# THE EFFICACY OF MULTIFOCAL SOFT CONTACT LENSES FOR THE ALLEVIATION OF ASTHENOPIC SYMPTOMS IN MYOPES WITH ACCOMMODATIVE LAG

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# THE EFFICACY OF MULTIFOCAL SOFT CONTACT LENSES FOR THE ALLEVIATION OF ASTHENOPIC SYMPTOMS IN MYOPES WITH ACCOMMODATIVE LAG

#### **Abstract**

*Purpose:* To evaluate the efficacy of multifocal soft contact lenses to reduce asthenopic symptoms in myopes with accommodative lag.

Methods: Twenty-four myopic participants, aged 18-35 years, with mean spherical equivalent (MSE) of  $\leq$  -0.75D, were recruited in a randomised, double-blind crossover study. All participants were existing contact lens wearer with near orthophoria or esophoria, presenting with subjective asthenopic symptoms at baseline [Convergence Insufficiency Symptom Survey (CISS) score  $\geq$  21] and a lag of accommodation  $\geq$  +0.75 D. All participants were initially fitted with single vision contact lenses for a one month period. Participants were then randomly assigned 1:1 to wear low add or high add multifocal soft contact lenses for a further month. After this period, the groups were reversed. Data were collected at baseline and following one month's wear of each lens. Change in CISS score was evaluated as the primary outcome measure, while secondary outcome measures were changes in accommodative lag and heterophoria status.

Results: Baseline CISS score was (mean  $\pm$  SD) 25.04  $\pm$  4.58. Post-intervention scores were as follows: single vision: 24.46  $\pm$  4.59, low add: 12.17  $\pm$  6.89, high add: 13.71  $\pm$  7.23. Both low add and high add multifocal soft contact lens wear was associated with an improvement in CISS score compared to baseline CISS and single vision (all p <0.01). No significant difference was found between the CISS score for the baseline CISS and single vision (p = 1.00). No significant difference was found in lag of accommodation between lens conditions (all p >0.05), however, there was an exophoric shift in near heterophoria between single vision and both multifocal contact lenses (low add: (mean difference 1.33  $\Delta$ , p = 0.02; high add: mean difference 1.23  $\Delta$ , p = 0.02) but not between habitual spectacle or any other modality (all p >0.05).

Conclusions: The use of multifocal soft contact lenses for a one-month period was associated with reduced severity of asthenopic symptoms in pre-presbyopic myopes with accommodative lag. Whilst improvement of symptoms does not appear to be mediated by a significant reduction in accommodative lag, changes in heterophoria may play a role in reducing asthenopic symptoms.

**Keywords**: Accommodative lag, asthenopia, esophoria, multifocal contact lens, myopia, near vision.

#### Introduction

Asthenopia is a common disorder [1-6] characterised by a sensation of visual fatigue, eye weakness, eyestrain or eye dryness [4]. It is frequently concomitant with activities in which high-demand, sustained near-viewing is required, such as reading, writing, and computer use, in which the accommodation and vergence processes are intense and protracted. Individuals with asthenopia suffer from the manifestation of non-specific, somatic or perceptive symptoms including: impaired reading capability [7], perceptual distortions [8], headaches, watery, red, burning or itching eyes, blurred vision, eye-ache, dry eye sensation, and diplopia [5, 6, 9-12]. The aetiology of asthenopia is known to be multifactorial [13]. Asthenopia can arise from or overlap with any form of eye discomfort including uncorrected refractive error, extraocular muscle imbalance, accommodative dysfunction unsuitable lighting and even with contact lens wear induce discomfort, such as dry eye and/or foreign body sensation. [10,13, 14].

An increasing reliance on computing and communication devices has been associated with a rising prevalence of asthenopia in recent years [15], further exacerbated by the close working distance at which some mobile devices are used [16]. Such close viewing distances may increase visual demands on both the ocular vergence and accommodation systems, further compounding visual fatigue. Accommodative lag has also been identified as a contributory factor to symptomatic ocular fatigue [17] with greater lags of accommodation associated with more profound symptoms of asthenopia [18, 19]. It seems reasonable to suggest that the reduced steady-state accommodative response and poorer blur sensitivity which have been reported in myopes may, therefore, escalate asthenopia in these individuals, as both are known to increase accommodative lag [20-23].

The ramifications of asthenopia in childhood are unclear, although evidence suggests that it may impair academic performance and attention [24]. In adults, asthenopia associated with digital eyestrain, which can be linked to dry eyes and other visual problems [15], has been shown to interfere significantly, though not permanently, with working productivity [2, 3, 25, 26]. Owing to the multifarity of asthenopia's contributory factors, numerous managements have been proposed [13]. More common managements often involve the treatment of associated visual conditions, ergonomic modifications [27, 28], eye exercises [29], the incorporation of more plus in the distance refractive correction, or the introduction of a near vision addition [30]. In recent years, advanced single vision spectacle lenses, which incorporate a small amount of plus in the inferior portion of the lens, have been marketed for the specific purpose of improving symptoms of visual fatigue in pre-presbyopes [31-33]. However, no detailed study was available regarding the use of near vision addition in soft contact lenses to reduce asthenopia at near distance for pre-presbyopic population.

Although multifocal soft contact lenses were originally designed to incorporate a near addition prescription in the contact lens to provide clearer vision for presbyopes, studies have suggested that multifocal soft contact lenses could also be used as a possible correcting option to reduce accommodation and binocular dysfunction of pre-presbyopes [34-39]. However, the ability of multifocal soft contact lenses as a successful treatment option for ocular asthenopia varies, and is not entirely understood [40,41]. Although limited evidence is available, multifocal soft contact lenses have been suggested as an option for pre-presbyopes with near vision disorders that require a near add [42,43].

