

HEALTH OUTCOMES FROM CATARACT SURGERY USING<sup>le</sup>  
PHACOEMULSIFICATION

THESIS

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For the Degree of  
Master of Science in Health Professions

By

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This thesis is dedicated:

- in memory to my grandmother, Lurlie Buddemeyer, who taught me “education is the key to a successful life”;
- my mother, Elaine Buddemeyer, who taught me the value of persistence and loyalty;
- in memory of my father, James Buddemeyer, here is that book I told you I would write one day;
- my husband, Scott Borders, without your support, this never could have been accomplished, thank you for helping me reach this life goal; and
- my son, Christopher Borders, your love, affection, and curiosity make each new day an adventure.

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## **ABSTRACT**

### **Health Outcomes From Cataract Surgery**

### **Using Phacoemulsification**

**by**

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Southwest Texas State University  
December 1998**

**Supervising Professor: Charles Johnson, Ph.D.**

With the success and popularity of treating cataract disorders, it is important to utilize health outcomes research to determine cataract surgery's effectiveness and benefits. Significant indicators that predict and measure success in cataract surgery need to be identified and verified. Statistical models can then be developed to predict successful outcomes. Better outcomes will enhance patient satisfaction and better utilize health resources.

The purpose of this study was to investigate patient visual acuity outcomes after the use of phacoemulsification during cataract surgery. The visual acuity outcomes from 140 consecutive surgeries were divided into three groups of improvement. One hundred-five eyes obtained better than or equal to 20/40 (0.500) visual acuity. The 20/40 visual acuity level is used in most states for an unrestricted driving license Masket (as cited in Lee, et al., 1993). Most literature uses the cutoff of 20/40 or better to designate successful visual

outcomes following surgery (Lee, et al, 1993, p. 3). Three eyes showed worse results from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity. Thirty-two eyes showed some improvement from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity.

Because patient visual acuity outcomes for the group that became worse was so few in number, only three, the cell size made analysis difficult. For this reason only one research question could be explored. This was:

1. What variables best predict those individuals likely to achieve 20/40 or better vision compared to those individuals who do not achieve the 20/40 standard?

This question is found in the literature (Schein, Cassard, and Javitt, 1995).

It should be noted that although an individual may not achieve the 20/40 or better level, they may still experience a substantial improvement in vision such that it improves their ability to function in daily life. An example of this would be an individual whose pre-operative best corrected vision was 20/200 and best post-operative corrected vision is 20/60. Although that individual may not be able to see well enough to drive, she can once again see well enough to enjoy watching television, read, and move around more safely with less risk of falling. The goal of improving visual functioning, even if the visual acuity did not obtain the 20/40 level, could still be justified to managed care companies and other health care payors. Knowing the predictor variables for this group is important. It is also important to determine the predictor variables for the group of individuals for whom their visual acuity becomes worse after surgery. Knowledge of the predictor variables for these groups, would assist the ophthalmologist in determining who the best candidates are for cataract surgery. It would also improve the use of health care resources.

In the process of answering the research question, there were some additional issues to be explored which included:

1. What are the significant indicators prior to receiving cataract surgery

(demographic - age, race sex; physiologic - age, diabetic, hypertensive, degree of nuclear sclerosis; and/or visual comorbidities - age-related macular degeneration (AMD), glaucoma, diabetic retinopathy, high myopia) that may help predict the patient's ultimate visual acuity outcome?,

2. Do significant differences exist in visual acuity outcomes between various populations, i.e. males and females, ethnic groups, diabetics and nondiabetics, hypertensives and nonhypertensives, "high" myopics and others who are not "high" myopics?,

3. Are there any interactions occurring between predictor variables?,

4. Are there any confounding factors, for example, high incidence rate of diabetes among Hispanics?

5. If there are confounding factors, how do those factors influence cataract surgery outcomes?,

6. Is there a significant difference in the mean average amount of phacoemulsification power required to pulverize the lens for each degree of nuclear sclerosis (hardness in the lens)?,

7. Is there a significant difference in the mean average amount of phacoemulsification power required to pulverize the lens and those individuals who have post-operative complications and for those individuals who do not have post-operative complications?,

8. Is there a significant association between pre-operative variables and post-operative complications?, and

9. Is there a significant association between post-operative complications and ultimate visual outcome?

Research was conducted utilizing 140 ophthalmological medical records made accessible to the Southwest Texas State University Department of Health Services and

Research. Data were collected and analyzed utilizing statistical modeling technique of logistic regression analysis. Using the results of the statistical modeling, an assessment was made regarding the most significant clinical indicators for cataract surgery.

The author reviewed 140 medical records and abstracted information to a data collection form (Appendix B). Variables on the questionnaire included demographic information, pre-existing medical conditions, ocular comorbidities, pre-operative and post-operative refractive measurements, and any post-operative complications. This information was entered into an Excel spreadsheet and analyzed in Excel and SPSS. The data were analyzed by descriptive analysis, univariate and comparative t-tests of sub-group means, chi-square analyses, linear regression and logistic regression.

Chi-square analyses indicated a significant association between group of improvement and age, and post-operative complications. Within this sample these factors tended to predict potential poor clinical visual outcome.

In answer to the issue of “Is there a significant difference in the mean average amount of phacoemulsification power required to pulverize the lens for each degree of nuclear sclerosis (hardness in the lens)?”, analysis of variance with the least squares differences (LSD) test indicated individuals with nuclear sclerosis of 4+ degrees should be grouped with individuals of 5+ degrees because there is no significant difference in means of average phacoemulsification power used between these two groups. Individuals with 0 to 3+ degrees of nuclear sclerosis should be grouped together because there is no significant difference in means for average phacoemulsification power used between those four groups. Nuclear sclerosis was recoded and chi-square analysis showed a significant association for both nuclear sclerosis and operative complications ( $p < .01$ ) and nuclear sclerosis and post-operative complications ( $p < .05$ ). Comparative t-tests of sub-group means indicated there was a significant difference ( $p < .05$ ) in mean average phacoemulsification power for those individuals who had operative complications (mean

was 1.72; CI 0.46,2.99) compared to those individuals who did not have operative complications (mean was 0.86; CI 0.66, 1.06). There was also a significant difference in mean average phacoemulsification power ( $p<.01$ ) needed for those individuals who did not experience post-operative complications (mean was 0.83; CI 0.63,1.02) compared with those individuals who did experience post-operative complications (mean was 1.67; CI 0.71, 2.64).

To answer the research question, the dependent outcome variable was coded dichotomously into zeros and ones. A logistic regression model was used to answer the question,

“What are the predictor variables for those persons who achieve 20/40 or better vision compared to those individuals who do not achieve the 20/40 standard?”

Individuals who achieved the 20/40 or better best corrected visual acuity level were coded as “1”. Individuals who did not achieve this level were coded as “0”. The logistic regression model indicated that an interaction of age with age-related macular degeneration (AMD), the interaction of nuclear sclerosis with average phacoemulsification power, and post-operative complications were the best predictors of achieving or not achieving 20/40 or better best corrected visual acuity outcome.

## **CHAPTER 1**

### **INTRODUCTION TO THE STUDY**

#### **What Is Health Outcomes Research?**

Slater (1997) defines outcomes research as “any research which attempts to link either structure or process or both to the outcomes of medical care at the community level, system level, institutional level, or patient level.” ([on-line] paragraph 3) Health outcomes research looks for indicators (variables) that measure quality and cost effectiveness. Quality can be measured by using individually or in combination patient clinical outcomes (physical or diagnostic), patient functional outcomes (pre- or post-procedure), or patient satisfaction surveys.

#### **Why Is Health Outcomes Research Important?**

Why do we research health outcomes? With the escalating costs of medical care, (Slater, 1997 [On-line], paragraph 21) we need increased financial accountability in health care. It should be the goal of any health care program to provide improving care with greater efficiencies. Managed care companies, and many others concerned with measures of health care quality, are looking for indicators to measure quality and cost effectiveness. The National Committee for Quality Assurance (NCQA) and the HEDIS Report Card, in turn, evaluates and compares quality among managed care providers. (NCQA, 1997, [On-line] paragraph 3)



Some examples of data that NCQA and HEDIS use to evaluate quality include:

1. Percentage of children between birth and age 2 who receive all of their required immunizations on time,
2. Percentage of pregnant women who received prenatal care during their first trimester, and
3. Percentage of diabetics who develop diabetic retinopathy.

Additional research needs to be done to establish standards of care and to determine if health care outcomes vary between different patient groups or geographic areas for each medical specialty and other factors in health care. There exists the potential for improving the clinical effectiveness of medical care through health outcomes research.

Health outcomes research also provides evidence of quality of life issues such as patient satisfaction and functional status surveys. These measures can be used as indicators for the effectiveness of differing techniques or standards of care.

### **Why Look At Cataract Surgery Outcomes?**

During the next several decades, our lives, work, family, friends, and neighborhoods will be dramatically altered by the rapid aging of the U.S. population. Because so many people will live longer lives, the strain on the national budget, the health care professions, and other major institutions will increase geometrically. (Detzner, 1986, p. 3)

Consider these facts: The aging population is more at risk for the development of cataracts (Massengill, 1986; Brint, 1989). With larger numbers of people living longer, the numbers of people with cataracts is increasing. Another factor is ozone depletion. Ozone depletion has caused an increase in ultraviolet radiation. One of the consequences of increased ultraviolet radiation exposure is the development of cataracts (Marwick, 1994). Brint (1989) goes on to explain, “. . . as we begin to understand the dangers of ultra-

violet, depletion of the atmosphere's ozone layer is adding to the amount of damage we can expect to our eyes as well as to our skin." (p. 17) Throughout the world, physicians are seeing an association with ultra-violet radiation exposure and the development of cataracts (Brint, 1989; Byrd & Byrd, 1971; Wang-Cheng, et al., 1995). Brint stated, "Doctors have begun to see a drop in the age of their cataract patients. The average patient now is between 65 and 75 years old; by the end of the century, the average age could be considerably younger." (Brint, 1989, page 18). Because the number of people receiving cataract surgery is increasing, there is a need to identify variables that predict visual acuity outcomes.

A second reason to look at cataract surgery outcomes is the need for financial accountability for use of Medicare and Medicaid funding. Ophthalmologists have increased their participation in the Medicare program. Participation with Medicare means the physician's willingness to accept Medicare's assignment of a specific designated amount of reimbursement. In October 1985, 27.3% of the ophthalmologists participated in the Medicare program. In January 1992, 66.1% participated, and by January of 1993, 73.2% of the ophthalmologists participated in Medicare. ([on-line] U.S. Department of Health and Human Services, 7/27/93 Press Release). "About 1.35 million cataract surgeries [were] performed in 1991 at a cost of approximately \$3.4 billion to Medicare alone." ([on-line] USDHHS, 2/25/93 Press Release) In 1992, ophthalmology accounted for 3,689 million Medicare dollars. This was 10.9% of the total Medicare dollars and 3.6% of these dollars were for in-patient care. "For cataract removals and related procedures in 1994, Medicare payment amounted to over \$1.4 billion for approximately 2 million procedures. The average amount was \$700.00." ([on-line], USDHHS, 10/5/95 Press Release).

Of the top 20 services billed by physicians under Medicare in 1992, cataract removal and intraocular lens implantation ranked second, accounting for \$1,947 million Medicare dollars and was 5.7% of the total services billed. Three specialties,

ophthalmology, general surgery, and orthopedic surgery accounted for nearly half of Medicare surgical care in both 1980 and 1992. The proportion among the specialties, has changed, however. In 1980, ophthalmology accounted for 13.6%, however, by 1991, their proportion had increased to 22.7%. This change was due to the increase in cataract surgery. ([on-line], USDHHS, 1996).

Managed care, as a funding mechanism, is increasing in market share and expanding in the Medicare and Medicaid populations. By 1996, managed care served 23% of the Medicaid population. ([on-line], Health Care Financing Review) “As of October 1997, more than 5.73 million Medicare beneficiaries were enrolled in a total of 415 managed care plans, accounting for 15 percent of the total Medicare population. That represents a 147 percent increase in managed care enrollment since 1992.” ([on-line], USDHHS, 1997). Managed care has outcome measurement requirements specified in most contracts. Effective variables for outcome measurement need to be identified for cataract surgery.

### **Statement Of The Problem**

With the success and popularity of treating cataract disorders, it is important to utilize health outcomes research to determine cataract surgery’s effectiveness and benefits. Significant indicators that predict and measure success in cataract surgery need to be identified and verified. Statistical models can then be developed to predict successful outcomes. Better outcomes will enhance patient satisfaction and better utilize health resources. See Appendix A for a diagram of this problem.

The purpose of this study was to investigate patient visual acuity outcomes after the use of phacoemulsification during cataract surgery. The visual acuity outcomes from 140 consecutive surgeries were divided into three groups of improvement. One hundred five eyes obtained better than or equal to 20/40 (0.500) visual acuity. The 20/40 visual acuity

level is used in most states for an unrestricted driving license Masket (as cited in Lee, et al., 1993). Most literature uses the cutoff of 20/40 or better to designate successful visual outcomes following surgery (Lee, et al, 1993, p. 3). Three eyes showed worse results from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity. Thirty-two eyes showed some improvement from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity.

### **Research Questions**

Because patient visual acuity outcomes for the group that became worse was so few in number, only three, the cell size made analysis difficult. For this reason only one research question could be explored. This was:

1. What variables best predict those individuals likely to achieve 20/40 or better vision compared to those individuals who do not achieve the 20/40 standard?

This question is found in the literature Schein, et al. (1995).

It should be noted that although an individual may not achieve the 20/40 or better level, they may still experience a substantial improvement in vision such that it improves their ability to function in daily life. An example of this would be an individual whose pre-operative best corrected vision was 20/200 and best post-operative corrective vision is 20/60. Although that individual may not be able to see well enough to drive, she can once again see well enough to enjoy watching television, read, and move around more safely with less risk of falling. The goal of improving visual functioning, even if the visual acuity did not obtain the 20/40 level, could still be justified to managed care companies and other health care payors. Knowing the predictor variables for this group is important. It is also important to determine the predictor variables for the group of individuals for whom their visual acuity becomes worse after surgery. Knowledge of the predictor variables for this group, would assist the ophthalmologist in determining who the best candidates are for

cataract surgery. It would also improve the use of health care resources.

In the process of answering the research question noted above, there were some additional issues to be explored which included:

1. What are the significant indicators prior to receiving cataract surgery (demographic - age, race sex; physiologic - age, diabetic, hypertensive, degree of nuclear sclerosis; and/or visual comorbidities - age-related macular degeneration (AMD), glaucoma, diabetic retinopathy, high myopia) that may predict the patient's ultimate visual outcome?,
2. Do significant differences exist in visual acuity outcomes between various populations, i.e. males and females, ethnic groups, diabetics and nondiabetics, hypertensives and nonhypertensives, "high" myopics and others who are not "high" myopics?,
3. Are there any interactions occurring between predictor variables?,
4. Are there any confounding factors, for example, high incidence rate of diabetes among Hispanics?
5. If there are confounding factors, how do those factors influence cataract surgery outcomes?,
6. Is there a significant difference in the mean average amount of phacoemulsification power required to pulverize the lens for each degree of nuclear sclerosis (hardness in the lens)?.
7. Is there a significant difference in the mean average amount of phacoemulsification power required to pulverize the lens and those individuals who have post-operative complications and for those individuals who do not have post-operative complications?,
8. Is there a significant association between pre-operative variables and post-operative complications?

9. Is there a significant association between post-operative complications and ultimate visual acuity outcomes?

### Hypotheses

**H<sub>01</sub>**: No association exists between demographic (age, race, sex), physiological (diabetes, nuclear sclerosis), or ocular comorbid conditions (age-related macular degeneration [AMD], glaucoma) and poor visual acuity outcomes.

$$H_{01}: \chi^2_1 = \chi^2_2 ; \quad H_{1A}: \chi^2_1 > \chi^2_2$$

A nonparametric measure, chi-square, will be used to measure the associations.

**H<sub>02</sub>**: The mean average phacoemulsification power required to pulverize and remove the cataractous lens is not significantly different for each nuclear sclerosis (hardness of the lens) group (coded as 0,1,2,3,4,5).

$$H_{02}: \mu_0 = \mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5 ; H_{2A}: \text{not all } \mu_j \text{ are equal (where } j = 1, 2, \dots, c)$$

(Berenson, et. al, 1983)

One-way analysis of variance will be used to evaluate this relationship. The dependent continuous variable will be the amount of phacoemulsification power. The independent ordinal variable will be the degree of nuclear sclerosis (lens hardness).

**H<sub>03</sub>**: The amount of phacoemulsification power required to pulverize and remove the cataractous lens is not significantly different for those individuals with post-operative complications compared to those individuals without post-operative complications.

$$H_{03}: \mu_0 = \mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5 ; H_{3A}: \text{not all } \mu_j \text{ are equal (where } j = 1, 2, \dots, c)$$

(Berenson, et. al, 1983)

One-way analysis of variance will be used to evaluate this relationship. The dependent continuous variable will be the amount of phacoemulsification power. The independent dichotomous variable will be post-operative complications (true = 1/false = 0).

$H_{04}$ : There is no significant relationship between ultimate visual acuity outcome following cataract surgery and demographic (age, race, sex), physiological (diabetes, nuclear sclerosis), comorbid visual conditions (AMD, glaucoma), average phacoemulsification power required to remove the cataract, and post-operative complications.

$$H_{04}: P_i \neq \frac{1}{1 + e^{-L_i}}$$

$$H_{4A}: P_i = \frac{1}{1 + e^{-L_i}}$$

$$L_i = \hat{\beta}_0 + \hat{\beta}_1 + \hat{\beta}_2 + \dots + \hat{\beta}_x$$

(Hamilton, 1992, p. 223)

Logistic regression will be used to evaluate these relationships.

### Study Limitations

Study limitations included:

1. Small sample size of 140 surgeries over a six month period. Cell sizes for particular conditions were small with only 3 cases becoming worse from pre-operative glare visual acuity to post-operative best corrected visual acuity, 26 minority cases, 25 AMD cases, 14 high myopic cases, and 23 diabetic cases.
2. Length of time required to abstract each medical record (ranged from 30 minutes to 1 hour per record).
3. Medical records are from only one physician. Results are not generalizable

because of any undefined factors related to this physician's extensive experience.

4. The three cases involving multiple surgeries should not have been included in the analyses due to any undefined confounding factors.

5. Cases were not limited to only those cases of first-time cataract surgery. They should have been limited to first-time cataract surgery in order to be consistent with prior studies, i.e. Schein, et al. (1995).

6. Additional measures such as pre-operative and post-operative visual function (VF-14) tests, cataract symptoms survey, or patient satisfaction surveys were not included to evaluate visual outcome. Group of improvement was based solely on the difference between pre-operative and post-operative visual acuity prescriptions.

7. Not including additional evaluation tools may have led to a seventh limitation of misclassification in regards to group of improvement. A person may have clinically changed from 20/200 (very poor vision) to 20/50 (just under 20/40-legal driving vision). This person was classified in the "some" improvement group. Yet this big clinical change in vision may dramatically increase this person's ability to function and provide tremendous improvement in quality of life. Another person may have a pre-operative visual acuity of 20/40 and a post-operative visual acuity of 20/40, yet still be bothered by symptoms, for example, of glare, and not feel like quality of life has improved, even though the cataract has been removed. Misclassification may also have occurred with ocular comorbidities, as there was not a strict definition or standardization regarding this variable.

8. Some medical records had incomplete information regarding pre-existing conditions including diabetes, hypertension, and smoking. Twenty records were missing data elements included in this analyses; one record was missing six variables, two records were missing four variables, five records were missing two variables, and twelve records were missing only one variable. SPSS uses casewise



deletion for missing data. Hypertension was not indicated to be present for 90 of the records, but the author was not comfortable in assuming the answer would be false to this question, since taking blood pressure readings is not a standard medical procedure in ophthalmologic practices. Many people have hypertension and do not realize it. Because smoking was not consistently noted as “yes” or “no” in the medical records, the author was not comfortable making the assumption that if smoking was not noted the answer was “no”.

Future recommendations are discussed in Chapter 5.

## **CHAPTER 2**

### **REVIEW OF THE LITERATURE**

#### **History and Background**

##### Definition

A cataract is the clouding of the lens in the eye. It causes an individual to have “blurry” or “foggy “ vision in that eye. According to Lee, et al. (1993) several things may contribute to the development of cataracts including: “aging, trauma, toxins, metabolic or nutritional disorders, ultraviolet light, or congenital diseases.” (p. 1) The Agency for Health Care Policy and Research (AHCPR) estimates that 1.35 million cataract surgeries are performed annually. [On-line]. See Appendix D for definition of ophthalmologic terms. See Appendix E for a drawing of the parts of the eye.

