Title: Examining the validity of a new method for the objective assessment of binocular accommodative facility (2Q-AF test): A comparison with ± 2.00 DS lens flippers

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Purpose: Recent technological advances have permitted to objectively record the accommodative response while shifting between two different levels of accommodation. This study is aimed at examining the concurrent validity of a new objective method for the qualitative and quantitative assessment of binocular accommodative facility, which is named 2Q-AF test, in comparison to the ±2.00 DS lens flippers.

Methods: 56 individuals took part in this study (36 healthy young adults [24.4±3.2 years] and 20 children [12.2±0.4 years]). Participants randomly performed the 2Q-AF and the ±2.00 DS lens flipper tests. For the 2Q-AF test, a binocular open-field autorefractor was used to record the magnitude of accommodative response during a 60-sec period, while participants repeatedly changed fixation from a 5m to a 40cm chart when clarity of vision was achieved at each level. Due to the advantages of the proposed method, we have determined the number of cycles and the 2Q-AF score, with the latter also considering the accuracy of changes in accommodation. A standard procedure was followed for the ±2.00 DS flipper test.

Results: Our data exhibited a moderate association between the number of cycles with the ±2.00 DS lens flippers and the number of cycles in the 2Q-AF test in the group of young adults ($p=0.005$, $r=0.46$ [0.15–0.68]) and children ($p=0.007$, $r=0.58$ [0.19–0.81]), whereas a stronger relationship was observed when considering the number of cycles with the ±2.00 DS lens flippers and the 2Q-AF score (young adults: $p<0.001$, $r=0.83$ [0.69–0.91]; and children: $p<0.001$, $r=0.78$ [0.52–0.91]).

Conclusions: The current findings show that the 2Q-AF test is a valid method for accommodative facility assessment, as suggested by its good levels of reliability and validity. This method allows to examine the accommodative facility in qualitative terms and solve most of the limitations associated with the ±2.00 DS lens flipper test.

Introduction

The assessment of the accommodative function is underpinned by measures of accommodative amplitude, response, and facility, with them being used for the diagnosis of accommodative and binocular disorders,[1,2] evaluation of visual discomfort,[3] and as independent predictors of myopia progression.[4] In clinical settings, these visual measures are commonly assessed by subjective methods (i.e., push-up method, monocular estimated method or ± 2.00 DS lens flippers, respectively), and the reliability and validity of these measures is somewhat limited.[5–9] For example, the use of subjective tests for the evaluation of the visual function in certain populations (e.g., pre-school children or persons with special needs), who may find difficult to understand the visual test, may be ill-advised. In this regard, autorefractors are demonstrably the most accurate and reproducible measurement devices for the objective evaluation of the accommodative function, and specifically, they have been validated for testing the accommodation amplitude and response.[10,11]

The ability of the visual system to alter accommodation rapidly and accurately when the dioptric stimulus to accommodation is set between two different levels is termed as accommodative facility. However, the clinical assessment of this visual ability only relies on subjective techniques, with the ± 2.00 DS lens flippers being the most commonly used method for the diagnosis of accommodative and binocular dysfunctions.[2,12] There are several limitations associated with the use of this methodology such as the time taken to change the lenses, the subjective criteria for judging when the target is clear or blurry, the accommodation/vergence conflicts caused by the stimulus and lenses demands and the changes in retinal image size by the positive and negative lenses among others.[13,14] Based on the mentioned limitations, the development and validation of objective methods for the evaluation of the accommodative facility may help to improve the diagnosis and management of different visual anomalies in the clinical practice.

Otero and colleagues proposed an automated extension of the flippers accommodative facility test in order to minimize the delays in flipping the lenses,[15] and other authors have incorporated recordings of dynamic accommodation during the flippers test in order to obtain qualitative data.[16,17] However, there still exist limitations associated with accommodation/vergence conflicts and retinal image size. As a result of this technological drawback, our research group recently developed an objective method for the qualitative and quantitative examination of the binocular accommodative facility in free-viewing conditions by the combination of the Hart Chart test and an open-field autorefractor.[18] This method has been demonstrated to provide comparable results to the Hart Chart test in the number of cycles per minute, and to be highly repeatable for the number of cycles per minute, the percentage of time one is incorrectly accommodated and dis-accommodated, and the mean magnitude of accommodative change.

