TITLE: **A PLACEBO-CONTROLLED TRIAL OF TINTED LENSES IN ADOLESCENTS WITH AND WITHOUT LEARNING DIFFICULTIES: READING ACCURACY AND SPEED**

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ABSTRACT

Purpose: A placebo-controlled, double-masked study was designed in order to evaluate the effect of tinted lenses in adolescents with and without learning difficulties. *Methods*: Teenagers from two different age groups were enrolled in this study, after ascertaining that no uncorrected visual anomalies were present. A rate of reading test was developed for Catalan as a first language and students were asked to read it aloud, in two different sessions, firstly without lenses and, later, again without lenses and, in a random order, with their lenses of choice and also with a placebo set of clear lenses. Reading speed and accuracy were monitored. *Results*: No significant difference was encountered between the baseline reading speed and accuracy from the first and second sessions, thus ruling out any effect due to experience or training. When comparing reading speed and accuracy without lenses, in placebo conditions, and with tinted lenses, reading accuracy was discovered to be more sensitive than reading speed in order to differentiate between these conditions, especially when the group with learning difficulties was evaluated, in contrast to the group without difficulties or the whole group. *Conclusion*: It was concluded that reading accuracy should be evaluated as well as reading speed and that lenses were more beneficial if only adolescents with learning difficulties were targeted.

KEY WORDS

Coloured Filters; Learning Difficulties; Reading Accuracy; Reading Speed; Visual Stress

I. INTRODUCTION

The term Meares-Irlen syndrome, previously Scotopic Sensitivity Syndrome, refers to the symptoms of asthenopia, visual perceptual distortion and, generally, visual fatigue, which accompany reading, even in the absence of any uncorrected refractive error or orthoptic anomaly[1,2]. Meares first reported a condition in which schoolchildren manifested reading difficulties when presented with certain combinations of text font, interlinear spacing and background *versus* text contrast[3]. Irlen further discussed these findings and advanced the possibility of using coloured filters as a means of ameliorating the symptoms[4]. In recent literature, this condition is usually associated with, or referred to, as visual stress.

Patients often describe perceptual distortion as blurring of text, doubling, moving or flickering letters or lines and shadowy outlines. Most of these symptoms are also acknowledged by patients with photosensitive epilepsy, autism[5], migraine[6], dyslexia and multiple sclerosis[7]. There have been many attempts at finding a common ground between these conditions in order to progress in the understanding of their aetiology. Patterns of stripes have been identified as triggers of discomfort (pattern glare) and headaches, provided that they sustain a spatial frequency within two octaves of 3 cycles per degree[8,9]. Some texts found in common school reading material may be equivalent to a pattern of horizontal stripes with a spatial frequency within this range[10]. These discoveries led to the suggestion of a magnocellular visual system deficit as the shared point of origin of most of these conditions, particularly in the case of dyslexia[11]. However, visual stress studies assessing the magno function have so far been unable to prove it to be abnormal[1,12]. A second line of inquiry points toward cortical hyperexcitability as the generic explanation for visual stress. Indeed, Wilkins has suggested that colour filters may change the distribution of firing within certain areas of the visual cortex[13], thus decreasing the summation of stimuli in such hyperexcitable regions as the visual area V2, where colour sensitive cells are organized topographically according to their chromaticity[14]. This last theory would require visual stress and dyslexia to be independent conditions.

Visual stress has usually been diagnosed by evaluating the success of its treatment, although recent efforts have been directed towards the development and normalization of a computerized visual stress screener[15] and a Patter Glare Test[16].

The use of colour to treat the symptoms associated with visual stress has been approached from three different directions: coloured overlays, tinted lenses and coloured ambient illumination.

