Is the Biocompatibles Proclear Lens Made of a Material That Can Truly Benefit the Dry Eye Patient?

BY: ROBYN L. FLOWERS

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Abstract:

This study compared the Biocompatibles Proclear lens with the Ciba Focus lens, in their ability to allow a dry eye patient to wear soft contact lenses comfortably. This was a double blind pilot study with seven subjects wearing each lens for one week and then wearing the lens in opposite eyes for week two. Each patient completed a McMonnies questionnaire and objectively qualified as a dry eye patient through assessment of tear thinning time with a keratometric reading as well as using the Eyemap. Tear break up time, and slitlamp evaluation was also performed. Tear thinning time with a keratometer concentrated on the central cornea, and TTT with the Topcon Eyemap revealed an overall corneal evaluation. Neither lens was identified objectively as a better lens for the dry eye patient. Subjective data obtained through a daily questionaire indicated 40% preferred proclear lens, 26% preferred the Focus lens and 33% had no preference.

INTRODUCTION:

A common encounter to all contact lens fitters is the patient who wishes to wear contact lenses and suffers from dry eye. "Ten to twenty percent of the optometric population suffers from marginal dry eye." (Jurkus) Dry eye patients may have a variety of tear film abnormalities that affect their outcome of successfully wearing contact lenses. The five dry eye mechanisms are lipid, aqueous, mucin, base and surface abnormalities . (Farris) Regardless of the type of abnormality, these patients face a problem that cannot be ignored. The universally accepted method is to prescribe a thicker, lower water content soft contact lens or using Rigid Gas Permeable lenses.(Jurkus) In Bennett's Contact Lens Problem Solving, he states that a high water content lens further dehydrates an already dry eye. And a thick lens provides more mass, thus increasing lens movement and minimizing adherence. These options can prove satisfactory to some, but proves all too often dissatisfactory. Our goal is to enhance comfort and compatibility of soft contact lenses for the dry eye patient.

Dry eye in combination with contact lenses is described as a "vicious circle." The tears which are typically responsible for washing debris and protein out of the eye are not functioning properly in the dry eye patient. This debris and protein is then found in more abundance and more likely to coat a contact lens. The contact lens placed on the dry eye has been noted to cause water to be drawn from the eye through evaporation. "Dehydration of the lens front surface by evaporation could create a hydration gradient between the two lens surfaces, thus facilitating the movement of water from deeper in the lens." (Bruce) The elimination of tear volume through these mechanisms results in an even greater increased concentration of tears, and thus an even greater means for build-up of debris and protein on the contact lenses. Bennett and Gordon proposed a non-HEMA, glycerol methacrylate lens material since it may be less prone to surface deposition than other lenses. (Jurkus)

The purpose of this study is to attempt to relieve symptoms of a dry eye patient by wearing a soft contact lens designed to resist build-up of debris and protein. The Biocompatibles PROCLEAR lens makes this claim. It is approved by the FDA not to require the enzymatic step of cleaning while on a 6 month replacement schedule. The lens is made of omafilcon A and phosphorylcholine. Phosphorylcholine is also referred to as PC. PC "is an anologue of a natural phospholipid called phosphatidylcholine" (Bowers)

which is present in all mammalian cell membranes. This includes red blood cells which are responsible for human biocompatibility.. "Natural PC" plays a role in repelling protein and lipid molecules in cell mebranes. It is considered an electrically neutral zwitterion.(Stryer) A zwitterion, by definition, is an amino acid in a predominantly dipolar state in neutral pH solution. "Dipolar ions typically resist both protein and lipid molecules." (Sodja) Phosphorylcholine, PC, commonly found in catheters, and prosthetic vessels utilized in bypass surgery and other various divisions of the medical field today. Since, "The presence of deposits on soft lenses can alter the lens dimensions, fitting relationships, and lens dehydration." (Jurkus) properties of the PROCLEAR lens may be significant enough to relieve the dry eye patient of symptoms. The following study compares the performance of the Biocompatibles PROCLEAR lens with the Ciba FOCUS lens on the dry eye patient.

