INSTRUCTIONS:

1) Protocol Title

Suture contamination rate in adjustable suture strabismus surgery

2) IRB Review History*

Not applicable.

3) Objectives*

1. To establish the culture positivity rate in adjustable suture strabismus surgery
2. To identify bacterial species and antibiotic susceptibility patterns of microorganisms cultured from suture material
3. To compare suture contamination rates with techniques to reduce the suture contamination rate

4) Background*

Contamination rate of sutures and needles used in strabismus surgery has been evaluated by several studies. Eustis and Rhodes\(^1\) recently identified bacterial contamination rates of sutures as high as 28%, which is similar to previously reported studies in the literature (15-25.2%).\(^2,3\) The contamination sites were suspected to be from the eyelid margins, eyelashes and conjunctivae, as the identified organisms mostly consisted of coagulase-negative Staphylococcus.\(^3\)

Adjustable suture technique for strabismus surgery allows the surgeon to change the eye muscle position in the immediate postoperative period. In this technique, the sutures used to attach the extra-ocular muscle to the globe, are left exposed and in contact with the conjunctiva and the eyelids. The average time of suture exposure is 6 hours (ranging from 5 and 24 hours), before the sutures are trimmed during the adjustment procedure. Some surgeons prefer delaying adjustment to the first postoperative day to allow for full recovery from anesthesia. This delay might increase the risk of contamination and theoretically may lead to higher numbers of postoperative infections.

Povidone iodine is an effective antiseptic agent that is widely used in preoperative surgical preparation to decrease the incidence of infections. In most ocular surgeries, the commercially available 5% concentration of povidone-iodine is used. Some surgeons opt also to instill a drop of povidone-iodine 5% at the conclusion of the case, after Apt et al. found that povidone-iodine 5% solution applied to the eye at the conclusion of ophthalmic surgery was more effective at minimizing the number of colony-forming units than a broad-spectrum antibiotic.\(^4\) In strabismus surgery performed at our institution, we routinely apply a strip of ophthalmic ointment containing antibiotics and corticosteroids into the conjunctival fornix at the end of surgery; however povidone-iodine is not instilled. To our knowledge no study has
evaluated the suture contamination rate in adjustable strabismus surgery or the impact of using povidone-iodine 5% at the conclusion of the case.

References


5) Inclusion and Exclusion Criteria*

Inclusion criteria

1. All strabismus patients age ≥ 18 years scheduled for strabismus surgery with adjustable sutures at the Bascom Palmer Eye Institute will be invited to participate. The physician involved in the pre-operative evaluation will determine if the patient is a candidate for adjustable suture and discuss the option with the patient. If the patient opts for the use of an adjustable suture, the physician will inform him/her about the study.

Exclusion criteria

1. Patient who has a history of allergy to povidone-iodine.
2. Disorders affecting immune function.
3. Patient who is unwilling to participate in the study.

6) Number of Subjects*

We plan to enroll a total of 100 patients.
7) Recruitment Methods*
   1. Recruitment will occur at the pre-operative clinic visit, during the time of consent for the strabismus surgery.
   2. All patients meeting Inclusion Criteria outlined above are considered potential subjects and will be recruited
   3. A verbal description of the study will be provided. It will be emphasized to the patients that participation is optional and will not alter the surgical plan or procedure.

8) Study Timelines*
   The duration of participation is from the time of surgery until completion of the suture adjustment procedure. This may vary from the same day of the surgery to one day after the surgery.

9) Study Endpoints*
   The subject is no longer willing to remain enrolled or after the suture has been obtained for culture.

10) Procedures Involved*
   1. After recruitment, a written consent will be obtained from subjects who agree to participate.
   2. A review of medical records will be performed to obtain demographics data, type of strabismus surgery, etc (see Data Collection Sheet).
   3. All subjects will receive standard preoperative preparation with 5% povidone iodine solution to the skin: from forehead to upper lip, to the nose medially and to the ear laterally. Five percent povidone iodine eye drops will be instilled into cul-de-sac.
   4. At the time of surgery, for subjects who undergo surgery in more than one muscle in the same eye as the adjustable suture muscle, a one cm piece of suture proximal to the knot will be harvested after the muscle is sutured to the sclera. The suture will placed in a tube with 2.2 ml of trypticase soy broth (TSB) as the control samples.
   5. At the conclusion of the surgery, all patients will receive a strip of ophthalmic ointment containing antibiotics and corticosteroids into the conjunctival fornix. The subjects will then be randomized (using a computer program to generate a numerical digit – Research Randomizer http://www.randomizer.org/form.htm) into two groups:
      Group 1: Patients will receive one drop of 5% povidone iodine instilled into the conjunctival fornix.
      Group 2: Patients will not receive 5% povidone iodine into conjunctival fornix.
6. The time between the completion of the strabismus surgery and the time of the adjustment procedure will be recorded.

7. At the end of the adjustable suture procedure, the 1 cm section of the suture proximal to the knot will be harvested and placed in a tube with 2.2 ml of trypticase soy broth (TSB).

