

Agreement between the QuickSee Free™ wavefront autorefractor and subjective clinical refraction in schoolchildren

Concordância entre o wavefront QuickSee Free™ e a refração clínica subjetiva em escolares

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ABSTRACT

Objective: To compare refractive measurements obtained with the QuickSee Free™ (QSFree) wavefront autorefractor, with and without a +2.00 D fogging lens, against subjective clinical refractometry (SCR) under cycloplegia in schoolchildren aged 7 to 17 years.

Methods: One hundred right eyes from 100 healthy Brazilian schoolchildren were evaluated using QSFree without cycloplegia, QSFree with a +2.00 D fogging lens, QSFree under cycloplegia, and SCR under cycloplegia. Refractions were converted into spherical equivalent (SE) and astigmatic vector components projected onto the 90° (MV90) and 135° (MV135) meridians according to Naeser's method. Comparisons were performed using Wilcoxon signed-rank and the Hotelling tests.

Results: Compared with cycloplegic SCR, QSFree without cycloplegia showed a clinically relevant SE difference of -1.06 ± 1.22 D ($p < 0.0001$). Similar results were observed with the +2.00 D fogging lens (-1.01 ± 1.22 D; $p < 0.0001$). In both comparisons, MV90 and MV135 differences were clinically irrelevant (< 0.25 D). When both QSFree and SCR were performed under cycloplegia, the SE difference was -0.48 ± 1.29 D ($p < 0.0001$), which was not clinically relevant.

Conclusion: QSFree demonstrated high agreement with subjective clinical refractometry under cycloplegia. The +2.00 D fogging lens did not provide accommodation control equivalent to cycloplegia and should not replace cycloplegic refraction in schoolchildren.

RESUMO

Objetivo: Comparar as medidas refrativas obtidas com o QuickSee Free™, sem ciclopégia e com lente de *fogging* de +2,00 D, e sob ciclopégia, em relação à refratometria clínica subjetiva sob ciclopégia, em escolares de 7 a 17 anos.

Métodos: Foram avaliados cem olhos direitos de cem estudantes brasileiros saudáveis, com idades entre 7 e 17 anos, utilizando o QuickSee Free™ sem ciclopégia, o QuickSee Free™ sem ciclopégia com lente de *fogging* de +2,00 D, o QuickSee Free™ sob ciclopégia e a refratometria clínica subjetiva sob ciclopégia. Com base nas medidas refrativas, foram calculados os equivalentes esféricos e os componentes vetoriais astigmáticos projetados nos meridianos de 90° e 135°. As comparações entre os métodos foram realizadas por meio do teste de Wilcoxon e do teste de Hotelling, adotando-se o nível de significância de 5%.

Resultados: A diferença média $\pm$ desvio-padrão entre o QuickSee Free™ sem ciclopégia e a refratometria clínica subjetiva sob ciclopégia para o equivalente esférico foi de $-1,06 \pm 1,20$ D ($p < 0,0001$), sendo considerada clinicamente relevante. Para o QuickSee Free™ com lente de *fogging* de +2,00 D sem ciclopégia versus refratometria clínica subjetiva sob ciclopégia, a diferença média no equivalente esférico foi de $-1,01 \pm 1,22$ D ($p < 0,0001$), sendo também clinicamente relevante. Em ambas as comparações, as diferenças nos componentes astigmáticos nos meridianos de 90° e 135° foram inferiores a 0,25 D e consideradas clinicamente irrelevantes. Quando QuickSee Free™ e refratometria clínica subjetiva foram realizados sob ciclopégia, a diferença média no equivalente esférico foi de $-0,48 \pm 1,29$ D ($p < 0,0001$), valor considerado sem relevância clínica, enquanto os componentes meridianos de 90° e 135° permaneceram sem diferenças clinicamente relevantes.

Conclusão: O QuickSee Free™ apresentou elevada concordância com a refratometria clínica subjetiva quando utilizado sob ciclopégia. A lente de *fogging* de +2,00 D não proporcionou controle acomodativo equivalente ao da ciclopégia e não deve ser considerada substituta da refração ciclopégiada em escolares de 7 a 17 anos.

