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Dynamics of the accommodative response and facility with dual-focus soft contact lenses for myopia control

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A R T I C L E I N F O

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A B S T R A C T

Objective: To assess the impact of using dual-focus soft contact lenses for myopia control on the dynamics of the accommodative response and facility.

Methods: 24 young adult myopes were fitted with dual-focus soft contact lenses for myopia control (MiSight®) and single-vision soft contact lenses (Proclear®). The WAM-5500 open-field autorefractor was used to measure the dynamics of the accommodative response (magnitude and variability) in binocular conditions, with accommodative data being gathered from the dominant eye, at three viewing distances (500 cm, 40 cm, and 20 cm) during 90 s. Also, the binocular accommodative facility was assessed with the WAM-5500 autorefractor. All participants performed the same experimental protocol with the dual-focus (MiSight) and single-vision (Proclear) soft contact lenses, with both experimental sessions being carried in two different days and following a counterbalanced order.

Results: This study showed greater lags of accommodation with the MiSight than the Proclear lenses at near distances (40 cm: 1.27 ± 0.77 vs. 0.68 ± 0.37 D, corrected p-value = 0.002, Cohen-d = 0.90; and 20 cm: 1.47 ± 0.84 vs. 1.01 ± 0.52 D, corrected p-value = 0.007, Cohen-d = 0.75), whereas a higher variability of accommodation was observed with the dual-focus than the single-vision lenses at 500 cm (0.53 ± 0.11 vs. 0.23 ± 0.10 D), 40 cm (0.82 ± 0.31 vs. 0.68 ± 0.37 D), and 20 cm (1.50 ± 0.56 vs. 1.15 ± 0.39 D) (corrected p-value < 0.001 in all cases, and Cohen-ds = 0.67–2.33). Also, a worse quantitative (27.75 ± 8.79 vs. 34.29 ± 10.08 cycles per minute, p = 0.029, Cohen-d = 0.48) and qualitative (23.68 ± 7.12 vs. 28.43 ± 7.97 score, p = 0.039, Cohen-d = 0.45) performance was observed with the MiSight when compared to the Proclear lenses.

Conclusions: The use of dual-focus soft contact lenses for myopia control alters the dynamics of accommodative response and facility in the short-term. Although this optical design has demonstrated its effectiveness for myopia control, eye care specialists should be aware of the acute effects of these lenses on accommodation performance.

1. Introduction

Myopia is a public health issue and its prevalence has been increasing over the years. It is estimated that 5 billion people will be myopes by 2050 [1]. Myopia can lead to pathological complications (e.g., choroidal neovascularization, myopic macular degeneration, etc.) and impairs vision-related quality of life [2,3]. The risk factors linked to myopia progression are under scientific debate, with baseline myopia level, distance and time spent at near viewing [4,5], patientś age and race [6], time spent outdoors [7], sedentary lifestyle [8] and degree of parental myopia [9] being the most prominent.

Due to the negative public health and economic impact of myopia, there are considerable research efforts to determine the most effective intervention to slow myopia progression [10-12]. Several pharmacological and optical strategies have been demonstrated to be helpful for this purpose [13-17]. Among optical interventions, the use of multifocal soft-contact lenses to reduce or eliminate peripherical hyperopic defocus has gained in popularity in the last years due to its effectiveness to decelerate eye axial elongation [16,18-20]. Regardless of the optical design, the contact lenses should provide an acceptable visual

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performance, but previous studies have shown that multifocal contact lenses affect quality of vision negatively [21-24]. In particular, due to the proposed association between myopia progression and ocular accommodation [25-27], several authors have assessed the effects of wearing multifocal soft contact lenses for myopia control on the accommodative function [28-34]. Most of the available studies on myopia control have been focused on evaluating the magnitude of the accommodative response. In this regard, multifocal contact lenses wearers seem to use the positive zone of the lens during near vision to relax accommodation [32,33]. However, there are other measures of the accommodative function such as the variability of accommodation and accommodative facility that have been associated with myopia progression and/or have been demonstrated to be altered by the use of multifocal lenses [35-38], but they have not yet been investigated while wearing concentric dual-focus contact lenses for myopia control.

