

The following information is intended to help you make an informed decision about having Conductive Keratoplasty (CK). Take as much time as you wish to make a decision about signing this form. You are encouraged to ask questions and have them answered to your satisfaction before you give your permission to have surgery. Every surgery has risks as well as benefits, and each person must evaluate the risk/benefits ratio for himself/herself in light of the information presented by your doctor and the information which follows.

Spectacles and contact lenses are the most common method of correcting farsightedness (hyperopia). When tolerated well, they are likely to be a good alternative to CK surgery. Refractive surgery is continuously evolving and other refractive procedures may be available as an alternative to CK. Although the goal of CK is to improve vision to the point of not being dependant on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed.

You should understand that CK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment. Also, CK does not correct the condition known as Presbyopia (the aging of the eye) which occurs in most people around the age of 40 and may require you to wear reading glasses for close up work. People over the age of 40 who have their farsightedness corrected may find that they need reading glasses for clear, closer vision. The correction you achieve from CK may be temporary.

During pregnancy, your refractive error can fluctuate, and this may influence your results. If you know you are pregnant, you should notify your surgeon. You should also tell your doctor about any medications that you are taking, as they may influence the healing process after surgery.

An Overview of the CK Procedure:

Prior to surgery your doctor will have performed an eye examination and several tests that determine your eligibility for having CK surgery. If you agree to have CK surgery, the following typical procedure will be used:

The surgery is performed using a topical anesthetic (drops in the eye). Due to the use of the anesthetic drops, there is expected to be little to no pain or discomfort during or after this procedure. You will be positioned underneath a microscope. The surgeon will make a series of marks on the cornea to indicate where the pattern of tiny dots are to be placed. The CK treatment utilizes a controlled release of radiofrequency (RF) energy to increase the temperature of corneal tissue. The treatment is applied with a probe that is introduced 8 to 32 times into the cornea in a circular pattern, which results in increased curvature of the cornea to correct your vision. The CK procedure itself should take no more than a few minutes to perform.

Potential Risks of CK:

There are risks involved in all surgical procedures. Some of the risks with this procedure can be predicted by the nature of the treatment. No one can predict how often these risks will occur, or if they will happen at all. The risks of CK surgery include, but are not limited to:

1. **Post treatment discomfort.** Some patients may feel a scratchiness or slight dryness in their eye, particularly during the first 48 hours after surgery. Your eye may also tear more than usual. You will receive medications to help prevent any discomfort.

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Potential Risks of CK (cont):

2. **Anisometropia.** The change in the shape of your cornea in the treated eye may create a condition called anisometropia, which is the difference in the focusing ability of one of your eyes compared to the other. This condition may cause some discomfort or disorientation, possibly causing eyestrain or difficulty with depth perception, until you are able to adjust to the new refractions.
3. **No improvement in vision.** This means that the treatment may have minimal or no effect on your vision.
4. **Vision gets worse.** This means that the treatment would not correct your vision, but would make your vision worse. In previous studies, many patients had a small increase in their astigmatism (secondary focus which cause some blurred vision), although their overall vision without glasses was improved.
5. **Change in vision** followed by a return pre-treatment vision. This means that the treatment would correct or worsen your vision, but would gradually return to the vision you had before the treatment. This is called “regression.” In studies full corrections of farsightedness were not achieved in some patients. In addition, depending upon the amount of regression, re-treatment of your eye and/or CK treatment of your other eye may not be effective.
6. **Damage to the cornea.** This may include perforations (holes in the cornea), scarring, infection, or ulceration.
7. **Damage to the eye or surrounding structures.** This could happen if the radiofrequency energy was misdirected or if you move during the treatment. This is an extremely unlikely possibility.
8. **Allergic reactions to medications.** There are medications used for pre-treatment and post-treatment procedures, for post-treatment discomfort, and for promoting the healing process. The use of medications involves the risk of an allergic reaction.
9. **Transient corneal haze.** The CK treatment spots are visible for the first few days because there are small, round, hazy areas where the cornea was heated. These will gradually fade and are only visible with the microscope in about three months. Your doctor will watch and measure these spots throughout your follow-up period.
10. **Photophobia.** You may experience photophobia (sensitivity to light) after treatment. This usually resolves within the first few weeks after treatment.

Alternatives to CK:

CK is purely an elective procedure, and you may decide not to have this operation at all. Among the alternatives are:

1. Eyeglasses/spectacles.
2. Contact lenses.
3. Laser Thermal Keratoplasty (LTK), used to treat farsightedness by delivering concentrated energy in eight small focal spots simultaneously to change the curvature of the cornea.

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4. Laser Assisted in-Situ Keratomelusis (LASIK), another method of surgically reshaping the cornea using the excimer laser. During LASIK, a part of the cornea is folded back to form a flap so that the laser can remove tissue from the inner corneal layers.
5. Photorefractive Keratectomy (PRK), also known as Laser Assisted Subepithelial Keratectomy (LASEK), another method of surgically reshaping the cornea using the excimer laser. While performing PRK/LASEK, a corneal flap is not created. This is to allow the outer layer of the cornea to remain in place for the laser to remove tissue directly from this outer layer.

Cost of Post-Procedure Care:

Costs for the follow-up care, excluding medications, are included for one year following the date of your initial CK procedure, provided the patient remains compliant with care. Enhancements performed within the first year of the initial surgery will cost \$150 per eye. After one year, the cost of enhancement is 50% of the current price of initial surgery.

Post-Operative Instructions:

After your surgery, you will be given medications and instructions to help prevent infection and control healing. It is imperative that you follow all instructions exactly as they are given to you.

Consent:

In signing this form, you are stating that you have read this consent form and, although it contains medical terms which you may not completely understand, you have had the opportunity to ask questions and had them answered to your satisfaction.

You also give your permission for medical data concerning your operation and related treatment, any video recordings of your surgery, to be released to physicians and others demonstrating a "need to know" basis for clinical study.

- I authorize the physicians and other health care personnel involved in performing my CK procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my CK procedure that they deem relevant to providing me with care.
- I agree to arrange for someone to drive me home after my surgery and to refrain from driving myself until I am comfortable with both my day and night vision.
- I have fully informed the operating physician and health care professionals about my medical history and use of prescription, over the counter medications, or other drugs.
- Neither my operating physician nor any of his/her employees or representatives have made any oral statements to me that are inconsistent with the information stated in this consent form.
- I have not taken any pre-operative medications prior to reading, understanding, and signing this Informed Consent form.

The follow-up effects of CK are unknown. CK has not been in use long enough to measure long-term effects (those occurring after 10 years or more) following the procedures, and unforeseen complications or side effects could occur. Not all risks to the patient, or in the case of female patients in childbearing years, the risks to the fetus or embryo, are known or predictable. Since it is impossible to list every complication that may occur as a result of this treatment, the list of complications in this form are not all-inclusive.

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I am making an informed decision in giving my permission to have Conductive Keratoplasty (CK) surgery performed on: Right Eye Left Eye Both Eyes

Printed Name of Patient

Signature of Patient

Date

Signature of Witness

Date

Signature of Physician

Date