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Kathy G. Mulier  
*Pacific University*

Kathy A. Milano  
*Pacific University*

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# Comparing the effects of artificial tears at room temperature and body temperature

## Abstract

This experiment was designed to determine the responses of 50 subjects to the instillation of room and body temperature artificial tears. All subjects were asked to comment on their subjective experience after instillation of Tears Naturale II ® at both temperatures. We hypothesized that subjects in general would prefer body temperature over room temperature. The subject group was divided into four sub-categories as follows: 1) eye condition (dry eye versus non-dry eye), 2) gender, 3) oral contraceptive use and 4) contact lens wearers versus non-contact lens wearers. Statistical significance was achieved only for the sub-category contact lens wearers versus non-wearers. These results suggest that increasing the temperature of Tears Naturale II ® for contact lens wearers versus non-wearers increases the comfort level, however for the general subject group there was no statistically significant preference. 2

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## Degree Name

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## Committee Chair

Lee Ann Remington

## Keywords

artificial tears, dry eye syndrome, contact lenses, tears naturale II

## Subject Categories

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COMPARING THE EFFECTS OF ARTIFICIAL TEARS  
AT ROOM TEMPERATURE AND BODY TEMPERATURE

BY

KATHY G. MULIER AND KATHY A. MILANO

A thesis submitted to the faculty of the  
College of Optometry  
Pacific University  
Forest Grove, Oregon  
for the degree of  
Doctor of Optometry  
May, 1995

Advisor: Lee Ann Remington, O.D., M.S.

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Authors: Kathy G. Mulier

Kathy G. Mulier B.S.

Kathy A. Milano

Kathy A. Milano M.A.

Advisor: Lee Ann Remington, O.D., M.S.

Lee Ann Remington O.D. M.S.

## **ABSTRACT**

This experiment was designed to determine the responses of 50 subjects to the instillation of room and body temperature artificial tears. All subjects were asked to comment on their subjective experience after instillation of Tears Naturale II<sup>®</sup> at both temperatures. We hypothesized that subjects in general would prefer body temperature over room temperature. The subject group was divided into four sub-categories as follows: 1) eye condition (dry eye versus non-dry eye), 2) gender, 3) oral contraceptive use and 4) contact lens wearers versus non-contact lens wearers. Statistical significance was achieved only for the sub-category contact lens wearers versus non-wearers. These results suggest that increasing the temperature of Tears Naturale II<sup>®</sup> for contact lens wearers versus non-wearers increases the comfort level, however for the general subject group there was no statistically significant preference.

**Key Words:** Artificial Tears, Dry Eye Syndrome, Contact Lenses, Tears Naturale II ®.

## INTRODUCTION

Artificial tear preparations are used frequently to aid in relieving dry eye symptoms. Pharmaceutical companies produce a variety of these products containing active chemical ingredients (e.g.; saline, methyl cellulose). These solutions vary in pH, preservatives and wetting agents. <sup>1</sup>

The artificial tear preparation used for this study was Tears Naturale II ®, (Alcon Laboratories, Inc.) which contains the active ingredients Duasorb with Dextran 70, (0.1%) and Hydroxypropyl Methylcellulose 2910, (0.3%). This solution also contains the preservative Polyquaternium, (0.001%). <sup>2</sup>

Patients with dry eye symptoms (e.g., burning, soreness, dryness, foreign body sensation, grittiness) are seen frequently in the optometric practice. Dry Eye Syndrome is an extremely common condition among the general public, <sup>3</sup> and may be described as a decrease in production or flow of the aqueous, lipid or mucin layers of the tear film caused by epithelial abnormalities, blink mechanism abnormalities, or lid abnormalities. These abnormalities are associated with many ocular and systemic diseases as well as contact lens wear. <sup>4</sup>

This study was designed to assess the relative comfort or discomfort of the instillation of Tears Naturale II ® at room and body temperature. We hypothesized that body temperature

artificial tears would provide a more comfortable experience for the subjects, possibly increasing the rate of compliance.

We considered factors that may influence our hypothesis by dividing the subjects into the following categories:1) eye condition, (dry versus non-dry), 2) gender, 3) oral contraceptives, 4) contact lens wearers versus non-wearers.

