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Non-invasive pre-lens tear film assessment with high-speed videokeratoscopy $\stackrel{\bigstar}{}$

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ABSTRACT

Purpose: To evaluate the effect of two types of daily contact lenses (delefilcon A and omafilcon A) on the tear film and establish whether it is dependent on pre-corneal tear film characteristics using a new method to analyse high-speed videokeratoscopy recordings, as well as to determine the sensitivity of the method in differentiating between contact lens materials on eye.

Methods: High-speed videokeratoscopy recordings were analysed using a custom made automated algorithm based on a fractal dimension approach that provides a set of parameters directly related to tear film stability. Fifty-four subjects participated in the study. Baseline measurements, in suppressed and natural blinking conditions, were taken before subjects were fitted with two different daily contact lenses and after four hours of contact lens wear.

Results: The method for analysing the stability of the tear film provides alternative parameters to the noninvasive break up time to assess the quality of the pre-corneal and pre-lens tear film. Both contact lenses significantly decreased the quality of the tear film in suppressed and natural blinking conditions (p < 0.001). The utilised method was able to distinguish between contact lens materials on eye in suppressed blinking conditions. The pre-corneal tear film characteristics were not correlated with the decrease in pre-lens tear film quality. *Conclusion:* High-speed videokeratoscopy equipped with an automated method to analyse the dynamics of the tear film is able to distinguish between contact lens materials in vivo. Incorporating the assessment of pre-lens tear film to the clinical practice could aid improving contact lens fitting and understand contact lens comfort.

1. Introduction

Approximately half of the contact lens wearers suffer from dryness and discomfort being the one of the major causes of contact lens intolerance and the consequent contact lens wear drop out [1,2]. The presence of a contact lens on the eye causes biophysical and biochemical changes in tear film structure and functions [3]. It has been evidenced that these changes lead to shorter break up times and increased rates of evaporation compared to those found for pre-corneal tear film [4–7] and that this decrease in tear film stability could induce signs and symptoms of dry eye and subsequent ocular damage [8].

There are many factors that play a role during the contact lens fitting process. Some of them can be controlled and adjusted by the clinician, such as those related to the contact lens geometry and material, but others are inherent to the subject and not easily controllable, like the quality of tear film and its distribution during a blink cycle, which have a determinant role in contact lens fitting and comfort [9]. Due to the number of factors involved, mechanisms of contact lens intolerance and discomfort are not well understood. Tear evaporation, related to tear instability, and contact lens dewetting have been proposed as the principal mechanisms that lead to contact lens related dry eye [6,10].

There are available a number of clinical tests that are performed prior to the fitting to assess the suitability for contact lens wear, however they are still unsuccessful in identifying the potential symptomatic patients. Some studies attempted to relate pre-corneal tear film characteristics with contact lens intolerance [6,9,11,12]. Non-invasive break-up time (NIBUT) and self-reported symptoms before contact lens wear were found to be the best discriminant tests to predict contact lens wear success [9,11,12]. However, in preliminary unpublished work in this area, the hypothesis has been reached that the quality of the prelens tear film seems to not only depend on tear film characteristics of the bare eye, but it is also influenced by the contact lens material and its specific interaction with the individual tear film. Similarly, Guillon

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et al. [13] did not find any differences in pre-corneal tear film stability between symptomatic and asymptomatic soft contact lens wearers.

Studying pre-lens tear film dynamics is important in order to gain information on how to improve the rate of successful contact lens fitting and to make it the least detrimental to the anterior eye health. The assessment of tear film dynamics on contact lens is challenging. While the pre-corneal NIBUT has been widely studied and it is quite well understood, this is not the case for pre-lens NIBUT, where the mechanisms that govern the dynamics of pre-lens tear film in terms of its formation, stability and disruption are not fully understood and the appropriateness of NIBUT in describing pre-lens tear film dynamics has been questioned [10,14,15]. The necessity of finding an alternative way to describe the pre-lens tear film dynamics arises.

Few studies have characterised the stability of the pre-lens tear film and compared it for different contact lenses [5,16,17]. All of them have agreed that the quality of the tear film is adversely affected when wearing contact lenses, but less is known about the relationship between pre-lens tear film kinetics and the biocompatibility of the lens with tear film of an individual. Pult et al. [18] have assessed the predictive potential in contact lens discomfort of different clinical tests and found that pre-lens NIBUT was not different between symptomatic and asymptomatic groups, whilst, Guillon et al. [15] found that symptomatic wearers have shorter pre-lens NIBUTs.

