

Visual Performance and Optical Quality of Standardized Asymmetric Soft Contact Lenses in Patients With Keratoconus

Asaki Suzuki,^{1,2} Naoyuki Maeda,³ Mutsumi Fuchihata,³ Shizuka Koh,³ Kohji Nishida,³ and Takashi Fujikado¹

¹Department of Applied Visual Science, Osaka University Graduate School of Medicine, Suita, Japan

²Clinical Research and Development Center, Menicon Co., Ltd., Nagoya, Japan

³Department of Ophthalmology, Osaka University Graduate School of Medicine, Suita, Japan

Correspondence: Naoyuki Maeda, Department of Ophthalmology, Osaka University Graduate School of Medicine, Room E-7, Yamadaoka 2-2, Suita, Osaka, 565-0871, Japan; nmaeda@ophthal.med.osaka-u.ac.jp.

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PURPOSE. To evaluate the visual performance and optical quality of a standardized asymmetric soft contact lens (SCL) used for correction of higher-order aberrations (HOAs) in eyes with keratoconus.

METHODS. We included 30 eyes (26 patients) with keratoconus (average K: 45.7 ± 2.3 diopters [D]). The patients were subjected to corneal tomography, aberrometry, measurements of manifest refraction and visual acuity (VA), and visual analog scale (VAS) assessments. The study lenses were made using a molding method and consisted of six standardized types, in which an asymmetric power distribution of approximately 2 to 12 D (2-D step) was used to correct HOAs. The lens type suitable for each eye was selected based on the corneal tomography and aberrometry data. The on-eye performance of the lens was evaluated using aberrometry (4-mm pupil), over refraction, VA, and VAS.

RESULTS. The standardized asymmetric SCL improved the best spectacle-corrected VA from -0.07 ± 0.09 to -0.11 ± 0.08 logMAR ($P < 0.05$) and the mean VAS score from 66.2 ± 21.8 to 75.4 ± 20.5 ($P < 0.05$). Vertical coma decreased significantly (-0.50 ± 0.36 μm without SCL; -0.36 ± 0.34 μm with SCL; $P < 0.01$). In subgroup analysis, subjects in the high VAS group (score ≥ 75) accounted for 70% of all subjects, and this was the group in which the vertical coma decreased significantly from the level without the lens.

CONCLUSIONS. A standardized asymmetric SCL can reduce HOAs and improve vision quality when compared with spectacles in patients with keratoconus who wear rigid gas-permeable lenses.

Keywords: aberrations, contact lens, keratoconus

Keratoconus is a progressive corneal disorder characterized by a central corneal protrusion and thinning of the clear stroma that causes higher-order aberrations (HOAs).¹ Higher-order aberrations or irregular astigmatism cannot be corrected with spectacles or soft contact lenses (SCLs). Therefore, rigid gas-permeable contact lenses (RGPCs), scleral RGPCs that cover the entire cornea, and hybrid contact lenses with a rigid center surrounded by a soft lens skirt^{2,3} are used to improve visual acuity in patients with keratoconus.

When patients with keratoconus wear RGPCs, the HOAs derived from the anterior surface of the cornea are alleviated because the anterior corneal surface is replaced by the RGPC, while the space between the contact lens and the cornea is filled with tears. This results in superior quality of vision with RGPCs than with spectacles or SCLs in eyes with keratoconus. However, recent studies of HOAs in patients with keratoconus have revealed a problem whereby the residual irregular astigmatism derived from the posterior surface of the cornea causes vision quality deterioration while wearing RGPCs.^{4,5} Anxiety and disruption of daily life occur because of the psychological pressure of tolerating the foreign body sensation

and the inability to use the lenses when playing sports.^{6,7} In addition, the risk of corneal warpage caused by mechanical stress on the cornea, the relatively higher cost associated with processing and manufacturing of the contact lenses, and the fact that prescription is generally difficult are potential problems that are specific to RGPCs.

Specially designed SCLs, which are comfortable to wear, easy to prescribe, and offered at a reasonable price, are expected to improve this situation for eyes with keratoconus. Given that there is a problem in correcting HOAs with SCLs, it has been necessary to develop custom-made optical surfaces for SCLs with a design based on wavefront aberrometry.⁸⁻¹⁰ It is difficult to prescribe a fully custom-made SCL for each patient because of the prohibitive manufacturing costs.