## **METHODS**

The subjects of this research were members of the entering optometry class at Pacific University. Fifty subjects participated and completed the experiment. There were 23 male and 27 female subjects ranging in age from 21 to 41 years. Contact lens wearers, (n=25), as well as spectacle wearers were included in this study.

Each subject served as her/his own control, therefore differences in temperature and pain sensation of the cornea in the two situations were minimized.

Subjects were expected to attend one appointment of approximately thirty minutes in order to complete paperwork, undergo the experiment and respond to a subjective questionnaire.

The research was conducted in two clinic rooms located adjacent to one another at Pacific University Family Vision Center, Forest Grove, Oregon. The room temperature could not be controlled by a thermostat, though both rooms were monitored with Taylor thermometers. The average temperature in the rooms was 76 degrees Fahrenheit with a standard deviation of 2.57.



The artificial tear solution, 0.1 fluid ounce bottles of Tears Naturale II<sup>®</sup>, were acclimated to this room temperature for a period of not less than three hours before instillation.

The body temperature Tears Naturale II<sup>®</sup> containers were placed in the researchers' pockets for a period of not less than three hours prior to subject instillation. The same brand of thermometer was placed in the pocket next to the Tears Naturale II<sup>®</sup> to monitor body temperature. The average temperature was 89 degrees Fahrenheit with a standard deviation of 3.80. Attempts were made by the researchers to wear similar materials and types of clothing.

The subjects completed a medical questionnaire form, (Appendix A) concerning allergies, history of artificial tear use, medications taken, medical conditions and contact lens wear. They were also asked to rate the frequency and severity of dry eye symptoms in four categories (i.e., burning, soreness, dryness, grittiness) as follows; Frequency: 0= none, 1= once a month, 2= once a week, 3= not every day, 4= a few hours a day, 5= all day long, constant. Severity: 0= none, 1= just noticeable, tolerable, 2= mild, 3= moderate, 4= severe, intolerable.

Subjects who were currently wearing contact lenses were required to remove them prior to the experiment to insure an accurate examination and to avoid permanent fluorescein staining of the soft contact lenses.

A slit lamp exam was performed to determine the baseline health and integrity of the lids, lashes, conjunctiva, cornea and tear film. The results were recorded on the exam recording form (Appendix B).

Fluorescein dye was introduced to both eyes with a single application strip and a Tear Break Up Time (TBUT) test was completed. An average of the two TBUT's for both eyes was recorded. Corneal staining was graded on a scale from 0 to 4 (Appendix B). Zero was equal to no staining, 1= mild, 2= moderate, 3= patches of staining, 4= coalesced patches, (See appendix C for a color illustration).<sup>5</sup>

The subject population was divided into subcategories based on the following criteria:

- 1) dry versus non-dry eye condition (dry eye condition determined by an average TBUT from both eyes of 7.5 seconds or less, or an average corneal staining grade from both eyes of greater than one)
- 2) gender
- 3) oral contraceptive use
- 4) contact lens wearers and non-wearers

The assignment of right/left eye and room/body temperature solution was randomly selected by the researchers. The subjects were asked to consider what they experienced upon instillation of a single drop of Tears Naturale II<sup>®</sup> (room temperature for example) in one eye. After the instillation of the first drop the subject was required to complete the first part of the subjective questionnaire assessing the sensations experienced (Appendix D).

The second instillation (body temperature for example) was followed by the subject completing the questionnaire in the same

manner. The final response elicited required the subject to choose which preparation he/she preferred, (right or left eye).

We utilized StatView 512 +11 on the Macintosh computer. Our study was a cross-sectional, single blind, within subjects model; therefore the Chi-Square test was appropriate.

Limitations and confounding variables of this research are listed as follows:

1) Control of room and body temperature as a dynamic process

We believe that body temperature, though it varies individually and changes over time, could best be represented in a "real life" situation, such as that replicated in our experimental condition, (i.e., solution placed in the researchers' pocket).