INTRODUCTION

Visual impairment is a major public health concern and is associated with substantial adverse effects on both individuals and society.⁽¹⁾ Uncorrected refractive error (URE) is one of the most easily treatable causes of visual impairment.⁽²⁾ The program Vision 2020: The Right to Sight, planned to enhance the provision of refraction services and eye care through early screening and by encouraging close monitoring of progress.⁽³⁾ Optical correction of low vision is hampered by inequality in access to eye care, with 90% of people with URE living in low- and middle-income countries,^(4,5) where they face a shortage of eye doctors, equipment, and facilities to provide refractive care services and optical dispensing units.⁽⁶⁾

In Brazil, the public unified health system has not yet been structured for the ophthalmological care of URE patients: there is a lack of human resources to implement actions to promote eye health, as well as a lack of physical infrastructure and equipment for refraction exams.⁽⁷⁾ The Brazilian Council of Ophthalmology points to the need to carry out new actions to control the growing flow of demand and expand access for URE patients to ophthalmology services.^(8,9)

In recent years, low-cost portable autorefractors have been developed to extend eye care coverage to a wider population, especially in low- and middle-income countries and in remote or care-gap areas, through the deployment of URE's screening and optical correction programs and large-scale spectacle delivery.⁽¹⁰⁻¹⁷⁾

The gold-standard clinical method for correcting refractive errors is subjective clinical refractometry (SCR) under cycloplegia.⁽¹⁸⁾ However, manual retinoscopy in children is a procedure that can become time-consuming and not produce consistent results, since not all ophthalmologists are able to perform it with precision and accuracy.⁽¹⁹⁾ An alternative to manual retinoscopy is the use of wavefront autorefractors, which are portable and allow measurement under non-cycloplegia conditions, and are considered to be an alternative for SCR.⁽²⁰⁾ The QuickSee Free™ (QSFree, PlenOptika) is a lightweight, portable, non-invasive monocular autorefractor that works based on the Shack-Hartmann wavefront technology and has a +2.00D fogging lens for exams in children 3 years of age and older to dispense the use of cycloplegia for accommodation control.⁽²¹⁾ The objective of this study was to compare refractive measurements obtained with the QSFree wavefront autorefractor, with and without a +2.00 D fogging lens, against SCR under cycloplegia in schoolchildren aged 7 to 17 years.⁽²²⁾

METHODS

The research was approved by the Ethics Committee of the University Nilton Lins of Amazonas, Manaus, Brazil (CAAE:78664624.40000.5015 with file number 6.751.904) and followed the tenets of the Declaration of Helsinki. Informed consent was obtained from the parents or legal guardians of all participants.

A total of one hundred schoolchildren aged 7 to 17 years enrolled in public preschools and elementary schools in the municipality of Manacapuru (AM), were selected for the study. Information was collected regarding age, gender, and ophthalmological findings. Children presenting with best-corrected visual acuity worse than 20/20 in either eye or any ocular pathology were excluded. All examinations were performed in the following sequence: uncorrected visual acuity assessment using a Snellen chart at 6 m; three QSFree measurements without cycloplegia; three QSFree measurements without cycloplegia using a +2.00 D fogging lens; induction of cycloplegia; three QSFree measurements under cycloplegia; SCR under cycloplegia supported by retinoscopy and a Greens refractor; best-corrected visual acuity assessment; slit-lamp biomicroscopy; and dilated fundus examination.

Cycloplegia was induced with one drop of 1% cyclopentolate (cyclopentolate 10 mg/mL, Allergan-AbbVie, Inc., North Chicago, IL, USA), followed 5 minutes later by one drop of 1% tropicamide (Mydracyl® 1%, Novartis, Basel, Switzerland). Refraction was performed 30 minutes after the first instillation. Refraction examination was performed 30 minutes after the first installation.