On the other hand, recent studies have shown a trend in HOA patterns in patients with keratoconus.^{4,11,12} Most of these eyes have vertical coma where the wavefront is fast in the superior portion and slow in the inferior portion due to a superior-inferior asymmetry of the shape of the cornea in eyes with keratoconus.⁴ Therefore, like standard clothing sizes (small, medium, large) or current toric SCLs, it might be



TABLE 1. Properties of Prototype Lens

Material	Asmofilcon A
FDA group	Group I (nonionic material)
Water content	40.0%
Oxygen permeability	Dk: 129×10^{-11} (cm ² /s)·[mL O ₂ / (mL·mm Hg)]
Optical design	Asymmetrical power distribution at back surface
Peripheral design	Double vertical asymmetric slab-off and horizontal right and left ballast
Back vertex power	Plano (no sphere or cylinder power)
Central thickness	0.15 mm
Back surface radius	8.60 mm
Diameter	14.5 mm
Method of manufacture	Molding

FDA, US Food and Drug Administration.

possible to create semicustomized SCLs for keratoconus with a standardized coma design (consisting of the standardized amount and a particular axis of coma) that could be easily and inexpensively prescribed as standardized sets of lenses.

We, therefore, devised a standardized asymmetric SCL for patients with keratoconus that has asymmetric diopters in the posterior surface and performed a preliminary study to investigate the feasibility of this prototype lens that has no sphere or cylinder power.

METHODS

Subjects

This study was approved by the institutional review board at Osaka University Hospital and conducted in accordance with the principles of the Declaration of Helsinki and ethical guidelines for clinical research. Informed consent was obtained from all study participants after they were provided with a complete explanation of the significance and details of the study.

The study subjects consisted of 50 eyes of 37 patients with keratoconus or keratoconus suspect recruited from the Department of Ophthalmology, Osaka University Hospital. Patients who had incomplete corneal tomography or wavefront aberrometry were excluded, leaving 30 eyes of 26 patients as valid cases. The study population included 20 men (24 eyes) and 6 women (6 eyes) of mean (\pm SD) age 34.7 ± 6.7

(range, 21–48) years, with mean average-keratometric power of 45.7 ± 2.3 (range, 39.8–51.7), mean steep-keratometric power of 47.5 ± 2.9 (range, 40.5–54.7), and a mean flat-keratometric power of 43.9 ± 2.1 (range, 39.0–49.4). All eyes were wearing RGPCLs. Keratoconus or keratoconus suspect was diagnosed by one experienced ophthalmologist (NM) on the basis of the presence of central thinning of the cornea with a Fleischer ring, Vogt's striae, or both, by slit-lamp examination¹¹. Keratoconus suspect was defined as those with abnormal localized steepening observed in the axial power map on visual inspection using the 1.5 diopter (D; Klyce/Wilson) scale,¹⁵ no abnormal findings on slit-lamp examination, and visual acuity examination of 20/20 or better.¹⁴

Study Lens

The prototype lens used in this study was made of a silicone-hydrogel material as shown in Table 1. Regarding the optical design, an asymmetric power distribution in a vertical direction was applied within 6 mm of the optical zone at the back surface of the lens (Figs. 1A, 1B). The vertical asymmetric power distribution was sigmoidal, with positive power superiorly and negative power inferiorly (Fig. 1B). This lens was designed to correct the vertical asymmetric pattern seen on corneal tomography. The peripheral design of the lens was set as follows: thinner in the 12 o'clock and 6 o'clock directions to fit the anatomy of the lids (double vertical asymmetric slab-off) and thicker in the 3 o'clock and 9 o'clock directions for stabilization of the axis of the lens (horizontal ballast). The guide mark on the lens was set at 270° to check rotation of the lens. The lens diameter was 14.5 mm and its central thickness was 0.15 mm. The other properties of the lens are shown in Table 1. A standardized lens set with six different levels of asymmetric power specification of approximately 2, 4, 6, 8, 10, and 12 D (vertical coma C_3^{-1} : 0.18, 0.36, 0.54, 0.72, 0.90, and 1.08 μ m, respectively) was prepared. In these prototype lenses, the optic zone of the back surface had a vertical asymmetric power distribution, and the spherical power and cylindrical power of the optic zone of the anterior surface were not added. For this reason, spectacles were used in addition to the contact lenses to evaluate visual performance.

