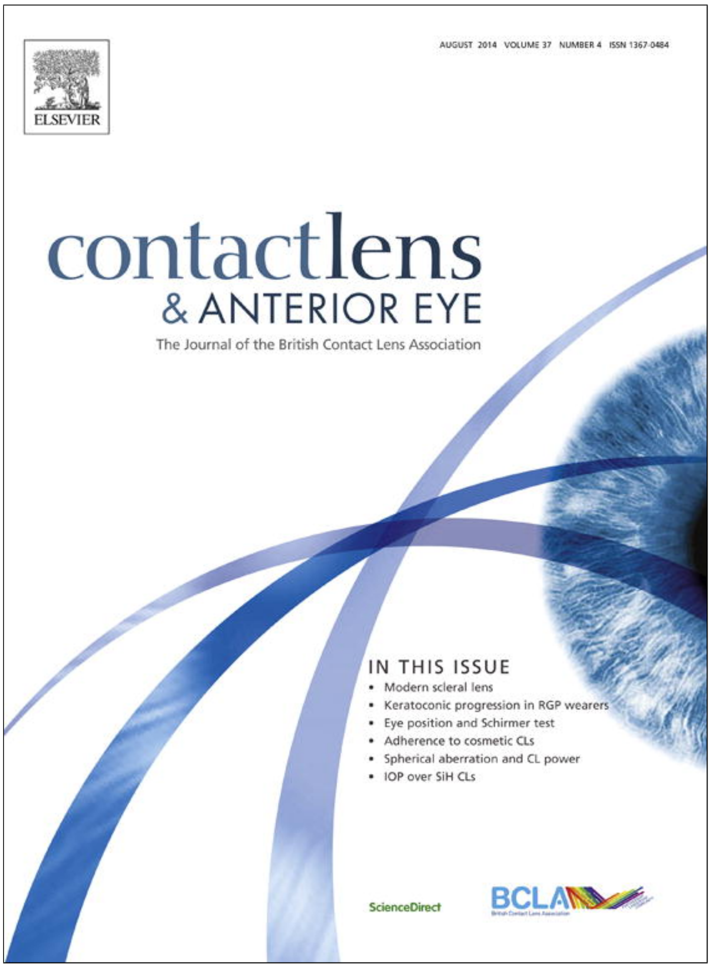
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Optical quality and intraocular scattering assessed with a double-pass system in eyes with contact lens induced corneal swelling

Victoria de Juan [a,*], Mikel Aldaba [b], Raul Martin [a,c], Meritxell Vilaseca [b], Jose Maria Herreras [a], Jaume Pujol [b]

[a] IOBA-Eye Institute, University of Valladolid, Valladolid, Spain
[b] Center for Sensors, Instruments and Systems Development (CD6), Technical University of Catalonia, Terrassa, Barcelona, Spain
[c] Department of Physics and Optics, School of Optometry, University of Valladolid, Valladolid, Spain

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ABSTRACT

Purpose: To evaluate the impact of contact lens (CL)-induced corneal swelling on the optical quality of the eye by means of the double-pass technique.
Methods: Measurements of 6 healthy subjects were obtained in 5 visits over 1 week, at baseline and after sleeping with 4 different CLs of +0.50 D, +2.00 D, +5.00 D and +8.00 D (Acuvue2), randomly fitted on 4 different days. The control eye wore no CL. Corneal pachymetry and optical quality of the eye (OQAS, Visiometrics) were measured once at baseline and at three interval times in the follow-up visits: immediately after CL removal, and 1 and 2 h after CL removal. Optical quality was evaluated by means of the Strehl ratio and OQAS values at 100%, 20% and 9% contrasts. Intraocular scattering was evaluated with the objective scatter index (OSI).
Results: Mean overnight swelling was 5.98 ± 4.29% in CL-eyes *versus* 0.30 ± 0.78% in control eyes ($p < 0.01$). Corneal swelling was maximal immediately after CL removal and decreased with time ($p < 0.01$). A significant worsening in all optical quality parameters and a significant increase of the OSI were found in eyes with corneal swelling ($p < 0.05$). Two hours after CL removal there were no statistically significant differences ($p > 0.05$) between CL-eyes and control eyes in any of the measured parameters.
Conclusions: Corneal swelling has a significant impact on the optical quality of the eye and on intraocular scattering as assessed with the double-pass technique.

1. Introduction

Contact lenses (CL) wear is associated with adverse ocular responses such as corneal swelling due to hypoxia [1,2]. This swelling is directly related to the oxygen transmissibility (Dk/t) of the CL [2,3] and can be measured by precise methods of detecting corneal thickness changes, such as optical coherence tomography (OCT) [3–5]. OCT is a non-invasive, non-contact imaging technique that uses infrared light to obtain high-resolution, cross-sectional *in vivo* images of the cornea [6].

