INTRODUCTION

Currently, the global prevalence of myopia is increasing, and this refractive error is associated with sight-threatening ocular comorbidities such as retinal detachment, macular degeneration and glaucoma. As an intervention to retard myopia progression, multifocal contact lenses (MFCLs) have been used for many years, and shown to be effective in slowing myopia progression and eye growth compared with single vision lenses. The design of MFCLs varies across lens types, and the most common designs currently used in clinical practice are concentric and progressive MFCLs. The centre of the MFCL is an optical correction zone for clear vision, surrounded by several concentric circles with additional plus power for treatment (concentric MFCLs). Alternatively, the treatment zone may be surrounded by gradually increasing plus power towards the lens periphery (progressive MFCLs). A recently introduced concentric MFCL is the Defocus Incorporated Soft Contact (DISC) lens. The design of this lens comprises a 3 mm central correcting area and a series of alternating defocus (+3.00 D) and correcting zones with a 50:50 ratio, similar to the MiSight contact lens (CooperVision Inc., coopervision.com). A previous study showed that daily wearing of DISC lenses significantly slowed myopia progression and axial elongation, and that the wearing time affected the lens efficacy.

ORIGINAL ARTICLE

The induced defocus by Defocus Incorporated Soft Contact lenses is dependent on visual distance and ambient illuminance

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Abstract
Purpose: Defocus Incorporated Soft Contact (DISC) lenses, a commonly used type of multifocal lens in clinical practice, may slow down myopia progression by inducing myopic retinal defocus. The purpose of this study was to explore whether the induced defocus across the retina could be affected by visual environments encountered in the real world, such as differences in viewing distance and ambient illuminance.

Methods: In this cross-over trial, 30 myopic adults wore both DISC lenses and single vision contact (SVC) lenses in random order. An open-view Hartmann–Shack scanning wavefront sensor was used to measure defocus at different retinal locations along the horizontal meridian under four experimental conditions: far target (3 m) and near targets (0.33 m) under scotopic (<1 lux) or photopic (~300 lux) conditions.

Results: The results showed that DISC lenses induced more myopic retinal defocus than SVC lenses in all conditions (all \( p < 0.05 \)), except for the scotopic near target. In addition, for DISC lenses, the defocus was greater in the photopic than the scotopic conditions for both the far and near targets (both \( p < 0.05 \)).

Conclusion: In conclusion, the retinal defocus induced by these multifocal lenses was dependent on both visual distance and ambient illuminance, indicating that the visual conditions might affect the anti-myopia efficacy of these devices.

KEYWORDS
defocus, multifocal lens, myopia
Multifocal contact lenses may inhibit myopia progression by creating relative peripheral myopic defocus.\textsuperscript{9–11} Previous studies have also confirmed that these lenses do indeed induce peripheral myopic defocus, although the defocus profile varies between different lens designs.\textsuperscript{12–15} However, the majority of investigations only measured the defocus profile under a single experimental condition. However, Flitcroft showed that the pattern of retinal defocus could be affected by multiple factors, including different visual conditions (e.g., indoor or outdoor scenarios), the three-dimensional structure of the environment and the required viewing distance.\textsuperscript{16} Given the impact of visual behaviour and environment on refraction-influencing factors such as accommodation and pupil size,\textsuperscript{17–19} different viewing distances and ambient illumination may also affect the induced retinal defocus profile for this MFCL. Therefore, the findings regarding the defocus profile for one specific experimental condition may not necessarily reflect the performance of the lens in the various visual environments encountered in the real world. Accordingly, this study measured the actual peripheral retinal defocus profile induced by DISC lenses for different viewing conditions using a custom-made open-view Hartmann–Shack wavefront sensor. The sensor was able to provide a resolution of 1° in the visual field, as noted previously.\textsuperscript{11,20–22}

\section*{METHODS}

\subsection*{Subjects}

This study was conducted according to the Declaration of Helsinki and approved by the Committee of Research Ethics of the AIER Eye Hospital Group (AIER 2021IRB03). Inclusion criteria were monocular best-corrected visual acuity of 0.00 logMAR or better, no prior use of orthokeratology or rigid gas permeable contact lenses and no contraindications for contact lens wear. Exclusion criteria were the presence of other ocular diseases except refractive error or a history of ocular surgery. A total of 30 Chinese myopic adults were recruited, all of whom provided written informed consent before the trial began.

