The evaluation of a novel keratometer mire as a non-invasive method of assessing the stability of the human pre-corneal tear film

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Abstract
A simple, non-invasive technique of assessing the stability of the human pre-corneal tear film is tested for usefulness in diagnosing subjects with dry eye. Changes are observed in the reflection of the keratometer mire, which is in the form of a grid pattern (HIR-CAL Grid). Thinning and breaks in the tear film appear as random discontinuities in the grid image. The stability of the pre-corneal tear film was assessed (based on tear pre-rupture phase time (TP-RPT)) in nine normal subjects and nine subjects with dry eye. There was a significant difference between the groups, the dry eye TP-RPT averaging 27% less than the TP-RPT of normal eyes. This supports the findings of other non-invasive approaches in measuring tear film stability. Applications of this technique include diagnosing dry eye and selecting successful contact lens wearers.

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THE EVALUATION OF A NOVEL KERATOMETER MIRE AS A NON-INVASIVE METHOD OF ASSESSING THE STABILITY OF THE HUMAN PRE-CORNEAL TEAR FILM

By

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Christine M. Kniffen was born and raised in Tyndall, South Dakota. She received a Bachelor of Arts degree in Music Education in 1991 and taught two years of public school before entering optometry school in 1995. Throughout her first year, she sang with the Pacific University Chamber Choir. During her second year, she was selected for the Air Force Health Professions Scholarship. Chris is a candidate to receive her Doctorate of Optometry Degree in May 1999. She hopes to make a career out of military optometry and continue music endeavors through singing and organ playing in church.
ABSTRACT

A simple, non-invasive technique of assessing the stability of the human pre-corneal tear film is tested for usefulness in diagnosing subjects with dry eye. Changes are observed in the reflection of the keratometer mire, which is in the form of a grid pattern (HIR-CAL Grid). Thinning and breaks in the tear film appear as random discontinuities in the grid image. The stability of the pre-corneal tear film was assessed (based on tear pre-rupture phase time (TP-RPT)) in nine normal subjects and nine subjects with dry eye. There was a significant difference between the groups, the dry eye TP-RPT averaging 27% less than the TP-RPT of normal eyes. This supports the findings of other non-invasive approaches in measuring tear film stability. Applications of this technique include diagnosing dry eye and selecting successful contact lens wearers.

KEY WORDS: dry-eye syndrome, tear pre-rupture phase time (TP-RPT), contact lenses, non-invasive, pre-corneal tear layer, HIR-CAL grid
The assessment of the pre-corneal tear film is helpful in determining if a patient will be a successful contact lens wearer (Holly, 1981) and in diagnosing dry eye disorders.

Most literature describes the tear layer as having three structures. The outer lipid layer is primarily secreted from the meibomian glands; the middle aqueous portion is produced by the main and accessory lacrimal glands; and the mucin layer of mostly acidic glycoproteins is secreted by the conjunctival goblet cells (Doane and Gleason, 1994). When the lipid layer contaminates the mucin layer, a local thinning results and breakup eventually occurs. Epithelial defects, contact lens deposits, and vertical convection currents in the tear increase the speed of this localized thinning (Holly, 1980) and eventually cause tear breakup. This tear thinning has been described as a first component of instability called the pre-rupture phase (TP-RPT). The complete rupture of the tear film is considered the second component (Hirji et al., 1989).

There are several techniques available for assessing pre-corneal tear film stability, a more popular one including staining of the tears with fluorescein and measuring the time it takes for the film to rupture after the patient blinks (Break Up Time (BUT))(Lemp, 1973). Vanley, Leopold, and Gregg (1977) found considerable variability and inconsistent reproducibility in their study on tear film breakup using this method. It has been proven that fluorescein reduces the tear film surface tension and increases the rate of evaporation of the tear film (Patel et al., 1985). Non-invasive techniques to gauge tear film integrity have been described which provide comparable alternative methods of assessment (Hirji et al., 1989; Mengher et al., 1984). This study qualifies the clinical usefulness of a reflecting grid attached to a keratometer in its non-invasive measurement of the TP-RPT (tear pre-rupture phase time) of dry and normal eyes.