Vision impairment, mainly manifested as a noticeable decrease in contrast sensitivity with corneal swelling, has been reported after CL removal [7]. The increase in scattering caused by corneal swelling [8–11] is one of the causes of optical quality (OQ) worsening. However, the role of wave-front aberrations changes after CL removal, the other possible cause of optical quality worsening, is still controversial. Whereas short-term use of PMMA CLs [12] reduced the optical quality of the cornea, no changes have been described after the use of RGP or soft lenses.

The double-pass technique [13] has proven to be a useful tool for the comprehensive evaluation of the optical quality of the eye in daily clinical practice [14–16]. In contrast with wave-front aberrometers, the double-pass technique contains all the information about the optical quality of the eye, including the contribution of all higher order aberrations and intraocular scattering (IS) (forward and backward scattering as measured by the OSI) that are generally missed by aberrometric techniques. As suggested by a previous study [17] and in comparison with double-pass systems, wave-front aberrometers cannot easily evaluate the impact of ocular transparency loss and they may overestimate retinal image quality in eyes with prominent scattered light.

To our knowledge, no comprehensive data on changes in the optical quality of the eye caused by overnight CL wear using

* Corresponding author at: IOBA, C/ Paseo de Belén, 17, E-47011 Valladolid, Spain. Tel.: +34 983 423 559; fax: +34 983 423 274.
E-mail address: victoria@ioba.med.uva.es (V. de Juan).

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objective techniques that take into account all the aberrations and scattering have been reported. As reviewed in the introduction, the overnight CL wear causes corneal oedema, which is related to optical quality worsening mainly due to the increase of scattering. Thus having objective measurements of these changes is important for its gradation and for a better knowledge of overnight CL wear impact on vision. The purpose of this study was to evaluate the impact of CL induced corneal swelling in the optical quality of the eye by means of the double-pass technique.

2. Materials and methods

2.1. Subjects

Six healthy subjects, three women and three men (mean age, 27.17 ± 4.1 years; range, 23–34), participated in this prospective, randomized, masked study. The refractive error in terms of spherical equivalent ranged from +0.50 to −3.00 D (−1.58 ± 1.49 D). Subjects were excluded if they had a history of ocular surgery, an active ocular surface disease such as a significant dry eye, papillary conjunctivitis, corneal opacities, current medication that could affect ocular physiology, astigmatism >0.50 D or if they had used CL for long periods. Subjects reported monocular best spectacle-corrected visual acuity of 20/20 or better. Informed consent was obtained from each participant after approval was granted by the Human Sciences Ethics Committee of the University of Valladolid. All subjects were treated in accordance with the Declaration of Helsinki.

2.2. Instrumentation

Corneal thickness was measured by means of an OCT instrument (3D OCT-2000, Topcon, Japan). Three consecutive measurements were obtained from each cornea on each visit. The mean of the three scans of each cornea was used as the final result. The same masked researcher performed all OCT scans during the study visits.

Retinal image quality was measured by means of the *Optical Quality Analysis System* (OQAS, Visiometrics S.L., Spain), a double-pass based instrument for measuring the optical quality of the eye clinically [18]. The device includes a motorized optometer within the −8.00 to +6.00 D range to correct the patient's defocus [13]. No trial frame was introduced during the measurements to correct astigmatism because it was smaller than 0.50 D in all cases. Data were referred to a pupil size of 4 mm for all patients and were obtained without pupil dilation. Room illumination was kept low during testing to ensure a natural pupil diameter larger than 4 mm. Three consecutive measurements were obtained for each eye and their mean was used as the final value.

Retinal image quality was assessed by means of several parameters closely related to the modulation transfer function (MTF): the Strehl ratio and the OQAS values (OV). The Strehl ratio is computed as the ratio between the areas under the MTF curve of the measured eye and the aberration-free eye [19]. The higher the Strehl ratio, the better the optical quality, with a maximum value of 1 and mean values in young populations close to 0.25 [19]. The OVs are related to the MTF values corresponding to three different spatial frequencies that describe the optical quality for three contrast conditions commonly used in ophthalmological practice: 100% (OV100%), 20% (OV20%), and 9% (OV9%). OV values higher than 1.00 are normally associated with good optical quality.

The system also quantifies intraocular scattered light from the acquired double-pass image by means of the OSI parameter. This parameter is defined as the ratio between the integrated light in a peripheral annular area (from 12 to 20 min of arc) and the central peak (1 min of arc). As the scattering increases more light is spread to the periphery (high OSI index), whereas in absence of scattering the light concentrates in the centre (low OSI index). Values of OSI below 1 are usually linked to eyes with low intraocular scattering [20].

