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### ORIGINAL ARTICLE

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# Randomised controlled trial of an accommodative support lens designed for computer users

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### Abstract

**Purpose:** Accommodative support (AS) lenses are a low add progressive addition spectacle lens designed to ease symptoms in computer vision syndrome (CVS). The study aims to investigate if (1) AS lenses improve CVS symptoms; (2) binocular/accommodative functions predict a benefit from AS lenses and (3) wearing AS lenses for six months impacts on binocular/accommodative functions.

**Methods:** Pre-presbyopic adults with symptoms of CVS (Computer Vision Syndrome Questionnaire,  $\text{CVS-Q}^{\circ}$ , score  $\geq 6$ ) were randomly allocated to wear AS lenses or control single vision (SV) lenses. The  $\text{CVS-Q}^{\circ}$  and a battery of optometric tests were applied at baseline and after three and six months. Participants and researchers were masked to participant group. After six months, the SV group were unmasked and changed to AS lenses and one week later asked to choose which they preferred.

**Results:** The change in CVS-Q<sup>©</sup> scores from baseline to six months did not differ significantly in the two groups. At the end of the one week period, when the control group wore the AS lenses, control group participants were significantly more likely to prefer AS lenses to SV lenses. No optometric functions correlated with the benefit from AS lenses. AS lenses did not have any adverse effects on binocular or accommodative function.

**Conclusions:** In pre-presbyopic adults, there was no greater improvement in CVS-Q<sup>©</sup> scores in the group wearing AS lenses than in the control group. No adverse effects on optometric function (including accommodation) are associated with wearing AS lenses.

#### **KEYWORDS**

accommodative support lenses, asthenopia, computer terminals, computer vision syndrome, digital eye strain, eyeglasses

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## INTRODUCTION

Computer vision syndrome (CVS) describes ocular and visual symptoms in users of visual display units. Up to 40% of adults and 80% of teenagers report significant symptoms when using electronic displays.<sup>1</sup> There has been a plethora of research on CVS, summarised in review papers.<sup>1–5</sup>

Computer vision syndrome symptoms include eyestrain, ocular discomfort, tired eyes, headaches, blurred vision, double vision and dry eyes.<sup>2–6</sup> These symptoms have been classified as external, associated with the ocular surface (burning, tearing, dryness, irritation) or internal, related to refractive, accommodative or binocular vision anomalies.<sup>7,8</sup> Low levels of uncorrected astigmatism (0.50–1.00 DC) can produce CVS symptoms.<sup>9,10</sup> The accommodative response only differs slightly when viewing certain electronic screens compared with hard copy tasks,<sup>11</sup> but accommodative problems can cause asthenopia,<sup>12</sup> and visual fatigue may be related to low-frequency micro-fluctuations of accommodation.<sup>6</sup> Vergence problems also can cause asthenopia<sup>12</sup> and have been implicated in CVS,<sup>6</sup> but probably only in a minority of cases.<sup>13</sup>

Other possible causes of CVS include changes in pupil size with computer tasks, possibly with spasm of the sphincter pupillae.<sup>14</sup> Blue light exposure from electronic screens has also been implicated,<sup>15</sup> although not supported by a recent randomised controlled trial.<sup>16</sup> For susceptible individuals the pattern caused by lines of text, and flicker from some monitors, can cause a sensory form of visual stress that may be alleviated by coloured filters or modifying the spectral output of the display,<sup>17-20</sup> although this is controversial.<sup>21</sup>

Many studies have employed questionnaires to assess CVS.<sup>22–25</sup> The Computer Vision Syndrome Questionnaire (CVS-Q<sup>®</sup>), is a validated questionnaire for diagnosing and assessing the severity of CVS in the workplace.<sup>26,27</sup>

Managing CVS may involve treating either a single cause or a combination of causes.<sup>12</sup> In recent years, new spectacle lens designs with a progressive power profile have been introduced for pre-presbyopes with CVS. These 'accommodative support' (AS) designs typically have 'adds' ranging from +0.50 to +1.25 DS, aiming to reduce accommodative demand during prolonged viewing of electronic displays, sometimes held closer than conventional reading materials.<sup>28</sup>