Parameters (Tyler's):

LENS	BASE CURVE	O.A.D.	O.Z.D.	c.t.	dK
Proclear	8.2/8.5/8.8	14.2	9.0	.07	33.0
Focus	8.6/8.9	14.0	7.8	.10	16.0

*Note: 7.8 O.Z.D of the Ciba Focus lens was not stated in Tyler's Quarterly, and provided by the Ciba Corp. Consultation department.

In the following, a clear understanding of procedures, analysis and a discussion of this research project are presented. There are three essential parts to this study. A comparison is made between lens performance when worn by dry eye patients objectively and subjectively. And an innovative way to measure NITTT by a corneal topographer, the Alcon EyeMap, was compared to the globally accepted keratometric method. The information has been outlined by inclusion criteria, methods, results and discussion.

INCLUSION CRITERIA:

Twelve eyes from caucasian subjects were assessed. Subject's ages ranged from 24 to 48. Diagnosis of dry eye was determined by following the global criteria (Lemp):

1) Validated questionnaire of symptoms 2) Demonstration of ocular surface damage

3) Demonstration of tear instability 4) Demonstration of tear hyperosmolarity

1) Validated questionnaire of symptoms:

Each candidate initially answered a McMonnies questionnaire. An example of this questionnaire is represented in APPENDIX A. "Because a therapeutic goal of dry eye is to improve symptoms, which include heaviness of the lids, foreign body sensation, burning, stinging and photophobia," (Lemp) this subjective questioning is important to the inclusive criteria. The McMonnies questionnaire is a currently accepted method of identifying dry eye patients effectively. "Each subject scored less than or equal to 14 constituting dry eye." (Little)

Each patient was interviewed with respect to compliance. Discrimination criteria screened subjects according to availability, past history with common cleaning systems and ability to follow detailed instructions.

2) Ocular surface damage:

Complete slit lamp evaluations including lids, lashes, conjunctiva, cornea, lens and anterior chamber were performed to rule out pathology . " It is recommended that surface damage be assessed by staining with vital dyes." (Lemp) Each subject demonstrated mild to moderate epithelial defects with fluorescein. Fluorescein tabs were utilized in the form of an impregnated tab and non-preserved saline which was to ensure the least invasive to the patient.

3) Demonstration of tear instability:

Non-invasive tear thinning time by method of keratometry was taken. Each patient's tear thinning time (TTT) measured a time of 10 seconds or less from completion of last blink to first distortion. "Values of less than 10 seconds are considered abnormal." (Lemp) According to Faber, normal eyes have a mean TTT of 33.5 sec +/-- 10.6. Non-invasive TTT methods utilizing a keratometer have been described as having 82 % sensitivity, 86% specificity for dry eye syndrome (Madden) and evaluates a central 3mm

diameter of the corneal surface. The Alcon EyeMap evaluates the corneal surface with 23 concentric circles and claims full coverage of the cornea. Five consecutive measurements were taken and recorded. The Alcon EyeMap NITTT was also utilized on 4 subjects for trial run purposes. Following the inclusion stage of this study, NITTT by a new method utilizing the Alcon EyeMap was compared to the widely accepted NITTT measured with keratometric mires. Advantages to this may result when considering the EyeMap covers a larger diameter of the cornea. By reading a larger portion of the corneal surface for TTT, we may get a clinically accurate value of NITTT.

4) Demonstration of tear hyperosmolarity:

It has been " suggested that hyperosmolarity is the common denominator between all forms of dry eye." (Lemp) However, the measurement techniques are not yet simple enough nor readily available. Thus this procedure was not utilized in this study.

Other inclusion criteria were visual acuity, refractive error, and potential allergies. Each participant met a minimum required corrected acuity level of 20/25 or better. The range of participants' was specifically -.75 to -5.50. No deliberate attempt was made to include or exclude mild Hyperopic patients. Center thickness as well as edge thickness vary with lens power. The literature states that a thick lens may decrease oxygen permeability to the underlying cornea. (Jurkus) Thus, severe hyperopic and myopic patients were excluded. Participants also had prior history of soft contact lens wear, but had no prior history of allergic response to the preservative present in Bausch and Lomb's Renu Cleaning system, Dymed. This system was chosen arbitrarily.