This paper presents a double-blind crossover study, designed to assess whether commercially available multifocal soft contact lenses offer an effective treatment option for the reduction of subjectively reported symptoms of asthenopia in pre-presbyopic myopes presenting with a lag of accommodation. Due to the link between prolonged lag of accommodation and visual fatigue [18], we hypothesise that the introduction of additional plus during near-work as offered by these lenses may modify accommodative lag and collaterally improve asthenopic symptoms.

#### Methods

#### **Ethics**

Approval for the study was obtained from Aston University Research Ethics Committee. The research and its protocols adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all subjects following the explanation of the nature and potential consequences of participation.

## **Participants**

Participants were recruited and data collected at a Singapore-based private optometric practice. Twenty-four pre-presbyopic myopes (9 male, 15 female), aged 18 to 35 years [ 22.83 ± 5.78], with no previous history of ocular abnormality or intraocular surgery were enrolled on the study. The inclusion criteria were; mean spherical equivalent (MSE) ≤-0.75 D in each eye, orthophoria or esophoria at near, and a lag of accommodation >+0.75 D. Participants were only included if they also recorded a 'Convergence Insufficiency Symptom Survey' (CISS) score for the presence of asthenopic symptoms of ≥21 at baseline.

All participants were existing contact lens wearers and had best-corrected visual acuities of ≤0.00 logMAR at distance and near. Participants with astigmatism of greater than -1.00 DC in either eye were excluded from the study. Of the 24 participants, 23 were of East Asian, and 1 of South Asian ethnicity.

#### CISS Form

To determine whether an intervention is effective, a grading scale should be used to obtain the symptom score before and after any intervention is administered [45,47,48]. The CISS was incorporated in this study because it consists of questions with regards to near visual complaints that an optometrist commonly asks during an eye examination [49, 50,51], and has been validated and shown to have good validity and reliability. In addition, studies have used the CISS to assess subjective contact lens satisfaction and discomfort with toric and multifocal contact lenses [47,48]. Moreover, previous work has suggested that the CISS can be used to quantify symptoms experienced with other binocular vision disorder [45,47]. Similarly, this study was designed to determine whether the use of multifocal contact lenses modify accommodative lag or binocular vision and collaterally improve asthenopic symptoms, therefore, the CISS was chosen as a grading scale to determine whether there will be significant difference before and after wearing the multifocal soft contact lenses.

## Sample size calculation

A target sample size of 12 participants was chosen from computations for repeated measures ANOVA testing, assuming a large effect size (f) of 0.40. For an assumed alpha value (a) of 0.05 and power (1-b) of 0.80, the total sample size recommended was 12 (G\*Power 3.1.3 software, Franz Faul, Universität Kiel, Germany) [44]. However, the optimum chohort size was increased to 18 to increase the power to 0.95. Assuming a 25% dropout rate, 24 participants were enrolled.

### Study design

The study was designed in a double-blind crossover format. Participants attended for a total of four appointments at monthly intervals (see Figure. 1). All participants underwent the same procedures for the collection of baseline data at visit one (see Protocol: baseline for protocol and procedures), and all data were collected by the same qualified optometrist throughout the study. Immediately following baseline data collection, all participants' anterior eye health was assessed and subsequently fitted with single-vision, spherical, soft contact lenses [Alcon Air Optix® Aqua (lotrafilcon B, water content 33 %, base curve 8.6 mm, total diameter 14.2 mm) Alcon Laboratories, Fort Worth, US]. Participants were instructed to wear these contact lenses for one month, for a minimum of 8 hours per day, five days a week. Participants used their preferred lens care solution used for cleaning and storing the contact lenses.

All participants returned one month later (visit two) for the collection of single vision data. Following data collection, participants entered block one, where they were randomised into

one of two study arms, starting with either a low add multifocal contact lens (*low-add first* arm) or a high add multifocal lens (*high-add first* arm). A randomisation document was generated by a member of practice staff who was not involved in the study. Each participant was randomly allocated to an arm, and intervention lenses were dispensed in identical unmarked packaging. The optometrist and participants were blind to treatment assignment. Though participants were aware that some of the study lenses would be of a multifocal design, they were unaware of at which stage in the study these would be issued and the speculated symptomatic improvement that they were hypothesised to induce.

The low add and high add multifocal soft contact lenses were of the same simultaneous-vision, centre-near design [Air Optix® Aqua Multifocal Low Add and Air Optix Multifocal High Add (Lotrafilcon B, water content 33 %, base curve 8.6 mm, total diameter 14.2 mm) Alcon Laboratories, Fort Worth, US], differing only in the power of the near addition. Though three near additions are commercially available [low (up to +1.25 D), medium (+1.50 D to +2.00 D) and high (+2.25 D to +2.50 D)], only the low add and high add designs were used for the purpose of this study. Participants remained on the assigned treatment lens for one month and then returned for visit 3 and entered block two: participants originally assigned to low add started high add wear, while those originally assigned to high add were issued with low add. All participants were instructed to follow the same wearing schedule as the first allocated contact lenses, regardless of lens allocation. Assessments occurred at the beginning and end of both block one and block two (see Protocol: follow up visit for protocol and procedures).

