

PENETRATING or LAMELLAR KERATOPLASTY (CORNEAL TRANSPLANTATION) CONSENT FORM

INTRODUCTION

Please read this document carefully and completely. If you require additional assistance, you may have this document read to you. If you have any questions, do not hesitate to ask your eye doctor. Do not sign this document unless you are satisfied that you understand what you are signing. Your decision should be based on your own visual needs following a thorough consultation with your eye doctor. You are under no obligation to undergo this surgery.

PROCEDURE

The cornea is the clear, dome-shaped tissue that covers the front surface of your eye (Figure 1). Light rays enter your eye through the cornea, which is the main focusing element of your eye. The cornea bends the light rays through your pupil. A healthy cornea is clear and brings light into a sharp focus inside the eye.

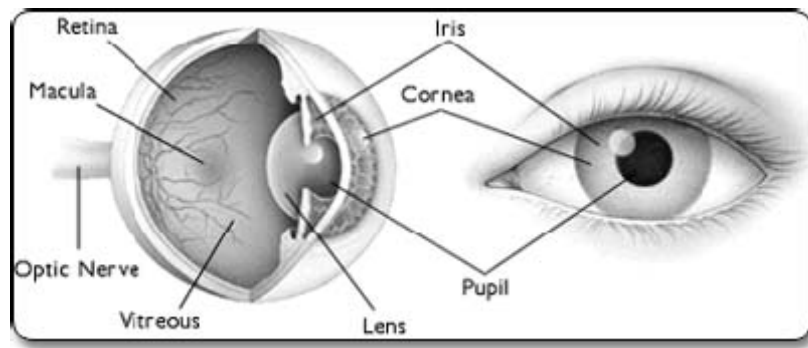


Figure 1. Human Eye Anatomy

Because of damage to the tissues of your cornea, light does not pass through your cornea and bend as needed to produce a sharp image inside your eye, resulting in significant visual impairment. Your doctor believes corneal transplantation surgery may be helpful to restore useful vision to your eye.

With the eye under local or general anesthesia, your doctor will create an incision to remove a portion of your cornea. Your doctor will then place a cornea from a tissue donor on your eye and secure it in place. Depending on your needs, a full thickness or partial thickness transplant may be used. Often your doctor will also perform other procedures at the same time such as cataract surgery, vitrectomy surgery, lens implantation, tarsorrhaphy (closing of the eyelid) repair of the iris, or punctal occlusion (for dry eyes) to take care of your specific eye problems.

Your surgery will take approximately one to two hours, and you will be able to go home the same day. You may be given postoperative topical antibiotics and topical corticosteroids after the surgery and will be instructed on their use. You may need to lie flat on your back for a while after the surgery, and lifting will also be restricted.

After the surgery, sutures may be adjusted or selectively removed as your eye heals. You may not achieve your full visual potential for a year or more following surgery because of changing refraction, slow wound healing, and/or corneal astigmatism (irregular focusing of light inside the eye due to variations in the corneal surface). In most cases, you will be taking long-term medications. Using these medications as directed by your doctor is very important.

In the United States, the Food and Drug Administration (FDA) approves drugs and devices for use in defined circumstances (indications). When a FDA approved drug or device is used for a reason different from those approved indications, it is called off-label use. Depending on your needs, the drugs or devices used during your procedure or care may be used for off-label indications.

RISKS OR DISCOMFORTS

Any surgical procedure carries potential risks, and it is possible this surgery may make your vision worse. Complications associated with corneal transplant surgery may include: corneal astigmatism, imbalance between the two eyes, unpredictability of glasses prescription, partial or total loss of your vision, loss of your eye, inflammation, infection, cataract formation, cystoid macular edema (swelling at the back of your eye), elevated pressure of the eye (glaucoma), drooping of your eyelid, retinal detachment, bleeding inside your eye, the need for contact lenses or glasses, and discomfort or possible pain. Rejection or displacement of the cornea may occur, causing the need for another surgery. These and other complications may occur and may result in poor vision, total loss of vision, or loss of your eye. Some complications could result in the need for further intervention.

Complications due to anesthesia are possible, such as drug reactions or other problems. These complications may involve other parts of your body, including the possibility of brain damage or even death. Since it is not possible to list every potential complication that may occur as a result of any surgery, this list may be incomplete, and there may be risks associated with this surgery that are currently unknown.

All patients, even those that have not had eye surgery, should wear safety glasses for situations where they may get struck in the eye, but this is especially important if you have had previous eye surgery.

Contact your doctor with any problems noticed after the surgery, such as an increase in pain, light sensitivity, loss of vision, or unusual mattering or discharge (other than tears) from the operative eye. Many complications are manageable if caught early. You are responsible for reporting any symptoms, taking medications as prescribed, and making arrangements to be evaluated, as well as any fees associated with the management of complications.

BENEFITS

Although the results of your surgery cannot be guaranteed, the potential benefit that may result from this surgery is improvement in your vision. Specific results from this surgery cannot be guaranteed.

ALTERNATIVE TREATMENTS

You may elect not to have this surgery. In this situation, normally your condition will stay the same, or perhaps worsen over time. Non-surgical treatments such as glasses or contact lenses may be partially helpful in some situations. Partial corneal transplants or excimer laser treatment may also be useful in some patients.

**PENETRATING AND LAMELLAR KERATOPLASTY
CONSENT TO PERFORM THE SURGICAL PROCEDURE**

I have been given an opportunity to ask any questions concerning the surgery. My doctor and his/her staff have answered my questions. I understand I am able to receive a copy of this consent form. By signing this document, I am stating I have read this document (or it has been read to me) and had explained to me the possible risks, complications, and benefits associated with the surgery.

I hereby willingly give my consent to have this surgery performed on my (circle one):

Right Eye

Left Eye

Patient Signature: _____ Date: _____

Printed Name of Patient: _____ Time: ____:____ a.m./ p.m.

Witness Signature: _____ Date: _____

Printed Name of Witness: _____

DOCTOR'S STATEMENT

I have discussed this surgery with the patient (and/or his or her legally authorized representative) using language that is understandable and appropriate. I believe I have informed the patient of the nature of this surgery and its possible benefits and risks, and I believe the patient understood this explanation.

Doctor's Signature: _____ Date: _____

Printed Name of Doctor: _____

On _____ / _____ / _____, this consent form was read to the patient by
(Date)
_____ (who has the relationship to the patient
(First and last name)
of _____), because the patient was unable to read this form.
(Relationship to patient)