Owing to the lack of scientific evidence in relation to the effects of using dual-focus soft contact lenses for myopia control on the dynamics of the accommodative response and facility, the main objectives of the present study were: (i) to determine the short-term effects of using dual-focus soft contact lenses for myopia control in comparison to single vision soft contact lenses on accommodative lag and variability, and (ii) to compare the dynamics of the accommodative facility between the dual-focus and single vision soft contact lenses, as assessed by an objective method for the qualitative and quantitative assessment of binocular accommodative facility [39]. Based on previous studies performed with multifocal lenses, it is hypothesized that the use of dual-focus would lead to greater lags of accommodation [19] and a reduced accommodative facility [36], whereas no hypothesis can be formulated for the stability of the accommodative response due to the lack of studies in this regard.

2. Methods

2.1. Participants

The minimum sample size required for this within-subjects experimental design was based on an a-priori calculation using the GPower 3.1 software [40]. Due to the lack of previous data, an effect size of 0.25 (Coheńs d) was assumed for the dependent variables used in this study. An alpha of 0.05, power of 0.80, and level of correlation among repeated measures of 0.5 were considered. This a-priori analysis predicted that the required sample size to achieve this desired level of accuracy is 20 participants. Subsequently, 24 young myopes (75% women, average age ± standard deviation = 20.5 ± 2.0 years) were recruited to participate in this study. All participants included in this study satisfied the following inclusion criteria: (i) have a spherical equivalent ranging from −0.5 to −6.0 D, including an astigmatism error ≤ 0.75D, (ii) have a visual acuity of 0.0 logMAR or better in each eye with the optical compensation, (iii) be free of any ocular disease, (iv) have amplitude of accommodation (push-up method) within the normal range as calculated by the Hofstetter's formula [41], (v) have fusion, as assessed by the standard Worth-4-dot test at near (40 cm) and far (5 m) distances, and (vi) belong to the low discomfort group with the Conlon survey [42]. All the procedures followed on this study adhered to the recommendations of the Declaration of Helsinki, and permission was granted by the University of Granada Institutional Review Board (IRB approval: 1786/CEIH/2020).

2.2. Procedure

Participants visited the laboratory in four separate occasions on different days. During the first visit a full optometric examination was conducted, which included an objective ocular refraction and keratometry with an autokeratorefractometer (WAM-5500; Grand Seiko Co. Ltd., Hiroshima, Japan), considering the mean value from three measurements in both cases. Following this, a full monocular and binocular subjective refraction, considering an end-point criterion of maximum plus consistent with best vision using a bichromatic test, was performed. Aiming to ensure the fulfilment of the inclusion criteria (see the *Participants* subsection), the presence of binocular or accommodative anomalies was evaluated following the recommendations of Scheiman and Wick [43], as well as any ocular pathology as assessed by slit-lamp and direct ophthalmoscopy examination. At this point, dual-focus and single vision soft contact lenses (MiSight 1-day and Proclear 1-day, respectively; CooperVision, Pleasanton, CA, USA), both composed of omafilcon A material, were ordered based on the corneal measures and exact refraction compensated for vertex distance. The second session was used to evaluate that both lenses were appropriately centered, had sufficient movement, over-refraction was ≤ 0.25 D, and visual acuity was satisfactory (≤0.00 logMAR in each eye). The lens power used was the same for both lens types. Following this evaluation procedure, participants were given verbal and written instructions about the experimental conditions, which were carried out in the third and fourth sessions. These two sessions were identical except for the randomized use of the dual-focus or single vision soft contact lens. In both sessions, participants wore the lenses for at least 15 min before the assessment of accommodative dynamics in order for their ocular surface to adapt to the new contact lenses [44]. All experimental sessions were scheduled at the same time of the day (±1 h) to minimize the influence of circadian variations, and participants were instructed to abstain from alcohol and caffeine consumption for 24 and 12 h, respectively, before visiting the laboratory.