As previously stated, the most commonly used test for the assessment of accommodative facility is the ± 2.00 DS lens flippers, and thus, it may be recognized as the “gold standard” for accommodative facility testing in optometric practice.[2,12] Notably, the utility of a new test requires the incorporation of some advantages over the available instruments, and importantly, its validity is subject to its level of agreement with a method that is well-established and has already been proven to be valid.[19] Based on this fact and considering that the proposed objective method incorporates substantial advantages over the existing tests, this study aimed to assess the concurrent validity of a new objective method for the qualitative and quantitative assessment of binocular accommodative facility, which has been named as 2Q-AF, in comparison to the ±2.00 DS lens flippers. This analysis was performed on a sample of healthy young adults and children in order to ascertain its utility in different age groups.

Methods

Ethical approval and participants

The study was approved by the University of Granada Ethics Committee and adhered to the tenets of the Declaration of Helsinki. A total of fifty-six volunteers were recruited to participate in this investigation, with the experimental sample being formed by thirty-six healthy young adults (16 female and 20 male; mean age ± standard deviation = 24.4 ± 3.2 year) and twenty children (10 female and 10 male; mean age ± standard deviation = 12.2 ± 0.4 year). All participants were screened for the following inclusion criteria: (i) free of any current or previous ocular condition or disease (i.e., suppression, diplopia, strabismus or amblyopia), (ii) have an uncorrected refractive error < 0.50 D of myopia, < 1.00 D of astigmatism or anisometropia, and/or < 1.50 D of hyperopia, (iii) have a corrected visual acuity of 0.1 logMAR or better in both eyes, and (iv) be able to perform at least one cycle with the ± 2.00 DS lens flippers.

Procedure

The study was performed in a single experimental session. Upon arrival to the laboratory, participants (or parents/guardians for children) read and signed the consent form, and underwent an optometric examination to check the accomplishment of the inclusion criteria. Briefly, the experienced optometrist performed a slit lamp and direct ophthalmoscopy examination, as well as a monocular and binocular subjective refraction using an endpoint criterion of maximum plus consistent best vision. Also, the fusion/suppression, using a standard Worth-4-dot test at near (40 cm) and far (5 m) distances, as well as the ability to perform a complete cycle with the ± 2.00 DS lens flippers, were checked. If participants met the inclusion criteria, they performed the ± 2.00 DS lens flippers and 2Q-AF tests in binocular conditions and in a random manner (see "*Accommodative facility assessment"* subsection for a description of these tests). A five minutes break was provided between tests, and participants were familiarized with the tests prior to data collection in order to ensure that they understood both procedures. All participants were naïve to accommodation testing (i.e., they were not optometry students).

Accommodative facility assessment

For the ± 2.00 DS flipper test, we used a Bernell test no. 9 placed at 40 cm with the letter size 20/30 (Bernell VTP, Mishiwaka, IN, USA), polarized glasses for controlling suppression, and the ± 2.00 DS lens flippers. Following standard procedures,[20,21] we placed the +2.00 in front of the subject's eyes and asked them to try and get the letters clear and single as quickly as possible, and when the letters were reported to be clear, the flipper was quickly shifted to the minus side. The number of times the patient utters 'clear' in 60 seconds was counted, and a complete cycle consisted of clearing both the plus and the minus lenses.

