

# Informed Consent for Excimer Laser Surface Ablation Surgery

(PRK, LASEK, epi-LASIK, and others)

Patient name (printed): \_\_\_\_\_

Patient date of birth: \_\_\_\_\_

Please review this information so you can make an informed decision about whether or not to have excimer laser surface ablation surgery. Because this surgery is elective, and because alternatives to the surgery exist, we want you to make an informed decision about whether this surgery is appropriate for you. By signing below, you agree that you understand the risks, potential benefits, and alternatives of the surgery, that all of your questions have been satisfactorily answered, and that you allow your surgeon to perform the surgery.

## **NATURE OF THE PROCEDURE**

Excimer laser surface ablation uses a sophisticated ultraviolet laser to reshape the clear dome covering the front of the eye (the "cornea") to improve the eye's optical properties. Prior to the laser being used, the eye is anesthetized with eye drops, so that you do not feel pain or discomfort during the procedure. An eyelid holder keeps your eye open so you do not blink during application of the laser. Your surgeon removes the surface layer of cells covering the eye (the "epithelium") to expose the structural part of the cornea (the "stroma"). The laser then reshapes the stroma according to a computer algorithm programmed into it by the laser's manufacturer, and data given to it by your surgeon. At the conclusion of the procedure, there may be some additional maneuvers, such as placement of eye drops, application of cooling devices and fluids, and placement of a contact lens.

Following the procedure, you can expect your eyes to be red, and to feel irritated. In most cases your eyes will not be painful, although this can occur. Your vision will be worse than before the procedure, until the epithelium regrows over the surface of the eye. This usually takes between three and seven days. During this time, you will have significant blurriness in your vision, and you will probably find it difficult to perform many of your daily activities. You may not be able to drive safely for some of this initial recovery period. You will need to use frequent medications, including eye drops and pills. You may not be able to work until the blurriness resolves. After the first week, vision without glasses is usually reasonably good, and continues to improve over the first month or so.

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The long term effects of surface ablation are generally stable, with most patients retaining their post-operative focus indefinitely. This is the typical course following surface ablation surgery, but your recovery may differ significantly from this.

## **OPTION TO HAVE SURGERY ON ONE EYE AT A TIME**

Some patients choose to have one eye corrected at a time. By doing this, the other eye retains its usual vision during the recovery period. Having the surgery on one eye at a time makes it easier to function (work, drive, carry out daily activities), than if both eyes have the surgery on the same day. The disadvantage of this is that you have to have surgery on two separate days, and are using drops and other medications for a longer period of time. In the interval between surgeries, there may also be a significant difference in the vision between the eyes, which can make some patients feel unbalanced or otherwise uncomfortable.

Most patients choose to have the surgery on both eyes on the same day. This minimizes the number of post-operative visits, limits the amount of time using medications, and is more convenient for many patients. The disadvantage of this approach is that your vision after the surgery may be poor for some of the recovery period, and it may be difficult to function.

Whether to have excimer laser surface ablation on one or both eyes at a time is a personal one. Before signing below, ensure you are comfortable with your decision.

## **POTENTIAL BENEFITS OF THE PROCEDURE**

Although the results of excimer laser surface ablation can not be guaranteed, the procedure has the potential benefit of reducing or eliminating your dependence on glasses or contact lenses. Most patients who have had the procedure can drive without glasses or contacts, and wake up in the morning with clear vision. They may also save money in the long term, because they no longer need to purchase glasses and contact lenses.

## **WILL I BE 20/20?**

The goal of surface ablation is to reduce or eliminate your dependence on glasses and contact lenses, and to make you happy with your unaided vision afterwards. You may be 20/20, better than 20/20, or worse than 20/20. Because of variations in healing, and the natural unpredictability inherent in any surgical procedure, there is no guarantee of 20/20 vision.

## **NEED FOR READING GLASSES AFTER SURFACE ABLATION IN PATIENTS OVER FORTY**

The eye works much like a camera. If a camera is focused at a far distance, images up close will appear to be blurry through the viewfinder, unless the camera lens is turned to change its focal power. Similarly, if the eye is focused at distance (with contact lenses, laser surgery, or glasses), it will need to change its focal power to see clearly at near. It does this by changing the shape and position of the natural lens (the one that you're born with) inside the eye. When the eye is under about forty years old, it does this automatically, so that if the eye is focused at distance, it will be able to focus on near objects too.

