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Clinical evaluation of the Korb goggle test for quantifying dry eye

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Abstract

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Methods: Participants (1 0 contact lens wearers and 10 non-contact lens wearers) completed a Comprehensive Dry Eye Questionnaire (CDEQ) and the Ocular Surface Disease Index (OSDI). Subjects were also asked to subjectively rank their dry eye symptoms from one to ten. Tear break-up times (TBUT) were measured non-invasively before, during and after goggle-wear using a modified Keratometer. The time it took to report relief of dry eye symptoms while wearing the goggles was recorded.

Results: We used the Pearson Correlation test to compare subjective and objective measurements of dry eye with the amount of time it took to report relief of symptoms with the goggles on. We found a correlation between initial subjective rank of dry eye symptoms and goggle-wear time ($p = 0.028$). However, we found no significant correlation between goggle-wear time and dry eye questionnaire scores nor length of TBUT. A one-way analysis ofvariance (ANOVA) was performed to compare the differences between the contact lens group and non-contact lens group. All comparisons yielded a p-value of greater than 0.05 (not significant).

Conclusions: Moisture chamber goggles are not recommended for the evaluation of dry eye severity in the clinical setting. There was little correlation between goggle wear-time and subjective and objective measures of dry eye. The test is time-consuming and patients will have difficulty assessing when relief of their dry eye symptoms is achieved. It would be more useful for assessing dry eye in a patient that wanted or required a noninvasive procedure.

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Keywords

moisture chamber goggles, dry eye, tear break-up time, questionnaire, modified keratometer

Subject Categories

Optometry

CLINICAL EVALUATION OF THE KORB GOGGLE TEST FOR QUANTIFYING DRY EYE

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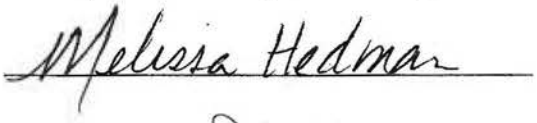
Melissa Hedman 

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Biographies

Andrea Eberle received her History Minor and Bachelor of Science degree in Biology from Gonzaga University in Spokane, Washington in 2002. During the 2000-2001 school year, she attended Gonzaga-in-Florence study abroad program in Florence, Italy where she received her Minor in History. Currently, she is in her fourth year of Optometry school at Pacific University College of Optometry. While in school, she was involved with the Amigos organization, PUCO student VOSH, serving first as the Vice President and then as the President. After graduating from PUCO in May 2007, she hopes to practice primary eye care and vision therapy back home in Anchorage Alaska.

Melissa Hedman received her Associative of Arts Oregon Transfer Degree from Blue Mountain Community College in Pendleton, Oregon in 1998. After graduating from BMCC, she attended Oregon State University where she participated in a study abroad program in Lancaster, England and was enrolled in the Marine Biology Program at Hatfield Marine Science Center. She graduated from Oregon State University in 2001 with a Bachelor of Science Degree in Zoology. Currently, she is in her fourth year of optometry school at Pacific University College of Optometry. Last year she served as the Amigos Historian and Third Year Class Secretary. After graduating from PUCO in May of 2007, she hopes to practice primary eye care in a rural area of the Pacific Northwest.

Robyn Peterson received her Bachelor of Science Degree in Health Science from the University of Wyoming in 2003. Currently, she is in her fourth year of optometry school at Pacific University College of Optometry. For the past three years Robyn has been a Western Interstate Commission for Higher Education (WICHE PSEP) recipient. While in school, she was involved with the Amigos organization and Golden Key International Honour Society. After graduating from PUCO in May of 2007, she hopes to practice primary eye care in Wyoming or South Dakota.

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Key words. moisture chamber goggles · dry eye · tear break-up time · questionnaire · modified keratometer

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Clinical Evaluation of the Korb Goggle Test for Quantifying Dry Eye

Dry eye, also known as keratoconjunctivitis sicca, can occur because of tear film abnormalities, contact lens wear, underlying disease processes such as Sjorgren's syndrome, or environmental factors. The most common symptoms are irritation, foreign body sensation, burning, and transient blurring of vision.[1]

Currently the severity of dry eye is often determined subjectively by a dry eye questionnaire and objectively by using procedures such as tear film break-up time and the Schirmer test.[1] The tear break up time test is performed by instilling sodium fluoroscein dye into the eye. The patient's tear film is then observed under the biomicroscope while the patient avoids blinking. Eventually tiny areas of absence of fluoroscein are observed. The time between the opening of the eye and the absence of noticeable fluoroscein in areas is termed the tear break up time. Generally a tear break up time greater than 10 seconds is considered normal. A low tear break up time is considered dry eye.

