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Polyethylene Cover *versus* Viscotears Gel for the Prevention of Corneal Abrasions in Critically Ill Patients: A Comparative Study

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Abstract. In unconscious ventilated patients, various eye protective measures have been used to prevent corneal abrasions. This is the first study in Saudi Arabia that compared the effectiveness of polyethylene films and eye instillations to prevent corneal abrasions. Our study aims to compare the effectiveness of polyethylene covers with Viscotears gel in the prevention of corneal abrasions in critically ill patients. This randomized controlled study was carried on 40 ventilated patients in intensive care units of King Fahad Hospital of the University. All participants were randomly assigned to receive polyethylene covers in one eye and viscotears gel in the other eye to prevent corneal abrasions. A fluorescein stain test was performed by staff ophthalmologist daily to detect any corneal abrasions. The study found that the use of polyethylene cover and viscotears gel were equally effective in prevention of corneal abrasions in critically ill patients ($p = 1.000$).

Keywords: Corneal abrasions, Eye care, Polyethylene, Critically ill.

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Introduction

The eye is a very specialized, highly vascular organ that is not only susceptible to complications from concomitant pathologies, but it is also vulnerable to infections, abrasions and other exogenous processes in the critically ill patient. Ophthalmological issues arising in the intensive care unit (ICU) can be seen with presentations that range from corneal abrasions and keratitis to more serious processes, like endophthalmitis and glaucoma[1-3].

Abnormalities of the cornea and conjunctiva may occur in association with neurological diseases, trauma, nocturnal lagophthalmos, coma, infection, and mechanical ventilation. However, there have been few reports on the incidence of eye complications in the intensive care unit[4]. Some reports imply that the prevention of eye complications in the ICU was the most effective way to avoid post recovery visual loss[4].

Patients in the intensive care units can experience a weakening of ocular defense mechanisms because of modifications in the level of consciousness, metabolic and immune system disorders. The use of mechanical ventilation (MV), face trauma, and a number of other causes. As such, these patients are vulnerable to numerous aggressions to the eye, although, the cornea is the most commonly affected structure[5].

The incidence of eye disorders in the intensive care population is difficult to quantify. Factors may include poor documentation and the fact that eye care is often seen as a relatively minor concern when the patient is critically ill[6]. Eye complications can range from a mild conjunctival infection to a serious corneal injury. Permanent ocular damage may result from ulceration, perforation, vascularization, and scarring of the cornea[7].

Materials and Methods

Design

A randomized controlled eye study comparing the effectiveness of polyethylene covers with Viscotears eye gel in preventing corneal abrasions in critically ill patients was conducted.

Setting and Participants

The study was conducted at the adult medical and surgical ICU of the King Fahad Hospital of the University (KFHU). The study design was

approved by the Local Committee of Biomedical Ethics at University of Dammam and KFHU.

Patients were recruited over a 6-month period and included in the study if they were aged over 18 years, mechanically ventilated, comatose and who were anticipated to require MV for more than 24 h. The frequency of eye opening was limited to less than five blinks per hour, to allow for patients who were unconscious, but opened their eyes briefly in response to stimuli, such as during suctioning.

Exclusion criteria were patients with a pre-existing eye condition (eye trauma, corneal abrasions, and eye infections) or patients with a previous admission to ICU within a month of enrollment. Patients excluded from the study received eye-care treatment determined by the bedside nurses' discretion. Written consent for general ICU care was obtained from the patient's family.

In the ICU patients meeting, the inclusion criteria were simply randomized to receive polyethylene cover (cling film™) over the right or left eye using a block envelope based randomization method. The other eye received Viscotears gel. A pilot study was done on five patients to test the applicability of the tools.

Material

Viscotears® (polyacrylic acid, also called carbomer), is a clear, colorless, highly viscous gel formed of a high molecular weight, cross-linked polymers of acrylic acid, which is a slightly hypotonic (250 mOsmol) formulation with a neutral pH of 7.3, and is preserved with cetrimide bromide 0.01%.

Polyethylene cover is a plastic wrap consists of a thin film of flexible, transparent polymer that clings to itself and to its surroundings to form a tight seal. The plastic protects the eye from air exposure, and prevents dryness and loss of moisture.

Procedure

All patients meeting, the inclusion criteria received a standard eye cleansing regime of eight hourly washes of the eyelids and surrounding skin using 0.9% saline and sterile gauze. Polyethylene was applied in one eye and Viscotears® in the other eye. A piece of polyethylene was cut to cover the eye from eyebrow to the cheekbone. To ensure the area was sealed, Micropore tape was used around the edges of the

polyethylene (Fig. 1). The polyethylene was changed every 8 h or as needed if they became soiled or torn. One drop of Viscotears® every 8 h was applied in the V pocket between the eyeball and the lower eyelid for the other eye.

