

Evaluating the Wavefront Aberration Properties of Senofilcon A Photochromic Contact Lenses

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Abstract

Purpose To assess the wavefront aberrations of photochromic senofilcon A contact lenses in both activated and inactivated states.

Methods In this cross-sectional study, 20 subjects who had previously used soft contact lenses were enrolled. Corneal topography and aberrometry measurements were performed on each subject during one session with Sirius Scheimpflug-Placido topography (Sirius, Costruzione Strumenti Oftalmici, Italy). Following the first measurement of an eye without a contact lens, the measurements were performed with the photochromic contact lens in the inactivated and activated states, respectively. The corneal topographic [flattest keratometry (K1), steepest keratometry (K2), the axis of the steep meridian (Axis)] and aberrometric [root-mean-square (RMS) of aberrations; optical path difference (OPD), higher-order (HOA), astigmatism, coma, spherical aberration, and residual aberration] measurements were evaluated.

Results The average contact lens sphere power was -2.33 ± 1.07 D. The mean refractive errors were 0.07 ± 0.18 D for sphere and -0.26 ± 0.15 D for cylinder when wearing contact lenses. The mean RMS values of all corneal aberrations showed no statistically significant difference in both activated and inactivated states ($p > 0.05$). In bivariate correlation analyses, all the aberration parameters showed no significant correlation with keratometric and contact lens associated variables (sphere power and refractive errors of eyes with contact lenses) in both states ($p > 0.05$).

Conclusions The photochromic contact lenses did not increase the corneal aberrations in both inactivated and activated states. This property may help to provide a more comfortable vision in the real-world. Even so, this conclusion needs to be verified.

Introduction

According to reports, approximately 2.2 billion people worldwide experience visual deficiencies, and 43% of visual impairments are attributed to uncorrected refractive errors [1]. Although surgical approaches to correct refractive errors have gained popularity nowadays, spectacles and contact lenses remain the most common preferable methods. By the 21st century, the increasing number of contact lenses indications, such as cosmetic, refractive, and therapeutic reasons, has led to accelerations of their widespread use.

The retinal image quality is influenced either by low-order optical aberrations (sphere and cylinder) or by higher-order aberrations (HOAs). Even contact lenses have advantages in correcting refractive errors over spectacles, the rotations on the ocular surface may induce asymmetrical parts of HOAs such as coma-like aberrations [2, 3]. There are main factors, such as lens design, lens thickness, and tear film, contributing to HOAs. Furthermore, even the small amount of lens decentration produces significant HOA [2]. Recent advances in technology have been focused on incorporating HOA elements into contact lens designs. Some manufacturers have incorporated aspheric optics into the design of soft contact lenses to reduce spherical aberration as a means of partially correcting HOAs [4, 5].

Current innovation in soft contact lenses has been developed regarding the addition of the naphthopyran monomer (photochromic additive), which may improve the visual performance in situations relatable to real-world experience. The first design of a photochromic contact lens (Acuvue® Oasys with Transitions™) was approved by the U.S. Food and Drug Administration in April 2018 [6]. These lenses react to darken in 45 seconds when exposed to ultraviolet (UV) and/or high energy visible (HEV) light. The photochromic lenses have dynamically absorbed visible light to a minimum of 84% transmittance in the inactivated state and a minimum of 23% transmittance in the activated state, dependent on the lens thickness and the intensity of UV and HEV radiation. The transmittance characteristics are less than 1% in the UVB (the range from 280 nm to 315 nm) and less than 10% in the UVA (the range from 316 nm to 380 nm) for the entire power range.

Recent available literature regarding the photochromic soft contact lens has emphasized its performance on visual recovery, contrast sensitivity, and driving [7, 8]. The wavefront aberrations of patients fitted with this lens have not yet been reported in the literature. Hence, we aimed to compare the wavefront aberration characteristics of the photochromic contact lenses, especially in the activated state.

Patients And Methods

In this cross sectional study, 20 participants who had previously used soft contact lenses were enrolled. The procedures followed were in accordance with the ethical standards of the responsible committee and adhered to the tenets of the Declaration of Helsinki. Enrolled participants provided written informed consent before any study-related procedures.

Inclusion criteria were any patient with mild-to-moderate myopia (more than - 1.00 D to - 6.00 D) aged > 18 years. The patient's vertex corrected spherical equivalent distance refraction had to be in the range of - 1.00 to - 5.50 D, and all patients had at least 20/25 visual acuity in each eye.