METHODS
Patient Selection

Nine randomly selected normal subjects (five women and four men, age range 20-45 years) were accepted into the study. Nine established dry eye subjects (seven women and two men, age range 20-45 years) were also selected. The patients were screened for no history of ocular allergy, no anterior eye infection, no surgery, no external eye disease or systemic disease. All patients were not taking topical or systemic drugs and were in good health. The subjects willingly volunteered to participate in the study after an explanation of the procedures.

Instrumentation design

An ophthalmic instrument was designed for non-invasive assessment of pre-corneal tear film stability based on the 1989 works of Hirji, Patel, and Callander. First a sheet of ordinary graph paper was photocopied on to black and white negative photographic paper and magnified X 2. A circular pattern of the HIR-CAL grid was cut to size and replaced the existing mire in a Bausch and Lomb keratometer. Components of the HIR-CAL grid are displayed in Figure 1. The patient’s view is illustrated in Figure 2, while an example of blurring and distortions of the reflected mire is demonstrated in Figure 3.

A mirror beam splitter (51 X 76 X 3) was glued at a 45-degree angle with the keratometer light in an attempt to fill the center blank spot with continuous mire image. The total coverage of the mire projection included the central 7.07 mm² (3-mm diameter).

The subjects were instructed to blink a few times while they held their chin and forehead in the keratometer restraints. Timing with a stopwatch began with the last complete blink and ended with the first sign of loss of tear film integrity: random
discontinuity of the mire reflection, the first defocus, or when the lines distorted. In this manner, three readings were taken for the right eye, then three for the left.

The laboratory environment consisted of a dark room to enhance the contrast of the reflected mires. Room temperature was monitored at 23°C and constant humidity. No ventilatory currents were evident.

108 measurements of TP-RPT were measured, 27 on dry right eyes, 27 on dry left eyes, 27 on normal right eyes, and 27 on normal left eyes (three per subject). Descriptive statistical analysis was applied to all normal eyes and all dry eyes. Student's t-test for 54 paired observations each was applied to check for a difference between dry right and left eyes and normal right and left eyes. Student's t-test was applied again, this time the paired observations applying to all normal eyes and dry eyes to determine a difference p<0.05. A histogram was plotted for frequency distribution of the normal eyes and a separate one for dry eyes.

RESULTS

Normal subjects

A frequency distribution of the tear pre-rupture phase time (TP-RPT) for 54 normal eyes (combined right and left) is illustrated in Figure 4. The tail is positively skewed, with 0% of observations between 0-5 seconds, 37% between 6-10 seconds, 47% between 11-15 seconds, 12% between 16-20 seconds, and 6% between 21-26 seconds. The mean TP-RPT of 12.02 seconds falls in the largest interval of 11-15 seconds. Table 1 shows the descriptive statistics of number of observations, minimum, maximum, median, mean, standard error, variance, and standard deviation.

Dry eye subjects
A frequency distribution of the tear pre-rupture phase time (TP-RPT) for 54 dry eyes (combined right and left) is illustrated in Figure 5. The tail, again, is positively skewed, this time with 13% of the observations falling between 0-5 seconds, compared with 0% of normal eyes. The largest category was from 6-10 seconds, comprising 65% of the dry eye subjects, compared to only 37% of normal eyes. 14% were between 11-15 seconds, 6% between 16-20 seconds, and 4% between 21 or more seconds. A mean of 8.76 seconds places it in the largest category of dry eye subjects, 6-10 seconds. Table 2 illustrates the descriptive statistics for dry eyes.

There was no significant difference of TP-RPT between right and left eyes of normal or dry eyes. When the Student's t-test is applied for the null hypothesis, i.e., there is no significant difference between the right and left eyes, it is accepted at the 5% level on data for normal eyes and data for dry eyes. (See Table 3).

