

## **HOLZMAN LASER VISION INFORMED CONSENT**

### **PHOTOREFRACTIVE KERATECTOMY (PRK)**

This information must be reviewed so you can make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce or eliminate your nearsightedness, farsightedness or astigmatism. Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to your doctor.

**IN GIVING MY PERMISSION FOR PRK SURGERY, I DECLARE THAT I UNDERSTAND THE FOLLOWING INFORMATION:**

The long-term risks and effects of PRK surgery are unknown. The goal of PRK with the excimer laser is to reduce or eliminate the dependence upon or need for contact lenses and/or eyeglasses; however, I understand that as with all forms of treatment, the results in my case cannot be guaranteed. For example:

1. There is no guarantee that I will completely eliminate my reliance on eyeglasses and/or contact lenses. It is possible that the treatment could result in under correction or overcorrection, requiring the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age. The treatment may also result in a change in my astigmatism that could require the use of glasses and/or contact lenses. I understand further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional surgery.
2. If I currently need bifocals, reading glasses over my contacts or I have to remove my glasses to read, I will likely need reading glasses immediately after this treatment. These are typically simple over the counter readers. If I am under 40 and have no trouble reading through my distance vision glasses or contact lenses currently, I understand that at some point I will need near vision glasses typically after the age of 40 when Presbyopia begins. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have PRK surgery.
3. Further treatment may be necessary, including a variety of eyedrops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK or other refractive surgery.
4. My best vision even with glasses or contacts, may become worse. There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.

## **ALTERNATIVES TO PRK SURGERY**

The alternatives to PRK include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK has been explained to me.

## **COMPLICATIONS AND SIDE EFFECTS**

I have been informed, and I understand, that certain complications and side effects have been reported in the post-treatment period by patients who have had PRK, including the following:

### **Possible Short-Term Effects of PRK Surgery**

The following have been reported in the short-term post treatment period and are associated with the normal post-treatment healing process: Mild discomfort or pain (first 72 to 96 hours); Corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity, and tearing.

**(Please initial after reading \_\_\_\_\_)**

### **Possible Long-Term Complications of PRK Surgery**

1. Haze: Loss of perfect clarity of the cornea, usually not affecting vision. which usually resolves over time.
2. Starbursting: After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties the risk may be increased in patients with very large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular exam data have been discussed with me.
3. Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
4. IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.
5. Mild or severe infection: Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation.
6. Keratoconus: Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While

there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal trans plant while mild keratoconus can be corrected by glasses or contact lenses.

**(Please initial after reading \_\_\_\_\_)**

### **Infrequent Complications of PRK Surgery**

The following complications have been reported infrequently by those who have had PRK surgery: Itching; Dryness of the eye, or foreign body feeling in the eye; Double or ghost images; Patient discomfort; Inflammation of the cornea or iris; Persistent corneal surface defect; Persistent corneal scarring severe enough to affect vision; Ulceration/infection; Irregular astigmatism (warped corneal surface which causes distorted images); Cataract; Drooping of the eyelid; Loss of bandage contact lens with increased pain (usually corrected by replacing with another contact lens); and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

**(Please initial after reading \_\_\_\_\_)**

I understand that there is a remote chance of partial or complete loss of vision in the eye that has had PRK surgery.

I understand that it is not possible to state every complication that may occur as a result of PRK surgery. I also understand that complications or a poor outcome may manifest weeks, months. or even years after PRK surgery.

I understand that this is an elective procedure and that PRK surgery is not reversible.

FOR WOMEN ONLY: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result.

**(Please initial after reading \_\_\_\_\_)**

**VARIANT TOPOGRAPHY.** Corneal Topography is a diagnostic testing technique that can be used to find irregularities in the shape of the cornea prior to surgery. If the testing shows that your corneal shape is atypical, you may be in a higher risk category for development of

keratectasia in the future if you undergo laser vision correction surgery. Keratectasia is a condition characterized by irregular thinning and weakening of the cornea that can lead to progressive changes in the refractive error. It may result in loss of uncorrected and best corrected vision. The progressive change which occurs is similar to that in a disease called Keratoconus. This condition occurs naturally in those with Keratoconus, but in keratectasia, individuals who are susceptible develop it after laser vision correction surgery. Mild topographic changes are very common in the normal population, and there may or may not be an increased risk of developing keratectasia. The risk of keratectasia in an eye with variant topography is higher with certain surgeries where laser treatment is applied deeper in the cornea under a flap, as compared to surface ablation treatment (which is used in PRK). While severe ectasia may need to be treated with a corneal transplant or corneal collagen cross-linking, mild keratectasia can frequently be corrected with the use of glasses or contact lenses.

