

TAILORED EYES

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PTERYGIUM EXCISION WITH OCULAR SURFACE RECONSTRUCTION AND AMNIOTIC MEMBRANE TISSUE GRAFT INFORMED CONSENT

WHAT IS A PTERYGIUM?

Pterygium (pronounced tur-IJ-ee-um) is a growth on the cornea (the clear front window of the eye) and the conjunctiva - the thin, filmy membrane that covers the white part of your eye (sclera). These growths are believed to be caused by dry eye, exposure to wind and dust and UV (ultra-violet) exposure.

WHAT ARE TREATMENT ALTERNATIVES?

In many cases no treatment is needed. Sometimes eyedrops and ointments may be used to reduce inflammation (swelling). If the growth threatens sight or causes persistent discomfort, it can be removed. You should understand that despite proper surgical removal, the pterygium may return. If a pterygium returns, additional surgery may be necessary, particularly if there is persistent inflammation or progression of the new growth towards the center of vision.

HOW WILL REMOVING THE PTERYGIUM AFFECT MY VISION?

The goal of pterygium excision (removal) is to decrease irritation/inflammation, achieve a normal, smooth ocular surface, improve the decreased vision caused by the pterygium, and prevent regrowth, if possible. It is possible however that you may have worse vision after the pterygium surgery.

WHAT IS MITOMYCIN-C?

Mitomycin-C (MMC) may be used during excision (removal) to minimize the recurrence of pterygium. MMC was first used as 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 the advantages and potential disadvantages in each individual case.

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.

POTENTIAL MMC COMPLICATIONS

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

AMNIOTIC MEMBRANE TISSUE GRAFT

When a pterygium is large, inflamed, recurrent, or for other indications, amniotic membrane tissue grafts can be used to aid healing of the wound and reduce inflammation that can lead to recurrence. These tissue grafts can also reduce post-operative pain. It may be used in selected cases for the management of both primary and recurrent pterygium to aid in rapid healing with reduced inflammation, scarring and unwanted blood vessel formation.

Amniotic Membrane Grafts

The amniotic membrane is the innermost layer of the placenta and enwraps the fetus during pregnancy. This membrane is harvested and processed after C-section surgery and provides a foundation for cells to grow over for a smooth ocular surface. The benefit of amniotic membrane grafts includes less scarring, shorter surgery, and faster recovery. These membranes deliver powerful healing properties to the tissues and are used in spinal cord surgery, for burn victims and in eye surgery.

WHAT IS CONJUNCTIVAL TRANSPLANTATION?

Conjunctival transplantation moves a piece of your own conjunctiva (filmy white part of the eye) to the area where the pterygium is excised (removed). This technique may be used for the management of both primary and recurrent pterygium.

WHAT ARE THE RISKS OF PTERYGIUM EXCISION?

All operations and procedures carry risk and can result in unsuccessful results, complications, and injury from both known and unknown causes. Complications that may occur days, weeks, or even months later include but are not limited to: recurrence of the pterygium, double vision, poor vision; eye pain, loss of corneal clarity; bleeding; infection; cornea or scleral melting, perforation of the eye, and injury to parts of the eye and nearby structures from the procedure or anesthesia. The pterygium may grow back. You may need additional treatment or surgery to treat these complications.

In addition to the usual complications of pterygium excision, Mitomycin-C 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, limbal stem cell deficiency, scarring of the conjunctiva or cornea, iritis, glaucoma, cataract, and possible need for further eye surgery.

If a 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.

PATIENT CONSENT AND ACCEPTANCE OF RISKS

I have had ample opportunity to read this consent form (or it has been read to me), ask questions of my surgeon, and have been offered a copy of this consent form to take home. I voluntarily give my authorization and consent to the performance of the procedure(s) described above (including the administration of blood and disposal of tissue) by my physician and/or his associates, assisted by hospital or surgery center personnel and other trained persons.

In signing this informed consent for pterygium removal surgery, I am stating that:

_____ I have been offered a copy of this consent to take home.

_____ I have filled in all the blank spaces.

_____ My ophthalmologist has answered all of my questions and this form has been fully explained to me.

_____ I fully understand the possible risks, benefits, and complications of surgery.

_____ I have read this informed consent or this consent was read to me by

_____ (name).

On the basis of the above statements, I voluntarily consent and authorize Steven Kane, MD, (my ophthalmologist) to perform a Pterygium excision surgery with ocular surface reconstruction and amniotic membrane graft surgery on my

_____ RIGHT eye or _____ LEFT eye.

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

Patient Printed Name