Corneal Tomography

Corneal tomography was performed using anterior segment optical coherence tomography (AS-OCT, SS-1000 CASIA; Tomey Corporation, Inc., Nagoya, Japan). Measurements were performed when the RGPCLs had not been worn for at least 30

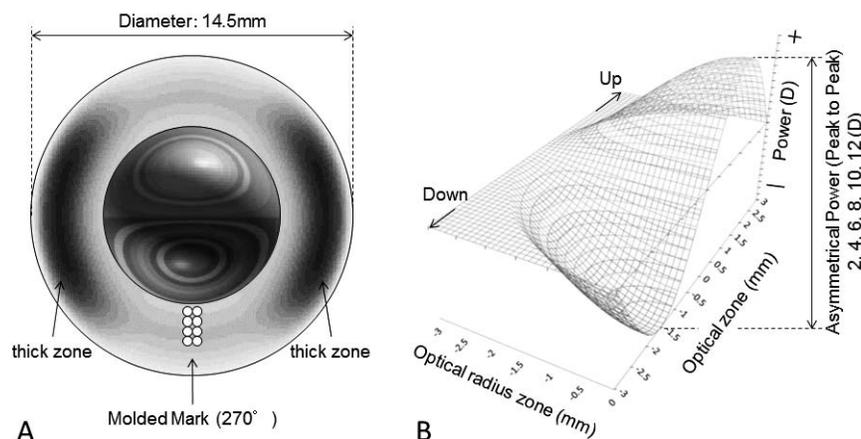


FIGURE 1. Lens design (A) and optical power map (B) of a prototype lens.

minutes. The light source is a swept-source laser and the center wavelength is 1310 nm.¹⁵ The measurement speed was 30,000 A-scans/second. This instrument had a 10- μ m resolution for a vertical plane and 30- μ m resolution for a horizontal plane. For corneal tomography, 16 radial cross-sectional images through the central 10-mm diameter of the cornea were obtained in 0.34 seconds. Each cross-sectional image consisted of 512 telecentric A-scans. The corneal tomographic data were recorded for the central 3-mm diameter, and four components (spherical, regular astigmatism, asymmetry, and higher-order irregularity) were identified by Fourier analysis.¹⁶

Visual Performance

Manifest refraction was conducted with the Jackson cross cylinder over the lens wear, and the best-corrected visual acuity was measured using a standard decimal visual acuity chart at 5 m. Visual acuity was converted from a decimal value to logMAR units. The manifest refraction was converted from diopters into a vector representation for analysis¹⁷: a spherical lens of power M (mean spherical equivalent refraction = sphere + [cylinder/2]); Jackson cross cylinder at axis 0° with power J_0 (= -[cylinder/2] cos [2 \times axis]) and Jackson cross cylinder at axis 45° with power J_{45} (= -[cylinder/2] sin [2 \times axis]).

The visual analog scale (VAS)¹⁸ score was used to compare quality of vision between the study lenses with spectacles and that of spectacles only. The VAS is a straight-line scale measuring 0 to 100 mm (in which 0 represents the worst blurred unstable vision and 100 the best clear crisp vision). The subject responds to the VAS by placing a mark on the line at a position that best reflects his/her current perception of quality of vision. The VAS is then scored by measuring the distance between the zero end of the scale and the point marked by the subject. We distinguished between subjects who experienced improvement and those who experienced exacerbation after fitting the study lens by dividing them into groups based on VAS score (low, 25–50; middle, 50–75; high, 75–100).

Higher-Order Aberrations

The ocular HOAs were measured using a Hartmann-Shack aberrometer (KR-1W; Topcon Corporation, Tokyo, Japan) for a 4-mm pupil diameter up to the sixth order by expanding the set of Zernike polynomials. For each pair of standard Zernike terms for trefoil, coma, tetrafoil, and secondary astigmatism, a single value for the magnitude of each term was calculated by Zernike vector analysis.⁴ Total HOAs were defined as the root mean square of the magnitudes for the third-order, fourth-order, fifth-order, and sixth-order aberrations. The spherical aberration was expressed as a positive or negative value, not as an absolute value. Aberrometry was performed for all subjects with and without the study lens after RGPCs had not been worn for at least 30 minutes. The measurements were repeated in each eye at least three times to obtain well-focused, correctly aligned Hartmann images in a dark room without topical mydriasis.

Selection of Contact Lens and Fitting Assessment

We selected the study lens from the standardized six-lens set and fitted this in the eye of the subject. The standardized lens was chosen to have the closest weaker asymmetric power on the basis of the corneal asymmetric power determined by the corneal tomography and the ocular vector coma found on aberrometry. If the selected design of the contact lens was different between corneal tomography and ocular aberrometry, the lens with better-corrected visual acuity was chosen.

