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**ABSTRACT** 

Purpose: To compare refractive values measured without cycloplegia, cycloplegia and

fogging lenses using an open-field auto-refractor.

Methods: One hundred and forty-two young adults were enrolled from a university

population; 96 were female (67.6%) and 46 were male (32.4%), the age range was 18 to

26 years (mean 22.3  $\pm$  3.7 years). The refraction measurement was obtained with

autorefractor Grand Seiko Auto Ref/Keratometer WAM-5500 (GS) under three

conditions, always in this sequence: 1) without cycloplegia (GS), 2) without cycloplegia

but using a +2.00D fogging lens (GS 2D) and 3) with cycloplegia (GS cycl).

**Results:** When the average values of spherical equivalent were compared both

accommodation control strategies were almost equally successful: GS,  $M = -0.85 \pm 2.21$ 

D; GC\_2D, M=  $-0.53 \pm 2.10$  D and GS\_cycl, M=  $-0.57 \pm 2.24$  D (Kruskal-Wallis Test,

p<0.001). When the results were analyzed separately for different refractive groups,

emmetropes and hyperopes show statistically significant differences while myopes did

not. When both accommodation strategies were compared there was a trend for more

myopic subject to display more negative values under cycloplegia, while low myopes,

emmetropes and hyperopes tend to display more negative values with the +2.00 D

fogging lenses (less effectiveness of accommodation control).

Conclusions: Over-refraction through +2.00 D fogging lenses is useful to achieve

additional relaxation of the accommodative response in a similar way than cycloplegia

when open-field autorefraction is performed in young adults.

**Keywords**: Open-field autorefraction, fogging lenses, cycloplegia, GrandSeiko.

## **INTRODUCTION**

Objective refraction is an important part of optometric examination. Despite retinoscopy is still today the best starting point for subjective refraction (Jorge *et al.* 2005a), auto-refraction is widely used by optometrists and ophthalmologist. Different research reports support the reliability (McBrien and Millodot 1985) of these systems particularly when autorefraction is performed under cycloplegia (Chat and Edwards 2001; Jorge *et al.* 2005b; Choong *et al.* 2006).

Most closed-field autorefractors have built-in automatic fogging mechanisms to avoid accommodation during measurement. However, the targets used in these instruments stimulate accommodation given more negative values than cycloplegic refraction (Jorge *et al.* 2005b), which leads to an overestimation of myopia degree and prevalence (Jorge *et al.* 2006b).

Nevertheless, the use of cycloplegia is limited by the time needed to achieve full effect, its association with patient discomfort, inconvenience, additional cost, risk of increase of intraocular pressure, and limited access to diagnostic drugs to optometrists in certain countries. In Europe, with the exception of Ireland, Netherlands and the U.K., it is forbidden for optometrists to use cycloplegic agents. In addition, most refractive exams in these countries and in the US are also performed without cycloplegia.

Open-field autorefractors were first introduced to the marketplace in the late eighties and the first research reports showed that they significantly overcome those difficulties by observation of real-world targets rather than enclosed viewing of internal fixation target. Even with these instruments, a minimal accommodative response could be expected to affect the final value particularly in children and hyperopes (Chat and Edwards 2001). Gwiazda and Weber compared the spherical equivalent refraction

obtained with three different autorefractors without cycloplegia: two open-field autorefractors (Grand Seiko WR-5100K and Canon R-1) and closed-field autorefractor (Nidek ARK-700). Not surprisingly both open-field autorefractors recorded more positive values than the Nidek closed field instrument by a difference of 0.65 D and 0.22 D, respectively; in the comparison between both open-field instruments the Grand Seiko gave more positive values by an average of 0.43 D (Gwiazda and Weber 2004). Open field autorefraction also demonstrated to be effective after LASIK surgery showing good agreement between subjective refraction under non-cycloplegic and cycloplegic conditions (Bailey *et al.* 2005).

