

Daniel F. Goodman, M.D.
2211 Bush Street, 2nd Floor
San Francisco, CA 94115
Phone: 415-474-3333
Fax: 415-474-3939

**INFORMED CONSENT FOR LASIK (LASER IN SITU KERATOMILEUSIS) and
PRK (PHOTOREFRACTIVE KERATECTOMY)**

Please read the following consent form very carefully. Please initial or sign each page where indicated. Do not sign this form unless you have read and understood each section. If you have any questions, please discuss them with Dr. Goodman.

Patient Name: _____

Date: _____ Date of surgery: _____

Treatment: Right Eye _____ Left Eye _____ Both Eyes _____

Monovision: Yes _____ No _____

PATIENT SIGNATURE: _____

My signature below indicates that I have read and agree to follow the pre-operative and post-operative instructions included with my packet.

PATIENT SIGNATURE: _____

Success rate for 20/ _____ or better is _____%; 20/ _____ or better is _____%.

Retreatment Rate is _____%

Surgeon Comments:

SURGEON SIGNATURE: _____

INTRODUCTION:

It is our intent to completely inform you concerning the benefits, alternatives, side effects, limitations, and complications of laser surgery. The first important message to understand is that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility.

This consent form in combination with the educational material provided and the entire consultation process is designed to enhance your understanding of the procedure. Laser Vision Correction procedure is an elective procedure. Any patient who does not wish to accept these risks can simply elect not to have surgery.

Patient Initials _____

BACKGROUND:

The cornea is the “window” to the eye -- a colorless, clear dome-shaped tissue -- much like the crystal on your wristwatch. The excimer laser reshapes the cornea in an attempt to reduce or eliminate the need for glasses or contact lenses. In cases of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (ovalness or uneven curvature of the cornea) the excimer laser is used to perform PRK (photorefractive keratectomy) on the surface of the eye or LASIK beneath the surface.

Photorefractive Keratectomy (PRK) and Laser in situ Keratomileusis (LASIK) are procedures utilizing an excimer laser. Refractive techniques that involve making a flap have been in existence for over 20 years. Shortly after the FDA approval of the excimer laser in 1995, surgeons began combining these flap-making techniques with excimer laser PRK. LASIK surgery involves two procedures: first a flap is created on the cornea and lifted to expose the underlying tissue. The excimer laser is then used to reshape the eye in order to reduce nearsightedness, farsightedness, or astigmatism. After the laser treatment, the flap is returned to its original position without sutures.

The cornea flap is made with the IntraLase laser. A suction ring is placed on the white part of the eye. When the suction is applied, the vision may temporarily fade out. The laser secures to the suction ring to create the flap. The flap is created by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea.

After the flap is made, the flap is then lifted to expose the inner layer of the cornea. The flap remains attached to the surface of the eye with a “hinge.” The laser application is performed within the corneal bed instead of on the corneal surface, as with PRK. Most people state that they do not feel any pain, but rather experience a slight pressure around the eye. During the laser treatment, the patient will hear a loud clicking sound and may smell a faint transient odor. Following the application of the laser, the surgeon replaces the flap, which adheres because of a natural suction force generated by the cornea. No stitches are required. Within hours the epithelium grows over the edge of the flap, adding to the firmness of its attachment. Over the following months, the flap

becomes more and more firmly attached, as the body generates new connective tissue between the flap and the main body of the cornea.

Alternative Treatments: Patients must have rejected alternatives to LASIK (Laser in situ Keratomileusis), which include not having the surgery or wearing glasses or contact lenses.

Contraindications: Patients with any residual, recurrent or active ocular disease or abnormality except for myopia, hyperopia or astigmatism in either eye are not candidates. Also excluded are patients with residual, recurrent or active systemic disease that may affect corneal wound healing. Such diseases include poorly controlled rheumatic arthritis, lupus, or other autoimmune disorders.

Follow-up Examinations: Patients are requested to return for follow-up care several times during the first six months following LASIK, then yearly after the surgery in order to monitor healing of the eye and patient progress following surgery. A typical schedule for post-operative visits is at one day, one week, one month, three months, six months, and then yearly.