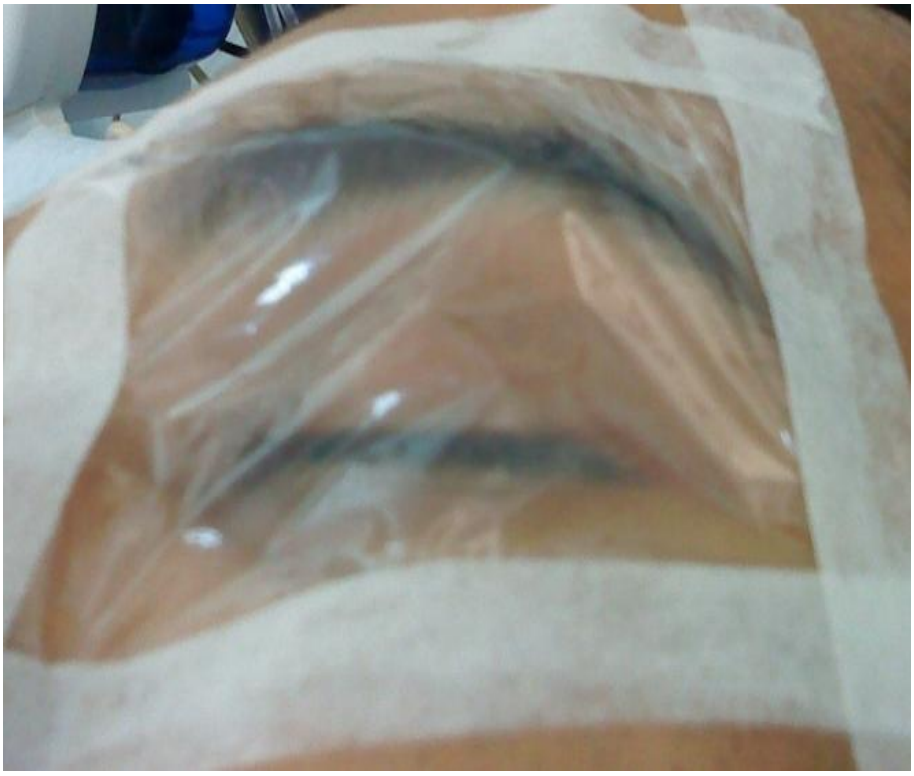

Fig. 1. Eye moisture chambers created with polyethylene film. (Sara Al-Ribh image).

Patients completed the study if they regained spontaneous eye opening or blink reflex, were discharged or transferred from the ICU during study enrollment, expired, developed a corneal ulcer or eye infection, had positive fluorescein test or if the study period ended while the patient was still on the study.

A detailed eye examination was performed at the bedside by staff ophthalmologist to assess eye blinking reflex, eyelid position and corneal changes. The fluorescein stain (Minims Lidocaine, Hydrochloride 4% and Fluorescein sodium 0.25%) was applied to the patients' eyes and examined under a blue light using portable slit lamp biomicroscopy for any corneal changes (Fig. 2).