To ensure a clinically acceptable fit, lens centration (horizontally and vertically), movement (digital push-up test,

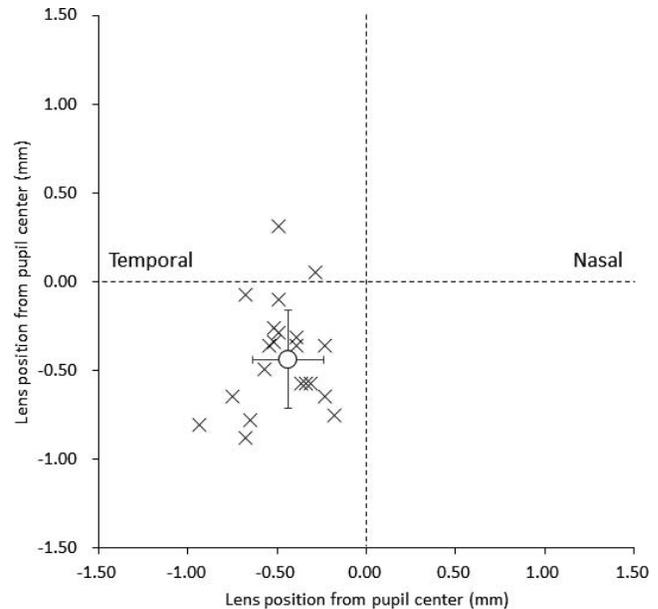


FIGURE 2. Lens position from pupil center.

with blink in the primary position and upon up-gaze, and both horizontal and vertical lag), corneal coverage, and lens orientation (primary position of the marker) were checked with a slit-lamp using established criteria¹⁹ 15 minutes after applying the study lens.

Visual acuity, VAS, and ocular HOAs recorded with or without the study lens were compared. The vertical coma (C_3^{-1}) and horizontal coma (C_3^1), calculated from the difference between values with and without the study lens, were compared with theoretical values for the trial lens.

Image analysis was performed using Placido rings to determine the geometric center of the lens, the decentration of the lens was calculated from the center of the pupil, and the guide mark on the study lens was used to measure the rotation of the lens. The relationship between the resting position of the study lens and residual coma aberration was analyzed.

Statistical Analysis

StatLight (Yukms Co., Ltd., Tokyo, Japan) was used for the statistical analysis. The paired t -test was used to compare the VAS scores and HOAs with and without the contact lens. The Wilcoxon signed-rank test was used to compare the manifest refraction and corrected visual acuity between with and without the contact lens. A P value less than 0.05 was considered to be statistically significant.

RESULTS

Selection of Standardized Contact Lenses

The contact lenses selected from the six standardized lens sets for the subjects comprised four 2-D standard lenses, eleven 4-D lenses, five 6-D lenses, seven 8-D lenses, and three 10-D lenses. No 12-D lenses were used.

Centration and Rotation of Contact Lenses

Figure 2 shows the centration of the lens. The mean position of the lens with respect to the center of the pupil was horizontally shifted by a mean of 0.44 ± 0.20 mm in the

TABLE 2. Manifest Refraction With and Without Contact Lens

Power Vector	Without CL	With CL	P Value
SE	-3.83 ± 2.94 D	-3.75 ± 2.76 D	0.5104
J0	-0.35 ± 0.94 D	+0.17 ± 0.86 D	<0.0001
J45	-0.22 ± 0.73 D	-0.08 ± 0.76 D	0.2757

SE, spherical equivalent. The results are expressed as the mean ± SD. P value, Wilcoxon signed-rank test.

temporal direction and vertically shifted by a mean of 0.44 ± 0.28 mm in the inferior direction. The mean distance between the center of the lens and the center of the pupil was 0.67 ± 0.22 mm. The mean position of the mark on the contact lens was 269.77° ± 5.40°, and was close to 270°.

Manifest Refraction

Table 2 showed the manifest refraction with and without the contact lens. No significant difference in spherical equivalent was observed between the two groups. However, the J0 refractive component was significantly altered in the presence of the contact lens when compared with its value without the contact lens (P < 0.0001, Wilcoxon signed-rank test).

Best Corrected Visual Acuity

The mean best-corrected visual acuity was -0.07 ± 0.09 logMAR without and -0.11 ± 0.08 logMAR with the contact lens. There was a statistically significant improvement in best-corrected visual acuity after fitting the contact lens (P = 0.0359, Wilcoxon signed-rank test).

Visual Analog Scale

The mean VAS score was 66.2 ± 21.8 under spectacle correction and 75.4 ± 20.5 under spectacle correction with contact lens wear. There was a statistically significant improvement in VAS scores after lens wear (P = 0.0335, paired t-test).

