

**INFORMED CONSENT TO HAVE PHOTO-REFRACTIVE
KERATECTOMY/LASEK SURGERY**

Please read the following consent form very carefully and initial each page where indicated. DO NOT SIGN form unless you have read and understand each page.

PATIENT'S NAME: _____ DATE OF PROCEDURE: _____

SURGEON'S NAME: Ming Chen., M.D. SURGERY CENTER: Pan Pacific Laser Vision

TREATMENT ~~(circle)~~: **RIGHT** Eye **LEFT** Eye **BOTH** Eyes _____ Please initial

MONOVISION ~~(circle)~~: Yes No Slight Which eye? _____

This information is to help you make an informed decision about having Photo-Refractive Keratectomy (PRK)/Laser Subepithelial Keratomileusis (LASEK) surgery to treat nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision before signing this form. You are encouraged to ask questions and have them answered to your satisfaction before you give your permission for surgery. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information presented.

Spectacles and contact lenses are the most common method of correcting nearsightedness (myopia), farsightedness (hyperopia), and/or astigmatism. When tolerated well, they are likely to be a good alternative to PRK/LASEK surgery. Refractive surgery is continually evolving and other refractive procedures may be available as an alternative to PRK/LASEK. You also should be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies.

The surgery is performed under topical anesthetic (drops in the eye). PRK/LASEK changes the shape of the cornea, as a result of removing thin layers of tissue from the surface of the cornea with the light from an excimer laser. This causes the center of the cornea to flatten, in the case of nearsightedness, which changes the focusing power of the cornea. Although the goal of PRK/LASEK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed.

You shall understand that PRK/LASEK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. PRK/LASEK does not correct the condition known as presbyopia (aging of the eye), which occurs to most people around the age of forty. Reading glasses may be required for close-up

work. People over forty years of age that have their nearsightedness corrected may find that they need reading glasses for close vision.

During pregnancy, your degree of myopia or hyperopia can fluctuate, which could influence your results. If you know you are pregnant, plan to, or become pregnant within the next six months, it is important that you notify your doctor immediately. You also should advise your doctor of any drug therapy you are on or any vascular or auto-immune diseases you may have.

POTENTIAL RISKS OF PRK/LASEK INCLUDE, BUT ARE NOT LIMITED TO THE FOLLOWING:

1. **LOSS OF VISION:** PRK/LASEK surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection, irregular scarring, or other causes, and unless successfully controlled by antibiotics, steroids, or other necessary treatment, could even cause loss of the infected eye. Vision loss can be due to corneal healing irregularities, which could add astigmatism and make wearing glasses or contact lenses necessary, which in turn, useful vision could be lost;
2. **VISUAL SIDE-EFFECTS:** Other complications and conditions that can occur with PRK/LASEK surgery include anisometropia (difference in power between the two eyes), aniseikonia (difference in image size between the two eyes), double vision, hazy vision, fluctuating vision during the day (from day to day), increased light sensitivity (may be incapacitating for some time and may not completely go away), and glare or halos around lights, which may not completely go away. Some of these conditions may affect your ability to read and judge distances. Driving should only be done when you are *certain* your vision is adequate. You also may feel like you have something in your eye(s) or experience dryness of the eye(s) for a period of time after surgery;
3. **OVERCORRECTION AND UNDERCORRECTION:** PRK/LASEK surgery may not give you the result you desire. The eye(s) may be undercorrected, in which case additional surgery may be necessary to fine tune or enhance the initial results. These results cannot be guaranteed. It is also possible that your eye(s) may be overcorrected to the point of remaining farsighted. It is also possible that your initial results could regress over time. In some, but not all cases, re-treatment could be considered;
4. **CORNEAL HAZE:** It is common for PRK/LASEK patients to develop some degree of corneal haze, which in some cases may not go away completely. If the haze is severe, re-treatment may be necessary. Corneal haze could cause loss of best-corrected vision and in rare cases the need for a partial or full thickness corneal transplant using a donor cornea. Topical corticosteroid drops also may be required to reduce the development of haze for a couple of months. However, if steroids are used for a number of months in multiple doses per day, some individuals may develop a condition called glaucoma, which could permanently damage the optic nerve. Cataracts also can be the result of using topical steroids for too long;