In previous research on low plus lenses, no clear consensus on efficacy has emerged,<sup>29–33</sup> fuelled by a scarcity of double-masked randomised controlled trials.<sup>34</sup> A recent study included a short-term double-masked randomised controlled trial of low power convex lenses (+0.50, +0.75, +1.25) for patients with CVS.<sup>35</sup> Most participants reported a subjective preference for low adds, with a +0.75 D add being optimal.<sup>35</sup> An exploration of potential mechanisms revealed no strong optometric correlates of the benefit from low plus, but in a few participants this was associated with decompensated esophoria,<sup>13</sup> that would be alleviated by adds.<sup>12</sup> A limitation of this work is that it only evaluated the short-term effects of low plus. Another research

### **Key points**

- For 90 pre-presbyopes with computer vision syndrome, symptoms (CVS-Q<sup>©</sup>) improved over six months following an updated refractive correction.
- The improvement in symptoms was not significantly different in groups wearing accommodative support lenses and single vision lenses.
- Accommodative support lenses did not have any adverse effects on binocular or accommodative functions.

question is whether the underaccommodation that these interventions elicit might have an adverse impact on accommodative function. This is important because AS lenses may be worn for many hours per day and this issue is considered further in the Discussion.

The study aims to investigate if AS lenses improve CVS symptoms; if binocular vision and accommodative functions predict a benefit from AS lenses and lastly if wearing AS lenses for six months impacts on binocular and accommodative functions.

### **METHODS**

### Design

The study is a prospective six month double-masked randomised controlled trial (*Figure 1*) carried out in two centres: University of Alicante in Spain and the Institute of Optometry, London, following a joint protocol.

The research adhered to the tenets of the Declaration of Helsinki and received ethical approval from the University of Alicante and the Institute of Optometry. The trial was registered at ClinicalTrials.gov (NCT03831919). The study followed an 'intention to treat'<sup>36</sup> principle: all participants were analysed in the groups to which they were originally assigned.

### Interventions

The experimental accommodative support (AS) intervention were Seiko AS lenses (seikovision.com). The control lenses were standard Seiko single vision (SV) lenses.

The AS lenses had a 'boost' power, of +0.75. These were selected because a recent study comparing +0.50, +0.75 and +1.25 single vision 'adds' found +0.75 to be the most commonly preferred option.<sup>35</sup> The control lenses were standard single vision aspheric lenses. Experimental and control lenses were made from plastic material of 1.6 refractive index (1.67 for participants with a prescription



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**FIGURE 1** Flow diagram of study design

<-4.00 D) and standard anti-reflection coating. Neither had blue-blocking coatings.

### Participants

In addition to the main selection criteria (*Table 1*), in Alicante, the following cases were also excluded: 10 participants with near exophoria outside the normal range (> $6\Delta$ ) and with a high gradient AC/A ratio; 2 participants with binocular accommodative facility of 0 cpm.

### Procedure

Potential participants were sought from workplaces and advertisements and contacted to see if they were likely to meet the selection criteria (*Table 1*). Following informed consent, participants were seen for a baseline assessment, at which the  $\text{CVS-Q}^{\circ}$  responses were collated. *Table 2* details the clinical tests assessed by optometrists at the baseline and follow-up appointments.

At the end of the baseline assessment, the participant ID, new spectacle prescription (Rx given), frame choice and

fitting parameters were sent to a researcher who did not see any participants (BE). BE used a table of random allocation codes to determine group membership. The spectacles were manufactured with no markings on the lenses and the research centres took care not to examine the lenses to see if

#### TABLE 1 Participant selection criteria

Inclusion criteria
Aged between 18 and 40 years In a typical working day, spends at least 2 h viewing computer displays (e.g., desktop, laptop, tablet, smart phone) Symptoms associated with the use of computer displays, quantified as a score of six points or more on the CVS-Q <sup>©</sup> questionnaire instrument <sup>26</sup> Use of spectacles for at least 6 months before the beginning of the study Refractive error between +6.00 to -8.00 sph with cylinder up to 4.00DC
Exclusion criteria
Previous use of AS lenses Ocular pathology requiring referral to an ophthalmologist Wears contact lenses when using computers

Strabismus

Abbreviation: AS, accomodative support.

