

Association between multifocal soft contact lens decentration and visual performance

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Purpose: The aim of this study was to assess the association between decentration of several commercial multifocal soft contact lenses (MFCLs) and various objective and subjective visual performance variables in presbyopic and non-presbyopic participants.

Materials and methods: All presbyopic (age >40 years, near add $\geq +1.25$ D) and non-presbyopic (age ≥ 18 years, no near add requirements, spherical equivalent ≤ -0.50 D) participants were each fitted bilaterally with six and two MFCLs (test lens), respectively, and with one single vision lens (control lens). Lens decentration, ie, the x - and y -differences between the contact lens and pupil centers, was objectively determined. Third-order aberrations were measured and compared. Visual performance (high- and low-contrast acuities and several subjective variables) was analyzed for any associations (Pearson's correlation, r) with MFCL decentration.

Results: A total of 17 presbyopic (55.1 \pm 6.9 years) and eight non-presbyopic (31.0 \pm 3.3 years) participants completed the study. All lenses displayed a temporal-inferior decentration ($x = -0.36 \pm 0.29$ mm, $y = -0.28 \pm 0.28$ mm, mean \pm SD). Compared to the control, a significant inferior decentration was found for the Proclear[®] MFCL Near lens in both groups ($y_{\text{presbyopic}} = -0.26$ mm, $y_{\text{non-presbyopic}} = -0.70$ mm) and for the Proclear[®] MFCL Distance lens in the non-presbyopic group ($y_{\text{non-presbyopic}} = -0.69$ mm). In both groups, lens-induced vertical coma ($C(3, -1)$) was, by at least tenfold, significantly more positive for the Proclear[®] MFCL Distance lens and significantly more negative for the Proclear[®] MFCL Near lens. In the presbyopic group, the correlation of total MFCL decentration with vision variables was weak ($r < |0.191|$). Conversely, a moderate but significant correlation with total MFCL decentration was found in the non-presbyopic group for most of the vision variables, indicating a decrease in vision as decentration increased.

Conclusion: Certain MFCLs decentered more than others; the same lens designs also induced significant amounts of third-order aberrations. An association between MFCL decentration and seven out of nine vision variables was found in the non-presbyopic group, ie, the group where lenses were most decentered, which had larger pupils and lower levels of inherent third-order aberrations.

Keywords: vision, multifocal contact lenses, decentration, higher-order aberrations

Introduction

With the increasing active lifestyles of older people, multifocal soft contact lenses (MFCLs) offer a practical alternate refractive correction when compared to traditional bi-/multifocal spectacle lenses or rigid gas permeable contact lenses. The globally increasing number of people requiring a presbyopic correction additionally reinforces the need for such an alternative correction method. Besides presbyopic refractive correction, the use of MFCLs has also been of increased interest in relation to controlling the progression of myopia.^{1,2} Such lenses permit the reduction in foveal or peripheral

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hyperopic retinal defocus, an intervention approach that has been suggested to counteract the stimulus for eye growth.^{3,4}

When compared to single vision (SV) or multifocal spectacle lenses, vision with current MFCLs is often compromised since the optical design of MFCLs requires the simultaneous presentation of images through the limited area of the pupil. Ghosting and haloes are often the consequence of this simultaneous imaging principle.⁵ Several studies have assessed the visual performance of commercial MFCLs in a presbyopic group⁶⁻⁹ and a non-presbyopic myopic group.^{2,10,11} In general, the quality of vision with MFCLs primarily depends on the power distribution across the optic zone, ie, the lens design (power profile),¹² the near add power,¹¹ and the size of the pupil.¹³

Differences in ocular and lens design parameters, ie, base curve (BC) and diameter, and material properties can affect the fit of MFCLs and thereby lens centration. It has been reported^{11,14} that some MFCLs (ie, Proclear® MFCLs; CooperVision, Pleasanton, CA, USA) decentered more than others and that vision with those lenses was also more reduced. Based on these observations, it has been suggested that decentration of MFCLs might impact vision. Empirical calculations have shown that contact lens (CL) decentration can affect retinal image quality and increase odd higher-order aberrations such as coma.^{15,16} Peyre et al¹⁰ measured higher-order aberrations with several commercially available MFCLs and found an increase in even and odd higher-order aberrations. Although they did not measure CL centration, they attributed this increase in odd higher-order aberrations to the decentration of the lenses relative to the pupil.¹⁰ Fernández-Sánchez et al¹⁷ designed special soft CLs with low, medium, and high values of coma and trefoil to assess the effect of third-order aberrations on vision. They found that only lenses with large values of $\sim 1 \mu\text{m}$ of coma and trefoil significantly reduced visual performance. However, they did not investigate any subjective visual performance variables, which previously have been suggested to be more sensitive indicators for the assessment of vision with MFCLs.^{7,11}

To our knowledge, no clinical studies have as yet assessed the association between decentration of commercial MFCLs and vision in a presbyopic or a non-presbyopic group. The objective of this study was therefore to measure the amount of CL decentration and the lens-induced third-order aberrations of commercially available MFCLs and to assess the association between decentration and high-contrast visual acuity (HCVA) and low-contrast visual acuity (LCVA) and several subjective visual performance variables in a presbyopic and a non-presbyopic group.

Materials and methods

Study design

This was a prospective, participant-masked, bilateral wear, crossover clinical trial conducted at the Brien Holden Vision Institute, Sydney, Australia. For the presbyopic group, criteria for inclusion were age >40 years and near add $\geq +1.25$ D, and for the non-presbyopic group the age was ≥ 18 years, without any near add requirements, and be myopic (spherical equivalent ≤ -0.50 D). Independent of the group, the additional inclusion criteria were vision correctable to at least 6/9 or better in each eye with CLs and astigmatism ≤ -1.00 DC, as the study was aimed to use spherical MFCLs to correct for distance refractive error. Exclusion criteria included previous corneal refractive surgery, any other ocular conditions, and any contraindications to CL wear. The protocols and informed consent were reviewed and approved by an independent ethics committee (Bellberry Limited, Eastwood, SA, Australia), and the research followed the tenets of the Declaration of Helsinki. Following the screening for clinical trial suitability, informed consent was obtained from each participant before any clinical trial procedures were performed. Each participant had to attend a baseline visit and up to six lens assessment visits.

