# AN EDUCATIONAL-BASED APPROACH TO PREVENT CORNEAL ABRASIONS

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A doctoral scholarly project submitted to the faculty of The University of North Carolina at Charlotte in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice in Nurse Anesthesia

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#### ABSTRACT

# EBONY JENKINS. An Educational-Based Approach to Prevent Corneal Abrasions. (Under the direction of DR. LUFEI YOUNG)

Corneal abrasions (CA) are one of the most common anesthesia-related adverse events. There is limited evidence about the effect of virtual education on anesthesia providers' knowledge regarding CA prevention. The purpose of this study project was to assess if a web based educational module effectively improved anesthesia providers' awareness of evidence-based preventative measures of CA. This was a quasi-experimental pretest-posttest study design. All participants completed a questionnaire regarding the knowledge on corneal abrasion prevention before and after the educational module. A student T-test was used to compare the differences in pre- and post- education knowledge scores. Among 26 participants, 15.4% were anesthesiologists, and 84.6% were CRNA. There was a significant pretest-posttest difference on the total knowledge score ( $6.54\pm1.14$  vs.  $8.55\pm1.53$ , p<.001). Overall, the average number of correct answers increased from  $6.54\pm1.14$  to  $8.55\pm1.53$  (t = 5.74, p < .001) The web-based educational module was effective in the enhancement anesthesia providers' knowledge in preventing surgical induced CA. The finding may add evidence on developing the effective guideline and standardizing provider education in CA prevention.

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# **DEDICATION**

I dedicate this project to my loving family and friends who have supported me throughout my academic journey. My deceased loved ones Bill Doe, Luberta Brown, Nancy Jenkins, and Charlie Jenkins Sr.- your loving memories remains a beacon of strength during my time of difficulty. My parents whose immeasurable support, inspiration, and prayer has always been by side. Lastly, my significant other, who has supported me physically and emotionally throughout this entire process- "We did it Joe."

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# LIST OF ABBREVIATIONS

CA	Corneal abrasions
STP	Steep Trendelenburg position
(QI)	Quality improvement
CRNA	Registered Nurse Anesthetist
MDA	Anesthesiologist
PACU RN	Post Anesthesia Care Unit Registered Nurse
SRNA	Student nurse anesthetists
NSAIDs	non-steroidal anti-inflammatory drugs
PDCA	Plan-Do-Check-Act
EHR	Electronic health record
F2F	Face-to-face
WBL	Web-based learning
SPO	Structure, process, outcome
ODSC	One Day Surgery Center
ORs	operating rooms
NORA	Non-operating room anesthesia
GYN	Gynecologic

ENT	Ear/nose/throat
ID	unique study code
IRB	Institution Review Board
HIPPA	Health Insurance Portability and Accountability Act of 1996
SD	standard deviation

#### **CHAPTER I: INTRODUCTION**

### 1.1 Background

Corneal abrasions (CA) are one of the most common ocular adverse events after surgery with an incidence rate between 1.4 to 15.1 per 10,000 procedures (Barash, 2017, p. 292). They are associated with significant pain, stress, and heightened anxiety for the patient in the postoperative setting. Furthermore, CA can lead to negative ocular sequelae such as corneal ulcer formation and bacterial infections (Porter, 2022). Consequently, these sequelae can increase the patient's length of hospital stay and warrant an ophthalmology consultation (Segal, 2014). This leads to an additional cost for the hospital with the median amount of compensation for this preventable injury being \$12,000 (Posner & Lee, 2014). Overall, the significance of this incident results in a reduction in quality patient care and dissatisfaction in the surgery's outcome.

# **1.2 Problem Statement**

The increased risk for CA related to positioning, provider awareness, and the surgical environment has been well documented. With the increasing use of robotic surgery, which requires the patient in steep Trendelenburg position (STP), the need to continue to promote providers' awareness on corneal abrasions is paramount. One study which reviewed the incidence of CA in robotic-assisted laparoscopic hysterectomies showed that "compared with open hysterectomy, risk of corneal abrasion was increased nearly four-fold with the laparoscopic technique and nearly 6.5-fold with the robotic technique" (Sampat, 2015). Another reported risk of CA is inappropriate eye protection during surgeries. According to McKevitt et al. (2022), most of the corneal injuries that occur under anesthesia are from incomplete eye closure. To avoid CA, the eyelids must be covering the eye (Nagelhout, p. 245). In the prone or Trendelenburg positions, venous congestion of the conjunctiva may occur which inhibits full

closure of the eye (McKevitt et al., 2022, p. 1). Other risk factors of CA include advanced age, the use of general anesthesia, length of the procedure, direct trauma, corneal exposure, dehydration and associated keratitis, or chemical injury (Porter, 2022; Papp, 2019; Nagelhout, 2018, pg 944-945; Barash, 2017, p. 1272-3484). The implementation of standardized CA prevention, early recognition and treatment has contributed to the reduction of CA; however, this adverse event remains a significant problem seen in the peri anesthesia period (Porter, 2022). One of the reasons is the lack of awareness of methods used to prevent and alleviate CA.

#### **1.3 Purpose of the Project**

To address this clinical issue, I propose a quality improvement (QI) project aimed to increase providers awareness on current evidence-based practice to reduce CA occurrence in perioperative patients. The purpose of this project is to study the effect of a web based educational module provided to anesthesia providers and its influence on providers' awareness of corneal abrasion in patients at a One Day Surgery Center. Providers' awareness will be investigated, regarding current literature recommendations on effective methods used to prevent and reduce CA and CA risks. An educational module will be provided, and providers will be given a pre-assessment and post-assessment. Current literature identifies the effectiveness of education modules on the awareness regarding up-to-date clinical practice among healthcare professionals.

# **1.4 Clinical Question**

After a thorough review of the literature and feasibility assessment, the overarching clinical question is as follows: Does a web-based educational module (**I**) provided to anesthesia providers (**P**) increase the awareness of evidence-based corneal abrasion prevention measures (**O**) during the perioperative period (**T**)?

## **1.5 Stakeholders**

After careful investigation, the stakeholders identified are Certified Registered Nurse Anesthetist (CRNA), Anesthesiologist (MDA), Post Anesthesia Care Unit Registered Nurse (PACU RN), Ophthalmologist, Risk Management Leader, Surgeon, facility of interest, and the patients. According to Sipes (2020), stakeholders are individuals who share common interest in the project and serve as valuable critics (p. 66). Although CAs are classified as an anesthesiarelated adverse event, collaboration with other individuals closely involved in patient care is optimal. The anesthesia providers serve as critical stakeholders as this investigation directly impacts their practice of care. During surgical procedures several instruments and devices are used to ensure patient safety. Ophthalmology consultations may be warranted dependent on facility protocol for CA, so ophthalmologist involvement is necessary. Lastly, when adverse events are documented, the risk management leader investigates the occurrence.

