AN EDUCATIONAL-BASED APPROACH TO PREVENT CORNEAL ABRASIONS

by

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ABSTRACT

MARA LEAVITT. An Educational-Based Approach to Prevent Corneal Abrasions. (Under the direction of DR. LUFEI YOUNG)

Corneal abrasions 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 corneal abrasion prevention. The purpose of this study project was to assess if a webbased educational module effectively improved anesthesia providers' awareness of evidencebased preventative measures of corneal abrasions. This was a quasi-experimental pretest-posttest study design. All participants completed a questionnaire regarding their knowledge of 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. There were 55 participants in the study. Among them, 23.6% were anesthesiologists and 76.4% were certified registered nurse anesthetists. There was a significant pretest-posttest difference in the total knowledge score $(6.49\pm1.23 \text{ vs. } 8.24\pm1.08, \text{ p}<.001)$. The average number of correct answers increased from 6.49 \pm 1.23 to 8.24 \pm 1.108 (t = 9.94, p < .001) Overall, the web-based educational module was effective in enhancing anesthesia providers' knowledge in preventing surgical-induced corneal abrasions. The finding may add evidence for developing effective guidelines and standardizing provider education in corneal abrasion prevention

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DEDICATION

I dedicate this paper to my parents, Mary and Daniel Leavitt. It is hard to write into words the love I share for them and the unwavering support and love they have showered me with. They have been my rock, my shoulder to cry on, and my cheering squad these last three years. I cannot thank them enough for the sacrifices they have made to get me to this point in my life. Love you beyond words. This journey has certainly taken a village, I would like to thank my brother Patrick, my sister-in-law Mackenzie, and my nephews Wyatt and Owen. I would also like to thank my study group (Megan Frowine, Cameron McClane, Caitlin McConnell, and Morgan Pullium) who went from study group to lifelong friends, Dr. Victoria Valencia, and Christian Bobo. And lastly, my cat Ru. I adopted her at the beginning of this program, and she has been my forced emotional support animal ever since (even if she does not always want to be).

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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

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 deviations

SECTION I: INTRODUCTION

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.

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 incidences 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 surgery. 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 eyes (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.

Purpose of the Project

To address this clinical issue, we proposed a quality improvement (QI) project aimed to increase providers awareness on current evidence-based practices to reduce CA occurrence in perioperative patients. The purpose of this project was to study the effect of a web based educational module provided to anesthesia providers and its influence on providers' awareness of corneal abrasions in patients at multiple facilities within a major healthcare organization. We investigated providers' awareness regarding current literature recommendations on effective methods used to prevent and reduce CA and CA risks. An educational module was provided, and providers were given a pre-assessment and post-assessment. Current literature identifies the effectiveness of educational modules on the awareness regarding up-to-date clinical practice among healthcare professionals.

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**)?

Stakeholders

As we conducted the investigation, the stakeholders we had identified are Certified Registered Nurse Anesthetist (CRNA), Anesthesiologist (MDA), Post Anesthesia Care Unit Registered Nurse (PACU RN), Ophthalmologist, Risk Management Leader, Surgeon, study site, 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 CA is classified as an anesthesia-related 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; thus, ophthalmologist involvement is necessary. Lastly, when adverse events are documented, the risk management leader investigates the occurrence.

SECTION II: LITERATURE REVIEW

Database Search

A literature review was performed using the search terms, "corneal abrasions", "corneal injuries," "general anesthesia," "prevention, surgery," "web-based learning," "anesthesia," "anesthesia providers," and "healthcare providers." 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. The keywords previously mentioned were used to target journal articles pertinent to the above PICOT question.

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. They are associated with significant pain, stress, and heightened anxiety during the postoperative 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 of which CA occurred in 35% of those cases (Aitkenhead, 2005). Furthermore, perioperative CA yields 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 should contribute to the overall reduction of CA incidence while increasing provider awareness.

CA Prevention and Control

An important facet when dealing with CA prevention is awareness of patient risk factors. Studies have differed slightly in their identification of risk factors that are the greatest perpetrators for increased frequencies of CA. In one study, 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) found 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. In a 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.

Recommendations for 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 eyes. 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 their new protocol, results showed a marked reduction in CAs. Porter et al. (2022) also achieved a noticeable reduction in CA through a similar manner of standardizing CA prevention. Their interventions included educating providers on causes, risk factors, and prevention measures throughout the perioperative period. Like Vetter et al.'s study (2012), they also 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. Through the use of these interventions, 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 in which 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 CA. The intervention was based on the belief that patients could 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 patient's nose to prevent the mask moving toward the eyes 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 various guidelines that support these interventions. These studies highlight the need for 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.