The majority of placebo-controlled trials study the effect of coloured overlays on reading speed and accuracy. Wilkins developed the *Intuitive Overlays*, which consist of nine differently coloured overlays and a grey overlay that can additionally be placed one on top of another of the same or similar chromaticity so as to obtain a pallet of 27 colours[17]. Extensive testing with these overlays has revealed that coloured overlays provide a greater benefit than both clear overlays and grey overlays that reduce the contrast and luminance by a similar amount, thus exploring the likelihood of the placebo effect as a possible explanation of the findings[18]. The choice of colour has been found to present a high level of consistence and repeatability among individuals and this consistence to be beneficial. Thus, when presented with the option, children who chose the same colour on two different testing sessions showed a greater improvement in reading speed than those who chose a similar colour and these group of children, in turn, performed better than those who opted for altogether different colours on each session[19]. Interestingly, the choice of colour has proved to distribute evenly among those available, although the work of

Scott and co-workers noted a weak relationship between colour and ocular accommodation, in which the colours reflecting longer wavelengths were chosen by children who had greater amplitude of accommodation[2].

The benefits gained by the use of colour overlays have proved to be dependent on the precision of colour selection. Reading speed decreases with departures from the chosen optimal chromaticity, whether as a result of changes in saturation or in hue[20]. This finding may be of importance when colour overlays are used under lighting conditions that differ from those under which the most beneficial colour was selected[21] or when the choice of colours is limited. This last aspect has been recently examined by Smith and Wilkins[22] by means of comparison between the *Intuitive Overlays* and the *Reading Rulers*, developed by Crossbow Education Ltd. The *Reading Rules* present a set of five differently coloured overlays which are large enough to cover 2 lines of text and which are designed to be repositioned over the portion of text that is being read. The limited choice of colours, together with the fact that they do not allow for combination, resulted in a failure to exhibit any increment in reading speed with their use.

It is relevant to note that, for a particular patient, the most beneficial colour for overlays is not necessarily the same as that considered to be the optimal for tinted lenses. Lightstone and co-workers designed a study in which patients were asked to read with no colour, with the chosen overlay, with the chosen lenses and with lenses matching the colour of the chosen overlay[23]. Only the second and third conditions resulted in a significant improvement. The reason for these discrepancies seems to be attributable to the colour adaptation that occurs when the entire field is coloured, such as in the case of tinted lenses, even though the exact governing mechanism remains unclear[24].

Haploscopic filters are a particular scenario of the application of coloured lenses to improve reading skills. Commercialized under ChromaGen™, this FDA approved system of filters consists of 16 lenses with eight different chromatic characteristics (*i.e.* two lenses of each colour). Patients choose the optimum colour for their non dominant eye first and, with the chosen lens in front of this eye, they determine the filter for the dominant eye. This method often results in the selection of different colours, which may lead to aesthetic considerations that are overcome by covering the lenses with a mirror overlay. This system was used in a randomized, double-masked, placebo-controlled trial in patients with dyslexia, resulting in a statistically significant improvement of the text distortion reported by the patient, which could not be explained solely by placebo effects[25]. As this was the method of choice for the present study, this type of filters is discussed in further detail below.

The effect of both overlays and coloured lenses on reading speed and accuracy is usually evaluated by means of the Wilkins Rate of Reading Test[26]. 15 repeated monosyllabic words are randomly distributed over 10 lines of text, each word appearing once in each line. The text utilizes closely packed words printed in a small font, so as to allow for a greater manifestation of any visual problem. The number of words read in a minute, and the number of errors committed, comprise the result of the test. This test is superior over similar tests in that it requires little comprehension and very basic reading skills. As such, its performance is independent of the language skills of the age group under study. Besides, it has been proved to have a high test-retest reliability, both in immediate retest (correlation between test and retest greater than 0.8) and when test and retest were 8 weeks distant[26,19].

The aims of this study were, firstly, to design a suitable rate of reading test for both the age groups under evaluation and the particular characteristics of our language (Catalan) and, secondly, to investigate the effect of tinted lenses on the reading speed and accuracy of a group of good students as compared with another group of students with a poorer academic performance. Additionally, the degree of test-retest improvement which could be attributed to training was explored, as well the intervention and importance of placebo effects.

II. METHODS

Subjects

Students from a public school near Barcelona were recruited for this study after obtaining a signed informed consent from their parents or legal guardians. Subjects were allocated to one of four groups according to age and academic performance. Subjects from groups 1 and 2 were between 14 and 15 years old, whereas groups 3 and 4 included subjects aged between 16 and 17. *Good* students were allocated to groups 1 and 3 and *poor* students to groups 2 and 4. A poor academic performance was defined as consistent negative reports obtained from two or more of that academic year subjects, with the exclusion of arts, technology and physical education, provided that such low scores could not be attributed to other factors such as language problems, mental health or personality disorders. Neither the examiner, nor the student, knew which group each person had been assigned to, even though certain clues were logically obvious to a keen observer.

