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DEVELOPMENT OF A SUBJECTIVE COMFORT QUESTIONNAIRE FOR

HYDROGEL CONTACT LENS WEARERS

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the University of North Texas Health Science

Center at Fort Worth in Partial Fulfillment of the Requirements for the Degree of

MASTER OF SCIENCE IN BIOMEDICAL SCIENCES

By

Brian Hunter Hays

December, 2003

DEVELOPMENT OF A SUBJECTIVE COMFORT QUESTIONNAIRE FOR
HYDROGEL CONTACT LENS WEARERS

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Major Professor



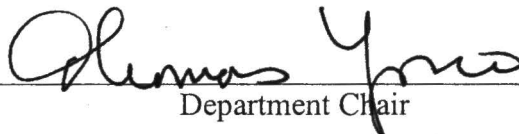
Committee Member



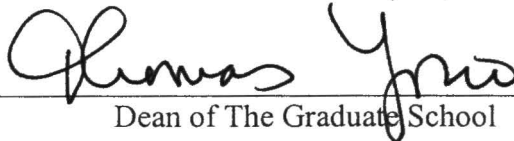
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For my wife Christine

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INTRODUCTION

Throughout this paper it is written that I would complete this study in its entirety. Due to time constraints and the length of this study, it was planned from the beginning that I would only accomplish the beginning phases, phases one and two. The reason why this paper was written this way, planning the complete research plan, is to aid the individuals that will finish this study in its entirety.

I. Purpose

The purpose of this project is to develop a questionnaire that can be used as a tool to measure the subjective symptoms of ocular comfort or discomfort reported by soft contact lens wearers. After a questionnaire has been developed, it will be tested to determine its reliability and validity in capturing the ocular sensations experienced by hydrogel contact lens wearers.

II. Overview of the Study

The research for the study will be conducted in six phases while pursuing three specific aims. The phases will consist of:

- A. reviewing literature in the form of reported soft contact lens symptomatology and interviewing skill improvement, compiling and

- B. examining previously developed questionnaires, developing open-ended interview questions and collecting data from the field.
- C. developing preliminary questionnaire items based on data gained during the first phase.
- D. administering the preliminary questionnaire to receive feedback from volunteers with regards to each item's appropriateness, and tallying the volunteer's responses to graphically analyze each item's answer distribution.
- E. refining each item based on the data obtained during the third phase to create a revised draft of the questionnaire.
- F. determining if the revised draft conveyed and captured the ideas reported by the volunteers by receiving feedback after it is administered.
- G. demonstrating reliability and validity by psychometrically validating the questionnaire.

During each administrative phase of the study (phases three, five and six) two groups of volunteers will be used to gain a broader spectrum of data. Each group will be composed of a sub-set of previously interviewed volunteers and a sub-set of new volunteers. Before any information is obtained, a confidentiality agreement will be discussed with each volunteer. All volunteers will be given a simple, easy to read informed consent form and a randomly assigned number.

III. Inclusion/Exclusion Criteria

Inclusion Criteria Phases One through Three

- All soft contact lens wearers willing to participate.

Exclusion Criteria Phases One through Three

- Individuals who haven't worn soft contact lenses in the past three months.

Inclusion Criteria Phases Four through Six

- All volunteers not described by the exclusion criteria.

Exclusion Criteria Phases Four through Six

- Volunteers that might have problems with their eyes or soft contact lens due to medications, allergies and noncompliance with a lens' care regimen. This will greatly increase the end questionnaire's ability to measure comfort that is associated with soft contact lens wear while not being influenced by the above factors.

IV. Roles and Responsibilities

Due to the length of this study and the time line of my internship, I propose to accomplish phases one and two. After the completion of my internship, the study will be assigned to a full-time employee at Alcon Laboratories Inc. who will accomplish the remaining phases. Statisticians will also be employed throughout the questionnaire development process. Their will include aiding in the following:

- A. data base development.
- B. item refinement.
- C. interpretation of data.

D. psychometric validation.

SPECIFIC AIMS

An estimated 155 million Americans, or 60 % of the population, need corrective eyewear.¹ The need for corrective lenses can leave an individual with many options to correct their vision. Options that are available to individuals, based on their preferences, can include the latest innovations in spectacles, refractive surgery or the use of high-tech contact lenses.⁵ Due to the expense of surgery, the bulkiness of framed lenses and personal vanity, many individuals prefer to use contact lenses instead of the other options. Although preferable for many individuals, contacts do not come without problems. These problems (e.g., dryness, scratchiness, watery eyes, corneal infection, peripheral vascularization, corneal warping and sterile ulcers)³⁻⁴ have led many individuals to be reluctant to begin or continue the use of contacts.⁸

Assessment of ocular symptoms is important for developing better contact lenses and lens care products. Current tools vary in their sensitivity, validity and precision. Currently used questionnaires can vary from simple binomial questions (e.g., uncomfortable or comfortable) to well-developed visual analog scales. A critical assessment of these current tools and development of new scales, if appropriate, will be a valuable contribution.

These issues will lead me to pursue the following objective: develop and validate a questionnaire designed to demonstrate the acceptability of soft contact lens care products.

I. To accomplish the objective of this application, I will pursue three specific aims:

- A. Develop a soft contact lens symptomatology questionnaire based on: (i) literature reviews; (ii) previous questionnaires; and (iii) interviews with all volunteers willing to participate in this study. Emphasis will be focused on individuals that are: (a) newly prescribed contact lens wears, zero to three months; (b) established hydrogel contact wearers, greater than six months; (c) intermittent lens wearers, two to three days of lens wear a week; and (d) a spectrum of individuals who range from no or few problems reported to those who experience a variety of difficulties.**
- B. Administer all forms of the questionnaire to determine if it captures the reported symptomatology of soft contact lens wearers.**
- C. Determine if the questionnaire is reliable and valid by means of psychometric validation.**

I expect, at the conclusion of the proposed period of study, to have gathered enough information from an accurate sample of the soft contact lens wearing population to formulate a questionnaire pertaining to lens care products and wearing contact lenses. Secondly, by administering and psychometrically validating the questionnaire, I plan to obtain an adequate level of data demonstrating its reliability and validity.

SIGNIFICANCE OF PROPOSED RESEARCH

This project is important due to the fact that individuals often develop problems causing soft contact lens wear to become unappealing over time. By assessing current questionnaires and potentially developing new scales, we will have readily assessable tools to assess the efficacy of existing products and the performance of new formulations leading to overall better quality of products and consumer satisfaction. This in turn will make using products more desirable to the soft contact lens wearing population.

I. Background

The demand for contact lenses has risen over the past decade. A survey conducted in December of 2000 by Health Products Research (VIS)SM, found that throughout the '90s the population of new contact lens wearers showed a steady increase for each consecutive year. Beginning with 1.6 million per year in 1991 and ending with 2.8 million per year in 2000, the data shows a cumulative decade-long increase of 57%.² Today an estimated 30 million Americans wear contact lenses.¹⁷ As the population of contact lens wearers rises it is important to have a tool to assess a product's ability to perform. One of the most important performance aspects is the measurement of comfort while wearing contact lenses. Of the complications that can arise from wearing soft

contacts, ocular dryness is the most commonly reported symptom among contact lens wearers.⁴ Symptoms of dryness cause many patients to reduce their contact lens wearing time or to discontinue contact lens wear completely.⁴

RESEARCH DESIGN AND METHODOLOGY

I propose to investigate currently available contact lens questionnaires and potentially develop new tools by pursuing three specific aims, each of which is outlined below:

Specific Aim #1:

Develop a preliminary questionnaire based on literature reviews, previously compiled questionnaires and interviews with soft contact lens wearers.

I. Introduction

To accomplish this portion of the experiment I plan to implement infield research, in the form of interviews, and the consultation of previously compiled questionnaires to achieve this section's objectives. The section objectives will be, therefore, to: (i) visit doctors' offices; (ii) interview a volunteer population that comprised of soft contact lens wearers; (iii) obtain and accurately record the data that pertains to the development of a preliminary questionnaire; and (iv) arrange the data to give a coherent order for interpretation.

II. Experimental Design

The objectives of this section will be accomplished by conducting the following study:

A. Literature Reviews

Information will be obtained to formulate open-ended questions, determine the extent of the volunteer response records to ensure an adequate level of data is obtained, anticipate error and bias, determine how to keep the interviewee interested and improve my interviewing skills.

B. Site Visits

The objective of this portion of the study is to collect information from various sites in order to create a database representative of the U. S. contact lens wearing population. To begin, I will search for sites that contain an adequate patient population to ensure that a complete data sample is obtained in relation to that area of the country. It is important to ensure that you have an adequate patient population to compensate for problems due to volunteer dropout.

Once at the site, I plan to ask volunteers open-ended questions, which requires more than a yes/no response. Examples of these types of question are, "please tell me what you like/dislike about the contact lens care regimen," or "please give me a list of words that describes how your eyes felt when you have had problems wearing hydrogel contacts and/or using contact lens care solutions in the past." Once again the idea is to obtain as much valuable information as necessary, in terms of words, of how individuals report their subjective symptoms.

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Secondly, at the end of the interview, so not to introduce bias, I will determine if the reported symptomatology is due to the lack of compliance⁶⁻⁷, volunteers will be asked a series of compliance related questions and/or to perform their normal lens care regimen. It is important to note that the data gained from these non-compliant volunteers will not be excluded from later portions of the study. It will be used to further categorize volunteers during the data analysis portion.

Lastly, to further increase the reliability of the data, I will act as the sole interviewer throughout the entire case history process. Problems can arise with respect to conveyance due to the fact that two individuals can interpret information differently. Using one interviewer will limit this source of unwanted variation in the obtained data.

C. Data Arrangement

Once the preliminary data has been obtained, it will be analyzed to compile a list of key words and phrases. This list will be used to prepare the questions on the preliminary questionnaire. The idea is to use the language used most often by the volunteers to make the terminology on the questionnaire understandable.

III. Expected Results

Upon completion of this section, I expect to have a preliminary questionnaire that employs a Likert scale (i.e., strongly agree, agree, neutral, disagree, strongly disagree) based on the input of the volunteers. Secondly, I will have an idea of what is comfortable to different types of people with regards to contact lenses.

IV. Anticipated Problems and Their Solutions

Participation at sites could become a major potential problem due to the volunteer's busy schedules. The volunteer's inability to participate for various reasons can be indicative of low interest in the study. To keep the volunteers interested in the study, we can compensate them for their time by offering either monetary compensation or free products. A second anticipated problem is that not everyone has the same threshold to discomfort⁹⁻¹¹. This problem can lead to a range of differing values on what the public's perception of comfort actually is. To alleviate this problem, I plan to conduct a statistical analysis, using the Pearson correlation coefficient, to determine if there is any kind of correlation between discomfort and categories such as sex, age and race. Lastly, volunteers can develop problems due to other factors (e.g. lack of compliance, allergies and medications)^{4,6-7} which can be confused with the products they use. In previous studies, only 26% of patients were fully compliant with the care and maintenance of their contact lenses.⁶ To limit this problem, I will collect data from all volunteers, but I will track those who might have difficulties due to the above confounding factors. This process of tracking will be used throughout the entire study not to discriminate, but to increase the interpretability of the data set.

Specific Aim #2:

Administer the preliminary questionnaire to volunteers to determine if it is indicative of capturing the reported symptomatology of soft contact lens wearers.

I. Introduction

To accomplish this portion of the clinical experiment I plan to administer two forms of the preliminary questionnaire. The first form will be used to gauge the actual responses of each volunteer. The second will employ a three-point scale to rate each item's appropriateness with respect to inclusion on the revised draft of the questionnaire. I will administer the two forms of the questionnaire to a soft contact lens wearing population that is composed of a group of previously interviewed volunteers (to see if their ideas were conveyed) and a set of new volunteers. The section objectives will be, therefore, to: (i) administer the questionnaire; (ii) tally the actual responses for graphical interpretation; (iii) tally each items respective appropriateness response; (iv) receive feedback with regards to completeness (did they feel that the questionnaire adequately described their reported ocular symptoms); (v) ask for general thoughts and suggestions on how to improve any aspect of the questionnaire; and (vi) refine the items based on the data obtained.

II. Experimental Design

I will accomplish the objectives of this section by using the following study:

A. Administration of Questionnaire

For the administration of the preliminary questionnaire, I will conduct an examination of the data set obtained in phase one to select the sites that had the most participation and diversification. The range of difficulties reported with regards to the data obtained will define diversification. The participants will be allowed to sit in a quiet area where they will have enough time to think about the questions they are answering. As in the preliminary interviewing portion of this study, administration of the questionnaire will be conducted in a non-biased manner.

B. Second Phase Data Review

The data that I obtain from the second phase of the study will be used to refine the items of the preliminary questionnaire. Upon completion of the entire preliminary questionnaire, I will ask the volunteers to take a second form of the questionnaire to rate the appropriateness and relevance of each item on an approval, neutral and disapproval scale. Comments for each item will be ordered such that the approval section will consist of comments that generally favor the inclusion of the item in the questionnaire. The neutral section will be composed of comments that reflect indifference toward the relevance of the item. The disapproval section will consist of negative comments reflecting the irrelevance or inappropriateness of the question item. At the end of the

interview the volunteers will also be asked to rate the questionnaire overall on this same three point scale.

For each item, approval, neutral and disapproval comments will be tallied. Items that show a positive skewed distribution will be automatically retained without further possible refinement. Items with predominantly neutral comments and an even distribution will be retained to see if they can be refined further. Items with predominantly disapproval comments and a negative skewed distribution will be retained only until the last (data comparison) phase. Items with responses that are strongly bimodal will be re-evaluated for content and wording.

As a next step, I will tally the actual responses that are given. The strategy is to create a graphical interpretation of the responses so they can be placed into one of three categories (i.e., retain, refine or eliminate) based on their distribution. Responses with a large range of answers and normal distribution will be placed into the retain category. Responses with a bimodal distribution will be placed into the refine category. Responses will only be placed into the elimination category if they have either a positive or negative skewed distribution (i.e., low or high-ended responses).

In the last portion of this section, I will use the following table to cross-reference the information gained in the previous two steps.

Table 1. Cross Reference

Question Number	Step One	Step Two
#1	+	+
#2	+	0
#3	-	0
Etc.	Etc.	Etc.

Legend for Cross Reference Table:

Step One	Step Two
Approval = +	Retain = +
Neutral = 0	Refine = 0
Disapproval = -	Eliminate = -

Interpretation and the actions that will be taken will be based on the following table.

Table 2. Question Retainment

+/+	Retained without further refinement
+/0 or 0/+	Retained with possible wording change
0/0	Retained with possible wording change and/or word rearrangement
-/0 or 0/-	Retained with possible wording change and/or word rearrangement
-/-	Question will be dropped

Items receiving either a neutral or medium rating will be manipulated to encourage the volunteers take a more advocated position. The aim of this strategy is to have all soft contact lens wearers, which take the final form of the questionnaire, to give an honest response about the products they use.

III. Anticipated Problems and Their Solutions

Locating previously interviewed individuals and having them participate is an anticipated problem with this portion of the study. To address this dilemma, I plan to ask the volunteers if they will be willing to return for a second interview during the last portion of the study. If the volunteer agrees to come back, I will ask them to complete an information card enabling them to be easily contacted to set an appointment time. We can further give incentive for a repeat visit by offering compensation, either in the form of money or free products, to those volunteers who might be reluctant for a second interview.

