

Do Blue-blocking Lenses Reduce Eye Strain From Extended Screen Time? A Double-Masked Randomized Controlled Trial



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- **PURPOSE:** To investigate if blue-blocking lenses are effective in reducing the ocular signs and symptoms of eye strain associated with computer use.
- **DESIGN:** Double-masked, randomized controlled trial.
- **METHODS:** A total of 120 symptomatic computer users were randomly assigned (1:1) into a “positive” or “negative” advocacy arm (ie, a clinician either advocating or not advocating for the intervention via a prerecorded video). Participants were further sub-randomized (1:1) to receive either clear (placebo) or blue-blocking spectacles. All participants were led to believe they had received an active intervention. Participants performed a 2-hour computer task while wearing their assigned spectacle intervention. The prespecified primary outcome measures were the mean change (post- minus pre-computer task) in eye strain symptom score and critical flicker-fusion frequency (CFF, an objective measure of eye strain). The study also investigated whether clinician advocacy of the intervention (in a positive or negative light) modulated clinical outcomes.
- **RESULTS:** All participants completed the study. In the primary analysis, for CFF, no significant effect was found for advocacy type (positive or negative, $p = .164$) and spectacle intervention type (blue-blocking or clear lens, $p = .304$). Likewise, for eye strain symptom score, no differences were found for advocacy ($p = .410$) or spectacle lens types ($p = .394$). No adverse events were documented.
- **CONCLUSIONS:** Blue-blocking lenses did not alter signs or symptoms of eye strain with computer use relative to standard clear lenses. Clinician advocacy type had no bearing on clinical outcomes. (Am J Ophthalmol 2021;226: 243–251. © 2021 Elsevier Inc. All rights reserved.)

COMPUTER USE IS UBIQUITOUS IN MODERN SOCIETY and is integral to daily life.¹ Up to 69% of computer users report eye strain, referred to as “computer vision syndrome (CVS).”² CVS is defined as a group of eye- and vision-related problems that results from prolonged electronic device use.² The most common symptoms of CVS are blurred vision, dry eye, redness, and headache.³

Recently, an increased number of patients symptomatic of CVS have presented to ophthalmology.⁴ CVS is estimated to affect 60 million people worldwide, with 1 million new cases identified each year.⁵ As such, there is substantial incentive for industry to produce therapies for this extremely common complaint. It has been hypothesized that CVS may be caused by blue light emitted from computer screens.⁶ A variety of specialist ophthalmic lenses that reduce blue light transmission to the eye have been marketed to reduce eye strain with computer use.⁷ These lenses, commonly known as “blue light-filtering lenses” or “blue-blocking lenses,” are being routinely prescribed to the public at increasing rates and not insubstantial cost.^{8,9} To date, only 1 randomized controlled trial (RCT) has investigated blue-blocking lenses for CVS, although this study had lens manufacturer sponsorship, had no preregistration, and tested participants (recruited from an optometry college) who might have had advanced knowledge of these lenses.¹⁰

A recent systematic review and meta-analysis investigated the benefits and harms of blue-blocking spectacle lenses on visual performance, macular health, and the sleep-wake cycle, and identified a paucity of high-quality evidence to guide practice. The authors further concluded that high-quality clinical trials are required to achieve greater clarity about the potential benefit of blue-blocking lenses on visual function and ocular health.¹¹

To address this evidence gap, we conducted a double-masked RCT to investigate if blue-blocking lenses are effective in alleviating ocular symptoms associated with computer use. A novel aspect of the study design involved a randomization step to modulate clinical advocacy of the intervention, whereby the investigator did/did not present the assigned intervention in a positive light. This approach allowed for clinical practice—where a prescribed therapy is almost always advocated—to be better simulated, in contrast to the deliberately equivocal tone commonly adopted in trials. A further novel aspect of the study was that all



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participants were led to believe they had received an active intervention. This again simulates clinical practice, where patients never expect to receive a placebo.

