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#### RESEARCH

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# Efficacy of coloured lenses for patients diagnosed with visual stress

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#### **ABSTRACT**

**Clinical relevance:** Colour overlays and lenses are used to relieve symptoms in some patients diagnosed with visual stress, but evidence to support this practice is lacking. In this small randomised crossover trial, a range of colours are beneficial and precise colour specification does not enhance this effect

**Background:** This randomised, double-masked crossover trial aimed to test effectiveness of precisely selected lens tints for visual stress.

**Methods:** Twenty-nine participants aged 11 to 72 (mean 30) years diagnosed with visual stress were issued with their selected coloured overlay then with tinted lenses at two colour settings. An eye examination and coloured overlay test were followed by intuitive colorimetry to select a colour to minimise symptoms (optimal tint) and the closest setting at which the symptoms returned (suboptimal, or placebo tint). The tints were worn for one month each in randomised order. Reading speed was measured using the Wilkins Rate of Reading Test, a subjective scale was used to gauge symptoms, and the patient was asked to indicate whether one of the tints alleviated their symptoms more than the other.

**Results:** Reading speed was significantly higher with colour than without (p < 0.001), but was similar with the overlay and both tints (p = 1.0). Discomfort/distortion rating (1–7) was lower with colour than without (p < 0.001), but no difference was found between the overlay and both tints (p > 0.1). About half (47%) of the patients preferred/strongly preferred their optimal tint, and 39% preferred/strongly preferred their sub-optimal tint, while 14% had no preference.

**Conclusions:** While our patients read more quickly and were more comfortable when using a tint, there was no difference in outcome between the optimal and sub-optimal tints. These results suggest that for patients diagnosed with visual stress, precision tints are no more helpful than sub-optimal, placebo tints.

#### **ARTICLE HISTORY**

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#### **KEYWORDS**

Coloured overlays; intuitive colorimetry; randomised controlled trial; reading speed; visual stress

#### Introduction

Symptoms of perceived visual distortions or discomfort while reading text or viewing patterns with a spatial frequency similar to that of the lines of text in reading material are reported by some individuals. If the symptoms are relieved when viewing through colour, a diagnosis of visual stress (also known as Meares-Irlen or Scotopic Sensitivity syndrome) may be made. 1-3 Research has found that interventions such as coloured plastic sheets (overlays) or tinted lenses help relieve visual stress, but systematic reviews have found that most of those studies are at high risk of bias 4,5 with methodological limitations and that the benefits reported by patients are likely due to placebo effects 4,7 or failure to exclude untreated refractive errors, accommodative or binocular vision disorders. 8

Coloured overlays and lenses are suggested by some organisations for the relief of reading difficulties in visual stress, raising awareness of them among patients, parents and teachers. Parents that coloured overlays or tinted lenses may help people with conditions such as visual stress but also including stroke, autism, and migraine are important to patients, parents and organisations hoping for an intervention to improve reading in those groups. They invest not only time and money but hope, and good evidence of effectiveness seems vital, but is currently lacking. Guidance

for ophthalmic practitioners and advice for patients provided by UK optometry professional organisations acknowledges the lack of strong evidence.<sup>15,16</sup> Coloured overlays or tinted lenses are prescribed by some eye care practitioners for reading difficulty,<sup>17</sup> so reliable evidence is urgently needed to quide clinical decision-making.

A list of international coloured lens prescribers on the Society for Coloured Lens Prescribers web site<sup>17</sup> suggests that the Intuitive Colorimeter is used globally by at least some optometrists to find the most effective lens tint colour for the alleviation of symptoms in visual stress. The patient is asked to select the colour setting at which discomfort and distortion is most reduced while viewing text.

