Effects of novel multifocal soft contact lens on peripheral refraction of myopic eyes when looking at distant and near targets

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Research article

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Abstract

Background It is generally accepted the association between hyperopic peripheral defocus and myopia progression. To search for a good optical method to slow the myopia progression for the children who need long-time near work, we compared the effects of novel multifocal soft contact lenses (MFSCLs) with single vision soft contact lenses (SVSCLs) on peripheral refraction when looking at both distant and near targets.

Methods The refraction of 25 young myopic subjects' right eye were measured at horizontal retina eccentricities in 10º steps from 30º temporal to 30º nasal, with no correction (baseline), novel MFSCLs and SVSCLs when looking at distant (5 m) and near (0.4 m) targets.

Results Subjects wearing MFSCLs presented significantly more myopic relative peripheral refractive error (RPRE) profile than SVSCLs at all horizontal retina eccentricities when looking at distant targets (all $p<0.01$). Compared with looking at distant targets, subjects wearing SVSCLs or MFSCLs showed a hyperopic shift of peripheral defocus when looking at near targets, owning to the effects of accommodative lag and hyperopic RPRE change during accommodation (except T20º and T30º wearing SVSCLs and N30º wearing MFSCLs, $p=0.822$, $p=0.950$, $p=0.390$, respectively, all other eccentricities $p<0.05$). But subjects wearing MFSCLs could still maintain a certain magnitude of myopic peripheral defocus at horizontal retina eccentricities when looking at near targets (T20° and T30°, $p=0.023$ and $p<0.001$, respectively).

Conclusions The novel MFSCLs imposed strong myopic peripheral defocus when looking at distant targets. They also maintain a certain magnitude of myopic peripheral defocus when looking at near targets, regardless of the hyperopic effect of accommodation lag and hyperopic shift in RPRE during accommodation.

Background

It is generally accepted that the worldwide prevalence of myopia has increased rapidly in the past few decades, especially in Asia [1-3]. It is estimated that by 2050, myopia will affect nearly 5 billion people globally, about 50% of the world population, and high myopia will affect 1 billion people, about 10% of the world population [4]. These projections represent a 2-fold increase in myopia, from 22% in 2000, and a 5-fold increase in high myopia, from 2% in 2000.

Many animal and human studies support the association between the relative hyperopic peripheral state of defocus and myopia progression, whereas inducing myopic defocus at the peripheral retina of progressive myopes might slow the progression of central myopia [5-8]. Thus, several optical means have attempted to reduce the magnitude of hyperopic peripheral defocus or peripherally impose myopic defocus while maintaining good correction of foveal refractive errors. Orthokeratology, multifocal soft contact lenses, custom-designed rigid gas permeable lenses, and some novel contact lens designs can effectively regulate peripheral refraction in myopic eyes [9-11]. If the hypothesis is correct, it is important to quantify the effect of these lenses on imposing peripheral myopic defocus.

Second, the relative peripheral refractive error (RPRE) profile might change during the process of accommodation. Earlier studies were not consistent with regard to how the RPRE profile was affected by accommodation. Walker and Mutti [14] showed that near work at the 3-diopter stimulus level immediately produced a significant hyperopic shift in the RPRE about 0.4 diopters from baseline. Calver et al. [15] also found a small hyperopic shift in the RPRE about 0.5 diopters that was restricted to the temporal retina during accommodation. However, most studies showed that increasing accommodative demand did not alter the RPRE profile [16, 17] or even made a slightly peripheral myopic shift[10, 18, 19]. The variability might due to diverse measurement techniques (e.g., open-field autorefractors, scanning photorefractor, and Hartmann-Shack aberrometers), subjects with different refractive status, various lenses were used, different measure time during the process of accommodation, and so on.

Third, how much is the effect of contact lenses' design on changing the defocus profile? In the study, we compared the effects of novel multifocal soft contact lenses (MFSCLs) with single vision soft contact lenses (SVSCLs) on peripheral refraction when looking at both distant and near targets.

Methods

Subjects

Twenty-five myopic young adults (male 13, female 12) were recruited at The Eye Hospital of Wenzhou Medical University. The inclusion criteria were participants having prescription ranged between −0.50 and −6.00 DS and no more than -1.50 DC of astigmatism (spherical equivalent of refraction's mean ± SD: -3.74 ± 1.32 D), best corrected binocular vision acuity of 1.0 (Decrimal Equivalent) or better. Age between 18-30 years (mean ± SD: 24.9±1.9 years). Participants with manifest strabismus, amblyopia, any ocular diseases, history of ocular surgery, recently contact lenses wearing (rigid gas-permeable lens within 4 weeks; soft contact lens within 2 weeks) were excluded from participation in this study.

Contact Lenses

In this study, we compared two different types of soft contact lenses (novel MFSCLs and common SVSCLs). (Table 1)

Table 1. Description of contact lenses

	SVSCLs	MFSCLs
Name	Biotrue ONEday	SOFTOK SMR
Company	Bausch & Lomb, Inc.	ArtMost Vision, Inc.
Material	Nesofilcon A	Methafilcon A
Base Curve	8.64 mm	8.80 mm
Diameter	14.2 mm	14.2 mm
Water content	78%	55%

Note: SMR, soft myopia retention; SVSCLs, Single vision soft contact lenses; MFSCLs, Multifocal soft contact lenses.