##### Ultraviolet Radiation

There are several sources that discuss how exposure to ultraviolet radiation increases the risk for development of cataracts (Brint, 1989; Marwick, 1994; Wang-Cheng, et al., 1995). Li, et al. (1995) discuss how the formation of cataracts is a leading cause of blindness in the developing countries and how ultraviolet radiation and other factors contribute to cataract formation. The World Health Organization (WHO) (1996, on-line) defines blindness as visual acuity worse than 20/400 in the better eye. In 1982, WHO estimated there were 23 million people classified as blind (p. 145-146). It was estimated

that cataracts were responsible for this visual impairment in 44 to 74 percent of these individuals, or 10 to 17 million people. In 1996, WHO estimated, more precisely, there were 15.8 million persons who were blind due to cataracts [On-line].

### Longitudinal Study

Sommer's review (as cited in Lee, et al., 1993) states "there were no reliable, validated, population-based rates of incidence or progression of cataract, visual impairment, or ocular disease in the United States published before 1990." Lee, et al., made reference to a longitudinal study in Beaver Dam, Wisconsin which supported using cataract surgery. According to Klein, Klein, and Moss (1996) this study, was:

a population based incidence study of age-related eye disease. Participants were seen for their baseline evaluation (n = 4926) between March 1, 1988, and September 14, 1990, and for a follow-up examination (n = 3684) an average of 4.8 years later. All examinations, interviews, lens photography, and grading were performed using standard protocols. The age range was 43 to 84 years at the census preceding the baseline examination. Results: For those with no cataract at baseline and without cataract surgery at follow-up, there was an average decline of 0.5 letters (on a logMAR scale) in the right eye by the follow-up examination. In persons with any cataract at baseline and without cataract surgery at follow-up, there was a decrease of four letters. When cataract surgery was done in the interval, it was associated with a significant ( $p < 0.0001$ ) nine-letter (2-line) improvement in visual acuity. Conclusion: Cataract surgery in this population was associated with a significant improvement in visual acuity. (Abstract, lines 7-21)

### Traditional Cataract Surgery

Massengill (1986) explains that traditional cataract surgery involved the removal of the lens, including the posterior capsule which is the clear membrane behind the lens. This traditional surgery necessitated the use of a large incision, several sutures, and a long recovery period. Afterwards the person was measured and fitted with "coke-bottle" glasses. The lens in these type of glasses never do restore one's vision to "normal". The individual loses their peripheral vision and there are other distortions and reflections. This

left the individual with an inability to judge distance and a susceptibility to falling and spilling things. The “coke-bottle” glasses also made people feel very old and unattractive.

### Phacoemulsification Cataract Surgery

Since the 1970’s, alternative surgical methods have been developed. One of these methods involves using a small incision, the use of phacoemulsification to pulverize and remove only the lens, and then the insertion of a small plastic, acrylic, or silicone intraocular lens (IOL) to replace the original lens. (Brint, 1989; Lee, et al., 1993; Massengill, 1986) Stark’s, et al. study (as cited in Lee, et al., 1993) as of 1989, “Recent surveys report that 96 percent of procedures performed for aging-related cataracts include the insertion of an IOL.” (p. 2)

What is phacoemulsification? Czygan and Hartung (1996) give this description, “Phacoemulsification is a cataract surgery technique during which the eye lens nucleus is carefully dissected by an oscillating hollow needle simultaneously serving as a suction line for lens fragments.”

Advantages of Phacoemulsification. There are many advantages for this method. A much smaller amount of anesthesia is needed; surgery can occur in an outpatient setting; with foldable IOLS, incision is smaller; cost is much less; recovery is more rapid; and finally, in most cases, with the use of IOLs, more “normal” vision can be restored. (Massengill, 1986)

Disadvantages of Phacoemulsification. Any surgery on the eye can cause complications including bleeding, infection, edema; and raised intraocular pressure can lead to acute glaucoma (Endophthalmitis-Vitrectomy Study Group, 1996; Lee, et al, 1993). Phacoemulsification with lens replacement can also lead to any of these complications:

expulsive choroidal hemorrhage, rupture of the posterior capsule, vitreous loss, corneal abrasions and cloudiness, retinal detachment, cystoid macular edema (retinal swelling), ptosis (lid droopiness), lens implant dislocation, intraocular pressure elevation, problems due to the intraocular injection of local anaesthetic, or eye infections such as uveitis or endophthalmitis (Endophthalmitis-Vitrectomy Study Group, 1996; Kapusta, Chen, & Lam, 1996; Lee, et al, 1993; Sekine, Takei, Nakano, Saotome, & Hommura, 1996). These complications are important to note because they can lead to acute or chronic poor vision as measured by poor clinical and functional visual outcomes.

Secondary Complications. With phacoemulsification, individuals often develop a secondary cloudiness in the posterior capsule, which then requires a YAG laser treatment to create an opening in the posterior capsule to allow light to get through to the retina. (Massengill, 1986) This YAG laser treatment, in turn, can cause retinal detachment. This is a serious concern because if the detachment is not immediately treated by laser surgery or a scleral buckling operation, it will cause permanent blindness. A nested case-control study conducted by Tielsch, et al., 1996, showed an odds ratio of 3.8 associated with ND:YAG and concluded that:

Performance of ND:YAG laser posterior capsulotomy is associated with a significantly elevated risk of retinal detachment in patients who have undergone extracapsular cataract extraction. Other independent risk factors for retinal detachment include axial length, myopia, posterior capsular rupture during surgery, history of retinal detachment or lattice degeneration, and ocular trauma after cataract surgery. (Abstract, lines 28-33).

Denmark Retinal Detachment Study. A study done in Denmark by Norregaard, et al., 1996 regarding lens implants and retinal detachments showed:

a 4 year cumulative risk of hospitalisation [sic] for RD [retinal detachment] of 0.93% (95% confidence interval (CI) 0.71-1.16) was observed following an extracapsular cataract extraction with a lens implant. A similar cumulative risk of RD [retinal detachment] was reported from the US study. Thus, no difference in outcomes concerning risk of RD [retinal detachment] was shown between Denmark and the USA. In a multivariate analysis, younger age, male sex, and intracapsular cataract extraction were all

associated with higher risk of post-operative RD [retinal detachment]. A reference group of 7636 people not undergoing any ocular surgery was created and the incidence of RD [retinal detachment] in this group was calculated. During the sixth year following cataract surgery, the incidence of RD [retinal detachment] in the cataract group was still 7.5 (95% CI 1.6-22.0) times higher than that observed in the reference group.

### **Measurement of Visual Acuity**

Visual acuity is described by Snellen notation. The standard measure of good vision is 20/20 (1.0). However, in most states vision of 20/40 (0.5) is considered to be good enough to obtain an unrestricted driving license according to Masket (as cited by Lee, et al., 1993). See Appendix F for a full description of the Snellen visual acuity scale.

What would happen if age-related cataracts were left untreated? According to two longitudinal studies, one conducted by Gloor and Farrell and the other by Milne (as cited by Lee, et al., 1993, p. 7) they found:

vision deteriorated among 60 to 70 percent of their samples after approximately two years of followup. . . . Gloor and Farrell . . . determined that the rate of vision loss over an average of 2.8 years was 1.5 lines of Snellen acuity per year among a cohort of 220 eyes with aging-related cataracts, and nearly 2 lines among those who experienced any loss of vision from cataracts. This contrasts to the presumed effect of age alone on vision, which was shown to be a decrease of one Snellen line per 13 years after age 50 in a population that had already undergone cataract extraction (ICCE) [study by Jay, Mammo, and Allan (as cited by Lee, et al., 1993)]. The rate of decline may be more rapid for those with posterior subcapsular cataracts than for those with nuclear sclerosis or cortical changes and for patients with insulin-dependent diabetes who had cataracts [studies by Cotlier; Fujiwara, et al.; Gloor and Farrell (as cited by Lee, et al., 1993, p. 7)].

### **Factors Potentially Influencing Cataract Surgery**

#### **Ocular Comorbidity and Poor Visual Outcomes**

The presence of cataract along with certain medical or ocular comorbid conditions has been found to be associated with poor visual outcomes. The literature discusses diabetes mellitus, glaucoma, and age-related macular degeneration as having a positive association with poor visual outcome, Schein, et al. (1995). These three conditions are

associated with causing damage to the retina. The retina is in the back part of the eye, where the optic nerve transmits the visual impulses from light waves to the brain. A patient could have an excellent cataract surgery, but to the extent the retina is not capable of receiving and transmitting the light wave impulses to the optic nerve, the patient will not have good visual acuity.

Lee, et al. (1993) noted the following:

The literature describing the association between cataracts and comorbid ocular disease suggests that diabetes mellitus, glaucoma, or macular degeneration may occur concomitantly in 10 percent or more of cases presenting to the ophthalmologist. These comorbid conditions are important because they can influence the outcome as well as the operative and post-operative complications of the surgery. They should thus be considered important factors when assessing the appropriateness of cataract surgery. Because these conditions can independently limit vision, the probable level of vision after removal of the cataract ("visual potential") is also considered when describing the indications for cataract surgery. (p. 8)

#### Identifying Predictor Variables for Poor Visual Outcomes

In order to identify the variables that would predict negative visual outcomes before undergoing cataract surgery, Schein, et al. (1995) conducted a study to identify pre-operative patient characteristics associated with a lack of improvement on one or more measures four months after cataract surgery. Principle outcomes were assessed by using (1) the traditional Snellen visual acuity measurement, (2) cataract symptom scores, and (3) Visual Function (VF-14) scores. Out of 552 patients undergoing first-eye cataract surgery, 91 patients (16.5%) failed to improve on one or more assessed outcome measures and only 2 (0.4%) failed to improve on all three measures. The following characteristics and odds ratios were associated with increased likelihood of not improving on one or more measures: Pre-operative age of 75 years of age or older (3.57), VF-14 score of 90 or higher (2.10), cataract symptom score of 3 or lower (3.29), and ocular comorbidity, i.e. glaucoma, diabetic retinopathy, or age-related macular degeneration (2.16). This study also noted that "The pre-operative level of Snellen visual acuity was

not associated with the likelihood of not improving on one or more of the outcomes assessed.” (Abstract, p. 817) In other words, the study found that a person with poor visual acuity pre-operatively, did not predict or show an association with having poor visual acuity post-operatively. So, the visual acuity measure is not a predictor variable.

Diabetes mellitus. This is a medical condition associated with poor visual outcome. Diabetics can develop diabetic retinopathy, a condition that destroys the retina. “Patients with diabetes mellitus are at a significantly increased risk for developing cataracts and are at a higher risk of poor outcomes from cataract surgery if their diabetes is associated with retinopathy.” [studies by Cheng & Franklin, 1988; Cunliffe, Flanagan, George, Aggorwoal, & Moore, 1991; Klein, Klein, & Moss, 1984; Leske, Chylack, & Wu, 1991; Nielsen & Vinding, 1984; Schwab, Armstrong, Friedman, et al., 1988; Straatsma, Pettit, Wheeler, et al., 1983 (as cited by Lee, et al., 1993)].

Lee also noted an association between diabetes and age.

Several age-matched surveys have reported that the relative risk of cataracts among diabetics is substantially greater than among healthy controls. The difference is more apparent in younger persons, perhaps because cataracts in diabetics have already appeared by age 65. Data from the Danish National Registry confirmed that the prevalence of diabetes among persons undergoing cataract extraction is almost three times greater among the general population and 16 times greater among those younger than 40 years of age [study by Bernth-Petersen and Bach, 1983 (as cited by Lee, et al. 1993)].

“The association of diabetes and the prevalence of cataracts has also been shown to be stronger among women and among persons receiving concomitant therapy for hypertension.” [studies by Klein, Klein, and Moss, 1985; Peduzzi, Debbia, Monzia, et al., 1989 (as cited by Lee, et al., 1993, p. 8)].

More recent studies have resulted in different conclusions. A study by Antcliff, Poulson, and Flanagan (1996) concluded the “outcome of cataract surgery in diabetics is



largely determined by the degree of maculopathy. Phacoemulsification and extracapsular cataract surgery give similar visual results. Diabetic retinopathy should not be considered a contraindication to small-incision cataract surgery and phacoemulsification.” (Abstract, lines 17-21)

A study by Henricsson, Heijl, and Janzon (1996) in Sweden concluded that the cataract surgery outcome was related to how well glycemic control was maintained. “Patients in this study, also those with PDR [proliferative diabetic retinopathy], obtained good visual acuity, better than in most previous studies. Poor glycaemic [sic] control was a factor of importance for the progression of diabetic retinopathy after cataract surgery.” (Abstract, lines 21-24)

These two studies are suggesting that it is not the diabetes that is the predictor variable in regards to poor visual outcome. Instead, it is how well patients maintain their blood sugar levels and the degree of damage to the retina. These studies suggest that these variables would better predict the ultimate visual outcomes.

Glaucoma. This is another ocular comorbidity that can result in poor visual acuity or blindness. Glaucoma is caused by the build up of intraocular pressure sufficient to damage the optic nerve. The intraocular pressure increases when the vitreous fluid does not drain properly. This increase in pressure then causes damage to the retina. The retina has to be healthy in order to have good visual acuity. According to Lee, et al. (1993) there are few case-control studies describing the association between cataracts and glaucoma, however the published data suggest a positive relationship.

In one study, the likelihood of glaucoma among subjects with cataracts was sixfold greater than among age- and sex-matched controls [van Heyningen & Harding, 1986 (as cited in Lee, et al., 1993)]. This finding is supported by a retrospective, uncontrolled study of consecutive patients undergoing cataract surgery in Canada, in which 11 percent of patients had coexistent cataracts and chronic glaucoma [Neima & Ramsey, 1987a; Neima & Ramsey, 1987b (as cited in Lee, et al., 1993)] and by the Danish National Registry Study, in which the prevalence of cataracts was over fourfold greater among patients with glaucoma than among the general population [Bernth-Petersen & Bach, 1983c (as cited in Lee, et al., 1993)].

These studies seem to indicate that persons who have glaucoma, have an increased risk for developing cataracts. Sometimes after cataract surgery, the intraocular pressure (IOP) increases. This increase in pressure can damage the optic nerve and, ultimately, the retina causing poor visual outcome.

Macular Disease. The macula is the area in the central part of the retina. A person must have a healthy macula in order to have good central vision. The health of the remaining part of the retina affects the peripheral (side) vision. As people age, they often develop age-related macular degeneration (AMD). It is "the leading cause of blindness among those 65 and older in the United States" [Liu, While, & LaCroix, 1989 (as cited in Lee, et al., 1993)]. It is "a frequent explanation of poor outcome following cataract extraction" [Stark, Terry, & Maumenee, 1983 (as cited in Lee, et al., 1993)]. "Several other studies observed a 10 to 30 percent higher prevalence of AMD among persons with cataracts." [Bernth-Petersen, 1982c; Graney, Applegate, & Miller, 1988; Graney, Applegate, & Miller, 1990; Naeser, Rask, & Hansen, 1986; Whitmore, 1989 (as cited in Lee, et al., 1993)]. (p. 10-11)

A study by Pollack, Marcovich, Bukelman, and Oliver (1996) evaluated the course of age-related maculopathy after cataract surgery. They studied:

47 patients with bilateral, symmetric, early age-related macular degeneration (AMD), documented by fluorescein angiography, who underwent extracapsular cataract extraction with intraocular lens implantation in one eye. The fellow eye served as the control. . . .AMD developed in nine eyes (19.1%) that were treated with surgery compared with two fellow eyes (4.3%). [All cases developed within 12 months of surgery.] . . . Conclusions: In this study, progression of AMD occurred more often in the surgical eyes compared with the fellow eyes. However, the reasons for the progression of AMD after cataract surgery are still uncertain. Further prospective studies are needed to investigate this observation. (Abstract, lines 2-16)

High Myopia. This is extreme nearsightedness. It is defined as the measurement of greater than or equal to -5.00 diopters. High myopia has been associated with an increased risk for retinal detachment, particularly in association with YAG treatments (Tielsch, et al., 1996). Retinal detachment, if not treated immediately, can lead to blindness. In people with high myopia, cataract surgery alone, has not been associated with poor visual outcomes. The Kohnen and Brauweiler study (1996) concluded that "Cataract surgery can be performed in highly myopic eyes without intraoperative complications. A posterior chamber IOL should be implanted for post-operative refraction and intraocular stability, even if negative lens power is required." (Abstract, lines 14-17)

## **Efficacy of Cataract Surgery**

Regarding the efficacy of cataract surgery, Lee states:

The ideal way to determine the efficacy of cataract surgery would be to conduct a randomized, controlled, double blind trial to evaluate the effect of cataract removal. No study of this kind has been or is likely to be conducted because of ethical, financial, and technical difficulties. Natural history studies reveal that significant regression of visual effect of cataract is not possible; similarly, complications specific to cataract surgery would not occur in the absence of such surgery.

An important consideration in reviewing the efficacy of cataract surgery is the measure of success. The literature, with only three rare exceptions, reports Snellen visual acuity as the measure of successful intervention. Only three sets of studies specifically examined the functional effect of cataract surgery, with two of these studies reporting results from patients who underwent surgery using techniques or devices no longer commonly employed. Similarly, the majority of studies also do not report the pre-operative vision, such that very few studies provide a detailed estimate of the degree of improvement from the cataract surgery. . . .the bulk of studies report that, in general, in excess of 90 percent of patients undergoing cataract surgery achieve a Snellen visual acuity of 20/40 or better after cataract surgery. Since Snellen acuity of 20/40 or better is the limit for unrestricted driving licensing in the United States, as well as a commonly accepted measure of good vision, the large majority of patients achieve a satisfactory outcome from cataract surgery.

The three studies that examine the functional effect of cataract surgery suggest that nearly all patients undergoing cataract surgery experience improvements in visual function and functional capabilities, even among those patients who do not achieve 20/40 vision or better. Because two of these studies reported patients in whom techniques or intraocular lenses were less advanced than those used by 1990, these results probably represent underestimates of the true functional benefits of [modern] cataract surgery. (Lee, et al., 1993, p. v-vi)

## **Validity of Visual Acuity Measurements**

For the majority of the studies in the ophthalmic literature, the measure of good visual outcome is based only on the “Best corrected visual acuity as determined by a Snellen Chart (rows of letters of decreasing visual angles),” (Lee, et al., 1993) “However, Snellen measures alone may not capture the full effect of a cataract on visual acuity,” [American Academy of Ophthalmology, 1989b (as cited in Lee, et al., 1993)]. “Some suggest that additional tests, including different acuity charts, contrast sensitivity, and glare sensitivity examinations are useful to augment the standard assessment of visual acuity,”

[Shields, 1987 (as cited by Lee, et al., 1993)]. “Others, however, have expressed concern over technical questions associated with performing and interpreting these additional measures. Given the relative newness of these techniques, the Snellen Chart remains the major standard by which visual acuity is measured in general clinical practice today,” [American Academy of Ophthalmology, 1987a (as cited in Lee, et al., 1993, p. 12)]. The Schein, et al. (1995) study tried to assess visual outcomes by using (1) the traditional Snellen visual acuity measurement, (2) cataract symptom scores, (3) Visual Function (VF-14) scores, and (4) patient satisfaction survey. All measures were assessed both pre-operatively and post-operatively. Visual acuity and visual functioning are so complex that having more than one measure to try and accurately describe and quantify these functions is probably a good idea to incorporate into future studies.

### **Reliability of Visual Acuity Measurements**

Lee, et al, 1993 noted some concerns regarding the reliability of visual acuity measurements, “. . . the reliability (i.e., the repeatability) of the measures is an important consideration. The reliability of the acuity measure can vary because of differences in background lighting, examination setups, and notations for reporting results [Frisen, 1990 (as cited in Lee, et al., 1993, p. 13)].” Accuracy and consistency influence the reliability of study results. They can impact on bias and error in a study.

