

PHOTOTHERAPEUTIC KERATECTOMY (PTK) Consent

What Is Anterior Basement Membrane Dystrophy (ABMD) And How Is It Treated?

ABMD is a condition of abnormal maturation of the epithelial cells and basement membrane that forms the outermost surface of the cornea, the clear part 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 Mytomycin-C?

Mytomycin-C (MMC) may be used during surgery to minimize the recurrence of ABMD, 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 risks in each individual case.

How is the PTK surgery performed?

A surgical spatula is used to remove the areas of the cornea involved with ABMD and corneal nodules. Once the surface cells have been removed, the Excimer Laser is used to remove deeper scars, smooth the surface of the cornea, treat cornea erosions or change the shape of a cornea that has been distorted by injury or surgery. PTK removes the diseased portion of the cornea. This hopefully will improve vision and comfort of the eye.

What are treatment alternatives?

You do not have to have the surgery, but that means you're blurry vision and symptoms are more likely to persist. It is important to try non-surgical alternatives before proceeding with surgery, like eye drops, ointments, and even contact lenses. These are used to smooth out the surface of the cornea thereby improving vision and reducing the incidence of painful corneal erosions.

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

The goal of excising ABMD 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 to anesthetize the eye in order to perform corneal excision or superficial keratectomy surgery.

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.

Post operative care

Following excision of these growths, a bandage contact lens is often placed 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. Rarely, oral pain medications are needed. You will need to be followed closely until the corneal surface heals.

What are the main risks of the surgery?

There is no guarantee that the surgery treatment will improve your condition. Sometimes it doesn't work. In addition, surgery always has risks. 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 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, re-activation of prior infections 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 PTK, 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 CONSENT

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.
- I understand Phototherapeutic Keratectomy (PTK) with the excimer laser may increase my need for glasses and may require the use of corrective lenses to achieve my best vision.
- I understand that not all the beneficial effects of PTK are currently known.
- I also understand that all the risks and complications are not known.
- Your doctor has answered your questions to your satisfaction.

I consent to have Photo-Therapeutic Keratectomy (PTK) in my _____ (state "right" or "left" or "both") eye.

Patient (or person authorized to sign for the patient)

Date

Witness