Specific Aim # 3:

Determine if the questionnaire is reliable and valid by means of psychometric validation.

I. Introduction

To accomplish this portion of the experiment I plan to use psychometric validation to demonstrate reliability (i.e., will the instrument yield the same score when administered to the same volunteer at different times)¹² and validity (i.e., does it actually measure what it claims to without errors in drawing conclusions from the data).¹³ The objectives of this section will be, therefore, to: (i) use an index of discriminating power to select more discriminating Likert items over less discriminating items; (ii) show an internal consistency (Cronbach's alpha); (iii) test-retest to show reproducibility; and (iv) demonstrate: (a) conclusion validity; (b) internal validity; and (c) construct validity.

II. Experimental Design

I will accomplish the objectives of this section of the study using the following experimental design:

A. Index of Discrimination

To refine the questionnaire, I will use the following protocol:

1. administer a revised draft of the questionnaire to a group consisting of a sub-set of previously interviewed individuals and a sub-set of new volunteers.
2. conduct data entry of each item's content score.
3. compute each item's mean score, and rank them from lowest to highest.
4. compute the top 25% and the bottom 25% for the range of mean scores obtained.
5. compute the DP coefficient (the difference between the top and bottom mean scores).
6. include items on further revised drafts that obtained higher DP coefficient values.

B. Reliability

To show that the questionnaire is reliable, I will employ two different methods to demonstrate the equivalency and stability of the items found within the evaluation. The first method, internal consistency, will assess equivalence throughout the entire questionnaire and will be accomplished by the following protocol:

1. Internal Consistency

- a. administer the questionnaire to a group of previously interviewed volunteers.
- b. have volunteers complete the entire questionnaire using a five point Likert scale.
- c. conduct data entry of each item's content score.
- d. enter the data set into statistical software to compute Cronbach's alpha.
- e. alphas ≥ 0.70 show a good measurement of a single unidimensional construct¹⁴ (individuals consistently respond to items).
- f. for the item set add or delete items as appropriate.

Note: In the occurrence of a low Cronbach's alpha, the questionnaire will be evaluated to determine if it exist as a multidimensional construct.¹⁵

2. Test-retest

To show that the measures are stable over time, the same test will be administered to a same group of volunteers at two points in time. During the two test periods, the individuals will be instructed to not change the soft contact lens products they currently use. This will ensure that the individual's perception of comfort stays relatively the same during the two test periods. The data obtained will be analyzed by statistical software to compute intraclass correlation coefficients. Coefficients closer to 1.0 show a stronger correlation.

C. Validity

By demonstrating validity, I can prove the claim that the questionnaire can be used to measure the subjective symptoms of ocular comfort. I will assess the questionnaire's validity by using the following methods.

1. Conclusion Validity

Conclusion validity establishes if there is a relationship between two variables, the questionnaire items and a comfort measurement. Conclusion validity can be assessed by answering the question, "is there a relationship between the volunteer's responses to the items on the questionnaire and a practitioner's findings during an eye examination?" Examples of objective signs that practitioners might look for which could possibly correlate to ocular comfort are corneal staining, blepharitis, deficient tear layer, fit of the lens and lens deposits. By analyzing these two variables, a relationship can be established by using the Pearson correlation coefficient to see if there is a linear relationship between the two variables. A score of 1 means a perfect positive linear correlation and a score of -1 equals a perfect negative linear correlation. For the purpose of this experiment, the absolute value for the score of 0.40 will be considered adequate for demonstrating conclusion validity.

2. Internal Validity

Internal validity is used to determine if the relationship established by the process of conclusion validity is a causal one. This process has to do with defending against sources of bias, which would affect the cause-effect process being studied by introducing covert variables.¹³ Provided that all-important factors defining selection are incorporated

into a set of measured independent variables, the method of two-stage least squares regression will be used to test for section bias.

3. Construct Validity

Using convergent validity, a type of construct validity, all items on the questionnaire will be analyzed, based on the each item's mean content score, to determine if any correlations exist among the individual items. The better the correlation between each of the items in the questionnaire, the better the indication of a well-designed construct.

III. Anticipated Problems and Their Solutions

As with any scientific test, it is difficult to prove claims one hundred percent. To compensate for this I plan to use a well-defined method to ensure that an adequate amount of data is obtained pointing to the direction that our questionnaire measures subjective symptoms of ocular comfort.

LIMITATIONS OF THE STUDY

Some key limitations include the following: (i) not all people will take the time to read and understand the questions so that they can answer them truthfully; (ii) sources of human error include not being able to convey or record exactly what the interviewee is trying to say; and (iii) the inability to rule out discomfort that is caused by factors that are not associated with contact lenses and lens care products.

DEMOGRAPHICS

Total number of interviewees: 73

Total number that consented to follow up interview: 73

Table 3. Location of Sites

Site Number	Location	Interviews per Site
1	Fort Worth, TX	11
2	Mansfield, TX	9
3	San Diego, CA	16
4	Salt Lake City, UT	15
5	Memphis, TN	14
6	Beachwood, OH	8

Table 4. Gender Representation

Sex	Number Observed
Male	19
Female	54

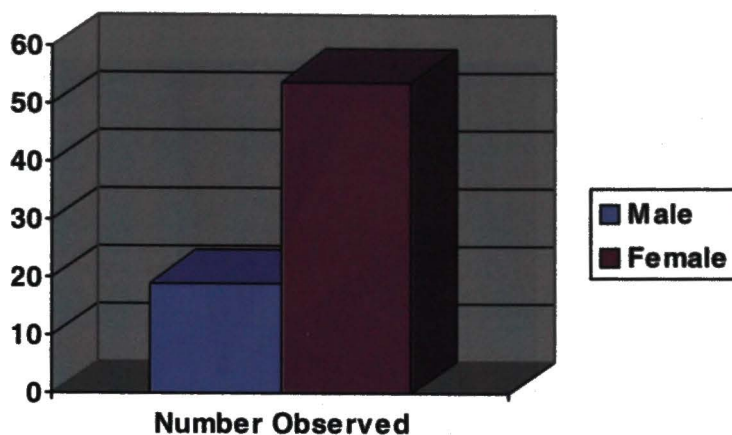


Figure 1 Graphical Representation of Gender

Table 5. Age

Gender	Min (Years)	Max (Years)	Mean (Years)	Standard Deviation	Range Within +1/-1 SD (68.3%)
Male	14.4	70.2	32.9	14.99	47.9-17.9
Female	12.1	66.6	36.9	13.99	50.9-22.9
Overall	12.1	70.2	35.5	14.27	49.7-21.2

Table 6. Race

Race	Number Observed	Percentage of Interviewees
Asian	1	1.37%
African-American	4	5.50%
Hispanic	6	8.22%
Caucasian	60	82.20%
Other	2	2.74%

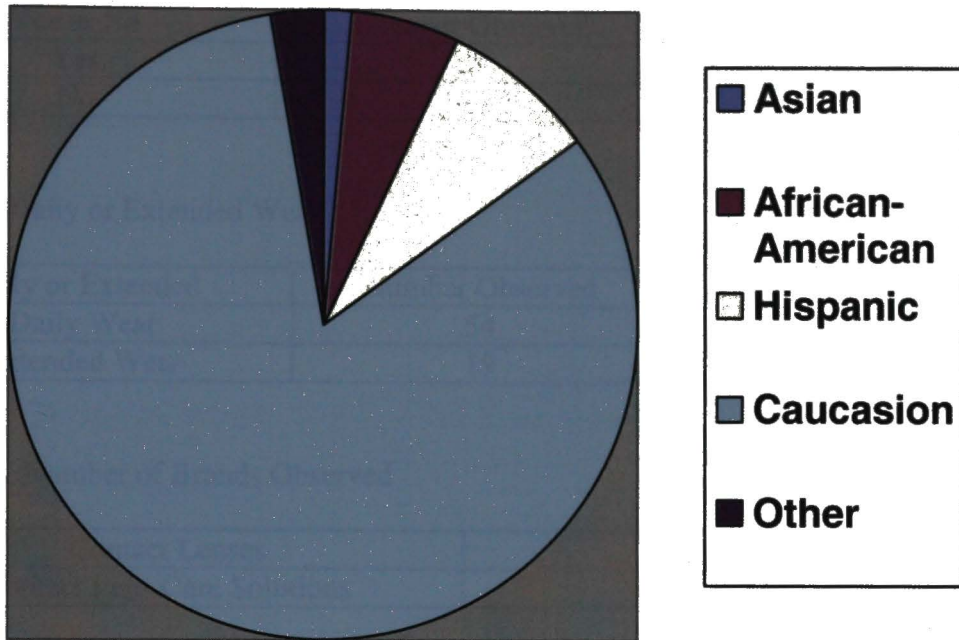


Figure 2 Graphical Representation of Race

Table 7. Presently On Any Medication(s) That May Cause Difficulties with Wearing Contact Lenses

Yes or No	Number Observed	Percentage of Interviewees
Yes	10	13.7%
No	63	86.3%

Note: Medications that may cause difficulties with wearing contact lenses that were reported: Advair[™], Estrostep[™], Ortho Tri-Cyclen[™], Travatan[™], Yasmin[™], Premarin[™], Maxidex[™] and Femhrt[™].¹⁶ It is important to track these individuals because their reported symptomatology could possibly be due to these medications and not the contact lenses themselves.

Table 8. Experiences Seasonal Allergies

Yes or No	Number Observed	Percentage of Interviewees
Yes	29	39.7%
No	44	60.3%

Table 9. Daily or Extended Wear

Daily or Extended	Number Observed	Percentage of Interviewees
Daily Wear	54	73.9%
Extended Wear	19	26.0%

Table 10. Number of Brands Observed

Contact Lenses	17
Contact Lens Care Solutions	11

Table 11. Length of Time in Contact Lenses

Gender	Min (Years)	Max (Years)	Mean (Years)	Standard Deviation	+/- 1 SD (68.3%)
Male	0.33	50	8.37	9.09	<0-17.46
Female	0.021	40	10.75	9.79	0.96-20.54
Overall	0.021	50	10.22	9.67	0.55-19.89

Table 12. Compliance

At Least 85% Compliant With a Good Lens Care Regimen	Number Observed	Percentage of Interviewees
Yes	49	67.1%
No	24	32.9%

RESULTS

I. Volunteer Responses

The results section contains two drafts of interview questions. The first, draft A, was used to interview volunteers at the Connor Clinic. After interviewing the volunteers at the clinic and not being able to obtain the desired responses, the questions were changed to the second version, draft B. Draft B questions were used to interview volunteers at the remaining sites.

A. Question One

1. Describe to me how your eyes felt in the past when you have had no problems with wearing contact lenses.

A1781 I really can't tell that they're in. They feel great. When I blink my eyes I can't tell that they're there.

A2497 Really I can't even tell that I wear contacts during the day. I put them when I wake up and I take them out when I go to bed and so when I don't have them in my eyes feel a little drier then when I do have them in.

A2947 They felt fine didn't even know that they were there.

A3570 They feel good through out the day I may have to use a re-wetting drop once a day, but I usually don't have to do that.

When I remove my lenses at night I can tell that I have worn my lenses maybe because I'm getting a little dry at that point in time.

A3843 They felt good, no problems.

A4645 Barely noticed the lenses were in my eyes.

A5045 Fine, I don't really notice my contact lenses. Don't notice my eyes at all.

A5572 Great. Well when I'm not having any problems they're comfortable especially since I've got the Acuvue 2 you hardly notice that there in there.

A5623 They feel just normal like there is nothing there

2. In which environments do you experience uncomfortable sensations while wearing your contact lenses?

B1570 I don't ever have uncomfortable sensations unless I sleep in them. No difference between inside and outside. If I went in to a bar I would have problems due to the smoke.

B1726 Well extremely dry ones. In the car with the air blowing in my face. Under a fan depending on how it is on.

B1727 In the wind and that's about it.

- B1728 I think that the only place that I have had problems with them is at the beach when it was kind of dry and windy. The air conditioning on high bothers them.
- B1767 Drier areas and where there is a lot of pollen.
- B1903 No particular environment. Air blowing in my face. Starring at a computer screen.
- B2015 Like in the Spring and Fall when you have a lot of pollen in the air.
- B2031 When it is windy outside or air conditioning directly in my face. Starring at a computer screen. It goes away after I blink a few times.
- B2314 Outside if the wind is blowing. If the wind gets in my eyes, but if they dry out I just remove them and wear my glasses.
- B2430 Anywhere that is smoky or high pollen. Driving with air-condition in my face
- B2570 When it is windy. In an air-conditioned environment. At a computer screen or watching TV late at night.
- B2719 When I have had them in for a long period of time after eight at night. Watching TV my vision gets a little fuzzy.
- B2818 All environments. Everyday, all day they hurt. I have problems all of the time. Starring at a computer screen. I

experience discomfort everyday.

- B2891 They never bother me.
- B2922 At night. Driving at night.
- B2947 Pretty dusty, windy or dry. During the day most of the time
not during the evening. Outdoors
- B2978 A lot of direct sun light.
- B3004 In the Spring with all the pollen in the air. Smoky
environments.
- B3009 When it's really dry and the air is really dry outside.
Smoky situations.
- B3109 If the weather is dry. Dry environments. Late at night
starring at a computer screen.
- B3119 Outside sometimes when it is really windy. Or air-
conditioning blowing on my face.
- B3367 When I am in a dusty area or a grassy area that has just
been mowed. Air-conditioning in my face. I have to blink
a few times to get my contacts moisturized.
- B3467 Anywhere where it is highly polluted. In the car with the
air blowing straight on my eyes. I have noticed that I have
more discomfort in higher humidity areas.

- B3468 Sometimes when it is cold outside and the defroster is on.
Sometimes in my office later in the day when the air is really dry. I have problems at the computer only when I am playing computer games. I have to blink more often and they get blurry.
- B3550 If I am in a place with a lot of smoke. If I am in a car with the air in my face.
- B3560 Smoky environments. Watching TV and staring at the computer screen.
- B3571 If it is breezy out. Directly under the fan.
- B3853 Dry down south.
- B4124 Smoke filled dusty areas.
- B4164 When there is a lot of dust or extremely windy outside.
When air is blowing on my eyes. Smoking areas.
- B4375 Dry places mostly. In the car with the air on. Around smoke.
- B4397 Usually only when I have had them in for extended period of time or when it's really dry. More problems inside under air-conditioners or under fans.
- B4445 When I am just rubbing my eyes. Sometimes starring at one thing.
- B4497 When I am outside and it is windy. In an air-conditioned

room they dry out a little.

B4613 When it is windy. At work looking at a computer screen.

B4665 When I am out at bars and there is a lot of smoke.

Working at a computer screen sometime my eyes go out of focus and I have to blink a few times to re-wet them.

B4880 Like late at night if I wear them too long they don't feel like that they fit right. Smoky areas.

B4975 Windy when there is dirt. Driving in my car with the vents on my eyes.

B5013 At work starring at a computer for a long time and in a smoky situation.

B5027 Mainly a lot of wind outside. A little tired at a computer screen. Smoke would bother me. Air-conditioning blowing directly in my face.

B5028 Air-conditioning or drafts like the wind. In the car with the windows down.

B5029 Smoky and certain kinds of lights like in the supermarket. Real dark environments like the show.