An alternate method was considered whereby the artificial tear preparation would be heated to body temperature artificially with the use of a Bunsen burner and a constantly controlled water bath temperature. This method would have been more clinically controlled, but we rejected it because it would be less of a "real life" condition. If our hypothesis rests on the assumption that the average person could increase comfort level and therapeutic usage of an artificial tear preparation by warming it to body temperature, then we assume that most people would place the solution in a place next to the body to warm it. However, we understand that our body temperatures could vary from that of the subjects.

2) The use of one Artificial Tear Product

Results may vary when different types of artificial tear products are compared.

### 3) The subjective questionnaire

We required only a subjective response from the subjects. Reliance on a subjective response gives results based on individual variation.

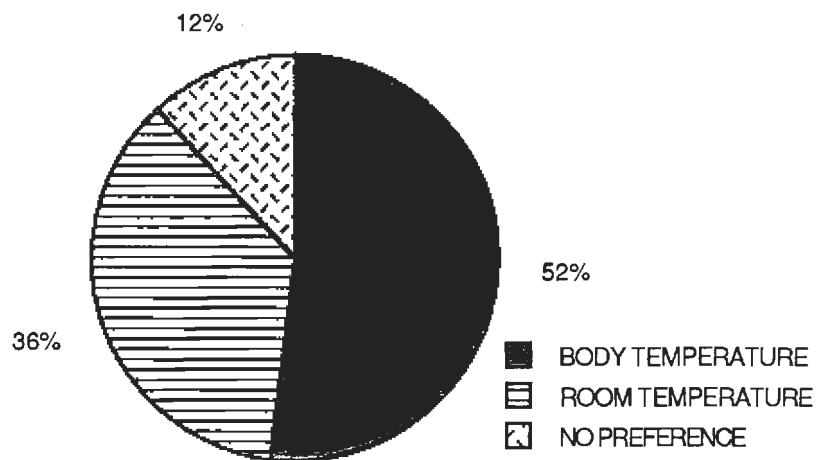
### 4) Forced choice

The subjects were asked to choose which preparation they preferred, and were not given the option on the form to prefer neither.

## RESULTS

Upon completion of subject experimentation, data from the subjective questionnaire was analyzed objectively with the use of the Chi-Square Test. A Chi-Square Test of all subjects resulted in values of 57.333, 49 degrees of freedom, with a probability of .1936 (Figure 1). Statistical significance was not achieved.

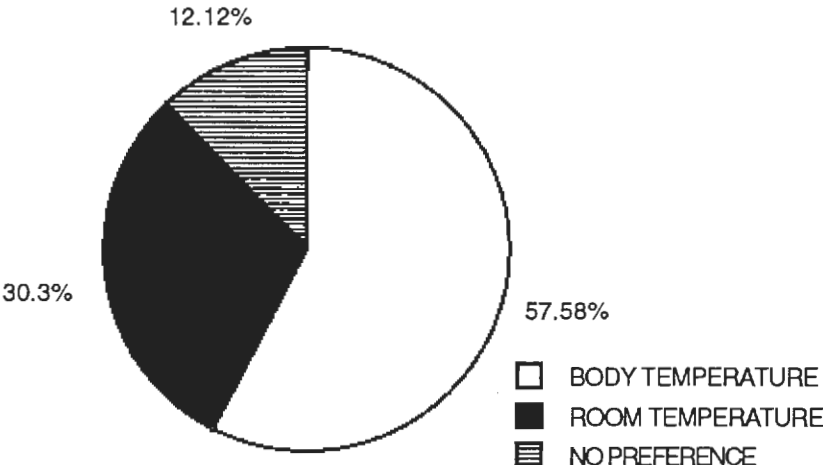
**FIGURE 1: PREFERENCE OF ALL SUBJECTS (n=50)**