The MFSCLs (SOFTOK SMR, ArtMost Vision, Inc., Australia) is a center-distance multifocal contact lens. It has five different zones (Fig. 1). The center optical zone (0.5 mm from the center, corresponding to approximately 2.5° retinal eccentricity each side) (Fig. 1a) is the central area used for far vision. The preferential visual span zones (PVS zone) (Fig. 1b) provide an active para-foveal function that widens the visual span for near vision. The PVS zone (annular diameter between 0.75 mm and 2.0 mm, corresponding to approximately 2-10° retinal eccentricity each side) was designed to move the center on-axis near image backward with significant blurriness (relax accommodation) and pull the para-axis near image forward for a clearer image. The intermediate zone (Fig. 1c) front surface curvature was designed to have a progressively steeper peripheral edge curve to produce a strong myopic peripheral defocus. The alignment zone (Fig. 1d) rested on the peripheral cornea and formed a tear channel for stabilization and better lubrication. The peripheral zone (Fig. 1e) rested on the limbal and scleral portions of the anterior surface for stabilization. Corneal topography of the MFSCls showed the special design simulated an orthokeratology treatment zone contour on top of the cornea (Fig. 2). The MFSCLs' medical device registration number in China is 20163220018. The SVSCLs (Biotrue ONEday Soft contact Lens, Bausch & Lomb, Inc., USA) chose in the study is widely used currently.

Study design

This is a cross-sectional, self-controlled study.

Every subject would go through the peripheral refraction measurement with uncorrection (UC) and SVSCLs during the first visit, with MFSCLs during the second visit after a two-week washout period. The centration, coverage movement and rotation were assessed by the same optometrist after wearing each contact lens for 30 minutes to confirm clinically acceptable fits. The horizontal peripheral refraction between 30º temporal (T) to 30º nasal retina (N) (in 10º steps) were measured by an open-field autorefractor (Grand Seiko WAM-5500, Grand Seiko Co., Ltd., Hiroshima, Japan). Subjects were instructed to occlude their left eyes by an eye patch and use the right eyes to fixate on the seven distant targets and the seven near targets. The seven distant targets (arranged 5m away, letter size 5M) and the seven near targets (arranged in a curved line with radius 0.4 m, letter size 1M) were set up in the positions corresponding to retinal eccentricities from 30º temporal to 30º nasal, in 10º steps. Subjects were requested to turn their eyes toward the peripheral fixation targets while keeping the refraction instrument and head (visually inspected by the examiner) fixed in position and keep the targets as clear as possible all the time during testing. Between each measurement, the subjects had 10 seconds to close their eyes for relaxation. The examination room illumination was dimmed enough to obtain sufficiently large pupil size to allow peripheral refraction measurements without using dilatation drops. To reduce the variance, we collected five measurements at each location over a short period and averaged the three measurements that were close to the median.

Data management and analysis

The sphero-cylindrical refractive error measurements were converted to the vector components of refraction, i.e., spherical equivalent of refraction (M), J45° astigmatic component refraction (J45°), and J180° astigmatic component refraction (J180°) using the equations recommended by Thibos et al. [20]:

(1) $M = sph + (cyl/2)$,

(2) $J45^{\circ} = (-cyl/2) \sin (2\alpha)$,

(3) $J180^{\circ} = (-cyl/2) \cos (2\alpha)$,

Sph, cyl, and α represented the manifest sphere, cylinder, and axis measurements, respectively. The RPRE was calculated as the difference in spherical equivalent refractive error between the eccentric peripheral retina and central retina. To calculate the near defocus profile, the measured average spherical equivalent refractive error at each location need to increase by a near demand of +2.50 diopters (0.4m target distance). Accommodation lag was calculated by subtracting distant central M value from near central defocus value.

Data analyses were conducted using SPSS 22.0. Repeated-measures ANOVA and pairwise comparisons adjusted by Sidak correction were used to determine if differences in M, J45°,J180°differed by 2 contact lens types (between-subjects factors), horizontal retina eccentricities or target distance (within-subjects variables). Repeated-measures ANOVA and pairwise comparisons adjusted by LSD correction were used to determine if defocus at any horizontal retina eccentricities was significantly different from zero. Paired t-tests were adopted to evaluate the differences of accommodation lag between the two types of lenses. For all statistical tests, the significance was set at the alpha < 0.05 level.

Results

In the study , we measured the horizontal peripheral refraction (M, RPRE, J45 º, J180 º) between 30º temporal (T) to 30º nasal retina (N) (in 10º steps) with UC, SVSCLs and MFSCLs when looking at distant and near targets (Table 2).

Looking at distant targets

Neither SVSCLs nor MFSCLs induced significant changes in the J45º astigmatic component profile compared to UC (except T30° wearing MFSCLs, p=0.047, all other eccentricities p>0.05) (Fig. 3C). The MFSCLs introduced significantly more negative J180° astigmatic component profile than SVSCLs (except N10º and 0º, p=0.770 and p=0.124, respectively, at all other eccentricities p<0.001) (Fig. 3D).