The Schirmer test takes a somewhat different approach to assessing the tear film without instilling diagnostic dye into the eye. It involves inserting a tiny paper tab in between the lower eyelid and the globe. It is removed after a few minutes and the dampened area is measured in millimeters; the longer the dampened area, the better the tear production. Both the Schirmer's test and the tear break-up time involve placing something foreign into the eye, whether it is a tab of paper or a dye, which is invasive for the patient. Patient comfort is also a concern.

Clinicians place a large emphasis on case history for diagnosing type and severity of dry eye.[2] Different dry eye questionnaires are available to aid physicians in gathering subjective evidence of dry eye syndrome. These are typically quick to perform and non-invasive, making them very convenient for the busy practitioner. One such questionnaire is the Ocular Surface Disease Index (OSDI), developed by the Outcomes Research Group at Allergan Inc. OSDI scores closely match scores from the McMonnies questionnaire and the NEI VFQ-25 (other questionnaires commonly used to assess dry eye.) With only 12 items to answer, it provides an immediate assessment of ocular irritation.[3]

In 1996, Korb et. al. studied the effect of periocular humidity on the tear film lipid layer by using moisture chamber goggles and objectively measuring the lipid layer. The

purpose of the study was to determine the relationship between the tear film and humidity. Korb examined whether alterations in periocular humidity influenced the thickness of the tear film lipid layer. He observed that moderate to total relief of dry eye symptoms was reported during goggle wear and generally persisted at a reduced level for about one to three hours following goggle removal. This study concluded that by increasing periocular humidity one can increase the tear film lipid layer. It was stated that the goggles may provide an environment that is more conducive to spreading lipid from the meibomian glands and helping to incorporate the lipid into the tear film.[4]

This study examined whether the goggle test is a viable option for determining the severity of dry eye in the clinical setting by comparing goggle results with subjective symptoms. The subjective symptoms of dry eye will be measured by using a comprehensive dry eye questionnaire, the Ocular Surface Disease Index, and a subjective ranking of dry eye symptoms on a scale of 1 to 10. A non-invasive measure of tear break-up time, using a modified Keratometer, was used as the objective measure of dry eye severity.

Subjects and Methods:

Students who responded to a handout asking for volunteers to participate in a dry eye thesis project were given a dry eye questionnaire to fill out. The questionnaire consisted of 50 questions covering symptoms, environmental factors, general health, ocular health, and contact lens wear. See Appendix A. Each dry eye questionnaire was scored by hand. Those individuals who scored over 35 points were asked to participate in an initial evaluation for eligibility in the study. The first ten contact lens wearers and first ten non-contact lens wearers who met the inclusion criteria were enrolled in the study.

Inclusion criteria included male or female subjects of any race, that were at least 12 years old at the time of the pre-treatment examination. All subjects had symptoms of non-pathologic dry eye including naturally occurring dry eye or contact lens-induced dry eye. All subjects were required to be treated bilaterally and exhibit dry eye symptoms bilaterally. They also had to be willing and capable of returning for all scheduled visits for a period of 3 months.

Exclusion criteria included female subjects who were pregnant, breast-feeding or intend to become pregnant over the course of the study. Any subjects with a history of any of the following medical conditions: collagen vascular disease, autoimmune disease, ocular allergies, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to active thyroid disorders and diabetes), lupus, and rheumatoid arthritis were also excluded. Subjects with a history of intraocular surgery (excluding refractive surgery), active ophthalmic disease or abnormality (including, but not limited to: blepharitis, keratoconus or other corneal degeneration or dystrophy, recurrent corneal erosion, neovascularization > 1mm from limbus), clinically significant lens opacity, or clinical evidence of trauma.

Subjects entering the study signed a Statement of Informed Consent approved by the Pacific University Institutional Review Board attesting to an understanding of the study purpose and procedures. All foreseeable risks, compensation for more than minimal risks, and potential benefits were clearly explained. The consent form included a statement describing the extent to which confidentiality will be maintained and contained the name of persons who may be contacted for answers to pertinent questions about the proposed research, subjects' rights or, if needed, research-related injury. Finally, a statement was included that stated study participation was voluntary and that refusal to participate or withdrawal from the study involves no penalty. See Appendix B.

Each subject underwent a baseline examination to determine eligibility to participate in the study. The subject filled out a short 12-item dry eye questionnaire, the Ocular Surface Disease Index (OSDI), before starting the examination. See Appendix C.