\subsection*{Materials}

DISC lenses: The Defocus Incorporated Soft Contact (DISC) lenses were manufactured by Zhuhai Lovelight Technology Co. Ltd. (disc-eye.com). They have a central correcting zone of 3 mm diameter and a series of alternating defocusing (+3.00 D) and correcting zones. Outside the 3 mm central correction zone, five defocusing rings, each with a width of 0.25 mm were found from the centre to the lens periphery, and the distance between the alternating defocusing annuli was also 0.25 mm (Figure 1). The DISC lenses were made from 2-hydroxyethyl methacrylate with a 55% water content, base curve was 8.60 mm and the lens diameter 14.20 mm.

The SVC lenses were manufactured by Clearlab SG Pte. Ltd. (clearlab.com), made of hioxifilcon with 58% water content, with identical lens parameters, that is, 8.60 mm base curve and 14.20 mm diameter, but no defocusing zones.

The Voptica Peripheral Refractor (VPR, Voptica SL, voptica.com): is a custom-made Hartmann–Shack wavefront sensor that provided peripheral wavefront aberration data in a time-efficient manner using 780 nm infrared light. The design and methodology of this instrument had been published previously.\textsuperscript{11,20–22} The target was placed directly

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{fig1.png}
\caption{Profile of a Defocus Incorporated Soft Contact lens having a diameter of 14.20 mm. Around the central correction zone (white) of 3 mm diameter, there are five defocusing rings (grey), each having a width of 0.25 mm.}
\end{figure}

\textbf{Key points}

\begin{itemize}
\item Compared with single vision contact lenses, the retinal defocus induced by Defocus Incorporated Soft Contact lenses varied with visual distance and ambient illuminance.
\item Specifically, the peripheral defocus induced by Defocus Incorporated Soft Contact lenses was minimal under scotopic conditions and during a near vision task.
\item Habitual visual activities and environmental conditions might affect the anti-myopia efficacy of these multifocal lenses, although this requires further investigation.
\end{itemize}
in front of the tested eye and viewed binocularly. Due to the open field design of the VPR, the examination did not interfere with the target fixation of the tested eye. The VPR was able to measure ocular aberrations per degree of the central 60° horizontal visual field in 1.3 s for each scan, including 61 Hartmann–Shack images. Although vertical data could have been obtained by instructing the subject to fixate up and down, only horizontal scans were performed in this study in consideration of the relative dislocation of the contact lens when the eye was away from primary gaze.

**Examination workflow**

For each subject, the initial power of the MFCL was determined as the spherical equivalent power (referenced to the corneal plane), using a standard of the most plus/least minus manifest refraction (obtained with a trial frame). After 10 mins of lens wear and assessment for an acceptable fit, the final prescription was calculated based on spherical over-refraction to achieve best-corrected visual acuity. Subjects were randomly allocated to wear one type of contact lens (multifocal or single vision) having the same refractive power. Prior to lens fitting, VPR measurements were performed unaided under scotopic illumination (<1 lux at the subject's eye), while they fixed a Maltese cross at a distance of 3 m. After 30 min of adaptation to the contact lenses, distance visual acuity was measured under photopic (~300 lux) light condition. The VPR measurements were obtained from the subjects' right eyes for two viewing distances: far (3 m) and near (0.33 m) and two ambient illuminations: scotopic (<1 lux) and photopic (~300 lux). The order of these four conditions was randomised and the interval between each condition was >10 min. Finally, the type of contact lenses was switched and the same steps repeated. **Figure 2** shows the examination workflow.