Looking at near targets

The subjects wearing SVSCLs experienced hyperopic defocus at nasal horizontal retina eccentricities when looking at near targets (N30° to 0°: p=0.006, p=0.007, p=0.048, p=0.018, respectively, all other eccentricities p>0.05). The subjects wearing MFSCLs showed myopic defocus at temporal horizontal retina eccentricities when looking at near targets (T20° and T30°, p=0.023 and p<0.001, respectively, all other eccentricities p>0.05) . (Fig. 4A)

The differences in J45º astigmatic components profile between the two lenses were not significant at all horizontal retina eccentricities (all p>0.05) (Fig. 4C). The MFSCLs showed significantly more negative J180° astigmatic component profile than SVSCLs (except at N10º and 0º, p=0.337 and p=0.830, respectively, all other eccentricities p<0.01). (Fig. 4D).

Comparisons between looking at distant and near targets

Wearing SVSCLs or MFSCLs showed more hyperopic defocus profile when looking at near targets compared to looking at distant targets at most horizontal retina eccentricities (except wearing SVSCLs at T30 º, p=0.08, all other eccentricities p<0.05) (Fig. 5A, 6A). Wearing SVSCLs or MFSCLs also showed more hyperopic RPRE change when looking at near targets compared to looking at distant targets at most horizontal retina eccentricities (except T20º and T30º wearing SVSCLs, p=0.822 and p=0.950, respectively, all other eccentricities p<0.05; except N30º wearing MFSCLs, p=0.390, all other eccentricities p<0.05) (Fig. 5B, 6B)

Looking at distance or near targets did not result in significant changes in J45º astigmatic components profile wearing either SVSCLs or MFSCLs at all horizontal retina eccentricities (all P>0.1) (Fig.5C, 6C). For subjects wearing SVSCLs, the J180º astigmatic component profile didn't significantly change between looking at distant or near target (except N30º p=0.024, all other eccentricities p>0.0.5) (Fig. 5D). However, for subjects wearing MFSCLs, the J180º astigmatic component profile showed less negative when looking at near targets compared to looking at distant targets (T10 º to T30 º , P<0.001, all other eccentricities p>0.05) (Fig. 6D).

Accommodation

When looking at near targets (accommodative demand is 2.5D), subjects' accommodation response were 2.14±0.22D while wearing SVSCLs and 1.67±0.31D wearing MFSCLs (t=-8.111, p<0.0001). Thus, MFSCLs increased accommodation lag compared to SVSCLs.

Discussion

Effects of SVSCLs and MFSCLs on RPRE when looking at distant targets

The ability of SVSCLs on changing RPRE varies among studies. Backhouse et al. [21] reported a highly significant shift from hyperopic RPRE to myopic RPRE when corrected with SVSCLs (Acuvue 1-Day Moist, Johnson& Johnson, USA) compared to UC. Moore et al. [22] found that SVSCLs (Biofinity, CooperVision, USA; Acuvue 2, Vistakon, USA; Air Optix Night & Day Aqua, Alcon, USA) caused a myopic shift on the temporal retina at greater eccentricities in comparison with UC. Shen et al. [23] reported that SVSCLs (Acuvue 2, Vistakon, USA) reduced the degree of relative peripheral hyperopia in half compared to UC. However, Kang et al. [24] and De la Jara et al. [25] reported that SVSCLs (Proclear Sphere SCLs, CooperVision, USA; Acuvue 2, Vistakon, USA) increased relative peripheral hyperopia compared to UC in both low and moderate myopes. In our study, we did not find significant differences in the RPRE between

SVSCLs (Biotrue ONEday SCL) and UC when looking at distant targets. Both of them exhibited hyperopia RPRE profiles in both the temporal and nasal retina, which was consistent with other single vision soft contact lenses (PureVision2 [22], Bausch & Lomb, USA). The various outcome of SVSCLs are likely to be influenced by many factors, including differences in lens design (manufacturers or lens parameters), lens fit, and individual variations of the study subjects. Given the lack of consistency among the studies, adopting SVSCLs to adjust peripheral defocus does not seem to be the ideal approach.

Studies generally agreed that many commercially available MFSCLs are incapable of reducing the amount of the relative peripheral hyperopia or inducing relative peripheral myopia [9, 10] [26-28]. In our study, the novel MFSCLs could imposed large relative myopic defocus on the periphery, especially in the temporal retina, up to -5.50 diopters at 30° eccentricity. If the myopic relative peripheral defocus does help slow myopic progression, we expect that the novel MFSCLs would be an efficient method.

Effects of SVSCLs and MFSCLs on defocus profile when looking at near targets

The near peripheral defocus profile can be attributed to three factors: (1) the hyperopic RPRE change during accommodation; (2) the hyperopic defocus change across the horizontal retina eccentricities due to accommodative lag; (3) the effect of contact lens on changing the defocus profile.

First, we found that the RPRE profile of myopic eyes became slightly hyperopic wearing either SVSCLs or MFSCLs during accommodation. This was consistent with the report by Walker et al. [14] who found the hyperopic change in RPRE immediately followed commencement of accommodation and remained unchanged after 1h of sustained accommodation. Walker et al stated it occurs because of the change of retinal shape. The prolate change in retinal shape is caused by choroidal tension during the initial accommodation, which increases the axial length [30-32]. But, some disagreed with it, Smith et al. [29] found an increase in curvature of field (a decrease in Petzval radius) during accommodation, which indicates a myopic shift in relative peripheral refractive error.