---- Insert Figure 1 here ----

Protocol: baseline [visit 1 (pre-blocking)]

Following the collection of consent documentation, the following protocol was employed:

- Monocular distance visual acuities were measured aided and unaided at a distance of six metres, using a System Chart SC-1600 Pola/1600 (Nidek, Japan) computerised LogMAR test chart and the individual-letter scoring system.
- 2) Monocular near visual acuities were measured at a distance of 0.40 m, using a LogMAR near-vision chart and the individual-letter scoring system.
- 3) Distance objective refraction and keratometry were performed using the Zeiss iprofiler®plus (Carl Zeiss, Germany). The instrument determines the refractive error distribution across the entire pupil aperture using Hartmann-Shack wavefront technology.

- Measures of corneal curvature were also collected using the instrument's ATLAS corneal topography function.
- 4) Distance subjective refraction was performed for a distance of 6 m. The end point was determined as the trial lens combination which gave maximum plus to achieve maximum acuity. Humphriss binocular balancing was then performed.
- 5) Amplitude of accommodation was measured monocularly and binocularly with the pushup technique using a Royal Air Force (RAF) near-point rule with the participant viewing an N5 letter target. An average of three readings was taken.
- 6) Assessment of Accommodative Lag was made objectively using monocular estimate method (MEM) retinoscopy. The participant wore their manifest subjective refraction for distance and instructed to maintain a clear focus on an N5 optotype at 40 cm under normal room lighting (~400 lux) conditions. MEM retinoscopy was performed along the horizontal meridian, and the movement neutralised using spherical lenses, placed briefly in front of the trial frame. The power of the lens used to achieve reversal was recorded as the accommodative lag.
- 7) Assessment of heterophoria at distance was made using the Von Graefe method. A dissociating prism of 6 prism dioptres (Δ) base-up was introduced in front of the right eye, and a measuring prism (12 Δ base-in) was placed in front of the left eye. The participant was instructed to fixate on a Snellen 6/7.5 letter at a distance of six metres with full habitual distance correction and told to keep the letters clear at all times. The participant was instructed to fixate on the lower target and asked to inform the examiner when the upper target appeared just above the lower target. The magnitude of the horizontal prism was changed in one-dioptre steps until the images were reported to be one above the other. The horizontal prism required to achieve this was recorded as the distance heterophoria.
  8) Assessment of heterophoria at near was determined using the Maddox Wing instrument. Participants wore the manifest subjective refraction for distance and were asked to report the position of the arrow relative to the scale through the instrument. The value reported was taken as the near heterophoria in prism dioptres.
- 9) Assessment of symptoms of asthenopia The severity of asthenopia was assessed using the CISS questionnaire. This 15-item questionnaire performs two-factor analysis by determining the presence and frequency of occurrence of symptoms of convergence insufficiency. The answers to each question may be scored on a five choice response scale as follows: never (score 0), infrequently (1), some-times (2), fairly often (3) and always (4) [45]. A combined total CISS score of ≥21 denotes significant symptoms [46]. All participants were instructed to complete the baseline CISS in the context of their contact lens wear.

- 10) Ocular health assessment Slit lamp biomicroscopy was conducted to ensure the ocular surface was healthy. Tear film assessment was also undertaken. Fundus examination was conducted to ensure there was no ocular pathology.
- 11) Assessment for and fit with single vision contact lenses After fitting and assessment of the single vision contact lenses, distance and near VAs were measured and overrefraction conducted. Once final contact lenses prescription was determined, MEM retinoscopy was conducted in the same way as mentioned in point 6, but with participant wearing the contact lenses. Lenses were then issued to participants.

Protocol: follow-up visits 2 (pre-blocking), 3 (block 1) and 4 (block 2).

The following data were collected at the beginning of each follow-up assessment, resulting in three sets of data, each following one month of single vision, low add or high add contact lens wear. The procedures used for data collection were the same as those performed at baseline.

- 1) Distance and near visual acuities wearing study lenses.
- 2) Assessment of accommodative lag wearing study lenses.
- 3) Assessment of distance and near heterophoria.
- 4) CISS symptom score.

All participants exited the study following completion of data collection at visit four.

### Data analysis

Statistical analyses were performed using SPSS Statistics 23 for Windows (IBM, Armonk, NY). Statistically significant differences were defined as p < 0.05. Although several ocular parameters were monitored during the treatment period, reported data analyses are limited to those parameters most likely to offer insight into the causation and ramifications of asthenopia. The primary outcome measure was change in CISS score, while secondary outcome measures were changes in accommodative lag and heterophoria status.

The relationships between CISS score, accommodative lag and heterophoria status (distance and near) were all analysed across the four refractive correction conditions using one-way repeated measures ANOVAs. Where Mauchly analysis found the data to violate the assumption of sphericity, Epsilon ( $\epsilon$ ) was used via a Greenhouse-Geisser correction to transform the data. Post hoc analysis with Bonferroni adjustment was made where appropriate, to determine multiple comparisons between modalities. A higher value for CISS score indicates a higher severity of asthenopic symptoms, while positive values for heterophoria denote esophoria, and conversely, negative values indicate exophoria.

Shapiro-Wilk analysis was used to determine the normality of the data. CISS score was normally distributed for low add (p =0.26) and high add (p =0.76), but not baseline CISS or single vision (both p < 0.05). Lag of accommodation was normally distributed for single vision (p = 0.23) but not for any other modality (habitual spectacle, low add, hight add, all p = <0.05). Distance heterophoria was normally distributed for habitual spectacle (p = 0.09) and low add (p = 0.09) but not for single vision or high add (both p < 0.05). Near heterophoria demonstrated a non-normal distribution for all conditions (all p <0.005).

