

Wang Vision Institute
1801 West End Avenue
Nashville, TN 37203
615/321-8881

The purpose of this consent form is to educate you about Conductive Keratoplasty. It is not intended to scare you, or deter you from surgery, but to inform you of the risks and benefits. It may contain words that you do not understand. Please ask the doctor or the staff to explain any words or information that you do not clearly understand. The surgeon will review your chart before you come in for your procedure and again the day of surgery.

ABOUT YOUR PROCEDURE

Conductive Keratoplasty (CK) uses radio frequency to induce a permanent change in the shape of the cornea resulting in an altered focus of the eye. The radio frequency current is applied to the peripheral cornea causing heating and shrinkage of the collagen fibers in the periphery, changing the shape of the central cornea.

The operation is performed as an outpatient procedure under topical anesthetic under a microscope. Anesthetic (numbing) eye drops are placed in the eye immediately prior to surgery in order to minimize pain during the procedure. In some cases, a mild sedative pill may be administered to reduce apprehension prior to surgery. The eyelid is cleansed and held open using a special instrument.

A pattern is marked on the cornea. Then the probe is applied to the peripheral cornea in a set grid. Each treatment spot takes a few seconds as the probe painlessly heats the cornea to 65 degrees centigrade. The pattern of gentle burns to the peripheral cornea may be visible for a while as white spots.

For the first few days after treatment minor surface irritation, glare sensitivity and over correction are common. Distance vision may be slightly blurred and the eye may be a little irritable.

The postoperative medication regimen is reviewed with the patient after surgery. In the immediate postoperative period, the patient may notice his/her vision is significantly improved compared to before surgery. Best vision, however, may take several days or weeks to achieve. Because the patient is blurry, light sensitive, and may have taken a light sedative, the patient will not be allowed to drive themselves home. Surgery will not be performed unless a driver is present (or other arrangements have been made).

In order to minimize the risk of infection and postoperative discomfort, as well as maximize the visual results of the CK procedure, it is important that the patient complies faithfully with the medication dosage and schedule. Medications are usually necessary for only a few days. We recommend the usage of artificial tears frequently – every 15 minutes for the first week, then even 30 minutes for the second week to alleviate dry eye symptoms common after surgery.

Although the vast majority of patients report markedly improved uncorrected vision quite soon after CK, an individual patient's best vision may not be realized for several weeks or months later. Patients who do not experience full correction may opt to wear glasses, contact lenses or could possibly have additional refractive surgery (either CK or other procedures). These

enhancements (re-operation of CK or other procedures) for residual refractive errors has been less than 10%. Generally, re-operation will not be performed for at least three months following the original procedures.

The purpose of CK is to reduce your refractive error such that you are visually comfortable without glasses. We cannot, however, guarantee that you will not have to wear glasses or contact lenses either some or all of the time to achieve your best corrected vision. Even if your uncorrected vision is significantly better than it was before surgery, you may still require glasses or contact lenses either full or part time in order to see well for distance tasks (such as driving or golf). Additionally, you may, depending on your age, need to wear reading glasses after LASIK. This is still true if you choose to have monovision correction.

PRESBYOPIA

If both eyes are corrected for distance, glasses for reading are needed sometime after the age of forty. This condition, known as “presbyopia”, occurs as a result of the natural aging process of the lens inside the eye. Without surgery, presbyopia results in the need for bifocals. After surgery, if the distance vision is good, near vision will be blurry and magnifiers will be needed.

One approach to address the issue of presbyopia is called “monovision” and involves intentionally correcting one eye such that a small amount of nearsightedness allowing the patient some intermediate or near vision. The result is for this eye to have good uncorrected near vision (but somewhat blurred distance vision) while the fully corrected eye will have good distance vision (and somewhat blurred near vision). However, not everyone can successfully adjust to monovision. Even successful monovision CK patients may require glasses for specific tasks (e.g. driving at night and reading small print in dim lighting). Also, it is important to note that the need for reading correction progresses as we age; if the need overcomes the degree of nearsightedness left in the “reading” eye in a monovision procedure, reading glasses may become necessary. We will demonstrate this for patients over 40 during the evaluation. Patients interested in monovision may benefit from a trial with contact lenses prior to surgery.