All patients are to understand and accept the fact that if an enhancement is needed or a complication occurs, they may require more frequent visits over a longer follow-up period, and additional costs may be incurred. Typically, regular office visit charges are incurred one year after the LASIK procedure. Enhancement surgery, when indicated, may not always be possible.

Patient Initials _____

RECOVERY/RISKS:

- 1) The risk of INFECTION is approximately 1/2000 with PRK and 1/10,000 with LASIK.

Patient Initials _____

- 2) PAIN is common immediately after the procedure for both PRK and LASIK. Typically, patients will experience pain, tearing, light sensitivity, redness and swelling for the first 4-6 hours after LASIK, and 24-48 hours for PRK. Some patients may experience symptoms of "dry eye" up to 6 months following surgery or, rarely, permanently.

Patient Initials _____

- 3) The risk of developing SCAR TISSUE or CORNEAL HAZE with LASIK is less than 0.01% (one per 10,000). The risk of scar tissue formation with PRK is approximately 0.5% (5/1000), increasing in incidence with the degree of attempted correction. Scar tissue is composed of collagen proteins that develop on the surface of the eye with PRK and beneath the corneal flap with LASIK. The development of haze may require retreatment with additional laser and application of an antimetabolite drop (mitomycin C).

Patient Initials _____

- 4) The two side effects that are similar for both LASIK and PRK are NIGHT GLARE and BLURRINESS. They are very common early in the healing process, and are observed by most patients. Both night glare and blurriness are more common when only one eye has been treated, and will usually improve over several months after both eyes have been treated. Typically, 6 months after both eyes have been treated, less than 0.1% (1/1000) of patients still experience significant night glare which seriously interferes with their night driving. Severe night glare can reduce vision in reduced-lighting conditions producing blurriness, ghosting or halos. Patients with large pupils and severe myopia and/or astigmatism are at greater risk for night glare.

Patient Initials _____

- 5) Almost all patients describe BLURRINESS immediately following surgery. Blurriness to one degree or another is common. With the LASIK procedure there is considerable improvement in vision within the first 24-48 hours. Approximately 80% of the visual recovery occurs within the first several days, with the last 20% of vision improving over 3-6 months. Patients typically experience significant improvement of vision within days. The qualitative "fine tuning" may take much longer, on the order of several weeks to months. Some patients do experience a profound and dramatic visual improvement and become able to read half or more of the eye chart the next day, but most state it is still not clear and crisp, and has been described as "Vaseline vision".

Approximately 0.1% (1/1000) of patients will develop corneal irregularities reducing the sharpness, crispness and/or clarity of their vision. This may prevent them from reading the bottom 2 or more lines on an eye chart. It may not be possible to correct this with glasses, contacts, or other surgery. There is no way of predicting or predetermining who will be in this 0.1%. A patient that loses sharpness may have vision that is permanently worse. Some patients in this group may require full-time contact lens wear (soft, rigid gas permeable, or scleral contact lenses). All forms of eye surgery alter human tissue and possess some risk.

Patient Initials _____

- 6) CORNEAL FLAP COMPLICATIONS: The entire incision time is approximately 20 seconds, but during this brief interval a lot of things need to go right. There is an approximate 0.1% (1/1000) risk that the eye will experience a corneal flap complication. Corneal flap complications may necessitate postponing surgery for three months, or indefinitely.

Patient Initials _____

7) EPITHELIAL INGROWTH: During the first several hours the epithelial protective layer grows over the corneal flap. There is a 0.5% (5/1000) risk that epithelial cells may grow underneath the flap. This is more common in people with weak protective layers which bond poorly to the eye surface. Any intra-operative breakdown of the protective layer may increase the incidence of epithelial ingrowth. Treatment involves lifting the flap and clearing the cells. Untreated epithelial ingrowth may distort vision and may actually damage the flap if it is severe and progressive. Small ingrowths do not usually present any visual problems and need only be monitored. This complication cannot occur with PRK, because it is flap-related.

Patient Initials _____

COMPLICATIONS:

Less than 1% of patients develop significant complications. NO ONE ever believes they will be in this group. LASIK performed for severe myopia and astigmatism is associated with a higher risk of complications, approximately 1%.