Though lag of accommodation measures were collected from both eyes, independent samples t-testing revealed no significant difference in accommodative lag between eyes for any correction modality (habitual spectacle: p = 0.29; single vision: p = 0.92; low add: p = 0.77; high add: p = 0.45). Resultantly, only right eye data is presented for lag analyses.

#### Results

A total of 24 existing contact lens wearers with CISS score  $\geq$  21 completed the study. Baseline manifest refractions ranged from mean spherical equivalent (MSE) -1.00 D to -7.88 D (mean MSE right eye (RE): -3.58 D  $\pm$  1.76; mean MSE left eye (LE): -3.56 D  $\pm$  1.54. Randomisation resulted in 12 participants assigned to each arm (Table 1)

---- Insert Table 1 here -----

## CISS score

Mean baseline CISS was  $25.04 \pm 4.58$  and  $24.46 \pm 4.59$  following single vision contact lens wear. Mean CISS score reduced to  $12.17 \pm 6.89$  and  $13.71 \pm 7.23$  following low add and high add contact lens wear, respectively (Figure 2). CISS score was significantly different between lens modalities (F(1.56, 35.91) = 44.68, p < 0.0005, partial  $\Box^2 = 0.66$ ). Post hoc analysis with Bonferroni adjustment revealed that there was no significant decrease in CISS score from baseline CISS to single vision ( $25.04 \pm 4.58$  vs  $24.46 \pm 4.59$ , p = 1.0). A significant decrease in CISS score was found following low add contact lens wear compared to both baseline CISS and single vision levels ( $12.17 \pm 6.89$  vs  $25.04 \pm 4.58$  vs  $24.46 \pm 4.59$ , respectively, p < 0.01). Similarly, a significant decrease in CISS score was found following high add contact lens wear compared to baseline CISS and single vision levels ( $13.71 \pm 7.23$  vs  $25.04 \pm 4.58$  vs  $24.46 \pm 4.59$ , respectively, p < 0.01). No significant difference in CISS score was observed between low add and high add measures [ $12.17 \pm 6.89$  vs  $13.71 \pm 7.23$ , p = 1.00].

## ---- Insert Figure 2 here ----

## Accommodative lag

By comparing the mean values of the lag of accommodation of RE for habitual spectacle, single vision, low add and high add (Figure 3), there was no statistically significant difference found, F (3,69) = 2.68, p = 0.05, partial  $\Box^2$  = 0.10. Although no statistically significant difference was found, slight changes to the lag of accommodation with the multifocal soft contact lenses were observed when compared to the single vison contact lenses. The lag of accommodation of RE was slightly lower after wearing the low add compared to single vision: 1.63 ± 0.50 vs 1.67 ± 0.36. A lower mean value of the lag of accommodation was also observed with the high add versus single vision: 1.43 ± 0.61 vs 1.67 ± 0.36, which brings the accommodative lag result very close to the mean value of the habitual spectacle condition (1.52 ± 0.48).

---- Insert Figure 3 here ----

#### Distance heterophoria status

Mean distance heterophoria for habitual spectacle was  $0.04 \Delta \pm 1.66$  and  $1.38 \Delta \pm 1.61$  following single vision contact lens wear. Mean distance heterophoria was  $0.90 \Delta \pm 1.50$  and  $1.17 \Delta \pm 1.54$  following low add and high add contact lens wear, respectively. A significant difference was found in distance heterophoria between correction modalities (F(3, 69) = 24.72, p < 0.01, partial  $\Box^2 = 0.24$ ). Post hoc analysis indicated differences between habitual spectacle versus single vison ( $0.04 \Delta \pm 1.66$  vs  $1.38 \Delta \pm 1.61$ , p = 0.01) and high add ( $0.04 \Delta \pm 1.66$  vs  $1.17 \Delta \pm 1.54$ , p = 0.02). When comparing the mean distance phoria change between habitual spectacle and low add, there was no significant difference between them ( $0.04 \Delta \pm 1.66$  vs  $0.9 \Delta \pm 1.50$ , p = 0.11). The overall result shows that the distance phoria was more esophoric when switching from habitual spectacle to all the other contact lenses used in the study, with single vision showing the highest shift in esophoric direction. Both low add and high add mean distance phoria were slightly less esophoric when comparing to the single vision, which means that the eyes were shifting slightly towards the exophoric direction. Ultimately, the heterophoric values of both low add and high add were still higher than habitual spectacle (Figure 4).

## ---- Insert Figure 4 here ----

## Near heterophoria status

Mean near heterophoria for habitual spectacle was 1.38  $\Delta$  ± 2.02 and 2.17  $\Delta$  ± 2.91 following single vison contact lens wear. Mean near heterophoria was 0.83  $\Delta$  ± 3.51 and 0.94  $\Delta$  ± 3.11 following low add and high add contact lens wear respectively. No significant difference was found in near heterophoria between correction modalities (one-way repeated measures ANOVA; F(1.90, 69) = 3.13, p = 0.06, partial  $\Box^2$  = 0.12). The finding shows a very similar trend to the distance phoria condition, where heterophoria shift in the esophoric direction was observed when changing from to single vision, with no significant difference between them (Figure 5). When comparing the mean near phoria of both low add and high add to single vision, *Post hoc* analysis using the Bonferroni correction shows significant differences detected between them [0.83  $\Delta$  ± 3.51 vs 0.94  $\Delta$  ± 3.11 vs 2.17  $\Delta$  ± 2.91, respectively, p = 0.02].