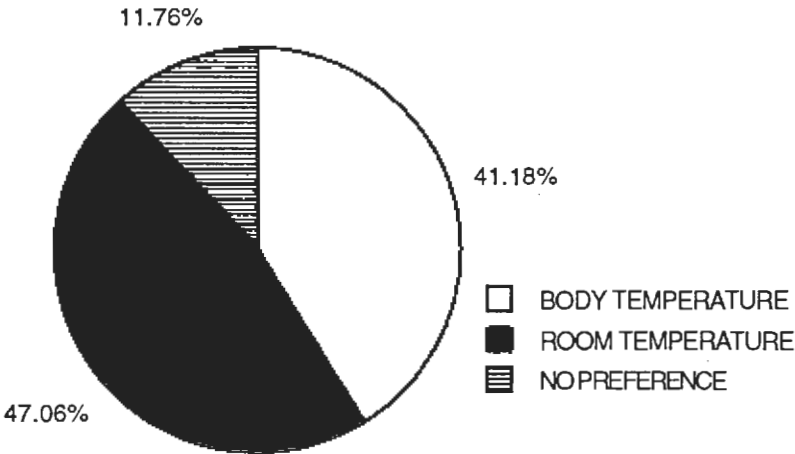
Subjects were asked to make a preferred choice between body and room temperature solutions. Six subjects indicated on the subjective questionnaire that they preferred neither body or room temperature Tears Naturale II<sup>®</sup>, hence the category of "no preference" referred to in figures 1 through 5.

Statistical results from the other factors considered are as follows: 1) eye condition (dry eye vs. non-dry eye),  $p=.4828$ , (Figure 2a and 2b), 2) gender,  $p= .4184$ , (Figure 3a and 3b), 3) oral contraceptive use,  $p= .2556$ , (Figure 4a and 4b). Statistical significance was not achieved for any of these variables, however, the variable of contact lens wear did reach statistical significance,  $p= .0091$ , (Figure 5a and 5b).

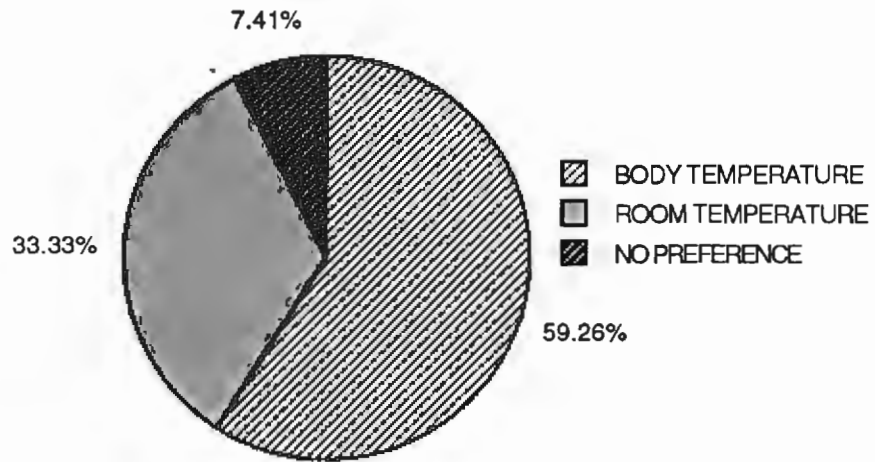
**FIGURE 2a: PREFERENCE OF DRY EYE SUBJECTS (n=33)**



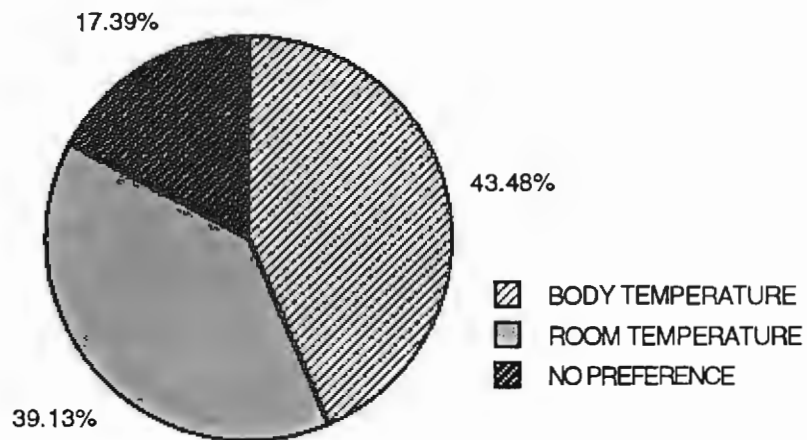
**FIGURE 2b: PREFERENCE OF NON DRY EYE SUBJECTS (n=17)**