The subject had their tear break-up time (TBUT) measured non-invasively using a modified Keratometer. A Keratometer was modified with a grid pattern printed on a transparent surface and placed directly behind the outer glass plate of the compartment containing the biprisms of the Keratometer. The grid pattern was then projected onto the cornea and observed in a magnified fashion with the Keratometer by the operator. The subject was asked to close his or her eyes and then to hold them open for as long as possible without blinking. A stopwatch was used to measure the time between the opening of the eye and the first noticeable break up of the projected pattern on the cornea. Three separate measurements were taken and averaged together to ensure the best possible accuracy.

Using a subjective scale of 1 to 10 (one being no symptoms of dry eye and ten being unbearable dry eye), each subject ranked how their eyes were feeling before putting the goggles on. A pair of Speedo Hydrospex© swimming goggles were fit on the subject to assure maximum comfort and seal. The subject wore the goggles until they noted relief, or until they were unable to notice a change in symptoms, over a 30 minute period. The time period that elapsed between putting the goggles on and relief of symptoms was documented, and the patients once again subjectively scaled their dry eye discomfort on a scale of 1 to 10. Another tear break-up time was measured non-invasively while the subject wore the goggles. The goggles were then removed and a final tear break-up time was measured as quickly as possible using the modified Keratometer. Once again, the subjects were asked to rank their dry eye symptoms from 1 to 10. At this initial visit, we felt it was important to do a slit lamp examination with sodium fluoroscien staining in order to evaluate the health of the cornea, conjunctiva and tear film of our subjects (see above for exclusion criteria.) We chose to do this after goggle wear and TBUT measurements were taken as to not disturb the tear film with staining while collecting our data.

All of our initial subjects, save one, were deemed eligible and returned for two additional visits. The one subject was deemed ineligible for this study due to severe bilateral nasal and temporal pterygia which were found during the biomicroscope evaluation performed during the initial visit to determine eligibility. Another non-contact lens wearer was chosen from the initial dry eye questionnaire and found to be eligible during the initial visit. During each visits, the subjects filled out the OSDI questionnaire upon arrival, had their tear break-up times measured before goggle wear, after they reported relief or plateauing of their symptoms with the goggles on, and immediately after removal of the goggles. They also ranked their dry eye symptoms from 1 to 10 before donning the goggles, after subjective relief of symptoms, and after the final TBUT measurement. The slit lamp examination was not performed on subsequent visits. The subject's participation in this study was terminated upon the completion of all visits.

Results

Subjects scored an overall mean of 47.6 ± 6.9 on the comprehensive dry eye questionnaire filled out prior to starting the study. The scores ranged from 35 to 59.5 out

of a possible 110 points. The three OSDI surveys that each subject completed were averaged together. The overall mean for all subjects participating in the study was 33.2 ± 15.9. Average individual scores ranged from 12.5 to 59.7. Table 1 shows the averages and standard deviations for both dry eye questionnaires, including those of the contact lens wearers and non-contact lens wearers.

Table 1. Mean scores on Dry Eye Questionnaires

	CDEQ	OSDI
Overall Ave.	47.6±6.8	33.2±15.9
CL wearer Ave.	48.5±5.9	32.8±17.8
Non-CL wearer Ave.	46.7±7.9	33.5±14.6

The goggle-wear time was averaged over the three visits for each subject. The overall mean goggle-wear time for all study participants was 15.7 ± 3.5 minutes. The contact lens wearers had a mean goggle-wear time of 14.4 ± 3.6 minutes and the non-contact lens wearers had a mean goggle-wear time of 17.2 ± 2.2 minutes.