Contact lenses

At the first lens assessment visit, participants were dispensed bilaterally with the AirOptix Aqua® SV lens (Alcon Laboratories, Inc., Fort Worth, TX, USA), which served as a control. During the next lens assessment visits, up to six commercially available MFCLs (test lenses) were randomly tested on separate days with a minimum washout period of 1 day between visits. The details of all study lenses are shown in Table 1. While the presbyopic group was fitted with all six MFCL test lenses, only two MFCLs, ie, Proclear® MFCL Distance and Near, were fitted to the non-presbyopic group, as those lenses would provide the greatest myopia control effect due to the greater plus area under the distance labeled power profile.¹² All measurements were performed after allowing a minimum of 10 minutes for the lenses to settle. Lenses remained on eye until all procedures were complete. The duration of each lens assessment visit was ~ 1 hour.

Procedures

Refraction

At the baseline visit, the participant's ocular refraction was determined under high illumination conditions (557 ± 11 lux at participant eye position). All non-presbyopic participants were fitted with medium add lenses (add $+2.00$ D). For the

Table 1 Description of CLs

CLs	Lens design	Manufacturer	Material	Power (D)	Diameter (mm)	BC (mm)
AirOptix® Aqua Single Vision	SV (negative control)	Alcon Laboratories, Inc. (Fort Worth, TX, USA)	Lotrafilcon B	+4.00 D to -10.00 D	14.2	8.6
Proclear® Multifocal Near	Center-near multifocal	CooperVision (Pleasanton, CA, USA)	Omafilcon A	+4.00 D to -10.00 D low/high add	14.4	8.7
Proclear® Multifocal Distance	Center-distance multifocal	CooperVision (Pleasanton, CA, USA)	Omafilcon A	+4.00 D to -10.00 D low/high add	14.4	8.7
CLARITI® I Day Multifocal	Center-near multifocal	Sauflon (London, UK)	Filcon II multifocal	+5.00 D to -6.00 low/high add	14.1	8.6
AirOptix® Aqua Multifocal	Center-near multifocal	Alcon Laboratories, Inc. (Fort Worth, TX, USA)	Lotrafilcon B	+6.00 D to -1.00 D low/med/high add	14.2	8.6
ACUVUE® Bifocal	Concentric bifocal	Johnson & Johnson (Jacksonville, FL, USA)	Etafilcon A	+6.00 D to -9.00 D +1.50/+2.50 D add	14.2	8.5
PureVision® Multifocal	Center-near multifocal	Bausch & Lomb Incorporated (Rochester, NY, USA)	Balafilcon A	+6.00 D to -10.00 D low/high add	14.0	8.6

Abbreviations: BC, base curve; CLs, contact lenses; SV, single vision.

presbyopic participants, the near add was obtained by the minimum plus required to comfortably read an N4-sized paragraph on a near-reading chart presented at 40 cm, which would be equivalent to a visual acuity of 0.08 logMAR. Distance over refraction was determined by providing maximum plus with which the participant was deemed to have acceptable binocular vision when looking at the 6/6 line on a computer-generated letter chart (Test Chart 2000 Pro; Thompson Software Solutions, Hertfordshire, UK) at 6 m.

Based on the presbyopic participants' spectacle near add, as determined at the baseline visit, participants were divided into two fitting groups (Table 2). As the objective of this study was to assess CL decentration and vision separately for each lens design, some MFCLs were fitted contrary to the manufacturers' fitting guides. Specifically, while the Proclear® MFCL fitting guide recommends to fit the center-near design lens in the nondominant eye and the center-distance design lens in the fellow dominant eye, participants in the current study were fitted the same design in both eyes. Further, the manufacturers' fitting guides for PureVision® MFCL and AirOptix® MFCL suggest to fit low add designs if the spectacle add is $\leq +1.25$ D. As there was only one participant enrolled with +1.25 D add, this participant was, for simplicity and logistics reasons, dispensed with a medium add AirOptix® MFCL and a high add PureVision® MFCL with an extra -0.25 D for distance as indicated in the PureVision fitting guide/instruction booklet.

Vision assessment

At each lens assessment visit, distance HCVA (100%) and LCVA (10%) were measured with a computerized logMAR letter chart (Test Chart 2000 Pro) at 6 m under high illumination

Table 2 Fitting groups for multifocal test lenses based on spectacle add of presbyopic participants

CLs	Spectacle add +1.25 D and +1.50 D	Spectacle add $\geq +1.75$ D
AirOptix® Aqua Single Vision	N/A (negative control)	N/A (negative control)
AirOptix® Aqua MFCL	Med add	High add
Proclear® MFCL Distance	+1.50 add	+2.50 add
Proclear® MFCL Near	+1.50 add	+2.50 add
PureVision® MFCL	High add	High add
ACUVUE® Bifocal	+1.50 add	+2.50 add
CLARITI® I Day MFCL	Low add	High add

Abbreviations: CLs, contact lenses; N/A, not applicable; MFCL, multifocal soft contact lens.

conditions (557 ± 11 lux at participant eye position). After 1 hour of lens wear, participants completed a computer-based questionnaire, rating on a numerical scale the performance of each study lens (ie, monocularly). This scale ranged from 1 to 10, where 1 indicates poorest performance and 10 indicates best performance. The resolution of the rating scale was ± 1 unit. The questions included ratings on vision clarity at distance, intermediate and near, vision immediately after a blink, ghosting at distance and near, and overall vision satisfaction. It should be noted that a study by Tilia et al¹⁸ used a similar numerical rating scale of 1–10 for the assessment of subjective comfort variables. Although the resolution of their rating scale was 0.1 increments, their results suggest that a group mean difference over 0.5 would represent a perceivable difference.

CL centration

Using a Nikon Photo Slit Lamp (Nikon FS-3V; Nikon Corporation, Tokyo, Japan) that facilitated good alignment, CL centration was objectively determined by photographing the

participant's anterior eye with the edge of the CL in focus (Figure 1A). The photograph was taken with the participant positioned in primary gaze and a few seconds after a blink, to ensure that the CL had stabilized, ie, no more movement.

The images were then uploaded into a dedicated custom-written MATLAB® (MathWorks, Inc. Natick, MA, USA) image analysis program, which was used to determine the difference between the CL center and the center of the eye's entrance pupil. A choice of different filters enabled the software operator to identify the image that provided the sharpest CL edge (Figure 1B). Due to the inherent low and varying contrast between the nasal and temporal CL edges against the white scleral background, attempts to automatically detect the CL edge were not successful. The program was therefore designed to allow manual selection of a minimum of six CL edge points and a minimum of six pupil edge points, to which best circles were fit using the least-square fitting approach (Figure 1D). Using the same camera setup, a calibration card, featuring a 15 mm × 15 mm grid, was also photographed to determine the scale factor for the conversion to the real-world coordinates of the post-processed images. The horizontal (x) and the vertical (y) differences between the circle centers obtained from the CL edge and the pupil edge were defined as the vertical and horizontal decentration of the CL in millimeter. Negative signs indicate temporal and inferior decentration, and positive signs indicate nasal and superior decentration. Total decentration was determined through trigonometric analysis, by calculating the square root of the sum of the squares of the horizontal and vertical decentration of each lens.