### TABLE 2 Clinical tests at baseline, and at 3 and 6 months

they were AS or SV. Participants were instructed to wear the spectacles for all work with electronic displays. They were reminded of this approximately monthly.

At the three and six months follow up appointments, the tests in *Table 2* were repeated (except for ophthalmoscopy and biomicroscopy). For all tests except ocular motility, the participant wore the same refractive correction as at the baseline assessment. When participants completed the  $CVS-Q^{\circ}$ , they were asked to do so considering any symptoms experienced with the research spectacles.

At the end of the six months appointment, the researcher inspected the lenses to see if they were AS or SV. Participants who had been wearing SV lenses were subsequently sent AS lenses (in identical frames but with a white mark on one side). The participant kept the pair with SV lenses, to compare both pairs in an unmasked comparison. After one week, the researcher telephoned the participant and asked, if they could keep only one pair, which it would be. Note, this is not a formal crossover trial: the SV group received AS spectacles for just one week. It was considered that a six months period with each intervention would have made a full crossover trial prohibitively lengthy.

Parameter	Test	Cut-off for defining abnormal
CVS	CVS-Q <sup>©</sup> (validated questionnaire) <sup>26</sup>	Score ≥ 6
Ocular pathology (only at baseline)	Direct or indirect ophthalmoscopy (dilation if required) and biomicroscopy	
Refractive error	Current spectacles, non-cycloplegic retinoscopy, subjective, Rx given	
Visual acuity (VA) <sup>a</sup>	ETDRS LogMAR chart; R, L, B	
Ocular motility	Pen torch in cardinal positions of gaze	
Ocular alignment (D and N) <sup>a</sup>	Cover test	D: ≥2∆ esophoria; ≥4∆ exophoria N: ≥1∆ esophoria; ≥6∆ exophoria (Morgan's norms from Scheiman and Wick, Table 2.2) <sup>37</sup>
Heterophoria (D and N) <sup>a</sup>	Dissociation test <sup>12</sup>	
Gradient stimulus AC/A ratio <sup>a</sup>	With dissociation test, -1.00 and +1.00 lenses	<2 $\Delta$ /D or >6 $\Delta$ /D (Morgan's norms from Scheiman and Wick, Table 2.2) <sup>37</sup>
Near point of convergence <sup>a</sup>	RAF rule push-up	≥6 cm (the cut-off used in convergence insufficiency exophoria syndrome) <sup>38</sup>
Near fusional reserves $(\Delta)^a$	Prism bar; blur/break/recovery (values at the test ceiling, >45, were scored as 50)	Divergent: ≤8/≤16/≤7 Convergent: ≤11/≤14/≤3 (Morgan's norms) <sup>39</sup>
Near stereopsis <sup>a</sup>	EyeGenius <sup>®</sup> test (random dot stereotest)	>50 s of arc (norms for the EyeGenius <sup>®</sup> test not available, so used norms for a similar test) <sup>40</sup>
Amplitude of accommodation <sup>a</sup>	RAF rule push-up, R, L, B	$\leq$ 15–(0.25 × age) D (Hofstetter norms) <sup>41</sup>
Lag of accommodation <sup>a</sup>	MEM retinoscopy (R, L)	≤0 D or ≥1 D (Tassinari <i>et al.</i> <sup>42</sup> )
Binocular accommodative facility <sup>a</sup>	±2.00 flippers, whilst viewing near target	$\leq$ 3 cpm (Zellers <i>et al</i> . <sup>43</sup> )
Vergence facility <sup>a</sup>	At 40 cm, 3 $\Delta$ base in/12 $\Delta$ base out (in Alicante from 3 months check)	

Note: Key: R, right eye, L, left eye, B. both eyes. D, distance; N, near (40 cm); FD, fixation disparity; RAF, Royal Air Force rule.

<sup>a</sup>Test undertaken with the participant wearing the 'Rx given', the distance optical prescription prescribed for use in the research, worn in an optometric trial frame.

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### Statistical analysis

Data were analysed using Microsoft Excel (version 2102, micro soft.com) and IBM SPSS (version 26, ibm.com). Normality was tested and parametric and non-parametric statistics used as appropriate. In addition to treating the optometric variables as continuous variables, the cut-off criteria in *Table 2* were used to dichotomise key variables as normal/abnormal.

