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Evaluating Retinal Image Quality for Myopia Control Lenses in a Synthetic Accommodative Wavefront Model.

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Abstract: This study uses a wavefront model to evaluate the effects of contact lenses on retinal image quality (RIQ) as a function of target vergence (TV). 300 synthetic eyes were generated using an accommodative wavefront model to simulate the changes in RIQ with accommodation. The synthetic eyes wavefronts were computationally combined using direct wavefront summation, with two myopia control CLs. One with +2.00D treatment zones dual-focus (DF) design (MiSight) and the other with an extended depth of focus (EDOF) design (Mylo). Peak image quality was calculated for the naked eye and with CLs, in the relaxed state and for an accommodative demand of -2.5D. Additionally, the predicted accommodative response (change in accommodative response that maximizes RIQ) was calculated. The mean RIQ (normalized between 0 and 1) for the relaxed eye was 0.42 ± 0.10 in the naked eye. It decreased to 0.26 ± 0.05 with the DF and threefold to 0.15 ± 0.04 with the EDOF. For a TV=-2.5D, the RIQ was 0.34 ± 0.09 in the naked eye condition, 0.24 ± 0.07 with the DF, and 0.19 ± 0.03 with the EDOF. For the TV the CL's effective add power, the accommodative RIQ showed a secondary peak, with RIQs of 0.08 ± 0.03 (DF) and 0.12 ± 0.04 (EDOF). The theoretical accommodative response (AR) of the naked eye was 2.33 ± 0.20 D, while with the DF and EDOF, it was 2.23 ± 0.39 D and 1.75 ± 0.22 D, respectively.Both myopia control CLs reduced RIQ at a TV of 0 D. At a TV = -2.5D, both lenses caused a secondary peak in the RIQ through focus. With EDOF, the secondary peak was less than 0.1 D from the maximum peak, likely due to its EDOF design. The theoretical AR was reduced with both myopia control CLs, 0.27 D for DF CLs, and 0.75 D for EDOF CLs. These results indicate that both lenses impose significant limitations on RIQ and theoretical AR, align with findings from previous studies on subjective optical performance, and validate the model as a useful testing tool.

1. Introduction

Myopia is a common refractive error that affects a significant portion of the global population.[1] It is characterized by a difficulty in seeing distant objects clearly while nearby objects might appear sharp when located in a conjugated plane between the near and remote point. Myopia can be categorized into low and moderate myopia, which primarily impact quality of life, and high myopia, which is associated with a higher risk of severe ocular conditions such as retinal detachment, myopic maculopathy, and glaucoma. The excessive eye growth that leads to myopia can result in several comorbidities that contribute to making it one of the leading causes of blindness in the world.[2] The prevalence of myopia has increased markedly over the past few decades, and projecting that by 2050, 50% of the world will have myopia, and close to 1 billion people with high myopia by 2050, 7.5 times more than in 2000.[1]

Currently, there are several commercially available options for managing myopia progression, including ophthalmic lenses and contact lenses (CLs).[3] The CLs were the first devices developed and utilized in myopia management, with various optical designs now

available. These myopia management treatments have demonstrated their safety[4] and effectiveness[5–7] in reducing the rate of eye elongation in children. [1,2][8]

Currently, two of the most effective soft CLs designs for myopia management are the MiSight lenses[9] (Coopervision, The Cooper Companies Inc., UK) with a dual-focus (DF) optical profile design and the Mylo lenses[10] (Mark'ennovy, Spain) with an extended depth-of-focus (EDOF) optical profile design.

These special CLs are based on multifocality designs and have the drawback of limiting retinal image quality (RIQ), referring to how clearly and accurately images are formed on the retina, since the light that enters the pupil is redistributed into different foci[5], so it is important not only to evaluate the subjective visual performance[11,12], but also the optical quality changes[10] and accommodative response changes[13,14] in clinical trials. Due to the complexity associated with these clinical trials, statistical eye models might be a suitable tool for the pre-clinical evaluation of these optical corrections. Several studies have evaluated RIQ by using eye models such as Atchison[15] or Navarro.[16] Although these models incorporate accommodation as a parameter, they rely on fixed parameters of the eye that do not represent the majority of the population. In contrast, the statistical model offers a more realistic approach by accounting for inter-subject variability.[17–19] It generates a series of sets of Zernike coefficients rather than providing a fixed set, thus better reflecting the diversity found in the general population.[20]