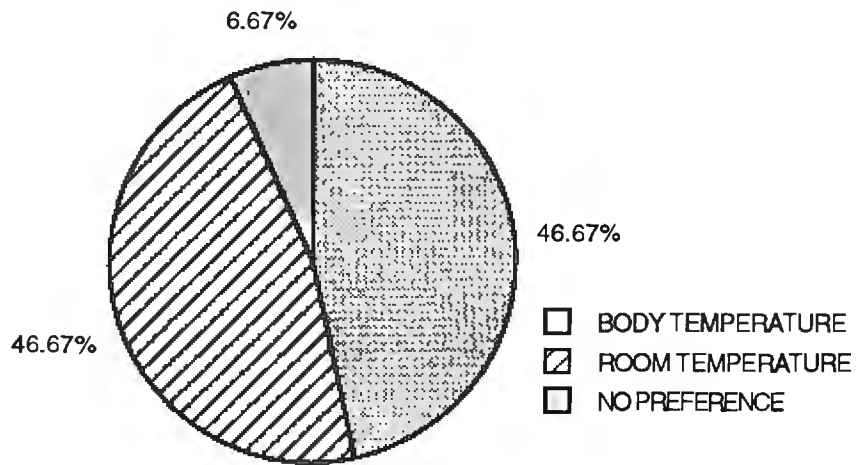
**FIGURE 3a: PREFERENCE OF FEMALE SUBJECTS (n=27)**



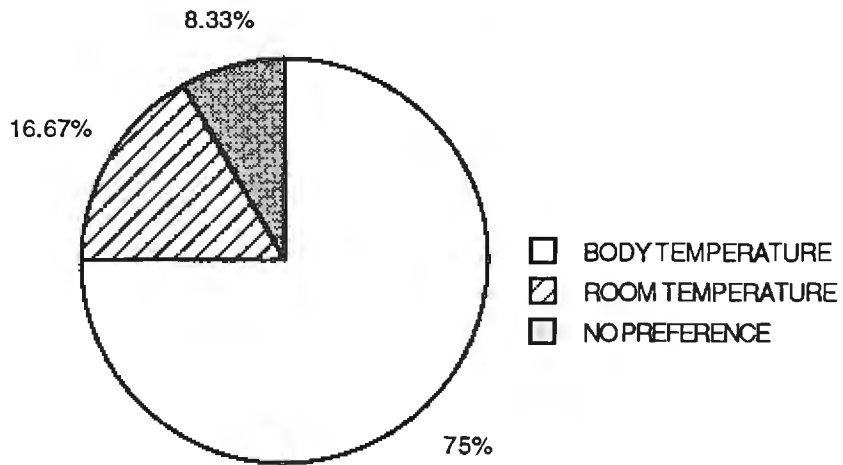
**FIGURE 3b: PREFERENCE OF MALE SUBJECTS (n=23)**