B5035 Like smoky environments. Sitting under a fan. In a car with the air on. Starring at a computer.

B5037 Smoky ones like a bar or concerts.

B5063 At night and in the car with the air-conditioning on and in

smoky environments

- B5303 For the last year with long term computer use. In the car with the air on my face.
- B5373 I notice that I will start have problems if I wear them longer than nine hours. It does not matter if I am inside or outside. The wind dries out my eyes and in the summer when it is warm. When I am around smoke they get drier.
- B5426 Outside during the pollen season.
- B5571 In windy conditions. Under the ceiling fan at night.
Getting tired and reading at night.
- B5572 Environments in the wind. When my allergies are bad in the Spring. Smoke bothers them. I need my glasses at night my night vision is not so good with them in. The lights starburst.
- B5649 When wind is hitting them if the windows are down in my car. If I have my eyes open for a long time like working at a computer screen or watching a movie.
- B5813 Probably when it is windy and blowing dirt. Air-conditioning blowing in my face. Standing next to a BBQ pit.
- B5818 Windy or if it is blowing sand. Smoky environments.
- B5822 Dusty like outside and sometimes in to office because there

is no humidity.

B5857 Most often windy. Sometimes in the car with the windows down. On rare occasions staring at a computer screen. Smoke filled rooms.

B5957 Outside during windy times. When I have taken allergy medicine my eyes become dry. Smoky rooms.

B6028 If I have worn them too long my eyes will start burning. Dusty areas. At night there is a halo around lights and I can't focus very well.

B6054 When it is really hot. Smoky environments, but when I get away from them it stops.

B6237 Really bright light. When hay fever is on. When it is windy.

B6247 More outside, dry weather like the desert or smoky environments. Flying on planes.

B6399 When there is a lot of wind. The light sometimes will bother me.

B6572 Desert, real dry areas or air-condition rooms. On airplanes. Smoky environments.

B6672 If it is windy or dusty. In the car with the vents on my eyes.

B7497 None. No wind no smoking.

B. Question Two

1. Describe to me how your eyes felt in the past when you have had problems with wearing contact lenses.

A1781 Dry.

A2497 They burn a little bit in the late evening.

A2947 They feel grainy or feels like there is actually something in my eye besides my contacts. A foreign body sensation, dryness.

A3570 My eyes experience a little dryness.

A3843 Foreign body sensation. I blink more. My eyes are tired.

A4645 Dry, itchy, foreign body sensation.

A5045 Dry, painful, scratchy, blurriness, itchy, irritating.

A5572 It feels like I have sand in my eye. Sometimes I have got to just take them out because they become too dry.

A5623 Dry especially at night you have to keep blinking and it is hard to take.

2. Can you please describe the sensations you feel when your eyes are uncomfortable while wearing your contact lenses?

B1570 Itchy sometimes dry. I fell like I have to rub them.

B1726 Dry and I need to peel them off my eyes. I need to put something in them to keep them from sticking to my

eyeballs. Harder to blink the surface of the eye feels gritty.

- B1727 Just burning and tearing.
- B1728 The only problem that I have is dryness.
- B1767 Feels like there is something underneath my lid. Itchy.
Dry. Feels like I need artificial tears.
- B1903 Dry and like there is a little something in my eye.
- B2015 Dry gritty feeling and that is usually when I use the re-wetting drops.
- B2031 Itchy and I want to rub them. I blink more. There are times after I put them in that they burn a little.
- B2314 A light stinging causing my eyes to water.
- B2430 Scratchy, itchy, dry and painful.
- B2570 Dry and itchy.
- B2719 They feel like there is not enough lubrication. Like it is rubbing against my eyes. Burning and stinging. Increased frequency in blinking and holding my eyes shut.
- B2818 Like something is on my contact. It feels like the contact is stuck to my eye. I have to use more re-wetting drops.
My right eye is dry all the time. Stings. I feel like I have to move the contact to relieve the sensation.
- B2891 Sometimes they feel like there is something in there like a

speck. I take them out and clean them and put them back in.

B2922 I feel unsure of distance when driving.

B2947 Dry and grainy like something constantly rubbing against my eye. Like there is something under there.

B2978 It is like something is in the eye. It is dirty. It's sore.

B3004 They get kind of scratchy. Like there is something in there. They get gritty. Burning and stinging around smoke.

B3009 Itchy, burning and dry.

B3109 A dry itch. The lens does not stick to my eyes, and they move around a lot.

B3119 I like to say that they fell like potato chips. They are dry and scratchy.

B3367 It gets cool and like water is running over it. Scratchy and dryness.

B3467 I feel like there is something in my eyes like a foreign body sensation. Sometimes when I hold my eyes open to long they are really dry and it gets worse by the end of the day.

B3468 Sometimes they get a little burning sensation. Sometimes they get a little watery. Sometimes they feel a little sticky when I try to blink over them. I feel like I have to moisten them a lot before my vision is clearer. Sometimes I have problems taking them out.

B3550 If I let them get a little bit dirty I can feel them on my eyes. You feel like something is there that just does not feel right.

B3560 It feels like it hurts. It's itchy, and It's like something pounding.

B3571 It makes them feel dry which makes me feel tired. I have to blink longer.

B3853 Really I don't have a problem, but I know when I need to change them because my head starts to hurt.

B4124 Sometimes stinging or like sand in your eyes. They don't feel like they are moistened enough.

B4164 Dry or that there might be something stuck in my eye I have to blink more often, and I have to keep them shut longer.

B4375 My eyes are watery. It feels like there is something in there. Stinging and burning occasionally.

B4397 Dryness, burning or itchiness.

- B4445** It feels like there is a piece of something in there. I try to blink it away, but it still feels like there is still something in there. Sometimes after I take them out of solution and put them in my eyes they sting a little bit, but it goes away after I blink a few times.
- B4497** Kind of dry. When I blink my eyes they don't move. They fell like they stick.
- B4613** Pretty uncomfortable. Scratchy, dry and itchy. A little redness.
- B4665** They feel like they are going to pop out. They feel dry and itchy.
- B4880** Itchy and they feel like they pop out of place. I feel like I have to blink more often and keep my eyes shut longer. My vision gets blurrier.
- B4975** I just want to get rid of them. My eyes fell gritty.
- B5013** Mainly just dry. Burning in the smoky areas. Blurry and I need to blink more.
- B5027** Feel like they're not only getting dry, but they are shrinking on my eye. Making a tighter feel. Burning. Tired.
- B5028** Scratchy and dry. I have to blink more often.
- B5029** It is just an irritation like a dry sensation.

- B5035 Itchy and dry. I have to rub them. I have to be careful if they are dry because they don't move.
- B5037 Itchy like I want to rub them out.
- B5063 They feel like my eyes are dried out. I try to blink a lot, but I usually have to use drops at that point.
- B5303 It feels like there is something under my lens. Dryness and them moving around. I feel like I need to blink more often
- B5373 Itchy, dry like it is sticking to my eyeball. It feels thicker.
- B5426 Burning, itching, redness and dry.
- B5571 Like they are sticking to my eyeballs. If I fall asleep with them in I have burning.
- B5572 They feel gritty like sand. At night they won't come off, and they get stuck on my eyes it hurts. They don't feel lubricated.
- B5649 Mainly just they feel like they get really dry. It feels like that when I blink that they feel like they are going to fold down. When the wind hits them it is like a burning sensation.
- B5813 Very dry and occasionally I get something underneath them, and I have to take them out to clean them. If I have slept in them they are dry.
- B5818 Dry and scratchy. They are normally comfortable.

- B5822 They either feel like they are stuck, or that they are moving too much. You have to blink more often.
- B5857 Dry sensations like they are stuck. Sometime I have problems removing them when they are dry.
- B5957 Scratchiness and like there is something in my eye like a lash or dust.
- B6028 Burning. An annoying type of sensation. It's not really painful.
- B6054 No problems really except when one ripped.
- B6237 They itch especially around the eyelids.
- B6247 They are dry, and my vision is cloudy. They feel like they are sticky. I can't blink fully.
- B6399 Burning and stinging. Itchy.
- B6572 The lens feels dry and they feel like they are sucking on my eyes.
- B6672 Like a tight dry feeling you almost feel like they are sticking to your eyeball.
- B7497 I don't feel anything uncomfortable. I only have had problems finding one that fit.

C. Question Three

1. At what time, during the day, have you experienced no problems with wearing contact lenses?

A1781 When you first put them on.

A2497 Eight to two.

A2947 Earlier in the day is better.

A3570 Probably 10 minuets after putting them in through to the next 5 to 6 hours.

A3843 Pretty much all the time until I fell its time to take them.

A4645 Afternoon.

A5045 They feel the best in the morning in the early hours of the day because they are still moist, and have not dried out yet.

A5572 Usually during the day. After I adjust to getting them on in the morning.

A5623 When I first put it on in the morning.

2. At what time(s), during the day, do you notice your contact lenses starting to bother you?

B1570 About nine o'clock at night.

B1726 Mainly when I am in extremely dry environments. Around eight at night.

B1727 Mostly at the end of the day.

B1728 More in the evening.

- B1767 It varies depending on the situation.
- B1903 Nine to eleven at night.
- B2015 Probably early evening after I have had them in all day.
- B2031 Later after eight thirty.
- B2314 Right before I go to bed.
- B2430 Later in the evening when I get off of work about five to six.
- B2570 At nighttime. About eight.
- B2719 After eight or nine at night.
- B2818 Mostly in the afternoon. Definitely at night.
- B2891 They never bother me.
- B2922 Probably about three to four in the afternoon.
- B2947 Evening. Later during the two-week period.
- B2978 Mid-day they dry out.
- B3004 They really don't bother me.
- B3009 At nighttime when I am about to get ready for bed.
- B3109 Toward the end of the day if they do bother me.
- B3119 Usually during the end of the day.
- B3367 Early in the morning when I put them in they are still getting use to my eyes.
- B3467 At the end of the day. By the end of the day they really bother me. It comes to a point where they really bother

me, and then I start to notice them.

B3468 Later wearing time in the evening. Anytime when I am staring a lot at the computer.

B3550 Late into the night around eleven at night they will start to feel a little dry.

B3560 Ten minutes after I put them on and then on and off through out the day.

B3571 Towards the evening. I can wear them the same amount of hours each day.

B3853 If I stay up late. I can get the same amount of time each day.

B4124 When I put them in in the morning there is a little stinging then goes away after I blink a few times.

B4164 Closer towards the evening when I have had them in longer for more than ten hours.

B4375 Really never. Unless they are getting old then they bother me in the middle of the day and at night.

B4397 Later at night. I have had them in for the same amount of time.

B4445 Towards night. About nine or ten at night.

B4497 When I am at work. About half way through my workday.

B4613 Usually about the end of the day. When I get tired no

matter what time it is.

- B4665 Late in the afternoon they get a little dry.
- B4880 Late at night. A little bit before I take them out.
- B4975 Around seven at night.
- B5013 Late in day. In the evening.
- B5027 Nine or ten in the evening.
- B5028 It depends on the day. Sometimes they don't bother me at all.
- B5029 Evening. Same amount of wear each day.
- B5035 Later at night. The end of the day. If they have been in longer than ten hours.
- B5037 It would be after a real extend period of time. Longer than sixteen hours.
- B5063 Toward the afternoon about two or three I have to put drops in. Again at about eight or nine I have to use drops again.
- B5303 On a normal day about ten hours, but at work on the computer I can go about three.
- B5373 After my nine hours.
- B5426 Like after school. At the end of the day.
- B5571 In the evening because I am sitting under the fan.

- B5572 In the afternoon after I get home from work. About six or seven.
- B5649 In the afternoon. At work when I keep my eyes open too long. Not so much at night.
- B5813 Evening. About eight at night about twelve hours.
- B5818 Not at all really. They don't usually bother me.
- B5822 Towards the end of the day.
- B5857 Later in the evening. Depending on the weather it can be earlier.
- B5957 Later at night seven or eight at night
- B6028 I guess nine or ten at night. They are okay for about twelve to thirteen hours.
- B6054 At night.
- B6237 When I first put them in in the mornings for about ten minutes and late at night.
- B6247 Maybe more after I get out of the shower because the water will dislodge them.
- B6399 At night most of the time. When I am up late typing a paper.
- B6572 About nine at night.
- B6672 Usually at the end of the day. When I get tired and the lenses age I can use them less.

B7497 At night, but if I take them out and clean and they are fine.

D. Question Four

1. At what time, during the day, have you experienced problems with wearing your contact lenses?

A1781 Eight to nine o'clock at night

A2497 Later if I wear them say nine to ten o'clock at night with out anything telling me that they're ready to come out.

A2947 End of the day. Late evening when I'm real tired and my eyes I can tell that there is a change in my tear structure so that they feel thicker and it feels like my contact lenses aren't getting as wet as they need to. Also late in the two week period.

A3570 During the afternoon hours.

A3843 Any time I'm out doors and it's windy. Other then that they fell fine from the beginning until the end.

A4645 Morning and evening.

A5045 Evening, because that's when they get so dry. I have to use more re-wetting drops in the afternoon.

A5572 Usually at night and by then my eyes are getting dry.

A5623 At night after long hours.

2. In which environments are you most likely to be unaware that you are wearing contact lenses?

- B1570 Indoors. I don't feel like I have them in at all.
- B1726 I really don't know. When I don't have to stare. Anytime
I am engrossed in something.
- B1727 At home when I am relaxed.
- B1728 I never realize that I have them in unless I have a problem.
- B1767 I don't notice it unless I have seasonal allergies.
- B1903 Most all the time in general. I never think about it.
- B2015 In a controlled environment where it is not real dry.
- B2031 Everywhere unless there is something bothering them.
- B2314 Anywhere. I have never got to the point that I was
unaware that I was wearing them. I just don't focus on it.
- B2430 At work I don't notice them in. When air is not rushing at
my face.
- B2570 Indoors. In general.
- B2719 Usually when I am doing something physical I am not
thinking of them.
- B2818 I am aware of them all the time. Right when I put them in
they feel the most comfortable.
- B2891 Pretty much everywhere.
- B2922 Right after I put them on at home.
- B2947 Anytime they are not irritating. Inside or if it's not real
windy outside. During the winter. Just dry air.

- B2978 Once they are in they are comfortable.
- B3004 Really anytime except for Spring with all the pollens in the
air.
- B3009 When I am inside regularly during the day.
- B3109 Most of the time for me. Most of the time I forget that I
have them in. Unless I am wearing toric lenses then they
seem to dry out faster.
- B3119 High humidity I can't feel them. A nice normal regular
place.
- B3367 When I am at school not doing any physical activity. Or
when I am relaxing.
- B3467 Outdoors I notice them more. So indoors I am better.
- B3468 When I am outside especially if it is a nice day. Earlier in
the day it does not matter where I am at it is better.
- B3550 At work and when I am driving in the morning. When I
am at home relaxing. Pretty much all the time.
- B3560 When I am doing something where I don't think about
them like walking.
- B3571 At home they are fine.
- B3853 Air-conditioned. I am really comfortable in them so I
think that I am comfortable everywhere.
- B4124 Most all of them.

