

CONSENT FORM

Procedure: Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)

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INTRODUCTION:

You have a condition that has affected your cornea (the front part of your eye). Your doctor has determined that you need a corneal transplant. This involves having surgery to replace your cornea with a cornea that has been donated by someone who has died. The cornea you will receive is referred to as the donor cornea. The donor cornea to be used for your transplant will be provided by a licensed and certified Eye Bank.

Your corneal surgeon has determined that you are a good candidate for the Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) technique of corneal transplantation. This technique is a form of "endothelial keratoplasty" and is used instead of the full thickness traditional method called "penetrating keratoplasty" (PK).

Your doctor wants you to know that your condition can be treated with either technique of surgery: PK or DSAEK. You may choose not to have DSAEK surgery at this time without fear of penalty or loss of medical care. Before you decide whether to have DSAEK, please take as much time as you need to ask any questions regarding the procedure with your surgeon and/or his medical staff.

PURPOSE: You have been advised that DSAEK would be a reasonable procedure for your treatment because only one part of your cornea is not working properly. The endothelial layer of your cornea is failing and is causing your cornea to become swollen. The endothelium is the layer of cells on the inside surface of your cornea. It is this layer that needs to be replaced. Until recently, the only way to replace that layer of cells was with a full thickness corneal transplant. (PK)

A split thickness transplant of this inner layer is called an "endothelial keratoplasty". The DSAEK technique would remove (or "strip") only the diseased portion of your cornea (like "stripping" wallpaper off a wall) and then use a lamellar transplant of a donor tissue to replace only the diseased tissue while leaving the rest of your cornea intact. In addition, a smaller incision will be used compared to a traditional PK. The post-operative care after DSAEK surgery is nearly identical to those of patients that have traditional PK surgery but they are usually fewer in number and sutures do not need to be removed at the office visits as in traditional full-thickness PK procedures.

Split thickness lamellar corneal transplants have been performed for many years to replace the front part of the cornea and have been successful. What is different about this procedure, DSAEK, is that the surgical procedure involves replacement of the back layer of the cornea rather than the entire thickness of the cornea. This replacement is done through a small one-quarter of an inch incision. By leaving the front surface of the cornea without sutures or incisions there is a much shorter healing and recovery time for the patient.

PROCEDURE:

If you choose to proceed with the DSAEK surgery, you will be scheduled at a time that is convenient for both you and your surgeon's schedule. The surgery will be performed under local anesthesia unless there is a reason for which you would do better with general anesthesia. Local anesthesia is when you are "numb" and cannot feel pain, but are awake enough to answer questions. General anesthesia is when you are completely asleep during the procedure.

The surgical procedure will take about 75 minutes to perform which is about the same amount of time as a traditional PK. If you also have a cataract, then often time's cataract surgery can be performed at the same time as DSAEK surgery but your surgeon may advise for you to have the cataract surgery done prior to the DSAEK surgery to aid in your overall recovery process. If cataract surgery and DSAEK are done together, then the surgery takes about 2 hours. Either way, you will be required to lie flat on your back, facing the ceiling for one hour immediately after the operation (in the recovery room) to help the new transplanted tissue to adhere. Surgery is usually done as an outpatient procedure at our surgery center and you are sent home with a patch on your eye that same day. We ask that you try to lie flat facing the ceiling as much as possible for the first 24 hours after surgery. It is okay to get up to use the restroom and eat. You should have minimal discomfort after surgery, and standard over-the-counter pain medications can be taken if necessary. You will return to see Dr. Liu the next day. The patch will be removed and your eye will be examined. You will be placed on an antibiotic and steroid eye drop to prevent infection and to help with healing. The first postoperative day visit after surgery will only take about 30 minutes, and is primarily done to check the eye pressure and to be certain that the donor disc is in good position. You will have a brief visit to the office one week later and then again three weeks later. You will need to be seen more frequently if any repositioning is performed. We will of course see you at any time should you have any concerns, questions or problems after your eye surgery.

RISKS AND COMPLICATIONS:

The following risks and complications of DSAEK endothelial corneal transplant surgery are the same whether you have a full thickness PKP transplant or a split-thickness DSAEK corneal transplant. These include:

- 1) Mild discomfort and "scratchiness" for one week after the surgery that may be treated with Tylenol or other pain medication by mouth. Immediately after surgery your eye will be red. There may be temporary discomfort to you from the eye examination or eye drops. This may include stinging, redness or itching.
- 2) A serious eye infection or bleeding occurs in 1 in 1,000 patients.
- 3) Serious problems caused by anesthesia occur in 1 in 10,000 patients including not awakening from anesthesia or having neurological problems from the anesthesia.

- 4) Developing high pressure in your eye (glaucoma).
- 5) Additional surgery due to healing problems, retinal swelling or detachment, or loss of vision.
- 6) About 15% of the time after traditional PK surgery, the body's immune system produces inflammation of the donor cornea. This is often called a "graft rejection" reaction. The rejection reaction is usually reversible if treated promptly with topical steroids but sometimes can lead to a failure of the transplant. Information to date (April 2009) indicates that DSAEK surgery may have a lower rejection rate than traditional PK.
- 7) The transplant may become cloudy either because of rejection, as described above, or for other reasons. If this happens it may be necessary for you to have another transplant. The risks of the transplant failing varies, depending upon what your current corneal condition is. Your doctor may be able to provide more precise information about your particular risk factors.

