

# TAILORED EYES

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## **Penetrating Keratoplasty (PK) Informed Consent**

I have been informed by my physician that I am a candidate for a corneal transplant surgery. This consent form is designed to educate me about the various options available to me. It is intended to make me better informed about the risks, benefits, and alternatives of traditional corneal transplant surgery called a penetrating keratoplasty.

**TO THE PATIENT: You have the right, as a patient, to be informed about your cornea condition and the recommended surgical procedure to be used, so that you may make the decision whether or not to undergo the cornea surgery, after knowing the risks, possible complications, and alternatives involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to cornea surgery and should reflect the information provided by your eye surgeon. If you have any questions or do not understand the information, please discuss the procedure with your eye surgeon prior to signing.**

### **INDICATIONS FOR CORNEAL TRANSPLANT SURGERY**

The human cornea has three main layers, the outer or epithelial layer, the middle or stromal layer, and the inner or endothelial layer. Often, PK surgery is indicated when the disease or degeneration of the cornea involves more than one of these layers. PK surgery can be used to treat many conditions including but not limited to corneal scars, infections that fail medical therapy, cornea perforations, cornea transplant failures, and diseases that warp the cornea like keratoconus.

### **DESCRIPTION, ADVANTAGES, AND DISADVANTAGES OF PK CORNEA TRANSPLANT**

A corneal transplant is a surgery to replace all or a portion of a damaged cornea with a human donor cornea.

### **FULL THICKNESS CORNEA TRANSPLANT: Penetrating Keratoplasty (PK or PKP)**

During PK surgery, a full thickness circular portion of the cornea is removed and replaced with a

full thickness human donor cornea. All 3 layers of the cornea are replaced and the cornea graft is sutured into position.

Since all layers of the cornea have been replaced, PK surgery carries the highest risk of rejection of all types of cornea transplant. Cornea graft rejection is where your own cells attack the transplant graft. For initial PK surgeries, the rejection rate is about 15% but that number can be significantly higher for repeat PK surgeries. Patients with a history of herpes or shingles in the eye are at risk of virus reactivation after surgery. Since the surgery involves suturing the graft in place it can take longer than other types of cornea transplant. These cornea sutures are very delicate and sometimes the sutures can break or loosen over time. A broken or loose suture can increase your risk of eye infection or graft rejection. It is also common that there can be significant astigmatism or an irregular shape to the cornea after PK surgery. This astigmatism may be so severe that glasses won't improve the vision and you may need a rigid contact lenses or more surgery to correct it.

The cornea graft typically remains as a weak spot in the eye forever, which increases the risk of a ruptured globe or perforated eye from even minor trauma. Lastly the healing time after a full thickness cornea transplant is long and it can take over a year or more for vision to improve or to be ready for new glasses or contact lens prescription.

A goal of PK is to stabilize the eye and to improve the decreased vision that was caused by the diseased cornea. A cornea transplant will not correct decreased vision caused by other eye conditions such as a cataract or glaucoma.

## **NONSURGICAL OPTIONS**

### **ALTERNATIVE TREATMENTS:**

I understand that I may decide not to have a cornea transplant operation, at all. However, if I do not have the cornea surgery, I understand my vision loss from the cornea usually will continue to get worse. Corrective lenses, eyeglasses, or contact lenses may or may not improve my vision, but they will not reverse the worsening of the cornea condition. I understand that worsening of the cornea condition may lead to development of eye pain, increased risk of infection, blindness, and in rare cases even loss of the eye.

Patients with certain corneal conditions such as scarring or warping (keratoconus) sometimes may be treated with eyeglasses, rigid gas permeable contacts, hybrid rigid contacts, scleral contacts, or intrastromal corneal ring segments. The choice of treatment depends upon the type and severity of the corneal condition or disorder. In some patients, only the inner layer of the cornea, the endothelium, needs to be replaced. These patients can be treated with a different type of corneal transplant surgery known as Descemet's stripping automated endothelial keratoplasty (DSAEK) or Descemet's membrane endothelial keratoplasty (DMEK).

## **RISKS AND COMPLICATIONS OF PK CORNEAL TRANSPLANT SURGERY**

The general risks of PK cornea transplant operation are similar to the risk of any eye surgery and include the risk of hemorrhage in or around the eye, infection, swelling of the retina causing temporary or permanent blurring of vision, a retinal detachment, glaucoma or high pressure in the eye, graft failure, rejection of the transplanted tissue, chronic inflammation, double vision, a droopy eyelid, loss of corneal clarity, poor vision, total loss of vision, or even loss of the eye. Rarely, the transmission of infectious diseases can occur such as Hepatitis, AIDS, and syphilis, although the corneal donor is routinely tested for these diseases before the tissue is approved and released for transplantation.

The donor cornea is kept in place with stitches or sutures. The sutures can come loose, cause infections, or change the shape of the cornea. This changed corneal shape is called astigmatism and can cause blurry vision. Astigmatism can be treated with glasses, but if it is severe, contact lenses or more surgery may be needed. Once the cornea is cut, it remains more delicate, and can break open from minor trauma or injury, even years after the surgery.

Please tell your doctor if you have history of brain aneurysm, brain arteriovenous malformation (AVM), or congestive heart failure (CHF) or kidney failure.

It takes over a year for vision to improve after PK surgery. The risk of rejection of the PK tissue is roughly 15% but this is much higher for repeat PK surgeries. If the surgery is not successful, or the transplant is rejected, you may need another corneal transplant or a different 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.

There is no guarantee that PK will improve your vision. As a result of the surgery and/or anesthesia, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. You may need additional treatment or surgery to treat these complications. This additional treatment is not included in the fee for this procedure.

## **OTHER RISKS**

Depending on the type of anesthesia used, other risks are possible. Local (eye block) anesthesia may damage the retina, damage the optic nerve or may lead to: bleeding in or behind the eye, double vision, permanent vision loss, perforation of the eye, a droopy eyelid, interference with the circulation of the blood vessels in the retina, respiratory depression, and hypotension. Useful vision can be permanently lost and in rare cases complications may include cardiopulmonary complications, coma, and death.

If you have other known medical conditions, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are taking medications such as Coumadin (a blood thinner) or other supplements or vitamins, tell your

ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

I understand that there may be other unexpected risks or complications that can occur that were not listed in the consent form or discussed by the doctor. I also understand that during the course of the proposed operation unforeseen conditions may be revealed that require the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment. I understand that there is no guarantee that cornea transplant surgery will improve my vision and that in some cases complications may occur weeks, months, or even years later.

Due to the complex nature of cornea transplant surgery, it is important to follow your eye doctor's instructions. Failure to follow instructions may increase the risk of graft failure and the need for additional surgery.

**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 PK cornea transplant 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 corneal transplant 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 Penetrating Keratoplasty (PK) cornea transplant surgery on my

\_\_\_\_\_ RIGHT eye or \_\_\_\_\_ LEFT eye.

\_\_\_\_\_  
Patient's signature (or person authorized to sign for patient)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print patient's name