Patient Initials _____

None of our patients have ever gone blind from excimer laser surgery BUT you can always be the first. Theoretical risks are potential problems that have not happened yet. The risk of blindness is estimated to be one per million procedures. There are no guarantees of perfect vision. There are no guarantees that you will not need glasses or contacts. There are no guarantees that you will not be in the small fraction of patients that have significant complications.

Patient Initials _____

LASIK carries a risk of flap complications that PRK doesn't, but it also has a lower risk of pain, infection, scarring, and has a faster recovery and less need for eye drops. LASIK carries a higher risk of intra-operative complications and lower risk of post-operative complications.

Patient Initials _____

EXPECTATIONS:

The goal is to achieve the best visual results in the safest way. The goal is NOT to eliminate glasses and contacts completely but to dramatically reduce your dependence upon them. Night driving glasses and readers may always be needed even with a successful procedure.

Patient Initials _____

The degree of correction required determines both the rate of recovery and the accuracy of the procedure. Severe prescriptions often require at least two procedures. Patient differences in healing will also greatly affect visual recovery and final visual outcome, and are impossible to predict.

Patient Initials _____

ENHANCEMENTS:

Enhancement surgeries are generally performed no sooner than 3 months after LASIK and six months following PRK. Within the first year, there is usually no need to create another flap for LASIK enhancements. The original flap can be lifted with specialized techniques. After 2 years, however, it may not be possible to safely lift the original flap, and enhancement procedures would then be done utilizing the PRK technique. In PRK enhancements, the epithelium, or outer layer of the cornea, is removed prior to laser treatment.

In order to perform any enhancement surgery, there must be adequate corneal tissue remaining. If the cornea is too thin, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.

Patient Initials _____

FDA APPROVAL

The excimer laser is FDA approved for LASIK treatment up to -14.00 diopters of correction for nearsightedness with or without astigmatism up to -5.00 diopters, and up to +6.00 diopters of correction for farsightedness with or without astigmatism up to +3.00 diopters. The excimer laser is approved for PRK treatment up to -12.00 diopters of correction for nearsightedness with or without astigmatism up to +4.00 diopters. If a patient has nearsightedness, farsightedness, or astigmatism greater than the approved range, Dr. Goodman may provide treatment to the patient if he/she is a suitable candidate and specifically requests correction beyond the FDA recommendations. This is also an accepted "standard of care" application of excimer laser surgery.

I request that Dr. Goodman treat my **nearsightedness** beyond the FDA approved treatment parameters for LASIK and PRK.

Patient Initials _____

I request that Dr. Goodman treat my **farsightedness** beyond the FDA approved treatment parameters for LASIK and PRK

Patient Initials _____

IMPROVEMENT OF VISUAL POTENTIAL:

Patients who do not see 20/20 or 100% before surgery, even with the strongest prescription, cannot expect or anticipate 20/20 or 100% after surgery. That is, after surgery the best vision a patient can attain is the vision they experienced before their procedure with their best correction. Rigid gas permeable lenses may actually provide certain patients with better vision than glasses, soft lenses or refractive surgery. This surgery does not improve visual potential. Each patient will continue to require routine annual eye examinations to rule out several conditions, including glaucoma, cataracts or retinal disease, which typically requires a yearly dilated comprehensive examination.

Legal driving vision is 20/40. If you cannot achieve corrected vision of 20/40 or better you may not qualify to renew your driver's license.

Patients with borderline visual function must understand that a loss of sharpness may prevent them from driving legally, or performing other equally demanding visual tasks (occupational and/or recreational).

Patient Initials _____

MONOVISION:

Everyone over the age of 40 will eventually experience presbyopia, resulting in the need for reading glasses or bifocals. In monovision the typical aim is to leave the non-dominant eye a little nearsighted to help reading vision. This involves giving up distance sharpness in the non-dominant eye, though binocular distance vision remains good. Patients may need night driving glasses, and reading glasses may still be required for fine print or prolonged reading. But, overall dependence on glasses or contacts is still dramatically reduced. Monovision helps with simple near tasks such as working at the computer, opening mail, reading price tags, or looking at your phone. Patients, who desire the best distance or night vision unaided, such as pilots or truck drivers, should avoid monovision. In our experience, people over 40 years of age should consider monovision correction.