An initial optometric examination for near vision was administered to all students in order to rule out any significant non corrected visual problem. Exclusion criteria were uncorrected retinoscopic findings larger than 1 dioptre in either myopia, hyperopia or astigmatism, near visual acuity lower than 20/30, binocular visual imbalance at near of more than 4 prism dioptres of esophoria or 10 prism dioptres of exophoria, near point of convergence over 15 centimetres, manifest cover test deviation, monocular amplitude of accommodation lower than 10 dioptres (push-up technique) and colour vision anomalies (as measured with the Ishihara test, 24 plates version, 1974).

Following the various exclusion criteria, a total of 56 students were enrolled in this study, with a similar proportion of males and females.

Rate of reading test

Catalan language differs from English both grammatically and phonetically. Therefore, a rate of reading test was developed for speakers of Catalan as first language and also for the age groups under evaluation. School texts for students of these age ranges were perused in order to compile a list of suitable words. The final version of the test was considered to be suitable for the aims of this study by an external team of educational psychologists.

The resulting text consisted of different combinations of mono, bi and trisyllabic words of increasing difficulty, that is, the first lines of the text contained more monosyllabic words and the last lines more trisyllabic ones. Texts were printed on Times New Roman, with a 9 point font and simple interlinear spacing. Text width and height was of 93 and 38 millimetres respectively (**Insert Figure 1 here**). Eight different versions of the text were constructed, allowing for a better randomization of word distribution.

Tinted lenses

As mentioned above, a set of coloured lenses was used in this study. This set consists of 8 pairs of tinted lenses (**Insert Figure 2 here**) from which the patient is asked, firstly, to select the most

appropriate colour for the non dominant eye and, secondly, and with this chosen filter in place, to decide on a colour for the contralateral dominant eye. The rationale behind this *modus operandi* resides in the fact that if the subject finally prefers to use only one lens, the tint would be less noticeable or distracting if worn in front of the non dominant eye instead of the dominant one. It is common for subjects to select lenses for both eyes, even if the colour of choice often differs. Colours are chosen by randomly placing the 8 different tinted lenses in front of one eye and the other and asking the subjects to select the lens which provides them with the best subjective visual comfort.

Procedure

A total of two sessions was necessary to conduct the study. The first session was devoted to defining the final groups of students for further evaluation and to determine baseline reading speed and accuracy as well as to investigate ocular dominance. Baseline reading speed and accuracy measurements were repeated at the start of the second session, following which students selected their tinted lenses of choice and were asked to read, in a random order, with those lenses and with a placebo set of lenses.

Thus, all students from the target age groups followed a complete standard optometric examination and the exclusion criteria presented above were implemented. Ocular dominance was decided on the basis of which eye was preferred by the subject when, while looking at the examiner through the central hole of an opaque card which was held at arm's length with both hands, he or she was asked to move the card closer to his or her face without losing fixation.

Subjects were then handed one of the eight rate of reading tests and asked to read it aloud during one minute. The number of correct words and, therefore, errors, was noted down. This result was later used as base reading speed and accuracy.

The second session, which took place 15 days later, started by the repetition of the reading speed and accuracy measurements on another randomly chosen reading card. The aim of this repetition was to investigate any possible effects due to training or subject experience and to establish the baseline reading speed and accuracy for the second session. Lenses were then selected, according to the procedure already described. Finally, subjects were asked to read aloud from two new, randomly chosen reading cards for an interval of one minute each, the order being altered also at random between the tinted lenses of choice and a placebo set of clear lenses. Subjects were convincingly told that these clear lenses had a new invisible tint, recently developed to provide the same effect as the coloured lenses.

Even if, on the one hand, both examiner and subjects were obviously aware of the age group that was under investigation, on the other hand, they were ignorant as to which subject was allocated to each academic performance group.

