

TAILORED EYES

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Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) 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 (a penetrating keratoplasty), versus DMEK (Descemet's Membrane Endothelial Keratoplasty), versus DSAEK (Descemet's Stripping Automated Endothelial 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 layers, the outer or epithelial layer, the middle or stromal layer, and the inner or endothelial layer. The inner or endothelial layer is made of thousands of small pump cells. These special pump cells are responsible for pumping fluid out of the cornea so it can remain clear and compact and provide good vision for the eye. If the pump cells stop working or become damaged or destroyed then the cornea swells causing it to turn cloudy. A swollen, cloudy cornea can make the vision blurry.

The endothelial pump cells can be lost for many reasons including aging, genetic diseases (like Fuchs' Corneal Dystrophy), trauma, and previous eye surgery. If enough pump cells are lost, then medical therapy is usually not helpful anymore and a corneal transplant is indicated. Often, the other layers of the cornea (the stroma and the outer epithelium) are usually still healthy and can be preserved.

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 will not improve my vision or 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.

DESCRIPTIONS, ADVANTAGES, AND DISADVANTAGES OF CORNEA TRANSPLANTS

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.

PK surgery can treat many diseases such as corneal scars, infections that fail medical therapy, cornea perforations, and diseases that warp the cornea like keratoconus. Because all layers of the cornea have been replaced, it carries the highest risk of rejection of all types of cornea transplant. Rejection is where your 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. 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 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.

DESCEMET'S STRIPPING AUTOMATED ENDOTHELIAL KERATOPLASTY (DSAEK):

This form of cornea transplant involves only removing and replacing the inner most layer of the cornea, the endothelium. This surgery is helpful for treating conditions where the endothelium pumps have been damaged such as after glaucoma surgery or in cases of PK graft failure and the

remaining layers of the cornea are healthy. Some surgeons also use this procedure to treat cornea edema after cataract surgery or for patients with Fuchs' cornea dystrophy.

In this surgery, your eye surgeon will remove the endothelial layer and replace it with a thin disc of donor cornea tissue. The cornea graft in DSAEK consists of donor endothelial cells plus a thin layer of donor cornea stromal tissue. The graft is held in place against the inside of the cornea with an air bubble. The air bubble slowly resolves over the next few days. Patients are instructed to lie supine (face up) for several days only taking short 10 min breaks each hour to do activities of daily living.

DSAEK typically is a faster surgery with faster recovery than traditional PK or full thickness transplant. The wound tends to heal faster and is less likely to rupture from trauma, compared to PK. Your vision is likely to improve faster than after a PK though it may still take 6 months or longer. As the surgery only involves replacing the inner layer there is less risk of rejection of the donor tissue and less risk of significant astigmatism. The disadvantages or challenges with DSAEK surgery include the positioning requirement to look up at the ceiling for a few days. This may be difficult for some patients with back or neck problems or in the elderly. Additionally, the DSAEK tissue could fail to clear or could detach or dislocate and may need to be re-pinned with another air bubble against the back of the cornea (rebubbling). If the DSAEK graft fails to clear (graft failure), you may need a repeat DSAEK surgery or a different cornea transplant such as a PK.

DESCEMET'S MEMBRANE ENDOTHELIAL KERATOPLASTY (DMEK)

This form of cornea transplant is one of the newest and most advanced. Similar to DSAEK, the DMEK surgery involves only removing and replacing the endothelium or inner most layer of the cornea. This surgery is helpful for treating conditions where the endothelium pumps are not functioning well (like Fuchs' dystrophy) or were damaged (like after cataract surgery) and the remaining layers of the cornea are healthy. In DMEK, the cornea graft is held in place against the inside of the cornea with an air bubble. The air bubble slowly resolves over the next few days. Patients are instructed to lie supine (face up looking at the ceiling) until the air bubble fully resolves (typically 4-7 days), only taking short 10 min breaks each hour to do activities of daily living.

A key difference between DSAEK and DMEK is in the thickness and composition of the donor graft. In DMEK, the graft is much thinner since only the endothelial cells on a thin membrane are transplanted (no stroma like in DSAEK). Generally, the thinner DMEK graft allows for faster vision recovery (typically 2-4 weeks), faster healing time, a lower risk of rejection, and higher quality final vision than DSAEK. The wound size in DMEK surgery is smaller than that for PK or DSAEK so even less risk of eye rupture.

Not all patients are candidates for DMEK surgery such as patients with a glaucoma tube in the eye or an anterior chamber lens.

Since the DMEK donor tissue is very thin (about 1.5 x as thick as a red blood cell), it can detach more easily from the back of the cornea during the initial healing period. This means DMEK surgery has a higher chance of needing a rebubbling procedure than DSAEK (about 15% risk). Additionally, DMEK has a slightly higher risk of primary graft failure which is when the donor tissue has poorly pumping cells (about 4% risk). If the donor DMEK pump cells fail to clear the cornea, you may need to have a repeat DMEK or a different type of cornea transplant.

RISKS AND COMPLICATIONS OF DSAEK CORNEAL TRANSPLANT SURGERY

The general risks of DSAEK are similar to a traditional PK cornea transplant operation 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.

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.

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.

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 DSAEK 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 DSAEK 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 Descemet’s Stripping Automated Endothelial Keratoplasty (DSAEK) 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