

DESCEMET'S STRIPPING AUTOMATED ENDOTHELIAL KERATOPLASTY

DSAЕК CONSENT FORM

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INTRODUCTION:

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

Your corneal surgeon has determined that you are a good candidate for the DSAЕК (Descemet's Stripping Automated Endothelial Keratoplasty) technique of corneal transplantation. This technique is a modification of a technique called DLEK (Deep Lamellar Endothelial Keratoplasty) that was introduced in the United States in the year 2000. DSAЕК simplifies the preparation of the donor tissue and provides a more consistent donor smoothness. DSAЕК is a form of "endothelial keratoplasty" and is used instead of the full thickness traditional method called "penetrating keratoplasty" (PKP).

First, we want you to know that your condition can be treated with any technique of surgery: PKP or DSAЕК. You may choose not to have DSAЕК surgery at any time without fear of penalty or loss of medical care. Before you decide whether to have DSAЕК, please take as much time as you need to ask any questions and to discuss the surgery with the doctor and the medical staff, or with family, friends or your personal physician.

PURPOSE:

You have been advised that DSAЕК 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 single layer of cells on the back inside surface of your cornea. The endothelium normally functions to pump water out of the cornea in order to keep it thin and transparent. It is this layer that needs to be replaced. Two common conditions that lead to the endothelium malfunctioning are Fuchs' corneal dystrophy and pseudophakic bullous keratopathy (swollen cornea following routine cataract surgery). In both these conditions, the number of functioning endothelial cells falls below the level necessary to keep pumping enough water out of the cornea. Until recently, the only way to replace that layer of cells was with a full thickness corneal transplant (PKP).

A split thickness cornea transplant of this inner layer is called an "endothelial keratoplasty". The DSAЕК technique would remove (or "strip") only the diseased portion of the back endothelial layer of the cornea similar to "stripping" wallpaper off of a wall and then use a posterior lamellar (back layer partial thickness) transplant of donor tissue to replace only the diseased tissue and leave the rest of your cornea intact. In addition, a smaller incision will be used to remove and replace your diseased tissue compared with a PKP. This procedure has been performed across the country since the year 2000 and published reports show that the surgery is successful in providing a clear cornea and getting rid of the preoperative corneal edema or swelling. The post-operative care clinic visits after DSAЕК are nearly identical to those of patients who have had traditional PKP surgery and will be outlined below under Procedures.

Split thickness lamellar corneal transplants have been performed for many years to replace the FRONT part of the cornea and have been highly successful. What is different about DSAEK is that the surgical procedure involves replacement of the BACK layers of the cornea rather than the front layers of the cornea. This replacement is done through a small pocket incision to avoid changes in the front surface of the cornea. By leaving the front surface of the cornea without sutures or incisions there is felt to be an advantage in healing and recovery time for the patient. Since most of the focusing of light is actually performed by the front surface of the cornea, performing a surgical procedure that minimizes refractive changes to the front surface allows faster visual rehabilitation and a more predictable refractive outcome compared to standard PKP procedures.

PROCEDURES:

If you choose to have DSAEK, surgery will be scheduled on a routine basis that is convenient for you and corresponds to our normal surgical schedule. The surgery can be performed under general or local anesthesia and this detail will be discussed with your surgeon. Local anesthesia is when your eye is “numb” and cannot feel pain but you are awake enough to answer questions. General anesthesia is when you are completely asleep during the procedure.

During the surgery a single 5 mm long line incision is made in the sclera (the “white” part of the eye), a pocket is formed, and just the diseased endothelial layer of your cornea will be removed by gently “stripping” the diseased tissue off, like peeling wallpaper off of a wall. The donor endothelium and back layer of the donor cornea (the lamellar “split thickness” corneal tissue) is then placed through the incision and pocket and placed into position on the back surface of the cornea to replace the diseased tissue which was removed. This donor tissue can be prepared by the surgeon in the operating room or provided to the surgeon from the eye bank. A small air bubble is placed to keep the tissue firmly for 10 minutes until it can adhere on its own. The initial incision is then closed with a small suture and the procedure is completed.