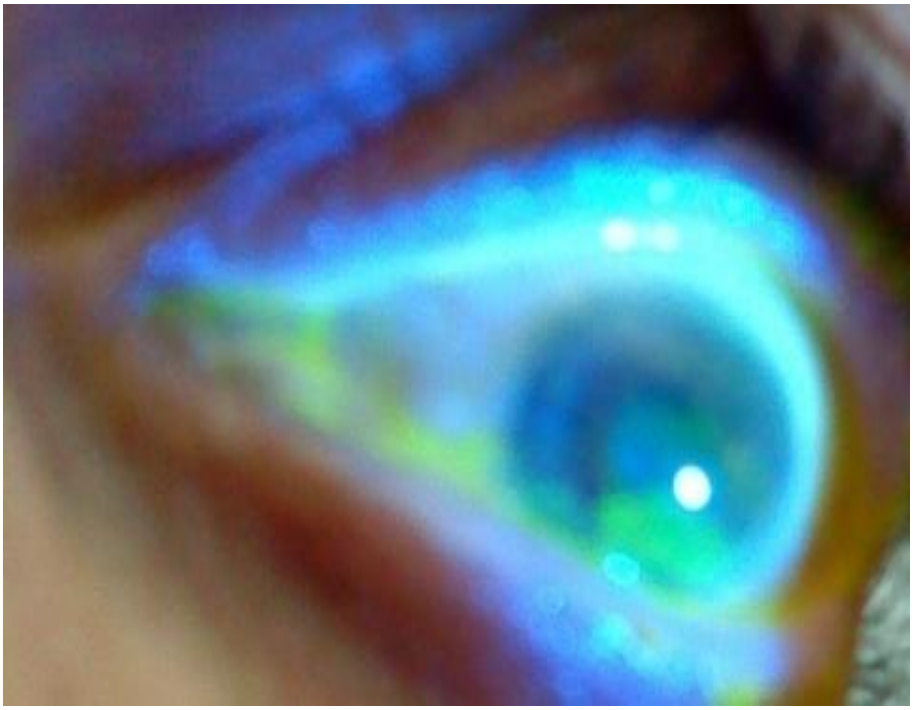

Fig. 2. Corneal abrasion stained with fluorescein and highlighted under a blue light using portable slit lamp biomicroscopy. (Sara Al-Ribh image).

Any corneal abnormalities would appear green with the fluorescein stain. The corneal fluorescein stains eye examination was performed prior to the study to ensure that the cornea was intact, and then checked daily on all patients enrolled in the study.

Data were collected on demographics including age, gender, diagnosis, APACHE II score, and ICU length of stay, plus hours on the study and reason for completing the study. Additional data were collected on potentially confounding variables including: Glasgow Coma Scale score, frequency of pupillary examinations, use of sedation, use of muscle relaxant, presence of lagophthalmos, and the highest positive end-expiratory pressure (PEEP) used.

Statistical Analysis

Demographics and potentially confounding variables were analyzed using the Mann-Whitney test and Fisher's exact tests, where appropriate.

McNemar's test was used to evaluate the association between the eye-specific intervention and development of corneal abrasions.

Results

Between February 2010 and July 2010, 53 patients from the King Fahad Hospital of the University (KFHU) ICU were screened for the trial within 24 h of ICU admission. Among these 53 patients, 13 patients were excluded and exited the study before randomization due to various reasons; 4 patients expired before the first eye examination, 9 patients had positive fluorescein stain test in the initial eye assessment. The remaining 40 patients (80 eyes) were recruited into the study.

Demographics and predisposing factors for the development of corneal abrasions were analyzed for both groups of the study (Table 1).

Table 1. Demographics and potentially confounding variables.

Demographics and Potentially Confounding Variables	Polyethylene Film Group (p)	Viscotears Eye Gel Group (p)
Age in years	0.056	0.926
Gender	0.0498	1.00
APACHE II score	0.064	0.023
ICU length of stay	0.001	0.064
Duration of study (h)	0.072	0.092
Glasgow Coma Scale score	0.175	0.538
Pupil examination l day	0.430	0.282
Positive end-expiratory pressure	0.149	0.058
Sedation	0.723	0.808
Presence of lagophthalmos	0.012	0.071

Twenty-eight (70%) patients exited the study due to the return of the blink reflex. Four (10%) out of 40 patients had a positive fluorescein stain test and 8 (20%) patients died (Table 2). Among the four patients with a positive fluorescein stain test, one patient develops bilateral corneal abrasions, one eye from Viscotears group, and two eyes from the polyethylene covers group develop punctuate epithelial erosion. This was not statistically significant (McNemar's test $p = 1.000$).

Table 3 showed the findings from McNemar's test, which indicated that there was no statistically significant difference between polyethylene

cover, and Viscotears gel in the prevention of corneal abrasions in critically ill patients (p = 1.000).

Table 2. Outcomes of patients receiving either polyethylene cover or Viscotears eye gel.

Patient's Outcome:	Frequency	Percentage
Patient had positive fluorescein stain	4	10%
Patient expired	8	20%
Patient regained spontaneous eye movement or blink reflex	28	70%
Total	40	100%

Table 3. Comparison between the polyethylene eye cover and Viscotears eye gel for the prevention of corneal abrasions in critically ill patients.

Polyethylene Eye Cover	Viscotears Eye Gel		Total	*P*
	Fluorescein Stain			
	(+ ve)	(- ve)		
Fluorescein stain (+ ve)	1 eye	2 eyes	3 eyes	1.000
Fluorescein stain (– ve)	1 eye	36 eyes	37 eyes	
Total (n = 40)	**2 eyes**	**38 eyes**	**40 eyes**	

Factors that had statistically significant effect in the development of corneal abrasions in critically ill patients include; longer length of stay in ICU, higher APACHE II score, and presence of lagophthalmos.