#### **CHAPTER II: LITERATURE REVIEW**

#### 2.1 Database Search

In determining the effectiveness of an educational module provided to anesthesia providers, a literature review was conducted within the following databases: CINAHL Complete, PubMed, Web of Science, Science Direct, and Medline between January 2005 to February 2023. **Keywords:** corneal abrasions, corneal injuries, general anesthesia, prevention, surgery, webbased learning, anesthesia, anesthesia providers, healthcare providers

#### **2.2 Background and Significance**

CAs are one of the most common ocular adverse events in patients undergoing general anesthesia. Morris et al. (2018) defines corneal abrasion as a defect on the cornea's epithelial surface. Patients undergoing general anesthesia are at greater risk due to the loss of natural corneal protective reflexes, reduced tear production, and incomplete eye closure. Documented trends in perioperative CA prevalence reveal a varying incidence rate dependent on the study being conducted, preventative measures being implemented, patient population inclusion criteria, patient position, comorbidities, and the overall objective of the study. However, Morris et al. (2018) mentions the marked increase from 0% to 44% when eye protective measures are not utilized. According to Barash (2017), CA incidence rate ranges between 1.4 to 15.1 per 10,000 procedures. Overall, CA raises significant concerns for patients during the perioperative period.

In addition, Porter et al. (2022) mentions numerous associated negative sequelae, such as corneal ulcer formation and bacterial infection. If left untreated, recurrent corneal erosion can occur months to years after the CA. Researchers express the rarity of long-term sequelae occurring, due to the rapid self-regeneration of the corneal epithelium. However, as stated by Segal et al. (2014), this unforeseen event can lengthen hospital stay as the patient awaits an ophthalmology consult for definitive treatment. Despite the implementation of preventive measures in the operative setting, the occurrence of CA leads to additional costs for the patient and hospital. Morris et al. (2018) explains the varying cost of treatment for CA, including topical antibiotics and oral non-steroidal anti-inflammatory drugs (NSAIDs) that contribute to the additional cost for the hospital encounter. According to the closed claims analysis study, eye injuries accounted for 3% of total claims against anesthesia, which CA occurred in 35% of those cases (Aitkenhead, 2005). Furthermore, perioperative CAs yield a median payout of \$3,000 per incident, accounting for 3% to 8% of anesthetic malpractice claims (Porter et al., 2022). Sustained practice change supporting recommendations from current literature can save \$637 per corneal injury prevented (Vetter et al., 2012). Overall, the significance of this incident results in reduced patient satisfaction in surgical outcomes, provider liability, and additional cost for the healthcare facility.

The impact that CAs can have on the patient, anesthesia provider, and healthcare facility is consistently stated in the literature. Many researchers commonly expressed the need for a universal protocol to promote appropriate implementation of preventative measures. Porter et al. (2022) presented an online learning module to anesthesia providers, which supported the change in practice, reducing the occurrence by 12-13%. In addition, Vetter et al. (2020) conducted a case-control study that introduced a reiterative approach to anesthesia providers, incorporating the Plan-Do-Check-Act (PDCA) cycle. Vetter et al. (2020) increased provider awareness and expanded on an already established knowledge base with current evidence-based practice.

Utilization of techniques such as these will contribute to the overall reduction of CA incidence while increasing provider awareness.

## **2.3 CA Prevention and Control**

An important facet when dealing with CA prevention is awareness of patient risk factors. Studies have differed slightly in risk factors that are the greatest perpetrators for increased frequencies of CA. The study by Segal et al. (2014) determined significant risk factors to be age, the use of general anesthesia, increased blood loss, Trendelenburg position, and supplemental oxygen during transfer. Conversely, Carniciu et al. (2017) determined the main risk factors to be surgery length greater than 3 hours and pre-existing ocular disease. This study showed no association of body positioning causing increased CA risk. Overall, in one systematic review, Papp et al. (2019) established the most common risk factors throughout various studies to be longer surgeries, advanced age, Trendelenburg positioning, robotic cases, and general anesthesia. Among studies found in the literature, it can be determined that there is not one list of confirmed risk factors for CA that is currently agreed upon.

Evidence-based guidelines and protocols have differed slightly amongst the literature as there are various methods for CA prevention that have been determined. Best practice guidelines described by Segal et al. (2014) and Porter et al. (2022) included applying either eye drops or ointment prior to taping the eye. Another study adopted a guideline that included complete closure of the eyelids with tape during general anesthesia, taping once the eyelash reflex was lost, and the utilization of aqueous gel as a protection method (Domino, 2017). Vetter et al. (2012) implemented a standardized CA prevention program that included a certain way of taping the eyes, the timing of taping the eyes, and a consistent method of eye protection documentation. After the rollout of this new standard, results showed a marked reduction in CA. Porter et al. (2022) also achieved a noticeable reduction in CA through a similar manner of standardizing CA prevention. This study educated providers on causes, risk factors, and prevention measures throughout the perioperative period. Like Vetter et al.'s study (2012), they created an intraoperative protocol aimed at standardizing eye care for all patients receiving general anesthesia which included taping the eyes prior to securing the airway, using a particular tape, and documenting eye checks hourly. The study showed an absolute reduction of 13% and 12% over two separate years.

Dixon et al. (2019) described a guideline adopted specifically for decreasing CA risks among patients undergoing endoscopic procedures – where sedation or monitored anesthesia care were used rather than general anesthesia. In procedures that do not require general anesthesia, taping of the eyes is generally not recommended. Instead, Dixon et al. (2019) adopted the practices of making sure patients' eyes were completely closed peri-procedurally and ensuring proper fit of ancillary oxygenation devices on patients' faces (such as, nasal cannulas). They also made sure patients' eyes avoided contact with the bed while in lateral position, which was the position required for the endoscopic procedures. Douthit et al. (2022) adopted a similar guideline, where it became a new standard to position patients from lateral to supine when traveling from endoscopic procedures to the post-anesthesia care unit to avoid potential CA. The idea was that patients would rub their eyes on their pillows and sheets, potentially harming their dependent eye. Conversely, Haghighat et al. (2021) employed a practice of bilaterally taping both eyelids during endoscopic procedures. Their study took place after the COVID-19 pandemic, when patients were required to wear masks. Therefore, they also standardized taping the mask to the bridge of the nose of these patients to prevent the mask moving toward the eves

and scratching the cornea. In this study, there were zero incidences of CA among 2,149 endoscopic procedures after the implementation of the practice change.

In summary, there are many different CA prevention measures that can be adopted and there are various guidelines that support these interventions. These studies highlight the need of educating providers on up-to-date information regarding prevention of CA, certainly when it comes to the importance of eye care during the intraoperative period.

#### 2.4 Effectiveness of Current Education

As previously mentioned, education models focused on improving anesthesia providers' knowledge of CA prevention are discussed in the literature. To assess the need for education regarding best practice measures against CA, one case-control study began by observing anesthesia providers' eye protection practices (Vetter et al., 2012). It was found that providers had various timing on when eyes were protected with tape and/or lubricant – either occurring before or after confirmation of mask ventilation of the airway during induction of anesthesia.

