

ABSTRACT

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Purpose: Non-compliant practices amongst contact lens wearers contribute to a high incidence of ocular complications and infections. During a contact lens-related adverse event, the infectious agent is almost always recovered from the contact lens storage case. This study measured the level of actual compliance with lens storage case hygiene, characterized the attitudes of contact lens wearers in regards to lens storage case hygiene, and correlated these factors with microbial contamination of the contact lens storage case. Since compliance is based upon patients' adherence to physicians' recommendations, this study also surveyed eye care practitioners about their knowledge of contact lens case care to identify areas of education that need to be addressed within both the practitioner and lens wearer populations.

Hypotheses: 1) Certain personality traits and negative attitudes toward compliance with contact lens wear and care may be indicative of non-compliant hygiene practices and, in turn, result in higher levels of contact lens storage case contamination. 2) Recommendations by eye care practitioners regarding contact lens storage case care may be inadequate and may contribute to inappropriate care practices and low compliance rates amongst lens wearers.

Methods: In the first arm of this study, a contact lens storage case drive was conducted at the University of Texas Southwestern Medical Center. During the contact lens storage case drive, participants completed anonymous, self-administered questionnaires, and submitted their used contact lens cases for analysis. Collected surveys served to characterize patient attitudes towards proper lens storage case hygiene and calculate compliance scores based on patient reported practices. The cases were then analyzed using a crystal violet assay to stain and quantify the level of biofilm (matrix of microorganisms) present within the wells. In the second arm of the study, 616 eye care practitioners were invited to complete a survey regarding their recommendations for proper lens storage case hygiene. Data summarizing the overall results of each set of surveys were compiled and statistical analyses were conducted to determine trends and correlations between variables.

Results: In the patient group, 90% of individuals were deemed as having positive attitudes (score of 1 and above). The average attitude score was 10 ± 6.7 with a range of -7 to 26. Average compliance was $64\% \pm 20\%$ with a range of 4-100%. Approximately 57% of subjects displayed poor compliance ($\leq 69\%$), 35% average compliance (70-89%), 7% had good compliance ($\geq 90\%$), and 1.5% had full compliance (100%). No significant relationship was found between the subjects' attitude scores and compliance grades ($p=0.516$). The average absorbance from the crystal violet assays, used to quantify the level of biofilm, was 1.9 ± 6.5 with a range of 0.0093 to 64.1. No significant relationship was found between compliance grades and absorbance values ($p=0.794$). Additionally, no significant relationship was found between attitudes and absorbance ($p=0.689$). Certain patient attitudes and improper contact lens storage case hygiene practices reflected the reported recommendations of practitioners.

Conclusions: Education about the importance of contact lens case replacement and cleaning is needed for both eye care practitioners and patients alike. Both of these educational goals could reduce the risks of infections in the contact lens wearing population.

**ANALYSIS OF PATIENT PRACTICES AND ATTITUDES
TOWARDS COMPLIANCE WITH CONTACT LENS STORAGE
CASES IN RELATION TO MICROBIAL CONTAMINATION
LEVELS**

INTERNSHIP PRACTICUM REPORT

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IN CLINICAL RESEARCH MANAGEMENT

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TABLE OF CONTENTS

CHAPTER I: INTRODUCTION	1
The Lamp of the Body	1
FDA Regulations for Clinical Research	2
Internship Practicum Study Project	4
CHAPTER II: CONTACT LENS HYGIENE BACKGROUND AND LITERATURE.....	9
CHAPTER III: HYPOTHESES AND SPECIFIC AIMS	12
CHAPTER IV: PRACTICUM PROJECT SIGNIFICANCE	17
CHAPTER V: PRACTICUM PROJECT METHODS.....	18
Study Design: Arm 1	18
Compliance and Attitude Assessment	21
Crystal Violet Assays.....	23
Study Design: Arm 2	25
Statistical Analysis.....	26
CHAPTER VI: PATIENT SURVEY RESULTS.....	27
Demographic.....	27
Contact Lens Wear Characteristics.....	28
Attitude Assessment.....	29
Compliance	30
Lens Case Care	32
Factors relevant to the care of contact lens cases	32
Hygiene Practices.....	33
Hand Hygiene	33
Contact Lens Case Replacement.....	34
Contact Lens Case Cleaning	34
Contact Lens Case Drying	35
Risky Practices.....	35
Compliance Assessment	36

Biofilm Concentrations	37
CHAPTER VII: EYE CARE PRACTITIONER SURVEY RESULTS	54
Demographics	54
Compliance Education	54
Hand Hygiene	55
Contact Lens Storage Case Care and Replacement	57
CHAPTER VIII: ANALYSIS OF ATTITUDES, COMPLIANCE, AND CONTACT LENS CASE BIOFILM CONCENTRATIONS	71
CHAPTER IX: PATIENT ATTITUDES TOWARD LENS CASE CARE	75
CHAPTER X: PATIENT PRACTICES IN CONTRAST TO PRACTITIONER RECOMMENDATIONS.....	76
Hand Hygiene	76
Contact Lens Case Replacement.....	80
Contact Lens Case Cleaning	81
Contact Lens Case Drying	83
Contact Lens Case Practical Considerations.....	84
CHAPTER XI: RISKY PRACTICES	87
CHAPTER XII: CONTACT LENS WEAR CHARACTERISTICS.....	89
CHAPTER XIII: EVALUATION OF STUDY METHODS	90
CHAPTER XIV: SUMMARY AND CONCLUSIONS	92
CHAPTER XV: INTERNSHIP SITE AND INTERNSHIP EXPERIENCE	94
APPENDIX.....	98
A: Patient Survey A with Attitude and Compliance Score Rubric	98
B: Study Flyer	102
C: Optometrist Letter and Survey	103
D: Daily Internship Journal.....	106
E: Copyright Permission for Figure 15.....	127
BIBLIOGRAPHY	129

LIST OF FIGURES

Figure 1. Patients Attitudes Towards Compliance.....	43
Figure 2. Compliance Grades.....	49
Figure 3. Patient Compliance And Crystal Violet Absorbance.	50
Figure 4a. Attitude And Absorbance	51
Figure 4b. Ages of Cases and Biofilm Levels	513
Figure 5. Attitude And Compliance	594
Figure 6. Eye Care Practitioners Practice Modality	599
Figure 7. Mode Of Compliance Education	61
Figure 8. Addressing the Health Risks of Non-Compliance	612
Figure 9. Practitioner Advised Lens Case Cleaning Frequency	645
Figure 10. Practitioner Advised Lens Case Cleaning Methods.	656
Figure 11. Practitioner Advised Lens Case Cleaning Agents	667
Figure 12. Practitioner Advised Lens Case Drying Methods	678
Figure 13. Practitioner Advised Lens Case Replacement Frequency	689
Figure 14. The Cases With The Highest Presence Of Biofilm.	70
Figure 15. Clinical Presentation Of Acanthamoeba Keratitis.	7071

LIST OF TABLES

Table 1. Patient Demographics. Part 1	38
Table 1. Patient Demographics. Part 2	39
Table 2. Patient Contact Lens Wear Related Characteristics. Part 1	40
Table 2. Patient Contact Lens Wear Related Characteristics. Part 2	41
Table 3. Summary of Patient Responses to Attitude Questions.....	43
Table 4. Hand Hygiene Practices. Part 1.....	45
Table 4. Hand Hygiene Practices. Part 2.....	46
Table 5. Contact Lens Care Practices. Part 1	47
Table 5. Contact Lens Care Practices. Part 2	48
Table 6. Risky Practices of Contact Lens Wearers	49
Table 7. Methods of Education for Hand Hygiene	63
Table 8. Methods of Education for Lens Case Care	64

CHAPTER I: INTRODUCTION

The Lamp of the Body

“The eye is the lamp of the body. If your eyes are healthy, your whole body will be full of light”

(Matthew 6:22 NIV). To an extent this statement can be taken literally in the context of

medicine. Ophthalmology is a branch of medicine concerned with the study and treatment of

disorders and diseases of the eye.¹ There are instances where ocular conditions can reflect signs

of systemic pathology. Examples include diabetic eye diseases such as diabetic corneal

neuropathy and retinopathy, that can potentially lead to blindness in patients with diabetes.²

Through clinical studies, researchers have made and continue to make discoveries like that

aforementioned. The results of these studies allow for earlier detection of pathology, provide

physicians with more effective treatment options, and allow physicians to better educate patients

at risk of ocular complications or vision loss. It is in this context that clinical research, a field of

science that involves human subjects willing to undergo experimental studies for the purpose of

contributing to science and medicine, is beneficial and important in Ophthalmology. Lifesaving

medical discoveries along with the development of drugs and medical devices are facilitated by

clinical investigations.

FDA Regulations for Clinical Research

Given that clinical research studies have experimental components, there are institutions in place to protect human subjects from unethical abuse. The United States Department of Health and Human Services is one of those institutions, and one of its agencies is the Food and Drug Administration (FDA). The FDA is the primary institution that oversees experimental studies of drugs and devices in human subjects within the United States. The FDA employs the Code of Federal Regulations (CFR), which is a set of rules that serves to ensure research is conducted ethically and that the safety and rights of human subjects are protected. Researchers as well as anyone involved in research should be familiar with CFR Title 21 Chapter I (21 CFR).³

Numerous trainings and educational opportunities are offered to individuals willing to learn the general rules and regulations covered within this government document. Five sections of CFR Title 21 are highly important and frequently emphasized in clinical research: 21, 50, 54, 58, and 56. 21 CFR part 21 emphasizes the protection of patient privacy and classifies the methods in place to keep patients' information safe from unauthorized and unlawful access and use. The rules outlined within this section are formatted to be in accordance with the Privacy Act of 1974. 21 CFR part 50 heavily emphasizes informed consent and the risk/benefit ratio of research as it pertains to the safety of human subjects. Section 21 CFR 54 explicates financial disclosure by clinical investigators and other allied research personnel. The purpose of this regulation is to

assess, account for, and reduce bias within research studies if there is financial gain and if there is a suspicion of financial coercion that could impact the quality of the research or the ethical conduct of the research. Section 21 CFR 58 details good clinical practices for nonclinical laboratory studies. It lists the applications and documentations required for different studies and outlines the length of time that data and other research records need to be kept on file. Lastly, section 21 CFR 56 outlines the duties of the Institutional Review Board (IRB) and the criteria each research institution's IRB should use to approve research studies. The IRB is made of individuals with and without a science background, who have the responsibility of overseeing that human subjects are protected, research trials are conducted ethically, and that FDA regulations are followed.

As mentioned above, training programs are in place to familiarize research personnel with CFR title 21. As part of my graduate studies, I completed a training program at the University of North Texas Health Science Center through an introduction to clinical research course. This course covered the Health Insurance Portability and Accountability Act (HIPAA), Human Subject Protection, and Informed Consent. At the start of this internship practicum at the University of Texas Southwestern Medical Center (UTSW), my previous training was validated and approved by the UTSW IRB. I then completed an additional training course covering:

Conflict of Interest and Good Clinical Practice (GCP). All training courses were completed through CITI (Collaborative Institutional Training Initiative), a web-based program. Upon completion and approval of all of the mandatory training requirements, I was credentialed to participate in research projects at the UTSW Medical Center.

Once I devised the protocol for my internship practicum it was submitted to the UTSW IRB for approval. After IRB approval, the study project was conducted under the mentorship of Danielle Robertson, O.D PhD, Associate Professor and research scientist in the Ophthalmology Department at the University of Texas Southwestern Medical School.

Internship Practicum Study Project

Patients often have a skewed perception of their level of compliance with proper contact lens wear and care practices; this is most likely due to their lack of knowledge of what proper compliance entails. A previous study has estimated that approximately 0.4% of contact lens wearers were fully compliant with the proper wear and care of their lenses as advised by their eye care practitioners, although 85% perceived themselves to be compliant.⁴ In a recent report, the Centers for Diseases Control and Prevention (CDC) indicated that 99% of contact lens wearers had at least one practice that could be increasing their risks for an eye infection.⁵ The

study conducted for this practicum was designed to further explore compliant hygiene practices by evaluating the attitudes of contact lens wearers, ascertaining their actual level of compliance, and measuring microbial contamination of their contact lens storage cases. The goal was to look for any correlations between patients' perceived importance of compliance (attitudes), their actual contact lens habitual hygiene care (practices), and the levels of microbial contamination within their contact lens storage cases. Participants in the study were asked to complete a survey to report demographic information, their attitudes, and their practices in regards to the care of their contact lens storage cases. In addition to the survey, participants were asked to donate one or up to three contact lens storage cases that were at least three months old.

Compliance is often generally defined as “following the prescriber’s recommendations”.⁶ As such, it makes sense that some patients believe themselves to be compliant simply because they are following the advice of their physicians. When assessing compliance, researchers often make the assumption that eye care practitioners are educating their contact lens wearing patients about the most effective and up-to-date hygiene practices for the proper care of their lenses and lens accessories. However, inconsistent and inadequate contact lens and lens case hygiene recommendations remain prevalent amongst various advisory bodies including optometrists.⁷ As a result, certain aspects of non-compliance may be unintentional as a result of inadequate patient

education by eye care practitioners. For the purpose of this study, compliance refers to adherence to the most effective and safe methods of contact lens and contact lens storage case care. In this study, the “most effective and safe methods” were defined as those recommended by the Center for Disease Control and Prevention (CDC) based upon literature review and scientific support. In the second arm of the study, the recommendations and mode of education offered by optometrists within the DFW Metroplex were evaluated. The goal was to determine the adequacy of the current eye care physicians’ recommendations to patients regarding the proper care of contact lens storage cases.

In all aspects of medicine, non-compliance (intentional or not) in the patient population is a risk factor for health complications. For contact lens wearers, certain associative factors of non-compliance are length of time wearing contact lenses, cost, and the indications for contact lens wear. Additionally, certain methods of patient education such as simple explanations in written and verbal form about each step of the contact lens care regimen are more effective and can contribute to compliance.⁸ The immediate consequences of non-compliance are greater microbial contamination of contact lens cases and increased risk or occurrence of ocular complications. These complications include bacterial, fungal, and amoebic infections of the cornea. An example of an amoebic infection is *Acanthamoeba Keratitis* (AK), one of the most destructive forms of

infectious keratitis. Amongst contact lens wearers, the incidence of Acanthamoeba Keratitis is between 1.65 and 2.01 per million per year.⁹ Figure 15 illustrates the clinical presentation of Acanthamoeba Keratitis in a male patient who stored his rigid lenses in tap water within a contact lens storage case that he never cleaned or replaced.¹⁰ Almost all cases of AK are associated with the exposure of contact lenses to water, a non-compliant practice that can result in a contact lens wearer falling victim to a blinding eye disease. Other forms of keratitis, such as microbial keratitis, are concerns in the lens wear population. There is an estimate of 930,000 doctor's office and outpatient clinic visits and 58,000 emergency department visits for keratitis or contact lens disorders occur annually at a cost of \$175 million each year to our health care system.⁵ Therefore, there is a motivation to reduce the occurrence of contact lens wear mediated keratitis and other lens related adverse events to promote safer contact lens wear.

Although prevention would be more effective in reducing the incidence of AK and other contact lens related adverse events, there is no conclusive data for early detection of non-compliance in patients. Therefore, in patients who may be at risk of supporting the consequences of non-compliance, successful intervention may not be taking place. Nonetheless, patient education is remains the most utilized method to address non-compliance.¹⁷ With the goal of educating patients about proper hygiene practices for their contact lenses and contact lens accessories, the

CDC has determined which practices are most effective in reducing microbial contamination of contact lens storage cases. If followed, these practices could diminish the incidence of ocular complications in the contact lens wearing population. This practicum project evaluates the educational methods employed by local eye care practitioners (ECPs) regarding recommended compliance practices with lens storage case hygiene. Other studies have evaluated methods of education (training, verbal, or written) and their impact on compliance and found that when given verbal and written instructions patients were more likely to be compliant.¹¹

However, not accounting for method of education, a drawback to previous compliance studies is the underlying assumption that patients are provided proper education. In contrast to prior work, the current study evaluated patient compliance on the basis of the optimal practices advised by the CDC. In addition, eye care providers within the DFW Metroplex were surveyed about their recommendations to contact lens wearing patients. The responses of the eye care practitioners about their recommendations and methods of education were evaluated to determine if mis-education or ineffective education might be contributing to the large incidence of non-compliance amongst contact lens wearers. While most studies are focused on contact lens hygiene procedures, this study is specifically centered on the proper hygiene practices associated with the care of contact lens storage cases. These practices include certain steps during handling

of contact lenses as well as all steps in the lens case care regimen (cleaning, drying, and replacing) that could be contributing to contamination levels within cases. Thus, compliance was measured and compared to a defined objective outcome: contact lens biofilm concentrations. In order to address the education aspect of non-compliance, the CDC has compiled a list of recommended healthy habits for contact lens wearers. This list of healthy practices was used as a standard for evaluating optometrist recommendations as well as patients' compliance levels. This study is different from others in that the goal is to evaluate the frequency of different practices and how they relate to risk of infection based on biofilm concentrations in contact lens cases in a population of contact lens wearers within an academic health institution.

CHAPTER II: CONTACT LENS HYGIENE BACKGROUND AND LITERATURE

The United States was introduced to soft contact lenses in 1971.¹² Initially classified by the FDA as a drug, contact lenses were later classified as a class II medical device. The FDA classifies medical devices based on risk to the safety or health of patients. There are three classes of devices: class I have the least amount of risk, class II have an intermediate level of risk, and class III have the highest level of risk. For each class of device, there is a set of regulations or documentation that must be provided to the FDA for marketing approval. Clinical data from

manufacturers is not required for contact lens storage cases. However, the FDA requires to be printed on the package of the lens cases the following warning, “Lens cases can be a significant source of microbial contamination. To help prevent eye infections, lens cases should be cleaned, rinsed, and air dried every day; and replaced frequently (as recommended by the manufacturer).”¹³

The warning just mentioned exists because most used cases will have some level of microbial contamination despite good compliance with hygiene practices.^{14, 15} Microorganisms bind to surfaces like the wet interior of contact lens cases and create a niche for themselves using biofilms. Biofilms are polymer matrixes of adherent organisms utilized by microorganisms to reside within certain environments and even build resistance to antimicrobial agents.¹⁴ Hygienic practices such as hand washing, cleaning contact lens cases, and replacing contact lens storage cases at a regular interval are all factors that contribute to the reduction of contamination within contact lens storage cases. Contact lens storage cases often act as a breeding ground for microorganisms contained in dense bacterial biofilms. Using crystal violet staining, a positive correlation was found between the age of contact lens storage cases and the density of biofilms.¹⁶ Microbial organisms can shed from the biofilm and attach to the surface of contact lenses. Once

attached to the contact lens, the lens then acts as a vector for the introduction of the organism to the cornea.

Non-compliance, the inappropriate practices of lens wearers in regards to recommended wear and care practices for their contact lenses and their contact lens storage cases, appears to be a common issue. According to Donshik et al.¹⁷, overall non-compliance rates amongst contact lens wearers ranges between 50% and 99%. Studies have evaluated multiple factors that may impact compliance, including patients' knowledge, perceptions, and their risk-taking propensities. These studies suggested that compared to behavioral practices, personalities may be more indicative of the patients' levels of compliance or non-compliance.

In a study, researchers assessed the perceptions of patients regarding their level of compliance, compliant behavior regarding contact lens wear, and risk awareness (Bui et al).²¹. This study used a grading scheme that stratified compliant behavior into one of three categories: good compliance, average compliance, or non-compliance. Patients' perceived compliance and their contact lens wear and care procedures were compared to their actual compliance. Interestingly, while most contact lens wearers greatly overestimated their level of compliance, about one-third met the criteria for excellent compliance. The same study showed that despite their knowledge of

the associated health risks of non-compliance, some patients remained non-compliant. It was also indicated that patients who reported a previous adverse event during lens wear (such as a red eye, irritation, or abrasion) were more likely to have improved compliance. Other researchers have investigated guidelines for the hygienic care of lenses and lens storage cases (Wu et al.)¹⁸. As part of their study, they surveyed eye care practitioners across Australia. They found varying recommendations amongst physicians and manufacturers regarding contact lens and contact lens storage case cleaning practices and concluded, “Future research is needed to establish evidence-based contact lens hygiene guidelines”.

CHAPTER III: HYPOTHESES AND SPECIFIC AIMS

Non-compliance with contact lens wear and lens storage case hygiene is a persistent and costly problem despite continuous education by eye care practitioners and printed recommendations from manufacturers of contact lenses and lens care solutions. A previous study indicates that recommendations for cleaning and replacement of the contact lens storage case vary greatly between manufacturers and physicians.¹⁸ The variety of recommendations could confuse patients or even lead them to formulate their own regimen since they are uncertain about what the right practices truly are. Moreover, the assessment of compliance becomes subjective since there is

not a single standard to use for comparison. This does not however exclude the suggestion that, the high incidence of non-compliance could result from patients not adhering to their ECP's instructions. To date, effective methods for patient education on the importance of, and adherence to correct hygiene practices are limited. Likewise, there is a lack of predictive measures that could identify patients who, after receiving proper education, remain non-compliant. It has been found that despite knowledge of risks, a high number of patients continue to be non-compliant with their contact lens wear and care behaviors.⁴ the risk-taking propensity of lens wearers in association to compliance has been evaluated and an association between risk taking and reduced compliance was found.¹⁹ Thus, even with proper education from eye care practitioners, intrinsic factors motivate certain individuals to be non-compliant despite being aware of the health risks. These studies suggest that the attitudes and personalities of the lens wearers could speak more to the frequency of non-compliance than lack of education alone. These reports support the hypothesis that certain personalities and negative attitudes toward specific aspects of compliance with contact lens wear may be more indicative of non-compliant behavioral practices, leading to higher levels of contact lens storage case contamination (Hypothesis 1).

Based on a review of current literature, it seems the relationship between reported lens case care practices, attitudes toward the importance of compliance with lens storage case hygiene, and levels of case contamination has not been previously investigated within one study. In controlled clinical trials, researchers have evaluated which hygiene practices are most appropriate for the care of contact lens storage cases and have characterized which microbial organisms usually tend to populate contact lens cases. They have further studied how the lens wearer's practices, such as swimming with lenses, impacts contamination of the lens case. In addition, separate studies strictly aimed to identify compliance/non-compliance amongst contact lens wearers in regards to actual behavioral practices with contact lenses and contact lens storage cases. Although non-compliance is a common problem amongst contact lens wearers, there are two major issues in addressing patient non-compliance. First, it is not clear among patients, and possibly some eye care practitioners, what the recommended compliance guidelines are for optimal care of contact lens storage cases. Studies indicate that these recommendations may differ between eye care physicians and manufacturers.¹⁸ Secondly, even with an established standard of practice, accurate measurements of compliance and means to identify patients at risk of being non-compliant do not exist.

Contact lens storage case hygiene care is a process involving multiple steps: hand washing, discarding used solutions, cleaning, and drying. Patients could be practicing risky behaviors during the hygiene care process. For this reason, the patient questionnaire was structured to include all hygiene practices associated with the lens care process during handling, storing, and replacement of contact lens storage cases. A concurrent segment of this study will focus on the behavioral practices of contact lens wearers to determine which positive behaviors lead to cleaner cases and which negative behaviors tend to be indicative of increased organism growth within cases. Compliance was evaluated by scoring the compliant practices based upon the CDC's evidenced based recommendations for the wear and care of contact lenses and contact lens cases.²⁰ It is anticipated that patients with higher actual compliance scores will also have lower levels of contamination within their contact lens storage cases. The second arm of the study evaluates the recommendations amongst practitioners regarding contact lens storage case care. Under this segment, the second hypothesis is that there is a disparity between the recommendations of optometrists and ophthalmologists and the CDC guidelines in regards to contact lens storage case use and care (Hypothesis 2). The hypotheses follow the two aims below:

(1) A set of the most frequently studied contact lens storage case practices has been compiled based on empirical clinical evidence of effectiveness and compared against the current recommendations by the CDC. Effectiveness relates to the practices that result in the least amount of microbial contamination of the contact lens storage case. This standard of care for contact lens storage case hygiene will be used as a measure to determine the level of compliance or non-compliance in this study. Deviations from this standard will be scored as an indicator of non-compliance. The goal of this study is to assess patient attitudes towards compliance with their contact lens storage case hygiene practices, and to evaluate the correlation of these attitudes and practices to measurable levels of microbial contamination in the lens case. In addition, this study will attempt to quantify the frequency of non-compliant practices. Thus, frequency, in addition to the behavior itself, will be used to assign each hygiene practice a weighted score. The final score will be used to determine whether the patient has good, average, or poor compliance.

(2) The second component of this study will evaluate the disparity between eye care practitioner recommendations within the Dallas Fort Worth Metroplex and common reported patient behavioral practices. A prior study in Australia has suggested that there is a large amount of variability in practitioner recommendations regarding the care of contact lenses and contact lens

storage cases.¹⁸ To our knowledge, a survey of eye care practitioner recommendations has not been previously evaluated in the U.S. Since medical standards and hygiene practices may vary, local eye care practitioners will be surveyed for information regarding their recommendations regarding lens storage case hygiene and their preferred mode of education.

