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A COMPARISON

OF THE EFFECTIVENESS OF EYE PROTECTION METHODS

USED IN GENERAL ANESTHESIA

by

Larry W. Johnson Bachelor of Science, Viterbo University, 1997

A Thesis

Submitted to the Graduate Faculty

of the

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Science

Grand Forks, North Dakota August 2000 T9000 JT678

This thesis, submitted by Larry W. Johnson in partial fulfillment of the requirements for the Degree of Master of Science from the University of North Dakota, has been read by the Faculty Advisory Committee under whom the work has been done and is hereby approved.

Stenda Lindseth

(Chairperson)

treat

This thesis meets the standards for appearance, conforms to the style and format requirements of the Graduate School of the University of North Dakota, and is hereby approved.

Graduate School Dean 6-30-00

Date

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Title A Comparison of the Effectiveness of Eye Protection Methods Used in General Anesthesia

Department Nursing

Degree Master of Science

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ABSTRACT

The purpose of this quasi experimental, clinical study was to determine whether taping of the eye or applying ophthalmic ointment along with taping of the eye yields a difference in occurrence and symptoms of corneal epithelial defects in surgical patients undergoing general anesthesia. Orem's Self-Care Deficit Theory provided the theoretical framework for this study.

Fifty subjects were randomly selected from a convenience sample of surgical patients in two 300 bed hospitals located in a Midwestern state. The subjects ranged from 18 to 60 years of age. The subjects had no history of previous eye surgery or glaucoma, and were not currently wearing contact lenses. Patients with known allergies to tape or Lacra-lube were excluded from the study. Subject times were limited to three hours of general anesthesia.

The measurement tool used in this study was the Ocular Eye Symptom Sheet (Alcon Labs, Ft. Worth Texas). This tool was used to assess subjective symptoms commonly found with corneal epithelial defects. A pilot study of ten subjects was done to assure reliability. The instrument reliability

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had a split-half correlation coefficient of .64. Subjects who fit the criteria were approached by the researcher and informed of the study.

A questionnaire was used to measure the effectiveness of the Lacra-lube and tape methods of eye protection within 24 hours after general anesthesia. Pearson's t-test and Pearson's correlation \underline{r} were used to compute the relationships between the variables. The probability was set at 0.05.

There were differences in the number of complaints between the two methods of eye protection. An overall scale score showed that the patients who had the ointment and tape applied had a significantly higher epithelial defect symptoms than the patients who had received tape alone ($\underline{t} =$ 5.05, $\underline{df} = 48$, $\underline{p} = 0.001$). Results indicate that younger subjects had more complaints about the eye with cintment and tape than older subjects. Results also showed that the method of applying only tape to the eye had more complaints when the surgical time is longer than 60 minutes.

From the data supplied in this study the use of routine ointment and tape for eye protection for young adults and those with short surgical procedures is not recommended. In older adults and those with longer surgical times Lacra-lube appears appropriate for use.

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CHAPTER I

INTRODUCTION

General anesthesia is the state in which depression of the central nervous system leads to a lack of response and perception from external stimuli (Barash, Cullen, & Stoelting, 1997). General anesthesia reduces tear production and abolishes protective reflexes that occur normally (White & Crosse, 1997). In patients who undergo general anesthesia and receive no eye protection, as many as 44% have been found with corneal epithelial defects (Batra & Bali, 1977). In another study, up to 90% of patients who did not receive eye protection had corneal defects (Grover, Kumar, Sarma, Sethi, & Grewal, 1998).

In a study of surgery related lawsuits it was discovered that corneal epithelial defects are the largest ophthalmic complication following general surgery. The median settlement payment of 3,000 dollars was awarded to those injured (Gild, Posner, Caplan, & Cheney, 1992).

Eye protection usually consists of taping the eye lid closed following intubation of the patient or instilling a paraffin-based ointment, Lacra-lube, into the conjunctival sac and then taping the eye shut. Taping the eye lid shut

is the easiest way to protect the eye. The post-operative incidence of corneal epithelial defects following taping ranges from 0.17% to 6.60% (Grover et al., 1998; Cucchiara & Black, 1988).

The instillation of eye ointment and then taping the eyes shut has an incidence of corneal defects that ranges from 0.17% to 3.30% (Grover et al., 1998, Cucchiara et al., 1988). Allergic reactions to the ointment, as well as halothane absorption to the ointment, can cause cornea damage and schlera edema (Barash et al., 1997).

Complications from instillation of eye ointment can and do occur by the anesthetist who accidentally may touch the eye and cause cornea damage. Furthermore, it has been observed post-operatively that patients who had ointment sometimes rub their eyes (Cucchiara et al. 1988).

Purpose of the Study

The purpose of this study was to compare the effectiveness of the two most common methods used to protect eyes during general anesthesia. The first method was taping the eyelid closed. The second method was instilling eye ointment and then taping the eyelid closed. This study compared the differences in eye discomfort reported by the participants after receiving either of the eye protective methods during general anesthesia.

Review of Related Literature

Anatomy of the Eye

The cornea is the clear transparent covering of the eye. It covers the anterior part of the eye. It is an avascular structure receiving its oxygen from the atmosphere and from anterior ciliary blood vessels (Miller & Keane, 1983, White & Crosse, 1998). A pre-corneal tear film is what protects the cornea. The tear film has a lipid outermost layer that increases surface tension and prevents the middle aqueous layer from overflowing. It also prevents drying of the eye. The inner aqueous layer that is secreted by the lacrimal glands helps supply oxygen to the cornea and keeps the cornea free of debris. The thickness of the film is maintained by blinking. The thickness is 8.7 μ m after blinking. Without blinking 30 seconds later, the film measures 4.5 μ m (Jones, 1966).

Treatment of Corneal Abrasion

When a patient wakes up after surgery and experiences severe eye pain, an examination should be performed. An ophthalmologist is usually consulted. If one is not available, the anesthesiologist or surgeon should accept the responsibility for treatment and diagnosis (Terry et al. 1965). The diagnosis of a corneal abrasion is made by the use of florescein strips that touch the eye then a

few drops of normal saline is applied to the eye. The eye is then examined under a blue light. The irregular surface of the abrasion will stand out against the smooth epithelial tissue of the eye. An antibiotic ophthalmic ointment is then applied and the eye is patched with enough pressure to prevent the eye lid from moving when the patient opens his or her eyes. Follow up by an ophthalmologist is usually done within 24 hours. Most defects or abrasions heal very quickly and are resolved in 24-48 hours (Lanros, 1982).