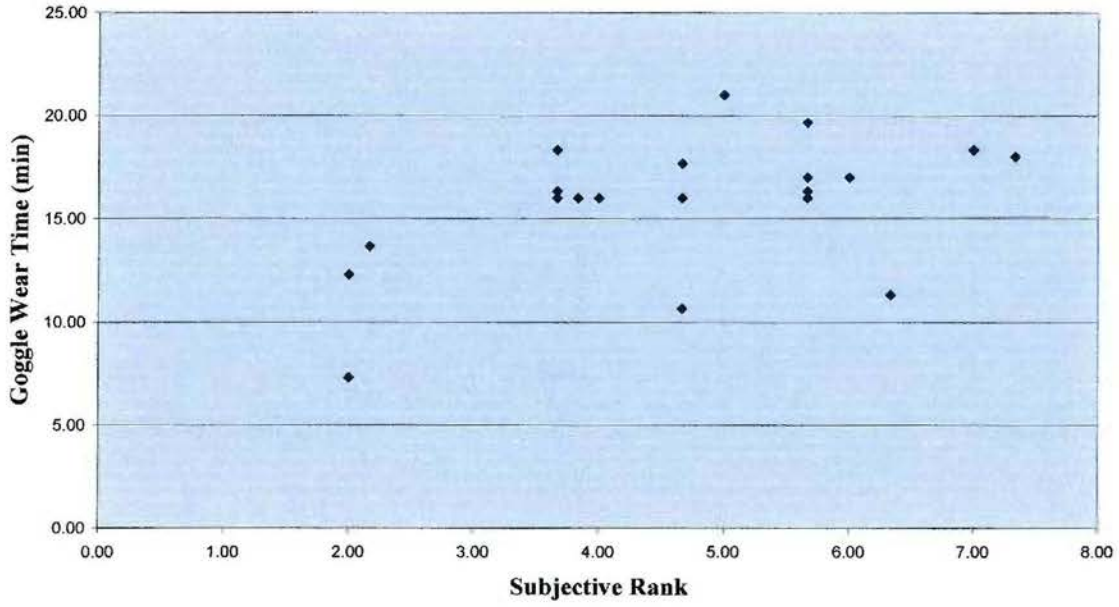
Average subjective ranking of dry eye symptoms (using a scale of 1 to 10) before goggle wear was 4.8 ± 1.5. After relief or plateauing of symptoms with goggle wear, the average ranking was 2.15 ± 0.9. After goggle removal, the average rank was 4.4 ± 1.5. We used the Tukey-Kramer Multiple Comparisons Test to compare subjective scores before, during, and after goggle-wear. There was a significant difference between "before" and "during" goggle-wear ($p < 0.001$). There was also a significant difference between subjective scores "during" and "after" goggle wear ($p<0.001$). However, the difference between "before" and "after" goggle-wear subjective scores was not significant ($p>0.05$).

Mean TBUT before goggle-wear was 7.3 ± 2.0 seconds. After dry eye symptom relief with the goggles on, the average TBUT was 15.2 ± 4.0 seconds. After the goggles were removed, the mean TBUT was 6.8 ± 1.4 seconds. Comparison of the tear break-up times before, during and after goggle wear was also calculated using the Tukey-Kramer Multiple Comparisons Test. Results showed significant differences between the "before" goggle-wear and "during" goggle-wear TBUT ($p<0.001$) and between the "during"

goggle-wear and "after" goggle-wear TBUT ($p<0.001$). There was no statistical significance between "before" and "after" goggle wear TBUT ($p>0.05$).

In order to see if there was any correlation between subjective and objective measurements of dry eye with the amount of time it took to report relief of symptoms with the goggles on, we used the Pearson Correlation Test. We found a significant correlation between initial subjective rank of dry eye symptoms and goggle-wear time ($r=0.490$, $p < 0.05$) with the two groups of subjects combined (contact lens wearers and non-contact lens wearers). See Graph 2.

Graph 2. Correlation Between Goggle Wear Time and Initial Subjective Rank of Dry Eye Symptoms (n=20, r=0.490)



We also compared goggle-wear time with the scores on the comprehensive dry eye questionnaire, the OSDI scores, and initial TBUT. However, none of these other comparisons showed any statistical significance. See Table 3.

Table 3. Correlation Between Goggle Wear Time and Subjective and Objective Measures of Dry Eye. n=20

	R	95% CI	P
Comprehensive Dry Eye Questionnaire	-0.371	-0.70 to 0.09	0.107
OSDI Survey	-0.096	-0.52 to 0.36	0.688
Initial Subjective Rank of Dry Eye*	0.490	0.06 to 0.77	0.028
Initial Tear Break-up Time	0.186	-0.01 to 0.73	0.433

We then decided to analyze the data from the contact lens group and non-contact lens group separately to see if the goggle test was more effective at diagnosing dry eye in one type of patient than the other. We found no evidence that the length of goggle-wear time correlated with any subjective or objective measurements that we took for either group. See Table 4.