METHODS

- **STUDY OVERVIEW:** This double-masked RCT was conducted in the Department of Optometry and Vision Sciences, The University of Melbourne. The study adhered to the tenets of the Declaration of Helsinki. Ethical approval was granted by the University of Melbourne Human Research Ethics Committee (ID #1852643). The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR, AC-TRN12619000057189). Written informed consent was obtained from each participant prior to enrollment. All authors vouch for the accuracy and completeness of the data, and fidelity of the trial to the *a priori* protocol (Supplemental Document 1; Supplemental Material available at AJO.com), except where noted.

- **PARTICIPANTS:** Potential participants were screened over the phone using a validated questionnaire for CVS.¹² The questionnaire surveyed 16 symptoms, and participants had to nominate the frequency and intensity of each symptom with computer use. Those with a diagnosis of CVS, as indicated by a questionnaire score of 6 or more, were invited to attend an in-person study visit. Participant inclusion criteria were consenting adults aged 18-40 years, habitual computer use without a spectacle correction, and unaided or contact lens-corrected binocular near vision of \geq N8 print at 40 cm. Potential participants were ineligible if they had a history of self-reported neurological disease or migraine, or nystagmus. Individuals with a professional background in eye care or spectacle lens products, or who were currently undertaking study in these fields, were also not eligible, as they were considered more likely to have *a priori* knowledge of, and opinions about, the interventions. All participants provided written informed consent to participate.

- **STUDY DESIGN:** This was a single-site, double-masked RCT to investigate the efficacy and safety of blue-blocking lenses for alleviating eye strain in CVS, and the role of clinician advocacy (presented using videos, with the clinician either advocating or not advocating for the intervention) in modulating clinical outcomes. A 2-tier randomization process was adopted (Figure 1). Eligible participants were randomly assigned (1:1) to either a “positive” or “negative” advocacy arm, and then further sub-randomized (1:1) to the lens intervention (blue-blocking or placebo [non-blue-blocking, ie, clear]), to yield 4 intervention arms. Though the study included a control (placebo) group, all participants were led to believe they had received an “active”

treatment. The rationale for this deception was that patients know unequivocally they have received a treatment in real-world clinical practice. This deception was included in the private details of the registered trial but was not described in publicly accessible study documentation (ie, ANZCTR entry, plain language statement, and participant advertisements) to prevent the deception from being disclosed. In addition, the nature of the active intervention involving a “blue-blocking” lens was not mentioned in any public-facing documentation, to reduce the potential for participants to research the topic in advance or induce any bias with preconceived perceptions about the lenses. In the study itself, the term “blue-blocking” was similarly not mentioned, with the intervention referred to as “spectacle lenses specifically designed to reduce CVS.”

- **RANDOMIZATION AND INTERVENTION ASSIGNMENT:** As detailed in the study, both the “advocacy” and “spectacle lens” interventions were administered in a double-masked manner, using a custom-written Matlab code that generated 2 files. The first file described which spectacle frames contained clear lenses and which contained blue-blocking lenses, as well as which of 2 computer file folders should contain the positive advocacy video. The second file determined what spectacle frame was assigned to the participant, and which video folder was to be used. As such, the spectacle lens and advocacy type could only be known by combining the information in both files, which was only actioned at the study conclusion. The investigator who glazed the frames and loaded the videos (based on the first file) was independent to the outcome assessor who selected the frames and video folder for the participant (based on the second file) and conducted the experimental tests.

- **DESCRIPTION OF THE INTERVENTIONS:**

Clinician advocacy video

In these videos, authors A.J.A. and L.E.D. explained the supposed purpose of the study, presenting the intervention in either a positive or negative light. Both videos were of similar duration (approximately 3 minutes); full video transcripts are provided in Appendix 1 of the protocol (Supplemental Document 1). To preserve masking, the outcome assessor (S.S.) left the room while the video played, under the guise of obtaining a glass of water for the participant.