Eye Problems Related to General Anesthesia

The problem of corneal epithelial defects has been associated with the most common ocular complication of general anesthesia (Gild et al., 1992). This problem has been associated not only with dry eyes following incomplete closure of the eyelid (lagophthalmos), but also with other risks that could cause corneal epithelial defects. During the induction phase, a patient is sedated and then paralyzed for facilitation of intubation. It has been reported that poor technique in intubation may possibly cause direct damage to the eye when performing direct laryngoscopy. Plastic ID cards that are worn by anesthetists on their vest pocket also can cause corneal abrasions if the anesthetist leans over the patient and inadvertently touches the unprotected eye (Watson & Moran, 1987). The eye can also be injured by the anesthetist's hands or even the face masks

placed inadvertely over the patient's still open eyes (Snow, Kripke, Norton, Chandra & Woodcome, 1975). Other mechanisms that can cause corneal epithelial defects include surgical drapes drawn across a patients face, or instruments such as a laryngoscope accidentally falling onto a patient's eye (White & Crosse, 1998, Gild et al., 1992).

The position of the patient can contribute to corneal epithelial defects. Patients who are in the prone position should have their heads in the neutral position. If the head is turned to one side or the other, this causes a decrease in venous return from the head and raises interocular pressure. This may cause corneal edema and lead to an abrasion (White & Crosse, 1998). Positioning is critical to prevent any ocular damage. Patients who are in prone or jack-knife positions and have pressure to the globe of the eye from lack of padding or shifting of padding over the eye are at risk for eye injury. Improper positioning and padding can cause a reduction of circulation to the eye (Barash et al., 1997). This finding was reported in a study of patients who experienced a higher incidence of corneal defects with their heads turned. All the patients with corneal defects had the defects in the down turned eye (Cucchiara & Black, 1988).

Protective Mechanisms of the Eye

When a patient falls asleep normally, Bells Phenomena occurs. This is a protective mechanism for the cornea in which the eyeball turns upward during sleep. This phenomena does not occur with general anesthesia. The blink reflex that promotes the tear film is also abolished (White & Crosse, 1998).

Eyelid closure is caused by a contraction of the orbicularis muscle when someone falls asleep normally (White & Crosse, 1998). Incomplete closure, or lagophthalmos, occurs in only 4.6% of the population (Fuchs & Wu, 1948). During general anesthesia, the rate of lagophthalmos rises to 59% (Batra & Bali, 1977).

This correlates very closely with post-operative examinations of eyes with corneal abrasions following general surgery. The eye is divided into three different zones: the upper, middle, and lower zone. The postoperative results show that no defects were found in the upper zone. In the middle zone, approximately 30% of abrasions were found. In the lower zone, approximately 69% of the abrasions were found (Grover et al., 1998). This correlation strongly suggests that incomplete eyelid closure accounts for the majority of abrasions.

General anesthesia has other effects on the eyes as well. A study of basal tear production among anesthetized patients found that the average production of basal tears was 2mm/ 5 minutes after one hour of anesthesia. Before anesthesia, the average rate of tear production was 23.3mm/ 5 minutes. This study shows a dramatic inhibition of basal tear production. The basal tear film is used as a wetting agent for lubrication for the cornea and eyelids. It also provides nutrition and hydration for the cornea (Cross & Krupin, 1977). Because of the inhibition of both protective reflexes and the decrease in basal tear production, general anesthesia can create an environment that enhances the chance for patients to develop corneal epithelial defects.

Effect of Protective Methods on Eyes

During General Anesthesia

A study was done and concluded that only taping the eyelids shut during surgery might not be enough protection to prevent drying of the eyes. The research suggested using both tape for mechanical closing of eyes and ointment for artificial replacement of tears (Krupin, Cross & Becker, 1977).

In a study of 4,652 patients, approximately half received taping of eyes and the other half received ointment and taping. The results showed that the incidence of corneal abrasion was the same (0.17%). The article

suggested that patients in whom eye ointment had been instilled were observed to be rubbing their eyes more frequently in the recovery room upon awakening. Rubbing their eyes increased the chance of giving themselves a corneal epithelial defect. The conclusion was that the use of eye ointment was optional during surgery (Cucchiara & Black, 1988).

In a study of 120 patients, paraffin ointment was compared to 4% methylcellulose drops for protection. It was found that there were no complications in the 4% methylcellulose group (water based). However, the paraffin ointment (Lacra-lube) group had a higher rate of blurred vision, conjunctival erythema, and eyelid edema. All three problems were higher in those who received halothane. Since halothane is 40 times more soluble in paraffin based products compared to methylcellulose, it is possible that the inflammation experienced by the eye was due to higher concentrations of halothane (Boggild, Bungarrd, Hammer & Jakobsen, 1981).

An article that used different protection methods concluded that routine instillation of ointment to the eye does not offer any sufficient protection. In fact, the practice of routine eye ointment instillation may contribute to greater ocular morbidity (White & Crosse, 1998).

In a study of 150 patients that compared eye protection methods of taping and ointment versus a control group that received no protection, interesting results were shown. A11 the patients in the study received pre-operative examinations by fluorescein staining. No corneal defects were found in any of the patients pre-operatively. Postoperative examinations were also performed by fluorescein The control group that received no protection had staining. a post-operative examination showing a 90% rate of corneal defects. Again, a post-operative examination was done on the group that received tape alone for protection and results showed that 6.6% had an incidence of corneal defects. The group that received ointment plus tape had a lower rate, 3.30%, of corneal defects (Grover, et al., 1998).

The chance of a corneal defect occurring during surgery is a real problem. The chance of one occurring using common protective methods such as taping or the use of ointment is fairly low. The literature review puts it at a low of 0.17% (Cucchiara & Black, 1988), to a high of 6.6% (Grover et al., 1998). The review shows that the data can be conflicting. Some articles advocate the use of ophthalmic ointment along with the taping of the eye (Cross & Krupin, 1977; Krupin et al., 1977).

Other articles advocate the use of tape alone stating that there is no advantage to using ointment because of possible adverse reactions to the ointment including schlera edema and increased concentrations of halothane accumulated in the ointment (White & Cross, 1998; Cucchiara & Black, 1988). Corneal epithelial defects during general anesthesia occur as a result when the normal protective reflexes that prevent the drying of the cornea are inhibited. Some mechanisms prevent the eye lid from completely closing such as lagophthalmos (White & Cross, 1998). Other mechanisms, such as decreased basal tear production, also contribute to the possibility of a corneal epithelial defect (Krupin et al., 1977).

The majority of corneal defects that occur during general anesthesia do not occur from trauma. Instead, most corneal defects are caused by exposure or drying of the corneal epithelial tissue. Few corneal abrasions that occur by exposure result in any permanent damage. However, the eye is often very sensitive after a corneal defect. Signs and symptoms of a corneal defect can include a foreign body sensation. Patients may also experience tearing and photophobia -- eyes sensitive to light (Terry, Kearns, Grafton-Love & Orwell, 1965; Barash et al., 1997).

