



Affiliated with Tufts University School of Medicine

INFORMED CONSENT

INFORMED CONSENT FOR CONDUCTIVE KERATOPLASTYSM (CKSM)

Please read the following consent form very carefully. Please initial each page where indicated. Do not sign this form unless you have read and understood each page.

Introduction

This information is being provided to you so that you can make an informed decision about the use of a device known as the ViewPoint™ CK System, which is utilized to perform CK. CK is one of a number of alternatives for correcting your vision. The CK procedure uses 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 an increased curvature of the cornea to treat your vision. The correction you achieve with CK may be temporary.

CK is an elective procedure. There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there might be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse.

Alternatives to CK

If you decide not to have CK, there are other methods of correcting your vision. These alternatives include, among others, eyeglasses, contact lenses, and other refractive surgical procedures.

Patient Consent

In giving my permission for CK, I understand the following: the long-term risks and effects of CK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

Vision Threatening Complications

I understand that it is possible that scarring, ulceration, or an eye infection that could not be controlled with antibiotics or other means could also cause damage to my cornea. I understand CK may induce astigmatism, which may lead to decreased vision.

Non-Vision Threatening Side Effects

1. I understand that visual acuity I initially gain from CK could regress, and that my vision could go partially or completely back to the level it was immediately prior to having the procedure.
2. I understand that I may not get a full correction from CK and that it may require future enhancement procedures or the use of glasses or contact lenses. This procedure may also cause an increase in my astigmatism, which may cause blurred vision.
3. I understand that an overcorrection could occur, causing me to become nearsighted, and that his nearsightedness could be either permanent or treatable.
4. I understand that the correction that I can expect to gain from CK may not be perfect and it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life.

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5. I understand I may need glasses to refine my vision for some purpose requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
6. I understand that there may be pain, scratchiness, a foreign body sensation, or slight dryness in my eye, particularly during the first 48 hours after surgery.
7. I understand that there may be increased sensitivity to light. I understand this condition usually resolves within the first few weeks following treatment, but it also may be permanent.
8. I understand that there may be a “balance” problem between my two eyes after CK has been performed on one eye, but not the other. This phenomenon is called anisometropia. If having both eyes done, I understand that my first eye may take longer to heal than is usual; prolonging the time I could experience anisometropia.
9. I understand I may temporarily experience corneal haze, small round hazy areas where the cornea was heated during the CK treatment. This haze will usually fade over time and may only be visible with a microscope within 3 months following surgery.
10. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable unless it is unwise or unsafe. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
11. I understand that there is a natural tendency for the eyelids to droop with age and that eye surgery may hasten this process.
12. I understand that I may be given medication in conjunction with the procedure. I understand that I must not drive for at least one day following the procedure and on until I am certain that my vision is adequate for driving.
13. I understand that the follow-up effects of CK are unknown, and that CK has not been in use long enough to measure long-term effects (those occurring after 10 years or more) following the procedures, and that unforeseen complications or side effects could occur.
14. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of surgery, the list of complications in this form may not be complete.

Patient Statement of Acceptance and Understanding

I have read and understand the information that has been provided to me. The details of the procedure known as CK have been presented to me in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I therefore consent to CK surgery.

I give permission to my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research or training of other healthcare professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand CK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist’s office or the center where my CK procedure will be performed.

Patient Signature

Date

Surgeon Signature

Date

Witness Signature

Date

I have been offered a copy of this consent form (please initial) _____

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