Care system vs transmitted light wavefront pattern of contact lenses

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ABSTRACT

Objectives. The paper compares the optical performance of soft contact lenses (CLs) treated with either multipurpose or hydrogen-peroxide care systems.

Methods. The investigated care systems were (i) 3% hydrogen-peroxide solution Oxysept (Abbot medical Optics) and (ii) multipurpose solution Regard (Vita research). Three types of silicone-hydrogel CLs were studied (comfilcon A, lotrafilcon B, balafilcon A), unworn and exposed for 30 times to the solutions, which were replaced every 8 hours. The optical performance of the CLs were evaluated through the on-eye transmitted light wavefront patterns by considering new CLs as references. The surface morphology of the CLs was investigated by scanning electron microscopy.

Results. Statistically significant modifications in the range 0.1–0.3 μm of Zernicke coefficients and modifications of the root-mean square of the wavefront aberration function were found for CLs treated with multipurpose solution, in agreement with the observed modifications of the surface morphology. Statistically significant changes were also found after exposure to the hydrogen-peroxide solution, but the variation of the Zernicke coefficients was found lower than 0.1 μm, thus being negligible in terms of CL optical performances.

Conclusions. Besides disinfection ability and ocular surface reactions, CL care systems are different in terms of solution-related CL optical performance. Multipurpose solutions may affect the CL surface morphology with significant modifications of the transmitted light wavefront pattern.

KEYWORDS: contact lenses, care solutions, optical wavefront pattern

INTRODUCTION

According to market statistics, more than one hundred million people use contact lenses (CLs) worldwide and soft CLs are estimated to be a large fraction of lens market. Since they are in contact with the cornea and the conjunctiva, maintenance and disinfection of the CLs are fundamental to minimize complications. Different types of CL maintenance solutions are available. Cleaning solutions typically contain surfactants and preservatives. Surfactants are molecules that possess hydrophobic and hydrophilic components, which enable them to solubilize different types of debris. Multi-purpose solutions integrate different functions by means of, first of all, cleaning and disinfection agents, but also lubrificants (for example hydroxypropylmethylcellulose, HPMC), preservatives, and chelating agents. The lack of proper care regimes may result in CL-related consequences such as microbial keratitis and other ocular surface reactions and symptoms.[1-8] By studying the occurrence of solution-related staining, some authors focused the attention on different combinations of (i) type of lens and (ii) maintenance solution and found clear evidence of combined clinical effects.[6,7,9,10] The advent of silicone-hydrogel (SH) CLs raised even more the attention on ocular surface reactions due to the physical and chemical characteristics of the materials.[5-8,10-13] Papas et al.[8] pointed out that lens care products developed for conventional hydrogel CLs may not be entirely compatible with SH CLs. For example, evidence of epithelial disruption associated with certain combinations of CL care products and SH materials recently emerged.[14]

When comparing different care methods, specific considerations hold for hydrogen-peroxide solutions. For its oxidant anti-microbial activity,[15] hydrogen-peroxide is often used for CL disinfection. Since it is toxic for the cornea,[16,17] it must be neutralized before CL wear. Many authors investigated the effect of hydrogen-peroxide.[18-21] For example, Pinna et al.[21] evaluated several solutions (Arion Cronos, Complete Revitalens, Dua Elite, Opti-Free Express, Regard, and Oxysept Comfort). Among them, only an exposure to 3% hydrogen-peroxide (Oxysept Comfort) for at least 6 h eradicated all the investigated fungi from CLs. The solution efficacy in removing deposited tear film constituents was also investigated by using atomic force microscopy (AFM) by

Cheung et al.[22] , who found differences between a hydrogen-peroxide based system and a multipurpose solution (containing polyhexamethylene biguanide). Besides the cleaning and disinfection activity, biocompatibility is also crucial, as also reported in details by many authors.[7,23-26] Finally, there is also the impact and influence of the lens care solution on the CL material properties. Only few studies are reported on this aspect. A recent study showed that some solution/material combinations result in significant changes in the Young's modulus.[27] These authors took into consideration both multipurpose and hydrogen-peroxide solutions and observed significant changes in the elastic modulus of the CLs depending on the care system. Lira et al. reported changes of CL surface roughness and refractive index induced by care systems.[28] The highest change in roughness was obtained with ReNu Multiplus applied to comfilcon A CLs (with an increase of 27.2 nm on 25 μm^2 area) and senofilcon A (with an increase of 16.7 nm on 25 μm^2 area). As far as the refractive index is concerned, the differences induced by the different care systems were interpreted as a consequence of the variation of the CL water content. Lens belonging to IV FDA group were found to be more prone to changes when immersed in peroxide-based solution, while I and II FDA groups (nonionic) behaved in the opposite way.