As the ratio between the CL diameter (CL Dia) and horizontal visible iris diameter (HVID) can affect CL fit¹⁹ and thus lens centration, the HVID was also measured for each participant using the same photograph and image analysis program.

Instruments

At the baseline visit, objective refraction and keratometry readings were obtained for each participant using the closed-view Auto Keratometer-Refractor Canon RK-3 (Canon Inc., Tokyo, Japan). Third-order aberrations were measured with and without study lenses on eye using the BHVI-EyeMapper (Brien Holden Vision Institute, Sydney, NSW, Australia). Details of this aberrometer instrument have been explained earlier.²⁰ With each study lens on eye, five repeats were performed for distance (ie, +1.00D fogging) at low illumination conditions and third-order aberration coefficients were retrieved for the 4 mm circular and natural on-axis pupil diameter. While the constant fixed circular pupil analysis diameter of 4 mm allows a direct comparison of the spherical aberration terms between

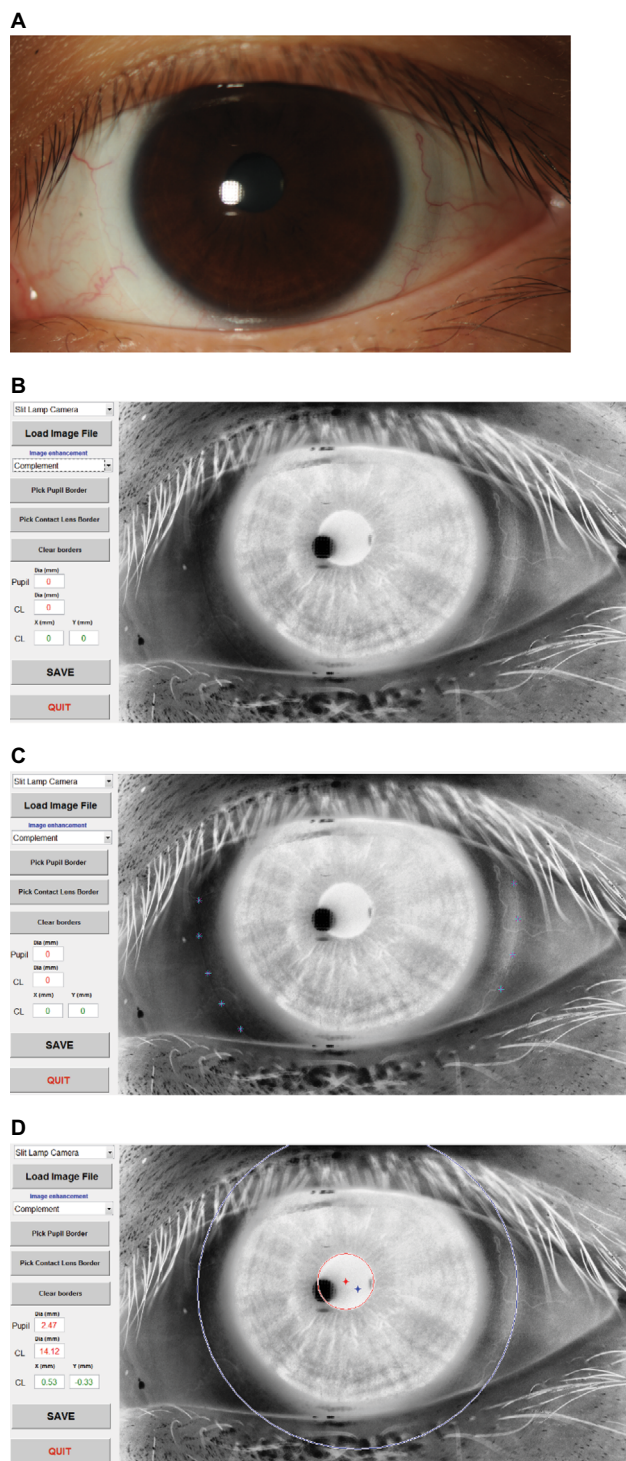


Figure 1 Measurement of contact lens centration.

Notes: A photograph taken on the slit-lamp camera setup with a CL on eye (A). To determine CL centration, the same picture was uploaded into the user interface of the dedicated CL centration program that enabled: 1) the enhancement of the CL edge by applying different filters (B), 2) a manual selection of a minimum of six points at the CL and pupil borders (C), and 3) the fitting of the best circles to determine the differences (x and y , in millimeter) between the CL and pupil centers (D).

Abbreviation: CL, contact lens.

lens types, the natural circular pupil diameter provides information on any associations with respect to vision.

Statistical analyses

Data are summarized as mean \pm standard deviation (SD) for variables measured on an interval scale. The ratio of corneal curvature (CC) to BC of the dispensed lenses and the ratio of the HVID to CL Dia were calculated to assess CL fit. CL decentration, third-order aberrations, and ratios of CC/BC and HVID/CL Dia were compared between lens types using linear mixed models with random participant intercept and repeated visits. If the overall lens effect was significant, post hoc analysis was performed comparing each lens to the control. Post hoc comparisons were adjusted using Bonferroni correction. The association between CL decentration, subjective and objective vision parameters, and third-order aberration coefficients was assessed using Pearson's correlation. The level of statistical significance was set at 5%. Analyses were performed using SPSS 21 (IBM Corporation, Armonk, NY, USA).

Results

A total of 17 presbyopic and eight non-presbyopic participants completed the study. The baseline details for both groups are summarized in Table 3. There was no significant difference in the CC between groups. However, the non-presbyopic group had a significantly smaller HVID and a significantly larger natural pupil diameter ($P=0.005$) than the presbyopic group.