### **Quantifying Visual Acuity Improvement**

It is difficult to quantify post-operative visual acuity. This due to several reasons. First of all, few studies include the pre-operative measurements. Second, it depends on when post-operatively one takes the visual acuity measurement. Vision often fluctuates during the post-operative period. As Lee, et al (1993) notes:

Quantifying improvement in visual acuity is often difficult because much of the efficacy literature reports only post-operative visual results. Fewer than 15 percent of the articles reviewed included pre-operative measurements of visual acuity. Even post-operative measurement is variable, with the interval between cataract extraction and the post-operative acuity varying from less than three to more than 60 months. Six months followup is generally regarded as adequate in most cases to assess the success of the procedure because a relatively stable refraction (including astigmatic changes) is usually achieved by two to four months after surgery . . . , and cystoid macular edema as a complication . . . peaks between six weeks and six months [Bradford, Wilkinson, & Bradford, 1988 (as cited in Lee, et al., 1993)]. However, other complications of surgery, particularly corneal decompensation, may not appear for several years after surgery. Finally, in measuring changes in visual acuity, it should be kept in mind that a patient's vision can be significantly improved from the pre-operative level, even if the post-operative visual acuity is worse than 20/40. (Lee, et al., 1993, p. 13)

### **Nuclear Sclerosis (Hardness Of The Cataract)**

One factor the cataract surgeon must estimate is the hardness of the lens. The hardness of the lens determines how much phacoemulsification power is needed and its duration of use during surgery. Gullapalli, Murthy, and Murthy (1995), noted in their study "that colour can be used more reliably to predict physical characteristics of the cataractous lens nucleus, the pre-operative knowledge of which would help the surgeon in planning small-incision surgery including phacoemulsification." (Abstract, lines 16-19) The hardness of the lens is noted in the medical records as trace, 1+, 2+, 3+, 4+, "early brunescence", "brunescence", or "advanced brunescence". The harder the lens, the greater the risk for surgical complications.

One study specifically looked at the effect of how the phacoemulsification power and duration of time influenced cataract surgery outcomes. This study conducted by Dick, Kohnen, Jacobi, and Jacobi specifically looked at the effect on central endothelial cell loss (ECL). The endothelial cells are located on the back of the cornea. They do not reproduce. One gradually loses them over a lifetime. Substantial loss of endothelial cells will

negatively effect visual acuity. This study found that “Phacoemulsification with 3.5 mm clear corneal incisions produced slightly less ECL (6.7%) than phacoemulsification with 5.0 mm incisions (7.9%). Total ECL of 7.3% at 1 year postoperatively compared favorably with ECL rates of other cataract extraction methods.” (Abstract, lines 19-23)

### **Phacoemulsification Effects on Astigmatism and Visual Outcomes**

Astigmatism is a visual distortion of the light waves as they come through the cornea into the lens and onto the retina. Astigmatism generally comes from irregularities on the surface of the cornea. The visual distortion may appear, for example, as extra lines around letters, numbers, or objects. It can be corrected with prescription lenses. The distortion is measured in amount and degrees of axis. The range of measurement is from 0 to 180 degrees. Several articles discussed the relationship between phacoemulsification and induced astigmatism.

#### **Extracapsular Extraction versus Phacoemulsification and Effect on Astigmatism**

One study done by Honda (1995) compared the quality of vision after extracapsular cataract extraction and phacoemulsification-aspiration. It was found that corneal astigmatism was significantly greater in the extracapsular group than the phacoemulsification group. This would be an advantage for using phacoemulsification over extracapsular extraction.

Other factors found in the literature concerning phacoemulsification and visual outcomes related to astigmatism included comparisons of different types of incisions, different incision techniques, different lengths of small incisions, types of sutures, and different IOL lenses. In addition to finding literature that supported specific techniques, I also found an article that sounded a word of caution regarding reported incision lengths.

### Types of Incisions and Effects on Astigmatism

Seven studies were found that looked at types of incisions and the effects on induced astigmatism. The first study conducted by Boku, Kamijo, Miyata, Kizaki, and Yaguchi (1996) looked at the effect from superior frown incisions.

We performed cataract surgery in 30 eyes with against-the-rule corneal astigmatism by phacoemulsification through a 4mm superior frown incision followed by implantation of cylindrical intraocular lens, IOL. A 2 diopter (D) cylindrical IOL was implanted in 17 eyes with astigmatism of 1.0 to 1.5D. A 3D cylindrical IOL was implanted in 13 eyes with astigmatism of 1.5 to 3.0D. Post-operatively, astigmatism was reduced by  $0.88 \pm 0.30D$  and by  $1.32 \pm 0.59D$  respectively. The present method was useful in its predictability and is recommended for cataract eyes with high corneal astigmatism. (Abstract, lines 1-8)

The second study conducted by Bellucci, Morselli, Pucci, and Palamara (1996) used superior sutured 8 mm scleral tunnel incisions closed with a continuous 10-0 nylon suture. The study concluded that the “sutured 8 mm tunnel incisions showed good results in terms of absolute cylinders but late against-the-rule shift could not be avoided.” (Abstract, lines 12-14)

The third study conducted by Weindler, Spang, Weik, and Ruprecht (1996) compared corneal incisions and temporal incisions and found:

In comparison to the pre-existing astigmatism, there was an increase of the astigmatism with cranial incision more than double, with temporal incision the astigmatism was significantly lowered. Post-operatively the astigmatism with temporal wound location was significant[ly] lower than with cranial incision. Conclusion under the aspect of a 1.5 D higher average astigmatism post-operatively, we conclude that a cranial 6-mm no-stitch tunnel incision in pre-operative astigmatism against the rule is contraindicated. (Abstract, lines 9-16)

Grote, Pham, and Wollensak (1996) conducted the fourth study on corneal tunnel incision. They found:



Cataract surgery can be combined with the correction of high preoperative astigmatism by using a corneal tunnel incision in the steep meridian. We examined 37 patients (mean age 70 years) with cataract and a mean pre-operative astigmatism of 3.6D (2.0 - 4.75 D). A 7-mm clear corneal incision was made for phacoemulsification and thus a reduction in the astigmatism was achieved. The mean induced astigmatism was 3.6D (SD 1.6 D minimum 0.8 D, maximum 7.5 D) on the first post-operative day and 2.7D (SD 0.9D, minimum 1.6D, maximum 4.9 D) after 10 months. By modification of the incision technique with a trapezoidal corneal incision and a single radial suture the wound closure was more stable, but the astigmatic correction did not change significantly compared to the results after the original 7-mm clear corneal incision technique. (Abstract, lines 1-11)

The fifth study conducted by Gross and Miller (1996) compared unsutured small scleral tunnel and temporal corneal incision. They found “significantly greater with-the-rule change in astigmatism in the scleral incision group than in the corneal incision group on the first postoperative day. The effect disappeared by the sixth post-operative week.”

Long and Monica (1996) conducted the sixth study and found:

Three-plane corneal tunnel incisions placed on the steeper meridian are safe, consistently self-sealing, and rapidly stable; and they produce less than a 1.00-diopter astigmatic change. Vertical incisions produce slightly more astigmatic change and different effects compared with horizontal incisions. (Abstract, lines 13-17)

The seventh study conducted by Haubrich, Knorz, Seiberth, and Liesenhoff (1996) used vector analysis to analyze four tunnel-incision techniques. They found:

The 4- and 5- to 6-mm scleral tunnel as well as the 4-mm clear cornea incision were shown to be nearly astigmatism-neutral. The 5.5-mm clear cornea incision reduced astigmatism of the central cornea by about 35%, but induced irregular astigmatism in the periphery. (Abstract, lines 20-23)

In summary, when a patient has severe astigmatism and cataracts, both can be corrected at the same time. The above studies seem to indicate that superior frown incisions, temporal incisions, and corneal tunnel incisions are successful, however, the specific needs of the patient need to be taken into consideration during the surgeon's decision making process.

## Cataract Surgery Incision Size and Astigmatism

Five studies were found that looked at the effect of incision size and its relationship with induced astigmatism. Kohnen, Dick, and Jacobi (1995) study found, “Vector analysis demonstrated that temporal corneal tunnel incisions induced clinically minimal astigmatism over six months post-operatively depending on incision size.” (Abstract, lines 17-19)

The El Kasaby, McDonnell, and Deutsch (1995) study found:  
One of the main aims of small incisions in cataract surgery is to reduce surgically induced astigmatism to a minimum. A prospective study was set up to compare sutured with unsutured 6 mm scleral pocket frown incision wounds for phacoemulsification. Videokeratography was used to study the topographical changes induced by surgery. Two groups of 15 patients were allocated to have either sutured or unsutured 6 mm frown incisions for their phacoemulsification. . . . The results show a modest flattening in the vertical meridian in both groups of patients which was slightly larger in the unsutured group. The astigmatic change did not differ significantly between the two groups. The 6 mm scleral pocket incisions induce a small amount of astigmatism whether sutured or unsutured. However, we felt it was perhaps safer to suture an incision of that size. (Abstract, lines 1-14)

This study indicates that larger incision sizes require suturing.

The third study found was conducted by Olsen, Dam-Johansen, Bek, and Hjortdal (1996). They evaluated surgically induced astigmatism using Fourier harmonic series analysis of corneal topography data. Using the following methods they:

evaluated the results of 46 phacoemulsifications with a 4 or 6 mm scleral tunnel sutureless incision based on the axis of the steepest meridian. . . . performed conventional keratometry and corneal topography before and up to 1 month after surgery. Using Fourier analysis, the corneal topographic images were broken into spherical power, regular astigmatism, and nonregular astigmatism for individual or aggregate analysis of surgically induced astigmatism. The induced refractive change (average of the difference between pre-operative and post-operative corneal topographies) was analyzed and normalized according to the surgical meridian and to right/left eye. Results: Regular astigmatism calculated by Fourier analysis of mires from the keratometer zone correlated well with conventional keratometry readings. Surgery induced a localized flattening in the superior region and a with-the-rule regular astigmatism component in the central area. Conclusion: Surgically induced corneal topography changes can be analyzed by Fourier series harmonic analysis, allowing aggregate data to be broken into optically meaningful quantities. (Abstract, lines 1-18 )

The Claoue and Hicks (1996) study evaluated main outcome measures related to complications, best corrected and uncorrected visual acuities 6 weeks after surgery, and number of visits before discharge. They found “Patients who had small and scleral incisions had better uncorrected visual acuities 6 weeks post-operatively because they had less astigmatism. Patients who had small and scleral incisions required significantly fewer post-operative visits before discharge. . . .” (Abstract, lines 3-13)

The fifth study found was conducted by Negishi, Bissen-Miyajama, Tomidokoro, Oshika, and Matsuzaki (1996). They “evaluated contrast visual acuity and irregular astigmatism during the early stage after self-sealing small-incision cataract surgery in 22 eyes.” (Abstract, lines 1-2). They found:

Three days after surgery, the corrected visual acuity and visual acuity for high-contrast chart reached the average values 3 months after surgery. It took 2 weeks for the visual acuity for medium-and low-contrast chart to reach the average value 3 months after surgery. Irregular corneal astigmatism showed significant increases 3 and 5 days after surgery from pre-operative values. It returned to the pre-operative value 2 weeks after surgery. There were no differences before and after surgery in regular astigmatism, surface regularity index and surface asymmetry index. The findings show that irregular astigmatism may be a factor in the recovery of visual acuity for medium-and low-contrast chart during the early stage after self-sealing small-incision cataract surgery. (Abstract, lines 1-13)

In summary the above studies seem to indicate that larger incision sizes require sutures. Smaller incision sizes reduce or eliminate the need for sutures. Patients with small incisions and with scleral incisions appear to recover more quickly and to have better uncorrected visual acuity 6 weeks post-operatively.

#### Cautionary Note regarding Reported Incisions Sizes

One study found, encouraged caution in interpreting study data regarding incision sizes. The Steinert and Deacon (1996) study found “The phacoemulsification incision enlarges at each step of the procedure. Irreversible incision stretching or incision tearing

occurs, rather than reversible elastic incision deformation. Clinical studies that assume the initial keratome size equals the final incision size may be erroneous.” (Abstract, lines 13-17)

#### Types of Sutures and Effects on Astigmatism

Three studies were found that looked at differences in effect on astigmatism due to types of sutures. The Vass, Menapace, Amon, Hirsch, and Youself (1996) study evaluated “the effect of a suture on surgically induced corneal topographic changes in 5.0 mm clear corneal incisions.” (Abstract, lines 1-2) This study concluded that “application of one radial 11-0 nylon suture in 5.0 mm temporal clear corneal incisions significantly reduced shape changes in the nasal corneal region.” (Abstract, lines 19-21)

The second study conducted by Benabent, Roig, and Martnez-Toldos (1996) found:

Proper wound closure is important in preventing post-operative endophthalmitis. We developed an intrastromal corneal suture technique that uses some principles of the running, locked, intradermal suture for light-tension skin wounds. It achieves close approximation of the wound edges, reduces post-operative wound care and the risk of wound infection in clean surgical wounds, and obviates suture removal. It may also help prevent endophthalmitis and early against-the-rule astigmatism without the complications associated with external suture exposure. (Abstract, lines 1-8)

In summary, preventing endophthalmitis, an eye infection, is important for short and long term recovery of good visual acuity.

The Lyhne and Corydon (1996) study evaluated changes in astigmatism in the first 6 months after using 5.2 mm superior scleral incision with phacoemulsification and three different closures. They stated:

This study comprised 75 consecutive patients who had 5.2 mm superior scleral incision phacoemulsification. Patients were randomly assigned to one of three groups based on type of incision closure: Group 1, one intraoperatively adjusted cross suture; Group 2, one unadjusted cross suture; Group 3, no suture. Inclusion criteria were pre-operative astigmatism of 2.00 diopters (D) or less (range of median 0.74 to 0.81 D) and no eye disease except cataract. Post-operative astigmatism was evaluated by keratometric cylinder, induced astigmatism (naeser), and induced cylinder (Jaffe) on the first day and after 1 week and 1, 3, and 6 months. Time before stability was estimated. Results: All groups had the same level of post-operative keratometric cylinder with no significant change between 1 week and 6 months (range of median 0.81 to 1.06 D). The groups reached the same level of induced astigmatism (Naesser) 3 to 6 months after surgery (range of median - 0.44 to -0.64 D). Group 3 (sutureless) reached that value after 1 week, and induced astigmatism was stable thereafter. Both sutured groups (Groups 1 and 2) had a highly significant change between the first week and third month ( $p < .01$ ). There were no significant intergroup differences in induced cylinder (Jaffe), which stabilized after 1 week in Groups 1 and 2 and after 1 month in Group 3 (range of median 0.61 to 0.87 D). During the early post-operative period, variation was highest in Group 2. Conclusions: Keratometric cylinder, induced astigmatism, and induced cylinder 3 to 6 months post-operatively were similar among the three groups, but early stability was only seen in the sutureless group. If a [cross] suture is used, intraoperative adjustment seems to result in lower variations in the early post-operative period. (Abstract, lines 1-27)

In summary, one study recommends the use of the 11-0 nylon suture, the second study recommends using the intrastromal corneal suture, and the third study found that early stability in changes in astigmatism were only seen in the sutureless group.

#### Type of Lens Used and Post-Operative Visual Acuity

Four studies were found that evaluated the effect of different types of lenses on visual acuity.

The Santacrose and Romeo (1995) study compared two intraocular lenses one of silicone and the other of PMMA to see which “post-operative refraction [was] closest to that which is expected with pre-operative biometry. The silicone lens has a difference of error of -0.80 (spherical equivalent), while the PMMA lens - 0.25 (spherical equivalent).” (Abstract, lines 4-6) This study indicates that the PMMA lens had less refractive error.

The Oshika, Suzuki, Kizaki, and Yaguchi (1996) study assessed “the efficacy and safety of a soft acrylic intraocular lens (IOL) in small incision cataract surgery.” (Abstract, lines 1-2) They found:

At day 1, 96.9% of patients had corrected visual acuity of 20/40 or better, and 50.0% had 20/20 or better. At 2 years post-operatively, 100% had 20/40 or better, and 86.3% had 20/20. Surgically induced keratometric cylinder remained quite stable throughout the 2 year follow-up period, with axis-based astigmatism of -0.3 diopters. . . . Neodymium: YAG laser capsulotomy was performed in seven cases (11.1%) without causing damage to the optic. No other post-operative complications were encountered. Conclusion: Soft acrylic IOLs have clinically apparent advantages in small incision cataract surgery. (Abstract, lines 4-9,11-14)

The Yoshida, Nishio, Obara, Senoo, and Meya (1996) study noted:

We performed cataract surgery with foldable intraocular lens (IOL) made of silicone and acrylic IOL made of PMMA in 30 eyes each. We evaluated the post-operative visual acuity, refraction, corneal topography, contrast sensitivity, decentration of IOL, corneal endothelial cells and anterior aqueous flare. Visual acuity during the early operative stage was better in foldable IOLs. Astigmatism in the foldable IOL group was lesser in amount and became stable in the early post-operative stage. There was no difference astigmatism between the two types of IOL at one month after surgery. Contrast sensitivity was less in the medium to high frequency ranges in the foldable IOL group. Decentration of IOL increased in the foldable IOL group. Aqueous flare at the first post-operative day was less in eyes receiving silicone than [than] acrylic IOLs. There was no reincrease in flare value in eyes receiving acrylic IOLs. All the parameters were more stable in eyes implanted with acrylic than silicone. (Abstract, lines 1-13)

The Bleckmann, Schmidt, Sunde, and Kaluzny (1996) study evaluated:

corrected and uncorrected near, intermediate, and distance visual acuities in eyes with a progressive multifocal intraocular lens (IOL) and to determine the effect of the lens on contrast sensitivity. . . . Results: Distance visual acuity improved from 0.13 Snellen lines uncorrected and 0.23 with best correction pre-operatively to 0.77 and 0.96 lines, respectively, post-operatively. Uncorrected pre-operative near acuity was 13.28 Jaeger lines and best corrected acuity, 8.93 lines. These improved to 4.75 and 2.69 lines, respectively. The differences between visual acuity at intermediate distances and best distance and near acuities were not significant. Patient satisfaction was highest with vision under good light conditions and when viewing larger objects. Conclusion: Visual performance with the multifocal progressive IOL was adequate at various distances without additional correction. It was less satisfactory under poor light conditions. (Abstract, lines 1-3, 9-18)

There was nothing stated in the abstract to determine how the multifocal intraocular lens might induce astigmatism.

In summary three out of the four studies regarding types of cataract surgery intraocular lenses found that soft acrylic lenses provided the best refractive correction (visual acuity). The progressive multifocal intraocular lens (IOL) provided adequate visual performance without additional prescriptive correction lenses. These intraocular lenses did not work as well under poor light conditions.

#### Measurements of Refractive Change as Related to Visual Outcomes

There were four studies that compared the use of various algorithms to predict refractive power. Refractive power impacts on visual acuity. Persons who are nearsighted (myopic) have long axial lengths and need increasingly negative diopters (power). Highly myopic persons are those people with very long axial lengths (greater than 26 mm) and who are equal to or greater than - 5.00 diopters. Farsighted people have very short axial lengths and they need increasingly positive diopters (power). A person with the measurement of zero diopters or “plane 0” has 20/20 (1.00) vision. The Olsen, Corydon, and Gimbel (1995) study in Denmark on formulas and axial length found:

When analyzed for axial length dependence, all formulas showed the least error in the normal range. Error of the Olsen formula was lower than that of the others in the axial length interval 20 mm to 26 mm. No differences in accuracy were found between the optical IOL calculation formulas in eyes with an axial length above 26 mm ( $p < .05$ ). The accuracy of IOL power calculation can be improved with optical formulas using newer-generation ACD-prediction algorithms. (Abstract, lines 13-19)

Olsen (1996) in a prospective study with a 4 month follow-up looked at 333 patients who had phacoemulsification with a 6 or 4 mm scleral tunnel incision. The study found:

the accuracy of predicting visual results after cataract surgery using a mathematical model of surgically induced refractive change and a previously published regression formula predicting uncorrected visual acuity as a function of the resulting spherocylinder [sic]. Results: A significant correlation was found between the observed and the predicted visual acuity in each eye ( $p < .01$ ). Conclusion: The visual outcome of cataract extraction can be predicted from a theoretical model of the surgically induced refractive change. (Abstract lines 1-7, 9-12)

Wilhem, Kietzmann, and Freitag (1996) studied a series of 103 patients using the SRK II formula for one type of IOL (A-constant 118,9) and found the accuracy of IOL calculation is satisfactory in respect of predicted refraction. Again, for eyes with elongated axial lengths, the accuracy was limited.