5. **OTHER RISKS:** Additional reported complications include corneal ulcer formation, endothelial cell loss, epithelial healing defects, and ptosis (droopy eyelid). There also are potential complications due to anesthesia and medications, which may involve other parts of your body. Some patients may not be able to successfully wear contact lenses after PRK/LASEK. If you are younger than the age of twenty-one, there is an additional risk of progressive myopia as you age, and possible under-correction despite having PRK/LASEK. Since it is impossible to state all potential risks of any surgery, this form is incomplete;
6. **FUTURE COMPLICATIONS:** You also should be aware that there are other complications that could occur, which have not been reported *before* the creation of this consent form. PRK/LASEK surgery has been performed only since the late 1990's and longer term results may reveal additional risks and complications;
7. **OFF-LABEL uses:** Associated with the use of the excimer laser are "off-label" uses of this FDA approved medical device. Off-label usage of FDA approved devices and drugs are commonly practiced by physicians without interference from the FDA and allows physicians to practice medicine in a manner they feel most beneficial to their patients.

The following are **off-label** uses of the excimer laser (*please initial where indicated*):

- The treatment of your second eye less than three months between the first eye. Your vision in the first eye may still be unstable and your final refraction may still continue to change.
_____ Please initial.
- The treatment of both eyes at the same time. The benefits of this procedure may include convenience and reduced imbalance between the two eyes. Disadvantages may include any of the above complications in both eyes at the same time (over and under-correction, etc.), and delayed visual recovery with the inability to drive or work.
_____ Please initial.
- The use of a "bandage" contact during the immediate healing phase may increase the risk of infection in front of the eye. _____ Please initial.
- The use of "laser/scrape" to remove the epithelium or skin on the front of the eye to prepare patients for PRK . _____ Please initial.

POST-OPERATIVE INSTRUCTIONS: After your surgery, you will be given medications and instructions to help prevent infection and control healing. It is imperative that you follow **ALL** instructions exactly as they are given to you. It also is imperative that you keep **ALL** follow-up visits, as directed.

Please mark the correct answer for statements 1 – 10.

1. **TRUE** or **FALSE**: PRK/LASEK will permanently change the shape of the cornea.
2. **TRUE** or **FALSE**: There are no guarantees as to exactly how well I will see after the procedure.
3. **TRUE** or **FALSE**: PRK/LASEK is the only way to correct vision.
4. **TRUE** or **FALSE**: I may experience vision irregularities such as haze, halos, and glare, in which some cases may be permanent.
5. **TRUE** or **FALSE**: Excimer surgery follow-up visits are not important.
6. **TRUE** or **FALSE**: Overcorrections and undercorrections can always be retreated.
7. **TRUE** or **FALSE**: It is very important that I stare at the fixating light during the laser treatment.
8. **TRUE** or **FALSE**: I may experience mild to moderate discomfort for several days after the procedure.
9. **TRUE** or **FALSE**: PRK/LASEK will eliminate my need for reading glasses when I am over 40 years of age.
10. **TRUE** or **FALSE**: All of the risks, side-effects and complications that could possibly occur with PRK/LASEK have been explained to me.

Please check your answers with the correct statements provided below. Mark any that you might have answered incorrectly. If you are still unsure as to why you missed any of these statements, present the form to the doctor or a staff member for an explanation. You may then continue reading this consent form.

ANSWERS:

1. **TRUE**. The purpose of PRK/LASEK is to permanently change the shape of the cornea.
2. **TRUE**. There are no guarantees as to how well you will see after PRK/LASEK.
3. **FALSE**. PRK/LASEK is an alternative to glasses and contact lenses. There may also be other refractive surgical procedures that could treat your refractive error.
4. **TRUE**. These side-effects are commonly experienced to some degree following PRK/LASEK. It also is possible they may not go away completely.
5. **FALSE**. It is extremely important that you comply with your doctor's post-operative instructions and keep all follow-up appointments.
6. **FALSE**. In many cases, undercorrections can be retreated. However, it is only possible if your surgeon feels that it will help.
7. **TRUE**. It is important *NOT* to move your eye during the laser treatment. However, a small amount of movement will not affect the outcome of the procedure.
8. **TRUE**. Many patients experience mild to moderate discomfort for a few days after PRK/LASEK. However, pain medications will be made available.
9. **FALSE**. PRK/LASEK does not treat a condition known as presbyopia, which occurs to most people above the age of forty and requires them to wear reading glasses for close work.
10. **FALSE**. Not all possible risks, side-effects, and complications of PRK/LASEK can be explained.