Considering that myopia control CLs induced some degree of peripheral blur and created a reduced contrast due to the complex redistribution of the light by zones with additional focal power, it is reasonable to assume they may also contribute to some degree of diminished visual performance.[21] This study aims to evaluate the changes in RIQ and accommodative response (AR) using two different myopia control CLs designs, on a data set randomly generated with theaccommodative wavefront eye model developed.[22]

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2. Methods

The synthetic accommodative wavefront model[22,23] was used to generate 300 random wavefronts for different accommodation states (from 0 D to 5 D), to simulate the changes in RIQ with theoretical accommodation. The mean C (2,0) 2.10 ± 2.56 μm, C (2, -2) 0.10 ± 0.19 μm, C (2,2) -0.12 ± 0.30 μm and C (4,0) 0.05 ± 0.05 μm.

The synthetic wavefronts were computationally combined with the measured wavefront of two commercially available soft CLs with distinct designs for myopia control.

2.1 Contact Lenses

The MiSight CL has a DF design (Table 1) with four alternating distance vision treatment zones surrounding the center-distance zone of 3.36 mm in diameter. The treatment zones have a +2 D add power providing a second focal point at approximately 0.6 mm in front of the retina that corresponds to approximately 1.53 D of defocus based on the paraxial approximation. [14] (Figure 1).

The Mylo CLs has an EDOF design (Table 1) with a non-monotonic and aperiodic power profile across the optic zone, with smooth transitions between the multiple zones. This CLs design incorporates spherical aberration, to achieve a through-focus up to +1.75 D from the distance refraction. This provides a good optical quality within a single-elongated focal point anterior to the retina while rendering a poorer optical quality of the image points posterior to the retina[10,24,25] (Figure 2).

Table 1. Contact lenses' manufacturer's information

	Misight	Mylo
Optical desing	Dual-focus Center-distance	Extended Depth of focus
Substitution	Daily	Monthly
Material	Omafilcon A (Hydrogel)	Filcon 5B (Silicone-Hydrogel)
Hydratation (%)	60	75
Dk/t	28	50
Diameter (mm)	14.20	13.50−15.50 (0.50 steps)
Radius (mm)	8.70	7.10−9.80 (0.30 steps)
Optical desing	Dual-focus Center-distance	Extended Depth of focus
Substitution	Daily	Monthly
Material	Omafilcon A (Hydrogel)	Filcon 5B (Silicone-Hydrogel)

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The CLs, Figure 1 and Figure 2**,** were measured using the NIMO TR-1504 (Lambda-X, Belgium), an optical mapping device designed to capture the power profile of contact lenses. This device operates on a patented quantitative deflectometry technique, which combines the Schlieren principle with a phase-shift method. Utilizing a 546 nm light source, it measures beam deflections to generate power maps. The instrument offers an accuracy and repeatability of 0.05 D for spherical soft contact lens powers and between 0.04 and 0.2 D for multifocal CLs.[26–28]

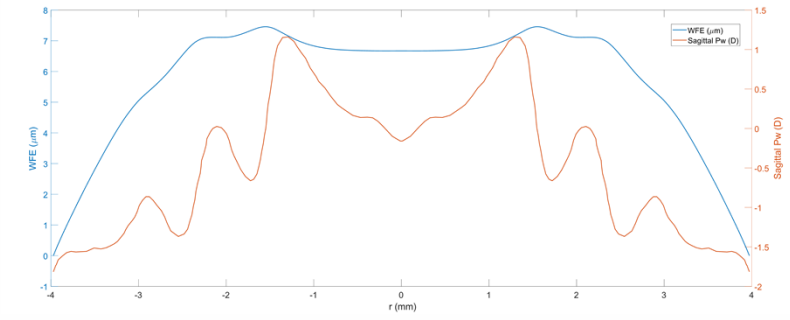


Figure 1. The sagittal power profile was measured with the NIMO distribution of a 0 D extended-depth-of-focus CLs for myopia control with up to +1.75 D of add power in diopters (orange) and the wavefront error profile in microns (blue).