Second, the accommodative lag pushes the near image shell backward. The defocus profile tends to be hyperopic across the horizontal retina eccentricities. Thus, it likely push the peripheral defocus to hyperopic status. In this study, we found the same subjects accommodated 2.14±0.22 D wearing the SVSCLs and 1.67±0.31D wearing the MFSCLs facing 2.50-diopter accommodation stimulus. Thus, MFSCLs showed more accommodation lag compared to SVSCLs with the purpose that move the center on-axis near image backward with significant blurriness in order to relax accommodation and pull the para-axis near image forward for a clearer image.

Third, we found the novel MFSCLs is capable of imposing strong myopic defocus on the periphery owing to the special design. Even though the RPRE became slightly hyperopic during accommodation and the accommodation lag pushed the image shell backward when looking at the near targets, the peripheral defocus could still showed a certain magnitude of myopic. Thus, we expect the MFSCLs could be efficient in myopia control especially for children need long-time near working.

Effects of SVSCLs and MFSCLs on astigmatic component profile

Compared to J45º astigmatic component, J180º astigmatic component is the dominent component of peripheral astigmatism. In the study, MFSCLs caused significantly negative peripheral J180º astigmatic component profile, which are consistent with the previous study of Kang et al. [26] Shen et al. [23] proposed a possible explanation that the increased astigmatism may be due to upsetting the optical balance between the cornea and the internal optics of the eye by contact lens, thereby increasing the oblique astigmatism. However, it is still unknown if off-axis astigmatism influences myopic development. The J180º astigmatic component profile changed slightly during accommodation. It showed negative change in the far periphery wearing the SVSCLs, which is consistent with the study of Whatham et al. [19] It didn’t change significantly wearing MFSCLs, which is in agreement with the study of Liu and Thibos [20]. They found that any effect of accommodation at axial or lateral positions of the pupil has negligible effect on ocular astigmatism.

Temporal–nasal asymmetry in spherical equivalent refraction and astigmatism

In our study, we found the magnitude of spherical equivalent refraction and astigmatism exhibited temporal–nasal asymmetry wearing MFSCLs when looking at distant and near targets. Both spherical equivalent refraction and the astigmatism of were greater in the temporal retina. Many other researchers also found that astigmatism across the retina exhibits temporal-nasal asymmetry [34-37] with the temporal astigmatism being greater. The asymmetry might be attributed to the misalignment of the visual axis with the optical axis. It suggests that the foveal astigmatism is not at the center of that symmetry, which is typically a combination of axial and oblique astigmatisms [33]. This idea was supported by Shen et al. [23] who found that the temporal-nasal asymmetry of J180 could be removed by referencing the optical axis, which is 5° temporal from the foveal line-of-sight. Another possible reason for this asymmetry is the temporal decentration of the contact lens that occurs when the eyelids blink, forcing the lens to move over the temporal–nasal asymmetry of the corneal shape.

There are two concerns regarding the asymmetry of peripheral refraction. First, it remains to be determined if the asymmetry can alter myopic progression. Second, the possibility that the asymmetric peripheral refraction may promote undesirable asymmetric ocular growth [26] will require a future longitudinal study

Limitations of the study

Our study design has some potential limitations. Firstly, all measurements were made on young adults rather than children. Second, when participants view the near target monocularly, the accommodation response could be underestimated to some degree since it might eliminate accommodation components companying converge. However, the study of Tarrant et al found the difference between monocular and binocular accommodative response measurements is clinically small. The average differences are <0.125 D for the 33 cm target distances [13]. Third, we only measured the change in peripheral refraction immediately after the commencement of accommodation. Thus, the data we collected could only indicate the initial effect of accommodation on the peripheral refraction, it can't represent the change after a long-time near task.

Conclusions

The novel MFSCLs imposed strong myopic peripheral defocus when looking at distant targets. They also maintain a certain magnitude of myopic peripheral defocus when looking at near targets, regardless of the hyperopic effect of accommodation lag and hyperopic shift in RPRE during accommodation. It may serve a good way of slowing the myopia progression.

Abbreviations

MFSCLs: multifocal soft contact lenses; SVSCLs: single vision soft contact lenses; UC: uncorrection; RPRE: relative peripheral refractive error; T: temporal; N: nasal; PVS: preferential visual span; SMR: soft myopia retention; M: spherical equivalent of refraction; J45°: J45° astigmatic component refraction; J180°: J180° astigmatic component refraction; sph: sphere; cyl: cylinder

Declarations

Ethics approval and consent to participate

The research was approved by the Ethics Committee of Wenzhou Medical University (Y2017-066) before commencement and was conducted in accordance with the tenets of Declaration of Helsinki. The purpose and procedure of the study were explained to all subjects and written informed consent was obtained prior to enrollment in the study.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Competing interests

The authors declare that they have no competing interests.

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The authors have no funding to disclose.

Authors' contributions

All authors have made substantive intellectual contributions to this study. All authors (XM, SW, LL, FL) contributed to the conceptualisation of the manuscript. XM, LL, SW contributed to the design of this work. LL contributed to data acquisition and extraction. SW performed the statistical analysis and write the manuscript. All authors reviewed and approved the final version of the manuscript.

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Additional file 1

The results data. The horizontal peripheral refraction (M, RPRE, J45 º, J180 º) between 30º temporal (T) to 30º nasal retina (N) (in 10º steps) with UC, SVSCLs and MFSCLs when looking at distant and near targets.

