CORNEAL TRANSPLANT CONSENT FORM

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Introduction

The cornea is the clear dome-shaped "window" in the front of the eye. Behind this clear window lies the iris, or colored portion of the eye. The cornea serves two purposes: 1. It forms the front part of the eye wall and thus protects structures inside the eye. 2. With its curved shape, the cornea acts like a camera lens to focus images on the retina at the back of the eye.

Following disease or injury, and in some genetic conditions such as keratoconus, the cornea may become weakened, cloudy, or irregular in shape. If medicines are ineffective, in some cases the damaged cornea can be replaced with a healthy cornea from a deceased person. This replacement procedure is called "corneal transplant" or "penetrating keratoplasty."

This document describes corneal transplant surgery. The information is designed to accompany but not replace your discussion with your doctor before and after surgery. If you have further questions, please ask us. It is important that you take as much time as you need to understand your condition and possible treatments.

History

Although attempts at corneal transplantation were made 100 years ago, the first consistent success was achieved by Dr. Castroviejo and Dr. Fine in the 1950's. Corneal transplants are the most successful of all tissue transplants. An estimated 40,000 such operations are performed in the United States each year.

The Donor Tissue

Tissue for transplantation comes from an eyebank. The process begins at the death of someone who has been generous enough to donate his or her eyes. The eyebank carefully screens the donor tissue to rule out any disease that might be transmitted to the recipient. The color of the donor eye is irrelevant, since only the transparent dome in the front of the eye is replaced, and not the colored iris behind it.

When healthy tissue becomes available, the local eyebank enters the information into a nationwide computer network. The corneal tissue is then flown to the site where it is needed. The tissue can be stored for several days in a nutrient fluid before use.

Preparing for Surgery

A general medical examination and routine laboratory tests are occasionally helpful to insure that you are well enough to undergo surgery. Aspirin is not used for a week prior to surgery, since it may cause bleeding during surgery. Antibiotic drops to protect the eye from infection are generally started one day before surgery. It is important not to eat or drink anything (except a sip of water for medicines) after midnight the day before surgery.

Corneal transplant surgery is done on an outpatient basis. You enter the surgery center approximately one hour prior to surgery and leave that same day, generally a couple of hours after the operation. At the surgery center, medication is given to relax you before surgery. An IV line is inserted in your arm. EKG leads are attached to your chest to monitor your heart. These are standard safety precautions and allow the anesthesiologist to monitor your vital signs during surgery.

The eyelids are carefully washed and covered with a sterile plastic drape. Fresh oxygen is provided by a plastic tube placed near the nose. Patients often doze off during the operation.

The Operation

Local or general anesthesia can be used. The decision as to which type is used should be discussed with your surgeon in the office before surgery, and is based on your age, general health, length of surgery, doctor's preference, and your anxiety level. Local anesthesia consists of a small injection in the lower eyelid. Sufficient sedation is given so that the local anesthetic is hardly felt. The entire procedure is done under a microscope. A circular instrument called a trephine is used like a cookie cutter to remove the center of the diseased cornea. A "button" of similar size is cut from a donor cornea using a similar trephine. This donor tissue is then sewn in place with extremely fine nylon sutures.

At the conclusion of the procedure, an eye patch and small metal shield are applied to protect the eye. You will then be taken to the recovery room to wait until you are fully awake before being discharged.

After Your Surgery

After surgery and for the rest of the day you should plan on spending in bed. Sleeping on the operated side is acceptable as long as you are wearing the eye shield for protection at night for the first two weeks after surgery. After the first day, shaving, brushing teeth, bathing, light housework, bending over, walking, reading, and watching TV will not hurt the eye. Shampooing, and light exercise can be resumed after one week.

Pain varies from person to person. Typically there is either mild pain or only slight soreness for a few days and it is usually relieved by Tylenol.

The doctor will see you in the office the day after your surgery. Since the new cornea is delicately sutured in place, a direct poke to the eye or pressing on the eye must be avoided. It is important to wear something hard in front of the eye (glasses or a metal shield) at all times to protect your new cornea. Typically, patients wear their glasses during the day. A metal shield is worn at night for several weeks. Contact sports are discouraged after corneal transplant.

Because the cornea has no blood supply, the transplant heals relatively slowly. Sutures are left in place for six months to one year, and in some cases they are left in permanently. The sutures are buried and therefore do not cause discomfort. Suture removal is a simple, painless office procedure.

Vision gradually improves as the new cornea heals. There is often useful vision within a few weeks. However, in some cases it may take several months to a year to achieve the best possible vision. Although vision may not be perfect after surgery, it is nearly always much better than before the corneal transplant.

To prevent rejection of the new cornea, steroid drops are placed in the eye for several months after surgery. In some cases, low dosage steroid drops are continued indefinitely. Unlike oral steroids, steroid eye drops cause no side effects elsewhere in the body.

Postoperative care is extremely important and by far the most time-consuming part of having a corneal transplant. Please show up for all postoperative appointments.

There is every reason to believe your graft will succeed and last a lifetime. With proper care and prompt attention to any sign of rejection, the new cornea will usually remain clear and healthy.

Risks and Complications

No surgical procedure is completely free of risk. Patients undergoing this operation should do so with a clear understanding of these facts.

It is important to call immediately (including weekends, evenings, and holidays) for any unusual symptoms, including <u>R</u>edness, <u>S</u>ensitivity to light, <u>V</u>ision loss, and <u>P</u>ain (**RSVP**).