Higher-Order Aberrations

Table 3 showed the ocular HOAs with and without contact lens wear. Total HOAs were 0.65 ± 0.36 μm before and 0.56 ± 0.36

TABLE 3. Ocular Higher-Order Aberrations With and Without Contact Lens

Zernike Terms	Without CL	With CL	P Value
Total HOA	0.65 ± 0.36	0.56 ± 0.36	0.0863
C ₃ ⁻³	0.10 ± 0.17	0.13 ± 0.16	0.3886
C ₃ ³	-0.05 ± 0.19*	0.14 ± 0.15*	<0.0001
C ₃ ⁻¹	-0.50 ± 0.36†	-0.36 ± 0.34†	0.0093
C ₃ ¹	-0.08 ± 0.12†	-0.17 ± 0.20†	0.0046
C ₄ ⁻⁴	-0.02 ± 0.06	-0.04 ± 0.06	0.2631
C ₄ ⁴	0.03 ± 0.07	0.01 ± 0.06	0.0988
C ₄ ⁻²	0.05 ± 0.09*	-0.04 ± 0.08*	<0.0001
C ₄ ²	-0.09 ± 0.11*	0.02 ± 0.09*	<0.0001
C ₄ ⁰	0.04 ± 0.12*	-0.10 ± 0.12*	<0.0001

The results are expressed as the mean ± SD. Unit of measurement: μm.

* P < 0.0001.

† P < 0.01, paired t-test.

μm after wearing the lens. There was no significant difference between the two groups (P=0.0863, paired t-test). Vertical coma (C₃⁻¹) was -0.50 ± 0.36 μm without and -0.36 ± 0.34 μm with the lens, indicating a significant decrease in vertical coma with the lens (P=0.0093, paired t-test). Trefoil (C₃³), horizontal coma (C₃¹), secondary astigmatism (C₄⁻² and C₄²), and spherical aberration (C₄⁰) showed significant differences between with and without the contact lens (P < 0.01, paired t-test).

Table 4 shows the subgroup analysis where ocular HOAs with and without the contact lens were compared among the three VAS score groups. Four eyes (13% of all eyes) in the low VAS group had a score of greater than 25 and less than 50, 5 eyes (17% of all eyes) in the middle VAS group had a score of greater than 50 and less than 75, and 21 eyes (70% of all eyes) in the high VAS group had a score of greater than 75, which indicate subjective visual performance; however, only those with a high VAS score showed a significant reduction in total HOAs with the lens (P = 0.0147, paired t-test). For trefoil (C₃³) and spherical aberration (C₄⁰), all three VAS groups had a significant positive shift in trefoil (P ≤ 0.05) and a negative shift in spherical aberration (P ≤ 0.05) with the lens. With regard to coma (C₃⁻¹ and C₃¹), the group with a high VAS score showed a significant reduction in vertical coma (C₃⁻¹) (P = 0.0016) with the lens. In contrast, the group with a middle VAS score showed a significant increase in horizontal coma (C₃¹)

TABLE 4. Comparison of Total Higher-Order Aberrations and Zernike Terms With and Without Contact Lens Between Three Groups

Zernike Terms	Low VAS Group, n = 4 (13%)			Middle VAS Group, n = 5 (17%)			High VAS Group, n = 21 (70%)		
	Without CL	With CL	P Value*	Without CL	With CL	P Value*	Without CL	With CL	P Value*
Total HOA	0.68 ± 0.18	0.75 ± 0.18	0.3049	0.80 ± 0.29	0.86 ± 0.52	0.6832	0.60 ± 0.40§	0.45 ± 0.30§	0.0147
C ₃ ⁻³	0.14 ± 0.14	0.27 ± 0.17	0.1748	-0.01 ± 0.15	0.04 ± 0.17	0.7599	0.11 ± 0.18	0.12 ± 0.14	0.8407
C ₃ ³	-0.18 ± 0.19§	0.22 ± 0.10§	0.0120	-0.10 ± 0.21§	0.17 ± 0.21§	0.0436	-0.01 ± 0.18*	0.11 ± 0.14*	<0.0001
C ₃ ⁻¹	-0.45 ± 0.20	-0.51 ± 0.19	0.6570	-0.67 ± 0.25	-0.65 ± 0.51	0.8783	-0.46 ± 0.40‡	-0.26 ± 0.26‡	0.0016
C ₃ ¹	-0.08 ± 0.12	-0.28 ± 0.23	0.2561	-0.16 ± 0.05§	-0.37 ± 0.20§	0.0490	-0.06 ± 0.13	-0.10 ± 0.16	0.0936
C ₄ ⁻⁴	0.02 ± 0.06	-0.05 ± 0.07	0.0533	0.01 ± 0.08	-0.10 ± 0.08	0.0876	-0.04 ± 0.06	-0.02 ± 0.05	0.0851
C ₄ ⁴	0.03 ± 0.10	-0.01 ± 0.09	0.4850	0.01 ± 0.11	-0.01 ± 0.07	0.7183	0.04 ± 0.06	0.02 ± 0.05	0.1419
C ₄ ⁻²	0.13 ± 0.10‡	-0.01 ± 0.07‡	0.0028	0.10 ± 0.09	-0.03 ± 0.11	0.1482	0.02 ± 0.08†	-0.05 ± 0.07†	0.0001
C ₄ ²	-0.18 ± 0.05‡	0.06 ± 0.03‡	0.0048	-0.16 ± 0.16	-0.04 ± 0.10	0.0834	-0.06 ± 0.09†	0.03 ± 0.09†	0.0002
C ₄ ⁰	0.19 ± 0.04‡	-0.09 ± 0.06‡	0.0016	0.12 ± 0.11§	-0.09 ± 0.10§	0.0149	0.00 ± 0.10*	-0.10 ± 0.13*	<0.0001