CHAPTER IV: PRACTICUM PROJECT SIGNIFICANCE

The CDC has established basic guidelines with respect to the safe wear and care of contact lenses. This study is to compare actual patient behavioral practices and attitudes towards the established basic guidelines to identify those factors that are most tightly associated with an objective measure of non-compliance: contamination of the contact lens case. To date, there are no well-defined measures of compliance or predictors of patients that are more likely to be non-compliant. Using the data from this study, a quick, yet comprehensive questionnaire could be established in order to be readily implemented into clinical practice to aid practitioners identify and educate non-compliant patients about proper handling and care of contact lenses and contact lens storage cases. The results of the questionnaire would allow eye care practitioners to better understand their patients, address their “negative” attitudes regarding healthy contact lens hygiene practices when needed, and guide these patients towards more compliant behaviors.

The practitioner questionnaire allows the assessment of the recommendations that eye care practitioners within the DFW Metroplex are giving their patients and the methods in which they are communicating these recommendations (ex: verbal and/or written instructions). Research done for this practicum project indicates that only one study has investigated the guidelines from eye care practitioners and manufacturers and discovered a large discrepancy between the guidelines for contact lens and contact lens storage care from these authorities. In the U.S, this practicum project is the first to compare general recommendations from eye care practitioners with the recommended CDC guidelines. The results of this survey could be used to emphasize areas of contact lens patient education that are currently lacking.

CHAPTER V: PRACTICUM PROJECT METHODS

The University of Texas Southwestern Medical School (UTSW) Institutional Review Board (IRB) approved all recruitment methods and study procedures.

Study Design: Arm 1

Participants were faculty, staff, students, or visitors of the University of Texas Southwestern Medical School (Dallas, Texas, United States). In this arm of the study, recruitment consisted of

the distribution of flyers around campus and a campus wide email blast containing the same information as the flyer (See Appendix B.) The study was approved under an exempt status since it involved no risk to participants and did not require the acquisition of any patient identifiers. Therefore, written informed consent was not required and, as such, participants were informed that completion of the questionnaire and the donation of their used lens storage case indicated consent. For inclusion in the first arm of the study, participants must have been new (defined as contact lens users of at least 3 months) or established contact lens wearers who were 18 years or older and did not wear daily disposable or rigid contact lenses.

Announcements about the study, the dates, location, and time of the lens case drive were sent out to the entire campus every Tuesday using Campus Update (campus wide email system). The Marketing and Communication Manager of the Ophthalmology Department approved the blurb submitted to Campus Updates' editors. In addition, IRB approved posters were placed around campus in designated advertisement areas. To assess compliance with hygienic care of contact lens storage cases and the attitudes of contact lens wearers, surveys were distributed to eligible and willing participants on the UTSW south campus. The surveys consisted of forced-choice (yes/ no), multiple-choice, and Likert scale questions. The questionnaire had a total of 51 questions and there were two forms of the questionnaire: A and B. The questions were the same

on both forms, but the order of the questions differed. For Form A, Likert scale questions regarding patients' attitudes were before the multiple-choice questions about actual behavioral practices; while form B queried behavioral practices prior to assessing attitudes towards such practices. (See Appendix A) Distributing the different forms in an alternating fashion randomized assignment to form A or B. The purpose of the two different questionnaires was to eliminate any bias due to the order that the questions were presented and to evaluate whether there was a difference in the responses when patients were asked, "What they do" before or after being asked, "How important it is to do the right thing". In addition to completing the questionnaire, each participant was asked to donate a used contact lens storage case. A total of 135 contact lens wearers participated in the study and 143 lens storage cases were collected. Surveys were completed and lens cases collected between the hours of 11:30 AM and 2:30 PM outside the campus food-court for a total of 16 days. The schedule was Wednesday, Thursday, and Friday with the exception of the final week when the drive took place Monday, Tuesday, Thursday and Friday. The drive took place throughout 5 weeks, 2nd, 3rd and 4th week of September and the 2nd and 3rd week of October. After participation in the study, each study subject received compensation: a gift bag containing a \$5 voucher to the UTSW food courts, a new lens case, a cleaning cloth for glasses, and a CDC handout about healthy contact lens hygiene habits.

Compliance and Attitude Assessment

Data obtained from the questionnaire were analyzed as follows:

(1) Compliance was measured using a similar grading scale to that previously reported.²¹

Practices were scored based upon the healthy lens care habits recommended by the CDC.

Answer choices to the questions that assessed compliance were pre-assigned a value of 0, 1, or 2.

If the practice was exactly what was recommended, the patient received a score of 2. A score of

1 was assigned for “acceptable” practices. The researchers deemed these as an indication of

attempts of compliance. A score of 0 was assigned to behaviors that were strictly unacceptable.

Example would be a score of 2 for “daily” cleaning of lens cases and a 1 for “every few days”

and a 0 for “once a week”. Based on the patients’ total score from the 15 compliance questions,

each patient was assigned a compliance grade. The maximum score possible was 24 points.

Good or excellent compliance was 90% and above, 70-89% for average compliance, and 69%

and below was poor compliance. All study participants received a compliance grade if their

survey was considered valid. If individuals marked more than one response, they were given the

lower compliance score of the answer choices. For the set of questions that followed each other,

inconsistent responses were discarded. If subjects selected two choices with the same compliance

score, an average of the two scores was noted. There were a total of 15 questions to measure

compliance. However, the score was given out of 12 questions with a maximum 24 points because there were two sets of complementary questions dependent upon each other. Each of these sets was considered a single question and as such a maximum of 2 points could be earned. One set of questions regarded swimming while wearing contact lenses. Those who reported never swimming with lenses received 2 points. The follow up question about swimming with goggles was only considered for those who answered anything besides never and non-applicable. If the individual swam with goggles they received one point. If they did not swim with goggles, but disposed of the lenses the same day they received one point. The second set of questions was about the method of hand drying and the follow up question about the frequency of hand towel replacement. Those who answered that they dried their hands using a bathroom hand towel needed to answer that they replaced their bathroom hand towel every few days (2-3) to receive a score of 2. Those who used a paper towel and a bathroom hand towel received a score of 2 if they changed the towel every few days. Those who used paper towel received a 2. The researcher did not make a choice between paper towel and hand towel because the two options had the same weight in regards to compliance. In all other cases, the lower valued practice was selected to evaluate a compliance score.

(2) In order to individually quantify the patients attitudes, scores of +2, +1, 0, -1, or -2 were assigned to each of the following answer choices respectively (strongly agree, strongly disagree, undecided, disagree, or strongly disagree). Depending on the statement, the scale was reversed and +2 was assigned to “strongly disagree” and -2 was assigned to “strongly agree”. (Appendix A has the score rubric to the survey’s attitude questions and answers). Attitude scores were tallied and based on the score the patient was labeled as having a “positive” or “negative” attitude. For the 16 questions, the total maximum score was +32 and the minimum score option was -32. Anyone with a score of 0 and below was labeled as having a negative attitude. Those with a total attitude score of 1 and above were labeled as patients with positive attitudes.

Crystal Violet Assays

Contact lens storage cases were processed at the University of Texas Southwestern Medical Center Department Of Ophthalmology. The left well of each case was assessed for the presence of biofilm using a crystal violet assay. The following protocol was adopted from Burnham G.W article, The impact of cellular debris on Pseudomonas Aeruginosa adherence to silicone hydrogel contact lenses and contact lens storage cases.¹⁶ All procedures were performed under a Biological Safety Cabinet (Thermo Scientific™, Waltham, MA). Crystal violet (CV) 1% Gram Stain (Fisher Science Education, Nazareth, PA) was added to the left well of each case and

incubated for 15 minutes at room temperature. Based on the varying volume capacity of each type of case, varying volumes of solutions (CV, distilled water, and Ethyl Alcohol) were used. The flip top cases had a volume capacity of 2.0 ml and screw-top flat well cases had a greater volume capacity, so 3.0 ml of each solution were used. After 15 minutes, the CV solutions were carefully suctioned out in order to not disturb the biofilm. The stained wells were then photographed before being rinsed twice with distilled water. The lens cases were air-dried face up for 2 hours. To dissolve the crystal violet, depending on the volume capacity of the case, 2.0 or 3.0 ml of Ethyl Alcohol - (Pharmco-AAPER, Brookfield, CT) were added to the wells, immediately recapped lightly (to avoid evaporation), and left still for 15 minutes. After 15 minutes, 300 μ l of the Ethyl alcohol solution was added in triplicate into a sterile polystyrene flat bottom 96 –well cell culture plate (Greiner bio-one, Monroe, NC). Absorbance was read on an iMark Microplate Absorbance Reader (Bio rad, Hercules, CA) at an OD of 595nm. If absorbance values were outside the range of the assay due to dense biofilms, the content of each well was serially diluted until a value was obtained. The final absorbance was then corrected by the appropriate dilution factor to determine the actual concentration of biofilm in each well. Control cases were new screw top cases (Bausch and Lomb, Rochester, NY) that were wiped with alcohol swabs then autoclaved.

Study Design: Arm 2

For inclusion in the second arm of the study, local eye care practitioners were identified using the Department of Ophthalmology mailing list for practicing ECPs in the DFW Metroplex. A total of 616 eye care practitioners were invited via mail to complete the surveys. Since all surveys were anonymous, completion of the survey indicated informed consent. To evaluate the recommendations and methods of education employed by practitioners, a separate survey was mailed to 616 DFW Optometry/Ophthalmology clinics. A letter was sent along with the survey describing the study (See Appendix C). Participants were asked to return the survey by either FAX or email within ten days of receipt. To maintain the anonymity of the surveys, the letter specified to avoid noting the name of their practice or their own name on the survey.

Optometrists were asked to report whether their practice was retail or private as well as the methods they employed to educate their patients as well as the advice they give patients about proper hygienic care of contact lens cases. The practitioners received no compensation for participating. The ECP survey correlated to the patient survey in the sense that both surveys had questions regarding hygiene practices for the care of contact lenses and contact lens storage cases. The survey consisted of 16 multiple-choice questions. The questions posed referred to compliance education, hygiene practices such as hand washing, and contact lens storage case

specific questions regarding cleaning methods and frequency of replacement. Common practices of patients were compared and contrasted to the responses of the eye care practitioners' recommendations. Answers to the practitioner surveys were quantified and displayed in graphs and tables.

Statistical Analysis

Statistical analysis was performed using Sigma Plot 12.5 (Systat Software Inc., San Jose, CA). All data are expressed in mean $\pm$ standard deviation. Normality and equal variance assumption testing were performed using the Kolmogorov-Smirnov test and the Levene median test. For comparison between two groups with normally distributed data, a t-test was performed. A Mann-Whitney test was performed on data that was without normal distribution. For comparisons of difference in proportions between groups (such as gender or levels or education) a Chi-Square of Fischer Exact test was used. To test for relationships between variables such as attitudes and compliance or compliance and absorbance) a Pearson or Spearman correlation test was used. Statistical significance was set at $p < 0.05$.

CHAPTER VI: PATIENT SURVEY RESULTS

Demographic

A total of 135 participants were recruited in the study. The patients were systematically and randomly assigned to group A or group B. Group A had 66 subjects and they completed survey A. Group B had 69 subjects and they completed survey B. A total of 143 cases were collected, of those, 6 were peroxide cases, which were not analyzed. Approximately 80% (98/123) of the study participants were female, which is consistent with the gender distribution of contact lens wearers in most contact lens studies. The ages of the participants ranged from 18 to 64 years with an average age of 39 ± 13 years. The average age for group A was 41.5 ± 13 years and that of group B was 37.015 ± 12.7 years. A t-test comparison revealed that there was a significant difference in age between the two groups ($p=0.0499$). The majority of the participants, 81% (107/132), were employees of the University of Texas Southwestern Medical School. Students made up the second highest group of participants, 13% (17/132). Three individuals did not indicate their status at the university. Besides age, gender, and professional status, participants were asked to report additional demographic information such as highest level of education, self-identification (ethnicity), and total yearly income. Thirty-two percent (43/135) of participants identified as Caucasians, thirty-one percent (42/135) identified as Black or African American, followed by 19% (26/135) Asians, and lastly 16% (22/135) Hispanic or Latino. The majority of

subjects, 43% (57/134), had a Bachelor level of education, followed by 22% with a high school diploma or high school equivalent. The next two groups, Associate and Master's degree, together made up about a quarter of the participant population. The last 10 percent were individuals who possessed a Doctorate or Professional academic degree. Altogether, those earning less than \$25,000 made up a quarter (33/131) of the study population, while 39% (51/131) earned about \$50,000 or just more than \$25,000. About 28% (37/131) of the population earned nearly \$100,000 or just more than \$50,000 a year. Table 1 summarizes all the demographic data (age, gender, income, etc.)

Contact Lens Wear Characteristics

Other information that related specifically to contact lens wear characteristics were obtained from the survey. All study participants were new or established contact lens wearers. New contact lens wearers were defined as individuals who had worn contacts for at least three months or more. Established contact lens wearers were those who had worn contact lenses for a year or more. The years of contact lens wearing experience was added to the survey toward the end of the study. Of the 45 individuals who reported how long they had worn contact lenses, 22% (10/45) estimated >10-15 years, 20% (9/45) estimated >5-10 years, 20% (9/45) >15-20 years, and 16% (7/45) estimated more than 20 years of contact lens wearing experience. Of all

participants, 95% (126/133) indicated that they wore contact lenses to correct their vision, 90% (121/134) wore soft lenses, and 71% (95/134) were daily lens wearers. Forty-four percent of individuals (59/134) reported using less than one bottle of solution each month, 24% (32/134) used about one bottle, and 27% (36/134) used between one and two bottles each month. The follow up question of whether the participants consistently purchased the same solution revealed that 77% (102/132) did. Of all subjects, 70% (94/135) report seeing their eye care practitioner once a year, while 13% (18/135) said they went every two years. Fifty three percent (71/135) of all participants reported having an eye visit within a few (2-3) months of their participation in the study. Also, 42% (57/135) had their last eye visit within the last year. When asked if they previously had a red or pink eye due to contact lens wear, 32% (43/135) responded affirmatively. See Table 2 describes the contact lens wearing characteristic data of each patient group (A and B).

Attitude Assessment

Participants were asked to use a Likert scale to indicate their position or the importance they placed on a series of sixteen statements. The statements pertained to compliance, hand washing, method of contact lens storage case cleaning and drying, factors such cost, time, and ease of use as they relate to the care of contact lens storage cases, and knowledge of recommended practices. The percentages that follow were calculated based on the total number of responses to each

question. Certain individuals failed to mark responses on a few questions. Thus, not all percentages are calculated from the total of 135 participants. Table 3 lists the statements as they were written on the survey, the Likert scale choice options, and the percentage of each response. The average attitude score was 10 ± 6.7 and the range was -7 to 26. Overall, 90% of individuals had positive attitudes. There were 66 individuals in group A and 69 in group B. There was not a statistically significant difference between the attitudes of those from Group A and those from Group B ($p=0.908$), indicating that the order of the questions did not introduce bias in the study. Figure 1 shows the spread of the attitudes for group A, B, and for the entire patient population.

Compliance

Since the propensity for risk taking has been negatively associated with compliance, patients were asked whether they considered themselves as risk takers. It was found that 46% (62/135) of subjects did not consider themselves risk takers, while 39% (53/135) did. In regards to compliance, a majority of subjects, 82% (111/135) perceived themselves as being compliant with their physicians' recommendations for the care of their lenses. Since no significant difference was found between the perceived compliance level of group A and group B ($p=0.732$), the data was analyzed as a whole. A significant relationship was found between the perception of compliance (attitude based and scored on Likert scale) and the overall compliance score of each

patient (practiced based and scored in comparison to CDC guidelines) ($p=0.0000228$). Similarly, a significant relationship was also seen between the perceived compliance levels (as measured on the Likert scale -2 to +2 by the subject) and the overall attitude score of the patient ($p=0.00000000376$). However, there was no significant relationship between perceived compliance and absorbance levels ($p=0.146$). A one way ANOVA test revealed that the differences in the mean values among the treatment groups are greater than would be expected by chance; there is a statistically significant difference ($p = <0.001$). There is a moderate positive trend between Likert scale responses (strongly disagree -2 to strongly agree +2) and increased compliance scores. Additionally, another ANOVA test indicated a significant difference between perceived compliance and attitude scores ($p = <0.001$). A moderate trend was also apparent between increasing Likert response scores and mean attitude scores. This trend was disturbed by the high mean attitude of the group of three individuals with very negative (Likert score of -2) perceptions of their compliance. Due to the small sample size, the mean attitude score did not align with the previously mentioned trend.

A majority of participants, 78% (104/134), strongly agreed or agreed with the statement “I am putting my eye health at risk by being “non-compliant”, indicating their awareness of the consequences associated with non-compliance. As for hand hygiene, 96% (127/132) viewed the

act of washing hands before handling their lenses as being important. Then, rubbing, rinsing, and properly storing contact lenses were viewed as important practices by 95% (127/134) of participants.

Lens Case Care

Only 70% (94/134) thought the practices of rubbing and rinsing were as important for the care of their contact lens storage cases as they were for the care of their contact lenses. Consistent is the fact that 73% (96/132) of participants thought it as important to clean their lens cases daily, and 72% (96/134) felt that cleaning their lens case with the same cleaning solution recommended by their doctor for their lenses was important. Still in the context of contact lens case care, 25% (33/132) were unsure about the importance of lens case air-drying, while 64% (84/132) felt it was important to air-dry their cases. Overall, 95% (126/132) considered good lens case hygiene important. Thirty-one percent disagreed or were unsure about the statement, “I believe lens case care is equally important as lens care”. Therefore, only 69% (92/133) deemed the care of their lens cases to be as important as that of their lenses. Finally, 71% (94/133) considered themselves knowledgeable about proper hygiene practices for the care of their contact lens storage cases.

Factors relevant to the care of contact lens cases

Eighty-five percent of contact lens wearers (114/134) said they were willing to spend whatever is necessary for the optimum health and care of their eyes. However, 63% (84/134) agreed that cost

was a factor in the way they cared for their cases. In regards to other factors that influence the manner in which patients care of their contact lens cases, 78% (105/134) indicated time as a crucial factor, and 89% (119/133) considered ease of use an important factor.

Hygiene Practices

Overall, between group A and group B, there was no significant difference in the hygiene practices reported. Tables 4, 5, and 6 indicate the p values greater than 0.05 obtained from the chi-square tests for each of the hygiene practices.

Hand Hygiene

About 91% (120/132) of participants reported that they always or most of the time washed their hands before handling their lens cases. Of all those who said they washed their hands, 87% (113/130) said they used water and soap. Of those who reported using water and soap, 47% (53/112) indicated that it took them 20 seconds or more to clean their hands, 33% (37/112) said it took between 5-20 seconds, and 20% (22/112) said less than 5 seconds. In actuality, about 63% of contact lens wearers in this study are ineffectively washing their hands. In regards to hand drying prior to handling lenses, a total of 59% (78/133) of participants mentioned that they used their bathroom hand towels to dry their hands, 32% (43/133) mentioned using a paper towel, and 15% (20/113) used their body towel. Of those who mentioned using a hand towel and answered the following question about the frequency of the bathroom hand towel replacement, 50%

(39/78) said every few days, and 41% (39/78) said weekly. A total of about 13% said they did not dry their hands or simply shook the water off their hands. Table 4 indicates the percentages for the different responses to the hand hygiene questions.

Contact Lens Case Replacement

When asked how often they replaced their lens cases, 29% (38/133) of subjects reported replacing their contact lens cases yearly, 21% (28/133) said every 6 months, another 21% (28/133) said every 3 months, 16% (21/133) said monthly, 11% (14/133) said they never replace, and 2% (2/133) added in the “other” option that they only replace “when needed or when dirty.” Overall, only 37% (49/133) of individuals are replacing their cases at a recommended interval (every three months or less).

Contact Lens Case Cleaning

Only 31% (40/133) of individuals said they cleaned their cases daily or after each use. A total of 14% (18/133) clean their cases every few days, 20% (26/133) clean their cases weekly, another 20% clean their cases monthly, and 15% (20/133) do not clean. Of those who cleaned their cases, the majority, 54% (61/113), rubbed and rinsed, while 40% (45/113) rinsed, and the remaining 6% (7/113) mentioned using cloths or tissue to wipe their cases.

The majority of subjects, 43% (49/113), used water (tap water and soap) to clean their cases.

Only 25% (28/113) of individuals used a name brand multi-purpose disinfecting solution versus 5% who used a generic disinfecting solution to clean their cases. Saline was used by 10 % (11/113) of respondents.

Contact Lens Case Drying

The methods of contact lens case drying reported were: air drying face up 24%, (32/131), followed by shaking and air drying face down (22%, 29/131). The next two most utilized practices were recapping wet (21%, 27/131) and shaking and recapping (17%, 22/131) which are actually not drying methods. A total of (2%) of subjects, reported wiping their cases and air-drying face down. Of those who reported a method of air drying (123), 32% said they air-dried their cases daily, 15% air dried every few days, another 15% air- dried weekly, 16% air-dried monthly, lastly 23% said they did not air dry their cases.

Table 5 indicates the different methods of lens case care and the percentage of study participants who utilize each method.

Risky Practices

The majority of participants in this study, 78% (104/134), reported using fresh solution to store their contact lenses. However, 18% (24/134) occasionally reuse their solution and 4% (6/134)

add new fresh solution to old solution “topping off”. This finding was followed by the fact that 74% (99/134) of individuals replaced their solution after each wear, 12% (16/134) replaced their solution “when needed”, another 12% replaced their solution weekly, and 2% (3/134) replaced their solution monthly. Along the line of risky behaviors, about 85% (113/132) of individuals swam while wearing their contact lenses. Of all those who reported swimming with their contact lenses, 66% (73/111) did not wear goggles. Of those who did not wear goggles, 90% (63/70) did not dispose of their contact lenses the same day. The last practice labeled as risky for contact lens wearers is the use of saliva to lubricate lenses prior to replacement onto the cornea. Survey responses indicate that 21% (28/133) of individuals use their saliva in case of emergencies and 1% (1/133) does so all the time. Table 6 details the frequency of “risky” practices of contact lens wearers.

Compliance Assessment

The rubric in Appendix A indicates the scores assigned to each answer choice. Average compliance was $64\% \pm 20\%$ with a range of 4-100%. No significant difference was discovered between the compliance of Group A and Group B. ($p=0.333$). Therefore the entire population was viewed as a whole for further analysis. The compliance grades of Group A, Group B, and the entire study population are illustrated in Figure 2. There was no significant relationship

between attitude scores and compliance ($p=0.516$). Figure 5 displays the spread of compliance as a dependent variable of attitude.

Biofilm Concentrations

Absorbance values after crystal violet staining indicated the level of biofilm concentration within the cases. Biofilm concentrations were not significantly different between group A and group B ($p=0.064$). The average absorbance value for the whole population was 1.9 ± 6.5 with a range of 0.0093 to 64.1. (Figure 14 shows the two cases with the highest absorbance values). There was no significant relationship between biofilm concentration (crystal violet absorbance) and overall attitude ($p=0.689$). Likewise there was no significant relationship between biofilm concentration and compliance ($p=0.794$). Figure 3 illustrates the relationship between compliance and biofilm concentration (log). Figure 4a illustrates attitudes versus biofilm concentration. A significant relationship was seen between the ages of the cases and the levels of biofilm ($p < 0.0001$). Figure 4b displays the positive trend between the age of cases and the absorbance value indicating biofilm levels.

Table 1. Patient Demographics. Part 1

Demographics	Total (n=135)	A (n=66)	B (n=69)	P
Age	<i>n=132</i>	<i>n=65</i>	<i>n=67</i>	—
	mean 39.1±13.0	mean= 41.5 ± 13.0	mean 37.0 ± 12.7	
	min =18 max =64	min =18 max 64	min =21 max =64	
Gender	<i>n=123</i>	<i>n=60</i>	<i>n=63</i>	0.199*
Female	79.67%	78.33%	80.95%	
Male	20.33%	21.67%	19.05%	
No Response	8.89%	9.09%	8.70%	
Self-Identification	<i>n=135</i>	<i>n=66</i>	<i>n=69</i>	0.220*
Asian	19.26%	18.18%	20.29%	
Black / African American	31.11%	30.30%	31.88%	
Hispanic / Latino	16.30%	13.64%	18.84%	
White	31.85%	34.85%	28.99%	
Other	1.48%	3.03%	0.00%	
Income Per Year	<i>n=131</i>	<i>n=64</i>	<i>n=67</i>	0.242*
<10K	9.92%	6.25%	13.43%	
<25K	15.27%	9.38%	20.90%	
<50K	38.93%	43.75%	34.33%	
<100K	28.24%	31.25%	25.37%	
>100K	7.63%	9.38%	5.97%	
No Response	2.96%	3.03%	2.90%	
Highest Level Education	<i>n=134</i>	<i>n=66</i>	<i>n=68</i>	0.099*
Below HS	0.75%	1.52%	0.00%	
High School or Equivalent	21.64%	19.70%	23.53%	
Associate	14.93%	19.70%	10.29%	
Bachelor	42.54%	36.36%	48.53%	
Master	10.45%	10.61%	10.29%	
Doctorate	5.97%	6.06%	5.88%	
Professional	0.75%	1.52%	0.00%	
Doctorate & Professional	2.99%	4.55%	1.47%	
No Response	0.74%	0.00%	1.45%	

Table 1. Patient Demographics. Part 2

Demographics	Total (n=135)	A (n=66)	B (n=69)	P
UTSW Label	<i>n=132</i>	<i>n=66</i>	<i>n=66</i>	<i>0.122*</i>
Student	12.88%	7.58%	18.18%	
Employee	81.06%	89.39%	72.73%	
Trainee or Fellow	2.27%	1.52%	3.03%	
Trainee or Fellow / Employee	2.27%	1.52%	3.03%	
None Applicable	1.52%	0.00%	3.03%	
No Response	2.22%	0.00%	4.35%	

* Indicates a Chi-Square test; ** indicates a Fisher exact; a blank indicates that a chi-square or fisher test could not be performed.