Exclusion criteria included high myopia (greater than - 6.00 D), the presence of corneal scarring, history of previous corneal surgeries or ocular pathology, history of systemic medications, collagen vascular diseases, corneal dystrophies, pregnancy or breastfeeding. Appropriate patients were fitted with photochromic contact lenses, which were assessed for position and movement. Table 1 summarizes the properties of the photochromic contact lens. The photochromic contact lenses were senofilcon A material and the product comprised a photochromic additive, improved by Johnson & Johnson Vision Care, in collaboration with Transitions Optical, Inc.

Table 1
The properties of the photochromic contact lens

Parameter	Acuvue Oasys with Transitions
Lens material	Senofilcon A
Water content	38%
Surface character	Hydrophilic
Nominal base curve at 22 °C (mm)	8.4
Nominal diameter at 22 °C (mm)	14.0
Dk/t	121 at -3.00 D
Lens design	Spheric
Visible light transmission (inactivated)	84% minimum
Visible light transmission (activated)	23% minimum
<i>Dk/t</i> units $\times 10^{-9}(\text{cm}/\text{sec})(\text{ml O}_2/\text{mL} \times \text{mmHg})$	

Measurements

All patients underwent a complete ophthalmologic examination, including measurement of refractive error with and without contact lenses, intraocular pressure (IOP), visual acuity, and dilated fundus examination.

Three corneal topography and aberrometry measurements were performed on each subject during one session with Sirius Scheimpflug Placido Topography System (Sirius, Costruzione Strumenti Oftalmici, Italy). From patients wearing the photochromic contact lens in both eyes, one eye was selected randomly for analysis. The same clinician evaluated the fit of the contact lenses using slit-lamp biomicroscopy. The first measurements were collected on each patient's eye without contact lenses. The measurements were repeated in the presence of photochromic soft contact lenses in one continuous session and performed in the inactivated and activated states, respectively.

Hammond et al. [7] explained that the activated state was achieved using a violet activator consisting of LEDs ($\lambda_{\text{max}} = 400$, half bandwidth = 10 nm). The degree of estimated activation measured with spectral sensitivity. HEV light, often referred to as blue light (from 400 to 500 nm), passes through the lens and reaches the retina. The cumulative exposure to blue-violet light can contribute to long-term irreversible changes in the retina [9]. Accordingly, the photochromic contact lens was illuminated by a blue-violet light ($\lambda_{\text{max}} = 420$ nm) for 45 seconds to reach an activated state. After the illumination, contact lenses were applied once again without waiting, and the third measurement was performed.

The central fixation light was used to achieve the patient's perfect alignment, eye movement of the subject regularly tracked by the system. All measurements were performed in automode over a 6-mm pupil scan diameter under mesopic illumination (~4.0 lux), as advised by the original manufacturer. Patients were asked to blink between the examinations to keep the tear film intact.

The corneal topographic [flattest keratometry (K1), steepest keratometry (K2), the axis of the steep meridian (Axis)] and aberrometric [root-mean-square (RMS) of aberrations; optical path difference (OPD), higher-order (HOA), astigmatism, coma, spherical aberration, and residual aberration] measurements were evaluated.

Statistical Analysis

All data summaries and statistical analyses were performed using SPSS software (version 22; SPSS Inc., Chicago, IL, USA). Quantitative data were presented as mean \pm standard deviation (SD) and range. The normality of the data was confirmed using the Kolmogorov-Smirnov/Shapiro-Wilk Test. According to the data, the Friedman test was used for the evaluation of the corneal aberration parameters without normal distribution. Parameters of the intergroup (repeated-measures) comparisons were conducted with post hoc Wilcoxon signed-rank test (Bonferroni corrected). Two-sided p value of $\alpha \leq 0.05$ was considered statistically significant.

Results

Of the patients enrolled in the study, 16 (84%) patients were female, and 4 (16%) patients were male. The average age was 28.5 ± 5.9 years. The characteristics of the participant's keratometric and contact lens associated variables are detailed in Table 2. The mean keratometric powers were 43.12 ± 1.55 D (K1) and 44.00 ± 1.44 D (K2), and the mean axis of steep meridian was 85 ± 18 degrees without contact lenses. The average contact lens sphere power was -2.33 ± 1.07 D. The mean refractive errors were 0.07 ± 0.18 D for sphere and -0.26 ± 0.15 D for cylinder when wearing contact lenses.

