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**Version 11/21/14**

NOTE: THIS FORM IS INTENDED AS A SAMPLE FORM. IT CONTAINS THE INFORMATION OMIC RECOMMENDS YOU AS THE SURGEON PERSONALLY DISCUSS WITH THE PATIENT. PLEASE REVIEW AND MODIFY TO FIT YOUR ACTUAL PRACTICE. GIVE THE PATIENT A COPY AND SEND THIS FORM TO THE HOSPITAL OR SURGERY CENTER AS VERIFICATION THAT YOU HAVE OBTAINED INFORMED CONSENT.

Informed Consent For Corneal Excision Or Superficial Keratectomy

**What Is Anterior Basement Membrane Dystrophy And How Is It Treated?**

Anterior basement membrane corneal dystrophy is a condition of abnormal maturation of the epithelial cells and basement membrane that forms the outermost surface of the cornea, the clear watch crystal on the front of the eye. These abnormal cells create an irregular corneal surface which can be comprised of parallel lines, white putty-like deposits, fine haze or scarring, and even elevated nodules.

**What is Mitomycin-C?**

Mitomycin-C (MMC) maybe used during excision (removal) to minimize the recurrence of anterior basement corneal dystrophy, corneal nodules, and scarring. MMC was first used as an anti-cancer drug. Ophthalmologists use MMC for other purposes "Off label" as part of the practice of medicine\*. The decision to use MMC is based on the evaluation of advantages and potential disadvantages in each individual case.

**What methods are employed to remove the corneal lesions?**

Excising or shaving off the areas of the cornea involved with anterior basement membrane corneal dystrophy and corneal nodules can include the use of a sharp metal blade, find diamond burr, and sometimes even the excimer laser in a procedure called PTK (phototherapeutic keratectomy). The cornea can be scraped if the lesions are superficial, or a deeper excision called a superficial keratectomy may be indicated

**What are treatment alternatives?**

This is an elective procedure. You do not have to have corneal excision or superficial keratectomy surgery. In many cases no treatment is needed. Sometimes eye drops, ointments, oral doxycycline pills, and even contact lenses may be used to smooth out the surface of the cornea thereby improving vision and reducing the incidence of painful corneal erosions. If these growths threaten site or cause persistent discomfort, they can be removed.

**How will removing the anterior basement corneal dystrophy affect my vision?**

The goal of excising anterior basement corneal dystrophy and corneal nodules is to decrease irritation\inflammation, achieve a normal, smooth ocular surface, improve any decrease in vision caused by these lesions, and prevent regrowth, if possible. Abnormal spots and scars can make an uneven and irregular corneal surface which can distort vision and cause intermittent painful corneal erosions.

If you do not have this surgery your vision can worsen and pain can persist. It can also make it more difficult to get accurate preoperative measurements before cataract or refractive eye surgery.

**What type of anesthesia is used and what are the main risks**

Typically, a surgeon utilizes topical anesthetic eye drops or ointments to anesthetize the eye in order to perform corneal excision or superficial keratectomy surgery. Occasionally, an anesthetic may need to be injected around the eye.

 The risks of anesthesia are minor, especially if topical medications alone are utilized. Topical anesthetics can cause ocular irritation, itching, redness, eyelid swelling, and delayed healing of the optical surface. Injected anesthetic medication has the added risks of hemorrhage of the eyelid or conjunctiva, eyelid swelling, droopy eyelids, double vision, blockage of blood flow to the eye, inadvertent injection into the blood stream, fainting, and loss of vision.

**Post operative care**

Following excision of these growths, a bandage contact lens is often inserted on the eye to reduce discomfort and assist in the healing of the corneal surface. Patients are usually treated with antibiotic eye drops to reduce the risk of infection, and steroid or non-steroidal anti-inflammatory drops to reduce post-operative pain and inflammation. Sometimes oral pain medications are needed. You will need to be followed closely until the corneal surface heals.

**What are the main risks of corneal excision and superficial keratectomy?**

There is no guarantee that the surgery treatment will improve your condition. Sometimes it doesn't work. In addition, surgery treatment is risky. Sometimes it can make the problem worse, cause an injury, or create a new problem; if it does, this is called a complication. Complications can happen right away or not until days, months, or years later. You may need more treatment or surgery to treat the complications. If the complication happens during surgery, your surgeon may need to perform another surgery right away to treat it. Your surgeon may discover a new condition or problem for the first time during the surgery. The surgeon may need to change the plan for surgery to treat this problem or condition right away.

It is impossible to list all risks and complications that may occur. The main risks and complications of surgery treatment are delayed healing, infection, bleeding, loss of corneal clarity or scarring, corneal melting or ulceration, corneal perforation, double vision, nighttime glare, poor vision and injury to parts of the eye and nearby structures from the procedure or anesthesia, and even blindness. The abnormal tissue from anterior basement corneal dystrophy including the nodules may grow back. You may need additional treatment or surgery to treat these complications.

In addition to the usual complications of corneal excision, MMC may cause blurred vision, worsened or loss of vision, ocular pain, ocular surface irritation, sensitivity to light, delayed healing, scleral or corneal melt with perforation, scarring of the conjunctiva or cornea, iritis, glaucoma, cataracts, and possible need for further surgery.

**\*FDA status of MMC in Eye surgery**

MMC was approved by the Food and Drug Administration (FDA) for the treatment of various types of cancer. Upon approval, the drug manufacturer produces a "label" that explains its use. Once a drug is approved by the FDA, physicians can use it for other purposes "off label "as part of the practice of medicine if they are well informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

**PATIENT’S ACCEPTANCE OF RISKS**

Your signature on this document means:

* You have read it (or it has been read to you) and you understand this information.
* You have been offered a copy of this document.
* Your doctor has answered your questions to your satisfaction.
* You consent to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (procedure) on your \_\_\_\_\_\_\_\_\_\_\_\_ eye (state “left”, “right”, or “both eyes”).

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Patient Signature (or person authorized to sign for patient) Date

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Print Patient Name