The QSFree used in this study measures refractive errors in eyes with pupils from 2 to 8 mm; the exam acquisition time is 5 to 10 seconds; spherical range from -13.00D to +10.00D in increments of 0.01D, 0.125D and 0.25D, and cylindrical range from -8.00DC to +8.00DC, with increments of 0.01DC, 0.125DC, and 0.25DC, and axial range zero to 180°, increments of 1°, 5°, 10°. It is factory-calibrated and does not require field recalibration. It stores more than ten thousand exams. It weighs 650 g and measures 30 cm x 5.5 cm x 18 cm. QSFree is registered as Food and Drug Administration (FDA) Class I 510(k) exempt medical device.^(21,22)

Only right-eye data were included in the statistical analyses to avoid inter-eye correlation. Measurements obtained from both eyes of the same participant are not statistically independent and may artificially inflate sample size estimates. Therefore, only right-eye measurements were used for all analyses.

Conventional spherocylindrical refractions were converted into vector notation according to Naeser's method.

Because sphere, cylinder, and axis values are interdependent and the cylindrical axis is circular in nature (0° equivalent to 180°), conventional notation is not suitable for statistical analysis. Refraction was therefore expressed as spherical equivalent (SE) and as astigmatic vector components projected onto the 90° (MV90) and 135° (MV135) meridians. The SE was calculated as the spherical power plus half the cylindrical power.

The astigmatic vector components were calculated using the following equations:

$$MV90 = m(\sin^2\alpha - \cos^2\alpha)$$

$$MV135 = m[\sin^2(\alpha - 45^\circ) - \cos^2(\alpha - 45^\circ)]$$

where m represents the cylindrical power in diopters and α represents the cylinder axis in degrees. To maintain consistency with the spherical-equivalent format, MV90 and MV135 values were divided by two.

Statistical analyses were performed using R software (R Foundation for Statistical Computing, Vienna, Austria). Differences in SE, MV90, and MV135 were calculated as QSFfree measurements minus SCR measurements. Paired comparisons were performed using the Wilcoxon signed-rank test. Trivariate analyses were conducted using Hotelling's T^2 test. Statistical significance was defined as $p < 0.05$.^(23,24) The level of statistical significance was set at 5% ($p < 0.05$).

RESULTS

A total of 100 schoolchildren, 48 male and 52 female, aged 7 to 17 years, were recruited for the study. The mean $\pm$ standard deviation (SD) age of the participants was 11.21 ± 2.91 years. The mean $\pm$ SD SE of the right eye refractive error was -1.54 ± 2.20 D, ranging from -9.75 D to $+8.50$ D.

Table 1 shows the differences between the refraction values measured by QSFfree without cycloplegia and SCR under cycloplegia. The mean $\pm$ SD difference in refraction in SE was -1.06 ± 1.22 D, and was considered clinically relevant. No relevant clinical differences were found between the diopter's components projected onto the 90° axis and the 135° axis.

Table 2 shows the differences between the refraction values obtained by QSFfree+2.00D fogging lens without cycloplegia and SCR under cycloplegia. The mean $\pm$ SD difference in refraction in SE was -1.01 ± 1.22 D, which was considered clinically relevant. No relevant clinical differences were found between the diopter's components projected onto the 90° axis and the 135° axis.

Table 1. Univariate analysis of differences between right eye refraction values obtained without cycloplegia by QSFfree and subjective clinical refractometry under cycloplegia in a sample of one hundred schoolchildren aged 7 to 17 years

	Variables	Average $\pm$ SD	Median	IC95%	p-value
QSFfree-SCR*	SE	-1.06 ± 1.22	-0.88	[-1.25; -0.75]	< 0.0001
	MV90	-0.01 ± 0.21	-0.03	[-0.07; 0.00]	0.8615
	MV135	0.01 ± 0.25	0.00	[-0.02; +0.03]	0.8615

* The difference between refraction values obtained by QSFfree without cycloplegia and subjective clinical refractometry under cycloplegia. Wilcoxon signed-rank test; statistically significant results with a p-value less than 0.05.