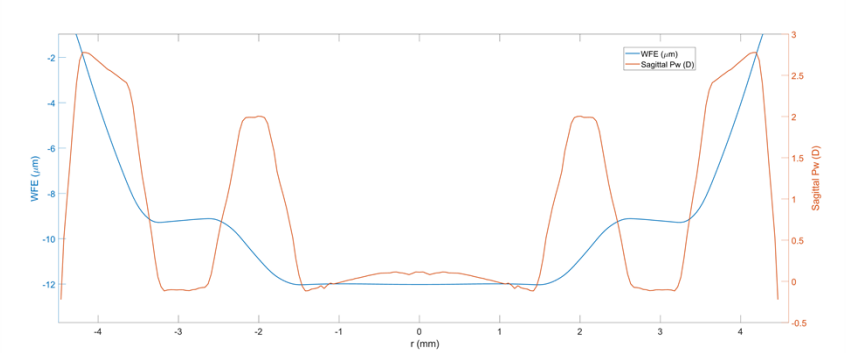


Figure 2. The sagittal power profile was measured with the NIMO distribution for a 0 D dual-focus CLs for myopia control with a +2 D add power in diopters (orange) and the wavefront error profile in microns (blue).

2.2 Image quality

Objective image quality was defined by the Visual Strehl (VS) computed in the frequency domain from the Optical Transfer Function (OTF), calculated using standard Fourier methods, written in Matlab R2022b (The MathWorks, MA, USA), and was weighted according to a standard contrast sensitivity function (CSF) of the human eye.[29]

$$RIQ = VSOTF = \frac{\iint_{-\infty}^{+\infty} NTF(f) \times OTF(f)\, df_x\, df_y}{\iint_{-\infty}^{+\infty} NTF(f) \times OTF_{DL}(f)\, df_x\, df_y} \quad \text{(equation 1)}$$

VSOTF (Visual Strehl Ratio based on the Optical Transfer Function) quantifies retinal image quality by comparing the eyes' neural weighted Optical Transfer Function (OTF) to that of a diffraction-limited system (OTF_{DL}), ensuring that the value is normalized between 0 and 1.

The Stiles-Crawford effect was incorporated into the amplitude transmission of the pupil function by applying a Gaussian apodization factor, centered on the pupil, with a value of 0.053.[30]

2.3 Theoretical accommodation response curves

The through focus performance of the eye is normally presented in the form of defocus curves. Defocus curves provide information on the visual performance of the patient at different vergence distances. They are used in clinical research related to optical solutions for presbyopia[31], but their clinical use can also be extended.

After correcting each wavefront map with its best spherical-cylindrical correction (using just the 2nd order terms), the maximum RIQ (equation 1) [ranged between 0 and 1], for each eye obtained after through-focus, was calculated in the six scenarios, with the naked eye, and with both CLs, for the unaccommodated eye and at a target vergence (TV) of 2.5 D, implemented in custom Matlab R2022b (The MathWorks, MA, USA) scripts. The simulation was performed virtually, by positioning the target at 0 D and -2.5 D, representing an object in the infinity and at 40 cm (TV=-2.5 D) (Figure 3). The entrance pupil of the synthetic eyes were determined from the accommodative statistical model[22], 4.66, 4.76, 4.47, 4.09, 4.07, 3.68 mm, for target vergences of 0 D to -5 D in -1 D steps. Accommodative demands lying in between were obtained by linear interpolation, making the entrance pupil diameter at TV=-2.5 D equal to 4.28 mm.

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The resulting image quality value was calculated and stored in a vector for each iteration. The algorithm then used MATLAB's built-in function *islocalmax* to identify local maxima in the six scenarios (two distances and three conditions). The selection criterion applied was to choose the two points with the highest values, thereby obtaining the maximum RIQ points.

In Figure 3, the three lines represent the two CLs (blue and green) and the naked eye (dash black). The asterisks indicate the identified peaks, which correspond to the near and distance optics points. These peaks vary depending on the treatment zone used in each case.

The accommodative lag is defined as the difference between the target vergence and the accommodation response that produces the highest RIQ quality value.

