)
SE	−1.22 ± 2.44 (−8.08, 2.84)	−1.28 ± 2.36 (−8.11, 3.16)	−1.26 ± 1.76 (−6.50, 0.67)	−1.13 ± 1.78 (−5.51, 0.77)
J_0	−0.09 ± 0.40 (−0.54, 1.21)	0.02 ± 0.37 (−0.35, 1.31)	0.00 ± 0.38 (−0.60, 1.25)	0.03 ± 0.47 (−0.78, 1.52)
J_{45}	-0.03 ± 0.12 (−0.23, 0.30)	−0.02 ± 0.20 (−0.39, 0.39)	0.02 ± 0.24 (−0.65, 0.54)	0.03 ± 0.24 (−0.60, 0.36)

Table 1. Mean subjective and objective refractive errors with and without MCL in terms of SE, J_0 and J_{45}. The mean difference ± SD (D) and range (D) are shown. (*Values are in dioptres (D)).*

	Mean difference ± SD (D) (Objective-subjective)	Pearson's correlation coefficient, $r(p)$	Paired sample *t* test (p)

Component	Without MCL	With MCL	Without MCL	With MCL	Without MCL	With MCL
SE	−0.06 ± 0.42	0.13 ± 0.42	0.98 (< 0.01)	0.97 (< 0.01)	0.55	0.18
J_0	0.12 ± 0.13	0.03 ± 0.32	0.94 (< 0.01)	0.73 (< 0.01)	0.00*	0.71
J_{45}	0.02 ± 0.15	−0.00 ± 0.17	0.65 (< 0.01)	0.75 (< 0.01)	0.66	0.92

(*) *Significant differences*

Table 2. Comparison between objective and subjective refraction with and without MCL. The mean difference ± SD (D), Pearson's correlation coefficients and their significance and the paired sample *t* test significance are shown. (*Values are in dioptres (D)).*

In terms of SE, the mean difference between subjective and objective measurements with MCL was nearly a quarter of dioptre, whereas without MCL the differences were close to zero (Table 2).

The correlation of SE with MCL between objective and subjective over-refraction, with a high, significant Pearson's correlation coefficient; as well as without MCL measurements (Table 1). The Bland and Altman plot of the SE with MCL is shown in figure 1. Pearson's correlation coefficient and its significance for the Bland and Altman plot were 0.037 and 0.873, respectively. Finally, no significant differences were obtained between measurements with and without MCL by means of a paired sample *t* test (Table 2). When performing the analysis by groups based on the contact lens used no significant differences were found. In terms of SE, we obtained $p = 0.072$ for the Air Optix® Multifocal lenses, $p = 0.699$ for the Acuvue® Oasys™ for presbyopia and $p = 0.835$ for the Proclear® Multifocal lenses.