To our knowledge, no studies are reported on the influence of the lens care solution on the CL optical performances. However, the optical/visual performance of the CL should also be taken into consideration besides other factors, such as the disinfection ability, the possible occurrence of ocular surface reactions, and the possible alterations of the CL material.. The optical performances of CLs can be evaluated by transmitted light wavefront aberration techniques based on Shack-Hartman analysis.[29,30] The methods for the wavefront analysis of a CL can be either on-eye or off-eye.[31] The application of off-eye methods is not straightforward due to some intrinsic limits. The water content, the dehydration, and the deformation of the CLs under their weight make difficult to measure the wavefront aberrations in air. Off-eye measurements could also be performed in a wet cell.[32] However, the obtained results must be corrected by taking into consideration the refractive index of the liquid. Recently, Kollbaum et al. compared the optical properties of soft CLs on- and off-eye.[31] These authors found that the measured on-eye sphere and spherical aberration values were comparable with the measured off-eye values. Some specific differences were noted, which were interpreted either as a tear lens or as a change of the lens thickness caused by lens flexure in the on-eye measurements. Also Dietze and Cox compared the on-eye measured spherical aberrations of soft CLs and the results of off-eye ray-tracing simulations.[32] The on-eye technique is more widely adopted. It allows to analyze in-vivo the optical quality of a CL by comparing wavefront aberrations for an eye with or without CLs, with different types of CLs, with unworn and worn CLs, etc. For example, Lu et al.[34] investigated the effect of CLs on the optical performance of the eye by measuring the ocular wavefront aberrations with or without CLs. For soft CLs, they found an increase of the root-mean-square values of wavefront aberrations when wearing CLs compared to non-CL condition. The same authors also compared rigid-gas-permeable (RGP) CLs and soft CLs and reported that soft CL wearing tends to induce more higher-order aberrations, whilst RGP CLs effectively reduce the astigmatisms. By applying the on-eye technique, Gifford et al. recently investigated the ocular aberrations with multifocal versus single-vision CLs.[35] Also Montes-Mico et al. reported the evaluation of the optical quality of hydrogel and SH CLs by on-eye wavefront pattern analysis.[36]

This paper investigates the differences between multipurpose and hydrogen-peroxide care systems in terms of optical/visual performances of the CLs. On-eye transmitted light wavefront patterns are analyzed to gather information on the solution-related optical modifications that alter the vision through the CL. The optical results were interpreted on the basis of the CL morphological changes observed by scanning electron microscopy.

MATERIALS AND METHODS

The investigated care systems are the multi-purpose solution Regard (Vita Research) and a 3% hydrogen-peroxide system Oxysept (Abbot medical Optics). The former solution contains boric acid, hydroxypropylmethycellulose (HPMC) with lubrificant properties, poloxamer with surfactant properties, and oxychlorite® with disinfectant activity. This solution is here denoted as multi-purpose, even if it does not contain preservatives. As far as Oxysept system is concerned, hydrogen-peroxide was neutralized by a tablet, as indicated by the manufacturer. The tablet contains catalase, HPMC, and cyanocobalamin. Based on the declaration of the manufacturer, the Oxysept neutralizer was formulated to prolong the CL exposure to hydrogen peroxide before neutralization begins. By applying a method described elsewhere for the measurement of the hydrogen-peroxide concentration in a solution,[37] we evaluated the decrease of its concentration as a function of time during the Oxysept neutralization. Our results indicate a decrease to 1/3 of the initial concentration after about 2 h, in reasonable agreement with the time evolution of the hydrogen-peroxide concentration declared by the manufacturer.