Comparison of centration data and CL fitting variables between study lenses

The mean x , y , and total decentration values for all lenses are shown in Table 4. On average, all lenses displayed a temporal-inferior decentration, which was independent of

Table 3 Baseline details

Baseline variables	Presbyopic group (n=17)	Non-presbyopic group (n=8)
Sex (female)	n=6 (35.3%)	n=5 (62.5%)
Ethnicity		
Caucasian	n=13 (76.5%)	n=2 (25%)
Asian	n=2 (11.8%)	n=5 (62.5%)
Others	n=2 (11.8%)	n=1 (12.5%)
Neophytes	n=5 (31.3%)	n=1 (12.5%)
Age (years)	55.1 \pm 6.9	31.0 \pm 3.3
Age range (years)	45.9–68.6	25.9–36.4
Spherical equivalent (subjective refraction, D)	-1.96 \pm 2.03	-3.51 \pm 1.79
Add power (D)	1.81 \pm 0.35	–
Natural pupil diameter (mm, low illumination)	4.62 \pm 0.89	6.08 \pm 0.64
HVID (mm)	11.49 \pm 0.43	11.10 \pm 0.47
CC (mm)	7.82 \pm 0.23	7.71 \pm 0.18

Notes: Data are presented as either n (%), or mean \pm SD.

Abbreviations: CC, corneal curvature; HVID, horizontal visible iris diameter; SD, standard deviation

the group. In both groups, the Proclear® MFCL Near lens was significantly more inferiorly decentered than the control lens. In the non-presbyopic group, total decentration with the Proclear® MFCL Distance and Near lenses was significantly greater than for the control lens. The distribution of CL decentration data points, as indicated by the SD, was similar for all lenses in the presbyopic group, which showed a slightly wider distribution along the horizontal meridian than along the vertical meridian. In the non-presbyopic group, the distribution of data points for the study lenses was generally much wider when compared to the control lens and the distribution was greater along the vertical meridian.

Table 5 lists the ratio between CC and BC of the dispensed lenses and the ratio between the HVID and CL Dia. When compared to the control, both ratios were significantly smaller for both Proclear® MFCLs in both groups.

Table 4 Mean x , y , and total decentration \pm SD (mm) of all study lenses

Group	Lens	x-Decentration			y-Decentration			Total decentration		
		Mean	SD	P-value	Mean	SD	P-value	Mean	SD	P-value
Presbyopes	AirOptix® Aqua	-0.32	0.30	0.978	-0.09	0.26	<0.05	0.46	0.22	0.528
	CLARITI® 1 Day MFCL	-0.37	0.31		-0.12	0.30		0.52	0.26	
	Proclear® MFCL Distance	-0.32	0.32		-0.23	0.27		0.53	0.22	
	Proclear® MFCL Near	-0.36	0.31		-0.26*	0.26		0.55	0.24	
	ACUVUE® Bifocal	-0.36	0.30		-0.16	0.28		0.52	0.24	
	AirOptix® MFCL	-0.35	0.25		-0.12	0.23		0.46	0.19	
	PureVision® MFCL	-0.36	0.31		-0.12	0.29		0.51	0.24	
Non-presbyopes	AirOptix® Aqua	-0.33	0.17	0.613	-0.29	0.24	<0.05	0.50	0.17	<0.05
	Proclear® MFCL Distance	-0.42	0.27		-0.69*	0.45		0.86*	0.42	
	Proclear® MFCL Near	-0.42	0.38		-0.70*	0.30		0.88*	0.34	

Note: The symbol * indicates significant difference when compared to the control ($P<0.05$).

Abbreviation: MFCL, multifocal soft contact lens.

Table 5 Ratio of CC/BC of the dispensed lenses and ratio of HVID/CL Dia

Group	Lens	CC/BC	HVID/CL Dia
Presbyopes	AirOptix® Aqua	0.909	0.809
	CLARITI® I Day MFCL	0.909	0.820*
	Proclear® MFCL Distance	0.899*	0.804*
	Proclear® MFCL Near	0.899*	0.799*
	ACUVUE® Bifocal	0.919	0.809
	AirOptix® MFCL	0.907	0.815
	PureVision® MFCL	0.910	0.821*
Non-presbyopes	AirOptix® Aqua	0.898	0.779
	Proclear® MFCL Distance	0.888*	0.770*
	Proclear® MFCL Near	0.883*	0.775*

Note: The symbol * indicates significant difference when compared to the control ($P<0.05$).
Abbreviations: BC, base curve; CC, corneal curvature; CLs, contact lenses; CL Dia, contact lens diameter; HVID, horizontal visible iris diameter; MFCL, multifocal soft contact lens.

For all lenses combined, a significant but weak negative correlation was found in the presbyopic group between CC/BC and y -decentration (Figure 2A; $r=-0.191$, $P<0.05$), but there was no correlation ($P=0.908$) between the ratio of HVID/CL Dia and y -decentration. In the non-presbyopic group, ie, the group showing a greater magnitude and spread of decentration, a strong and significant correlation between HVID/CL Dia was found with y -decentration (Figure 2B; $r=0.550$, $P<0.05$), indicating the steeper the CC and the smaller the HVID, the greater was y -decentration. There was no correlation ($P=0.269$) between CC/BC and y -decentration in the non-presbyopic group.

Third-order aberrations

Figure 3A compares the unaided and lens-induced third-order aberrations (ie, the difference of the aberrations measured with and without lens) for the different study lenses of both groups. To allow direct comparison of the different lenses, all data shown in Figure 3A were obtained for a 4 mm pupil analysis diameter. In both groups, lens-induced vertical coma (C[3, -1]) was, by at least tenfold, significantly more positive for the Proclear® MFCL Distance lens and significantly more negative for the Proclear® MFCL Near lens when compared to the control.

Figure 3B shows the third-order aberrations as measured with and without lens on eye for natural pupil sizes under low illumination condition. Due to the increased negative inherent C(3, -1) in the presbyopic group, the positive lens-induced C(3, -1) of the Proclear® MFCL Distance lens (Figure 3A) was canceled out and became close to zero (Figure 3B). Conversely, C(3, -1) with lens on eye became more negative for all the other lens types in this group. As for