A 1994 randomised controlled study<sup>18</sup> compared the efficacy of lens colour selected by patients with visual stress as the most beneficial colour for reading and the nearest nonbeneficial colour, and found that symptoms were reduced more with the chosen tint than the similar tint. The design of the study allowed double-masking and therefore reliability of the findings. Only two other randomised studies on Intuitive Colorimetry lenses in visual stress were identified by a 2016 systematic review.<sup>6</sup> The present study attempts to repeat the double-masked study by testing whether an optimal tint selected using the Intuitive Colorimeter is more effective in the relief of visual stress symptoms than



a similar but sub-optimal tint or a selected coloured overlay. Outcome measures in the present study were reading speed, a rating scale to subjectively assess discomfort and an overall preference rating. This report follows the guidelines provided by the extension to the CONSORT 2010 statement for cross-over trials.<sup>19</sup>

#### **Methods**

A crossover design was used to allow direct comparisons within patients in a condition likely to remain stable for the duration of the trial, allowing a relatively small sample to be recruited. A sample size calculation based on broadly comparable reading speed data<sup>20</sup> indicated a minimum sample of 23 for statistical power 0.9 and confidence level 0.05. A protocol published on www.clinicaltrials.gov (registration number NCT02680223) was later modified to extend the period for recruitment and the age range of patients (from 18-30 years to 8 years and over), since recruitment was impeded by the more restrictive age range. Therefore, patients with visual stress aged 8 years and over were eligible to participate in the study and were recruited via the City Sight clinic at City, University of London and via flyers posted within the University. The study was approved by the University's Optometry proportionate review human ethics committee. Adult participants and parents of those under 18 years of age signed a declaration of informed consent. Children were provided with written and pictorial information in an appropriate format and gave assent. Information provided to prospective participants stated that the study aimed to investigate whether precise colour specification is needed to improve reading speed in people who find colour helpful. It also stated that they would be provided with two pairs of glasses, one with a colour they found beneficial and one with a slightly different colour, and that they would undergo a reading speed test and would be asked about their symptoms with these glasses. They therefore knew that the two pairs of glasses would have different tints and that one of the tints was that which they had initially found most comfortable or least distorting.

## Assessment of vision and ocular health

Ocular or visual anomalies such as uncorrected refractive error, poor convergence or poorly controlled heterophoria could explain symptoms such as those which define visual stress including perceived blur, doubling or movement of letters (see below). Previous studies have found reduced stereopsis and vergence reserves,<sup>21</sup> and have reported low frequency fluctuations in accommodation (but normal steady state accommodation) in visual stress.<sup>22</sup> Improved reading speed with coloured overlays has been associated with associated heterophoria at near (at a p value of 0.04) but not with visual acuity, refractive error, stereoacuity, amplitude of accommodation, near point of convergence, ocular motility or colour vision deficiency.<sup>23</sup> Evans and colleagues indicated that while anomalies such as reduced stereopsis or vergence reserves occur in visual stress they may be correlates rather than causative factors.<sup>21,24</sup> In the present study, participants underwent tests of vision and ocular health prior to assessment of reading with and without colour. A wall-mounted monitor test chart was used to measure habitual visual acuity. If the patient did not have a current prescription or statement showing no refractive correction was needed, dry retinoscopy and subjective refraction were carried out to determine the type and magnitude of any refractive error. The following tests were conducted to look for binocular vision anomalies: distance and near cover test; ocular motility test; near point of convergence; binocular amplitude of accommodation (the latter in patients of non-presbyopic age). Near stereopsis, prism cover test and prism fusion range were also conducted when considered clinically appropriate. No fixed criteria were used. The researchers conducted these tests in participants individually and separately, did not discuss their findings, and in each case made subjective clinical judgements about the participant's vision, binocularity and ocular health based on symptoms and test results. Those with corrected acuity logMAR 0.1 or better and without a binocular vision or accommodation anomaly as assessed above underwent testing with coloured overlays. The overlays reduce the luminance contrast between the text and background by about 2%, and this reduction is similar for all of the overlay colours, including grey.<sup>25</sup> Wearing their current refractive correction for reading (if needed), the participant was asked to look at the text provided with the Intuitive Overlays, 26,27 and to report whether discomfort or visual symptoms such as blur, doubling, shapes/lines, colours, movement, flicker, wobble or glare (descriptors suggested by the Intuitive Overlay record sheet) were experienced. If at least one such symptom was reported, the participant was then asked to observe the text through each of the 10 Intuitive Overlays, individually and in combinations of two of these following the procedure previously described.<sup>27</sup> Participants were diagnosed with visual stress if they reported one or more symptoms of visual discomfort or distortion while reading, and they reported consistent alleviation of symptom(s) with a coloured overlay over a two week or longer time period. This approach follows that of previous studies on the benefits of coloured overlays or tints<sup>20,27</sup> or about preference, ease and comfort while viewing or reading text<sup>28</sup> but may allow the inclusion of participants with mild or borderline symptoms. More stringent diagnostic indicators were published after our data collection was underway, so were not applied.8