8. At the end of each day all sutures collected in the TSB tubes will be transferred to the microbiology laboratory at the McKnight Research Vision Center. The TSB tubes will be monitored for growth of bacteria at 48 hours. In case of bacterial growth in broth, 1 ml of TSB solution will be plated to identify the organism(s). Susceptibility patterns for common antibiotics will be performed. The quantification and sensitivity of the organisms will be identified.

11) **Data and Specimen Banking**

   The TSB tubes with the suture will be labeled with a number.

   The broth will be stored for 14 days. If no growth occurs, the TSB tubes will be discarded.

**Data Management**

All data will be recorded on Excel spreadsheet. Both descriptive and standard paired t-test will be used to identify the difference between incidence of bacterial growth with or without the povidone eye drop at the end of the procedure. The ID code number will be stored in a separate file that will be password protected. Only study team members will have access to the password and file.

12) **Provisions to Monitor the Data to Ensure the Safety of Subjects**

Povidone iodine eye drops have been used as a standard of care for the preoperative sterilization (American Academy of Ophthalmology Cataract and Anterior Segment Panel. Preferred Practice Pattern Guidelines. Cataract in the adult eye. San Francisco, CA: American Academy of Ophthalmology; 2011). The application of povidone iodine drops exposes the subjects to no greater than minimal risk. The suture material collected for our study would have typically been discarded as waste.

*Withdrawal of Subjects*

Subject is withdrawn from the study if he expresses unwillingness to participate.
13) **Risks to Subjects***

There is no greater than minimal risk to the subjects as the result of participating in this study. Theoretically, the drop of povidone iodine might cause irritation and burning, however the effects of anesthesia delivered during surgery will mitigate these symptoms.

14) **Potential Benefits to Subjects***

The subjects might have potential benefit from postoperative prophylaxis of infection from the povidone iodine eye drop. In cases of infection, the pathogen and susceptibility to antibiotics are already identified, which would expedite appropriate antibiotic treatment.

15) **Vulnerable Populations***

This study will not involve vulnerable populations.

16) **Multi-Site Research***

Not applicable

17) **Sharing of Results with Subjects***

It will be expressly stated to the patients that enrollment and participation in the study in no way affects their clinical care. The arms of the study compare various standards of care, and the intervention they receive may be the standard of care had they chosen to perform the procedure at a different institution. Also it will be explained that there are bacteria that live in the human body and do not cause infection. Additionally, colonization of suture material does not always correlate with clinical infection. In our pilot project, we demonstrated that even though 2/3 of sutures obtained after adjustment were colonized with bacteria, there were no cases of clinical infection. If the study identifies an unexpected microorganism or high rate of contamination, the result will be discussed with the surgeon who will then contact the patient to discuss warning signs and potential interventions.

18) **Setting***

The recruiting and consenting processes will take place in the clinics of the Bascom Palmer Eye Institute.

The procedure will take place in the operative rooms on the sixth floor of Bascom Palmer Eye Institute. The adjustable suture procedure will take place in the 4th floor clinic of Bascom Palmer Eye Institute.

The specimen will be handled by a member of the research team and the microbiology laboratory at McKnight Research Vision Center. Specimens will be stored at McKnight in line with the laboratory protocol for
processing specimens. Patient data will be stored in a secure and locked cabinet within the pediatric ophthalmology and strabismus clinic.

19) **Resources Available**

One of investigators (Dr. Miller) is the Scientific Director of the Ocular Microbiology Laboratory and has significant experience in ocular microbiology. Her laboratory will serve to identify the microorganisms, quantify and assess antimicrobial susceptibilities of the microorganisms.

The Bascom Palmer Eye Institute Pediatric Ophthalmology Service is a high-volume clinical practice with surgeons experienced in adjustable suture techniques. As all adult strabismus patients who are scheduled for surgery are potential subjects, recruitment is unlikely to be problematic.

20) **Prior Approvals**

Not applicable

21) **Local Number of Subjects**

We plan to enroll a total of 100 patients.

22) **Confidentiality**

The suture specimen will be labeled by code number on broth without subject identification. The data collection sheets will not contain protected health information.

23) **Provisions to Protect the Privacy Interests of Subjects**

In order to adequately protect patient’s privacy interests, only study personnel will have access to the information obtained during the course of the study participation.

24) **Compensation for Research-Related Injury**

This study poses minimal risk to the participants as all interventions could be deemed standard of care. It is acceptable standard of care for either the providone iodine drop to be used or omitted post-operatively for this procedure. In our institution we typically utilize providone iodine prior to initiating the surgery.

25) **Economic Burden to Subjects**

There is no additional cost for subjects in this study.

26) **Consent Process**

All eligible adult strabismus patients who are scheduled for adjustable strabismus surgery at the Bascom Palmer Eye Institute will be invited to participate. The consent processes will occur during the preoperative clinic
visit. The patients will have the opportunity to discuss the study, review the consent form, and sign the consent form during the course of the visit. This study will follow the SOP: Informed Consent Process for Research (HRP-090).

**Non-English Speaking Subjects**

We will exclude subjects whose English proficiency precludes reading the form and understanding its contents.

27) **Process to Document Consent in Writing**

The proposed study will follow the SOP: Written Documentation of Consent (HRP-091). Please see attachment for the consent forms.

28) **Drugs or Devices**

This study does not involve the development of drug or device.