Unit of measurement: μm.

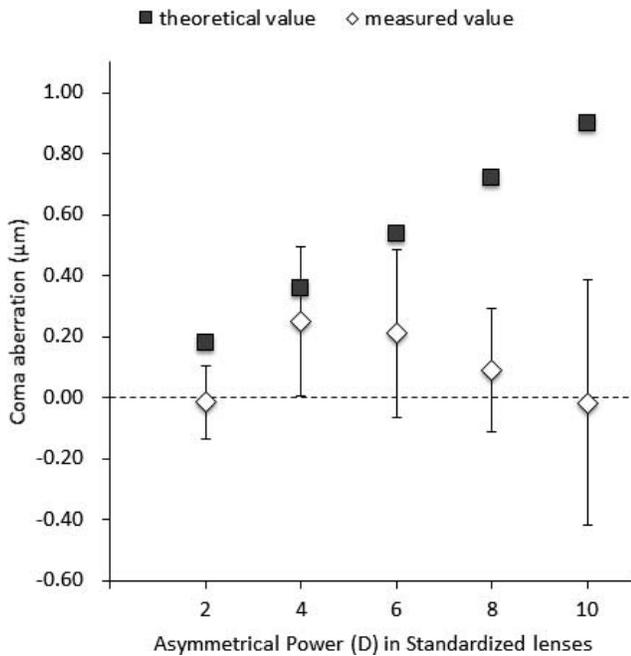
* P < 0.0001.

† P < 0.001.

‡ P < 0.01.

§ P < 0.05, paired t-test.