Different types of SH CLs (+3.00D) were taken into consideration (Table I). For each material, ocular wavefront aberrations on the same eye of the same subject in a dark environment were investigated in the following conditions: (a) wearing a new CL taken from the packaging, (b) wearing an unworn CL of the same material after the exposure of the CL to the hydrogen-peroxide solution, including its neutralizing tablet (solution and tablet replaced every 8 hours for 30 times to simulate the night maintenance for one month), (c) wearing an unworn CL of the same material after the exposure of the CL to the multipurpose solution (solution replaced every 8 hours for 30 times to simulate the night maintenance for one month). The (a)-(b)-(c) analyses were repeated at least seven times on different samples of the same material. In each case, the wavefront aberration map (W) was measured by using an ocular Optikon Keratron Onda aberrometer as the difference between the measured wavefront and a reference ideal wavefront. The map W is given in polar coordinates $W(\rho,\varphi)$. It was fitted by Zernicke polynomials up the 4th-order for 5-mm pupil with Zernicke coefficients $Z_{n,m}$ (Table II).[30] The root-mean-square (RMS) of $W(\rho,\varphi)$ was also calculated. The Zernicke coefficients and the RMS value describe the ocular optical aberrations in a specific condition. For the (a)-(b)-(c) acquisitions, the three analyses were performed sequentially on the same eye of the same subject to avoid possible changes in wavefront aberrations from individual to individual. Since at least seven samples of the same materials were analyzed for each condition ((a), (b), and (c)), statistical significance of differences among these conditions was obtained by Student's t statistic ($p < 0.05$). The mean values of the results of the seven samples for each condition were also calculated. To investigate the only effects of the maintenance solution, the condition (a) (i.e. wearing a new CLs) was taken as a reference condition. Therefore, the mean RMS and the mean $Z_{n,m}$ coefficients of conditions (a) were subtracted to the corresponding mean values for conditions (b) and (c). $(\Delta Z_{perox})_{n,m}$ is the difference $(Z_{n,m})_{(b)} - (Z_{n,m})_{(a)}$ among the mean Zernicke coefficients $Z_{n,m}$ obtained in the conditions (b) and (a), respectively. Similarly, $(\Delta Z_{multip})_{n,m}$ is the difference $(Z_{n,m})_{(c)} - (Z_{n,m})_{(a)}$ among the mean Zernicke coefficients $Z_{n,m}$ obtained in the conditions (c) and (a), respectively. Finally, $\Delta(RMS)_{perox}$ and $\Delta(RMS)_{multip}$ are the differences among the mean RMS of conditions (b),(a) and (c),(a).

Scanning electron microscopy (SEM) micrographs were obtained using a tungsten electron microscope (Tescan Vega TS5136XM). Before analyses, samples were freeze dried (-55 °C, 0.63 mbar, 24 h) using an ALPHA 1–2 LDplus freeze dryer (Martin Christ, Osterode am Harz, Germany). Then, a film of gold was sputtered on the lens surface with thickness of approximately 10 nm (to avoid charging the samples) using a Semprep 2 sputter coater (Nanotech Ltd., Prestwick, UK) at 10 mA.

RESULTS AND DISCUSSION

For the different materials, Figs. 1-3 shows the results of the analysis of the transmitted light wavefront patterns. The labels indicate the corresponding Zernicke terms. Empty diamonds correspond to the hydrogen-peroxide solution. The abscissa of each experimental point provides the difference $(\Delta Z_{perox})_{n,m}$ between the mean Zernicke coefficients $Z_{n,m}$ obtained in the conditions (b) and (a). Similarly, the abscissa of each experimental point indicated by full diamond provides the difference $(\Delta Z_{multip})_{n,m}$ between the mean Zernicke coefficients $Z_{n,m}$ obtained in the conditions (c) and (a), thus corresponding to the multipurpose solution. Generally speaking, $(\Delta Z_{perox})_{n,m}$ and $(\Delta Z_{multip})_{n,m}$ are non-negligible in terms of optical performances of the CL if their absolute value is larger than about 0.10-0.15 μm, with important consequences on vision in case of values larger than 0.25 μm.[29] In the same figures 1-3, the ordinate values are the *p*-values obtained by Student's t statistic, which indicate the statistically significance of the difference between the two conditions (b)-(a) and (c)-(a). Statistical difference among treated CLs and new CLs is considered for $p<0.05$, but also slightly higher *p* values are reported in Figs. 1-3 up to 0.15, since these relatively low *p* values may indicate a tendency to statistical difference. Data for $(\Delta Z_{perox})_{n,m}$ and $(\Delta Z_{multip})_{n,m}$ larger than 0.3 μm were not measured, whilst *p* values larger than 0.15 were found. However, the corresponding data points are omitted in Figs. 1-3 because no statistically significance of the difference between the two conditions (treated CL and new CL) can be inferred. The gray background in Figs. 1-3 shows the region of statistically-significant and relatively large optical differences among treated and new CLs. The grayscale indicates the statistical relevance of the difference (the darker is the grey, the more significant is the difference). After using the multipurpose solution (full diamonds), a relatively large (in the range 0.1–0.3 μm) and statistically-relevant changes were found for all the investigated materials in $Z_{2,-2}$, which represents oblique astigmatism. This maintenance solution induced also non-negligible changes in defocus ($Z_{2,0}$) for comfilcon A (panel a) and balafilcon A (panel c). On the contrary, even if statistically-significant changes ($p < 0.05$) in some Zernicke coefficients were detected when CLs were treated with the hydrogen-peroxide solution, the absolute value of the difference was lower than 0.1 μn, namely definitely lower than the threshold value of interest from the visual point of view.[29]

