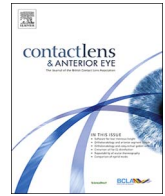




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The utility of measuring tear film break-up time for prescribing contact lenses

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ABSTRACT

Purpose: To evaluate the clinical value of non-invasive keratograph tear film breakup time (NIK BUT) in the assessment of pre-corneal and pre-lens tear film quality for prescribing contact lenses (CLs).

Methods: Forty-six subjects aged 25.5 ± 4.3 (mean \pm standard deviation) years were recruited. Visual acuity (VA), anterior eye health checks and NIK BUT were evaluated. On the following day, subjects were fitted with a daily Silicon Hydrogel (SiHy) CL in one eye and a Hydrogel (Hy) CL in the other. After four hours one material for both eyes was chosen based on a qualitative analysis which included VA, CL fitting and comfort. Information about the first and the mean NIK BUT was then contrasted against the prescription decision.

Results: Thirty-four subjects were fitted with SiHy and twelve with Hy CL. No statistically significant differences were found for both NIK BUT parameters between left and right eye at baseline ($p = 0.38$ and $p = 0.50$, respectively) and post four hours of CL wear ($p = 0.61$ and $p = 0.06$). The chosen lens did not always correspond to longer NIK BUT. In 39.1% and 34.8% of cases (i.e., 18 and 16 out of 46), there was a match between prescription decision and the first and the mean NIK BUT results, respectively.

Conclusions: Although there is no evidence whether tear film surface quality measurement has a superior diagnostic values compared to other traditional clinical measures used in practice, NIK BUT measurements have provided additional information that could be of interest during CL fit.

1. Introduction

Contact lens (CL) wear is becoming more popular worldwide with a rapid growth [1]. It has been estimated that there are approximately 140 million CL wearers across the globe [2] with soft CL wear being the first mode of choice for prescribing contact lenses (CLs) [3].

A typical fitting assessment in a clinical practice with soft lenses would include anterior eye health check followed by lens centration, corneal coverage, lens movement upon blink, lag and push up, as well as surface wettability, subjective comfort and visual acuity (VA) rating [4,5]. These measurements are often recorded as either acceptable or unacceptable with a variation on recording methods between practitioners [4]. Upon lens insertion, fitting is usually assessed within half an hour [6,7], the follow up in two weeks and further reviewed at annual aftercare. With soft lenses, there are limitations with the range of parameters (base curve and diameter) and choice of availability. However, it is important that appropriate lens selection is made based

on lens material, dimensions, refractive error, mode of lens wear and sufficient recording methods ensuring successful lens wear [4].

Adequate tears are required to keep the eye surface lubricated and nourished and lens hydrated. CLs divide the tear film (TF) into pre and post lens films [8] and impacts the TF stability, leading to a shorter tear film break up time [9]. Numerous studies have investigated the interaction and relationship between CL and TF surface quality (TFSQ) [10,11]. It has been shown that CL wear affects the ocular surface with changes observed and seen similar in dry-eye syndrome [12]. Contact lens discomfort (CLD) has been defined as a condition related to lens wear, in which episodic or persistent adverse ocular sensations are present, and it is one of the main reasons for discontinuing lens wear and dropping out [13]. Although many studies have investigated the level of contact lens discontinuation, the true rate dropout from contact lens wear remains unclear. Recent estimates have varied from 12% to 43% for permanent discontinuations [1,14,15].

Keratograph 5M (K5M, Oculus Optikgeräte GmbH, Wetzlar,

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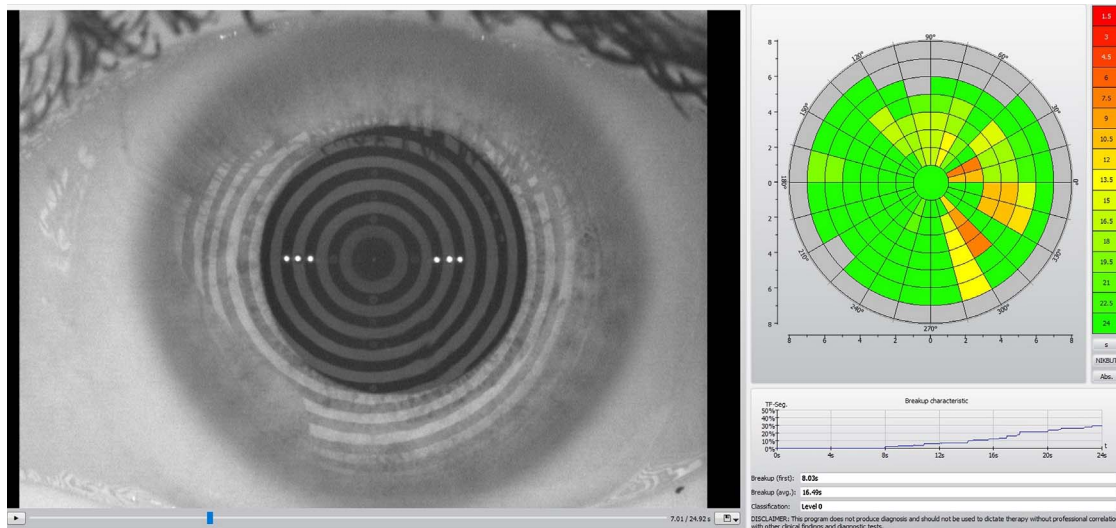


Fig. 1. Interface of the Keratograph 5 M. The left panel shows the first image of the eye with the superimposed Placido rings from a 23-s sequence whereas the right panel shows the distortion map of the rings and the respective estimated break up times.

