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Assessment of corneal thickness and tear meniscus during contact-lens wear $\!\!\!\!\!\!^{\bigstar}$

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ABSTRACT

Purpose: To assess the effect of seven different daily disposable contact lenses upon corneal thickness, as well as upon tear meniscus volume, by using optical coherence tomography (OCT). *Methods:* Thirty-four young healthy subjects wore seven different types of daily disposable soft contact lenses, each for a period of 12 h: Delefilcon A, Nelfilcon A, Omafilcon A, Filcon II3, Narafilcon A, Etafilcon A and Hilafilcon B. Central and mid-peripheral corneal thickness and lower tear meniscus volume (TMV) were measured using an OCT device during contact-lens wear at 4-h intervals throughout a 12-h period. Measurements were also recorded without any contact lenses being worn during a day.

Results: In the no-lens scenario a small but significant (p < 0.05) thinning in the cornea was observed after the 12-h period. Overall, as for contact-lens wear, it was the Hilafilcon B lens that caused the greatest thickness increase in the central area, whereas the Etafilcon A caused it in the mid-peripheral cornea. Delefilcon A was the lens that showed the most similar behavior to the naked eye. As for TMV, it decreased with all the lenses, but it was the Delefilcon A lens the one that caused the smallest drop in TMV (p = 0.007). *Conclusions:* OCT makes it possible to evaluate both corneal thickness variations and TMV changes as a result of contact-lens wear. The changes in corneal thickness hereafter presented are not clinically significant. On the other hand, TMV drop could indicate discomfort for contact-lens users.

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1. Introduction

The change in corneal thickness with contact-lens wear can be considered to be a measure of corneal hypoxic stress induced by the contact lenses [1]. Many studies have demonstrated central corneal swelling after short periods of soft-contact-lens wear [2–4]. It is well known that the cornea undergoes small but significant diurnal changes in thickness, the most pronounced of which occur upon awakening [5,6]. Studies have also shown a slight thinning of the cornea as the day progresses (morning to afternoon) [5,7]. Failure to adequately account for these natural corneal diurnal changes can potentially lead to inaccurate outcomes in those studies investigating contact lens-induced corneal changes, for both daily and

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extended-wear conditions. It is important to quantify the possible changes in corneal thickness due to the contact-lens wear, since edema (corneal swelling due to hypoxia) can compromise the visual function [8].

Moreover, contact lenses can also cause changes in the tear film of the eye [9]. Tear volume is essential to preserve a smooth optical surface, corneal health and transparency, among others [10-12]. Tear volume is distributed across three continuous compartments: the cul-de-sac, the conjunctival tear menisci, and the preocular tear film, and it depends on the rates of tear production, drainage, and evaporation. It has been reported that tear meniscus variables, such as height, width, cross-sectional area, and meniscus curvature are useful for the diagnosis of dry eye [13-19]. It is reasonable to use lower tear meniscus parameters as objective indicators of tearfilm status, since Wang et al. [20] showed that upper and lower tear menisci have almost identical volume in healthy eyes.

All these structures (cornea, lens, lower tear meniscus, etc.) can be easily assessed nowadays thanks to the various non-invasive techniques that have been developed for the evaluation of the eye's anterior segment, such as Scheimpflug techniques, Placido's disc based techniques, optical coherence tomography (OCT), etc. Among them, OCT [21] is one of the most suitable methods to





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Main features of the daily soft contact lenses assessed in this study.	

Parameter	Delefilcon A	Nelfilcon A	Narafilcon A	Etafilcon A	Hilafilcon B	Omafilcon A	Filcon II 3
FDA group	II	II	I	IV	II	II	II
Water content	33% to >80%	69%	46%	58%	59%	60%	56%
BOZR (mm)	8.5	8.7	8.5	8.5	8.6	8.7	8.6
TD (mm)	14.1	14.0	14.2	14.2	14.2	14.2	14.1
tc (mm) @ -3.00D	0.09	0.10	0.085	0.084	0.09	0.09	0.07
DK/t (@ -3.00D)	156	26	118	26	24	36.6	86
Design	Bicurve lens	Tri-curve front and back surfaces	Spherical lens	Spherical lens	Aspheric lens	Aspheric front surface	Aspheric lens
Manufacturer	Alcon	Alcon	Johnson & Johnson Vision Care	Johnson & Johnson Vision Care	Bausch & Lomb	Cooper vision	Sauflon

FDA: food and drug administration (USA); BOZR: back optic zone radius; TD: total diameter; tc: central thickness; DK/t: oxygen transmissibility.

image the human eye's anterior segment (i.e., cornea and contact lens) [22,23], thanks to its ability to capture cross-sectional (or volumetric) images of tissue with high axial resolution, along with its high-speed acquisition rates. Fourteen studies using OCT technology for contact-lens assessment were recently identified and reviewed in the literature [24].