Lighting conditions, which corresponded to those of a well illuminated classroom, remained constant during both sessions. The Declaration of Helsinki tenets of 1975 (as revised in Tokyo in 2004) were followed throughout the study and the research was approved by the Ethics Committee of the Technical University of Catalonia.

Data Analysis

Paired data Student's t-tests were used to investigate the statistical significance of the differences between baseline reading speed and accuracy and the results obtained with the coloured or the placebo lenses, as well as between the tinted and placebo lenses themselves. A *p*-value of 0.05 or less was considered to denote statistical significance.

Additionally, data were also analysed through tests of Pearson's correlation, whenever it was deemed appropriate.

III. RESULTS

As was to be expected, baseline reading speed and accuracy was highly sensitive on both the age of the subject and his or her academic performance. Thus, taken as a whole, older subjects read faster than younger ones. *Good* students from the younger age group read 15 words per minute (wpm) more than their *poorer* counterpart, this difference decreasing to 10 wpm for the older age group. The number of errors per minute displayed a similar trend, that is, older students read more accurately than younger ones and, within each age group, *good* students performed better than *poor* ones. It may be relevant to note that *poor* students from the older age group read significantly slower and with more errors than *good* students from the younger age group, even if they were, on average, two years older. **Table 1** summarizes descriptive statistics regarding demographic data and baseline reading speed and accuracy.

No statistically significant differences were discovered between the baseline reading speeds and accuracy measured from both sessions, neither for the whole group ($p=0.21$) nor for any paired combination of age and academic performance (all $p>0.05$). Indeed, a good correlation ($r=0.74$; $p<0.0001$) was encountered when plotting together the reading speeds for the first and second sessions (**Insert Figure 3 here**).

All subjects selected two coloured lenses, one for each eye. 46.4% of the subjects manifested their preference for lenses of exactly the same colour whereas the rest favoured different colours. It was not possible to identify any particular linking pattern between same or different colours and good or poor academic performance ($p=0.87$) or homonymous or crossed ocular/hand dominance ($p=0.81$). Furthermore, when comparing reading speed and accuracy with lenses of the same or different colour, results failed to reveal any statistically significant disparity between these groups of subjects (all $p>0.05$).

Taken the group as a whole, a statistically significant difference was encountered when comparing baseline reading speed and reading speed with both placebo lenses ($p=0.0008$) and tinted lenses ($p=0.0009$) (**Insert Figure 4a here**). Placebo and chromatic conditions were not found to be different ($p=0.86$). When analysing the number of errors that students committed during their reading, no statistically significance was revealed between baseline results and placebo lenses ($p=0.17$) but a notable improvement was accomplished with tinted lenses ($p=0.0002$). In this case, placebo and chromatic conditions displayed a significant disparity ($p=0.038$).

A further analysis of the results according to the allocation of students in groups of dissimilar academic performance revealed interesting differences. Thus, on the one hand, *good* students evidenced statistically significant differences between baseline reading speed and reading with both placebo lenses ($p=0.0007$) and chromatic filters ($p=0.016$) (**Insert Figure 4b here**) and also between baseline errors and errors committed while wearing placebo lenses ($p=0.031$) and tinted lenses ($p=0.011$). In this group of students it was not possible to ascertain significant differences in behaviour between placebo and tinted lenses in either reading speed ($p=0.099$) or accuracy ($p=0.71$). On the other hand, even if *poor* students failed to elucidate any difference between baseline reading speed and reading with placebo lenses ($p=0.24$) but showed an apparent improvement with tinted lenses ($p=0.028$) (**Insert Figure 4c here**), a subsequent investigation was not successful in proving a statistically significant difference between the behaviour of placebo and chromatic lenses ($p=0.17$). This was not the case of reading accuracy, where with placebo lenses students read almost as accurately as with no lenses whatsoever

(p=0.75) but displayed a pronounced improvement as soon as reading was repeated with tinted lenses (p=0.006). Placebo and chromatic conditions were found to be significantly different (p=0.038).

IV. DISCUSSION

A first approximation to the results reveals a surprisingly low baseline reading speed, both for the whole group of students and for each age group analyzed individually. Indeed, published Catalan reading speeds for the same age groups ranges from 140/169 wpm for younger students to 170/189 wpm for older students. These scores are significantly better than the results obtained from the groups of students that participated in the present study.