After observing CRNA, student nurse anesthetists (SRNA), anesthesiology residents, and attendings over a seven-day period, it was found that there was no standard practice for eye protection. Post observation, educational presentations were provided to all anesthesia providers to implement a standard of practice for eye protection and documentation in the electronic health record (EHR) regarding CA. Vetter et al. (2012) and Martin et al. (2009) were two studies that discussed education provided in-person via lectures, grand rounds presentations, or quality improvement conferences. Martin et al. (2009) employed a unique method of dividing anesthesiologists and CRNAs/SRNAs into separate sessions of educational lectures. However, each group received the same education on CA prevention. In a more recent study by Douthit et al. (2022), researchers worked directly with anesthesia providers and hospital administrators to

develop an evidence-based practice change to prevent CA. After change implementation, anesthesia providers were educated via in-services and were provided hard copy summaries for review.

In more recent years, education has begun to shift to an online or digital platform. Porter et al.'s (2022) quality improvement study involved the creation of an online module to expand provider knowledge of CA. The module consisted of a presentation that informed providers of proposed causes, risks, and prevention measures against CA. The preventive measures were separated into three categories – preoperative, intraoperative, and postoperative. After viewing the module, providers had to complete a series of questions to assess their knowledge gain.

In other studies, there is a combination of in-person as well as electronic strategies to expand provider knowledge of CA. In Martin et al.'s (2009) case-control study, e-mail technology was used to initially notify providers of CA occurrence among patients in their care. This was then followed up with formal teaching on effective preventive measures. This included an in-person lecture series that focused on CA awareness, risk factors, and prevention methods. Vetter et al. (2012) employed a similar practice. Providers that were involved in cases of CA were informed of the incidents and re-educated about the facility's new standardized eye protection protocol. This re-education took place between the provider and a representative from the hospital's quality department.

Another element of CA education found in the literature includes instruction on incident reporting and intraoperative eye protection documentation in the EHR. In one study, presentations as well as audiovisuals were created to inform anesthesia providers of the correct CA documentation process (Vetter et al., 2012). To further increase documentation compliance, researchers in this study were able to add a reminder button to the EHR. This would alert the provider to document eye protection measures given to the patient. Prior to this addition, providers would have to rely on their own intuition to ensure they complete eye protection documentation.

After a review of the literature, it can be concluded that education regarding CA prevention has been provided to anesthesia providers in various ways. There are several strategies that have been employed and one method has not proven to be more advantageous than others. As previously mentioned, there has been a shift to the incorporation of online learning in recent years. Porter et al. (2022) is the only study found that used an online module for its primary education method.

Overall, the desired effect of CA education is reduced CA incidence. In Martin et al.'s (2009) case-control study, rates of CA were followed throughout the education initiative and fell substantially compared to the beginning phases (Papp et al., 2019). The results from Vetter et al. (2012) were similar and revealed that rates of CA fell from 1.20 per 1000 to 0.09 per 1000 after institution of a standardized eye protection protocol (Papp et al., 2019). Additionally, in one quality improvement project, the creation of an educational module reduced CA incidence from 0.22% to 0.09% over a two-year study period (Porter et al., 2022). Vetter et al. (2012) also reported a sustained reduction in CA incidence over a three-year period. The consistent reduction in CA that occurred after implementation of the education programs in these studies is a testament to their overall effectiveness.

As previously discussed, there were a few studies that aimed to increase provider compliance to CA reporting and eye protection documentation in the EHR. Therefore, this was another outcome measure that was used to assess education effectiveness. The efforts of one study increased provider documentation of eye protection from 3.4% during the beginning of education to 74.9% (Vetter et al., 2012, p. 494). Improved electronic documentation of CA in one study flagged the patients which led to ophthalmology consults. Patients being flagged led to faster treatment overall to reduce the risk of further, more complex complications (Martin et al., 2009, p. 322).

#### **2.5 Effects of Web-Based Education on Practice**

As previously mentioned, there has been a shift to providing education via electronic and web-based routes. The COVID-19 pandemic proved that education programs can be administered through an online platform. Prior to the COVID-19 pandemic, many educational programs for healthcare providers were completed using a face-to-face (F2F) platform. However, the pandemic forced educational programs to shift more to the web-based spectrum. The use of web-based educational programs has the advantages of providing access to time sensitive information and accommodating learners' varying schedules. Abbas et al. (2020) conducted a comparative study to investigate the effectiveness of a web-based module on preventative measures presented to 401 healthcare workers. Statistical analysis revealed a significant increase in hand hygiene completion when comparing the pre-intervention percentage (25.2%) and the post-intervention percentage (57.4%). Researchers concluded that a concise web-based educational module is an effective tool to educate healthcare workers and promote practice change.

Multimedia advancement offers the potential to expand the competencies of nurses in clinical practice. 67 nurses participated in a randomized control study, where web-based learning (WBL) was provided to simulate a clinical setting. The clinical performance of the participants in the experimental group improved significantly compared to the control. Liaw et al. (2015) concluded that web-based simulations provide an educational tool where large groups require training, and grant accessibility to repetitive training to promote retention of clinical competency.

Participants of WBL perceive the platform as being more suited to meeting the needs of their demanding work schedules. Furthermore, providing a platform that is conducive to the demand of the learners' schedules is imperative to promote the successful completion of the learning module.

Additionally, socio-cognitive factors have the potential to predict provider adherence to updated clinical guidelines and completion of web-based modules. Depending on self-efficacy, some providers are less likely to adhere to guidelines during difficult clinical situations (Ruijter et al., 2018). The evaluation of practice nurses' adherence to patient smoking cessation guidelines was studied using a randomized controlled trial, which utilized an e-learning program to promote provider adherence. Evidence showed that the e-learning program resulted in better smoking cessation guideline adherence, which lead to greater patient outcomes (Ruijter et al., 2018). Furthermore, patient safety and satisfactory outcomes are always the core of delivering optimal patient care. It is vital to ensure a sufficient level of knowledge in healthcare professionals built on evidence-based practice (Van de Steeg et al., 2015). E-learning allows for self-paced learning and quality assurance. However, barriers to e-learning such as the level of computer literacy must be considered.

Researchers most often provide participants with a baseline knowledge exam prior to beginning the online course. The knowledge test is utilized as a comparison tool to determine if the module was effective in provider awareness. Van de Steeg et al. (2015) expressed that a postexam score of 80% or higher demonstrated successful completion of an online program. Statistical analysis revealed that there was a small difference in the score based on age. However, each nurse that participated in the study benefited significantly from the module. Van de Steeg et al. (2015) concluded that e-learning demonstrated a positive effect on the nursing staff. Like previously mentioned studies, web-based learning demonstrates an effective method to expand healthcare providers' knowledge base in efforts to promote quality improvement.

In contrast, Maloney et al. (2012) concluded that WBL and F2F platforms similarly produce comparable outcomes, such as satisfaction, participation, and knowledge acquisition. After investigating the two platforms' effects on fall prevention education, it was further concluded that WBL was more cost-effective for educational providers. WBL opened opportunities to overcome barriers, such as time and cost (Maloney et al., 2012). Researchers also determined that WBL can provide better maintenance of knowledge that is frequently lost with short-term courses (Maloney et al., 2012). WBL produces positive effects on the retention of current evidence-based practice, quality improvement, as well as patient outcomes.