A: Vertical Coma



B: Horizontal Coma

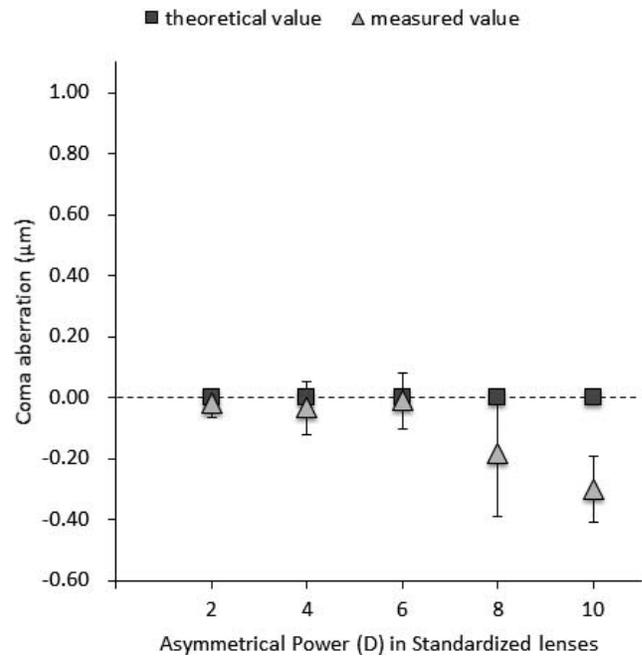


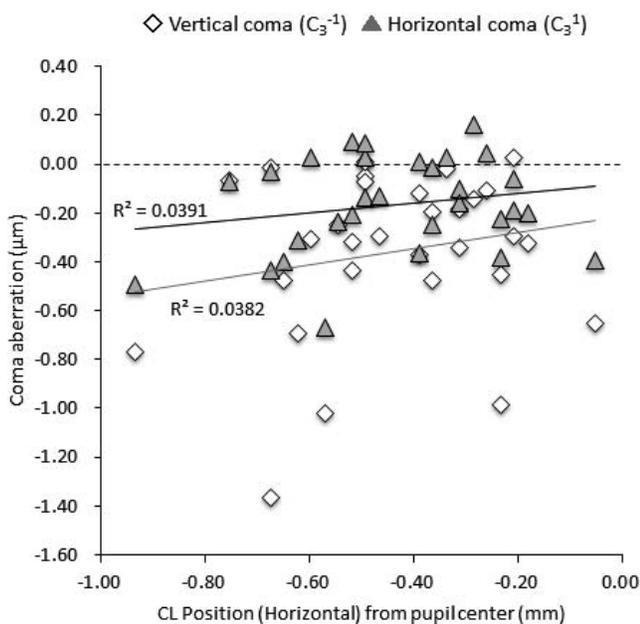
FIGURE 3. Theoretical and measured coma values in five standardized asymmetric soft contact lenses ([A] vertical coma; [B] horizontal coma). The measured value indicates the difference between coma with the lens and that without the lens.

with the lens ($P = 0.049$). There was a significant difference in secondary astigmatism (C_4^{-2} and C_4^2) between the high and low VAS score groups with and without the lens ($P < 0.01$).

Figure 3 shows the values for theoretical coma and measured coma obtained from the difference between with and without a lens for the five standardized contact lenses.

Correction of vertical coma by the lens was decreased when lenses with an asymmetric power of 6 D and above were used (Fig. 3A). Horizontal coma was increased dramatically in the negative direction for contact lenses with an asymmetric power of 8 D or more (Fig. 3B).

A: Horizontal decentration



B: Vertical decentration

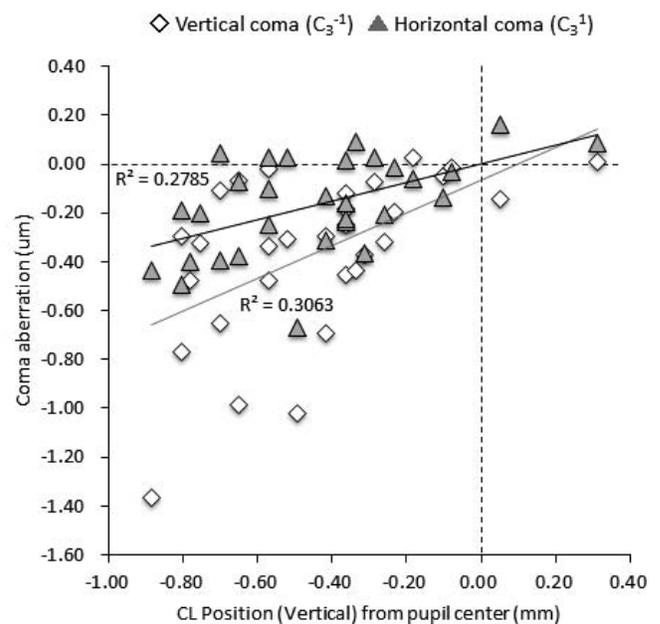


FIGURE 4. Correction of coma by the lens and position of contact lens from pupil center ([A] horizontal; [B] vertical).

Figure 4 indicates the relationship between the coma by the lens and the position of the lens from the pupil center (Fig. 4A, horizontal; Fig. 4B, vertical). As shown in Figure 4A, there was no significant correlation between the horizontal decentration of the contact lens and horizontal ($P = 0.7274$) or vertical ($P = 0.6641$) coma. However, there were significant correlations between the vertical decentration of the contact lens and horizontal ($P = 0.0108$) and vertical ($P = 0.0273$) coma (Fig. 4B).

DISCUSSION

Previous studies have indicated that there is a regular pattern of HOA in eyes with keratoconus.^{4,11,12} The vertical coma is dominant and the angle of coma is in a similar range for the majority of eyes with keratoconus. Therefore, the purpose of this study was to assess whether six standardized SCLs made using silicone hydrogel and having different vertically asymmetric power distributions could effectively correct irregular astigmatism in patients with keratoconus.