**FIGURE 4a: PREFERENCE OF FEMALE SUBJECTS WHO USE ORAL CONTRACEPTIVES (n=15)**

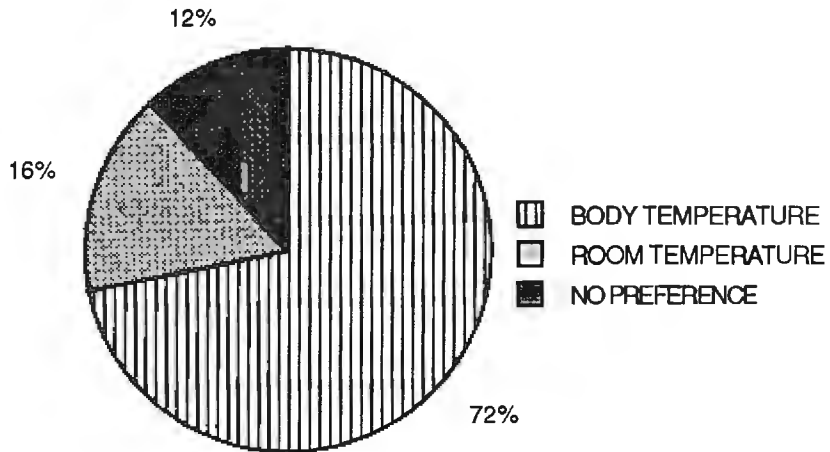


**FIGURE 4b: PREFERENCE OF FEMALE SUBJECTS WHO DO NOT USE ORAL CONTRACEPTIVES (n=12)**

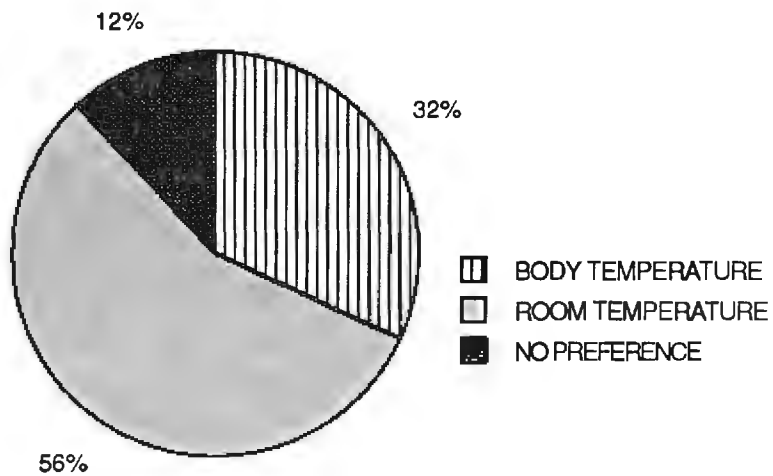




**FIGURE 5a: PREFERENCE OF CONTACT LENS SUBJECTS (n=25)**



**FIGURE 5b: PREFERENCE OF NON-CONTACT LENS WEARERS (n=25)**



## DISCUSSION

The original purpose of this study was to determine whether or not subjects preferred body temperature over room temperature artificial tears, and we hypothesized that body temperature would be preferred. It is clear from the results that statistical

significance was not achieved in that regard. However, in order to answer the question of a subjective preference, various sub-categories were considered with the emphasis on identifying a variable or variables that might lead us to a characteristic that demonstrated scientific as well as clinical significance. Contact lens wear appears to be that variable, while others such as a dry eye condition, gender, and oral contraceptive use did not reveal a relationship to the comfort factor.

Subjects who were contact lens wearers preferred body temperature Tears Naturale II ®. We might have postulated that there was a connection between contact lens wear and a concomitant dry eye condition, but that was not the case; therefore it is not clearly understood for what reason(s) the contact lens wearers preferred the body temperature solution. This result could be investigated further.

The use of a larger population of subjects, (n= 100 for example), might affect the overall result.

We accept our hypothesis as valid in regard to the sub-category of contact lens wear, however we reject the hypothesis in regard to the general population of subjects used in this study.

# APPENDIX A: MEDICAL QUESTIONNAIRE FORM

NAME \_\_\_\_\_ AGE \_\_\_ SEX \_\_\_ DATE  
ADDRESS \_\_\_\_\_

PHONE \_\_\_\_\_

Are you allergic to fluorescein dye?    yes            no

Are you allergic to any artificial tear solutions or contact lens solutions? (If yes please describe which type or name of the solution.) \_\_\_\_\_

Do you currently use artificial tears regularly? yes    no

Occasionally? yes            no

Are your eyes sensitive to any of the following conditions:  
(circle the ones that apply.)

Cigarette smoke/fumes/smog  
Hot air vents

Central Air Conditioner  
Bright lights

Are you currently taking any of the following medications:  
(circle ones that apply.)

Antihistamines (cold med.)  
Oral contraceptives  
Sleeping Tablets

Medication for high blood pressure  
Medication for digestive problems  
Eye Drops ( list type) \_\_\_\_\_

Diuretics (water pills)

Other \_\_\_\_\_

Notes:

Please rate the following dry eye symptoms for each eye according to the scale provided.

**Frequency:** 0=none, 1=once a month, 2=once a week, 3=not every day, 4=a few hours per day, 5=all day long, constant.

**Severity:** 0=none, 1=just noticeable, tolerable, 2=mild, 3=moderate, 4=severe, intolerable.

Frequency                      Severity

**Burning:**                      right eye\_\_left eye\_\_    right eye\_\_left eye\_\_

**Soreness:**                      right eye\_\_left eye\_\_    right eye\_\_left eye\_\_

**Dryness:**                      right eye\_\_left eye\_\_    right eye\_\_left eye\_\_

**Grittiness:**    right eye\_\_left eye\_\_    right eye\_\_left eye\_\_

Have you had or currently have any of the following: (circle the ones that apply.)