Table 2. Patient Contact Lens Wear Related Characteristics. Part 1

Contact Lens Wear Related Characteristics	Total (n=135)	A (n=66)	B (n=69)	P
Length of Lens Wear Experience	n=45	n=19	n=26	0.399*
6 months-1 year	2.22%	5.26%	0.00%	
1-2 years	6.67%	5.26%	7.69%	
>2-5 years	13.33%	5.26%	19.23%	
>5-10 years	20.00%	15.79%	23.08%	
>10 -15 years	22.22%	21.05%	23.08%	
>15-20 years	20.00%	26.32%	15.38%	
>20 years	15.56%	21.05%	11.54%	
Eye Care Visits Per Year	n=135	n=66	n=69	0.220*
<1(every few years)	9.63%	12.12%	7.25%	
1	69.63%	68.18%	71.01%	
1-2	2.22%	3.03%	1.45%	
2	13.33%	10.61%	15.94%	
>2	5.19%	6.06%	4.35%	
Last Eye Visit	n=135	n=66	n=69	0.199*
Months ago or less	52.59%	62.12%	43.48%	
1 year ago	42.22%	28.79%	55.07%	
2 years ago	5.19%	9.09%	1.45%	
Smoke	n=135	n=66	n=69	1.000**
Yes	2.22%	1.52%	2.90%	
No	97.78%	98.48%	97.10%	
Red/ Pink Eye	n=135	n=66	n=69	1.000**
Yes	31.85%	31.82%	31.88%	
No	68.15%	68.18%	68.12%	
Indication for Lenses	n=133	n=64	n=69	0.259*
Corrective	94.74%	96.88%	92.75%	
Cosmetic	0.75%	1.56%	0.00%	
Corrective & Cosmetic	3.76%	1.56%	5.80%	
Eye Disease or Surgery	0.75%	0.00%	1.45%	
No Response	1.48%	3.03%	0.00%	

Table 2. Patient Contact Lens Wear Related Characteristics. Part 2

Contact Lens Wear Related Characteristics	Total (n=135)	A (n=66)	B (n=69)	P
Place of Lens Purchase	n=134	n=65	n=69	0.220*
Eye Practitioner	52.99%	49.23%	56.52%	
Retail	25.37%	27.69%	23.19%	
Online	14.93%	13.85%	15.94%	
Multiple	6.72%	9.23%	4.35%	
No response	0.74%	1.52%	0.00%	
Type of Lenses	n=134	n=65	n=69	0.199*
Soft	90.30%	89.23%	91.30%	
Rigid	9.70%	10.77%	8.70%	
No Response	0.74%	1.52%	0.00%	
Wearing Schedule	n=134	n=65	n=69	0.234*
Daily	70.90%	70.77%	71.01%	
Extended	11.19%	9.23%	13.04%	
Conventional	12.69%	16.92%	8.70%	
Daily Disposable	2.99%	1.54%	4.35%	
Occasional Overnight	1.49%	1.54%	1.45%	
Multiple	0.75%	0.00%	1.45%	
No Response	0.74%	1.52%	0.00%	
Bottles of Solution Per Month	n=134	n=66	n=68	0.244*
<1	44.03%	39.39%	48.53%	
1	23.88%	28.79%	19.12%	
1-2	26.87%	24.24%	29.41%	
3-4	4.48%	7.58%	1.47%	
>4	0.75%	0.00%	1.47%	
No response	0.74%	0.00%	1.45%	
Always same solution	n=132	n=66	n=66	0.199*
Yes	77.27%	81.82%	72.73%	
No	22.73%	18.18%	27.27%	
No Response	2.22%	0.00%	4.35%	

*** Indicates a Chi-Square test; ** indicates a Fisher exact**

Table 3. Summary of Patient Responses to Attitude Questions

Attitudes (A)N=66, (B)N =69	Strongly agree		Total	Agree		Total	Undecide d		Total	Disagree		Total	Strongly disagree		Total
1. I consider myself to be a risk taker. (A) n=66 (B) n=69	A= 13.64% (9/66)	B=17.39 % (12/69)	16%	A=21.21% (14/66)	B=26.09% (18/69)	24%	A= 16.67% (11/66)	B=13.04% (9/69)	15%	A=43.94% (29/66)	B=31.88% (22/69)	38%	A=4.55% (3/66)	B=11.59% (8/69)	8%
2. I am compliant with my doctor's recommendations for the proper wear and care of my lenses. (A) n=66 (B) n=69	A=33.33% (22/66)	B=27.54% (19/69)	30%	A=43.94% (29/66)	B=59.42% (41/69)	52%	A=4.55% (3/66)	B= 5.80% (4/69)	5%	A=12.12% (8/66)	B=7.25% (5/69)	10%	A= 6.06% (4/66)	B=0% (0)	3%
3. It is important to wash my hands before handling my lenses. (A) n= 66 (B) n=66	A=65.15% (43/66)	B=72.73% (48/66)	69%	A=28.79% (19/66)	B=25.76% (17/66)	27%	A=6.06% (4/66)	B=0% (0)	3%	A=0% (0)	B=1.52% (1/66)	1%	A=0% (0)	B=0% (0)	0%
4. It is important to rub, rinse, and properly store my lenses. (A) n=66 (B) n=68	A=48.48% (32/66)	B=54.41% (37/68)	51%	A=46.97% (31/66)	B=39.71% (27/68)	43%	A=1.52% (1/66)	B=4.41% (3/68)	3%	A=1.52% (1/66)	B=1.47% (1/68)	1%	A=1.52% (1/66)	B=0% (0)	1%
5. It is important to rub and rinse my lens case like I do my lenses (A) n= 66 (B) n=68	A=34.85% (23/66)	B=29.41% (20/68)	32%	A=33.33% (22/66)	B=37.18% (29/68)	38%	A=18.18% (12/66)	B=17.65% (12/68)	18%	A=12.12% (8/66)	B=10.29% (7/68)	11%	A=1.52% (1/66)	B=0% (0)	1%
6. It is important to maintain good lens case hygiene. (A) n= 65 (B) n=67	A=55.38% (36 /65)	B=55.22% (37/67)	55%	A=41.54% (27 /65)	B=38.81% (26/67)	40%	A=3.08% (2/65)	B=5.97% (4/67)	5%	A=0% (0)	B=0% (0)	0%	A=0% (0)	B=0% (0)	0%
7. It is important to clean my lens case daily. (A) n=65 (B) n=67	A=38.46% (25 /65)	B=43.28% (29/67)	41%	A=27.69% (18 /65)	B=35.82% (24/67)	32%	A=13.85% (9/65)	B=7.46% (5/67)	11%	A=16.92% (11/65)	B=11.94% (8/67)	14%	A=3.08% (2/65)	B=1.49% (1/67)	2%
8. It is important to clean my lens case daily using the cleaning solution my doctor prescribed for my lenses i.e multi purpose or hydrogen peroxide. (A) n=65 (B) n=69	A=35.38% (23 /65)	B=42.03% (29/69)	39%	A=32.31% (21 /65)	B=33.33% (23/69)	33%	A=20.00% (13/65)	B=14.49% (10/69)	17%	A=12.31% (8/65)	B=8.70% (6/69)	10%	A=0% (0)	B=1.45% (1/69)	1%
9. It is important to air dry my lens cases. (A) n= 64 (B)	A=26.56% (17/64)	B=33.82% (23/68)	30%	A=28.13 (18/64)	B=38.24% (26/68)	33%	A=32.81% (21/64)	B=17.65% (12/68)	25%	A=9.38% (6/64)	B=5.88% (4/68)	8%	A=3.13% (2/64)	B=4.41% (3/68)	4%
10. I am willing to spend whatever is necessary for the optimum health and care of my eyes i.e. doctor visits, lenses, lens cases, and contact lens solutions. (A) n=65 (B) n=69	A=47.69% (31 /65)	B=39.13% (27/69)	43%	A=35.38% (23/65)	B=47.83% (33/69)	42%	A=12.30% (8/65)	B=7.25% (5/69)	10%	A=3.08% (2/65)	B=4.35% (3/69)	4%	A=1.54% (1/65)	B=1.45% (1/69)	1%
11. Cost is an important factor in how I clean and care for my lens cases. (A) n=65 (B) n=69	A=21.54% (14 /65)	B=24.64% (17/69)	23%	A=41.54% (27/65)	B=37.68% (26/69)	40%	A=9.23% (6/65)	B=10.14% (7/69)	10%	A=18.46% (12/65)	B=18.84% (13/69)	19%	A=9.23% (6/65)	B=8.70% (6/69)	9%
12. Time is a factor in how I clean and care for my lens cases. (A) n= 65 (B) n=69	A=33.85% (22 /65)	B=33.33% (23/69)	34%	A=49.23% (32/65)	B=40.58% (28/69)	45%	A=7.69% (5/65)	B=13.04% (9/69)	10%	A=6.15% (4/65)	B=11.59% (8/69)	9%	A=3.08% (2/65)	B=1.45% (1/69)	2%
13. Ease of use is an important factor on how I clean and care for my lens cases. (A) n= 65 (B) n=68	A=41.54% (27 /65)	B=42.65% (29/68)	42%	A=47.69% (31 /65)	B=47.06% (32/68)	47%	A=6.15% (4/65)	B=8.82% (6/68)	8%	A=3.08% (2/65)	B=1.47% (1/68)	2%	A=1.54% (1/65)	B=0% (0)	1%
14. I believe lens case care is equally as important as lens care. (A) n=64 (B) n=69	A=35.94% (23/64)	B=36.23% (25/69)	36%	A=31.25% (20/64)	B=34.78% (24/69)	33%	A=23.44% (15/64)	B=17.39% (12/69)	20%	A=9.38% (6/64)	B=11.59% (8/69)	11%	A=0% (0)	B=0% (0)	0%
15. I am putting my eye health at risk by being non-compliant. (A) n=65 (B) n=69	A=50.77% (33 /65)	B=34.78% (24/69)	43%	A=36.92% (24/65)	B=33.33% (23/69)	35%	A=6.15% (4/65)	B=13.04% (9/69)	10%	A=3.08% (2/65)	B=11.59% (8/69)	7%	A=3.08% (2/65)	B=7.25% (5/69)	5%
16. I know the recommended hygiene practices for proper lens case care. (A) n=65 (B) n=68	A=35.38% (23 /65)	B=26.47% (18/68)	31%	A=36.92% (24/65)	B=42.65% (29/68)	40%	A=13.85% (9/65)	B=17.65% (12/68)	16%	A=13.85% (9/65)	B=13.24% (9/68)	14%	A=0% (0)	B=0% (0)	0%

Figure 1. Patient Attitudes towards Compliance

Of all individuals who completed survey A (n=66), 88% who received a total score of 1 or above, indicating that they had a positive attitudes. For group B (n=69), 93% had a positive attitude score. There was no significant difference between the two groups (p=0.908). Overall 90% of all participants had positive attitudes.

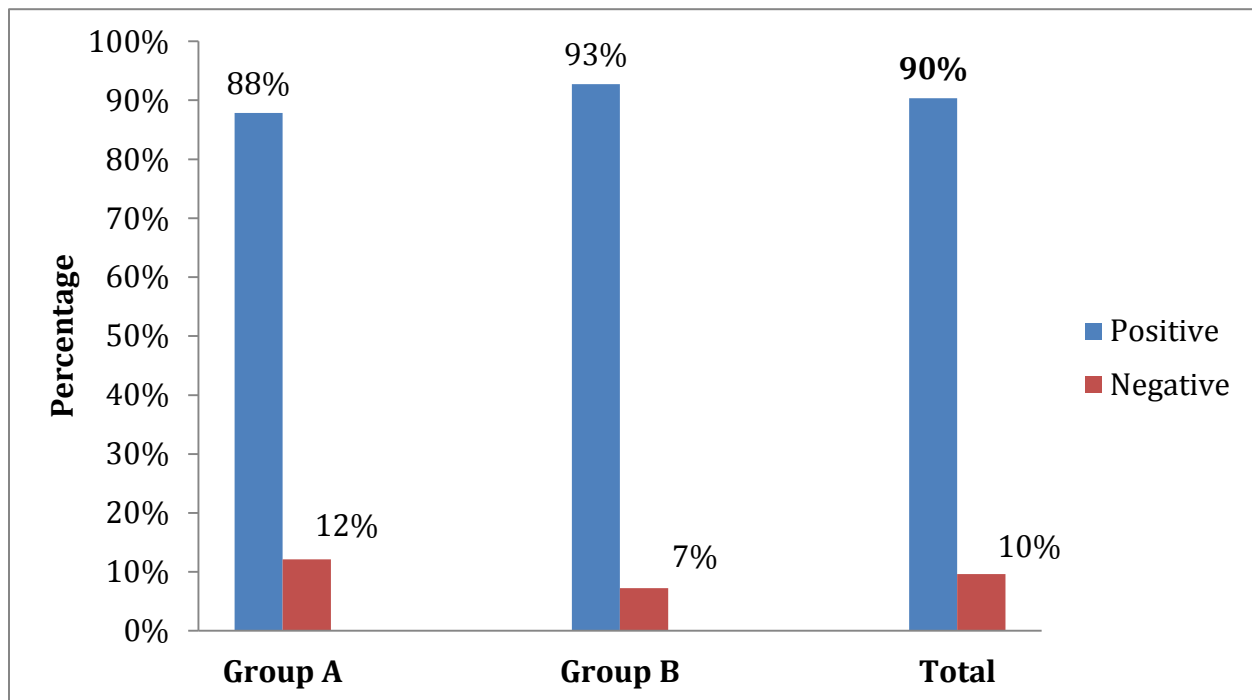


Table 4. Hand Hygiene Practices. Part 1

Hand Hygiene	Total (n=135)	A (n=66)	B (n=69)	P
How often do you clean your hands before handling your lens cases?				
				0.242*
Always	66%	63%	69%	
Most of the time	25%	23%	27%	
Occasionally	5%	5%	4%	
Rarely	3%	6%	0%	
Never	2%	3%	0%	
No Response/Discarded	2%	2%	3%	
How do you clean your hands before handling lens cases?				
				0.259*
Water	8%	10%	7%	
Water & Soap	86%	84%	90%	
Hand Sanitizer	2%	0%	3%	
Do not clean	4%	10%	1%	
No Response/Discarded	2%	3%	1%	
If you use water and soap when cleaning your hands how long does it take?				
				0.213*
Less than 5 seconds	20%	13%	25%	
Between 5 and 20 seconds	33%	35%	32%	
More than 20 seconds	47%	52%	43%	
No Response/Discarded	1%	0%	2%	
How do you dry your hands before handling your lenses?				
				0.135*
Paper Towel	32%	34%	31%	
Bathroom Hand Towel	59%	54%	63%	
Body Towel	15%	11%	4%	
Clothes	3%	5%	1%	
Whatever is near	1%	0%	1%	
Simply shake off water	8%	8%	10%	
Do not dry	5%	8%	3%	
Multiple	14%	17%	12%	
Answer Non-applicable	1%	2%	0%	
No Response/Discarded	0%	0%	1%	

Table 4. Hand Hygiene Practices. Part 2

If you use your hand towel, how often do you change your hand towel?			0.082*
Few Days	50%	63%	40%
Weekly	41%	34%	47%
Monthly	4%	0%	7%
Few Months	1%	0%	2%
Never	1%	0%	2%
"2 weeks"	1%	0%	2%
Answer Non-applicable	1%	0%	0%

* Indicates a Chi-Square test

Table 5. Contact Lens Care Practices. Part 1

Contact Lens Case Cleaning	Total (n=135)	A (n=66)	B (n=69)	P
How often do you replace your lens cases?				0.087*
Monthly	16%	14%	18%	
3 Months	21%	23%	19%	
6 Months	21%	31%	12%	
1 Year	29%	20%	37%	
>1	2%	0%	3%	
Never Replace	11%	12%	9%	
"When needed/ when dirty"	2%	0%	3%	
No Response, N/A, or Discarded	1%	2%	1%	
How often do you clean your lens cases?				0.177*
Daily	29%	23%	34%	
Few Days	14%	17%	10%	
Weekly	20%	26%	13%	
Monthly	20%	15%	25%	
Do not clean	15%	15%	15%	
"Each Use"	2%	2%	1%	
"Occasionally"	1%	2%	0%	
When it bothers	1%	0%	1%	
No Response, N/A, or Discarded	1%	2%	1%	
How do you clean your lens cases?				0.241*
Rinse	40%	44%	36%	
Rub & Rinse	54%	42%	57%	
Wipe w/ cloth or tissue	3%	4%	2%	
Multi (Rinse & wipe)	3%	2%	3%	
Other	1%	0%	2%	
Which do you use to clean your lenses cases?				0.242*
Water (Water & Soap)	43%	51%	36%	
Saline	10%	11%	9%	
Peroxide	4%	2%	5%	
Name Brand Multi-Purpose Solution	25%	18%	31%	
Generic Disinfecting Solution	5%	7%	3%	
Multiple Solutions	13%	11%	16%	

Table 5. Contact Lens Care Practices. Part 2

Contact Lens Case Cleaning	Total (n=135)	A (n=66)	B (n=69)	P
How do you dry your case?				0.199*
Recap Wet	22%	19%	21%	
Wipe and Recap	5%	7%	6%	
Shake and Recap	17%	16%	17%	
Shake and Air Dry Face Up	25%	24%	24%	
Shake and Air Dry Face Down	24%	21%	22%	
Wipe and Air Dry Face Up	0%	4%	2%	
Wipe and Air Dry Face Down	3%	1%	2%	
Recap With fresh solution	2%	0%	1%	
Multiple	2%	6%	4%	
"Do Not Dry"	0%	1%	1%	
No Response, N/A, or Discarded	5%	1%	3%	
How often do you air-dry your case?				0.243*
"Each Use"	2%	0%	1%	
Daily	25%	38%	32%	
Few Days	15%	16%	15%	
Weekly	24%	8%	15%	
Monthly	12%	20%	16%	
Do not air dry ("never" and "do not clean")	27%	19%	23%	
No Response, N/A, or Discarded	6%	4%	5%	

* Indicates a Chi-Square test

Table 6. Risky Practices of Contact Lens Wearers

Risky Practices	Total (n=135)	A (n=66)	B (n=69)	P
Do you use fresh solution to store your lenses?				
				0.213*
All time	78%	77%	78%	
Occasionally Reuse	18%	20%	16%	
Add fresh solution to old solution " top off "	4%	3%	6%	
No Response/ Discarded	1%	0%	1%	
How often do you replace the solution in your case?				
				0.220*
After each wear	74%	73%	75%	
Weekly	12%	12%	12%	
Monthly	2%	2%	3%	
When needed	12%	14%	10%	
No Response/ Discarded	1%	0%	1%	
During the summer, when participating in water sports, swimming, or attending water parks, how often do you wear your contacts?				
				0.224*
Always	51%	56%	45%	
Most time	20%	17%	23%	
Occasionally	6%	5%	8%	
Rarely	9%	8%	11%	
Never	14%	15%	14%	
No Response/ N/A/Discarded	2%	0%	4%	
When participating in these water activities do you wear goggles?				
				0.199*
Yes	34%	35%	34%	
No	66%	65%	66%	
No Response/ N/A	2%	2%	2%	
If you do not wear goggles do you throw your lenses away the same day?				
				0.199*
Yes	10%	15%	6%	
No	90%	85%	94%	
No Response	4%	6%	3%	
Do you use saliva to clean lenses before inserting lens?				
				0.238*
Yes, only in emergencies	21%	20%	22%	
Never	78%	80%	76%	
All the time	1%	0%	1%	
No Response/ N/A/Discarded	1%	0%	3%	

* Indicates a Chi-Square test

Figure 2. Compliance Grades

The compliance of each patient was graded based on their reported practices. The grades were divided into 3 categories, good (90% and above), average (70-89%), and poor (69% or below). There was no significant difference between the compliance of group A and group B ($p=0.333$). Overall 57% of all participants had poor compliance, 35% had average compliance, and only 7% had good compliance.

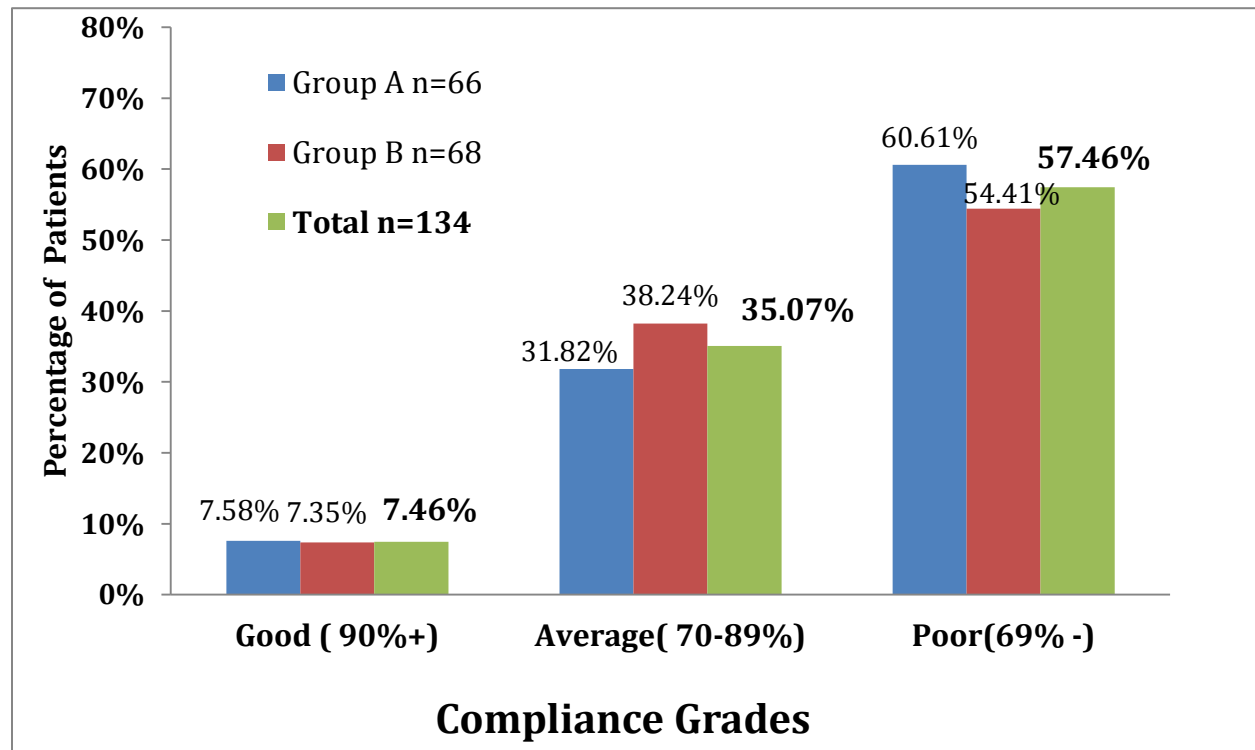


Figure 3. Patient Compliance and Crystal Violet Absorbance.

There was no significant relationship between the compliance grades of patients and the absorbance values of the crystal violet assay done on their cases ($p=0.794$). The average absorbance value was 1.889 ± 6.498 with a range of 0.002 to 64. The logarithm of the absorbance values was calculated in order to create a better visual of data. There were two patients with a score of 100% compliance. Actual compliance level for the entire sample population was $64\% \pm 20\%$ with a range of 4% - 100%.