Spectacle lenses

The “active” intervention group received blue-blocking lenses (Prevencia; Essilor, Dallas, Texas, USA) that filtered blue light by front surface coating between 10% and 30% in the range of 400-500 nm. These lenses almost completely blocked transmission below 400 nm and had approximately 95% transmission between 500 and 700 nm.⁷ We selected this lens because it offered the greatest level of blue-light attenuation out of a representative sample of commercially available blue-blocking lenses investigated by Leung and

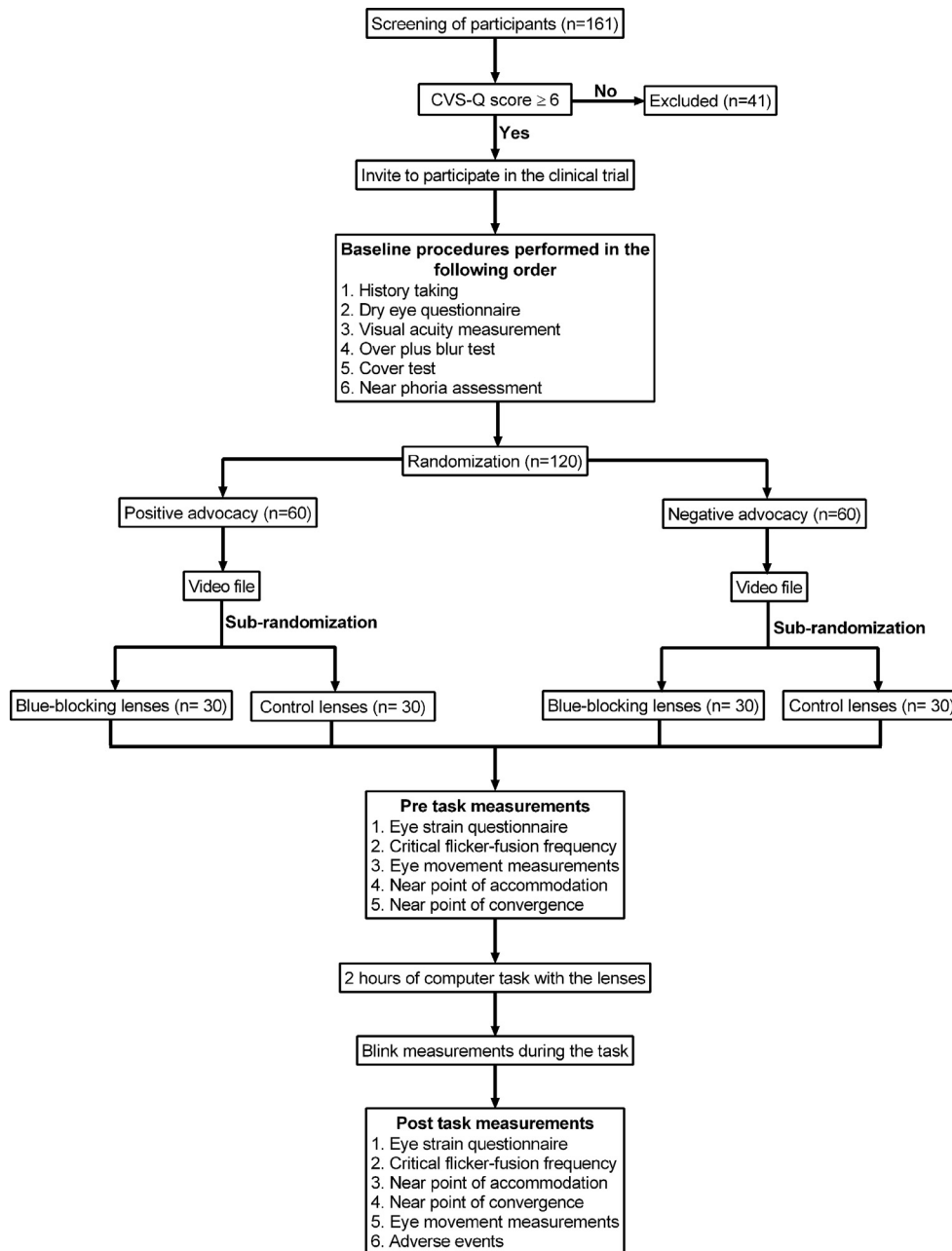


FIGURE 1. Summary of clinical trial design. CVS-Q = computer vision syndrome questionnaire.

colleagues.⁷ The “control” (placebo) group received UV-coated lenses (Crizal; Essilor) with a conventional antireflection coating that did not filter blue light. Both lens types had no power (0.00 diopter). As blue-blocking lenses have a subtle blue surface reflection, the outcome assessor wore yellow glasses to mask him from this reflection.