2.4 Statistical analysis

The IBM SPSS (version 29.0, IBM Corp, Armonk, NY) software was used for statistical analysis. Data was represented as the mean ± standard deviation (SD). The normality of data distribution was first checked with the Kolmogorov-Smirnov test ($n > 50$). The comparisons between the naked eye and CLs (DL and EDOF designs) were analyzed using the one-way ANOVA (univariate analysis of variance) with post-hoc Bonferroni corrections. The statistical significance (*p*-value) was set at $\alpha=0.05$.

3. Results

The accommodative RIQ through-focus produced two peaks, a 1st peak (Near optics peak in Figure 3) before the maximum peak (2nd peak, Distance optics peak in Figure 3), correspondent to the focusing power of the treatment zones[32], depending on the design of the myopia control CLs.

Additionally, the theoretical AR (change in the RIQ as a function of the TV) that maximizes RIQ was calculated obtaining the maximum point in the through-focus, which is not always the peak correspondent to the distance focus. The predicted accommodation lag was calculated as the difference between the maximum peak and the expected response, -2.5D, for the naked eye and the two myopia CLs designs (DL and EDOF).

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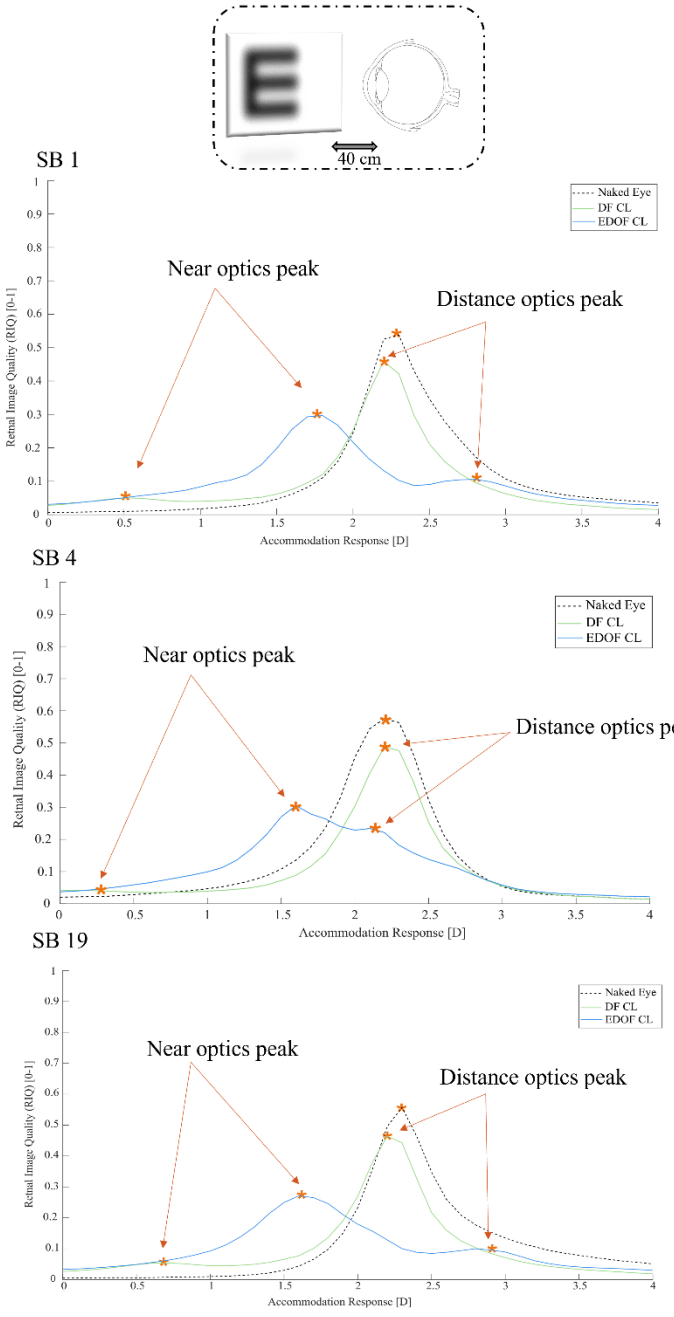


Figure 3. Schematic change in image quality for three generated wavefront eyes looking at a target located at 40 cm (TV = 2.50 D), each with different behaviour. Green and blue curves correspond to the through-focus image quality obtained for the different myopia control CLs, Dual focus design (DL), and extended-depth-of-focus CLs design (EDOF) respectively. The dashed line corresponds to the accommodative through-focus image quality obtained for the naked eye. The asterisk represents the local maxima points Found by the algorithm.