2.3. Procedures

This study included 5 visits over 1 week: at baseline and after one night of sleeping with one of the four different CL of +0.50 D, +2.00 D, +5.00 D and +8.00 D (Acuvue 2, Etafilcon-A material, Johnson & Johnson Vision Care, USA). Each CL was randomly fitted in one eye and the fellow eye was used as a control. An independent investigator scheduled the random fittings.

Etafilcon-A is a type of hydrogel lens that has been approved in the United States for 7 days extended wear (EW). The hypothesis was that the difference in power and crucially, the difference in thickness of the CL would produce various levels of hypoxia and thus various degrees of corneal swelling.

During the baseline visit (day 0), inclusion criteria were verified on all participants. Pachymetry with OCT, and OQ and IS with the OQAS system were performed. All baseline measurements were performed between 4 p.m. and 8 p.m. since some authors have suggested that this is the time of day when the eye is physiologically more stable [21]. All follow-up visits were in the morning (between 8 a.m. and 10 a.m.) and the eye with the CL was firmly occluded with gauze and taped to ensure that induced overnight corneal oedema was present at the time of measurement. In the four follow-up visits, the same measurements were obtained at three different interval times: immediately after CL removal, and 1 and 2 h after CL removal.

2.4. Data analysis

Statistical analysis was performed using a commercial package (SPSS 19.0 statistical package for Windows; SPSS, Chicago, IL). The results were expressed as the mean ± standard deviation.

A multivariate analysis of variance (ANOVA) was used to detect statistically significant differences between the control and study eyes in different time periods (before and after CL wear). Repeated-measures analysis of variance (Re-ANOVA with Bonferroni correction) was used to detect statistically significant differences in corneal thickness attributable to the time period after CL removal or CL power. A p value less than 0.05 was considered statistically significant. Correlations between the OQ, IS and corneal swelling were analyzed by means of the Pearson coefficient.

3. Results

None of the subjects had significant biomicroscopic signs (grade > 1, Efron grading scale [22]) of CL complications (corneal staining, limbal injection, striae, folds, or others).

3.1. Corneal swelling

We found an increase in corneal thickness (Table 1) in the eyes wearing CL compared with the control eyes. Mean corneal pachymetry for all CL was higher immediately after removal ($p < 0.01$ ANOVA with Bonferroni correction) and decreased 1 and 2 h after CL removal, without significant statistical differences in relation to the baseline pachymetry ($p = 0.45$ and $p = 1.00$ respectively, ANOVA with Bonferroni correction).

Corneal swelling was higher in eyes with CL, with significant statistical differences between both groups ($p < 0.01$ ANOVA) (Table 1 and Fig. 1). Corneal swelling was maximal immediately after CL removal ($p < 0.01$ Re-ANOVA) in all eyes, and decreased 1 and 2 h after CL removal. Eyes with lower Dk/t lenses, due to more positive

Table 1
Corneal swelling with respect to the baseline corneal thickness of eyes wearing CL (CL-eyes) and control eyes in all visits.

	Immediately after CL removal	1 h after CL removal	2 h after CL removal	Re-ANOVA[b]
Visit 1 (+0.50D)				
CL eye	8.22 ± 3.65	3.98 ± 2.39	1.85 ± 1.09	<0.001
Control eye	0.59 ± 0.73	0.26 ± 0.31	−0.37 ± 0.30	0.135
ANOVA *p* value[a]	0.001	0.003	0.003	
Visit 2 (+2.00D)				
CL eye	10.79 ± 3.30	5.23 ± 1.94	1.95 ± 1.03	<0.001
Control eye	0.71 ± 0.35	0.25 ± 0.03	−0.18 ± 0.53	0.069
ANOVA *p* value[a]	<0.001	<0.001	0.001	
Visit 3 (+5.00D)				
CL eye	11.75 ± 5.15	5.86 ± 2.66	2.65 ± 1.56	<0.001
Control eye	0.86 ± 0.19	0.08 ± 0.61	0.11 ± 0.73	0.251
ANOVA *p* value[a]	<0.001	<0.001	0.005	
Visit 4 (+8.00D)				
CL eye	11.93 ± 2.95	5.82 ± 1.99	2.39 ± 1.14	<0.001
Control eye	0.96 ± 0.16	0.16 ± 0.26	0.04 ± 0.47	0.021
ANOVA *p* value[a]	<0.001	<0.001	0.002	

Corneal swelling summary in percentage with respect to the baseline corneal thickness of eyes wearing CL (CL-eyes) and control eyes in all visits. Mean and standard deviation are shown.

[a] ANOVA *p* value of the differences between corneal swelling between the CL-eye and control eyes at each time period.

[b] Re-ANOVA *p* value of the difference in corneal swelling in the same eye along all time periods (Baseline, H0, H1 and H2).