To address the research questions, two variables were calculated, the CVS-Q<sup>©</sup> change to three months (CVS-Q<sup>©</sup> score at baseline – CVS-Q<sup>©</sup> score at three months) and the equivalent for CVS-Q<sup>©</sup> improvement from baseline to six months. Positive values indicate an improvement in CVS symptoms.

### RESULTS

### General descriptive data and group matching

There were no serious adverse events. There were two dropouts, both in London, who failed to respond to communications before the three months visit.

Ninety participants completed the study, 60 seen in Alicante and 30 in London. The mean age was 28.4 years (Cl 27.0–29.7; range 16–40), and 60% were female. The mean electronic screen use per day was 9.5 h (Cl 8.9–10.1; range 3–17). In accordance with the selection criteria, all participants were symptomatic with a CVS-Q<sup>©</sup> score of at least 6. Owing to the randomisation process and attrition, the number of participants completing the study was 42 in the AS group and 48 in the SV group.

The baseline CVS-Q<sup>©</sup> score (before randomisation; *Figure 2*) is not normally distributed (Shapiro-Wilk test, p < 0.001). Similarly, the CVS-Q<sup>©</sup> score at three months is not normally distributed in the AS (p = 0.02) and SV (p < 0.001) groups; and also at six months in the AS (p = 0.003) and SV (p = 0.001) groups. This may be explained to some extent by the selection criterion of CVS-Q<sup>©</sup>  $\ge$  6 curtailing the left hand side of the distribution (*Figure 2*).

The variable quantifying the improvement of  $\text{CVS-Q}^{\odot}$  score from baseline to three months was not normally distributed in the AS group (Shapiro-Wilk test; p = 0.001), but was normally distributed in the SV group (p = 0.31); and from baseline to six months was normally distributed in both the AS (p = 0.12) and SV group (p = 0.11).

There were no statistically significant differences between the groups in the following variables: gender; age; hours of computer use per day; baseline CVS-Q<sup>©</sup> score or any of the variables in *Table 2* (chi-square test, unpaired t-test and Mann-Whitney U test, as appropriate, p > 0.22). Using the cut-off criteria in *Table 2*, the proportion of abnormal cases did not differ significantly in the two groups (chi-square test, p > 0.14).

# Research question 1. Do accomodative support (AS) lenses reduce symptoms of computer vision syndrome (CVS)?

*Table 3* compares CVS-Q<sup>©</sup> improvement to three months and six months in both groups. For both timescales and in both groups, the central measure (mean/median) showed



**FIGURE 2** Distribution of the CVS-Q<sup>©</sup> score at baseline and standardised normal distribution (black curve)

**TABLE 3** CVS-Q<sup>©</sup> improvement from baseline in the two groups



$\text{CVS-Q}^{\otimes}$ improvement	Group	Mean/median	95% CI	Range	p-value
Baseline to 3 months	AS	3.0 (median)	2.0-4.0	-8 to 21	p = 0.03 Mann-Whitney
	SV	5.0 (median)	4.0-7.0	-11 to 14	
Baseline to 6 months	AS	3.0 (mean)	1.5–4.6	-8 to 21	<i>p</i> = 0.17 unpaired <i>t</i> -test
	SV	4.5 (mean)	3.0-6.0	–11 to 14	

Note: 95% CI, 95% confidence interval of the mean or median, as appropriate following tests of normality applied to each dataset.



**FIGURE 3** Boxplot of  $\text{CVS-Q}^{\odot}$  improvement to three months. Positive values represent improvement (reduction) in  $\text{CVS-Q}^{\odot}$  symptoms. The box represents the upper and lower quartiles (interquartile range; IQR). The median is the horizontal line inside the box. The two lines outside the box extend to the highest and lowest observations, excluding outliers (circles, 1.5 x IQR) and extremes (stars, 3 × IQR). The numbers on the plots represent case numbers, for comparison with later graphs

an improvement over time (positive value). At three months the improvement was slightly but significantly (p = 0.03) greater in the SV than in the AS group and at six months the improvement did not differ significantly in the two groups. The finding at three months is explored graphically in *Figure 3*.

