



Informed Consent for DSEK Descemet's Stripping Endothelial Keratoplasty

I have been informed by my physician that I am a candidate for a corneal transplant operation. 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 the DSEK, the Descemet's Stripping Endothelial Keratoplasty.

INDICATIONS FOR CORNEAL TRANSPLANT SURGERY

The human cornea is composed of three layers, the outer or epithelial layer, the middle or stromal layer (which comprises about 90% of the total corneal thickness), and the inner or endothelial layer. The endothelial layer is composed of a single layer of thousands of small pump cells. These endothelial pump cells are responsible for pumping fluid out of the cornea so it can remain clear and thin and provide good vision for the eye. If the pump cells should become dysfunctional, damaged, or destroyed, the cornea fills up with fluid and becomes swollen and cloudy, and causes blurry vision.

The endothelial cells can be lost due to aging, from inherited diseases (such as Fuchs' Corneal Dystrophy), from trauma, or from previous intraocular surgery. If a critical number of endothelial cells are lost, and the cornea becomes swollen and cloudy, medical therapy is usually not helpful and a corneal transplant operation is indicated. The remainder of the corneal layers, the stroma and the outer epithelium, are usually healthy. A large number of patients requiring corneal transplant surgery have these sorts of problems where only the endothelial cells have been or injured or lost.

ADVANTAGES AND DISADVANTAGES OF TRADITIONAL TECHNIQUE

Standard corneal transplant surgery has consisted of removing the entire cloudy cornea and replacing it with a full thickness donor cornea, thereby replacing all three layers of the cornea. This surgery was first developed one hundred years ago, and the wonderful 90% success rate reported today is based on numerous refinements to this same basic technique. It has certainly stood the test of time.

Ophthalmic researchers and surgeons have long recognized that for many patients needing a corneal transplant, only the diseased or missing endothelial cells needed to be replaced, as the stroma and epithelial layers were otherwise normal. Recently, a new technique called DSEK has

evolved in corneal transplant surgery which accomplishes the goal of replacing only the endothelial cell layer. A thin button of donor tissue containing only the endothelial cell layer is inserted onto the back surface of the patient's cornea. This new technique appears to be a significant improvement over the standard operation. The surgical skill and expertise required is the same, but the surgery itself takes less time with an experienced surgeon, involves a smaller surgical incision, requires far fewer sutures, heals faster and more reliably, and the vision returns faster.

The advantage of the traditional corneal transplant operation is the long and successful track record that we have with it. There is a 90% success rate. The rate of rejection is only about 8%. It is relatively easy to combine other surgery with it such as cataract extraction or glaucoma surgery. The disadvantages of the traditional corneal transplant operation are the time involved in performing the actual operation (45 to 60 minutes), the difficulties in suturing the new cornea in place, and occasional problems with the sutures which can come loose, cause infections, or cause astigmatism (an irregular corneal shape). The astigmatism after traditional corneal transplant surgery can be so significant that eyeglasses alone won't give adequate vision and some patients ultimately require contact lenses or additional surgery to reduce or eliminate the astigmatism. Because the wound is a full 360 degrees, and the sutures used are finer than human hair, the corneal transplant wound is always very delicate and at risk to rupture or break open from mild or incidental trauma, even several years after the surgery. The visual recovery can take 6 to 12 months.

ADVANTAGES AND DISADVANTAGES OF DSEK TECHNIQUE

There are several significant advantages to the DSEK operation compared to the standard corneal transplant operation. Once the surgeon is skilled in the technique, the operation is faster. The wound is smaller and closer in size and location to a cataract surgery incision. The smaller wound is more stable and less likely to break open from inadvertent trauma. Because the wound is smaller and requires far fewer sutures, there is very little postoperative astigmatism which can delay the visual recovery. The maximum return in vision takes only about 3 to 4 months following DSEK. Since only the thin inner layer of the cornea is replaced, over 90% of the patient's own cornea remains behind contributing to greater structural integrity and a reduced incidence of rejection.

DSEK is not for everyone. Some patients with corneal scarring or other conditions are not suitable candidates for DSEK. There are risks involved with the DSEK operation. Since corneal specialists have only been performing DSEK for the past 2 to 3 years, there is no long-term follow-up. There is a risk of the thin button of endothelium becoming displaced within the first few days or weeks after surgery and requiring a return trip to the operating room to reposition it. If the DSEK operation fails, the operation can be repeated with another button of donor endothelium. If the DSEK fails, either after one or multiple attempts, a traditional corneal transplant operation can be performed.

RISKS AND COMPLICATIONS OF DSEK CORNEAL TRANSPLANT SURGERY

The general risks of the DSEK that are similar to the traditional corneal transplant operation include the risk of hemorrhage in the eye, infection, swelling of the retina causing temporary or permanent blurring of vision, a retinal detachment, glaucoma or high pressure in the eye, 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.

There are also complications from the local anesthesia including perforation of the eyeball, damage to the optic nerve, a droopy eyelid, interference with the circulation of the blood vessels in the retina, respiratory depression, and hypotension. On rare occasions, useful vision can be permanently lost.

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.

PATIENT CONSENT

I have had ample opportunity to read this consent form, 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 DSEK corneal transplant surgery, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of DSEK corneal transplant surgery, and

- I have read this informed consent _____ **(patient initials)**
- The consent form was read to me by _____ **(name)**.

I wish to have a DSEK corneal transplant procedure on my _____ (state “right” or “left” eye).

Patient’s signature (or person authorized to sign for patient)

Date

Print patient’s name