Table 4. Comparison of the Correlation Between Goggle-Wear Time and Subjective and Objective Measures of Dry Eye Among Contact Lens Wearers vs. Non-Contact Lens Wearers

	Contact Lens Wearers			Non-Contact Lens Wearers		
	R	95% CI	P	R	95% CI	p
CDEQ	-0.416	-0.82 to 0.29	0.232	0.322	-0.39 to 0.79	0.364
OSDI	-0.462	-0.85 to 0.24	0.179	0.323	-0.38 to 0.79	0.363
Initial Subj. Rank	0.393	-0.31 to 0.82	0.262	0.575	-0.09 to 0.88	0.082
Initial TBUT	0.128	-0.54 to 0.70	0.128	0.233	-0.46 to 0.75	0.516

A one-way analysis of variance (ANOVA) was performed to compare the differences between the contact lens group and non-contact lens group. A p-value greater than 0.5 was found for all comparisons, meaning there were no statistically significant differences between the two groups. See Table 5.

Table 5. ANOVA Comparison of Contact Lens Wearers and Non-Contact Lens Wearers

	Mean Difference	p-Value	95% Confidence Interval
CDEQ CL vs. non-CL	1.750	>0.05	-7.819 to 11.319
OSDI CL vs. non-CL	-0.7470	>0.05	-10.316 to 8.822
Subjective Scale CL vs. non-CL	-0.6660	>0.05	-10.235 to 8.903
Ave. TBUT CL vs. non-CL	-0.3630	>0.05	-9.932 to 9.206
Goggle Wear Time CL vs. non-CL	-2.833	>0.05	-12.402 to 6.736

Discussion:

Our aim in this study was to see how well the "goggle test" correlated with other dry eye tests (objective and subjective) in the diagnosis of dry eye. We compared the length of goggle-wear time with scores of two different dry eye questionnaires; a very comprehensive one compiled by former Pacific University College of Optometry students and the shorter Ocular Surface Disease Index. We also compared the subjects' initial subjective scaled score of dry eye symptoms and initial tear break-up time with goggle-wear time.

Throughout our study we ran across a few challenges which included discrepancies with the initial goggle-wear time, measuring the TBUT through the goggles, and differences in the time periods between the removal of the goggles and the measurement of the final TBUT.

During the initial measurement of goggle-wear time some of the participants noticed a distinctive difference between their initial dry eye symptoms and their relief, but others did not. The participants who noticed definite changes were able to give the most dramatic changes in their subjective responses. The participants who were not able to notice distinctive changes, or those whose symptoms leveled off but were not fully relieved, were able to give less reliable data. In examining the final data collected, the contact lens wearers made up the majority of participants who had shorter goggle-wear time and the most distinctive changes from initial to final relief of symptoms.

Measuring the tear break-up time through the goggles was a separate challenge during our data collection. Some participants had a larger amount of moisture within the goggles which caused them to become foggy and more difficult to obtain accurate measurements. Due to this situation, these recordings were obtained from the clearest location of the goggles which did include the very sides of the goggles, probably causing some distortion and less accurate measurements.

The final difficulty we ran into was the differences in time between the removal of the goggles and the final TBUT measurement. Each subject was instructed to remove the goggles and then as quickly as possible be placed in the keratometer. Some subjects were very quick at this while others were a few minutes slower in their response The differences in this time period may have affected the accuracy of the test.

With all the challenges we had in conducting our thesis, none of the previous mentioned complications proved to be detrimental to the final conclusion of our study.

Conclusion:

The purpose of this study was to determine whether moisture chamber goggles can be used to subjectively quantify dry eye. Our results show that moisture chamber goggles are most effective while on but not clinically practical.. The only significant correlation between subjective and objective measures of dry eye and goggle-wear time was the initial symptom ranking on a scale of one to ten. Neither dry eye questionnaire nor TBUT showed any correlation with the length of goggle-wear time needed for symptom relief.

This is also a very time-consuming test and would be difficult to accurately monitor in a busy clinical setting.

With the two dry eye questionnaires used with this study, our non-contact lens patients scored lower on the CDEQ questionnaire and higher on the OSDI questionnaire than the contact lens patients. The CDEQ was developed by students and was quite a bit longer. It also asked specific questions about contact lens wear and care. This could be the reason that contact lens wearers scored higher than non-contact lens wearers.

Based on our findings, we recommend that moisture chamber goggles be used as a diagnosis method and not as a treatment method. Although subjects experienced improvement of dry eye symptoms while wearing the goggles, upon removal, they immediately felt the return of dry eye sensation. However, moisture chamber goggles as a treatment option should be explored further. In fact, there is currently a product on the market using the idea of moisture chamber goggles to treat dry eye syndrome.[7, 8, 9] Tranquil Eyes use padded goggles with removable pads, which can be immersed in water. These allow an increase of peri-ocular humidity, and thus the subjective (and temporary) relief of dry eye.