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Table 2

Due to technical limitations, table 2 is only available as a download in the supplemental files section.

Figures

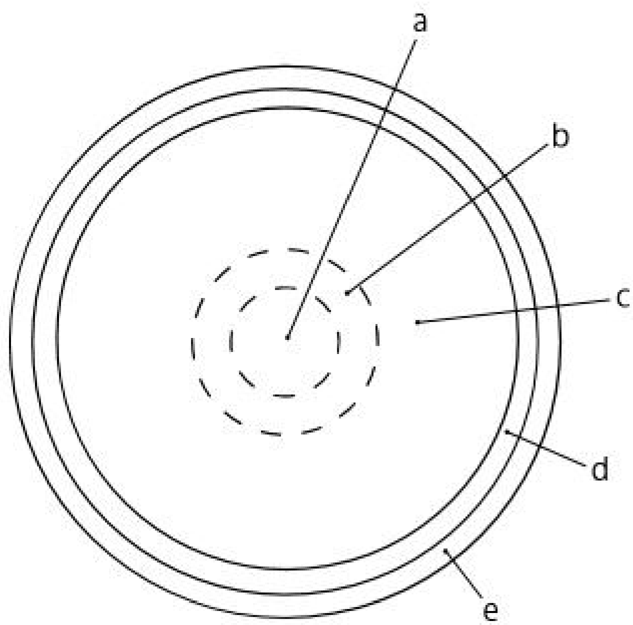

Figure 1

Structure of the SOFTOK SMR MFSCLs It is the front view of SOFTOK SMR MFSCLs. a: center optical zone; b: preferential visual span zones; c: intermediate zone; d: alignment zone; e: peripheral zone. SMR: soft myopia retention. MFSCLs: multifocal soft contact lenses.

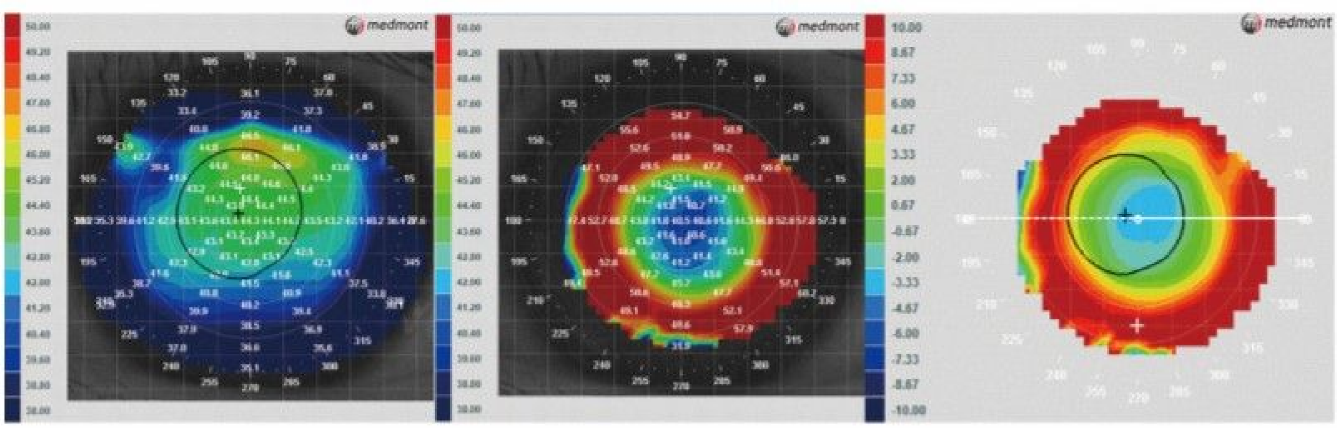

Figure 2

Corneal topography with and without MFSCLs A: Corneal topography without the MFSCLs. B: Corneal topography with the MFSCLs. C: The image of B minus A; MFSCLs: multifocal soft contact lens