2.3. Assessment of the dynamics of the accommodative response and facility

The lag and variability of the accommodative response were recorded using a binocular open-field Grand Seiko WAM-5500 autorefractor (Grand Seiko, Hiroshima, Japan), in HI-SPEED mode. This device has been validated to acquire reliable and valid accommodation data at a temporal resolution of~ 5 Hz and with a sensitivity of 0.01 D [45,46]. Recording was conducted in binocular conditions from the dominant eye, as determined by the hole-in-the-card method [47], and while participants rested their chin and forehead on the corresponding supports. First, the monocular refractive state was measured using the WAM-5500 static mode, with measured values being further used for calculating the lag of accommodation. Then, the accommodative response was recorded continuously during 120 s while participants fixated on a stationary target (Maltese cross, Michelson contrast = 79%, base luminance = 31 cd m^{-2}) at three different distances (500 cm, 40 cm and 20 cm). During dynamic recordings, an experienced examiner ensured that the reference marker of the WAM-5500 autorefractor was within the pupil area. A three-minute break was taken between two consecutive recordings. The data were curated following the established recommendations of removing data points of ±3 standard deviations from the mean spherical refraction, as they are considered to be blinks or recording errors [48]. Accommodative lag was calculated as the difference of mean accommodative response (recorded in dynamic mode) and the corresponding accommodative demand (i.e., 2.5 D at 40 cm). In order to account for the residual refractive error, and as proposed by Poltavski et al. [49], the lag of accommodation was also corrected by subtracting the baseline static refraction at far distance. For example, a subject with a mean accommodative response of 1.85 D at 40 cm, and with a residual refractive error of +0.10 D (after being optically corrected), has a near refractive state of 1.75 D. Therefore, considering that the ideal response is −2.50 D (40 cm), this subject has a lag of accommodation of 0.75 D (i.e., −1.75 – [-2.50] = 0.75 D). The measure of variability of accommodation was taken as the standard deviation of the continuous accommodative data measurements, with higher values of this parameter showing a lower stability of accommodation.

The facility of accommodation was assessed by a recently developed objective method for the qualitative and quantitative assessment of binocular accommodative facility in free-viewing conditions [39]. This method, known as the 2Q-AF test, combines the use of an open-field autorefractometer (WAM-5500, Grand Seiko Co. Ltd., Hiroshima, Japan) in continuous recording mode and a modified version of the Hart chart test, which includes far and near targets placed at 5 m and 40 cm, respectively. A more detailed description of the procedures required for data acquisition and analysis with the 2Q-AF test can be found in Vera et al. [39]. Briefly, participants were asked to shift their focus of accommodation between the far and near targets when the letter became clear, and the refractive state was recorded with the autorefractometer. Data acquisition lasted for 60 s, and subsequent analyses allow us to obtain the number of cycles, percentage of incorrect cycles of accommodation and dis-accommodation, and mean magnitude of accommodative changes between the far and near targets. For the analysis of the accuracy of each accommodative change in the 2Q-AF test, a near error was considered to occur when the accommodative response for the near distance was greater (+1SD; i.e., more positive) than the baseline near measurement, whereas a far error was considered to occur accounted when the accommodative response for the far distance was smaller (−1SD; i.e., more negative) than the baseline far measurement. The mean magnitude of accommodative change was calculated as the average change between the two accommodative levels (i.e., far and near targets) in the facility test. The qualitative examination of accommodative facility was performed with the 2Q-AF score, which is calculated as described in equation (1).

$$2Q - AFscore = cpm - cpm \times \left(\frac{\%ofnearerrors + \%offarerrors}{2}\right) \quad (1)$$

2.4. Study design and statistical analysis

The present study followed a within-participants design to determine the short-term effects of wearing dual-focus soft contact lenses on the dynamics of the accommodative response and facility. The within-participants factors were the type of soft contact lens (MiSight, Proclear) and the target distance (500, 40, and 20 cm). The dependent variables were the lag and variability of the accommodative response, as well as the qualitative and quantitative measures of binocular accommodative facility.