In a series of 103 patients the predicted refraction - calculated by the SRK II formula for only one type of IOL (A-constant 118,9) - was compared to the received early and late (3 month) post-operative refraction. Results: The accuracy of IOL calculations in 95% was acceptable - within a range of 2 diopters. The prediction errors of extender values were only shown in cases of axial length of more than 26 millimeters. Conclusions: The results confirm the fact that by means of SRK II formula the accuracy of IOL calculation is satisfactory in respect of predicted refraction [sic]. In eyes of elongated axial length the accuracy is limited. (Abstract, lines 3-11)

Celikkol, Pavlopoulos, Weinstein, Celikkol, and Feldman (1995) study concluded that, "after radial keratotomy, using the keratometric value derived from computerized videokeratography in intraocular lens calculations is more accurate than using keratometric values measured by routine methods." (Abstract, lines 23-25)

In summary, there are formulas available to help ophthalmologists predict the refractive change that will occur with the use of the intraocular lens (IOL). These formulas will help the ophthalmologists calculate the amount of power needed in the IOL. There is also available new technology, computerized videokeratography, that may prove to be highly valuable in assisting the ophthalmologist with the keratometric measurements and calculations.



## **CHAPTER 3**

### **METHODS**

#### **Study Sample Data**

The sample data for this study came from the medical records of an ophthalmologist in San Marcos, Texas. According to the 1990 U.S. Census Data [on-line], the general population of San Marcos, Texas (on the county level) is composed of 60% caucasian, not of Hispanic origin, 34% Hispanic, 5% African-American, and 1% other race, not of Hispanic origin. This makes a combined summary of the minority population equal to 40%. This compares with the general population of the state of Texas, which has a distribution of 50% caucasian, not of Hispanic origin, 25% Hispanic, 12% African-American, 13% other, not of Hispanic origin. So the state of Texas has an equal distribution between caucasians and minorities. The United States distribution is 71% caucasian, not of Hispanic origin, 9% Hispanic, 12% African-American, and 8% other race, not of Hispanic origin. For the United States, the combined summary of the minority population equals 29%. The study sample was composed of 114 (82%) caucasian, not of Hispanic origin; 24 (17%) Hispanic origin; and 2 (1%) African-American, with a combined summary of minority population equaling 18%. This shows that the sample population does not have the same racial distribution as San Marcos (county level), the State of Texas, or the United States.

The age distribution for San Marcos is 72% under age 35, 21% between age 35 to age 65, and 7% over age 65. This compares with the general population of the state of Texas, which has a distribution of 58% under age 35, 32% between age 35 to age 65, and 10% over age 65. The United States distribution is 53% under age 35, 34% between age 35 to age 65, and 13% over age 65. This indicates that San Marcos has a smaller distribution of older people over age 65, compared to the state of Texas and the United States.

From January 2, 1997 to June 25, 1997 one hundred forty cataract surgeries were completed. Out of the 140 reviewed records, the sample included 61 men and 71 women. Eight subjects, one man and seven women, received cataract implants in each eye during two different surgeries during the study period. The subjects' ages ranged from 37 - 97 years of age, with a mean of 73.56 years.

### **Data Source**

Research was conducted utilizing ophthalmological medical records made accessible to the Southwest Texas State University Department of Health Services and Research. Medical record data were abstracted from March through November 1997, following the cataract surgeries which had occurred from January 2, 1997 to June 25, 1997. One hundred forty medical records were reviewed and information abstracted to a data collection form (see Appendix B). Information was abstracted by the author. Information was then entered into an Excel spreadsheet and analyzed in Excel and SPSS. Appendix C is the data dictionary for the database. The original data collection form contained 162 variables. The database contains over 200 fields. Additional fields were added to facilitate analysis of transformed or recoded variables.

After the abstraction, twenty variables were included in the final analyses. These were based on predictor variables mentioned in the literature. The twenty variables

included demographic variables (age, sex, race), medical variables (diabetic, hypertension), ophthalmologic variables (AMD, glaucoma, high myopia, which eye receiving cataract surgery - left or right, degree of nuclear sclerosis, had the fellow eye received cataract surgery, had the eye receiving cataract surgery received any previous surgery, any comorbidity (i.e. AMD, diabetes, glaucoma - true/false)), surgical variables (pre-operative risks - true/false, average power of the phacoemulsification found by multiplying the power of the phacoemulsifier times the duration, was more surgery in addition to the cataract surgery occurring during the same time, operative complications - true/false), and post-operative variables (post-operative complications - true/false, number of post-operative visits noting presence of infection, post-operative prescriptive visual acuity, group of improvement - worsened, some improvement, best). The data were analyzed by descriptive analysis, univariate and comparative t-tests of sub-group means, chi-square analyses, linear regression and logistic regression.

### **Design Of Data Collection Instrument**

A three page data collection instrument was developed after reviewing the literature, prior instruments used, and discussing with the ophthalmologist the kind of information needed for future analyses. The instrument included the following parts: demographic information, pre-existing medical conditions, ocular comorbidities, pre-operative and post-operative measurements, and post-operative complications. After data collection was substantially complete, two additional variables, were added. A VF14 (Visual Function Test) pre-operative and post-operative score. They will be collected on surgeries after November 1997 and will be included in future analyses. Appendix B is the updated data collection instrument, which includes the additional variables.

## **Definition Of Terms**

Appendix C contains the data dictionary for the data collection instrument and database. Definitions of ophthalmological terms are found in Appendix D.

## **Statistical Analysis Procedures**

Appendix A shows a diagram of the research problem. One will notice there are four sets of variables. There are pre-existing variables, the intervention - cataract surgery variables, surgical outcome (i.e. operative complication variable), and visual outcome (i.e. group of improvement).

Pre-existing variables can be divided into sub-groups. The demographic variables included age, race, sex. The physiological variables included age, nuclear sclerosis, and diabetes. The ocular comorbidity variables included high myopia, AMD, diabetic retinopathy, and glaucoma. It should be noted that diabetic retinopathy was not specifically included in the original data collection and it is recommended that this variable be included in future studies. Additional discussion regarding future data collection recommendations is in Chapter 5. Some additional pre-existing or pre-operative variables that were included in the original data collection included smoking, coumadin usage; a true/false variable to indicate if cataract surgery had occurred already on the fellow eye; and if the eye receiving cataract surgery had previously had other surgery.

Each of the pre-existing variables were analyzed by chi-square to determine if there was a significant association with group of improvement. They were also analyzed by ANOVA and means tests to determine if there were any significant differences by age, sex, and race. Chapter 4 discusses the variables that were determined to be significantly associated with group of improvement. Discussion of the other variables and other significant associations is found in Appendix G.

Next the author analyzed the surgical variables which included the average phacoemulsification power and if there were any operative complications. A means test was used to determine if there was a significant difference in average phacoemulsification power used between those individuals who had operative complications compared to those individuals who did not have operative complications.

An analysis of variance with a Least Squares Difference Test (LSD) evaluated the differences in means between the six nuclear sclerosis groups and the average amount of phacoemulsification power needed to pulverize the lens. Based on the results from the LSD analysis, the author decided to recode nuclear sclerosis such that groups 0 to 3 were grouped together and recoded as 0 and group 4 and 5 were grouped together and recoded as 1. Then chi-square analysis analyzed the association between nuclear sclerosis and operative complications. Chi-square analysis found, however, there was not a significant association between operative complications and visual acuity at the 20/40 or better level. Chi-square analysis determined there is a significant association ( $p < .001$ ) between post-operative complications and visual acuity at the 20/40 or better level.

To determine if there was any interaction or confounding occurring among age and AMD and age, individuals were divided into two groups. The first group included individuals less than or equal to 75 years of age. The second group included individuals greater than or equal to 76 years of age. Odds ratios for the stratum were calculated for AMD and group of improvement. The odds ratios for the stratum were compared to the crude and adjusted odds ratios. The patterns indicated there was interaction and confounding. A new variable was created to account for the interaction. Because of empty cells analysis could not be done regarding if there was an interaction or confounding occurring between age and nuclear sclerosis.

Because patient visual acuity outcomes for the group that became worse was so few in number, only three, analysis could only occur for the following research question:

1. What variables best predict those individuals likely to achieve 20/40 or better vision compared to those individuals who do not achieve the 20/40 standard?

This question is found in the literature Schein, et al. (1995). All variables found to be significant and the new variable created to account for the interaction between age and AMD and nuclear sclerosis and average phacoemulsification power were entered into a logistic regression model. Results of these analyses are discussed in Chapter 4.

## **CHAPTER 4**

### **RESULTS**

#### **Descriptive Analyses of the Sample Population**

From January 2, 1997 to June 25, 1997 there were 140 cataract surgeries completed by the ophthalmologist who provided data for this study. Twenty records were missing data elements important to the analyses; one record was missing six variables, two records were missing four variables, five records were missing two variables, and twelve records were missing only one variable. SPSS uses casewise deletion for missing data.

#### Demographics

Of the 140 cataract surgeries, 61 were men and 71 were women. Eight subjects, one man and seven women, received cataract implants in each eye during two different surgeries during the study period. The data includes information on 62 (44%) male eyes and 78 (55%) female eyes. The patients ranged in age at the time of surgery from 37 to 97 years old. There was no significant differences in age between men and women; the mean age for the men was 72.34 years and the mean age for the women was 74.54 years. There were 114 (81%) Caucasian eyes, 24 (17%) Hispanic eyes, and 2 (1%) African-American eyes. Because of small sample sizes, for analysis purposes the Hispanics and African-Americans were grouped together.

#### Outcome Variable: Group Of Improvement

Improvement was broken into three categories. Three eyes showed worse results from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity. Thirty-two eyes showed some improvement and one hundred five eyes obtained better than or equal to 20/40 (0.500) visual acuity. Because the cell size was so small for the group that became worse, some of the analyses compared the group that achieved the 20/40 level or better with the group that did not achieve this.

Age. Group of Improvement by age at time of surgery with one-way analysis of variance showed significant differences between groups ( $p < .01$ ) as shown in Table 4.1.

**Table 4.1: Analysis of Variance for Age and Group of Improvement**

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig of F
Improvement Group	1707.238	2	853.619	7.575	<.001
Residual	15439.183	137	112.695		
Total	17146.421	139	123.356		

$H_{01}$ : There is no significant difference in mean age for each group of improvement

(worse, some, best).

$H_{01}$ :  $\mu_1 = \mu_2 = \mu_3$  ;  $H_{1A}$ : not all  $\mu_j$  are equal where  $j = 1, 2, 3$

(Berenson, Levine, and Goldstein, 1983)

Where  $\mu_1$  = mean age of individuals associated with worse visual outcome.

$\mu_2$  = mean age of individuals associated with some improvement in  
visual outcome.

$\mu_3$  = mean age of individuals associated with 20/40 or better visual outcome.



**Table 4.2: One-way ANOVA with Scheffe' Post Hoc Test**

Variable	Mean	SD	No. of Cases	Group of Improvement	0	1	2
Entire Population	73.34	11.11	140				
Worse = 0	83.0	5.20	3	Grp 0			
Some = 1	79.2	9.05	32	Grp 1			*
Best = 2	71.57	11.12	105	Grp 2			

	D.F.	Sum of Squares	Mean Square	F	Significance
Between Groups	2	1707.2384	853.6192	7.5746	<.001
Within Groups	137	15439.1830	112.6948		
Total	139	17146.4214			

\* Indicates Significance.

Age as Predictor Variable. Table 4.2 shows the null hypothesis is rejected. The mean age of the group that had some improvement in visual acuity after surgery is significantly different from the mean age of the group that achieved the 20/40 or better visual acuity level. There is not a significant difference in mean age for the group that had some improvement compared to the mean age of the group that became worse. In this sample, mean age increases as group of improvement becomes worse. The three cases with worse visual acuity from pre-operative to post-operative had a mean age of 83 years. The 32 cases that showed some improvement had a mean age of 79.2 years. The 105 cases with best corrected visual acuity of equal to or better than 20/40 level post-operatively had a mean age of 71.6 years. Age, therefore, is a potential predictor variable for poor visual outcome.

Gender. In this sample there were no significant differences between males and females regarding race, age, ocular comorbidities such as age-related macular degeneration,

glaucoma, high myopia, or diabetes. There were also no significant differences in gender regarding previous eye surgery for same eye, or previous cataract surgery on the fellow eye, operative risks, operative complications, or post-operative complications. There were no differences in the two groups in terms of nuclear sclerosis or average amount of phacoemulsification power used. There were no significant differences between males and females for visual outcome groups.

Racial or Ethnic Associations. In regards to race, no significant association was found between race and group of improvement. Chi-square analysis indicated a significant association between diabetes and minority race with an odds ratio of 4.7 ( $p < .01$ ) as shown in Table 4.5. There was a significant association with being caucasian, not Hispanic and having previous surgery on the eye receiving cataract extraction ( $p < .05$ ) shown in Appendix G, Table G.7. A description of pre-existing variables that were not significantly associated with visual outcomes is found in Appendix G.

### **Pre-existing Variables Associated with Outcome**

#### Age-related Macular Degeneration (AMD)

The literature has noted that there is an association between severe AMD and poor visual acuity after cataract surgery, i.e. poor outcome (Pollack, et al., 1996; Schein, et al., 1995). To have good visual acuity, the retina must be healthy. The macula is the central part of the retina. Good central vision is dependent upon a healthy macula. If the macula has degenerated, good vision is not possible. Conversely just because there is some AMD present, does not consistently predict bad visual outcome and cataract surgery can improve the visual acuity.

Twenty-five ophthalmological medical records noted the presence of AMD prior to surgery. If AMD was not noted in the medical record, then an assumption was made, by

the author that due to the expertise of the ophthalmologist, the answer would be false. Of the 25 cases of AMD, 9 (36%) were male eyes, 16 (64%) were female eyes, 6 (24%) were minority eyes, and 19 (76%) were caucasian eyes. One record was missing the portion of the record that would indicate information on this condition. In this data set, chi-square analysis found there was not a significant association between AMD and gender or AMD and race.

The mean age for the 114 individuals who did not have AMD was 72 years. The mean age for the 25 individuals with AMD was 80 years. A t - test for independent samples results shown in Table 4.3 indicates the differences in means to be significant at ( $p < .001$ ).

**Table 4.3: T- test for Independent Samples for the Mean Age of Individuals with AMD Compared to Individuals without AMD**

<b>Variable</b>	<b>No. of Cases</b>	<b>Mean</b>	<b>SD</b>	<b>SE of Mean</b>
AMD - False	114	72.11	11.217	1.051
AMD - True	25	80.88	6.591	1.318
<b>t-value</b>	<b>DF</b>	<b>2-Tail Sig.</b>	<b>SE of Diff</b>	<b>95% CI</b>
-3.76	137	<.001	2.331	(-13.375,-4.157)

$H_{02}$ : AMD is not associated with achieving the 20/40 or better level.

$$H_{02}: \chi^2_1 \leq \chi^2_2; \quad H_{2A}: \chi^2_1 > \chi^2_2$$

**Table 4.4: Chi-Square Results for AMD and Group of Improvement**

	< 20/40	>= 20/40	Totals
<b>AMD-True</b>	13 ( 9%)	12 ( 9%)	<b>25 (18%)</b>
<b>AMD-False</b>	22 (16%)	92 (66%)	<b>114 (82%)</b>
<b>Totals</b>	<b>35 (25%)</b>	<b>104 (75%)</b>	<b>135 (100%)</b>

<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	11.63859	1	<.001

$$\chi^2 = 11.64 > \chi^2_{.999,1} = 10.83$$

Table 4.4 shows the null hypothesis is rejected. In this sample, AMD is significantly associated with group of improvement at ( $p < .001$ ) and is a potential predictor variable for visual outcomes.

### Diabetes

The presence of diabetes was noted to be true for 23 individuals. Again the answer was determined by what was present in the medical record. If diabetes was not noted in the medical record, an assumption was made the answer was false. It is possible this was not always a valid assumption, since diabetes can go undetected. Three records were missing the portion of the medical record that included this information.

Another limitation in the data collection was there was no indication regarding when the diabetes had been diagnosed (and therefore no approximation regarding how long the individual may have had the condition). The literature states there is a positive relationship

between length of time the patient has had diabetes and severity of damage, particularly if blood sugar levels are not maintained at an optimal level (Berson, 1993). In this data set there were no clear indicators regarding the severity of damage the diabetes may have caused. It is recommend in the future that additional variables regarding the presence of diabetic retinopathy and its degree of severity be collected on the medical record abstraction form.

The medical records noted 11 men and 12 women to be diabetic. There was not a significant association between gender and diabetes. There were 13 (57%) caucasian and 10 (43%) minority individuals identified as diabetic. Table 4.5 shows a significant association at ( $p < .01$ ) with a higher proportion of minority individuals 10/26 (39%) compared to caucasian, not Hispanic 13/111 (12%) noted to be diabetic.

$H_{03}$ : Diabetes is not associated with race.

$$H_{03}: \chi^2_3 \leq \chi^2_4 ; H_{3A}: \chi^2_3 > \chi^2_4$$

**Table 4.5: Chi-Square Results for Diabetes and Race**

<b>Race</b>	<b>Diabetes-True</b>	<b>Diabetes-False</b>	<b>Totals</b>
<b>Minority</b>	10 (7%)	16 (12%)	<b>26 (19%)</b>
<b>Caucasian</b>	13 (10%)	98 (71%)	<b>111 (81%)</b>
<b>Totals</b>	<b>23 (17%)</b>	<b>114 (83%)</b>	<b>137 (100%)</b>

<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	10.79	1	<.01

$$\chi^2 = 10.79 > \chi^2_{.99,1} = 6.63$$

The Texas Department of Health (TDH) noted that within Texas there is a higher prevalence of diabetes in minority population groups. Diabetes has been diagnosed in 11.4% African Americans and 9.3% of Hispanics as compared to 5.8% of “Anglos”

(1997). It is estimated that 865,347 (6.5%) Texas adults, 18 years of age or older have been diagnosed with diabetes. Another 6.5% are estimated to have undiagnosed diabetes, which would make the population percentage equal to 13% of adult Texans having diabetes (1997). In this sample, 23 (16%) of the individuals were diagnosed with diabetes, indicating a higher prevalence in this sample compared to the general Texas population.

Noting the presence of diabetes is important because of the potential for development of diabetic retinopathy. Like AMD, severe diabetic retinopathy causes damage to the retina and would prevent good post-operative visual outcome, no matter how successful the cataract surgery. In Texas "it is estimated that as many as 915 to 1,830 Texans will go blind this year as a result of diabetic retinopathy" (TDH, 1997, p. 8). Using chi-square analyses, diabetes was not found to be significant with the group of improvement or with achieving the 20/40 or better level.

Texas Department of Health annually conducts a survey for the Texas Behavioral Risk Factor Surveillance System. In 1995, the percentage of respondents who answered "yes" to the question "Have you ever been told by a doctor that you have diabetes or sugar diabetes?", broke out in the following age distribution: 18-24 years (1.7%); 25-34 years (3.1%); 35-44 years (5.6%); 45-54 years (6.3%); 55-64 years (17.3%); and 65 years and older (10.9%) (TDH, 1997, p. 9). This indicates that, in Texas, diabetes is more prevalent in people older than 54 years. Using t-tests for independent measures, this sample, however, did not show a significant difference in age between those individuals reported to have diabetes and those individuals who did not have diabetes.

### Nuclear Sclerosis

The last pre-existing variable to consider is nuclear sclerosis. As a person ages, the lens in their eyes become harder. Ophthalmologists classify nuclear sclerosis as none (coded 0), trace (coded 0.5), 1+ (coded as 1), 2+ (coded as 2), 3+ (coded as 3), 4+ (coded

as 4), and early brunescence or extremely hard (coded as 5). The literature states that the nuclear sclerosis is graded based on color (Gullapalli, et. al, 1995). Because the nuclear sclerosis is classified based on human judgement, rather than an objective quantitative measurement, the variable is a categorical variable rather than a continuous variable.

**H<sub>04</sub>**: The mean age for each nuclear sclerosis group (0,1,2,3,4,5) is not significantly different.

$$H_{04}: \mu_0 = \mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5 ; H_{4A}: \text{not all } \mu_j \text{ are equal where } j = 1, 2, 3$$

(Berenson, et. al, 1983)

Where  $\mu_0$  = mean age of individuals associated with trace nuclear sclerosis (coded 0).

$\mu_1$  = mean age of individuals associated with 1+ nuclear sclerosis (coded 1).

$\mu_2$  = mean age of individuals associated with 2+ nuclear sclerosis (coded 2).

$\mu_3$  = mean age of individuals associated with 3+ nuclear sclerosis (coded 3).

$\mu_4$  = mean age of individuals associated with 4+ nuclear sclerosis (coded 4).