• **STUDY PROCEDURES:** After baseline study procedures (see trial protocol, Supplemental Document 1), eligible participants underwent a series of pre-task assessments, comprising (1) a subjective measure of eye strain, being an symptom score questionnaire,¹³ consisting of 9 differ-

ent symptom domains; and (2) objective measures of eye strain: critical flicker-fusion frequency (CFF [Hz]; the frequency at which a flickering light stops appearing to flicker and instead appears continuously illuminated), saccadic eye movements, near point of accommodation (cm), near point of convergence (cm), and blink rate (blinks per minute).

CFF was measured using a green light-emitting diode stimulus (2-degree-diameter circle, 240 cd/m²). Participants were asked to discriminate between a stimulus presented at a fixed frequency well above CFF (100 Hz, square wave flicker, 100% contrast) and another stimulus initially presented at 25 Hz whose frequency was then altered

TABLE 1. Participant Demographics and Clinical Characteristics.

Demographic Factor	Positive Advocacy + Blue-blocking Lenses (N = 30)	Positive Advocacy + Control Lenses (N = 30)	Negative Advocacy + Blue-blocking Lenses (N = 30)	Negative Advocacy + Control Lenses (N = 30)
Age (years), median (IQR)	25 (22, 28)	25 (23, 28)	22 (21, 24)	24 (20, 30)
Sex (N)				
Male	14	10	7	9
Female	16	20	23	21
Contact lens use (N)				
Yes	7	5	10	7
No	23	25	20	23
Hours of computer use/day, median (IQR)	6 (5, 9)	6 (5, 8)	6 (4, 8)	6 (4, 8)
Days of computer use/week, median (IQR)	7 (7, 7)	7 (6, 7)	7 (7, 7)	7 (7, 7)
OSDI score (/100), median (IQR)	19 (7, 30)	21 (11, 32)	18 (10, 25)	18 (11, 32)
CVS score (/32), median (IQR)	9 (6, 12)	10 (8, 13)	10 (7, 12)	9 (7, 11)

CVS = computer vision syndrome; IQR = interquartile range; OSDI = Ocular Surface Disease Index (dry eye symptom score); N = number of participants

by a staircase procedure (2-up, 1-down, 2-interval forced choice).¹⁴ Step size was initially 5 Hz, followed by 1 Hz steps after the first 2 reversals. Each stimulus was presented for a duration of 0.5 seconds, with an inter-stimulus interval of 0.25 seconds, with the order of the fixed and variable frequency stimulus randomized on a trial-by-trial basis. The test was completed after 4 reversals, with the CFF being calculated as the average of the last 2 reversals.

Eye movement parameters were measured using a Saccadometer (Ober Consulting, Poznan, Poland).¹⁵ Blink rates were measured offline using a web camera (Logitech C2790; Logitech, Alexandria, NSW, Australia), at the start (5 minutes) and end (5 minutes) of the time period that participants performed the computer task. Participants were unaware that their blinking was being monitored, to allow natural blinking characteristics to be captured. Near point of accommodation and convergence were measured using the push-up method.¹⁶

After pre-task measurements, participants were provided with their randomly assigned spectacle lens intervention and were given standardized computer tasks involving spreadsheet data entry and data checking (as detailed in the study protocol) to perform for 2 hours. The same test measurements were repeated immediately after the computer task.

To assess the integrity of the outcome assessor masking, at the end of each participant visit, the outcome assessor guessed which advocacy and intervention group the participants were allocated to.

• **OUTCOME MEASURES:** A full description of primary and secondary outcome measures is provided in the trial protocol. In brief, primary outcome measures relating to eye strain were the mean change from pre-task, at the post-task time point, for (1) total eye strain symptom score (/900)¹³; and (2) CFF¹⁰ (Hz). An *a priori* sub-analysis of the 9

sub-items of the symptom score questionnaire was also performed.

Prespecified secondary outcome measures were the mean change from pre-task, at the post-task time point, for the following: eye movement parameters (latency [ms], duration [ms], amplitude [deg], peak velocity [deg/s], and mean velocity [deg/s]), blink rate (blinks per minute), near point of accommodation (cm), and near point of convergence (cm).