An additional analysis investigated the hypothesis that, if there is a subgroup of participants who show a marked benefit from AS lenses, the improvement should become greater over time; the 'sustained benefit hypothesis'. The participants who showed an improvement in CVS-Q<sup>©</sup> from baseline to three months and a further improvement from three months to six months were selected to form two new sub-groups, the sustained improvement subgroups. A non-significantly higher proportion (43%) of the AS group than the SV group (33%) showed a sustained improvement, (chi-square, p = 0.35).

# Do participants with severe computer vision syndrome (CVS) benefit most from accommodative support (AS) lenses?

The correlations between the baseline CVS-Q<sup>®</sup> scores and the improvement in CVS-Q<sup>®</sup> score from baseline to six months were investigated to discover whether participants with the most severe CVS are those whose CVS-Q<sup>®</sup> scores improve most. In the control group, there is a modest correlation (Kendall tau,  $\tau = 0.484$ , p < 0.001) and a slightly higher correlation ( $\tau = 0.509$ , p < 0.001) in the experimental group. This was investigated further, by repeating the main analysis (comparison of the groups' improvement in CVS-Q<sup>®</sup> score) after removing participants with mild CVS (baseline CVS-Q<sup>®</sup> score below 10). The sub-group sizes were 27 in the AS group and 37 in the SV group. The CVS-Q<sup>®</sup> improvement variables were normally distributed in all THE COLLEGE OF

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the sub-groups except the AS group improvement to three months. There was no significant difference between the sub-groups in the improvement from baseline to three months (Mann-Whitney U test, p = 0.41) or from baseline to six months (unpaired *t*-test, p = 0.77).

The sustained benefit hypothesis was also tested in the the sub-groups with a CVS-Q<sup>©</sup> baseline score of 10 or worse. Members of the AS sub-group were almost twice as likely (59%) to demonstrate a sustained benefit as members of the SV sub-group (32%). The difference in proportions in the two sub-groups was statistically significant (chi-square, p = 0.03).

### Dichotomising variables as normal/abnormal

A binomial regression analysis considered the presence or absence of CVS at three and six months as the dependent variable, and AS/SV group as the independent variable. There was no significant difference in the presence of CVS at three months or at six months (p > 0.15).

### Research question 2. Do binocular vision or accommodative functions predict whether participants benefit from accommodative support (AS) lenses?

As found in previous research,<sup>13,44–47</sup> many of the optometric variables are not normally distributed (AS group; Shapiro-Wilk test, p < 0.05), including near visual acuity, distance and near heterophoria, astigmatic component of refractive error, accommodative lag, AC/A ratio, near point of convergence and stereopsis.

In the AS group, Kendall correlations ( $\tau$ ) were calculated between the improvement in CVS-Q<sup>©</sup> scores to three and to six months and each variable in *Table 2*. Corroboration of significant correlations was sought by considering correlations of related variables, in a form of triangulation (see Discussion).

The improvement in CVS-Q<sup>©</sup> scores to six months was significantly correlated with convergent fusional reserves to break point ( $\tau = 0.250$ , p = 0.03), convergent fusional reserve recovery point ( $\tau = 0.295$ , p = 0.009; *Figure 4*), and near point of convergence ( $\tau = -0.236$ , p = 0.04). The near point of convergence was recorded in centimetres, so a negative value indicates, like the fusional reserves, that participants with the best convergence showed the greatest improvement in CVS-Q<sup>©</sup> scores after wearing AS lenses. The improvement in CVS-Q<sup>©</sup> scores to three months showed a non-significant correlation with the convergent fusional reserve to break point ( $\tau = 0.173$ , p = 0.13), a significant correlation with the near point of convergence ( $\tau = -0.200$ , p = 0.09).

## Accommodative support (AS) sub-group with most severe computer vision syndrome (CVS)

Participants with mild CVS (CVS- $Q^{\circ}$  < 10) were excluded, leaving participants with moderate or severe CVS. The



**FIGURE 4** Correlation between convergent fusional reserve recovery point and the improvement in CVS-Q<sup>©</sup> score from baseline to six months in the accommodative support (AS) group. Overlapping points are shown as larger dots (see scale)

improvement in CVS-Q<sup>©</sup> to six months showed a significant correlation with the convergent fusional reserve to break point ( $\tau = 0.286$ , p = 0.05), convergent fusional reserve recovery point ( $\tau = 0.421$ , p = 0.003) and near point of convergence ( $\tau = -0.450$ , p = 0.003). These results mirror those for the whole AS group, but the AS sub-group with most severe CVS show higher correlations.