It may be stated, however, that the tests which are commonly used to evaluate reading speeds do not follow the same principles as the Catalan reading test which was employed in the present study and do not avoid the presence of comprehension clues that tend to significantly increase the number of words correctly read. A clear understanding of these factors is essential to allow for a standardized reading speed measurement that may be easily interpreted and analysed without having to consider the particular comprehension clues that might be found in each text. In this sense, the test of reading speed that was utilized in this study is considered to be of optimal characteristics. Furthermore, the text was sufficiently sensitive to clearly classify students according to their academic performance and, thus, it might be used as an additional tool for the evaluation of this performance, together with conventional examination resources, always taking into account that artistic and technological subjects were not included in the appraisal of the academic profile of each particular student.

It must be acknowledged that the Catalan reading test was designed keeping in mind that Catalan language (as well as Spanish) is quite different from English in many aspects, one of which is the frequency of monosyllabic words. Indeed, most Catalan words are bi or trisyllabic, and meaningful monosyllabic Catalan words are sparse (if articles and prepositions are not included). It was therefore believed that reading accuracy could play a more important role in Catalan language than English (an error in a trisyllabic word might lead to this word not being read at all). While in a purely monosyllabic text, reading speed and reading errors are probably measuring the same, and independent evaluation of both concepts was considered of relevance in the Catalan reading test.

The comparison of baseline reading speeds from session one and two revealed that learning and training effects were nonexistent. This finding, which was also encountered by Wilkins and co-workers[20], may be explained by taking into consideration several factors. Thus, on the one hand, the interval between both sessions was of several days. On the other hand, excluding comprehension clues from the texts, all subjects could rely on in order to gain an improvement in their skills by means of training was the actual memory of the exact word order which comprised each text. This factor could have been of significance if only one text was used or if more reading sessions had taken place than the number of different texts which were employed. As it was, only four randomly chosen texts were read, out of a total of the eight different versions which were available.

Filter selection proved to be bilateral in all cases, that is, all subjects preferred to wear a coloured lens in front of each eye, being the lenses, in almost half of the subjects, of identical chromaticity. This finding somehow undermines the philosophy which governs lens selection. Indeed, if all subjects end up with a pair of lenses, the need to start lens selection in the non dominant eye in order to minimize any collateral effect due to the use of colour filters is less justified. Swarbrick and colleagues reported similar results in this aspect[27].

This particular set of coloured lenses offers a relatively narrow range of colours for the subject to choose from. This might be of special relevance for the outcome of the study and for the performance, in general, of the lenses. Wilkins and collaborators[21], during the evaluation of the effect of ambient illumination chromaticity on reading speed, revealed that a moderately small departure (of the order of 6 JNDs) from the colour of choice substantially decreased any advantage which might have been gained by the initial colour selection. Therefore, results seem to be highly sensitive on the precision of the colour that each individual deems to be the most appropriate. This precision was not obtainable with the present set of lenses. Therefore, it may be safely speculated that a more noticeable effect would have arisen if this limitation could have been overcome.

Notwithstanding the above appreciation, a statistically significant difference was encountered when comparing baseline reading speed and reading speed through coloured filters (an improvement of 5 wpm or more was usual). It may be noticed, however, that an analysis of the group as a whole exposed a similar statistically significant difference between baseline reading speed and reading speed through placebo lenses. These results are in agreement with the work of Robinson and Foreman, in which they failed to encounter any noticeable improvement with coloured filters over placebo lenses when evaluating the performance of students with good or normal academic grades[28].

Consequently, one of the most interesting findings of the present study was the significant difference that arose when comparing the reading speeds with filters and with placebo lenses of a selected group of students with poor academic grades. Indeed, when students with learning difficulties were targeted, a noticeable improvement in their reading speed was accomplished if the selected tinted lenses were worn, while little benefit was obtained from placebo lenses. Previous studies did not fail to observe this specific advantage of coloured filters over placebo conditions when the group under investigation was defined by their learning difficulties, with independence of their age. Positive results were attained from both a group of schoolchildren and another of adult students[29,30]. Unfortunately, however, a further analysis comparing placebo and tinted lenses did not disclose the level of statistical significance that was considered appropriate at the beginning of the study. Reading accuracy, nevertheless, proved to be much more sensitive to the differences between placebo and tinted lenses, giving rise to statistically significant differences between the conditions under evaluation.