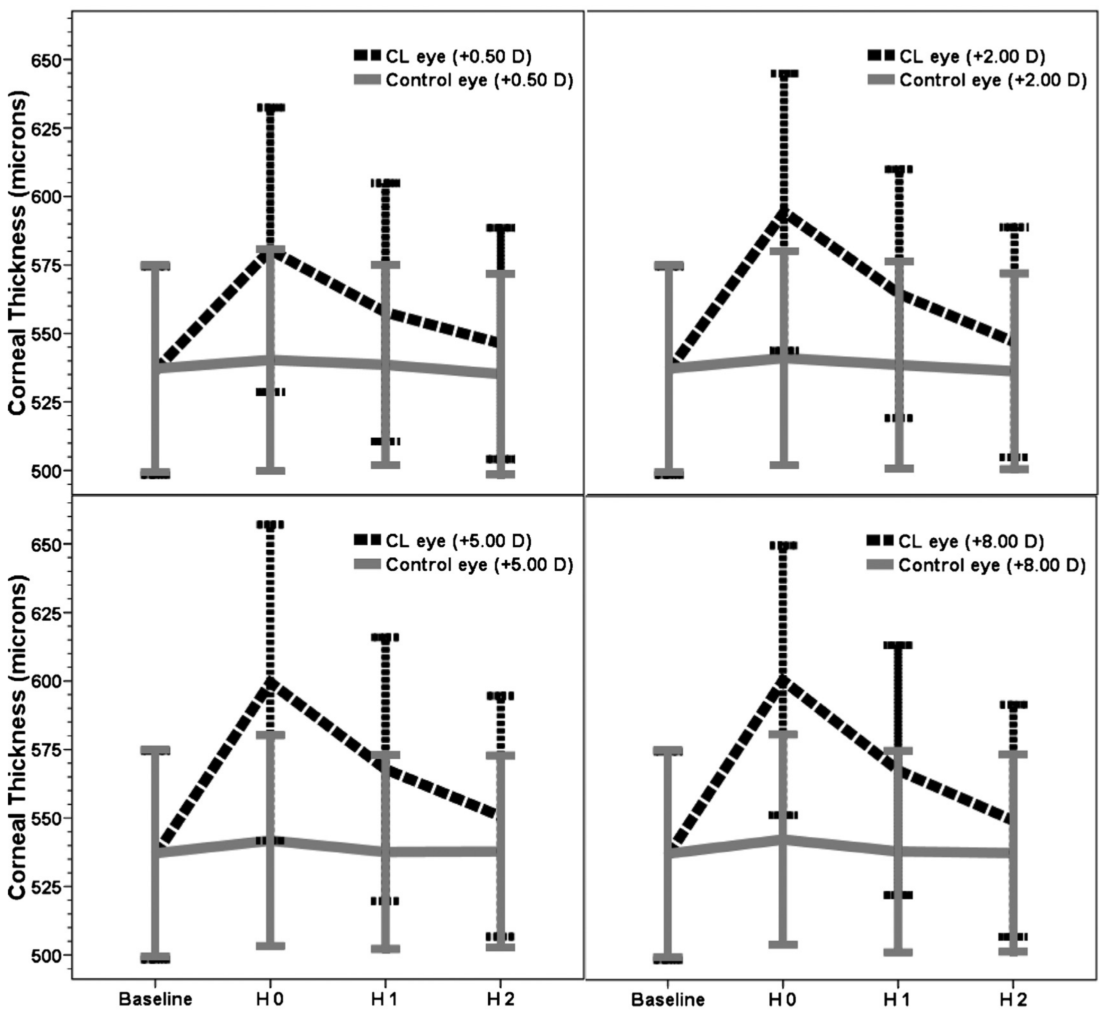

Fig. 1. Corneal pachymetry of the eyes wearing CLs (CL eyes) and control eyes at all interval times analyzed. Mean and 95% confidence intervals are shown. Corneal pachymetry results measured in different times and eyes were significantly different ($p < 0.01$ Multivariate ANOVA). Control eyes showed significantly lower pachymetry than CL eyes ($p < 0.01$ ANOVA) without significant differences along the study ($p = 0.96$ ANOVA). CL eyes showed statistically significant differences immediately after CL removal ($p < 0.01$ ANOVA with Bonferroni correction), but after 1 and 2 h corneal pachymetry was similar to baseline ($p > 0.05$).

power (thicker lens), showed higher corneal swelling, although no significant differences were found (+0.50 D, +2.00 D, +5.00 D and +8.00 D $p = 0.61$ ANOVA).