**FIGURE 2** Flow diagram of the study. DISC lenses, Defocus Incorporated Soft Contact lenses; SVC lenses, single vision contact lenses; VA, visual acuity; VPR, Voptica Peripheral Refractor.
Statistical analysis

Spherical equivalent refractive error (SER), astigmatism and higher order aberrations (HOA) were obtained for each retinal location (61 points in the horizontal meridian) and experimental condition. Pupil diameter was measured from three random Hartmann–Shack images using the VPR at each trial (61 images) and condition. Data were analysed using custom scripts in MATLAB (MathWorks, mathworks.com). All data were taken from the right eye. The Lilliefors test was conducted to analyse the normality of the data. The following parameters were normally distributed: SER, peripheral refraction, power vectors J0 and J45 and pupil diameter, which were presented as means (standard deviations). Non-normally distributed variables including age, visual acuity and the root-mean square (RMS) of the HOA, were presented as medians (25th percentile, 75th percentile). A paired t-test was used to analyse the differences in peripheral refraction, J0 and J45 between the two types of contact lenses under the various experimental conditions, and the difference in pupil size under the two illumination levels. Wilcoxon signed rank test was applied to compare the visual acuity and the RMS of the HOA between the DISC and SVC lenses. The level of statistical significance was set at 0.05 (two-tailed) using p-values that were adjusted for multiple comparisons using the Benjamini and Hochberg false discovery rate (FDR) correction.

RESULTS

All participants (n = 30; 13 men and 17 women; 22–36 years old), completed the entire experiment successfully. Table 1 shows the demographics and characteristics of the participants.

Differences between the DISC and SVC lenses

Visual acuity

Best corrected distance visual acuity under photopic (~300 lux) light conditions for subjects wearing the DISC and SVC lenses was 0 (−0.1, 0) and −0.1 (−0.1, 0) logMAR, respectively. This difference was not significant (p = 0.14).

Table 1 Demographics, characteristics of the participants and data from the right eyes (n = 30).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>26 (24, 30)</td>
</tr>
<tr>
<td>Sex: male/female</td>
<td>13/17</td>
</tr>
<tr>
<td>Spherical equivalent refraction (D)</td>
<td>−4.19 (1.98)</td>
</tr>
<tr>
<td>Best-corrected visual acuity (logMAR)</td>
<td>−0.1 (−0.1, −0.1)</td>
</tr>
</tbody>
</table>

Note: Data are presented as mean (standard deviation) or median (25th percentile, 75th percentile).

Defocus

Figure 3 shows the average peripheral refraction under the different experimental conditions. Figure 3a–d represent fixing a far target in the scotopic room, near target in the scotopic room, far target in the photopic room and near target in the photopic room, respectively. Overall, DISC lenses induced significantly more myopic defocus than SVC lenses at all retinal positions under all of the experimental conditions except when viewing the near target in the scotopic illumination (Figure 3b).

To better demonstrate the defocus difference between the two types of contact lenses, the horizontal meridian was divided into three regions: temporal, central and nasal. The mean differences in each region were then calculated by averaging the difference in retinal refraction generated by the DISC and SVC lenses in the corresponding retinal locations. Table 2 summarises the defocus differences between the two types of contact lenses under the four experimental conditions.

To indicate the effect of ambient illumination on pupil size, Table 3 shows the average pupil diameter for the different experimental conditions. There was a significant difference in pupil diameter between scotopic and photopic light conditions for all four conditions (all p < 0.01).

In order to reveal the characteristics of the change in relative peripheral refraction, the difference in defocus between the two lenses was calculated at each eccentricity. Figure 4 shows the average difference in peripheral refraction between the two lenses for the four experimental conditions.

Astigmatism

Astigmatism data from the VPR were analysed. Figures 5 and 6 show the average J0 and J45 vector components, respectively, for the four experimental conditions.

Root-mean square of the higher order aberrations

Figure 7 shows the RMS of the HOA for the four experimental conditions. When compared with the SVC lenses, the use of DISC lenses led to a significant increase in HOA at almost every retinal position (all p < 0.05), especially in the temporal region under all four experimental conditions.

Effects of the ambient illumination on retinal defocus

The effects of ambient illumination on the retinal defocus induced by the contact lenses were investigated by comparing the results under different illuminations (scotopic or photopic). While wearing the DISC lenses, myopic defocus was significantly greater under photopic than scotopic
The differences in defocus produced by changes in illumination between the two lenses were least in the nasal retina.