Table 2
The characteristics of patient's keratometric and contact lens related variables

Number of Eyes	K1 flat (D)	K2 steep (D)	Axis-steep (Degrees)	Contact lens sphere power (D)	Refractive errors with contact lens (D)	
					Sphere	Cylinder
1	43.25	44.70	94	-3.00	0.25	-0.50
2	41.65	42.44	95	-1.75	0.00	-0.25
3	43.80	44.15	66	-5.25	0.25	-0.25
4	44.35	45.26	83	-2.25	0.25	-0.50
5	41.39	41.76	99	-1.25	0.00	-0.25
6	43.90	42.53	90	-2.50	0.00	-0.25
7	40.58	42.85	107	-2.25	0.25	-0.25
8	44.00	44.57	71	-3.00	0.00	-0.25
9	42.81	43.73	72	-2.50	0.25	-0.50
10	45.33	45.65	101	-3.50	-0.25	0.00
11	44.93	45.98	91	-3.50	0.25	-0.25
12	43.39	44.10	73	-1.00	0.00	-0.25
13	42.31	42.53	30	-3.00	0.00	-0.25
14	43.15	44.28	107	-2.75	0.25	-0.50
15	42.42	44.50	94	-2.25	0.00	-0.25
16	45.26	45.97	73	-1.00	0.25	-0.25
17	45.39	46.82	95	-1.00	0.00	-0.25
18	42.26	42.91	82	-2.50	-0.25	0.00
19	42.46	43.22	97	-1.00	0.25	-0.25
20	39.84	42.09	97	-1.50	-0.25	0.00
<i>D</i> diopter, <i>K</i> Keratometry						

Mean RMS results of corneal wavefront aberrations were showed in Table 3, with statistical significance levels in Fig. 1. When we compared the mean RMS values of all corneal aberrations, we did not observe any statistically significant difference among the groups ($p > 0.05$ for all).

Table 3

Root Mean Square (RMS) Results of Corneal Wavefront Aberrations in microns

	Without contact lens (n=20)	Contact lens in inactivated state (n=20)	Contact lens in activated state (n=20)	* <i>p</i> value
OPD	0.64 ± 0.36 (0.46 to 0.81)	0.62 ± 0.35 (0.45 to 0.78)	0.63 ± 0.30 (0.49 to 0.78)	0.450
HOA	0.30 ± 0.11 (0.24 to 0.35)	0.33 ± 0.13 (0.27 to 0.39)	0.32 ± 0.13 (0.26 to 0.39)	0.627
Astigmatism	0.53 ± 0.39 (0.35 to 0.72)	0.47 ± 0.35 (0.31 to 0.64)	0.50 ± 0.34 (0.34 to 0.66)	0.513
Coma	0.20 ± 0.10 (0.15 to 0.25)	0.23 ± 0.13 (0.17 to 0.29)	0.19 ± 0.12 (0.13 to 0.25)	0.284
Spherical Aberration	0.09 ± 0.04 (0.07 to 0.11)	0.09 ± 0.03 (0.07 to 0.10)	0.08 ± 0.04 (0.06 to 0.11)	0.518
Residual Aberration	0.18 ± 0.08 (0.15 to 0.22)	0.21 ± 0.07 (0.17 to 0.24)	0.23 ± 0.10 (0.18 to 0.27)	0.258
<i>OPD</i> optical path difference, <i>HOA</i> higher orders aberration				
The data represents mean ± SD and %95 Confidence Interval				
*Friedman test				

Bivariate correlation analyses were performed between keratometric and contact lens associated variables with the corneal aberrations. No significant correlation was observed with the keratometric values ($p > 0.05$ for all). Also, no significant correlation of contact lens sphere power was noted with the corneal aberrations, even in inactivated and activated states ($p > 0.05$ for all). All the aberration parameters showed no significant correlation with refractive errors when wearing contact lenses ($p > 0.05$ for all).

Discussion

The aim of a soft contact lens is not only to restore visual acuity but also to obtain a better quality of vision. In bright light conditions, the contact lens does not affect visual function due to its transparency, but scattering causes deterioration of vision [10]. The advanced design of a contact lens with photochromic additive, which filters in a dose-dependent manner depending on the intensity and wavelength of light, has been created for improving vision in such circumstances. The photochromic contact lenses would be expected to change optical density, and the lens had an optical density of about 0.20 in the activated state [7].