Firstly, the Shapiro–Wilk and Levene's tests were performed to assess the normality of the data and the equality of variance, respectively ($p > 0.05$ in all cases). Subsequently, parametric statistics were applied for data analyses. For the dynamics of the accommodative response (lag and variability of accommodation), two separate two-way ANOVAs with the lens type (MiSight, Proclear) and the target distance (500, 40, and 20 cm) as the within-participants factors were conducted. The analysis of the binocular accommodative facilities was carried out by separate t-tests for related samples, considering the type of soft contact lenses as the only within-participants factor (MiSight, Proclear), for each of the measures derived from the binocular accommodative facility test. The level of significance was established at 0.05, and multiple comparisons were corrected with the Holm- Bonferroni procedure. Standardized effect sizes were reported by means of the partial η^2 (η^2_p) for Fs and the Cohen's d (d) for t-tests.

3. Results

Table 1 shows the descriptive values for the dynamic of the accommodative response (lag and variability of accommodation) and pupil size with both contact lens types.

There was a statistically significant effect for the lag of accommodation with the lens type ($F_{1,23} = 9.74$, $p = 0.005$, $\eta 2_p = 0.30$), target distance ($F_{2,46} = 89.66$, $p < 0.001$, $\eta 2_p = 0.80$), and the interaction "lens type × target distance" ($F_{2,46} = 14.27$, $p < 0.001$, $\eta 2_p = 0.38$). *Post hoc* comparison between the three targets distances revealed greater lags of accommodation at 20 cm than 40 cm (corrected p-value = 0.002, d = 0.65) and 500 cm (corrected p-value < 0.001, d = 2.63), as well as at 40 cm when compared to 500 cm (corrected p-value < 0.001, d = 1.97). The comparison between the dual-focus and single vision, contact lenses exhibited greater lags of accommodation for the dual-focus lenses at 40 cm (corrected p-value = 0.002, d = 0.90) and 20 (corrected p-value = 0.007, d = 0.75), but no differences were observed at far distance (corrected p-value = 0.510, d = 0.13) (Fig. 1, panel A).

Table 1
Descriptive (mean ± standard deviation) values of the dynamics of the accommodative response (lag and variability of accommodation) and pupil size while wearing the dual-focus and single vision soft contact lenses.

		Dual-focus	*Single-vision*
Lag of accommodation (D)	500 cm	0.22 ± 0.67	0.13 ± 0.16
	40 cm	1.27 ± 0.77	0.68 ± 0.37
	20 cm	1.47 ± 0.84	1.01 ± 0.52
Variability of accommodation (D)	500 cm	0.53 ± 0.11	0.23 ± 0.10
	40 cm	0.82 ± 0.31	0.53 ± 0.19
	20 cm	1.50 ± 0.56	1.15 ± 0.39
Pupil size (mm)	500 cm	5.74 ± 0.81	5.51 ± 0.64
	40 cm	5.40 ± 0.82	5.39 ± 0.74
	20 cm	4.76 ± 0.90	4.67 ± 0.74

The analysis of the variability of accommodation showed statistically significant differences for the main effect of lens type ($F_{1,23} = 37.69$, $p < 0.001$, $\eta 2_p = 0.62$) and target distance ($F_{2,46} = 145.50$, $p < 0.001$, $\eta 2_p = 0.86$), but not for the interaction "lens type × target distance" ($F_{2,46} = 0.300$, $p = 0.743$, $\eta 2_p = 0.01$). *Post hoc analysis* between the three target distances demonstrated a lower stability of the accommodative response at 20 cm than 40 cm (corrected p-value < 0.001, d = 2.35) and 500 cm (corrected p-value < 0.001, d = 3.40), as well as at 40 cm when compared to 500 cm (corrected p-value < 0.001, d = 1.05). Pairwise comparisons between both lens types indicated a reduced stability of accommodation while wearing the dual-focus in comparison to the single vision lenses at 500 cm (corrected p-value < 0.001, d = 2.33), 40 cm (corrected p-value < 0.001, d = 1.25) and 20 cm (corrected p-value < 0.001, d = 0.67) (Fig. 1, panel B).