METHODS:

Procedures:

The same optometric lane as approved by the Michigan College of Optometry as FSU was utilized at each evaluation during this double blind pilot study. The instruments were calibrated and kept consistent throughout the study. Light levels for each test remained constant. Dim illumination was established as the ideal light level setting to minimize reflex tearing for the patient, and decrease reflections observed by the measuring clinician.

The lighting was set with two overhead condescent lamps, one located directly over the subject and one located in the center of the room. The room door was closed at each assessment to minimize distractions. The order of eyes tested was randomized for each test.

Contact lens fittings were then performed on each subject to be included in the study. Both lens types, Biocompatibles PROCLEAR and Ciba FOCUS , were fit in each eye.

Baseline data was taken on each patient before lenses were worn in the study. During this period, measurements were taken once approximately four hours after subject waking, and once in the evening to unveil any variability of tears throughout the day. This data was later compared to time intervals when lenses were worn.

	SUN	MON	TUE	WED	THUR	FRI	SAT
BASELINE		1	2	3	4	5	
WEAR WK1		1	2	3	4	5	
WEAR WK2		1	2	3	4	5	

The lenses were dispensed and each subject given written and verbal instructions of "do's and don'ts". A rendition of this is displayed in APPENDIX B. Each person clearly understood that the lenses were to be removed if any discomfort, blurry vision, or redness were to present. Instructions also stated to contact the clinician immediately by means provided if conditions persisted. Lenses were worn daily for a five day period called wear week 1, followed by wear week 2. During week 2, the lenses were reversed repeating the previous wear period. "Usage of the contralateral eye is an excellent control for hydrogel comparisons." (Efron) Lenses for week 1 were assign to O.D./O.S. by a second clinician tossing an American coin. i.e. heads = left eye = FOCUS. New lenses were dispensed for wear week 2 in the opposite assignment. The clinician taking measurements at each visit was kept consistent and was unaware of assigned lenses.

During a five day wear time, patients were evaluated on days one, three and five. On these days, the subjects were evaluated twice each day. Once between 12:00 and 1:00 p.m. and once between 5:00 and 6:30 p.m.

At each visit, NITTT was measured by two methods, the Keratometric and the Alcon EyeMap. The subjects were instructed to "blink freely until asked to hold eyes open, eyes are not to appear in a "surprised" position rather a relaxed but open state.

Each subject was also given a daily log to compile each day of lens wear. A copy of this daily log is located in APPENDIX C. Subjective data collected will later be compared with objective NITTT by both methods.

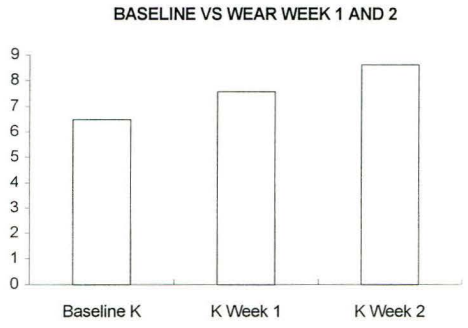
ANALYSIS:

Objective data:

The data has been divided into sections in order to address each aspect of this study in an organized matter. These sections are again addressed in the discussion of the project.

Baseline data by Keratometric methods vs. Data with lenses in wear week 1 and 2:

Figure 1

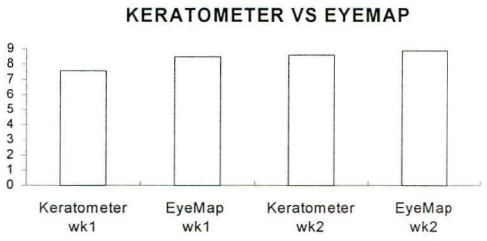


In section one of the study, baseline data collected when patients were not wearing lenses is compared to wear week one and two. Baseline data was collected at noon and in the evening each day tested. Figure 1 displays the mean of baseline data collected at noon, the mean of baseline data collected in the evening , and the mean of keratometric readings taken during wear week 1 and wear week 2. Measurements taken at noon averaged to 6.787 and in the evening, 6.205. This marginal difference of .583 allowed us to average the two means for purposes of discussion.