**(Please initial after reading \_\_\_\_\_)**

**MONOVISION.** This is an option for patients age 40 and older who have difficulty reading due to the natural aging process. Monovision is a technique in which one eye (typically the dominant eye) is corrected for distance and the other eye is corrected for near or intermediate vision. Monovision provides a viable option for active people who require both distance and near vision in their daily activities. Because monovision is a compromise, reading glasses may still be needed for fine print and distance vision may not be as crisp for night driving and certain sporting activities such as golf and tennis. Depth perception may also be affected. You may be asked to trial monovision prior to surgery with contact lenses if you are considering this option. Keep in mind that near vision always worsens with age, and despite having a monovision technique done, your near vision will still weaken with time.

**CO-MANAGEMENT.** You have the right to choose to have your personal eye care provider (ECP) involved in your pre and/or post-operative care. We call this collaboration between your ECP and your surgeon “co-management”. If your care is co-managed, your surgeon will perform the surgery and also be available to you and your ECP for any pre and/or post-operative issues. If you decide to have your care co-managed, a portion of the fee you pay to Holzman Laser Vision may be distributed to your ECP for providing this care.

**Please indicate your choice to treatment today:**

**Right Eye** \_\_\_\_\_ **Patient Initials** \_\_\_\_\_

**Left Eye** \_\_\_\_\_ **Patient Initials** \_\_\_\_\_

**Both Eyes** \_\_\_\_\_ **Patient Initials** \_\_\_\_\_

\_\_\_\_\_ I choose Monovision as my treatment choice      Patient's Initials: \_\_\_\_\_

I choose to have my \_\_\_\_\_ eye targeted for near vision      Patient's Initials: \_\_\_\_\_

**STATEMENT OF CONFIDENTIALITY**

All information in my patient records will be kept in confidence but my examination data may be maintained in a central database for future evaluation of the PRK treatment. While my specific treatment data will be kept confidential, generic compilation of data possibly including (without identification) my results may be utilized in advising future patients of the safety and efficacy of the treatment. However, no specific patient data relating to my treatment will be released except as required by law.

(Please initial after reading \_\_\_\_\_)

**STATEMENT OF VOLUNTARY PARTICIPATION**

In signing this Informed Consent Form for the use of the excimer laser for performing Photorefractive Keratectomy, I am stating that I have read this Informed Consent (or it has been read to me) and I fully understand it and the possible risks, complications and benefits that can result from the treatment. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all my questions to my satisfaction.

**I understand that if I have any questions with respect to the treatment I can call:**

**# 855-995-2745**

(Please initial after reading \_\_\_\_\_)

**By signing below, I agree that:**

- **The Photorefractive Keratectomy procedure has been explained to me in terms that I understand**
- **I have had the opportunity to have my questions answered.**
- **I fully understand the possible risks, complications and benefits that can result from the treatment**
- **I am competent in clear mind and have fully read the informed consent form**
- **I agree to return for follow up visits and follow all post-operative instructions**
- **I am responsible for the cost of any medications, contact lenses, eyeglasses or other ophthalmic devices, if required, after vision correction surgery. I am also responsible for the cost of post-op visits which occur after the time period set forth in my patient agreement.**
- **I understand that vision correction surgery will not prevent naturally occurring eye**

- problems such as glaucoma, cataracts, retinal degeneration or retinal detachment.

I understand that I am responsible for fees associated with any eye problems that may occur in the future including but not limited to, glaucoma, pink eye, allergies, dry eyes, injury to my eyes or cataract formation.

My decision to undergo the PRK procedure has been my own and has been made without duress of any kind.

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**PATIENT NAME (Type or Print)**

**DATE**

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**PATIENT'S SIGNATURE**

**DATE**

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**PHYSICIAN'S SIGNATURE**

**DATE**

**PATIENT CONSENT TO CO-MANAGEMENT (IF APPLICABLE)**

I desire to have my eye care provider (ECP) perform my pre and/or post-operative care associated with my vision correction procedure. I understand that my ECP and my surgeon may communicate with one another regarding my post-operative care and that my ECP will promptly contact my surgeon and plan for the transfer of care should I experience any complications related to my vision correction procedure. I also understand that I may contact or be seen by my surgeon at any time during the post-operative period should I so desire.

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**PATIENT'S SIGNATURE**

**DATE**

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**PHYSICIAN'S SIGNATURE**

**DATE**