The Wilkins Rate of Reading Test (WRRT)<sup>29</sup> was used to measure reading speed with no overlay and with the selected overlay. This test is intended to minimise the need for linguistic and semantic aspects of reading ability, for application in those with and without a diagnosis of reading or learning difficulty, such as those with dyslexia.<sup>29</sup> The patient was audio-recorded reading the text, and the recording was used when necessary to check reading speed at a later time. The advantage of this approach was that the recording could be played and replayed so that the number of words read correctly and the number of errors made could be measured more carefully than would be possible without the recording. The patient was asked to rate discomfort/distortion with no overlay and with the overlay in place on the text. Note that, in error, some participants were asked to rate on a scale from 0 to 10 and some from 1 to 10, where 0 or 1 indicated 'no discomfort or distortion at all' and 10 indicated 'so much discomfort or distortion that it is impossible to view the text'. For this reason, the rating was converted for analysis to a 7-point scale where 1 = ratings 0 to 1, 2 = 1.5 to 2.5, 3 = 3to 4, 4 = 4.5 to 5.5, 5 = 6 to 7, 6 = 7.5 to 8.5 and 7 = 9 to 10. The overlay was taken by the patient to use for two weeks whenever they felt it was helpful for reading.

After the two-week period, the patient returned to the clinic to report whether the overlay had been beneficial while reading. If so, intuitive colorimetry was carried out to find the patient's optimal lens tint for reading, at the hue and lowest saturation at which the patient found reading was most comfortable and least distorted. Following an established method,<sup>30</sup> intuitive colorimetry involved the participant sitting at the Intuitive Colorimeter<sup>31</sup> in a darkened room and indicating whether each of 12 hue settings made text any more or less comfortable to read than with white light, and to compare against each other any hues found to lessen symptoms. The saturation of the preferred hue was then adjusted to find the least saturation at which symptoms were minimised. Brightness was also adjusted to find the optimal level. This process resulted in estimates of hue, saturation and an 'attenuation' value (indicative of the preferred brightness level). The nearest hue setting at which symptoms returned was found by changing the hue setting slowly until the patient first reported that the discomfort or distortion began to be noticeable again (a sub-optimal setting).<sup>18</sup> Two pairs of identical frames were glazed (with refractive correction if needed) and tinted by Cerium Visual Technologies,<sup>31</sup> one pair with the optimal and one with the sub-optimal (placebo) tint. The researchers and patients were unaware which pair housed which tint, to minimise the chance of a placebo effect.

A random number was generated using Excel to determine whether the patient would be provided with the optimal (odd number) or sub-optimal (even number) tint first, and the other tint second. This number generation and provision of the spectacles in the required order was conducted by an individual who was not one of the researchers, and who prepared the spectacles in the randomised order for collection. The patient was provided with the first pair to wear for one month, after which they wore neither pair for about one week (a washout period) then the second pair was worn for one month. At the point of collection of each pair of glasses, the WRRT was used to test reading speed with the tinted lenses and the patient was asked to rate discomfort/distortion as before. After the second pair had been worn for one month the patient was asked to indicate which tint was preferable for reading, selecting from five options: Strongly preferred tint 1/tint 2; Preferred tint 1/tint 2; No preference.

# Statistical analysis

A Shapiro-Wilk test was conducted to check normality before using repeated-measures one-way analysis of variance with Bonferroni correction to look for differences between reading speeds in the four different viewing conditions. Friedman and Wilcoxon (non-parametric) tests were used to compare the subjective discomfort/distortion ratings between the viewing conditions. Statistical significance was indicated by *p* values < 0.05.

# Results

Participant recruitment began in January 2016 and continued to September 2019. The original protocol included adults aged 18 to 30 years. In March 2017 the protocol and ethical approval were modified to include all people diagnosed with visual stress aged 8 years and over, to allow us to test effectiveness in children as well as adults of all ages.