The 2Q-AF test is an objective method for the qualitative and quantitative assessment of binocular accommodative facility, and it has been described in detail elsewhere,[18] and is depicted in **Figure 1**. The number of cycles performed when changing the dioptric power between two accommodative demands is important, but the accuracy of these changes is also of relevance. As result, we have considered appropriate to determine the 2Q-AF score, which accounts for imprecise accommodative changes by adjusting the cycles count (see below for a description of this calculation). For this test, we used a Grand Seiko WAM-5500 binocular open-field autorefractor (WAM-5500, Grand Seiko Co. Ltd., Hiroshima, Japan) in Hi-Speed mode for the continuous recording of the refractive state. For this test, the first step is to record the accommodative response while viewing a high-contrast target in front of their eyes (0.19 logMAR, which corresponds to ~20/31 in Snellen) during 60 seconds at distance (5 m) and near (40 cm). These two measures are used for the qualitative assessment of binocular accommodative facility. Subsequently, the 2Q-AF test was conducted using a far and near targets (0.19 logMAR) positioned at 5 m and 40 cm, both being positioned along the midline, with a font type Helvetica (capital letters), and a luminance of 42.7 cd/m^2 and 44.2 cd/m^2, respectively. For the near target, there was an eccentricity of 4.3° (interpupillary distance of 60 mm), which is clearly within the 15° range of stable accommodative measurements with the WAM-5500 reported by Kundart and colleagues[22]. The near target was designed to allow participants to look at the far target without interfering with their gaze. For data acquisition, participants were instructed to focus one letter for the far target, and then shift their focus to the near target once peak sharpness of the letter was achieved following established recommendations of clinical testing.[2,23] Recording of the refractive state started in synchrony with the test, since the beeping sound of the start button of the autorefractor indicated the commencement of the test to the participants. Accommodative values varying more than 3 standard deviations from the AR mean were considered blinks, recording errors on in-transit measurements (measurements taken as the eye's lens power is shifting from far to near and back), and thus eliminated.[24,25] Baseline accommodation measurements for each distance were used to analyze accuracy in each accommodation level and to evaluate the frequency of accommodative changes. This measure was obtained by subtracting the mean value from the dynamic measures and the baseline static refractive value (i.e., far distance) to the accommodative demand at each distance (0 and 2.5 D).

For the analysis of the 2Q-AF test, our algorithm takes the accommodation measurement signal as input, from which we first estimate an approximate frequency by counting the signal's zero-crossings. Using this approximate frequency as initialization, we iteratively fit a sinusoid at that frequency to the input signal with amplitude, phase and DC offset as free parameters using the Levenberg-Marquardt damped least-squares method. We implemented our optimization method using a solver from the Matlab Optimization Toolbox. The similarity of the accommodation measurement signal and the fitted sinusoid is validated by cross-correlating the cleaned-up signal with the fitted sinusoid. We finally obtain the number of cycles, percentage of incorrect cycles of accommodation and dis-accommodation, i.e., incorrect cycles divided by the total number of cycles, and the mean magnitude of accommodative change between the far and near targets (see Figure 2 for an illustration of this process). [18]

Aiming to consider both the quantitative and qualitative data obtained from the proposed method for the assessment of accommodative facility, we have defined the following equation for the calculation of the 2Q-AF score, which takes into consideration the number of cycles (quantitative data) and the percentage of cycles under-accommodated and under-relaxed (qualitative data) (equation 1). An incorrect cycle was considered when the accommodative response varied more than one standard deviation, either over- or under-accommodation, from the mean refractive state at each distance.

$$2Q - AF\ score = cpm - cpm \times \left(\frac{\%\ of\ near\ errors\ +\ \%\ of\ far\ errors}{2}\right)$$

Statistical analysis

Descriptive data are presented as means and standard deviations. Pearson´s product-moment correlation coefficients with the corresponding 95% confidence intervals were calculated to determine the level of association between the number of cycles with the ± 2.00 DS lens flippers and the score and number of cycles with the proposed objective test. The criteria to interpret the strength of the r coefficients were as follows: $r < 0.3$ as a weak correlation, $0.8 > r > 0.3$ as a moderate correlation, and $r > 0.8$ as a strong correlation.[26] Linear regression equations with the associated mean error of the models were calculated to test the predictive validity of the score and number of cycles of the new objective binocular accommodative test with the number of cycles of the ± 2.00 DS lens flippers in the samples of young adults and children. All validity calculations were performed by means of a custom spreadsheet developed by Hopkins,[27] and other statistical analyses were carried out using the JASP software (version 0.14.1). The level of statistical significance was set to 0.05.

Results

Descriptive data for the ± 2.00 DS lens flipper and 2Q-AF tests, as well as the differences observed between the groups of young adults and children, are shown in **Table 1**.

There was a moderate to strong positive association between number of cycles with the ±2.00 DS lens flippers and the score obtained in the 2Q-AF test for the sample of young adults ($p < 0.001$, r = 0.83 [0.69 – 0.91]) and children ($p < 0.001$, r = 0.78 [0.52 – 0.91]). The linear regression models were Y = 0.461 X + 1.065 and Y = 0.429 X + 1.060, and with a mean error of the models of 2.47 (95% CI = 2.00 – 3.24) and 2.73 (95% CI = 2.06 – 4.04) for the groups of young adults and children, respectively (**Figure 3**).