Effectiveness of Current Education

As previously mentioned, educational modules 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 CRNAs, 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) also studied the effects of 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, educational interventions have 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 digital 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 electronic health records (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 HER that 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. Several strategies have been employed and no single method has not proven to be more advantageous than others. Of note, 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 a reduction in CA incidences. In Martin et al.'s (2009) case-control study, rates of CA were followed throughout the education initiative and noted a substantial reduction compared to the beginning phases (Papp et al., 2019). Vetter et al. (2012) found similar results 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 sustained reduction in CA after implementation of the education programs in these studies is a testament to their overall effectiveness.

As previously discussed, there were a few studies aimed to increase provider compliance of 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).

Effects of Web-Based Education on Practice

More recently there has been a shift to provide education via electronic and web-based platforms. The COVID-19 pandemic proved that educational 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. Sixty-seven 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. Based on the results, Liaw et al. (2015) concluded that web-based simulations provide an effective

educational tool where large groups require training, and grant accessibility to repetitive training to promote retention of clinical competency. In addition, participants of WBL perceived 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.

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. The results found 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 post-exam 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, and patient outcomes.

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).

Review of Findings

In summary, CA remains 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).

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 positive practice changes. 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.

Conceptual/Theoretical Framework

For this quality improvement project, we followed the structure, process, outcome (SPO) model. The structure refers to the environment where care is provided. My structure included the facility I distributed CA education which was the study site. The process refers to the actions

being performed to affect care delivery. My process was to provide education to anesthesia providers regarding CA best practice prevention measures with the web-based method. Finally, the outcome refers to the end results of the QI project. My outcome included increasing provider awareness of CA prevention, which I anticipate will result in a reduction of CA incidence and increased patient satisfaction at the healthcare facility of interest.

SECTION III: METHODOLOGY

Study Design

This project is a quantitative, quasi-experimental design using a pre-test post-test design. The goal of this quality improvement project was to assess the effectiveness of an educational module on the awareness of CA prevention strategies among anesthesia providers. 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 and follow 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 (Ogrinc 2026). Both the clinical site and the university Institutional Review Boards were obtained prior to the implementation of the project (Appendix E, both IRB approval letters).

Setting

The project took place within a surgical center associated with a comprehensive healthcare system situated in the southeastern region of the United States. The health system is the largest hospital in the region, boasting a world-class facility that offers a comprehensive range of services. With over 1,100 specialized physicians and providers covering all areas of medicine, it stands as the region's only Level 1 trauma center. Additionally, it is an approved transplant center for heart, kidney, pancreas, and liver procedures. The entire health system, including the associated surgical center, also operates as one of five teaching facilities, providing residency training for more than 200 physicians across 15 specialties.

Population

The population for this project consisted of anesthesia providers, including MDAs and CRNAs, from the facility of interest. Convenience sampling was the method used to obtain subjects. The potential sample consisted of 158 CRNAs and 71 MDAs at the study site. In the pre-test portion of the project's intervention, participants were asked what their professional role is and how long they have been practicing. The purpose was to investigate whether this information altered pre-test and post-test results.

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 CA, prevention method strategies, and treatment measures supported by the literature. Easel.ly was the platform used to create said infographic. This platform allows for straightforward navigation to build a visual aid that includes pictures, graphs, and text. Easel.ly meets IRB requirements of protection confidentiality. The infographic was easily created into a PDF that was included in the main educational portion of the module. Review Appendix B for the infographic presented in the module.

The following strategies were used to enhance and maintain the intervention fidelity. For study design, we developed clear and detailed intervention protocols that outlined specific education components and expected outcomes. We provided standardized education materials that aligned with the intervention protocol. To improve the intervention fidelity, all team members participated in training in developing online surveys and web-based educational modules. To ensure the delivery and receipt, we regularly monitored the average time spent on completing the online educational module and scheduled team meetings to identify and trouble shoot any challenges encountered by the participants in completing the online learning module. We also sent regularly scheduled emails to encourage active participation and completion, provide guidance on how to access the web-based learning module, and identify areas that may need further clarification. For enactment, we included handouts 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, we made effort to improve the intervention fidelity, ensuring that the intervention is implemented as intended and produces meaningful outcomes.