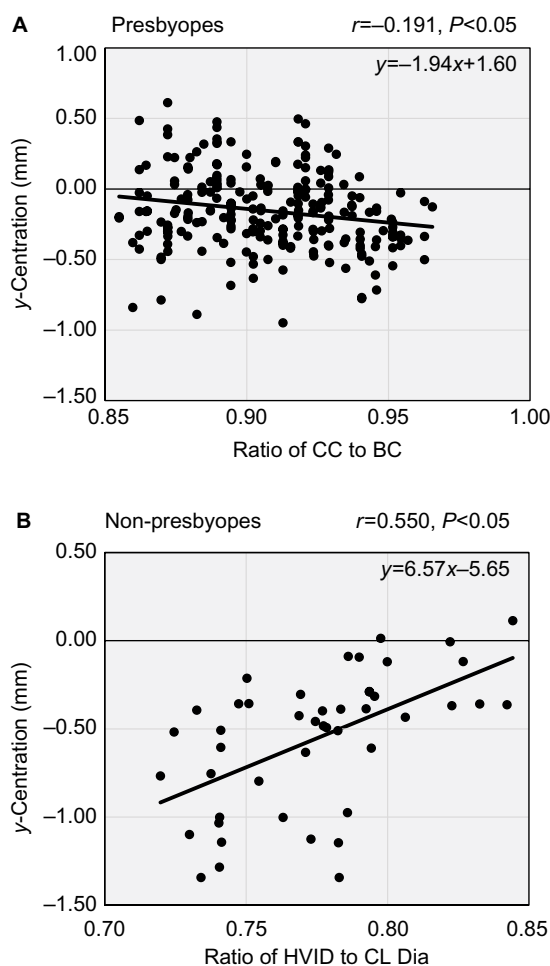


Figure 2 Correlation between the ratio of CC/BC and y -decentration in the presbyopic group (A) and the ratio of the HVID/CL Dia and y -decentration in the non-presbyopic group (B).

Abbreviations: BC, base curve; CC, corneal curvature; CL Dia, contact lens diameter; HVID, horizontal visible iris diameter.

the non-presbyopic group, inherent third-order aberrations were small overall, and thus there was no significant difference between lens-induced measurements and measurements obtained with lens on eye.

CL decentration and vision

Figures 4–6 show the association between total decentration for the combined study lenses tested and all the visual performance variables in the presbyopic and non-presbyopic groups. Independent of the group, there was no statistically significant correlation for the HCVA with total decentration. For LCVA measurements, the only exception was in the non-presbyopic group, which showed a decrease in LCVA when total decentration increased (Figure 4).

In the presbyopic group, the correlation of total MFCL decentration with subjective vision variables was weak (Figure 5; $r < |0.191|$), but a significant positive correlation ($P < 0.05$) was found for the ratings on near vision (Figure 5C) and vision after

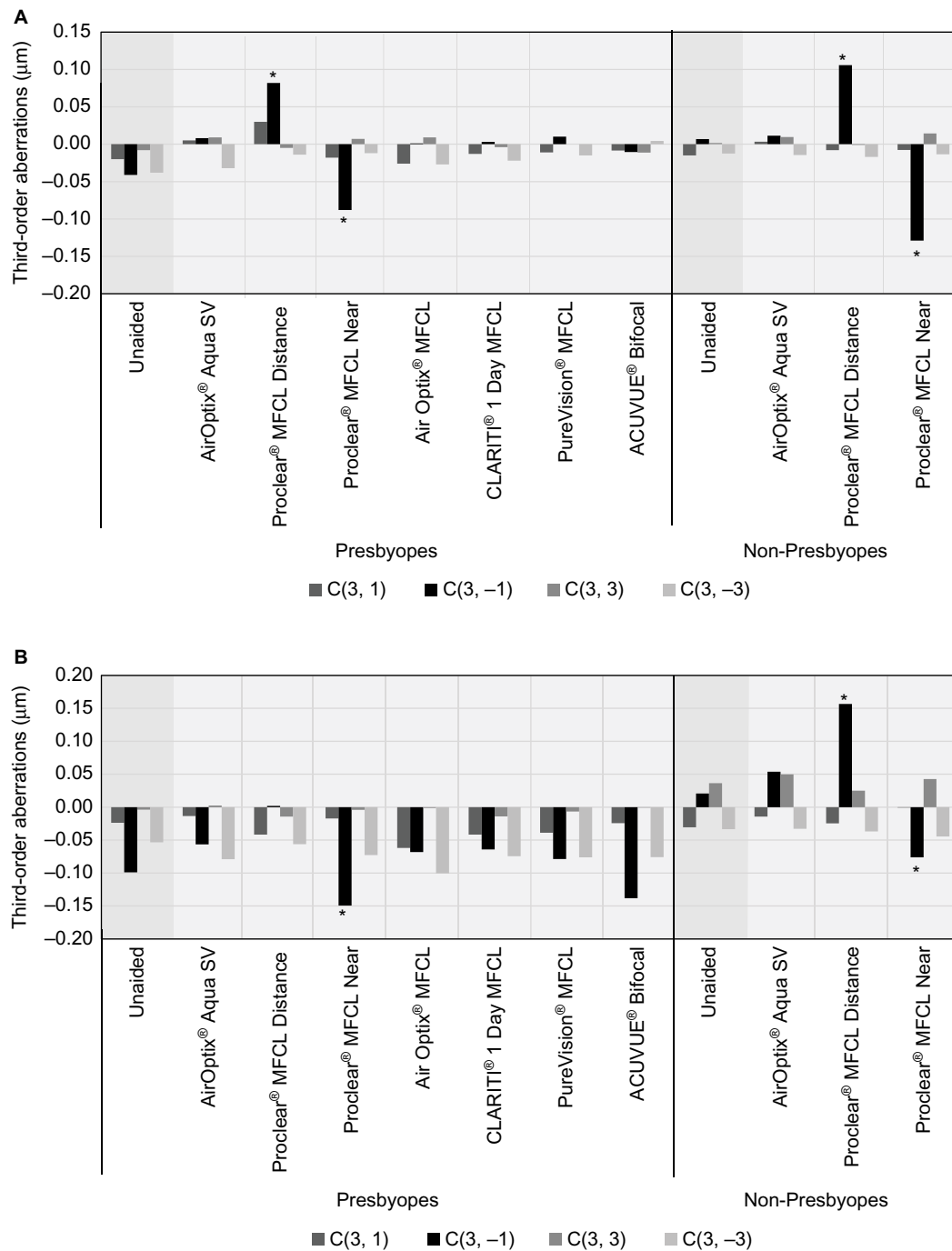


Figure 3 Third-order aberrations

Notes: (A) Unaided and lens-induced (ie, difference of aberrations measured with and without lens) third-order aberrations (μm; 4 mm pupil diameter) for the different study lenses. (B) Third-order aberrations measured with and without (unaided) lens on eye (μm, natural pupil diameter) for the different study lenses. * indicates significant difference ($P < 0.05$) when compared to the control.