The analysis of the level of correlation between the number of cycles with the ±2.00 DS lens flippers and the number of cycles in the 2Q-AF test revealed that both variables were moderately associated for the sample of young adults (p = 0.005, r = 0.46 [0.15 – 0.68]) and children (p = 0.007, r = 0.58 [0.19 – 0.81]). The linear regression models were Y = 0.169 X + 5.508 and Y = 0.247 X + 3.193, and with a mean error of the models of 3.95 (95% CI = 3.19 – 5.17) and 3.56 (95% CI = 2.69 – 5.26) for the groups of young adults and children, respectively (**Figure 4**).

Discussion

This study was designed to explore the concurrent validity of a new objective method for the qualitative and quantitative assessment of binocular accommodative facility (2Q-AF) in comparison to the ±2.00 DS lens flippers test. Our data evidenced that there was a moderate to strong correlation between the number of cycles with the ±2.00 DS lens flippers and the 2Q-AF method when considering quantitative and qualitative data (2Q-AF score; range of r = 0.78-0.83). However, the level of association was significantly lower when only considering quantitative results from the 2Q-AF method (cycles per minute; range of r = 0.46-0.58). Taken together, the current findings show that the proposed index (2Q-AF score) for the evaluation of the binocular accommodative facility may be considered as an improvement of the ±2.00 DS lens flippers, with the advantages that this test gives qualitative information and allows to assess the accommodative facility in a more realistic fashion (e.g., vergences demands are not altered and image size is kept constant).

The quality and usefulness of a new test, which has been designed to solve the limitations of the currently available tools, are based on its level of consistency (test-retest reliability) and accuracy (validity). In a recent study, we found that the reliability of the new proposed method (i.e., 2Q-AF), when assessed in two different occasions, was excellent (reliability values ranging between 0.95 and 0.98).[18] However, the validity analysis requires that the given test is compared with the "gold standard", which in this case is the ±2.00 DS lens flippers test.[21] In this regard, data from this study show that there is a moderate to strong level of association (Pearson r = 0.78-0.83) between the score obtained in the 2Q-AF test (quantitative and qualitative data) and the number of cycles with the ± 2.00 DS lens flippers, but this association was considerably lower (Pearson r = 0.46-0.58) when only considering quantitative data (number of cycles with 2Q-AF and lens flippers tests).

Previous studies have observed a considerable level of inter-individual subjective variability for accommodative facility due to difficulties in understanding the test procedure or the "clear/blur" concept[16,28] as well as due to age-related changes in accommodative function.[29] Based on this, we considered relevant to separately explore this association for two different populations (young adults and children), as well as to compare the results obtained in both groups. On the one hand, the level of association between the classical ± 2.00 DS lens flippers test with the number of cycles and the score obtained in the 2Q-AF test were quite similar for both groups (see Figures 2 and 3). On the other hand, the comparison of accommodative facility results between the group of young adults and children revealed that children performed a statistically significant higher change in the magnitude of accommodation when shifting the focus between the far and near targets (mean difference = 0.34D). This result may be due to the differences in the individual´s amplitude of accommodation, with the proportion of available accommodation being highly different for children with a mean age of 12.2 ± 0.4 years, and young adults with a mean age of 24.4 ± 3.2 years,[25] as well as to the higher variability of accommodation present in children.[30,31] Another possible reason that explain these differences in accommodative facility could be the vergence and interpupillary differences between children and young adults. Indeed, larger interpupillary distances would lead to increased convergence demands during near viewing, which could play a role on the differences observed between children and young adults.