$\mu_5$  = mean age of individuals associated with 5+ nuclear sclerosis (coded 5).

One-way analysis of variance of this sample shown in Table 4.6 did not show significant differences in mean age between age and degree of nuclear sclerosis ( $p < .06$ ).

**Table 4.6: One-way ANOVA for Mean Age by Nuclear Sclerosis**

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F prob.
Between Groups	5	1286.48	257.30	2.15	0.06
Within Groups	130	15539.52	119.54		
Total	135	16826.00			

These results, however, did not make sense to the author because as a person ages, the lens of the eye becomes harder. Using the one-way analysis of variance with least squares differences, a less conservative test, showed the following results in Table 4.7.

**Table 4.7: Analysis of Variance with Least Squares Differences (LSD) Test Results for Age and Degree of Nuclear Sclerosis**

No. Cases	Mean	Nuclear Sclerosis	Grp 3	Grp 1	Grp 2	Grp 0	Grp 4	Grp 5
61	71.4263	Group 3						
14	71.7857	Group 1						
27	73.7037	Group 2						
11	74.1818	Group 0						
18	78.1111	Group 4	*					
5	84.4000	Group 5	*	*	*	*		

Least Squares Differences (LSD) test with significance level .05 Matrices

(\*) Indicates significant differences.

Table 4.7 indicates that individuals with nuclear sclerosis of 4+ degrees should be grouped with individuals of 5+ degrees because there is no significant difference in means between these two groups. Individuals with 0 to 3+ degrees of nuclear sclerosis should be grouped together because there is no significant difference in means between those four groups.

This would indicate a dividing point to be at approximately 76 years. So prior to 76 years, an individual will probably have 3+ degrees or less of nuclear sclerosis. After 76 years, an individual will probably have 4+ or greater degree of nuclear sclerosis. The Schein, et. al. study (1995) found a preoperative age of 75 years of age or older to have an odds ratio of 3.57 of having an increased likelihood of not improving on one or more of the outcome measures (including visual acuity) that were used in that study.



A chi-square analysis indicated there was a significant association ( $p < .05$ ) between nuclear sclerosis (recoded) and if an individual achieved the 20/40 or better level. Results are shown in Table 4.8.

$H_{05}$ : Nuclear sclerosis (recoded) is not associated with  $\geq 20/40$  post-operative visual acuity level.

$$H_{05}: \chi^2_5 \leq \chi^2_6 ; H_{5A}: \chi^2_5 > \chi^2_6$$

**Table 4.8: Chi-Square Results for Nuclear Sclerosis (Recoded) and < 20/40 Compared with  $\geq 20/40$  Post-operative Visual Acuity Level**

NSRC	< 20/40	> = 20/40	Totals
Levels 0 - 3+	23 (17%)	90 (66%)	113 (83%)
Levels 4+ - 5+	10 ( 7%)	13 (10%)	23 (17%)
Totals	33 (24%)	103 (76%)	137 (100%)

Chi-Square	Value	DF	Significance
Pearson	5.56	1	<.05

$$\chi^2 = 5.56 > \chi^2_{.95,1} = 3.84$$

### Surgery Related Variables

Surgery related variables would include nuclear sclerosis, average phacoemulsification power, and operative complications. The ophthalmologist had an interest in examining the relationship between the average amount of phacoemulsification power used and nuclear sclerosis (degree of hardness of the lens).

### Nuclear Sclerosis and Average Phacoemulsification Power

**H<sub>06</sub>**: The mean average phacoemulsification power for each nuclear sclerosis group (0,1,2,3,4,5) is not significantly different.

$$H_{06}: \mu_0 = \mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5; \quad H_{6A}: \text{not all } \mu_j \text{ are equal where } j = 1, 2, 3$$

(Berenson, et. al, 1983)

Where  $\mu_0$  = mean average phacoemulsification power associated with trace

nuclear sclerosis (coded 0).

$\mu_1$  = mean average phacoemulsification power associated with 1+ nuclear sclerosis (coded 1).

$\mu_2$  = mean average phacoemulsification power associated with 2+ nuclear sclerosis (coded 2).

$\mu_3$  = mean average phacoemulsification power associated with 3+ nuclear sclerosis (coded 3).

$\mu_4$  = mean average phacoemulsification power associated with 4+ nuclear sclerosis (coded 4).

$\mu_5$  = mean average phacoemulsification power associated with 5+ nuclear sclerosis (coded 5).

ANOVA results in Table 4.9 determined that there is a significant difference in the mean average amount of phacoemulsification power needed at different degrees of nuclear sclerosis ( $p < .001$ ). The null hypothesis is rejected.

**Table 4.9: Analysis of Variance for Average Phacoemulsification Power and Nuclear Sclerosis**

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig of F
Average Power	78.104	1	15.621	20.11	<.001
Residual	97.096	125	0.777		
Total	175.200	130	1.348		

Looking at the least squares differences test, the following was found:

**Table 4.10: Analysis of Variance with Least Squares Differences Test for Average Phacoemulsification Power and Degree of Nuclear Sclerosis**

Source of Variation	DF	Sum of Squares	Mean Square	F	Sig of F
Between Groups	5	78.1041	15.6208	20.11	<.001
Within Groups	125	97.0962	0.7768		
Total	130	175.2002			

Group	Count	Mean	SD	SE	95% CI
Group 0	11	0.2264	0.1281	0.0386	0.1403, 0.3124
Group 1	14	0.2879	0.2627	0.0702	0.1362, 0.4395
Group 2	23	0.3774	0.2373	0.0495	0.2748, 0.4800
Group 3	60	0.7950	0.7766	0.1003	0.5944, 0.9956
Group 4	18	2.3100	1.6345	0.3852	1.4972, 3.1228
Group 5	5	3.1440	1.8573	0.8306	0.8379, 5.4501
Total	131	0.9176	1.1609	0.1014	0.7169, 1.1182

**Table 4.11 Least Squares Differences (LSD) test for Phacoemulsification Power**

Mean	Nuclear Sclerosis	Grp 0	Grp 1	Grp 2	Grp 3	Grp 4	Grp 5
0.2264	Group 0						
0.2879	Group 1						
0.3774	Group 2						
0.7950	Group 3						
2.3100	Group 4	*	*	*	*		
3.1440	Group 5	*	*	*	*		

(\*) Indicates significant differences.

Tables 4.10 and 4.11 indicate that individuals with nuclear sclerosis of 4+ degrees should be grouped with individuals of 5+ degrees because there is no significant difference in means of average phacoemulsification power used between these two groups. Individuals with 0 to 3+ degrees of nuclear sclerosis should be grouped together because there is no significant difference in means for average phacoemulsification power used between those four groups.

#### Nuclear Sclerosis and Operative Complications

Nuclear sclerosis, as described above is the degree of hardness of the cataractous lens. Operative complications are those complications that occur during the cataract surgery. On the data collection form they are listed as vitreous loss, post capsular rupture, increased intraocular pressure, corneal problems, lens dislocation, anesthetic problems, bleeding, and "other". There were only 10 cases involving operative complications. Because the cell sizes were so small, operative complications data were recoded as true = "1" and false = "0".

**H<sub>07</sub>:** The degree of nuclear sclerosis is not associated with operative complications.

$$H_{07}: \chi^2_{13} \leq \chi^2_{14}; \quad H_{7A}: \chi^2_{13} > \chi^2_{14}$$

Table 4.12 shows that the null hypothesis is rejected. Operative complications by degree of nuclear sclerosis (recoded as 0 for nuclear sclerosis of 0 to 3+ degrees, and 1 for nuclear sclerosis 4+ to 5+ degrees) showed a significant association at ( $p < .01$ ).

**Table 4.12: Chi-Square Results for Operative Complications and Degree of Nuclear Sclerosis (Recoded)**

Operative Complications			
Nuclear Sclerosis	True	False	Totals
4+ to 5+ = 1	5 (4%)	18 (13%)	23 (17%)
0 to 3+ = 0	5 (4%)	106 (79%)	111 (83%)
Totals	10 (8%)	124 (92%)	134 (100%)
Chi-Square	Value	DF	Significance
Pearson	8.194	1	<.01

$$\chi^2 = 8.19 > \chi^2_{.99,1} = 6.63$$

#### Phacoemulsification Power and Operative Complications

**H<sub>08</sub>:** The mean amount of average phacoemulsification power required to pulverize the lens is not significantly different for those individuals who have operative complications, compared to those individuals who do not have operative complications.

$$H_{08}: \mu_1 = \mu_2; \quad H_{8A}: \mu_1 \neq \mu_2$$

A one-way analysis of variance was conducted with average phacoemulsification power (dependent variable) and operative complications (factor). Results are in Table 4.13 indicate that the null hypothesis can be rejected. There is a significant difference in mean

average amount of phacoemulsification power at ( $p < .05$ ) level between those individuals who have operative complications (mean was 1.72) compared to those individuals who do not have operative complications (mean was 0.8577). Therefore these variables will be included in the final model.

**Table 4.13: One-way ANOVA and Means Test of Average Phacoemulsification Power and Operative Complications**

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig of F
Between Groups	6.3614	1	6.3614	4.8604	<.05
Within Groups	168.8388	129	1.3088		
Total	175.2002	130			

Operative Complications	Count	Mean	SD	SE	95% CI
False	122	0.8577	1.1029	0.0998	0.6600, 1.0554
True	9	1.7289	1.6457	0.5486	0.4639, 2.9939
Total	131	0.9176	1.1609	0.1014	0.7169, 1.1182

Using the chi-square test no association was found between operative complications and achieving the 20/40 or better level, or average phacoemulsification power and achieving the 20/40 level or better. Therefore these variables will not be included in the final logistic regression model.

### **Post-Operative Related Variables**

Post-operative variables would include post-operative complications, looking at the differences in age and post-operative complications, associations between operative complications and post-operative complications. And finally looking at the variables and their association with group of improvement. Post-operative complications are those

complications that occur after the cataract surgery. On the data collection form they are listed as retinal detachment, cystoid macula edema, corneal edema, and “other”. There were only 15 cases involving post-operative complications. Because the cell sizes were so small, post-operative complications data were recoded as true = “1” and false = “0”.

#### Age and Post-operative Complications

One-way analysis of variance determined that there was not a significant difference in age between those who had post-operative complications and those who did not have post-operative complications.

The author had hypothesized that there would be a significant association between diabetics and post-operative complications and a positive relationship between diabetics and number of post-operative visits indicating infection. A chi-square analysis of this sample with the variables diabetics and post-operative complications, however, did not find any significant association. A logistic regression of this sample did not find any significant relationship between diabetics and number of post-operative visits indicating infection.

#### Nuclear Sclerosis and Post-operative Complications

**H<sub>09</sub>:** The degree of nuclear sclerosis is not associated with post-operative complications.

$$H_{09}: \chi^2_{15} \leq \chi^2_{16} ; \quad H_{9A}: \chi^2_{15} > \chi^2_{16}$$

The Chi-square for post-operative complications and nuclear sclerosis showed a significant association at (p <.05). Results are shown in Table 4.14.

**Table 4.14: Chi-Square Results for Post-Operative Complications and Degree of Nuclear Sclerosis**

<b>Post-Operative Complications</b>			
<b>Nuclear Sclerosis</b>	<b>True</b>	<b>False</b>	<b>Totals</b>
5+	3	2	5
4+	3	15	18
3+	5	56	61
2+	2	24	26
1+	1	13	14
0 to trace (0.5)		11	11
Totals	14	121	135
<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	15.9577	6	<.05

$$\chi^2 = 15.96 > \chi^2_{.95,6} = 12.59$$

#### Phacoemulsification Power and Post-operative Complications

**H<sub>010</sub>:** The mean amount of average phacoemulsification power required to pulverize the lens is not significantly different for those individuals who have post-operative complications, compared to those individuals who do not have post-operative complications.

$$H_{010}: \mu_1 = \mu_2; \quad H_{10A}: \mu_1 \neq \mu_2$$

A one-way analysis of variance was conducted with average phacoemulsification power (dependent variable) and post-operative complications (factor). Results in Table 4.15 indicate that the null hypothesis can be rejected. There is a significant difference in mean average amount of phacoemulsification power at (p < .01) level between those individuals who have post-operative complications (mean was 1.67) compared to those



individuals who do not have post-operative complications (mean was 0.83). Therefore these variables will be included in the final model.

**Table 4.15: Analysis of Variance and Means Test of Average Phacoemulsification Power and Post-Operative Complications**

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig of F
Between Groups	8.9424	1	8.9424	6.9384	<.01
Within Groups	166.2579	129	1.2888		
Total	175.2002	130			

Post-Operative Complications	Count	Mean	SD	SE	95% CI
False	117	0.8272	1.0580	0.0978	0.6335, 1.0209
True	14	1.6729	1.6738	0.4473	0.7064, 2.6393
Total	131	0.9176	1.1609	0.1014	0.7169, 1.1182

Table 4.15 shows there was a significant difference at ( $p < .01$ ) in mean average phacoemulsification power between those who had post-operative complications (mean was 1.67) and those who did not have post-operative complications (mean was 0.83).

This sample did not show a significant association between operative risk factors and operative complications. It did not show a significant association between operative risk factors and post-operative complications. Operative complications did not show a significant association with post-operative complications.

### Post-operative Complications and Group of Improvement

$H_{011}$ : Post-operative complications is not associated with achieving the 20/40 or better level.

$$H_{011}: \chi^2_{17} \leq \chi^2_{18}; \quad H_{11A}: \chi^2_{17} > \chi^2_{18}$$

Post-operative complications by 20/40 level or better showed a significant association ( $p < .001$ ).

**Table 4.16: Chi-Square Results for 20/40 Level or Better and Post-Operative Complications**

Post-Operative Complications			
Group of Improvement	True	False	Total
$\geq 20/40$	6 ( 4%)	99 (71%)	105 ( 75%)
$< 20/40$	25 (18%)	9 ( 7%)	34 ( 25%)
Totals	31 (22%)	108 (78%)	139 (100%)
Chi-Square	Value	DF	Significance
Pearson	11.49397	1	<.001

$$\chi^2 = 11.49 > \chi^2_{.999,1} = 10.83$$

Table 4.16 shows that of the 139 medical records that had enough information to classify by achievement level, 31 (22%) individuals had post-operative complications and 108 (78%) individuals did not. Thirty-four individuals (25%) did not achieve the 20/40 visual acuity level post-operatively. Of those 34 individuals, 25 (18%) also had post-operative complications. Ninety-nine (71%) of the individuals who achieved the 20/40 or better post-operative visual acuity level did not have any post-operative complications.

### Potential Predictor Variables

Upon completing the above analyses, it appeared that the potential predictor variables would include achievement group, age at time of surgery, AMD, average amount of phacoemulsification power, degree of nuclear sclerosis, operative complications, and post-operative complications.

### **Confounding and Interactions of Variables**

Before determining the potential predictor variables to enter into the logistic regression model, the effect of confounding or interaction between variables needed to be explored. The following question was developed:

1. What effect does variable *a* have on the condition of variable *b* when the outcome is less than 20/40 versus better than or equal to 20/40? (The less than 20/40 group coded as 0, the better than or equal to 20/40 group coded as 1.)

### Age as Effect Modifier on AMD

What effect does age have on the condition of AMD when the outcome is < 20/40 versus  $\geq$  20/40?

**Table 4.17: Effect of Age on AMD comparing < 20/40 to  $\geq$  20/40 for Individuals  $\leq$  75 years**

	<20/40	$\geq$ 20/40	Calculations	Odds Ratio	95% CI
AMD- True	1	4	$1 \times 56 = 56$	<b>2.00</b>	(0.20,20.47)
AMD- False	7	56	$4 \times 7 = 28$		
* Not significant					

**Table 4.18: Effect of Age on AMD comparing < 20/40 to >= 20/40 for Individuals >= 76 years**

	<20/40	>= 20/40	Calculations	Odds Ratio	95% CI
AMD- True	12	8	12 x 36 = 432	<b>3.6</b>	(1.22,10.58)
AMD- False	15	36	15 x 8 = 120		
Pearson $\chi^2 = 5.70$ (p < .05)					

**Table 4.19: Effect of Age on AMD Crude Odds Ratio**

	<20/40	>= 20/40	Calculations	Crude Odds Ratio	95% CI
AMD- True	13	12	13 x 92 = 1196	<b>4.53</b>	(2.96,6.92)
AMD- False	22	92	22 x 12 = 264		
Pearson $\chi^2 = 11.64$ (p < .001)					

**Table 4.20: Effect of Age on AMD Mantel-Haenszel Adjusted Summary OR**

$\frac{(1 \times 56)/68 + (12 \times 36)/71}{(4 \times 7)/68 + (8 \times 15)/71} = \frac{0.82 + 6.08}{0.41 + 1.69} = \frac{6.9}{2.1} = 3.29 \quad (95\% \text{ CI} = 1.34, 8.05)$ <p style="text-align: right;"><b>OR = 3.29</b></p>					
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(Kelsey, p. 223-226)

Because the odds ratios for the stratum are different (Table 4.17, OR = 2.00; Table 4.18, OR = 3.6) and the crude odds ratio (Table 4.19, OR = 4.53) falls outside the two age stratum, this indicates that age is both a confounder and an effect modifier (i.e. interaction) for the condition of AMD when comparing the group that achieved 20/40 or better vision to the group that did not achieve this (Kleinbaum, Kupper, and Morgenstern, p. 246-247).

#### Age as Effect Modifier on Nuclear Sclerosis

What effect does age have on the degree of nuclear sclerosis when the outcome is < 20/40 versus >= 20/40? Because of empty cells, this question could not be evaluated.

### Nuclear Sclerosis, Phacoemulsification Power and Operative Complications

Because there was a highly significant association between nuclear sclerosis and average phacoemulsification power ( $p < .00001$ ), the author investigated the following question:

What effect does nuclear sclerosis have on the average amount of required phacoemulsification power on the outcome of operative complications?

Nuclear sclerosis was coded as 0 for 0 to 3+ degrees and coded as 1 for 4+ to 5+ degrees. Average amount of phacoemulsification power was coded as 0 for power  $< 1.50$  and coded as 1 for power greater than or equal to 1.50. Operative complications were coded as 0 for false and coded as 1 for true.

**Table 4.21: Effect of Nuclear Sclerosis on Average Phacoemulsification Power and Operative Complications for Nuclear Sclerosis  $< 4+$  degrees**

	<b>Operative Complica- tions True</b>	<b>Operative Complica- tions False</b>	<b>Calculations</b>	<b>Odds Ratio</b>	<b>95% CI</b>
Average Phaco Power $\geq 1.50$	2	5	$2 \times 99 = 198$	<b>19.8</b>	(0.83,171 )
Average Phaco Power $< 1.50$	2	99	$5 \times 2 = 10$		
Pearson $\chi^2 = 2.8$ ( $p < .09$ ) * Not significant					

**Table 4.22: Effect of Nuclear Sclerosis on Average Phacoemulsification Power and Operative Complications for Nuclear Sclerosis 4+ to 5+ degrees**

	Operative Complications True	Operative Complications False	Calculations	Odds Ratio	95% CI
Average Phaco Power $\geq 1.50$	2	12	$2 \times 6 = 12$	<b>0.33</b>	(0.04,2.53 )
Average Phaco Power $< 1.50$	3	6	$3 \times 12 = 36$		
Pearson $\chi^2 = 2.8$ (p < .09) * Not significant					

**Table 4.23: Crude Odds Ratio for Effect of Nuclear Sclerosis on Average Phacoemulsification Power and Operative Complications**

	Operative Complications True	Operative Complications False	Calculations	Odds Ratio	95% CI
Average Phaco Power $\geq 1.50$	4	17	$4 \times 105 = 420$	<b>4.94</b>	(1.21,20.23)
Average Phaco Power $< 1.50$	5	105	$5 \times 17 = 85$		
Pearson $\chi^2 = 2.8$ (p < .09) * Not significant					

**Table 4.24: Effect of Nuclear Sclerosis on Average Phacoemulsification Power and Operative Complications Mantel-Haenszel Adjusted Summary OR**

$\frac{(2 \times 99)/108 + (2 \times 6)/23}{(5 \times 2)/108 + (3 \times 12)/23} = \frac{1.83 + .52}{0.09 + 1.56} = \frac{2.35}{1.65} = 1.42 \text{ (95\% CI = 0.36,5.64)}$ <p style="text-align: right;"><b>OR = 1.42</b></p>
--

(Kelsey, p. 223-226)

Because the odds ratios for the stratum are different (Table 4.21, OR = 19.8; Table 4.22, OR = 0.33), this indicates there is an interaction and nuclear sclerosis is an effect modifier on the average amount of phacoemulsification power required as related to operative

complications. The crude odds ratio (Table 4.23, OR = 4.94) and adjusted odds ratio (Table 4.24, OR = 1.42) fall between the two age stratum and they are not equal. This indicates confounding is occurring (Kleinbaum, Kupper, and Morgenstern, p. 246-247).