The results indicated a lesser shift in the esophoric direction for both low add and high add, which was similarly seen in the distance phoria result when comparing single vision to both multifocal contact lenses. However, a larger shift towards the exophoric direction was observed for the near phoria of low add and high add, resulting in the mean near phoria of both multifocal contact lenses having a lower mean result when comparing to the habitual spectacle  $[0.83 \ \Delta \pm 3.51 \ vs \ 0.94 \ \Delta \pm 3.11) \ vs \ 1.38 \ \Delta \pm 2.01)$ , respectively, p = 1.00].

---- Insert Figure 5 here ----

#### **Discussion**

The use of low plus lenses for near correction is a key and long-established treatment for individuals with near point stress [30]. As such, the present investigation explored the impact of short-term use of centre-near multifocal contact lenses on accommodative lag, heterophoria status and CISS score in a cohort of pre-presbyopic individuals as a means of improving asthenopic symptoms. It was hypothesised that the introduction of a near addition in the form of these lenses would decrease visual discomfort and result in an improvement in CISS score. Furthermore, it was speculated that such improvements in symptoms might be associated with changes in accommodative lag and heterophoria status. The study results indicate a marked and significant improvement in CISS scores following one-month wearing period of both low

add and high add multifocal soft contact lens wear, and suggests that multifocal soft contact lenses could be employed to reduce asthenopia.

CISS score was not significantly altered while wearing single-vision contact lenses compared to baseline CISS (single vision mean 24.46 ± 4.59 vs. baseline CISS mean 25.04 ± 4.58), with both groups falling within the bracket of 'significant symptoms' (CISS score ≥21) [45]. However, after wearing the centre near design multifocal soft contact lenses, CISS score improved from baseline by 12.8 points for the low add and 11.3 points for the high add design, lowering the post-wear CISS scores well below the threshold level for 'significant symptoms'. The fact that the reduction in CISS score was only achieved with multifocal lenses and not with single vision contact lenses suggests that it is an innate feature of this particular multifocal optical design, and not contact lens wear in general, which is responsible for the improvement. The findings of the current study show consistency with the work of Jong and colleagues [52], who fitted 26 university students with centre-near multifocal soft contact lenses and found that participants preferred multifocal lenses for prolonged near work with corresponding improvements in visual performance. However, unlike the present study, these participants were asymptomatic, and the type of survey form used in their study was not indicated [52]. Nonetheless, their conclusion does align with this study showing that centre-near multifocal soft contact lenses did improve the visual comfort of their participants at near, especially for near reading. Another study by González-Meijome et al. [40] evaluating the ability of centre distance low-add multifocal soft contact lenses to relief symptoms of asthenopia in prepresbyopes, also showed that asthenopic symptoms were improved. Similar to Jong et al. [52], the type of symptom survey form use in the study was not indicated.

A recent study by Rueff and colleagues [47] was also conducted to determine whether multifocal soft contact lenses can ameliorate contact lens discomfort symptoms. According to the Tear Film and Ocular Surface Society (TFOS), contact lens discomfort can result from contact lens or the environmental factors or both at the same time [53]. However, Rueff et al. acknowledged that contact lens discomfort reported by contact lens wearer, does not always present with significant signs of dry eye or ocular surface issues. Rueff et al. highlighted that vision, which comprises both accommodative and binocular vision disorders, can be another source that contributes to overall contact lens discomfort. Any form of contact lens discomfort may therefore also be a form of ocular asthenopia. In Rueff and colleagues' study [47], besides using the Contact Lens Dry Eye Questionaire-8 (CLEDQ-8) survey, CISS was also incorporated to assess their participants' satisfaction and discomfort level before and after wearing multifocal contact lenses in pre-presbyopic participants. As mentioned previously, some of the discomfort symptom questions listed in the CISS forms are similar to those in the CLEDQ-8, it is reasonable to use the CISS forms to assess the improvement in the ocular

fatigue condition. Improvement with overall contact lens discomfort symptom was observed for both CLEDQ-8 and CISS score, while wearing either the single vision or multifocal contact lenses, as compared to the participants habitual lenses. However, no significant difference was observed in the CLEDQ-8 and CISS score between single vision and multifocal contact lenses, showing that multifocal contact lenses alone did not significantly improve the contact lens discomfort. The study also reported that participants approaching 40 years of age were more favourable for the multifocal contact lenses than single vision.

Previous studies have reported a significant correlation between accommodative lag and symptoms of visual discomfort experienced during near-work [54]. However, the present study's cohort, selected to have manifest accommodative lag and symptoms of asthenopia, failed to exhibit any significant change in lag for any contact lens condition, despite a marked improvement in CISS score with multifocal contact lens wear. This finding is, however, consistent with several other studies which have used centre-near [38,39,55-57] or centredistance multifocal lenses [35] and have detected no significant change in accommodative lag compared to single vision distance contact lenses. Conversely, some studies have reported an increase in lag [34,35,58], while one study investigating bifocal contact lenses found that lag decreased [20]. It should be noted, however, that these studies were pilot investigations, with data collected on a single occasion, with minimal adaptation time, a limited range of multifocal contact lenses, and in most cases a very limited sample size.

Studies attempting to evaluate accommodative and binocular outcomes of multifocal contact lenses in pre-presbyopes have reached mixed conclusions on how wearers utilise the lens design and near add. Studies of adults [38] and children [59] have reported no change in accommodative function between single vision and multifocals and have suggested that this indicates that the participants appear to be accommodating normally through the distance portion of the multifocal for near tasks [59]. In the current study, the accommodative lag observed using MEM retinoscopy on pre-presbyopic participants, while wearing centre-near multifocal soft contact lenses, shows that there was no statistically significant difference in the lag of accommodation between all corrective modalities. Comparable findings in the current study would similarly seem to infer that, due to their relatively larger pupil size, the participants used more of the distance optics of the contact lens for near work.