Quantitative comparison between different eyes and different conditions are often made by using the RMS value of the wavefront aberration function. It is a generic parameter, which is not immediately correlated to vision, since it is calculated as an average across the pupil area and different kinds of aberrations may have equal RMS, but different effects on the optical properties of the transmitted light. Within these limits, the measured RMS values confirmed the previous results since larger variations were found only in the (c) condition (multipurpose solution) compared to the new CLs. Table III shows the difference $\Delta(RMS)_{perox}$ among the mean RMS in the conditions (b) and (a) and the difference $\Delta(RMS)_{multip}$ among the conditions (c) and (a).

The results of the wavefront aberration analysis motivated us to characterize the morphological properties of the CLs. Figure 4 shows the typical SEM micrographs obtained on lotrafilcon B CLs after exposure to hydrogen-peroxide (left panel) and after exposure to the multipurpose solution (right panel), together with the typical micrograph obtained for new lotrafilcon B CLs (inset). For this material, the optical differences among multipurpose and hydrogen-peroxide solutions were found to be particularly large. $\Delta Z_{multip})_{2,-2}$ was found to be equal to almost 0.3 μm (p = 0.004) in the case of the multipurpose solution to be compared to $\Delta Z_{perox})_{2,-2}$ ~ 0.05 μm (p = 0.596) and the RMS was measured to be larger than 0.25 μm (p = 0.001) against the negligible RMS value in the other case (Table III). In the case of the hydrogen-peroxide solution, the SEM micrograph suggests the formation of bulges and regions of swelling, which could be attributed to a relaxation of the polymeric network, at least close to the surface. The oxidant nature of the hydrogen-peroxide is, indeed, expected to produce surface physical changes after exposure. Similar effects due to swelling were observed in SEM micrographs (here omitted) of other SH materials treated with the hydrogen-peroxide solution. Also Young et al. discussed a physical modification, namely the change of the elastic modulus due to hydrogen-peroxide.[27] However, for all the investigated materials, the morphological modifications induced by hydrogen-peroxide did not dramatically alter the optical properties of the CLs, as deduced from wavefront optical aberration analyses. Also in the case of the multipurpose solution (condition (c)), the SEM micrographs show differences compared to the new CLs, but a different scenario was observed compared to the condition (b). Surface appeared more wrinkled in agreement with previous results of Lira et al.,[28] who found significant modifications of the roughness when using multipurpose solutions on SH CLs. They evaluated roughness by AFM analyses and found variations of tens of nanometers on the investigated area (25 μm^2), much more than observed when using hydrogen-peroxide solutions. A possible explanation is the adsorption of solution constituents on the polymeric matrix. In particular, one component of the Regard solution, which can be tentatively attributed to the adsorbed component, is poloxamer. It cannot be found in the Oxysept system, including the neutralizer tablet. Poloxamer is a surfactant and it is known to form in water micelles of various shape.[38] Its amphiphilic properties could also be responsible for its interaction with the surface of SH CLs. Also Young et al. reported that, in the case of the multi-purpose solutions, the changes of elastic modulus were attributed to uptake of the formulation components, in contrast to hydrogen-peroxide solutions, whose effects were attributed to chemical changes to the polymer.[27] Our conclusion is that, in contrast to hydrogen-peroxide, the multipurpose solution induced modifications to the material which are no more negligible in terms of visual performances from the clinical point of view.

