OUTCOMES OF CATARACT SURGERY: PROBABILITY OF SUCCESS IN PATIENTS WITH OCULAR AND HEALTH COMORBIDITIES

THESIS

Presented to the Graduate College of
Southwest Texas State University
In Partial Fulfillment of
The Requirements

For the Degree of

Master of Science in Health Professions

By

Ginger Dieterle

San Marcos, TX
August, 2000

ACKNOWLEDGEMENTS

I would like to thank the following people: Charles Johnson, Jean Brender, Deanie French, Rex Cole, James Pickett, and Donna Thompson.

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ABSTRACT

OUTCOMES OF CATARACT SURGERY: PREDICTORS OF SUCCESS

IN PATIENTS WITH OCULAR AND HEALTH COMORBIDITES

By

Ginger Dieterle, (B.S.)
Southwest Texas State University
August 2000

Supervising Professor: Charles Johnson

A cataract is a clouding of the lens of the eye, which develops when some destructive factor such as excessive sunlight, smoking, disease, drugs, or aging, causes proteins in the lens to aggregate It has been reported that about half of Americans aged 65 to 74 have a cataract and approximately 70% of those age 75 and over have a cataract (Agency for Health Care Policy and Research [AHCPR], 1998). Because of the large number of people having cataract surgery, and the larger number of people estimated to need cataract surgery in the future, assessment of cataract surgery outcomes is needed to justify this increasing expense. "Medicare beneficiaries undergo more than 1.35 million cataract extractions each year, at an estimated cost of $3.4 billion." (Agency for Health Care Policy and Research [AHCPR], 1995). Predictors of surgical success and failure need to be identified not only to plan for Medicare funding, but also to better counsel prospective cataract surgery patients about their probable visual outcome following

surgery. A study done by Tielsch, et al., (1995) evaluated preoperative patient expectations and post-operative outcomes among patients undergoing first eye cataract surgery. Findings were that older patients and patients with some comorbidity had a high discrepancy between expected results of surgery and actual visual outcome. Although success rates for all patients undergoing cataract removal are high, those individuals with ocular comorbidities and older age have a greater probability of having visual outcomes that are disappointing. Therefore, there is a need to predict the probability of outcomes based on individual patient characteristics.

The purpose of this study was to investigate predictors of low visual acuity outcomes following cataract removal and intra-ocular lens (IOL) insertion. Using the methods of a previous researcher, Julie Borders, surgical outcomes and patient data were abstracted from patients' files at a local ophthalmology practice (Borders, 1998). Borders's thesis analyzed 140 surgeries, separating them into two groups: worse than previous visual acuity, better than previous visual acuity. Slight modifications to Borders methodology were implemented to achieve this study's goals. Outcomes were classified into 2 groups based on their final corrected post-operative visual acuity taken at their final refractive visit: Good Outcome = 20/15 - 20/40, Poor Outcome = 20/50 or worse. Most studies use Snellen notation of 20/40 to define a "successful" outcome. Appendix B contains an explanation of the Snellen visual acuity scale and its decimal conversions as shown in most major ophthalomolgy journals. Logistic regression was used to estimate the probability of achieving 20/50 or worse visual acuity, with a special emphasis placed on those individuals with ocular comorbidities or other poor outcome predictors.

The sample consisted of 236 surgeries performed by 2 surgeons in San Marcos, Texas. Subjects were limited to those receiving either first or second eye cataract surgery with no concomitant surgical procedure and no previous surgery on the operated eye. Surgical data were abstracted during 2 six-month periods: January through June 1997 (collected by Julie Borders) and October through March 2000 (collected by author). One hundred and twenty surgeries used in this study came from the database of Julie Borders, while 116 surgical records were collected by the author. Appendix D contains a copy of the data collection form used for both studies. Data from the collection form can be divided into 3 major areas: pre-existing variables, surgical variables, and post-operative variables.

Poor outcome was more likely to be associated with ages 81-100 than with younger ages (odds ratio, 6.038; 95% CI, 1.837 to 19.842), with ages 71 – 80 than with younger ages (odds ratio, 3.159; 95% CI, 1.038 to 9.616), with diabetics rather than non-diabetics (odds ratio, 4.164; 95% CI, 1.722 to 10.068), with patients with ARMD rather than patients without ARMD (odds ratio, 2.945; 95% CI, 1.258 to 6.892), and with high degrees of nuclear sclerosis rather than low degrees of nuclear sclerosis (odds ratio, 2.863; 95% CI, 1.099 to 7.463). Within this sample, the smallest single threat (that was studied) to achieving visual acuity of 20/40 or better is nuclear sclerosis. Those 71 – 80 with nuclear sclerosis alone only have a 25.3% probability of a poor outcome. For those 81 – 100, the probability increases to 39.3%. Within this sample, the largest single threat (that was studied) to achieving visual acuity of 20/40 or better for individuals of all age groups is diabetes. Those 71 – 80 with diabetes and no other comorbidity have a 33.0% probability of a poor outcome. Those 81 – 100 with diabetes and no other comorbidity

have a 48.5% probability of a poor outcome. The probability of a poor outcome increases within each age group for patients with multiple comorbidities. For example, patients 81 – 100 with diabetes and ARMD have a 73.5% probability of a poor outcome. A complete listing of all calculated probabilities can be found in Table 4.18.

CHAPTER 1

Introduction

Outcomes research is an emerging field that incorporates the disciplines of epidemiology, clinical trials, effectiveness studies, psychometrics (e.g., quality of life), cost-effectiveness and cost-benefit analysis, and disease management. By approaching medicine in this multidisciplinary manner, standards of care and patient outcomes can be improved. Unlike traditional medicine which relied on the general consensus of physician's on optimal methods of care, outcomes research attempts to identify optimal methods of care based on systematic population and evidence-based clinical, economic, and humanistic measurements (Epstein and Sherwood, 1996). Several factors have driven the shift in approach to care, such as concerns about health care costs by patients and payers, increased patient education and involvement in care, and the computerization of the health care industry. The ultimate goal of outcomes research is to identify protocols of care or interventions that maximize effectiveness of treatment and benefit to the patient while simultaneously minimizing cost. The starting point on the path to this goal is the collection and analysis of data on all aspects of care, including current and emerging methods. Therein lies the solution that satisfies the clinical, economic, and humanistic needs of providers and receivers of medical care.

Cataracts - The Scope of the Problem

The development of cataracts is a common problem for older adults around the world, and many studies have been done to assess the condition's prevalence. The Framingham Eye Study (Kahn, et al., 1977b) found that of 2477 men and women aged 52 - 85, 15.5% were positive for cataracts in one or both eyes, 3.1% had diabetic retinopathy, 8.8% had age-related macular degeneration (ARMD), and 3.3% had open angle glaucoma. Another well-known study, the Beaver Dam Eye Study, found that adults aged 43 and older had a prevalence of 30.8% and 15.3% for early and late cataracts, respectively (Klein, B., Klein, R., Linton, 1991). An Italian-American study reported a cataract prevalence of 15.8% in adults aged 45 and older (Maraini, Pasquini, and Sperduto, 1991). Within a diabetic population aged 30 and older, the prevalence of older onset cataracts in either eye was found to be 8.7% (Klein, B., Klein, R., Moss, 1992). It has also been reported that about half of Americans aged 65 to 74 have a cataract and approximately 70% of those age 75 and over have a cataract (Agency for Health Care Policy and Research [AHCPR], 1998). When one couples the above prevalence findings with the fact that the U.S. population is aging at a rapid pace, the scope of the problem becomes clear. The U.S. Census Bureau estimates that roughly 6.0% of the U.S. population is aged 75 and older. According to the 1990 census, there are 250 million people living in the US. That would mean that 15.2 million people in the US are aged 75 and older and 70% of those people have a cataract in one or both eyes.

Because of the large number of people having cataract surgery, and the larger number of people estimated to need cataract surgery in the future, assessment of cataract outcomes is needed to justify the anticipated expense. "Medicare beneficiaries undergo

more than 1.35 million cataract extractions each year, at an estimated cost of $3.4 billion." (Agency for Health Care Policy and Research [AHCPR], 1995). The median cost for a typical cataract surgery episode is approximately $2500 (AHCPR, 1995). The increased popularity and success of cataract surgery indicates that outcome measurements need to be assessed.

Predictors of surgical success and failure need to be identified not only to plan for the allocation of funds, but also to better counsel prospective cataract surgery patients about their probable visual outcome following surgery. A study done by Tielsch, et al., (1995) evaluated preoperative patient expectations and postoperative outcomes among patients undergoing first eye cataract surgery. Findings were that older patients and patients with some comorbidity have a high discrepancy between expected results of surgery and actual visual outcome. This indicates that these patients are not adequately counseled about their probable outcome prior to surgery. Although success rates for all patients undergoing cataract removal are high, those individuals with ocular comorbidities and older age have a greater probability of having visual outcomes that are disappointing. Therefore, there is a need for a system to predict a probability of outcome based on individual patient characteristics. This would provide prospective patients with a probability of achieving the benchmark visual acuity of 20/40 among individuals with similar presenting characteristics, facilitating their decision to have or not to have cataract surgery.

Purpose of the Study

The purpose of this study was to investigate predictors of low visual acuity outcomes following cataract removal and intra-ocular lens (IOL) insertion. Outcomes

were classified into 2 groups of outcome based on their final corrected postoperative visual acuity taken at their 3 week refractive visit: Group 1 = 20/15 - 20/40, Group 2 = 20/50 or worse. Most studies conducted on the outcome of cataract surgery use Snellen notation of 20/40 to define a "successful" outcome. Visual acuity of 20/40 is the standard level of vision required to obtain a driver's license and is therefore a benchmark level of vision that most individuals can relate to. Appendix B contains an explanation of the Snellen visual acuity scale and its decimal conversions as listed in ophthalmology journals. Logistic regression was used to estimate the probability of achieving 20/50 or worse, with a special emphasis placed on those individuals with ocular comorbidities or other poor outcome predictors. It should be noted that the final logistic equation computes the probability that an individual achieves any final postoperative visual acuity, ranging from 20/50 to hand motion. Although an individual may fall into the "poor" outcome category of 20/50 or worse, they might have significantly improved vision from preoperative visual acuity. The usefulness of the probabilities determined in this manner, is to provide patients who present with indicators of poor outcome with a more accurate probability of achieving a level of vision that they expect.