Abbreviations: MFCL, multifocal soft contact lens; SV, single vision.

a blink (Figure 5F), indicating an improvement in vision as the total decentration increased. A total MFCL decentration of 0.50 mm, which is similar to the mean total decentration found in this presbyopic group, led to an average improvement in visual performance of these two subjective variables of 0.81 units, which can be considered a perceivable difference.

A moderate and significant negative correlation ($r \leq -0.300$, $P < 0.05$) with total MFCL decentration was found in the non-presbyopic group for six out of seven subjective vision variables (Figure 6A–G), where negative correlation indicates a decrease in visual performance as total decentration increases. On average, a total decentration of 0.50 mm led to an average

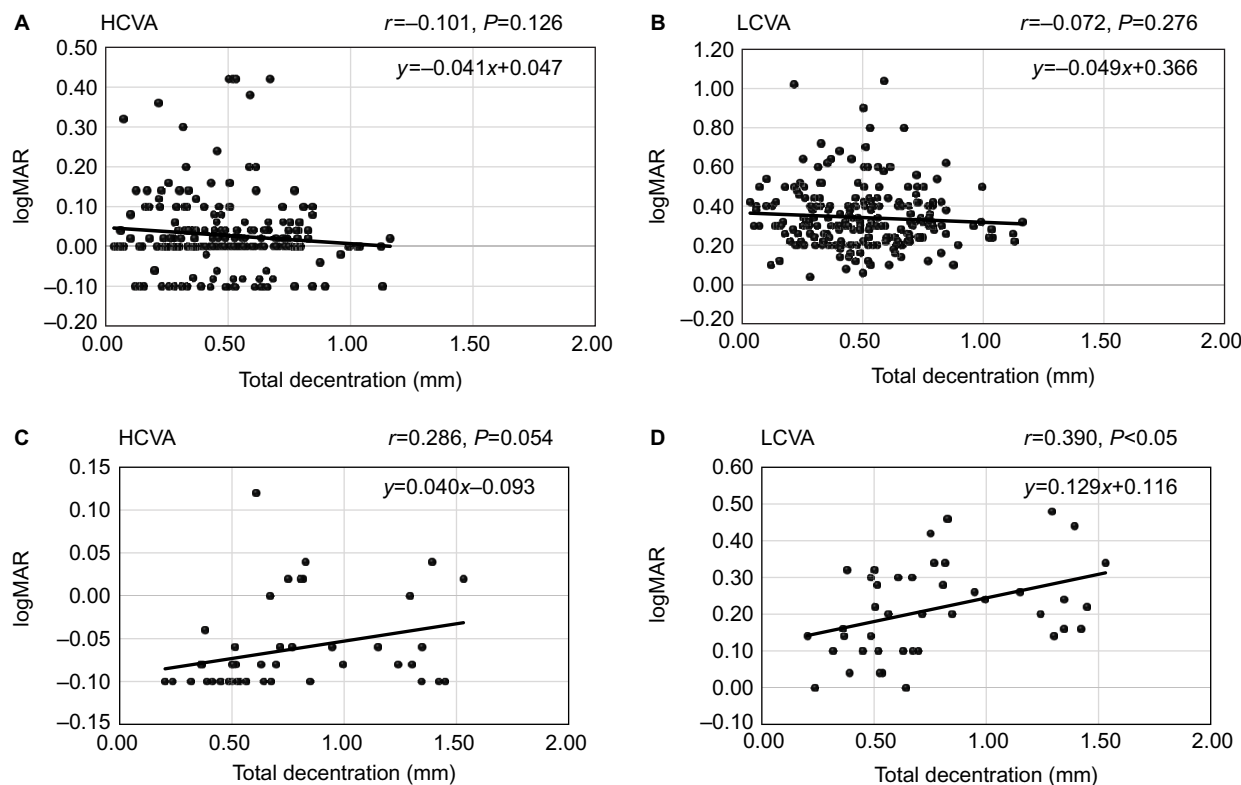


Figure 4 HCVA and LCVA as a function of total decentration in the presbyopic (**A, B**) and non-presbyopic (**C, D**) groups, respectively.
Abbreviations: HCVA, high-contrast visual acuity; LCVA, low-contrast visual acuity.

reduction in visual performance (all seven subjective variables combined) of 1.45 units, which is a perceivable difference.

Discussion

CL centration

Increased decentration of Proclear® MFCL has been noticed earlier.^{11,14} Lens parameters such as BC and CL Dia in combination with the related ocular parameters of the individual CCs and HVIDs can provide an indication of the differences found in lens centration.²¹ Results from the current study showed that, independent of the group, the ratio of CC/BC and the ratio of HVID/CL Dia of the Proclear® MFCLs were significantly smaller when compared to the control lens. This would explain the generally looser fit on eye, and thus the greater decentration with the Proclear® MFCLs in the two groups assessed in the current study. Although it is anticipated that the centration of the MFCLs could have been improved with a lens featuring a steeper BC and/or a smaller CL Dia, unlike with SV lenses for which manufacturers usually offer more than one BC and/or CL Dia, all MFCLs tested in the current study were only available in one BC and one CL Dia.

When compared to the presbyopic group, the increased decentration in the non-presbyopic group can be attributed to the smaller HVID of this group. Previous studies have shown

that Asian eyes have generally smaller HVIDs than Caucasian eyes,^{22,23} which would explain why the non-presbyopic group in the current study comprising 62.5% of Asians had a significantly smaller mean HVID than the presbyopic group that comprised only 11.8% of Asians. Due to the limited selection available on BCs and CL Dia in MFCLs, care needs to be taken in terms of CL centration when aiming to fit certain MFCLs to a certain population group.