#### 2.6 Gaps in Literature

After a review of the literature, there are several gaps that remain in CA research as it pertains to anesthesia. A major gap includes the lack of studies providing online educational modules that address CA prevention. Much of the literature found pertains to F2F education provided to anesthesia providers. Porter et al. (2022) is one of the only studies that discussed a positive outcome from an online educational module with a significant reduction in CA incidence. Since Porter et al.'s (2022) education initiative led to a substantial decrease in CA incidence, it is worth investigating this strategy further.

Another gap in the literature is coverage of CA occurrence during moderate sedation cases. Dixon et al. (2019) and Douthit et al. (2022) are two studies that discuss CA occurring after endoscopic procedures where general anesthesia is not utilized. Porter et al. (2022) shared that 14 out of 23 CA cases that occurred in the facility of interest occurred in patients under deep sedation and not general anesthetics. Considering much of the literature discusses the pathophysiology of CA due to general anesthesia's effects on the body, this topic needs to be investigated further. There may be an even higher rate of CA among patients where general anesthesia is not utilized. In moderate sedation procedures, it is typical to leave the eyelids without tape. However, when the eye is unprotected in this fashion, constant monitoring by the CRNA would be required throughout the procedure to prevent eyelid opening (Grixti et al., 2013, p. 115). The theory of higher incidence of CA during moderate sedation procedures is largely unknown due to the lack of research studies covering this phenomenon.

As discussed previously, another gap in the literature is the inconsistency of a standardized way of preventing CA. The overall patient risk factors vary slightly with some agreed upon throughout studies and some risk factors being contested. One comprehensive review by Kaye et al. (2019) indicated that positioning (i.e., lateral, prone, and Trendelenburg) and higher estimated blood loss have not been consistently found to cause an increased risk of CA. This review also included several methods of preventing corneal injuries such as manual closure of eyelids, use of eye ointment, and bio-occlusive dressing. However, researchers also agreed that none of these methods have been shown to be completely effective (Kaye et al., 2019). There are many mechanisms of injury for CA, and studies differ slightly on best practice recommendations for CA prevention. More research involving large randomized controlled trials is needed to evaluate prevention measures against CA in patients undergoing anesthesia (Grixti et al., 2013, p. 117).

## 2.7 Review of Findings

In summary, CA remains as one of the most common ocular injuries in non-ocular surgery requiring general anesthesia. Despite preventative measures in place, CA remains a significant issue. Although there are many preventative measures that can be implemented, a universal protocol has not been established. Researchers have revealed that one intervention is not superior to the next in the prevention of CA. Furthermore, Morris et al. (2018) revealed a marked increase from 0% to 44% when eye protective measures were not utilized. It is evident that implementation of CA prevention reduces the risk of occurrence. However, studies vary on the most effective tape to use for eye protection and the advantage of utilizing eye drops/ointment. It has been consistently determined that the establishment of a CA protocol and provider education have successfully reduced the risk. In addition, CA protocols and provider education have improved anesthesia provider awareness and knowledge acquisition as proven by Vetter et al. (2012) and Porter et al. (2022).

As previously mentioned, WBL offers the potential to expand the competencies of nurses in clinical practice. Implementation of a web-based module provided to anesthesia providers on CA prevention has produced practice change. The literature reveals that WBL yields positive effects on the retention of current evidence-based practice, quality improvement, as well as patient outcomes. The literature has made it evident that CA is consistently reduced after providers are introduced to an educational program, reflecting the program's overall effectiveness. Despite the many interventions that can be practiced, and the gaps in the literature relative to the procedures completed without general anesthesia, the literature supports the effectiveness of WBL on providers' awareness and patient outcomes.

# **2.8 Conceptual/Theoretical Framework**

For this quality improvement project, the structure, process, outcome (SPO) model was followed. The structure part of the SPO model refers to the environment where care is provided. The structure included the facility the CA education was distributed to — a Surgery Center affiliated with a large trauma center. The process refers to the actions being performed to affect

care delivery. The process included providing a web-based education method to anesthesia providers regarding CA best practice prevention. Finally, the outcome refers to the end results of the QI project. The outcome included increasing provider awareness of CA prevention, which the anticipated results will be a reduction in CA incidence and increased patient satisfaction at the healthcare facility of interest.

#### **CHAPTER III: METHODOLOGY**

### 3.1 Study Design

This project is a quantitative, quasi-experimental design using a pre-test post-test design. The project investigated the following PICOT question: Does a web-based educational module (I) provided to anesthesia providers (P) increase the awareness of evidence-based corneal abrasion prevention measures (O) during the perioperative period (T)? The plan was to facilitate a pre-test to assess general knowledge of CA best prevention practices at baseline, followed with a short educational module. To assess knowledge gain, a post-test was completed thereafter, and the score used for comparison to pre-test score. SQUIRE 2.0 guidelines were followed when reporting this scholarly project (Orgrinc et al., 2016). Both the clinical site and the university Institutional Review Boards (IRB) were obtained prior the implementation of the project (Appendix E)

# 3.2 Setting

The project took place within a One Day Surgery Center (ODSC) affiliated with a comprehensive healthcare system located in the southeastern region of the United States. The health system is one of the largest hospitals in the region, boasting a world-class facility that offers a range of services and specialties. It stands as the region only Level 1 trauma center, as well as an approved transplant center for hearts, kidney, pancreas, and liver procedures. The entire healthcare center, including the surgical center, operates as a teaching facility. Additionally, the ODSC houses 11 ORs that provides a range of outpatient surgical procedures. These procedures include general surgery, gynecologic (GYN), pelvic health, robotics, orthopedics, plastics, ophthalmic, ear/nose/throat (ENT), urology and diagnostic procedures.

Uniquely, this surgery center provides pediatric services that are not limited to general surgery, orthopedic, plastics, ophthalmic, ENT, urology, and diagnostic procedures.

# **3.3 Population**

The population for this project consisted of anesthesia providers, including MDAs and CRNAs, from the ODSC. Convenience sampling was the method used to obtain subjects. The potential sample consisted of approximately 25 CRNAs and 16 MDAs, and several anesthesia providers that worked between the ODSC and trauma hospital. In the pre-test portion of the project intervention, participants were asked to identify their professional role and years of clinical experience. The purpose was to investigate whether this information altered pre- and post-test results.

## **3.4 Intervention**

The educational module utilized an infographic to encourage participant engagement while learning about CAs. An infographic maximizes understanding and information is more likely to be retained via this method (Murray et al., 2017). An infographic is defined as a visual presentation of information, minimizing the amount of text, and utilizing pictures, charts, and graphs. It also ensures that the education provided will be concise and easy to follow, which may potentially increase the number of participants willing to complete the module. The educational module consisted of a one-time session, with all parts included to allow the participant to complete it in one sitting. The time to review the infographic depended on the participant with an average time frame of around 10 minutes. The infographic included a discussion on the pathogenesis of CAs, prevention method strategies, and treatment measures supported by the literature. The website Easel.ly assisted in the generation of the infographic that was presented to the anesthesia providers. Easel.ly offers a variety of templates that were beneficial to the development of the web-based module. Easel.ly design tool allowed the opportunity to visualize any information and transform it into an easy-to-read platform (Easelly, 2021). This platform allowed straightforward navigation to build visual aid that includes pictures, graphs, and text. The infographic was easily created into a PDF that was included in the main educational portion of the module. Review Appendix B for an example of an Easel.ly template and layout.

