

INFORMED CONSENT FOR CORNEAL TRANSPLANT SURGERY

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’s outer wall or shell and thus protects the inside of the eye. 2. With its curved shape, the cornea acts like a camera lens to transmit light and focus images on the retina at the back of the eye.

Following disease or injury, the cornea may become weakened, cloudy, or irregular in shape. If medicines, contact lenses, or other treatments 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 Consent describes corneal transplant surgery. The information is designed to accompany but not replace our discussions before and after surgery. You are encouraged to ask questions about the procedure, alternative treatments, risks, benefits, medical terms, or language in this form. 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. Ramon Castroviejo and Dr. Max Fine in the 1950s. Corneal transplant is the most successful of all tissue transplants. An estimated 40,000 such operations are performed in the United States each year. Dr. Shahinian and Dr. Volpicelli, Board-Certified ophthalmologists, are both corneal and external disease specialists.

THE DONOR TISSUE

Corneal tissue for transplantation comes from an eye bank. The process begins when someone who has been generous enough to donate his or her eyes following their death. The eye bank carefully screens the donor cornea to ensure it meets their quality standards. The color of the donor eye is irrelevant, since only the transparent dome in the front of the patient’s eye is replaced, and not the colored iris behind it.

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

PREPARING FOR SURGERY

When indicated, a general medical examination and routine laboratory tests such as blood count and EKG are done to help insure that one is well enough to undergo surgery. Aspirin should not be taken for two weeks prior to surgery, since it may cause bleeding during surgery. To help protect the eye from infection, you will start antibiotic drops one day before surgery. It is important not to eat or drink anything (except a sip of water when taking medicines) after midnight the night before surgery.

In most cases, the surgery is done on an outpatient basis. You enter the surgery center two hours prior to surgery and leave that same day, generally a few 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.

The eyelids are carefully washed and covered with a sterile plastic drape. A plastic tube placed near the nose provides air. 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, Dr. Volpicelli or Dr. Shahinian, in the office before surgery, and is based on your age, general health, anticipated 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. This donor tissue is then sewn in place with extremely fine nylon sutures.

Corneal transplant surgery is completely painless. Also, the patient sees nothing during surgery because the local anesthesia temporarily blocks the vision. At the conclusion of the procedure, a patch and 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, the rest of the day should be spent in bed. Sleeping on the operated side is acceptable. After the first day, shaving, brushing teeth, bathing, light housework, bending over, walking, reading, and watching TV will not hurt the eye. Shampooing, sexual activity, and vigorous exercise can be resumed after one week.

Pain varies from person to person. Typically there is mild pain or slight soreness for a few days after surgery, relieved by Tylenol.

The doctor will see you in the office the day after surgery. The operated eye is patched until the epithelium (surface layer of the cornea) is healed, usually 1 to 4 days. Since the new cornea is delicately sutured in place, a poke to the eye must be avoided. It is important to wear something for protection in front of the eye (glasses or a plastic shield) at all times to protect your new cornea. Typically, patients wear their glasses during the day. The protective shield is worn at night for 2-3 weeks postoperatively. Contact sports are discouraged after a corneal transplant.

Because the cornea has no blood supply, the transplant heals relatively slowly. Sutures are left in place for three months to one year, and in some cases they are left in permanently. The sutures are buried in the corneal tissue 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 mature consideration of these facts.

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 very rare occasions, diseases have been transmitted to a recipient patient through 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.

It is important to call immediately (including weekends, evenings, and holidays) for any unusual symptoms, including Redness, Sensitivity to light, Vision loss, and Pain (RSVP).

You must also call your doctor immediately if you see flashing lights, newly appearing spots or shapes, known as floaters, or loss of peripheral vision. These symptoms can indicate possible retinal tear or detachment.

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, donor tissue must be used.

Q: Will my eye color be the same after a corneal transplant?

A: Yes. Only the central portion of the cornea, the clear dome-shaped “window” in the front of the eye, is replaced, and not the colored iris behind it. However, in some 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. Your age, general health, anticipated length of surgery, doctor’s preference, and your anxiety level are factors weighed in deciding which route to take.

Q: What exactly does the surgery involve?

A: Briefly, a circular 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 sutured (sewn) in place with extremely 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 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.

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 60-90 minutes 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 epithelium (surface layer of the cornea) is healed, usually 1 to 4 days. After the patch is removed, it is important to wear something for protection in front of the eye (glasses or a plastic shield) at all times to give it mechanical protection. Typically, patients wear their glasses during the day. A protective shield is worn at night for several weeks.

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 put 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 endothelium is the innermost cell layer of the cornea that normally pumps water out of the cornea to keep it clear. Therefore, if rejection occurs, which happens occasionally, 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 a healthy graft depends 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 as well.

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 and/or oral 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 3 months and 1 year, although in some cases they are left in permanently. Suture removal is a simple, painless office procedure.

Q: How often will I visit the ophthalmologist after my corneal transplant?

A: You will be seen daily or every other day for the first week, at gradually longer intervals over the first year, and yearly thereafter. At these visits we will be checking for such things as graft clarity, eye pressure, infection, and surface healing. Postoperative care is extremely important and by far the most time consuming part of having a corneal transplant.

The corneal transplant (penetrating keratoplasty) procedure, along with the alternative treatments, advantages and disadvantages, risks and possible complications of this procedure, have been explained to me by the doctor. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction.

I understand that information gathered about my procedure and postoperative course may be used to further study corneal transplant. I give permission for my case to be presented at scientific meetings or published in scientific journals, as long as I am not identified by name.

I give permission to be photographed by still camera, movie camera, or videotape, and for these photographs to be shown at scientific meetings or published in scientific journals, as long as I am not identified by name.

I wish to have corneal transplant (penetrating keratoplasty) performed on my _____ eye (s).

Patient's Signature

Patient's Name (printed)

Date _____ **Time** _____ **Place** _____

Witness's Signature **Date** _____

Witness's Name (printed)