Summary

The goal of general anesthesia is to promote a smooth state of unconsciousness. This often is not achieved without diminishing protective reflexes that protect the cornea (White & Crosse, 1998). It is the anesthetist's responsibility to provide adequate protection for the unconscious patient. Selecting the appropriate eye protection is imperative. Research shows that without proper eye protection, a corneal defect is likely (Batra & Bali, 1977). An anesthetist must consider the positioning of the patient to prevent any pressure on the ocular eye (Barash et al., 1997). Using proper technique is important during intubation. Avoiding touching of eyes and using properly fitted face masks reduces the risk of corneal defects. Research shows that direct trauma to the eye can cause a corneal abrasion (Watson & Moran, 1987). The signs and symptoms of corneal defects include pain of the eye after waking up, photophobia, foreign body sensation, and tearing of the eyes (Terry et al., 1965; Barash et al., 1997).

It is clear from the studies that a form of eye protection is needed during general anesthesia (Batra & Bali, 1977). However, it is not clear from the literature which method, taping or using ointment with tape, is best. Both methods have advantages and potential disadvantages

when used. Taping has the advantage of being the easiest to administer, but does not provide artificial moisture to the eye (Krupin et al., 1977). Ointment provides the artificial moisture, but may expose the eye to adverse reactions (Barash et al., 1997). Therefore, it is important to be aware of and compare different protection methods. A knowledge base, which is made through comparative studies, is required for choosing the best selection of protective methods for each patient undergoing general anesthesia. The purpose of this study will attempt to add to the pool of knowledge by using human subjects in this study.

Significance of the Study

Since the eye is one of the major sense organs, it is important to protect during surgery. A non-protected eye can lead to permanent damage. The most common eye-related injury following general anesthesia is corneal abrasion. In litigation of damages, the average claim against the provider for this type of injury is 3,000 dollars (Gild et al., 1992). The literature review shows that there is a conflict of information related to the importance of using ophthalmic ointment in general anesthesia. Other sources of information conclude that the use of ophthalmic ointment is imperative in preventing corneal epithelial defects (Krupin et al., 1977).

The significance of this study was to determine which protection methods have the least incidence of corneal epithelial defect symptoms in patients who undergo general anesthesia. The information that is gained in this study will have a bearing on the use of proper protection for all patients who undergo general anesthesia in surgeries no longer than 3 hours.

No nursing studies have been done in this area. Consequently, a potential impact exists to provide better care to patients undergoing general surgery.

Definitions

Corneal epithelial defect: A corneal epithelial defect is an injury to the outermost and nonvascular layer of the cornea. This includes cornea abrasion and injury associated with drying of the cornea. Signs and symptoms include: Foreign body sensation, tearing, photophobia, and pain (Barash et al., 1997).

Foreign body sensation: A foreign body sensation is the feeling of an object or substance in tissue or an organ where it does not normally belong (Mosby, 1998).

General Anesthesia: State in which depression of the central nervous system leads to a lack of response from external stimuli and perception from external stimuli (Barash et al. 1977).

<u>Pain</u>: A unpleasant sensation caused by stimulated nerve terminals is called pain (Miller and Keane, 1983).

<u>Paraffin ophthalmic ointment</u>: A purified hydrocarbon that is used to protect the eye from drying. Lacra-lube is a common trade name (White and Crosse, 1998).

<u>Photophobia</u>: Eyes that are abnormally sensitive to light (Mosby, 1998).

<u>Taping of eyes</u>: The application of tape across the eyelid to shut the eye mechanically, and to prevent the eye from being open.

Research Questions/Hypothesis

The research questions that are being explored in this study are as follows:

 What is the incidence of corneal epithelial defect symptoms following general anesthesia using eye protective methods?

2. To what extent do overall symptom scores differ between corneal epithelial defect symptoms when using paraffin based ointment and tape compared to only taping patients' eyes following general anesthesia?

3. What is the relationship between the symptoms of corneal epithelial defects of an eye treated with tape and ointment versus an eye treated with tape only?

The hypothesis of this study was as follows: The incidence of signs and symptoms of corneal epithelial

defects will be greater in those patients who receive tape during general anesthesia compared to those who use paraffin based ointment.

Theoretical Framework

Orem's self-care deficit theory can be used to give direction for the nurse anesthetist in the practicing arena. It also gives a structure to organize nursing knowledge (Orem, 1991). The major assumption is that a person has universal needs such as air, food and rest. Health deviation needs, according to Orem, are the needs in which the individual has an inability to care for oneself. Health deviation needs can arise from a disease process which would form a dependence on caretakers. Those caretakers would provide care that the individual is eventually unable to perform. Anesthesia is also a health deviation in which self care deficits exist (Vasquez, 1992). Therefore, Orem's theory is very applicable to the practice of anesthesia.

The nursing action on behalf of the patient with a self care deficit can be described as wholly compensatory, partly compensatory, and educative-developmental. The wholly compensatory system is used by the nurse when the patient cannot take care of oneself. During anesthesia, this would mean that the nurse would maintain ventilatory support, fluid management, body temperature, and protection of the body due to lost reflexes during anesthesia. These lost

reflexes would be Bell's phenomena and the blink reflex (White & Crosse, 1998). Protection by the nurse anesthetist would include taping or instillation of ophthalmic ointment. Partially compensatory systems are used when a patient can perform some, but not all, self care functions. Actions performed by the nurse would be assisting in ambulating and removing of eve protection before discharge. The educational-developmental system would also be used by the nurse when the patient is ready to be discharged. This would include educating the patient and family how to implement home care activities; teaching the patient and family about new medications that could be started; educating them in appropriate follow-up instructions. The patient's final eye status would then be assessed before discharge (Orem, 1991).

Assumptions

The following assumptions were made for this study:

1. Patients with corneal and epithelial defects will probably complain of post-operative eye discomfort.

2. Patients undergoing general anesthesia will want their eyes protected.

3. Patients who are under general anesthesia feel no pain and cannot protect their own eyes.

4. Hospitals will want the most effective method of eye protection to protect patients eyes.

Limitations

The limitations recognized in this study are as follows:

1. The study is limited to patients aged 18 to 60 undergoing general anesthesia.

2. Inadvertent direct trauma on an eye during intubation could cause a corneal epithelial before eye protection methods are started.

3. A patient could possibly give themselves a corneal epithelial defect when waking up from anesthesia by rubbing his or her eyes regardless of protection methods used.

4. The study sample size is 50 subjects undergoing general anesthesia.

5. Data collected by the researcher could have resulted in inadvertent bias.

CHAPTER II

METHODOLOGY OF THE STUDY

Introduction

This study was designed to document the different ocular symptoms reported post-operatively by patients using paraffin based ointment and taping eyes during general anesthesia. In addition, this study attempted to determine whether a positive association exists between taping eyes during general anesthesia and a higher rate of signs and symptoms of corneal epithelial defects. This study was guided by Orem's self care deficit theory, explored through the following research questions:

 What is the incidence of corneal epithelial defect symptoms following general anesthesia using eye protective methods?

2. To what extent do overall symptom scores differ between epithelial defect symptoms when using paraffin based ointment and tape compared to only taping patients' eyes following general anesthesia?

3. What is the relationship between the symptoms of corneal epithelial defects of an eye treated with tape and ointment versus an eye treated with tape only?