You must also call your doctor immediately if you notice flashing lights, new floaters, or loss of peripheral vision. These symptoms can indicate possible retinal tear or detachment.

Complications include but are not limited to astigmatism, infection, bleeding, retinal detachment, glaucoma, and cataract. Occasionally, the donor cornea is rejected (becomes cloudy). Following such complications, vision may end up the same or worse after surgery.

Problems unrelated to the corneal transplant surgery, such as retinal scarring (macular degeneration) or optic nerve damage from increased eye pressure (glaucoma) may lead to poor vision even if the corneal transplant operation is successful.

On extremely rare occasions, there is a remote possibility of death or brain damage due to adverse reactions to general anesthesia or medications.

Frequently Asked Questions

- Q: Will I need glasses or contact lenses after my surgery?
- A: A small percentage of transplant patients do obtain good vision without glasses or contacts. But in most cases, glasses or contact lenses are necessary after surgery.
- Q: Can artificial corneas be used for transplants?
- A: No. Plastic implants are used only to replace a cloudy lens (cataract) inside the eye. For corneal transplants, living tissue must be used.
- Q: Will my eye color be the same after a corneal transplant?
- A: Yes. Only the transparent dome in the front of the eye is replaced, and not the colored iris behind it. In rare cases, existing corneal scars block the true color of the eye, and therefore the eye appears to have changed color after the operation.
- Q: Will I be asleep or awake for my operation?
- A: This surgery is done under either local or general anesthesia. Age, general health, length of surgery, and patient preference are factors weighed in deciding which route to take.
- Q: What exactly does the surgery involve?
- A: Briefly, a round instrument called a trephine is used like a cookie cutter to remove the center of your diseased cornea. A "button" of similar size is trephined from a donor cornea. This donor button is then sewn in place with fine nylon sutures. The entire procedure is done under an operating microscope.
- Q: Do blood vessels have to be reconnected?
- A: No. The cornea has no blood supply and gets its nourishment from the fluid inside the eye.
- Q: What complications can occur with corneal transplant surgery?
- A: No surgical procedure is completely free of risk. Possible complications include but are not limited to infection, bleeding, retinal detachment, glaucoma, and cataract; occasionally the donor cornea is rejected and becomes cloudy. Following such complications, vision may end up the same or worse after surgery. On rare occasions systemic diseases have been transmitted to a recipient patient from a donor cornea. As with any kind of surgery, there is a remote possibility of death or brain damage due to adverse reactions to anesthesia or medications. Patients undergoing this operation should do so with mature consideration of these facts.
- Q: How long will I be in the surgery center, and how long does the surgery last?
- A: You enter about one hour before surgery, and usually go home 1-2 hours after surgery. The procedure is typically about 1.5-2.0 hours in duration.
- Q: Does my eye hurt after surgery?
- A: Pain varies from person to person. Typically there is mild soreness for a few days,

relieved by Tylenol.

- Q: How long will my eye be patched?
- A: Until the surface epithelium is healed, usually 1 to 3 days. After the patch is removed, it is important to wear something hard in front of the eye (glasses or a metal shield) at all times to give it mechanical protection. Typically, patients wear their glasses during the day. A metal shield is worn at night for one month.
- Q: When will I be able to see?
- A: Vision improves gradually as the new cornea heals. There is often useful vision within several weeks. However, in some cases it may take several months to a year for full visual potential to develop.
- Q: Will I be on special medications after transplant surgery?
- A: Yes. You will be on steroid drops in the eye for several months to prevent rejection of the new cornea. In some cases daily steroid drops are used indefinitely. Occasionally other eye medications are necessary.
- Q: What is a rejection?
- A: If the body's immune system recognizes the new cornea as foreign tissue, cells start to attack the endothelium of the donor cornea, the innermost cell layer that normally pumps water out of the cornea to keep it clear. Therefore, the new cornea becomes swollen and cloudy.
- Q: What are the warning signs of rejection?
- A: Redness, Sensitivity to light, decreased Vision, or Pain ("RSVP"). It is important to immediately report these warning signs, since graft survival depends heavily on early detection and treatment of rejection episodes.
- Q: When do rejections occur?
- A: Most occur in the first year, but they can happen later than that.
- Q: Does the new cornea fall out if it is rejected?
- A: No. It simply becomes cloudy, blurring the vision.
- Q: Is there any treatment for rejection?
- A: Yes. When detected early, rejection can be reversed 90% of the time by intensive use of topical, oral, and subconjunctival steroids.
- Q: In case of graft failure, can the operation be repeated?
- A: Yes, in many cases.
- Q: When are the sutures removed?
- A: This varies, depending on the age of the patient, nature of the corneal disease and type of sutures used. Usually sutures are removed sometime between 4 months and 1 year, although in some cases they are left in permanently. Suture removal is a simple office procedure.
- Q: How often will I visit the eye doctor after my corneal transplant?
- A: You will be seen the first day after surgery, one week after, then monthly and gradually at longer intervals over the first year, and yearly thereafter. At these visits we will be checking for such things as graft clarity, wound leaks, eye pressure,

infection, and surface healing. Postoperative care is extremely important and by far the most time consuming part of having a corneal transplant.

CONSENT

I have read the information about corneal transplants and agree to proceed with surgery. The risks, benefits and alternative therapies have been explained to me. Dr.Liu has answered all of my questions.

Patient's name (print)		
Patient's signature	Date	
Witness signature	Date	
Where applicable:		
Signature of Parent or Legal Guardian		Date