Even though previous studies have highlighted its visual performance, there have been no reports about the corneal wavefront aberrations of the photochromatic contact lenses in the literature. In this study, we evaluated the corneal wavefront aberrations of the photochromic contact lenses in both inactivated and activated states.

Renzi-Hammond et al. [7] measured photostress recovery, glare disability, glare discomfort, chromatic contrast, and vernier acuity. There was a beneficial influence on visual function with the photochromic contact lens, except vernier acuity. In a study by Buch et al. [8], its visual and driving performance were compared. Research showed that the photochromic soft contact lens was no different to non-photochromic soft contact lens or photochromic spectacles in both daytime and nighttime lighting under real-world conditions. According to the results of this study, the wavefront aberrations are consistent with the currently available literature regarding the photochromic soft contact lenses. These lenses may improve the visual performance via the dynamic photochromic balance between how dark the lens gets outdoor and the acceptability of the aberration profile.

HOAs have a noticeable influence on vision not correctable by glasses or contact lenses. Correcting refractive power and astigmatism, as well as HOAs induced by various contact lens designs, are the significant factors about the visual quality [11]. Numerous contact lenses related factors have been reported for the variability of HOAs, including lens design, lens material, position and movement of lenses on the eye [2, 11, 12]. Moreover, there are also variations in ocular surface-related HOA, such as fluctuations in the tear film [13].

The general population has positive spherical aberration [14], and most of the commercially available single vision contact lenses are primarily intended to reduce this. Multiple contact lens manufacturers' lenses include aspheric designed optics, which provide much more precise light guidance. McAlinden et al. [11] reported that the aspheric front surface design of Balafilcon A and Comfilcon A might have caused an increase in some aberrations. However, these increases were not clinically meaningful when the clinically significant change in magnitude was considered to be 0.1 μm . Efron et al. [15] found that the fitting of aspheric design soft contact lenses did not result in superior aberration control compared with equivalent spherical design soft contact lenses. These aberrations did not alter the daily performance of soft contact lenses. Even though the photochromic soft contact lenses had a spheric design, the average corneal aberrations were not affected in the current study.

The clinical relevance of aspheric over spheric contact lens remained controversial. Theoretical calculations have been demonstrated that spherical contact lenses induced HOA and reduced overall optical performance [16]. Roberts et al. [17] suggested that soft spherical contact lenses for myopia increased HOA compared to not wearing a contact lens. However, the alterations were not statistically significant when individually evaluated. Jiang et al. [18] examined three different types of soft spherical contact lens and reported that the differences in aberrations could be attributed to the variation in the manufacturing. Nevertheless, lens material and design could not be excluded. Our findings seem to support that the photochromic spherical contact lenses did not induce HOAs, especially under changing

light conditions. When we compared HOAs in both inactivated and activated states, we did not observe any difference. The findings of this study may be associated with the photochromic additive part as the differences in the methods of manufacture.

Previous studies reported that spherical aberration induced by contact lens depends on lens power [19, 20]. We found no significant correlations between all aberrations with the contact lens sphere power in both inactivated and activated states. The refraction of the enrolled patients was a variation between -1.00 D and -5.25 D. Also, the age distribution was limited in the range of 19 to 39 years to minimize the variation of aberration. Further studies will elucidate the impact of lens power on HOA in the population with different powers.

This study aimed to interpret the effect of the photochromic contact lens on wavefront aberrations in daily conditions. Therefore, the aberrations in inactivated and activated states were reported. There will be other approaches to determine the specific aberrations, but our study was mainly interested in the clinical performance of photochromic lenses. The photochromic filter always adapts to the changing light conditions, both indoors and outdoors conditions. Our study suggested that the adaptation did not increase corneal wavefront aberrations. Accordingly, these lenses could be offered to patients bothered by light to provide all-day vision. Photochromic contact lenses reduce the visual discomfort caused by aberration and might be helpful for performing outdoor activities such as sports.

One of the limitations was the relatively small sample size. Also, there was a limitation due to using a single type of contact lens and a single type of aberrometer. Moreover, the aberrometer used in this study was the Sirius Scheimpflug Placido Topography System. If a different measurement principle based aberrometers were chosen, results would be different due to aberrometer inconsistency. Another limitation was the patients who comprised young adults and habitual contact lens wearers. The broader heterogeneous adult population should be included in further studies to confirm our findings.

In summary, the characteristics of the photochromic contact lens on wavefront aberration did not change in both inactivated and activated states. These lenses may enhance visual performance by adapting to changing light conditions with a stable aberration profile in outdoor activities. Further investigations of aberration differences caused by lens design are necessary.