When this compiled data is compared to when subjects actually wore lenses in wear week 1, a difference of 1.09 is presented. When compared to wear week 2, a difference of 2.127 was demonstrated with longer NITTT being demonstrated during both wear weeks as opposed to the baseline week.

Keratometric data vs. Topographer data :

Figure 2



When the keratometric data is compared to the topographer data, as displayed in Figure 2, the difference in wear week 1 was .904 sec . In wear week 2 , the Alcon EyeMap demonstrated a mean larger than with keratometric methods, but at a considerably closer margin of .275 sec.

Proclear vs. Focus on the Dry Eye patient:

Next, a comparison is made between lens types. Figures 3 demonstrates means of Keratometric NITTT from wear week one. Figure 4 demonstrates means of Topographer NITTT from wear week one. The Proclear lens wearing eyes displayed a minimally longer mean NITTT than of Focus wearing eyes at a difference of .072 sec. Figures 5 and 6 display the difference in means when the lenses are switched in wear week two. While in contrast, Figure 5 demonstrates during wear week 2, the Focus lens proved marginally greater by .138 sec. The data collected from Topographer methods does not support data from Keratometric wear week 1, where the Focus lens wearing eyes showed a longer mean NITTT with a difference of .988 sec

Figure 3

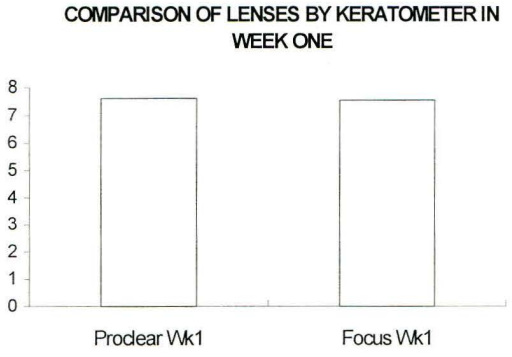


Figure 4

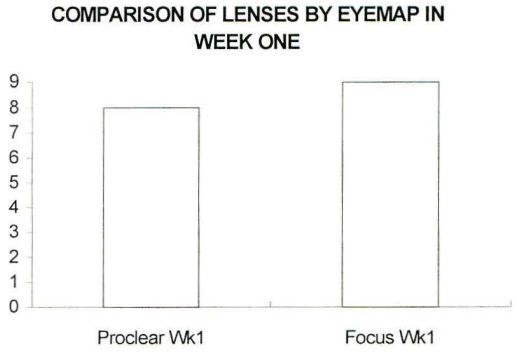


Figure 5

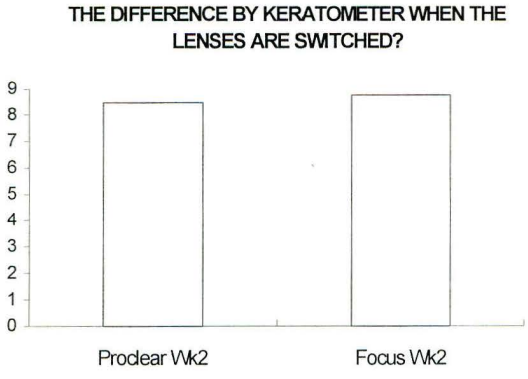
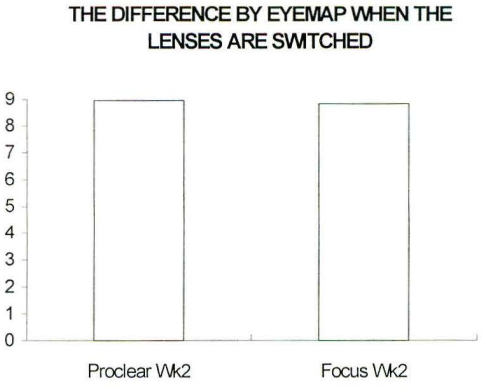
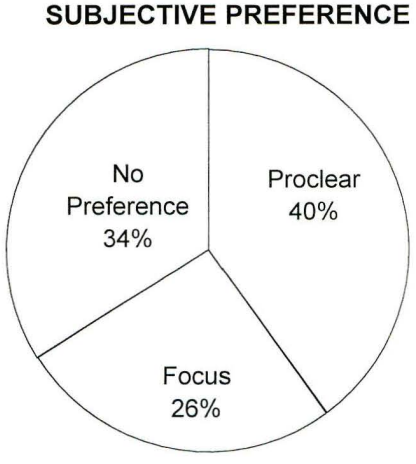