- B4164 I don't really feel my contacts during the day.
- B4375 Mostly everywhere.
- B4397 I don't feel them if unless there is a problem. Smoke filled environments.
- B4445 Just driving or at the movie theater.
- B4497 When I am in doors doing stuff around the house.
- B4613 At school.
- B4665 In a dark room when I am working.
- B4880 All the time I really don't notice them unless I have a problem.
- B4975 Just areas with no wind. They don't bother me indoors. I don't really pay attention to them too much.
- B5013 When I am outside, or when I am not looking at something close up.
- B5027 I have worn contacts for so many years really that I am not much aware of them during the day at all. It is many just during the evening that me eyes feel tired.
- B5028 Meetings. When I am occupied with other things.
- B5029 At home early in the day.
- B5035 I am usually unaware that they are in.
- B5037 I am fine everywhere.
- B5063 Just normal activity. When I work or do my normal

routine.

- B5303 Just about all environments except for the computer or reading small print for extended time periods.
- B5373 Usually I don't feel like I have contacts on when I put on a new pair in. I can't even tell that I am wearing contacts no matter where I go as long as they are a new pair.
- B5426 I guess all times like at school or church.
- B5571 I can't tell that they are in just as long as I don't have dirt from the wind. They are comfortable pretty much everywhere.
- B5572 When they are brand new I don't notice them at all. No matter where I am at.
- B5649 When I am doing stuff like basketball or running. For the most part I have gotten pretty use to them.
- B5813 Probably when I am working or busy.
- B5818 I have to be careful swimming. Indoors and outdoors I am fine.
- B5822 At home or outside if it is not real windy. I need to wear my sunglasses when I am driving.
- B5857 Office buildings if I am busy.
- B5957 In my classroom they do not bother me at all.
- B6028 It would be that they have not been in very long. If I am

outside and it is not very bright.

B6054 All environments.

B6237 Like office environments. I really don't notice that they are there most of the time.

B6247 Unless I am in one of the problem areas I am unaware of them.

B6399 I really don't think about it that often anymore.

B6572 Normal moister. In the office under normal conditions.

B6672 Playing sports.

B7497 Socially. I wear them so much that I don't think of them.

E. Question Five

1. In what environment(s) are you least likely to experience problems?

A1781 In a controlled environment under the air-conditioner.

A2497 Inside.

A2947 One that's not too cold like the air-conditioning is too high. Because the air will be drier. So if it's warmer, or um but not like central heat not like during the winter. It's just an average ambient temperature like the humidity hasn't been decreased.

A3570 Indoors because it's more controlled setting. All temperatures are fine.

A3843 Indoors I have no problems like at work. If I do house
work I might have problems.

A4645 Outside.

A5045 Inside. In an air-condition environment free of allergens or
pollutants. No problems in this area of the country close to
sea level.

A5572 When the weather is perfect and nothing is blooming.
Inside because there is no wind and allergens floating
around and if there is enough humidity.

A5623 Indoors. Regular temperature.

2. Can you please describe the sensation(s) your eyes feel while you are
comfortably wearing your contact lenses versus when you are not wearing
contact lenses at all?

B1570 I can't see. When I wear them for a long period of time,
and I take them out they are like ah I needed that out.

B1726 My eyes feel a little more relaxed and a little moister.

B1727 No, I don't have a difference at all.

B1728 I have never notice anything like that.

B1767 It feels the same as long as I am not experiencing any
allergies.

B1903 I could not tell you any difference.

B2015 The only difference would be in the vision. The comfort is

the same.

- B2031 There are times I can't tell that they are in. Sometimes it feels good to take them out.
- B2314 I don't notice a difference, except for the vision.
- B2430 My eyes dry out quicker when I have the lens in, but other than that I don't really notice a difference.
- B2570 My eyes feel like they can breathe more.
- B2719 It feels like its getting more air on it, and it's not as constricted.
- B2818 Not necessary. Unless I am having some discomfort.
- B2891 They feel the same.
- B2922 I can feel something under my lid. I have always known that they are there. I feel like I have a line under my eye.
- B2947 Feel the same between in and out.
- B2978 Vision would be worse. No other difference.
- B3004 Other than the fact that I would not be able to see. Really that is the only thing that I would not be able to see across the room.
- B3009 Not really. My contact lenses have been really good. I haven't really noticed a difference. They feel like they can breathe more.
- B3109 It's not a huge difference. If one where to come out I

probably would not feel it.

B3119 Not really when they are comfortable I really don't notice that much.

B3367 At the end of the month I tell my mom that I think that I need new contacts. It tends to stay the same, but at the end it is a little uncomfortable.

B3467 I can tell the lenses are in there. Definitely a lot less dry with them out.

B3468 I am always aware that I have contacts in versus not having anything at all, but it is so minimal that I really don't notice it. My eyes tear more when I take them out.

B3550 Not really unless I am having problems.

B3560 It feels like there is nothing in my eyes like my eyes can breathe more.

B3571 Really no difference when they are new. The only thing is when I blink I can feel them slightly.

B3853 If I don't wear them I have a headache. I feel more comfortable with them in.

B4124 I don't feel any difference.

B4164 I don't think that I would be able to tell a difference unless I have been wearing longer than ten hours.

B4375 I don't really know if I can tell a difference.

- B4397** When I have contacts in my eyes stay moist more than when I don't have them in. My eyes tend to dry out faster.
- B4445** Other than just rubbing my eyes I can't tell that they are in there. There is little relief when I take them out, but other than that I can't tell that they are in there.
- B4497** Depends on the time of day. They feel more relaxed and a little more comfortable.
- B4613** I don't know other than the vision. It feels kind of good because you can shut your eyes and there is nothing there.
- B4665** I really can't tell a difference.
- B4880** I can't tell a difference except my vision. I can't tell a difference in the comfort.
- B4975** There is a little difference. They feel moister.
- B5013** There is no difference. When they are comfortable I don't even feel like I have them on.
- B5027** My eyes feel like that they can breathe more, and they feel moister when I have them out.
- B5028** When they feel fine I don't even notice a difference. They feel a little moister when they are not in. A halo effect at night when I am driving.
- B5029** More comfortable with them out. My eyes don't feel tired.

- B5035 I have been in contacts so long that I am usually more comfortable in my contacts. They would feel the same if they are in or out.
- B5037 I would have to say that my eyes are more strained with them out.
- B5063 I can't tell any difference. When they are uncomfortable I fell like they can breathe more.
- B5303 I don't feel any difference at all.
- B5373 I can't even tell that they are on. I have to squint to see. They more refreshed and cool when I don't have them in.
- B5426 When they are in you can feel that they were in.
- B5571 I can't tell that they are in unless that they rotate. I could not tell a difference if I was to take them out.
- B5572 They feel moister when I take them out. I wear them so often that when I take them out my eyes are almost more comfortable with them in. Because I think that they have been covered for so long. I can feel stuff on them. Sometimes they feel worse when I take them out.
- B5649 In the mornings they almost feel a little heavy. At night when I take them out they feel a little moister when I am not wearing them. The wind use to not really bug me at all when I didn't have them in.

- B5813 Bright lights will bother me at night if I have them in. I
feel like a little pressure around my eye with them in.
- B5818 Not that I am aware of. They are very comfortable. I
don't notice a difference.
- B5822 I am usually somewhat aware that they are in. They
usually do feel better when they are not in.
- B5857 Occasionally I will have a lens that feels like it is off.
They feel moister like they can breathe better.
- B5957 I really don't notice a difference.
- B6028 I can tell that they are in. They feel like an added layer.
- B6054 You can feel more air around your eyes. I feel like the
contacts protect your eyes. They help me cut onions
without crying.
- B6237 When I take them out they feel like they are more
comfortable, but there is not much of a difference.
- B6247 I am oblivious to the fact that I can tell a difference. I
could lose my contact and I could not tell that they are out.
They feel natural to me.
- B6399 They do feel a little moister. If they are dry they are harder
to remove.
- B6572 If they are comfortable I can not tell a difference.
- B6672 Hardly a difference. I don't even know that I have them in

right now.

B7497 No noticeable difference. If anything they feel better in.

F. Question Six

1. In what environments are you most likely to experience problems?

A1781 Outside, dusty, windy environment.

A2497 Windy. More of a dusty area in the country or something.

A2947 Place where the air-conditioning is too high. Or in the middle of the winter when the heat is on because it gets real dry. The air dries them out. Or if I'm out and about outside and there is a lot of dust or even if there are a lot of allergens. Seasonal allergies too can my eyes seem like they film up faster too. Around late Spring.

A3570 Intense smoke field environments, dusty environments.

A3843 The beach, outside.

A4645 In the office.

A5045 High altitude areas and environments that are really dusty or windy. In a car with the windows down. In a hot climate for a long period. Also anytime when I am at the beach or at the pool. When it smoky my eyes get irritated

A5572 In Spring and Fall when everything is blooming, or if it is really windy outside I have to protect them by wearing

sunglasses or something.

A5623 Driving at night with the A/C on.

2. At what time(s), during the day, are you unaware that you are wearing contact lenses?

B1570 The middle of the day and in the morning.

B1726 Earlier in the day. From the time I put them in until late afternoon.

B1727 In the morning after I put them in after the initial comfort starts.

B1728 Other than when I first wake up, I don't really notice them through out the day.

B1767 Most of the time if not all the time.

B1903 All day until late at night. Then when I am really tired it might bother me.

B2015 In the morning after I put them in, and in the afternoon.

B2031 The middle of the day when I am at school I am engrossed in something.

B2314 All day long especially while I am at school.

B2430 In the morning when I first put them in and for the first four hours. After that I start to notice them.

B2570 The middle of the day.

- B2719 Usually right as I put them in until noon.
- B2818 I am always aware that I am wearing contact lenses.
- B2891 All of the time.
- B2922 One to three hours after placing them in.
- B2947 Pretty much anytime they are not irritated.
- B2978 All day long after I put them in they are pretty comfortable.
- B3004 Pretty much all day.
- B3009 Around noon and mid-afternoon.
- B3109 Most of the day morning and afternoon.
- B3119 When I first put them in through out most of the day.
- B3367 They feel comfortable most of the time.
- B3467 Right when I put them in.
- B3468 In the morning and early afternoon.
- B3550 When I first put them on in the morning up until I drive home from work.
- B3560 The middle of the day.
- B3571 All day up until seven at night.
- B3853 Throughout the day I feel perfectly fine with them.
- B4124 All day.
- B4164 Usually after a few minutes after putting them in they are comfortable for a good ten hours.

- B4375 At school. When I am concentrating on something.
- B4397 Pretty much any point after the morning. Then I don't think about them.
- B4445 Just during school hours or at work. Really all the time.
- B4497 The first few hours after I put them in.
- B4613 Just during the afternoon and early evening.
- B4665 Pretty much all the time. Except the problem areas.
- B4880 For the first five to ten minutes I can tell that they are in after that I can't tell that they are in.
- B4975 All day about twelve hours. For a couple seconds they sting after I put them in.
- B5013 In the morning depending on where I am at. Anything that is not right up in my face I am unaware that I am wearing them.
- B5027 Well, I know that I have them on so I am not unaware of them, but I don't have any negative feelings of wearing them during the day. I guess that I am not focusing on them so I guess that does mean that I am unaware of them. Occasionally I have problems.
- B5028 Most of the day.
- B5029 Early.
- B5035 Very early morning to the afternoon.

- B5037 Most of the time.
- B5063 Most of the day I don't have any trouble.
- B5303 Mostly all day.
- B5373 Around mid morning about ten.
- B5426 A couple hours after I put them in.
- B5571 When I am at work.
- B5572 Usually during the day during normal working hours.
- B5649 In the morning when I first start working I don't think about them. When I am busy.
- B5813 Mostly all day. Anything where I am doing something physical.
- B5818 Never. I can't really feel them.
- B5822 An hour after I first put them in. After that I pretty much know that they are in.
- B5857 Mid morning to about lunch time I am fine.
- B5957 From about nine in the morning to about five or six in the afternoon.
- B6028 In the morning up until the afternoon.
- B6054 I have to look in the mirror to make sure that I have them on. I have lost them before and not notice it.
- B6237 Most of the time.
- B6247 All day.

- B6399 In the morning when I have just fixed them.
- B6572 Thirty seconds after I put them in until nine at night.
- B6672 In the morning and early afternoon.
- B7497 Always.

G. Question Seven

1. Through out the life of a pair of contact lens, can you tell me if there is any noticeable difference in how your eyes feel?

- A1781 I can't tell because sometimes I have to stop and think how long it has been.
- A2497 Yea I guess a little bit, it's about the two week mark if I go a few days over they start burning a bit more. Not that it's real bad but it's a little more than normal.
- A2947 They get more tired and they get more irritated earlier in the evening the longer that I wear them. So later in the two weeks.
- A3570 Towards the end of the life of the contact I can tell that I starting getting some deposits or something on the lens because it's just not the same as when I first put it on. I can tell that this is getting old.
- A3843 Only when it's windy. It doesn't matter if it's an old pair or a new pair. I can't usually tell a difference.

A4645

No.

A5045

Sometimes. Not every month. Sometimes I go the thirty days and not have any problems and I'll be fine, but there are times that I am fifteen to twenty days in to it and I'll notice them getting drier faster.

A5572

Yes, when you first put these on its like ahhh. They feel great and after a couple of weeks or so I try to make them last longer. They start getting scratchy like sand and I try to clean them and make them last as long as they can, but they finally get to a point where they don't feel right, and they kind of hurt. So I just throw them away.

A5623

I can't really tell if I throw it out on time but if I go longer it's like a foreign body sensation.

2. Through out the life of a pair of contact lenses, do your eyes remain comfortable or do you notice a difference in the sensations that your eyes experience?

B1570

I do notice a difference as they get older. The earlier at night it gets more uncomfortable. As I got older it made difference. I can't wear them as long

B1726

The time shrinks. And if its been long enough I can tell when I first put them in.

B1727

They remain comfortable. I throw them away on time.

- B1728 I guess that because I change them more frequently they are not in long enough. They always seem fresh.
- B1767 Not really. The vision might be a tad clearer.
- B1903 If it begins to bother me I just throw it out.
- B2015 Usually when it gets close to two weeks they start getting really uncomfortable feeling. I usually throw them away. No difference from when I first started wearing them.
- B2031 No. They are usually good. I throw them away on time.
- B2314 It stays the same the whole time.
- B2430 I wear the monthlies. The last week is just uncomfortable. The time that I can comfortably wear them each day shrinks.
- B2570 They are usually pretty comfortable. Just towards the end you can tell that you need to take them out. It used to be a couple of hours when I first started wearing them, but now it is much longer.
- B2719 When they were new, I could wear them longer.
- B2818 It doesn't matter if they are new or old they feel the same.
- B2891 Sometimes I can tell that I need to change them because they get a little foggy.
- B2922 They remain comfortable. It feels the same two months after I started wearing a new pair.

- B2947 Yea I notice a difference. It's later in the two-week period
the last three or four days late at night I will notice it
progressively getting irritating to my eyes.
- B2978 They are the same. When I first started wearing them it
was getting use to them now I can't tell that they are in.
- B3004 When it is about time to change them out my eyes will be a
little bit drier. My eyes will water a lot. When they don't
feel comfortable going in, I know its time for a new pair.
- B3009 It stays about the same. If I wear them a little bit over the
time that I am supposed to, I can tell they need to come
out.
- B3109 Towards the end, they are foggy and they are not
comfortable and they dry out faster.
- B3119 Once I get to the end of fourteen days I know its time for a
change. It's earlier in the day that I notice that they are in.
- B3367 It just feels like that there is not anything in my eye.
- B3467 Question does not apply.
- B3468 I think that thorough out the course of the day, it remains
about the same. I am not that uncomfortable through out
the fourteen days to the point where I don't think that I can
make all the way to day fourteen.
- B3550 I really can't tell a difference.