Safety was evaluated by comparing inter-group differences in the incidence of adverse events. Also, participants' error rates (%) and absolute number of unique data entry tasks performed during the computer task were assessed.

• **STATISTICAL ANALYSES:** Sample size was calculated based on detecting a 1.8 Hz inter-group difference (Cohen's effect size of 1.3) in CFF, based on a previous study comparing blue-blocking lenses with a placebo.¹⁰ For 80% power, and allowing for 20% potential participant attrition, we calculated that 15 participants would be required per group. However, our study also sought to consider the effect of clinician advocacy. We could not identify a relevant quantitative reference to base a formal sample size calculation for this effect. The final sample size was based on an assumption that at least twice as many participants would be required to account for our double randomization procedure. The final target sample size was thus 30 participants per arm (120 participants in total).

An *a priori* statistical analysis plan (Supplemental Document 2; Supplemental Material available at AJO.com) was developed in consultation with the Statistical Consulting Centre, The University of Melbourne, before performing any data analyses and prior to unmasking. Statistical analyses were performed using the Statistical Package for the Social Sciences (IBM SPSS, Armonk, New York, USA). For between-group comparisons of the baseline and demographic variables, a 1-way analysis of variance (ANOVA) or

χ^2 test was used, as appropriate. ANOVA was used because it preserves the magnitude information of the dataset. Because there were only 2 primary outcome measures, no adjustments were performed for multiple comparisons as the risk of an inflated type I error rate was low. For the secondary outcome measures, no adjustment was performed, but the results were interpreted with caution.

To assess for potential interactions between advocacy type and spectacle lens type, a 2-way ANOVA was performed. This test is robust to violations of normality if the sample sizes are equal between groups, as in our study.^{17, 18} The masking integrity of the outcome assessor to participants' assigned advocacy and spectacle intervention types was assessed using the χ^2 test.

All outcomes are presented using descriptive statistics: normally distributed data by the mean and standard deviation (SD) and non-normal distributions by the median and interquartile range (IQR).

RESULTS

A total of 120 participants (30 per intervention arm) were enrolled between March 14, 2019 and January 15, 2020. All participants completed the study. Participants' demographics and baseline clinical characteristics in each study group are presented in Table 1.

- PRIMARY OUTCOMES:** Figure 2 shows the change, from pre-task, at the post-task time point, in each group, for the primary outcomes. For CFF, there was no significant difference between blue-blocking and control spectacle lenses (between-group point estimate difference: -1.33 Hz, 95% confidence interval [CI], -3.22 to 0.55, $P = .164$) and no effect of advocacy type (between-group point estimate difference: -0.98 Hz, 95% CI, -2.86 to 0.90, $P = .304$). There was also no significant interaction ($F_{(1, 115)} = 0.159$, $P = .691$). Similarly, for eye strain symptom score, there was no effect of lens type (between-group point estimate difference: -18.3 units, 95% CI, -60.8 to 24.1, $P = .394$) or advocacy type (between-group point estimate difference: -17.6 units, 95% CI, -59.9 to 24.6, $P = .410$). The sub-analysis of each item in the symptom survey showed no inter-group differences (Table 2).

- SECONDARY OUTCOMES:** Figure 3 shows the mean change, from pre-task, for the secondary outcomes. No significant differences were found for advocacy or spectacle lens types for most outcomes. There was a significant effect of advocacy type on the mean duration of eye movements (between-group point estimate difference: -3.57 ms, 95% CI, -6.88 to -0.27, $P = .034$).

- PARTICIPANT PERFORMANCE ON THE COMPUTER TASK:** There was no significant difference between groups