Declarations

Funding/Support

None of the authors have reported funding/support.

Conflict of interest

The authors declare that there are no competing interests.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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Figures

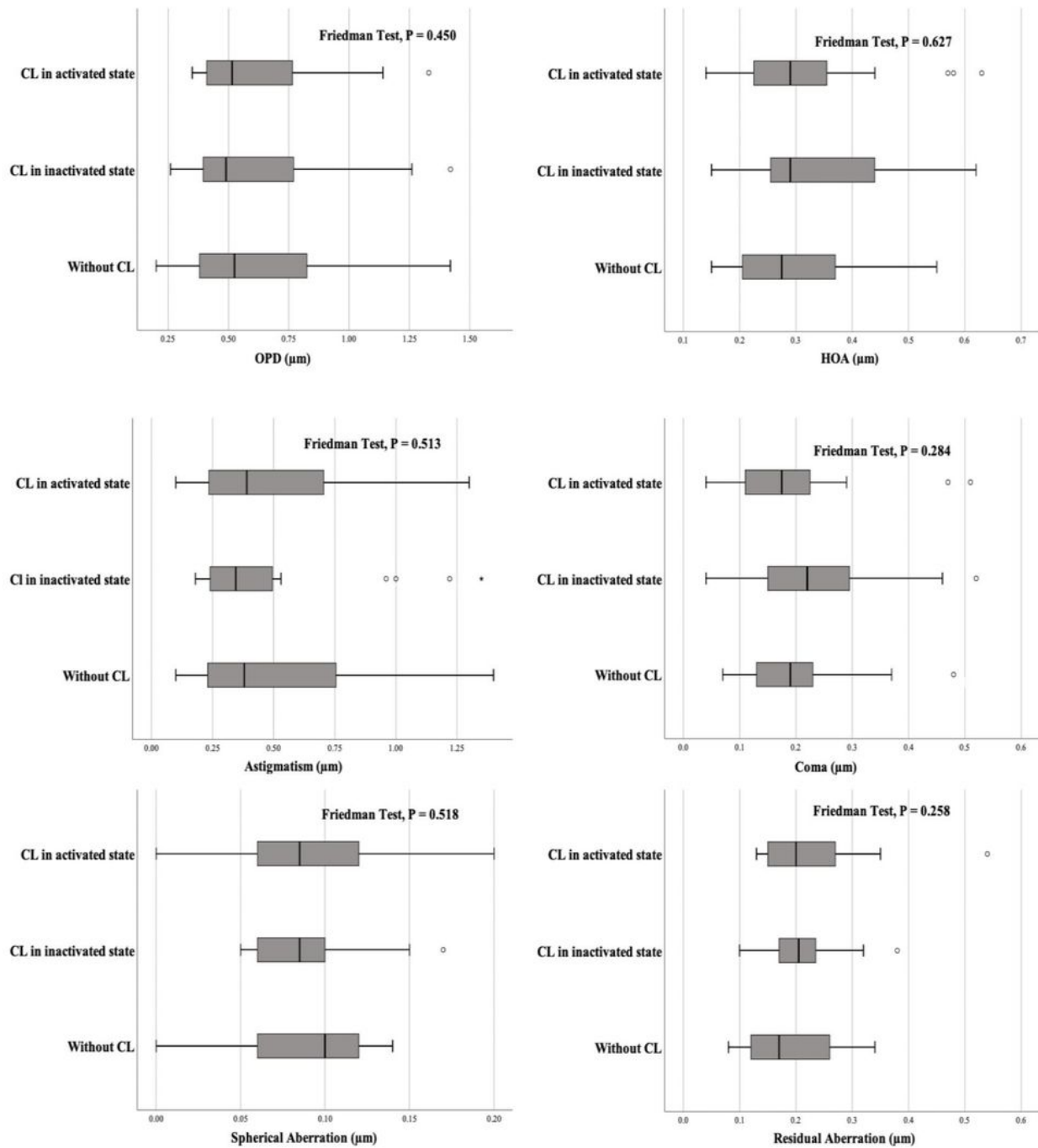


Figure 1

Corneal wavefront aberration (OPD, HOA, astigmatism, coma, spherical aberration, and residual aberration) findings with and without contact lenses tested. No significant differences were found for each group ($p > 0.05$ for all). Error bars represent 95% Confidence Interval. Outliers are identified with small circle for out values and star for extreme values.