### Vergence facility and fixation disparity

Data on vergence facility were only available in Alicante and from the three months appointment. There was a significant correlation between the improvement in CVS-Q<sup>©</sup> from baseline to six months and the vergence facility data at the three months follow-up ( $\tau = 0.362$ , p = 0.001). Better performance on vergence facility was associated with a greater improvement in CVS-Q<sup>©</sup> scores.

Data on the Mallett aligning prism (associated heterophoria; the minimum prism to eliminate a fixation disparity on the Hoya EyeGenius<sup>®</sup> version of Mallett unit)<sup>12,48</sup> were only available from London. At baseline only one participant had a distance vision fixation disparity (aligning prism  $0.5\Delta$  base out). Three participants had a near vision fixation disparity, with total aligning prisms of  $3\Delta$  base out,  $2\Delta$  base out and  $1\Delta$  base in. The higher prevalence of eso-fixation disparity than exo-fixation disparity in CVS, is in contrast to the normal findings of higher prevalence of exo-fixation disparity and replicates a statistically significant finding in previous research with a larger sample.<sup>13</sup> By chance, all three participants were randomised to the control group and these data are not analysed further.

### Dichotomising variables as normal/abnormal

For each of the accommodative and binocular variables with cut-offs in *Table 2*, a binomial regression analysis investigated whether participants with abnormal vs normal results at baseline had a lower prevalence of CVS at six months, and whether the AS and SV group differed in this regard. For all the optometric tests, the CVS prevalence ratio difference between the groups at six months did not reach significance (p > 0.12).

### Research question 3. Is accommodative support (AS) lens wear for six months associated with changes in binocular and accommodative functions?

Using the Wilcoxon signed ranks test with the variables in *Table 2* in the AS group, the following variables were significantly different at six months compared with baseline: near vision horizontal heterophoria (p = 0.01), gradient AC/A ratio with -1.00 D lenses (p = 0.007), amplitude of accommodation right eye (p < 0.001), amplitude of accommodation left eye (p < 0.001), accommodative facility (p < 0.001) and stereopsis (p = 0.02). The Wilcoxon test is highly sensitive to small changes (see Discussion), and therefore the clinical significance of these findings is explored using boxplots (*Figure 5*), which also show the three months data.

### One week period when control single vision (SV) group wore accommodative support (AS) lenses

At the end of the trial, the SV group were dispensed with AS lenses to compare for one week with the SV lenses. Of the 48 control group participants, 32 (66.7%) preferred AS lenses, 8 (16.7%) preferred SV lenses and 8 (16.7%) reported no difference. For those who expressed a preference, significantly more participants preferred AS than SV lenses (Sign test, p = 0.0002).

# The aetiology of computer vision syndrome (CVS)

Kendall correlations were investigated between the CVS- $Q^{\circ}$  result and each optometric variable at baseline in all 90 participants. Only one correlation reached significance, that between baseline CVS- $Q^{\circ}$  and convergent fusional reserves to recovery ( $\tau = 0.183$ , p = 0.02). This correlation is paradoxical: worse CVS symptoms are associated with better fusional reserves.

## DISCUSSION

The non-parametric distribution of the CVS-Q<sup>®</sup> results is likely, at least in part, to result from the selection criterion of a CVS-Q<sup>®</sup> score of 6 or more (floor effect) rather than a limitation of the test. For continuous variables, emphasis is placed on the analyses treating these data as continuous rather than using norms to dichotomize as normal/abnormal,<sup>49,50</sup> which discards variance and introduces an arbitrary cut-off. This approach is often used clinically<sup>43,51–53</sup> and therefore was adopted as a secondary approach. These analyses support the main findings.