SD: standard deviation; IC95%: 95% of confidence interval; SCR: subjective clinical refractometry; SE: spherical equivalent; MV90: magnitude vector on the 90° axis; MV135: the difference between diopter components projected on the 90° axis and the 135° axis.

Table 2. Univariate analysis of differences between right eye refraction values obtained without cycloplegia by QSFfree+2.00 and subjective clinical refractometry under cycloplegia in a sample of one hundred schoolchildren aged 7 to 17 years

	Variables	Average $\pm$ SD	Median	IC95%	p-value
QSFfree+2.00D-SCR*	SE	-1.01 ± 1.22	-0.88	[-1.19; -0.69]	< 0.0001
	MV90	-0.01 ± 0.22	-0.02	[-0.07; +0.01]	0.1606
	MV135	0.03 ± 0.22	+0.02	[-0.02; +0.05]	0.3319

* QSFfree+2.00D-SCR: the difference between refraction values obtained by QSFfree+2.00D fogging lens without cycloplegia and subjective clinical refractometry under cycloplegia. Wilcoxon signed-rank test; statistically significant results with a p-value less than 0.05.

SD: standard deviation; IC95%: 95% of confidence interval; SCR: subjective clinical refractometry; SE: spherical equivalent; MV90: magnitude vector on the 90° meridian; MV135: magnitude vector on the 135° meridian.

Table 3 shows the differences between the refraction values obtained with QSFfree and those measured by SCR, both under cycloplegia. The mean $\pm$ SD difference in SE was -0.48 ± 1.29 D ($p < 0.0001$). Although statistically significant, this difference was below the 0.50 D threshold considered clinically meaningful and was therefore deemed clinically irrelevant. Similarly, no clinically relevant differences were detected for the astigmatic vector components MV90 and MV135.

Table 3. Univariate analysis of differences between right-eye refraction values obtained by QSFfree and subjective clinical refractometry, both under cycloplegia, in a sample of one hundred schoolchildren aged 7 to 17 years

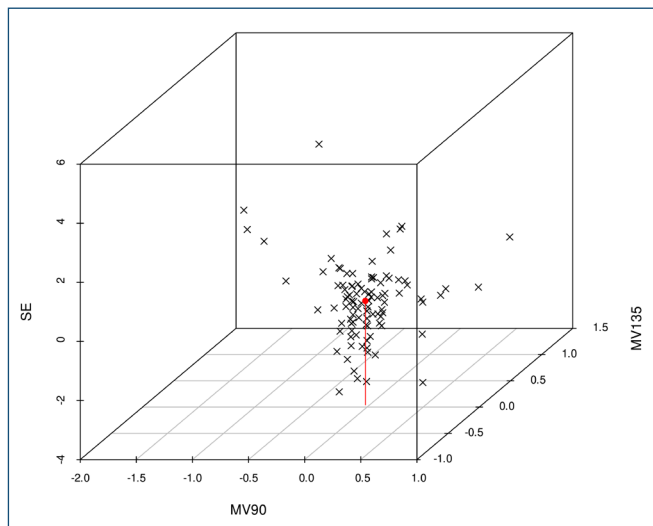
	Variables	Average $\pm$ SD	Median	IC95%	p-value
QSFfree-SCR*	SE	-0.48 ± 1.29	-0.62	[-0.81; -0.37]	< 0.0001
	MV90	-0.04 ± 0.30	-0.03	[-0.08; +0.02]	0.1769
	MV135	$+0.04 \pm 0.24$	+0.02	[0.00; +0.06]	0.0647

* QSFfree-SCR: the difference between refraction values obtained by QSFfree and subjective clinical refractometry both under cycloplegia. Wilcoxon signed-rank test; statistically significant results with a p-value less than 0.05.

SD: standard deviation; IC95%: 95% of confidence interval; SCR: subjective clinical refractometry; SE: spherical equivalent; MV90: magnitude vector on the 90° meridian; MV135: magnitude vector on the 135° meridian.