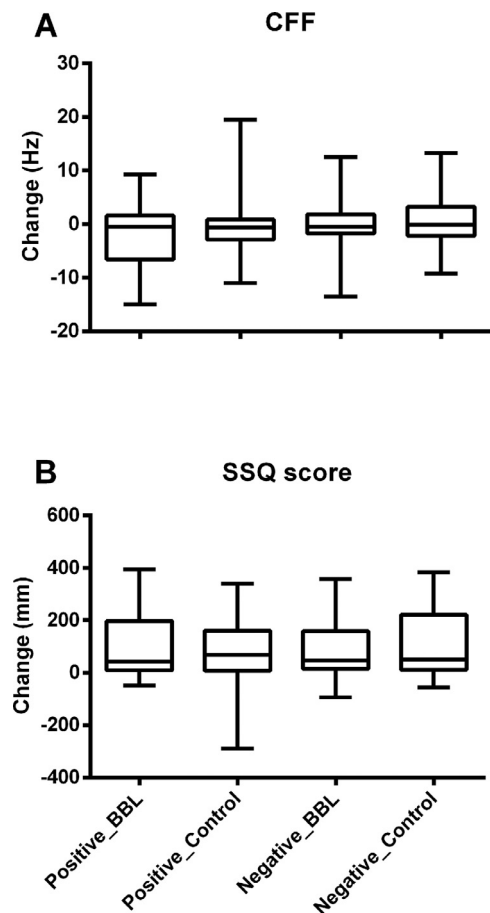


FIGURE 2. Box-and-whisker plots of the change, from pre-task, at the post-task time point (ie, after completion of the 2-hour computer task), in each group (blue-blocking [BBL] vs clear [Control] lenses, and positive vs negative advocacy for the intervention), for the primary outcome measures. The box-and-whisker plots denote the minimum, the 25th percentile, the median, the 75th percentile, and the maximum. (A) Critical flicker-fusion frequency (CFF), and (B) Subjective symptom questionnaire (SSQ) score.

for data entry error rate or the absolute number of unique data entered during the computer task (Supplemental Table 1; Supplemental Material available at AJO.com).

- ADVERSE EVENTS:** No participant experienced an adverse event.

- MASKING INTEGRITY:** The outcome assessor correctly guessed the participant's assigned advocacy type in 52% of cases (binomial 95% CI = 42%-61%, Clopper and Pearson Exact), which was not significantly different from chance ($P = .855$). The outcome assessor correctly guessed the assigned spectacle lens type in 67% of cases (binomial 95% CI = 57%-75%, Clopper and Pearson Exact), which exceeds chance ($P = .003$).

TABLE 2. Median Change, Between Pre- and Post-Task, in Each Treatment Group, for Each of the Subjective Symptom Score Items.

Questionnaire Items (/100 on a Visual Analog Scale)	Positive Advocacy + Blue-blocking Lenses (N = 30) Median (IQR)	Positive Advocacy + Control Lenses (N = 30) Median (IQR)	Negative Advocacy + Blue-blocking Lenses (N = 30) Median (IQR)	Negative Advocacy + Control Lenses (N = 30) Median (IQR)	P Value
Eye pain	2 (0, 20)	6 (0, 28)	0 (0, 18)	2 (0, 21)	.917
Eye strain	12 (1, 21)	17 (0, 37)	19 (6, 37)	16 (1, 34)	.890
Blurred vision	4 (0, 21)	2 (0, 6)	6 (-1, 22)	2 (0, 16)	.696
Irritation	3 (0, 25)	0 (-1, 15)	0 (0, 17)	0 (0, 22)	.617
Double vision	1 (0, 4)	0 (0, 2)	0 (0, 6)	0 (0, 4)	.299
Burning sensation	1 (0, 9)	4 (0, 12)	4 (0, 13)	1 (0, 23)	.703
Dry eye	5 (1, 16)	10 (-1, 37)	12 (0, 35)	14 (0, 29)	.473
Tearing	0 (0, 16)	0 (-6, 1)	1 (-1, 3)	1 (0, 7)	.075
Headache	0 (0, 25)	4 (0, 16)	1 (0, 20)	1 (0, 10)	.879

IQR = interquartile range.

DISCUSSION

In this double-masked RCT, blue-blocking spectacle lenses were found not to alleviate symptoms or signs of eye strain associated with computer use, compared to non-blue-blocking (clear) lenses. Clinical advocacy (positive/negative) for the participants' assigned intervention did not affect the primary or secondary efficacy outcomes (except for the mean saccadic eye movement duration) or safety outcomes. Participants in the positive advocacy group took longer to complete a saccade compared to those in the negative advocacy group. Although this intercondition comparison was statistically significant, its clinical relevance is unclear, particularly given that the magnitude of the effect is small (<4 ms) and it is not apparent how increased saccadic duration could improve or worsen CVS. There is also no plausible mechanism for clinician advocacy causing this outcome. Furthermore, that saccadic amplitudes and velocities did not change would also suggest durations should not change, given that amplitude, velocity, and duration are not independent. As such, there are no obvious mechanisms for an isolated change in the saccade duration parameter when all other associated eye movement findings were nonsignificant.