There was a significant difference of TP-RPT between dry eyes and normal eyes. When the Student's t-test is applied for the null hypothesis, i.e., there is no significant difference between the dry eyes and normal eyes, it is rejected at the 5% level. (See Table 4).

DISCUSSION

The average measurements of tear stability for dry eyes were expectedly lower than normal eyes for the HIR-CAL grid. The times obtained in this study were lower than those obtained by a similar method of non-invasive technique used by
Mengher (1985). In his study, a grid pattern was inscribed inside a 20 cm-radius hemispherical bowl that mounts on a slit lamp. Comparing the averages of Mengher (normal right eye mean 47.9 seconds, normal left eye mean 35.1 seconds; dry right eye mean 22.2 seconds, dry left eye mean 11.3 seconds), the averages of this study are much lower (all normal eyes mean 12.0 seconds, all dry eyes mean 8.8 seconds). One reason for this could be the wide variation between normal subjects in Mengher’s experiment. Another could be that with the HIR-CAL grid on the keratometer, the experimenter is only viewing the central 3.0 mm whereas the view is across the entire cornea in Mengher’s apparatus. The wider view allows for more area to be scanned. Hence the observer does not detect areas of thinning as quickly.

The TP-RPT was lower for normal eyes in this study using almost the same technique than when it was first studied by Hirji and Callander (1989). The mean for normal eyes is 12.0 seconds in this study, compared to 18.3 seconds in 1989. Several factors could have influenced this result. One could be the interpretation of the grid discontinuities by the examiner. Another factor could be the environment including temperature, air drafts, and humidity. Measurements were gathered in a dark room, a criteria not mentioned in the Hirji-Callander study. Such contrast could enhance the grid lines making it easier to notice a slight unevenness. Perhaps the addition of the central reflecting mirror attached to the keratometer in this study made the assessment more accurate across the central cornea as well.

The right and left eyes showed no significant difference between them, agreeing with the results of the Hirji and Callander study of 1989. The measurements of TP-RPT are so short that reflex tearing in the left eye after the other eye has been measured probably will not have much effect. Another study on the sequence of measuring could investigate that factor further.

The TP-RPT was lower in normal eyes compared to the normal tear thinning time (12.0 seconds compared to 18 seconds) (Patel, 1985). Tear thinning time is a similar assessment of the stability of the pre-corneal tear film with the use of the regular mires on a keratometer. Even with flourescein added, the tear thinning time was still higher at 14.4 seconds.
CONCLUSION

The results of this study show that the simple, non-invasive technique of a reflecting HIR-CAL grid off the cornea projected from a common B & L keratometer is useful as an alternative approach to assessing dry eye conditions. This method would be useful in evaluating contact lens surface abnormalities resulting from physiologically unstable tears or the characteristics of the lens itself. With automated keratometry becoming more popular, more and more clinicians may have an idle keratometer collecting dust that could be utilized with this technique.

ACKNOWLEDGEMENTS

Dr. Karl Citek, O.D., Ph.D., aided in the assembling of the special keratometer.
REFERENCES


Figure 1 Components of the HIR-CAL grid
Figure 2 Patient's view
Figure 3  Examiner's view
Distribution of TP-RPT in normal eyes

Figure 4  Distribution of tear film pre-rupture phase time (TP-RPT) for normal subjects
<table>
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<td>SE</td>
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<td>Variance</td>
<td>10.78</td>
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<td>SD</td>
<td>3.28</td>
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Distribution of TP-RPT in Dry Eyes

Figure 5 Distribution of tear film pre-rupture phase time (TP-RPT) for all data
Table 2  TP-RPT (in seconds) amongst nine dry eye subjects using the HIR-CAL grid

<table>
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Table 3 t-test for paired observation

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<td>Variance</td>
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<td>t Stat</td>
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<td>Degrees of freedom</td>
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<td>Ha: mean TP-RPT normal eyes not= mean TP-RPT dry eyes</td>
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<td>Therefore reject</td>
<td>Ho (p&lt;0.05)</td>
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<td>Dry eye OD</td>
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Table 4: Comparison of normal and dry-eye means