Altoaimi et al. (2015) reported that young adult participants, aged between 21 and 28 years, do take advantage of the addition power in the multifocal contact lenses to reduce their accommodation effort. However, due to the influence of binocular convergence, it will tend to dominate the accommodation response when there is a degradation of the blur stimulus, which resulted in negative relative accommodation below normal level [60]. In the study, although

there was no significant difference in the accommodative lag with all corrective modalities, it was noted that accommodative lag was slightly lower while wearing low add and high add when compared to single vision (RE:  $1.63 \pm 0.50$  vs  $1.43 \pm 0.61$  vs  $1.67 \pm 0.36$ , and the LE:  $1.65 \pm 0.47$  vs  $1.51 \pm 0.46$  vs  $1.68 \pm 0.38$ , respectively). The result might indicate that some addition power might have been utilised. Besides that, as MEM retinoscopy was conducted at a clinical testing distance of 40 cm, it might not accurately replicate the near work distance adopted by the participants during their daily near work routine. As multifocal soft lenses are pupil size dependent [61], if the participants were to hold their daily near task closer than 40 cm, their corresponding pupil size might be smaller than when MEM retinoscopy was conducted in this study constricting further into the higher near optics zone of the contact lenses; this could explain the reason for the observed CISS score improvement.

Theoretical differences in vergence demands and oculomotor response have been established when changing from spectacle lens to single vision contact lens wear [62-64]. Myopes fixating at a near target through spectacle lenses experience an induced base in prismatic effect, resulting in a decreased stimulus for convergence [63]. However, as contact lenses remain centred at all distances, when wearing contact lenses in place of spectacles this effect is lost, resulting in a comparatively increased convergence effort requirement [62]. With more convergence effort required, the near vision triad may lead to more accommodation and therefore a higher esophoria. Clinical findings have also reflected this with myopes shown to exert more accommodation and vergence when wearing single vision contact lenses compared to spectacles and, conversely, hypermetropes exert less accommodation and vergence when wearing single vision contact lenses compared to spectacles [63]. Interestingly, the current study found that there was no significant difference in near heterophoria for any contact lens modality compared to habitual spectacle wear, contrary to the expectations based on the above theoretical vergence interactions. However, both low add and high add multifocal contact lenses showed a significant exophoric shift compared to single vision contact lenses, which would appear to suggest that participants are utilising the near addition, contrary to the lag findings of this study. Gong et al. [34] also reported near exophoric shift among their participants while wearing centre-distance multifocal contact lenses, but with elevated accommodative lag. The authors explained that the exophoric shift observed might be due to relaxation of the participants' the accommodation because of the near addition power. Additionally, the positive spherical aberration induced by the multifocal contact lenses might have created an enlarged depth of focus, resulting in a wider range of clear vision indirectly reducing the need to accommodate for pre-presbyope wearer. In the present study, centre-near multifocal contact lenses also induced spherical aberration, but in the negative form. A previous study [65] had indicated that spherical aberration, whether positive or negative, can increase depth of focus. Therefore, the exophoric shift observed in this study while wearing multifocal contact lenses compared to single vision, might be due to the similar effect suggested by Gong et al [34]. However, it should be noted that all heterophoria data demonstrated significant variability and though statistically significant, it is unclear whether such shifts are of clinical significance.

At distance, the phoria was shifted in the esophoric direction for all contact lens modalities compared to habitual spectacle. Discarding the possibility of changes in the vergence system with multifocal soft contact lenses compared to single vision contact lenses, and the fact that an eye focussed for distance should not exert accommodation, it could be speculated that accommodation may be stimulated by the slightly blurred images presented by the multifocal soft contact lenses, which may shift the visual axis inwards through accommodative convergence. Indeed, the Cambridge Antimyopia Study [66] showed that contact lenses with negative spherical aberration are capable of stimulating the accommodative system, however, this does not tally with the fact that the low add multifocal contact lenses shift was not significantly different to habitual spectacle despite single vision being significantly more esophoric than habitual spectacle.

The potential influence of binocular summation should also be considered. Slight alterations in accommodative lag may be subject to a summation effect when the participant performs near tasks binocularly, improving visual performance. Plainis and colleagues [67] showed that visual performance while wearing multifocal soft contact lenses was much better when viewing binocularly opposed to monocularly. The authors suggested that the improvement was likely due to binocular summation enhancing the superimposed multiple images on the retina. It was also highlighted in the study that the improvement of the visual performance could not be predicted using objective or computational techniques. It is also necessary to mention here that multifocal contact lens geometry may have the potential to interfere in the clinician's observations during MEM and that this may influence the estimation compared to the single vision.

This study considered whether the use of multifocal soft contact lenses alleviate general asthenopic symptoms, noting that any uncomfortable feeling arising during contact lens wear may be a form of asthenopia. It is well established that contact lens wear is one of the risk factors for dry eyes (68). In turn, dryness can cause significant discomfort around the eye. Additionally, it has also been highlighted that patient may present with contact lens discomfort without signs of ocular surface evidence, suggesting that the discomfort may be related to other visual function disorders (69). As described by Sheedy et al., asthenopia can result from any external symptoms such as burning, irritation, tearing, and dryness of the eyes, and/or due to internal symptoms such as strain or headaches experience from accommodative or

binocular vision stress (13,15). In general, therefore, contact lens discomfort can be considered as a form of asthenopia.