3.2. Changes in OQ and IS induced by corneal swelling

Fig. 2 shows a double pass image before CL wear (baseline), immediately after CL removal and 1 and 2 h later. We found a worsening of the OQ and an increase in the IS in eyes with corneal swelling with statistically significant differences in all parameters ($p < 0.05$ Re-ANOVA) except OV100% ($p = 0.19$, Re-ANOVA) (Table 2); OQ and IS data are the mean of all CL. These differences were maximal immediately after CL removal ($p < 0.01$, Re-ANOVA with Bonferroni correction). One hour later only the Strehl ratio ($p = 0.02$, Re-ANOVA with Bonferroni correction) and the OV9% ($p = 0.03$, Re-ANOVA with Bonferroni correction) showed statistically significant differences; 2 h after CL removal there were no statistically significant differences in any of the optical quality parameters (Fig. 3).

3.3. Correlation between corneal swelling and OQ and IS

Good significant correlations were found between corneal swelling and the following eye image quality parameters: Strehl ratio $r = -0.93$ ($p < 0.01$); OV100% $r = -0.60$ ($p = 0.04$); OV20% $r = -0.84$ ($p < 0.01$); OV9% $r = -0.81$ ($p < 0.01$); and OSI $r = 0.84$ ($p < 0.01$). However, we found poor agreement between mean corneal swelling and the mean percentage change of OQ and IS.

4. Discussion

Corneal swelling, caused by hypoxia and osmotic fluid changes, is a common complication of CL wear [23]. Corneal swelling is also common after cataract surgery and it is a feature of some eye conditions such as Fuch's endothelial dystrophies [24].

In this study, low-Dk/t (Etafilcon-A) soft CLs with different refractive powers to induce different grades of corneal swelling were used to describe the impact of corneal swelling on eye optical performance with the double-pass system. The Acuvue2 was selected due to its relatively low Dk/t value, which generally ensures corneal swelling after extended wear.

4.1. CL-induced corneal swelling

The mean corneal swelling found in all study visits (5.98%) was lower than the corneal swelling reported by others authors [9,25]. Fonn et al. found 8.66% of overnight swelling after 8 h of sleep with Etafilcon-A, as measured with an optical pachymeter. They compared the corneal thickness at baseline (measured at 4 p.m.) with overnight swelling (measured at 7 a.m. after CL removal) and after 8 h of sleep with a CL and eye closure in one eye. In contrast, we compared corneal thickness at baseline (measured between 4 and 8 p.m., at the time of day when the eye is most stable physiologically) with overnight CL swelling (measured between 8 a.m. and 10 a.m., after 8 h of sleep). These differences could be attributable to the accuracy of optical pachymeters (10–100 μm) [26] *versus* the accuracy of OCT-based instruments (<6 μm) [27], and also with differences in the hour of the day when corneal thickness was assessed. Differences in overnight swelling found by Fonn et al. have been previously reported even with ultrasound and OCT pachymetry [3]. Wang et al. [25] reported 12.1–13.4% of corneal swelling after 3 h with PMMA and soft CLs, respectively, measured with OCT pachymetry. Measurements were obtained in the morning (after 10 a.m.), immediately after CL removal. However, they used soft HEMA lenses with a Dk/t of 2.2, and the Etafilcon-A lenses used in our study had a higher Dk/t of 25.5, which could probably explain the differences found in induced corneal swelling.

On the other hand, we measured a mean corneal swelling of 0.78% in the control eyes immediately after CL removal, a lower result than that reported by Fonn and co-workers [9], who found a sympathetic corneal swelling of 2.34% in control eyes using the same type of CL. They also found significant differences as a function of time after CL removal; they measured the deswelling profile immediately after the eye was open and every 20 min during the next 3 h. One and two hours after CL removal, we found 0.20 and −0.08% corneal swelling, respectively, which agree with their results.