CONCLUSIONS

Hydrogen-peroxide based system and multipurpose solution were compared as care systems in terms of effects on the optical properties of silicone-hydrogel CLs. Even if the former was found tomodify the transmitted light wavefront pattern with statistically-significant differences compared to the new CL and also to modify the CL surface characteristics observed by SEM analyses, the absolute value of these differences was found to be not relevant from the visual point of view. The results were interpreted as a relaxation and swelling of the polymeric network, at least close to the CL surface, without relevant consequences on the CL geometry, namely on the i.e. visual performances. On the contrary, the multipurpose solution was found to change both the morphology of the surface, which was found more wrinkled, and the CL optical properties with variations of the

Zernicke coefficients in the range 0.1–0.3 μm. A possible explanation is the adsorption of constituents of the multipurpose solution on the polymeric matrix.

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FIGURE CAPTIONS

Figure 1

Data obtained from the transmitted light wavefront analysis of comfilcon A CLs. For each empty diamond, the abscissa value is the difference $(\Delta Z_{perox})_{n,m}$ between the mean Zernicke coefficients $Z_{n,m}$ obtained in the condition (b) and the condition (a). For each full diamond, the abscissa value is the difference $(\Delta Z_{multip})_{n,m}$ between the mean Zernicke coefficients $Z_{n,m}$ obtained in the condition (c) and the condition (a). The ordinate value is the *p*-value obtained by Student's t statistic, which indicates the statistically significance of the difference between the two conditions. The labels of each diamond indicate the values n,m of the corresponding $Z_{n,m}$.

Figure 2

Data obtained from the transmitted light wavefront analysis 0f lotrafilcon B. Empty and full diamonds and the corresponding labels are defined as in Fig. 1.

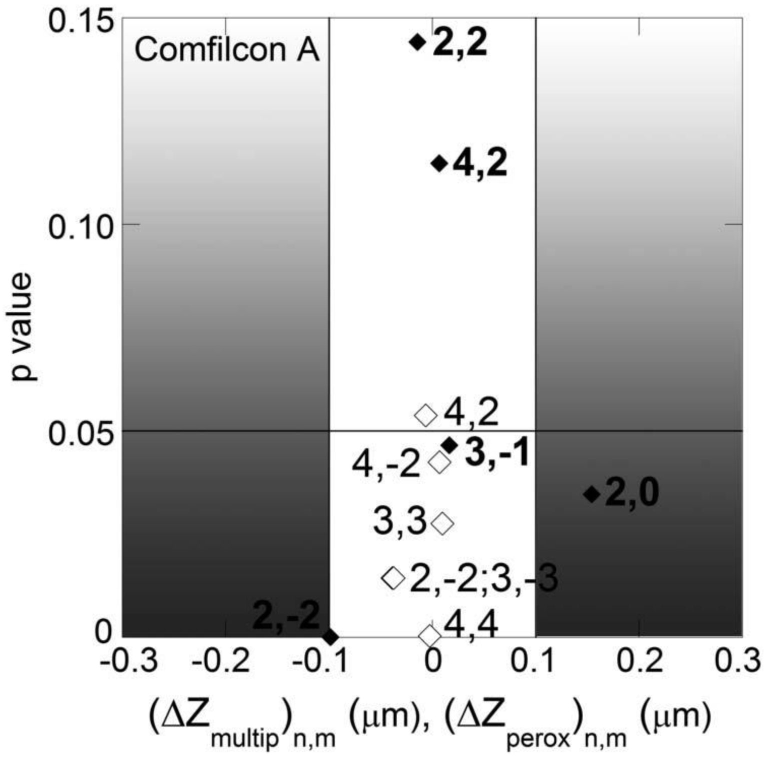
Figure 3

Data obtained from the transmitted light wavefront analysis of balafilcon A CLs. Empty and full diamonds and the corresponding labels are defined as in Figs. 1 and 2.

Figure 4

SEM micrographs obtained on lotrafilcon B CLs after exposure to hydrogen-peroxide (left panel) and after exposure to the multipurpose solution (right panel), together with the typical micrograph obtained for new lotrafilcon B CLs (inset). The bar corresponds to 10 μm and it refers to both micrographs and to the inset.

