Bandage Contact Lens Application for the Management of Corneal Abrasion in the Emergency Department

NCT04159714

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IRB Minimal Risk Protocol Template

General Study Information

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Study Title: Bandage Contact Lens Application for the Management of Corneal Abrasion in the Emergency Department

Protocol version number and date: V2. 1/24/2019

Research Question and Aims

Hypothesis: Will the use of a bandage result in alleviation of symptoms from corneal abrasions.

Aims, purpose, or objectives: This study is designed to answer the following questions:

I. Does the use of a bandage contact lens decrease pain and discomfort associated with corneal abrasion?
II. Is the addition of bandage contact lens more helpful in alleviating the pain associated with corneal abrasion compared with current practice/usual care (topical antibiotic ointment, oral analgesia, etc.)?
III. Is the use of a bandage contact lens a safe and practical intervention for emergency physicians to administer and for patients to use?

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):
Corneal abrasion is a traumatic erosion of the corneal surface, often resulting from accidental contact by fingernails, hairbrushes, airborne particles, branches and other suspended objects, as well as from poor contact lens technique or over-wear. Most corneal abrasions heal spontaneously within 48 hours, but significant pain at the time of injury prompts many patients to visit the Emergency Department for evaluation and symptomatic management. Management usually includes topical antibiotic ointment and analgesia; however, there is widespread variation in treatment, consultation with ophthalmology and follow-up patterns. To my knowledge, the use of bandage contact lenses has not been prospectively studied in the Emergency Department. Although the use of bandage contact lenses is described in Roberts and Hedges Clinical Procedures in Emergency Medicine and Acute Care, Seventh edition, this practice has not gained widespread acceptance in most Emergency Departments. Because the pain associated with corneal abrasions is often significant and frequently results in opioid prescribing, bandage contact lens use offers the potential for avoidance of these medications as well.

Study Design and Methods

Methods: *Describe, in detail, the research activities that will be conducted under this protocol*:
A randomized trial of a bandage contact lens or usual care will occur in patients presenting to the Emergency Department. Patients diagnosed with superficial corneal abrasion in the Emergency Department will be asked to participate in the study. After voluntary, informed consent has been obtained, those patients wishing to

participate will be randomized (www.randomization.com) to the bandage contact lens (BCL) group or usual care (UC).Using a validated pain scale, subjects will be asked to rate their level of pain before treatment and immediately after treatment in the ED. BCL subjects will have a BCL soaked in antibiotic solution placed in the affected eye. UC subjects will have usual care provided in the ED per the ED consultant.

- Patients in both groups will be contacted **via telephone** between 12-24 hours after ED treatment to assess their pain scores. Additional questions pertaining to comfort, complications, etc. may also be queried at that time. Patients will be re-contacted **via telephone** between 36-48 hours after ED treatment to assess their pain scores. Additional questions pertaining to comfort, complications, etc. may also be queried at that time.

A follow-up appointment with Ophthalmology will occur at 1 day, 3 days, and/or 5 days post-discharge, depending on specific patient factors, patient needs, clinic availability, day of the week, etc. **This follow-up appointment is standard of care; any patient presenting to the ED with a corneal abrasion will be scheduled for a follow-up visit with Ophthalmology.** The contact lens will be removed when the examining follow-up provider has deemed that the abrasion has healed. This will be communicated to the patient in the ED following enrollment, in the patient follow-up instructions document (attached in participant contact materials), and in the letter to the follow-up provider (attached in participant contact materials). All patients will be given follow-up instructions regarding when to return to the ED, ophthalmology clinic, etc. for BCL removal and recheck prior to ED discharge. The use of oral analgesia, including opioids, NSAIDs and/or acetaminophen will also be recorded and quantified across the two groups.

Data will be obtained from the follow-up ophthalmology visit regarding safety, adverse events and any complication of the lens wear.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*: Recruitment will take place in the SMH Emergency Department by the EM consultant and/or the ED research coordinators. ED patients presenting to the ED with acute eye pain will be screened to determine if they meet eligibility requirements for this study.

☐ (1a) This is a multisite study involving Mayo Clinic and non Mayo Clinic sites. *When checked, describe in detail the research procedures or activities that will be conducted by Mayo Clinic study staff.*

☐ (1b) Mayo Clinic study staff will be engaged in research activity at a non Mayo Clinic site. *When checked, provide a detailed description of the activity that will be conducted by Mayo Clinic study staff.*

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 200

Subject population (children, adults, groups): Patients >18 years of age presenting to the Emergency Department with superficial corneal abrasion due to trauma.

Inclusion Criteria: Diagnosis of Superficial Corneal Abrasion

Exclusion Criteria:

- Incarceration
- Pregnancy
- Inability to Provide Informed Consent
- Infectious keratitis
- Retained foreign bodies in the eye
- Active infection involving the orbit or periorbital region
- Patients who are not able to or who are deemed unlikely to follow-up with ophthalmology
- A history or recent contact lens wear
- A lack of trauma or an unclear history of trauma as the inciting cause of the abrasion
- Allergy to the antimicrobial solution (POLYTRIM)
- Women who are currently breastfeeding
- Chronic eye drop use
- A history of eye surgery other than cataract surgery (greater than 6 months prior to abrasion)
- Diabetes (Patients with even mild diabetic neuropathy can have decreased pain sensation and also delayed corneal epithelial healing)
- Any eye condition that may be deemed to interfere with the conduct of the protocol or outcome measurement.

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☒ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☐ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☒ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☐ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☐ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

(3) Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☐ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*

HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name	X	
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	X	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	X	
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☐ None

Data Analysis

Data Analysis Plan: Comparison of pain scores. Will also evaluate and determine if there are any advantages/disadvantages to application of BCL versus usual care.


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