Although it was beyond the aims of this study, an analysis of the pupil size while fixating at the three target distances with both lens types was carried out. Pupil size was associated with the target distance ($F_{2,46} = 48.40$, $p < 0.001$, $\eta 2_p = 0.51$), showing a smaller pupil diameter at closer distances. However, pupil size did not show statistically significant differences for the main effect of lens type ($F_{1,23} = 1.63$, $p = 0.214$) and the interaction "lens type × target distance" ($F_{2,46} = 1.70$, $p = 0.194$).

For the binocular accommodative facility test, descriptive values and pairwise comparisons between the dual-focus and single vision soft contact lenses are shown in Table 2. The analysis of quantitative and qualitative binocular accommodative facility showed statistically significant differences for the number of cycles per minute ($t_{23} = 2.34$, $p = 0.029$, Coheńs d = 0.48) and the 2Q-AF score ($t_{23} = 2.19$, $p = 0.039$, Coheńs d = 0.45), observing a better performance with the single vision than the dual-focus soft contact lenses (Fig. 2).

4. Discussion

The present study was designed to assess the short-term effects of using dual-focus soft contact lenses for myopia control on the dynamics of the accommodative response and facility. The analysis of accommodative data evidenced greater lags of accommodation at near distances, and a lower stability of accommodation with the MiSight than the Proclear lenses at far and near distances. For the accommodative facility, wearing the MiSight lenses affected the frequency and precision of this visual ability negatively. Taken together, data from this study show that wearing dual-focus soft contact lenses significantly alters the dynamics of the accommodative response and facility in young myopes.

Several clinical trials have demonstrated the effectiveness of the

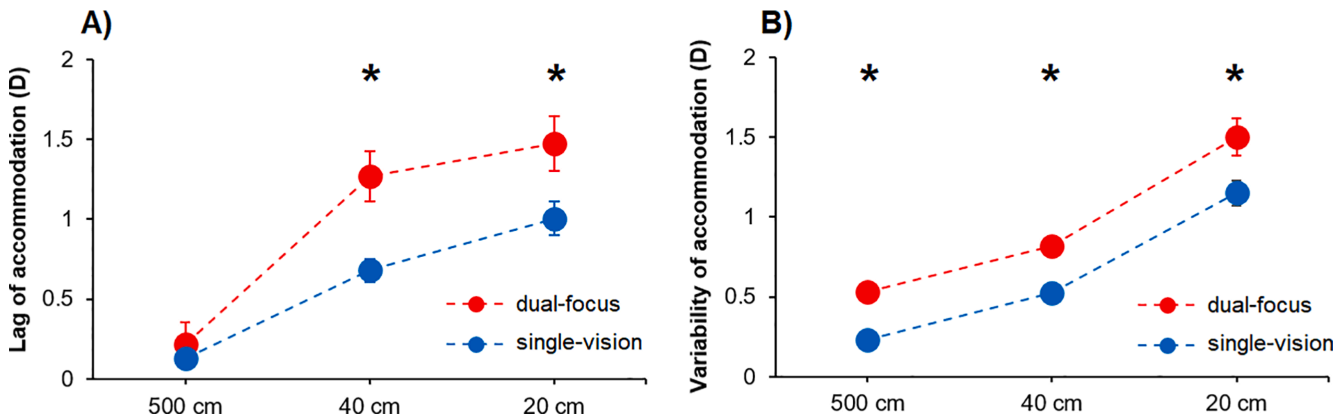

Fig. 1. Effects of using the dual-focus (MiSight; in red) and single vision (Proclear; in blue) soft contact lenses on the accommodative lag (panel A) and variability (panel B) at three viewing distances. * denotes a statistically significant difference between both types of soft contact lenses (corrected p-value < 0.05). Error bars show the standard error. All values are calculated across participants (n = 24). D = diopter.