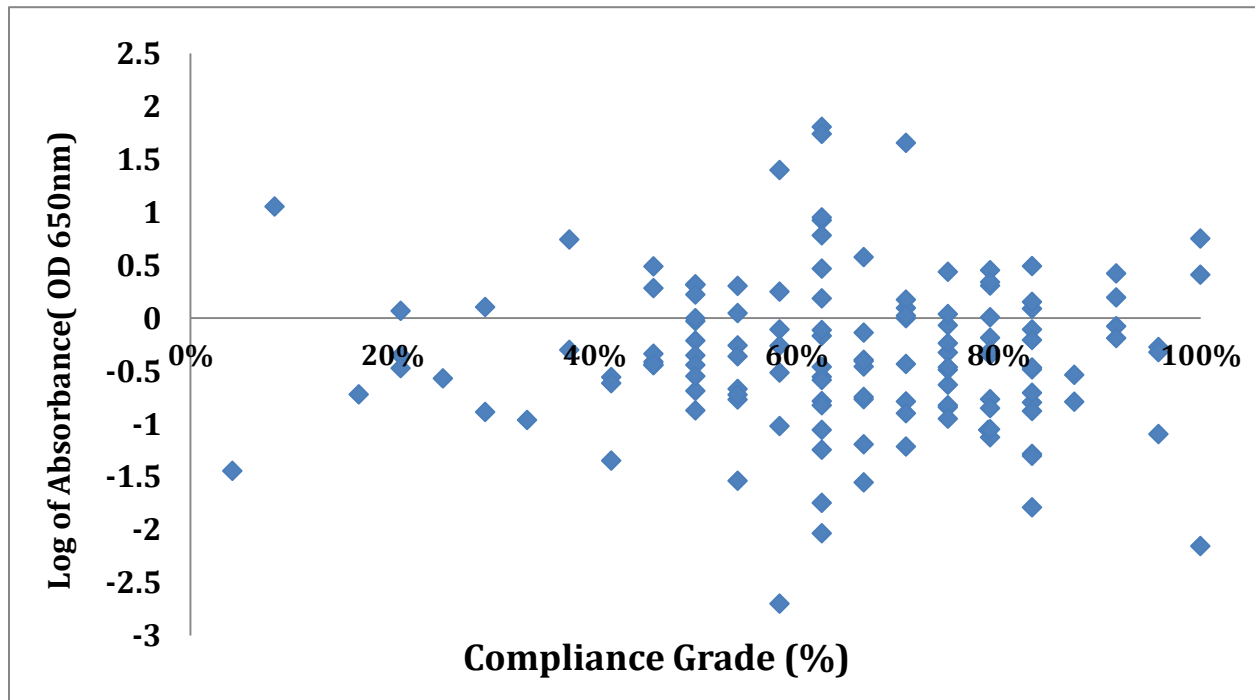


Figure 4a. Attitude and Absorbance

There was no significant relationship between patient attitude and absorbance and the graph below depicts the lack of correlation between the two variables ($p=0.689$). This is a just indication that no correlation exists between a patient's attitude toward compliance and the biofilm levels within his or her contact lens case.

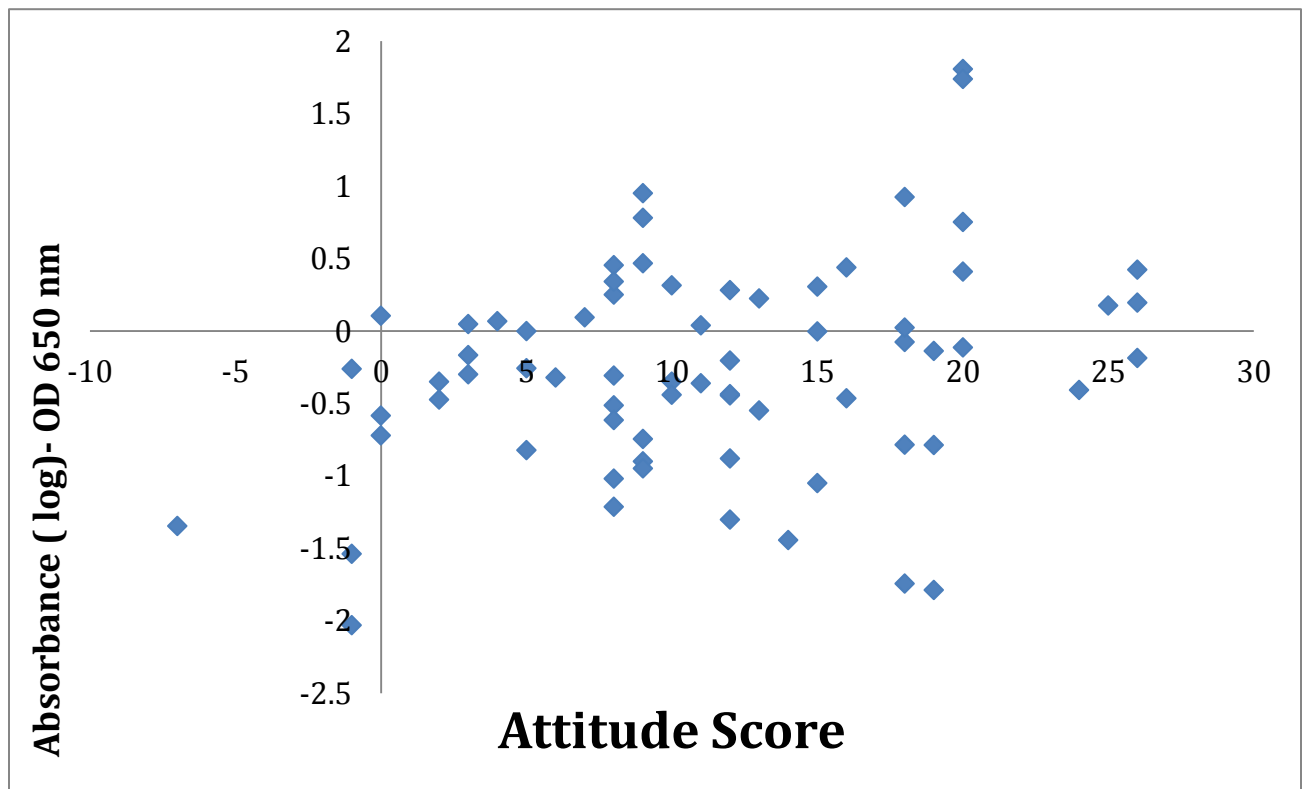


Figure 4b. Ages of Cases and Biofilm Levels

There was a significant relationship between the age of the contact lens cases and the level of biofilm ($p < 0.0001$). The spread of the data in this figure confirms that older cases have more microbial contamination as it has previously been studied. The first row of values indicates cases of 3 months old, the second row are 6 months old cases, the third row are 9 month old cases, the fourth row is made up of 12 month old cases, and the final row is of cases of 24 months. The absorbance values increases as the age of the case increasing.

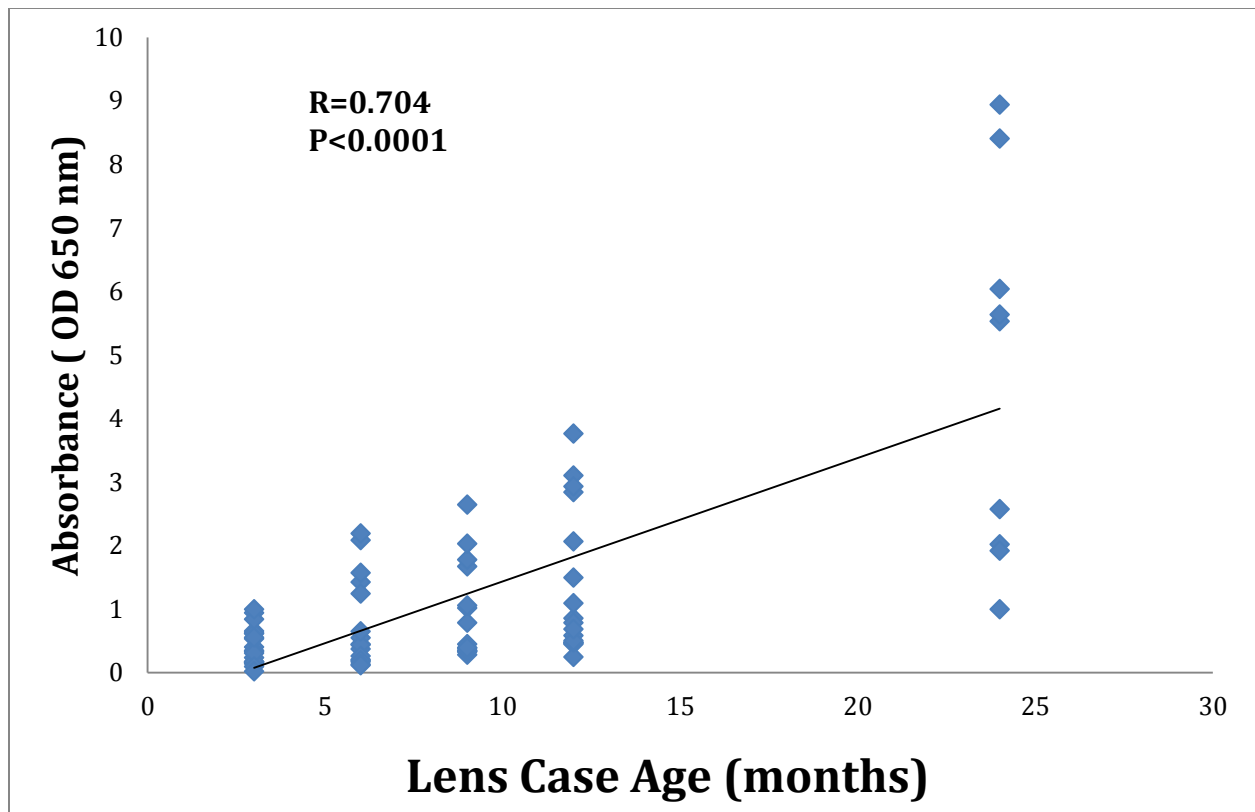
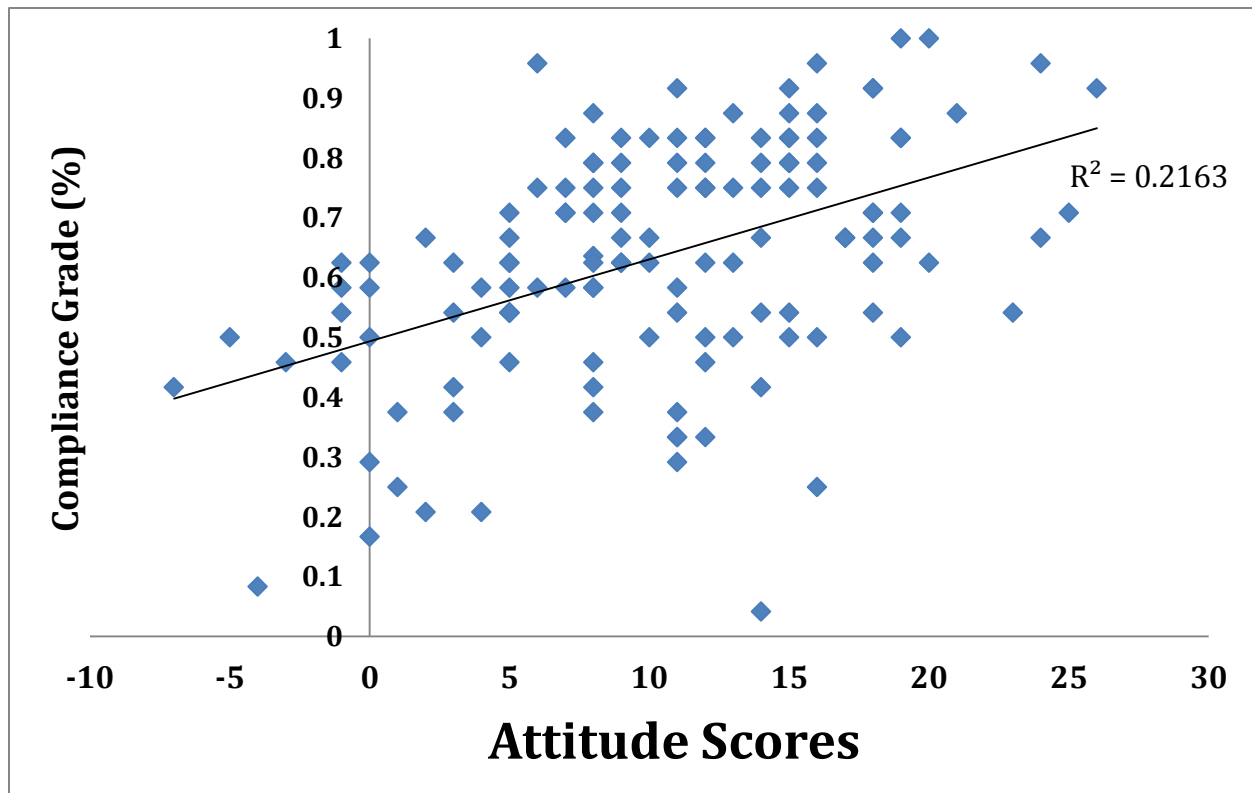


Figure 5. Attitude and Compliance

No significant relationship was found between the study subjects' attitude scores and compliance grades ($p=0.516$). However, a positive trend is visible between attitude and compliance ($R^2=0.216$). Attitude scores were measured based on the responses of patients to 16 statements. The average attitude score was 10.3 ± 6.7 with a range of -7 to 26. Compliance was measured based on the reported practices of patients. Actual compliance level for the entire sample population was $64\% \pm 20\%$ with a range of 4% - 100%.



CHAPTER VII: EYE CARE PRACTITIONER SURVEY RESULTS

Demographics

A total of 616 surveys were mailed to eye care practitioners within the Dallas Fort Worth Metroplex, Texas. Of all surveys mailed, 45 were returned due to a mailing error, and 51 surveys were faxed or emailed back by eye care practitioners. The response rate was 51/571 (8.9%). Of those who responded, 92% (47/51) practiced in an optometry clinic. The distribution within the group of those who practiced within optometry clinics is as follows: 60% private clinics, and 32% retail. Four study participants in this arm of the study did not indicate whether their practice was retail or private. Figure 6 provides demographics data as indicated by the practitioners.

Compliance Education

A total of 39 practitioners, 76.50% of respondents, reported utilizing multiple methods of communication (hands-on trainings, verbal, and written) to educate their patients about the importance of compliance. The most reported method of compliance education by this same group was training in combination with handouts, 59% (23/39), followed by 21% (8/39) who used all three methods and 18% who used trainings and verbally relayed information to patients. Out of the entire group of respondents, 12% (6/51) of the practitioners only used verbal

communication as their method of patient education on compliance, while 10% (5/51) only used hands-on trainings. Figure 7 illustrates the different methods of education in a bar graph.

In addition, 96% (49/51) of the practitioners reported discussing the health risks of non-compliance with their contact lens wearing patients. Of this group, nearly half, 49% (24/49), of the practitioners addressed the health risks associated with non-compliance verbally. This was followed by 33% (16/49) who utilized verbal and written notice to communicate with patients on this topic. Five practitioners responded yes without indicating their method of education. Figure 8 illustrates the comparison between the methods of education utilized.

Hand Hygiene

All 100% of the practitioners reported emphasizing the importance of hand hygiene with regards to proper lens care. Greater than half, 51% (26/51) responded that they simply inform patients verbally, 41% said they used verbal and written forms of communication documentation. Only, 1.96% responded that they address hand hygiene via written notice. Similarly, all 51 eye (100%) care providers said they advised patients to wash their hands before handling their contact lenses and accessories. It was nearly an even split between the methods of education; 43% (22/51) said they only verbally informed patients to wash their hands and 41% (21/51) said they used both

written and verbal communication for this purpose. Table 7 describes the percentages of responses to each hand hygiene questions.

The duration of hand washing was only addressed by 14% (7/51) of practitioners. Of the 14% (7/44) who said they specify the duration of hand washing, 86% (6/7) said they did so verbally, and 14% (1/7) said verbally and with written information. However, 88% (45/51) reported specifying the use of water and soap for properly cleaning hands. The methods utilized to communicate this information to patients were 51% (23/45) for verbal and 29% (13/45) for verbal and written. In the same line of hand hygiene, the survey revealed that 35% (18/51) of practitioners do not address hand drying as part of the hand hygiene process prior to handling lenses. Of the 65% (33/51) who advocate for hand drying, 61% (20/33) reported using verbal communication only and 21% (7/33) said they used both written and verbal means of communication. The remaining 6% (2/33) used written communication only.

Hand drying is not addressed by 44% (22/50) of ECPs during the education of patients on proper habits for the care of their lenses. Of the 46% (28/50) of respondents who said they addressed hand drying, 82% (23/ 28), advised patients to use a clean paper towel, while clean hand towels was advised by 14% (4/28).

Contact Lens Storage Case Care and Replacement

The importance of contact lens storage case cleaning is discussed by 90% (46/51) of eye care doctors who completed the survey. Of these 46 practitioners, 48% (22/46) reported verbally informing patients about this topic while only 33% (15/46) reported using both written and verbal methods of education. Roughly 84% (43/51), said “yes” to informing patients about the importance of contact storage lens case replacement. Of those 43 individuals who said yes, 49% (21/43) said they verbally communicated the information and 35% (15/43) said they used written and verbal instructions. This data is presented in Table 8.

There was a scattered spread of responses from eye care practitioners about the advice they gave patients in regards to the frequency of lens case cleaning: 43% (22/51) advised patients to clean daily, followed by 24% (12/51) who advised monthly cleaning, 16% (8/51) who said weekly, and 20% (10/51) who said they do not address the topic to patients. Figure 9 depicts this information.

Specific to the method of lens case cleaning, 55% (28/51) recommended patients to rub and rinse, while 33% (17/51) said rinsing only was their recommendation to patients. Just about 12%

mentioned that they do not address the topic. Figure 10 illustrates this information. The most proposed cleaning agent to patients for contact lens cases was water and soap by 60% (30/50) of eye care practitioners. In contrast, 36% (18/50) recommended the use of disinfecting solutions. Eight percent reported not discussing this point with their patients. Note: two practitioners mentioned more than one cleaning agent and their answer was tallied for each of the two answer choices. This data is shown in Figure 11.

There is discord within the practitioner population about the correct method of contact lens case drying as well as the favorable position for air-drying. Within this sample group, 39% (20/51) recommended that patients air dry their cases face up, the same percentage, 39% recommended cases to be dried facedown. Only 2% of practitioners, 1/51, selected “clean tissue wipe and air dry face down as his recommendation to patients. Nine of the 51 practitioners (18%) marked that they do not address the topic of lens case drying. There were other options available to practitioners on the survey, “clean tissue wipe and air dry face up”, “recap wet”, and “do not specify”. However, none of the study subjects selected those options. This data is illustrated in Figure 12. All 51 respondents addressed lens case replacement and 59 % (30/51) said they advise patients to change cases every 3 months, 27% (14/51) said monthly, and 6% said bi-monthly. The data is presented in Figure 13.

Figure 6: Eye Care Practitioners Practice Modality

The majority of respondents in this survey study were optometrists (92.2 %) of all reported practice modality. Private indicates the percentage of the sample population of eye care practitioners who practice in private or stand-alone clinics. Retail indicates the percentage of respondents from corporate entities such as Target, Wal-Mart, Costco, etc. No label indicates that the optometrist did not specify the practice modality.

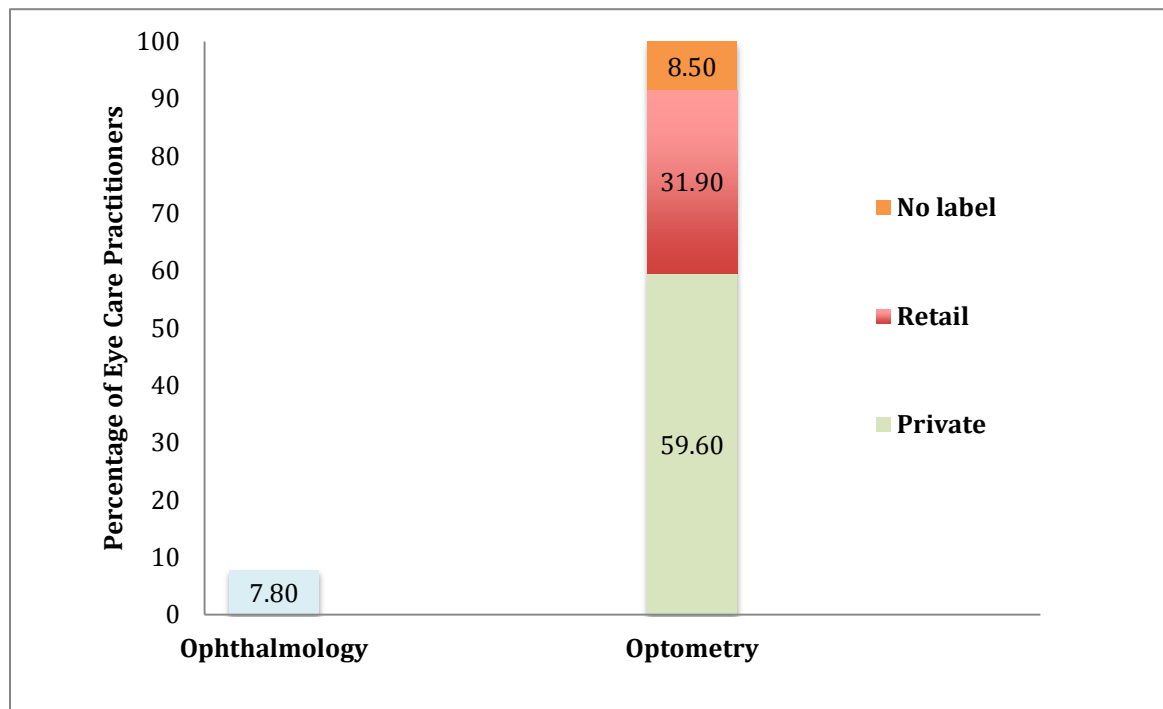


Figure 7: Mode of Compliance Education

Eye care practitioners were asked the methods they utilized to educate patients about compliance. The majority, 77% (39/51) utilized more than one mode of education to communicate the importance of compliance for contact lens wearers. The modes of education listed as the independent variable for this graph (training, verbal, and handout) are all commonly used methods of communication for patient education.

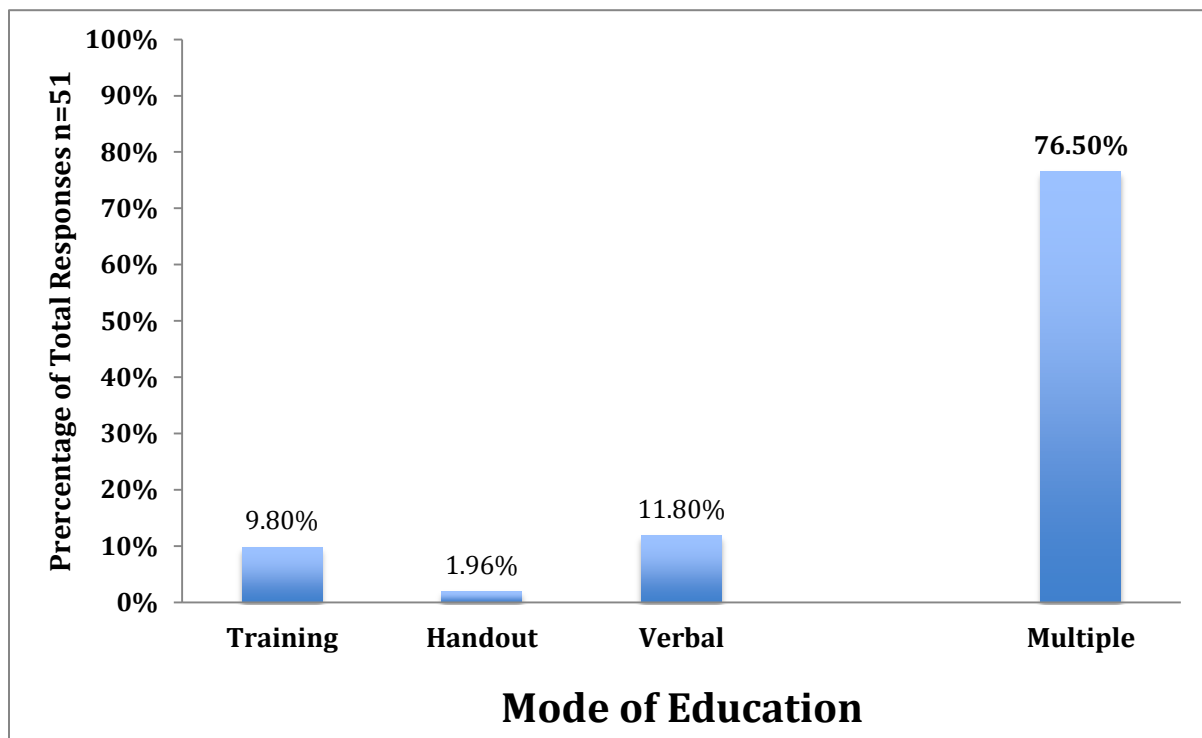


Figure 8. Addressing the Health Risks of Non-Compliance

There are many health risks to non-compliance. For contact lens wearers these risks include conjunctivitis or infections such as microbial, fungal, and amoebic keratitis that could potentially lead to blindness. The graph below illustrates the percentages of eye care practitioners who addressed these topics or more while educating patients about non-compliance.