Our study did not find moisture chamber goggles to be an effective tool for assessing the severity of dry eye. However, for patients that desire a non-invasive

measurement, it is a tool that can be utilized, in conjunction with a dry eye questionnaire for optimum results.

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Appendix A:

Dry Eye Questionnaire

Name:_____ Age:_____

Occupation:_____ Gender: Male Female

Please answer the following questions by circling the appropriate answer:

1. Have you been previously diagnosed with dry eye?
   Yes (1) No (0)

2. Do you believe you suffer from dry eye?
   Yes (1) No (0)

3. Are your dry eye symptoms worse in one eye?
   Yes (1) No (0)

4. Do you currently use eye drops to relieve any dry eye symptoms?
   Yes (1) No (0)
   If yes, which brand of eye drops do you use?_____
   How many times a day?_____

5. How frequently do your eyes seem dry in a day?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

Symptoms:

1. Do you ever experience scratchiness or grittiness?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

2. Do you ever experience soreness?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

3. Do you ever experience burning?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

4. Do you ever experience red eyes?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

5. Do you ever experience watery eyes?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

6. Do your eyes ever seem blurry, and then clear up after you blink?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

7. When your symptoms arise, do they seem to worsen as the day progresses?
   Yes (1) No (0) Sometimes (.5)

8. Do you have eye irritation as you wake from sleep?
   Yes (1) No (0) Sometimes (0.5)

Environmental Conditions:

1. Are your eyes sensitive to cigarette smoke?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

2. Are your eyes sensitive to dry climates?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

3. Are your eyes sensitive to wind?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

4. Are your eyes sensitive to air pollution?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

5. Are your eyes sensitive to air-conditioning, heating, or defrost in a car?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

6. Are your eyes sensitive to dust?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

7. Are your eyes sensitive to airplane flights?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

8. Do your eyes become irritated after swimming in chlorinated water (pools, hot tubs)?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

9. Do your eyes seem dry and irritated when drinking alcohol?
   A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

10. Do your eyes seem dry and irritated the day after drinking alcohol?
    A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

11. Do your eyes seem to get dry during prolonged computer use?
    A) Never (0) B) Seldom (1) C) Sometimes (2) D) Often (3) E) Always (4)

General Health:

1. Do you suffer from arthritis?
   Yes (1) No (0) Uncertain (0.5)

2. Do you suffer from thyroid abnormalities?
   Yes (1) No (0) Uncertain (0.5)

3. Do you suffer from dryness of the mouth, nose, or vagina?
   Yes (1) No (0) Uncertain (0.5)

4. Do you suffer from recurrent respiratory problems (bronchitis, pneumonia)?
   Yes (1) No (0)

5. Do you suffer from recurrent bladder infections?
   Yes (1) No (0)

6. Do you suffer from any skin abnormalities (seborrhea, rosacea, atopic dermatitis, eczema)?
   Yes (1) No (0) If yes, which one?_____

7. Do you suffer from Parkinson's, Bell's palsy, or Multiple Sclerosis?
   Yes (1) No (0) If yes, which one?_____

8. Do you take any of the following medications? Please circle:
   Birth control pills (1)
   Diuretics (1)
   Anti-hypertensives (1)
   Sleeping tablets (1)
   Ulcer medication (1)
   Digestive medication (1)
   Tranquilizers (1)
   Hormonal supplements (1)

General Eye Health:

1. Do you have any previous history of eye problems (trauma, infections, abnormalities)?
   Yes (1) No (0)
   If yes, please describe the eye problem:_____
   _____

2. Are you known to sleep with your eyes partially open?
   Yes (1) No (0) Sometimes (0.5)

3. Do you have any allergies that affect your eyes?
   Yes (1) No (0)
   If yes, please continue to next question. If no, skip to question 8.

4. Are they seasonal allergies?
   Yes (1) No (0)

5. Are they year-round allergies?
   Yes (1) No (0)

6. Do you take any antihistamines?
   Yes (1) No (0)

7. Do you take any eye drops?
   Yes (1) No (0) If yes, which one?_____

Contact Lenses:

1. Do you currently wear contact lenses?
   Yes (1) No (0)
   If yes, please continue. If no, please stop here.

2. Please indicate the type of lenses you wear:
   Soft Rigid gas permeable

3. Please indicate the replacement schedule of your current lenses:
   Daily disposable (0)
   Weekly (one, two, or three week interval) (1)
   Monthly (one, two or three month interval) (2)
   Yearly (3)

4. Do you ever sleep in your contact lenses overnight?
   Yes (1) No (0)

5. Do you clean your contact lenses as indicated by packaging directions?
   Yes (1) No (0)

6. Do you clean your contact lenses every night?
   Yes (1) No (0)

7. What solution(s) do you use? Please circle all that apply:
   Aquify Boston Advance Complete Ultracare
   Optifree Boston Original Renu Clear Care
   B&L Moisture Loc

8. Do you thoroughly rinse your lenses before insertion?
   Yes (1) No (0)

9. Do your eyes burn or feel dry after removing your lenses?
   Yes (1) No (0)

10. Do you experience dry eye sensations when wearing contact lenses?
    Yes (1) No (0)
    If yes, please answer the next question.