WHO SHOULD HAVE CK?

CK is only able to correct low levels of hyperopia or induce small amounts of myopia (to reduce presbyopic symptoms). Patient with myopia or astigmatism are not candidates for the procedure.

CK should not be performed on persons:

- Who are immune-compromised or on drugs or therapy which suppress the immune system
- With signs of kerataconus (steepening of the cornea)
- With a previous history of keloid formation
- Who are pregnant, nursing or expecting to become pregnant within six months following the CK procedure
- With residual, recurrent, or active ocular disease(s) or abnormality except for myopia (or hyperopia or astigmatism) in either eye

- With active or residual disease(s) likely to affect wound healing capability
- With unstable or uncontrolled diabetes
- With pacemakers
- With progressive myopia (or hyperopia)
- With heart disease
- With drug interactions

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions, which might affect your decision to undertake CK surgery, you should discuss them with your physician.

RISKS, COMPLICATIONS, AND SIDE EFFECTS OF CK:

There are risks involved in all surgical procedures. As this is a new procedure the long term risks and results are unknown. However some of the risks with this procedure can be predicted by the nature of the treatment in which there is no removal of tissue and in which the central cornea is avoided.

The individual response to treatment is variable and this may result in under or over correction, and remodeling of the cornea. Time may cause regression. The treatment can be repeated if required. Irregular response to the burns can cause distortion resulting in astigmatism. Damage to the cornea , infection and scarring are theoretical risks.

Pain: Some patients may feel discomfort or pain immediately after surgery. Occasionally, analgesics may be necessary. Pain or tenderness of the eyelids resulting from the instrument used to keep the lids open during surgery may occur. If you have postoperative discomfort or if pain increases or extends beyond 72 hours, you should report this immediately to the medical staff.

Loss of best-corrected vision: This may occur with infections, scarring, or due to poor healing. It may be permanent. The incidence of this happening is less than 1%.

Light Sensitivity: Light sensitivity following CK is quite common. This sensitivity, though mild in degree and usually most intense for the first 48 hours or slightly longer, may necessitate the use of sunglasses.

Blurred Vision: Your vision may be somewhat blurred in the early postoperative period, particularly in the first 48-72 hours, and this may interfere with functions such as driving, working and hobbies. The actual level of vision necessary for people to comfortably function is quite individual and varies with individual healing. Therefore it is impossible to precisely predict when your vision will be good enough for you to feel comfortable.

Tearing: Tearing commonly occurs after CK, but is usually limited to the first 24-48 hours after surgery. In rare cases, tearing may be so profuse as to blur vision and interfere with functions such as driving.

Sedation-related: Many patients feel more comfortable taking a light sedative prior to the LASIK procedure. If you receive sedation you may not feel sufficiently comfortable to drive or operate machinery for 24 hours after surgery.

Under correction and regression: It is not possible to accurately predict how your eyes will respond to the treatment. While our goal is provide you with the vision we demonstrate in the office, you may be left with a residual refractive error (nearsightedness, farsightedness, astigmatism, or some combination). In fact, mild nearsightedness may be preferable because of the “protection” it may offer against the need to wear glasses or contact lenses. Should you desire an enhancement (or “touch up procedure”), this cannot be completed until your vision is stable, a fair amount of healing has occurred, and it is medically safe to proceed. These conditions are typically met 3-6 months after the procedure.

Glare, halos and night vision problems: Mild glare, halos, shadows, or “ghosting images” are not uncommon immediately after surgery. In most patients these will slowly return to normal over time. Driving at night is always more difficult than driving in daylight, and some patient request glasses for night driving. In rare cases, they may be severe and glasses may not improve them.

Infection: Infection is a potential complication following CK surgery. In order to minimize the risk of post-operative infection, it is critical that you use the medications and preservative-free artificial tears precisely as your doctor recommends following your surgery. Should infection occur in the cornea following CK, a potentially lengthy course of treatment may be necessary. This may include invasive laboratory tests, special medications requiring frequent usage, multiple doctor visits, and hospitalization. Infections may result in corneal scarring, perforation, spread of infection to outside the eye, and loss of vision. Since health care workers are thought to be at higher risk for such infections, it is recommended that our patients in the health care field minimize their exposure to potentially infective situations. If you have had infections in the past, please let your doctor know prior to surgery.