# Research question 1. Do accommodative support (AS) lenses reduce the symptoms of computer vision syndrome (CVS)?

Both groups showed an improvement in  $\text{CVS-Q}^{\odot}$  score from baseline to three months and from baseline to six months, highlighting the importance of including a control group. This may result from updating the refractive correction at baseline, or from regression to the mean.<sup>54,55</sup> There



FIGURE 5 Boxplots for optometric variables that changed from baseline to six months in the accommodative support (AS) group. For key, see Figure 3

was little difference in the magnitude of improvement in symptoms (CVS-Q<sup>©</sup>) of the two groups, with the surprising finding of slightly more improvement at three months in the control group. The change in CVS-Q<sup>©</sup> score from baseline to six months did not differ significantly in the two groups.

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The separate finding that both groups showed a moderate correlation between the improvement in CVS-Q<sup>©</sup> to six months and the severity of CVS-Q<sup>©</sup> at baseline also could be explained by the benefit of an updated refractive correction, and/or by regression to the mean.<sup>55</sup> The correlation was only marginally higher in the AS group ( $\tau = 0.509$ ) than in the SV group ( $\tau = 0.484$ ).

Considering only participants with most severe CVS, the improvement in CVS-Q<sup>©</sup> from baseline to three months and to six months did not differ significantly in the AS subgroup and the SV sub-group. A further analysis found that

in the sub-groups with the most severe CVS, the AS subgroup was significantly more likely than the SV sub-group to demonstrate a sustained improvement in symptoms. One interpretation of this finding is that only participants with most severe CVS demonstrate a benefit from AS lenses. However, this further (tertiary) analysis was not investigating an a priori hypothesis and is therefore an exploratory finding that should be treated with caution.

In the main groups, the non-superiority of AS lenses could be explained by several factors. The most obvious explanation is that AS lenses do not alleviate the symptoms of CVS. A recent short-term study, a randomised control trial with the same CVS-Q<sup>©</sup> selection criterion as the present study, found a significant subjective preference for +0.75D single vision lenses.<sup>35</sup> However, in that study the subjective preference involved an immediate comparison viewing through different convex lenses,

which differs from the present study. Also, Yammouni and Evans used full aperture convex lenses, unlike the accommodative support lenses in the present research, which are more similar to a low add progressive addition lens. Yammouni and Evans found that +0.75 D was optimal of three single vision 'adds' (+0.50, +0.75, +1.25). It could be speculated that when an accommodative support progressive power lens format is used, a higher add may be more beneficial than the +0.75 found optimal for a single vision add.

In contrast to the main findings, at the end of six months when the SV group wore AS lenses for one week, significantly more participants expressed a preference for AS than for SV lenses. However, this phase only involved the AS group and placebo<sup>56</sup> or recency<sup>57</sup> effects could have confounded the result. The finding in other research<sup>35</sup> of an immediate benefit from a +0.75 D add in CVS in a double-masked randomised controlled trial warrants further investigation.

### Research question 2. Do binocular vision or accommodative functions predict whether participants benefit from accommodative support (AS) lenses?

Very few of the optometric variables correlated significantly with the improvement in CVS-Q<sup>©</sup> scores after wearing AS lenses for three and six months. With the large number of correlations, there is a risk of spurious correlations reaching significance by chance. A Bonferroni adjustment would reduce the risk of a type 1 error, but is considered over-conservative, increasing the risk of a type 2 error.<sup>58</sup> Instead, triangulation was used, seeking concordant evidence. Concordance was demonstrated because the optometric variables that most strongly correlated with improvement in CVS were convergent fusional reserves to break and recovery and near point of convergence.

For all significant correlations, participants with the lowest convergent fusional reserves (or more remote near point of convergence or slowest vergence facility) are least likely to benefit from AS lenses. This is plausible, since the fusional reserves were measured for near vision, when additional plus power from AS lenses will reduce accommodative convergence. This could place greater demands on convergent fusional reserves. However, *Figure 4* demonstrates that CVS-Q<sup>©</sup> scores only deteriorated (marginally) from baseline to six months in five AS participants, and these were not the participants with the lowest convergent fusional reserves. Therefore, it seems unlikely that low convergent fusional reserves should be considered a contra-indication for AS lenses. Nonetheless, in symptomatic computer users, fusional reserve exercises<sup>12</sup> may be indicated for those with very low fusional reserves, regardless of whether AS lenses are prescribed.