Another widely used open-field autorefractor, the Shin-Nippon NVision K-5001 correlated well with subjective refraction; furthermore, subjective refraction gave more myopic or less hyperopic values by an average 0.14 D, which suggests a good control of instrumental accommodation stimulus by the instrument (Davies *et al.* 2003). Markedly different results had been previously found with closed field autorefractors (Nayak *et al.* 1987).

Thus, whatever the technique used to obtain an objective starting point for subjective refraction, it is important to overcome the effect of accommodation (Suryakumar and Bobier 2003; Zhao *et al.* 2004; Choong *et al.* 2006). Apart from cycloplegia, accommodative response can be controlled by using plus lenses. This is a common practice during noncycloplegic retinoscopy. This procedure is referred to as optical fogging and is recognized as a clinical optometric procedure for testing of the pre-school child (Ward and Charman 1987; Ciner 1997). However, the effectiveness of using fogging lenses to perform open-field autorefraction either with or without cycloplegia to avoid accommodative activity is yet to be investigated. This study will

help to understand if additional accommodation control can be achieved using fogging lenses and/or cycloplegia during open-field autorefraction.

The purpose of this study was to evaluate objective automatic refraction with an open-field autorefractor without and with accommodation control using plus fogging lenses and cycloplegia.

#### MATERIAL AND METHODS

One hundred and forty-two young adults, university students, of which 96 were female (67.6%) and 46 were male (32.4%), had been enrolled for this study. Subject's ages ranged from 18 to 26 years old (mean  $\pm$  SD: 22.3  $\pm$  3.7 years).

In order to analyse separately the potential effect of plus lenses and cycloplegia on accommodation control for different refractive status (emmetropia, myopia and hyperopia), three refractive groups were established according to the spherical equivalent [M=sphere+(cylinder/2)] as follows: myopia (M≤-0.50; n=38; 26.8%), emmetropia (-0.50<M<+0.50; n=42; 29.5%) and hyperopia (M≥+0.50; n=62; 43.7%) (Jorge *et al.* 2007).

After the nature of the study was explained, a consent form was signed by the patient before being enrolled. The research followed the Declaration of Helsinki rules and was reviewed and approved by the Scientific Committee of the School of Sciences of Minho University (Portugal). Inclusion criteria required that the subjects did not suffer from any current eye disease or injury, was not taking any ocular or systemic medication that could affect the accommodative response and had best correct visual acuity of 20/20 or better in each eye. The intraocular pressure was checked with an noncontact tonometer (Nidek Model NT-4000, non-contact tonometer optically) (Queiros *et al.* 2006).

Autorefraction was measured with an open-field instrument, the Grand Seiko Auto Ref/Keratometer WAM-5500 (Grand Seiko Co., Ltd., Hiroshima, Japan. This instrument is an infrared autorefractor that provides an open binocular field of view, while the patient is looking at a distant fixation target. In its static mode used in this study, the Grand Seiko takes one reading per second.

The subject was seated erect with the head stabilized in a chin-rest. The refraction measurement was obtained in three conditions and in this sequence: first without cycloplegia (GS), second, without cycloplegia with the +2.00D fogging lenses at 12 mm from corneal vertex (GS\_2D) and finally with cycloplegia (GS\_cycl). For each condition three independent readings were taken, converted to vector format and then averaged in order to avoid errors by averaging refractive values in clinical notation. Measurements only from the right eye of each patient were considered. Non-cycloplegic refraction was taken first followed by cycloplegic refraction obtained 30 minutes later. Cycloplegia was achieved by instillation of one eyedrop 1%, cyclopentolate (Colircusí Cyclopegic) in each eye twice with a 5-min interval.

Descriptives (mean±S.D.) were obtained for the vector components of refraction M, J0 and J45 according to Fourier analysis as recommended by Thibos (Thibos *et al.* 1997). For comparison purposes, to all the results obtained with the +2.00D to fogging lenses this value was subtracted. This value is the equivalent refraction in the ocular plane for a vertex distance of 12 mm.