SurveyMonkey was utilized as a tool to present the education module to the desired population as well as evaluate the results of the pre-test and post-test. SurveyMonkey provides a platform to share online surveys and track results in real-time. This platform allows for a module that is easily accessible, as SurveyMonkey permits for the completion of the survey using a mobile device, tablet, or computer. It offers extensive features that were beneficial to the creation, accessibility, and evaluation of this quality improvement project. Secondly, SurveyMonkey assisted in the development of an easily accessible QR code that is linked to the module URL.

The following strategies were used to enhance and maintain the intervention fidelity. For study design, a clear and detailed intervention protocol was developed, that outlined specific education components and expected outcomes. Standardized education materials that aligned with the intervention protocol were provided. To improve the intervention fidelity, all team members participate training in develop online surveys and web-based education modules. To ensure the delivery and receipt, monitored regularly was the average time spent on completing the online education module. A team meeting was scheduled to identify, and trouble shoot any challenges encountered by the participants in completing the online learning module. Emails

were sent out to encourage active participation and completion, provided guidance on how to access the web-based learning module, and identified areas that may need further clarification. For enactment, handouts were included to encourage participants to apply the knowledge and skills they have gained from the intervention. By addressing each of these components in the design, training, delivery, receipt, and enactment stages of the educational intervention, an effort was made to improve the intervention fidelity, ensuring that the intervention is implemented as intended and produces meaningful outcomes.

#### **3.5 Data Collection**

SurveyMonkey was utilized to create a one-link, self-reported module that provided the pre-evaluation, infographic, and post-evaluation. SurveyMonkey measures the pre- and post-test scores of participants. This measurement is used to determine if there is any change in baseline knowledge of CA prevention methods after educational module completion. The SurveyMonkey link was sent out via secure emails to all CRNAs and MDAs at the affiliated One Day Surgery Center. A reminder email was sent each week to encourage the anesthesia providers participation. In addition, a QR code for this link was made available at the facility for easy access and distributed in areas that were frequently used by MDAs and CRNAs (including breakrooms and meeting areas).

# 3.6 Method of Data Collection

In both the pre- and post-evaluations on SurveyMonkey, clear questions were asked to identify knowledge regarding the prevention of CAs. Similar questions were used between the pre- and post-evaluation, to identify the completion of the module and whether learning occurred from the infographic. According to Bellg et al. (2004), measuring provider knowledge during and after training is essential to assess education effectiveness. In the pre-test, additional questions were asked to quantify anesthesia providers: the title of the anesthesia provider taking the module (CRNA or MDA) and the number of years of anesthesia experience. This helped determine which subset of providers were taking the module and would not have any impact on the overall score of the pre- and post-evaluation. The information gathered from these questions was also used "to evaluate differential effectiveness by professional experience" with results after the pre- and post-evaluations are completed as this accommodated provider differences (Bellg et al., 2004). The rest of the questions asked were closed-ended and based on education provided in the module. The platform that was utilized keeps track of the number of participants completing the module and stores the results from the evaluations.

#### 3.7 Inclusion and Exclusion Criteria

Inclusion criteria for participation included any anesthesia provider that currently provides anesthesia care to surgical patients at the facility. Exclusion criteria included nonanesthesia providers in the surgical arena – such as circulating nurses, surgical scrub technicians, anesthesia technicians, and SRNAs. Additional exclusion criteria included CRNAs or MDAs that do not work at the facility. The reason for exclusion of these participants was to limit the project sample to only the facility of interest.

# 3.8 Data Management and Security

Completion of the module remained confidential, only identifying the participants by the IP address provided upon completion of the module. Each participant was assigned a unique study code (ID), which was used for data entry, tracking, and analysis. All questionnaires are identifiable; however, each participant was assigned a unique ID. Each participants' ID was stored in a secured, IRB approved web-based folder. This web-based folder is password

protected and only accessible by the project personnel. A consent form was provided to participants prior to completing the module. This consent informs participants that their years of experience and provider role would be used for study purposes. Participants were reassured that their identity remained confidential and secure. In addition, the participant ID number is associated with the pre- and post-test for tracking purposes.

Furthermore, UNCC and the participating healthcare facilities share a uniform policy on the protection of patient privacy that satisfies all the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The proposed project and personnel abide by both organizations' policies, and strictly adhered to the detailed human subject protection regarding data analysis. This was utilized during this project intervention period to preserve participants' privacy and security. Participants were provided the option to opt out of participating in the project.

# **3.10 Data Analysis and Evaluation**

All statistical analyses were performed using R Statistical Analysis Software (version 4.0.2, R Foundation for Statistical Computing, Vienna, Austria) with a significance level of 0.05 (De Micheaux et al., (2013). Pre-analysis data screening was performed prior to statistical analysis to examine coding errors, outliers, and data skewness to determine if any data cleaning procedures are needed. Coding errors often occur when the questionnaires are used as assessment tools. To reduce coding errors, the statistician was consulted, and statistical procedures were used to recode the study questionnaires.

Descriptive statistics (means, standard deviations, or median, interquartile range, or number, percentages, and frequencies) were calculated for all variables. Demographic characteristics of the study population were analyzed as means and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables. All statistical tests are 2-tailed. The variables were checked for normality and the mean and standard deviation was used as a measure of central tendency since the data are normally distributed.

The  $\chi^2$  were performed to describe and compare frequencies. The Student t-test were utilized to test for significant differences between pre and post-survey scores. Pearson's correlation coefficients were used to determine the relationships between key concepts. Univariate and multivariate logistic regression or linear regression analyses were performed to determine the relationships between the pretest and posttest.

#### 3.11 Timeline

A Gantt Chart was utilized to illustrate the timeline of this quality improvement project. According to Sipes (2020), a Gantt Chart outlines a project plan by defining the start and end dates of each task. Each phase of the project correlates with the development and completion of each individual category. The corresponding dates of tasks were predictions as the development of any project may experience unforeseen delays. Some tasks required more time than predicted. According to Bellg et al. (2004) addressing possible setbacks is important to the consistency of the course of the project. Phase one was initiated by performing a needs assessment on providers' awareness and education on corneal abrasions. During phase two, a literature review was completed in March 2023.