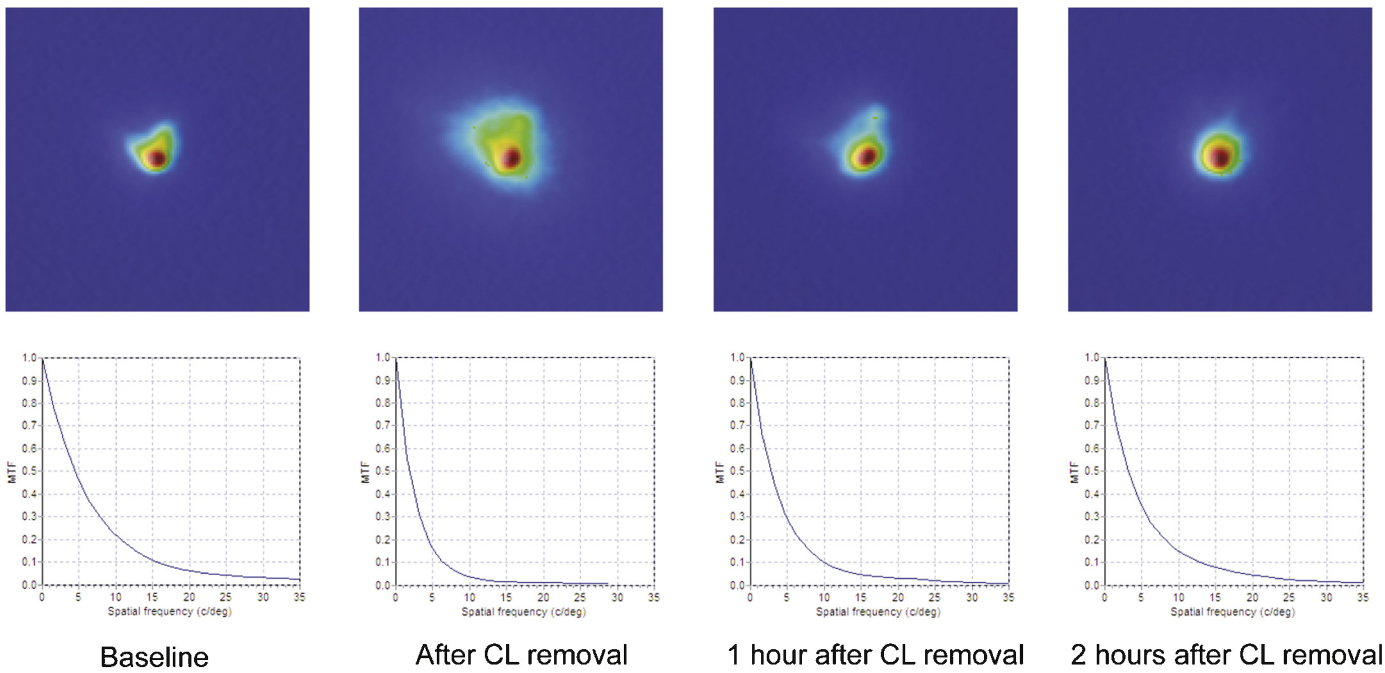

Fig. 2. Double pass images and related MTF curves at all interval times analyzed.

At the baseline visit (without CL wear), no statistically significant differences in corneal thickness between both eyes were found ($p = 0.68$, ANOVA). However, after CL wear we found statistically significant differences in corneal swelling between the eyes that wore CLs and the control eyes ($p < 0.01$, ANOVA). These results agree with previous published studies [9].

4.2. Optical quality worsening after CL wear

Double-pass retinal image quality assessment, an objective and non-invasive technique, has already permitted *in vivo* evaluation of optical performance in eyes wearing monofocal [15] and multifocal [28] CLs. However, to our knowledge no previous reports on the application of the double-pass technique to determine the effect of corneal swelling in the optical quality and in the scattering of the eye exist.

The Strehl ratio with corneal swelling (Table 2) showed a worse optical quality with statistically significant differences ($p < 0.01$ ANOVA with Bonferroni correction) before and after one night of sleeping with CL. The mean decrease for the Strehl ratio immediately after CL removal was 25.92%, with statistically significant differences between the eyes which wore CLs and the control eyes ($p < 0.01$ ANOVA). In relation to OV changes, a statistically significant optical quality impairment was found for OV9% ($p < 0.01$ ANOVA with Bonferroni correction) and OV20% ($p < 0.01$ ANOVA with Bonferroni correction). In contrast, differences were not