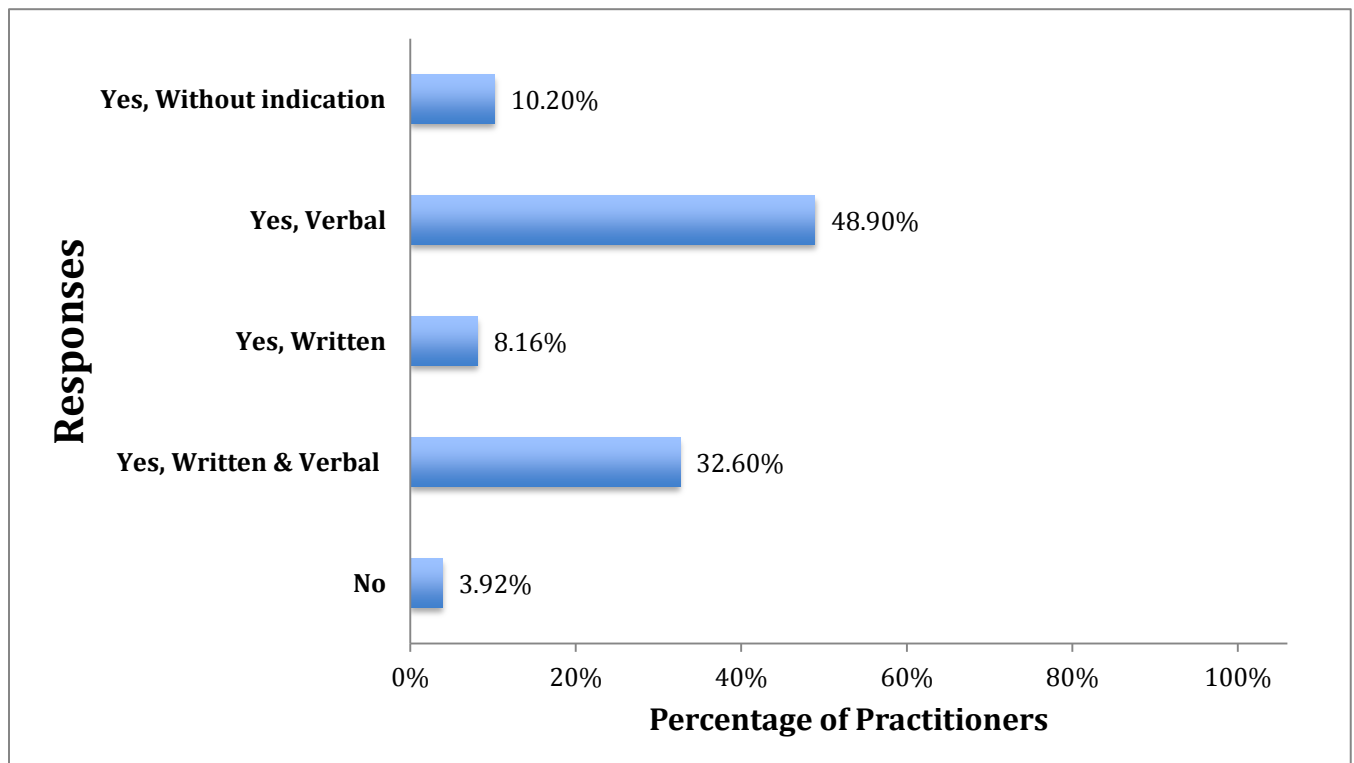


Table 7. Methods of Education for Hand Hygiene

All 51 practitioners indicated that they addressed hand washing for the proper care of lenses. The table below depicts the way in which they communicated with patients about hand hygiene.

	Advise patients to wash hands before handling contact lenses or contact lens accessories	Inform patients about the importance of hand hygiene for proper lens care
Written + Verbal	41.20%	41.18%
Verbal	43.10%	50.98%
Written	3.92%	1.96%
Nonspecific "Yes"	11.80%	5.88%

Table 8. Methods of Education for Lens Case Care

The cleaning and replacement of contact lens storage cases is an important part of compliance and proper hygiene habits for contact lens wearers. The report is 90 % (46/51) of practitioners address cleaning while 84% (43/51) address replacement. The majority address the former topics verbally, 48% (22/46) and 49% (21/43) respectively. Only (6%) of practitioners reported using verbal and written communication (the most effective) to educate patients about lens case replacement. This is an indication that practitioners might need to place more emphasis on communicating the importance of lens case replacement to their patients. Such a measure could reduce the incidence of contact lens related adverse events.

	Inform patients about the importance of lens case cleaning	Inform patients about the importance of lens case replacement
No	9.80%	15.69%
Yes	90.20%	84.30%
Written	15.20%	34.90%
Verbal	47.80%	48.80%
Written + Verbal	32.60%	5.88%
Non-specific "Yes"	4.30%	7.80%

Figure 9. Practitioner Advised Lens Case Cleaning Frequency

The CDC recommends daily cleaning of contact lens storage cases as the most effective practice for reducing microbial contamination of lens cases. Patients are often non-compliant with this recommendation. The following graph depicts the how often practitioners in this study are advising their patients to clean their contact lens storage cases. The majority, 22/51 or 43% are advising daily cleaning, 12/52 or 24% advised for monthly cleaning, while 10/51 or 20% did not specify the frequency of cleaning. Lastly, 16% or 8/51, advised weekly cleaning.

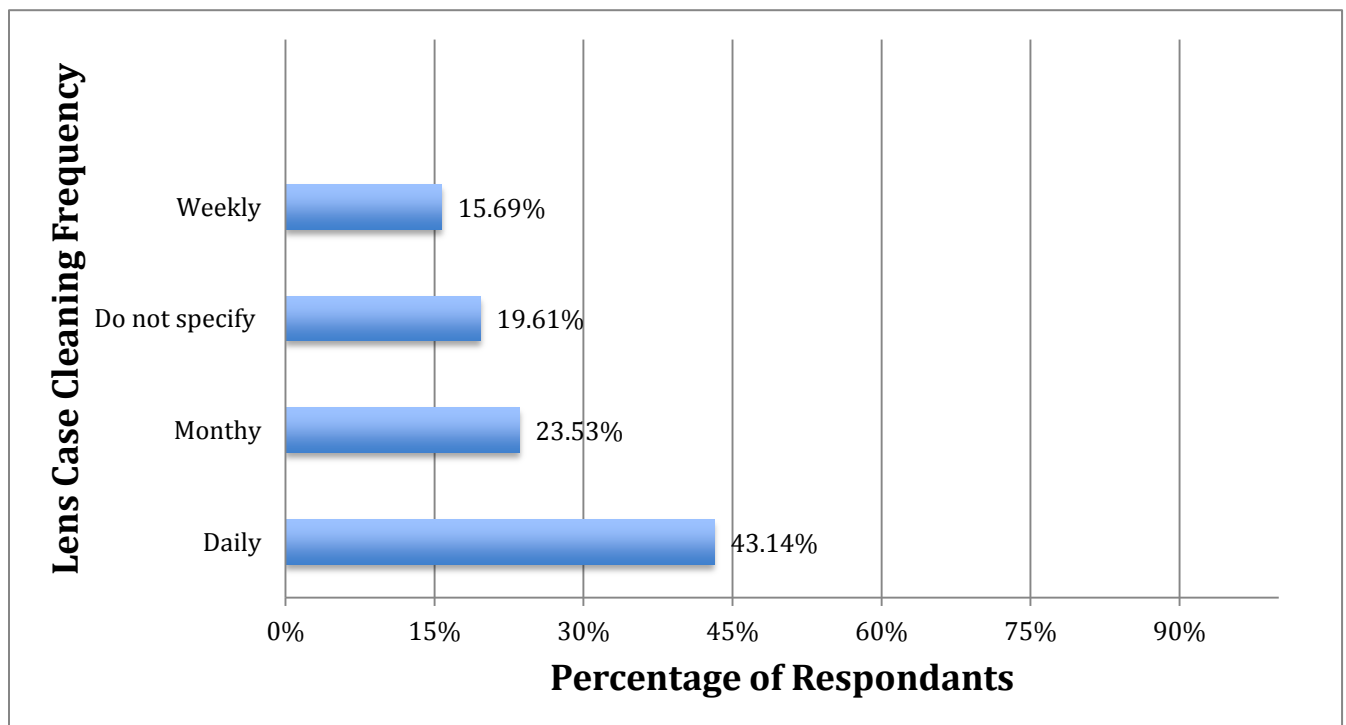


Figure 10. Practitioner Advised Lens Case Cleaning Methods

Rubbing and rinsing or simply rinsing are common methods of contact lens case cleaning. The CDC recommends patients to rub and rinse cases. To determine if doctor recommendations reflected this fact, practitioners were asked to report what they told their patients to do. The figure below illustrates that 55% (28/51) recommended both rubbing and rinsing, 33% (17/51) advised rinsing only, while 12% (6/51) did not mention anything to patients.

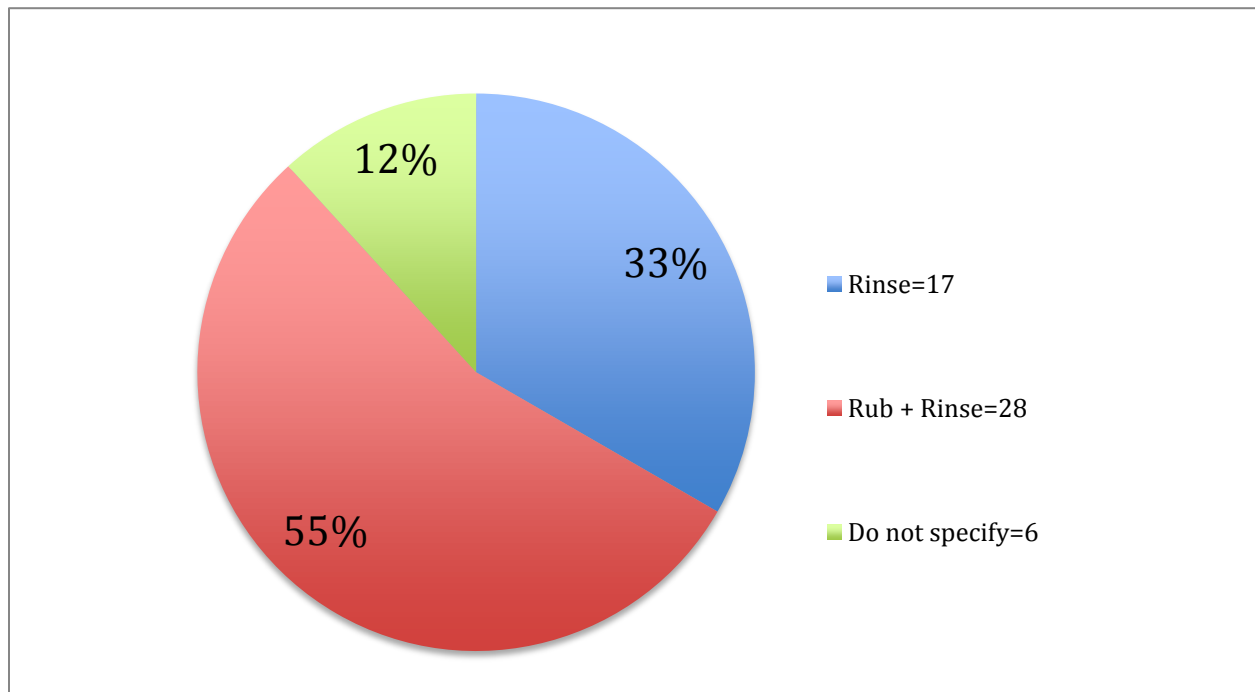


Figure 11. Practitioner Advised Lens Case Cleaning Agents

Frequently utilized cleaning agents for contact lens cases are tap water and soap, multi-purpose disinfecting solutions, and at times even saline although it is unlikely that practitioners make that recommendation to patients. Therefore saline was not listed as an option. The CDC advises patients to use the same disinfecting solution they use for their lenses to clean their lens storage cases. About 60% (30/50) of practitioners in this study are recommending that their patients use water and soap to clean their lens cases. In contrast, 35% (18/50) are asking patients to use disinfecting solutions instead.

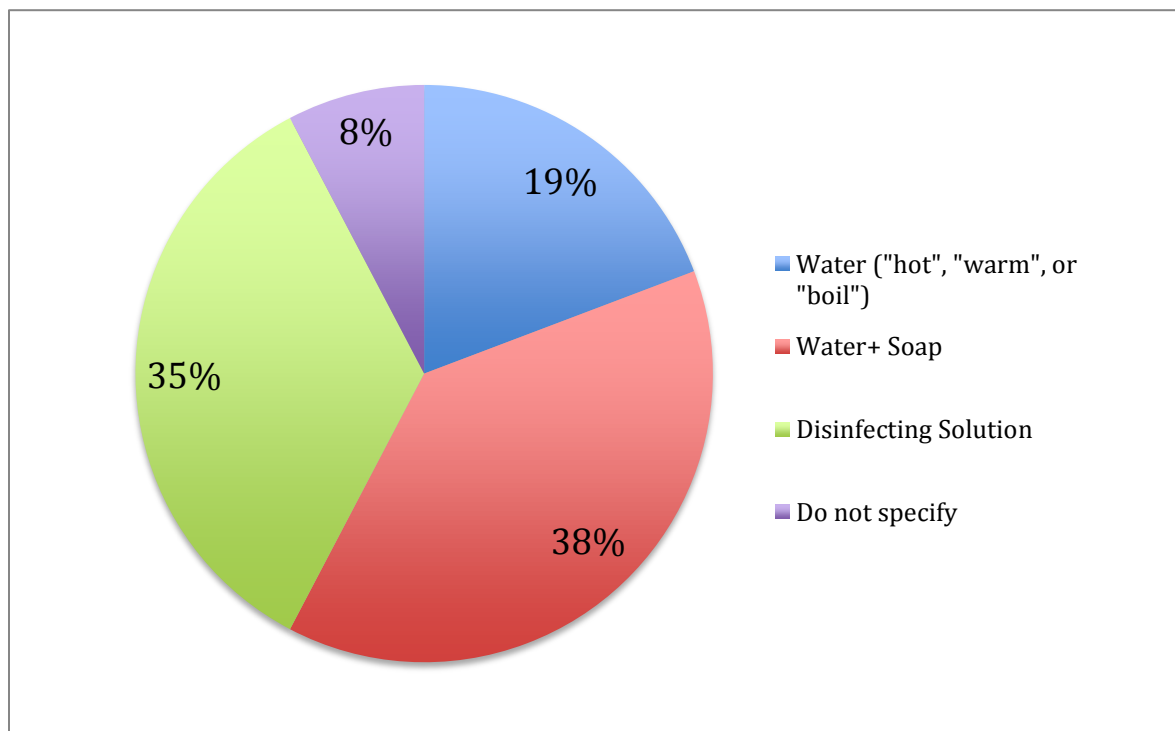


Figure 12. Practitioner Advised Lens Case Drying Methods

Important in the hygienic care of cases is air-drying to further reduce the amount of organisms present within the wells of the cases. The position of air-drying is important because when facing up, the cases are likely to accumulate airborne microbes. The CDC recommends cases to be wiped dry with a clean tissue and then left to air-dry face down. The figure below depicts the knowledge base of practitioners in regards to case drying. One individual out of 51, in other words, only 2% of the sample population correctly chose the CDC recommended drying method and position. Nearly 18% (9/51) do not address case drying. Note (One practitioner recorded “air-dry” without indicating the position.)

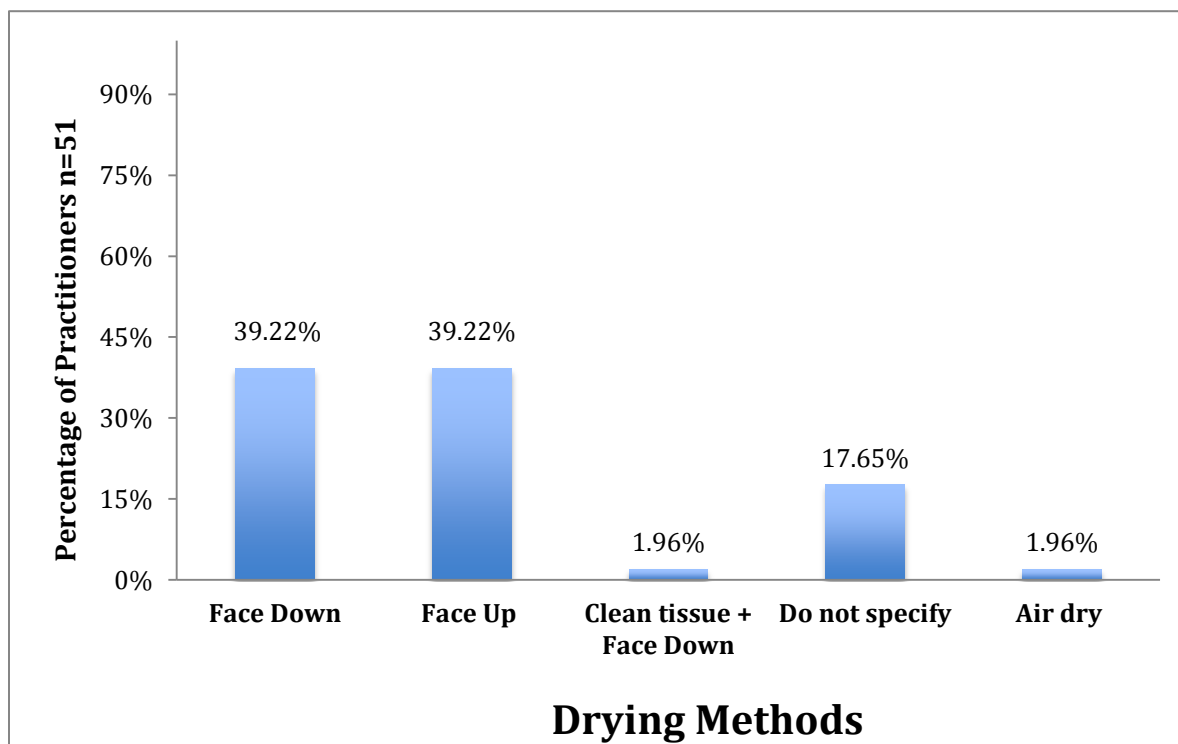


Figure 13. Practitioner Advised Lens Case Replacement Frequency

Lens storage case replacement is the last step of the hygienic maintenance of contact lens storage cases. Contact lens cases ought to be replaced every three months. The majority of practitioners are properly advising patients to replace their cases at an interval of three months or less.

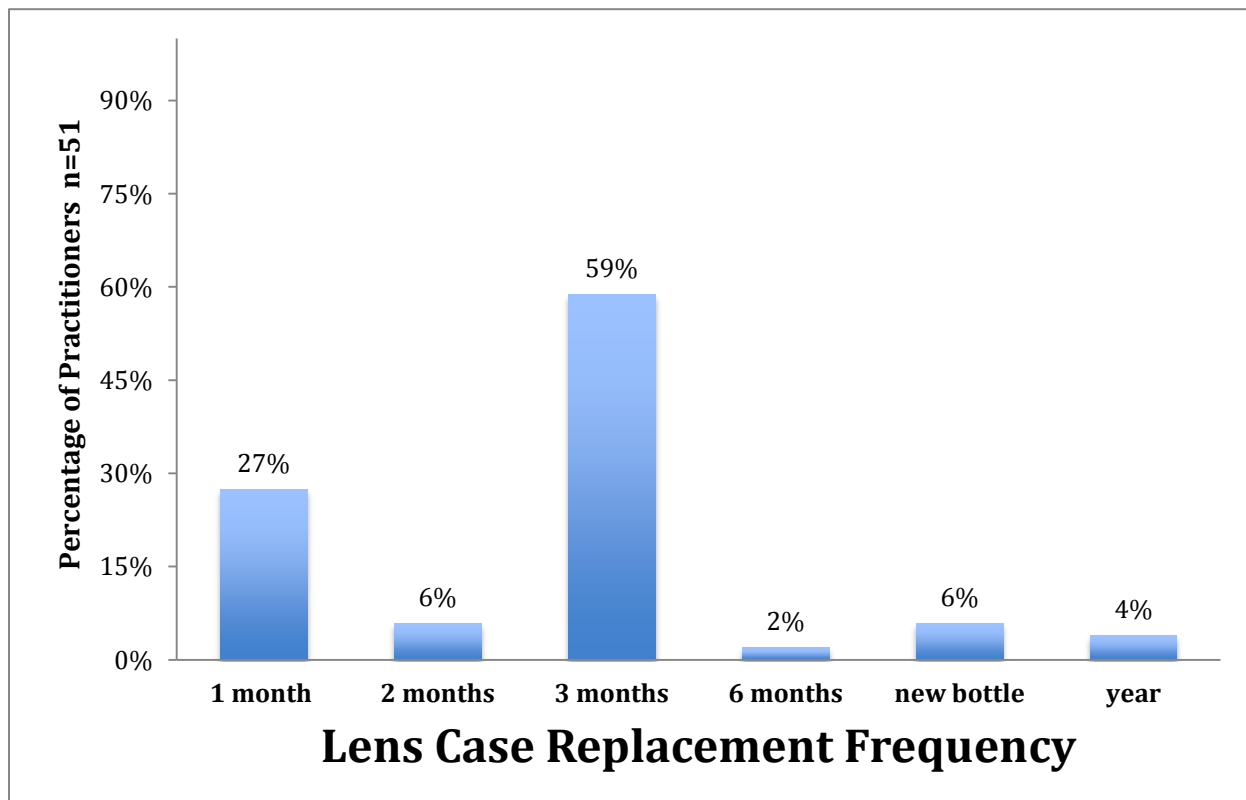


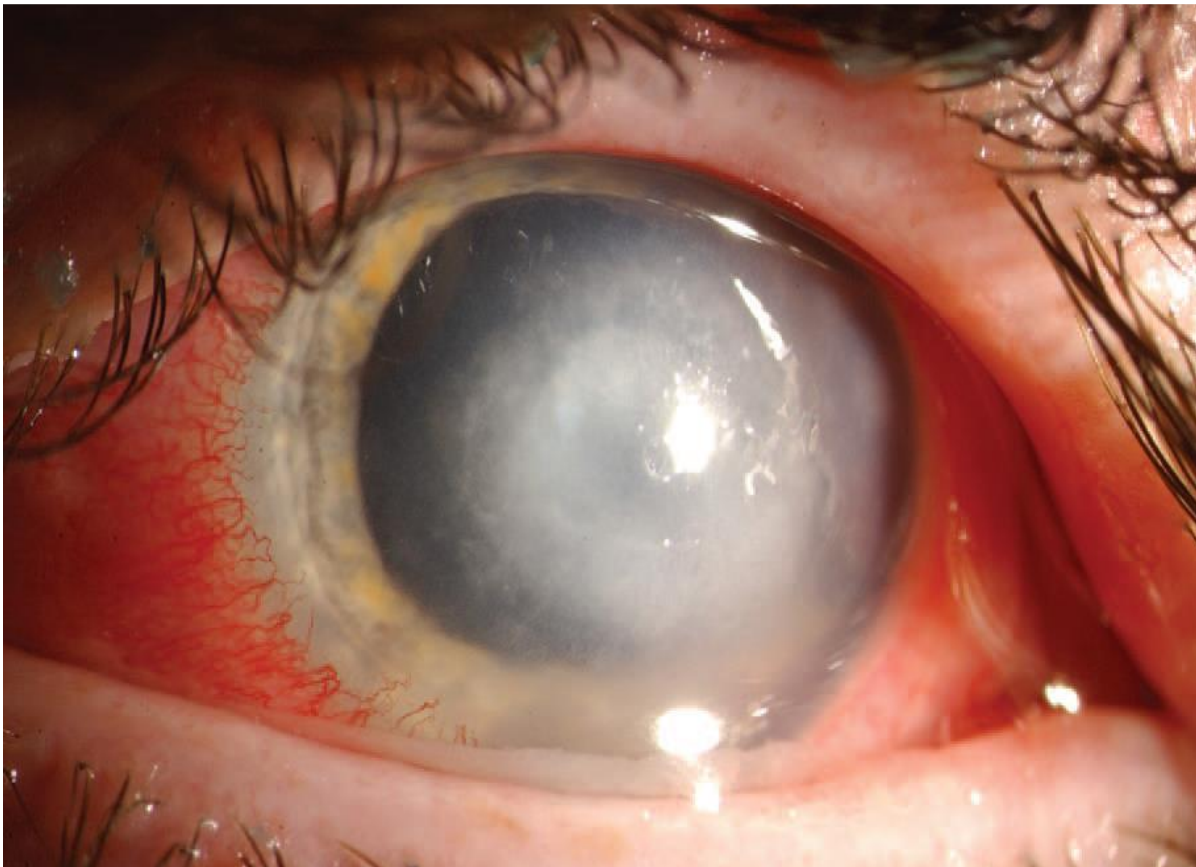
Figure 14. The cases with the highest presence of biofilm.

Crystal violet assays were done on all cases to quantify the presence of biofilm by measuring absorbance. The absorbance value of the pink and lime green case was 64.1, the greatest outlier within the set of all absorbance values. The case that immediately follows, (green top) has the second highest absorbance value 54.8. The female participant who donated these cases reported that the cases were older than two years old. The patient's compliance score was 63%.



Figure 15. Clinical Presentation of Acanthamoeba Keratitis.

The patient in the image below was diagnosed with Acanthamoeba Keratitis after having washed his rigid contact lenses with tap water and not cleaning his lens case. The Acanthamoeba destroyed the patient's cornea, leaving him blind in the affected eye. ¹⁰



CHAPTER VIII: ANALYSIS OF ATTITUDES, COMPLIANCE, AND CONTACT LENS CASE BIOFILM CONCENTRATIONS

This study investigated the attitudes towards compliance of contact lens wearers as well as actual levels of compliance in comparison to biofilm concentrations within contact lens storage cases.