- |                     |                 |                      |
|---------------------|-----------------|----------------------|
| Allergies           | Cough (chronic) | Eye Infection/Trauma |
| Arthritis           | Hay Fever       | Ear Trouble          |
| Asthma              | Post Nasal Drip | Diabetes             |
| Frequent Headache   | Glaucoma        | Heart Problems       |
| Occasional Headache | Bronchitis      | Eye Secretions       |
| Contact Lenses      | Nasal Problems  | Thyroid Problems     |
| Dry eyes            | Skin Conditions |                      |

Other \_\_\_\_\_  
Notes:

## APPENDIX B: RECORDING FORM

Name \_\_\_\_\_

**Slit lamp evaluation** before fluorescein (15 mag, 3mm wide paralleliped, low illumination.) Check structures viewed, report if abnormalities.

OD

OS

cornea \_\_\_\_\_ | \_\_\_\_\_

conjunctiva \_\_\_\_\_ | \_\_\_\_\_

lids \_\_\_\_\_ | \_\_\_\_\_

trichiasis \_\_\_\_\_ | \_\_\_\_\_

puncta \_\_\_\_\_ | \_\_\_\_\_

other \_\_\_\_\_ | \_\_\_\_\_

**TBUT**

OD \_\_\_\_\_, \_\_\_\_\_,

OS \_\_\_\_\_, \_\_\_\_\_,

**Degree of Corneal Staining**(0=clear, 1=mild, 2=moderate, 3=large patches of coalesced staining, 4=severe, corneal epithelial erosions)

OD \_\_\_\_\_

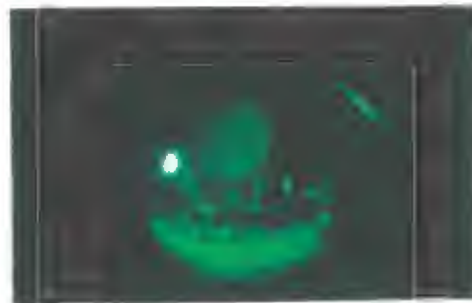
OS \_\_\_\_\_

# APPENDIX C: CORNEAL STAINING ILLUSTRATIONS

Grade 1 Mild Staining



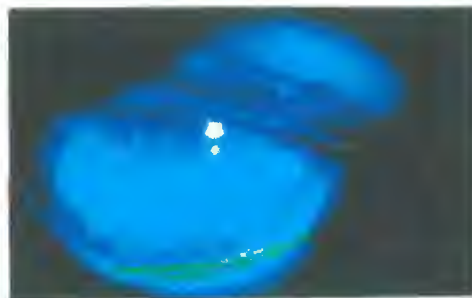
Grade 2 Moderate Staining



Grade 3 Large Patches of Coalesced Staining



Grade 4 Severe Corneal Epithelial Erosions



## APPENDIX D: SUBJECTIVE QUESTIONNAIRE

NAME \_\_\_\_\_

1. Which of the following did you experience when the drop was placed in your eye? Please check all those that apply.

|                 |                     |                          |
|-----------------|---------------------|--------------------------|
| no sensation___ | burning/stinging___ | [BT/RT OD/OS] itching___ |
| gritty___       | warm___             | cold___                  |
| comfortable___  | uncomfortable___    | soothing___              |
| blurry___       | other_____          |                          |

**stop here for now**\_\_\_\_\_

2. Which of the following did you experience when the drop was placed in your eye? Please check all those that apply.

|                 |                     |                          |
|-----------------|---------------------|--------------------------|
| no sensation___ | burning/stinging___ | [BT/RT OD/OS] itching___ |
| gritty___       | warm___             | cold___                  |
| comfortable___  | uncomfortable___    | soothing___              |
| blurry___       | other_____          |                          |

3. Which preparation did you prefer?

left eye\_\_\_\_\_ right eye\_\_\_\_\_

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