The surgical procedure will take about one hour to perform. If you also have a cataract of the lens of the eye, then cataract surgery can be performed at the same time as DSAEK surgery. Some surgeons prefer to take the cataract out in a separate surgery and then perform the DSAEK surgery a few weeks later. Your surgeon will explain this option to you, if necessary. If cataract and DSAEK surgery are done together, then the surgery takes about one and a half hours. You will be required to lie flat on your back, facing the ceiling for one to two hours immediately after the operation to enable the air bubble to help the tissue to adhere. Surgery is usually done as an outpatient procedure at the hospital 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 after you get home for the first night of surgery. 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. Geggel the next day. The patch will be removed and your eye will be examined. You will be placed on antibiotic and steroid drops to prevent infection and to help with healing. This first visit after surgery will only take about 15-30 minutes, and is primarily done to check the pressure and to be sure that the donor disc is in good position. You will be asked to wear a protective shield over the eye (without a patch) at night while sleeping for the first month. No eye protection is needed during the day, but if you normally wear glasses for the other eye, go ahead and wear them. Normal activities are permitted even the first day after surgery. We ask that you do not go swimming or in saunas for one month and use common sense to avoid any activities that may lead to taking a direct hit to the eye. You can shower and wash your hair after surgery. You will have a brief visit to the clinic one week after surgery, one month after surgery and then every 6-12 weeks until one year elapses. We will of course see you at any time that you have any concerns, questions or problems after your surgery.

The tests that you will have performed at the clinic visits are a vision test, a check for glasses, examination with the standard clinic biomicroscope, a pressure check, and measurements of your cornea with various optical machines which record topography and endothelial cell counts. None of these tests will be difficult or uncomfortable for you. The day after surgery, your vision will be cloudy as the new back layer begins pumping water out of your swollen cornea. The vision should improve slowly over the first few weeks and months. The final vision will be determined by the health of your retina, macula (central retinal area) and optic nerve since most patients will attain a clear cornea.

RISKS AND DISCOMFORTS:

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

1. Mild discomfort and “scratchiness” for one week after surgery that may be treated with Tylenol or another drug 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 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 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 20 percent of the time after PKP surgery the body’s immune system produces an inflammation of the donor cornea. This is often called a rejection reaction. This rejection reaction is usually reversible if treated promptly but sometimes leads to failure of the transplant. The treatment usually consists of steroid eye drops. Information will be given to you so you can become educated regarding the signs and symptoms of rejection. Information indicates that DSAEK may have a lower rejection rate than PKP, but more study needs to be done to determine if this is true.
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 risk 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.

Risks of split thickness corneal transplant (DSAEK) surgery that are unique to this surgery include:

1. Movement of the lamellar corneal transplant tissue (“disc”) within the eye. If the disc is in good position on the day 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 (5-10 percent incidence), then it would require another surgery to either put the tissue back into the proper position, or if the tissue could not be repositioned, then a full thickness corneal transplant could be done. Repositioning only takes about 15-20 minutes and is successful over 90 percent of the time. Nonetheless, the risk of infection and other problems is present with any surgical intervention, even with simple repositioning of the donor disc.
2. During surgery, Dr. Geggel may find that it is not possible to continue or complete the endothelial keratoplasty (DSAEK) procedure safely. Because safety of your eye is the highest priority, Dr. Geggel may decide to stop the DSAEK procedure and change the surgery to a standard full thickness PKP transplant. This actually is one of the advantages of DSAEK, i.e. a standard PKP can always be done and its results not compromised by having DSAEK.
3. The area over the pupil where the donor tissue attaches to your own cornea is an area of healing. During the healing process, this attachment area (the “interface”) has the potential to develop a haze

or clouding that can decrease your vision from its full potential. If this happens, then a full thickness corneal transplant (PKP) could be necessary to restore the vision. Full understanding of the healing of the interface and its effect on final vision is still a matter of research in DSAEK surgery.