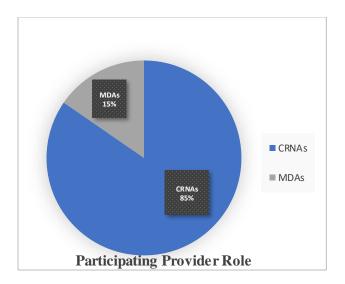
Phase three began with the development of the educational module. IRB approval was obtained in July 2023. The web-based module was introduced to the anesthesia providers at the end of July 2023. Data collection and intervention took place for five consecutive weeks. This allowed opportunity for full time and PRN providers to successfully complete the module. Refer

to Appendix A for a visualization of the progress of the project and the anticipated dates of completion for each task.

### **CHAPTER IV: RESULTS**

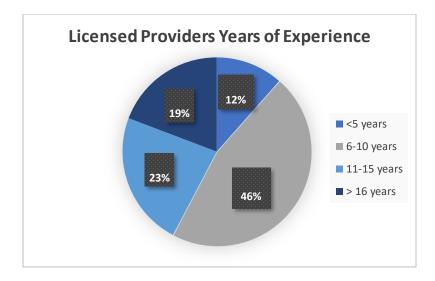
# **4.1 Sample Characteristics**

An invitation to participate was sent out to 77 providers, excluding any anesthesia provider that did not work at the facility of interest. A total of 26 anesthesia providers participated in the web-based educational module, resulting in an overall participation rate of 33%. Most of the participants identified as a CRNA (n=22). The minority participants included four MDAs. The providers were further questioned to obtain their years of experience. Of the 26 participants, 3 providers had less than 5 years of experience (12%), 12 providers had 6 to10 years of experience (46%), 6 providers had 11 to15 years of experience (23%), and 5 providers revealed greater than 16 years of experience (19%) (refer to Figure 2).





Participating anesthesia providers role





Participating providers' years of experience

# 4.2 Findings and Interpretations

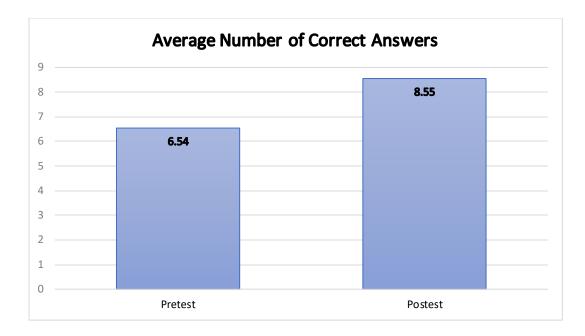
# Table 1

Pretest and posttest comparison for each question and total score

		Pretest $(n = 26)$	Posttest ( <i>n</i> =	<i>p</i> -value
		% correct	22)	<i>p</i> -value
		70 concer	% correct	
1.	What is the most common ocular adverse	100	100	1.00
	event related to anesthesia?			
2.	In the preoperative area, which finger is optimal for pulse oximeter probe placement?	80.8	81.8	1.00
3.	All of the following are common offenders of corneal abrasion EXCEPT:	84.6	100	.162
4.	When is the optimal time to tape the eyes closed during induction?	57.7	81.8	.138
5.	Which statement is TRUE:	23.1	63.6	.011
6.	What is the proper method to remove protective eye tape prior to patient emergence?	57.7	77.3	.260
7.	Which is NOT a risk factor for corneal abrasions:	65.4	90.9	.080
8.	According to the American Society of Anesthesiologists Closed Claims analysis, the mechanism of injury was identified in what percentage of corneal abrasion claims?	34.6	81.8	.003
9.	All of the following heightens the risk for corneal abrasions during general surgery, EXCEPT:	92.3	81.8	.511
10	All of the following agents have been used for CA treatment EXCEPT:	57.7	95.5	.007
Total score		6.54 (1.14)	8.55 (1.53)	<.001

Note. *p*-values for the individual questions were based on chi-squared tests. The p-value for

testing total score difference was based on paired t-test.





# Participant average number of correct answers

The findings from each question provided in the educational module is reflected in Table 1. Of the 26 participants, only 22 participants completed the posttest evaluation. In addition, there were 3 questions with significant differences in the pretest-posttest. Each of the individual questions were based on a chi-squared test. Prior to the introduction of the infographic, question 5 reflected less than 24% (n=6) of participants were aware that there is no significant improvement in CA prevention by applying lubricating eye ointment prior to taping eyelids. Pretest analysis of question 8 showed that 35% (n=9) of participants were able to correctly identify the percentage of corneal abrasion claims by the American Society of Anesthesiologist Closed Claims analysis. Question 10 revealed that 95.5% of participants were aware of the agents used for CA treatment after education was provided. Overall, questions 5 (pretest= 23.1, posttest= 63.6), 8 (pretest=34.6, posttest= 81.8), and 10 (pretest 57.7, posttest= 95.5) displayed a significant difference between pretest and posttest scores. Most participants answered these

questions correctly on the posttest. Furthermore, question 9 assessed providers knowledge on heightened risk for CA during general surgery. Question 9 reflected a 10.5% reduction between the pretest and posttest.

The frequencies from the majority of each question reflects a consistent rise in the percentage of correct responses. Furthermore, Figure 3 depicts the average number of correct answers increased from 6.54 (SD=1.14) to 8.55 (SD=1.53). A Paired T-Test was performed to examine correlation between participants' pretest and posttest scores. A t-value of 5.74 and associated p-value < 0.001 was determined. These values are indicative of statistical significance between anesthesia providers' pretest and posttest scores. An explanation for these finding can infer that a web-based educational module provided to anesthesia providers does increase the awareness of evidence-based corneal abrasion prevention measure during the perioperative period.

#### **CHAPTER V: DISCUSSION**

#### 5.1 Summary

To our knowledge, this QI project was the first reported project that examined the effect of a web-based education module on anesthesia providers' knowledge on CA prevention. Many anesthesia providers lack awareness of the updated literature recommendations for CA prevention and alleviation. The purpose of this project was to increase anesthesia providers' awareness on current evidence-based practice using a web-based educational module. The findings demonstrated that a concise web-based education module has a positive influence on providers' awareness of CA prevention. Tools such as an infographic, provides an easy-to-follow visual presentation of information. Providing an easily accessible QR code endorsed the participation from providers in a very busy clinical setting. The minimally identifiable component of the module allowed for a bias free learning opportunity, and the reduction of participants' concerns for judgement of pretest and posttest scores. Provider responses displayed significant progress after the completion of the module. Ongoing provider education is paramount during the parallel evolution of healthcare.

#### **5.2 Interpretation**

The literature revealed that implementation of a web-based module provided to anesthesia providers on CA prevention has produced practice change. According to Abbas et al. (2020) a concise web-based educational module has proven to be an effective tool to educate healthcare workers. A baseline knowledge test was used as a comparison tool to determine if the education was effective after the introduction of the infographic. Table 1 details the improvement in the average total of correct answers between the pretest (6.54) and posttest (8.55) scores. An exam score of 80% or higher has demonstrated a successful completion of an online program (Van de Steeg et al., 2015). The paired T-test analysis with an associated p-value <0.001 revealed the statistical significance between the two scores.