11. How long after inserting your lenses do your eyes become dry?_____

Appendix B:

Ocular Surface Disease Index© (OSDI©)[2]

Ask your patient the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

HAVE YOU EXPERIENCED ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 ☐

HAVE PROBLEMS WITH YOUR EYES LIMITED YOU IN PERFORMING ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 ☐

HAVE YOUR EYES FELT UNCOMFORTABLE IN ANY OF THE FOLLOWING SITUATIONS *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 ☐

ADD SUBTOTALS A, B, AND C TO OBTAIN D (D = SUM OF SCORES FOR ALL QUESTIONS ANSWERED) ☐

TOTAL NUMBER OF QUESTIONS ANSWERED (DO NOT INCLUDE QUESTIONS ANSWERED N/A) ☐

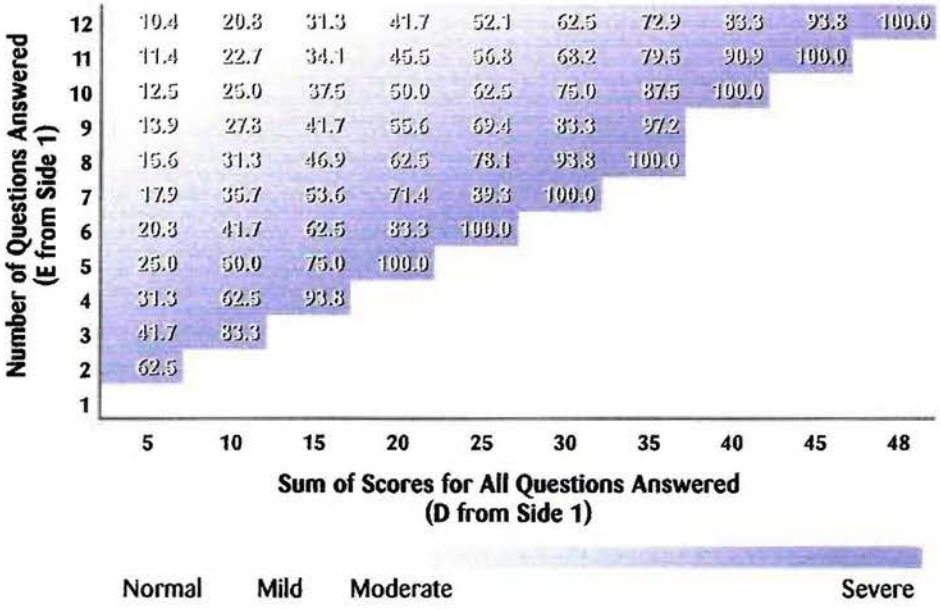
Please turn over the questionnaire to calculate the patient's final OSDI© score.

Evaluating the OSDI© Score[1]

The OSDI© is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI© is a valid and reliable instrument for measuring dry eye disease severity (normal, mild to moderate, and severe) and effect on vision-related function.

Assessing Your Patient's Dry Eye Disease[1,2]

Use your answers D and E from Side 1 to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below.*
Find where your patient's score would fall. Match the corresponding shade of red to the key below to determine whether your patient's score indicates normal, mild, moderate, or severe dry eye disease.



*Values to determine dry eye disease severity calculated using the OSDI© formula:

$$\text{OSDI}^{©} = \frac{(\text{sum of scores}) \times 25}{(\text{\# of questions answered})}$$

Patient's Name: _____ **Date:** _____

How long has the patient experienced dry eye? _____

Eye Care Professional's Comments: _____

_____

_____

_____

_____

_____

Tear and place in patient's chart for follow-up care on next visit.

Reference: 1. Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. *Arch Ophthalmol.* 2000;118:615-621. **2.** Data on file, Allergan, Inc.