**DISCUSSION**

The results indicated that DISC lenses induced varying degrees of peripheral myopic defocus, which varied with viewing distance and illuminance. Specifically, the induced peripheral defocus was minimal under scotopic conditions.(all \( p < 0.05 \)). The differences in defocus for the temporal, central and nasal regions are summarised in Table 4. It was observed that the differences in defocus produced by changes in illumination between the two lenses were least in the nasal retina.
DEFOCUS INDUCED BY MULTIFOCAL LENSES

conditions during a near vision task. Regarding the spatial distribution of the defocus, it was consistently most pronounced on the temporal side of the retina across all tested conditions. In addition, the degree of defocus was greater under photopic conditions, compared with scotopic conditions, regardless of whether the subjects were viewing far or near targets.

In this study, not only was the relative peripheral refractive data (the foveal values were subtracted) analysed but also the absolute peripheral refractive data (without subtracting the foveal values). This allowed us to explore the actual optical signals received by the retinal cells in the real world. It was determined that both the relative and the absolute peripheral refractive data were similar, and that DISC lenses induced more myopic defocus than SVC lenses when viewing the far target in the scotopic condition or both the near and far targets in the photopic condition. These findings support the rationale of using DISC lenses for myopia control. However, it was observed that these lenses induced little myopic defocus when viewing a near target under scotopic conditions, suggesting that the efficacy of DISC lenses for myopia control might be attenuated in this scenario.

It is worth noting that unlike the theoretical design to induce peripheral defocus, DISC lenses also created mild myopic defocus in the central retina. Empirically, no difference between these two types of contact lenses was expected in the central retina. One possible explanation could be decentration of the contact lenses in some cases and/or subjects. This could add additional on-axis defocus. Alternatively, different accommodative responses could alter the central refraction for the two types of contact lenses. It is unclear whether this mild myopic defocus will impact visual acuity? In fact, the visual acuity with the DISC lenses was slightly poorer than for the SVC lenses (median values were logMAR 0.00 and −0.10, respectively), although this difference was not statistically significant. Nevertheless, further research regarding visual acuity with the DISC lenses is warranted.
results suggest that DISC lenses did not result in blurred vision, which may be due to the depth-of-focus of the eye. Previous work has shown that the depth-of-focus increases linearly from 0.89 D at the fovea to 3.51 D at a retinal eccentricity of 8°. Therefore, defocus within this range of depth-of-focus is not likely to lead to the perception of blur. In addition, the multifocal design may produce additional HOA and depth-of-focus, which could be a potential mechanism to slow eye growth.

Defocus Incorporated Soft Contact lenses induced more myopic defocus in the temporal retina under all of the conditions tested, which aligned well with the results of other multifocal contact lens studies. Further, this asymmetry can be explained by a combination of several factors, including the difference between the optical axis and visual axis (angle alpha), asymmetries in the vitreous chamber depth and corneal curvature and the differences between myopic and emmetropic individuals. As a result, greater inhibition of ocular growth has been reported in the temporal side of the globe compared with the nasal side. Further, the relative hyperopic defocus appeared around 15° nasally, which may be related to the anatomical location of the optic disc.

With this optical design, the additional defocus rings in the DISC lenses have a power of +3 D. But when compared with SVC lenses, the actual difference in myopic defocus was not more than 0.8 D on average temporally, and this smaller magnitude, compared with the designed amount, has also been shown in other studies. This may partly be due to the defocus being averaged at just one position in all subjects, but other reasons worth exploring could be reduced accommodative responses after wearing DISC lenses or the optical profiles of the lens itself.

These results indicate that in order to optimise the design during the development of a new multifocal contact lens, it is crucial to measure the actual peripheral defocus in the wearer under varied visual conditions because the optimal additional power may improve the efficacy for myopia control.

An interesting observation is that lighting conditions affected the induced peripheral defocus. Intuitively, defocus would increase when the pupil size became larger under...
scotopic condition, but the present results did not show this effect. We speculate that as the pupil size increases, the area of retinal defocus becomes larger. However, this study measured the magnitude of defocus at each retinal point with the VPR device, not the area of the defocus. Therefore, a larger pupil does not necessarily correspond with a greater degree of retinal defocus. Previous studies have shown that increased illumination causes the pupil to constrict and the accommodative response to increase or accommodative lag to decrease, thereby increasing myopic defocus at almost all eccentricities in SVC lens wearers. But then why was the retinal defocus induced by the DISC lenses significantly influenced by the ambient illumination, rather than just a slight change being observed? As mentioned above, the amplitude of accommodative response has been shown to decrease after wearing multifocal lenses, and we presume that the light can stimulate this accommodation to reoccur, especially when fixating near targets.