Figure 6



Subjective data:

Figure 7



From the daily logs kept by each subject (refer to APPENDIX C), 40% preferred the Proclear lens, 26% preferred the Focus lens, and 33% had no preference. Refer to Figure 7. Three subjects chose Proclear as their lens of choice and was subsequently supported during the second week when the assigned eyes were reversed.

One subject chose the Focus lens and was supported by choices made in week 2. Another subject chose the Focus lens during wear week 1 and had no preference in wear week 2. One more subject chose the Proclear lens consistently in wear week 1, and consistently chose the Focus lens in wear week 2.

Participants reported wearing lenses 6-7 hrs. per day and removed lenses 2 hours prior to daily evaluations. When asked " did you have eye irritation upon waking?" 33% of the time the answer was yes, 65% of the time the answer was no, and 2% had no answer.

Objective vs. Subjective data:

Comparisons of objective and subjective data were made on Mondays, Wednesdays, and Fridays of each wear week when objective measurements were taken. On Monday of wear week 1, four out of six subjects preferred the lens that also displayed the longest NITTT by keratometer. The remaining two out of six did not prefer the lens which displayed the longest NITTT. Again on Wednesday of wear week 1, four of the six subjects correlated between objective and subjective data. And the remaining two out of six had no preference which directly correlated with objective data which showed a marginal difference. On Friday of wear week 1, only two of the six subjects correlated between objective and subjective data. On this day, one subject left the question blank, and another did not show a trend. On Monday of wear week 2, only two subjects out of six directly correlated with objective data, one subject had no preference and three subjects chose a particular lens which was inversely supported by objective data. On Wednesday of wear week 2, one subject out of six had a preference that was supported by objective data, two subjects were inversely supported by objective data, two subjects had no preference, and one subject did not address the question. On Friday of wear week 2, one subject out of the six had preferred the lens with the longer NITTT, three subjects had no preference, while only one subject was inversely supported by the objective data and two subjects failed to address the question.

A statistical review of this data was performed and proved inconclusive. To restate, this is a pilot study in which the arithmetic means are illustrated to mark the beginnings of a more extensive study.

DISCUSSION:

As baseline data was collected, the decision was made to measure NITTT approximately four hours or more following waking, and in the evening hours. This was in reference to the literature that imply diurnal changes in TTT may exist. Before beginning the lens wear periods, the baseline data was examined . No trend to signify diurnal changes was noted. Thus, all measurements after the baseline data were collected consistently at evening appointments only.

The decision to measure NITTT two hours following the daily lens wear period was decided according to the literature. According to Faber, tear film stability is adversely affected by hydrogel lens wear. After lens removal, recovery of tear film stability to prewear levels requires a substantial period of time, after one hour of wear, approximately .5 hr. was required for 95% recovery. " (Faber) In theory, the time lag before collecting data would allow comparability to the initial baseline data. In section one of the results this comparison was made. A slight difference between wear weeks and baseline data was noted. This supports what has been stated by the literature.

In section two of this study, the Alcon EyeMap topographer was compared to the globally accepted method of measuring NITTT. The overall time in seconds measure by the EyeMap was longer than by Keratometry. This may be due to reflex tearing. Comments on subjective daily log sheets and during testing sessions suggested that the topographer light source expelled excessive heat, and was of intense luminance. It was difficult for subjects to fuse the placedo's disc. All of these factors may easily produce reflex tearing of amounts necessary to account for the discrepancy and inconsistency noted when compared to the Keratometer. Another factor that need be considered in the comparison of these two methods is the lack of randomization. Due to the multiplicity of factors considered in this study, it was decided to give precedence to the Keratometric method to allow comparisons of baseline and subjective data.