Research Questions

The following research questions were asked:

1. What variables best predict those individuals likely to achieve visual acuity less than 20/40 following cataract surgery?

2. What is the probability of poor outcome (20/50 or worse) associated with the independent variables entering into the logistic regression model?

Secondary research questions were examined prior to the final logistic analysis. They were:

1. Are there any associations occurring between pre-existing, surgical, and postoperative variables and outcome group?
2. Do significant differences exist in postoperative visual acuity for different populations, i.e., males vs. females, ethnic groups, diabetics vs. non-diabetics, etc?
3. Are there significant differences in the continuous variables of age, pre-operative VF-14 score, and average amount of phacoemulsification power required to pulverize the lens in the two outcome groups?
4. Are there any interactions (associations) between the pre-existing variables and age, race, or sex?
5. Is there a significant difference in the average amount of phacoemulsification power required to pulverize the lens in patients with high and low levels of nuclear sclerosis?
6. What are the odds ratios for any significant associations between predictor variables and outcome group?

Research Hypotheses

H_{01}: There is no association between pre-existing, surgical, or postoperative variables and outcome group.

$$H_{01}: p_1 = p_2; \quad H_{A1}: p_1 \neq p_2$$

The chi-square test for independence was used to measure the association.

H_{02}: There is no significant difference in postoperative visual acuity for different populations consisting of two groups, i.e., males vs. females, right vs. left eye, diabetics vs. non-diabetics, etc.

$$H_{02}: \mu_1 = \mu_2; \; H_{A2}: \mu_1 \neq \mu_2$$

The independent t-test was used to assess these differences.

H_{03}: There is no significant difference in postoperative visual acuity for different populations consisting of more than two groups, i.e., ethnic groups, degree of nuclear sclerosis, 10-year age interval, etc.

$$H_{03}: \mu_1 = \mu_2 = \mu_j; \; H_{A3}: \text{not all } \mu_j \text{ are equal (where } j = 1,2,\ldots,c)$$

One-way analysis of variance (ANOVA) was used to evaluate differences in these groups. The Least Significant Difference test was used to determine which means differ and to define homogeneous subsets of means using multiple pairwise comparisons.

H_{04}: There is no significant difference in age, pre-operative VF-14 score, and average amount of phacoemulsification power required to pulverize the lens in the two outcome groups.

$$H_{04}: \mu_1 = \mu_2; \; H_{A4}: \mu_1 \neq \mu_2$$

The independent t-test was used to assess these differences.

H_{05}: There is no significant difference in the average amount of phacoemulsification power required to pulverize the lens in patients with high and low degrees of nuclear sclerosis.

$$H_{05}: \mu_1 = \mu_2; \; H_{A5}: \mu_1 \neq \mu_2$$

The independent t-test was used to assess these differences.

H_{06}: There is no significant association between the pre-existing variables and age, race, or gender.

$$H_{06}: p_1 = p_2; \quad H_{A6}: p_1 \neq p_2$$

The chi-square test for independence was used to measure the associations.

H_{07}: There is no significant relationship between final corrected postoperative visual acuity following cataract surgery and pre-existing variables.

$$H_{07}: \beta_1 = 0 ; H_{A7}: \beta_i \neq 0$$

Logistic regression was used to evaluate these relationships.

Study Limitations

There were several limitations to this study. They were:

1. Defining an outcome as "poor" if visual acuity of at least 20/40 is not reached can be misleading. Any improvement in vision that improves the patient's quality of life is a success, whether or not the 20/40 level of acuity was obtained.
2. The probabilities obtained in the final logistic equation estimate visual acuity outcome in the range of 20/50 to hand motion. The large size of the range may not facilitate the patient's decision-making process due to the possibility of life improvement associated with the larger end of the range. For example, a patient with a pre-operative visual acuity of 20/200 and a postoperative visual acuity of 20/50 or 20/70 would most likely be happy with the results, even though they did not reach the 20/40 level.
3. Cases included both first-eye and second-eye cataract surgeries. Previous studies limited cases to first-eye cataract surgeries.

4. VF-14 scores were only available for one surgeon and were only pre-operative scores.
5. Some medical records were missing information on pre-existing, surgical, and postoperative variables, making sample sizes for those variables too small for analysis. SPSS defaults to case-wise deletion for missing data.
6. Data used in this study were collected in two six-month periods, January through June 1997 and October 1999 through March 2000. Although there were no significant differences in outcome, race, age, gender, or comorbidity status in the two groups, unmeasured differences in the two groups could have been introduced and not accounted for.

CHAPTER 2

Review of the Literature

A cataract is an opacity of the lens of the eye, which develops when some destructive factor such as excessive sunlight, smoking, disease, drugs, or aging, causes proteins in the lens to aggregate. The protein clumps create glare, scatter light, blur images, and dull colors. The term cataract is used to describe any opacity, from those creating minor vision loss to those causing total blindness (Consumer Reports on Health, 1998). About half of the general population between the ages of 65 and 75 has cataracts, making cataracts the most common treatable cause of vision loss in older adults. Cataracts often occur concomitantly with other eye ailments such as glaucoma, age-related macular degeneration (ARMD), astigmatism, diabetic retinopathy, and high myopia. The following definitions are located in Basic Ophthalmology for Medical Students and Primary Care Residents by F. Berson (1993). Glaucoma is defined as excessively elevated intra-ocular pressure (IOP) due to a decrease of the outflow of aqueous humor from the eye. Prolonged elevation of IOP can lead to optic nerve damage and, if left untreated, can lead to visual field loss and blindness. Glaucoma is the second most important cause of blindness in the US and the single most important cause of blindness in African Americans. ARMD is the degeneration of the macula, which is located within the center of the retina. The macula is the area of the eye that allows for

central vision. In the US, ARMD is the leading cause of irreversible central vision loss (20/200 or worse) among people aged 52 and older. Astigmatism is caused from irregularities in the surface of the cornea and can be easily corrected with eyeglasses or contact lenses. Diabetic retinopathy, an ocular disease of the retina that diabetics can develop, permanently damages the retina when capillaries leak and become occluded. The longer a person suffers from diabetes, the greater the likelihood of developing diabetic retinopathy. Five years after diagnosis, 23% of patients with insulin-dependent diabetes mellitus (IDDM, Type I) develop diabetic retinopathy, 80% after 15 years. Individuals who have non-insulin-dependent diabetes mellitus (NDDM, Type II) have a slightly lower incidence of retinopathy. In non-proliferative diabetic retinopathy (NPDR), patients experience visual loss only if there is significant macular edema, which is present in 5% - 15% of diabetic patients, depending on the type and duration of the disease. Forty percent of patients with severe NPDR go on to develop proliferative diabetic retinopathy (PDR), which is responsible for the most acute vision loss from diabetes. Myopia, or nearsightedness, occurs when the axial length of the eye is too long so that convergence of light through the cornea and lens falls in front of the retina. High myopia is a measure of the axial length greater than or equal to -5.00 diopters. It is associated with an increased risk of retinal detachment.

Risk Factors for the Development of Cataracts

Many studies have been done to determine the risk factors for cataracts. The Framingham Eye Study found low education level, elevated blood sugar, systemic blood pressure, height, vital capacity, serum phospholipid level, and hand strength to be

associated with cataracts (Kahn et al, 1977a). The India - U.S. case control study found low education level, decreased cloud cover at place of residence, use of aspirin less than once per month, low nutrient diet, high blood pressure, lower body-mass index, low antioxidant level, and use of cheaper cooking fuels to be significantly associated with cataracts (Mohan et al, 1989). The Italian-American Study Group found the aforementioned risk factors as well as female gender, brown irises, job location in sunlight, leisure time spent in sunlight, positive family history of cataracts, and history of cortisone use to significantly increase the risk for development of cataracts (Maraini et al, 1991). Exposure to high levels of ultraviolet light is also a significant risk factor for the development of cataracts (Bochow, et al., 1989). Smoking has been identified as a risk factor for cataracts (West, Munoz, and Taylor, 1989; Christen, et al, 1992; Hankinson, et al., 1992; Harding and van Heyningen, 1987), as well as for ARMD (Delcourt, Diaz, Ponton-Sanchez, Lapoz, 1998). The study by West, et al. (1989) found a dose-response relationship between smoking and severity of cataracts. In the study by Christen, et al. (1992), compared with individuals who never smoked, after controlling for other potential risk factors, current male smokers of 20 or more cigarettes per day had a relative risk (RR) of 2.05; 95% CI, 1.38 - 3.05. The study by Hankinson, et al. (1992) found that women who had smoked at least 65 pack-years were 1.63 times more likely to have cataracts than women non-smokers in their age group (95% CI 1.18 - 2.26). The study by Harding and van Heyningen (1987) found a doubling of the relative risk values in subjects who smoked heavily compared to subjects who did not smoke (RR 1.97; 95% CI 1.05 - 3.67). The same study found long-term steroid use to elevate the risk of cataracts (RR 1.79; 95% CI 1.09 - 2.93). In contrast, the Beaver Dam Eye Study found a very

modest association between smoking and incidence of cataract (OR 1.05, 95% CI 1.01 - 1,09 per 10 pack years), (Klein, Klein, and Lee, 1999). See Appendix A for a summary table of risk factors and associated odds ratios (OR) found in previous studies.

Protective Factors Against Cataracts

Preliminary studies have suggested that some protective mechanisms exist against cataract development. Harding and van Heyningen (1988) found the following aspirin-like analgesics to be protective: acetaminophen (RR 0.45, 95% CI 0.29 – 0.71) and ibuprofen (RR 0.41, 95% CI 0.19 – 0.89). A nutritional study by Jacques, et al. (1997) found that among women, vitamin C supplement intake >= 10 years was associated with a 77% lower prevalence of early lens opacities compared with no supplemental vitamin C intake (OR 0.23; 95% CI 0.09 - 0.60). Vitamin E has also been associated with a lower prevalence of cataracts in Emory mice in a nutritional study by Varma (1991). In that study, <20% of mice receiving a vitamin E supplement developed cataracts while >80% of mice not receiving vitamin E supplements did develop cataracts.