Figure 1



Comfilcon A
p value
0.15
0.10
0.05
0
-0.3
-0.2
-0.1
0
0.1
0.2
0.3
2,2
4,2
4,2
3,-1
4,-2
2,0
3,3
2,-2;3,-3
2,-2
4,4
(ΔZ multip)n,m (μm), (ΔZ perox)n,m (μm)

Figure 2

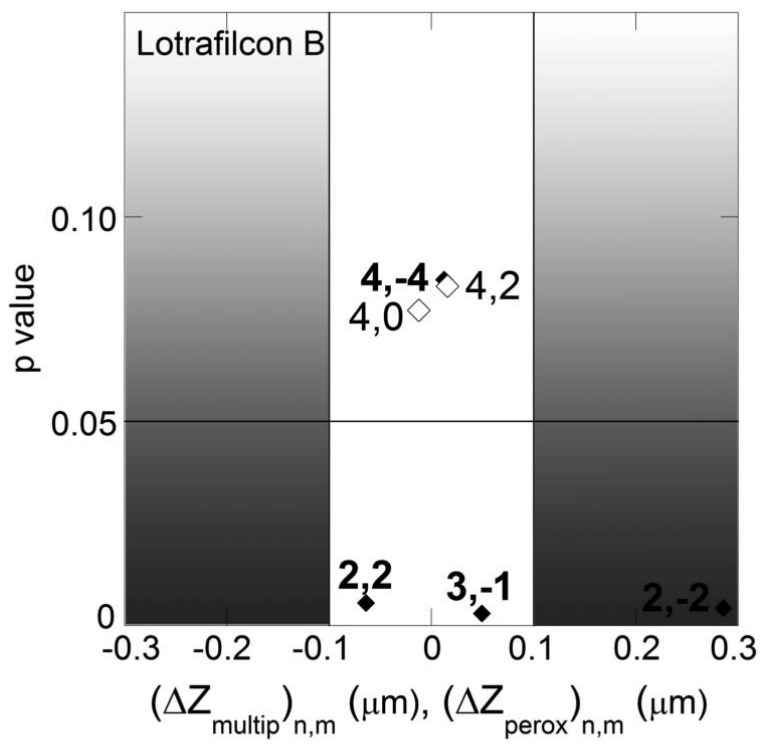
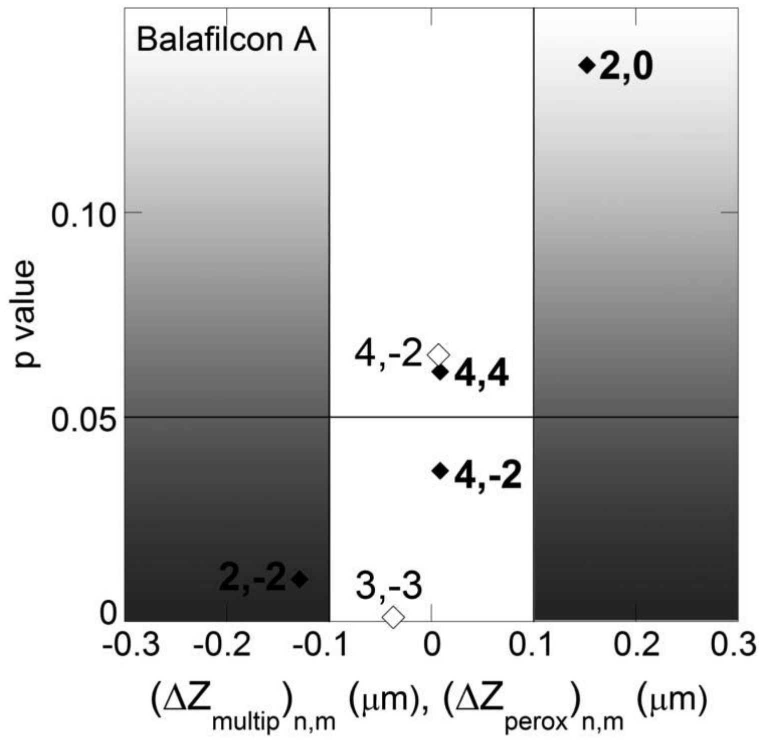

Lotrafilcon B
p value
0.10
0.05
0
4,-4
4,2
4,0
2,2
3,-1
2,-2
-0.3
-0.2
-0.1
0
0.1
0.2
0.3
$(\Delta Z_{multip})_{n,m}$ (μm), $(\Delta Z_{perox})_{n,m}$ (μm)

Figure 3



Balafilcon A
p value
0.10
0.05
0
-0.3
-0.2
-0.1
0
0.1
0.2
0.3
2,0
4,-2
4,4
4,-2
2,-2
3,-3
$(\Delta Z_{multip})_{n,m}$ (μm), $(\Delta Z_{perox})_{n,m}$ (μm)