The results of peripheral astigmatism follow previous reports and since the data patterns for the two lenses were similar for values of $J_0$ and $J_{45}$, these vectors may not be associated with DISC lens induced myopia control. From the results for the RMS of the HOA, the retinal peripheral image quality with the spherical equivalent correction was reduced by DISC lenses (compared with SVC lenses), which agrees with the published literature. However, whether the differences in the HOA have an effect on myopia progression remains controversial.

One limitation of this study was that all of the subjects were young adults rather than children. Although their ages were relatively young, whether the findings from these young adults could be applied in children needs further confirmation. Another limitation might be that the far target was only 3 m away from the subject due to the spatial constraints of the laboratory. Whether a similar conclusion could be drawn for targets placed at distances of 5 m or greater is worthy of further exploration.

In summary, under both lighting conditions (photopic and scotopic) and both distances (near and far), the induced retinal defocus was generally greater with
HAO et al. compared the DISC lenses with SVC lenses, except when viewing a near target under scotopic illumination. These findings suggest that the myopia control effect may vary with ambient lighting as well as the viewing habits of the wearer.

**AUTHOR CONTRIBUTIONS**

**Jiangdong Hao**: Conceptualization (equal); data curation (equal); formal analysis (equal); funding acquisition (equal); investigation (lead); methodology (equal); project administration (equal); resources (equal); software (equal); supervision (equal); validation (equal); visualization (equal); writing – original draft (lead); writing – review and editing (equal).

**Zhenghua Lin**: Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); project administration (equal); software (equal); supervision (equal).

**Xiaoyun Xi**: Data curation (equal); investigation (equal); resources (equal); supervision (equal).

**Zhikuan Yang**: Conceptualization (equal); funding acquisition (equal); project administration (equal); resources (equal); supervision (equal); validation (equal).

**Pablo Artal**: Conceptualization (equal); data curation (equal); methodology (equal); project administration (equal); resources (equal); software (equal); supervision (equal); validation (equal); writing – original draft (equal); writing – review and editing (equal).

**Weizhong Lan**: Conceptualization (lead); data curation (equal); methodology (equal); project administration (equal); resources (equal); software (equal); supervision (equal); validation (equal); writing – original draft (equal); writing – review and editing (equal).

**TABLE 4** Differences in retinal defocus (dioptres [D]) with illumination levels (photopic minus scotopic findings) for the four experimental conditions.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Temporal (−30° to −11°)</th>
<th>Central (−10° to +10°)</th>
<th>Nasal (+11° to +30°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Far (SVC)</td>
<td>−0.30 D (0.09)*</td>
<td>−0.12 D (0.05)*</td>
<td>−0.15 D (0.07)*</td>
</tr>
<tr>
<td>Near (SVC)</td>
<td>−0.16 D (0.09)*</td>
<td>−0.09 D (0.02)*</td>
<td>−0.08 D (0.06)*</td>
</tr>
<tr>
<td>Far (DISC)</td>
<td>−0.28 D (0.03)*</td>
<td>−0.32 D (0.05)*</td>
<td>−0.11 D (0.11)*</td>
</tr>
<tr>
<td>Near (DISC)</td>
<td>−0.56 D (0.05)*</td>
<td>−0.56 D (0.05)*</td>
<td>−0.44 D (0.10)*</td>
</tr>
</tbody>
</table>

Note: Data are presented as mean (standard deviation).

Abbreviations: DISC, Defocus Incorporated Soft Contact lens; SVC, single vision contact lens.

*p < 0.01 (statistically significant from zero).
(equal); formal analysis (equal); funding acquisition (lead); investigation (equal); methodology (equal); project administration (lead); resources (lead); software (equal); supervision (lead); validation (equal); visualization (equal); writing – original draft (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT
The authors declare no conflicts of interest.

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