Discussion

This is the first randomized study to compare the efficacy of eye care between polyethylene film and polyacrylic acid (Viscotears®) in Saudi Arabia.

Many critical care interventions that assist in patient recovery also carry the risk of patients harm. For example, the use of heavy sedation to facilitate mechanical ventilation affect all skeletal muscles, including muscles that facilitate eyelid closure and the blink reflex[8]. Inadequate eyelid closure permits an increase in tear film evaporation. Without these protective mechanisms, the patient's corneas are at risk for drying, and acquire infections that can lead to permanent scaring and blindness[8,9].

In addition, patients requiring artificial ventilation may suffer decreased tear production, decreased resistance to infection and a decrease in venous return leading to conjunctival chemosis (edema)[6].

Conjunctival chemosis (edema), otherwise known as 'ventilator eye' is viewed as the result of the adverse physiological effects of ventilatory support and the drugs used to facilitate artificial respiratory support[6]. Introduction of positive pressure mechanical ventilation (MV) with the addition of positive end expiratory pressure (PEEP) may have deleterious effects on the eye by increasing intra-ocular pressure, which in turn compromises eye perfusion. In addition, high intra-thoracic pressures and PEEP in excess of 5cmH_2O encourages sodium and water retention, thus aggravating edema[10]. These factors lead to an increased risk of eye disorders. Other predictive factors for superficial keratopathy include the Glasgow Coma Scale score, intubation, length of stay, and APACHE II score, and the frequency of pupil examination, sedation plus the presence of lagophthalmos.

To improve the evidence- based practices within our ICU, a study was undertaken to evaluate the effectiveness in preventing corneal abrasions of two methods of eye care: Viscotears® eye gel versus polyethylene covers secured over the eye.

In our study, the incidence of corneal abrasions as detected by positive fluorescein stain was 7.5% (3 out of 40 eyes) in the polyethylene group and 5% (2 out of 40 eyes) in the Viscotears group. The low incidence of corneal abrasions in this study was attributed to the early attention given to those high-risk patients, effective treatment prescribed, and the use of a standardized protocol for eye care.

Some data do exist to compare moist chamber treatments by using polyethylene with ocular lubricants, including three randomized controlled trials by Koroloff *et al*.[11], So *et al*.[12] and Cortese *et al*.[13]. However, the external validity of these studies may be limited as only corneal ulceration has been considered as an endpoint, and no assessment of less severe forms of corneal damage, such as superficial punctuate keratitis/keratopathy (SPK) was made.

Our study demonstrates that there was no statistically significant difference between the polyethylene cover and Viscotears eye gel in the prevention of corneal abrasions in the critically ill patients (p=1.000). These results are in accordance with the work of So *et al*.[12], who studied

116 ventilated patients admitted to the ICU. They were randomly assigned to receive either polyethylene covers or lanolin eye ointment. Seven (6.0%) patients had staining of the cornea with fluorescein, four (6.8%) were in the polyethylene covers group (n = 59) and three (5.3%) were in the lanolin eye ointment group (n = 57). This was not statistically significant (p = 0.519). One patient in the lanolin eye ointment group had an eye infection. The authors found that polyethylene cover is equally effective in preventing corneal abrasions when compared with lanolin eye ointment.

Again, the results of this study match the results obtained by Koroloff *et al.*[11] who compared 110 ICU patients with reduced or absent blink reflex. He divided them into a group that received hypromellose drops, and LACRI-LUBE® lubricant eye ointment every 2 h and a second group that had polyethylene covers placed over the eyes to create a moisture chamber. The eyes of the patients in both groups were also cleaned every 2 h with saline. Thus, it was found that zero patients had corneal ulceration in the polyethylene group, and four patients had ulceration in the hypromellose group. In this trial, the difference was not statistically significant (p = 0.12). The ease of application and the lower cost of polyethylene covers, led them to make moisture chambers their standard preventive treatment for all unconscious patients in their ICU.

Moisture chamber created by using polyethylene film has been proposed as a way to protect the cornea even if the eye is open[13]. The application of polyethylene film has a twofold benefit. First, the film seals in the moisture around the cornea. Second, it assist in keeping the eyelid closed[13]. In one randomized controlled trail by Cortese *et al.*[13], a moisture chamber created with polyethylene film was found to be more effective than using lubricating drops.

Cortese *et al.*[13] conducted the first randomized controlled trial; he studied 60 critically ill patients with a limited or absent blink reflex. This study compared instillation of methylcellulose (METHOPT Eye Drops Forte) drops every 2 h with a moisture chamber created by a polyethylene film. Only one out of 30 patients in the polyethylene group had positive fluorescein stain and this compared favorably with eight patients in the eye drops group ($p < 0.05$). These results suggest that moisture chamber is more effective than lubrication drops in preventing corneal epithelial breakdown in critically ill patients.