The mean RIQ for the relaxed eye (unaccommodated state) was 0.42 ± 0.10 in the naked eye condition. This value decreased to 0.26 ± 0.05 with the DF CLs design and further reduced to 0.15 ± 0.03 with the EDOF CLs design (Figure 4). Statistically significant differences were observed between the naked eye and both myopia CLs designs in the relaxed state of the eye (p-value < 0.001, one-way ANOVA with Bonferroni correction, Figure 4).

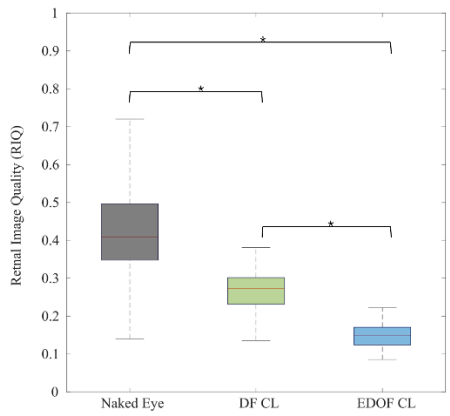


Figure 4. Box-plot showing the distribution of image quality for each of the three scenarios: naked eye (grey), eye with the DF design lens (green), and eye with the EDOF design CLs (blue), when the eye was unaccommodated. *Denotes statistically significant difference between them, p-value < 0.05.

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For TV = -2.5D the maximum peak RIQ was 0.34 ± 0.09 in the naked eye, 0.24 ± 0.07 with the DF CLs, and 0.19 ± 0.03 with the EDOF CLs design. For target vergences with demands close the effective add power of the CLs, the accommodative RIQ through-focus produced another peak (smaller in magnitude than the maximum peak), correspondent to the focusing power of the treatment zones.[32] The DL CLs design yielded an RIQ of 0.08 ± 0.03, occurring before the maximum peak, while the EDOF CLs design showed an RIQ of 0.12 ± 0.04, appearing after the maximum peak. This phenomenon is illustrated in Figure 3. Statistically significant differences were observed between the naked eye and both myopia control CLs designs when the RIQ through-focus was performed, (p-value < 0.001, one-way ANOVA with Bonferroni correction, Figure 5).

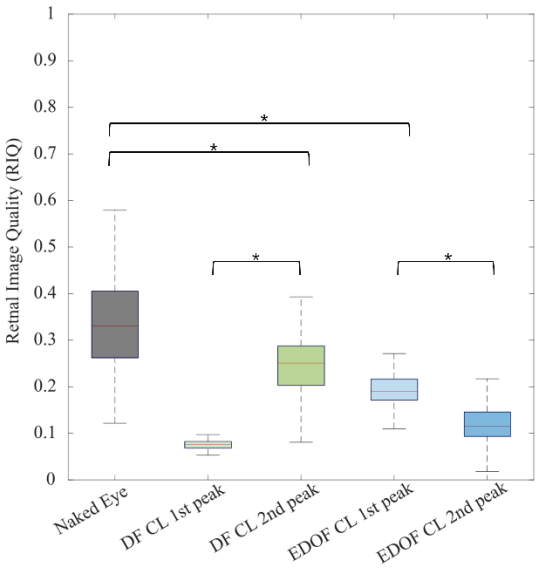


Figure 5. Box-plot showing the distribution of image quality for the naked eye (grey), with the DF CLs design 1st peak (light green) and 2nd peak (green), the maximum one, and with the EDOF CLs design 1st peak (light blue), the maximum one and 2nd peak (blue), when the eye was in accommodating at -2.5D. *Denote statistically significant difference between them, *p*-value < 0.05.