Kolmogorov-Smirnov Test was produced in order to evaluate normality of data distribution. Mann-Whitney Test was used to compare the measurement between the male and female subjects. Kruskal-Wallis Test was done to evaluate if statistically different values were given by different instruments and different conditions for M, J0 and J45. Wilcoxon Signed Ranks Test was used for pairwise comparison between instruments. Graphical regression analysis was also produced to illustrate the relationship between M, J0 and J45 values obtained using different instruments under different conditions.

The statistical procedures used to compare results among different instruments and conditions, were described by Bland and Altman (Bland and Altman 1986). The 95% limits of agreement (mean of the difference ± 1.96 \* S.D. of the difference) were also calculated. This type of analysis makes it easier to assess the level of agreement between techniques, spot outliers and see whether there is any trend in bias. SPSS statistical package v.15 (SPSS Inc., Chicago, IL, USA) was used.

## **RESULTS**

The mean objective refraction for the whole sample, as per the autorefractor with cycloplegic (GS\_cycl), ranged from -9.00 to + 2.25 D; mean spherical equivalent was -  $0.57 \pm 2.24$  D (mean  $\pm$  S.D.) with the maximum amount of astigmatism being -3.25 D. According to the refractive classification, 26.8% (n=38) of the sample were myopes, 29.5% (n=42) were emmetropes and 43.7% (n=62) were hyperopes.

Table 1 presents descriptive results and statistical comparison of the refractive components M, J0 and J45 between instruments and conditions. Statistically significant differences were found for the spherical equivalent (p<0.001, K-W Test). The same analysis was repeated by splitting the sample into the three refractive groups. Again, the spherical equivalent showed statistically significant differences between the three methods but only for emmetropes and hyperopes. The astigmatic component J45 also showed statistically significant differences between methods for hyperopic group.

Table 2 presents the pairwise comparison between different refractive methods. For the spherical equivalent there was statistically significant differences between autorefraction without fogging lenses or cycloplegic (GS) and refraction over the +2.00 D lenses (GS\_2D); mean difference was -0.32 D with GS being more negative than GS\_2D (p<0.001, Wilcoxon Signed Ranks Test). Graphical analysis of difference against means is shown in *figure 1*. The narrower limits of agreement were presented for J45 followed by J0 and the largest interval was for the comparison of spherical equivalents. Surprisingly, the two conditions where the accommodation was supposed to be under control display the largest limits of agreement, but the least spread around the regression line (highest correlation coefficient). The trend of GS\_2D to render more positive or less negative values (higher hyperopic shift) is more evident for moderate

and high myopes and this trend was statistically significant. Again, when comparing GS\_2D with GS\_cycl a higher hyperopic shift was observed with GS\_2D in for moderate and high myopes.

When cycloplegic was used (GS\_cycl) mean difference with GS was -0.28 D; in this case the difference only approaches statistical significance (p=0.064), however the average value has the same clinical meaning as that previously obtained in the comparison of GS with GS\_2D, with both values being above  $\pm 0.25$  D. Conversely, there was not any difference between the two conditions that control the accommodative response, GS\_2D vs GS\_cycl (p>0.05).

Regarding the astigmatic components there was only statistically significant differences between GS and GS\_2D for the J0 component (mean difference -0.02 D; p<0.001).

## **DISCUSSION**

In this study, the used of fogging lenses was used in order to evaluate if an addition effect on accommodation control can be achieved in open-field autorefractors using a fogging lens instead of cycloplegia. Our results show that the average spherical equivalent refraction in such circumstances is very similar to that obtained under cycloplegia, while both situations (cycloplegia or fogging lenses) give more positive or less negative values than open-field autorefraction with no additional control of accommodative response. Considering that more positive spherical equivalent indicates less accommodative activity present results show that open-field autorefractor itself was not totally effective showing more negative or less positive values than the remaining two measures. As expected, this effect of myopic shift was not statistically significant for myopes, despite the 0.40 D difference between fogging lens method and regular autorefraction (GS). Although this result could be expect based on the less active accommodative system in myopes, the larger variability of refraction in this group could also account for the lack of statistical significance. Conversely, emmetropic and hyperopic groups displayed significant evidence that fogging lenses method was as effective as cycloplegia to prevent myopic shift. Fogging lenses seems to be effective for emmetropes, cycloplegia was more effective for hyperopes; however, differences between both methods were 0.15 D and 0.16 D, respectively. This result could be expected based on the more active accommodation in hyperopes.