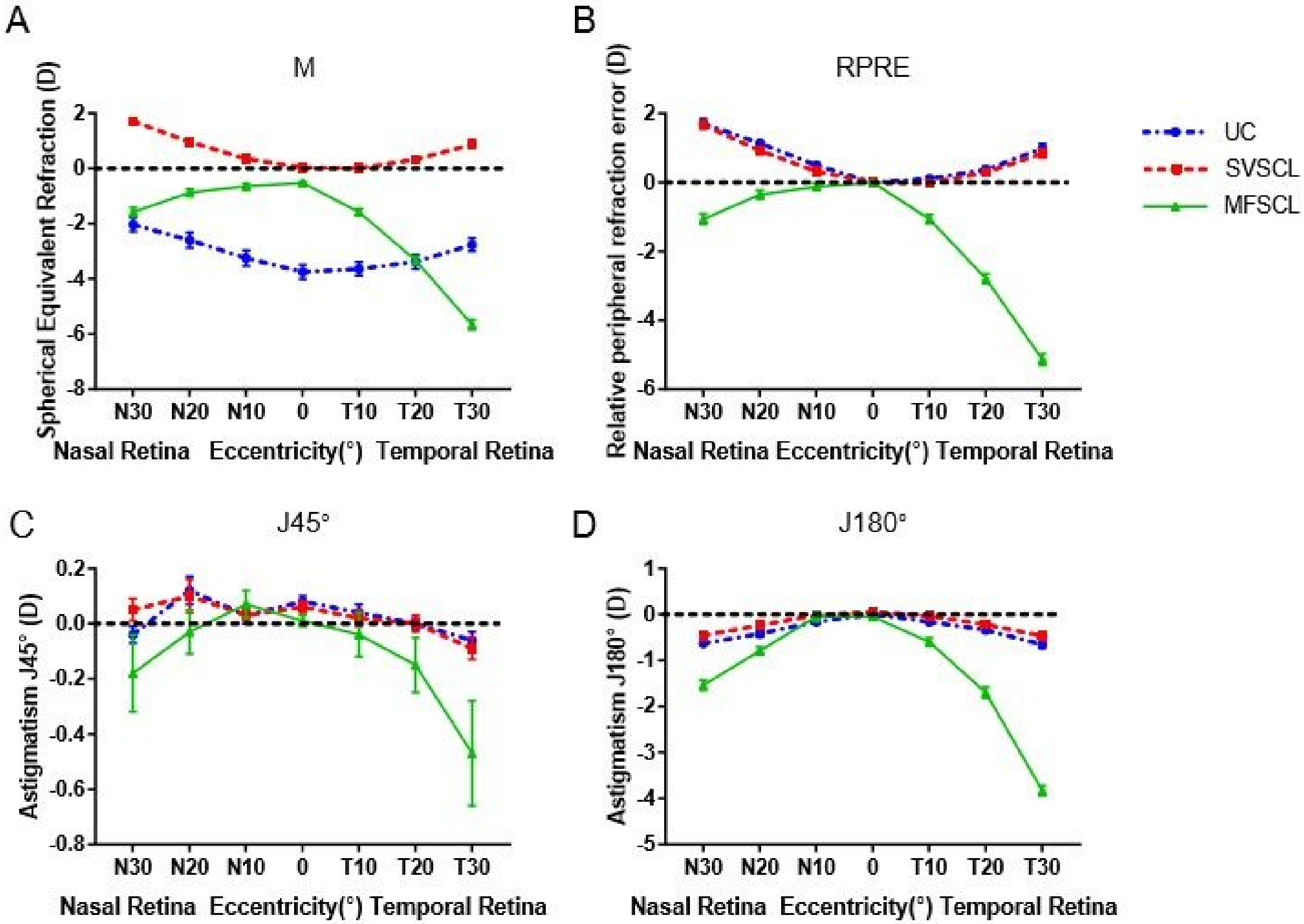

Figure 3

. Peripheral refraction during looking at distant targets Spherical equivalent refraction (M), relative peripheral refractive error (RPRE), J45º and J180º astigmatic component refraction profiles (J45º and J180º) were measured during looking at distant targets (5m), with uncorrection or two types of contact lenses (SVSCLs and MFSCLs). SVSCLs, single vision soft contact lenses; MFSCLs, multifocal soft contact lenses. Error bars represent standard error of the mean.