Table 2
Descriptive (mean ± standard deviation) and statistical values for the parameters obtained with the binocular accommodative facility test while wearing the dual-focus and single vision soft contact lenses.

	Dual-focus	Single-vision	t	P-value	Cohen's d (95% CI)
Number of cycles (cpm)	27.75 ± 8.79	34.29 ± 10.08	−2.34	0.029	−0.48 (−0.90 to −0.05)
Under-accommodated (%)	26.67 ± 18.38	3.46 ± 5.48	6.20	<0.001	1.27 (0.72 to 1.80)
Under-relaxed (%)	2.44 ± 6.60	28.77 ± 19.40	−7.26	<0.001	−1.48 (−2.06 to −0.90)
Magnitude (D)	1.62 ± 0.36	1.51 ± 0.39	1.367	0.185	0.28 (−0.13 to 0.68)

Abbreviations: cpm = cycles per minute; D = diopters, CI = confidence interval.

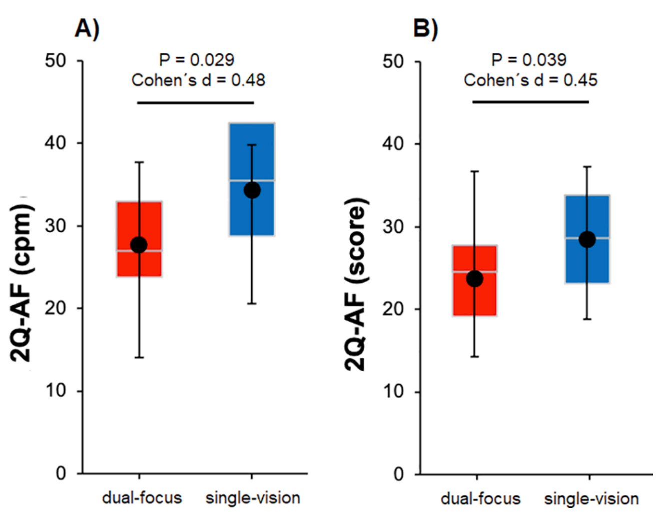

Fig. 2. Effects of using the dual-focus (MiSight; in red) and single vision (Proclear; in blue) soft contact lenses on the quantitative (panel A) and qualitative (panel B) measures of binocular accommodative facility. P-values and effect sizes (Coheńs d) are displayed above each comparison. The box plots represent 75th, 50th and 25th centiles. Horizontal lines and filled circles into the box represent median and mean values, respectively. The whiskers show the maximum and minimum values. All values are calculated across participants (n = 24). Note: The equation used for 2Q-AF score is reported in the text. cpm = cycles per minute.

MiSight lenses in slowing changes in spherical equivalent refraction and axial length over multiple years [16,34,50]. However, in the short-term, the use of multifocal contact lenses for myopia control has been associated with a reduced accommodative response due to the use of the positive addition at near [31]. This is consistent with the findings of the current study since it was found a meaningful reduction of the accommodative magnitude at 40 and 20 cm (̃0.50D) while using the MiSight in comparison to the Proclear lenses. Remarkably, previous studies have suggested a positive association between accommodative lag and myopia progression [26,27]. With this study it is not possible to confirm that all participants were looking through the positive zone of the lens during the entire duration (or some moments) of the different visual tasks. Therefore, the impact of using (or not using) the added positive power of this optical design (i.e., dual-focus lenses) on the accommodative function, and its long-term effect on myopia control deserves to be explored in more detail.