Some studies suggest that noncycloplegic autorefraction has reasonable accuracy and repeatability when compared with noncycloplegic retinoscopy and subjective refraction (Jorge *et al.* 2005a). However, in that study, which compared three techniques of refraction without the use of a cycloplegic agent: closed field

autorefraction, retinoscopy and subjective refraction, noncycloplegic autorefraction displayed more negative values of spherical equivalent refraction by 0.45 D, and this was clinically significant. Myopic shift induced under certain clinical conditions and instruments is a concern particularly in hyperopic patients and it's a phenomenon common to autorefraction (McCaghrey and Matthews 1993; Bullimore *et al.* 1998; Gwiazda and Weber 2004; Jorge *et al.* 2005b) and other modern devices such as clinical aberrometers (Cervino *et al.* 2006).

Direct comparison of values obtained from the three refractive methods can only be compared by subtracting 2.00 D to all refractive values obtained with the fogging lens in place, in order to discard the optical effect induced by the fogging lenses in the spectacle-eye system. This avoids the systematic error induced by over refraction with autorefractors (Kimura *et al.* 2007). Ward and Charman observed that above a value equal or higher than 2D of fogging, it is expected that the accommodative system returns to its resting position in a small group of adult myopes and hyperopes (Ward and Charman 1987).

Differences in agreement between methods for the three refractive groups are evident in the graphical analysis presented in *figure 1*. As a consequence, when both methods of accommodation control were compared, fogging lenses gave more positive values of refraction than cycloplegic refraction, while a significant trend towards the opposite effect was observed for emmetropes and hyperopes. Compared to regular open-field autorefraction the use of fogging lenses was effective to control the accommodative response, particularly for moderate and high myopes ( $\leq$  -2.00D), and less effectively for emmetropes and hyperopes. Despite this, when fogging lenses were used, 90% (128/142) of the sample show a good control of accommodative response

(GS\_2D more positive than GS, difference between methods > 0), which was quite similar to 93% (132/142) that could be achieved with cycloplegia. One curious feature of the results is the fact that blurring high myopes moves refractive error in a more positive direction than cycloplegia. We cannot explain this finding at present but we can argue that increased spherical aberration in the myopic eyes which becomes more important when the pupil is dilated could account for this effect of overestimation of myopia under cycloplegia (Benjamin 2006). An underestimation of myopia with the fogging lens is not discarded but the first possibility is more likely. This subject disserves further investigation.

In summary, the present study has demonstrated that the use of fogging lenses can be effective to control undesirable accommodative response while performing autorefraction, adding an important relaxation effect to the already reduced accommodative stimulus which is an important advantage of open-field autorefraction in young adults. Other potential application of this methodology is on non-pharmacological accommodative control in massive screening of pediatric populations. Although the present study did not tested this hypothesis, it is expected that open-field autorefraction in addition to optical fogging by using plus lenses in front of the eye while performing autorefraction in children, will provide more reliable values than regular open-field autorefraction itself. Fotedar et al. demonstrated that in the absence of cycloplegia as much as 17.8 % of 12 year-old children will be misclassified as myopic (Fotedar et al. 2007). If the effectiveness of fogging lenses to avoid accommodative stimulus in children will be proven, the use of cycloplegic could be avoided in large scale screening without risk of myopia overestimation. The impact of such an approach in the actual incidence of refractive error is also of enormous importance, (Jorge et al.

2006a; Ferrer-Blasco et al. 2007) particularly regarding the overestimation of myopia

prevalence worldwide in many studies conducted without cycloplegic agent or whatever

other control of accommodative response. In addition to the absence of adverse

response from the administration of the cycloplegic, this methodology could be used by

non-medical staff and optometrists not allowed to use diagnostic drugs.

