

CORNEAL ULCER TREATMENT WITH FAR-UV STERILRAY™ (222nm) LIGHT Informed Consent

Your Doctor has determined that you have an infected corneal ulcer. We are asking you to participate in an investigational corneal ulcer treatment that can potentially cure the infection within 60 seconds. The treatment involves the use of investigational FAR Ultraviolet light at a specific wavelength that has been shown to kill bacteria and fungus and viruses, three common infections in Florida. This treatment involves research on the response of your eye to the standard of care for similar corneal ulcers in ADDITION to the Ultraviolet Light treatment.

PURPOSE OF RESEARCH

The purpose of this research is to determine if we can cure your corneal infection faster than routine therapy currently employed for ulcers of this type. We routinely culture corneal ulcers before we begin therapy, using an anesthetic on your eye to eliminate any pain. We will repeat the culture after the Ultraviolet light treatment to determine if all of the organisms (bacteria, fungi, or viruses) have been eliminated. Most corneal ulcers require one to four weeks of topical drops on the eye to stop the infection. We anticipate that your infection will be sterile (without any more bacteria/fungi) within 20 seconds of treatment. We will therefore re-culture your ulcer after the treatment to verify that you have no more organisms.

DURATION OF YOUR PARTICIPATION

Most corneal ulcers take 1-4 weeks of topical antibiotics to cure the infections. We would ask you to return to the clinic at least 2 times per week for this period of time. This is similar to our current requirement without Ultraviolet light treatment. No additional visits beyond the standard corneal ulcer treatment is anticipated

DESCRIPTION OF THE PROCEDURE TO BE FOLLOWED

The normal clinical practice for corneal ulcers is as follows, with the modification of our investigational protocol noted in CAPITAL letters for your recognition:

1. Eye exam: You have already had this accomplished to make the diagnosis of a corneal ulcer.
2. A culture of the ulcer. Topical anesthetic (numbing drops) are applied to your eye. An eyelid speculum is placed between your eyelids to hold the eyelids open for a brief time. A cotton tip (calcium alginate) applicator is gently wiped over the ulcer to remove some of the infected material. This is placed on culture plates and slides to determine the type of infection present.
3. THE FAR-UV STERILRAY™ INVESTIGATIONAL LAMP WILL BE PLACED APPROXIMATELY ONE INCH FROM YOUR CORNEAL ULCER AND TURNED ON FOR 60 SECONDS, AND THEN REMOVED.
4. A SECOND COTTON TIP (CALCIUM ALGINATE) APPLICATOR IS GENTLY WIPED OVER THE ULCER TO REMOVE SOME OF THE INFECTED MATERIAL. THIS IS PLACED ON CULTURE PLATES AND SLIDES TO DETERMINE THE TYPE OF INFECTION PRESENT AND THE NUMBER OF ORGANISMS STILL LIVING, IF ANY.

5. Topical eye drops will be placed in your eye in the clinic and prescriptions for the appropriate eye drops will be given to you for the pharmacy to fill. You will be on eye drops every hour while awake to stop the infection.
6. You will be asked to return to the clinic 24 hours after treatment to determine if any infection still remains, or if your ulcer is responding to treatment. The eye drops will be modified according to your response and healing and culture results. We normally see patients every day until their ulcer is healing. If your ulcer is severe, or demonstrates danger to your eye, we will admit you to the hospital for more intensive eye drops. Surgery to remove the infection is rarely needed, but may be required to save your vision and eye.

IDENTIFICATION OF RESEARCH PROCEDURES

The Research Procedures, in CAPITAL LETTERS above, include the addition of the investigational treatment for 60 seconds with Far-UV Sterilray™ light and the additional culture of your corneal ulcer to determine the number of organisms that remain on the cornea.

RISKS OF THE FAR UV TREATMENT

Corneal ulcers are inherently risky to vision because the infection can spread across and through the clear cornea, or window of the eye. This spreading infection can cause the eye to perforate, or have a hole in the cornea with loss of the contents of the eye, and blindness. The infection can cause scarring of the cornea with poor vision or require a corneal transplant. No additional risks of the treatment with Far-UV Sterilray™ light are known. The lid speculum to hold your eye open for 60 seconds is not associated with additional known risks, but has discomfort from holding the eye open to avoid blinking, even though your eye is completely numb with anesthetic. Far-UV Sterilray™ light administration of over 60 minutes may damage the corneal endothelium, but the current treatment plan is only 60 seconds. No known skin or eye toxicity of Far-UV Sterilray™ light has been observed with this short treatment. No known fetal affects of treatment of the eye with Far-UV Sterilray™ light are known, if you are pregnant.