I want my correction to include monovision (please initial):

Yes _____ No _____

PATIENT CONSENT:

Please initial after each paragraph, and rewrite in your own handwriting the bold faced phrases as indicated.

1. I understand the basic nature of the procedure and benefits as well as the possible risks and complications of PRK and LASIK. All of my questions have been answered to my satisfaction. I understand that it is impossible for my surgeon to inform me of every conceivable complication that may occur.

Patient Initials _____

2. I understand that, as with any form of surgery, the outcome can never be guaranteed. I specifically understand that the benefits of the PRK and LASIK procedures cannot be guaranteed. PRK and LASIK may be of no benefit to me and may in fact be harmful.

Patient Initials _____

3. I understand that **“there are no guarantees”**.

Please write out: _____

4. I understand that as a result of surgery using the excimer laser that there is a small risk that my vision may be worse and not correctable to the level of my preoperative vision even with glasses or contact lenses.

Patient Initials _____

5. I understand that **“my vision may be made worse”** from laser surgery.

Please write out: _____

6. Complications that may occur include -- but are not limited to -- retinal tears, retinal detachments, central retinal artery occlusion (eye stroke), corneal infection, intraocular infection, corneal scarring, recurrent corneal erosions (breakdown of the protective surface layer), decrease in best corrected vision, permanent night vision problems, corneal decompensation (persistent corneal swelling), corneal ectasia (bulging of the cornea), corneal perforation, dry eye, and ocular pain. These complications are rarely permanent. Although vision-threatening complications are quite rare, it is possible that a significant reduction in vision may be produced. As a result of these complications, I may require a corneal transplant. Blindness resulting from LASIK may occur as a result of perforation and/or infection under very rare circumstances.

Patient Initials _____

7. I understand that I could develop a corneal ectasia after refractive surgery. Corneal ectasia is a steepening of the cornea that can worsen with time and can lead to a reduction in visual acuity. In some cases, ectasia may be associated with keratoconus or other related corneal disorders.

Keratoconus is a relatively rare 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 and related disorders may occur naturally, there is no absolute test that will ensure a patient will not develop ectasia following laser vision correction. Severe ectasia may need to be treated with a corneal transplant while mild ectasia can be corrected by glasses or contact lenses.

Patient Initials _____

8. I understand that **“I may not achieve the level or quality of vision I hope for”**

Please write out: _____

9. I understand that the correction obtained may not eliminate all of my myopia, hyperopia, or astigmatism, and that additional correction with glasses, contact lenses or further surgery may be needed.

Patient Initials _____

10. I understand **“I may still need to wear glasses or contact lenses”**

Please write out: _____

11. I understand that partially and fully sighted eyes have been treated with excimer laser since 1987 and that Lamellar Keratoplasty has been performed since the 1970s with the combined LASIK procedure being performed since 1991. The very long-term effects associated with this procedure are not known.

Patient Initials _____

12. I understand that no financial compensation or reimbursement is available to me from my surgeon, my ophthalmologist or optometrist, any doctor involved in my LASIK follow-up care, or the laser manufacturer in the event of any complication related to excimer laser LASIK surgery or my dissatisfaction with the results of the LASIK surgery.

Patient Initials _____

13. My surgery may be videotaped and/or audio taped. These tapes will be used for teaching and/or research purposes only. My identity **will not** be disclosed.

Patient Initials _____

14. A copy of this consent form is available to me upon request.

Patient Initials _____

15. I have read the pre-operative and post-operative instructions.

Patient Initials _____

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

Patient Initials _____

VOLUNTARY CONSENT:

In signing this Informed Consent Form I certify that I have read the preceding information and understand the contents. Any questions I have concerning the consent form or concerning PRK and LASIK have been answered by my surgeon. My decision to proceed with surgery has been voluntarily and freely given.

RIGHT EYE _____ **LEFT EYE** _____ **BOTH EYES** _____

Patient Full Name (print): _____

Patient Signature: _____ Date: _____

Witness Full Name (print): _____

Witness Signature: _____

Surgeon: _____

Date of Procedure: _____