A literature research gave rise to few publications in which reading accuracy was assessed in addition to reading speed. Mitchell and co-workers reported a statistically significant improvement in visual discomfort symptoms with the use of coloured lenses in a group of subjects with visuo-perceptual reading disabilities[31]. However, the same authors described inconsistent results when reading speed and accuracy was evaluated, with some subjects gaining a perceptible advantage with their lenses while others performed as good with tinted lenses as in placebo conditions. The need to correctly discover the most suitable target group was stressed.

In conclusion, the evaluation of reading accuracy as well as reading speed and the precise identification of the group or groups of subjects which shall gain the biggest profit from this form of treatment might be the first step towards a better understanding of the neurophysiologic mechanisms at work and to helping these patients with the correct combination of coloured filters, overlays or ambient illumination. The exploration of this rich and extremely complex field of research, both via transversal and longitudinal studies, and in larger and more diverse

samples of subjects, is of great importance as every little step may yield benefits of scientific and clinical relevance.

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FIGURES

Figure 1: Example of text employed in this study for the evaluation of reading speed and accuracy

ma pop riu mel nas te gat pot sol dos nou pal nas dit pi veu ou be no mes
fet com sac la nom peu nen sal cos cap pa gos tot pel cop si te mar ple
nas gat casa groc pruna nas fort mel prat pel mira gran tot fil cop regal
mar pati sol nen fada nou marta groc dit noi parc peu sal llamp pla canta
cinc tro llet nas parc cau riu pot llop ple lluna sota coix herba conill llit
pot museu color crit mel poma veu riu meló pastís cap pruna forat mòbil
cinc dinar colom casa pati fada lluna plaça roba cel llista anell terra
plàtan lletra pasta canta oli dreta pera saltar porta llauna fusta amic
minut germà bossa costa ciutat vermell porta falta pena baixa últim pilot
animal pati marró minut poma conill ànec vaca centre planeta llista porta
ferro acció música cultura llimona camisa farmàcia lectura història plata