Statistical vs. Practical Benefits and Use of Subjective Measures

Most studies conducted on the outcome of cataract surgery use Snellen notation of 20/40 to define a "successful" surgical outcome. The standard measure of good vision is 20/20, and in most states vision of 20/40 is sufficient to obtain an unrestricted driving license (as cited by Lee, et al., 1993). See Appendix B for an explanation of the Snellen visual acuity scale and its decimal conversions. It should be noted that the reliability of the acuity measurement can vary due to differences in background lighting, examiner,

examination setup, and notation used in reporting results. Ophthalmologists have long recognized that visual acuity is not a perfect measure of impairment caused by cataracts. Subjective measurement scales can provide information on functional impairment that cannot be conveyed by Snellen measurement scales. Several studies have included subjective visual tests in order to better determine a practical improvement in vision. In a study by Mangione, et al., (1994) 80% of patients who underwent cataract surgery reported an improvement on their Activities of Daily Vision Scale (ADVS) score whether they attained the 20/40 criteria or not. The ADVS is a proven, reliable, valid measure of visual function consisting of 20 common visual activities categorized into 5 subscales: night driving, daytime driving, distance vision activities that do not require driving, near vision activities, and activities subject to glare. Scores range from 0 to 100 with 100 representing no difficulty. Tielsch, et al., (1995) used the Visual Function 12-Item Scale (VF-12) to measure patient-recorded level of trouble and satisfaction with vision both preoperatively and 4 months postoperatively. Patients were also asked questions addressing their preoperative expectations regarding the outcome of surgery. The VF-12 is a modification of the VF-14, a reliable and valid measure of cataract-related functional impairment. (The VF-12 was used in lieu of the VF-14 in the Tielsch, et al. study because of insufficient data on two of the questions.) Scores on the VF-12 range from 0 (indicating inability to perform any of the 12 tasks) to 100 (indicating that the patient is able to perform the task without difficulty). The Patient Outcomes Research Team (PORT) led by Dr. Earl Steinberg determined that regardless of Snellen visual acuity, cataract removal is warranted whenever the patient is disabled enough to want the surgery. The PORT found the VF-14 to be a stronger predictor of patients' self-reported

satisfaction with vision than the Snellen visual acuity scale (Steinberg, et al., 1994a). Additionally, the PORT found that changes inVF-14 scores correlated more strongly with patients' ratings of satisfaction with their vision than with changes in visual acuity. Appendix C contains a listing of the functional activities included on the VF-14. Scoring methods are identical for the VF-12 and the VF-14. Several studies by leaders in the field have used the VF-14 index (Steinberg, et al., 1994b, Schein, et al., 1995b). In addition to subjective measures of vision, some new objective measures other than the Snellen visual acuity scale can predict surgical outcome following cataract surgery. The Potential Acuity Pinhole (PAP) test is a relatively reliable and simple method that estimates visual outcome after uncomplicated cataract surgery in eyes with no ocular comorbidity. Melki, Safar, Martin, Ivanova, and Adi (1998) found the PAP test able to predict postoperative visual acuity within 2 Snellen lines in their sample. A similar test, the Potential Acuity Meter (PAM) test is another option ophthalmologists have to measure the potential improvement of vision following cataract surgery. The limitation of the last two kinds of tests is their inability to predict outcome in patients with ocular comorbidities, a significant portion of patients receiving cataract surgery.

Surgical Intervention Outcomes

Most modern cataract surgeries have a high success rate, especially for those individuals with no ocular comorbidity or confounding health factor such as diabetes. Among all subjects with and without ocular comorbidities, a study comparing the outcomes of cataract surgery in the US, Canada, Denmark, and Spain reports postoperative normal or near normal visual acuity (Snellen fraction >= 0.67) in 83% of

US patients, 74% of Canadian patients, 73% of Danish patients, and 50% of Spanish patients (Norregaard, Hindsberger, Alonso, et al., 1998). Another study shows a greater improvement. For all patients, 96% improved in median Snellen visual acuity from 20/70 prior to surgery to 20/30 by 3 months after surgery ($p < 0.001$) (Mangione, et al., 1994).

Factors Possibly Affecting Outcome

Pre-existing variables such as age, sex, race, nuclear sclerosis, diabetes, and the presence of an ocular comorbidity may have an association with cataract surgery outcome. Predictors of poor outcome have been identified in several studies.

Gender. In a population-based cross-sectional study in India, women had an increased OR of 2.55 (95% CI, 1.06 – 6.16) for a poor outcome defined as presenting distance visual acuity of 20/60 to 20/200 following cataract surgery (Dandona, et al., 1999). Results found in the US, Canada, Denmark, and Spain study showed that men were 1.9 times more likely to have an adverse operative event (95% CI 1.2 – 2.8), although sex was not significant in final visual acuity outcome (Norregaard, Bernth-Peterson, Bellan, et al., 1998).

Age. In the US, Canada, Denmark, Spain study, those aged 70-80 were 2.45 times more likely to have a poor outcome (95% CI 1.21 – 4.92) compared to the reference age category of 50 – 60 year olds. Those over 80 were 5.2 times more likely to have adverse outcomes (95% CI 2.48 – 10.92). Likewise in a study of patients with retinal disease, age 80 years and younger was a predictor of surgical success (Graney, et al., 1990).

Nuclear Sclerosis. The Beaver Dam Eye Study determined nuclear sclerosis, or hardness of the lens, to be inversely related to change in visual acuity following cataract surgery (Klein, B., Klein, R., Moss, 1996).

Comorbidities. In general, studies have found that ocular comorbidities are associated with poorer outcomes of cataract surgery. Approximately 31.6% of eyes undergoing cataract removal present with some form of ocular comorbidity (Norregaard, Bernth-Peterson, Bellan, et al., 1999). Poor outcome in the US, Canada, Denmark, and Spain study was significantly associated with comorbidity in patients from the US (OR 1.78; 95% CI 1.08 - 2.93) (Norregaard, Hindsberger, Alonso, et al., 1998). Another demonstration of this can be seen in a study by Lundstrom, Stenevi, and Thorburn (1999). Using a valid and reliable questionnaire, the Catquest, ocular comorbidity was strongly related to "no benefit" ($p < 0.01$) as assessed by the patient. Young age and second eye cataract surgery were related to a "very good benefit" ($p< 0.001$ and $p < 0.001$ respectively) as assessed by the patient. Desai, Minassian, and Reidy (1999) found that 92% of patients with no ocular comorbidity achieved 20/40 or better vision, while only 77% of patients with any comorbidity achieved the same level. The following paragraphs list specific ocular comorbidities found to be associated with poor outcome in previous studies.

Retinopathy is a cause of vision loss in people with diabetes. Studies have shown that glycemic control reduces the risk of retinopathy in individuals with IDDM. However, even those with good glycemic control are at risk for retinopathy. Assessing the extent of damage to the retina in patients with cataracts can be difficult because the cataractous lens obstructs the view of the retina. In a study by Klein, et al. (1997) it was

determined that 4 years after diagnosis of diabetes, retinopathy could be identified in 5.1% of the cohort. After controlling for age, those subjects with a glycosylated hemoglobin level of 12% or greater were 3.2 times more likely (95% CI 1.1 – 9.9) to have retinopathy. This implies that the longer a person is diabetic and the more uncontrolled the glucose levels in the blood, the more damage that is done to the retina, possibly indicating a contraindication for cataract surgery. A study by Desai, Minassian, and Reidy (1999) found diabetes to be a risk factor for poor outcome and surgical complications. Eighty-six percent of patients in this study without diabetic retinopathy achieved visual acuity of 20/40 or better, while only 68% of patients with diabetic retinopathy achieved the same visual acuity. Subjects with diabetic retinopathy demonstrated a 64% failure rate following cataract surgery when a 20/40 or better criterion denoted "success" in a study by Graney et al, (1990). Krolicki and Tasman (1995) found that 10 of 13 eyes with premature retinopathy showed improvement following cataract removal. The contradictory high success rate in the latter study may be attributable to the small sample size and the premature nature of the retinopathy.

ARMD is also difficult to assess in patients with dense cataracts due to obstruction of the retina. In the study by Mangione et al., (1994) 22% of the study population had ARMD. In the Beaver Dam Eye Study, Klein, B., Klein, R., and Moss (1996) identified ARMD as a cause of poor outcomes in cataract surgery. In the study by Desai et al (1999), 89% of patients without ARMD achieved visual acuity of 20/40 or better while, while only 72% of patients with ARMD reached the same level. In a study of patients with ARMD and receiving cataract surgery, 81% of cases had improvement in visual acuity but only 67% of the cases felt that the surgery was worthwhile; indicating

that the improvement for a large portion of the patients was not practically significant (Shuttleworth, Luhishi, Harrad, 1998). In India, 2.5% of patients with poor outcomes also had ARMD (Dandona, et al., 1999).

Glaucoma is another ocular comorbidity that can result in poor visual acuity or blindness. Glaucoma is caused by the build-up of vitreous fluid in the eye. As the intra-ocular pressure builds, damage is done to the optic nerve. Desai et al (1999) found that patients with glaucoma achieved poorer levels of postoperative visual acuity than patients without glaucoma. Only 77% of patients with glaucoma achieved 20/40 or better vision compared to 87% of patients without glaucoma. Glaucoma has also been associated with postoperative and intra-operative adverse events at a rate 5.5 times that in non-glaucoma patients (Norregaard, Bernth-Peterson, Bellan, et al., 1999). The same study shows that any peri-operative adverse event is significantly associated with a worse 4-month visual outcome after controlling for preoperative patient characteristics. Mandal, Gothwal, and Opt (1998) found that patients with glaucoma have success rates (visual acuity of 20/40 or better) of 76.5% - 60.7%.