Forty-one participants were recruited to the study. No patients were found to have binocular or accommodative anomalies that the researchers considered might explain their symptoms, so none were excluded on this basis. Eleven of the 41 did not complete the study, failing to return for follow up during the study period. One additional participant reported no benefit with the overlay, but the 11 provided no feedback so we do not know whether they failed to return for this reason. Twenty-nine participants aged from 11 to 72 years (median age 28 years) reported benefit and completed the study. Most (23; 79%) were female. Seventeen reported having been diagnosed with dyslexia while 12 had no diagnosis of specific learning difficulty.

Of the 29 participants, 11 reported having found colour useful for reading in the past, two of whom indicated that colour generally was helpful, with nine reporting a particular colour. Four of the nine went on to choose an overlay in a different colour than they had used previously (green versus orange + rose; grey versus pink; blue versus yellow; and pink versus green) and five chose the same colour.

All four sets of reading speed data were tested for normality (Shapiro-Wilk test p > 0.57 in each case) and a repeated measures ANOVA with post-hoc Bonferroni tests was used for comparisons. As shown by Figure 1, reading speed was significantly lower when measured without (baseline) than with the chosen overlay or either of the tints (95% confidence intervals 107-132, 129-148, 126-148 and 126-150 words per minute for baseline, overlay, optimal and sub-optimal tints, respectively; p < 0.001). Median baseline reading speeds for the four children (aged 11, 13, 14 and 16 years) and the adults included in this study are 82 and 130 words per minute. These are lower than reading speeds obtained in children (median 110) and adults (median 156) not identified as having visual stress (Gilchrist et al., 32 data from their Table 2 using group B (limitations identified in group A) and group D (data collected in an English-speaking cohort)). This difference is unsurprising since according to protocols for diagnosis reading speed can be enhanced (when reading through colour) in visual stress but not in controls.

No significant difference in reading speed was found between the three colours (the chosen overlay, optimal tint or sub-optimal tint; p = 1.0). Table 1 shows the reading speeds for each individual, illustrating a range of differences between reading with and without colour. Note that all reading speed data were excluded from one of the 29 participants and some data were excluded from five others due to inconsistencies in the reading speed recording method in these cases. Specifically, the text differed in font size across these tests, so could not be directly compared.

The subjective discomfort rating data were not all normally distributed (Shapiro Wilk test, overlay data p < 0.05, baseline, optimal and sub-optimal tint data p > 0.3). As shown by Figure 2, ratings were significantly different across the viewing conditions (Friedman test p < 0.001) and significantly lower when viewing through any of the three colours than at baseline without colour (Wilcoxon test p < 0.001; significant with correction for multiple comparisons). However, no significant difference was found between the overlay and the optimal or sub-optimal tint (p = 0.684 and p = 0.073respectively) or between the optimal and sub-optimal tints

At the end of the study, participants were asked which of the two spectacle tints they preferred wearing. One



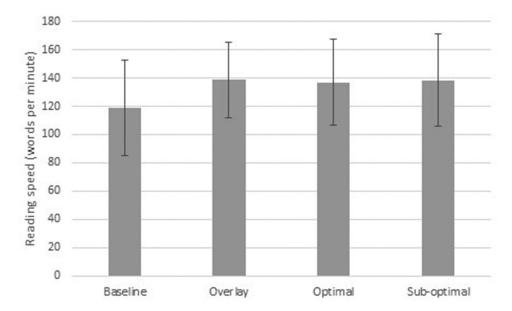


Figure 1. Mean reading speed in each viewing condition. WRRT = Wilkins Rate of Reading Test; wpm = words per minute; Baseline = viewing text with no filter; Overlay = viewing text through selected overlay; Optimal = viewing text while wearing filter chosen for optimum comfort while reading; Sub-optimal = viewing text while wearing filter through which reading was less comfortable. Error bars indicate standard deviation.

participant was asked this question by email and did not respond. Thirteen of the remaining 28 participants (47%) preferred the optimal tint (8 strongly preferred; 5 preferred); 11 participants (39%) preferred the sub-optimal tint (5 strongly preferred; 6 preferred), while 4 (14%) expressed no preference for one pair over the other.