- B3560 Question did not apply.
- B3571 I notice that they dry out faster. I have to blink more often and use re-wetting drops more often. The time shrinks per each day.
- B3853 Towards the end the vision gets blurry. As soon as it is time to change I change them right away.
- B4124 No, they are the same I have the same amount of time that I can wear them each day.
- B4164 Sometimes towards the end of the month my vision seems blurrier.
- B4375 They will start hurting a little more. As time progresses the will hurt earlier in the day.
- B4397 Most of the time they are pretty comfortable unless I keep them in for an extended period of time. Maybe an extra week I can't keep them then in as long.
- B4445 After the allotted time that they give, they kind of get itchy half way through the day. They feel the same the whole day.
- B4497 I notice that I don't see quite as clearly and they are not as comfortable. I have to use drops more often.
- B4613 I can tell that they are getting older. The fourth week you can tell that they are pretty uncomfortable. Vision

becomes blurrier.

- B4665 Question did not apply.
- B4880 They feel the same up until the two weeks, but if I go longer I can't see as well.
- B4975 Towards the end of the two weeks I knew that they need to be thrown away. They felt the same all day.
- B5013 I definitely notice a difference.
- B5027 You notice the sensation when you get a new pair and put them in. As you gradually wear them over the month it is gradual. I don't really notice it. The time shrinks as the month goes along that you can comfortably wear it.
- B5028 Towards the end the left felt really scratchy towards the end of my last cycle. I would take it out sooner when I got home.
- B5029 It starts getting filmy. I can wear them the same amount the whole day through.
- B5035 If it is toward the end of the cycle they are drier and itchy. I have to take them out earlier each day.
- B5037 They remain pretty comfortable until they get dirty and you can't clean them. I can wear them longer now than I could when I first started.

- B5063 I have more discomfort at the end and my vision is blurred and I caught myself rubbing my eyes more.
- B5303 After about twenty-two to twenty-five days I notice a small difference, which really is not uncomfortable. I don't think that the time that I can wear them per day shrinks.
- B5373 They remain comfortable up until the eight to nine hours. They start itching or my eye will get red around the lid. The time gets smaller that I can wear them towards the end.
- B5426 When it gets old it would tear. The time would shrink that I could wear them.
- B5571 I have never had a pair get old enough to notice that. When I first stated wearing them I have had problems with them feeling too thick.
- B5572 There is a difference when I get past that two-week mark. They get harder. They may feel good when I first put them in, but by the end of the day I need to change them out because it's not even the end of the day.
- B5649 I kind of notice that they feel a little different. They are a little less comfortable at the end then they are at the beginning.

- B5813 Pretty much they remain comfortable. Towards the end of the month I can tell that I need a new pair because they start to feel rough.
- B5818 Toward the end of the cycle they are not as comfortable, and they feel a little drier. I usually change them out at that point. I can wear them longer now than I could when I first started.
- B5822 The older that they are the less that I can wear them. I can not wear them as long now as I could when I was younger.
- B5857 Usually I'm pretty good about changing them on time. Usually they are just as comfortable at the end as they were in the beginning.
- B5957 I don't notice a difference.
- B6028 I don't notice much difference in them now, but in the past I could tell that they need to be replaced.
- B6054 They feel a little drier. They feel thinner in the beginning.
- B6237 There is a difference. Towards the end they are not as comfortable.
- B6247 Near the end they feel like they have a film on them. My vision becomes blurry.
- B6399 After I put them in they are perfect up to about three months. At that point they start to get a little dry.

B6572 The last couple of days my vision starts to drop. Comfort is really never a problem with me. The last two or three years I have had a lot of problems with dryness.

B6672 At the end of thirty days the time that I can wear them shrinks

B7497 Question did not apply.

H. Question Eight

1. What do you like about your contact lens care regimen?

A1781 I like not having to use the enzyme cleaner, do the rubbing of the lenses. I like just putting them in the case.

A2497 I like the no rub. I just throw them in there.

A2947 I like the fact that what I use is no rub so it's real easy. I can just take them out and put them away and, at the end of the two weeks I can just throw them away and get a new pair.

A3570 It's easy. Now its just take them put them in the holder and put drops in there and pretty much done.

A3843 It's easy to use. Convenient. One step. Not having to remember what you need to do that week.

A4645 It keeps my lenses feeling about the same.

A5045 I love the Opti-Free No RubTM. I like having one solution

instead of two or three.

A5572 Now a days it's a piece of cake because I use the no rub.

A5623 I like it, it's convenient.

2. What do you like about you contact lens care regimen?

B1570 Its very easy and low maintenance. I use the same solutions.

B1726 It's easy it does the job.

B1727 I feel like it cleans the contacts really well.

B1728 These I love because it is so easy. You can clean these a lot quicker.

B1767 I don't have to take them out. I love it.

B1903 It's easy and quick.

B2015 I like to take them out every night because the contact lenses seem to last longer than the extended pair.

B2031 It is convenient. It makes sure that there is nothing on there.

B2314 I like it just fine. There is nothing wrong with it. It keeps it clean and it keeps taken care of them.

B2430 I like that I don't have to rub the lenses to clean them and I don't have to use the enzyme.

B2570 It's easy.

B2719 They are easy to put them in and take them out.

- B2818** It is easy. It has progressively gotten better.
- B2891** I like not having to wear glasses.
- B2922** It is so easy.
- B2947** It's really easy because you use that one thing. You don't have to worry about anything.
- B2978** You can see the protein drops.
- B3004** It's simple and quick.
- B3009** It's really easy and fast to get done. I don't have to sit there and do a bunch of steps.
- B3109** That I don't have to do the enzymes, and it's just one solution.
- B3119** Noting really because I use to be in a daily wear.
- B3367** It feels much better because they are clean.
- B3467** Question does not apply.
- B3468** Its one of the only solutions that does not sting when I put the lens in my eyes.
- B3550** I think that it helps me wear them longer than the three months.
- B3560** I like contacts better than glasses.
- B3571** It is easier for me now because they are disposable.
- B3853** It's easy for me. It's pretty routine.
- B4124** I like the multipurpose solution.

- B4164** It is easy to use. I don't have to rub. I feel like I can wear them much longer.
- B4375** They are easy.
- B4397** It's pretty straightforward and simple and easy to keep clean.
- B4445** I like it. There has been a few times that I forgot to screw the cap back on and they have stung the next day.
- B4497** Once I do it I can see.
- B4613** I don't know really what to compare it to. It is quick and easy.
- B4665** I can throw them away daily.
- B4880** It is easy. It is convenient.
- B4975** That I don't have to wear glasses, and that it is fairly quick.
- B5013** I like that they have the multi-care thing so I don't have to do so much to them.
- B5027** It's very easy. I use a one-stop solution.
- B5028** I like the fact that it is a one-step process.
- B5029** I guess not having to wear glasses.
- B5035** It is so easy.
- B5037** It is easy to use. It is one solution
- B5063** It is easy. I don't feel like I have to do anything. It is a very quick cleaning time.

- B5303 It is two minutes to take care of my lenses. I like the Express™ and the Supra™.
- B5373 I don't have to rub them. It is easy.
- B5426 It gave me something extra to do, which I didn't like.
- B5571 I love it I don't have to use fifty products to take care of my lenses.
- B5572 I love it. How much easier can you get? The same solution.
- B5649 I like the fact that I can see. They are more work than I thought that they would be. It is a pain to take care of them everyday.
- B5813 I like feeling like I clean them. And that I can store them in a cleanser.
- B5818 I like the kind that you take out every night because I feel like my eyes can rest at that point.
- B5822 It cleans them very well. All in ones don't work for me.
- B5857 It doesn't take much time. I like just one solution. It is easy.
- B5957 I like that it is easy compared to my husbands. It is a one step solution. That you able to have more than one pair on hand.
- B6028 It is simple. I just have to use one solution and it doesn't

take me long to do it.

B6054 That they have sensitive eye solutions. You have so many varieties.

B6237 It's pretty straightforward. I can tell if I have done it right.

B6247 It is no fuss no muss. I can just leave them in for a week at a time.

B6399 I don't take care of them really at all. I like how you got the left and right on the case. It is down to a fine science.

B6572 It is easy. It is a no brainer. It's all in one.

B6672 Every year they make it easier and easier.

B7497 It is very easy because I throw them away daily.

I. Question Nine

1. What do you dislike about your contact lens care regimen?

A1781 I don't dislike anything.

A2497 I don't really have any complaints about any of them.

A2947 I guess kind of, I rinse my contacts with saline before I put them in my eyes because my eyes are highly sensitive and if I do directly with the multipurpose solution my eyes have a tendency to if they are already irritated like if I had a ruff night sleep or something they make my eyes sting.

Where if I use saline they won't make them sting as much.

No effect on vision. Makes my eyes water real fast.

A3570 I don't really have anything.

A3843 Nothing really.

A4645 I have to do it every night.

A5045 I dislike that they dry out, and have to put drops into my eyes. I dislike taking them out. I don't like trying to put them in my eye.

A5572 Nothing it's really quite easy.

A5623 Nothing.

2. What do you dislike about your contact lens care regimen?

B1570 The solution I use if I take out my contact lenses and want to put them back in I can't because they burn.

B1726 The one that I am using now I am not sure if it is getting all of the deposits.

B1727 It takes longer than most regimens.

B1728 I guess that there is nothing.

B1767 Nothing really.

B1903 Finding the marks to line it up to put them in your eyes the right way.

B2015 You have to clean them every night.

B2031 There is nothing really.

B2314 I don't dislike anything about it.

B2430 I don't like having to rinse the lens case after I use it.

B2570 I don't really dislike anything.

B2719 If I am falling asleep I feel like I have to take them out.

B2818 That I have to take them out so early.

B2891 Changing them. Taking them out at night. I liked when I
could sleep in them.

B2922 Nothing. It does not bother me at all.

B2947 Having to wear contacts.

B2978 Having to do it daily.

B3004 Nothing it's quick and simple.

B3009 I don't have any dislikes.

B3109 Noting that I really don't dislike. I am pretty happy.

B3119 The fact that I have to do it.

B3367 I have to do it a lot I have to clean it a lot, and some times I
don't do it.

B3467 Question does not apply.

B3468 Nothing.

B3550 I hate having to put them in the thing for three to four
hours, and when you want to go somewhere you can't just
clean them and go.

B3560 Putting them in, and that they bother my eyes.

B3571 That I have to clean them at all.

B3853 Nothing really except having to take them out every night.

B4124 The make the holders way too big so that you use way too much solution.

B4164 I can never put the H₂O₂ solution directly in to my eyes with out neutralizing it.

B4375 Really nothing.

B4397 Having to take them out and put them back in.

B4445 If the solution is in there for more than one day you can feel it.

B4497 Putting them in the morning because you have to allow your self-extra time to do it.

B4613 I really don't have any complaints, but maybe stay moister long.

B4665 Noting really.

B4880 Sometimes I lose my case.

B4975 It is one more thing to do. I can't think of a major dislike.

B5013 That I have to wear them.

B5027 It's very easy I use a one-stop solution.

B5028 Nothing, I mean you have to put with something.

B5029 It takes time.

B5035 Nothing. Just that I have to wear them at all.

B5037 That we need them. Other than that I have no complaints.

B5063 Nothing really and it is a whole lot better than wearing my
 glasses

B5303 I don't have any dislikes. Before the Express™ I would
 have to use a lot of saline to rinse the lenses.

B5373 Noting that I dislike about it. The solutions that I have
 used so far have been good.

B5426 It takes a lot of time to do.

B5571 I don't. I love it. Especially coming from fourteen years
 ago.

B5572 In a perfect world I would not have to do anything. It's
 pretty easy now a day, and there is nothing really except
 the cost.

B5649 You have to take care of them everyday. Sticking my
 finger in my eye is one of my favorite things to do.

B5813 I can't take the little vial in my over night bag with out it
 leaking. I don't like having to rub them.

B5818 Not really anything. I am a very satisfied customer.

B5822 It is a little more time consuming than throwing them in a
 case.

B5857 There are times that I feel like I need to take them out, but
I can't because I don't have the solutions with me.

B5957 That you have to do it. Being able to tell if they are inside
out.

B6028 I don't really dislike anything because it is about as simple
as you can get.

B6054 That you have to throw them away. That they wear out.

B6237 You have to give it enough time for it to work. There is
not a quicker way to do it.

B6247 Nothing because it is easy.

B6399 I like that they came out with the night and days so that I
don't have to take them out.

B6572 Nothing it is so simplistic. I like the two-tone case.

B6672 Just having to do it. It is just one more thing that you have
to do.

B7497 Be able to find lens plus in a small can.

J. Question Ten

1. If you could change anything about the contact lens care solutions that are presently on the market, what would it be?

A1781 I would not change anything about the Opti-Free™.

A2497 I don't. I don't know if I would make any changes. I don't really have any complaints.

A2947 If they could keep my contacts from getting quiet so irritating toward the end of the two week period. If they could keep my contacts feeling brand new.

A3570 I really don't have anything for that answer.

A3843 Something like the solution indicating how the cleaning of the lens is. Like when you need to replace the lenses.

A4645 Make it where you could skip a few days between cleaning.

A5045 You would not have to rinse them at all, not rising after putting in the solution.

A5572 If they could design one that could keep moister in your eyes longer it would be nice.

A5623 The packaging.

2. If you could change anything about the contact lenses care solutions that are on the market today, what would it be?

B1570 Maybe be cheaper.

B1726 I would like them to be the same comfort through out the day. Something to do better with the hydrating part.
Better deposit removal.

B1727 The price.

- B1728** I never tried the other ones to know if there is much of a difference. The cost of them.
- B1767** They could find a preservative that didn't irritate. A more gentle preservative.
- B1903** The size bottles that they come in. To fit in my purse better, and not run out as fast.
- B2015** You still get deposits even if you use the no rub. Better cleaning with out having to rub.
- B2031** Make it so that they are softer longer and they don't dry out.
- B2314** I don't' see anything worth changing. Because they are doing what they are supposed to do.
- B2430** Less price. More options for soft contact lens users.
- B2570** I don't think that there would be anything that I could think of.
- B2719** I like it when they make your eyes feel cooler.
- B2818** The price. If I go with something cheaper my discomfort is more.
- B2891** They work fine.
- B2922** I would like to try the no rub. They have solved my problem. I have just not been able to try it.
- B2947** If they could make them comfortable to the end of the two

weeks.

- B2978** Add the protein drops to the cleansing solution.
- B3004** Less expensive.
- B3009** I really wouldn't change anything. I like how it's set up.
- B3109** Some are too soapy and some sting.
- B3119** Nothing really it's easy enough.
- B3367** Every solution would be a type of no rub.
- B3467** Have some kind of prolonged effect with out blurring my vision.
- B3468** I would make them so that everyone was comfortable, and that they safe for everyone to use. Easy to use.
- B3550** I haven't had problems with any of them that I have used. Maybe cheaper.
- B3560** When you put them in they don't hurt at all.
- B3571** I don't think that I would change anything at all because it is so easy.
- B3853** Something for more sensitive eyes.
- B4124** I don't think I would change anything.
- B4164** Cheaper.
- B4375** I don't really know. Probably nothing that I could think of except make them last longer.
- B4397** They have already done it be making one solution do

everything.