Figure 2: Set of coloured lenses

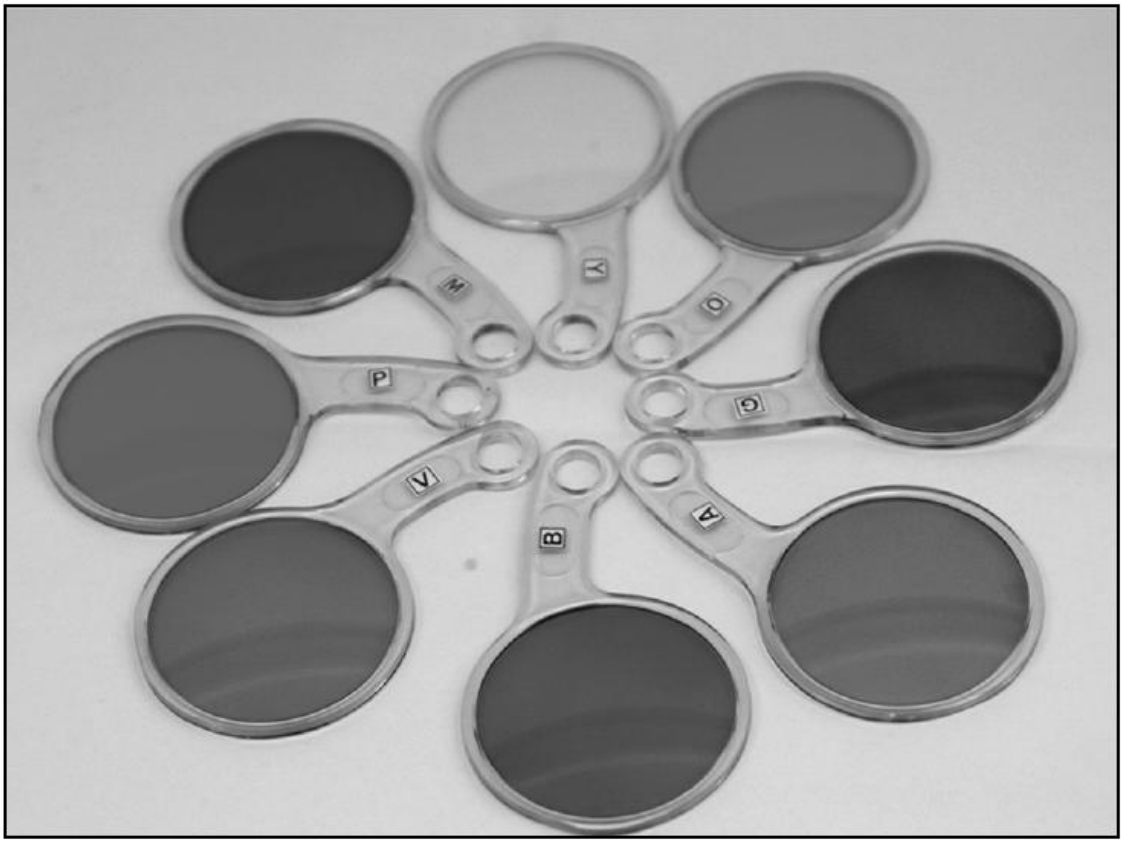

Figure 3: Scatter plot and correlation line of the baseline reading speed results obtained during the first and second sessions (r=0.74; p<0.0001; y = 0.913 x + 12.477)

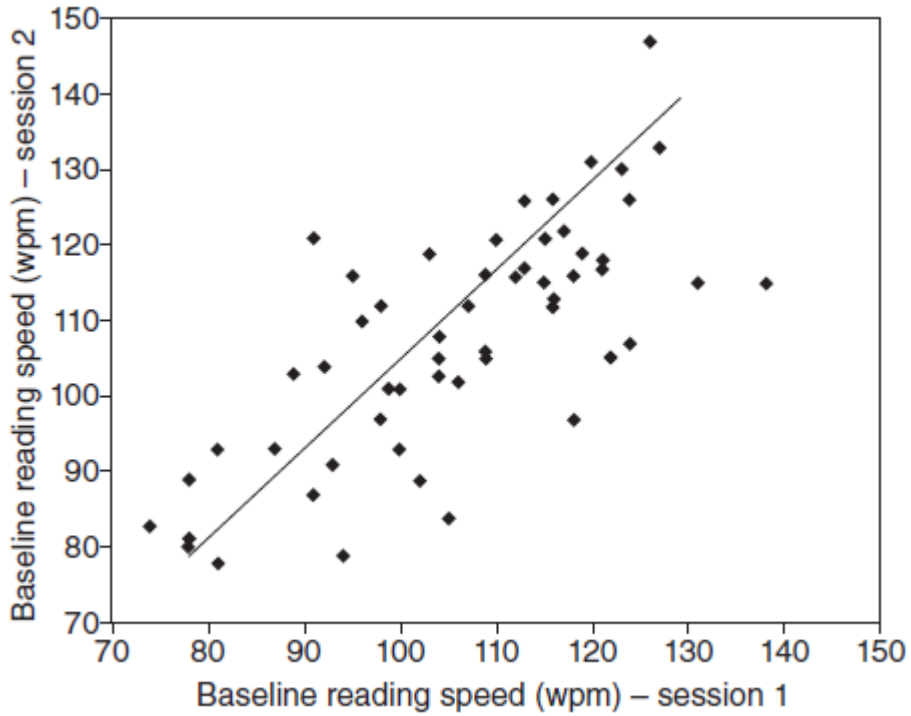

Figure 4:

a: Baseline, placebo and chromatic reading speed of the group as a whole

b: Baseline, placebo and chromatic reading speed of *good* students

c: Baseline, placebo and chromatic reading speed of *poor* students

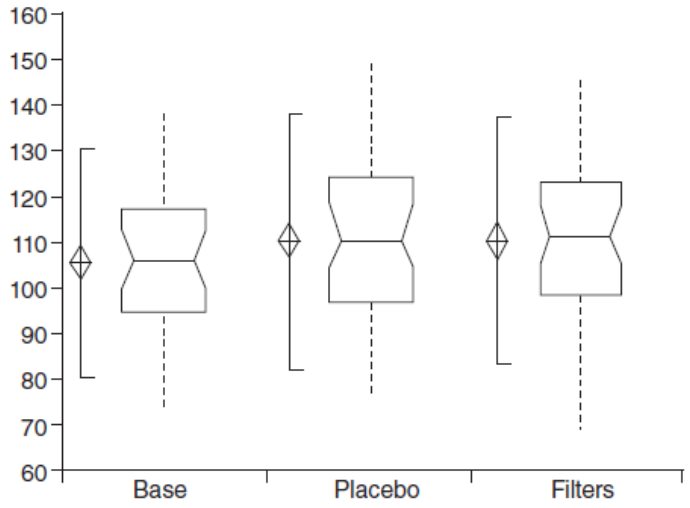

Figure 4a Baseline, placebo and chromatic reading speed (in wpm) of the group as a whole.

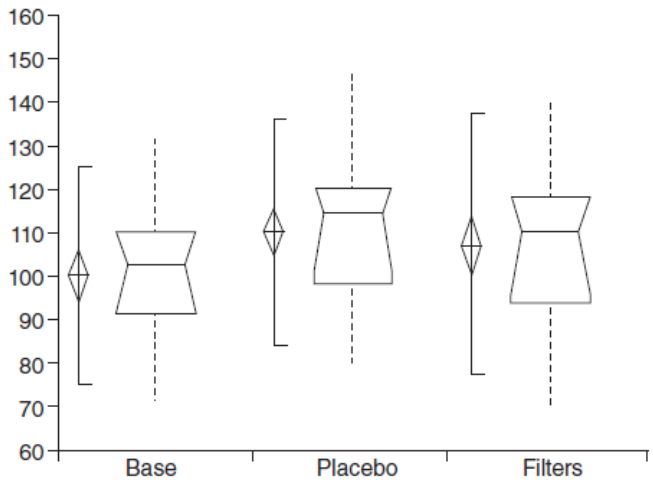

Figure 4b Baseline, placebo and chromatic reading speed (in wpm) of *good* students.

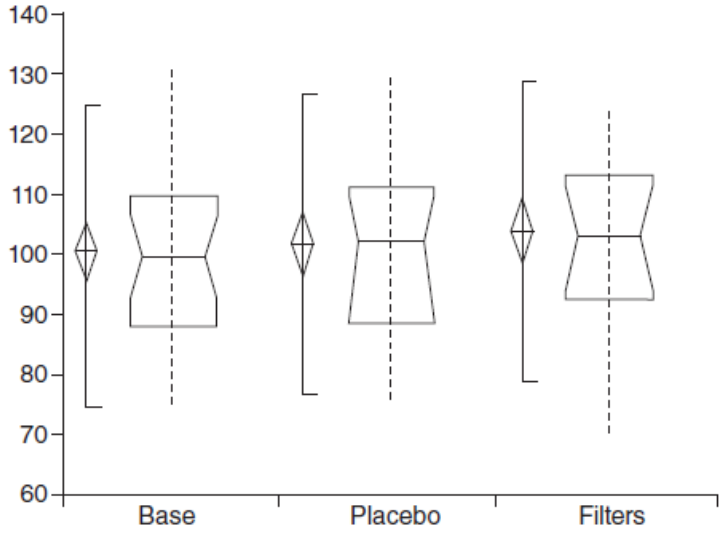

Figure 4c Baseline, placebo and chromatic reading speed (in wpm) of *poor* students.

TABLES

Table 1: Demographic data and baseline reading speed and accuracy (in words per minute and number of errors)

	Age 14 to 15			**Age 16 to 17**		
	n	Age (mean ± SD) Gender (M;F)	Base reading speed and accuracy	n	Age (mean ± SD) Gender (M;F)	Base reading speed and accuracy
Good academic performance	11	14.55 ± 0.52 10M; 1F	113.18 2.45	15	16.64 ± 0.52 9M; 6F	112.14 2.07
Poor academic performance	14	14.36 ± 0.5 8M; 6F	97.93 3.43	16	16.71 ± 0.59 5M; 11F	101.82 3.71