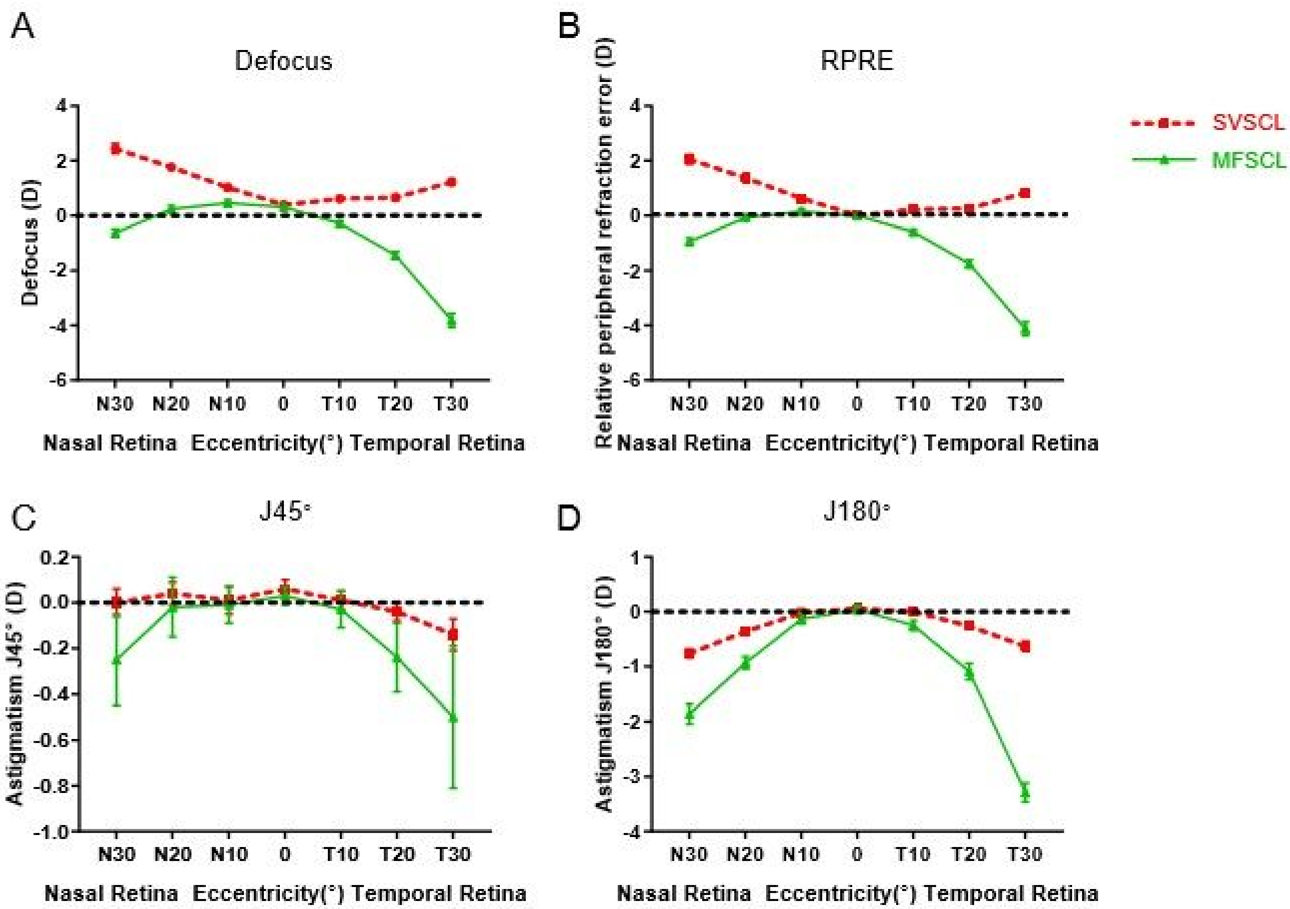

Figure 4

Peripheral refraction during looking at near targets Defocus, relative peripheral refractive error (RPRE), and J45ºand J180º astigmatic component refraction profiles (J45ºand J180º) were measured during looking at near targets (0.4 m), with 2 types of contact lens (SVSCLs, MFSCLs). SVSCLs, single vision soft contact lenses; MFSCLs, multifocal soft contact lenses. Error bars represent the standard error of the mean.