Design

A comparative, quasi-experimental design was used to determine whether taping or using ophthalmic ointment, Lacra-lube, would result in a difference in the number of major complaints associated with corneal epithelial defects. The term comparative design was used because the scores of the dependent variable (the ocular symptoms, discomfort, itching, foreign-body sensation, and tearing) were used to compare the two groups of the independent variables (taping eyes or using ophthalmic ointment with tape on eyes) (Polit & Hungler, 1999). A quasi-experimental design was used because the independent variable was manipulated, and it lacked a control group because ethically the eyes need some type of protection (Polit and Hungler, 1999). This study is designed differently than other studies because it evaluates the symptoms associated with corneal epithelial defects and therefore more sensitive to changes associated corneal defects.

Population and Sample

Using a convenience sample, data was collected from male and female patients undergoing general anesthesia in an ambulatory surgery setting. The setting was in an urban community located in a Midwestern state. The size of the hospitals was approximately 300 beds. Other surgical sites were used when needed. The subjects selected for this study

were from 18 years to 60 years of age. They had no history of previous eye surgery or glaucoma, and did not wear contact lenses. Any deviation from these requirements would exclude the subjects from participating in the study. Patients with known tape allergies, or allergies to ophthalmic ointment (Lacri-Lube), were also excluded in the study. Lacra-lube was chosen because it is the most common ophthalmic ointment used in the surgical setting. The patients in this study were not subjected to general anesthesia for more than 3 hours (most surgeries are done by 3 hours). They were not in the prone position due to the possibility of pressure applied to the eye unknown to the anesthetist.

Subjects who fit the criteria were approached by the researcher and informed of the study. They were given the opportunity to participate or decline participation. The subjects could refuse to participate without bias.

Data Collection Methods

During the pre-anesthetic interview, possible subjects were enrolled in the study by verbally agreeing and understanding the potential risks and benefits associated with the study. A consent form was then signed by both subject and researcher. Subjects signing the consent form agreed to participate in the study. A copy of the questionnaire was left with the subject and questions that

were to be asked were explained to them before surgery. Participants were then called within 24 hours after general anesthesia, and the post anesthesia ocular questionnaire was administered over the phone.

The researcher was responsible for gathering all data. This process was repeated until 50 subjects had completed the study. The number of subjects was chosen by the researcher to assure a minimum of 100 eyes were evaluated during this study. The patient schedule and the preoperative anesthetic worksheet provided the names of the patients who were possible subjects for the research study. Treatment and Protocol

After agreeing to participate in the study, the subject was identified prior to receiving general anesthesia to ensure that proper technique was used for the study. The procedure for induction was either intravenous (thiopental or propofal) or by inhalation (halothane or sevoflorane). Once eyelid reflex was lost, a dose of a fast-acting muscle relaxant (succinylcholine or rocuronium) was given to facilitate endotracheal intubation. The subject was then intubated with care not to touch or cause any direct trauma to the eyes. Once proper placement of the endotracheal tube was verified and secured, the different protection methods of the eyes were initiated.

To ensure randomized treatment in this study, each subject's hospital number was used to determine treatment order. With an even hospital number, Lacra-lube was instilled in the subject's right eye and then taped and the left eye was taped shut without Lacra-lube. If the subject's hospital number was odd, the patient's right eye was taped shut without Lacra-lube and the left eye had Lacra-lube instilled and then taped shut. After surgery, when the subject's anesthesia was lightened and protective reflexes returned, the tape was removed from the patient's If any trace of ointment was observed under the eves. patient's eye, it was wiped off with a sterile 2x2 or 4x4gauze to prevent any bias from the subject when they completely recovered from anesthesia.

Before any data of the study was collected, the researcher reviewed the proper steps to assure reliability. The first step included assuring that the subject fit the proper selection criteria. The second step was to verify that the protection methods were applied toward the appropriate eyes based on the subject's hospital number. The subject was then called by the researcher, and the questionnaire was administered over the phone.

The demographic questions in the questionnaire included the subject's age, sex, the length of surgical procedure, and a description of other eye symptoms. To assure

reliability, the length of surgical procedure was filled out by the researcher.

Instrument Reliability and Validity

The instrument used was called the Ocular Symptom measurement sheet. It was provided by Alcon Labs of FT. Worth, Texas. The instrument was used by Alcon Labs to evaluate ocular symptoms. The survey tool for this study was used with permission from Alcon Labs in Ft. Worth, Texas. This tool was designed to score the common symptoms of corneal epithelial defects. The common symptoms include pain, photosensitivity, foreign body sensation, tearing, and itching of the eyes.

The patients' pain levels were scored on a scale from 0 to 9. The number 0 represented no pain and the number 9 represented extreme pain.

Foreign body sensation was assessed on a scale from 0 to 3. The number 0 represented no foreign body sensation, 1 represented a mild foreign body sensation, 2 represented a moderate foreign body sensation, and 3 represented a severe foreign body sensation.

Tearing of the eye was also assessed with the same 0 to 3 scale. The number 0 represented no tearing, 1 represented mild tearing, 2 represented moderate tearing, and 3 represented severe tearing. Itching of the eye was assessed in a slightly different manner. The following scale was used: 0.0 represented an absence of itching; 0.5 represents an intermittent tickling just in the corner of the eye; a score of 1.0 represented an intermittent tickling involving more than one part of the eye; 1.5 represented an intermittent tickling involving the whole eye; 2.0 represented a continuous itch not requiring rubbing; 2.5 represented a moderate continuous itch that the patient would like to itch; 3.0 represented a severe itch that the patient would like to rub; 3.5 represented a severe itch which requires minimal rubbing; and, a score of 4.0 represented an incapacitating itch that requires much rubbing.

The original tool was modified by adding demographic questions and by changing the questions to lay language. This was done with permission from the author. The author stated that reliability and validity had not been published. A pilot study of ten subjects was done to assure reliability. A split-half Spearman-Brown performed showed $r^{1}=.64$.

To assure content validity, the revised questionnaire was sent to a panel of five experts. The experts consisted of an Ocular Researcher, Ophthalmologist, Anesthesiologist, Certified Registered Nurse Anesthetist (CRNA), and a Nurse Researcher. They suggested that the symptoms included

tearing, photophobia, foreign body sensation, itching, and pain. The questionnaire was divided to measure both right and left eyes.

Data Analysis

Data was reported using descriptive statistics since the study tested the differences between two independent variables -- taping eyes and applying ophthalmic ointment, Lacra-lube, then taping. Pearson's r was used to compute the relationship between the variables. To prevent inaccurate results, the probability (P) was set at 0.05%. Chi-square determines the significance of the differences in the occurrences of subjective symptoms.

Protection of Human Subjects

Data collected, including the returned Ocular Symptom Measurement sheet is being locked in a file for 3 years. This is to assure that the protection of human subjects remained confidential and anonymous. Approval for this study was obtained from the Institutional Review Board at the University of North Dakota and from the Institutional Review Board at the participating hospitals where the data was collected.