B4445 Maybe a bigger bottle.

B4497 I am happy with what I use. They are pretty good.

B4613 I don't really know what I would change.

B4665 The fact that there are so many of them, and I don't know
if the price matters.

B4880 I like it the way that it is. Nothing really bothers me.
Sometimes I can't find littler travel size bottles.

B4975 Cheaper.

B5013 I haven't found anything that is great with dry eyes.

B5027 They could be cheaper.

B5028 They would stay hydrated longer so that you would not
have to use re-wetting drops.

B5029 Smaller bottles for travel.

B5035 I don't know I could give you an answer for that one.

B5037 Price.

B5063 Make them cheaper.

B5303 Nothing. I am real happy with what I have.

B5373 Take the cheap brands of the market.

B5426 Have the solution and re-wetting drops in one.

B5571 I think that it is pretty good now. Price or giving more
coupons.

- B5572 Something that would keep moister in my eyes all day long.
- B5649 Cheaper.
- B5813 Something that I would not have to rub.
- B5818 Not really anything. They price is fine for what it does.
- B5822 You could do it for five seconds and it would be clean.
- B5857 I would not change anything.
- B5957 Drop the price.
- B6028 Make it a different color. Make your eyes feel better, but to me it just feels normal.
- B6054 If they made them last longer.
- B6237 No preservatives.
- B6247 They are better now than they were years ago. I would not change anything.
- B6399 Nothing really. I can't complain.
- B6572 All in one including eye drops. Make it better at disinfecting.
- B6672 Make solutions that you can use to re-wet, store and clean in one.
- B7497 They're way too many of them.

K. Question Eleven

1. Any additional comments?

- A1781 Nothing.
- A2497 Nothing.
- A2947 I wish I did not have to wear contacts at all.
- A3570 The more I have worn them the easier it has become.
Great difficulty getting it in and take them out of the eye
when I started.
- A3843 Nothing. I like them enough to not consider lasik.
- A4645 No.
- A5045 I wish contacts didn't dry out as fast.
- A5572 Nothing.
- A5623 I've been wearing contacts for the past twenty yrs and until
lately I haven't had any problems.

2. Do you have any additional comments that you would like to make about contact lenses or this interview?

- B1570 No.
- B1726 Not really. I can't think of any.
- B1727 No.
- B1728 I love mine.
- B1767 Not really.

B1903	They help me play the piano because I can't do it with my bifocals.
B2015	Nope not really.
B2031	No.
B2314	No.
B2430	No. Nothing that I can think of.
B2570	No.
B2719	I like that the toric is easier to tell that it is inside out.
B2818	No.
B2891	No.
B2922	No.
B2947	No.
B2978	No.
B3004	No.
B3009	I like my contacts. I haven't had many problems. Unisol™ helps my eyes more than the Opti-Free™.
B3109	Nope.
B3119	Have one day bifocals that you can just throw away.
B3367	They are a lot easier to wear than glasses.
B3467	If I keep my eyelids clean it helps me with the comfort of my lenses.
B3468	No.

B3550 I am glad that they invented contacts.

B3560 No.

B3571 I wish that I didn't have to wear them.

B3853 Nope not really.

B4124 I don't think so. My contacts are very comfortable.

B4164 Nope I love them.

B4375 Nothing.

B4397 I have really enjoyed them.

B4445 They are great.

B4497 They have improved contact lenses so much, and I am
really happy with them.

B4613 They are good.

B4665 No, I think that we pretty much covered everything.

B4880 No not really.

B4975 Nope.

B5013 I am glad that they exist.

B5027 I am glad that they are here.

B5028 You have done a fine job, and I like them because I don't
have to fish around for my glasses.

B5029 No I feel like the advancements have been terrific.

B5035 Nope.

B5037 It's a great product.

B5063 I can't think of anything.

B5303 No I am fine.

B5373 No I think you did okay.

B5426 They are nice, but there are pros and cons.

B5571 I would like to have contacts that straightened out the curvature of your eyes that you could wear at night. Like braces.

B5572 No.

B5649 I think that they are good over all. I am pretty happy with them.

B5813 No.

B5818 I think that the freedom is great for the quality of life.

B5822 They need to come out with a daily wear high toric lens.

B5857 Not that I can think of.

B5957 I love the bifocals. The mono vision did not work for me.

B6028 I wish that they would make bifocal lenses in different colors.

B6054 I am glad that they invented them.

B6237 I love contact lenses.

B6247 I feel like it has liberated my life.

B6399 It has been very informative.

B6572 No.

B6672

No.

B7497

I am thrilled.

II. Question Statistics for Draft B Questions

Table 13. Question 1. In which environments do you experience uncomfortable sensations while wearing your contact lenses?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
Smoke	26	35.6
Wind/Windy/Breezy/Drafts	25	34.2
Dry/Drier environments	16	21.9
Outdoors in general	14	19.2
In the car with the air-conditioning/vents in the face	12	16.4
Starring at a computer screen/TV	11	15.1
Dust/Dusty areas	7	9.59
Under a fan	5	6.85
In a high pollen area	5	6.85
Air-conditioned environment	4	5.48
Windows down while driving in the car	3	4.11
Flying on planes	2	2.74
No environments	2	2.74
Low humidity	1	1.35

Table 14. Question 2. Can you please describe the sensation(s) you feel when your eyes are uncomfortable while wearing your contact lenses?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
Dry/Dryness	46	63
Itchy/Itchiness	20	27.4
Like there is something under my eyelid/Foreign body sensation	17	23.3
Burning/Burn	16	21.9
Sticky/Sticking to my eyeballs/stuck to my eyes	9	12.3
Scratchy	9	12.3
I have to blink more often	8	10.9
Stinging/Stings	8	10.9
Gritty	5	6.85
I have to rub my eyes	4	5.48
I need artificial tears/re- wetting drops	4	5.48
Not lubricated enough/moistened enough	4	5.48
They are shrinking on my eye/They feel tight	3	4.11
Vision is blurry/cloudy	3	4.11
Eyes are tired	3	4.11
Increased tearing/watering	3	4.11
Painful	3	4.11
Hurts	3	4.11
Keep my eyes shut longer	3	4.11
Like sand in your eyes	3	4.11
Grainy	2	2.74
I don't have problems	2	2.74
They feel like they don't fit right	1	1.37
Sore	1	1.37
I need to peel them off of my eyes	1	1.37
Pounding	1	1.37

Table 15. Question 3. At what time(s), during the day, do you notice your contact lenses starting to bother you?

Word or Phrase	Number of Occurrence (Frequency)	Percentage of Responses (%)
6:00PM-12:00AM	48	65.8
12:00PM-6:00PM	11	15.7
I can wear them the same amount of time each day	7	9.59
6:00AM-12:00PM	5	6.85
They never bother me	4	5.48
12:00AM-6:00AM	2	2.74

Table 16. Question 4. In which environments are you most likely to be unaware that you are wearing contact lenses?

Word or Phrase	Number of Occurrence (Frequency)	Percentage of Responses (%)
All places/Generally everywhere	23	31.5
At home/Relaxing	9	12.3
At work/Office environments	8	11.0
I don't notice them/realize that I have them in	7	9.59
Indoors	5	6.85
In a controlled environment/normal moisture	4	5.48
Outside	4	5.48
At school	3	4.11
When I am doing something physical/Playing sports	3	4.11
Areas with no wind	3	4.11
I am always aware of them	2	2.74

Table 17. Question 5. Can you please describe the sensation(s) your eyes feel while you are comfortably wearing your contact lenses versus when you are not wearing contact lenses at all?

Word or Phrase	Number of Occurrence (Frequency)	Percentage of Responses (%)
I do not notice a difference/They feel the same	31	42.5
I can't see/Vision is affected	8	11.0
My eyes feel moister with them out	8	11.0
My eyes feel like they can breathe more	6	8.22
My eyes feel more comfortable with them in	3	4.11
My eyes feel more relaxed with them out	2	2.74
My eyes dry out faster with them in	2	2.74

Table 18. Question 6. At what time(s), during the day, are you unaware that you are wearing contact lenses?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
I don't notice them the whole day	24	32.9
6:00AM-12:00PM	24	32.9
12:00PM-6:00PM	18	24.7
6:00PM-12:00Am	2	2.74

Table 19. Question 7. Throughout the lie of a pair of contact lenses, do your eyes remain comfortable or do you notice a difference in the sensation(s) that your eyes experience?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
They remain comfortable/Stays the same the whole time/I can't tell a difference	21	28.8
The time shrinks each day/It gets uncomfortable earlier at night	15	20.5
Vision becomes blurry/foggy	12	16.4
I can tell that they need to be changed	8	11.0
They are uncomfortable the whole day through	7	9.59
My eyes are a little bit drier/dry out faster	7	9.59
I have to use re-wetting drops more often	2	2.74

Table 20. Question 8. What do you like about your contact lens care regimen?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
Easy/Simple/Convenient	27	37.0
It is just one solution	12	16.4
It cleans them quicker	10	13.7
It does the job/Cleans them well	6	8.22
It helps them stay clean longer	3	4.11

Table 21. Question 9. What do you dislike about your contact lens care regimen?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
Nothing/I have no complaints	25	34.2
You have to do it at all	9	12.3
It takes too long	6	8.22
After I take them out of solution they burn when I first put them in	4	5.75
I can't sleep in them	4	5.75
It doesn't get all the deposits off	1	1.37

Table 22. Question 10. If you could change anything about the contact lens care solutions that are on the market today, what would it be.

Words or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
I would not change Anything	17	23.3
Cheaper	16	22.0
Better Hydrating	7	9.59
Make the lenses last longer	6	8.22
Better deposit removal	5	6.85
Less choices	3	4.11
More size choices	2	2.74
Take less time to clean	1	1.37
More gentle preservatives	1	1.37
I have not found anything that is good with dry eyes	1	1.37

Table 23. Question 11. Do you have any additional comments that you would like to make about contact lenses or this interview?

Word or Phrase	Number of Occurrences (Frequency)	Percentage of Responses (%)
No/Nothing	36	49.3
I love/like them	17	23.3
They are better than glasses	4	5.48
They help me do things that I can't with my glasses	1	1.37
Have one day bifocals	1	1.37
A daily disposable high toric lens	1	1.37

DISCUSSION

Using the above results, ninety-six items were generated to serve as the basis for a preliminary questionnaire to be used in the remainder phases of this study (see appendix) that will be continued at Alcon Laboratories Inc. The items are placed into six categories based on the relevance of the item. These categories are as follows:

- Environments
- Sensations Experienced
- When They Are Uncomfortable
- Likes/Dislikes About Present Contact Lens Care Regimen
- If Anything Could Be Changed About The Contact Lens Care Solutions
- General Questions

Categories one through three specifically deal with comfort and wearing soft contact lenses. Categories four through six, although they do not concern comfort, can be used for improving various aspects of the soft contact lens market and helping practitioners determine the best course of action to improve their patients experience while wearing soft contact lenses.

Each item is listed in accordance to its frequency, how many times was the word or phrase mentioned, in a descending manor. The items appearing first had the highest frequency, and the items appearing last had the lowest frequency.

The above gathered data that was used to make the questionnaire items is based on open-ended interview questions (see appendix). After several revisions I was able to gather enough data from the volunteers without having to prompt them too much to keep their answers in a specific direction. During the previous drafts of the interview questions, I experienced difficulties with the volunteer responses not being adequate enough in length and relevance to what I was trying to measure. I took the results that I received from the Connor Clinic that is located on the Alcon campus located in Fort Worth, TX (version A interview questions) and formulated the version B interview questions which improved my ability to make adequate measurements.

The population that was used to create this questionnaire can arguably be considered indicative of the whole population of soft contact lens wearers. The group of volunteers is comprised mostly of Caucasian females that wear daily wear soft contact lenses. The population had an adequate representation of age and length of time of wearing contact lenses with over two-thirds of the population falling in the ranges of 21.2 to 49.7 and 0.55 to 19.89 years, respectively.

The compliance of each volunteer was measured at the end of each interview. 67.1 % of the population interviewed was at least 85% compliant with a well defined contact lens care regimen. This number is high due to the fact that the limit to be considered for the next phase of the study was set at 85%. Had the limit been higher, I would expect the percentage to drop dramatically to coincide with previously measured contact lens care compliance levels. Eleven of the seventy-three volunteers were found

to be compliant with all aspects of their lens care regimen. This equates to 15.1% of the population.

To stay in accordance with the proposed research, a list of volunteer identification numbers that would be excellent for second interview (preliminary questionnaire administration) was composed (see appendix). The criteria for the selection of this list is based on the volunteers being at least 85% compliant and not presently be on any medications that may cause difficulties with wearing contact lenses.

The sites that were visited in this study were selected based on geographical location, elevation, temperature range and how arid of a climate it is. While picking the locations, I had to keep in mind to select locations that would have an adequate population that could volunteer due to the fact that I was trying to interview at least fifteen volunteers per site. The majority of the country was covered with exception to the north east and the north west. It could further validate the end questionnaire to adequately test it throughout these regions in addition to the ones that I visited.

There was an ample response to this study. All sites did an excellent job of recruiting volunteers. Thus, I was able to obtain more than the proposed number of volunteers for the first phase of this study. The proposed number of volunteers for this portion of the study was set at 60 with having 15 volunteers per site. The number sixty not only keep the data manageable, but it gave a power of 0.80 at a significance level of 0.05. With the 73 interviews that were obtain, the power of the study can be raised to 0.85 while keeping the same significance level. This will allow smaller differences in the data to be detected during the analyses.

Due to the skewed distributions of the population that was sampled, not having equal numbers represented in each category, a Pearson Correlation Coefficient would not be a good indication for a correlation between race, sex and comfort level. Therefore, one was not calculated for each category. To help compensate for this other studies can be cited to help develop scales to improve the final questionnaires measurement of comfort.

DESCRIPTION OF INTERNSHIP EXPERIENCE

06/09/03

1. Attended the following training sessions:

- Training orientation 1 hr.
- Archives and tour 1 hr.
- Diseases and Alcon products 1 hr.

2. Met with on-site mentor and received literature to read about different aspects of contact lenses (i.e. compliance, chemical depositions, dry eyes, measurements of attitudes).

06/10/03

1. Attended the following training session:

- IRB/IEC basics 1 hr.
- Systems and organization/project development 2 hrs.

2. Continued to read about different aspects of contact lenses.

3. Received articles about questionnaires with regards to dry eye and macular disease.

4. Read the above articles.

5. Started outline of research proposal.

06/11/03

1. Attended the following training session:

•

- Financial disclosure basics 1 hr.
 - Intro into Alcon clinical research 1 hr.
2. Had an eye exam at the Connor clinic to be fitted for contact lenses.
 3. Continued to work on outline for research proposal.

06/12/03

1. Attended the following training sessions:
 - Clinical monitoring basics 1 hr.
2. Was fitted for contact lenses/was taught the proper procedure for the handling of contact lenses.
3. Finished outline of proposal.
4. Started typing research proposal.