Procedures

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-test 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 study site to complete. In addition, a QR code for this link was made available at the facilities for easy access

and distributed in areas that are frequently used by MDAs and CRNAs (including breakrooms and meeting areas). The data collection took place over a five-week period, weekly reminder emails were sent to eligible anesthesia providers with the SurveyMonkey link.

Method of Data Collection

In both the pre- and post-tests on SurveyMonkey, clear questions were asked to identify knowledge regarding the prevention of CA. Similar questions were used between the pre- and post-test to identify that the module was completed 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 had no impact on the overall score of the pre- and post-test. The information gathered from these questions was also used "to evaluate differential effectiveness by professional experience" with results after the pre- and post-test 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 infographic. The platform that was utilized keeps track of the number of participants completing the module and stores the results from the evaluations.

Inclusion and Exclusion Criteria

Inclusion criteria for participation included any provider that currently provides anesthesia care to surgical patients at the study site. Exclusion criteria included non-anesthesia providers in the surgical arena – such as circulating nurses, surgical scrub technicians, and anesthesia technicians. Additional exclusion criteria included CRNAs or MDAs that do not work

at the study site. The reason for exclusion of these participants was to limit the project sample to only the facility of interest.

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, Institution Review Board (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 informed participants that their years of experience and provider role would be used for study purposes only. Participants were reassured that their identity remained confidential and secure. In addition, the participant's ID number was associated with the pre- and post-test for tracking purposes.

Furthermore, REDCAP is an online password protected data storage site utilized by project personnel to access all stored data. REDCAP is only accessible to the project personnel, the sponsor of this research, IRB, and any other persons required by law. The University of North Carolina at Charlotte (UNCC) and the participating healthcare facility 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 abided by both organizations' policies, and strictly adhered to the detailed human subject protection regarding data analysis. This was utilized during this project's intervention period to preserve participants' privacy and security. Participants were provided the option to opt out of participating in the project.

Data Analysis and Evaluation

All statistical analyses were performed using R (version 4.0.2, R Foundation for Statistical Computing, Vienna, Austria) with a significance level of 0.05 (de Micheaux, 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. Additionally, the missing data caused by unanswered questions was reviewed for patterns that would introduce bias to the results. Participants were asked to go back and fill out the questionnaires completely. If some data items remain missing, these issues were resolved via consultation with the statistician and major advisor.

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 is normally distributed.

The $\chi 2$ were performed to describe and compare frequencies. The student t-test was utilized to test for significant differences between pre and post-test 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.

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 project initiation was developed when assessing the need to address providers' awareness and education on corneal abrasions. The project topic was finalized in December 2022, and a literature review was conducted in March 2023. The proposal defense was successfully completed at the end of April 2023. Approval from both Wake Forest School of Medicine IRB and UNCC IRB was obtained in July 2023, see Appendix E for approval letters from both institutions. The web-based module was introduced to the anesthesia providers and data collection started in August 2023. Data collection continued to the first part of September 2023. The module was available over a five-week period for anesthesia providers to complete. This allowed opportunity for full time and PRN providers to successfully complete the module. Data analysis and report generation were finished at the end of September 2023. Refer to Appendix A for a visualization of the progress of the project and the dates of completion for each task.

SECTION IV: RESULTS

Sample and Setting Description

In total fifty-five individuals participated in taking this online educational module from the study site, which is a large urban trauma center. The following were the demographics of these participants: 23.6% were anesthesiologists and 76.4% were CRNA, this is reflected in Figure 1 of provider roles. Out of these participants, 47.3% had less than 5 years of experience, 16.4% had 6 to 10 years of experience, 12.7% had 11 to 15 years of experience, and 23.6% had 16 or more years of experience (refer to Figure 2). Overall, demographic variables did not relate to either the pretest or post test scores, with a *ps>*.205. These findings show that the questions investigated as to whether provider role and experience affect corneal abrasion knowledge, have no impact on the difference between the pretest and posttest scores.