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Over time, the natural lens inside the eye becomes stiffer, and less able to change the focal power of the eye. After about the age of forty, the eye becomes more like a fixed focus camera, so that if it is focused at distance, it will have trouble seeing clearly up close. Patients over the age of forty will therefore need reading glasses to see at near if their surface ablation surgery corrects their distance vision in both eyes.

## **MONOVISION OPTION**

Some patients elect to have one eye corrected with surface ablation to see at distance, and the other eye corrected to see at near. This allows them to be more independent of glasses when they are over forty years of age. With this "monovision" option, one eye sees distant objects clearly, and near objects are blurry. The other eye sees near objects clearly, and distant objects are blurry. Used together, clear vision is possible at all distances.

Many patients feel that monovision would make them feel unbalanced, and that they would have trouble adapting. These patients choose to have both eyes corrected for distance, and to wear reading glasses for near vision when they are over forty years old. Adaptation to monovision depends heavily on the patient's personality and goals. Some patients love it, and others have great difficulty adapting. If monovision is something you wish to consider, you must discuss this option with your surgeon prior to the surgery.

## **ALTERNATIVES TO SURFACE ABLATION SURGERY**

The alternatives to this procedure include, among others, glasses, contact lenses, and other refractive surgical procedures. LASIK is an alternative laser vision correction procedure. LASIK has a generally shorter recovery time than surface ablation, but may not be appropriate for all patients. Other procedures exist, including implantation of lenses inside the eye. You should discuss these options with your surgeon prior to undertaking excimer laser surface ablation to ensure you choose the best one for you.

## **RISKS OF THE SURGERY**

Although the vast majority of laser vision correction patients do very well, it is important to realize that like all medical and surgical activities, there are risks. Just as in driving an automobile, most people have no problems. In rare cases, however, disasters can occur. While the risk of major morbidity is worse with driving than with this procedure, it is important that you understand the risks of excimer laser surface ablation prior to surgery:

1. Under- and over-correction of optical errors. Although the laser is usually quite precise and predictable, under- and over-correction of optical errors in the eye are possible. This could result in blurred vision, and require the use of glasses or contact lenses to see well after the surgery. These errors are usually treatable with a second laser surgery, but not always.
2. Loss of best corrected vision. Your vision after the surgery may not be as sharp as it was before the surgery, even with the best glasses or contact lenses.

Please initial: \_\_\_\_\_

3. Glare, halos, and other optical distortions. It is possible to have glare (starbursts around lights) or halos (rings around lights), or other distortions, such as ghost or double images. If present, these are usually most noticeable at night. They may affect the quality of your vision, annoy you, and even interfere with your visual function, such as making night driving difficult. They often resolve with time, but not always.
4. Dryness or chronic irritation. Long-term irritation is rare, but short-term irritation (especially in the first week after surgery) is common. Artificial tears to lubricate the eye (s) or other treatments may be necessary to improve this.
5. Haze and scarring on the surface of the eye. Haze and scarring can develop on the surface of the eye after the surgery. Medications used during and after the surgery help to prevent this. If haze or scarring occurs, it is usually not visually significant, and usually disappears with time. In the rare cases where it is severe, it can cause decreased vision, and can require secondary procedures or medications to improve.
6. Elevation of pressure inside the eye(s). High pressure after surface ablation, if it occurs, generally results from a side effect of steroid eye drops. It is usually treatable with medications to reduce eye pressure, but if it is persistent and severe, it could permanently damage vision ("glaucoma"). In severe cases, secondary surgical procedures may be needed to control eye pressure.
7. Human errors. As with any human activity, human errors are possible. Wrong data entry into the laser, operating on the wrong eye, and other errors are reported complications of this procedure. Although we make strenuous efforts to avoid human error, they are still possible and could cause problems with your vision or ocular health.
8. Infection. Antibiotic eye drops are used after surface ablation surgeries, but infection on the surface of the eye is still possible. In most cases an infection is treatable, with no permanent effect on vision. If the infection were severe, however, it could cause permanent loss of sight, or even loss of the eye.
9. Stretching of the cornea ("keratoconus" or "ectasia"). For reasons that are largely unknown, rare cases of stretching of the cornea occur after excimer laser surgeries. This can cause a loss of uncorrected and best-corrected vision, and may require glasses or contact lenses to restore vision. In severe cases, corneal transplantation may be required to improve the situation.
10. Allergic reactions. Medications or surgical supplies could cause allergic reactions. Although rare, severe allergic reactions can be life-threatening.
11. Failure to heal. Success of the surface ablation procedure depends on the ability of your eye to heal. Persistent defects in the surface layer of cells on the eye can prevent the full recovery of vision, and may require additional medical and surgical treatments.
12. Irregular astigmatism. For a variety of reasons, including decentration of the laser, irregular healing, infection, or cells under the flap, the surface of the eye could become irregular. This could cause visual distortions or loss of vision, and may or may not be correctable.