Regarding stability of accommodation, a number of studies have reported that myopes show a lower stability of accommodation than emmetropes [37,38,51-53]. In relation to the effects of using multifocal soft contact lenses on the stability of the accommodative response, Shibata and colleagues found differences in accommodative stability between multifocal and single vision soft contact lenses [35]. The behaviour of the "steady-state" accommodation response is highly dependent on optical changes in the retinal image (e.g., spatial frequency, contrast, blur perception, etc.) [54], which may be linked to the greater levels of accommodative fluctuations observed with the dual-focus lenses for myopia control. A recent study by Garcia-Marqués et al [24] found that using the MiSight lenses impairs photopic and mesopic contrast sensitivity, higher order aberrations, light disturbance and subjective perceptions of vision quality. It may also partially explain the heightened accommodative variability recorded with the dual-focus when compared to the single vision soft contact lenses as it has been demonstrated that accommodative variability is indicative of eye strain or visual fatigue [55]. In addition, Garcia-Marques and colleagues [56] found a slight reduction of pre-lens tear stability with the MiSight soft contact lenses, and thus, this may also contribute to the differences observed for the variability of the accommodative response. Furthermore, it is reasonable to expect that transitions between the two optical powers of the lens may induce an accommodative conflict causing the reduced stability observed with this contact lens design in far and near viewing.

The 2Q-AF test allows to objectively acquire qualitative and quantitative measures of accommodative facility in free-viewing conditions [39]. The ability of the visual system to stimulate and relax accommodation rapidly and accurately is of great relevance in real-word contexts (e.g., driving, sports practice, school), and has been demonstrated to be worse in myopes [57] and in eyes fitted with multifocal contact lenses [36]. In line with this, a worse binocular accommodative facility performance was obtained with the dual-focus soft contact lenses for number of cycles/minutes and the AQ-AF metrics. Remarkably, Ozkan et al. [36] found a significant reduction in monocular accommodative facility with multifocal soft contact lens wearing, as assessed with the ±2.00 DS lens flipper test, and they suggested that this effect may be due to the reduced visual performance achieved with multifocal designs. Therefore, it is reasonable to presume that the reduced binocular accommodative facility observed in the current study may be primarily attributed to the reduced visual performance obtained with the use of dual-focus soft contact lenses.

This study provides evidence that dual-focus soft contact lenses for myopia management alter the dynamics of the accommodative response and facility, and although their effectiveness to slow myopia progression and axial elongation are well-documented [16,50], the impact of these lenses on ocular accommodation should be taken into consideration. These findings seem to be of relevance in clinical and applied settings, since the changes observed in accommodative response and facility could deteriorate visual performance in a range of daily activities as well as affect visual comfort during near work, as demonstrated in various studies [48,55]. However, there are limitations that may restrict the generalizability of the current findings listed here. First, a specific type of soft contact lens for myopia control (i.e., multi-zone bifocal) was chosen, and the current results cannot be extrapolated to other optical designs. Second, the MiSight lenses contain a large central correction area of 3.36 mm surrounded by multiple refractive concentric rings of alternating distance and near powers, resulting to the retina receiving in-focus and out-of-focus images. In this case, pupil size plays an important role on visual performance with these lenses; as pupil size increases, the pupil area covered by the concentric rings increases. Future studies may consider the influence of pupil size or rings configuration of dual-focus soft contact lenses on ocular accommodation. Third, results from this study must be interpreted according to the crossover, self-controlled design carried out in this work, and the long-term effects of using the MiSight lenses on the dynamics of the accommodative response and facility require further investigation. Fourth, changes in the dynamics of ocular accommodation have been associated with visual strain in symptomatic young subjects [48,55] and during prolonged near viewing [58]. The external validity of these results to visually symptomatic individuals and during longer near tasks requires further investigation, since the experimental sample of the current study was formed by visually asymptomatic young adults and the near task was relatively short. Lastly, most investigations with MiSight lenses have been conducted in children, and it will be of interest to assess visual performance and comfort in this population, as children have different blur sensitivity than adults [59].

5. Conclusions

This study found acute changes in the dynamics of accommodative response and facility as a consequence of wearing dual-focus soft contact lenses for myopia control. Greater accommodative lags and variability of accommodation were observed at near, and at far and near distances, respectively, when wearing the Mi-Sight bifocal than the single vision (i.e., Proclear) soft contact lenses. Also, the accommodative facility was quantitatively and qualitatively affected by the use of the dual-focus lenses. Eye care providers should be aware of these outcomes when prescribing these lenses for myopia management.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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