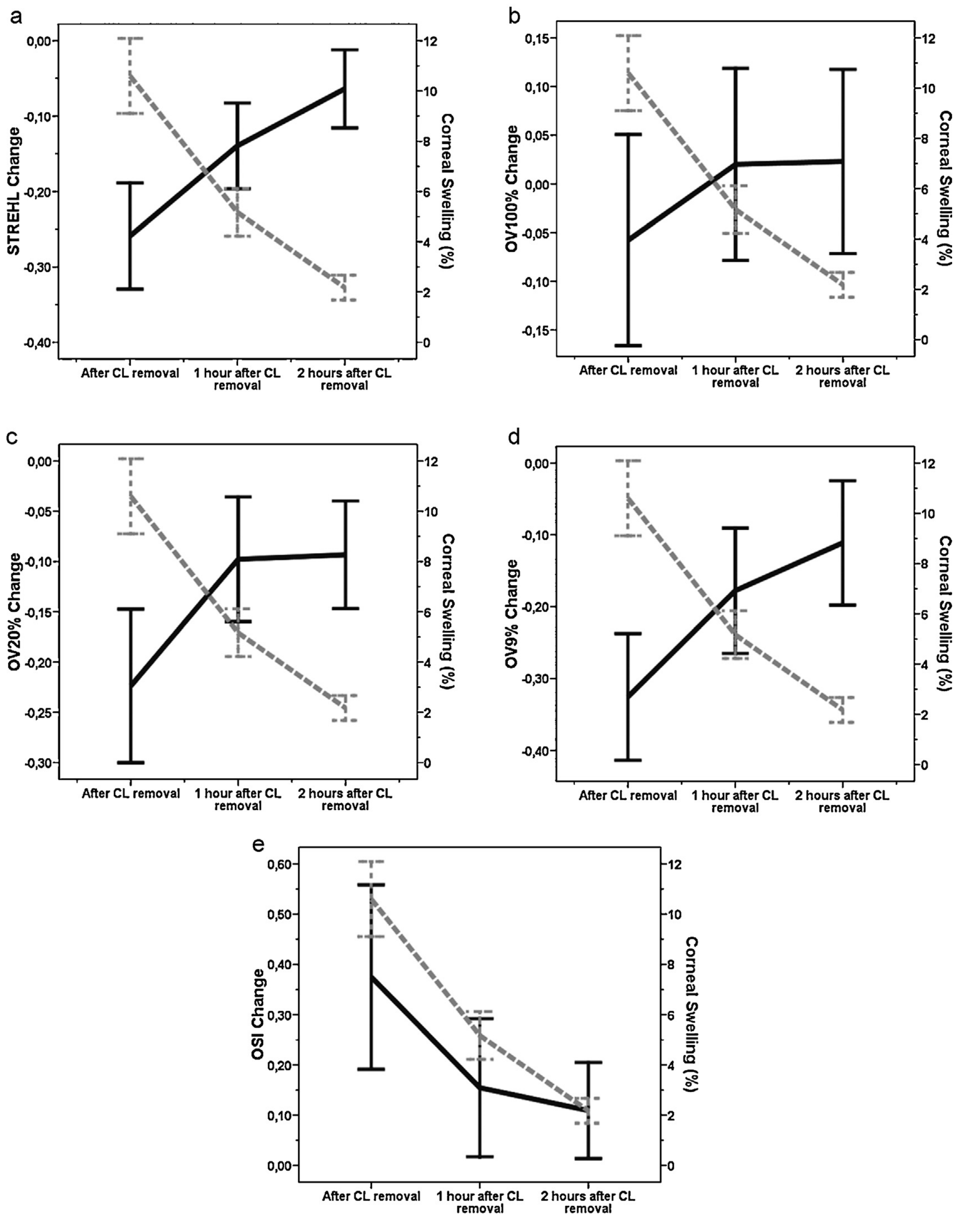

Fig. 3. OQ ((a) strehl, (b) OV100%, (c) OV20%, (d) OV9%) and IS ((e) OSI) change in eyes with CL-induced corneal swelling. Mean and 95% confidence intervals are shown.

Table 2
OQ parameters measured in CL eyes and control eyes at different interval times.

	Before CL wear	Immediately after CL removal	1 h after CL removal	2 h after CL removal	Re-ANOVA[b]
Strehl ratio					
CL eye	0.26 ± 0.03	0.19 ± 0.06	0.22 ± 0.04	0.24 ± 0.04	<0.001
Control eye	0.25 ± 0.04	0.25 ± 0.04	0.23 ± 0.05	0.23 ± 0.04	0.219
ANOVA *p* value[a]	0.474	<0.001	0.438	0.397	
OV100%					
CL eye	1.52 ± 0.16	1.32 ± 0.26	1.43 ± 0.20	1.44 ± 0.21	0.190
Control eye	1.50 ± 0.23	1.45 ± 0.24	1.37 ± 0.24	1.40 ± 0.24	0.140
ANOVA *p* value[a]	0.287	0.069	0.223	0.493	
OV20%					
CL eye	1.60 ± 0.23	1.32 ± 0.26	1.43 ± 0.20	1.44 ± 0.21	0.001
Control eye	1.58 ± 0.30	1.52 ± 0.32	1.41 ± 0.31	1.44 ± 0.32	0.240
ANOVA *p* value[a]	0.764	0.010	0.755	0.912	
OV9%					
CL eye	1.57 ± 0.24	1.08 ± 0.43	1.28 ± 0.36	1.38 ± 0.36	<0.001
Control eye	1.57 ± 0.27	1.49 ± 0.43	1.31 ± 0.41	1.33 ± 0.43	0.079
ANOVA *p* value[a]	0.941	0.002	0.764	0.667	
OSI					
CL eye	0.50 ± 0.12	0.72 ± 0.35	0.58 ± 0.20	0.56 ± 0.18	0.017
Control eye	0.44 ± 0.13	0.48 ± 0.18	0.55 ± 0.19	0.55 ± 0.19	0.060
ANOVA *p* value[a]	0.060	0.006	0.627	0.895	

Summary of the OQ parameters measured in eyes wearing CL (CL eyes) and control eyes at different interval times. Mean and standard deviation are shown. cpd: cycles per degree.