Again, the meta-analysis by Rosenberg and Eisen[14] showed that the rates of exposure keratopathy are significantly lower when moisture chambers are used to protect the eye compared with lubricating ointments. Eight (7.1%) of 113 patients in the moisture chamber group *vs.* 32 (21.2%) of 151 patients in the lubrication group developed exposure keratopathy (p = 0.001). This meta-analysis showed that moisture chambers are significantly better than lubrication at preventing exposure keratopathy in ICU patients.

Another type of moisture chamber that was created with swimming goggles and moistening eyelids with gauze soaked in sterile water, was found to be more effective than using a combination of ocular lubricants, and placing a securing tape in one randomized controlled trail by Sivasankar *et al*.[15].

Sivasankar *et al*.[15] demonstrated the importance of creating a moist and closed chamber with the use of sterile water soaked gauze and swimming goggles in preventing corneal epithelial breakdown in sedated and semiconscious ICU patients. In this study, 61 patients (122 eyes) were randomized into an open chamber group (ocular lubricants and securing tape) and 63 patients (126 eyes) into a closed chamber group. A total of 40% of the patients had exposure keratopathy. Among those with exposure keratopathy, a total of 32% (39 out of 122 eyes) were from the open chamber group and 8% (10 out of 126 eyes) were from the closed chamber group. This was statistically significant (p = 0.001).

A variety of eye care regimes are available which is not evidence based, and there is no clear consensus defining the best form of eye care. One survey in the United Kingdom found that 75% of ICUs used Geliperm routinely as eye care, and 25% using ocular lubricants[16]. Geliperm is a polyacrylamide hydrogel dressing, which was originally designed as a wound dressing and there is no evidence to support it's use in eye protection[17].

Ezra *et al*.[18] studied 40 critically ill patients (80 eyes) with absent blink reflex. Each patient received both LACRI-LUBE® preservative-free eye ointment and Geliperm dressing, which were allocated at random to either the left or right eye. The results showed no statistically significant difference in the maximum corneal exposure score between the eyes treated with LACRI-LUBE® and Geliperm (p = 0.38). The

author found that Geliperm is as effective as LACRI-LUBE® in the prevention of exposure keratopathy in the critically ill patients.

Another study was conducted by the same author, Ezra *et al*.[16] who compared the effectiveness of three types of eye care measures; namely simple eye toilet, ocular lubricant LACRI-LUBE® alone or Geliperm alone. The incidence of exposure keratopathy in simple eye toilet group, LACRI-LUBE® and Geliperm group were 54%, 15% and 90%, respectively. These data indicate that the use of LACRI-LUBE® is more effective than Geliperm in prevention of exposure keratopathy in the critically ill patients.

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غطاء البولي إيثيلين مقابل استخدام جل الفيسكوتير للوقاية من سحجات القرنية لمرضى العناية المركزة: دراسة مقارنة. مستشفى الملك فهد الجامعي بالخبر. المملكة العربية السعودية. عام ٢٠١٠م

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المستخلص. تستخدم طرق مختلفة للوقاية من سحجات القرنية في المرضى الفاقدين للوعي والمعتمدين على أجهزة التنفس الصناعي. تعد هذه الدراسة الأولى بالمملكة التي تقارن بين فعالية البولي إيثيلين واستخدام القطرة العينية للوقاية من سحجات القرنية. الهدف من الدراسة هو المقارنة بين فعالية غطاء البولي إيثيلين وجل الفيسكوتير للوقاية من سحجات القرنية لمرضى العناية المركزة. هذه الدراسة العشوائية الضابطة تمت على ٤٠ مريض معتمد على أجهزة التنفس الصناعي في أقسام العناية المركزة بمستشفى الملك فهد الجامعي. بعد إجراء القرعة تم وضع غطاء البولي إيثيلين في احدى العينين، والعين الأخرى تم وضع قطرة الفيسكوتير فيها لكل المشاركين في الدراسة. ولقد قام طبيب العيون بفحص عيون جميع

المشاركين يوميا باستخدام صبغة الفلوريسين لاكتشاف أي تغيير في القرنية. أظهرت الدراسة أن استخدام غطاء البولي إيثلين أوقطرة الفيسكوتير متساويا الفعالية في الوقاية من سحجات القرنية لمرضى الحالات الحرجة . هذه النتيجة مهملة إحصائيا (٠،٠٠١).