

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK) AND ADVANCE SURFACE ABLATION (ASA)

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

ALTERNATIVES TO PRK OR ASA SURGERY:

The alternatives to PRK or ASA include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK or ASA 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 or ASA, including the following:

- **Possible short-term effects of PRK or ASA 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.
- **Possible long-term complications of PRK or ASA surgery:**
 - Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
 - 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 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 pupil size and amount of correction have been discussed with me.
 - Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
 - 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.

I have read and understood this page. Patient Initials _____

- 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.
- 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 transplant while mild keratoconus can be corrected by glasses or contact lenses.
- **Infrequent complications.** The following complications have been reported infrequently by those who have had PRK or ASA 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.

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

The long-term risks and effects of PRK or ASA surgery are unknown. The goal of PRK or ASA with the excimer laser is to reduce 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. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
2. If I currently need reading glasses, I will likely still need reading glasses after this treatment. 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 or ASA surgery.
3. Further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK or ASA or other refractive surgery.
4. My best vision, even with glasses or contacts, may become worse.
5. 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.

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

I have read and understood this page. Patient Initials _____

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

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

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

I understand my postoperative care will be comanaged by an optometrist(s) for more convenience, flexible appointment times, and less wait time. The optometrist will contact your surgeon immediately if you should experience any complication. You may contact your surgeon at any time after your surgery.

I understand the Advanced Surface Ablation is a type of PRK in which treatment is customized according to wavefront data of my eyes. Furthermore, I understand that this is off label. I have spoken with my physician, who has explained PRK or ASA, its risks and alternatives, and answered my questions about PRK or ASA surgery. I therefore consent to having PRK or ASA surgery on:

_____ **Right eye** _____ **Left eye** _____ **Both eyes**

Furthermore, monovision has been discussed with me, and I elect

_____ **No monovision** _____ **Monovision with left eye for near** _____ **Monovision with right eye for near**

Patient signature

Date

Witness signature

Date

I have been offered a copy of this consent form_____

I have been informed that an annual comprehensive eye exam is important to protect my vision and my eyes as well as to maintain my limited lifetime warranty. My package includes postoperative visits related to my surgery for one year, but this does not include comprehensive eye exams completed at any time EVEN DURING THE FIRST YEAR. (initial here _____)

ADDENDUM MITOMYCIN-C (MMC) WITH REFRACTIVE SURGERY

INDICATIONS AND ALTERNATIVES

The correction of high degrees of nearsightedness (or myopia) using the excimer laser is associated with a higher chance of developing corneal scarring or “haze.” This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK or ASA), Laser-Assisted Subepithelial Keratomileusis (LASEK), and Advanced Surface Ablation (ASA) have been associated with corneal haze in some individuals.

Since 1997, a medication called Mitomycin-C (MMC) has been used to treat patients who develop corneal haze. Several studies have shown that the use of MMC decreases the likelihood of developing haze after PRK or ASA, LASEK, and ASA. For this reason, ophthalmologists are also using MMC prophylactically, as a preventive measure.

MMC is an antitumor antibiotic that has been used in the medical field for a number of decades. It is used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells, such as those seen in tumors. It also stops cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980’s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgery. The use of MMC for the treatment and prevention of corneal haze is a newer use of this medication.

COMPLICATIONS

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

Although the complications listed above have been seen in various types of eye surgeries, **no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery.** This techniques uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for one to two minutes. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

I have read and understood this page. Patient Initials _____



Monday, February 05, 2018
«LastName», «FirstName»
Date of Birth: «DOB»

Patients who received preventive MMC treatments have shown improvement in visual acuity and a decrease in corneal haze. No corneal haze developed during an average follow-up period of one year. However, there is no guarantee that you will obtain a similar result. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

My surgeon has indicated to me that I either have corneal haze, or that I may be more likely to develop corneal haze following PRK or ASA, LASEK, or ASA. I have read and understood the information presented above about the risks, benefits, and alternatives to using MMC for both treatment and prevention of corneal haze. I have had the opportunity to ask questions and have them answered to my satisfaction.

I understand that administering MMC for treatment and prevention of corneal haze is considered an “off-label” use of an FDA-approved medication. When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a “label” to explain its use. Once a medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

I understand that there are no guarantees as to the success of the procedure for removing or preventing haze and that toxic side effects may develop.

I give my informed consent to my surgeon (indicated below) and/or his or her assistants to use MMC on my _____ eye (patient should write in right, left, or both).