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The mean and SD of the theoretical AR without CLs were 2.33 ± 0.20 D for the naked eye, 2.23 ± 0.39 D with DF CLs, and 1.75 ± 0.22 D with EDOF CLs. The mean predicted accommodative lag was 0.17 D for the naked eye, 0.27 D for DF CLs, and 0.75 D for EDOF CLs, compared to the expected AR of -2.5D (dashed red line in Figure 6). The mean predicted accommodative lag compared to the naked eye condition with CLs was 0.10 D with DF CLs and 0.58 D with EDOF CLs.

The repeated measures of one-way ANOVA revealed statistically significant differences in the theoretical AR between the different scenarios (*p*-value < 0.001). Post-hoc comparisons using the Bonferroni correction indicated that the naked eye condition significantly differed from the EDOF CLs (*p*-value < 0.001, Figure 6) and the DF from the EDOF CLs (*p*-value < 0.001, Figure 6) in the theoretical AR. However, the comparison between the naked eye and the DF CLs was not statistically significant (*p*-value = 0.386, Figure 6).

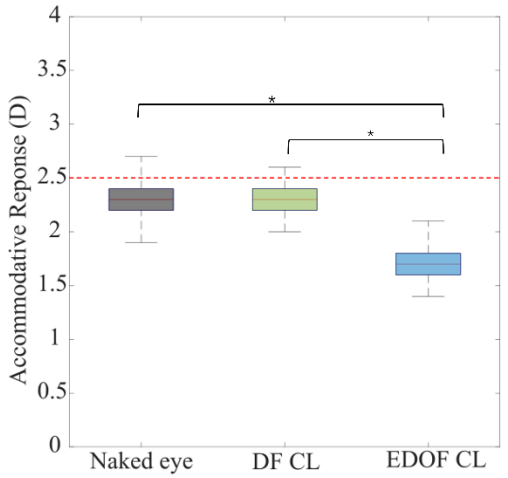


Figure 6. Box-plot showing the distribution of the theoretical AR for each of the three scenarios: naked eye (grey), eye with the DL CLs design (green), and eye with the EDOF CLs design (blue), when the eye was in accommodating at -2.5D. * Denotes statistically significant difference between them, *p*-value < 0.05.

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4. Discussion

Most of the studies published on the evaluation of CLs for myopia control focus on determining their efficacy in slowing down the elongation of the eyeball as a function of changes in parameters such as spherical equivalent and axial length. However, few studies have analysed objectively the actual impact of different CLs designs for myopia control on aspects such as RIQ, or even RIQ under the effect of accommodation. The present study compared the optical effects of two myopia management CLs with different designs, here characterized in terms of their power profiles (Figure 1 and Figure 2), using accommodation wavefronts generated from a statistical accommodative eye model.[22] The aim was to use synthetic wavefront data to document changes in accommodative lag and RIQ. These properties are believed to be linked to myopia progression, making it important to objectively test their performance. Results were also compared to those of the naked eye.

The mean RIQ in the unaccommodated state of the naked eye was significantly higher than with each of the two myopia management CLs (Figure 4). This result aligns with previous studies that have highlighted the impact of these CLs designs on RIQ.[12,33–35] While multifocal CLs can improve the overall vision of near targets in presbyopic eyes, these complex optical designs introduce aberrations and photic phenomena, which reduce the mean RIQ compared to single-vision CLs.[32,36]

When simulating near viewing conditions at a target vergence of -2.5D, two maximum peaks were observed with each lens. These peaks are consistent with the part of the power profile of each lens covered by the pupil diameter of the model for the correspondent accommodative state (4.28 mm) and align with the findings reported by Faria-Ribeiro et al.[32]

The accommodation response curve with DF CLs reaches its maximum peak around -2.5D, with a smaller peak around 0.5 D, aligning with the accommodative stimulus and the lens focal power in the treatment zones. With the EDOF CLs, the peaks were less pronounced compared to those of the DF design. Additionally, the RIQ peaks with the EDOF lens do not coincide with the accommodative demand; instead, its maximum peak occurs before reaching -2.5D.

This discrepancy leads to a reduction in the predicted accommodative response of the subjects, attributed to the depth of focus (DoF) characteristics of the EDOF lens and the pupil size estimated for that specific target vergence (Figure 1).

