

Consent Form for Corneal Transplant: PKP (Penetrating Keratoplasty) Technique

INTRODUCTION

This information is being provided to help you may make an informed decision regarding full thickness (penetrating) corneal transplant surgery. A balanced appreciation of the benefits of surgery (pain relief, improved vision) and the potential risks are key to making any decision. This information is not meant to frighten or alarm you. You should take as much time as needed to make a decision about signing this informed consent form. You are encouraged to ask questions about this procedure and their underlying condition before agreeing to have the operation.

GOALS OF CORNEAL TRANSPLANT SURGERY

In most cases, the primary goal of corneal transplant surgery to improve the vision of the operated eye. In doing so it is hoped that one's ability to function at home or at work will also improve. Corneal transplant surgery may also be done to provide more comfort to patients with recurrent corneal pain from blisters. In cases of severe corneal infection or perforation, corneal transplant surgery may be performed to save the eye. When the primary reason for surgery is chronic pain, infection or structural damage, corneal transplantation may preserve the eyeball, but may not result in an improvement in one's vision.

It is important that you understand that improvement in visual and functional status is dependent not only on having a clear cornea, but also a healthy eye. Diseases such as glaucoma (pressure in the eye), cataract, and retinal swelling and scarring will adversely influence the final visual result. The effect that these problems have on the final vision is often difficult to predict prior to corneal transplantation surgery.

ALTERNATIVE TREATMENTS

You may decline to have a corneal transplant operation. Other treatment alternatives may be applicable to the specific condition affecting your eye. These may include the following:

1. OBSERVATION:

Many of the conditions that affect the cornea and lead to decreased vision are non-progressive or very slowly progressive. Careful and regular observation is an alternative in some of these conditions when other treatment approaches are undesirable or have proved unsuccessful. No improvement in vision or increased comfort would be expected with this approach.

2. EYE DROPS:

Eye drops that reduce corneal swelling and intraocular pressure may improve vision or reduce ocular discomfort in some patients. These drops are most helpful in patients with symptoms due to small amounts of corneal swelling. There are few risks associated with these medications.

3. CONTACT LENSES:

Conditions of the cornea that are associated with surface irregularity or scarring may sometimes achieve visual improvement with soft or hard contact lenses. Occasionally a contact lens can be used as a bandage to reduce ocular discomfort. Handling of a contact lens is difficult for some individuals, and not everyone can tolerate them.

4. CONJUNCTIVAL FLAP or AMNIOTIC MEMBRANE:

Patients who have persistent ocular pain due to corneal disease may achieve symptomatic relief from a conjunctival flap or amniotic membrane. This surgical alternative is less involved than a corneal transplant. It involves removing the thin tissue layer (epithelium) covering the cornea and placing a flap of tissue (conjunctiva or amniotic membrane) over the cornea. Because this surgery does not improve corneal clarity, it is not a good choice for patients interested in visual improvement.

5. CORNEAL TRANSPLANTATION:

Corneal transplantation is a surgical procedure in which a donated human cornea is used to replace a portion of your diseased cornea. It is capable of correcting certain corneal disorders that are associated with decreased vision or pain. A full-thickness cornea transplant is being recommended for you. In some cases, a partial thickness cornea transplant (Descemet's stripping automated endothelial keratoplasty or DSAEK, DMEK, lamellar keratoplasty, etc.) may be a suitable alternative procedure.

WHAT TO EXPECT AND POSSIBLE COMPLICATIONS, RISKS, AND SIDE EFFECTS OF CORNEAL TRANSPLANT SURGERY

1. There is often mild to moderate pain and irritation for several days after the surgery. The pain is usually controlled with drops and Tylenol. Narcotics are generally not needed. The eye may be red and the eyelids may be swollen.
2. One of the most common causes of graft failure is a "rejection" reaction. In a graft "rejection" the body's immune system (inflammation) attacks the donor cornea. The rejection is usually reversible if treated promptly, but sometimes rejections lead to clouding and failure of the corneal transplant. In most patients undergoing corneal

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transplant surgery, the risk of graft failure from rejection is less than 5% to 20%. In some cases, the risk may be much higher.