Behavioral Characteristics. Smoking has also been implicated as a variable possibly contributing to poor outcomes of cataract surgery. West, et al., (1989) found a dose-response relationship between quantity of cigarettes smoked and the prevalence of cataract. Christen, et al., (1992) found that those men who smoked 20 or more cigarettes per day were 2.16 times more likely to develop cataracts than never smokers. Similar results were found for women by Hankinson, et al. (1992). It has not been determined whether smoking or degree of smoking has an affect on cataract surgery outcomes.

Surgical Technique. Modern cataract surgery is usually performed using two methods: phacoemulsification and extracapsular extraction. Schein, et al. (1995) found that phacoemulsification is used for more than 75% of routine cataract surgery by 46% of a random sample of members of the American Academy of Ophthalmology. Extracapsular extraction is used for more than 75% of cataract surgery by 41% of respondents. The US, Canada, Denmark, and Spain study found that 2/3 of US surgeries use phacoemulsification. The choice of technique is usually determined by the surgeons' beliefs regarding safety and effectiveness (Schein, et al., 1995a). Extracapsular extraction is generally used if the lens is evaluated to be extremely dense.

Phacoemulsification is defined by Czygan and Hartung (1996) as "...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." In a study by Stark, et al., (as cited by Lee, et al., 1993), "Surveys report that 96% of procedures performed for aging-related cataracts include insertion of an intraocular lens." IOLs are generally plastic, silicone, or acrylic. This is in contrast to the use of "coke bottle" glasses in years past before IOLs were available. Phacoemulsification has several advantages over other techniques. The incision size is minimal, a smaller amount of anesthesia is used, cost is less, surgery can occur in an outpatient setting, recovery is more rapid, and with the use of IOLs, more "normal" vision can be restored (Massengill, 1986). However, there are several complications that phacoemulsification can lead to which can result in acute or chronic poor outcomes. The complications are: expulsive choroidal hemorrhage, rupture of the posterior capsule, vitreous loss, corneal abrasions and cloudiness, retinal detachment, cystoid macular edema, ptosis, lens implant

dislocation, intraocular pressure elevation, problems stemming from the injection of local anesthesia, and infections such as uveitis or endophthalmitis (Endophthalmitis-Vitrectomy Study Group, 1996; Kapusta, Chen, and Lam, 1996; Lee, et al., 1993). It should be noted that secondary complications can arise from the use of phacoemulsification. Individuals often develop a secondary cloudiness in the posterior capsule, which then requires a YAG laser treatment to create an opening that allows light to get through (Massengill, 1986). YAG laser treatment can cause retinal detachment and if not treated immediately will cause blindness.

Average Phacoemulsification Power. The hardness of the lens (degree of nuclear sclerosis) determines how much phacoemulsification power is needed and its length of use during surgery. The surgeon must evaluate this in order to plan for surgery. The hardness of the lens is recorded as trace, 1+, 2+, 3+, 4+, early brunescence, brunescence, or advanced brunescense. This is a subjective measurement. A harder lens, and in turn, use of greater phacoemulsification power during surgery has been linked to a greater risk for surgical complications and a possible negative affect on visual outcome. For this reason, when a lens is determined to be extremely hard, the surgeon may choose to use extracapsular extraction rather than phacoemulsification. Dick, Kohnen, Jacobi, and Jacobi (1996) found that a higher phacoemulsification power produces greater endothelial cell loss (ECL), which negatively affects visual acuity.

Operative Complications. A host of operative complications exist that may ultimately affect visual acuity outcome. Those complications include, but are not limited to, posterior capsule rupture, anesthetic problems, various kinds of hemorrhaging, lens dislocation, vitreous loss, and increased IOP. Posterior capsule rupture is the most

frequent complication encountered by new surgeons, but is less common in the experienced surgeon. This complication can result in cystoid macular edema and retinal detachment, which can cause blindness. High risk for posterior capsule rupture is seen in phacoemulsification of brunescent (dense) cataracts, posterior pole cataracts, or very soft cataracts encountered in young patients. The use of high power, high vacuum, high aspiration phacoemulsification increases the likelihood of this complication (Steinert, 1995). Retrobulbar hemorrhage (or any excessive bleeding) is another operative complication that can lead to decreased visual acuity. Excessive bleeding can cause an increase in IOP which is very threatening to vision and can lead to other complications such as iris prolapse and vitreous loss.

Postoperative Complications. Like operative complication, many postoperative complication possibilities exist. Wound dehiscence, corneal edema, and glaucoma are examples of postoperative complications that may affect visual acuity outcome. Wound dehiscence is a weakness of the eye where the incision was located. Two years following an incision of the eye, structural integrity at that location is only 75% - 80% of what it was originally (Steinert, 1995). The incidence of a complication due to wound dehiscence is rare, occurring in less than 5% of cataract surgery patients, usually those patients with profound systemic illness and malnutrition. Corneal edema, another rare complication, is caused by trauma from the surgical instruments or IOL, prolonged use of phacoemulsification, and toxicity by chemical contaminants. Glaucoma, a common postoperative complication, can also affect visual acuity. The odds of developing a glaucoma complication are greater in those with pre-existing glaucoma. Viscoelastic

agents, which protect tissue surfaces from mechanical damage during surgery, may be associated with an early increase in IOP following surgery.

CHAPTER 3

Methods

Sample Data Source

Sample data for this study came from the medical records of an ophthalmology practice in San Marcos, Texas. Subjects were limited to patients receiving cataract surgery with no other surgery performed concomitantly and no previous surgery on the operated eye. Surgical data were abstracted during 2 six-month periods: January through June 1997 and October through March 2000. Two surgeons performed all cataract surgeries in the study. A data collection form containing 162 variables and developed by the ophthalmologists and previous researchers, (Borders, 1998) contained all necessary information for this study. Appendix D contains a copy of the data collection form. All data were abstracted from the collection form to an Excel database. SPSS 10.0 was used for all statistical calculations. Data from the collection form can be divided into 3 major areas: pre-existing variables, surgical variables, and postoperative variables. Appendix E contains the data dictionary for the collection instrument and spreadsheet (Borders, 1998). Data collected under each category are as follows:

1. Pre-existing variables
    a. Demographics (age, sex, race)
    b. Medical conditions (diabetic, hypertensive, coumadin use)

c. Ophthalmology data (ARMD, glaucoma, high myopia, which eye receiving surgery, degree of nuclear sclerosis, had fellow eye received cataract surgery)

d. Behavioral data (smoker)

e. Preoperative best-corrected glare visual acuity

f. Preoperative best-corrected distance visual acuity (2000 data only)

g. Preoperative VF-14 scores (2000 data only; one surgeon only)

2. Surgical variables

a. Pre-operative risk factors (true or false, if true: pseudoexfoliation, Fuch's, post-op vitrectomy, posterior polar cataract, small pupil)

b. Sutures used (true or false)

c. Average power of phacoemulsification (found by multiplying the power of the phacoemulsifier by the duration of use)

d. Surgeon performing surgery

e. Operative complications (true or false, if true: vitreous loss, post capsule rupture, increased IOP, corneal problems, lens dislocation, anesthetic problems, bleeding)

f. Type of anesthesia used (retrobulbar, peribulbar, topical, or general)

3. Postoperative variables

a. Postoperative complications (true or false)

b. Number of days from surgery to final refraction visit

c. Postoperative best-corrected distance visual acuity taken at 3 week postoperative refraction visit

d. Group of outcome (20/40 or better, 20/50 or worse)

Statistical Analysis

Each patient was dichotomously coded as either a 0 (outcome 20/40 or better) or 1 (outcome 20/50 or worse). A continuous outcome score was calculated by converting the fractional Snellen notation into a decimal value. For example, Snellen notation of 20/40 is equivalent to 0.5. This method of conversion is regularly published in the Journal of Cataract Refractive Surgery. Appendix B contains the Snellen conversions.

First, descriptive statistics were calculated for each variable. Second, ANOVA and independent t-tests determined if there were any significant differences between the variables in each category and postoperative visual acuity. The Least Squares Difference (LSD) post hoc test was used to evaluate the difference in mean acuity outcome between the races, ages, and degrees of nuclear sclerosis. Degree of nuclear sclerosis was recoded into two groups based on the LSD test: group one consists of trace, 1+, 2+, and 3+ degrees of nuclear sclerosis and group 2 consists of 4+, early brunescence, brunescence, and advanced brunescnece. Race was recoded to represent 2 groups: all patients of Hispanic ethnicity and all patients not of Hispanic ethnicity. Age was recoded to represent 3 groups, 37-70, 71-80, and 81-100. Further analyses used the recoded variables. Third, t-tests were used to determine if significant differences exist in the average amount of phacoemulsification used for patients with high and low levels of nuclear sclerosis. Fourth, chi-square tests of association were performed to determine the association between each pre-existing, surgical, and postoperative variable and outcome group. In the instance that expected cell sizes were too small for analysis, Fisher's exact

test was used in lieu of chi-square. Fifth, chi-square tests of association were performed to determine if there were interactions between the pre-existing variables and age, race, or sex. Sixth, a logistic regression model was formed to determine those variables most significantly related to predicting poor visual outcome. Logistic regression predicts outcome group membership (20/40 or better and 20/50 or worse) when the dependent variable is dichotomous. Probability values for an outcome of 20/50 or worse given the independent patient characteristics were determined from the logistic model. Adjusted odds ratios were calculated for all significant variables in the regression model. An alpha level of 0.05 was used for all statistical tests.

CHAPTER 4

Results

Descriptive Analyses of the Sample Population

Demographics. The sample consisted of 236 surgeries. Sample demographic proportions approximate the San Marcos and national proportions. The city of San Marcos is 48.8% male, 78.5% Caucasian, and 21.5% all minorities combined according to the 1990 U.S. Census [on-line]. The U.S. population is 80.3% Caucasian and 19.7% all minorities combined. Table 4.1 contains the demographic proportions for the sample. The age distribution of San Marcos is 72% under age 35, 34% age 35 to 65, and 7% over age 65. The U.S. age distribution is 53% under age 35, 34% between 35 and 65, and 13% over age 65. Subjects ranged in age from 37 to 99 years with a mean age of 74 years.