06/13/03

1. Attended the following training session:
 - AE basics 1 hr.
2. Met with Renee Garofalo to discuss:
 - ½ day at the Connor Clinic with staff optometrist to observe eye exams.
 - Fit with contact lenses.
 - ½ day with either Don Brotherman or Marianne Anderson observing eye exams.
3. Finished first draft of research proposal.

06/16/03

1. Attended the following training sessions:
 - EZ web training 1 hr.

- CRF basics.
2. Met with Patricia Meuse to discuss research project and limitations.
 3. Continued revision of research proposal.

06/17/03

1. All day training 8:30 AM – 5:00 PM.

06/18/03

1. All day training 8:30 AM – 5:00 PM.

06/19/03

1. Attended the following training sessions:
 - Study file basics 1 hr.
 - Report completion basics 1 hr.
 - Clinical forms basics 1 hr.
2. Continue revision of proposal.
3. Met with Patricia Meuse to discuss proposal.
4. Had eye exam with contact lenses.
5. Sent proposal to committee members for review.

06/20/03

1. Met with Renee Garofalo to discuss proposal and receive feedback.
2. Met with Patricia Meuse to discuss proposal and receive feedback.
3. Revised first draft of research proposal.

06/23/03

1. Attended the following training sessions:

- Site audits 1 hr.
 - Introduction into CQAU 1 hr.
2. Finished second draft of research proposal and forwarded it to Renee Garofalo, Jerry Stein and Patricia Meuse.
 3. Started revision of second draft.

06/24/03

1. Attended the following training sessions:
 - Introduction to biostats 1 hr.
 - Introduction to global reg. 1 hr.
2. Received feedback from Jerry Stein and Renee Garofalo on second draft of proposal.
3. Started working on third draft of the research proposal.

06/25/03

1. Attended the following training sessions:
 - Investigational device manufacturing/pilot lines tour 1.5 hr.
 - Monitoring basics 1 hr.
2. Continued revision of third draft of research proposal.

06/26/03

1. Attended the following training sessions:
 - Traveling 1 hr.
 - Eye clinic 2 hr.
2. Met with Renee Garofalo to discuss the second draft of research proposal.
3. Learned about eye examination equipment.

4. Finished third draft of research proposal.

06/27/03

1. Attended the following training session:
 - Introduction into clinical supplies 1 hr.
2. Department meeting discussed proposal agenda.
3. Discussed traveling to Denver to observe closeout visit.
4. Discussed what is an ideal time for each phase of the study.

06/30/03

1. Received feed back from Luis Atilas about proposal – made suggested changes.
2. Contacted Harold Sheedlo about proposal – had to fax a copy due to problems with e-mail.
3. Started literature search on conducting interviews.
4. Started reviewing statistical literature to determine how to validate questionnaire.

07/01/03

1. Continued review of literature with regards to statistics.
2. Started development of psychometric validation in proposal.
3. Met with the following individuals to discuss proposed research:
 - Renee Garofalo.
 - Jerry Stein.
 - Patricia Meuse.
 - Kitty Venkataraman.

07/02/03

1. Continued research for psychometric validation of questionnaire.
2. Continued revision of research proposal.
3. Asked lots of questions about the following statistical parameters:
 - Cronbach's Alpha.
 - Test-retest.
 - Validity.

07/03/03

1. Continued Research for psychometric validation.
2. Finished revision of fifth draft of proposal.
3. Forward fifth draft to all committee members, Renee Garofalo and Patricia Meuse.

07/07/03

1. Performed literature search for proposal citations.
2. Performed revision of proposal.
3. Met with Renee Garofalo to discuss proposal and travel to Denver for closeout visit.
4. Started designing database for study.
5. Sent proposal out for review.

07/08/03

1. Reviewed comments from Luis Atilas.
2. Revised proposal.
3. Performed literature search for preliminary questions.
4. Worked on database.
5. Received feedback about study statistics from Patricia Meuse.

07/09/03

1. Contacted Harold Sheedlo about proposal.
2. Faxed copy of proposal to Harold Sheedlo.
3. Received feedback from Renee Garofalo.
4. Performed literature search for proposal on Medline™.
5. Had problems finding sources for two citations.
6. Contacted Don Brotheman's office about ½ day visit.

07/10/03

1. Continued to have problems locating sources for citations.
2. Set appointment for Don Brotheman's office for 28 July 2003.
3. Received feedback from Harold Sheedlo.
4. Revised proposal.
5. Started preliminary open-ended questions.

07/11/03

1. Performed literature search on Medline™.
2. Went to library to review journals.
3. Received feedback from Jerry Stein.
4. Revised proposal.
5. Worked on open-ended questions.
6. Worked on expected study time line.
7. Finished all suggestions for proposal.

07/14/03

1. Went to Denver for closeout monitoring visit.
2. Reviewed case report forms.
3. Reviewed source documentation.
4. Reviewed study binder.
5. Noted discrepancies.

07/15/03

1. Continued review of all items for discrepancies.
2. Worked with coordinator to fix discrepancies.
3. Started organization of all binders.
4. Made copies of missing documents.

07/16/03

1. Finished correction of all observed discrepancies.
2. Finished organizing study binders.
3. Retrieved all items necessary for close out of the site.
4. Packed documents, study material and shipped back to Fort Worth, Texas.

07/17/03

1. Went to Connor Clinic to watch eye exams.
2. Learned more about the eye exam equipment.
3. Looked at corneal staining through slit lamp.
4. Contacted HPR about published survey.
5. Started planning database for preliminary data.

07/18/03

1. Used Microsoft Access to start creating database.
2. Generated random patient number system.
3. Worked on system to give percentage of patient compliance.
4. Made inquiry on how to fill out time sheet for travel.

07/21/03

1. Continued to work on Access database.
2. Made three forms for data entry.
3. Created a relationship for each form.
4. Discussed trip to Denver with Jerry Stein and Renee Garofalo.

07/22/03

1. Consumer Products clinical meeting.
2. Continued to work on Access database.
3. Consulted Adam Byer about problem with formulas and modules.
4. Filled out paper work for reimbursement for trip to Denver.

07/23/03

1. Continued to work on Access database.
2. Received feedback from Adam Byer.
3. Created formula to handle averages on a yes/no/not applicable basis to estimate patient compliance.

07/24/03

1. Went to clinic for contact lens follow up exam.

2. Conducted research on patient interviews.
3. Worked on preliminary interview script.
4. Worked on time-line for project.
5. Made copies for distribution to Jerry Stein and Renee Garofalo.

07/28/03

1. 8:30 AM – 12:30 PM visited Don Brotheman's office for observation of patient examinations.
2. Worked on Access database.
3. Worked on questions (compliance and open-ended) for presentation to Jerry Stein and Renee Garofalo.

07/29/03

1. Meeting with Jerry Stein and Renee Garofalo to discuss questions, interviewing process and interviewing script.
2. Worked on Access database.
3. Revised questions (open-ended).
4. Mailed proposal signature page to Luis Atilas.

07/30/03

1. Worked on Access database.
2. Researched informed consent form.
3. Started working on script for interview.
4. Received suggestions on sites to visit for questionnaire development.

07/31/03

1. Worked on forms and filing.
2. Meeting with Ralph Stone.
3. Finished database.
4. Continued refinement of questions.
5. Contacted Harold Sheedlo to inform status of the project.

08/01/03

1. Prepared documents:
 - informed consent form.
 - questionnaire for patient to read.
 - preliminary patient data form.
2. Revised CV.
3. Contacted Victoria Rudick to inform status of project and required documents.

08/04/03

1. Filled out degree plan.
2. Started drafting informed consent form.
3. Finished patient data form.
4. Received feed back about preliminary questions.
5. Filled out forms for school.

08/05/03

1. Met with Renee Garofalo to discuss patient forms.
2. Continued to work on informed consent form.
3. Started revision of preliminary questions.

4. Met with Harold Sheedlo to fill out annual evaluation form.

08/06/03

1. Submitted final research proposal.
2. Submitted annual evaluation to the graduate school.
3. Went through practice interview session.
4. Finished informed consent form.
5. Finished second draft of preliminary questions.

08/07/03

1. Went through practice interview session.
2. Submitted patient interview forms for review.
3. Worked on creating Internet form for data capture.

08/08/03

1. Worked on creating Internet form for data capture.
2. Went through practice interview session.
3. Revised patient data forms.

08/11/03

1. Worked in Internet form for database.
2. Called Information Technology to ask for help.
3. Worked on online questionnaire.
4. Gave degree plan to Jerry Stein.

08/12/03

1. Worked on web data capture for database.

2. Received help form IT – told me to call Daniel Sear.
3. Met with Jerry Stein to discuss project.
4. Met with Tolgar Bayraktaroglu to discuss ideas for Internet questionnaire.

08/13/03

1. Worked on web data capture for database.
2. Met with Renee Garofalo to discuss project.
3. Decided to go in different direction with database.
4. Revised database to one form for data entry.

08/14/03

1. Continued revision of web data capture database.
2. Finished database in final form.
3. Tried to find ways to access database from remote sites:
 - N drive.
 - Intranet.
 - PC Anywhere.

08/15/03

1. Decided to try PC Anywhere for access to database.
2. Spent ½ day trying to set host computer up.
3. Called IT for help.
4. Mailed degree plan to Luis Atilas.

08/18/03

1. Called Robin David about setting up interviews at the clinic.

2. Finished revising all forms for interviews.
3. Made copies of forms.
4. Met with Renee Garofalo to discuss regions of the country to visit, how to contact sites, and what will have to be discussed with sites.

08/19/03

1. Contacted IT about getting a loaner laptop for data entry from remote sites.
2. Conducted two practice interviews.
3. Went through the data entry process to see how long it would take.
4. Inquired about how to get a recorder to record interviews.

08/20/03

1. Conducted six interviews at the Connor Clinic.
2. Data entry.
3. Met with Renee Garofalo to discuss how much of the responses should be recorded.
4. Decided to only enter the relevant information to the question.

08/21/03

1. Data entry.
2. Burned CD to maintain record of interviews.
3. Worked on report presentation to display only patient number and relative responses to each question separately.
4. Worked on typing journal for thesis.
5. Went to clinic for eye examination.

08/22/03

1. Worked on typing journal for thesis.
2. Worked on reports.
3. Met with Patricia Meuse to discuss project and meeting occurring on August 28 2003.

08/25/03

1. Worked on typing journal for thesis.
2. Reviewed articles for thesis.
3. Worked on refining database and reports.
4. Worked on setting computer up for PC Anywhere.

08/26/03

1. Worked on typing journal for thesis.
2. Reviewed articles for thesis.
3. Revised interview questions.
4. Met with Renee Garofalo to discuss ways to reword questions.

08/27/03

1. Typed journal for thesis.
2. Reviewed articles for thesis.
3. Met with Renee Garofalo to discuss revised questions.

08/28/03

1. Went to clinic for fallow up eye exam.
2. Met with Jerry Stein, Patricia Meuse and Renee Garofalo to discuss project status:
 - time line.

- which doctors would be good to contact.

3. Started working on memo to send to potential sites.

08/29/03

1. Worked on memo.
2. Submitted for review.
3. Picked up loaner laptop.
4. Attended PAL training 1 hr.
5. Set up laptop for data entry from remote sites.

09/01/03

Labor Day

09/02/03

1. Met with Renee Garofalo to discuss schedule for remaining internship.
2. Created presentation for the above meeting.
3. Developed questions to ask people at the meeting.
4. Typed journal for thesis.

09/03/03

1. Worked with Renee Garofalo to determine:
 - sites.
 - compensation.
 - patients per site.
2. Worked on memo to send to doctors.
3. Submitted memo to Renee Garofalo for review.

4. Talked with Robin David about compensation for practice interviews.

09/04/03

1. Went to the clinic for eye exam, new contacts and to return defective contacts.
2. Received comments from Renee Garofalo about memo.
3. Revised memo.
4. Submitted memo to Jerry Stein for comments.

09/05/03

1. Clinical meeting.
2. Received comments from Jerry Stein on memo.
3. Revised and completed memo.
4. Looked up address for potential sites.

09/08/03

1. Mailed memo to four potential sites.
2. Typed journal for thesis.
3. Discussed project with Patricia Meuse on what could be done next.
4. Reviewed various contact lens related articles.

09/09/03

1. Tried to set laptop and desktop up to communicate with each other.
2. Sent e-mail to Leslie Napier to see if she needed help with reviewing CRFs.
3. Asked Tolgar Bayraktaroglu if he needed any help on his project.

09/10/03

1. Called Robin David to set up an eye exam.

2. Worked on presentation binder for patient interviews.
3. Article review for thesis.
4. Typed journal for thesis.

09/11/03

1. Went to clinic for an eye exam.
2. Worked on presentation binder for patient interviews.
3. Asked Renee Garofalo for way to improve binder.
4. Made revisions to binder.
5. Talked to James Mathis about using his office as a site for the study he said that he sold his practice.
6. Called Marianne Anderson's office to see if they wanted to participate in the study.

09/12/03

1. Made corrections to binder.
2. Asked various co-workers for feedback on question binder.
3. Rearranged database to coincide with new order of questions.
4. Worked on thesis.

09/15/03

1. Met with Leslie Napier on how to review case report forms for her study.
2. Reviewed case report forms for four sites.
3. Talked with Patricia Meuse about status of project.

09/16/03

1. Worked on report form for study.

2. Gave forms to Tolgar Bayraktaroglu and Patricia Meuse for review.
3. Received feedback from the above individuals.
4. Revised report forms.

09/17/03

1. Worked on expense report for site visit from July.
2. Tried to contact Marianne Anderson's office for follow up calls.
3. Met with Renee Garofalo about making phone calls to potential study sites.
4. Worked on phone script for talking to sites.
5. Revised calendar for the time remaining.

09/18/03

1. Called sites for study and left messages.
2. Received phone call from Eric White.
3. Explained study to Eric white.
4. Worked on e-mail letter to Eric White to give more in depth information about the study.
5. Called Marianne Anderson's office to give more information about the study.

09/19/03

1. Made multiple follow up calls to
 - David Evans
 - Mary Jo Stiegemeier
 - Robert Wooldridge.
2. Scheduled day with Robert Wooldridge.

3. Made travel arrangements.
4. Typed e-mail letter to Robert Wooldridge to give more in depth explanation of the study.

09/22/03

1. Received e-mail from Eric White stating that the selected day would not be a good day for the visit.
2. Called travel to see if flight could be changed.
3. Called Eric White to reschedule for the 6th of October.
4. Called David Evan's site.
5. Called Marianne Anderson's office to see how the scheduling was going.
6. Contacted Information Technology about a computer problem.

09/23/03

1. Called Mary Jo Stiegemeier's office.
2. Set up day for visit to the office.
3. Contacted David Evans' site to set up day for interviews.
4. Answered Greg Steel's questions about the study.
5. Sent out e-mails to give more in depth information about the study.

09/24/03

1. Worked on thesis.
2. Talked with Renee Garofalo about payment to the sites and how to write the memo to accounts payable.
3. Showed presentation binder/interview questions to Renee Garofalo.

4. Looked into joining the ACRP.

5. Made travel arrangements.

09/25/03

1. Went to TCOM for interview (all day).

09/26/03

1. Worked on thesis

2. Worked on calendar for next month.

3. Conducted the following training:

- Emergency evacuation.
- Tornado emergency.