### Research question 3. Is the wearing of accommodative support (AS) lenses for six months associated with any changes in binocular and accommodative functions?

Multifocal spectacle lenses have long been advocated for pre-presbyopes suffering from problematic near vision eso-deviations.<sup>59</sup> The literature highlights concerns over the risk of such interventions adversely impacting accommodative function.<sup>60</sup>

The repeated-measures analysis (Wilcoxon signed ranks), by concentrating on within-subjects changes, is highly sensitive to detecting small differences. Although statistically significant findings emerged, it is not necessarily the case that these would be clinically significant. Therefore, these findings were investigated graphically (*Figure 5*), revealing no clinically significant differences over time in any of the statistically significant findings. Indeed, the two graphs showing a mild change in the median result (amplitude of accommodation and accommodative facility), demonstrated an improvement. In conclusion, the use of accommodative support lenses is not associated with deterioration of binocular and accommodative functions.

The additional analyses concerning the aetiology of CVS are exploratory in nature. As in previous research,<sup>13,35</sup> no single optometric deficits emerge as strong correlates of this multifactorial condition.

# The multifactorial nature of computer vision syndrome (CVS)

The finding of no significant effects of AS lenses on CVS-Q<sup>©</sup> scores and no strong optometric correlates of CVS may be related to the multifactorial nature of CVS. For some sufferers, the condition may result from uncorrected refractive errors (excluded in this work, by prescribing an updated refractive correction), dry eye or simple fatigue not related to any optometric deficits. For all these aetiologies, AS lenses would not be expected to help more than single vision lenses. Such cases would have 'diluted' any genuine benefit from AS lenses. In practice, clinicians may use a more targeted approach, and recommend AS lenses for those with a clinically significant near esophoria or accommodative dysfunction,<sup>12</sup> or those who report a subjective benefit from a near add in the consulting room. The present research does not detract from the face validity of these approaches. The efficacy of AS lenses for cases identified in this way is a topic for future research.

The present study concentrates on symptoms. Other research reveals individuals with CVS who report an immediate benefit from low addition lenses are likely to show improved rate of reading.<sup>35</sup> Therefore, it may be helpful to prescribe AS lenses in some cases even if an improvement in symptoms is not likely to occur.

## **Strengths and limitations**

Strengths of the study are a total sample size of 90 and the use of two sites, which makes the results more generalisable. The design allows a fairly long-term view, with six months follow-up. At all appointments, the binocular vision and accommodation tests were carried out with the refractive correction found at baseline, worn in an optometric trial frame. Therefore, repeat testing compares like-with-like.

The choice to update refractive corrections at the same time as the interventions were supplied is both a strength and a limitation. The changed refractive correction would have resulted in members of the control group perceiving a change, enhancing the placebo control. A disadvantage is that the change in  $\text{CVS-Q}^{\circ}$  score from baseline would have been confounded by the effect of an updated refractive correction.

The research used a product (Seiko AS) that has since been superseded by a newer free-form design of accommodative support lens. It is possible that other designs of accommodative support lenses and other boost powers would be more effective. The present work indicates that it should not be assumed that such products will reduce symptoms and further investigations with randomised controlled trials are therefore recommended.

### CONCLUSIONS

Over three months and six months, the improvement in  $CVS-Q^{\odot}$  is no greater in those wearing accommodative support (AS) lenses than in a control (SV) group. Immediately on changing from SV lenses to AS lenses, most of the control group reported a preference for AS lenses, although this phase of the study was not masked. No strong optometric correlates of CVS were detected, supporting its multifactorial nature. AS lenses do not have any adverse effects on accommodative or binocular function.

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### CONFLICT OF INTEREST

MdM Segui Crespo, None; E Ronda Perez, None, R Yammouni, None; BJW Evans, has provided consultancy to and received honoraria (lecturing) from Hoya. Ruben Arroyo is an employee of Hoya Lens Iberia.

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**Ma Del Mar Seguí-Crespo:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Funding acquisition (equal); Investigation (equal); Methodology (equal); Project administration (equal); Resources (equal); Validation (equal); Visualization (equal); Writing-original draft (equal); Writing-review & editing (equal). **Elena Ronda-Pérez:** Conceptualization (equal); Data curation (equal); Formal

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