BENEFITS TO YOU WITH FAR-UV STERILRAY™ TREATMENT

The risks of corneal ulcers are numerous, with standard therapy, including pain, spread of infection, corneal scarring, perforation of the eye and blindness. We anticipate that instead of the usual time of treatment with topical antibiotics for two to four weeks that your corneal ulcer will be no longer infectious after 60 seconds of treatment. The BENEFITS of this decrease in active infection time is that your pain from the infection will be greatly reduced and the potential for blinding complications will be decreased dramatically. Although we will continue to treat your ulcer with the current standard antibiotics, prior studies have shown that reducing the bacteria or other organisms as rapidly as possible reduces the risks of the infection.

ALTERNATIVE PROCEDURES TO FAR UV LIGHT TREATMENT

We will be utilizing the standard antibiotic treatment for your corneal ulcer in addition to the Far-UV Sterilray™ treatment. YOUR PARTICIPATION IN THIS INVESTIGATION IS VOLUNTARY AND YOU MAY ELECT NOT TO PARTICIPATE IN THIS INVESTIGATION. The standard treatment of corneal ulcers will still be utilized, including topical and subconjunctival antibiotics, as indicated, if you elect not to participate in this investigation.

CONFIDENTIALITY OF YOUR MEDICAL RECORDS

Your medical records are kept confidential and locked at St. Michaels Eye and Laser Institute. We anticipate publishing the insights and conclusions of our research. Your name will not be used at any time and your personal records will not be reviewed or revealed to any person except as required for your insurance purposes.

COMPENSATION FOR RESEARCH

No compensation is provided for this research. Each of the investigators is a Board Certified Ophthalmologist with all of the facilities available to diagnose and treat the complications of cornea ulcers or sight threatening progression of your infection. Both bacterial and fungal infections can spread rapidly and you may require emergency surgery to save your eye. This can occur with or without the use of Far-UV Sterilray™ light treatment. All necessary diagnostic and treatment procedures will be available to you to preserve your vision. No additional costs for Far-UV Sterilray™ light treatment of your ulcer are anticipated beyond those normally incurred with corneal ulcers of your type.

RESEARCH, RIGHTS OR INJURY

You may contact any of the following investigators if you have questions about the research protocols or feel that you have experienced an injury:

J. James Rowsey, MD: St. Michaels Eye and Laser Institute, 1030 West Bay Drive, Largo, Florida 33770. Phone 727-585-2200.

John Michaelos, MD: St. Michaels Eye and Laser Institute, 1030 West Bay Drive, Largo, Florida 33770. Phone 727-585-2200.

Bradley Fouraker, MD: Brandon Cataract Center and Eye Clinic, [403 Vonderburg Dr Ste 101, Brandon, FL 33511](#) Phone 813-681-1122

Please be aware that your participation in this investigational study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled

If you decide not to participate, then your corneal ulcer will be treated with the same standard of care provided to all patients with corneal ulcers that are referred to us. Our dedication is to preserving your best vision.

All new data and conclusions from the study will be provided to you at the study progresses. We anticipate that 20 patients with corneal ulcers will be included in this study.

TERMINATION OF YOUR PARTICPATION IN THE STUDY

If your surgeon feels that your eye disease is extending, and surgery is required, in spite of treatment, you may be terminated from the study for the safety of your eye. You may be terminated from the study if you are not able to utilize your eye drops in a safe manner or if you are not able to return for follow up examinations. Your eye health and safety are paramount to us.

If you feel that you can no longer participate in the study, your corneal ulcer will still require treatment to protect your vision. If you desire to be seen by another ophthalmologist, you may notify us and we will transfer your records to the doctor of your choice, terminating your participation in the study.

Signature of Patient

Date

Signature of Doctor/ Date

Printed Name of Patient

Printed Name of Doctor