4. Responded to e-mails about study.

09/29/03

1. Conducted the following training:

- R&D environmental policy.
- Waste minimization.
- Control of non-critical consumption.

2. Worked on thesis.

3. Lined up practice interviews.

09/30/03

1. Made copies of forms.

2. Called to confirm time at Marianne Anderson's office.

3. Worked on thesis.

4. Set computer up to record interviews.

10/01/03

1. Conducted practice interviews while being observed by Renee Garofalo.
2. Contacted sites for study to set up dates on the 20th of October.
3. Made travel arrangements.

10/02/03

1. Went to Marianne Anderson's office for interviews.

10/03/03

1. Clinical meeting.
2. Data entry of interviews.

10/06/03

1. Traveled to Eric White's office.
2. Conducted 17 interviews.

10/07/03

1. Stayed in San Diego, CA to wait for flight to Salt Lake City, UT.
2. Transcribed interviews using a word processor.

10/08/03

1. Traveled to Salt Lake City, UT.

10/09/03

1. Conducted 15 interviews at Robert Wooldridge's office.

10/10/03

1. Traveled back to Dallas, TX.

10/13/03

1. Traveled to Memphis, TN.

10/14/03

1. Interviewed 14 Volunteers at David Evans' office.

10/15/03

1. Traveled back to Dallas.
2. Transcribed interviews using a word processor.

10/16/03

1. Data Entry.
2. Transcribed interviews using a word processor.

10/17/03

1. Data Entry.
2. Transcribed interviews using a word processor.

10/20/03

1. Interviewed 9 volunteers at Mary Jo Stiegemeier's office.

10/21/03

1. Traveled back to Dallas.

10/22/03

1. Data Entry.
2. Transcribed interviews using a word processor.

10/23/03

1. Data entry.

2. Transcribed interviews using a word processor.

10/24/03

1. Data entry.
2. Transcribed interviews using a word processor.
3. Filed expense report.

10/27/03

1. Typed interviews using a word processor.

10/28/03

1. Typed interviews with a word processor.
2. Entered transcribed interviews into database.

10/29/03

1. Entered transcribed interviews into database.
2. Printed out responses and distributed to:
 - Jerry Stein.
 - Patricia Meuse.
 - Renee Garofalo.

3. Sent database to Jerry Stein through e-mail.
4. Set up a database meeting.

10/30/03

1. Database meeting discussed confidentiality of volunteers and what is wanted in the final database.
2. Meeting with Jerry Stein about project.

3. Created new fields in database for doctor's offices and brands of contact lens care solutions.
4. Talked with Patricia Meuse about ways to statistically measure demographics.

10/31/03

1. Last day.
2. Reception for interns.
3. Finished entering data into database.
4. Removed identifying fields in database.
5. Put together volunteer info binders to be kept at doctor's offices.
6. Sent final database to Jerry Stein and Patricia Meuse.
7. Meeting with Bryan Debenport.
8. Shredded volunteer identifying information.
9. Received info of what day would be good for thesis defense.

APPENDIX

Informed Consent Form

ID No.: _____

Volunteer

Initials: _____

AN AGREEMENT TO BE IN A RESEARCH STUDY

INFORMED CONSENT

INTRODUCTION

As a soft contact lens wearer, you have been asked to participate in a research study. This form will explain the purpose, design, risks, and benefits of the study. It will also outline your rights and responsibilities as a volunteer study patient.

You are being asked to volunteer for a research study. Before you decide to volunteer, you should read this form carefully. This form, called a consent form, explains the study. Please ask as many questions as needed so that you can decide whether you want to be in the study. Signing this form acknowledges that this study has been explained to you and that you agree to participate.

PURPOSE

The purpose of this project is to develop a questionnaire that can be used as a tool to measure the comfort or discomfort reported by soft contact lens wearers.

WHAT WILL HAPPEN DURING THE STUDY

You understand that before you sign this consent form, you must meet the qualification of not being an individual who has discontinued the use of contact lenses for more than three months before the start of the study in order to participate. If you should qualify for this study, you will be asked to participate in an **audio recorded** interview, lasting about twenty (20) minutes.

NUMBER OF VOLUNTEERS EXPECTED TO PARTICIPATE

About 60 volunteers will participate in the first interview. About 120 volunteers will participate in the second interview.

SIDE EFFECTS AND OTHER RISKS

This study should not involve any side effects or foreseeable risk. No marketed or investigational products will be distributed to study subjects.

PAYMENT FOR PARTICIPATION

You will receive \$15.00 for the interview.

PRIVACY AND CONFIDENTIALITY

By signing this form you agree to be recorded by audio means. You will be assigned a randomly generated ID number to ensure your anonymity. Your responses to the interviews will only be accessible to the appropriate individuals at Alcon Laboratories Inc. who will keep your information confidential within the limits of the law. Further you understand that the results of this study may be used in medical and scientific publications. If the study results are published your name will not be used.

VOLUNTARY PARTICIPATION / LEAVING THE STUDY

Your decision to be in this study is up to you and is voluntary. You have the right to leave this study at any time. If you do not want to be in the study, refuse to answer any questions during the interviews, or if you leave this study, there will be no punishment or loss of benefits that you deserve.

Your part in this study may be stopped at any time without you being asked. The following people can stop your participation:

- the Investigator
- Alcon Research, Ltd.

This consent form contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent form, please ask one of the study staff. Please answer yes or no to the following questions in the space provided:

1. Have you understood the consent form? _____
2. Have you had opportunity to ask questions and discuss this study? _____
3. Have you received satisfactory answers to all of your questions? _____
4. Have you received enough information about the study? _____
5. Do you understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care? _____

If you answered no to any of the five questions listed above, you should not sign this consent form.

By signing this form you agree that:

- you have had a chance to ask questions
- you understand English
- you volunteer to be in this study

Printed Name Here

Signature of Volunteer

Date

Investigator's Signature

Date

Signature of Person Explaining Informed Consent (If other than the Investigator) **Date**

Volunteer Background Information Form

Date / /
Mo. Day Year

Last Name First Name Middle Initial

Address

City State Postal Code

Home Phone Number Alternate Phone Number E-mail Address

Date of Birth / / Sex Race
Mo. Day Year

List of Any Known Allergies

List of Current Medications

Brand of Contact Lenses

Check One: Daily Wear Extended Wear

Replacement Schedule

Brands of Contact Lens Care Solutions

How Long Have You Worn Contact Lenses

Interview Questions

1. In which environment(s) do you experience uncomfortable sensations while wearing your contact lenses?
2. Can you please describe the sensation(s) you feel when your eyes are uncomfortable while wearing contact lenses?
3. At what time(s) during the day, do you notice your contact lenses starting to bother you?
4. In which environment(s) are you most likely to be unaware that you are wearing contact lenses?
5. Can you please describe the sensation(s) your eyes feel while you are comfortably wearing your contact lenses versus when you are not wearing contact lenses at all?
6. At what time(s) during the day, are you unaware that you are wearing contact lenses?
7. Through out the life of a pair of contact lenses, do your eyes remain comfortable or do you notice a difference in the sensations that your eyes experience?
8. What do you like about your contact lens care regimen?
9. What do you dislike about your contact lens care regimen?
10. If you could change anything about the contact lens care solutions that are on the market today, what would it be?
11. Do you have any additional comments that you would like to make about contact lenses or this interview?

Contact Lens Care Compliance Questions

Question	Yes	No	Not Applicable
1. Washes hands before putting in lenses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Washes hands before taking lenses out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Uses a disinfecting solution?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Disinfects every time lenses are removed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Uses enough solution to cover the lenses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Replace lens caps while soaking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Soaks lens for more than four hours at a time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Discards solution after each use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Rinses lens case with water after each use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Lets the lens case air dry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Sleeps with lens in?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Uses lenses for only prescribed period of time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Changes lens case every three months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

List of Volunteer Identification Numbers for Second Interview

A1781	B2031	B3560	B5063	B6028
A2947	B2314	B3853	B5373	B6237
A3570	B2430	B4164	B5426	B6247
A3843	B2891	B4375	B5571	B6572
A4645	B2947	B4497	B5649	B7497
B1570	B2978	B4880	B5818	
B1727	B3109	B5013	B5822	
B1903	B3367	B5027	B5857	
B2015	B3467	B5037	B5957	

Preliminary Questionnaire Items

Environments

A. Most likely to have problems.

1. In areas that are smoky my eyes feel uncomfortable while wearing my contact lenses.
2. When I am outside and it is windy my eyes feel uncomfortable while wearing my contact lenses.
3. When I am in a dry environment my eyes feel uncomfortable while wearing my contact lenses.
4. In general while I am outdoors my eyes feel uncomfortable while wearing my contact lenses.
5. When I am driving in my car with the vents or air-conditioning blowing in my face my eyes feel uncomfortable while wearing my contact lenses.
6. When I am working on a computer my eyes feel uncomfortable while wearing my contact lenses.
7. When I am watching TV my eyes feel uncomfortable while wearing my contact lenses.
8. When I am in a dusty area my eyes feel uncomfortable while wearing my contact lenses.
9. When I am sitting around a fan my eyes feel uncomfortable while wearing my contact lenses.
10. If I am in a high pollen area my eyes feel uncomfortable while wearing my contact lenses.
11. If I am in an air-conditioned environment my eyes feel uncomfortable while wearing my contact lenses.
12. If I have the windows down while in a car my eyes feel uncomfortable while wearing my contact lenses.
13. While flying on a plane my eyes feel uncomfortable while wearing my contact lenses.

14. If I am in an environment with low humidity my eyes feel uncomfortable while wearing my contact lenses.
- B. Least likely to have problems.
15. Generally everywhere that I am at my eyes do not feel uncomfortable while wearing my contact lenses.
16. When I am home my eyes do not feel uncomfortable while wearing my contact lenses.
17. When I am relaxing my eyes do not feel uncomfortable while wearing my contact lenses.
18. When I am at work my eyes do not feel uncomfortable while wearing my contact lenses.
19. When I am in an office environment my eyes do not feel uncomfortable while wearing my contact lenses.
20. When I am at school my eyes do not feel uncomfortable while wearing my contact lenses.
21. When I am indoors my eyes do not feel uncomfortable while wearing my contact lenses.
22. When I am in a controlled environment my eyes do not feel uncomfortable while wearing my contact lenses.
23. When I am outside my eyes do not feel uncomfortable while wearing my contact lenses.
24. When I am doing something physical my eyes do not feel uncomfortable while wearing my contact lenses.
25. When I am playing sports my eyes do not feel uncomfortable while wearing my contact lenses.
26. When I am in an area with no wind my eyes do not feel uncomfortable while wearing my contact lenses.

Sensations Experienced

- A. While having problems.
27. While wearing my contact lenses my eyes feel dry.
28. While wearing my contact lenses my eyes feel Itchy.
29. While wearing my contact lenses my eyes feel like there is something under my eyelid.
30. While wearing my contact lenses my eyes feel a burning sensation.
31. While wearing my contact lenses my eyes feel sticky.
32. While wearing my contact lenses my contacts feel like they are stuck to my eyeballs.
33. While wearing my contact lenses my eyes feel scratchy.
34. While wearing my contact lenses I have to blink more often.
35. While wearing my contact lenses my eyes feel a stinging sensation.
36. While wearing my contact lenses my eyes feel gritty.

37. While wearing my contact lenses I have to rub my eyes more often.
38. While wearing my contact lenses I need to use re-wetting drops.
39. While wearing my contact lenses my eyes do not feel lubricated enough.
40. While wearing my contact lenses my eyes do not feel moistened enough.
41. While wearing my contact lenses my contacts feel like they are shrinking on my eyes.
42. While wearing my contact lenses my vision becomes blurry.
43. While wearing my contact lenses my eyes feel tired.
44. While wearing my contact lenses I have increased tearing.
45. While wearing my contact lenses I have watery eyes.
46. While wearing my contact lenses I have a painful sensation.
47. While wearing my contact lenses my eyes hurt.
48. While wearing my contact lenses I have to keep my eyes shut longer.
49. While wearing my contact lenses my eyes feel like they have sand in them.
50. While wearing my contact lenses my eyes feel grainy.
51. My contact lenses do not feel like they fit right.
52. While wearing my contact lenses my eyes feel sore.

B. Comfortly wearing vs. not wearing contact lenses at all.

53. My eyes feel the same with or without wearing my contact lenses.
54. My eyes feel moister when I am not wearing my contact lenses.
55. My eyes feel like they can breathe more when I am not wearing my contact lenses.
56. My eyes feel more relaxed when I am not wearing my contact lenses.
57. My eyes dry out faster when I am wearing my contact lenses.

When They Are Uncomfortable

58. My contact lenses remain comfortable throughout the time that I wear them.
59. I am always aware that I am wearing contact lenses.
60. I do not notice my contact lenses the whole time that I am wearing them.
61. While wearing my contact lenses my eyes are uncomfortable between 6:00AM and 12:00PM.
62. While wearing my contact lenses my eyes are uncomfortable between 12:00PM and 6:00PM.
63. While wearing my contact lenses my eyes are uncomfortable between 6:00PM and 12:00AM.
64. While wearing my contact lenses my eyes are uncomfortable between 12:00AM and 6:00AM.
65. My eyes are uncomfortable the whole time I am wearing my contact lenses.
66. Toward the end of my replacement schedule the time I can wear my contracts comfortably shrinks.
67. Toward the end of my replacement schedule my eyes remain comfortable while wearing my contact lenses.

68. The time that I can wear my contact lenses stays the same throughout my replacement cycle.
69. I can not tell a difference in the way my eyes feel while wearing my contact lenses from the beginning to the end of my replacement cycle.
70. At the end of my contact lenses' replacement schedule my vision becomes blurry.
71. At the end on my contact lenses' replacement schedule my vision becomes foggy.
72. At the end of my contact lenses' replacement schedule I can tell that my lenses need to be replaced.
73. At the end of my contact lenses' replacement schedule my contact lenses are uncomfortable the whole day through.
74. At the end of my contact lenses' replacement schedule my eyes feel like they dry out faster.
75. At the end of my contact lenses' replacement schedule I have to use re-wetting drops more often.

Likes/Dislikes about Present Contact Lens Care Regimen

76. My contact lens care regimen is easy.
77. My contact lens care regimen is simple.
78. My contact lens care regimen is convenient.
79. My contact lens care regimen cleans my lenses quicker.
80. My contact lens care regimen cleans my lenses well.
81. My contact lens care regimen helps my contact lenses stay clean longer.
82. I have no complaints about my contact lens care regimen.
83. My contact lens care regimen takes too long.
84. My contact lens care regimen does not do a good enough job of cleaning my contact lenses.
85. I do not like the fact that I can not sleep in my contact lenses.

If Anything Could Be Changed About the Contact Lens Care Solutions

86. I would not change anything about the contact lens care solutions that are on the market today.
87. I would make all contact lens care solutions cheaper.
88. I would make all contact lens care solutions better at hydrating my contact lenses.
89. I would make all contact lens care solutions better at removing deposits.
90. I would make all contact lens care solutions better at making my contact lenses last longer.
91. I would like to have more size choices when it comes to the contact lens care solution bottles.
92. I would like it to take less time to clean my contact lenses.
93. I would like a solution that works well with dry eyes.

General Questions

- 94. Contact lenses have improved the quality of my life.
- 95. Contact lenses help me do things that I can't with my glasses.
- 96. Contact lenses are better than glasses.

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