This study did not have a control group because of the legal and ethical issues that would arise from having no eye protection during general anesthesia. This study compared protective methods that are used commonly during general anesthesia. Therefore, the risks of this study were the same for the researcher's subjects as were the risks of those who chose not to participate in this study during general anesthesia. The risks include the possible tearing or corneal abrasion. Therefore, this study was done to see which method had fewer ocular symptoms.

The benefits of this study include the possibility of showing a difference in subjective eye symptoms in post general anesthesia patients. This will lead to better treatment of patients' eyes when undergoing general anesthesia. The individual participants had the benefit of being involved in a study that may improve treatment of patients undergoing future general anesthesia.

CHAPTER III

RESULTS OF THE STUDY

Introduction

The purpose of this study was to explore the effectiveness of the two most common methods of eye protection used on general anesthesia patients. The first method of eye protection that this study included was the instillation of an ointment, Lacra-lube, in the eye and then taping the eyelid shut. The second method used was taping the eyelid shut with no eye ointment.

The following research questions are addressed in this chapter:

 What is the incidence of corneal epithelial defect symptoms following general anesthesia using eye protective methods?

2. To what extent do overall symptom scores differ between epithelial defect symptoms when using paraffin based ointment and tape compared to only taping patients' eyes following general anesthesia?

3. What is the relationship between the symptoms of corneal epithelial defects of an eye treated with tape and ointment versus an eye treated with tape only?

This chapter provides a description of the sample population used in this study. Data analysis and notable findings from statistical analysis are also presented.

Description of the Sample

The sample population consisted of fifty adults who were enrolled in the study upon meeting the qualification criteria. The group consisted of fifteen adult males, 30.0%, and thirty five adult females, 70.0%. This data is supplied in Table 1.

Table 1. Gender of 50 Surgical Patients

| Gender | <u>n</u> | 8 |
|--------|----------|------|
| Male | 15 | 30.0 |
| Female | 35 | 70.0 |

The mean age of all subjects was 38.82 years, (<u>SD</u> = 10.76), with the minimum age being 18 years and the maximum age being 60 years. The length of surgical time was measured in minutes. The mean time was 79.06 minutes, (<u>SD</u> = 46.32), with a range of 8 minutes to a maximum of 175 minutes.

Study Findings and Analysis

The first question to be addressed was, "What is the incidence of corneal epithelial defect symptoms following general anesthesia using eye protective methods?" The defect symptoms were as follows: itching, tearing, foreign body sensation, photosensitivity, and pain. The complaint of itching for the eyes with Lacra-lube and tape was expressed by five subjects (10.2%). The complaint of itching for the eyes with tape was mentioned by only one subject (2%). The complaint of tearing in the eyes with Lacra-lube and tape was made by 12 patients (24%). The complaint of tearing in the eyes with tape was expressed by only one subject (2%). Six subjects, (12%), complained of foreign body sensation in the eyes with Lacra-lube and tape. No subjects complained of foreign body sensation in the eyes which had only tape applied. The complaint of photosensitivity in eyes with tape and Lacra-lube was expressed by four subjects (8%). The complaint of photosensitivity in eyes with tape alone was expressed by only one subject (2%). The complaint of pain in eyes with tape and Lacra-lube was expressed by only one subject (2%). When using tape alone no complaints of pain were expressed. The overall results for eyes with Lacra-lube and tape showed that 25 subjects (50%) reported no symptoms associated with epithelial defects, symptoms while 24 (48%) of the subjects

experienced symptoms of corneal epithelial defects. The overall results for the eyes with only tape show that three subjects (6%) experienced corneal epithelial defect symptoms. Subjects were scored if they had 1 or more complaints of any symptoms. The overall incidence of these symptoms is shown in Table 2.

Table 2. Overall Incidence of Corneal Epithelial Defect Symptoms in Patients Following General Anesthesia

| Taped Eyes | Taped and Lubricated | Eyes |
|---|----------------------|------|
| Defect Symptoms 3 | 24* | |
| No Defect Symptoms 47 | 25 | |
| $X^{2} = 23.048, \ df = 1, \ p = 0.000$ | | |
| fisher's exact $p = 0.000$ | | |
| *One subject's data was missing. | | |

A chi-square, performed on the above overall data comparing taped versus taped and lubricated eyes. It shows that $X^2 = 23.048$ and the <u>p</u> = 0.000. A fisher's exact test was used because the cells contained less then 5 subjects and indicated a significance of <u>p</u> = 0.000 when comparing the incidence of overall corneal epithelial defect symptoms. Using chi-square on the subscales showed no statistically significant findings for pain, photosensitivity, or itching. However, the symptom of tearing was significant ($X^2 =$ 10.698, <u>df</u> = 1, and <u>p</u> = 0.001). Likewise, foreign body sensation was significant $(X^2 = 6.383, \underline{df} = 1, and \underline{p} = 0.012)$ for taping compared to lubricated and taped eyes.

The subjects were asked to describe other eye symptoms. For example, a common symptom reported was blurriness, or the inability to focus the right or the left eye. Patients with complaints of other eye symptoms were divided into the three following categories: left eye felt better or right eye felt worse; right eye felt better or left eye felt worse; and, no difference was felt between the patient's two eyes.

The results in Table 3 showed that 11 subjects (45.8%) out of the 24 subjects who had ointment in the right eye felt that the left eye was better. The 20 subjects (76.9%) with ointment in the left eye felt that the right eye was better. 50.0% of patients who had ointment in the right eye felt no difference in either eye. 19.2% of the patients who had ointment in the left eye felt no difference in either eye. A chi-square showed a statistically significant difference in the perceived eye problem ($X^2 = 28.37$, df = 2, $p = \le 0.001$).

| | Right eye better | | Left eye better | | No difference | |
|----------------------------|---------------------|------|--------------------|------|------------------|------|
| | <u>n</u> | 00 | <u>n</u> | 90 | n | 90 |
| Ointment | | | | | | |
| Right Eye | 1 | 4.2 | 11 | 45.8 | 12 | 50.0 |
| Left Eye | 20 | 76.9 | 1 | 3.8 | 5 | 19.2 |
| $x^{2} = 28.37, df = 2, p$ | = < 0 | .001 | | | | |

Table 3. Eye Complaints by Feelings Between Ointment and Feeling Score

Since more complaints were noted with ointment and tape, the length of surgical time was used to see if there were fewer complaints with longer lengths of surgery.