## **Discussion**

The present findings show no difference between precision tinted lenses and sub-optimal tints in terms of reading speed, visual discomfort or distortion. The lack of difference suggests a placebo effect when viewing through colour, as has been discussed previously.33 In some of the previous research on the effects of coloured overlays and lenses in visual stress, placebo controls have been used, but they have had some limitations, as discussed in recent systematic reviews. For example, a grey overlay has been used for comparison with coloured overlays.<sup>25</sup> A UV filter overlay labelled as a 'special filter' has been used<sup>20</sup> in an attempt to find any placebo effect, but perhaps could have the opposite effect (a nocebo effect).34

Our findings are broadly in agreement with Wilkins et al. 18 who found that reading speed, accuracy and comprehension were similar when children with visual stress viewed through the optimal tint located using the intuitive colorimeter and a similar tint with which symptoms were reported.

Using a subjective rating scale of discomfort or visual distortion we found no more benefit with the optimal tint than with the sub-optimal tint. In fact, the overlay was the most beneficial of all three colours, and this is surprising because it is a much less precisely specified colour than the optimal tint. These findings are not in agreement with Wilkins et al.<sup>18</sup> who used similar methods and reported that an optimal tint reduced symptoms significantly more than a placebo control tint. In that study, 36 children (10 to 15 years) diagnosed with visual stress kept a symptom diary while wearing each tint over separate one-month periods. Six had no symptomatic days with either the optimal or control tint, 11 had fewer symptomatic days with the control tint and 19 had fewer symptomatic days with the optimal tint. The optimal tint was worn for 18 days on average in the onemonth period, about 14 of which (71%) were symptom-free. The control tint was also worn for an average of 18 days in a month, and 12 of these (66%) were symptom-free. Thus, the participants with visual stress chose to wear each tint for about the same amount of time (18 days in a month for the control and the optimal tint) and reported two more symptom free days with the optimal than the control tint. While two additional symptom-free days are valuable, the number of days without symptoms does not necessarily indicate fewer or less severe symptoms on each day; statistical significance does not necessarily indicate clinical significance or positive impact for the patient.

In our group of people diagnosed with visual stress, just under half preferred the optimal tint and the remainder either preferred the sub-optimal tint or had no preference. Together with the findings described above, this raises questions about the value of precise specification of colour for lens tinting in patients diagnosed with visual stress.

## Strengths and limitations

The randomised double masked controlled design of this study helps to minimise bias, but it is important to consider whether masking was achieved and maintained. The optimal and sub-optimal tints differed so it is theoretically possible that the researchers or participants may have recognised the tint type and known which glasses contained which tint. However, when each tint was selected the participant viewed it only in the Intuitive Colorimeter without context. The colour would appear different when viewed as part of a natural scene, so is not likely to have been recognised by the participant. In addition, we have previously found that repeated selection of optimal tints by people with visual stress differ by at least three just noticeable differences.35 This indicates that they would be distinguishable, at least by young normal trichromats, if viewed side by side. However, in the present study neither the participant nor researcher saw the tints side by side, and the tinted lenses were mounted in identical

Table 1. Shows the age of each patient, whether they had previously been diagnosed with dyslexia, had previously used coloured overlays and their refractive error for reading, which was corrected in their tinted lenses. The table also shows the colour of their selected overlay (two superimposed colours in some cases), the colour of their optimal and sub-optimal tint and their reading speed with no colour (baseline) with the overlay, optimal tint or sub-optimal tint. Note that the tint colours are described by the colorimeter manufacturer in terms of hue (blue (B), purple (P), Rose (R), turquoise (T), orange (O), yellow (Y)) and from high to low saturation (1 to 6). In addition, reading speed in each viewing condition is shown (missing data are those that were excluded from analysis).