A trivariate analysis was performed to jointly assess the differences in SE, MV90, and MV135 between QSFfree and subjective clinical refractometry (SCR), both obtained under cycloplegia. The distribution of these differences is illustrated in a three-dimensional plot (Figure 1).

The conversion of refraction in vector values for the conventional form revealed that, on average, the



SE: spherical equivalent; MV90: astigmatic vector component projected onto the 90° meridian; MV135: astigmatic vector component projected onto the 135° meridian; SCR: subjective clinical refractometry.

Figure 1. Three-dimensional plot of the differences in spherical equivalent (SE) and astigmatic vector components (MV90 and MV135) between QuickSee Free™ (QSFREE) and subjective clinical refractometry (SCR), both measured under cycloplegia.

difference between the QSFREE measurement and the SCR, both under cycloplegia, was -0.52DE with $+0.09 \times 87.71$, with SE of -0.48D for each student's right eye.

DISCUSSION

The UREs remain one of the leading causes of preventable visual impairment worldwide and continue to represent a major public health challenge, particularly in underserved populations.⁽²⁾ Although optical correction is highly effective and relatively inexpensive, access to refractive care remains limited in many regions because of shortages of trained personnel, equipment, and specialized ophthalmic services.⁽²⁵⁾ Consequently, portable technologies capable of expanding access to refractive assessment have attracted increasing interest, particularly for school-based vision screening programs.⁽⁷⁾

The present study evaluated the agreement between the QSFREE autorefractor and SCR in schoolchildren aged 7 to 17 years and assessed whether incorporating a $+2.00\text{ D}$ fogging lens could provide accommodation control comparable to cycloplegia.⁽¹⁸⁾ The principal finding was that non-cycloplegic measurements obtained with QSFREE, regardless of the use of a fogging lens, differed substantially from cycloplegic SCR measurements. In contrast, when both examinations were performed under cycloplegia, the agreement between methods was high, and the observed difference was not clinically relevant.⁽¹⁹⁾

The comparison between QSFREE without cycloplegia and cycloplegic SCR revealed a mean SE difference of $-1.06 \pm 1.20\text{ D}$, while the comparison between QSFREE with a $+2.00\text{ D}$ fogging lens and cycloplegic SCR showed a similar difference of $-1.01 \pm 1.22\text{ D}$. These findings indicate that the fogging strategy failed to eliminate the accommodative influence sufficiently to achieve agreement with cycloplegic refraction. The similarity between these values suggests that the $+2.00\text{ D}$ fogging lens provided little additional benefit in controlling accommodation in this pediatric population.⁽²¹⁾

Accommodation is a particularly important source of refractive measurement error in children and adolescents because accommodative amplitude is substantially greater than in adults. When accommodation is not fully relaxed, refractive measurements tend to become more myopic, resulting in overestimation of myopia or underestimation of hyperopia. This phenomenon likely explains the clinically relevant differences observed between non-cycloplegic QSFREE measurements and cycloplegic SCR in the present study.

The influence of accommodation may vary according to refractive status. Hyperopic children often accommodate continuously to maintain clear retinal images, thereby masking latent hyperopia during non-cycloplegic examinations. Consequently, non-cycloplegic autorefractors may underestimate the true hyperopic refractive error. Conversely, myopic individuals may exhibit accommodative fluctuations that can contribute to more negative refractive measurements. Emmetropic individuals may also demonstrate residual accommodative activity despite the use of fogging techniques.⁽²²⁾ These physiological mechanisms help explain why accommodation control remains challenging in pediatric populations and reinforce the importance of cycloplegia when accurate refractive assessment is required.

Our findings are consistent with those reported by Queirós et al., who demonstrated that positive fogging lenses reduce accommodative activity but do not consistently reproduce the effects of cycloplegia.⁽²⁶⁾ Their study showed that accommodation control through fogging may vary among myopic, emmetropic, and hyperopic subjects and that positive lenses are less effective than pharmacological cycloplegia in fully relaxing accommodation. The present results extend those observations to a school-aged population and suggest that a $+2.00\text{ D}$ fogging lens is insufficient to replace cycloplegia in children and adolescents.