Figure 4

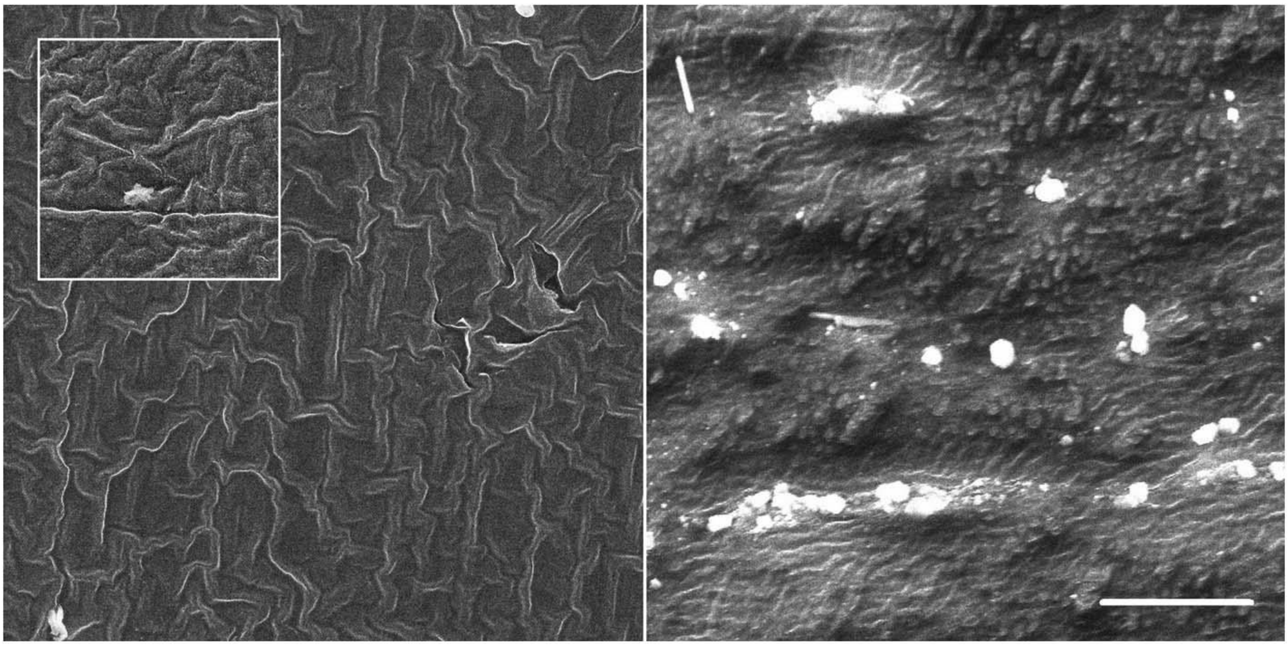


TABLE 1. *Types of Contact Lenses Investigated*

Type	Manufacturer	Material	FDA Group	Water Content (%)
Biofinity	CooperVision	Comfilcon A	I	48
O_2 Optix	Ciba Vision	Lotrafilcon B	I	33
PureVision	Bausch & Lomb	Balafilcon A	III	36

TABLE 2. *Names Associated to the Zernicke Polynomials of Index n,m*

n	m	Name
2	0	Defocus (longitudinal position)
2	−2	Oblique astigmatism
2	2	Vertical astigmatism
3	−1	Vertical coma
3	1	Horizontal coma
3	−3	Vertical trefoil
3	3	Oblique trefoil
4	0	Primary spherical
4	2	Vertical secondary astigmatism
4	−2	Oblique secondary astigmatism
4	4	Vertical quadrafoil
4	−4	Oblique quadrafoil

TABLE 3. *Differences $\Delta(RMS)_{perox}$ Between the Mean RMS in the Conditions (b) and (a) and $\Delta(RMS)_{multip}$ Between the Mean RMS in the Conditions (c) and (a)*

	$\Delta(\mathrm{RMS})_{\mathrm{perox}}$ (μm)	$\Delta(\mathrm{RMS})_{\mathrm{multip}}$ (μm)
Comafilcon A	−0.0015 (P=0.799)	0.1366 (P=0.540)
Lotrafilcon B	0.0718 (P=0.729)	0.2512 (P=0.001)
Balafilcon A	−0.1050 (P=0.831)	0.1600 (P=0.157)

The corresponding *P*-values obtained by Student *t* statistic are reported in parenthesis.