The author suspected an effect modification was occurring between degree of nuclear sclerosis, the average amount of phacoemulsification power required, and post-operative complications. The calculations, however, could not be completed due to empty cells.

#### New Variables Created

In order to account for the interactions, new variables were created for the model. Age was multiplied by AMD. Nuclear sclerosis was multiplied by the average phacoemulsification power.

#### Multicollinearity

Correlation coefficients were analyzed for multicollinearity on the following variables: age at surgery, the interaction of age with AMD, AMD, average phacoemulsification power, nuclear sclerosis recoded, operative complications, post-operative complications, the interaction of nuclear sclerosis with average phacoemulsification power. The correlation coefficients indicated that only age interacting with AMD, nuclear sclerosis interacting with average phacoemulsification, operative complications, and post-operative complications should be entered into the logistic regression model.

#### **Use of Logistic Regression to Determine Best Predictor Variables**

The next step was to utilize logistic regression to answer the research question “What are the predictor variables for those persons who achieve 20/40 or better vision

compared to those individuals who do not achieve the 20/40 standard?” The following variables were initially placed in the logistic regression model: age multiplied by AMD, nuclear sclerosis multiplied by average phacoemulsification power, operative complications, and post-operative complications. These variables are listed in Table 4.25.

**Table 4.25 Variables Entered in Initial Logistic Regression Model for  
< 20/40 Compared with > = 20/40**

Variables		Dichotomous Variables
AGE by AMD	Continuous (If AMD = 0, then variable = 0; If AMD = 1, then variable = AGE)	0 = False 1 = True
NS by AVGPWR	Continuous	
OPCOMPRC	Dichotomous 0,1	
POCMPRC	Dichotomous 0,1	

The author used the following statistical package: SPSS Graduate Pack Advanced Version Power Mac v6.1.1 to analyze these data. Because logistic regression is not a linear model, an iterative process is used to estimate the parameter.

Using the conditional backward stepwise method, the overall fit at this initial point was a 77.10% a “Goodness of Fit” with the -2 Log Likelihood at 140.9755. On the second step after four iterations, operative complications was removed from the model leaving the variables listed in Table 4.26. These variables had a 77.10% overall fit with a “Goodness of Fit” at 125.352, the -2 Log Likelihood at 121.190 and the Model  $\chi^2 = 19.786$  at  $p < .001$ .



**Table 4.26 Variables in Final Logistic Regression Model for < 20/40  
Compared with >= 20/40**

Variable	B	S.E.	p-value	Wald	DF	R	Exp (B)
AGE by AMD	-0.0197	0.0065	.0023	9.2813	1	-0.2273	0.9805
NS by APP	-0.0735	0.0422	.0814	3.0363	1	-0.0857	0.9291
POCOMPRC	1.3933	0.6510	.0323	4.5814	1	0.1353	4.0282
Constant	0.6422	0.6679	.3363	0.9246	1		

When answering the question “Who is likely to achieve the visual acuity of 20/40 or better as compared to the group that not achieve the 20/40 or better?”, one can apply the following equation:

$$P_i = \frac{1}{1 + e^{-L_i}}$$

$$L_i = 0.6422 - .0197 (\text{AGE by AMD}) - .0735 (\text{NS by APP}) + 1.3933 (\text{POCOMPRC})$$

(Hamilton, 1992, p. 223)

This equation indicates that individuals with post-operative complications, the interaction of age with AMD, and the interaction of nuclear sclerosis with average phacoemulsification power (or some combination of these situations/conditions) are at increased risk for not achieving 20/40 or better visual acuity with cataract surgery. Table 4.27 shows examples of the formula.

**Table 4.27 Examples of Individual Probabilities for < 20/40 or >= 20/40  
Visual Acuity in Given Situations**

Age x AMD	NS x Average Phacoemulsification Power	Post- operative Comp.	$L_i$ Equation Value	Probabilities < 20/40 $e^{-L_i}$	>=20/40 $e^{L_i}$
70 x 0	3 x .82	F = 0	0.4614	61%	39%
70 x 0	3 x 1.62	T = 1	1.6783	84%	16%
70 x 1	4 x .82	F = 0	-0.978	27%	73%
70 x 1	4 x 1.62	T = 1	0.1802	55%	45%
75 x 0	3 x .82	F = 0	0.4614	61%	39%
75 x 0	3 x 1.62	T = 1	1.6783	84%	16%
75 x 1	4 x .82	F = 0	-1.076	25%	75%
75 x 1	4 x 1.62	T = 1	0.0817	52%	48%
80 x 0	3 x .82	F = 0	0.4614	61%	39%
80 x 0	3 x 1.62	T = 1	1.6783	84%	16%
80 x 1	4 x .82	F = 0	-1.175	24%	76%
80 x 1	4 x 1.62	T = 1	-0.017	50%	50%
85 x 0	4 x .82	F = 0	0.4011	60%	40%
85 x 0	4 x 1.62	T = 1	1.5592	83%	17%
85 x 1	5 x .82	F = 0	-1.334	21%	79%
85 x 1	5 x 1.62	T = 1	-0.234	44%	56%

This model may be able to partially predict cataract surgery outcomes, but it does not fully predict the outcomes. With a larger sample of data the question “What are the predictor variables for determining who gets worse compared to who has any improvement?” could be explored. For the question “What are the predictor variables for those persons who achieve 20/40 or better vision compared to those individuals who do not achieve the 20/40 standard?”, there was a 77% fit. More research must be done to determine additional predictor variables that better determine cataract surgery outcomes.

## **CHAPTER 5**

### **DISCUSSION AND CONCLUSION**

#### **What Does This Study Mean?**

This study showed that within this small sample of cataract patients in San Marcos, Texas there is a significant increased prevalence of diabetes and ocular comorbidities among minority individuals. Individuals with AMD tended to be significantly older than individuals in the remainder of the sample with a mean age of 80.88 years. Individuals with high myopia tended to be significantly younger with a mean age of 62.36 years.

Group of improvement was broken into three groups. Three eyes showed worse results from pre-operative best corrected glare visual acuity to post-operative best corrected visual acuity. Thirty-two eyes showed some improvement and one hundred five eyes obtained better than or equal to 20/40 (0.500) visual acuity. In answer to the question, “What are the predictor variables for those persons most likely to achieve 20/40 or better vision compared to those individuals who are not most likely to achieve the 20/40 standard?”, found an interaction of age with AMD, an interaction of nuclear sclerosis with average phacoemulsification power, and post-operative complications were the best predictors of 20/40 or better level for post-operative visual acuity outcome.

This study also showed a significant association between nuclear sclerosis (lens hardness) and the amount of average phacoemulsification power. It also showed a

significant association with nuclear sclerosis and operative complications. There was also a significant association between average phacoemulsification power and operative complications. Nuclear sclerosis and average phacoemulsification also showed a significant association with post-operative complications.

### **Suggestions for Further Investigation**

Additional study should occur to better define the variables that predict cataract surgery visual acuity outcomes. Future studies should include additional variables such as date of diagnosis for diabetes. The length of time from diagnosis of diabetes to the date of cataract surgery would indicate an approximation of the duration of time for that individual to have that health condition. This would only be a surrogate measure, though, because individuals often have diabetes without knowing they have diabetes. In the meantime their blood sugar levels are uncontrolled and damage is occurring to their internal organs. There also needs to be a true/false variable to indicate the presence of diabetic retinopathy and a numerical variable to indicate the degree of severity of damage to the retina from the diabetic retinopathy. For age-related macular degeneration (AMD), there needs to be a numerical variable to indicate some measure of the severity of damage to the retina. Additional variables need to be defined for smoking, hypertension, and retinal damage to better describe and quantify the associations and relationships between these factors. For smoking, data should be collected on the number of years the individual smoked; the average number of packs per day, and the degree of severity of damage to the retina due to poor circulation.

These kind of data are not typically collected by ophthalmologists. Data regarding the severity of damage to the retina are only obtainable through the use of special ophthalmological instruments utilized by retinal specialists. Retinal specialists are ophthalmologists who have had more specialized training and have more specialized equipment. Obtaining accurate measurements of the retina can be inhibited by the density

of the cataractous lens. Often an accurate assessment of retinal damage can only be obtained after a cataract surgery and intraocular lens implantation occurs, because there is then a clear lens through which to view the retina. Utilizing retinal specialists cost more in health care dollars and resources. It is a challenge obtaining enough information to decide if and when to have cataract surgery balanced with having cataract surgery in the attempt to improve vision only to find out that vision is not able to be improved due to retinal damage, which could not be viewed prior to cataract surgery. Health outcomes analysis can assist in this complex decision making process.

In summary, this study has shown that within this sample visual acuity outcomes are associated with an interaction of age with AMD, an interaction of nuclear sclerosis with average phacoemulsification power, and post-operative complications.

## **APPENDIX A - Diagram of Research Problem**

(Continues on following page)

## DIAGRAM OF RESEARCH PROBLEM

1	2	3	4
Pre-existing Variables	Intervention - Surgery Surgical Variables	Surgical Outcome Post-Operative Complications	Visual Outcome Group of Improvement
<u>Demographic:</u> - Age - Race - Sex <u>Physiological:</u> - Age - Nuclear Sclerosis - Diabetes <u>Ocular Comorbidity:</u> - AMD - Diabetic Retinopathy (in literature) - Glaucoma	Average Phacoemulsification Power (Continuous)  Operative Complications (True/False)	Post-operative Complications (True/False)	Group of Improvement First Coded: - Worse = 0 - Some = 1 - Best = 2  To use logistic regression and answer outcome questions, recoded to 0 and 1.

### Questions to be asked:

#### Part 1 - Pre-existing Variables

1. What is the association between each of these variables and visual outcome (group of improvement)?
2. Are there any significant differences within these variables?
3. Is there any interaction or confounding between these variables?

#### Part 2 - Surgical Variables

1. What is the association between each of these variables and visual outcome (group of improvement)?
2. Is there any interaction or confounding between these variables?
3. Is there any interaction or confounding between these variables and the variables in Part 1?
4. What is the relationship between average phacoemulsification power and nuclear sclerosis?

#### Part 3 - Post-operative Complications

1. What is the association between post-operative complications and visual outcome (group of improvement)?
2. What is the association between variables in Part 1 and post-operative complications?
3. What is the association between variables in Part 2 and post-operative complications?

#### Part 4 - Predictor Variables of Outcome

1. Which variables are most significantly related to predicting visual outcome?

### Statistical Analyses

Chi-square  
ANOVA, Means Tests  
Odds Ratios Evaluation

Chi-square  
Odds Ratios Evaluation  
Odds Ratios Evaluation  
Linear Regression

Chi-square  
Chi-square  
Chi-square

Logistic Regression

## **APPENDIX B - Data Collection Instrument**

(Continues on following 3 pages)



# Cataract Surgery Data Collection Instrument

Note: Bolded fields are computer calculated #1, 4, 11, 20, 37, 38, 39, 45, 69, 74, 78, 83, 87, 92, 96, 101, 105, 110, 114, 119, 123, 147, 155, 156, 157, 158, 159, 160 Rev 01/10/98 Page 1

## Background and Demographic Variables:

\_\_\_\_\_ Y N M F 1. African-American 3. Caucasian  
 ID Code (1) Name (2) Birthdate (3) Age at Surgery(4) Smoker? (5) Sex (6) Race (7) MD Initials (8) \_\_\_\_\_  
 2. Hispanic 4. Other \_\_\_\_\_

## Pre-existing Medical Conditions:

Y N Y N Y N Y N Y N Y N Y N  
 Diabetes (9) Glaucoma (10) High Myopia (11) Hypertension (12) Coumadin Use (13) Macular Degeneration (14) Cataract Surgery on Fellow Eye (15)

Previous Eye Surgery on Operated Eye (16) Y N Kind? (17) \_\_\_\_\_

## Pre-Operative Measurements:

R L EYE? (18) Office Visit Date (19) \_\_\_\_\_ VLA1 (20) \_\_\_\_\_  
 \_\_\_\_\_ + \_\_\_\_\_ x \_\_\_\_\_  
 Axial Length (21) Axial Length Sphere (23) Cylinder (24) Axis (25) Distance VA (26) Near VA (27) VA w/PRX (28) Desired Refraction (29)  
 of Fellow Eye (22)  
 x \_\_\_\_\_ x \_\_\_\_\_  
 Pre-op Flat K (30) Pre-op Steep K (31) Pre-Op Axis (32) Sim Flat K (33) Sim Steep K(34) Pre-Op Sim K Axis (35) Pre-Op K RP (Eff RP) (36)  
 (Keratometer) (Keratometer) (Keratometer)  
 Pre-Op Corneal Astigmatism - Keratometer (37) \_\_\_\_\_ Pre-Op Axis of Corneal \_\_\_\_\_ Pre-Op Spherical Equivalent (39) \_\_\_\_\_  
 (31-30;SteepK - FlatK) Astigmatism - Sim K (38) (34 - 33) (1/2 cylinder (24) + sphere(23)) VF14PreOp

## Surgery Variables:

Date of Surgery (40): \_\_\_\_\_ Axis of Cataract Incision (48) (usually 180 degrees)  
 IOL Style (41) IOL Power (42) Total Phaco Time (43) Average Power (44) 100% Phaco Time (45) Degree of Nuclear Sclerosis (46) IOP (47)  
 (Model # of Lens) (in diopters) (43 \* 44)

Increased operative risk factors? (49): Y N If yes, why? (50):

1. Pseudoexfoliation 4. Posterior polar cataract
2. Fuch's 5. Small pupil
3. Post op vitrectomy 6. Other: \_\_\_\_\_

Type of Anesthesia (51): 1. Retrobulbar 2. Peribulbar 3. Topical 4. General

Initial Wound (52): 1. Scleral Pocket 2. C.C. Tract

Sutures used? (53): Y N Incision Length (54): \_\_\_\_\_

If yes, type? (55): 1. 10/0 nylon 2. vicryl 3. Other: \_\_\_\_\_

Suture method used (56):

1. Interrupted radial 3. Circumferential 5. Vertical mattress
2. Shoestring radial 4. Infinity 6. Other: \_\_\_\_\_

IOL Position (57): 1. A.C. 2.BAG 3. SULCUS 4. EXTRACAPSULAR

Astigmatic Keratotomy? (58): Y N Axis of AK (59): \_\_\_\_\_

Length of AK cuts (60): \_\_\_\_\_ #AK cuts (61): \_\_\_\_\_

Operation Complications? (62): Y N

If yes, what? (62, 63, 64,65):

1. Vitreous loss 4. Corneal problems 7. Bleeding
2. Post capsule rupture 5. Lens dislocation 8. Other: \_\_\_\_\_
3. Increased IOP 6. Anesthetic problems

Decreased Post-Op Visual Acuity Suspected? (66): Y N

If yes, why? (67): 1. Diabetic Retinopathy 2. Macular Degeneration 3. Amblyopia  
 4. Other ( ): \_\_\_\_\_

Patient Name: \_\_\_\_\_

Birth date: \_\_\_\_\_

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<b>Post-Op Measurements - First Visit:</b>				Date (68): _____		# Days Post Surgery (69): _____	
_____	_____	_____	_____	AC FL (75)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		
Visual Acuity (70)	Cornea (71)	IOP (72)	Posterior Capsule (73)	<b>VLA (74)</b>	AC Cell (76)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4	
<b>Post-Op Measurements - Second Visit:</b>				Date (77): _____		# Days Post Surgery (78): _____	
_____	_____	_____	_____	AC FL (84)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		
Visual Acuity (79)	Cornea (80)	IOP (81)	Posterior Capsule (82)	<b>VLA (83)</b>	AC Cell (85)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4	
<b>Post-Op Measurements - Third Visit:</b>				Date (86): _____		# Days Post Surgery (87): _____	
_____	_____	_____	_____	AC FL (93)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		
Visual Acuity (88)	Cornea (89)	IOP (90)	Posterior Capsule (91)	<b>VLA (92)</b>	AC Cell (94)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4	
<b>Post-Op Measurements - Fourth Visit:</b>				Date (95): _____		# Days Post Surgery (96): _____	
_____	_____	_____	_____	AC FL (102)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		
Visual Acuity (97)	Cornea (98)	IOP (99)	Posterior Capsule (100)	<b>VLA (101)</b>	AC Cell (103)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4	

75

Additional Post-Op Visit information and YAG treatment information found on third page.

<b>Post-Op Measurements - Refraction Visit (3 - 6 weeks Post-op):</b>				Date (122): _____		# Days Post Surgery (123): _____	
_____	_____	_____	_____	AC FL (129)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		
Visual Acuity (124)	Cornea (125)	IOP (126)	Posterior Capsule (127)	<b>VLA (128)</b>	AC Cell (130)	a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4	
(Post-Op Refraction) _____ + _____ x _____				Post-Op Spherical Equivalent (158) _____			
Sphere (131)		Cylinder (132)	Axis (133)	Distance Visual Acuity (134)	(1/2 cylinder (132) + sphere(131)) Post-op K RP (Eff RP) (135)		
_____ x _____	_____ x _____	_____ x _____	_____ x _____	_____ x _____	_____ x _____	_____ x _____	_____ x _____
Post-op Flat K (136)	Post -op Steep K (137)	Post-op K Axis (138)	Post-op Sim Flat K (139)	Post-op Sim Steep K(140)	Post-op Sim K Axis (141)		
Post-Op Complications (142): Y N							
If yes, what? (143): 1. Retinal Detachment 2. Cystoid Macula Edema 3. Corneal Edema 4. Other: _____							

Decreased Vision? (144): Y N

Cause (145): 1. Diabetic Retinopathy 2. Age-related Macular Disease 3. Cystoid Macular Edema 4. Pre-retinal fibrosis 5. Bulious Keretopathy

Patient Name: \_\_\_\_\_

Birth date: \_\_\_\_\_

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<b>Post-Op Measurements - Fifth Visit:</b>	Date (104): _____	# Days Post Surgery (105): _____
_____ AC FL (111) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4 Visual Acuity (106) Cornea (107) IOP (108) Posterior Capsule (109) <b>VLA (110)</b> AC Cell (112) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4		

<b>Post-Op Measurements - Sixth Visit (6-9 months Post-op):</b>	Date (113): _____	# Days Post Surgery (114): _____
_____ AC FL (120) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4 Visual Acuity (115) Cornea (116) IOP (117) Posterior Capsule (118) <b>VLA (119)</b> AC Cell (121) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4  VF14PostOp		

<b>YAG Data:</b> Date (146): _____	# Days Post Surgery (147): _____
Pre-YAG VA (148): _____	Pre-YAG IOP (149): _____
Post-YAG VA (150): _____	Post-YAG IOP (151): _____
Laser Power used (152): _____	# Shots administered (153): _____
Complications (154): Y N what? (155) _____	

Post Op Calculations to be calculated by the computer:		
_____ <b>Post-Op K Corneal Astigmatism (156)</b> (137-136; SteepK - FlatK)	_____ <b>Post-Op Sim K Corneal Astigmatism (157)</b> (140 - 139; Sim Steep K - Sim Flat K)	_____ <b>Post-Op Spherical Equivalent (158)</b> (1/2 cylinder + sphere of cyclopegic refraction)
_____ <b>Difference between Post-Op Spherical Equivalent &amp; Desired Refraction (159)</b> (157 - 29, include + and - signs.)	_____ <b>Change in Axis of Astig. (160)</b> (As previously discussed) **	_____ <b>Difference in VLA (161)</b>

## **APPENDIX C - DATA DICTIONARY in Alphabetical Order**

ACCEL1V	Condition of the anterior chamber cells on the first post-op visit. See scale in Appendix F.
ACCEL2V	Condition of the anterior chamber cells on the second post-op visit. See scale in Appendix F.
ACCEL3V	Condition of the anterior chamber cells on the third post-op visit. See scale in Appendix F.
ACCEL4V	Condition of the anterior chamber cells on the fourth post-op visit. See scale in Appendix F.
ACCEL5V	Condition of the anterior chamber cells on the fifth post-op visit. See scale in Appendix F.
ACCEL6V	Condition of the anterior chamber cells on the sixth post-op visit. See scale in Appendix F.
ACCELRV	Condition of the anterior chamber cells on the refractive post-op visit. See scale in Appendix F.
ACFL1V	Condition of the anterior chamber fluid on the first post-op visit. See scale in Appendix F.
ACFL2V	Condition of the anterior chamber fluid on the second post-op visit. See scale in Appendix F.
ACFL3V	Condition of the anterior chamber fluid on the third post-op visit. See scale in Appendix F.
ACFL4V	Condition of the anterior chamber fluid on the fourth post-op visit. See scale in Appendix F.
ACFL5V	Condition of the anterior chamber fluid on the fifth post-op visit. See scale in Appendix F.
ACFL6V	Condition of the anterior chamber fluid on the sixth post-op visit. See scale in Appendix F.
ACFLRV	Condition of the anterior chamber fluid on the refractive post-op visit. See scale in Appendix F.