Use the space provided below to write any questions or concerns you still wish to ask the doctor or one of our staff members.

My signature indicates that I have read and understand the contents of this consent form. Although the form may contain medical terminology that I may not understand, my signature indicates I have had the opportunity to ask questions to doctors and everything has been explained to me to my satisfaction. I understand the statements presented on this form.

I also give my permission for medical data concerning my operation and related treatment and any video recordings of my surgery to be released to physicians and others demonstrating a "need to know," for clinical study.

To assure that you understand the information presented, please WRITE the following statement in your own handwriting: *"I understand the information presented and I am willing to accept the fact that I may need to wear glasses or contact lenses or have further surgery following PRK/LASEK to achieve my best level of vision."*

I am making an informed decision in giving my permission to have Photo-Refractive Keratectomy/Laser Subepithelial Keratomileusis surgery performed on my *(please write in your own handwriting which eye(s) are to be performed)*.

Signature of Patient: _____

Date: _____

Signature of Witness: _____

Date: _____

Signature of Surgeon: _____

Date: _____

----- End of Consent Form -----

(LASEK Informed Consent.doc)

Informed Consent For the use of Mitomycin-C/Keratectomy

Background:

The correction of high degrees of nearsightedness (or myopia) using the excimer laser is associated with a significant chance of corneal scarring or "haze". This corneal haze may occur years after the original procedure, and can result in decreased vision.

In 1997, mitomycin-C (MMC) was first used to treat patients who developed this visually debilitating condition. This was published (*Ophthalmology*, January 2000 issue, Vol. 107, pp. 89-94). Since that time, MMC has been used prophylactically (as a preventive measure) to decrease the possibility that corneal haze will develop after Photorefractive Keratectomy (PRK) and Laser-Assisted Subepithelial Keratomileusis (LASEK). These procedures have been associated with corneal haze in certain individuals. It is anticipated that, with the use of MMC, the likelihood of developing haze will be minimized.

Mitomycin-C:

MMC is an antibiotic that has been used in the medical field for a number of decades. It has been 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, and also those cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgeries. The use of MMC for treatment and prevention of corneal haze is a relatively new potential indication for this medication.

MMC is very potent and potentially toxic, under certain circumstances. Some of the eye-related complications that have been reported following the use of MMC (for other conditions) include, but are not limited to: conjunctival injection (redness of the eye), permanent stem cell deficiency, corneal or scleral thinning or perforation requiring corneal transplantation, corneal decompensation, cataract, and retinal vascular occlusion.

The complications listed above were seen following various types of eye surgeries, but **no complications have been reported following the technique for corneal haze removal and prevention**. The technique uses a low dose (0.02%) of MMC delivered to the central cornea for two minutes or less. This technique minimizes the chance of complications, (compared to the types of surgeries in which MMC has been associated with such complications).

As of January 2001, hundreds of eyes have been treated in the U.S. with MMC, both for haze induced by prior refractive surgery, and as a preventive measure at the time of surgery. Additionally a number of internationally renowned eye surgeons from around the world have embraced this technique and reported good results at national meetings. All patients with haze have seen improvements in visual acuity and a decrease in corneal haze. Those patients that received preventive MMC treatment have not experienced corneal haze over an average follow-up period of 1 year. However, there is no guarantee that you will obtain a similar result. The possibility does exist, that over longer periods of time, corneal haze and/or unforeseen toxicity may develop in the future.

Consents:

My Surgeon (Dr Ming Chen) has indicated to me that either I have Corneal haze, or that I may be more likely to develop corneal haze following PRK or Epi-LASEK. I have read and understood the above, and understand the benefits, risks and alternatives to using MMC as described to me. I have had the opportunity to ask questions, and understand that the use of MMC is considered experimental and an "off-label" use of an FDA-approved medication. I understand that there are no guarantees as to the success of the procedure in removing or preventing haze and that toxic side effect may develop.

I give my informed consent to my surgeon (Ming Chen.,M.D), and/or his assistants to use MMC on my Right/Left/Both eye(s) (circle one) as described above.

Patient's Name (Printed)	Signature	Date
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Witness' Name(Printed)	Signature	Date
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Ming Chen, M.D. Surgeon's Name (Printed)	Signature	Date
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