We have shown that attitudes towards good compliance do not translate into actual compliant behavior practices or levels of biofilms. To control for potential response bias, there were two survey formats (A and B), both consisting of the same questions. There were two sections to the survey, the first presented patients a set of statements to quantify and qualify their attitude toward compliance using a Likert scale. The second section questioned the hygiene practice of patients. The order of questions (behavior then attitudes) was opposite between form A and B of the survey. This study did not find a significant difference between the attitudes of those who completed form A versus those who completed form B. Likewise, there was no significant difference between the behaviors and compliance grades of patients between group A and group B. Thus the order of the questions had no effect on either the attitudes or behavioral findings, allowing for analysis of the dataset as a whole.

Negative attitudes were assigned scores of 0 and below (lowest score possible was -32) and scores of 1 and above (maximum score of 32) were considered positive. The average attitude score was 10.3 ± 6.7 with scores ranging from -7 to 26. Overall, 90% of patients had positive

attitudes toward compliance. However, this number would decrease substantially if a more stringent model was employed which used a higher cut-off value. Interestingly, the average actual compliance level for the entire sample population was $64\% \pm 20\%$ with a range of 4% - 100%. Compliance grades were divided into three categories, poor (69% and below), average (70-89%), and good compliance (90% and above). Altogether, 57% of individuals had poor compliance, 35% average, and 7% had good compliance. Therefore, 90 % of subjects had positive attitude toward compliance, yet only 42% had average to good actual compliance. One explanation for this discord in the comparison between attitude and compliance is the fact that individuals' perceptions of compliance are often greatly overestimated. In this study, about 82% of individuals considered themselves to be compliant with the recommendations of their doctors for the proper care of their lenses. The misperception of compliance may also be due to the fact that individuals do not know the recommended practices for the proper care of their lenses and lens cases, or they have received inaccurate information from their eye care practitioner; this will be discussed later. Similar to the findings on perceived compliance, about 71% of individuals considered themselves knowledgeable about the proper care for contact lens storage cases. The reports of positive attitudes toward compliance may be interpreted as a willingness from individuals to be compliant. Additionally, it may reflect that individuals know the importance of being compliant, yet may still fail to exhibit good compliant practices. This interpretation is in

line with previous studies that have shown that patients are non-compliant despite knowledge of the risks of non-compliance.²¹ This persistence in non-compliance could indicate that patients may be aware of the risks they face by being non-compliant, yet are limited by factors such as education or resources needed to ensure the health of their eyes. It is apparent from this practicum study that willingness to be compliant and the understanding of the importance of compliance do not translate into actual compliance. Another possible explanation to account for the disparity between attitudes and compliance is the arbitrary cut-off mark (a score of 1 or greater on a scale of -32 to +32) used to classify patients as having positive attitude. A more stringent definition of a positive attitude, such as a score of 16 and higher would result in significantly fewer patients exhibiting positive attitudes and may bring both attitudes and behavior into closer agreement. Further studies are needed to validate the scaling method utilized to determine the optimal threshold for establishing a true criterion for assessing attitudes.

When compared to biofilm concentrations within cases, as measured by the absorbance results of the crystal violet assays, neither overall compliance nor overall attitudes showed significant relationships. This finding is similar to the results of another study where a significant relationship between good compliance and biofilm formation or density could not be established.¹⁴ The average absorbance value was 1.889 ± 6.498 with a range of 0.002 to 64

(Measured at an optical density of 650 nanometers). The wide range of the values reflects the many variables in the hygiene care process of lens cases that could be contributing to biofilm formations and contamination levels. Additionally, the large standard deviation is due to a few outlier values, amongst which the largest were 64.1 and 54.8 (recovered from two cases, older than two years old that were donated by the same individual). The case with the greatest density of biofilm was a non-ordinary case, pink and lime green in color (See Figure 14). This finding is similar to an earlier study by our laboratory group which also found that multi colored lens cases had the highest levels of microbial contamination (unpublished data). This discovery argues against the use of multi-colored (visually appealing) lens cases since patients tend to hold on to these cases longer. In addition, clinicians should re-emphasize the importance of lens storage hygiene and replacement to patients who have the multi-colored lens cases.

Research has shown that most cases, 60-80%, recovered for clinical studies, will have some level of microbial contamination.¹⁵ The fact is not surprising since all items, especially those used frequently, are prone to high levels microbial contamination. Microbial identification may have a more significant relationship with compliance or risky behaviors such as swimming with contact lenses. In patients with a corneal infection due to contact lens wear, the microorganism is almost always recovered from the lens case. Since crystal violet, the biofilm marker used in this study

can also stain proteins and non-viable cellular debris, we hypothesize that confounding variables may be included in the absorbance results from the crystal violet assay.

CHAPTER IX: PATIENT ATTITUDES TOWARD LENS CASE CARE

Our results support a critical need for more emphasis to be placed on the importance of lens cases in the hygienic care process. Only 71% of patients considered themselves knowledgeable about the proper methods of case cleaning. The need for education is also supported by the fact that a majority of patients demonstrated greater knowledge about the appropriate methods of lens cleaning, but not for contact lens cases. Approximately 95% of individuals felt it was important to rub, rinse, and properly store lenses, but only 70% of them thought rubbing and rinsing lens cases was important.

With this in mind, the attitude of patients reflects less concern for the cleanliness of their cases compared to their lenses. Although 95% of individuals thought it important to maintain good lens case hygiene, only 69% of patients found lens case cleaning as important as contact lens cleaning, and only 73% thought it important to clean contact lens cases daily. In other words, patients think cleaning their cases is important, but assign a lower priority to the lens case when compared to their lenses.

Likewise, time and ease of use were considerable factors for the hygienic care of cases for 78% and 89% of individuals, respectively. It takes maybe one or a maximum of two minutes to rub, rinse, wipe dry, and leave a case to air dry, this is not a demanding task for patients and, on its own, it is very self-explanatory. The ease of these instructions are considered because studies report that the more complex a medical regimen is, the less compliant patients may be.⁸ The lack of knowledge of risks and about proper care of the lens case represent two crucial areas for improved education, are not willing to take the time to clean their cases.

CHAPTER X: PATIENT PRACTICES IN CONTRAST TO PRACTITIONER RECOMMENDATIONS

Hand Hygiene

Considerable comparisons can be made between the recommendations of local eye care physicians and the compliance practices of patients. Some of the comparisons are positive and represent the fact that there are helpful or encouraging data stemming from the current mode of education between patients and practitioners. However, there are some areas that reflect the need of education for both practitioners and patients. The findings of this study support the hypothesis

that patients are receiving from their eye care providers improper recommendations about certain aspects of the care of their contact lens storage cases.

The first practice evaluated was hand hygiene. In the patient cohort this was evaluated by asking one attitude question and three behavior questions that pertained to the cleanliness of hands prior to handling lens cases and lenses. The attitude question posed to individuals was whether or not they considered it important to wash their hands prior to handling their lenses. The result was that almost all individuals agreed or strongly agreed to this statement. In contrast, the behavioral questions about hand hygiene were posed in a manner that was not to hint too much at “hand washing” prior to handling lenses. Therefore, the first of the three questions was, “how often do you clean your hands before handling your lens cases?” The term “lens case” was used in place of “lenses” because the care of lenses and lens cases should be simultaneous in the hygiene regimen of a compliant contact lens wearer. It is recommended to wash hands prior to handling contact lenses and in order to handle contact lenses one needs to handle a contact lens case. For those who are not compliant and do not wash their cases daily or after each wear, it is still important to wash their hands to handling their lens cases. Contamination of the lens case could lead to contamination of the lenses, as organisms in the case can transfer to the lens. Once on the eye, a contaminated lens could promote an eye infection depending on the pathogen.

Approximately 96% of individuals said they always, most of the time, or occasionally cleaned their hands. This percentage is in exact agreement with our earlier report of 96% of individuals agreeing to the importance of hand washing. Moreover, this datum is also in accord with the 100% of practitioners who advise patients to wash their hands before handling contact lenses.

There are two possible explanations that may contribute to this finding. One, this study was conducted at a medical institution, where individuals are likely to be aware and sensitive to basic healthy practices such as hand washing. The other explanation relates to the finding that 100% of the surveyed practitioners reported that they emphasized the importance of hand hygiene for proper lens care and reported advising patients to wash their hands prior to handling their contact lenses and contact lens accessories. Around 51% of these practitioners reported using strictly verbal communication while 41% used both verbal and written communication to drive their point across. Further analysis of the hand hygiene practices of patients revealed concerning facts. Data showed that 86% of individuals reported using water and soap to clean their hands. Of those who used water and soap, and 33% took between 5-20 seconds or more to wash their hands and 47% reported washing for at least 20 seconds or more. Fewer than 15% of eye care practitioners made a recommendation regarding the duration of hand washing. The percentage of individuals, who report using water and soap, 86%, is close to the 88% of practitioners who

specifically recommended patients use water and soap to clean their hands. About 51% of practitioners verbally recommended the use of water and soap to patients while 29% used both written and verbal methods of education. It was important to determine the method of education used by practitioners because previous studies indicate that there are effective and ineffective methods of patient education.^{8,11} Multiple methods of education are likely to be more effective in helping patients grasp certain information, since repetition is a defining factor in effective communication. The duration of hand washing, however, was not addressed by 86% practitioners, even though it is the next most important detail in the disinfecting process. The CDC recommends that individuals clean their hands for at least 20 seconds, stating that true disinfection begins after at least 15 seconds of washing with water and soap.

The next questions about hand hygiene pertained to the method of hand drying. The majority of individuals selected multiple choices; therefore, the total amount of any one choice “mentioned” was recorded. A total of 59% of participants mentioned that they used their bathroom hand towels to dry their hands, 32% mentioned using a paper towel, 15% used their body towel, and about 13% did not dry or simply shook their hands. Only 50% of those who used their hand towels changed their towels every few days (approximately 2-3 days) and even less reported

changing their towel daily. Studies have found that microbes are most likely to be transmitted from wet hands than from dry hands. Moreover, wet hands may introduce water borne organisms to the lens or the lens case.²² Thus, the method of hand drying or the lack thereof could represent a source for contamination of hands and cross contamination of contact lenses. Since hand towels are often left moist, this creates a favorable environment for microbes and patients should be advised to use a clean hand towel (changed daily) or a clean paper towel. For contact lens wearers, it is preferable to use low lint towels, but also to completely dry hands. Both lint and water residue when attached to lenses could cause discomfort (itchy or dry sensation) to patients upon lens insertion.

Contact Lens Case Replacement

In this study, 84% of physicians discussed the importance of replacing contact lens cases and 86% of physicians advised patients to replace their lens cases either every three months or less. During the education process, 49% of physicians reported verbally communicating the replacement recommendation to patients. While 35% handed flyers or pamphlets to patients, only 6% of physicians spoke and shared a written document about the importance of lens case replacement and the frequency. The contrast between the eye care practitioners and patient practices is considerable because only 37% (49/133) of patients are replacing their cases at a

recommended interval (every three months or less). This is important because prior studies have shown that lens cases older than 6-9 months have significant levels of contamination.¹⁶

Contact Lens Case Cleaning

A total of 85% of individuals reported that they cleaned their cases. Of that set of individuals, only 31% cleaned their cases daily while 54% cleaned every few days, weeks, or months and 15% did not clean their cases. A confounding factor to this information is that the frequency of cleaning could be specific to the lens-wearing schedule. For example, those who wore weekly-extended wear lenses may only be using their cases once each week or each month. Therefore, if patients are only cleaning their cases after each wear, they would be compliant with lens case cleaning. Because the lens characteristics of our study population reflect that 71% were daily lens wearers, we assume that the scarcity in case cleaning is due to occasional lens case use. Interestingly, 43% of physicians reported recommending daily contact lens case cleaning, about 39% said monthly or weekly, and 20% stated they did not specify to their patients the frequency of lens case cleaning. These reports from ECPs highlight one important area where both practitioner and patient education are lacking.

The CDC recommends that patients rub and rinse their cases when they clean. The majority of patients who cleaned their cases, 54% (61/113) did so by rubbing and rinsing, while 40% (45/113) only rinsed their cases. A major concern with lens case hygiene is that a large proportion of patients are using water (tap water and soap) to clean their cases and are thereby exposing themselves to the risks of an *Acanthamoeba* infection. Only about 30% of patients used disinfecting solution (name brand or generic) to clean their cases. More worrisome is that only 35% of physicians recommend using actual cleaning solutions, while 57 % recommend using water or water and soap. The comparison between the patients' practices and physicians' recommendations are similar. Both indicate a lack of knowledge that water and soap are not the current evidence based methods of lens case cleaning and that the use of water could potentially introduce harmful organisms to the lens or the lens case. If the lenses are contaminated with an infectious pathogen like *Acanthamoeba*, the patient could suffer from a sight threatening disease like *Acanthamoeba* Keratitis. The low percentage of individuals using name brand multi-purpose disinfecting solutions and the high percentage using tap water suggests that there is a need for "correct" education for practitioners and patients alike. A second consideration is financial. Patients who use water may be attempting to limit use of their disinfecting solutions. Our findings did indicate a financial concern amongst the patient cohort, because although 85% of patients say they are willing to spend whatever is necessary for the optimum health and care of their eyes,

63% agreed that cost played a factor in how they cared for their contact lens cases. Lens cleaning solutions, depending on the frequency of lens wear, can be costly for certain individuals who properly use the solutions for both the cases and lenses. In this study, 69% earned equal to or less than \$50,000 and likewise amongst the same study subjects a total of about 68% reported using one bottle or less than one bottle of solution each month. Advising patients to use their disinfecting solutions to clean their cases could promote other non-compliant practices in other areas such as reusing solutions in their lens cases to store their lenses.

Contact Lens Case Drying

Half of the patient cohort reported air-drying their cases, yet only 2% of those participants that air-dry their cases do so according to the CDC recommendations, wipe and air-dry face down. Likewise, only 2% of physicians advised patients to dry their cases face down after wiping with a clean tissue. Among the physicians surveyed, it was assumed that air-drying was their recommendation and as such the question practitioners were asked was which method of air-drying they advised patients to use. About 39% advised air-drying the cases face down and the same percentage said they advised patients to air dry cases face up. Yet, 18% admitted that they did not address the topic, probably an indication that they do not know the correct recommendation. Similar results were evident in the patient group, where the two most utilized

methods of drying were shaking and air drying face up (24%), followed by shaking and air-drying face down (22%). In regards to patients' attitudes about air drying, 64% felt it important to air dry cases and 25% were unsure about the importance. Data revealed that 11% disagreed with the importance of air drying. In terms of actual behavioral practices, 44% of study participants reported recapping their cases without air-drying (recap wet, wipe and recap, or shake and recap). Of all those who reported a method of air-drying, only 32% said they air-dried their cases daily. Air drying lens cases face-down, especially after wiping, is a recommended evidenced-based practice by the CDC and has been shown to be more effective than other methods.^{23,25} Wet, humid environments such as wet sealed cases are favorable to bacterial growth. Again this highlights another area for more education of eye care practitioners.

Contact Lens Case Practical Considerations

Since most manufacturers are also instructing lens case users to replace their cases every three months, there are a few practical considerations. The first is that patients remain unaware of the need to replace their lens cases at least every three months. This may be greatly influenced by the education they receive from their eye care practitioners. During an office visit, often there is little time and depending on the context of the visit, patients are not likely to remember a verbally spoken detail like "replace your case every three months". Also, when patients are given a

pamphlet with instructions for the care and replacement of their contact lenses, most are not likely to read if they are busy or if they are long-term contact lens wearers. This is supported by findings that increased years of lens wearing experience is a detriment to compliance and even the discovery of greater rates of microbial contamination within the lens cases of patients with greater years of lens wear experience.²⁴ Therefore, education techniques and methodologies by eye care practitioners may need to be revised.

One consideration in regards to in regards to patient education is that verbal communication or written communication used individually is not effective. It is estimated that within minutes of leaving office visits, patients forget about 50% of the information they received.¹⁷ Methods of patient education greatly influences patient compliance. A combination of these methods may be more effective in relaying the importance of contact lens case care. Certain eye care practitioners reported in their surveys that they trained new contact lens wearers about proper lens care, but did not do so for established contact lens wearers. Continued re-emphasis of the importance of hygiene care practices should occur for all patients at every visit.

Outside of the eye care practitioner, patients themselves carry the ultimate responsibility of maintaining their ocular health. As such, aside from the education received from practitioners,

the other factors that influence compliance are directly tied to the patient. A few factors that hinder patients' compliance with the hygienic care of the lens storage case include attachment, inability to see dirt on the case, and the failure to keep track of the age of their case. Attachment to "pretty" or "efficient" contact lens cases is common. Individuals openly discussed during the lens case drive how much they "loved" their cases or the kind of cases they preferred to have. Some were even unwilling to donate their cases and explained the reason to be because the case was "special", or the case did not allow leakages, or even that the cases had a lower volume capacity and therefore used up less solution than other cases. It is not surprising that the only "pretty case" in the study was greater than 2 years old and had the highest crystal violet absorbance value of all 137 cases.

The inability to see dirt within the cases is another reason patients do not clean or replace their cases often. The misconception here is that visible dirt within the wells of the cases are the only signs to take cautionary measures. There were about 4 individuals who reported on the survey that they replaced their cases when it was "needed" or when "dirty". If not already being discussed, the topic of non-visible bacterial contamination should be addressed during when educating contact lens wearers.

One possible intervention to help promote regular lens case replacement would be to use a method that would help patients track the age of their cases. One method could be a visual indicator that would alert patients that their cases are no longer safe for use and need to be replaced. An example would be a litmus indicator incorporated into lens case material so that a color change would caution patients to get a new case. Other strategies include telling patients to replace their case every time they replace their toothbrush, which most of people know to replace at least every three months. The last consideration would be automated text message alerts from eye care practitioner offices that would remind patients to replace their cases after three months or less depending on the physician recommendation to the patient.

CHAPTER XI: RISKY PRACTICES

Similar to a previous report,²¹ the majority of participants in this study reported using fresh solution to store their contact lenses. This finding was followed by the fact that 74% of individuals replaced their solution daily or after each wear. However, a more in-depth analysis reveals that the predominant compliant practice of using fresh solution and replacing those solutions on a daily basis reveals that there are many behaviors that are inconsistent with the numbers above. In regards to using fresh solution, it is important to consider that 18% occasionally reuse their solution and 4% add new fresh solution to old solution “top off”. In

terms of the frequency of solution replacement, 12% replaced their solution “when needed”, another 12% replaced their solution weekly, and 2% replaced their solution monthly. Not replacing disinfecting solutions daily and adding new solution to the old are all behaviors that increase the risks of eye infections. This is because disinfecting solutions lose their efficacy and are no longer “fresh” after one use. Thus, bacteria that are not killed initially will continue to grow in the lens case and become resistant to the disinfecting solutions.

In terms of risky behaviors, about 85% of individuals swam while wearing their contacts lenses. Of all those who reported swimming with their contact lenses, 66% did not wear goggles. Of those who did not wear goggles, 90% did not dispose of their contact lenses the same day.

Exposure to water, especially water sports or activities, has been strongly associated with Acanthamoeba corneal infection. Acanthamoeba itself has been recovered from nearly all water sources: lakes, rivers, pools, and even tap water, etc.^{9,10} Therefore, patients are placing themselves at risk by swimming with contact lenses, that risk is increased if they do not wear goggles, and the risk is even greater if the lenses are not disposed of the same day. The reason that stored lenses that have been exposed to water pose a greater risk for an Acanthamoeba infection (that in turn poses the risk for blindness) is due to the fact that the bacteria already present in the lens case serves as food for the amoeba. This results in growth of the amoeba which may be transferred back to the eye via the lens. The lenses when placed on the cornea,

present the pathogen with a route to be able to burrow through and destroy the cornea. Figure 15 depicts an *Acanthamoeba* keratitis infection due to water exposure.

The last practice labeled as risky for contact lens wearers is the use of saliva to lubricate lenses prior to replacement onto the cornea. Survey responses indicate that 21% of individuals use their saliva in case of emergencies and one patient reported doing so all the time. The eyes and mouth are different environments in terms of moisture, temperature, enzymes, pH, and the types of bacteria. The mouth contains a greater variety of microbes compared to the eye. The CDC does not recommend patients ever use saliva, the risks of infection are too great and research supports this fact.

CHAPTER XII: CONTACT LENS WEAR CHARACTERISTICS

The study determined that 95% of participants wore contact lenses to correct their vision and the other 5% wore for either both cosmetic and corrective purposes or simply for cosmetic reasons. Additionally, 90% of participants wore soft contact lenses and of those 71% wore daily lenses.

Of all participants, 68% reported having a history previous red eye or conjunctivitis, indications of an eye infection, ocular complication, or other adverse event of some type. Our prior study indicated that patients that had experienced a contact lens-related adverse event were more likely to replace their case more regularly.²¹ Upon completion of our microbiological testing, a multivariate analysis will be conducted to determine if that same parameter is reflected in this study cohort. The hypothesis is that those patients who have experienced of an eye infection or adverse event due to contact lens wear are more likely to have received greater education about the proper methods of contact lens case care.

CHAPTER XIII: EVALUATION OF STUDY METHODS

Since the lens case drive was conducted in front of the cafeteria during the hours of 11:30 and 2:30 pm, time may have played a factor in whether or not individuals were able to participate. As far as completion of the survey itself, inattention was another factor that may have influenced data results. Some individuals mistakenly skipped questions; one individual skipped an entire page. The use of the financial compensation, (\$5 voucher for the food court) was for some individuals the main motivation for participation. It is also possible that certain individuals reported false information; however, the use of anonymity of the self-reported questionnaire

minimized this potential bias. Moreover, some individuals marked answers that reflected that they met exclusion criteria such as using daily disposable lenses. Assuming that some may have mistakenly marked “daily disposable” instead of “daily wear”, due to inattention or the lack of knowledge regarding the difference, the responses were closely analyzed to determine whether or not the individual was in fact a daily disposable lens wearer. The biggest issue in the study was that some individuals completed surveys, but did not return to donate their lens cases. At the start of the study, the food vouchers were handed to participants as soon as they completed the survey, some of these individuals, did not return for the entirety of the study (16 days over the span of two months). Noticing this early on, a change was made, participants only received the food voucher when they completed both the survey and donated a used contact lens case.

The individuals interested in participating in the study were verbally asked pre-screen questions. The questions were: Do you wear contact lenses? Do you wear daily disposable lenses (lenses that you dispose of at the end of each day)? Those who answered “yes” and “no” respectively were invited to complete the survey and donate their used contact lens cases. Patients were not consistently asked how long they had worn contact lenses. Also, answers could not have been verified even if they answered correctly that they had been using non-daily disposable contact lenses for least 3 months.

CHAPTER XIV: SUMMARY AND CONCLUSIONS

This study was unable to detect significant relationships between patients' attitudes and compliance grades. Moreover, the study was unable to demonstrate a conclusive relationship between the compliance grades of patients and the crystal violet absorbance values that indicate the presence of biofilms. Although these measures were not significantly correlated, further analysis is needed before definitive conclusions can be made.

Multiple factors can contribute to the findings in this study. First, the measures utilized to grade patient attitudes and compliance may not have been stringent enough. While many of the findings are in agreement with our prior work, additional analysis will be made to investigate the impact of increasing level of stringency for attitudes and behavioral measures and relationships with the level of microbial contamination. Additional tests will then be needed to validate the level of scrutiny required to use measures of attitudes and compliance as a clinical screening tool to identify potential high-risk patients. Secondly, there are numerous variables in the hygiene care process of contact lens wearers that need to be accounted for since many, if not all of them, could contribute to biofilm formation and contamination levels within lens cases. While several of them were addressed in this study, it is by no means all-inclusive. Examples of the other variables not addressed in this study include the inappropriate use of contact lens cleaning

solutions, the types of disinfecting solutions, and the designs of individual types of lens cases.

Further studies will be needed to separately investigate each of these.

While crystal violet levels did not correlate with level of patient non-compliance, we hypothesize that the isolation and identification of microorganisms from the contact lens cases may be a more meaningful measure for level of microbial contamination. Currently, our laboratory is working to culture, identify, and determine the identity and level of growth of bacteria, fungi, and amoebas from the collected cases in this study. For bacteria, this will include an analysis of antibiotic sensitivities. This information will provide significant insight into the environmental isolates that live within contact lens cases.

Finally, positive attitudes did not translate into either positive behaviors or increased compliance. Despite this, both compliance and attitudes toward healthy contact lens practices can be improved upon with proper education. Many patients are placing a lower value of importance on the care of the contact lens storage case in comparison to the care of their contact lenses. Part of this is due to inadequate education by eye care practitioners, as illustrated by the parallels between patient and eye care practitioner responses. Thus, eye care practitioners need to provide more effective education and/or training specifically targeting the appropriate care and

replacement of contact lens cases. These recommendations need to be in accord with recent evidence-based data that favor healthier practices amongst the contact lens wearing patient population.

CHAPTER XV: INTERNSHIP SITE AND INTERNSHIP EXPERIENCE

Prior to the internship practicum, I met Dr. Bonnie Miller at an Association of Clinical Research Professional (ACRP) meeting. Dr. Miller is the Manager of the UTSW Ophthalmology Department Research Program. She extended me the opportunity of completing my clinical research management practicum with Dr. Danielle Robertson, Associate Professor at UTSW. I accepted the opportunity to be part of exciting research at UT Southwestern Medical Center, a prominent institution for biomedical research and Nobel Laureate awards. Dr. Robertson and I began to communicate and she shared with me information about the research she was doing and what to expect upon arrival at the site.