All participants were existing contact lens wearers and were fitted with single vision and multifocal soft contact lenses. Therefore, there is a possibility that the baseline CISS score and those scores acquired after wearing the three different test lenses, might have been affected by the external ocular surface discomfort induce by contact lens wear. However, the possibility of external ocular surface discomfort factors differentially affecting the asthenopic symptom score in this study is unlikely. Firstly, the CISS score showed no significant difference between the baseline data and after wearing the single vision contact lenses. Moreover, participants in this study reported significant improvements in the CISS score after wearing the low add and high add multifocal contact lenses. This finding differs from Rueff et al. study (47), where their participants reported improved symptom scores for single vision and multifocal contact lenses compared to habitual contact lenses. The result in Rueff et al. study shows that changes to the material or fit of the contact lenses reduced the asthenopic symptoms score. These improvements indicate that the external ocular surface discomfort experienced by their participants might have resulted in the high asthenopic symptom score rather than any accommodation or binocular vision stress (47). Both the single vision and multifocal contact lenses used in this study are of the same material, water content, and base curve; therefore, any form of contact lens related dryness or discomfort, experienced with the single vision contact lenses should also be reflected in the multifocal contact lens wear. In addition, none of the participants in this study developed any significant anterior ocular signs of dry eye, which require them to reduce lens wear during each review visit. As acknowledged by Rueff and colleagues, contact lens discomfort can result from either exterior discomfort such as dryness, or internal discomfort, such as binocular or accommodative disorder (71). Therefore, as discussed previously, the improvement in the symptom score with multifocal contact lenses may be associated with the changes to accommodative lag, the binocular vision function or a summation effect of both, rather than dryness or discomfort caused by the contact lenses wear.

As the ability to sustain clear and comfortable near vision decline with age [70], asthenopic symptoms may be more commonly observed in the older individual rather than the younger age. This study focused on the accommodative lag and heterophoria condition and most importantly, whether the use of multifocal contact lenses improve asthenopic symptoms. In line with two previous studies by González-Meijome et al. [40] and Jong et al. [52], the present study examined a single pre-presbyopic cohort without delineating for age. Differences in intragroup response profiles could, therefore, exist in the cohort due to individual accommodative response profiles. Consequently, future studies with a larger sample size

designed to investigate these putative age-related symptoms scores during multifocal soft contact lenses wear are indicated. The results will provide valuable information for clinical use.

#### Conclusions

This study provides support for the prescription of centre-near multifocal contact lenses for the reduction of symptoms of asthenopia in pre-presbyopic myopic adults. As any discomfort in or around the eye can be a form of asthenopia and this can be presented as a form of contact lens discomfort during contact lens wear. Treatment targeting the ocular surface alone to relieve asthenopia may not yield favourable results as asthenopia may be caused by other factors (13,71). Therefore, binocular vision stress or accommodation should be evaluated as well.

The centre-near multifocal contact lenses offer a promising decrease in subjectively reported symptoms of asthenopia, relative to conventional single-vision spectacle and contact lens wear. However, the mechanism by which this improvement is achieved remains elusive, with no evidence to suggest that the reduction of symptoms was mediated by a reduction in accommodative lag. There is possibly potential for some sort of synergistic relationship between elements of the near-vision triad, lag and phoria whereby small changes in lowering lag and in each have an additive effect, improving symptoms more than predicted from these measurements, but more study is required in this area.

Low-add multifocal contact lens provided the largest reduction in CISS score, so are therefore more clinically viable and appropriate to provide an optimal balance between efficacy and safety in these individuals. Nevertheless, one major undesirable corollary for using any form of multifocal correction in a pre-presbyope is the undue adjunct of visual compromise [71]. Despite evidence to suggest that neural adaptation can diminish this unintended consequence in presbyopic wearers [72], adaptation effects in pre-presbyopes fitted with multifocal contact lenses warrants additional investigation [71].