From Table 4, we see that a total of eighteen subjects had surgeries that were 60 minutes or less. Of those eighteen subjects, ten, 55.6%, had no complaints of corneal defect symptoms. Eight subjects, 44.4% had complaints. This was compared to those who had surgery 61 minutes or longer. Fourteen people, 46.7%, had no corneal defect symptoms with surgery 61 minutes or longer. Sixteen subjects, 51.6%, had complaints. A chi-square indicated there was not a significant relationship between numbers of subjects with corneal epithelial symtoms and surgical times.

| | No Complaints | | Complaints | | |
|---|---------------|------|------------|------|--|
| | <u>n</u> | 90 | <u>n</u> | 8 | |
| 60 minutes or less | 10 | 55.6 | 8 | 44.4 | |
| 61 minutes or more | 15 | 48.4 | 16 | 51.6 | |
| $x^2 = 0.234$, <u>df</u> = 1, <u>p</u> = 0.628 | | | | | |

Table 4. Incidence of Corneal Epithelial Defect Symptoms with the Ointment and Tape Method by Time in Surgery

Responses to the next research question, "To what extent do overall symptom scores differ between epithelial defect symptoms when using paraffin based ointment and tape compared to only taping the patient's eyes following general anesthesia?" are presented in Table 5. An overall scale score was used to compare the differences in eyes that had ointment and were taped versus eyes that were only taped. This score was computed by adding the scores for each category. Pain was scored from 0-9. Photosensitivity, foreign body sensation and tearing symptoms were scored from 0-3. Itching was scored from 0.0-4.0. The sum of these numbers is 22. Therefore the possible range of scores was from 0-22.

A paired t-test was performed on the differences in corneal epithelial defect symptoms comparing the lubricated eye with tape to only taping the eye. This was done to see if there were any differences in eye complaints. Included are the categories of each symptom and an overall score. The subscale scores were statistically significant in three of the five subscales using the paired t-test, using $\underline{p} \leq$ 0.05. Looking at the data in Table 5, we see that the differences in the scores in complaints of photosensitivity, ($\underline{t} = 1.77$, $\underline{df} = 49$, $\underline{p} = 0.083$), and pain, ($\underline{t} = 1.00$, $\underline{df} =$ 48, $\underline{p} = 0.322$) are not statistical significant. However, the differences in complaints for itching, ($\underline{t} = 2.25$, $\underline{df} =$ 48, $\underline{p} = 0.029$), foreign body sensation ($\underline{t} = 2.59$, $\underline{df} = 49$, $\underline{p} =$ 0.013), and tearing, ($\underline{t} = 3.26$, $\underline{df} = 49$, $\underline{p} = 0.002$) were significant.

| Defect | M | <u>SD</u> | <u>t</u> | <u>df</u> | g |
|---|-------|-------------------|----------|-----------|----------|
| Itching | | | | | |
| Ointment eye | 0.14 | 0.45 | 0.05 | 4.0 | 0.000++ |
| Taped eye | 0.02 | > 0.14 | 2.25 | 48 | 0.029** |
| Tearing | | | | | |
| Ointment eye | 0.30 | 0.58 | 2 2 2 | 4.0 | 0 000++ |
| Taped eye | 0.02 | > 0.14 | 3.20 | 49 | 0.002^^ |
| Foreign body | | | | | |
| Ointment eye | 0.12 | 0.33 | | 4.0 | 0 012+ |
| Taped eye | 0.00 | 0.00 | 2.59 | 49 | 0.013 ^ |
| Photosensitivity | | | | | |
| Ointment eye | 0.08 | 0.33 | 1 77 | 10 | 0 002 |
| Taped eye | 0.02 | 0.14 | 1.// | 49 | 0.083 |
| Pain | | | | | |
| Ointment eye | 0.02 | 0.14 | 1 00 | 4.0 | 0.000 |
| Taped eye | 0.00 | 0.00 | 1.00 | 49 | 0.322 |
| Overall | | | | | |
| Ointment eye | 0.67 | 0.85 | | 4.0 | 0 001+++ |
| Taped eye | 0.04 | > 0.20 | 5.05 | 48 | 0.001*** |
| * <u>p</u> ≤ 0 [%] 05, ** <u>p</u> ≤ | 0.01, | *** <u>p</u> < 0. | 001 | | |

Table 5. Differences in Corneal Epithelial Defect Symptoms Comparing the Lubricated Eye with Tape Method to the Taped Eye Method

An overall scale score for all post-operative symptoms was used as a final comparison of the lubricated eye with tape method of eye protection against the method of only taping the eye during general anesthesia. Again, a statistically significant difference in symptoms was evident, ($\underline{t} = 5.05$, $\underline{df} = 48$, $\underline{p} = 0.001$) between the two common eye protection methods. In the previous tables, data showed that more complaints were reported regarding the eyes that had Lacra-lube applied than those which did not have Lacra-lube applied.

Responses to the research question, "What are the relationships of using paraffin based ointment and tape versus only taping patients' eyes to the symptoms of corneal epithelial defects following general anesthesia?" are presented in Table 6. Pearson's correlation coefficients were used to examine possible relationships among age, surgical time, and the sum scale score of all complaints.

When looking at the results from Table 6, age had a nonsignificiant correlation with scale scores of eyes that were taped $\underline{r} = 0.0360$, $\underline{p} = 0.805$). The data on the eyes with ointment and tape had a significant relationship with age $\underline{r} = -0.302$, $\underline{p} = 0.035$). It was statistically significant that the overall scale score decreased as the age of the patients increased -- a negative correlation.

The results show older patients had fewer complaints when using Lacra-lube and tape.

When comparing the score of complaints against the length of surgical time, there was a statistically significant correlation for the overall scale score for tape alone $\underline{r} = 0.295$, $\underline{p} = 0.040$, $\underline{n} = 49$). This means that there were more symptoms when using tape alone during longer lengths of surgeries. In contrast, there was no correlation for overall scale score and time with the lubricated and taped eyes.

Table 6. Correlation's Between Lubricated Eye with Tape and the Taped Eye Scores for Patients -- Age and Surgical Time

| Variable | Age | Surgical Time |
|-------------------|----------------------------|---------------------------|
| Ointment eye | r = -0.302 (p = 0.035*) | r = -0.176 (p = 0.231) |
| Taped eye | r = 0.360 (p = 0.805) | r = 0.295 (p = 0.040*) |
| * <u>p</u> ≤ 0.05 | | |
| (n=50) | | |

CHAPTER IV

DISCUSSION, CONCLUSIONS

Summary and Discussion

This prospective clinical study examined the effectiveness of eye protection methods used in general anesthesia. This chapter begins with a discussion of the researcher's findings and is followed by the conclusions and recommendations of the researcher.

The following research questions were addressed by this study:

 What is the incidence of corneal epithelial defect symptoms following general anesthesia using protective eye methods?

2. To what extent do overall symptom scores differ between epithelial defect symptoms when using paraffin based ointment and tape compared to only taping patients' eyes following general anesthesia?

3. What is the relationship between the symptoms of corneal epithelial defects of an eye treated with tape and ointment versus an eye treated with tape only?

The tendency for patients to have corneal epithelial defect symptoms after general anesthesia can be related to

many things. The most common cause is due to the eyelid being left slightly open due to incomplete closure causing the cornea to dry. This causes a small defect in the epithelial layer of tissue. Consequently, anesthesia providers must protect the eye from drying out and from being scratched by closing the eyelid with tape or by applying ointment in the eye and then applying tape. This study examined the overall effectiveness of the two different methods used to protect patients' eyes during general anesthesia.