Taken together, the new proposed objective method for accommodative facility testing (2Q-AF) has demonstrated an excellent inter-session reliability[18] and a good level of agreement with the ± 2.00 DS lens flippers test. Based on these results, we encourage the consideration of the 2Q-AF score, which reflects the qualitative and quantitative performance, for accommodative facility testing. The incorporation of the new proposed method would solve most limitations associated with the use of ± 2.00 DS lens flippers such as the time required to switch the flipper, as well as changes in retinal image size and vergence/accommodation conflicts due to the use of positive and negative lenses and the constant target distance.[13,14,16] Notably, the new metric (i.e., 2Q-AF score) permits to identify if the patient is not able to identify blur (i.e., he/she indicates that the target is clear when it is not) or the procedure is not well understood (i.e., the concept of blurry/sharp is confusing). In addition, this metric would be valuable for the objective monitoring of the qualitative and quantitative effects of visual therapy programs on the dynamics of accommodative facility in optometric clinical practice.

Due to the novelty of the current method and results, further research is required to confirm the validity and possible implications of the proposed method and metric for the objective assessment of the binocular accommodative facility. The scientific evidence about the 2Q-AF test is limited to two studies (Vera et al.[18], and the current work), and thus, it must be cautiously interpreted according the following limitations: (i) this method has been validated for binocular viewing conditions in healthy adults and children, but its external validity in clinical populations requires investigation; (ii) the ± 2.00 DS flippers lenses stimulate +0.50 D and +4.50 D at 40 cm whereas the current 2Q-AF test stimulate +0.20 D (5m) and +2.50 D (40cm) accommodative demands without using lenses. We consider of interest to match the accommodative demands of both tests (i.e., focusing at 2m and 22cm in the 2Q-AF test) to determine the impact of altering the image size and the vergence/accommodation relationship with the lens flippers test; and (iii) refractive error has been shown to influence the dynamics of accommodative facility,[4,16,32] and these results need to be confirmed with the 2Q-AF test.

There are a number of potential developments that would permit to enhance the utility of the proposed method in clinical settings: (i) to determine if different autorefractometers to the one used in this study (i.e., WAM-5500) could provide valuable qualitative and quantitative data of accommodative facility; (ii) to develop a user-friendly software for data analysis and interpretation, which could permit to easily incorporate this measure in clinical routine; and (iii) to assess the applicability of the 2Q-AF test for designing and controlling visual therapy programs, since it would allow the incorporation of objective tools in this field.

Conclusions

Our findings seem to support that the 2Q-AF method is a valid option for accommodative facility assessment due to its high level of reliability and validity. We believe that this method may be useful in clinical and research settings, since it allows to solve most of the limitations associated with the ± 2.00 DS lens flippers test, and provide qualitative and quantitative data of accommodative facility. Future research is required to determine the validity of the 2Q-AF test in clinical populations and different testing conditions.

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Figure captions

Figure 1. Schematic illustration of the objective test for qualitative and quantitative assessment of binocular accommodative facility (2Q-AF test). The far and near targets consist of three black letters on a white background (90% contrast; 0.19 logMAR), respectively, with the near target being placed slightly inferiorly to avoid interfering with the participant´s gaze when looking the far target.

Figure 2. Accommodative data processing sequence. (a) Raw accommodation measurements over time as acquired by the autorefractor. (b) The reconstructed piecewise-continuous signal of accommodation. (c) The first step of the iterative fitting process. A sinusoid is initialised with an approximate signal frequency by counting the signal's zero-crossings. (d) The last step of the iterative optimisation process using the Levenberg-Marquardt damped least-squares solver from the Matlab Optimization Toolbox. The sinusoid has been fit to the input accommodation signal. A frequency, amplitude, phase and DC offset have been estimated.

Figure 3. Relationship of the score obtained with the new objective method for testing binocular accommodative facility (2Q-AF) and the number of cycles with the ±2.00 DS lens flippers in the sample of young adults (panel A) and children (panel B). The regression lines with the corresponding 95% confidence intervals are showed. Density plots for each variable are also displayed. The score of the 2Q-AF is described in the main text (equation 1). Note: 2Q-AF = quantitative and qualitative assessment of accommodative facility; cpm = cycles per minute.

Figure 4. Relationship of the number of cycles with the new objective method for testing binocular accommodative facility (2Q-AF) and the number of cycles with the ±2.00 DS lens flippers in the sample of young adults (panel A) and children (panel B). The regression lines with the corresponding 95% confidence intervals are showed. Density plots for each variable are also displayed. Note: 2Q-AF = quantitative and qualitative assessment of accommodative facility; cpm = cycles per minute.