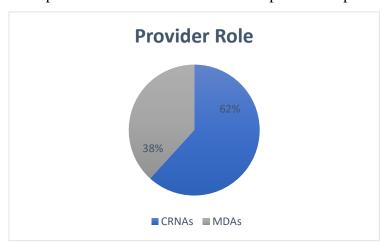


Figure 1. Comparison of provider roles

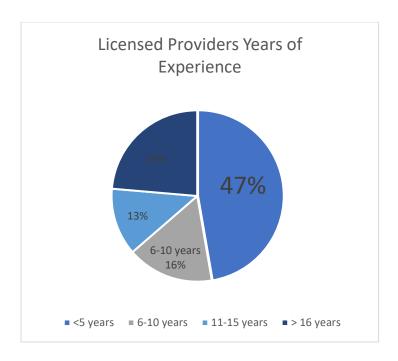


Figure 2. Years of experience among participating anesthesia providers

Primary Findings

Table 1 shows the comparison of scores from the pretest and posttest for each of the ten questions. There was a significant increase in scores after reviewing the infographic for the following questions: Question 2: optimal finger to place pulse ox (χ 2(1) = 6.69, p = .083); Question 5: lubrication has shown no significant improvement in reducing corneal abrasions (χ 2(1) = 6.00, p = .014); Question 6: proper method of removing eye tape (χ 2(1) = 5.40, p = .020); Question 7: risk factors of corneal abrasions (χ 2(1) = 7.10, p = .008); Question 8: percentage of identified mechanism of injury for corneal abrasions (χ 2(1) = 49.40, p < .001); and Question 10: treatment methods for corneal abrasions (χ 2(1) = 7.74, p = .005). Overall, there was an increase in total score after reviewing the module, the average score changed from 6.49 with a standard deviation of 1.23 to 8.24 with a standard deviation of 1.08, t = 7.26, p < .001. This is reflected in Figure 4 which shows the comparison of the average pretest and posttest scores.

anesthesia providers knowledge on corneal abrasion education and prevention methods, and that after reviewing the learning aid, overall, anesthesia providers increased their score on the posttest compared to the pretest.

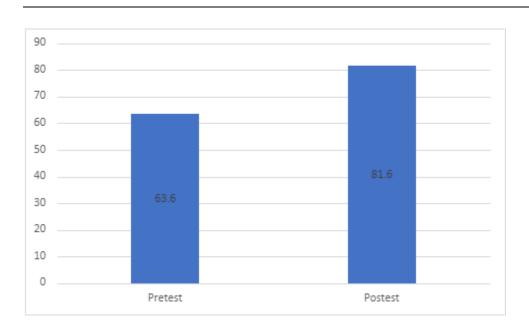
Table 1. Pretest and posttest comparison for each question and total score

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.

		Pretest (<i>n</i> = 55)	Posttest (n = 42)	<i>p</i> -value
		% correct	% 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	74.5	90.5	.083
	optimal for pulse oximeter probe placement?			
3.	All of the following are common offenders of	80.0	88.1	.430
	corneal abrasion EXCEPT:			
4.	When is the optimal time to tape the eyes	67.3	38.1	.008
	closed during induction?			
5.	Which statement is TRUE:	43.6	64.3	.070
6.	What is the proper method to remove	65.5	88.1	.020
	protective eye tape prior to patient			
	emergence?			
7.	Which is NOT a risk factor for corneal	61.8	88.1	.008
	abrasions:			

Table 1. Pretest and posttest comparison for each question and total score (continued)

8.	According to the American Society of	16.4	90.5	< .001
	Anesthesiologists Closed Claims analysis, the			
	mechanism of injury was identified in what			
	percentage of corneal abrasion claims?			
9.	All of the following heightens the risk for	72.7	83.3	.322
	corneal abrasions during general surgery,			
	EXCEPT:			
10	. All of the following agents have been used for	67.3	92.9	.005
	CA treatment EXCEPT:			
	Total score	6.49 (1.23)	8.24 (1.08)	< .001



SECTION V: DISCUSSION

Summary

This quality improvement project was the first reported initiative at the study site to investigate the impact of a web-based educational module on anesthesia providers' knowledge of perioperative CA prevention. CA are the most common ocular adverse events after surgery, with increased risks associated with positioning, provider awareness, and surgical environment. At the study site, there is no standardized method for prevention. The project aimed to assess how a web-based educational module could enhance providers' knowledge of perioperative CA prevention. This module presented recommendations synthesized from a comprehensive literature review of effective strategies for preventing perioperative corneal abrasions. Based on data collected from 55 anesthesia providers, which included CRNAs and MDAs, the web-based education was effective in improving providers' knowledge about preventing corneal abrasions. Following the education, participants gained knowledge in understanding the mechanisms of corneal abrasion injuries, recognizing risk factors, and implementing prevention and treatment methods.