The results indicate that the theoretical accommodative response of the naked eye was close to the expected -2.5D, with a small, predicted lag of accommodation of approximately 0.17 D (Figure 5). This indicates that the synthetic wavefront data generated by the model accurately reproduces the accommodative responses of real eyes.[37–39] This naked eye condition can thus be seen as a baseline, highlighting the natural efficiency of the eye's accommodative mechanism.

Conversely, using myopia control CLs designs led to varying degrees of reduced accommodative efficiency, raising recent concerns about whether these CLs affect the accommodative mechanism of their wearers.[13,40–42] Both types of CLs evaluated in this study—DF and EDOF—produced a reduction in RIQ for the target vergence of --2.5D. The DF CLs caused a predicted lag of accommodation (0.27 D), which was slightly higher compared to the naked eye condition. Although the increase in predicted lag was modest, it reflects a discernible impact on the eye's ability to adjust focus rapidly and accurately. Studies by Redondo et al.[13], Signes-Soler et al.[43], and Vera et al.[44] revealed that when measured subjectively, individuals wearing DF CLs experienced greater accommodation lag, higher variability in accommodation, and longer reaction times compared to those wearing single-vision soft CLs. These results are consistent with the findings of the present study.

In contrast, the EDOF CLs showed a more pronounced variation in the predicted accommodative response compared to the baseline condition. The substantial increase in the predicted lag of accommodation (0.75 D) observed with EDOF lenses suggests a significant reduction in the accommodative response. Pauné et al.[40] observed a decrease in accommodative lag, 0.37 ± 0.42 D, after one year of wearing these CLs. In contrast, Ruiz-Pomeda et al.[45] did not find significant variations in accommodative lag after two years of wearing a without the CLs in place. Corpus et al.[46] reported that the use of this CLs could induce some changes in accommodative response in the short term, although with limited clinical relevance (small magnitude). Despite the results obtained in the different studies, they were all measured with subjective methods, which implies a large intersubject variability.[47]

The design of EDOF CLs extends the DoF across a more continuous range of target vergences compared to the DF design, but this can compromise the eye's ability to make precise accommodative adjustments. This makes EDOF CLs particularly suitable for individuals with presbyopia, who require continuous multifocal vision, have no active accommodation, and seek to improve their DoF.

One significant limitation of the multifocal CLs is their dependency on pupil size and the interaction between the distance and power-added zones. This dependency is influenced by the ratio of these zones as noted in previous studies. [32,36,48–52] Additionally, the use of a synthetic model in these evaluations, where pupil diameter is fixed for each vergence, introduces another layer of complexity. In this model, smaller vergences correspond to larger pupil diameters, which can impact the overall performance of the lenses. Nonetheless, the results should still be representative of the general behaviour of the real population. the alignment of accommodation to the RIQ maximum is an assumption in this case. This simplification may introduce some limitations in how the results directly correspond to the actual accommodation response, and future studies are suggested to investigate the relationship between RIQ and the real accommodative response, possibly incorporating the bandwidth of frequencies that the eye prioritizes during accommodation.

Despite these limitations, utilizing the model to generate a limited number of wavefronts for preliminary visual quality testing with various optical devices can be valuable. Furthermore, as we can see in Figure 4, the use of the model allows us to reproduce the variability of different behaviors in different subjects, which is an important application compared to the use of fixed models[53], moreover, average eye (with average aberrations) does not correspond to average

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image quality experienced by the eye. [54] This approach can help clinicians predict the behavior of these devices and support their development during the design phase.

5. Conclusion

In conclusion, both myopia control CLs effectively reduced the RIQ in both relaxed and predicted accommodated states of the eye. At a viewing distance of 40 cm, both CLs introduced a secondary peak in the RIQ through focus, with the EDOF CL design displaying this peak less than 0.1 D from the maximum peak, likely due to its extended DoF. Additionally, both lenses decreased the predicted accommodative response compared to the naked eye condition, with the EDOF design exhibiting a higher predicted lag of accommodation of 0.75 D. The results and methodology used in this study offer an objective assessment of the expected clinical behavior of these lenses, providing valuable insights during the design phase and preclinical evaluation.

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Disclosures. The authors declare no conflicts of interest.

Data availability. Data of the results are available under reasonable request from the corresponding authors.

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