Germany) is a commercial instrument offering infrared ring illumination based on the Placido disc pattern principle to measure noninvasive keratography tear film break up time (NIK BUT) [16]. The possibility of using pre-lens NIK BUT measurement has been suggested earlier but not eventuated [17].

The aim of this study was to evaluate the clinical value of NIK BUT in the assessment of pre-corneal and pre-lens tear film quality for prescribing the contact lenses (CLs). Here, it is assumed that NIK BUT, which essentially measures tear film surface levelling/de-levelling properties, is a measure of tear film quality on either eye or a CL. The aim was to establish whether the NIK BUT estimates match other clinical assessments routinely used for CL fit or constitute additional information.

2. Methods

2.1. Subjects

Forty-six healthy young regular or occasional contact lens wearers (13 M and 33 F), aged 25.5 ± 4.3 years (mean \pm standard deviation, ranging from 20 to 37) were recruited for this study. Study adhered to the tenets of the Declaration of Helsinki and informed consent was obtained from all subjects after the goals of the research and consequences of participation had been discussed. All subjects were advised to cease wearing their habitual contact lenses and instilling ophthalmic solutions at least three days prior to commencing the study. This was to ensure subjects previously wearing different contact lens modalities achieving more consistent baseline (bare eye) results [7]. Exclusion criteria included signs and symptoms of eye dryness, inflammation or any tear flow impairment as well as eye surgeries and seasonal allergies. In addition, the refractive error was limited to ± 4.50 spherical and ± 0.75 cylindrical dioptres. Laboratory temperature was monitored and all measurements were performed at the same time of the day. Laboratory temperature was 24.5 ± 1.2 ($^{\circ}$ C) and the relative humidity was 32.2 ± 4.8 (%RH). The study protocol spanned two days.

2.2. Study protocol and techniques

The baseline evaluation, performed on the first day, included review of medical history, Ocular Surface Disease Index (OSDI) questionnaire [18], NIK BUT measurements with K5M and anterior eye slit lamp examination – including the central lower tear meniscus by carefully

observing for excess dryness or tearing and assessment of lid margins and Meibomian glands making sure there is no obstruction grading according to the Efron's grading scale [19], as well as fluorescein tear film break-up time estimation. Exclusion criteria were applied to subjects who demonstrated at least two out of the following OSDI ≥ 25 , conjunctival staining present ≥ 2 , corneal staining present ≥ 2 , and fluorescein tear film break-up time ≤ 7 s.

Fluorescein dye was used to assess corneal staining. A drop of 0.9% saline solution was used to wet the sodium fluorescein (NaFl) 1 mg ophthalmic sterile strips (BioGlo, HUB Pharmaceuticals), which was applied gently to the subject's lower fornix. Subjects were requested to blink several times to ensure adequate mixing of the dye and to keep their eyes open. Cornea and conjunctiva were examined under standard illumination using a slit-lamp microscope with a cobalt-blue light and a yellow filter (Wratten 12).

NIK BUT measurements were performed in mesopic conditions. K5M allows non-invasive and automatic measurements of tear film break-up. The infrared illumination was used as it prevents glare during the examination. Subjects were asked to fixate centrally, blink twice in natural way and suppress their blink for as long as they could. The recording started automatically right after the second blink and lasted maximum 23 s. The majority of the subjects had no difficulty keeping their eyes open for 23 s.

NIK BUT is described as the time between the last complete blink and the distortion of Placido rings reflected from the pre-corneal tear film surface which the device detects automatically. K5M generates two measures for NIK BUT: the first NIK BUT as the time at which the first discontinuity or disturbance in the reflected Placido disk pattern occurs and the mean NIK BUT which is the average time of all detected discontinuities and disturbances that could be, in essence, related to localised tear film break-ups. NIK BUT measurements have been validated in earlier studies [20].

Fig. 1 shows the graphic User Interface of the K5 M after the measurement of NIK BUT was estimated. NIK BUT assessment was performed three times per eye alternately with one minute break between measurements.

On the following day subjects were fitted with two different types of daily disposable CLs, Silicon Hydrogel (SiHy, Delfilcon A, BC: 8.5 mm Diameter: 14.1 mm) on the right eye and Hydrogel (Hy, Omafilcon A, BC: 8.7 mm Diameter: 14.2 mm) on the left eye and an acceptable fit, as defined in [21], was ensured for both lenses. The fitting process has been performed by a trained optometrist. Subjects were masked to which lens was inserted on their eyes. After four hours of wear, further

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