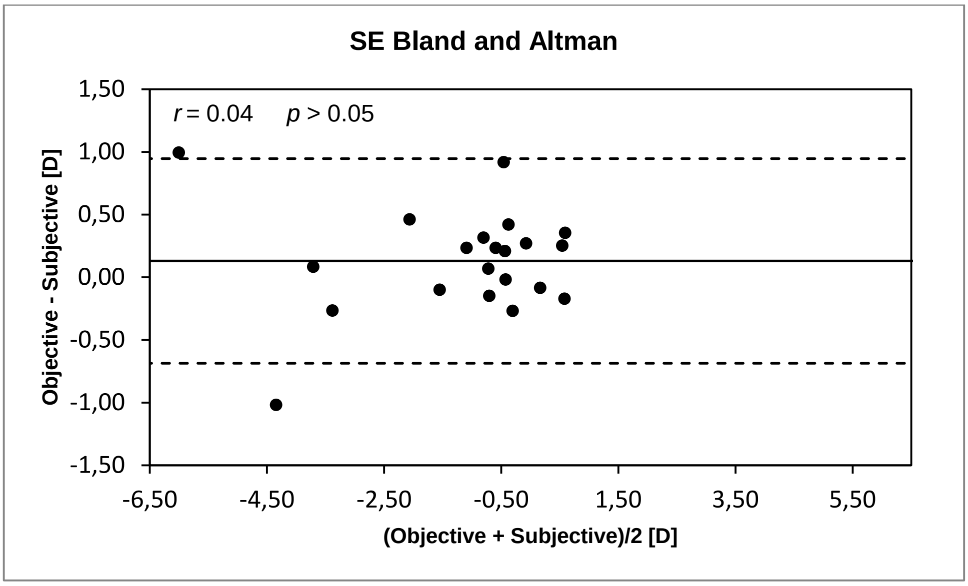

Figure 1: Bland and Altman plot of the SE with the mean difference and the confidence limits (CL) comparing the objective and the subjective over-refraction.

With regard to the astigmatic vectors J_0 and J_{45}, the mean differences for both vectors with and without MCL measurements were close to 0.). Although lower than in the SE, the Pearson's correlation coefficients are still high and significant. Comparing these results with the results without MCL, the Pearson's coefficients are almost the same for J_0 and J_{45} (Table 2). The Bland and Altman plot for J_0 and J_{45} with MCL is shown in figure 2. The Pearson correlation coefficient for the Bland and Altman differences was 0.28 and 0.19, respectively, and it did not reach statistical significance in any of the cases (0.22 and 0.93).

Finally, no significant differences were found in the paired sample *t* test carried out with J_0 and J_{45} over-refraction data when wearing MCL (Table 2). In contrast, the comparison of results without MCL found significant differences for J_0. The statistical analysis performed with the different MCL used showed no significant differences for J_0 or J_{45} (p = 0.635 and 0.877 for the Air Optix® Multifocal, 0.773 and 0.380 for the Acuvue® Oasys™ for Presbyopia and 0.899 and 0.696 for the Proclear® Multifocal).

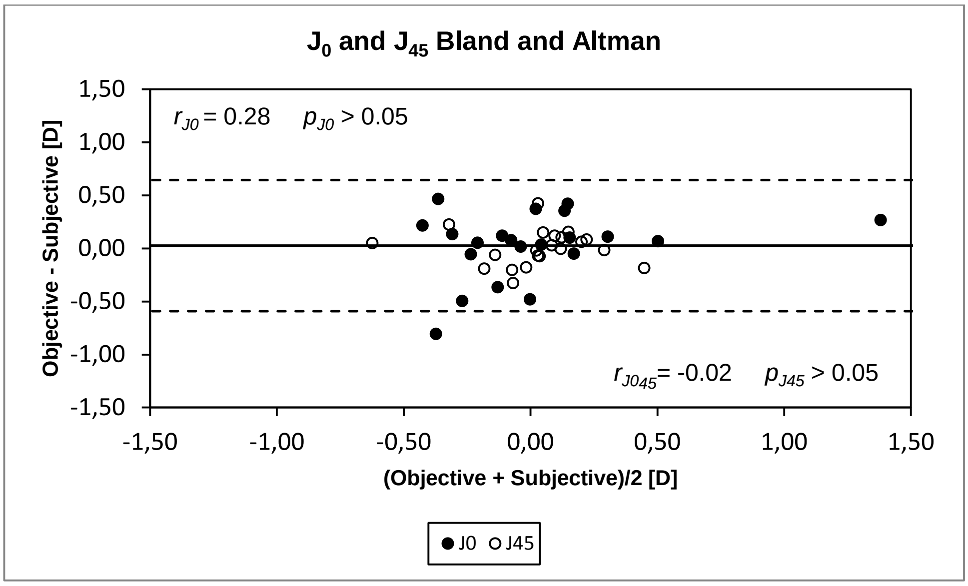

Figure 2: Bland and Altman plot of J_0 and J_{45} with the mean difference and the confidence limits (CL) comparing the objective and subjective over-refractions.

Discussion

Autorefraction is commonly used as a screening method of over-refraction [9][10]. The usefulness of autorefraction has been demonstrated for monofocal [11] but not for MCL. As a first attempt, in this study we assessed the MCL over-refraction over a population of healthy young adult patients.