In section three, the lens types were compared objectively. Both lenses support Faber's hypothesis that tear stability following lens wear is comparable to tear stability without lenses if a certain time lag is considered before measurements are collected.

When compared to each other, no advantage was identified for the Proclear lens nor the Focus lens for the dry eye patient . This conclusion from wear week 1 is strongly supported by wear week 2.

At times this objective data was supported by subjective responses. But overall, the Proclear lens was preferred subjectively on the basis of comfort by a marginal amount of 40%. This may be due to the unique properties of the Proclear lens. It would be of interest for a future project to follow lens wear for a longer period of time. This subjective difference may be more evident when taken over a lengthy wear period of 4-6 months.

CONCLUSION:

This pilot study attempted to evaluate two important aspects of dry eye patients. First, can we increase comfort of the dry eye patient by prescribing the Biocompatibles PROCLEAR lens? And second, can we accurately measure TTT with the Alcon EyeMap?

Data collected in this study is supportive of attempting to utilize the unique properties of the Proclear lens to please dry eye sufferers. The Proclear soft contact lens has proved comparable to the Focus lens objectively, and marginally preferred subjectively by the dry eye patient. Since dry eye patients are such a challenge to fit with lenses asymptomatically, we must keep striving to solve their inconvenience and discomfort.

In comparison of two methods of NITTT, much discrepancy was noted between the topographer and the globally accepted keratometer. Specifically, it was difficult to correlate NITTT with the "true" measurement of the patient's tear stability. The data supports the continuation of the topographer method to aid in the assessment of dry eye patients.

Further analysis of this data is recommended to have a complete understanding of dry eye and successfully wearing soft contact lenses. One interesting adjunct to this study would be to explore the measurement of tear osmolarity. It is quite possible that if we could develop a clinically useful method of measuring osmolarity, we may eventually cure the dry eye patient.

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APPENDIX A

QUESTIONNAIRE FOR THE CONTACT LENS PATIENT

1.	NAME_____		
2.	AGE GROUP:	LESS THAN 25 25 - 45 GREATER THAN 45	
3.	DO YOU EVER EXPERIENCE ANY OF THE FOLLOWING SYMPTOMS?	SORENESS SCRATCHINESS	GRITTINESS BURNING
4.	HOW OFTEN DO YOUR EYES HAVE THESE SYMPTOMS?	NEVER SOMETIMES	OFTEN CONSTANTLY
5.	DO YOU SUFFER FROM THYROID ABNORMALITY?		YES NO
6.	DO YOU SUFFER FROM ARTHRITIS?		YES NO
7.	DO YOU EVER EXPERIENCE DRYNESS OF THE NOSE, MOUTH, THROAT, OR CHEST?		YES NO
8.	DO YOU REGARD YOUR EYES AS BEING UNUSUALLY SENSITIVE TO SMOKE, SMOG, AIR CONDITIONING, CENTRAL HEATING OR OTHER?		YES NO SOMETIMES
9.	DO YOUR EYES EASILY BECOME VERY RED AND IRRITATED WHEN SWIMMING IN CHLORINATED FRESH WATER?		YES NO SOMETIMES NOT APPLICABLE
10.	DO YOU TAKE ANY OF THE FOLLOWING MEDICATIONS? LIST MEDICATIONS CURRENTLY TAKING: _____ _____ _____ _____		ANTIHISTAMINES DIURETICS SLEEPING TABS TRANQUILIZERS ULCER MEDS BLOOD PRESSURE ORAL CONTRACEPT DIGESTIVE
11.	ARE YOUR EYES DRY AND IRRITATED THE DAY AFTER DRINKING ALCOHOL?		YES NO
12.	ARE YOU KNOW TO SLEEP WITH YOUR EYES PARTLY OPEN?		YES NO SOMETIMES
13.	DO YOU HAVE EYE IRRITATION AS YOU WAKE FROM SLEEP?		YES NO SOMETIMES