For this study, the eyes were protected at all times. Even so, differences were noted in the incidence of corneal epithelial defect symptoms. The number of subjects with complaints when using Lacra-lube and tape was 24 out of 50. The number of subjects with complaints when using tape alone was 3 out of 50 (Table 2). Chi-square analysis ($X^2 = 23.048$, df = 1, p = 0.000) and a fisher's exact test (p = 0.000) indicated statistical significance. This conflicts with the study done by Cucchiara et al., 1988. In a similar study the overall incidence of corneal abrasions was found to be 0.17%. It also stated that no statistically significant differences were found in using tape or Lacra-lube and tape. In a study by (Grover et al., 1998) the rate of corneal epithelial defects was 6.6% in tape alone and 3.3% in the Lacra-lube and tape method. In contrast the results of the

present study show relatively opposite results.

Significantly greater defects were reported by patients' treated by Lacra-lube and tape as compared to those treated with tape alone. One explanation was that the present study recorded the symptoms of corneal epithelial defects, rather than the actual diagnosis of corneal epithelial defects by fluorescein examinations. Since fluorescein exams were not conducted in the present study it is unclear whether patients' complaints had actual corneal epithelial defects in the present study.

The subjects were asked if there were any other eye symptoms or complaints. When ointment and tape were used in the right eye, 45.8% said their right eye felt worse. Only one subject, 4.2%, said their right eye felt better. 12 subjects, 50.0%, said they felt no difference. When ointment and tape were used in the left eye, 20 patients, 76.9%, said their left eye felt worse. Only five subjects, 19.2%, said they felt no difference. One subject, 3.8%, said the left eye felt better (Table 3).

When chi-square was used to report the difference in symptoms between the two methods of eye protection, the eyes with the ointment and tape yielded the most complaints, $(X^2 = 28.37, * df = 2, p = \le 0.001)$.

In a study done by Boggild et al., 1981 comparing Lacra-lube against methylcellose drops it found that 75% of

subjects complained of blurry vision post-operatively when using Lacra-lube. It also stated that a foreign body sensation occurred in 62.5% of the participants. This was very similar to the subjective results found in this study.

Table 4 was used to explore the incidence between the number of complaints with Lacra-lube and tape and the lengths of surgery. By using chi-square analysis, the results were nonsignificant ($X^2=0.234$, df = 1, p = 0.628). The conclusion was that there appears to be no correlation for overall scores with length of surgical time when using Lacra-lube and tape.

This study also examined the differences in the types of complaints such as pain, tearing, foreign body sensation, photosensitivity, and itching. Results show that by using the ointment and tape method of eye protection, a higher overall score, $\underline{M} = 0.67$, $\underline{SD} = 0.85$, was obtained compared to the method of using tape alone, $\underline{M} = 0.04$, $\underline{SD} = 0.20$, $\underline{P} =$ 0.001 (Table 5). In all cases the eyes that had ointment and tape had higher scores then the eyes with tape alone.

The highest number of complaints was with tearing, followed by itching and foreign body sensation. The complaints of photosensitivity and pain were also higher than expected. It was observed by the researcher when subjects were in recovery that tearing was often visible (not related to pain) in the eye with ointment and tape. A

possible explanation was tearing related to the foreign sensation of ointment in the eye.

A paired t-test was used to examine the difference in symptoms by treatment. Some differences were statistically significant. With the symptom of itching, there were significant differences ($\underline{t} = 2.25$, $\underline{df} = 48$, $\underline{p} = 0.029$). The \underline{p} for tearing was at 0.002. The \underline{p} for foreign body sensation was at 0.013. And the overall score was $\underline{p} =$ 0.001. The differences for the other two symptoms, photosensitivity and pain, were not statistically significant.

These results showed that the eye protection method of using ointment with tape yielded a higher number of complaints or symptoms compared to the eye protection method of using tape alone. The results also showed that the most common symptom or complaint was tearing when using the ointment with tape method of eye closure.

The results of the present study supports of a previous study that questions the routine use of Lacra-lube in patients and, in fact, may add to ocular morbidity in patients (White et al., 1998).

The relationships in Table 6 shows that a few relationships exist between the two methods of eye protection. When using ointment and tape, even though ointment and tape had more overall complaints, the older the individuals were, the less complaints they had ($\underline{p} = 0.035$).

Another interesting finding was that with longer surgical procedures, patients started to have more complaints with the eye with tape (p = 0.040) Since basal tear production is decreased with patients during general surgery this is possible explanation for the above results. Studies examining tear production with general anesthesia have shown that tear production is decreased up to 13 times following general anesthesia(Krupin et al., 1977; Cross et al., 1976).

Conclusions

This study compared the effectiveness of eye protection methods used in general anesthesia. All participants in this study received protection of their eyes. Subjects were selected randomly and were chosen by using criteria that reduced variables in this study. Since all eyes were protected in this study, the incidence of corneal epithelial defect symptoms were minimal. However, the results did show that a greater number of complaints were made regarding the eyes which had the ointment and tape applied. Similar studies show that this occurred in patients with Lacra-lube and taping of eyes (Siffring and Poulton, 1987; White et al., 1998). These complaints are not conclusive of a corneal epithelial defect, but do reflect the degree of

effectiveness of the two most common eye protection methods.

The most common complaints in this study were tearing, itching, and foreign body sensation of the eye. The complaints were statistically significant with $p \leq$ 0.05. However, there were fewer complaints by subjects about the eye with the ointment and tape as the ages of the subjects increased.

One conclusion regarding this decrease in complaints with age is that as a person gets older, the likelihood of dry eyes increases. Consequently, the extra moisture in the eye from the ointment could result in fewer complaints for older people. However, the findings indicate there was no correlation between age and number of complaints in taped eyes alone. This argues against that possibility. An alternative explanation possibility is that older subjects tend to be more stoic and this would result in fewer complaints. Older subjects may also have had other eye injuries that would at comparison rate the current discomfort minimal or none. The data in Table 6 reflects this. Overall, more complaints were made when the ointment and tape method of eye protection was used. However, when the method of using tape alone was used, the number of complaints increased as the length of time in surgery increased. One possibility would be again the decrease in basal tear production caused by general anesthesia.

Recommendations

Practice

Based upon the results, it is recommended that during general anesthesia, the tape alone method of eye protection be used. There are two exceptions to this recommendation. Data showed that with elderly patients, the ointment and tape method produced better results. Also, for subjects who underwent general anesthesia for longer periods of time, the ointment and tape method produced slightly better results, or fewer complaints. But overall, the method of using tape alone for eye protection during general anesthesia produced the least amount of statistically significant complaints.

Anesthesia practice could be affected by the results of this study. Knowing that more complaints are caused by using tape and ointment compared to tape alone to protect the eyes is a significant finding. This study could cause a change in the practice of how patients' eyes are protected for many people undergoing general anesthesia. But, to promote change, anesthesia staff would need to know the facts of this study.