Table 4.1

Sample Demographics

Variable	No.	%
Gender		
Male	91	38.6
Female	145	61.4
Race		
Black	3	1.3
Hispanic	39	16.5
Caucasian	193	81.8
Missing	1	0.4

Medical, Comorbidity, and Behavioral Variables. Table 4.2 contains the medical, comorbidity, and behavioral variable proportions. Scores on the preoperative VF-14 score ranged from 15.4 to 98.2 with a mean of 74.1. Preoperative glare visual acuity ranged from hand motion (0.009) to 20/15 (1.33), with a median of 20/300 (.067).

Table 4.2

Medical, Comorbidity, and Behavioral Proportions

Variable	No.	%	Variable	No.	%
Smoker	26	11.0	**Coumadin use**	15	6.4
Non-smoker	130	55.1	**Non-coumadin use**	219	92.8
Missing	80	33.9	**Missing**	2	0.8
Diabetic	41	17.4	**Hypertension**	114	48.3
Non-diabetic	192	81.4	**Non-hypertension**	119	50.4
Missing	3	1.3	**Missing**	3	1.3
Glaucoma	40	16.9	**Right eye**	111	47.0
Non-glaucoma	193	81.8	**Left eye**	125	53.0
Missing	3	1.3			
High Myopia	14	5.9	**1st eye cataract surgery**	144	61.0
Non-high myope	210	89.0	**2nd eye cataract surgery**	91	38.6
Missing	12	5.1	**Missing**	1	0.4
ARMD	43	18.2			
Non-ARMD	192	81.4	**Degree of nuclear sclerosis**		
Missing	1	0.4	**Trace**	17	7.2
			1+	27	11.4
			1-2+ and 2+	61	25.8
			2-3+ and 3+	94	39.8
			3-4+ and 4+	23	9.7
			Brunescence	0	0
			Advanced Brun.	8	3.4
			Missing	6	2.5

Surgical Variables. Table 4.3 contains the sample proportions of the surgical variables. The mean average power of the phacoemulsifier was 0.728, with values ranging from 0.01 to 5.76. The mean preoperative intraocular pressure was 13 with values ranging from 3 to 27.

Postoperative variables. Table 4.4 contains the proportion of sample subjects within each category of postoperative variable. Number of days post-surgery for the refractive visit ranged from 1 to 197 with a mean of 30. Best corrected visual acuity taken at the refractive visit ranged from finger count (0.01) to far sighted (20/15) with a mean of approximately 20/30 (0.689).

Table 4.3

Surgical Variable Proportions

Variable	No.	%
Performing surgeon		
One	43	18.2
Two	193	81.8
Preoperative risk factor		
Yes	52	22.0
No	178	75.4
Missing	6	2.5
Anesthesia		
Retrobulbar	168	71.2
Peribulbar	13	5.5
Topical	45	19.1
General	3	1.3
Missing	7	3.0
Sutures used	26	11.0
Not used	205	86.9
Missing	5	2.1
Operative complications		
Yes	14	5.9
No	219	92.8
Missing	3	1.3

Table 4.4

Postoperative Variable Proportions

Variable	No.	%
Postoperative complications		
Yes	13	5.5
No	216	91.5
Missing	7	3.0
Outcome Group		
20/50 or worse	47	20.0
20/40 or better	189	80.0

Analysis of Variance with LSD Post Hoc Tests and *T* tests for Significant Differences in Postoperative Visual Acuity Outcome

Race. One-way ANOVA and LSD test results on the variable race indicted a significant difference between Hispanics, white non-Hispanics, and African Americans and postoperative visual acuity, with the Hispanic patients obtaining significantly lower postoperative visual acuity (M = 0.57, SD = 0.25) than the white non-Hispanics and African Americans (M = .71, SD = 0.26). Based on the results of the LSD test, race was recoded into 2 groups: non-Hispanic ethnicity and Hispanic ethnicity. Table 4.5 and 4.6 summarize the results.

Table 4.5

ANOVA Table for Variable Race

Source of Variation	SS	DF	MS	F	Significance
Race	0.608	2	0.304	4.48	< 0.05
Error	15.171	232	0.067		
Total	16.325	234			

Table 4.6

LSD Table for Variable Race

Number of Cases	Race	Black	Hispanic	Caucasian
3	Black		*	
39	Hispanic	*		*
193	Caucasian		*	

Note. Asterisks (*) indicate significant differences.

Age. One-way ANOVA and LSD test results on the variable age indicted a significant difference between the ages when they were grouped into 10-year intervals and continuous outcome. Based on the results of the LSD test, age was recoded into 3 groups: 37-70, 71-80, 81-100. Table 4.7 and 4.8 summarize the results. Mean corrected distance visual acuity for each age group can be seen in Table 4.9.

Table 4.7

ANOVA Table for Variable Age

Source of Variation	SS	DF	MS	F	Significance
Age	2.284	5	0.457	7.475	<0.001
Error	14.053	230	0.061		
Total	16.337	235			

Table 4.8

LSD Table for Variable Age

Number of Cases	Age Group	37-50	51-60	61-70	71-80	81-90	91-100
10	37-50				*	*	*
11	51-60				*	*	*
55	61-70				*	*	*
106	71-80	*	*	*		*	*
48	81-90	*	*	*	*		
6	91-100	*	*	*	*		

Note. Asterisks (*) indicate significant differences.

Table 4.9

Final Visual Acuity Means for the Three Age Groups

Age Group	N	Mean Visual Acuity Outcome	SD	Snellen Notation
37-70	76	0.80	0.22	20/25 – 20/30
71-80	106	0.68	0.25	20/40 – 20/50
81-100	54	0.55	0.27	20/50 – 20/60

Degree of Nuclear Sclerosis. One-way ANOVA and LSD test results on the variable degree of nuclear sclerosis indicted a significant difference between the degree of nuclear sclerosis and postoperative visual acuity. Based on the results of the LSD test, degree of nuclear sclerosis was recoded into 2 groups: low nuclear sclerosis (trace through 3+ degrees) and high nuclear sclerosis (3-4+ through advanced brunescence). The mean postoperative visual acuity was 0.72 (SD = 0.25) for patients with lower degrees of nuclear sclerosis and 0.55 (SD = 0.25) for patients with higher degrees of nuclear sclerosis. Table 4.10 and 4.11 summarize the results.

Table 4.10

ANOVA Table for Variable Degree of Nuclear Sclerosis

Source of Variation	SS	DF	MS	F	Significance
Degree of Nuclear Sclerosis	0.912	5	0.182	2.737	<0.05
Error	14.918	224	0.066		
Total	15.830	229			

Means tests also identified significantly lower postoperative visual acuity for the following groups: diabetics, non-high myopes, patients with ARMD, patients with

operative complications, and patients with postoperative complications. Table 4.12 contains the group means and standard deviations.

Table. 4.11

LSD Table for Variable Degree of Nuclear Sclerosis

Number of Cases	Degree of NS	Trace - 1+	1-2+ - 2+	2-3+ - 3+	3-4+ - 4+	All brunes.
44	Trace - 1+				*	*
61	1-2+ - 2+				*	*
94	2-3+ - 3+				*	*
23	3-4+ - 4+	*	*	*		
8	All brunes.	*	*	*		

Note. Asterisks (*) indicate significant differences.

Chi-square Analysis of the Associations Between Pre-existing Variables and Gender, Race, and Age

Race. There were no associations between recoded race and the following pre-existing variables: degree of nuclear sclerosis, hypertension, glaucoma, ARMD, smoking, coumadin use, right or left eye, or whether it was the patient's first or second cataract surgery. However, there was an association between recoded race and diabetes, χ^2 (1, N = 233) = 13.193, $p < 0.001$, with a larger number of Hispanics (37.5%) positive for diabetes than non-Hispanics (13.5%). As previously stated, the postoperative visual acuity for the Hispanic portion of the sample was significantly lower than the non-Hispanic portion.

Gender. There were no associations between gender and the following pre-existing variables: race, degree of nuclear sclerosis, glaucoma, ARMD, smoking, coumadin use, right or left eye, or whether it was the patient's first or second cataract surgery. However, there was an association between gender and hypertension, χ^2 (1, N =

233) = 4.74, $p < 0.05$. Only 35 males (38.5%) had hypertension compared to 79 females (54.5%). There was no significant difference in postoperative visual acuity for either gender or hypertension status.

Table 4.12

Group Outcome Means for Postoperative Visual Acuity

Group	Mean	SD	*t*	Significance
Hispanic	0.57	0.251	-3.084	< 0.01
Non-Hispanic	0.71	0.261		
High nuclear sclerosis	0.55	0.252	-3.444	< 0.01
Low nuclear sclerosis	0.72	0.258		
Diabetic	0.59	0.244	-2.799	< 0.01
Non-diabetic	0.71	0.263		
Non-high myope	0.68	0.222	2.161	< 0.05
High myope	0.84	0.264		
ARMD	0.52	0.252	-4.724	< 0.001
Non-ARMD	0.73	0.252		
Operative complication	0.42	0.243	-4.148	< 0.001
No operative complication	0.71	0.253		
Postoperative complication	0.44	0.253	-3.579	< 0.001
No postoperative complication	0.70	0.255		

Age. Recoded age group was associated with 3 pre-existing variables: hypertension, ARMD, and degree of nuclear sclerosis. Fifty-nine percent of the 81-100 age group were positive for hypertension while the percentage of hypertensives in the 37-70 and 71-80 age groups was 33% and 55%, respectively. ARMD was present in 39% of the 81-100 group but only 5% and 17% in 37-70 and 71-80 groups. High degrees of nuclear sclerosis were present in 24% of the 81-100 group, but only 20.3% of the other age groups combined were positive for high degrees of nuclear sclerosis. Table 4.13 summarizes the findings. As mentioned previously, patients with ARMD and high levels of nuclear sclerosis had significantly lower postoperative visual acuity than their

counterparts. There was no significant difference in postoperative visual acuity for either patient's with hypertension or without.