							Reading speed (words per minute)			
Age (years)	Dyslexic (Y/N)	Refractive correction	Prior use of colour (Y/N)	Selected overlay	Optimal tint colours	Sub-optimal tint colours	Baseline	Overlay	Optimal	Sub- optimal
21	Y	R plano L plano	N	Aqua	B2+P6+P4	B5+B4+B3+P6 +P5+P4	131	129.5	123.5	131
22	Υ	R Plano L plano	N	Yellow	R6+R5+R4 +R3+O4	P6+R5+R4+R3	106	107	128.5	121.5
24	Υ	R plano L plano	N	Mint green	T5+T2+B5	T5+T4+T3+B5 +B3	99.5	114.5	98	115.5
19	N	R plano L plano	N	Blue	T5+T4+B5+B4 +B2	T2+B5+B3	132	166.5	177.5	183.5
19	Υ	$R - 0.25/-0.25 \times 180 L - 0.25/-0.25 \times 50$	Y	Orange + Rose	R6+R4+R3 +O5	R6+R3+O3	63	94.5	86.5	75
23	Υ	R plano/ $-0.50 \times 80 L$ plano/ $-0.50 \times 115$	N	Orange	R4+O5+O4 +O2	05+04+03+Y3	103.5	112.5	91	99.5
37	N	R + 4.50/-2.00 × 180 L + 4.75/-2.00 × 180	Y	Pink	B2+P4+P6	B5+B4+B3+P6 +P5+P4	145.5	140	156	162
18	Υ	R plano L plano	N	Aqua + Aqua	T5+T4+B5+B4 +B2	B3+B2+P6+P5	129	147.5	145.5	156.5
34	Υ	R - 1.75/-0.50 × 90 L plano/-1.00 × 85	N	Aqua	R5+R3+O5 +O4+O3	P6+P5+R6+R5 +R4+R3	163.5	167.5	176	173.5
32	N	R plano L plano	N	Pink	P6+P5+P3+R3 +G2	P3+R6+R4+R3 +G2	183.5	183.5	191.5	197.5
54	Υ	R + $1.50/-0.25 \times 75 L + 1.50/-0.50 \times 70$	N	Yellow	R6+R4+R3 +O5	R4+R3+O4	139.5	173.5	153	167
72	N	R - 5.50/-0.25 × 57 L - 9.25/-1.00 × 105	N	Yellow + Yellow	G4+G3+T5 +T3	G4+T3	142.5	143.5	134.5	
16	Υ	R plano L plano	N	Purple	B4+P6+P3	P4+R3	50.5		110	105.5
11	Υ	R plano Lplano	N	Pink	P3+R3	P5+P4+R5+R4 +R3	107	116	125	116.5
46	Υ	$R + 0.75/-1.50 \times 110 L + 1.50/-2.75 \times 89$	Y	Yellow	R4+O2	R3+O5+O4+O3	120.5	131	131.5	134.5
21	N	$R - 2.50/-0.50 \times 180$ $L - 1.75/-0.50 \times 15$	N	Lime green + Lime green	02	O3+O5+R4	99	120.5	118.5	123.5
29	Υ	R −0.25 L + 0.25	Υ	Lime green	Y5+Y4	04+03	162	167	169	176.5
29	N	R plano L plano	Y	Orange + Yellow	P6+R3	R3+O4	149	163.5		151
28	N	R plano L plano	N	Aqua + Aqua	P6+B2	B5+B4+B3+P3	80	110	121.5	111.5
32	N	R plano L plano	Y	Purple	B3+P3+B4 +P4+B5	B4+P5+P4	143		195	180
32	N	R plano L plano	Υ	Aqua	G4+T4	G5+G4	165	171	164	176
13	N	R plano/ $-0.25 \times 5$ L plano/ $-0.50 \times 180$	Y	Blue + Purple	O2+R5	R5+R3+O5+O4 +O3	60.5	82.5	100	103.5
28	N	R plano L plano	Υ	Yellow	R3+O5+O3	R4+R3+O4	146	167		
23	Y	R +0.25 L + 0.25/-0.25 × 180	N	Grey	G2+B3	G3+B3	120	139	153	164
49	Υ	$R + 0.50/-1.25 \times 100 L + 0.75/-1.25 \times 75$	N	Lime green	G2+T5+T3	G2+T2	62.5	115.5	93.5	81
14	Y	R plano L plano	N	Blue	R5+R3+O5 +O4+O3	R6+R5+O2	103.5	154.5	154	130
24	Y	$R - 6.75/-0.50 \times 180 L -$ $6.25/-0.50 \times 175$	Y	Blue	G5+G4+G2 +T5+T3	G4+G3+T5+T2	115	152	141	139.5
45	Υ	R + 2.25/-0.25 × 140 L + 2.50/-0.50 × 60	Y	Yellow	T5+T4+B5+B4 +B2	T5+T3+T2	116	133	125.5	119.5
41	N	R + 0.75/-0.25 × 55 L + 1.00/-0.25 × 180	N	Rose	R5+R3+O5 +O4+O3	R6+R5+O2				

frames, making it unlikely that the participant or researcher would know which was the sub-optimal or optimal tint. We are therefore confident that double masking was maintained throughout our study.

