

INFORMED CONSENT FOR NEARVISIONSM CK[®] (CONDUCTIVE KERATOPLASTY[®])

Introduction

Vision-correcting surgery such as Conductive Keratoplasty, LASIK and PRK can precisely and accurately correct fixed focal errors of the eye such as farsightedness, nearsightedness, and astigmatism. These optical conditions are fundamentally different than presbyopia, the loss of adjustability of focus for near viewing. Presbyopia is the reason that reading glasses become necessary, typically in the age range of mid-40, even for people who have excellent unaided distance vision. For those that require prescriptive correction to see clearly at distance, bifocals or separate (different prescription) reading glasses become necessary at that age to see clearly at close range.

This information is being provided to you so that you can make an informed decision about the use of a device known as the ViewPointTM CK System, which is utilized to perform the NearVision CK procedure. NearVision CK is one of a number of alternatives for correcting your vision. The NearVision 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 24 times, depending on the desired correction, 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 NearVision CK may be temporary.

NearVision 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 NearVision CK

There are several options available to those who are presbyopic, besides wearing bifocals or separate reading glasses. For example, for some individuals, wearing a contact lens in one eye for distance vision, and a contact lens in the other eye for reading, affords a reasonable solution. This is called monovision (mono for one; one eye for distance, one eye for near vision).

If a person enjoys and functions well with monovision in contact lenses, the same option can be created on a more permanent basis with a vision-correcting procedure such as NearVision CK. If you are contemplating such correction for yourself, it is important to understand the advantages and drawbacks of such care.

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

Patient Initials _____

Patient Consent

At this time, there is no perfect treatment or cure for presbyopia. The typical solutions described above are all, to some extent, a compromise of one form or another. For many people, wearing reading glasses for near vision correction is troublesome enough, and wearing bifocals is even less pleasant.

In giving my permission for NearVision CK, I understand the following: the long-term risks and effects of NearVision 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.

Non-vision Threatening Side Effects

- 1) I understand that I may experience a reduction in my depth perception. For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for near and distance. Eye care professionals refer to this as binocular vision. Monovision can impair depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is important that you complete a successful demonstration trial of monovision or have a history of monovision wear using glasses or contact lens prior to contemplating a surgical correction.
- 2) I understand that ocular dominance and choosing the 'near' eye correctly is important when considering monovision. Tests can be performed to determine which eye, right or left, is dominant, or preferred eye for viewing, in a particular person. Conventional wisdom holds that if contemplating monovision, the non-dominant eye corrected for near, and the dominant eye should be maintained or corrected for distance. While this is a guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant (similar to being ambidextrous), and in rare circumstances a person may actually prefer using the dominant eye for near viewing. The methods for testing and determining ocular dominance are not always 100% accurate; there is some subjective component in the measurement process; and different eye doctors may use slightly different methods of testing. It is critical to determine through use of glasses or contact lenses which combination is best for each person prior to undertaking any surgical intervention. I understand this and have discussed with my surgeon which eye should be corrected for near, and if applicable, which eye for distance. If I have any doubts or uncertainty, I understand surgery should be delayed until a solid comfort level is attained through use of monovision contact lenses. Under no circumstances will I consider undertaking monovision surgical correction before I am convinced it will be right for me. I understand that once surgery is performed, it is not always possible to undo what is done, or to reverse the near and distance eye without some loss of visual quality.

Patient Initials _____

- 3) I understand that visual acuity I initially gain from NearVision CK could regress, and that my vision could go partially or completely back to the level it was immediately prior to having the procedure.
- 4) I understand that I may not get a full correction from NearVision CK and that I 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.
- 5) I understand that an overcorrection could occur, causing me to become nearsighted, and that this nearsightedness could be either permanent or treatable.
- 6) I understand that the correction that I can expect to gain from NearVision 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. 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.
- 7) 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.
- 8) I understand that there may be increased sensitivity to light, and that I may experience glare and halos around lights. I understand this condition usually resolves within the first few weeks following treatment, but it also may be permanent.
- 9) I understand that there may be a "balance" problem between my two eyes after NearVision CK has been performed on one eye, but not the other. This phenomenon is called "anisometropia." I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.
- 10) I understand I may temporarily experience corneal haze, small round hazy areas where the cornea was heated during the NearVision CK treatment. This haze will usually fade over time and may only be visible with a microscope within 3 months following surgery.
- 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 until I am certain that my vision is adequate for driving.
- 13) I understand that the follow-up effects of NearVision CK are unknown, and that NearVision 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 NearVision CK will not prevent me from developing naturally occurring eye problems, such as glaucoma, cataracts, retinal degeneration or retinal detachment.
- 15) 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 Initials _____

Patient Statement of Acceptance and Understanding

I have read and understand the information in the Patient Information booklet that has been provided to me. I understand there is also a 40 page comprehensive FDA regulatory document that is also available to me for review if I so choose to request it. The details of the procedure known as NearVision CK have been presented and explained to me in this document. My ophthalmologist has further reviewed and answered all my questions to my satisfaction. I therefore consent to NearVision CK surgery.

I understand that my surgeon may elect to use a spot pattern that is different from that approved by the FDA in order to meet specific refractive results he/she feels is best for me. I further understand that this is off-label use and agree to allow my surgeon to make this decision as necessary.

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 NearVision 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 NearVision CK procedure will be performed.

Patient Name

Date

Patient Signature

Date

Witness signature

Date

Ming Chen MD Physician Signature

Date

I Consent to having my _____ eye correct for Near vision.

I have been offered a copy of this consent form, Pre- & Post surgery instruction. Please initial _____.