An important observation in the present study was the stability of the astigmatic vector components. Across all

comparisons, differences in MV90 and MV135 remained below clinically relevant thresholds.⁽²⁷⁾ These findings suggest that accommodation predominantly affects the spherical component of refraction, whereas astigmatic measurements remain comparatively stable. The consistency of the vector components further supports the use of vector analysis according to Naeser's method, which allows appropriate statistical evaluation of both astigmatism magnitude and axis orientation. The good agreement observed between QSFree and SCR when both measurements were obtained under cycloplegia reinforces the device's validity for pediatric refractive assessment.⁽²⁶⁾

The mean SE difference of -0.48 ± 1.29 D, although statistically significant, remained below the threshold generally considered clinically meaningful and therefore was not clinically relevant.⁽²⁴⁾ These findings are broadly consistent with those reported by Hernández et al., who demonstrated satisfactory agreement between QSFree and subjective refraction in adults.⁽²⁷⁾ However, unlike the adult population studied by Hernández et al., our participants were children and adolescents with substantially greater accommodative capacity. This difference likely explains why accommodation had a much greater impact on non-cycloplegic measurements in the present investigation.

Beyond its refractive accuracy under cycloplegic conditions, QSFree offers several practical advantages. The device is lightweight, portable, easy to operate, and capable of acquiring measurements rapidly in non-clinical environments. These characteristics make it particularly attractive for school-based screening initiatives and community eye health programs, especially in regions with limited access to ophthalmic care. By enabling refractive assessment directly within schools, QSFree may help reduce absenteeism associated with referrals to specialized centers and improve access to eye care services among vulnerable populations.

Taken together, the findings of this study demonstrate that QSFree provides clinically acceptable refractive measurements when accommodation is adequately controlled through cycloplegia. However, the incorporation of a +2.00 D fogging lens alone does not provide accommodation control equivalent to cycloplegia and therefore should not be considered a substitute for cycloplegic refraction in schoolchildren.⁽²⁸⁻³⁴⁾

LIMITATIONS

The sample size was relatively modest, and participants were recruited from a single geographic region, which may limit the generalizability of the findings to other pediatric

populations. In addition, only right-eye data were included in the statistical analyses to avoid inter-eye correlation; therefore, the results may not fully capture potential bilateral variability. Although the study included a broad range of refractive errors, individuals with very high refractive errors were underrepresented, limiting extrapolation of the findings to extreme refractive conditions.

Despite these limitations, the study has important strengths. Refractive assessments were performed directly in the school environment, reducing barriers to participation and minimizing absenteeism commonly associated with referrals to ophthalmic clinics. Furthermore, the use of cycloplegic SCR as the reference standard and the application of vector analysis for astigmatism assessment strengthen the validity of the findings. These characteristics enhance the study's clinical relevance and support its applicability to school-based vision screening programs, particularly in underserved settings.

CONCLUSION

The QSFree provided refractive measurements that closely matched subjective clinical refractometry when used under cycloplegia in schoolchildren aged 7 to 17 years. The incorporation of a +2.00 D fogging lens without cycloplegia did not adequately control accommodation and therefore cannot replace cycloplegic refraction in this population. These results reinforce the importance of cycloplegia for accurate refractive assessment in pediatric patients. Given its portability, rapid acquisition, and satisfactory performance under cycloplegic conditions, the QSFree may be a useful instrument for large-scale school vision screening programs and for expanding access to refractive care in underserved regions.

AUTHORS' CONTRIBUTION

All authors contributed equally to the conception and design of the study, data collection, analysis and interpretation of the data, manuscript preparation, and critical revision of its intellectual content. All authors approved the final version of the manuscript and are accountable for all aspects of the work, including ensuring its accuracy and integrity.

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