Table 4.13

Significant Associations Between Recoded Age and Pre-existing Variables

Variable	N	df	χ^2	Significance
ARMD	235	1	23.870	< 0.001
Hypertension	233	1	11.045	< 0.01
Degree of Nuclear Sclerosis	230	1	6.858	< 0.05

For each of the above significant associations, interaction terms were created and entered into the stepwise logistic regression. Interaction terms were created in SPSS by using the interactions term option in designing the logistic model. This option allows the user to build interaction terms in any layer from the given variables in the dataset.

Chi-square Analysis of the Association between Outcome Group and Pre-existing, Surgical, and Postoperative Variables

The following variables were found to be significantly associated with the poor outcome group: diabetes, glaucoma, hypertension, ARMD, and high degree of nuclear sclerosis. Thirty-nine percent of diabetics had a poor outcome compared to only 15.6% of non-diabetics. Thirty-five percent of all patients with glaucoma also had poor outcome compared to only 17% of patients without glaucoma. Twenty-five percent of all hypertensives in the sample had a poor outcome compared to only 15% of the non-hypertensives. Only 15% of patients without ARMD had a poor outcome while 41.8% of patients with ARMD had a poor outcome. Lastly, 38.7% of patients with high degrees of nuclear sclerosis had a poor outcome compared to only 16.6% of patients with low degrees of nuclear sclerosis. Several variables had expected cell frequencies less than 5,

therefore, chi-square tests could not be performed. Those variables were: smoker, high myopia, type of anesthesia, IOL position, operative complications, and postoperative complications. Fisher's exact test was used to assess relationship when expected cell sizes were less than 5. Variables associated with outcome group using Fisher's exact test were: operative complications ($p<0.001$) and postoperative complications ($p < 0.05$). No further analysis was performed on operative and postoperative complications due to the small number of individuals in either category. Because the occurrence of both operative and postoperative complications was significantly associated with outcome group, future studies should be geared toward analyzing the variables predicting those events. Table 4.14 contains the chi-square values and p-values for the significant variables.

Table 4.14

Chi-square and Associated Probability Values for Variables Associated with Outcome Group

Variable	χ^2	Significance
Diabetes	11.675	< 0.001
Glaucoma	6.594	< 0.01
Hypertension	3.845	< 0.05
ARMD	15.719	< 0.001
Degree of nuclear sclerosis	8.344	< 0.01

Means Tests for the Difference in Age, Pre-operative VF-14 Score, and Average Amount of Phacoemulsification in the Outcome Groups

Means tests identified significant differences in age for the two outcome groups. The mean age of patients achieving 20/40 or better outcome was 72, while the mean age for patients not achieving 20/40 vision was 79. Table 4.15 summarizes the results for both the significant and non-significant results.

Table 4.15

Mean, Standard Deviation, Calculated T Value, and Significance for each Outcome Group by Age, Pre-operative VF-14 Score, and Average Amount of Phacoemulsification Power

Variable	Mean	SD	T	Significance
Age				
20/40 or better	72	10.40	-4.183	< 0.001
20/50 or worse	79	7.35		
Pre-operative VF-14 score				
20/40 or better	74.7	19.3	0.600	NS
20/50 or worse	70.3	27.7		
Average phacoemulsification power				
20/40 or better	0.685	0.726	-1.512	NS
20/50 or worse	0.893	1.148		

T-tests for Significant Differences in Average Power of Phacoemulsification Used for High and Low Degrees of Nuclear Sclerosis

No significant difference exists in average amount of phacoemulsification required to pulverize the lens in patients with high and low levels of nuclear sclerosis.

Logistic Regression to Determine Variables Best Predicting Poor Outcome

Initially, all pre-existing variables and interaction terms were placed in the logistic model. The forward stepwise logistic regression procedure was used to determine the variables that best predict postoperative corrected visual acuity of 20/50 or worse. An iterative process is used to estimate the logistic coefficients. All predicted values with an estimated probability of 0.5 or greater were classified as 1, postoperative corrected visual acuity of 20/50 or worse. None of the interaction terms entered into the final model, and

identified the following variables as predictors of postoperative visual acuity of 20/50 or worse:

1. ARMD
2. Diabetes
3. High levels of nuclear sclerosis (3-4+ through advanced brunescense)
4. Age 81-100 years
5. Age 71-80 years

The final logistic model had a –2 log likelihood of 172.6, a Nagelkerke R Square of 0.26 (26.0%), and a significant model chi-square of 38.38 ($p < 0.001$). The Hosmer and Lemenshow chi-square test, which tests the difference between the observed and expected predicted values, and consequently the model fit, was not rejected $\chi^2 (1, N = 225) = 5.22$; $p > 0.05$. Therefore, the model fits the data. The overall prediction accuracy of the model was 79.7%. The logistic model statistics summary is shown in Table 4.16 and the odds ratios and β coefficients are listed in Table 7.17.

Table 4.16

Final Logistic Model Summary

Measure	Value	Significance
-2 Log Likelihood	172.6	
Nagelkerke R Square	0.26	
Overall Prediction Accuracy	79.7%	
Model Chi-square	38.38	< 0.001
Hosmer & Lemenshow Chi-Square	5.22	> 0.05

Table 4.17

β Coefficients, Standard Error, Wald Statistic, Adjusted Odds Ratios, and 95% Confidence Intervals for Variables in Final Logistic Regression Model

Risk Factor	β	S.E.	Wald	p-value	Odds Ratio	95% CI for Odds Ratio Lower	Upper
Age 81-100	1.798	0.607	8.772	< 0.01	6.038	1.837	19.842
Age 71-80	1.150	0.568	4.102	< 0.05	3.159	1.038	9.616
Diabetes	1.427	0.450	10.031	< 0.01	4.164	1.722	10.068
ARMD	1.080	0.434	6.196	< 0.5	2.945	1.258	6.892
High Nuclear Sclerosis	1.052	0.489	4.634	< 0.05	2.863	1.099	7.463

Individual probabilities predicted by the final logistic model, given the presence (1) or absence (0) of the risk factor, are listed in Table 4.18. Note that the prediction accuracy for the model is 79.7%. Therefore, other factors not measured in this study affect visual acuity outcome. More research should be done to determine the additional variables that predict poor visual acuity outcome.

Table 4.18

Outcome Predictions Given Patient Characteristics

ARMD	Diabetes	High Nuclear Sclerosis	Age 81-100	Age 71-80	Probability Of ≤ 20/50	Probability Of ≥ 20/40
0	0	0	0	0	3.6	96.4
0	0	1	0	0	9.7	90.3
1	0	0	0	0	9.9	90.1
0	0	0	0	1	10.6	89.4
0	1	0	0	0	13.5	86.5
0	0	0	1	0	18.5	81.5
1	0	1	0	0	24.0	76.0
0	0	1	0	1	25.3	74.7
1	0	0	0	1	25.8	74.2
0	1	1	0	0	30.9	69.1
1	1	0	0	0	31.5	68.5
0	1	0	0	1	33.0	67.0
0	0	1	1	0	39.3	60.7
1	0	0	1	0	40.0	60.0
0	1	0	1	0	48.5	51.5
1	0	1	0	1	50.0	50.0
1	1	1	0	0	56.8	43.2
0	1	1	0	1	58.5	41.5
1	1	0	0	1	59.2	40.8
1	0	1	1	0	65.6	34.4
0	1	1	1	0	73.0	27.0
1	1	0	1	0	73.5	26.5
1	1	1	0	1	80.6	19.4
1	1	1	1	0	88.8	11.2

Note. 0 = Absence of Characteristic, 1 = Presence of Characteristic

CHAPTER 5

Discussion

The percentage of eyes in this study with final corrected postoperative visual acuity of 20/40 or better (80.0%) approximates the percentages found in other studies. For example, a meta-analysis of the cataract outcomes of 90 studies calculated a pooled percentage of eyes with postoperative visual acuity of 20/40 or better to be 89.7% (Powe, et al., 1994). The finding in this study that older age and the presence of ocular comorbidities increases the odds of poor postoperative visual acuity are also consistent with other studies (Desai, Minassian, and Reidy, 1999; Powe, et al., 1994; Norregaard, et al., 1998).

The odds ratios calculated in this study are similar to those found in other studies. A study by Norregaard, et al. (1998) calculated odds ratios and 95% confidence intervals for age 70 – 80, 81+, and ARMD to be 2.45 (1.21-4.92), 5.20 (2.48-10.92), and 1.47 (0.89-2.44), respectively. Refer to Table 4.17 for a listing of the odds ratios associated with age in this study.

Within this sample, the largest single threat to achieving visual acuity of 20/40 or better for individuals of all age groups is diabetes. This may indicate that diabetes inflicts more severe damage to the retina than ARMD. Future studies on cataract outcomes should collect information on the number of years since patients were diagnosed with

diabetes. Potentially, a "dose-response relationship" between time since diabetes diagnosis and visual outcome could be found, which would aid in the prediction of postoperative acuity for diabetic patients. In this sample, the odds of a poor outcome in patients with diabetes are 4.16 times that of patients without diabetes.

The smallest single threat investigated in this study to achieving visual acuity of 20/40 or better is high levels of nuclear sclerosis. However, this finding should be interpreted with caution. Because cataracts are uncommon at young ages, high levels of nuclear sclerosis are also unlikely, making this finding impractical for the youngest of the 70 and younger age group. In this sample, the odds of experiencing a poor outcome in patients with high levels of nuclear sclerosis is 2.86 times that for patients without high levels of nuclear sclerosis.

Although an interaction between both age and nuclear sclerosis and age and ARMD was identified, the interaction terms did not enter into the final logistic model. As the name implies, ARMD is a condition that worsens with age, as is nuclear sclerosis. It is known that older individuals are at increased risk of poor outcomes for many surgical interventions. The Blue Mountains Eye Study by Wang, et al. (1999), verified that ARMD occurs independent of cataract development. However, there is a synergistic effect on visual outcome related to both ARMD and age. Knowledge of the time since diagnosis with ARMD might be useful in the same way that time since diagnosis with diabetes would be useful. A potential dose-response relationship between length of ARMD and visual outcome might exist.