With regard to the spherical equivalent measured without MCL, only a small mean difference between autorefractor and subjective measurements was found, as well as an excellent correlation and no statistically significant differences, which is in good agreement with the results of previous studies without CL [19]. The results obtained in the measurements without MCL corroborate the good performance of the protocol. When the measurements were performed with MCL, an excellent correlation between autorefractor values and subjective refraction was found. The results of the mean difference and the SD and their behaviour were represented by means of a Bland and Altman plot. When the data for the different MCL were analyzed, no differences among MCL were found. The mean difference had a value of 0.13 ± 0.42 D although it was not significant.Other authors [15] measuring refraction in MIOL (diffractive multifocal Tecnis® ZM900, Abbott Medical Optics, Inc.) found equivalent mean differences (−0.12 D) between autorefractor and subjective values. Additionally, the standard deviations were also similar in both cases (Bissen-Miyajima 0.38 D; this study 0.42 D) and comparable to those obtained in measurements without contact lenses (Sheppard 0.38 D; this study 0.42 D) [19]. Consequently, the accuracy and precision of the autorefractor measurements in MCL over-refraction is comparable to MIOL over-refraction. On the other hand, Muñoz *et al*. [16] found mean differences of −1.00 ± 0.61 D and statistically significant differences when measuring a refractive MIOL, a result that differs from the measurements performed in this preliminary study and from Bissen-Miyajima's data. Muñoz *et al*. argued that these differences were caused by the geometry of the IOL they used (refractive multifocal ReZoom®, Abbott Medical Optics, Inc.), which can interfere with the infrared beam of the autorefractor.

The obtained data support that the spherical over-refraction measured with the WAM-5500 autorefractor when wearing MCL is similar to the subjective over-refraction. Indeed, it is lower than the minimum dioptric change applied in clinical practice (0.25 D). Moreover, these differences are not significant and the precision of the measurement is similar to that obtained in monofocal measurements. We can thus conclude that the autorefractor provides a good estimate of the spherical refraction in patients wearing MCL.

With regard to astigmatic vectors when evaluating without MCL, the mean difference, Pearson's correlation coefficient, the Bland and Altman plot and the *t*-test results showed the good agreement between autorefractor and subjective measurements, except for the *t*-test results in J_0, where significant differences were found. In their study of the clinical evaluation of the Grand Seiko WAM-5500, Sheppard *et al*. [19] also found significant differences in J_0 with similar values in the mean difference (0.04 D). Although statistically significant differences are found, they are below 0.25 D and therefore of no clinical significance. Indeed, results in astigmatic subjects also demonstrate the good performance of the protocol. In the results with MCL, the mean differences for the astigmatic vectors were close to zero, there was a good Pearson's correlation coefficient and the Bland and Altman plot showed the good agreement between measurements for both J_0 and J_{45} vectors. Finally, in astigmatic vectors the differences found were not statistically significant for all MCL considered together and when the different MCL were analysed. The results with MCL are in good agreement with the results obtained by other authors [15][16] that used autorefraction in patients with MIOL and who found mean differences close to zero and good Pearson's correlation coefficients. Moreover, when comparing the performance of the autorefractor with and without MCL, the results can be considered similar. Consequently, we conclude that the performance of the WAM-5500 autorefractor with MCL is as valid as without MCL. Furthermore, the autorefractor gives a good estimation of the astigmatic refraction of MCL wearers.

Open-field autorefractors, such as the WAM-5500 autorefractor, are becoming more popular in the clinical setting since they are not as influenced as close-field autorefractors by proximal accommodation. Nevertheless, similar results are expected if a close-view autorefractor is used.

In summary, it can be concluded that the Grand Seiko WAM-5500 is a valid screening method of over-refraction in the clinical fitting of MCL. Further studies with larger sample size and older participants are required to analyse the MCL over-refraction in eyes with different refractive conditions, such as those with presbyopia, and to confirm the findings of this preliminary study.

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