

TAILORED EYES

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INFORMED CONSENT FOR REMOVAL OF ABNORMAL CELLS FROM THE SURFACE OF THE EYE WITH OCULAR SURFACE RECONSTRUCTION, CRYOTHERAPY, AND AMNIOTIC MEMBRANE TISSUE GRAFT

You have abnormal cells on the surface of your eye. Cells grow on the conjunctiva. The conjunctiva is the clear tissue that covers the white part of your eye. These cells can become abnormal or turn into cancer cells. There are two medical terms for these abnormal cells. Ophthalmologists call them OSSN (ocular surface squamous neoplasia) or CIN (conjunctival intraepithelial neoplasia). When the cells become abnormal or turn into cancer, they need to be removed.

There are two ways to remove abnormal cells from the surface of your eye. Your eye surgeon can cut off the abnormal cells. The eye surgeon then uses a probe to freeze the area around them to kill any abnormal cells that are left. The eye surgeon may also use some medical eye drops to kill any abnormal cells that are left. After the cells are removed, the surgeon may leave your eye to heal on its own, or place a tissue graft over the treated area. There is more information about medical eye drops and tissue grafts below in this document.

There is a second way to remove the abnormal cells without surgery. The surgeon can put the medical eye drops on the abnormal cells first. These eye drops may need to be used for many weeks or months. Your eye surgeon will not know for many months if the medical eye drops have killed the abnormal cells. If the eye drops do not kill the abnormal cells, you might need surgery to have them removed.

Here is more information about the medical eye drops

There are two medical eye drops your eye surgeon might use in your eye. These medications are called Interferon Alpha 2b and Mitomycin-C. When your eye surgeon uses these medical eye drops to treat abnormal cells on the surface of your eye, this treatment is called “off-label.” This means that the U.S. Food and Drug Administration (FDA) approved these drugs to treat other cancers and diseases. Eye surgeons now use these medical eye drops to treat abnormal surface cells on the eye and prevent scarring.

Here is more information about tissue grafts

There are two types of tissue grafts that your surgeon might use to help your eye heal. Your surgeon might take a piece of your own conjunctiva and place it where the abnormal cells used to be. Or the eye surgeon might place a graft called an amniotic membrane tissue graft. The amniotic membrane is part of the placenta and wraps the fetus while it is developing in the womb. The amniotic membrane can act like a graft and contains powerful factors that can promote healing and help with pain after surgery. After women give birth by C-section, they donate the placenta that

contains this membrane to a tissue bank. The tissue bank prepares the membrane as a graft. These grafts are used in spine surgery, on burn victims, and in eye surgery to promote rapid wound healing and reduce scarring.

The goal of removing the abnormal cells is to make the surface of your eye smoother.

Removing the cells may also keep the cancer from coming back.

There are risks when the abnormal cells are removed

There are problems (risks) that can happen with any procedure or surgery. These problems may happen right away or not for weeks or months later. You may need treatment for these problems.

Here are some of the problems you might have after the abnormal cells are removed:

- the abnormal cells may grow back
- the abnormal cells may invade the eye or other tissues
- poor vision
- loss of vision
- loss of the eye
- the clear cover of your eyeball (the cornea) might become less clear
- limbal stem cell deficiency (surface skin cells may have trouble repopulating)
- bleeding
- infection
- scarring
- double vision
- injury to parts of the eye from the procedure or anesthesia

The medical eye drops can also cause problems

Interferon Alpha 2-b may irritate the surface of the eye, or make you feel like you have the flu.

Mitomycin-C may cause these problems:

- blurry vision
- loss of vision
- loss of the eye
- eye pain
- irritation of the surface of the eye
- limbal stem cell deficiency (surface skin cells may have trouble repopulating)
- sensitivity to light
- slow healing
- the abnormal cells may grow back
- the abnormal cells may invade the eye or other tissues
- a hole in the sclera (white part of the eye) or cornea (clear covering of the eye)
- scarring of the conjunctiva or cornea
- swelling or inflammation of the iris (colored part of the eye)
- high eye pressure (glaucoma)
- cataract (cloudy eye lens)

You may need eye surgery to treat these problems.

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 by my physician and/or his associates, assisted by hospital or surgery center personnel and other trained persons.

In signing this informed consent for 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 the 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 removal of abnormal cells from the surface of the eye with ocular surface reconstruction, cryotherapy, and amniotic membrane graft on my

_____ RIGHT eye or _____ LEFT eye.

Patient (or person authorized to sign for patient)

Date