Of the few studies that have investigated blue-blocking lenses for CVS,^{10, 19, 20} only 1 is an RCT (by Lin and colleagues¹⁰). Lin and colleagues¹⁰ reported that blue-blocking lenses with optical properties similar to most commercially available products did not reduce eye strain symptoms with computer use, compared to standard (clear) lenses. However, this study has limitations. The protocol for this study was not published or registered, and the study involved participants recruited from an optometry college (who may have had professional knowledge about blue-blocking lenses, and could potentially have been able to recognize blue-blocking lenses by sight). The success of the study's masking methods was also not formally assessed.

A further consideration is that this study did not specifically recruit symptomatic computer users, despite this being a population to which blue-blocking lenses are marketed. The current study sought to address each of these methodological limitations. Findings from our study, which minimized risks of bias, are in alignment with the outcomes of Lin and colleagues.¹⁰ Lin and colleagues¹⁰ did report an improvement in eye strain with an obviously brown-colored type of blue-blocking lens, however. It is difficult to conclude whether this symptomatic improvement was specifically related to the blue-blocking lens property, as these lenses reduced light transmission by 20%-40% over half of the visible spectrum. The obvious brown tint of the lens also presumably creates a greater risk of placebo effects. Of note is that computer users show a low preference for brown-tinted lenses, compared with blue-blocking lenses of the sort we investigated.⁷

How blue light emitted from electronic devices might cause eye strain is unclear. Consequently, the mechanism of action for how blue-blocking lenses could alleviate digital eye strain is also unknown.¹¹ The amount of blue light emitted from electronic devices ranges from 0.034 to 0.380 $\text{W m}^{-2} \text{sr}^{-1}$, well within safety standards defined by the International Commission on Non-ionising Radiation Protection for causing ocular damage ($100 \text{ W m}^{-2} \text{sr}^{-1}$ for long-term viewing).²¹ Blue light emitted from electronic device screens is about 1,000-fold less than from natural daylight.²¹ Despite these objective data strongly indicating that the amount of blue light emitted from electronic devices does not pose an ocular hazard, ophthalmic lenses are being routinely prescribed for this purpose.^{8, 9} Furthermore, software (eg, night shift mode),⁸ blue light addition filters to computer screens,⁸ and vitamin supplements²² are being advertised with an intent of "protecting" the eyes from computer-related blue light emissions.

The amount of blue light filtered by the lenses used in the current study was the highest among a representative sample of commercially available blue-blocking lenses.⁷