The final logistic model for this study yields a relatively low coefficient of determination (0.26), meaning that variables not accounted for in this study explain a

significant proportion of the variation in visual outcome. The strong possibility exists that subjective preoperative tests such as the VF-14 could explain some of the unknown variation in outcome. Formulation of a model that includes both objective measurements (patient characteristics, comorbidities, etc) and subjective measurements (VF-14) is a likely solution to the problem. Due to the small number of patients who completed the VF-14 in this study, analyses using subjective measures were inappropriate.

In summary, the five predictors of an unsuccessful cataract surgery are age 81-100, the presence of diabetes, a high level of nuclear sclerosis (3-4+ and worse), ARMD, and age 71-80. If an 81-100 year old patient presents with ARMD, diabetes, and 3-4+ nuclear sclerosis, there is only an 11% probability that the cataract surgery will allow the patient to see 20/40 or better. A patient with diabetes, ARMD, 3-4+ nuclear sclerosis and aged 71-80 has a 19% probability of attaining 20/40 or better vision. This information should facilitate a patient's decision to have or not to have cataract surgery. The more accurate probabilities of success determined in this study should also minimize disappointment in visual outcome in patients with ocular and health comorbidities related to poor outcome.

A future recommendation for this study is the utilization of a proven, reliable subjective index of functional impairment such as the VF-14. Subjective measures might possibly explain a larger proportion of the variation in visual outcome in patients with health and ocular comorbidites. Preoperative and postoperative subjective measures have correlated strongly with visual outcomes of cataract surgery in previous studies (Schein, et al., 1995; Tielsch, et al., 1995).

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APPENDIX A

Cataract Risk Factors and Significant Odds Ratios

Authors	Journal	Risk Factor	Odds Ratio
Chatterjee and Thyle, 1982	British Journal of Ophthalmology	Living in city slums Low caste Widowed Illiterate Low consumption of beans and lentils vegetables Low height Low weight Low weight/height Life-threatening diarrhea one episode more than one	1.8 3.0 2.2 7.5 2.3 1.8 1.8 1.9 1.6 4.1 21.0
Schwab, et al., 1988	Archives of Ophthalmology	Family history of cataract Diabetes mellitus Syphilis Single marital status Gout	2.6 2.8 6.0 1.9 5.0
Maraini, Pasquini, and Sperduto, 1990	American Journal of Epidemiology	Females (C) Less than high school education (All) Brown irises (N, M) Job location in sun (C, M) Leisure activities in sun (C, M) Family history of cataracts (PS, C, M) History of cortisone use (PS)	2.2 1.53 1.43 1.75 1.45 1.88 8.39

Type of cataract C indicates cortical, N, nuclear, M, mixed, PS, posterior subcapsular

APPENDIX B - Snellen Visual Acuity Scale Conversions

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
FC10 = Finger Count at 10	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	1.330

APPENDIX C

Functional Activities Included in VF-14 Questions

1. Reading small print, such as labels on medicine bottles, a telephone book, or food labels
2. Reading a newspaper or book
3. Reading a large-print book or newspaper or the numbers on a telephone
4. Recognizing people when they are close to you
5. Seeing steps, stairs, or curbs
6. Reading traffic, street, or store signs
7. Doing fine handwork such as sewing, knotting, crocheting, or carpentry
8. Writing checks or filling out forms
9. Playing games such as bingo, dominos, card games, or mahjong
10. Taking part in sports such as bowling, handball, tennis, or golf
11. Cooking
12. Watching television
13. Daytime driving
14. Nighttime driving

APPENDIX D - 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: 1. African-American 3. Caucasian 2. Hispanic 4. Other_____

ID Code (1) | Name (2) | Birthdate (3) | Age at Surgery(4) | Smoker? (5) Y N | Sex (6) M F | Race (7) | MD Initials (8) _____

Pre-existing Medical Conditions:

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

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

Pre-Operative Measurements: R L EYE? (18) Office Visit Date (19) _____ VLA1 (20) _____

Axial Length (21) | Axial Length of Fellow Eye (22) | Sphere (23) + Cylinder (24) x Axis (25) | Distance VA (26) | Near VA (27) | VA w/PRX (28) | Desired Refraction (29)

Pre-op Flat K (30) (Keratometer) x Pre-op Steep K (31) (Keratometer) x Pre-Op Axis (32) (Keratometer) | Sim Flat K (33) | Sim Steep K(34) | Pre-Op Sim K Axis (35) | Pre-Op K RP (Eff RP) (36)

Pre-Op Corneal Astigmatism - Keratometer (37) _____ (31-30;SteepK - FlatK) | Pre-Op Axis of Corneal Astigmatism - Sim K (38) _____ (34 - 33) | Pre-Op Spherical Equivalent (39) _____ (1/2 cylinder (24) + sphere(23)) | VF14PreOp _____

Surgery Variables: Date of Surgery (40): _____ Axis of Cataract Incision (48) _____ (usually 180 degrees)

IOL Style (41) (Model # of Lens) | IOL Power (42) (in diopters) | Total Phaco Time (43) | Average Power (44) | 100% Phaco Time (45) (43 * 44) | Degree of Nuclear Sclerosis (46) | IOP (47)

Increased operative risk factors? (49): Y N If yes, why? (50):
1. Pseudoexfoliation
2. Fuch's
3. Post op vitrectomy
4. Posterior polar cataract
5. Small pupil
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
2. Shoestring radial
3. Circumferential
4. Infinity
5. Vertical mattress
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
2. Post capsule rupture
3. Increased IOP
4. Corneal problems
5. Lens dislocation
6. Anesthetic problems
7. Bleeding
8. Other: _____

Decreased Post-Op Visual Acuity Suspected? (66): Y N
If yes, why? (67): 1. Diabetic Retinopathy 2. Macular Degeneration 3 Amblyopia
4. Other ( ): _____

Post-Op Measurements - First Visit): 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) VLA (74) AC Cell (76) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4

Post-Op Measurements - Second Visit: 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) VLA (83) AC Cell (85) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4

Post-Op Measurements - Third Visit: 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) VLA (92) AC Cell (94) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4

Post-Op Measurements - Fourth Visit: 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) VLA (101) AC Cell (103) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4

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

Post-Op Measurements - Refraction Visit (3 - 6 weeks Post-op): 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) VLA (128) 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_____ _____ _____
Sphere (131) Cylinder (132) Axis (133) Distance Visual Acuity (134) Post-Op Spherical Equivalent (158) (1/2 cylinder (132) + sphere(131)) Post-op K RP (Eff RP) (135)

_____ 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

Post-Op Measurements - Fifth Visit: 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) **VLA (110)** AC Cell (112) a. 0 b. trace c. 1 d. 1 - 2 e. 2 f. 2 - 3 g. 3 h. 3 - 4 i. 4

Post-Op Measurements - Sixth Visit (6-9 months Post-op): 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) **VLA (119)** 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

YAG Data: 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:

_____ _____ _____
Post-Op K Corneal Astigmatism (156) (137-136;SteepK - FlatK)
Post-Op Sim K Corneal Astigmatism (157) (140 - 139; Sim Steep K - Sim Flat K)
Post-Op Spherical Equivalent (158) (1/2 cylinder + sphere of cyclopegic refraction)

_____ _____ _____
Difference between Post-Op Spherical Equivalent & Desired Refraction (159) (157 - 29, include + and - signs)
Change in Axis of Astig. (160) (As previously discussed) **
Difference in VLA (161)

APPENDIX E – Data Dictionary in Alphabetical Order

ACCEL1V	Condition of the anterior chamber cells on the first post-op visit. Subsequent post-op visits numbered as ACCEL2V, ACCEL3V, etc.
ACCELRV	Condition of the anterior chamber cells on the refractive post-op visit.
ACFL1V	Condition of the anterior chamber fluid on the first post-op visit. Subsequent post-op visits numbered as ACFL2V, ACFL3V, etc.
ACFLRV	Condition of the anterior chamber fluid on the refractive post-op visit.
AGESUR	Age at time of cataract surgery.
ARMD	Age-related Macular Degeneration, CODE: 0 = False, 1 = True NOTE: This answer was determined by what was present on the data collection form. If AMD was not noted on the form, an assumption was made the answer would be false.
ANESTH	Type of anesthesia used during surgery. CODE: 1 = Retrobulber; 2 = Peribulber; 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.

CORN1V	Condition of cornea on the first post-op visit.Subsequent post-op visits numbered as CORN2V, CORN3V, etc.
CORNRFV	Condition of cornea on the refractive post-op visit.
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 cannot analyze dates. Subsequent post-op visits numbered as DATE2V, DATE3V, etc.
DATE1VN	Number of days for the first visit after surgery. Subsequent post-op visits numbered as DATE2VN, DATE3VN, etc.
DATEOFVS	Date of the pre-op office visit. SPSS cannot analyze dates.
DATEREFN	Number of days post surgery for the refraction visit.
DATEREFV	Date of refractive post-op visit. SPSS cannot analyze dates.
DATESURG	Date of intraocular lens replacement/cataract surgery. SPSS cannot analyze dates.
DESREF	Desired refraction. Goal for post-op refraction measurement.
DIABETES	CODE: 1 = True; 0 = False. NOTE: This answer was determined by what was present on the data collection form. If diabetes was not noted in the medical record, an assumption was made the answer would be false.
DIFVA	Difference in pre-op distance visual acuity and post-op visual acuity.
DIFVLA	Difference in VLA pre-op and post-op.