Our findings suggest that correction using the above-mentioned lenses is a promising option for some patients with mild keratoconus or keratoconus suspect who wear RGPCLs. Use of standardized lenses with spectacles resulted in statistically significant improvements in corrected visual acuity, VAS score, and all the endpoints for HOAs when compared with spectacles without these lenses.

Marsack et al.²⁰ described an attempt to correct irregular astigmatism in patients with keratoconus using custom-made SCLs created to fully correct all ocular HOAs based on Zernike polynomials and reported that the visual performance was significantly improved in the patients, although the correction was not 100%. Jinabhai et al.²¹ and Katsoulos et al.⁸ used custom SCLs designed to achieve 50% to 100% correction of third-order coma aberration, and their results showed that the visual performance of patients with keratoconus improved without correcting all the Zernike terms.

Our results are consistent with those of previous studies in terms of the correction of vertical coma aberration with SCLs. However, in our study, we used contact lenses that were standardized with several different vertically asymmetric power configurations rather than custom-made lenses adjusted for patients individually. This is similar to the situation with toric SCLs, which are already standardized and can improve visual performance even if regular astigmatism cannot be 100% corrected.²² Use of standardized SCLs may reduce the complexity and manufacturing costs that are inevitable for custom-made lenses and may be made available on prescription as simply as toric SCLs. These standardized lenses are potentially beneficial for both patients with keratoconus and eye care professionals.

Although our standardized lenses achieved a statistically significant reduction in HOAs in patients with keratoconus, the reduction was not satisfactory from the clinical point of view. In five of the six different types of standardized lenses, there were significant disparities between the theoretical values and measured values for coma correction, and there were increases in horizontal coma aberration. We think that there are at least three possible causes for these observations.

First, standardized lenses were determined to have the closest coma aberration that is less than the patient's coma. Therefore, the actual correction with a standardized lens should always be undercorrected.

Second, there might be undercorrection due to misalignment in the angle of coma. Standardized lenses have rotation errors that are virtually stable at $269.77^\circ \pm 5.40^\circ$. Therefore,

the effect of the rotation error of lenses on the decreased correction effect is likely to be less.²³

Third, the decentration of the resting position of the lens is associated with a reduction of the correction. Although custom-made SCLs were designed to correct all HOA components in the previous studies as reported by Marsack et al.²⁰ or all the third-order coma aberration, as reported by Jinabhai et al.,²¹ they could not always achieve 100% correction. Both these studies suggested that the undercorrection could be due to the decentration of the lenses. Using optical simulation, da Brabander et al.²³ showed that visual performance declined when the decentration of a custom-made SCL exceeded 0.5 mm. In our study, the mean error of the resting position of the standardized lenses from the center of the pupil was 0.67 ± 0.22 mm. The relationship between the resting position of the lens and the residual coma showed that the residual vertical and horizontal coma tended to increase, particularly when the deviation in the vertical direction was large, and that the amount of coma corrected with a lens decreased according to the amount of error in the resting position. Therefore, it is reasonable to conclude that the ability of our standardized lenses to correct coma deteriorated mainly as a result of vertical decentration of the lens.

The subgroup analysis based on VAS scores suggested that, for a success rate of 70% or more using the current standardized lenses for patients with keratoconus, eyes with VAS scores greater than or equal to 75 should be enrolled. This is because eyes in the high VAS score group (score ≥ 75) comprised 70% of all eyes, and this was the group in which the vertical coma was significantly reduced from the level without the lens.

This study has some limitations. In addition to the small sample size, we could not fit the lenses in patients with advanced keratoconus, and thus could not evaluate a standardized lens with a vertical power difference of 12 D. The reason for this is that patients who had incomplete wavefront aberrometry before fitting of the lens were excluded. Therefore, it is difficult to determine from our results the effective degree of irregular astigmatism that can be corrected using these standardized lenses in patients with keratoconus. Future studies should test these lenses in larger numbers of patients with keratoconus and with a broad range of disease severity. Another limitation is that the extent to which spectacle blur or contact lens induced corneal warpage affected the results of the study is unknown. For this reason, we are conducting another clinical study in which subjects are asked not to wear their contact lenses for the day of examination. The other limitation is that the efficacy of correction using the current standardized lens design did not correlate with the theoretical asymmetric power due to decentering in the resting position. We are presently modifying the optical design of the lens to reduce the decentration and conducting a study to evaluate the improvement in optical performance using the modified SCL.

In conclusion, we have devised a standardized SCL for correction of irregular astigmatism in patients with keratoconus or keratoconus suspect who wear RGPCLs, and have demonstrated that such standardized lenses are capable of correcting vertical coma and improving visual performance in some of these patients.

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