AGESUR	Age at time of cataract surgery.
AGExAMD	Age multiplied by the recoded AMD.
AGExNS	Age multiplied by nuclear sclerosis.
AK	Was an astigmatic keratotomy surgery performed at the same time as the intraocular lens implant surgery? CODE 1 = Yes; 2 = No Because none were done for the sample of medical records that were reviewed, this variable was not included in the analysis.
AKAXIS	Axis of the astigmatic keratotomy. (None done in this sample, therefore variable not included in the analysis.)
AKCUTS	Number of AK cuts. (None done in this sample, therefore variable not included in the analysis.)
AKLENG	Length of the AK cuts. (None done in this sample, therefore variable not included in the analysis.)
AMD	Age-related Macular Degeneration, CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True NOTE: This answer was determined by what was present in the medical record. If age-related macular degeneration was not noted in the medical record, an assumption was made the answer would be false. NOTE: The literature has indicated that there may be an association between the presence of age-related macular degeneration and poor post-op visual acuity. The macula is the center of the retina. Good central vision is dependent upon a healthy macula. If the macula has degenerated, good vision is not possible.
ANESTH	Type of anesthesia used during surgery. CODE: 1 = Retrobulbar; 2 = Peribulbar; 3 = Topical; 4 = General
ANTSUB	Anterior subcapsular changes in the lens.
AVGPWR	The average amount of phacoemulsification power used to pulverize the lens. This was a calculated field. FORMULA: PHACOTIM x PERCENT.
AXIS	Axis measurement of eye to be operated on.
AXIS2	Axis measurement on the refractive visit.
AXISCAT	Axis of the cataract incision. (Almost always 180 degrees.)
AXLNGTH	Axial Length of eye to be operated on. A Code of -99 was used to indicate missing information.

BDATE	Birth date
CHNGAXIS	Change in Axis of Astigmatism. Calculated field. FORMULA: For numbers that were < or = 90 degrees, it would be equal to that number. For numbers that were > 90 degrees, the formula is: (180 degrees - Larger number) + smaller number = change in axis of astigmatism.
CORN1V	Condition of cornea on the first post-op visit. See scale in Appendix F.
CORN2V	Condition of cornea on the second post-op visit. See scale in Appendix F.
CORN3V	Condition of cornea on the third post-op visit. See scale in Appendix F.
CORN4V	Condition of cornea on the fourth post-op visit. See scale in Appendix F.
CORN5V	Condition of cornea on the fifth post-op visit. See scale in Appendix F.
CORN6V	Condition of cornea on the sixth post-op visit. See scale in Appendix F.
CORNASG	Post-op K Corneal Astigmatism. Post operative corneal astigmatism minus the keratometer, calculated as post-op Steep K - Post-op Flat K. Not included in the analysis as these measurements were not taken.
CORNRFV	Condition of cornea on the refractive post-op visit. See scale in Appendix F.
COUMADIN	CODE: 1 = True; 2 = False  NOTE: This answer was determined by what was present in the medical record. If coumadin usage was not noted in the medical record, an assumption was made the answer would be false.  NOTE: The use of coumadin, a blood thinner, would indicate the need to use a topical anesthetic. One problem with the use of this variable is that it does not capture other blood thinners or other medication that may influence the choice of anesthetic or influence surgery outcomes.
CYLND2	Cylinder measurement on the refractive visit.
CYLINDER	Cylinder measurement of eye to be operated on.
DATE1V	Date of First Post-op visit. SPSS can not analyze dates.
DATE2V	Date of second Post-op visit. SPSS can not analyze dates.
DATE3V	Date of third Post-op visit. SPSS can not analyze dates.
DATE4V	Date of fourth Post-op visit. SPSS can not analyze dates.
DATE5V	Date of fifth Post-op visit. SPSS can not analyze dates.

DATE6V	Date of sixth Post-op visit. SPSS can not analyze dates.
DATE1VN	Number of days for the first visit after surgery.
DATE2VN	Number of days for the second visit after surgery.
DATE3VN	Number of days for the third visit after surgery.
DATE4VN	Number of days for the fourth visit after surgery.
DATE5VN	Number of days for the fifth visit after surgery.
DATE6VN	Number of days for the sixth visit after surgery.
DATEOFVS	Date of the pre-op office visit. SPSS can not analyze dates. Not included in analysis file.
DATEREFN	Number of days post surgery for the refraction visit.
DATEREFV	Date of refractive Post-op visit. SPSS can not analyze dates.
DATESURG	Date of intraocular lens replacement/cataract surgery. SPSS does not calculate date fields, so not included in analysis.
DATEYAG	Date of post-operative YAG procedure.
DATEYAGN	Number of days post surgery for YAG procedure.
DESREF	Desired Refraction. Goal for post-operative refraction measurement.
DIABETES	CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True  NOTE: This answer was determined by what was present in the medical record. If diabetes was not noted in the medical record, an assumption was made the answer would be false.
DIFF	Difference between post-op spherical equivalent and desired refraction. Calculated field.
DIFVA	Difference in pre-op distance visual acuity and post-op visual acuity.
DIFVLA	Difference in VLA pre-op and post-op. Discussed and decided not to use this surrogate variable. Not in analysis.
DVARVCAL	Surrogate variable for DVARVPO based on scale in Appendix F.
DVARVPO	Distance visual acuity on the refractive visit. SPSS not able to analyze, so used scale in Appendix F for surrogate variable DVARVCAL.

DVISCS1 What was the cause of the decreased vision? CODE: 1 = Diabetic Retinopathy; 2 = Age-related macular degeneration; 3 = Cystoid macular edema; 4 = Pre-retinal fibrosis; 5 = Bulious keretopathy; 6 = Other

DVISCS2 Reason for decreased visual acuity. CODE: 1 = Diabetic Retinopathy; 2 = Age-related macular degeneration; 3 = Cystoid macular edema; 4 = Pre-retinal fibrosis; 5 = Bulious keretopathy; 6 = Other

DVISCSTX Text for unsuspected visual acuity decreased post-operatively.

DVISUNS Decreased visual acuity unsuspected pre-operatively? CODE: 1 = Yes; 2 = no.

EFFRP2 Post-op K RP , Effective RP. Not included in analysis because none of the records in the sample contained this measurement.

EYER-L Operated Eye, CODE: 1 = Right; 2 = Left

FELEYECS Has cataract surgery already occurred in the fellow eye? CODE: 1 = True, 2 = False, - 99 = Not applicable, person does not have a fellow eye.; Recoded as 0 = False, 1 = True

FEXLNGTH Axial Length of fellow eye. A Code of -99 was used to indicate missing information.

FLATK2 Post-op Flat K measurement. Not included in analysis because none of the records in the sample contained this measurement.

GLAUCOMA CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True

NOTE: This answer was determined by what was present in the medical record. If glaucoma was not noted in the medical record, an assumption was made the answer would be false.

GRPIMPRC Group of Improvement Recoded: 0 = Worse, 1 = Some Improvement, 2 = Best Improvement, (equal to or better than 20/40 (0.500)) post-operative visual acuity.

GRPNOBST = Group of Improvement comparing worst to best. CODE: 0 = Worst, 1 = Best

GRPNOSM = Group of Improvement comparing worst to some improvement. CODE: 0 = Worst, 1 = Some Improvement

GRPSMBST = Group of Improvement comparing some improvement to best improvement. CODE: 0 = Some Improvement, 1 = Best improvement.



HYPERTEN	CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True  NOTE: This answer was determined by what was present in the medical record. If hypertension was not noted in the medical record, an assumption was made the answer would be false.
ID	First and Last initials
INCLENG	Incision length.
IOLPOS	Interocular lens position, CODE: 1 = Anterior chamber; 2 = Bag; 3 = Sulcus; 4 = Extracapsular
IOLPOW	The power of the interocular lens in diopters.
IOPSTYAG	Interocular pressure after the YAG procedure.
IOLSTYL	Style of interocular lens that was used.
IOP	Interocular pressure of the operative eye during the pre-op visit.
IOP1V	Interocular pressure on the first post-op visit.
IOP2V	Interocular pressure on the second post-op visit.
IOP3V	Interocular pressure on the third post-op visit.
IOP4V	Interocular pressure on the fourth post-op visit.
IOP5V	Interocular pressure on the fifth post-op visit.
IOP6V	Interocular pressure on the sixth post-op visit.
IOPPRYAG	Interocular pressure before the YAG procedure.
IOPRFV	Interocular pressure on the refractive post-op visit.
KAXIS2	Post-op Steep K, Axis measurement. Not included in analysis because none of the records in the sample contained this measurement.
KINDSURG	Kind of prior surgery that has occurred in the operated eye. This is a variable with text. The data sample was so small that there was not enough similar cases to be able to code the text, therefore it was not included in the analysis file.
MD	Initials of physician who did the interocular lens implant and cataract surgery

MYOPIAHI	Myopia-High, CODE: 1 = True, if the sphere is $\geq -5.00$ ; 2 = False, if the sphere is $< -5.00$ ; Recoded as 0 = False, 1 = True  NOTE: The literature has noted that the condition of high myopia, nearsightedness, is associated with complications of retinal detachment and glaucoma.
NAME	Full name, only on physician's copy of data.
NO	Unique ID number based on account number and first and last initials.
NOTES	Text field to explain anything that appeared to need further explanation. Not included in SPSS analysis.
NOVINP	Number of post-operative visits that indicated some infection present.
NUCSLR	Degree of nuclear sclerosis, that is the degree of hardness of the lens.
OCYES1	If there were operative complications, what were they? CODE: 1 = Vitreous loss; 2 = Post capsular rupture; 3 = Increased interocular pressure (IOP); 4 = Corneal problems; 5 = Lens dislocation; 6 = Anesthetic problems; 7 = Bleeding; 8 = Other
OCYES2	If there were operative complications, what were they? CODE: 1 = Vitreous loss; 2 = Post capsular rupture; 3 = Increased interocular pressure (IOP); 4 = Corneal problems; 5 = Lens dislocation; 6 = Anesthetic problems; 7 = Bleeding; 8 = Other
OCYES3	If there were operative complications, what were they? CODE: 1 = Vitreous loss; 2 = Post capsular rupture; 3 = Increased interocular pressure (IOP); 4 = Corneal problems; 5 = Lens dislocation; 6 = Anesthetic problems; 7 = Bleeding; 8 = Other
OPCOMP	Where there any operative complications? CODE: 1 = Yes, 2 = No; Recoded as 0 = False, 1 = True
OPRISK	Does this person have any increased operative risk factors? CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True
PAXCASK	A calculated field. Pre-operative axis of corneal astigmatism minus the Sim K, that is the Sim Steep K minus the Sim Flat K.
PAXIS	Pre-operative Axis measurement
PCASK	A calculated field. Pre-operative corneal astigmatism minus the keratometer, that is the Steep K minus the Flat K.
PERCENT	The percent of phacoemulsification power actually used to pulverize the lens.
PFLATK	Pre-operative Flat K measurement.

PFLATKAX	Pre-operative Flat K axis measurement. Too few records had measurement, not included in the analysis.
PHACOTIM	The total amount of time the phacoemulsifier was on.
PKRP	Pre-operative K RP or effective RP (measurement taken with simulator.)
POCOMP	Where there any post-op complications? CODE: 1 = Yes, 2 = No; Recoded as 0 = False, 1 = True
POCOMPRC	Where there any post-op complications? Recoded as 0 = False, 1 = True
POCOMPR	If POCOMP = 1, then the reasons for post-op complications, CODE: 1 = Retinal Detachment; 2 = Cystoid Macula Edema; 3 = Corneal Edema; 4 = Other
POCOMPR2	If POCOMP = 1, then the second reason for post-op complications, CODE: 1 = Retinal Detachment; 2 = Cystoid Macula Edema; 3 = Corneal Edema; 4 = Other
POCOTEXT	Post-op complications text. Text to explain “Other” in POCOMPR and POCOMPR2. Not included in SPSS analysis.
POSCAP1V	Condition of the posterior capsule on the first post-op visit. See scale in Appendix F.
POSCAP2V	Condition of the posterior capsule on the second post-op visit. See scale in Appendix F.
POSCAP3V	Condition of the posterior capsule on the third post-op visit. See scale in Appendix F.
POSCAP4V	Condition of the posterior capsule on the fourth post-op visit. See scale in Appendix F.
POSCAP5V	Condition of the posterior capsule on the fifth post-op visit. See scale in Appendix F.
POSCAP6V	Condition of the posterior capsule on the sixth post-op visit. See scale in Appendix F.
POSE	Post-op Spherical Equivalent (as calculated by this formula: $1/2$ post-op cylinder + post-op sphere).
POSTCPRV	Condition of the posterior capsule on the refractive post-op visit. See scale in Appendix F.
POSTSUB	Posterior subcapsular changes in the lens.

PREVSUR	Has the operated eye had any previous surgery? CODE: 1 = True, 2 = False; Recoded as 0 = False, 1 = True  NOTE: This answer was determined by what was present in the medical record. If previous surgery was not noted in the medical record, an assumption was made the answer would be false.  NOTE: The literature has associated an increased risk for complications, such as infection when there has been previous surgery or trauma to an eye.
PSHEQ	Pre-operative spherical equivalent (as written in the medical record.)
PSHEQCL	Pre-operative spherical equivalent (as calculated by this formula: 1/2 the cylinder + sphere.)
PSIMKAX	Pre-operative Sim K Axis measurement (taken with simulator.)
PSTEEPK	Pre-operative Steep K measurement.
PSTPKAX	Pre-operative Steep K axis measurement. Too few records had this measurement, therefore not included in analysis.
RACE	CODE: 1 = African-American; 2 = Hispanic; 3 = Caucasian; 4 = Other
SEX	Gender, CODE: 1 = Male; 2 = Female; Recoded as 0 = Male, 1 = Female
SIMFLK	Pre-operative Sim Flat K measurement taken with simulator.
SIMFLK2	Post-op Sim Flat K measurement. Not included in analysis because none of the records in the sample contained this measurement.
SIMFLKAX	Pre-operative Sim Flat K axis measurement taken with simulator.
SIMSTK2	Post-op Sim Steep K measurement. Not included in analysis because none of the records in the sample contained this measurement.
SIMSTPK	Pre-operative Sim Steep K measurement (taken with simulator).
SKCRNASG	Post-op Sim K Corneal Astigmatism. Calculated field. Measurements not taken, therefore not included in analysis.
SPHERE	Sphere measurement of eye to be operated on. A measurement of $\geq -5.00$ indicates high myopia and potential complications.
SPHERE2	Sphere measurement on the refractive visit.

SMOKE	Does the medical record indicate if this person ever smoked regularly? CODE: 1 = True; 2 = False; 3 = Unknown
SSKAXIS2	Post-op Steep Sim K axis measurement. Not included in analysis because none of the records in the sample contained this measurement.
STEEP K	Post-op Steep K measurement. Not included in analysis because none of the records in the sample contained this measurement.
SUMETHOD	Suture Method, CODE: 1 = Interrupted radial; 2 = Shoestring radial; 3 = Circumferential; 4 = Infinity; 5 = Vertical mattress; 6 = Other
SUTURENO	If CODE = 1 for variable SUTURES, then enter number of sutures.
SUTURES	Where there any sutures used? CODE: 1 = Yes; 2 = No
SUTYPE	Suture Type, CODE: 1 = 10/0 nylon; 2 = vicryl; 3 = Other
SUTYPE2	Suture Type, second one, if more than one used.
VA1V	Visual Acuity on the first visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA1VCAL.
VA2V	Visual Acuity on the second visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA2VCAL.
VA3V	Visual Acuity on the third visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA3VCAL.
VA4V	Visual Acuity on the fourth visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA3VCAL.
VA5V	Visual Acuity on the fifth visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA5VCAL.
VA6V	Visual Acuity on the sixth visit after surgery. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VA6VCAL.
VA1VCAL	Surrogate variable for VA1V based on scale in Appendix F.
VA2VCAL	Surrogate variable for VA2V based on scale in Appendix F.
VA3VCAL	Surrogate variable for VA3V based on scale in Appendix F.
VA4VCAL	Surrogate variable for VA4V based on scale in Appendix F.
VA5VCAL	Surrogate variable for VA5V based on scale in Appendix F.
VA6VCAL	Surrogate variable for VA6V based on scale in Appendix F.

VADECSUP	Is a decrease in post-op visual acuity suspected? CODE: 1 = Yes; 2 = no
VADIS	Pre-operative distance visual acuity. Because SPSS could not calculate fractions or text, a scale was developed (see Appendix F) and used in variable VADISCAL.
VADISCAL	Used scale in Appendix F to calculate pre-operative distance visual acuity.
VANEAR	Pre-operative near vision visual acuity. Because SPSS could not calculate fractions or text, a scale was developed (see Appendix F) and used in variable VANEARCL.
VANEARCL	Used scale in Appendix F to calculate pre-operative near vision visual acuity.
VAPREYAG	Visual acuity before the YAG procedure.
VAPRX	Pre-operative visual acuity with prescription. Because SPSS could not calculate fractions or text, a scale was developed (see Appendix F) and used in variable VAPRXCAL.
VAPRXCAL	Used scale in Appendix F to calculate pre-operative visual acuity with prescription.
VAPSTYAG	Visual acuity after the YAG procedure.
VAREFCAL	Surrogate variable for VAREFV based on scale in Appendix F.
VAREFV	Visual Acuity on the day of the refractive visit. SPSS not able to analyze, so used scale in Appendix F for surrogate variable VAREFCAL.
VAWHY1	Why is there a decrease in post-op visual acuity suspected? CODE: 1 = Diabetic retinopathy; 2 = Macular degeneration; 3 = Amblyopia; 4 = Other.
VAWHY2	Why is there a decrease in post-op visual acuity suspected? (second reason) CODE: 1 = Diabetic retinopathy; 2 = Macular degeneration; 3 = Amblyopia; 4 = Other.
VAWHYTXT	Text for why there is a suspected decrease in post-op visual acuity. This variable not included in SPSS analysis.
VF14PO	Post-operative Visual Function 14 Test Score. (Not completed with this data sample, therefore not included in analysis.)
VF14PREO	Pre-operative Visual Function 14 Test Score. (Not completed with this data sample, therefore not included in analysis.)

VISIOND	Was there decreased vision post-operatively? CODE: 1 = Yes; 2 = no
VLA1	Visual Lines of Acuity 1 (Pre-op visit). Discussion was held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA1, was not included in data collection or analysis.
VLA2	Visual Lines of Acuity 2 (First post-op visit). Discussion was held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA2, was not included in data collection or analysis.
VLA3	Visual Lines of Acuity 3 (Second post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA3, was not included in data collection or analysis.
VLA4	Visual Lines of Acuity 4 (Third post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA4, was not included in data collection or analysis.
VLA5	Visual Lines of Acuity 5 (Fourth post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA5, was not included in data collection or analysis.
VLA6	Visual Lines of Acuity 6 (Fifth post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA6, was not included in data collection or analysis.
VLA7	Visual Lines of Acuity 7 (Sixth post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLA7, was not included in data collection or analysis.