Furthermore, providers demonstrated knowledge gain in concepts such as: superiority of prevention methods (question 5), percentage of closed claims related CA (question 8), and treatment modalities for CA (question 10). Several studies found in the literature revealed the improvement in provider awareness after an educational module was presented. However, researchers did determine that WBL can provide better maintenance of knowledge that can be lost after time (Maloney et al., 2012). On the other hand, the demographics collected in this QI project showed no statistical significance on the participants' scores. One study revealed there was a small difference in scores based on age. Age was not a demographic collected in this module. Parallel with the findings, the literature supports the effectiveness of WBL on providers' awareness. Implementation of a web-based module has the potential to expand competencies in clinical practice.

#### **5.3 Limitations**

A major limitation that was anticipated and evident was provider participation. The clinical setting is an extremely busy environment, especially the operating room. Provider engagement was a huge challenge that was very difficult to combat alone. Providers can become overwhelmed with the numerous surveys they receive via email. In addition, the expertise of a clinical expert was sought, to assist in providing strategies to promote provider participation. Despite weekly reminder emails, participation remained minimal until the last week of data collection. Providers' participation appeared favorable during the introduction of the educational module to the facility. However, by week 2 of data collection the participation rate plateaued.

Out of 77 providers that were sent an email invite to participate, 26 anesthesia providers participated in the module. This yielded a final participation rate of 33.7%.

In addition, the study participants were from a ODSC affiliated with a large urban teaching facility. The potential participants administered anesthesia between the facility of interest and the affiliate hospital. The most significant limitation of this type of design is the lack of a control group, potentially introducing bias and threats from confounding factors. To reduce the impact of potential bias and confounding factors, a secured email was sent explicitly to all providers who migrated between the two. However, there was not a definite approach to determine if anesthesia providers from the affiliated facility participated in the module. Furthermore, the utilization of a small convenience sample could affect the validity of the results. The study is limited by measuring the short-term effect of the online educational module. Due to feasibility and time constraints, an assessment of the long-term effect of the online learning module was undetermined.

#### **5.4 Recommendations**

The observed findings from this project are consistent with expected findings that were established from the literature. As previously stated, the statistical significance that was revealed in the results are congruent with the finding of several studies found in the literature. However, minimizing bias and confounding factors that can threaten the validity of the project is imperative. To mitigate the undetermined factor of provider employment at the facility of interest, it is recommended to observe the effects of providing education to anesthesia providers of facilities that are not located on the same campus. This reduces the risk of an uncontrolled sample. In addition, it is recommended that a web-based educational module is available to anesthesia providers as a reference. Assessment of the incidence rate of CA at the facility of interest, before and after the introduction of the educational module, can determine the long-term effect of the online learning module.

#### **5.5 Conclusion**

The findings from the current literature and baseline knowledge assessment scores exposed the implications for practice on expansion of anesthesia providers' awareness on current literature related to corneal abrasion prevention. Corneal abrasions remain one the most common ocular adverse events related to general anesthesia (Barash, 2017, p. 292). It is evident that a WBL module displays statistical significance between pre- and posttest scores. The WBL module allowed anesthesia providers at the facility of interest the opportunity to examine their knowledge on CA prevention and learn about the most current recommendations. After the project concluded, anesthesia providers were given an electronic copy of the infographic to use as a concise reference. An approach that can be implemented to expand anesthesia providers' awareness and reduce the occurrence of CA are learning refreshers that are easily accessible. In addition, future investigation into the occurrence of CA before and after the administration of an educational module would be beneficial to future research at a similar facility. Porter et al. (2022) revealed the reduction in the occurrence of CA by 12-13%, after an online learning module was introduced. In summary, it can be concluded that a web-based educational module provided to anesthesia providers does increase the awareness of evidence-based corneal abrasion prevention measures during the perioperative period.

#### 5.6 Funding

Expenses for the tools required for implementation did not receive funding. SurveyMonkey cost to access extensive features totaled to \$400. This expense was a major limitation as the survey engine had to be paid out of pocket by the project developer. Despite the limitations that were encountered, strategies were utilized to reduce the strength of these effects.

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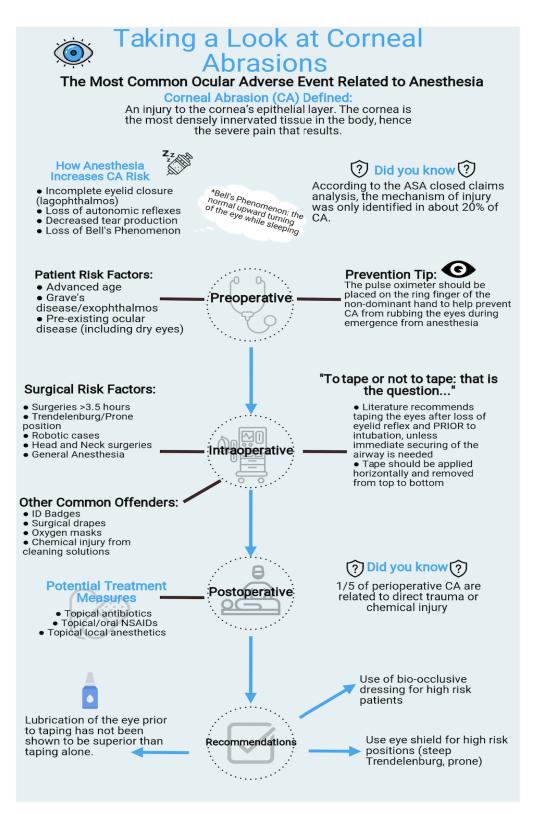
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# **APPENDIX A: GANTT CHART**

#### GANTT CHART



# **APPENDIX B: EASEL.LY INFOGRAPHIC**



# **APPENDIX C: PRE-TEST EVALUATION**

What is your role with Atrium Health anesthesia?

- a. Anesthesiologist (MDA)
- b. Certified Registered Nurse Anesthetist (CRNA)
- c. Student Registered Nurse Anesthetist (SRNA)

If you are a licensed anesthesia provider, how long have you been practicing?

- a. <5 years
- b. 6–10 years
- c. 11-15 years
- d. 16+ years
- 1. What is the most common ocular adverse event related to anesthesia?
  - a. Postoperative vision loss

#### **b.** Corneal abrasions

- c. Increased intraocular pressure
- d. Conjunctivitis
- 2. In the preoperative area, which finger is optimal for pulse oximeter probe placement?
  - a. Index finger of non-dominant hand
  - b. Middle finger of non-dominant hand
  - c. Ring finger of dominant hand

# d. Ring finger of non-dominant hand

- 3. All of the following are common offenders of corneal abrasion except:
  - a. ID badges

b. Surgical drapes

# c. Tegaderm dressing

- d. Oxygen masks
- 4. When is the optimal time to tape the eyes closed during induction?