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Appendix C:

Pacific University
Informed Consent To Act As A Research Participant

Clinical Evaluation of the Korb Goggle Test for Quantifying Dry Eye

Investigators and Contact Information:

Patrick Caroline 503-680-7389 Pacific University College of Optometry

Dr. Peter Bergenske at 503-352-2278 Pacific University College of Optometry

Andrea Eberle at 503-992-0434 Pacific University College of Optometry

Melissa Hedman at 503-866-6857 Pacific University College of Optometry

Robyn Peterson at 503-504-3976 Pacific University College of Optometry

Project Location: Pacific University College of Optometry, Forest Grove, OR

Dates of Project: January 2006 to May 2006

1. Introduction & Background Information:

You are invited to be in a research study being conducted by the Pacific University College of Optometry. Please read this form carefully and ask any questions you may have before agreeing to be in this study.

It has been reported that swimming goggles provide relief from dry eye symptoms by increasing the humidity upon the eye. This study will examine whether the goggle test is a viable option for determining the severity of dry eye in the clinical setting. We will be measuring subjective symptoms using a comprehensive dry eye questionnaire.

2. Procedure:

If you agree to participate in this study, you will be asked to undergo the following; you will be examined by one of the investigators to determine your eligibility to participate in this study. During this process you will sit for a slit lamp examination and fill out a comprehensive dry eye questionnaire. If you are deemed eligible, you will need to return for a minimum of two visits. During these visits your tear break up time will be measured non-invasively prior to being fit with the goggles. Tear break up time using a modified keratometer will be our objective measure of dry eye severity. Next you will be asked to wear a pair of

goggles until you experience relief of your dry eye symptoms or for a maximum of 45 minutes. Tear break up time will be assessed again after goggle wear. Upon the completion of the visit you will be provided a card to document the time at which your dry eye symptoms return.

3. Risks & Benefits:

There are possible risks associated to participating in this study. There is a possibility for an allergic reaction to the goggle material that comes in contact with the skin. Great care was taken in choosing the most hypoallergenic goggles available on the market today but the risk still exists. If you notice any redness, itch, pain or discomfort in or around the eye during or after the study please notify us. The goggles are only to be worn during the scheduled office visits and then only for the purpose of evaluation. No harmful effects are expected from any of the examination procedures used in the study. There are no direct physical benefits to you for your participation in this study. You will not be receiving complete eye, vision, or health care as a result of participation in this project; therefore, you will need to maintain your regular program of eye, vision, and health care.

4. Alternatives Advantageous to Subjects:

The goggles are not intended to correct your vision or your dry eye symptoms. Currently available alternatives to the goggles are artificial tears or punctal plugs. Your eye care professional can discuss these alternatives.

5. Participant Payment:

You will not receive payment or compensation for your participation.

6. Promise of Privacy:

The records of this study will be maintained in a confidential manner (locked in a file cabinet) and identifiable names or information will not be released or used in publication or presentation.

7. Voluntary Nature of the Study:

Your participation in this study is completely voluntary. You are free to withdraw your consent and to discontinue your participation in this study at any time and your decision to not participate will not affect your current or future relations with Pacific University. If you miss a study visit or move out of the area, you may be discontinued from the study.

8. Compensation and Medical Care:

During your participation in this study you are not a Pacific University clinic patient or client nor will you be receiving comprehensive ocular health care as a result of your participation in this study. If you are injured during your participation in this study and it is not the fault of Pacific University, the experimenters, or any organization associated with the study, you should not expect to receive compensation or medical care from Pacific University, the investigators or, any organization associated with the study.

9. Conflict of Interest Disclosure:

Not applicable

10. Contacts and Questions:

The study investigators will be happy to answer any questions you may have at any time throughout the course of this study. During your participation in the project you are not a Pacific University clinic patient or client therefore, all questions should be directed to the study investigators, Patrick J. Caroline 503-680-7389 or Dr. Peter Bergenske at 503-352-2278. If you are not satisfied with the answers you receive, please call Dr. Krista Brockwood, Chair of the Pacific University Institutional Review Board (503-352-2616) to discuss your questions or concerns further. Although Dr. Brockwood will ask your name, all complaints will be kept in confidence.

11. Statement of Consent:

I have read and understand the above. All my questions have been answered. I am either 18 years of age or over, or my parent / guardian has given consent for my participation. I have been given a copy of this form to keep for my records.

_____

Participant's Signature Date

_____

Parent / Guardian's Signature Date
(ONLY if minors are involved)

_____

Participant's Address / City / State / Zip Code

_____

Participant's Phone Number and E-mail Address

_____

Investigator's Signature Date