VLARV	Visual Lines of Acuity (Refractive post-op visit). Discussion held regarding using a surrogate measure for the visual lines of acuity, since the statistics packages can not analyze a fraction or text, for example 20/40 or FC for finger counting. Eventually a different scale was developed and this variable, VLARV, was not included in data collection or analysis.
WHYOPR1	Why does this person have increased operative risk factors? CODE: 1 = Pseudoexfoliation; 2 = Fuch's; 3 = Post op vitrectomy; 4 = Posterior polar cataract; 5 = Small pupil; 6 = Other
WHYOPR2	Why does this person have increased operative risk factors? (second reason, if more than one.) CODE: 1 = Pseudoexfoliation; 2 = Fuch's; 3 = Post op vitrectomy; 4 = Posterior polar cataract; 5 = Small pupil; 6 = Other
WHYOPTXT	Text that explains "Other" for increased operative risk factors. Not analyzed in SPSS.
WOUND	Type of initial wound used in surgery. CODE: 1 = Scleral pocket; 2 = Clear corneal tract.
YAGCOMP	YAG complications. CODE: 1 = Yes; 2 = No Not enough occurred in this data sample, therefore not included in analysis.
YAGCOMPW	What were the YAG complications (text). Not enough occurred in this data sample, therefore not included in analysis.
YAGNSHT	Number of YAG shots administered. Not enough occurred in this data sample, therefore not included in analysis.
YAGPWR	Laser power of the YAG. Not enough occurred in this data sample, therefore not included in analysis.
>= 20/40	Post-operative visual acuity achieved was greater than or equal to 20/40; Code 0 = False; 1 = True



## **APPENDIX D - Definition of Terms**

### **Definition of Terms**

Accommodation. The ability of the ciliary muscle to contract and the lens to become more convex is called accommodation. With increasing age, the lens of every eye undergoes a progressive hardening, with loss of ability to change its shape. Loss of accommodation is manifested by a decreased ability to focus on near objects (i.e., presbyopia), while corrected distance visual acuity remains normal. (Berson, 1993)

Acute. Immediate health effect, condition, or disease.

AMD = Age-related macular degeneration. This is degeneration of the macula, which is located within the center of the retina. This is the area of the eye that allows for central vision. Without good central vision, one is not able to see well. In the United States, age-related macular degeneration is the leading cause of irreversible central visual loss (20/200 or worse) among people aged 52 or older. (Berson, 1993)

Anterior chamber. The space that lies between the cornea anteriorly and the iris posteriorly. The chamber contains a watery fluid called aqueous humor. (Berson, 1993)

Astigmatism. This occurs when there are irregularities in the surface of the cornea, which causes one of the meridians to be different from another. It affects visual acuity, but can be corrected with eyeglass or contact lenses. (Berson, 1993)

Axial length. The horizontal length of the eyeball. An axial length of 26 mm or greater is an indicator of high myopia.

Choroid. The vascular, pigmented tissue layer between the sclera and the retina. The choroid provides the blood supply for the outer retinal layers. (Berson, 1993)

Choroidal hemorrhage. Hemorrhage (profuse bleeding) of the vascular, pigmented tissues between the sclera and the retina.

Congenital. Condition present at birth.

Cornea. The transparent front “window” of the eye that serves as the major refractive surface. (Berson, 1993)

Corneal abrasions. Abrasions, “scratches” on the cornea.

Corneal decompensation. Corneal damage causes scarring, clouding of the cornea, which leads to permanent visual loss.

Chronic. Ongoing health effect, condition, or disease.

Cortical changes.

Cystoid macular edema. Swelling of the macula, the central part of the retina. See macula. Can lead to permanent poor vision or blindness.

Diabetic Retinopathy. This is ocular disease of the retina that diabetics may develop. The longer a person suffers from diabetes, the greater the likelihood of developing diabetic retinopathy. About 5 years after diagnosis, 23% of patients with insulin-dependent diabetes mellitus (IDDM, Type I) have diabetic retinopathy, after 15 years, 80% have retinopathy. Diabetic patients who have non-insulin-dependent diabetes mellitus (NIDDM, Type II) have a similar but slightly lower incidence of retinopathy. In nonproliferative diabetic retinopathy (NPDR) capillaries develop leaks and later become occluded. Patients experience visual loss only if there is significant macular edema, which is present in from 5% to 15 % of diabetic patients, depending on the type and duration of the disease. The disease can progress to severe NPDR. Of patients diagnosed with severe NPDR, 40% will develop proliferative diabetic retinopathy (PDR). PDR is responsible for most of the profound visual loss from diabetes. (Berson, 1993)

Endophthalmitis. Eye infection.

Endothelial cell loss (ECL). Cell loss from the endothelium.

Extracapsular extraction. This is a technique used to remove a cataract in one whole piece.

Fluorescein angiography. An evaluation technique to determine damage to the retina. It is often used to determine the extent of damage from AMD.

Glaucoma. Elevated IOP can indicate glaucoma. Prolonged elevation of intraocular pressure can lead to optic nerve damage. Untreated glaucoma can lead to visual field loss and blindness. Glaucoma is the second most important cause of blindness in the United States and the single most important cause of blindness in African Americans. (Berson, 1993)

Glycemic control. Control of blood sugar, especially important for diabetics.

IOP = Intraocular pressure. IOP is determined largely by the outflow of aqueous humor from the eye. The greater the resistance to outflow, the higher the intraocular pressure. Alterations in the actual production of aqueous humor also have an effect on the intraocular pressure. Intraocular pressure varies among individuals. An IOP of 15 millimeters of mercury (mm Hg) represents the mean in a “normal” population. However, an IOP in the range from 10 to 21.5 mm Hg is acceptable, and falls within 2 standard deviations of the mean. (Berson, 1993)

Iris. The colored part of the eye that screens out light, primarily via the pigment epithelium, which lines its posterior surface. (Berson, 1993)

Lattice degeneration. This is degeneration of the retina in a lattice pattern. The blood vessels in the retina break down and cause a negative impact on visual acuity. It can be a precursor to AMD.

Lens. The transparent, biconvex body suspended by the zonules behind the pupil and iris; part of the refracting mechanism of the eye. (Berson, 1993)

Macula. The area of the retina at the posterior pole of the eye responsible for fine, central vision. The oval depression in the center of the macula is called the fovea. (Berson, 1993)

Maculopathy. Disease process that damages the macula.

Myopia. (nearsightedness) Myopia occurs when the axial length of the eye is too long, so that the convergence of light through the cornea and lens falls in front of the retina. (Berson, 1993)

High myopia. This is defined as a measure of equal to or greater than - 5.00 diopters. It is associated with an axial length of 26 mm or greater. High myopia is associated with an increased risk for retinal detachment.

ND:YAG. Neodymium:YAG is a laser technique used when an IOL implant becomes cloudy. The laser places a small hole in the IOL, allowing light to pass through to the retina. This restores vision.

Nuclear sclerosis. Hardening of the lens of the eye. Also known as cataract. It is described (measured) as trace, 1+, 2+, 3+, 4+, early brunescence or “very hard”.

Ocular disease. Eye disease.

Optic disc. The portion of the optic nerve visible within the eye. It is comprised of axons whose cell bodies are located in the ganglion cell layer of the retina. (Berson, 1993)

Peripheral vision. Side vision.

Posterior capsule. Clear membrane behind the lens.

Posterior subcapsular cataract. Cataractous hardening of the lens on the back lower side of the lens.

Posterior chamber. The small space filled with aqueous humor behind the iris and in front of the vitreous. (Berson, 1993)

Ptosis. Eye lid droopiness.

Pupil. The circular opening in the center of the iris that adjusts the amount of light

entering the eye. Its size is determined by the parasympathetic and sympathetic innervation of the iris. (Berson, 1993)

Radial keratotomy. A surgical procedure used to correct astigmatism.

Retina. The neural tissue lining the vitreous cavity posteriorly. Essentially transparent except for the blood vessels on its inner surface, the retina sends the initial visual signals to the brain via the optic nerve. (Berson, 1993)

Retinal detachment. Detachment (separation) of the retina from the back of the eye. If not immediately treated with laser surgery, will cause permanent blindness.

Sclera. The thick outer coat of the eye, normally white and opaque. (Berson, 1993)

Toxin. Poison.

Trabeculectomy. A surgical procedure to improve the drainage of eye fluid, so as to reduce the build up of intraocular pressure. Excessive intraocular pressure is a condition known as glaucoma. Untreated glaucoma can lead to blindness. This occurs because of excessive intraocular pressure damages the retina.

Uveitis. Eye infection.

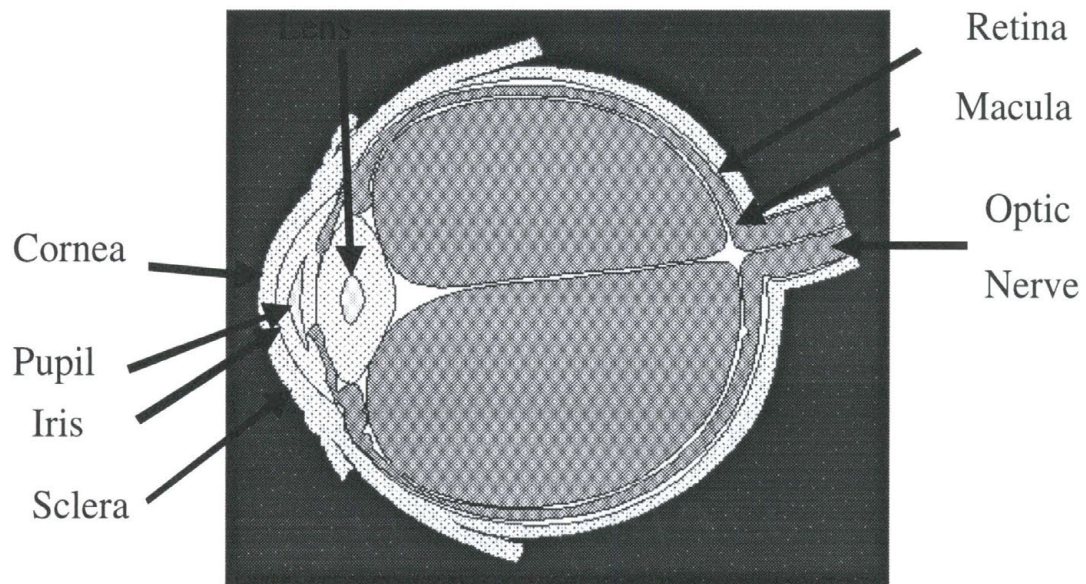
Vitreous cavity. The relatively large space (4.5 cc) behind the lens that extends to the retina. The cavity is filled with a transparent jelly-like material called vitreous humor. (Berson, 1993)

Vitreous loss. This is the loss of the transparent jelly-like material called vitreous humor. It can be one complication of cataract surgery.

YAG. See ND:YAG.

## APPENDIX E - Anatomy of the Eye

### Anatomy of the Eye



Modification of eye.gif, Anderson, 1998, [on-line]

## APPENDIX F - Scales

### Visual Acuity Scale

HM = Hand Motion	0.009
FC = Finger Count	0.010
FC1' = Finger Count at 1 foot	0.015
FC2' = Finger Count at 2 feet	0.018
FC3' = Finger Count at 3 feet	0.020
FC4' = Finger Count at 4 feet	0.024
FC5' = Finger Count at 5 feet	0.027
FC6' = Finger Count at 6 feet	0.030
FC7' = Finger Count at 7 feet	0.033
FC8' = Finger Count at 8 feet	0.036
FC 10' = Finger Count at 10 feet	0.040
20/400 =	0.050
20/300 =	0.067
20/200 =	0.100
20/160 =	0.125
20/125 =	0.160
20/100 =	0.200
20/80 =	0.250
20/70 =	0.286
20/60 =	0.333
20/50 =	0.400
20/40 =	0.500
20/30 =	0.667
20/25 =	0.800
20/20 =	1.000
20/15 = (Far Sighted)	1.33

### Corneal Condition Scale

1 = clear
2 = few folds
3 = trace
4 = 1+
5 = 1-2+
6 = 2+
7 = 2-3+
8 = 3+
9 = 3-4+
10 = 4+

### Posterior Capsule, AC Fluid, and

### AC Cell Condition Scales

1 = clear
2 = trace
3 = 1+
4 = 1-2+
5 = 2+
6 = 2-3+
7 = 3+
8 = 3-4+
9 = 4+

## **APPENDIX G - Other Results**

### **Pre-existing Variables Found to not be Significant Predictor Variables**

Data were collected on several pre-existing and ocular comorbidity conditions. The variables that were found through chi-square analyses to not be significantly associated with group of improvement. These included smoking, coumadin usage, the presence of high myopia, and hypertension. Although glaucoma is mentioned in the literature as being significantly associated with visual outcome (Schein, et al., 1995), in this set of data, there was no significant association. Previous eye surgery also did not show any significant association.

Smoking. Although the literature talks about the association of smoking and pre-existing medical conditions, only 19 records indicated whether the individual had ever been a smoker. On at least 87 records no information on smoking was noted and the author was not comfortable making the assumption the answer would be no. For this reason this variable was excluded in the analyses.

Coumadin and Other Blood Thinners. In discussions with the ophthalmologist regarding what variables he wanted to include in the database, he wanted to note if the patient used coumadin. Coumadin is a powerful blood thinner and it's usage would indicate the need to use a topical anesthetic. There were 13 medical records that noted the patient used coumadin. If the medical record did not note this, an assumption was made that the answer was false. Two records were missing that portion of the record that would indicate this information. One problem with the use of this variable was that it did not capture other blood thinners (for example, aspirin) or other medication that may influence the choice of anesthetic or influence other surgery choices or outcomes. For these reasons, this second variable was not included in the final analyses.



High Myopia. This is extreme nearsightedness and is defined as having a  $\geq -5.00$  sphere. The literature has noted that this condition is associated with complications of retinal detachment (Tielsch, et al., 1996). Fourteen records noted a spherical measurement of  $\geq -5.00$ . There were 8 (57%) male eyes and 6 (42%) female eyes. There were 2 (14%) minority eyes and 12 (86%) caucasian eyes. There was not a significant association between high myopia and gender and high myopia and race.

A t-test for independent samples results shown in Table G.1 determined the difference in means.

**Table G.1: T-test for Independent Samples for the Mean Age of Individuals with High Myopia compared to Individuals without High Myopia**

Variable	No. of Cases	Mean	SD	SE of Mean
High Myopia - False	126	74.81	10.210	0.910
High Myopia - True	14	62.36	12.894	3.446
t-value	DF	2-Tail Sig.	SE of Diff	95% CI
4.21	138	<.001	2.956	6.608, 18.297

T-tests showed a significant difference at ( $p < .0001$ ) in age for those individuals with high myopia. The mean age at cataract surgery for the 14 high myopics was 62.36 years compared to the mean age of 74.81 years of the 126 individuals not classified as high myopic.

**H<sub>0</sub>:** High myopia (because of retinal detachment) is not associated with group of improvement and poor visual outcome.

$$H_0: \chi^2_1 = \chi^2_2 ; \quad H_1: \chi^2_1 > \chi^2_2$$

**Table G.2: Chi-Square Results for High Myopia and Group of Improvement**

Group of Improvement			
	< 20/40	>= 20/40	Totals
High Myopia - True	2	12	14
High Myopia - False	33	93	126
Totals	35	105	140
<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	.95238	1	Not Significant

$$\chi^2 = 0.95238 < \chi^2_{.95,1} = 3.841$$

Table G.2 shows that the null hypothesis can be accepted. In this sample, high myopia was not associated with group of improvement and was not a predictor variable for poor visual outcome.

### Hypertension

Hypertension was noted in 50 records. If hypertension was not noted in the medical record, an assumption was made the answer was false. This may not be a valid assumption since hypertension can often go undiagnosed. Three records were missing the portion of the record that contained this information.

Hypertension and Gender. Table G.3 shows a significant association was found in this sample between sex and hypertension ( $p < .05$ ); 15 men and 35 women were noted to have hypertension.

**Table G.3: Chi-Square Results for Hypertension and Gender**

	Male	Female	Totals
Hypertension-True	15	35	50
Hypertension-False	44	43	87
Totals	78	59	137
<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	5.48	1	< .05

$$\chi^2 = 5.48 > \chi^2_{.95,1} = 3.841$$

Hypertension and Diabetes. TDH cited the National Institutes of Health (1995) as saying high blood pressure affects 60-65% of people with diabetes (TDH, 1997, p. 8). In this sample, however, no significant association was found between diabetes and hypertension.

Hypertension and Age. T-test for independent samples results in Table G.4 showed the mean age for the 50 individuals noted to have hypertension was 76.88 years. This was significantly different ( $p < .01$ ) from the mean age of 71.87 years of the 87 individuals classified as not having hypertension.

**Table G.4: T-test for Independent Samples for the Mean Age of Individuals with Hypertension compared to Individuals without Hypertension**

Variable	No. of Cases	Mean	SD	SE of Mean
Hypertension - False	87	71.87	12.13	1.300
Hypertension - True	50	76.88	8.30	1.174
<b>t-value</b>	<b>DF</b>	<b>2-Tail Sig.</b>	<b>SE of Diff</b>	<b>95% CI</b>
-2.59	135	<.05	1.934	(-8.831,-1.128)

### Hypertension and Group of Improvement.

**H<sub>0</sub>:** Hypertension (because of potential retinal damage) is not associated with group of improvement and poor visual outcome.

$$H_0: \chi^2_3 = \chi^2_4 ; H_2: \chi^2_3 > \chi^2_4$$

**Table G.5: Chi-Square Results for Hypertension and < 20/40 and >= 20/40**

	< 20/40	>= 20/40	Totals
<b>Hypertension-True</b>	16	34	<b>50</b>
<b>Hypertension-False</b>	19	68	<b>87</b>
<b>Totals</b>	<b>35</b>	<b>102</b>	<b>137</b>
<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	1.723	1	Not Significance

$$\chi^2 = 1.723 < \chi^2_{.95,1} = 3.841$$

Table G.5 shows that the null hypothesis is accepted. In this sample, hypertension was not associated with group of improvement and is not a potential variable for use in the final outcomes prediction models.

### Glaucoma

Glaucoma was noted to be present in 39 of the records. If glaucoma was not noted in the medical record, an assumption was made the answer was false. Two records were missing that portion of the record that contained this information. There were 17 (44%) male eyes and 22 (56%) female eyes. There were 9 (23%) minority eyes and 30 (77%) caucasian eyes. There were no significant associations between glaucoma and gender and glaucoma and race.

**H<sub>0</sub>:** Glaucoma (because of potential retinal damage) is not associated with group of improvement and poor visual outcome.

$$H_0: \chi^2_5 = \chi^2_6 ; \quad H_3: \chi^2_5 > \chi^2_6$$

**Table G.6: Chi-Square Results for Glaucoma and < 20/40 and >= 20/40**

	< 20/40	>= 20/40	Totals
<b>Glaucoma-True</b>	12	27	<b>39</b>
<b>Glaucoma-False</b>	23	76	<b>99</b>
<b>Totals</b>	<b>35</b>	<b>103</b>	<b>138</b>
<b>Chi-Square</b>	<b>Value</b>	<b>DF</b>	<b>Significance</b>
Pearson	.83958	1	Not Significance

$$\chi^2 = 0.65192 < \chi^2_{.95,1} = 3.841$$

Table G.6 shows the null hypothesis is accepted. In this sample, glaucoma was not associated with group of improvement and was not a predictor variable of poor visual outcome.

#### Cataract Surgery of Fellow Eye

Additional pre-existing variables included the question of whether cataract surgery had been completed on the fellow eye and whether there had been previous surgery done on the eye to be operated on. Fifty-seven individuals had already had cataract surgery done on the fellow eye prior to the study period. Eight individuals had their second eye done during the study period. Sixty-nine individuals had not had cataract surgery done on the fellow eye. One individual was missing his fellow eye. Five records were missing the portion of the record that contained this information.

### Previous Eye Surgery

Nineteen of the records noted that the eye receiving cataract surgery had received past surgery on the same eye. Table G.7 shows a positive association with being caucasian, not Hispanic and having previous surgery on the eye receiving cataract extraction ( $p < .02$ ).

**Table G.7: Chi-Square Results for Previous Eye Surgery and Race**

Previous Surgery			
Race	Yes	No	Totals
Minority	0	26	26
Caucasian	19	94	113
Totals	19	120	139
Chi-Square	Value	DF	Significance
Pearson	5.06	1	< .05

$$\chi^2 = 5.06 > \chi^2_{.95,1} = 3.841$$

These results may be due to the issue of better access to health care for caucasians or higher socioeconomic groups. That issue, however, is outside of the purview of this study. Chi-square analysis found that previous eye surgery was not significantly associated with group of improvement.

### Additional Surgical Procedures at Time of Cataract Surgery

There were three surgeries involving not only cataract surgery, but additional surgery. One situation included a trabeculectomy, which is an additional surgery to correct for increased intraocular pressure caused by glaucoma. Two other surgeries involved a vitrectomy, in addition to the cataract surgery. Because of the small sample size, having multiple surgeries at the same time as the cataract surgery could not be analyzed to determine if this influenced the ultimate visual outcomes.

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