# a. Before confirming mask ventilation

- b. After confirming mask ventilation
- c. Just before intubation
- d. Just after intubation

# 5. Which statement is true:

- a. Tegaderm/biooclusive dressing has been found to be the best prevention intervention with lower rates of ocular injuries
- b. Studies have shown no significant improvement in corneal abrasion prevention by applying lubricating eye ointment prior to taping eyelids
- c. All perioperative CA are related to direct trauma or chemical injury
- d. Intra-operative CA can be attributed to the enhancement of Bell's phenomenon
- 6. What is the proper method to remove protective eye tape prior to patient emergence?
  - a. Bottom to top
  - b. Top to bottom
  - c. Horizontally
  - d. The literature says it shouldn't matter
- 7. Which is NOT a risk factor for corneal abrasions:

a. Surgeries lasting longer than 3.5 hours

#### b. Obesity

- c. Supplemental oxygen en route to the Post-Anesthesia Care Units
- d. Trendelenburg position

8. According to the American Society of Anesthesiologists Closed Claims analysis, the mechanism of injury was identified in what percentage of corneal abrasion claims?

- a. 10%
- b. 15%
- c. 20%
- d. 25%

9. All of the following heightens the risk for corneal abrasions during general surgery, except:

- a. Loss of autonomic reflexes
- b. Decreased tear production
- c. Absence of the blink reflex

# d. Complete closure of the eyelids (lagophthalmos)

10. All of the following agents have been used for CA treatment except:

- a. Topical antibiotic ointments/drops
- b. Topical or oral NSAIDs
- c. Topical anesthetics
- d. Antihistamine drops

# **APPENDIX D: POST-TEST EVALUATION**

- 1. What is the most common ocular adverse event related to anesthesia?
  - a. Postoperative vision loss

#### b. Corneal abrasions

- c. Increases intraocular pressure
- d. Conjunctivitis
- 2. In the preoperative area, which finger is optimal for pulse oximeter probe placement?
  - a. Index finger of non-dominant hand
  - b. Middle finger of non-dominant hand
  - c. Ring finger of dominant hand

#### d. Ring finger of non-dominant hand

- 3. All of the following are common offenders of corneal abrasion except:
  - a. ID badges
  - b. Surgical drapes
  - c. Tegaderm dressing
  - d. Oxygen masks
- 4. What is the optimal time to tape the eyes closed during induction?

# a. Before confirming mask ventilation

- b. After confirming mask ventilation
- c. Just before intubation
- d. Just after intubation
- 5. Which statement is true:

- a. Tegaderm/biooclusive dressing has been determined to be the best prevention intervention with lower rates of ocular injuries
- b. Studies have shown no significant improvement in corneal abrasion prevention by applying lubricating eye ointment prior to taping eyelids
- c. All perioperative CA are related to direct trauma or chemical injury
- d. Intra-operative CA can be attributed to the enhancement of Bell's phenomenon
- 6. What is the proper method to remove protective eye tape prior to patient emergence?
  - a. Bottom to top

#### b. Top to bottom

- c. Horizontally
- d. The literature says it shouldn't matter

7. Which is NOT a risk factor for corneal abrasions:

a. Surgeries lasting longer than 3.5 hours

### b. Obesity

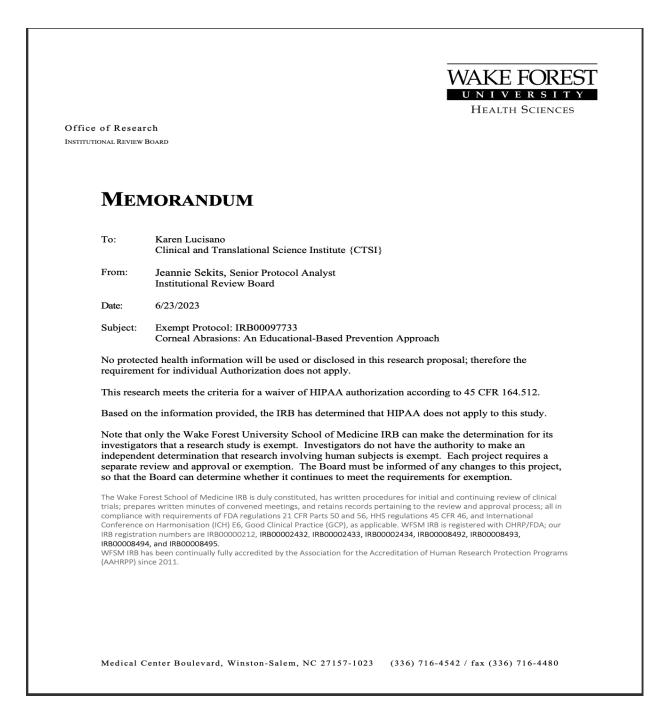
- c. Supplemental oxygen en route to the Post-Anesthesia Care Units
- d. Trendelenburg position

8. According to the American Society of Anesthesiologists Closed Claims analysis, the mechanism of injury was identified in what percentage of corneal abrasion claims?

- e. 10%
- f. 15%
- g. 20%
- h. 25%

- 9. Patients are at an increased risk for corneal abrasions during general anesthesia except for:
  - a. Loss of autonomic reflexes
  - b. Decreased tear production
  - c. Absence of the blink reflex
  - d. Complete closure of the eyelids (lagophthalmos)
- 10. All of the following agents have been used for CA treatment except:
  - e. Topical antibiotic ointments/drops
  - f. Topical or oral NSAIDs
  - g. Topical anesthetics
  - h. Antihistamine drops

# **APPENDIX E: IRB APPROVAL LETTERS**





Megan Frowine

To:

	University of North Carolina at Charlotte		
From:	Office of Research Protections and Integrity		
Approval Date:	28-Jul-2023		
RE:	Notice of Determination of Exemption		
Exemption Category:	1		
Study #:	IRB-24-0007		
Study Title:	An Educational-Based Approach to Prevent Corneal Abrasions		

This submission has been reviewed by the Office of Research Protections and Integrity (ORPI) and was determined to meet the Exempt category cited above under 45 CFR 46.104(d). This determination has no expiration or end date and is not subject to an annual continuing review. However, you are required to obtain approval for all changes to any aspect of this study before they can be implemented and to comply with the Investigator Responsibilities detailed below.

Your approved consent forms (if applicable) and other documents are available online at Submission Page.

#### Investigator's Responsibilities:

- 1. Amendments **must** be submitted for review and the amendment approved before implementing the amendment. This includes changes to study procedures, study materials, personnel, etc.
- 2. Researchers must adhere to all site-specific requirements mandated by the study site (e.g., face mask, access requirements and/or restrictions, etc.).
- 3. Data security procedures must follow procedures as described in the protocol and in accordance with <u>OneIT Guidelines for Data Handling</u>.
- 4. Promptly notify the IRB office (<u>uncc-irb@charlotte.edu</u>) of any adverse events or unanticipated risks to participants or others.
- 5. Five years (5) following this approval/determination, you must complete the Admin-Check In form via Niner Research to provide a study status update.
- 6. Be aware that this study is included in the Office of Research Protections and Integrity (ORPI) Post-Approval Monitoring program and may be selected for post-review monitoring at some point in the future.
- 7. Reply to the ORPI post-review monitoring and administrative check-ins that will be conducted periodically to update ORPI as to the status of the study.
- 8. Complete the Closure eform via Niner Research once the study is complete.