3. The transplant may also become cloudy due to late functional failure of the tissue, scarring, uncontrollable pressure or nonspecific inflammation. If a corneal transplant fails, the vision usually deteriorates. The transplant may be repeated in most cases, but the prognosis is not as good for a repeat corneal transplant operation. The patient's doctor may be able to provide more precise information about each patient's particular risk.
4. The eye is never is structurally as strong as a normal eye after corneal transplant surgery, even many years later. Eye trauma may result in a rupture of the corneal transplant wound and this can lead to possible loss of vision or even the eye. Protection of the eye from minor and major trauma with glasses or a protective shield is extremely important and cannot be overemphasized.
5. The corneal transplant is secured in place with many small non-dissolvable sutures (stitches). The doctor will begin to remove sutures several months after your surgery. Some sutures may be left in place indefinitely. Until all sutures are removed, there is a small risk of developing an infection from a broken suture. Patients should be examined at regular intervals until all sutures are removed.
6. A successful corneal transplant results in a clear cornea. Most eyes will have some astigmatism and will be either near or far sighted. Glasses are the most common method to correct for these changes. Sometimes the glasses are unacceptably thick or strong, or the vision cannot be adequately corrected with glasses. In these cases, a rigid contact lens, or additional surgery may be needed to help improve vision. Unfortunately, there is no guarantee that a corneal transplant will ultimately result in improved vision.
7. Less commonly, other eye problems may develop after corneal transplant surgery. Some of these conditions include elevated pressure, worsening of glaucoma, retinal swelling, retinal detachment and persistent corneal irregularity. You may need additional treatment or surgery to treat these and other possible complications. Additional treatment or surgery is not included in the fee for this procedure.
8. Rarely (approximately 1 in 500) a severe hemorrhage or infection occurs that results in loss of all vision or loss of the eye.
9. The donor cornea is obtained from the Michigan Eye Bank. The Eye Bank is regulated by state and federal law and is certified by the Eye Bank Association of America (E.B.A.A.). The donor is carefully screened for evidence of potentially transmissible infectious or neurologic disease. The donor blood is tested for hepatitis, AIDS, syphilis and other diseases. Every effort is made to exclude donors that could transmit diseases. While it is possible that a serious disease or infection could be transmitted from the donor cornea, the current E.B.A.A. standards are strict enough that this risk is felt to be extremely small.

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10. As with all types of surgery, there is the possibility of complications due to anesthesia, drug reactions or other factors which may involve other parts of the patient's body, including the rare possibility of brain damage or even death. Some anesthetic complications can include: perforation of the eyeball, damage to the optic nerve, bleeding around the eye, drooping of the lid. Since it is impossible to state every complication that may occur as a result of surgery, the list of complications in this form is incomplete.

NEED FOR EXTENDED FOLLOW-UP AFTER CORNEAL TRANSPLANT SURGERY

You should be prepared to return to see the corneal surgeon for regular follow-up visits for an extended period of time. It usually takes 6-18 months for the transplant to heal and stabilize enough for new glasses to be prescribed. While sutures are often left in place when vision has stabilized, there is a risk that these sutures may break and lead to an infection. It is possible for a rejection reaction to develop years after surgery. In some cases a steroid drop is continued as a preventative measure – when this is the case the eye and intraocular pressure will need to be monitored a number of times each year. Safety glasses are strongly recommended in all patients after corneal transplant surgery since the junction between the new transplanted cornea and your own tissue will never be as strong as it was prior to corneal transplant surgery. If at any point you notice pain, loss of vision or other eye problems, notify your corneal surgeon and arrange to be seen promptly.

Your post-operative follow-up appointments for ninety (90) days after your surgery are included in the original surgery billing. After ninety (90) days, or if an office visit is unrelated to the surgery, you and/or your health insurance company will be responsible for all charges.

Pregnancy Warning:

It is advised that pregnant patients do not undergo elective corneal transplant surgery. It is possible that the medications used during anesthesia and after the operation could have adverse effects on the fetus. Women of child bearing potential should be certain they are not pregnant prior to corneal transplant surgery. For women at risk for pregnancy, a blood or urine pregnancy test must be obtained prior to the surgery.

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PATIENT NAME: _____

PATIENT STATEMENT

By signing below, I agree that corneal transplantation surgery, its advantages and disadvantages, risks and possible complications, as well as the treatment alternatives have been explained to me by my doctor. I recognize that it is impossible for my doctor to inform me of all complications and that no guarantee of the final result can be given. I have read this informed consent. My questions have been answered to my satisfaction. I understand and accept the risks and benefits of this surgery.

I wish to have a penetrating corneal transplant on my _____ (right/left) eye.

I understand that at the time of surgery other, unanticipated, reconstructive procedures may be necessary. These may include:

- cataract removal with or without intraocular lens implantation
- removal of an intraocular lens
- exchange of an intraocular lens
- removal of vitreous gel
- production of an alternate pathway for the drainage of ocular fluid (glaucoma procedure)

I understand that post-operative follow-up appointments for ninety (90) days after surgery are included in the original surgery billing. After ninety (90) days, or if an office visit during that 90 day period is unrelated to the surgery, I and/or my insurance company will be billed and responsible for all charges.

PATIENT'S SIGNATURE _____

LEGAL GUARDIAN'S SIGNATURE _____

WITNESS' SIGNATURE _____

DOCTOR'S SIGNATURE _____

DATE _____