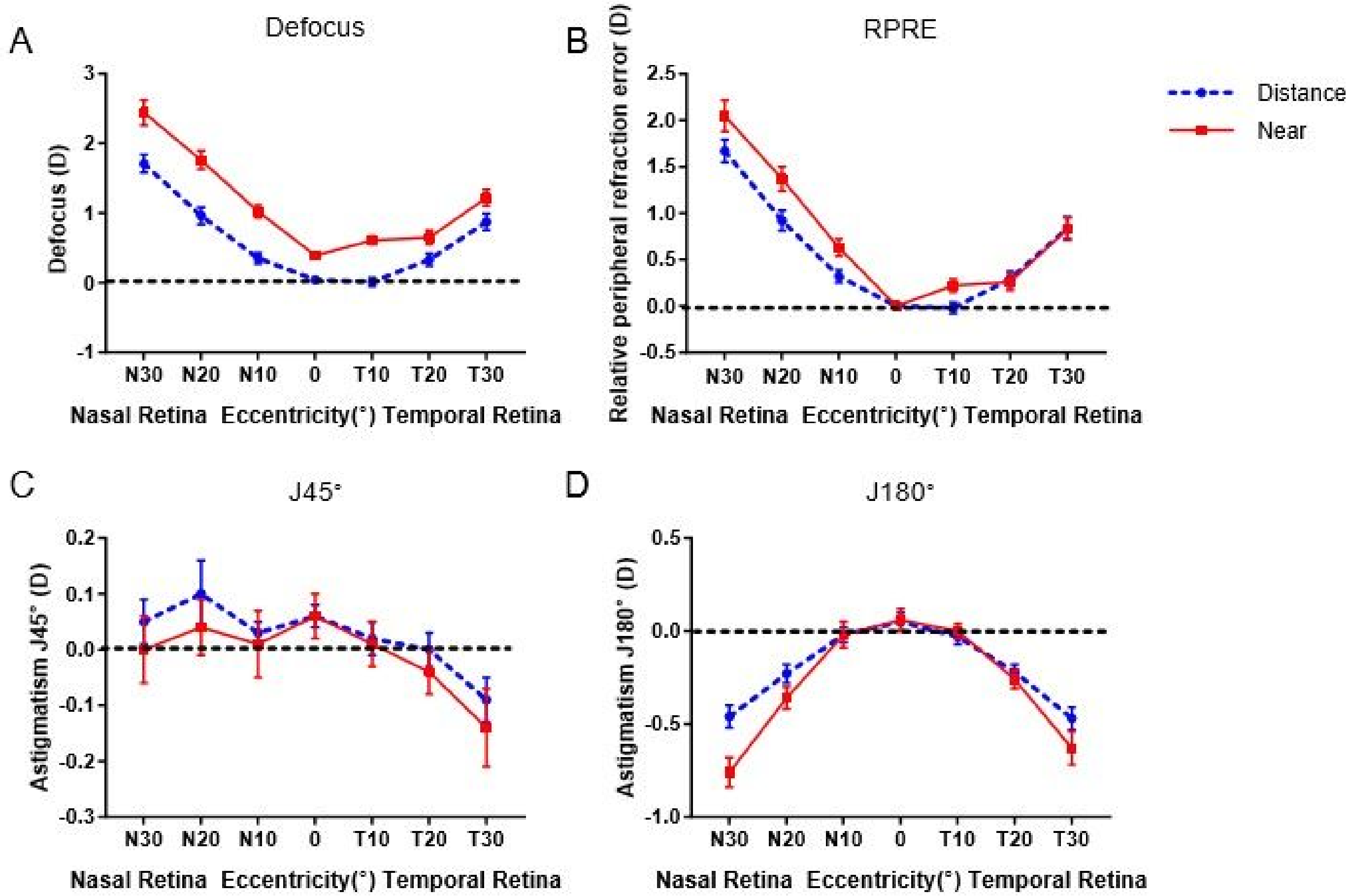

Figure 5

Comparisons between looking at distant and near target wearing SVSCLs Defocus, relative peripheral refractive error (RPRE), and the J45º and J180º astigmatic component refraction profiles (J45º and J180º) were measured during looking at both distant and near target (0.4 m and 5 m), wearing single vision soft contact lenses (SVSCLs). Error bars represent the standard error of the mean.

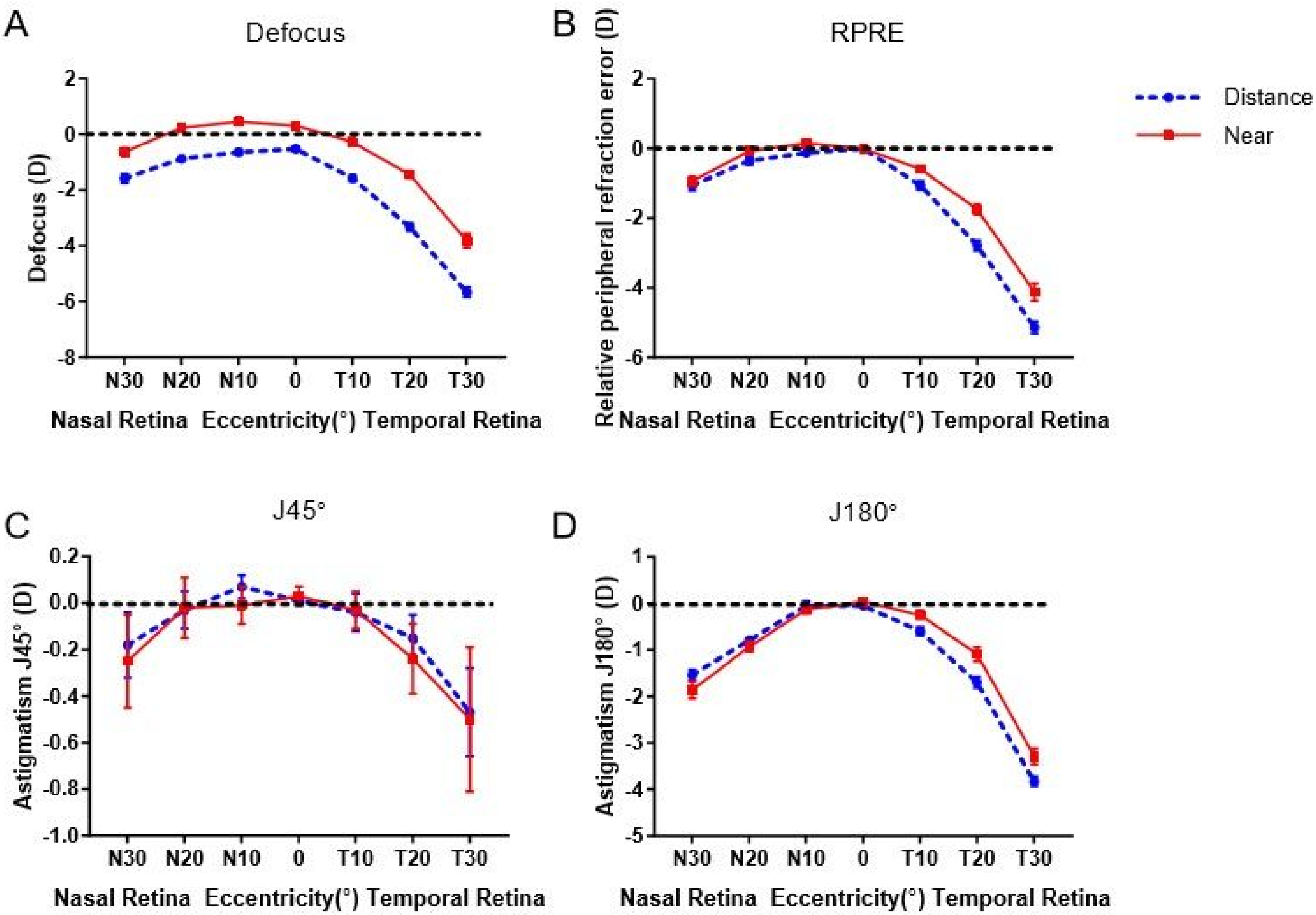

Figure 6

Comparisons between looking at distant and near target wearing MFSCLs Defocus, relative peripheral refractive error (RPRE), and the J45ºand J180º astigmatic component refraction profiles (J45ºand J180º) were measured during looking at distant and near target (0.4 m and 5 m), wearing multifocal soft contact lenses (MFSCLs). Error bars represent the standard error of the mean.

Supplementary Files

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- Additionalfile1.pdf