This internship practicum started June 1st, 2015. That day, Dr. Robertson gave me a tour of her research facilities. Then we went to the James W Aston Ambulatory Care Ophthalmology/Optometry Clinic where she sees patients for her clinical research studies. While

there she introduced me to Ms. Bianca Larsen. During the first few weeks, Ms. Larsen, a clinical research coordinator working closely with Dr. Robertson took time to help me complete all the training programs required in order for me to receive credential and approval to participate in Dr. Robertson's research studies. Bianca actively demonstrated and informed me of the duties and responsibilities of a clinical research coordinator. When I took the initiative to write phone scripts, construct study flyers, and even complete study modifications she gave me tips and productive criticism. She also contributed to the submission of my own study project to the IRB.

Dr. Danielle Robertson, was in the process of starting one of her recently IRB approved studies. The study was investigator initiated (protocol devised by the researcher) and sponsored by the National Institute of Health (NIH). The study was titled Corneal Sensitivity and Nerve Fiber Morphology in Patients with Sleep Apnea. The purpose of the study was to investigate whether corneal sensitivity contributes to corneal problems commonly reported in patients with Obstructive Sleep Apnea (OSA). For this purpose, four categories of patients were sought (patients with sleep apnea, or sleep apnea and diabetes, diabetes alone, or healthy (without either condition)). Obstructive sleep apnea, often a secondary condition to other health concerns such as obesity, is often associated with corneal complications.

My participation in this study was mainly in regards to patient recruitment. I constructed flyers that I submitted for IRB approval and later marketing approval. Along with the other research coordinators, I placed the flyers around campus at approved locations. Additionally, I handled email communication with patients who inquired about the study. I made phone calls to both patients who reached out to our research team or patients we were attempting to recruit for the study based on referrals from co-investigators. Once I communicated with patients and determined their eligibility, I scheduled appointments and sent confirmations and reminder emails about those study visit appointments. As part of the protocol at UTSW medical center, all patients should be entered into the Epic patient information system. Patients involved in studies were required to be listed as study subjects in the Velos research study information system. Therefore, I completed these patient registration steps as well. During the lens case drive for my own project, I further shared information with patients about the study and was thus able to recruit more patients for this OSA study.

Prior to the study visits, I verified that the visit room was equipped with all tools necessary for the study visit. Therefore, I was also in charge of placing orders for items such as fluorescein dye (used for dry eye testing) or micro-capillary tubes (used for tear collection). During the study visits, I assisted in the tear collection process, recorded medical history or ocular history, and

took measurements (blood pressure, height, weight). After the study I updated patients' statuses as "off-study" on the Velos system.

The second study that I contributed to was titled Defining the Tear Film Proteome. Using the IRB online system of UTSW, I created and submitted two modifications (changes to the study) as directed by Dr. Robertson. This study is also an investigator sponsored study that was started years prior to my internship practicum. The purpose of the study is to identify and characterize tear proteomes in normal individuals to provide a framework for larger proteomic studies that will be focused on identifying biomarkers in ocular and systemic disease. The modifications to the study were mainly in regards to widening the study population and adjusting study aims.

Overall, this internship practicum served me well in many ways. I learned a tremendous amount about clinical research and the work that goes into designing, executing, and maintaining an active study. In addition, I gained experience in designing study protocols, IRB study submissions or modifications, and recruitment.

APPENDIX

A: Patient Survey A with Attitude and Compliance Score Rubric

Direction: Circle the choice that applies to you best.

1. **Age:** _____ **Gender:** Male/Female **Years of contact lens wearing experience:** _____
2. **Self-Identification:** Hispanic or Latino/American Indian or Alaska Native /Asian /Black or African American /White Other: _____
3. **Income per year:** ≤ \$10,000 / ≤ 25,000 / ≤ 50,000 / ≤ \$100,000 / ≥ \$100,000
4. **Highest degree completed:** Below high school /High school or equivalent /Associate/Bachelor / Master /Doctorate /Professional
5. **Are you currently a/an:** Student /Trainee or Fellow /Employee
6. **How many times a year do you visit the eye doctor?** 0/1 /2 / >2/ once every few years
7. **When was your last eye visit?** Few months ago /1 year ago /2 years ago/ >2 years ago
8. **Do you smoke?** Yes /No
9. **Have you ever had a pink/ red eye while or after wearing contact lenses?** Yes /No
10. **Why do you wear contacts?** To correct my vision (I am nearsighted or far sighted) / to change my eye color / I had eye surgery or an eye disease that requires contact lenses.
11. **Where do you purchase your contact lenses?** Eye care practitioner /Retail store /Online /Other:
12. **How old is the case you are donating today?** ≥3months/ ≥6months/ ≥9months/ ≥1yr/ ≥2yrs/ other _____
 - a. **If donating more than one case how old is the second case?** ≥3months/ ≥6months/ ≥9months/ ≥1yr/ ≥2yrs/ other _____
 - b. **If donating more than two cases how old is the third case?** ≥3months/ ≥6months/ ≥9months/ ≥1yr/ ≥2yrs/ other _____

Directions: Using the scale answer the following questions by marking the corresponding box.

	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
13. I consider myself to be a risk taker	-2	-1	0	+1	+2
14. I am compliant with my doctor's recommendations for the proper wear and care of my lenses.	+2	+1	0	-1	-2
15. It is important to wash my hands before handling my lenses.	+2	+1	0	-1	-2
16. It is important to rub, rinse, and properly store my lenses	+2	+1	0	-1	-2
17. It is important to rub and rinse my lens case like I do my lenses	+2	+1	0	-1	-2
18. It is important to maintain good lens case hygiene.	+2	+1	0	-1	-2
19. It is important to clean my lens case daily.	+2	+1	0	-1	-2
20. It is important to clean my lens case daily using the cleaning solution my doctor prescribed for my lenses i.e. multi-purpose or hydrogen peroxide.	+2	+1	0	-1	-2
21. It is important to air dry my lens cases.	+2	+1	0	-1	-2
22. I am willing to spend whatever is necessary for the optimum health and care of my eyes i.e. doctor visits, lenses, lens cases, and contact lens solutions.	+2	+1	0	-1	-2
23. Cost is an important factor in how I clean and care for my lens cases.	-2	-1	0	+1	+2
24. Time is a factor in how I clean and care for my lens cases.	-2	-1	0	+1	+2
25. Ease of use is an important factor on how I clean and care for my lens cases	-2	-1	0	+1	+2
26. I believe lens case care is equally as important as lens care.	+2	+1	0	-1	-2
27. I am putting my eye health at risk by being non-compliant.	+2	+1	0	-1	-2
28. I know the recommended hygiene practices for proper lens case care.	+2	+1	0	-1	-2

Direction: Circle the choice that applies to you best.

29. **Which type of lenses do you wear?** Soft /Rigid (hard)
30. **What is your wearing schedule?** Daily disposable (throw away each day) /Daily wear (replaced every 2-4 weeks)/ Occasional overnight wear /Extended wear (regularly sleep in lenses) /Conventional daily wear (replace annually or less)
31. **How often do you clean your hands before handling your lens cases?** Always +2/Most of the times+1 /Occasionally 0/Rarely +1/Never +2
32. **How do you clean your hands before handling lens cases?** Water 0 /Water + soap +2 /Hand Sanitizer+1 / I do not clean my hands 0
33. **If you use water and soap when cleaning your hands how long does it take?** ≤ 5 seconds 0 / ≥ 20 seconds +2/Between 5 and 20 seconds +1
34. **How do you dry your hands before handling your lenses?** Using: Clean paper towel +2/Bathroom hand towel (see Q. 35) /Body towel 0/ The clothes I am wearing 0/Whatever is nearby0/ Simply shake the water off 0/Nothing, I do not dry 0
35. **If you use your hand towel, how often do you change your hand towel?** Every few days +2/ Weekly 0/Monthly0/Every few months0/ Never0
36. **How often do you replace your lens cases?** Monthly +2/Every three months+2 /Every 6 months +1 /Once a year 0/ Never I do not use a case **(Discard)** / Never I have had the same case for several years 0
37. **How often do you clean your lens cases?** Daily +2/ Every few days +1 /Once a week 0/Once a month0 / Do not clean 0/ Never (I do not use a lens case) **((Discard))**
38. **How do you clean your lens cases?** Rinse +1/Rub & Rinse +2/ Wipe with cloth or tissue 0/ Other: _____

39. **Which do you use to clean your lenses cases?** Water **0**/ Saline **0**/ Peroxide **+2**/ Name Brand Multi- purpose disinfection solution **+2**/ Generic disinfecting solution **+1** / None, I don't use a lens case **(or do not clean)**
40. **How many bottles of fresh contact lens disinfecting solution do you use in a month?**
 <1/ 1 / 1- 2 / 3-4 />4
41. **When buying solutions, do you always buy the same product?** Yes/ No
42. **How do you dry your case?** Recap while wet **0** /clean tissue wipe and recap **0** / shake off the water and recap **0**/shake off the water and air dry face up **+1** /shake off the water and air dry face down **+1**/ clean tissue wipe and air dry face up**+1**/clean tissue wipe and air dry face down **+2**
43. **How often do you air-dry your case?** Daily **+2**/ Every few days **+1** /Once a week **0**/Once a month **0** /Do not clean **0** /Never (I do not use a lens case) **or do not air dry**
44. **Do you use fresh solution to store your lenses?** All time **+2**/ Occasionally reuse **0**/Usually add fresh solution to old solution **0**
45. **How often do you replace the solution in your case?** After each wear **+2**/Weekly **0**/Monthly**0**/When needed **0**
46. **During the summer, when participating in water sports, swimming, or attending water parks, how often do you wear your contacts?** Always /Most of the time / Occasionally/Rarely/Never **+2** (all other See Q 47-48)
47. **When participating in these water activities do you wear goggles?** Yes**+1**/No **0**
48. **If you do not wear goggles do you throw your lenses away the same day?** Yes **+1**/No **0**
49. **Do you use saliva to clean lenses before inserting lens?** Yes, only in emergencies **0** /Never **+2**/A

How do you clean your contact lenses?

The UT Southwestern Department of Ophthalmology is looking for volunteers to participate in a research study.

PARTICIPANTS MUST:

- All healthy volunteers of any sex and race, ages 18 and up, who are new or established contact lens wearers.
 - New contact lens wearers are defined as patients that have worn lenses for at least 3 months.
- Be willing and able to donate used contact lens storage cases and complete the study questionnaire.

WHAT IS INVOLVED?

- Volunteers must report to the "Lens Case Drive" Desk in front of the food court on the first floor of the South Campus D Building.
- The Lens Case Drive will be held from **11:30 AM to 2:30 PM** on the following days **Wednesday October 7th, Thursday October 8th, Friday October 9th, Monday October 12th, Tuesday October 13th, Thursday October 15th and Friday October 16th.**
- The time commitment is about 5 minutes.
- Participation includes donation of used contact lens cases and completion of an anonymous questionnaire.

IF YOU WOULD LIKE TO PARTICIPATE IN THIS STUDY YOU WILL RECEIVE THE FOLLOWING:

- A new contact lens storage case and financial compensation



For more information contact us at: 214-648-8577 or
SarahB.Ndedi@utsouthwestern.edu

UT Southwestern
Medical Center

C: Optometrist Letter and Survey

Dear Colleague,

As you know, patient compliance with contact lens wear remains an on-going problem and a significant risk factor for infection. Despite new and improved lens designs and care products, risk for microbial infection has remained unchanged in past decades with incidence rates of 4/10,000 wearers per year for daily and 20/10,000 wearers per year for overnight lens wear. With approximately 135 million patients wearing contact lenses worldwide, the identification and elimination of critical risk factors is imperative to maximizing contact lens safety.

With this in mind, I am writing to invite your participation in a research study titled: *Analysis of patient practices and attitudes towards compliance with contact lens storage cases in relation to microbial contamination levels*. The focus of this project is to assess compliance with lens storage case hygiene by examining common non-compliant behaviors among lens wearers, the frequency of their behaviors, and factors such as cost and attitude towards compliance. We will also be evaluating the current recommendations on lens storage case care by practicing optometrists in the DFW Metroplex.

Please find the enclosed survey regarding instructions for proper lens storage case care. If you are willing to participate, please complete the anonymous survey and return no later than 10 days upon receipt of this letter. You may fax the completed form to 214-648-2382 or email it to SarahB.Ndedi@UTSouthwestern.edu.

Completion of the survey indicates your consent to participate in this research study. To maintain anonymity, please do not include your name or your practice's name on the survey form.

You may contact at Danielle.Robertson@UTSouthwestern.edu for more information.

Sincerely,

Danielle Robertson, OD, PhD

CC: Regulatory Binder

Direction: Please circle your choice to each of the questions.

- 1. Please select your mode of practice:**
 - a. Ophthalmology Clinic b. Optometry Clinic: (Retail / Private)
- 2. How do you educate your contact lens wearing patients about compliance?**
 - a. Training b. Handout c. Training and Handout d. Verbally
- 3. Do you usually inform patients about the importance of hand hygiene with regard to proper lens care?**
 - a. No b. Yes (Written/ Verbal)
- 4. Do you usually inform patients about the importance of lens case cleaning?**
 - a. No b. Yes (Written/ Verbal)
- 5. Do you usually inform patients about the importance of lens case lens case replacement?**
 - a. No b. Yes (Written/ Verbal)
- 6. Do you advise patients to wash their hands before handling their contact lenses and accessories?**
 - a. No b. Yes (Written/ Verbal)
- 7. Do you specify the duration of the hand wash?**
 - a. No b. Yes (Written/ Verbal)
- 8. Do you specify the use of water and soap for hand cleaning?**
 - a. No b. Yes (Written/ Verbal)
- 9. Do you advise patients to dry their hands before handling contact lenses?**
 - a. No b. Yes (Written/ Verbal)
- 10. Do you discuss the health risks of non-compliance with your patients?**
 - a. No b. Yes (Written/ Verbal)
- 11. How do you advise patients to dry their hands before handling their contact lenses?**
 - a. I do not address hand drying b. I advise patients to use clean paper towel
- 12. How do you advise patients to clean their lens cases?**
 - a. Rinse
 - b. Rub + Rinse
 - c. I do not specify
- 13. What do you advise patients use to clean their cases?**
 - a. Use the same disinfecting solution for lenses
 - b. Use water and soap
 - c. Use just water
 - d. I do not specify

14. How often do you advise patients to clean their cases?

- a. Daily
- b. Weekly
- c. Monthly
- d. I do not specify

15. How do you advise patients to dry their cases?

- a. Air-dry Face up
- b. Air-dry Face down
- c. Clean tissue wipe & air dry face up
- d. Clean tissue wipe & air dry face down
- e. Recap Wet
- f. I do not specify

16. How often do you recommend your patients replace their contact lens cases?

- a. Every 3 months
- b. Every month
- c. Every 6 months
- d. Once a year
- e. Replacement is not necessary
- f. I do not advise

D: Daily Internship Journal

Week 1 -Day 1- (6/ 1/ 15)

11:30- 12:30

- Introduction and Chat with Dr. Robertson
- Briefing about the projects
- Alcon study- study corneal epithelium biology after use of the DAILIES new lens. Supposedly this lens mimics the body's natural cell shedding process and thus provides more comfort. We will be testing this hypothesis by evaluating the state of the corneal epithelium in patients.
- NIH study- Obstructive Sleep Apnea- assessing corneal epithelium biology and corneal nerve morphology in patients with OSA
- Tour of facilities
- Research Labs- across the hall from the office
- Specimens obtained & Machines used
- Confocal microscope- uses red light wavelength to measure thickness of epithelium layer and obtain an image the cells and nerve fibers at base of tissue layer.
- Eye wash- Machine that shoots water on the eyeball & obtains sample of epithelium
- Met the team
- Laboratory: two ladies – analyze specimens and obtain measurements
- Coordinators: Brian, Jenny, Bianca Mobley (main coordinator on Dr. Rob's projects)

12:30-1:25

- Lunch with Bianca and Dr. Rob
- Covered protocol outlines for the 2 studies
- Discussed the different tests to be performed on patients
- Tear collection, corneal touch threshold, Tear Break-up Time (TBUT)

1:30-3:00

- Advisory Committee Meeting
- Attendance: Dr. Gwartz (Graduate Advisor) , Dr. Robertson (on-site mentor), Dr. Miller (Contract and Research Grant Coordinator) , Dr. Eisenberg (Professor/ Committee Member)

3:00-6:00

- Dr. Rob printed Consent forms, HIPAA release forms for the 2 studies
- Read the synopsis of the protocols Bianca printed and covered at lunch
- Constructed TO-DO list for Week 1

- Emailed Dr. Rob and Bianca the CRM Handbook
- Homework- Read Dr. Rob's articles and the forms and protocols she gave. Construct and outline idea of my thesis project. Find & review previous thesis projects of CRM students

Week 1- Day 2 (6/ 2/ 15)

9:30 -11:25

- Read protocol, consent form, HPI release form for the Obstructive Sleep Apnea study entirely
- Started reading protocol for Alcon lens study.
- Added notes to my Thesis proposal draft

11:30-12:30

- Meeting with Bianca- Clinical Research Coordinator
- Bianca gave me two folders (one for the obstructive sleep apnea-OSA study and the other for the contact lens study)
- In the folders were protocols, HPI, informed consent forms, and referral letters (for other physicians to help in the recruitment process for the studies).
- In addition, the folder for the Alcon study had a flyer, the synopsis to be sent via email to reach potential participants
- The OSA study folder also had a telephone script
- We covered each document of the folders in detail. Bianca answered my questions about the nature of her work and updated me on the current state of affairs of the department (clinical research manager of 18 years leaving the department, new staff, recent changes and regulations, etc.)
- Discussed goals of internship, current work load, ways for me to be of assistance(ex: will work on reorganizing folders according to the new Standard Operating Procedures, create phone script for the Alcon study, create flyer for the OSA study)

12:35-1:30 -Lunch

1:35- 3:15

- Created the telephone script for the Alcon study using the template for the OSA study script and the protocol details.
- Emailed completed script to Bianca and Dr. Rob

3:15- 5:00

- Reading Protocol for Alcon study
- Work on flyer for the OSA study
- Thesis proposal draft

- Homework finish reading Alcon protocol, read consent form and HPI release form of Alcon study, flyer for OSA study

Week 1 -Day 3- (6/3/15)

9:30-10:30

- Observed informed consent / HIPAA release process for Dr. Rob's lab student who will be participating and conducting one of her research studies. Bianca, the research coordinator performed this process and told me the dos & don'ts. Example: do give time to the volunteer to read over the forms on his or her own in a quiet room, then return and confirm their understanding. Do not rush the process. Do remind the volunteer of their right to refuse to sign the form.

10:35- 12:30

- Updated the OSA study flyer- edited and transferred text unto the approved template
- Updated the Alcon study phone transcript – using suggestions Bianca proposed.

12:45- 2:30

- Discussed Thesis project ideas with Dr. Rob
- Obtained research articles to read and derive a more specific study outline
- Project will be evaluating ocular hygiene compliance of contact lens wearer in conjunction to the growth of foreign organisms in the contact lens cases
- Contact case drive
- Give questionnaire to participants and obtain their lens cases- incentive free new case
- Will start the project from infancy and go through all the processes: IRB application and review, informed consent, compilation of protocol, etc.
- If successful this literature can be published

3:00-5:00

- Meeting with Bianca
- Discuss plans for the Alcon study
- Inventory list
- Organization of binder according to SOP

Day 4- (6/ 4/ 15)

10:00 – 12:00

- Reading literature on lens care compliance

12:00- 1:00

- Department's vision science seminar series
- Presentation of research relating Endoplasmic Reticulum stress, Myocilin gene, and Chop gene block to open angle glaucoma

1:10-4

- Working on thesis proposal draft
- Reading articles on lens care compliance

Day 5- (6/5/15)

9:00-10:30 Draft of project proposal

10:35- 11:50 Meeting with Dr. Robertson

- Discuss project
- Project Ideas & focus
- Questions to include on questionnaire
- Articles to read

12:00-1:00 Lunch

- Farewell to lab student

1:00-3:00

- Create project outline
- Research articles on compliance

Week 2

Day 1- (6/5/ 15)

9:40 - 10:20-

- Searching for Parking
- Spoke with campus police about parking situation
- Visited Parking service

10:30-12:00

- Dr. Robertson revised and signed Week 1 journal entries
- edited Questionnaire for thesis project

12:10-3:00

- Obtained badge, parking decal, completed HR orientation

3:10-5:30

- Revise and edit questionnaire with Dr. Rob and lab colleagues (Juliet 2nd year medical school student and Nathan undergraduate school senior)

Day 2- (6/6/ 15)

10:00- 11:00

- Dr. Robertson and I did an experiment. I was the research subject and we were assessing the cause of my right lens discomfort. Thus far I get an irritating feeling in my right eye during and after using the trial-fit lenses (Air Optic Aqua) my eye doctor gave. Dr. Robertson and I compared two “new” Right Eye lenses (same brand, one Air Optic Aqua day and night lens and the other simply Air Optic Aqua) she gave me to try to the trial-

lens my doctor gave. I assessed comfort and she used the microscope to observe and check for anything abnormal within my eye and the lenses. I noticed better comfort with the day and night lens, but felt the irritation with the simply Air Optic Aqua “old” and “new”. She did not find anything abnormal when examining my eye and lenses with the microscope. As observed in her previous studies, it is fairly normal to have patients using the same lens type feel discomfort in one eye and not the other. Thus we concluded that my discomfort is simply due to the fit of the lens on my right eye.

11:10-3:30

- Edited the Questionnaire for the project
- Read Dr. Rob’s published article on lens compliance

Day 3- (6/7/15)

10:30- 12:30

- Emailed Dr. Gwartz update of internship, project summary, and questions about the proposal.
- Worked on thesis draft summary section
- Edited Project Questionnaire

1:00- 3:00

- Read Dr. Robertson’s article on *Pseudomonas aeruginosa* and noted the types of assays done in that project.

3:10-3:30

- Chat with Dr. Rob
- OSA study posters- where to post?
- Practicum project- focus on lens cases only
- IRB question- is a separate informed consent form needed for the practicum project or can the questionnaire serve as an informed consent document so long as a statement is written on the form.

3:30

- Meeting with Bianca about OSA study
 - IRB information regarding use of questionnaire as consent

Day 4- (6/8/15)

9:00- 10:20

- Meeting with Bianca, Bryan, and Priscilla – Research Coordinators about the OSA study. Bianca assigned duties and updated us on the preparations of the study. I was assigned the following tasks/ responsibilities: post study flyers, email an order request for a non-preservative fluorescein dye (to be used in the study), Dr. Robertson’s studies, Update the Subject ID code list, manage the regulatory documents, manage the patient documents , and correspond with the P.I and IRB, and patient recruitment and resignation.

10:30- 1:30

- Updated the Subject ID code list, emailed UT Southwestern Temps to follow-up on my username, password, and email info, created and email signature, posted flyers.

Day 5- (6/9/15)

10:00 Lab Safety Meeting

- Dr. Rob and Dr. Petroll led the meeting
- Lab students and Research lab assistants were present

- The purpose was to inform us on safe lab practices and regulations
- We all signed a form stating that we were informed about the handling of blood and certain microbial organisms

10:45

- Chat with Dr. Rob
 - Advice on project paper
 - Follow Alcon protocol for the proposal
 - Add to proposal details strictly pertaining to clinical research management such as design
 - Derive sample size estimate for my project
 - Will use a computer program
 - Multi and Bivariate data will be sent to Biostatistician

11:00

- New Employee Training with Bianca
 - Set up UTSW email/ obtain username / reset password
 - Print CITI training report from UNTHSC
 - Affiliate UTSW to CITI account

1:30 -2:30

- Observed informed consent practice process
 - Took notes and of important points to cover during this process
 - Have thorough understanding of the study to be able to explain to participants the purpose on an 8th grade level
 - Leave room for subject to obtain and reiterate 100% voluntary participation
 - Read statements on purpose, risks, benefits of study as written on consent form
 - If unsure, defer the questions to the PI

2:30-5:00

- CITI training – Conflict of Interest module complete
- eIRB - complete and submit the COI form
- Gather documents to submit to next week for new employee regulatory documentation : CV, Immunization record, etc.

Week 3

Day 1 6/15/15

11:00- 2:30

- CITI training- GCP (good clinical practice)
- New Employee Orientation

3:00- 5:00

- Scan and email required documents for employee regulatory compliance
- Schedule time for IRB training, eResearch training, review IRB binder.

Day 2 6/16/15

11:00 – 12:30

- Email Professors for project approval. Worked on project proposal outline

1:30- 2:30

- Reviewed IRB orientation and information binder

2:40-4:00

- Posted OSA study flyers

4:00-5:00

- Complete health survey and immunization questionnaire for new student/employee

Day 3 6/17/15

10:30

- Posted remaining OSA flyers

11:00 -2:30

- Edited draft of Thesis Proposal

Day 4 6/18/15

10:30- 11:50

- Read compliance article– risk taking propensity and lens care compliance

12:00 -1:45

- “Works in Progress ” Presentation- topic covered Immune suppression in corneal graft implants .