Please initial: \_\_\_\_\_

13. Optical drift. The results of surface ablation are usually very stable, but your eye's optics may experience a natural drift over time, or the optics may change because of disease conditions, such as cataract formation. This may cause you to need glasses or contact lenses again.

14. Strabismus. In a few susceptible patients, usually with pre-existing conditions, surface ablation could create or exacerbate problems with eye alignment. This could cause deviating eyes and double vision, and necessitate secondary procedures to re-align the eyes.

15. Other complications. The above list of risks is not exhaustive. It is not possible to state all the possible risks associated with any surgery. Other problems may occur. Because excimer laser surgeries have been performed for a limited period of time, the long-term risks are not known. Complications or a poor outcome may occur weeks, months, or even years after the surgery.

## **USE OF MITOMYCIN-C TO PREVENT HAZE**

Depending on certain surgical factors, your surgeon may decide to use mitomycin-C during your surgery. Mitomycin-C is a medication that prevents scarring (haze) on the surface of the eye after application of the laser. It is a medicine that in the past has been used for cancer chemotherapy and certain kinds of eye surgery. In higher concentrations than is used for surface ablation surgeries, its use has sometimes resulted in serious side effects. These have included glaucoma (high pressure in the eye causing visual loss), thinning or swelling of the cornea (the clear dome over the front of the eye) or the sclera (the white part of the eye), cataract formation ( haziness developing in the natural lens in the eye), blockages of blood vessels in the eye (causing loss of vision), irritation, redness, sensitivity to light, pain, and other serious problems. In the low concentrations used for excimer laser surface ablation, however, these side effects have generally not been seen, and the use of mitomycin-C has generally been a safe and effective way to prevent haze formation.

As with the use of many medications in ophthalmology, use of mitomycin-C for excimer laser surface ablation is considered an "off label" use. This means that the medication is used for a purpose for which it was not originally approved by the U.S. Food and Drug Administration. Your physician uses mitomycin-C based on scientific and medical evidence of safety and efficacy of the medication in this role, and on a consideration of the risks, potential benefits and alternatives of its use.

## **PUBLICATION OF INFORMATION**

Your physician may use data, video or photographic images, or other information related to your surgery for research, publication, presentations, or other professional medical activities. Your information would be used in accordance with professional ethical standards, and would not identify you personally.

Please initial: \_\_\_\_\_

## CERTIFICATION

By signing below, you certify that you have actually read the information above and that you have discussed excimer laser surface ablation with your surgeon. You certify that you understand the risks, potential benefits, and alternatives of the procedure, have had your questions answered, and would like to proceed with the surgery on your:**(circle one)**:

LEFT EYE

BOTH EYES

RIGHT EYE

## MONOVISION OPTION

Some patients elect to have one eye corrected for distance, and one eye corrected for near to reduce the need for reading glasses when they are forty years or older. **Please circle your preference regarding this option:**

•I DO NOT elect monovision, and prefer to see distance clearly with both eyes. I will need reading glasses for near work when I am over the age of forty.

•I DO elect monovision. I prefer that the eye I use as my DISTANCE/FAR VISION eye is my:

•RIGHT EYE

•LEFT EYE

Patient name and signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness name and signature: \_\_\_\_\_ Date: \_\_\_\_\_