4. It is unknown whether the split thickness tissue has a higher risk of becoming cloudy than full thickness corneal tissue. Current information suggests that the risk is less than standard PKP surgery. However, there is the possibility that the endothelial cells of the split thickness tissue could fail and the tissue become cloudy. This cloudy disc could be removed and replaced with a new donor disc. However, if there is any problem after your DSAEK surgery, you *always* have the option of a standard, full thickness PKP surgery.

Although we have tried to list all possible risks and discomforts with this DSAEK procedure, there may be others that we do not know about 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 DSAEK have been shown to have a smoother corneal surface than patients who have a full thickness standard PKP 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 PKP. Many patients who have had PKP in one eye and DSAEK in the other state that their *quality* of vision in the DSAEK eye is superior to the quality of the vision in the PKP eye. This has been true even when the PKP eye measures 20/20 vision and the DSAEK eye measures 20/25 or 20/30 vision. This subjective preference by the patient for the DSAEK eye is currently being studied.
2. The one to three tiny sutures that are used in the DSAEK procedure to close the scleral wound are not irritating. Patients who have a standard PKP require either 16 sutures or one to two long continuous sutures in a circle, 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 PKP.
4. A smoother surface for focusing and a clearer transplant has allowed many patients to see better in a matter of weeks as compared to months or years with a standard PKP.
5. Because there are no sutures in your surface cornea in DSAEK, the cornea is stable more quickly requiring fewer changes of glasses than with a full thickness PKP. Also, after full thickness corneal transplants, up to 20 percent of patients require a contact lens to see well and cannot simply wear glasses. After DSAEK, almost all patients can wear glasses for best-corrected visual acuity. In addition, after routine full thickness PKP, 20-25 percent of patients need further surgery called relaxing incisions to refine the corneal curvature. Unless you have high levels of preexisting astigmatism, this would not be necessary after routine DSAEK surgery.
6. Because the corneal surface remains smooth and relatively unchanged from the curvature before transplant surgery, there is expected to be better matching between the focusing power of your lens (or 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 or having an imbalance in refraction between your two eyes after DSAEK surgery compared with standard PKP surgery.

If the data on DSAEK patients demonstrates other improvements over standard full thickness transplant surgery, then patients in the future with similar conditions will benefit from your having had DSAEK surgery.

ALTERNATIVE PROCEDURES OR TREATMENTS:

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

UNAVAILABILITY OF A DONOR CORNEA FOR THE DSAEK PROCEDURE:

In the unlikely event that a donor cornea is not available, your surgery would have to be cancelled and rescheduled. You would be notified at least 24 hours prior to the time of surgery if this were to occur. This unavailability of tissue has not occurred once in the past 15 years and is a credit to the Sight Life Eye Bank in Seattle.

COSTS:

The surgery and all of your follow-up care would be needed whether you had PKP or DSAEK transplant surgery. Therefore, these costs will be yours or your insurance company's responsibility. Pre-authorization will be obtained from your insurance company to cover the costs of this surgery in the same manner that they would cover for the cost of a routine full thickness corneal transplant surgery. DSAEK is considered to be simply another less invasive form of PKP surgery, and is billed in the same manner as routine standard PKP surgery. Over the long term, because DSAEK surgery has no corneal sutures or incisions to worry about, it is expected to cost much less in follow-up care than standard PKP surgery. This ultimately saves the patients and insurance company a substantial amount of money.

RELATED INJURY:

Just as is the case with any surgery, you are responsible for the costs of your medical care for injury resulting from treatment; however, these costs may be covered, at least in part, by most major insurance companies or Medicare. Virginia Mason will not assume financial responsibility for such treatment or provide financial compensation for such injury. Should you suffer any injury as a result of DSAEK surgery, emergency treatment will be available.

QUESTIONS OR PROBLEMS:

If you have any questions about DSAEK surgery, please contact:
Harry Geggel, MD at (206) 223-6840.

CONSENT

I have read the information about DSAEK. The risks, benefits and alternative therapies have been explained to me. Dr. Geggel has answered all of my questions.

Patient's name (print)

Patient's signature

Date

Witness signature

Date

Surgeon signature

Date