DVARVCAL	Surrogate variable for DVARVPO.
DVARVPO	Distance visual acuity on the refractive visit. SPSS cannot analyze, so used surrogate variable DVARPO.
EFFRP2	Post-op K RP, effective RP. Not included in analysis.
EYER-L	Operated eye, CODE: 1 = Right; 2 = Left.
FELEYECS	Has cataract surgery already occurred in the fellow eye? CODE: 1 = True; 0 = False; 99 = Not applicable, person does not have a fellow eye.
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.
GLAUCOMA	CODE: 1 = True; 0 = False. NOTE: This answer was determined by what was present on the data collection form. If glaucoma was not noted on the data collection form, an assumption was made the answer would be false.
HYPERTEN	CODE: 0 = False, 1 = True. NOTE: This answer was determined by what was present on the data collection form. If hypertension was not noted on the data collection form, an assumption was made the answer would be false.
ID	First and last initial.
INCLENG	Incision length.
IOLPOS	Intraocular lens position. CODE: 1 = Anterior chamber; 2 = Bag; 3 = Sulcus; 4 = Extracapsular.
IOLPOW	The power of the intraocular lens in diopters.
IOLSTYL	Style of the 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. Subsequent post-op visits numbered as IOP2V, IOP3V, etc.

IOPRFV	Interocular pressure on the refractive post-op visit.
KAXIS2	Post-op Steep K, axis measurement. Not included in analysis.
KINDSURG	Kind of surgery that has occurred in the operated eye. This is a text variable. Not included in analysis.
MD	Initials of physician who performed surgery.
MYOPIAHI	Myopia-High, CODE: 1 = True, if the sphere is >= -5.0; 0 = False, if the sphere is < -5.0.
NAME	Full name, only on physician's copy of data.
NO	Unique ID number.
NOTES	Text field to explain anything that appeared to need further explanation. Not included in statistical analysis.
NUCSLR	Degree of nuclear sclerosis (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.
OPCOMP	Where there any operative complication? CODE: 1 = True; 0 = False.
OPRISK	Does this person have any increased operative risk factors? CODE: 1 = True; 0 = False.
PAXCASK	A calculate field. Pre-operative axis of corneal astigmatism minus the Sim K, that is the Sim K minus the Sim Flat K.
PAXIS	Pre-operative axis measurement.
PCASK	A calculated field. Pre-operatively 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. Not included in analysis.

PHACOTIM	The total amount of time the phacoemulsifier was on.
PKRP	Pre-operative K RP or effective RP (measurement taken with simulator).
POCOMP	Were there any post-op complications? CODE: 1 = True; 0 = False.
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 statistical analysis.
POSCAP1V	Condition of the posterior capsule on the first post-op visit. Subsequent post-op visits numbered as POSCAP2V, POSCAP3V, etc.
POSE	Post-op spherical equivalent (as calculated by this formula: ½ post-op cylinder + post-op sphere).
POSTCPRV	Condition of the posterior capsule on the refractive post-op visit.
POSTSUB	Posterior subcapsular changes in the lens.
PREVSUR	Has the operated eye had any previous surgery? CODE: 1 = True; 0 = False.
PSHEQ	Pre-operative spherical equivalent (as written on data collection form.)
PSHEQCL	Pre-operative spherical equivalent (as calculated by formula: ½ 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.

RACE	CODE: 1 = African American; 2 = Hispanic; 3 = Caucasian; 4 = Other.
SEX	Gender, CODE: 0 = Male; 1 = Female.
SIMFLK	Pre-operative Sim Flat K measurement taken with simulator.
SIMFLK2	Post-op Sim Flat K measurement.
SIMFLKAX	Pre-operative Sim Flat K axis measurement taken with simulator.
SIMSTK2	Post-op Sim Steep K measurement.
SIMSTPK	Pre-op Sim Steep K measurement taken with simulator.
SKCRNASG	Post-op Sim K corneal astigmatism. Calculated field.
SPHERE	Sphere measurement of eye to be operated on. A measurement of >= -5.0 indicates high myopia and potential complications.
SPHERE2	Sphere measurement on the refractive visit.
SMOKE	Does the collection form indicate if this person ever smoked regularly? CODE: 1 = True; 2 = False; 3 = Unknown.
SSKAXIS2	Post-op Steep K axis measurement.
STEEPK	Post-op Steep K 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	Were 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. Subsequent post-op visits numbered as VA2V, VA3V, etc. SPSS cannot analyze. Surrogate variable, VA1VCAL, created.

VA1VCAL	Surrogate variable for VA1V based on Snellen visual acuity conversions in Appendix B. Subsequent post-op visits numbered as VA2VCAL, VA3VCAL, etc.
VADECSUP	Is a decrease in post-op visual acuity suspected? CODE: 1 = Yes; 2 = No.
VADIS	Pre-op distance visual acuity. A scale was developed because SPSS cannot calculate fractions or text.
VADISCAL	Used scale in Appendix B to calculate pre-operative near vision visual acuity.
VAREFCAL	Surrogate variable for VAREFV based on scale on Appendix B.
VAREFV	Visual acuity on the day of the refractive visit. A scale was developed because SPSS cannot calculate fractions or text.
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. Not included in statistical analysis.
VF14PREO	Pre-op VF-14 score.
VISIOND	Was there decreased vision postoperatively? CODE: 1 = Yes; 2 = No.
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.
WHYOPRTXT	Text that explains "Other" reason for increased operative risk factor. Not included in statistical analysis.

WOUND	Type of initial wound used in surgery. CODE: 1 = Scleral pocket; 2 = Clear corneal tract.
>=20/40	Postoperative visual acuity achieved was greater than or equal to 20/40; CODE: 0 = False, 1 = True.

APPENDIX F – New Data Collection Form

(Continues on following 3 pages)

Cataract Surgery Data Collection Instrument (Rev. 08/02/00)

Background and Demographic Variables:

ID Code (1) _____ Name (2) _____ Birthdate (3) _____ Age (4) _____ Sex (5) M F Race (6) 1 African American 2 Hispanic 3 Caucasian 4 Other MD Initials (7) _____

Smoker (8) Y N # Cigarettes Smoked/Day (9) _____ # Years Smoking (10) _____

Pre-existing Medical Conditions:

	Mark with X	Year of Diagnosis
Diabetes (11)		
Glaucoma (12)		
High Myopia (13)		
Hypertension (14)		
Coumadin (15)		
ARMD (16)		
Cataract Surgery on Fellow Eye? (17)		
Previous Surgery on Operated Eye? (18)		
Type of Surgery on Operated Eye (19)		

Surgery Variables:

Date of Surgery (40) _____
IOL Style (41) _____
IOL Power (42) _____
Phaco Time (43) _____
Average Power (44) _____
100% Phaco Time (45)

Degree of NS (46) _____
IOP (47) _____

Preoperative Measurements:

Eye R or L (20) _____
Office Visit Date (21) _____
Axial Length (22) _____
Axial Length of Fellow Eye (23) _____
Sphere (24) _____
Cylinder (25) _____
Axis (26) _____
DVA (27) _____
NearVA (28) _____
Desired Refraction (29) _____
Preop Flat K (30) _____
Preop Steep K (31) _____
Sim Flat K (32) _____
Sim Steep K (33) _____
Preop Sim K Axis (34) _____
Preop K RP (35) _____
Preop Corneal Astigmatism - Keratometer (36) (Steep K - Flat K) _____

Preop Axis of Corneal Astigmatism - Sim K (37) (Sim Steep K - Sim Flat K) _____
Preop Spherical Equivalent (38) (1/2 Cylinder + Sphere) _____
VF-14 Preop (39) _____

Increased Operative Risk Factors (48)			Y	N	IOL Position (55)	1. AC	
If yes, why? (49)	1	Pseudoexfoliation				2 BAG	
	2.	Fuch's				3 Sulcus	
	3	Postop vitrectomy				4 Extracapsular	
	4	Posterior polar cataract			Astigmatic Keratotomy (56)		
	5	Small pupil			Axis of AK (57)		
	6	Other			Length of AK Cuts (58)		
Type of Anesthesia (50)	1	Retrobulbar			# AK Cuts (59)		
	2.	Peribulbar			Operative Complications (60)		
	3	Topical			If yes, what? (61)	1 Vitreous loss	
	4	General				2. Post capsule rupture	
Initial Wound (51)	1	Scleral Pocket				3 Increased IOP	
	2	CC Tract				4. Corneal problems	
Sutures Used (52)			Y	N		5 Lens dislocation	
If yes, what type? (53)	1	10/0 nylon				6 Anesthetic problems	
	2.	Vicryl				7 Bleeding	
	3	Other				8 Other	
Suture Method (54)	1	Interrupted radial			Decreased postop VA Suspected (62)		Y N
	2.	Shoestring radial			If yes, why? (63)	1 Diabetic retinopathy	
	3	Circumferential				2 ARMD	
	4.	Infinity				3 Amblyopia	
	5	Vertical mattress				4 Other	
	6	Other					

Postop Measurements - First Visit: Date (64) _____ # Days Post Surgery (65) _____

Visual Acuity (66) _____ Cornea (67) _____ IOP (68) _____ Posterior Capsule (69) _____ VLA (70) _____

Postop Measurements - Second Visit: Date (71) _____ # Days Post Surgery (72) _____

Visual Acuity (73) _____ Cornea (74) _____ IOP (75) _____ Posterior Capsule (76) _____ VLA (77) _____

Postop Measurements - Thrid Visit: Date (78) _____ # Days Post Surgery (79) _____

Visual Acuity (80) _____ Cornea (81) _____ IOP (82) _____ Posterior Capsule (83) _____ VLA (84) _____

Postop Measurements - Refraction Visit (3-6 weeks postop): Date (85) _____ # Days Post Surgery (86) _____

Visual Acuity (87) _____ Cornea (88) _____ IOP (89) _____ Posterior Capsule (90) _____ VLA (91) _____

Postop Complications (92) Y N

If yes, what? (93)
1 Retinal detachment
2 Cystoid macular edema
3 Corneal Edema
4 Other

VITA

Ginger Dieterle was born in Enid, Oklahoma on February 2, 1975, the daughter of Carl and Barbara Dieterle. After completing her work at Drummond High School, Drummond, Oklahoma, in 1993, she entered Southwest Texas State University in San Marcos, Texas and received the degree of Bachelor of Science in Microbiology in August 1998. In August 1998, she entered the Graduate School of Southwest Texas State University, San Marcos, Texas.

Permanent address: 1917 Ramona

San Marcos, TX 78666

This thesis was typed by Ginger Dieterle.