The aim of this study was to investigate the effect of one-day contact-lens wear upon the central, mid-peripheral corneal thickness and also in the tear meniscus volume. For this purpose, several types of soft contact lenses were evaluated. Moreover, natural (i.e., naked eye; no contact-lens scenario) diurnal changes occurring in corneal thickness were also measured and used as baseline data, which allowed us to provide an accurate measure of the corneal changes directly attributable to the contact lenses.

2. Subjects and methods

2.1. Subjects

This study included 34 left eyes from 34 individuals, 15 male and 19 female, aged 23–34 (mean: 25.40 ± 1.94 years). Spherical refractive errors ranged between -3.50 and -3.00 diopters (D) (mean: $-3.21 \pm 0.18D$). They all had clear intraocular media and no known ocular pathologies. All subjects were informed about the details of this study, and a written informed consent was obtained after verbal and written explanation of the nature and possible consequences of the study, in accordance with the Declaration of Helsinki. Institutional Review Board approval was required for this study. Subjects having best-corrected visual acuity worse than 0.0 logMAR, ocular or systemic diseases, a history of ocular surgery, intraocular pressure above 21 mmHg or presence of retinal or optic disc pathology, were excluded from this study. None of the subjects were regularly using either contact lenses, or any ocular or systemic medication. A series of preliminary tests were conducted to ensure that all subjects had normal tear film (BUT of more than 10 s and Schirmer test score of more than 5 mm) and central corneal thickness.

2.2. Contact lenses

In order to have a representative sample of the daily disposable soft contact lenses available in the market, the following seven types of soft-contact lenses from five different lens manufacturers were evaluated: Delefilcon A and Nelfilcon A (Alcon Laboratories, TX, United States), Omafilcon A (CooperVision, CA, United States) Narafilcon A and Etafilcon A (Johnson & Johnson Vision Care, NJ, United States), Hilafilcon B (Bausch & Lomb, NY, United States), and FIlcon II 3 (Sauflon, Twickenham, United Kingdom). The main technical specifications of the lenses under evaluation are summarized in Table 1. The lens power and total diameter were also rechecked by one of the authors and were found to conform to the manufacturer's stated tolerances.

All the contact lenses used in this study had the same power of -3D, and for each contact lens type and subject, the fitting was performed in an optimal or acceptable way. Subjects wore in their left eye each type of contact lens for 12 h. Each lens type was worn and assessed on a different day, following a randomized order. New lenses were used for each subject and for each trial.

2.3. Ocular coherence tomography

The Topcon SL SCAN-1 is a spectral-domain OCT instrument that provides high-resolution cross-sectional images of the posterior and anterior segments of the eye. The SL SCAN-1, using as light source a super-luminescent diode (SLD) with a wavelength of 840 nm, has an axial resolution of 8–9 µm, a lateral resolution below 20 µm and a scanning speed of 5000 A-scans/s. This device has the following options for scan patterns: horizontal line, vertical line, cross, raster, grid, radial and circle. For each subject, lens type and time of the day, an 6-mm width grid-pattern scan was acquired. This pattern comprises six scanning lines, the distance between adjacent vertical or horizontal lines being 3 mm. With this approach, six scans are obtained with just one simple measure, as shown in the left part of Fig. 1. The central point can be measured with both the vertical and horizontal scans, that is the reason why only five scans are showed in the right part of Fig. 1. The instrument has an eye preview camera to assist with the alignment of the subject. External illumination was used in order to improve the eye preview image quality.

2.4. Corneal thickness

Measurements of the cornea were taken four times throughout the 12-h period that the subjects wore each contact lens. The first measurements were taken around 9 a.m., right after the fitting of the contact lens, but we made sure that the subject had been awake for at least 2 h to avoid the well-known corneal thickness peak that occurs immediately after waking up [5]. Then, successive measurements were taken every 4 h, until approximately 9 p.m. After each day of lens wear, the subject was allowed a 2-day recovery period before being fitted with the next lens. Baseline measurements i.e., with the subject wearing no contact lenses were also recorded in a similar manner: on the left eye starting at 9 a.m. until 9 p.m. at 4-h intervals, so as to record each individual's natural diurnal variations in corneal thickness.

All these measures were recorded with the abovementioned OCT device, while the subject was looking at an external fixation target. Three sets of measures were taken at the center of the pupil, using the grid scanning pattern (Fig. 1) where corneal thickness was measured at different positions. Once the set of scans was saved, corneal thickness were measured at the center of the cornea and

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