Interpretation

Consistent with the findings of the only study that used WBL for CA awareness (Porter et al., 2022), our project also demonstrated that online education is effective in increasing awareness and knowledge about the prevention of perioperative corneal abrasions. The rise in posttest scores indicates an enhancement in knowledge through an online approach. This project provides additional evidence that a single-session web-based educational module is an effective method for improving anesthesia providers' awareness and knowledge about preventing perioperative corneal abrasions.

Among the questions presented in the module, many showed statistically significant improvements in correct answers after reviewing the online module. Specifically, for question two, which asked which finger is optimal for pulse oximeter probe placement, the correct answer rate for this item increased from 74.5% to 90.5%. The low pretest score revealed a lack of knowledge regarding this simple prevention intervention. Another question that demonstrated a significant increase was question eight, which inquired about the knowledge of mechanisms of corneal abrasion injury. The low average pre-education scores indicated that participants had little to no understanding of the mechanism of corneal abrasion injury. Following the education, the correct answer rate for this item increased from 16.4% to 90.5%. Question ten was used to assess provider knowledge regarding effective treatment methods for an identified perioperative corneal abrasion. The correct answer rate for this item increased from 67.3% to 85.5%. The low average pretest score indicated a lack of knowledge and understanding about treatments for perioperative corneal abrasions. Anesthesia providers play a crucial role in early detection and treatment of perioperative corneal abrasions. Therefore, knowing a treatment plan is imperative and should be included in regular continuing education provided to anesthesia providers.

The only question that showed a decrease in score after reviewing the online module was question four, which asked when the optimal time is to tape the eyes closed during induction. The percentage of anesthesia providers who answered correctly decreased from 67.3% on the pretest to 38.1% on the posttest. Possible reasons for this could be that the answer might not have been clear on the infographic or that, due to the busy nature of the operating room, participants may have rushed through some questions, including this one.

Limitations and Challenges

A limitation to the study design included a lack of a control group. It is unknown the effectiveness of the intervention at the study site as there is no comparison between the group that completed the module and those that did not. The second limitation was the fact that this project utilized a small convenience sample which can lead to selection bias and difficulty in generalization (Jager et al., 2017). There was a potential for 165 CRNAs and 73 MDAs at the study site that could have taken the module. Out of this sample, only about 21% of CRNAs and 28.6% of MDAs participated. Participation was an anticipated challenge while developing the module. Attempts to mitigate this challenge included distributing QR code flyers for quick access and weekly reminder emails during the data collection phase. These recruitment measures helped secure 55 participants, which overall showed an improvement in scores. There were also 14 participants that did not complete the post-test, which was also anticipated with the busy nature of the OR, this was mitigated by having a concise and easy to follow module.

The third limitation to this QI project was the limited time frame to complete data collection which extended over a five-week period. This module was able to be completed in one sitting and even though answers to the questions were not presented till the completion of the module, the longevity of the information learned was not assessed. There was no follow-up survey presented to the participants to determine if the information was retained and whether it could be recalled later. It is unknown as to whether the corneal abrasion prevention methods presented in the module were performed by the anesthesia providers as follow up was limited due to the time constraints. This limitation presents an opportunity to continue this QI project through investigating whether the information learned was applied in the clinical setting. This

could be performed through tracking reported corneal abrasions at the study site since the roll out of this module or a follow-up survey as to whether prevention methods have been applied.

Recommendations and Implications

Overall, the results that were analyzed in this project were consistent with the literature. It is recommended in the future to consider providing a comprehensive protocol at the study site that details best practice for preventing corneal abrasions. The study site has no set protocols for corneal abrasions prevention, and creating a protocol would allow for consistency throughout the perioperative setting. With the anesthesia provider's enhancement of knowledge about corneal abrasions, the hope is that the study site will see a decrease in corneal abrasions by applying the recommendations detailed in the module. Additionally, through the marked increase in posttest scores, the delivery of the content (being online) along with the formatting (the use of an infographic) showed positive results that this method can be used to disseminate information and continued education to anesthesia providers at the study site.

Another recommendation includes changing some of the questions asked in the module. Some questions were too simple, this included questions one and three. Question one asked about what the most common ocular adverse event is related to anesthesia; 100% of participants got the answer correct on both the pretest and posttest. For question three which asked about the common offenders of corneal abrasion, the score only increased from 80.3% to 88.7%, which showed that most participants knew this information. This question could be omitted or changed to increase the difficulty. Question four should also be changed which asked about the optimal time to tape eyes during induction. As previously mentioned, the number of participants that answered correctly decreased from the pretest to the posttest. The question could be reworded, or the infographic changed to make this answer clearer to participants.