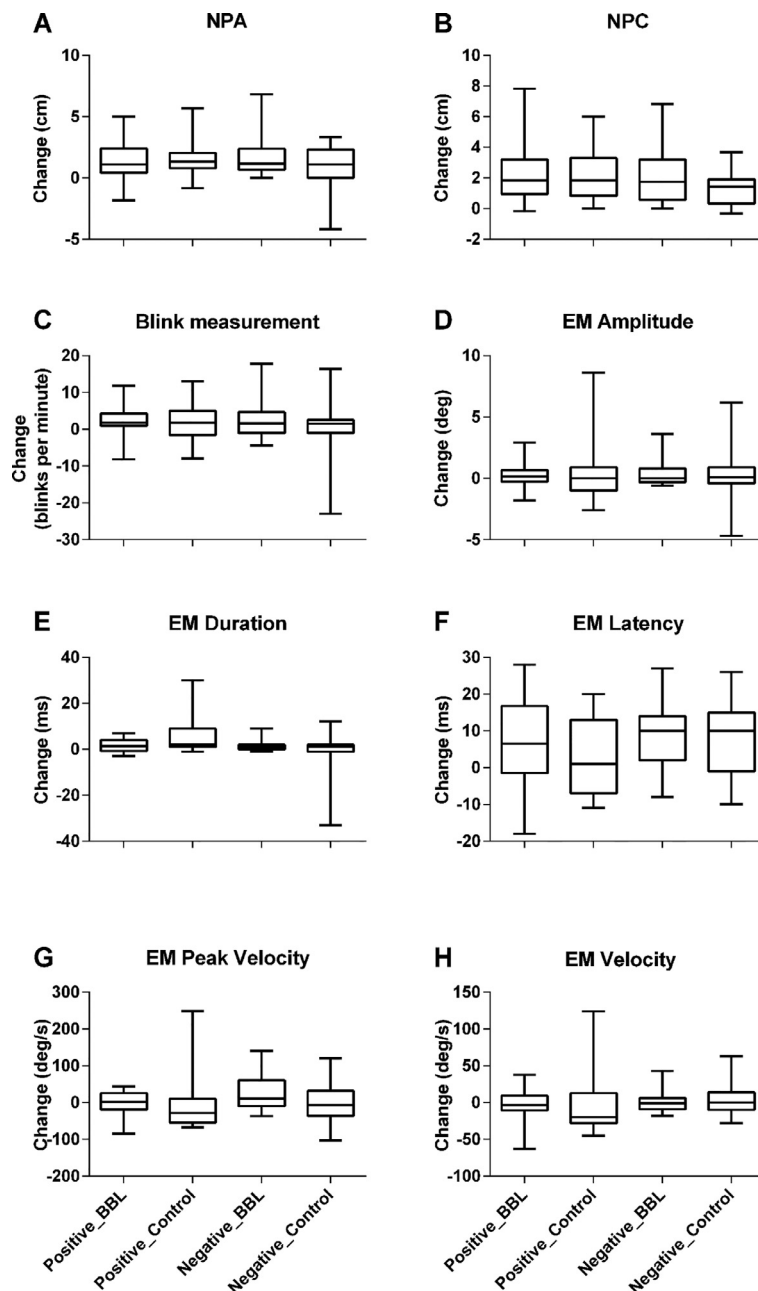


FIGURE 3. Box-and-whisker plots of the change, from pre-task, at the post-task time point (ie, after completion of the 2-hour computer task), in each group, for the secondary outcome measures (A-H). The box-and-whisker plots denote the minimum, the 25th percentile, the median, the 75th percentile, and the maximum. EM = eye movements; NPA = near point of accommodation; NPC = near point of convergence.

Because of this, we consider it unlikely that other commercially available lenses would yield a beneficial effect on reducing eye strain with computer use as a result of their blue light-filtering properties. The results of our study, combined with the low blue light emission from electronic devices and the lack of a plausible causative mechanism, mean that it is extremely unlikely that blue light is a contributory factor to eye strain associated with computer use. As such,

other factors likely cause CVS. Potential causative factors include underlying uncorrected refractive error, binocular vision anomalies, greater screen time (more than 4 hours per day), reduced blink rate, reflections and glare on the computer screen from surrounding lighting, and poor ergonomics.³ Given that the etiology of CVS may be multifactorial, a comprehensive eye examination and review of

computer workstation ergonomics is thus advisable in cases of CVS.

A potential query about our study is whether the 2-hour computer task was sufficient to induce eye strain. A comparison of the eye strain symptom scores pre- and post-task confirmed a significant increase in eye strain symptoms across all groups (Supplemental Table 2; Supplemental Material available at AJO.com). Although we took measures to mask the outcome assessor to which intervention group the participants were allocated to, the outcome assessor correctly guessed the participant's spectacle type allocation 67% of the time. This percentage differed significantly from the expected 50% ($P = .003$), indicating that our masking efforts were insufficient for this level of sub-randomization.

Our 2 primary outcome measurements were CFF and a participant-completed, written questionnaire—both of which involve no subjective assessment by the outcome assessor. As such, we would not expect these parameters to be influenced by assessor bias. Indeed, we found no significant difference between our primary or secondary outcome measures that requires explaining through appeal to such a bias. Overall, it is unlikely the incomplete masking of spectacle type had any substantial influence on our results.

In conclusion, the study provides evidence that blue-blocking spectacle lenses do not reduce computer-induced eye strain, irrespective of whether or not they are advocated by a clinician. This finding agrees with the lack of a plausible physiological mechanism through which the relatively low amounts of blue light emitted from computer screens could induce eye strain.

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