Third-order aberrations

To our knowledge, only a few studies^{10,11,24} have reported on lens-induced higher-order aberrations with commercial MFCLs. The study by Patel et al²⁴ found a significant correlation in C(3, 1) with and without Focus Progressive® MFCLs on eye; however, they did not assess whether possible decentration of the lenses led to the lens-induced changes. In a group of non-presbyopes, the study by Peyre et al¹⁰ assessed third, fourth, and fifth higher-order aberrations as measured after pupil dilation with eight commercial MFCLs. Three of their MFCLs, ie, Proclear® MFCL Distance, Proclear® MFCL Near, and ACUVUE® Bifocal, were also tested in the current study. In agreement with the study by Peyre et al, out of all MFCL test lenses, the two Proclear® MFCLs induced the greatest amounts of even

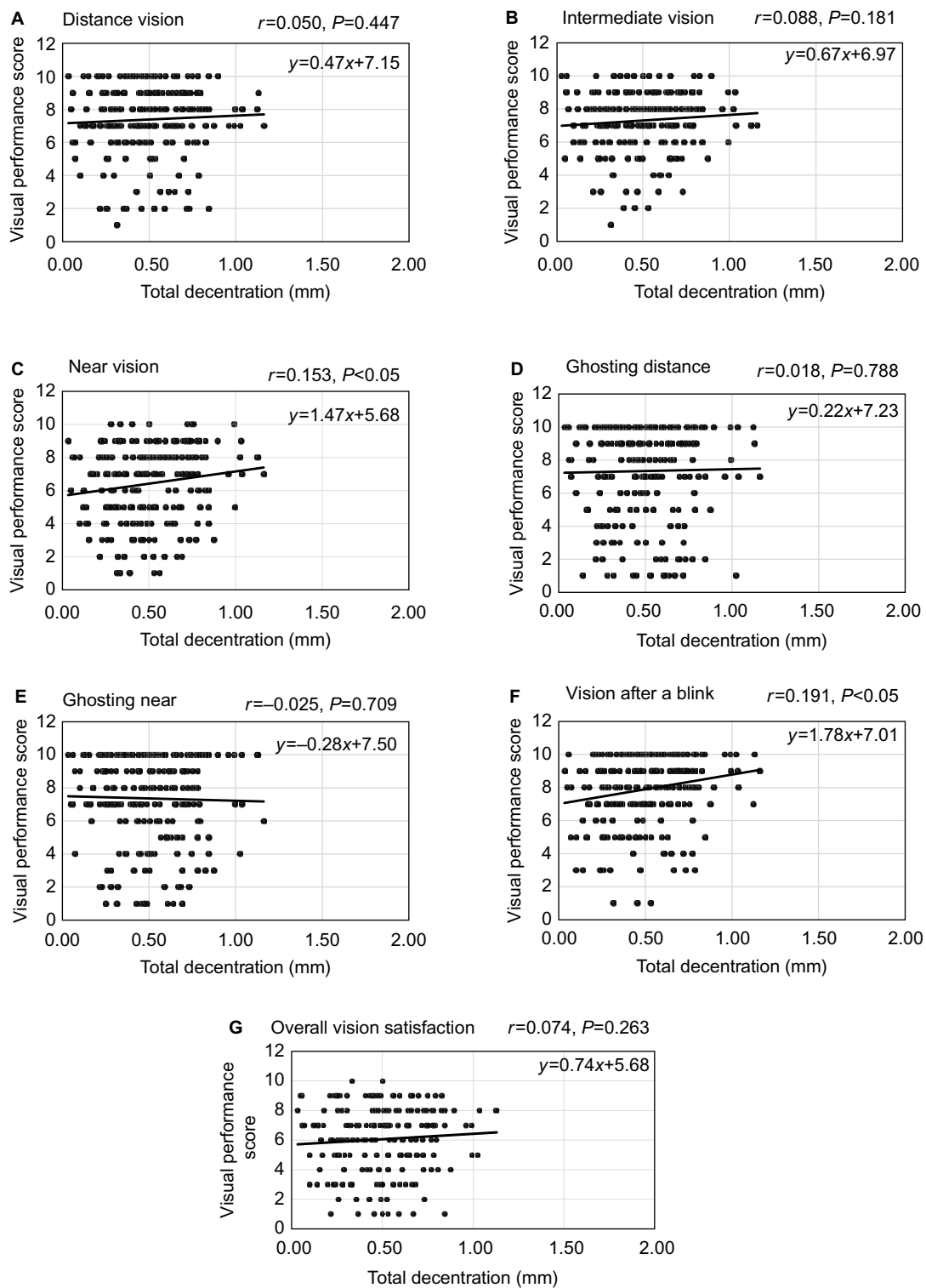


Figure 5 Subjective visual performance variables as a function of total decentration in the presbyopic group (A–G).

and odd higher-order aberrations. Although they also did not measure lens decentration, they attributed the increase in odd higher-order aberrations to the possible relative decentration of the MFCLs to the pupil. Another recent study in non-presbyopes¹¹ measured third- and fourth-higher-order aberrations as well as lens decentration with

five commercial SV and eleven commercial MFCLs on eye. Out of all MFCLs, only the Proclear® MFCLs exhibited a significant difference in C(3, -1) when compared to an SV control and they were also the only MFCLs that were significantly decentered, which is in agreement with the findings in both groups of the current study.