[a] ANOVA *p* value of the differences in OQ and IS between the CL-eye and control eye at each time period.

[b] Re-ANOVA *p* value of the difference in OQ and IS in the same eye along all interval times (Baseline, H0, H1 and H2).

significant for OV100% ($p = 0.19$ ANOVA with Bonferroni correction). The mean decrease after CL removal for OV100%, 20% and 9% was 5.76%, 22.37% and 32.57%, respectively (Fig. 3). The Strehl ratio is a global optical quality parameter which takes into account all the frequencies in the MTF, while the OV are related to specific contrast values. We can therefore conclude that there is an overall optical quality worsening with CL-induced corneal swelling as measured with the Strehl ratio; the OV highlighted that worsening was higher at low (9% and 20%) than at high contrast values (100%).

In agreement with our OV results, optical quality worsening after CL removal has been mainly attributed to scattering [8–11]. Moreover, we found an increase in the OSI ratio with corneal swelling (Table 2) with significant differences ($p = 0.02$ ANOVA with Bonferroni correction). The results of this study showed a variation in the OSI parameter ranging from 0.50 at baseline to 0.72 immediately after CL removal, *i.e.*, an increase of 44%. Some measurements show reduced OSI indices (*i.e.*, improved scatter) after contact lens wear. However, they all correspond to the same individual and could be due to an incorrect baseline measurement.

The corneal swelling induces an increase in the IS which could explain the OQ impairment. Indeed, a high correlation ($r = 0.70$, $p < 0.01$) was found between the percentage change of Strehl ratio and the OSI immediately after CL removal (Fig. 4). Accordingly, we can conclude that IS is a contributor of OQ worsening. Some authors [12] studied other possible causes of OQ worsening such as changes in corneal wave-front aberrations after CL removal and found differences in the higher order aberrations after PMMA CL removal. These differences were not statistically significant when wearing RGP or soft lenses, but corneal swelling was higher in corneas with PMMA lenses compared with RPG or soft lenses. While IS increase and its effect on OQ is accepted, changes in aberrations have not been adequately studied and differences were only found when using PMMA CL. Consequently, IS could be the main contributor to OQ worsening due to corneal swelling.

We found a good correlation between changes in OQ and corneal swelling immediately after CL removal. Indeed, corneal swelling higher than 10.59% (mean corneal swelling immediately after CL removal) produces a significant worsening of the retinal image quality. One and two hours after CL removal, corneal swelling decreases (with means of 5.92% and 2.18%, respectively), simultaneously to an improvement in optical parameters.

In conclusion, this is the first study that uses optical quality measurements performed with a double-pass system to evaluate the impact of CL-induced corneal swelling in the optical quality of the eye. It also describes the differences between eye aberrations and scattering related to CL-induced corneal swelling. Our results suggest that corneal swelling worsened the optical quality of the eye and increased intraocular scattering. Further studies with larger populations and different CL materials and/or extended wear are needed. The double-pass system is useful in the evaluation and monitoring of clinical conditions that present corneal swelling and

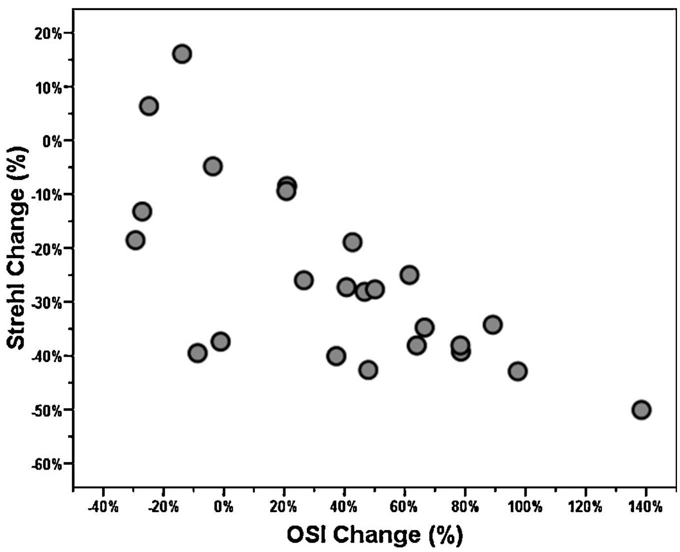

Fig. 4. Correlation between the change in the Strehl ratio and OSI in eyes with corneal swelling after contact lens wearing. The percentual change in Strehl and OSI values is calculated as the difference between pre- (baseline) and post- values divided by the baseline value ($n = 24$; all study eyes immediately after (H0) wearing each four study lenses).

to improve our understanding of the effect of corneal swelling in eye vision.

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Conflict of interest

Jaume Pujol is investor and consultant for Visiometrics S.L.

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