Patient signature

Date

Witness signature

Date

ADDENDUM: CONSENT FOR BILATERAL SIMULTANEOUS PRK

While many patients choose to have both eyes treated at the same surgical setting, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. **If you elect to have PRK surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.**

Safety: The risk of infection and other healing complications is applicable to both eyes simultaneously. Therefore, if an infection occurs in one eye, it may also occur in the other eye. Although rare, a serious infection in both eyes can cause significant loss of vision and even legal blindness. By choosing to have PRK performed on separate days, you will avoid the risk of having one or more of these complications in both eyes at the same time.

Accuracy: If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye if necessary. In some patients, this may improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Visual Recovery: Some patients may experience symptoms such as blurred vision, night glare or ghost images that may delay recovery of normal vision. Blurred vision may continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with your fellow eye while the first eye is healing. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes may be restored more rapidly if they are operated on the same day.

Satisfaction: Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated.

By having each eye treated on separate dates, you will have the opportunity to determine whether the PRK procedure has produced satisfactory visual results without loss of vision or other undesirable side effects. If you are over age 40, you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

I have read and understood this page. Patient Initials _____

Convenience: It may be inconvenient for you to have each eye treated at separate visits because it would necessitate two periods of recovery from the laser surgery and might require additional time away from work.

Cost: Professional and facility fees may be greater if the eyes are operated on different days, and the additional time off work can be costly.

Consent Statement:

“I have read and understand the above risks and benefits of bilateral simultaneous PRK, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous PRK. My doctor has answered all of my questions about the PRK procedure. I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.

Patient signature

Date

Witness signature

Date

PRK/ASA “Limited Lifetime Warranty” by Sugarland Eye & Laser Center

Sugarland Eye & Laser Center is pleased to present a “Limited Lifetime Warranty” for our PRK/ASA patients. Beneficiaries of this warranty are entitled to LASIK enhancements at a reduced fee should certain vision problems persist following the procedure or re-develop after the procedure. Enhancements are sometimes needed due an every individual’s unique response to laser treatments. For 12 months following your treatment, eligible enhancements shall be completed at no cost to the patients. After one year, enhancements will be completed at 25% off our non-discounted full charges at the time of enhancement. Sugarland Eye & Laser Center reserves the right to adjust this rate reduction at any time.

Eligibility:

Patients must have been completed by Sugarland Eye & Laser Center. Myopic, astigmatic, and hyperopic treatments cannot exceed -8.00 D, 3 D, and +3 D respectively. The patient’s best-uncorrected vision must be 20/40 or worse at least 3 months after treatment. The patient must be fully compliant with the post-operative treatment, including follow-up visits, as prescribed by your Sugarland Eye & Laser Center physician. Additionally, the patient must have annual (one exam within a twelve month period) comprehensive eye exams with the Sugarland Eye & Laser Center following laser treatment. Annual exams following laser vision correction will be the financial responsibility of the patient. Eligibility is contingent on the Sugarland Eye & Laser Center physician agreeing that an enhancement is medically safe, appropriate and has a high probability of correcting the patient’s vision to at least 20/40.

Exclusions:

- Patients who fall outside of treatment limitations specified above.
- Patients who are noncompliant in any way with the course of treatment and/or follow-up prescribed by the Sugarland Eye & Laser Center physician, including the annual comprehensive eye exams as explained above.
- Patients whose affected vision is the result of trauma to the eye(s), irregular astigmatism, drug-induced myopia, uncontrolled blood glucose levels, pregnancy, or nursing.
- Patients with diabetes, autoimmune or collagen vascular disorders, corneal dystrophies.
- Patients whose cornea is too thin for successful retreatment.
- Patients who, before or after their laser vision correction with Sugarland Eye & Laser Center, had any eye surgery performed at a site other than Sugarland Eye & Laser Center.
- Patients with any ocular disease that would compromise a successful retreatment.
- Patients seeking an enhancement as a result of presbyopia.
- Patients whose prescription, in the opinion of the Sugarland Eye & Laser Center doctor, represents an unacceptable risk in performing an enhancement procedure.

Questions regarding this “Limited Lifetime Warranty” should be directed to the Sugarland Eye & Laser Center laser vision correction counselor at (281) 240 – 0478.

_____ **I have been informed that an annual comprehensive eye exam is important to protect my vision and my eyes as well as to maintain my limited lifetime warranty. My package includes postoperative visits related to my surgery for one year, but this does not include comprehensive eye exams completed at any time EVEN DURING THE FIRST YEAR.**

_____ **Please initial here if you consent to photography and/or video being taken and published on our website or affiliated websites with your name displayed.**

_____ **Please initial here if you consent to any written feedback you provide us being published on our website, affiliated websites, or printed material with your name displayed.**

Patient Signature

Date