Contact Lens Participants

Name: _____

Lens insertion time: _____

Lens removal time: _____

Instructions for lens wear:

1. Clean your lenses before storing them overnight
   cleaning is preferred immediately following removal but I realize this may be difficult to fit into your schedule. Follow the instructions included in the Renu kit. Enzyming is not necessary.
2. Assessment at the clinic will occur Monday, Wednesday, and Friday
   evenings. It is crucial to the study that these appointments are kept. If the door to the building is locked, there will be someone down shortly to let you in.
3. Friday evening, August 9, you will be dispensed a new pair of lenses
   that are to be worn starting Monday, August 12. Please bring your initial pair of lenses to this visit, an exchange will be made. The weekend of the 10th and 11th contact lenses are not to be worn and questionnaires are not necessary. Any comments you feel helpful are appreciated.

In the following I have outlined some specific guidelines in which to follow. Beyond what is listed, please go about your day as you usually would. An appointment calendar will be given to you today and I would like you to post it in your home as a reminder of our scheduled dates and times.

I. Time line of events

A. Week 1: Fitting

Each subject in the study will complete a McMonnies questionnaire, be fit with contact lenses and performed NITTT. At this time Cleaning system will be discussed.

B. Week 2: Baseline data collection

On day 1 and 3 of this week (Monday, July 22 and Wednesday, July 24 OR 23 and Thursday July 25) each patient will visit the clinic for NITTT in the afternoon, and in the evening (appt: noon-1:00; 5:00-6:00) CONTACT LENSES ARE NOT TO BE WORN THIS WEEK! This especially applies to those days you will be coming to the clinic.

C. Week 3: Lens wear

Lenses are worn for five weekdays. Appointments will be on day 1, 3, and 5 of this week for NITTT evaluation thorough review of daily questionnaire, cleaning system usage, and instructions. On day 5, each patient will be dispensed a fresh pair of lenses. Saturday and Sunday (July 27 and 28) will be a rest period where NO CONTACT LENSES ARE TO BE WORN.

D. Week 4: Lens wear

Follow procedures listed for week 3. This will complete the study.

DAILY QUESTIONNAIRE
PLEASE FILL OUT THIS QUESTIONNAIRE **3 TIMES** THROUGHOUT THE DAY.

MORNING

1. WHAT TIME DID YOU INSERT YOUR LENSES? _____
2. DID YOU HAVE ANY EYE IRRITATION WHEN YOU WOKE UP THIS MORNING? **Y/N**
3. MEDICATIONS TAKEN THIS MORNING?_____
   _____
   _____

4. DID YOU DRINK ALCOHOL LAST NIGHT? **Y/N**

AFTERNOON

5. HAVE YOU USED REWETTING DROPS? **Y/N**
6. IF YES, WHEN WERE DROPS USED? RECORD TIME:
   1:_____ 3:_____
   2:_____ 4:_____

7. ARE THE LENSES COMFORTABLE? **Y/N**
8. IS ONE EYE MORE COMFORTABLE THAN THE OTHER? **Y/N**
9. IF YES, WHICH EYE FEELS BETTER? **RIGHT/LEFT**
10. WHAT TIME DID YOU REMOVE THE LENSES?

EVENING

11. LIST YOUR DAILY ACTIVITIES:_____
_____
_____
_____
_____
_____
(FEEL FREE TO UTILIZE BACK OF SHEET IF NECESSARY)

12. WERE YOU IN A: **WINDY, SMOKY,** OR **AIR CONDITIONED** ENVIRONMENT TODAY? (CIRCLE WHICH APPLY)
    *THIS INCLUDES CAR, WORK, HOME
13. WHILE WEARING LENSES DO YOUR EYES FEEL DRY OR WATERY?

	DRY	WATERY
RIGHT EYE:	**Y/N**	**Y/N**
LEFT EYE:	**Y/N**	**Y/N**

14. COMMENTS:_____
_____
_____
_____