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**Table 1.** Mean refractive error (mean  $\pm$  S.D.) obtained of whole sample and individual groups refractive for M, J0 and J45 components of under different conditions: autorefractor GS, GS\_2D and GS\_cycl (n=142, values are expressed in diopters).

		N	<b>GS</b> (Mean ± S.D.)	<b>GS_2D</b> (Mean ± S.D.)	<b>GS_cycl</b> (Mean ± S.D.)	р
М		142	-0.85 ± 2.21	-0.53 ± 2.10	-0.57 ± 2.24	<0.001
J0	Whole sample	142	+0.13 ± 0.30	+0.15 ± 0.29	$+0.13 \pm 0.30$	0.605
J45		142	+0.01 ± 0.23	-0.01 ± 0.22	0.02 ± 0.25	0.117
	Myopia	38	-3.77 ± 2.51	-3.37 ± 2.25	-3.59 ± 2.41	0.736
М	Emmetropic	42	-0.05 ± 0.33	+0.25 ± 0.40	+0.10 ± 0.26	<0.001
	Hyperopic	62	$+0.39 \pm 0.33$	+0.67 ± 0.30	+0.83 ± 0.27	<0.001
	Myopia	38	+0.23 ± 0.41	+0.24 ± 0.36	+0.25 ± 0.41	0.752
J0	Emmetropic	42	$+0.06 \pm 0.24$	+0.06 ± 0.23	$+0.09 \pm 0.24$	0.846
	Hyperopic	62	+0.11 ± 0.24	+0.16 ± 0.26	+0.08 ± 0.25	0.300
	N4		0.00 + 0.40	0.00 + 0.07	0.04 + 0.40	0.000
	Myopia	38	$-0.00 \pm 0.40$	+0.02 ± 0.37	-0.01 ± 0.43	0.982
J45	Emmetropic	42	$+0.00 \pm 0.13$	-0.01 ± 0.12	$+0.00 \pm 0.11$	0.876
	Hyperopic	62	+0.01 ± 0.13	-0.02 ± 0.15	+0.04 ± 0.16	0.007

N, number of subjects; GS, autorefraction noncycloplegic; GS\_2D, autorefraction with fogging lenses +2.00D noncycloplegic; GS\_cycl, autorefraction with cycloplegic. Comparison among three conditions (Kruskal-Wallis Test).

**Table 2.** Mean difference, S.D. and significance level and 95% limits of agreement for the components M, J0 and J45 for the GS, GS\_2D and GS\_cycl.

	Mean ± S.D.	C:~ *	Limits of agreement					
	Mean ± 5.D.	Sig. *	Mean + 1.96 x S.D.	Mean - 1.96 x S.D.				
Autorefraction GS vs Autorefraction GS with fogging +2.00D								
М	-0.32 ± 0.32	<0.001	0.31	-0.94				
J0	-0.02 ± 0.14	<0.001	0.25	-0.29				
J45	+0.01 ± 0.11	0.230	0.23	-0.20				
Autorefraction GS vs Autorefraction GS_cycl								
М	-0.28 ± 0.29	0.064	0.29	-0.85				
J0	$+0.00 \pm 0.16$	0.299	0.32	-0.31				
J45	-0.01 ± 0.11	0.228	0.21	-0.23				
Autorefraction GS with fogging +2.00D vs Autorefraction GS_cycl								
М	$+0.04 \pm 0.34$	0.495	0.70	-0.63				
J0	$+0.02 \pm 0.19$	0.094	0.40	-0.36				
J45	-0.03 ± 0.13	0.050	0.23	-0.28				

<sup>(\*)</sup> Wilcoxon Signed Ranks Test

**Figure 1.** Plots of difference vs mean of M component for different comparisons GSvsGS\_2D (A), GSvsGS\_cycl (B) and GS\_2DvsGS\_cycl (C).