This study has several significant limitations. First, we used a subjective rating scale to quantify our participants' experience of discomfort or visual distortion when viewing text with and without colour. Subjective ratings are used widely to gauge comfort and other ergonomic factors but have been criticised for sources of error such as a lack of shared meaning.<sup>36</sup> We used the scale on three different occasions: to collect ratings with and without the overlay, then with the

first tint and finally the second tint. The participant was given anchors ('no discomfort or distortion' at 0 or 1, as explained in Methods, and 'so much discomfort or distortion that it is impossible to view the text' at 10) and since our comparisons were within individuals the meaning of terms such as 'discomfort' seem likely to be consistent across our comparisons.

Second, the sample size was small, and some data were missing from individuals due to inconsistencies in the reading speed measurement method at different stages of the study in those cases. This reduces the possibility of finding a significant difference between the viewing conditions. However, even with missing data the sample was above the

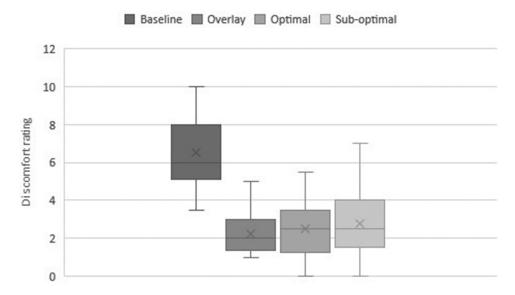


Figure 2. Subjective discomfort ratings categorised within ranges from 0-1 (rating 1) to 9-10 (rating 7) when viewing text through no filter (Baseline), the selected overlay (Overlay), the tint selected for minimal discomfort (Optimal) and the tint with which discomfort was reported (Sub-optimal). Box shows interquartile range, line within box shows median, cross shows mean, and error bars show maximum and minimum ratings.

sample size of n = 23 calculated prior to the study (see Methods) so the study is not likely to have been underpowered, but a larger sample would more clearly indicate whether differences exist between these conditions.

Third, patients in this study were diagnosed with visual stress if they reported one or more symptoms of visual discomfort or distortion while reading, and consistent alleviation of symptom(s) with a coloured overlay over at least a two-week time period. Relatively recent recommendations indicate that while one or more symptoms are suggestive of visual stress, at least three symptoms and two signs are required for a diagnosis,8 so our criteria may not have been sufficiently stringent. It is possible, therefore, that our sample included patients with mild or borderline visual stress, and that a sample with more severe symptoms may yield different results.

Fourth, our optometric assessment, to look for anomalies that might explain perceptual distortions, did not follow fixed criteria and was based on clinical judgement in each patient. This means that levels of convergence, accommodation or other ocular or visual functions considered acceptable may have varied between the researchers and depending on the patient's history and symptoms. A 2016 systematic review indicates that while in clinical practice such anomalies should be corrected before a diagnosis of visual stress is made, 'it is less important for research studies to apply this criterion because ophthalmic factors only infrequently account for symptoms of visual stress'. However, a lack of clear criteria could allow inclusion of patients whose symptoms are related to vergence or other ocular anomalies, and not amenable to colour as a form of treatment. Results from those patients may have limited the scope of this study to demonstrate a significant effect of viewing through colour.

Finally, a significant proportion (11 of 41) of participants withdrew from the study without reporting whether they found the tints beneficial. We therefore do not have data on whether these participants found the tints beneficial and even whether they experienced adverse effects with them. In similar future studies, these data would be important to

help understand whether patients diagnosed with visual stress find tinted lenses helpful.

#### **Conclusion**

The use of coloured overlays and lenses for patients with visual stress is controversial, in part due to sources of bias in research reporting a benefit, as discussed in systematic reviews.<sup>37</sup> Due to its limitations, the present study cannot resolve this controversy, but suggests that coloured lenses are not effective for visual stress beyond a placebo effect. The results pose a challenge for advocates of precision tints for visual stress to conduct further placebo-controlled research with larger samples and with methods addressing these limitations to establish whether coloured overlays and precision tints are more than placebo.

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