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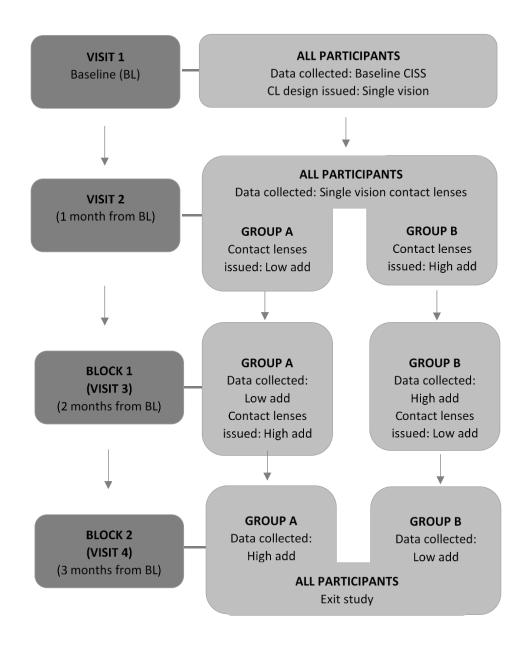
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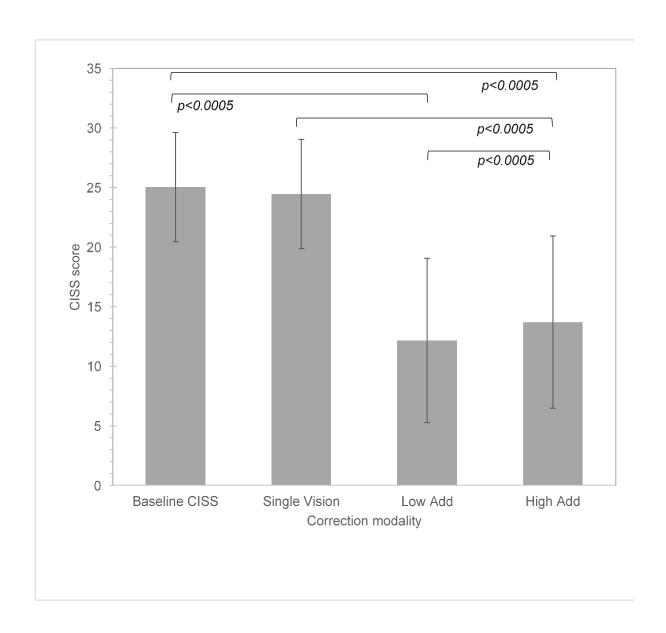
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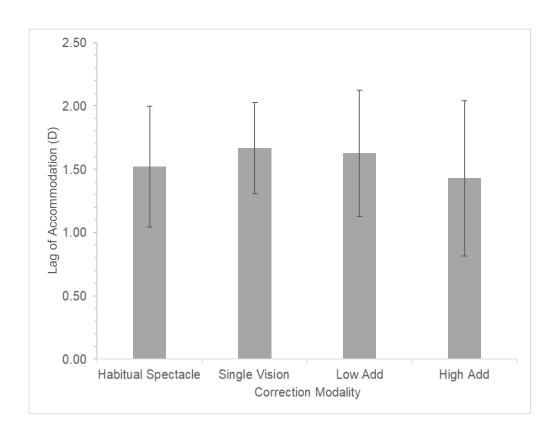
**Figure 1.** Schematic representation of cross-over study design and experimental protocol. Participants were randomly allocated to one of two groups (A = low-add first group, B = high-add first group) prior to multifocal lens issue at the  $2^{nd}$  visit. Each participant underwent three, one month contact-lens wearing periods, over a total of 4 assessments. CISS score, accommodative lag and heterophoria status data were collected at all assessments.

|         | Male | Female | Mean Age     | Mean Amplitude of Accommodation | Mean MSE RE   | Mean MSE LE   |
|---------|------|--------|--------------|---------------------------------|---------------|---------------|
| Group 1 | 6    | 6      | 22.83 ± 5.78 | 10.28 ± 1.80                    | -3.74D ± 2.08 | -3.59D ± 1.69 |
| Group 2 | 3    | 9      | 22.83 ± 6.21 | 10.24 ± 1.72                    | -3.43D ± 1.45 | -3.53D ± 1.45 |

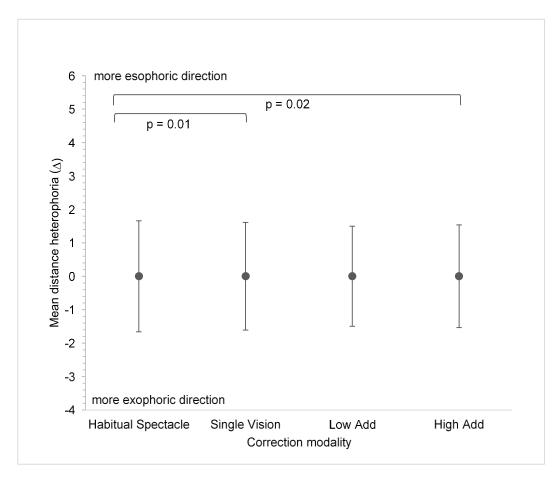
**Table 1**. Demographic, age, mean amplitude of accommodation and mean MSE of the Right eye (RE) and Left eye (LE) of participant randomised into each arms of the study. Data presented are mean  $\pm$  standard deviation.



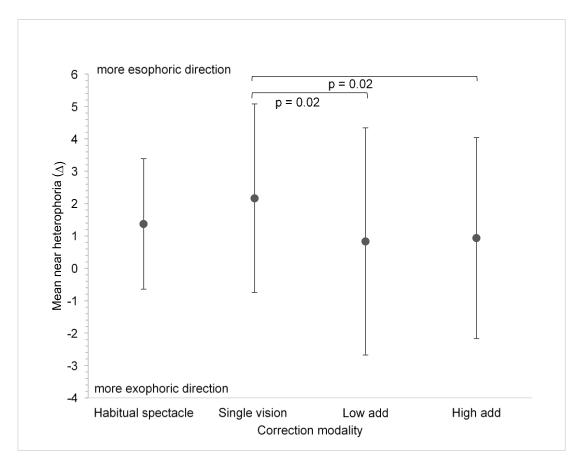
**Figure 2.** Comparison of mean and standard deviation CISS score for each treatment modality. Error bars represent  $\pm$  standard deviation. Square brackets indicate statistically significant differences between groups and their associated p values.



**Figure 3.** Bar chart representing the mean values of the lag of accommodation for RE for each test condition regardless of whether participants started with low or high add. Error bars represent  $\pm$  one standard deviation (SD). There was no statistically significant difference between the lag of accommodation for the RE (p = 0.05) and the LE (p = 0.07) for the four test conditions.



**Figure 4.** Comparison of mean distance heterophoria for each test lens condition. Error bars represent  $\pm$  standard deviation. Square brackets indicate statistically significant differences between groups and their associated p values.



**Figure 5**. Comparison of mean near heterophoria for each test lens condition. Error bars represent  $\pm$  standard deviation. Square brackets indicate statistically significant differences between groups and their associated p values.