Risks of split thickness corneal transplant surgery that are unique to split thickness surgery include:

- 1) Movement of the lamellar corneal transplant tissue ("disc") within the eye. If the disc is in good position on the first day or two after surgery, then it is extremely rare for the disc to dislodge later. Should the donor tissue disc be found on the first day after DSAEK surgery to be dislocated or dislodged, then it would require another minor surgery to either to put the tissue back into the proper position, or if the tissue could not be repositioned successfully then a full thickness corneal transplant could be done at a later date. This repositioning only takes about 30 minutes and it can be done in our office minor operating suite without having to return to the operating room. None-the-less, the risk of infection and other problems is present with any surgical intervention, even with simple repositioning of the donor disc.
- 2) The area over the pupil where the donor tissue attaches to your own cornea is the area of healing. During the healing process, this attachment area (the "interface") has the potential to develop haze or clouding which can decrease your vision from its full potential. If this happens, then a full thickness PK transplant could be necessary to restore the vision in the future.
- 3) General Anesthesia: The risks are the same or as with any other surgery requiring general anesthesia. Serious risk or injury such as neurological (brain) damage or death occurs less than 1 in 30,000 cases. Your individual risk can be more thoroughly discussed with the anesthesiologist prior to the time of your surgery. We wish to avoid ANY risk to your general health, and that is why we usually recommend DSAEK surgery with local anesthesia.

Although we have tried to list all the possible risks and complications with the DSAEK procedure, there may be others that cannot be predicted at this time.

BENEFITS:

There are possible direct benefits to you as a patient receiving DSAEK surgery; however, there are no guaranteed benefits.

- 1) Patients who have a split thickness corneal transplant such as a DSAEK have been shown to have a smoother corneal surface than patients that have a full thickness PKP standard corneal transplant. This occurs because the natural surface of the cornea is not replaced so the focusing power of the cornea remains more natural than with a full thickness corneal transplant. Of the patients that have had a PK in one eye and a DSAEK transplant in the other eye, almost all have stated that the *quality* of vision of the DSAEK eye is superior to the quality of the vision the PKP eye. This has been true even when the PKP eye measures 20/20 vision and the DSAEK eye measures slightly worse at 20/25 or 20/30 vision.
- 2) The few sutures that are used in the DSAEK procedure to close the wound are not irritating. Patients who have a standard full thickness corneal transplant require either 16 sutures or more, all of which cause more discomfort and more irregularity to the surface than has been shown with the DSAEK technique.
- 3) If the endothelial cells that are transplanted by this split thickness corneal transplant function normally as expected, then the cornea will lose its swelling and become clearer at a much faster rate than with a standard full thickness corneal transplant.
- 4) A smoother surface for focusing and a clearer transplant has allowed many patients to see better in a matter of 4-6 weeks as compared to 6-8 months (or even several years) with a standard full thickness corneal transplant.
- 5) Because there are no sutures in your central cornea, the cornea is stable more quickly than with a full thickness corneal transplant. This requires less frequent changes in your glass prescription than with a full thickness corneal transplant. Also, after traditional full thickness corneal transplant procedures, approximately 25% of patients require a contact lens to see well and they cannot simply wear glasses. After DSAEK surgery, patients do not have to wear a contact lens or undergo other refractive surgery procedures in order to see well. Patients can usually wear normal glasses for their best vision.
- 6) Because the corneal surface remains smooth and relatively unchanged from the curvature before DSAEK transplant surgery, there is expected to be better matching between the focusing power of your lens (or the artificial lens you received at the time of cataract surgery) and the focusing of the surface of your cornea. Therefore there is less of a chance of requiring thick glasses after transplant surgery with the DSAEK technique compared to full thickness corneal transplant surgery or PK.

ALTERNATIVE PROCEDURES OR TREATMENT:

You do not have to have the DSAEK technique surgery to receive a corneal transplant. Your surgery can be done with a standard full thickness corneal transplant (PK).

UNAVAILABILITY OF A DONOR CORNEA FOR THE EYE BANK:

In the unlikely event that a donor cornea is not available, your surgery would have to be canceled and rescheduled. You would be notified at least 24 hours prior to the time of your surgery if this were to occur. (The unavailability of tissue is extremely rare and can be expected to happen only occasionally since we source our tissue from all over the country through Tissue Banks International).

QUESTIONS OR PROBLEMS:

If you have any questions about surgery, please contact: Dr. Jeffrey Liu, M.D. at (650) 961-2585.

CONSENT:

I have read the information about the DSAEK procedure and voluntarily agree to participate. The risks, benefits and alternative therapies have been explained to me. Dr. Liu and his office staff have answered all of my questions and I agree to proceed with the procedure.

Patient's Name (print)

Patient's Signature

Date

Witness Signature

Date