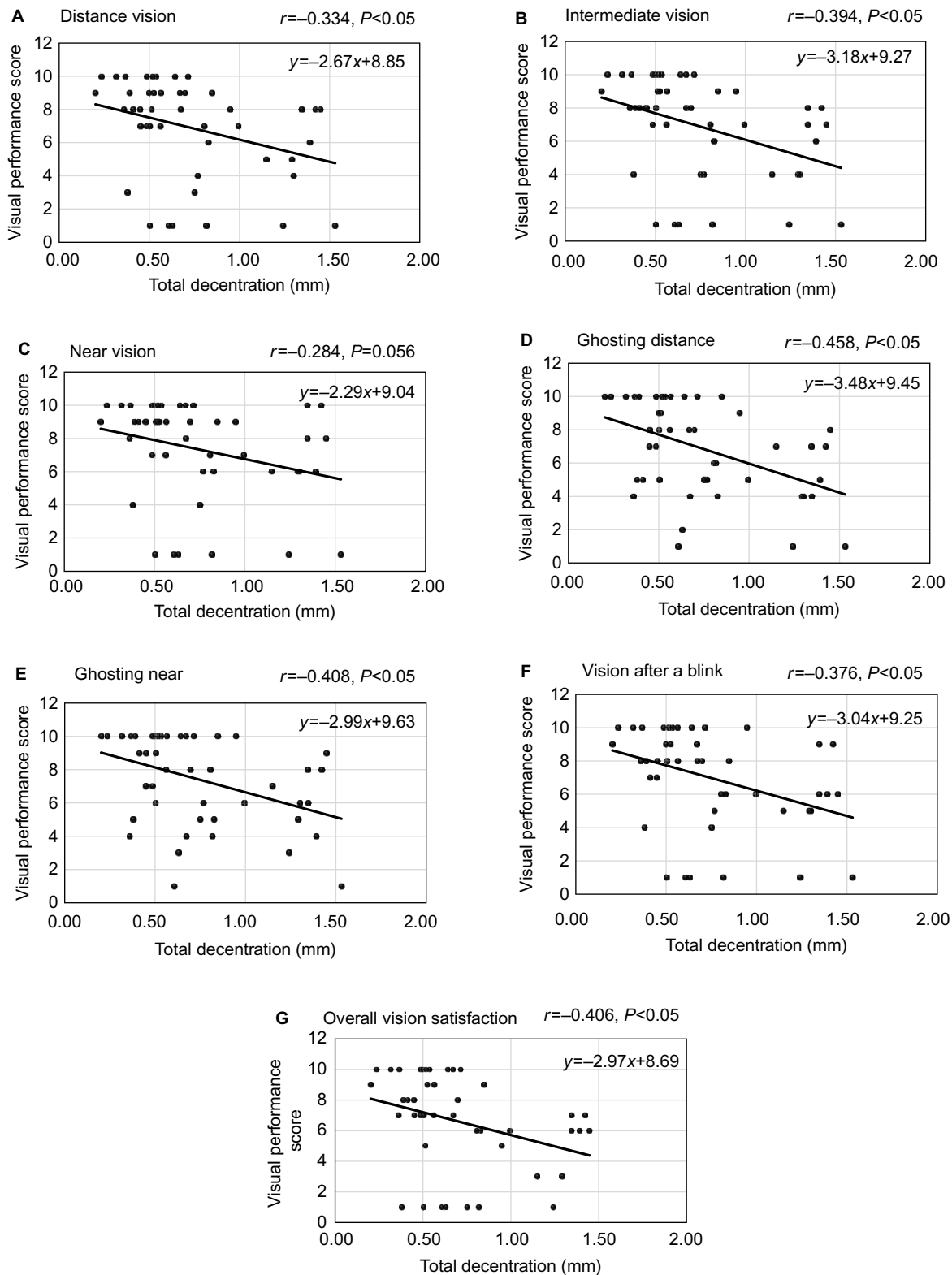


Figure 6 Subjective visual performance variables as a function of total decentration in the non-presbyopic group (A-G).

A computational model assessing the effect of translation of an optical device on eye describes the dependency of spherical aberration with $C(3, -1)$.¹⁶ This model confirms the results with the Proclear® MFCLs in the current study, which showed that when decentered in the same direction, MFCLs with positive spherical aberration would induce $C(3, -1)$ of opposite sign than MFCLs with negative spherical aberration.

In general, it should be noted that there are some methodological limitations when higher-order aberrations are measured with MFCLs on eye. Previously, it has been discussed¹¹ that the impact of multiple refractive zones across the pupillary zone can lead to the canceling out of aberrations across the measured pupil, making a direct comparison of induced aberrations between the different MFCL types difficult. This is particularly the case for concentric bifocal lens designs, and thus the presented aberration measurements with the ACUVUE® Bifocal lens in this study need to be interpreted with caution. However, as there were no significant differences between pupil sizes for the measurements obtained with the study lenses in each group, a good indication of the direction and magnitude on the average lens-induced third-order aberrations for the group-specific pupil size is given. Although, it would also have been of interest to assess the impact of certain third-order aberration coefficients, such as $C(3, -1)$, on vision, such an analysis was not performed due to the different illumination measurement conditions, ie, aberration measurements were conducted under low illumination conditions and visual performance was assessed under mesopic pupil conditions.

Multifocal CL decentration and vision

The current study aimed to assess the association between MFCL decentration, HCVA and LCVA, and subjective vision variables in presbyopes and non-presbyopes. A perceivable and statistically significant association was found for most vision variables in the non-presbyopic group, but not in the presbyopic group. Primarily, the difference between groups can be attributed to the greater magnitude of total decentration and the larger natural pupil diameters in the non-presbyopic group, leading to an increase in aberrations when compared to the presbyopic group. Further, it should be noted that the sample size and number of lenses tested in the non-presbyopic group were lower, which limits the direct comparison of group results. The study by Fernández-Sánchez et al¹⁷ assessed the impact of lens-induced third-order aberrations (coma: 0.05 μm , 0.13 μm , and 1.03 μm ; trefoil: 0.07 μm , 0.17 μm ,

and 0.96 μm) on objective vision in the non-presbyopic group and they found that only the large values ($\sim 1 \mu\text{m}$) of coma and trefoil induced with purpose-designed soft CLs significantly reduced HCVA and LCVA. In the current study, it was shown that significantly decentered commercial MFCLs (Proclear® MFCLs) induced third-order aberrations of $|0.08| - |0.13| \mu\text{m}$ (4 mm pupil analysis diameter). These values are much lower than the values which showed a significant change in HCVA and LCVA in the study by Fernández-Sánchez et al;¹⁷ nevertheless it was shown that there was an association between increased MFCL decentration and a reduction in LCVA, eg, total MFCL decentration of 0.75 mm reduced LCVA by 0.10 logMAR in the non-presbyopic group.

Surprisingly, in the presbyopic group, a significant improvement was found in the subjective responses given for near vision and vision after a blink as the total decentration increased. There are a few possible explanations why decentration did not lead to a decrease in visual performance, as it did in the non-presbyopic group, and why the association between MFCL decentration and vision was generally lower in the presbyopic group. First, the threshold of sensation to blur during aging is raised, which implies that more change is required to become aware of a change. It could be speculated that the presbyopic group may therefore be generally less sensitive to lens decentration. Second, in agreement with previous studies,²⁵⁻²⁷ it was shown that the presbyopic group in the current study presented with increased levels of inherent third-order aberrations, which could have already decreased their distance-corrected image quality.²⁷ With lens on eye, the magnitude of third-order aberrations was similar or even reduced for the majority of test lenses when compared to the magnitude of inherent third-order aberrations. This could explain why the association between lens-induced third-order aberrations, and thus decentration, and vision was small. Further, the two visual performance variables that showed a significant improvement with increase in total decentration were dynamic measures, ie, vision after a blink and near vision clarity (looking downwards). It could be speculated that a combination of lens decentration and an additional lens movement caused by performing those dynamic visual tasks could have led to this improvement in the ratings. Finally, it should be noted that this study was set out to assess only third-order aberrations. However, it is possible that a combination of other inherent and/or lens-induced higher-order aberrations could have also led to a change in visual performance.

Conclusion

Certain MFCLs decentered more than others, which can primarily be attributed to differences in lens design and fitting parameters. The same lens designs also induced significant amounts of third-order aberrations. An association between MFCL decentration and seven out of nine vision variables was found in the non-presbyopic group, ie, the group where lenses were most decentered, which had larger pupils and lower levels of inherent third-order aberrations.

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Disclosure

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