Corneal Scarring: By definition, the CK procedure causes small scars were at the site if each burn where the probe contacts for cornea. However, the central axis of the corneal is untouched with this procedure, and scarring should not occur in the center of the visual window. If it occurs due to unforeseen complications, such as infection, there may be a permanent loss in vision. Not complying with the post-operative medication regime increases the risk for scarring.

Ptosis: Droppy of the upper eyelid is a rare occurrence following CK. The cause is not fully understood. Generally, it is mild in degree and resolves spontaneously over the several months.

Cataracts: CK is not related to the development of cataracts but you develop them with age. A cataract is an opacification of the lens within the eye that develops slowly over time. They are commonly found at an early stage in anyone over 50 years of age. Prolonged use of post-operative medications may increase the risk of cataracts.

Specific Occupations: Having refractive surgery, including CK, could conceivably disqualify you from some professions (particularly military) and it is your responsibility to investigate any requirements and/or exclusion criteria for any profession and/or sport/hobby in which you are interested.

Pregnancy: If you are pregnant or breastfeeding, you should not undergo CK. We require three months pass after delivery and/or cessation of breastfeeding prior to surgery. If you are able to become pregnant, you must agree to use birth control for at least one month after surgery, and possibly up to three months, because this is when the majority of healing takes place.

In addition to the above mentioned, it is possible to experience unknown or as yet unreported complications following LASIK, in spite of the fact that we have nearly 50 years experience with lamellar refractive surgery and nearly a decade of experience with excimer refractive surgery. As noted above, complications can occur after LASIK and it is conceivable that, if severe enough, these may cause partial loss of vision or even blindness or may require prolonged treatment and/or further surgery.

EXPECTED BENEFITS TO LASIK

ALTERNATIVES TO CK

CK is an elective procedure. There are alternatives to CK. These include:

- Glasses
- Contact lenses
- Radial keratotomy (RK) – surgical alternative where the surgeon makes cuts on the corneal to change your refractive error
- Laser-Assisted In-situ Keratomileusis (LASIK) – a flap is created, folded back, and the cornea is resurfaced to allow correct focusing of images on the retina. The Flap is then replaced in the original position.
- Photorefractive Keratectomy (PRK) -- surgical alternative where the surgeon gently removes the epithelium of the cornea and uses the excimer laser to resurface the eye.
- Laser Thermal Keratoplasty (LTK) – laser burns are created peripherally to cause a tightening of the cornea and a decrease in hyperopia.

If you have any questions at any time during this process, please feel free to call **651/321-8881** and our technicians and doctors will be happy to assist you.

CONSENT

In signing this consent form for CK, I state that I have read this document completely or that it has been read in full to me, and I that I understand its content and purpose. I understand that no warranty or guarantee is being made to me regarding my outcome, the effectiveness, or the safety of CK. I further state that I have no questions regarding CK and my questions have been answered to my satisfaction.

I hereby give permission for Dr. Ming Wang to perform CK on my eye(s). By signing this form, I have not waived any of my legal rights, which I otherwise would have as a participant in a research study.

To assure that you understand the information presented, please copy the following statement in your own handwriting in the space below: “I understand the information presented and am willing to accept the fact that I may need glasses or contact lenses or further surgery following CK to achieve my best possible level of vision.”

Uncommonly, a patient might experience a corneal complication, such as severe infection, corneal scarring, or other problems that would require consultation and treatment to another specialist. If this situation arises, I understand that I am financially responsible for those consultations and treatments. I understand that prescription eye drops and oral medications, along with post-operative optical appliances such as contact lenses and glasses are also my financial responsibility.

I am making an informed decision in giving my permission to have CK performed on:
(please circle your choice) Both eyes Right eye Left eye

I understand that I may receive a copy of this consent for if I request it.

Patient's signature

Date

Witness's signature

Date

Doctor's signature

Date