2:00-5:00

- Edited questionnaire for the project

Day 5 6/ 19/ 15

10:30-11:50

- Read and take notes on articles about compliance and lens case contamination

12:00- 1:20

- Review Project questionnaire with Dr. Rob

1:30 0-3:30

- Edit and format project questionnaire

Week 4

Day 1

8:00-11:30-

- Velos and eIRB study registration training
- Velos is an online system to register studies
- eIRB –convenient system to submit IRB documents for approval

11:45- 1:30-

- Review OSA study protocol and research procedures to be used in study
- Slit lamp test
- Shirmer
- Edit Practicum project subject questionnaire

1:45-2:30

- Dropped EDC (Electronic Bianca)
- Enrolled in more training courses for the online systems

2:45- 4:10

- Created Project Questionnaire for Physicians

4:20- 5:00

- Dr. Rob taught me how to calculate sample size for my study
- Using Sigma Plot and a data from a previous survey study

- Calculated mean of averages and determined a minimum difference of mean based on an arbitrary percentage
- Calculated Std Dv
- The larger the spread of data the larger the sample size
- Power for clinical study – set 0.8
- Number of groups- how many groups will we be comparing
- Input the above values in Sigma Plot and submit to obtain estimated sample size
- We discussed the data analysis method – how to evaluate the compliance level of participants based on questionnaire responses.
 - Use an excel sheet
 - Rate the answers (arbitrarily but consistent- preferable to use the system Dr. Rob employed in the previous research as a model with a little adjustment)
 - Create hypothesis – detailed- regarding groups / compliance ratings and expected difference in findings
 - Create a plan for on compliance rating and likert scale rating
 - Dr. Rob asked if I could input my project study and her own study with Dr. Petroll (colleague) into Velos–follow up with this

Day 2

- Discussed with Dr. Rob changes to be made on a Proteomic study. The changes need to be updated on the electronic eIRB and Velos system. I updated the study protocol, HIPAA release, and informed consent documents accordingly. Once Dr. Rob gives her final approval then I will make the modifications on the electronic systems.
- Created the flyer and campus wide blurb for the study
- Worked on the project draft

Day 3

- Visit to the Occupational Health Clinic
- Edited Project draft (hypothesis section)
- Edited Project physician questionnaire

Day 4

- I made modifications/ changes on the UTSW eIRB system for the proteomic study. (Bianca oriented me)
- Follow up with email to Spanish translator
- Read “patient compliance in a contact lens wearing population” – the article is not yet published and referred many concepts I will cover in my project

Day 5

- Sent Proteomic study flyer for marketing verification
- Emailed translator for proteomic study title translation
- Completed eIRB modification of proteomic study
- Attended Epic Patient Registration training- (all research study patients have to registered online through the Epic and Velos system)
- Follow up- Edit Referral letters

Week 5

Day 1 (6/ 29/ 2015)

- Edited referral letter for proteomic study, flyer, and Spanish HIPAA authorization form
- Discussed and edited the following documents with Dr. Rob:
- Project proposal draft
- Project Questionnaire for patients and physicians
- Template of project summary to be used for my project's irb submission
- Template for referral letter to be used for my project
- Follow up- find optometrist questionnaire used in Wu. Y study on advice to follow for lens care compliance- questionnaire was not a part of the article- further research needed
- Established deadlines
 - July 6th –submit complete project proposal draft to Dr. Rob
 - July 10th – submit final proposal to UNTHSC
 - July 15th – submit study to eIRB

Day 2 (6/ 30/ 2015)

- Finalized and submitted modification for proteomic study
- Edited my project proposal draft
- Attempted to resolve the issue of my personal contact phone number appearing on the Clinical trials details volunteer page

Day 3 (7/1/ 2015)

- Literature review on compliance for project
- Added notes to word doc for future reference
- Email Order fluorescein for OSA study
- Edited Template of project summary to be used for my project's IRB submission
- Edited Template for referral letter to be used for my project
- Follow up- optometrist questionnaire used in Wu. Y study on advice to follow for lens care compliance was not a part of the article-

Day 4 (7/02/2015)

- Followed up order fluorescein
- Worked on project proposal
- Pre-screened patients for the OSA study and registered them in the online systems (Epic and Velos)

Day 5 (7/03/2015)

- Contacted patients for OSA study- via email and phone
- Requested access to "O" drive " Ophthalmology folder" on the computer network systems. Documents pertaining to all research in the ophthalmology department are found on this drive.
- Worked on project proposal

Week 6

Day 1 (7/ 6/ 15) 10-5pm

- Called potential patient participants to schedule study visits (Corneal Sensitivity)
- Contacted the Pharmacy to order the fluorescein needed for the Corneal sensitivity study
- Edited Project Proposal and sent it to Dr. Rob for review

Day 2 (7/ 7/ 15) 10-5pm

- Called patients to schedule study visits
- Finalized fluorescein order
- Edit project proposal

Day 3 (7/ 8/ 15) 8am- 6pm

- Ambulatory Epic Rgs 8am-4pm
- Edits to thesis proposal

Day 4 (7/ 9/ 15) 8am-5pm

- IRB training 8am- 12 pm
- Reviewed proposal draft of thesis proposal with Dr. Robertson
- Made final edits to the Thesis proposal

Day 5 (7/ 10/ 15)

- Edited IRB Project Summary
- Started Velos New Study Submission form
- Completed order form for dipstick pregnancy tests for corneal sensitivity clinical research study

Week 7

Day 1 (7/13 / 15) 10:30-5pm

- Final changes to the Thesis proposal
- Worked on IRB Project Summary

Day 2 (7/14 / 15) 10-4pm

- Reviewed OSA study material
- Submit Thesis Proposal
- Worked on class registration for Fall 2015 – Need to remove student account hold. Contacted the responsible parties to take care of the matter. Need to follow up.

Day 3 (7/15 / 15) 10-5pm

- Corneal Sensitivity / OSA Study Recruitment Meeting with Dr. Won Lee (Pulmonologist at the UTSW Sleep Center)
- We discussed the study, it's objective, and the ways that Dr. Lee's team can help with recruitment by referring patients with severe Obstructive sleep apnea.
- Shadowed Bianca- witnessed her interaction with another physician for whom she is a research coordinator
- Went through the list of the study procedures with Bianca and listed the items we needed and counted the amount of each item present.

Day 4 (7/16 / 15) 10-5pm

- Works In Progress Seminar- Two of Dr. Robertson's students presented the work they have done in the lab during the summer.

- Corneal Sensitivity / OSA Study Dry Run
- Created an excel sheet to record the inventory of OSA study supplies

Day 5 (7/17 / 15) 7:30-4pm

- First Study patient
- Bianca performed the informed consent process
- Dr. Rob completed specific procedures: Slit lamp microscopy, confocal microscopy (to image the epithelium, stroma, cells, and nerves of the cornea), Tear break up time (TBUT), Tear collection
- Bryan (research coordinator) – blood draw and OCT
- I observed and assisted where I was needed
- During a meeting with the entire study team we discussed changes to the study protocol and changes to the order of the procedures
- Reorder procedures list for the study to streamline the process and be more efficient

Week 8

Day 1 (7/20/15) 10:30-5pm

- Submitted study project via Velos
- eIRB study project application
- Worked with Bianca- she gave me a format to follow

Day 2 (7/21/15)

- Research Week 2015 Conference at Children's Hospital- Day 1
- Defining Research
- Systematic investigation to generate knowledge
- Defining Quality improvement
- Systematic actions that lead to measurable improvement in health care services and health status of patients
- Clinical Effectiveness programs
- Development of initiatives to improve quality care for patients
- Using published research for new clinical recommendations
- Using evidence from literature reviews

Day 3 (7/ 22/15)

- Research Week 2015 Conference at Children's Hospital- Day 2
- Some of the presentations were on topics that regarded Quality Improvement and Evidence Based Practice to help reduce Healthcare Acquired Conditions
- Barriers faced when implementing Evidence based practices
- Lack of research resources for healthcare workers
- Lack of time, confidence, and awareness
- Steps to achieve Children's Hospital Aspiration of becoming one of the top 10 pediatric institution renowned for clinical research
- Increasing research funding
- Partnerships with academic institutions like UTSW

Week 9

Day 1 (8/ 3/ 15) 8:30-5pm

- Corneal Sensitivity Obstructive Sleep Apnea Study –study visit for a volunteer with diabetes
- Training
- How to measure Visual Acuity
- How to Pipet dyes into the eye for the dry eye tests
- How to insert Schirmer strips
- Extracting tears from capillary tubes using suction cap

Day 2 (8/ 4/ 15) 10:00-5pm

- eIRB Application for my thesis project-
- Edited the protocol to follow IRB template
- Setup of next day study visit
- Print necessary documents (Informed Consent (IC) form, HIPAA release, IC checklist, Inclusion/ Exclusion criteria checklist, exam form, study questionnaires, and gift card log.
- Gather all necessary equipment

Day 3 (8/ 5/ 15) 8:00-5pm

- Corneal Sensitivity –OSA Study patient
- Healthy volunteer
- IRB application for my study
- Created Verbal Informed consent document and flyer

Day 4 (8/ 6/ 15) 8:00-5pm

- Epic Ambulatory Scheduling Training
- We reviewed registering patients and learned to schedule patient appointments using Epic.
- Visual science seminar/ lunch
- Presentation regarded research in efficacious drug delivery in the eye for macular degeneration. Also discussed was the effects of macular degeneration on the visual capacity of the patient especially in dim lit environments

Day 5 (8/ 7/ 15) 10:30-5pm

- eIRB Application
- Submitted application for Exempt Review
- Exempt review is justified for the following reasons: no patient identifiers will be obtained, less than minimal risk to the patients is present, medical records are not being reviewed, and the study maintains patients' anonymity.

Week 10

Day 1 (8/10/15)

- Corneal Sensitivity Study Modification created and submitted
- Changes in study personnel and addition of an avenue for patient recruitment (Research Match)
- Contacted Marketing and Communication Manager to know about the timeline of our Campus Update announcements
- Contacted Study patients PCP office to obtain medical records using the medical record release form signed by the patient.

Day 2 (8/11/15)

- Optometry Database Delegation
- Meeting with Study team personnel
- Discussed organization to contact patients from the data base
- Calls will be made using assigned lists and team members will rotate turns daily
- Each member will update the group list as they make their calls
- Efforts will be made to obtain amount of patients for each strata

Day 3 (8/12/ 15)

- Edited formal, emailed, and mailed referral letters to optometrists for proteomic study
- Uploaded the inventory list to the electronic file for the Corneal sensitivity study
- Called patients from the Corneal Sensitivity Study Database
- Many pre-screen fails and no answers

Day 4 (8/13/15)

- File / organize electronic documents for proteomic study
- Informed of two successful patient pre-screens
- Handled registration, scheduling, and other documentation pertaining to these patient's participation in the study of these patients

Day 5 (8/14/15)

- Meeting with Bianca
- Reviewed a complete list of tasks for the Corneal Sensitivity study that I created
- Purpose is to not forget, fall behind, or make mistakes on
- Reorganized "Ophthalmology" drive- (electronic file that holds all study important documents and information- only accessible by personnel with granted access to UTSW desktop computers)
- Created for accessibility and audit purposes
- Took notes and made a to-do list for the creation of a regulatory binder for the proteomic study
- Reviewed pre-screen fails
- Recalled two patients and ended with 1 pre- screen pass.

Week 11

Day 1 (8/ 17/15) 9:00 am- 2:30pm

- Went through the informed consent process with study patient JZ
- Study patient refused participation due to anxiety regarding blood draw

- Noted this encounter in study subject document logs
- Called a patient with the pre-screen pass from last week – no answer
- Pre-screened another patient- pass
- Registered and scheduled patient for study visit
- Meeting with Bryan- research coordinator
- Discussed the delegation of new database list
- Inventory for Corneal sensitivity study
- Assigned responsibilities for Corneal Study patient visits

Day 2 (8/ 18/ 15) 10:30am-5pm

- Using a database of patients who have recently been seen at the optometry clinic and who have a diagnosis of Type 2 Diabetes, I made calls to patients
- For the interested patients who were eligible I scheduled appointments, added the patients to our pre-screen log and subject ID list, as well as registered the patients to the study through Epic and Velos.
- Informed the PI Dr. Rob and Coordinator Bryan of the appointments

Day 3 (8/ 19/ 15) 11am-5: 30pm

- Appointment email confirmations to patients
- Along with informed consent copy
- Meeting with Bryan Coordinator
- Discussed details regarding the study
- Updating the pre-screen questionnaire
- Extending pre-screen log
- Up-keep of pre-screen binder
- ICD-10 Online training
- ICD –International Classification of Disease
- HIPAA Online training
- HIPAA- Health Information Portability Accountability Act

Day 4(8/ 20/ 15) 10- 3

- Updated the pre-screen questionnaire to reflect the inclusion and exclusion criteria
- Called patients to confirm appointments for Friday
- Set-up the exam room for Friday study visits
- Printed the study visit documents

Day 5 (8/ 21/ 15) 8:00-3

- Assisted during the study visit and took notes of items to order or tasks to follow-up on in regards to the study
- One follow-up is to check if our study team is able to obtain database of Parkland patients who have had sleep studies done
- Check is patient sleep study visit info is available on EPIC or if it needs to be obtained via Medical Release doc
- Wrote order for micro capillary tubes used for tear collection
- Organized Proteomic Study e-Files and binders – advertisement section, Protocol, HIPAA, and Informed consent documents.
- Contacted (emailed and called) study patient who was a “no-show” to her morning appointment. Successfully rescheduled the appointment.

Week 12

Day 1 (8/24/15)

- Registered new patient into EPIC and scheduled appointment for study visit
- Sent email communication to Dr. Miller, Dr. Robertson, and Ms. Jennifer Roemer, a UTSW marketing specialist to facilitate the process to set up a meeting. The meeting will address the location of the lens case drive and requirements to fulfill in order to have the drive and conduct my thesis project.
- Started Constructing Regulatory Study Binder for Proteomic Study

Day 2 (8/25/15)

- Reviewed/ Updated patients' study statuses on Velos
- Contacted Epic and Velos Trainers to resolve duplicate patient profile issue from Monday
- Submitted order for micro capillary tubes to be used in current Corneal Sensitivity study
- Email communication to schedule date to defend thesis with committee
- Scheduled a meeting to discuss details regarding thesis project
- Location of the lens case drive and steps required to proceed with plan
- Dr. Bonnie Miller, Dr. Robertson, Jennifer Roemer (UTSW Ophthalmology Marketing / Communication Manager) will be attending

Day 3 (8/26/15) 9:00-1:30

- Made calls to patients from the diabetic database for the Corneal Sensitivity Study. Unfortunately, I was not lucky enough to get a pre-screen pass.
- Followed up with Chuck Akers from IRB in regards to my internship study project. I explained my time frame and answered his questions about the study. He let me know that he will look over the study submission today and send me a notification via eIRB.

Day 4 (8/27/ 15) 8:00-2:30

- Training course- Epic for Research Coordinators
- Updated pre-screen log for pre-screen fails from yesterday's calls.
- Spoke to Bonnie- will work Continuing review for a few studies, will consider helping with resident protocol, will continually check OphthaResearch Inbox for study inquiries.

Day 5 (8/ 28/ 15) 10-1:00

- Regulatory binder for Proteomic Study
- Set-up clinic visit room / inventory of equipment
- Delivered Micro capillary tubes to the clinic study visit room

Week 13

Day 1 (8/ 31/ 15) 9:30

- Corneal Sensitivity (CS) Study Patient visit
- Recruitment calls to potential study participants

Day 2 (9/ 1 / 15)

- Corneal Sensitivity Study Patient visit
- Meeting regarding Lens Case Drive
- Emailed Co-PI for recruitment follow-up

Day 3 (9/ 2 / 15)

- Corneal Sensitivity Study Patient visit
- Research Match - registration
- Posted flyers for CS Study
- Edited Pre-screen script

Day 4 (9/ 3 / 15)

- Corneal Sensitivity Study Patient visit
- Ordered items for thesis project –lens case drive
- WIPS- Works In Progress Seminar / lunch
- IRB Stipulations for my Thesis Project Study

Day 5 (9/ 4 / 15)

- Received IRB Approval letter for study
- Recruitment calls/ Patient pre-screens
- Edited format of Referral Letter and Survey for Optometrist
- Printed documents to be mailed out to optometrists

Week 14

Day 1 (Tuesday 9/8/15) 9:00am-5:00pm

- Recruitment calls to Research Match Volunteers
- Reminder calls to patients about their next day's appointments
- Respond to email inquiries about the study
- Package and mailed surveys to physicians (for thesis project on contact lens case hygiene compliance)
- Mail Ticket Form with account number for cost coverage
- Streaked Pseudomonas onto agar gel and incubated
- Bacteria will be used for practice purposes
- Practice lab techniques to be used for my lens case hygiene compliance project

Day 2 (Wednesday 9/9/15) 9:00am-5pm

- Study Visit with a new patient for Corneal Sensitivity Study
- 9:30 am patient was a no-show
- 11 am patient showed and visit went well
- Incubate bacteria into lens cases
- First diluted bacteria into media solution
- Diluted solutions were of the following 3 concentrations: 10^8 , 10^6 , 10^4
- Dr. Rob –gave me tips and instructions to adhere to while in the lab, Proper techniques, how to operate equipment
- Ordered MTT assay kit and bottle of 1% crystal violet (gram staining)
- Package and mailed surveys to physicians (or thesis project on contact lens case hygiene compliance)

Day 3 (Thursday 9/10/15)

- Packaged and mailed surveys to physicians (for thesis project on contact lens case hygiene compliance)
- Write protocol for Crystal Violet Assay

- Recruitment calls to patients
- Email responses to patient inquiries about study

Day 4 (Friday 9/11/15) 8:30 am

- Study Visit with patient for Corneal Sensitivity Study
- 9:00 AM patient was a no-show
- 11:00 AM patient
- Completed the crystal violet assay on the cases – incubated earlier in the week

Week 15

Day 1 (9/ 14/ 15)

- Print documents for thesis project: study flyers, CDC handout and surveys,
- Package into gift bags for participants of thesis study project: CDC handout (about healthy habits for contact lens wearers), Study flyer (to advertise our study on-campus), glass lens cleaning cloth, new contact lens case, and \$5 voucher to the UTSW cafeteria (financial compensation for time).

Day 2 (9/ 15/ 15) 7:30-3:00

- Study Patient for Corneal Sensitivity Study at 8:00
- Optometrist surveys mailed out last week (for thesis project) were being faxed back (more than a dozen were received)
- Campus update (campus wide newsletter) failed to advertise our study. As a result we expected a low turnout rate to the next day's lens case drive.

Day 3 (9/ 16/ 15) 7:30-3:00

- Study Patient for Corneal Sensitivity Study at 8:00
- Lens case drive 11:30- 2:30 pm
- Accompanied by Teresa- Administrative Associate
- The turn out was about 5 completed surveys with donated cases- most participants were referred by Teresa.

Day 4 (9/ 17/ 15)

- Annual Research Conference at Scottish Rite Children's Hospital 8:00- 11am
- The keynote speaker, Dr. Scott Lipkin, IRB chair, discussed the standards by which the IRB abides by and the criteria that they look for each study to fit before approval.
- The 45 CFR 46.111- outlines requirements for research approval and the content corresponds to 21 CFR 56.111
- Lens case drive 11:30- 2:30
- More of a turn out – about 10 more cases and surveys were received

Day 5 (9/ 18/ 15)

- Study Patient for Corneal Sensitivity Study at 9:30
- Lens case drive 11:30- 2:30
- More of a turn out – about 15 more cases and surveys were received

Week 16

Day 1 (9/ 21/ 15) 9:30-5:00

- Study Patient for Corneal Sensitivity Study at 10:00
- Edited and submitted IRB modification for a “proteomic study” Dr. Rob will work on with a colleague and a resident.
- Created a flyer for the study and completed the eIRB smart form
- Ordered fluorescein for the Corneal Sensitivity study
- Read and annotated proposal

Day 2 (9/ 22/ 15) 9:30-5:00

- Study Patient for Corneal Sensitivity Study at 10:00
- Recruitment calls to patients for the corneal sensitivity study
- Prepared for the next day’s contact lens case drive
- Printed flyers and gathered surveys and gift bags

Day 3 (9/ 23/ 15) 7:45-5:00

- Patient scheduled for the 8:00 AM visit was a no-show
- Lens case drive
- Good yield of participants due to the fact that
- Ophthalmology Seminar
- Color vision and the female advantage
- Neuronal cell activation on the basis of X-chromosome activation in regards to trichromatic and dichromatic vision

Day 4 (9/ 24/ 15) 7:45-5:00

- Recruitment calls
- Lens case drive
- Collecting cases and surveys for my thesis project

Day 5 (9/ 25/ 15) 12:30-5:00

- Lens case drive
- Collecting cases and surveys for my thesis project

Week 17

9/28/ 15

- Composing Thesis Draft
- Construct timeline for project
 - Oct 1st - draft sent to Dr. Rob
 - Oct 5-12th analyze cases in lab
 - Statistician Oct 15th
 - 2nd draft with results- Oct 26
 - Final draft Nov 6th - committee
 - Thesis Defense Nov 20th

9/ 29/ 15 8:30 -5pm

- Composing Thesis Draft
- Inform Marketing Department of changes

9/ 30/ 15 9:00 5pm

- Composing Thesis Draft
- Lunch with Clinical Research Coordinate Candidate and rest of research team

10/ 1/ 15 7:30-1pm

- Study patient 1 (8am) and Study patient 2 (9am) – first time multiple patients schedule on the same day all show up.
- Gave consent, obtained medical plus ocular history, conducted survey, collected and stored tear samples, assisted with dry eye testing by inserting dyes in patients' eyes.
- Reviewed Optometrist Surveys, inserted data in Excel, tallied responses to each question

10/ 2/ 15 7:30-7pm

- Dr. Rob, Dr. Cavanagh (MD, PhD and Dr. Rob's mentor and colleague), and I met to discuss a modification to the study-
- Follow up- construct IRB mod
- Identification of the microbes in the collected contact lens cases (fungi, gram positive, gram negative, Acanthamoeba)
- Ordered all material and reagents to culture the microbes
- Reviewed Optometrist Survey data
- Follow-up construct descriptive statistics
- 10 am study patient was no-show
- Practiced crystal violet Assays

Week 18

10/ 5/ 15 10:30 -

- Practiced Crystal violet staining of contact lens cases
- Submitted draft of thesis to Dr. Rob
- Updated my Campus Update (UTSW campus wide email/ announcement) blurb to reflect new dates for the lens case drive– submitted changes to Ophthalmology Marketing Department
- Received items (Sabouraud agar broth and three other compounds for nutrient agar)

10/ 6/ 15 9:30- 3:30 pm

- Campus Update Released with my study information
- Received items (small petri dishes and non-nutrient agar) ordered for the study

10/ 7/ 15 (10:00-4:00pm)

- Lens Case Drive 11:30-2:30 pm
- Optometrist Survey Data- creating graphs, tables, and deciding which questions could be correlated

10/ 8/ 15 (10:30- 3:30 pm)

- Lens Case Drive 11:30-2:30 pm
- Thesis Draft- Material and Methods- new microbial analysis protocol

10/ 9/ 15 (9:30- 7pm)

- Received call from the IRB agent currently reviewing the modification submitted for the proteomic study
- Lens Case Drive 11:30-2:30 pm
- Practiced crystal violet assays
- Made and plated Sabouraud Agar (to grow fungus)

10/ 10/ 15 (2pm-8pm)

- Crystal violet assay on collected lens cases
- Made and plated Sabouraud Agar

10/ 11/ 15 12pm-7pm

- Crystal Violets assay on collected lens cases

Week 19

10/12/15 7:30 AM – 5pm

- 8 am patient visit for OSA study
- Edit thesis draft
- Submit Thesis draft to Dr. Rob

10/13/15 8:00 AM – 5pm

- 8:30 am patient visit for OSA study
- Performed Crystal violet assay of collected lens cases

10/14/ 15

- 9:30 am patient visit for OSA study
- Review Dr. Rob's suggestions on the thesis draft
- Performed crystal violet assay of collected lens cases.

10/ 15/ 15 10 AM – 6pm

- Lens case drive 11:30- 2:30 pm
- More edits to the thesis draft

10/ 16/ 15

- Final day of lens case drive 11:30-2:30 pm
- Construct Spreadsheet for patient survey data

10/ 17/ 15- Saturday 10-6 pm

- Performed crystal violet assay
- Made non-nutrient agar and make plates
- Edit Thesis draft

10/ 18/ 15 Sunday 11- 7 pm

- Performed crystal violet assay
- Made non-nutrient agar and plates

Week 20

10/19/15

- Edited Thesis draft
- Material and methods for microbial identification

10/20/15

- Edited Thesis draft
- Material and methods for microbial identification

10/21/15 7:30-5pm

- 8am patient for OSA study
- Edited Thesis draft
- Material and methods for microbial identification

10/22/15 9-5pm

- 11am patient for OSA study
- Spreadsheet for patient surveys
- Statistical analysis

10/23/15 7:30 -5pm

- 8am patient for OSA study
- 10:30am OSA study patient
- Spreadsheet for patient surveys
- Statistical analysis

10/ 24-25/ 15

- Spreadsheet for patient surveys
- Statistical analysis

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