Conclusion

The aim of this online module was to increase anesthesia's knowledge about corneal abrasions using an online educational approach. The results of an increase post intervention score showed that this project was successful in enhancing knowledge about up-to-date information regarding corneal abrasions at the study site. It also showed that an online module is an effective method for delivery continuous education to anesthesia providers. Directions for the future include developing an effective guideline for standardizing corneal abrasion prevention.

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 A Quality Improvement Project to Decrease Perioperative and Periprocedural Corneal

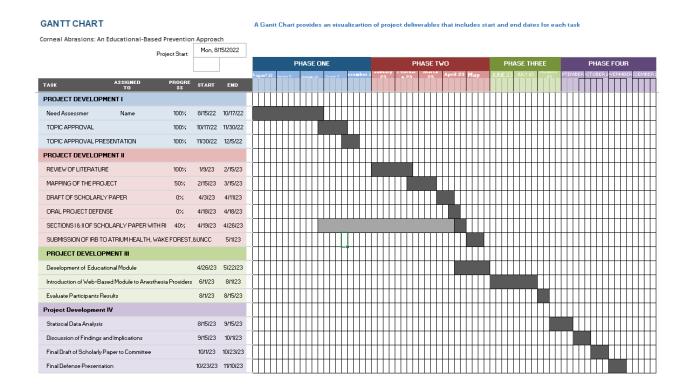
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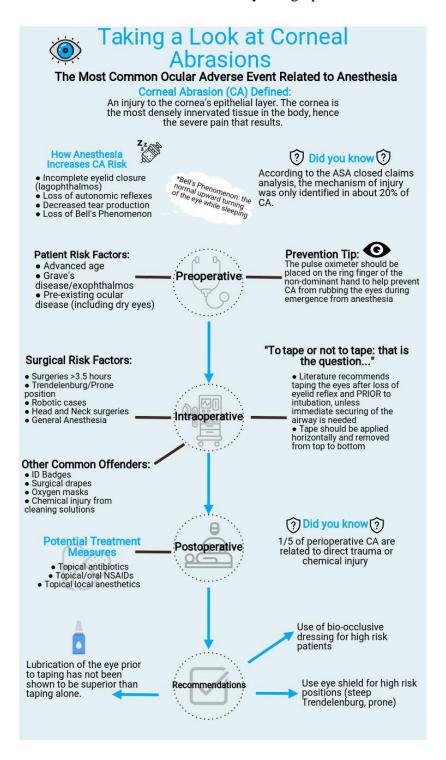
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APPENDIX A: GANTT CHART



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?

- d. <5 years
- e. 6–10 years
- f. 11-15 years
- g. 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. 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 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: UNCC and Wake Forest School of Medicine IRB Approval Letters



To: Megan Frowine

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:

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:

- Amendments must be submitted for review and the amendment approved before implementing the amendment. This includes changes to study procedures, study materials, personnel, etc.
- Researchers must adhere to all site-specific requirements mandated by the study site (e.g., face mask, access requirements and/or restrictions, etc.).
- Data security procedures must follow procedures as described in the protocol and in accordance with OneIT Guidelines for Data Handling.
- Promptly notify the IRB office (<u>uncc-irb@charlotte.edu</u>) of any adverse events or unanticipated risks to participants or others.
- 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.
- 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.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).



Office of Research

MEMORANDUM

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To: Karen Lucisano

Clinical and Translational Science Institute {CTSI}

From: Jeannie Sekits, Senior Protocol Analyst

Institutional Review Board

Date: 6/23/2023

Subject: Exempt Protocol: IRB00097733

Corneal Abrasions: An Educational-Based Prevention Approach

No protected health information will be used or disclosed in this research proposal; therefore the requirement for individual Authorization does not apply.

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

Based on the information provided, the IRB has determined that HIPAA does not apply to this study.

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study is exempt. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. Each project requires a separate review and approval or exemption. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to meet the requirements for exemption.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 42 CFR Parts 50 and 56, HHS regulations 42 CFR Ad, and International Conference on Managedistrial (ICIM) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHIRP/FDA; our IRB registration numbers are IRB00000212, IRB00002432, IRB00002434, IRB00002434, IRB00008493, IRB00008494, and IRB00008495.

WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.