<u>Research</u>

Before recommending that changes be made, more research with a larger subject group is to be recommended. A study comparing both eyes taped against both eyes having ointment and then taped should also be recommended. Also, a preoperative and post-operative test should be done on future patients to eliminate those with sore eyes before surgery. By sharing the knowledge gained in this study perhaps other researchers may want to duplicate this study and redo the study with the goal of finding ways to improve on current eye protection methods.

Education

The education of nurse anesthesia programs should include current studies directed at prevention of ocular complications following general anesthesia. This study has the possibility to change certain ways eyes are protected during general anesthesia. The sharing of the researcher's findings at a conference is a way to disseminate information. Another possibility is to have this study presented in a peer reviewed journal. The findings of this study is useful to anesthesia care providers in providing them with information that is useful in prevention of ocular complaints.

APPENDIX A

PARTICIPATION LETTER

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Consent Form Ocular Study

Investigator: Larry W. Johnson SRNA (701)777-9556 Advisor: Dr. Glenda Lindseth (701)777-4506

Dear Participant:

Hello. My name is Larry Johnson. I am a graduate student at the University of North Dakota studying protective measures used during general anesthesia. Part of my training is to conduct research in the area of anesthesia related practice. I am currently working on my thesis to compare current eye protective measures used during general anesthesia. I am examining the effectiveness of eye protection during surgery by comparing subjective differences from a questionnaire that will be administered within 24 hours of surgery. The information obtained will help medical personnel determine future types of eye protection that are best for patients who are undergoing surgery. You are invited to participate in this study that will add to the quality of health care. All information will be kept confidential.

Participants 18-60 years of age, without a history of current contact use, glaucoma, or previous eye surgery are encouraged to participate. Your hospital number will determine the type of protection that will be used. This will ensure randomization. After Surgery, a questionnaire will be administered to you by myself within 24 hours of surgery. This will be the same as the example questionnaire I give to you. Since this a comparison of commonly used eye protection methods used in surgery today, the risks and potential discomforts would be the same. The potential benefits are that you are contributing to the knowledge base that could provide better care for patients undergoing general anesthesia.

Your consent form will be locked in a file by myself for a period of three years and then destroyed. The information that is collected will not become a part of your medical record. Your name will not be on the questionnaire. No information will be released to anyone not involved in this study.

Whether you decide to participate or not will not change any future relations with this hospital. If you decide not to

participate, you may do so at any time and there will be no repercussions of any kind against you. Any questions about this study that you may have, can be asked by calling myself or my advisor at the top of this form. A signed copy of this consent form will be given to you.

"In the event that this research activity results in the physical injury, and the project conducted in a health care facility, medical treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Payment for any such treatment must be provided by you and your third party payer, if any (such as health insurance, Medicare, and so forth). All of my questions have been answered and I am encouraged to ask any questions that I may have in the future."

Thank you for participating in this valuable study. Your cooperation is appreciated.

I have read all of the above and willingly agree to participate in this study explained by

Researcher's Signature

Patient's Signature

Date

APPENDIX B

QUESTIONNAIRE

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LEFT EYE OCULAR EYE SYMPTOM SHEET

Please fill out with assistance from the researcher.



Any right eye pain experienced?ExtremeNoneExtreme0123456789

Is your left eye sensitive to light?

- 0 = absent
- 1 = mild. Very minimal intolerance to light which may require some degree of sunglass protection to eliminate the symptoms, noticed primarily in sunlight.
- 2 = moderate. Intolerance to light associated with exposure to room light or sunlight which is only partially relieved by dark sunglasses or subdued light. The symptoms still persist to some degree even with sunglasses.
- 3 = severe. Intolerance to light that is not relieved by sunglasses and is only relieved by total occlusion of the eye.

Have you experienced foreign body sensation in your left eye?

- 0 = Absent
- 2 = Moderate. Similar to sensation of sand or dust in eye resulting in moderate tearing & blinking.
- 3 = Severe. Similar to a sensation of a hot cinder in the eye, associated with constant tearing.

Any tearing of your left eye?

- 0 = Absent.
- 1 = Mild. Positive sensation of eyes watering without tears spilling over eyelid.
- 3 = Severe. Constant or nearly constant spilling of tears over eyelid, associated with blowing nose.

Have you experienced itching of your left eye? 0.0 = None

2

- 0.5 = An intermittent tickling sensation, possibly localized just in the corner of your eye.
- 1.0 = An intermittent tickling sensation, involving more than just the corner of the eye.
- 1.5 = An intermittent all over tickling sensation of the eye.
- 2.0 = A mild continuous itch (can be localized), not requiring rubbing.
- 2.5 = A moderate, diffused, continuous itch that you would like to rub.
- 3.0 = A severe itch, which you would like to rub.
- 3.5 = A severe itch, improved with minimal rubbing.
- 4.0 = An incapacitating itch, which requires significant eye rubbing.

Please describe other LEFT EYE symptoms.

RIGHT EYE OCULAR EYE SYMPTOM SHEET

Please fill out with assistance from the researcher.



Any right eye pain experienced?NoneExtreme0123456789

Is your right eye sensitive to light?

- 0 = absent
- 1 = mild. Very minimal intolerance to light which may require some degree of sunglass protection to eliminate the symptoms, noticed primarily in sunlight.
- 2 = moderate. Intolerance to light associated with exposure to room light or sunlight which is only partially relieved by dark sunglasses or subdued light. The symptoms still persist to some degree even with sunglasses.
- 3 = severe. Intolerance to light that is not relieved by sunglasses and is only relieved by total occlusion of the eye.

Have you experienced foreign body sensation in your right eye?

- 0 = Absent
- 2 = Moderate. Similar to sensation of sand or dust in eye resulting in moderate tearing & blinking.
- 3 = Severe. Similar to a sensation of a hot cinder in the eye, associated with constant tearing.

Any tearing of your right eye?

- 0 = Absent.
- 1 = Mild. Positive sensation of eyes watering without tears spilling over eyelid.
- 2 = Moderate. Infrequent or intermittent spilling of tears over eyelid.
- 3 = Severe. Constant or nearly constant spilling of tears over eyelid, associated with blowing nose.

Have you experienced itching of your right eye? 0.0 = None

0.5 = An intermittent tickling sensation, possibly localized just in the corner of your eye.

1.0 = An intermittent tickling sensation, involving more than just the corner of the eye.

- 1.5 = An intermittent all over tickling sensation of the eye.
- 2.0 = A mild continuous itch (can be localized), not requiring rubbing.
- 2.5 = A moderate, diffused, continuous itch that you would like to rub.
- 3.0 = A severe itch, which you would like to rub.
- 3.5 = A severe itch, improved with minimal rubbing.
- 4.0 = An incapacitating itch, which requires significant eye rubbing.

Please describe other right eye symptoms.

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