There are different techniques that have been used to non-invasively assess the dynamics of the tear film, one of which is based on the Placido disk high speed videokeratoscopy [19]. The advantage of this technique, compared to other more sophisticated techniques (such as interferometry, confocal microscopy or aberrometry), is that it is easily accessible to the clinicians, it provides a large surface coverage (up to 10 mm) and it is not as affected as other techniques by eye movements [20]. Its utility in describing the dynamics of the tear film have been already reported [21-23]. Nowadays there are some commercially available Placido disk based videokeratoscopes that already incorporate a function to analyse tear film dynamics. However, they are not designed to evaluate the dynamics of the tear film on contact lenses. Some studies have attempted to analyse the raw videokeratoscopic sequences of the pre-lens tear film using custom written algorithms, but the sensitivity achieved was not as high as with other more sophisticated laboratory instruments [17,24].

The main aim of this study was to evaluate different parameters of pre-lens tear film stability and assess how they relate to the biocompatibility of two different contact lenses with tear film of an individual subject, using a recently proposed automated method for analysing high speed videokeratoscopy recordings [25]. Also, the aim was to determine if there is any relationship between pre-lens and precorneal tear film quality.

2. Methods

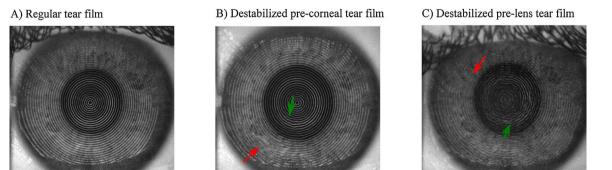
2.1. Subjects and clinical protocol

Fifty-four subjects volunteered to participate in the study (19 males and 35 females, mean age: 25.5 ± 4.3 years). The study followed the tenets of the Declaration of Helsinki and all participants signed an informed written consent. Inclusion criteria included: no evidence of ocular history anomaly, ocular surgery, ocular infection or inflammation, no reported dry eye, allergy or any ocular surface or systemic disease that may affect the tear film or contraindicate the use of contact lenses, as well as an astigmatism prescription higher than 0.75 dioptres. If subjects were contact lens wearers they were asked not to use them at least three days before the study.

The stability of the tear film was assessed with high speed videokeratoscopy, first in natural blinking conditions (NBC), where the subject is told to look at the fixation point and blink normally, for a period of about 30 s to ensure acquisition of several full inter-blinks. Later the tear film was assessed with high speed videokeratoscopy in suppressed blinking conditions (SBC). For those measures, subject was asked to look at the fixation point, blink once and maintain the eyes open as much as they could. The measurement was automatically terminated after the acquisition of 300 frames (about 23 s). In SBC each eye was measured twice. Between each of the measurements there was a 3 min break.

Before contact lens fitting high speed videokeratoscopy baseline measurements on pre-corneal tear film were acquired. Later subjects were fitted with two different daily contact lenses (on right eye Delefilcon A (L1), base curve: 8.5 mm, diameter: 14.1 mm; on left eye Omafilcon A (L2), base curve: 8.7 mm, diameter: 14.2 mm) in a doublemasked study modality. All the patients were fitted with spherical correction, using the spherical equivalent. An initial adequacy of lens fit was ensured for both lenses. After 4 h of contact lens wear, the same scheme of high speed videokeratoscopy measurements was repeated on pre-lens tear film and an additional standard clinical evaluation of the fitting, that included centration, corneal coverage, horizontal lag, blink movement, and the binocular corrected visual acuity for distance and near vision, was made by an experienced clinician who decided, based on this findings, which lens should be prescribed. The Omafilcon A lens was chosen because it achieved the best tear film performance in the study conducted by Szczesna-Iskander et al. [17], while the Delefilcon A was selected for its recently claimed superior wetting performance [26,27].

2.2. Instrumentation and data analysis



high speed videokeratoscopy measurements were conducted with E300 videokeratoscope (Medmont Pty., Ltd, Melbourne, Australia) using the dynamic topography recording option (Medmont Studio 6), a

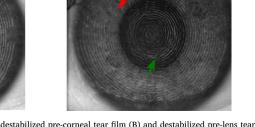


Fig. 1. The appearance of Placido disk reflections for different scenarios. Stable pre-corneal tear film (A), destabilized pre-corneal tear film (B) and destabilized pre-lens tear film (C). Green arrows indicate local distortions of the tear film and red arrows indicate breaks of the tear film. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

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