

Clear Advantage Vision Correction Center

INFORMED CONSENT FOR PRK

PLEASE READ THE FOLLOWING PAGES CAREFULLY AND INITIAL AND SIGN WHERE INDICATED.
PLEASE DO NOT SIGN ANY SECTION THAT YOU HAVE NOT READ OR DO NOT UNDERSTAND.

SECTION 1: GENERAL INFORMATION ON INFORMED CONSENT

It is our hope to fully inform you concerning the side effects, limitations and complications of PRK surgery. We continually strive to balance the benefits of laser surgery with the known and unknown risks. It is important to understand 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 materials provided and the entire consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both the procedure and the healing process.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing laser surgery, as most of our patients will never encounter any serious complications, and the vast majority are thrilled with the improvement they achieve. It is our intention to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated or be better prepared to deal with any unexpected complications or side effects which may arise. PRK is a purely elective procedure, and you may decide not have this operation at all. The only way to avoid all surgical risk is by not proceeding with surgery.

SECTION 2: LASER VISION CORRECTION BACKGROUND SUMMARY

Photorefractive keratectomy (PRK), a form of laser vision correction, reshapes the part of the eye known as the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (ovalness). There are two primary techniques for reshaping the cornea with laser surgery, PRK and LASIK. Both procedures are able to treat myopia, hyperopia, and astigmatism but have benefits, limitations and risks. In both forms of laser vision correction, the transparent cornea at the front of the eye is reshaped with your prescription. PRK or photorefractive keratectomy sculpts the surface layer of the cornea, while LASIK reshapes the inner corneal layers with the excimer laser. The excimer laser produces a cool beam of ultraviolet light energy, capable of removing very precise amounts of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision.

There is a modification of the PRK procedure in which an attempt is made at preserving the surface layer of cells (epithelium) during the laser treatment, and replacing that layer at the conclusion of the procedure. This modified PRK procedure is sometimes referred to as LASEK, but it resembles PRK much more than the similar sounding LASIK procedure. We will use the term "PRK" to encompass both traditional PRK and modified PRK/LASEK.

PRK is performed on an outpatient basis and takes only 15 – 20 minutes to complete. Although patients sometimes feel some pressure sensation, the procedure is generally painless. Topical anesthetic drops are used to numb the eye and an eyelid holder is used to prevent blinking. The self-regenerating surface layer of cells (epithelium) is removed from the center of the cornea either by wiping or with the assistance of alcohol solution. (In PRK this layer is discarded; in modified PRK (LASEK), an attempt is made to preserve this epithelial layer in order to encourage faster healing) Patients focus on a red target light throughout the procedure. When the laser pulses are completed, a bandage contact lens will be placed, and a protective eye shield will be needed. Although the vision is blurry immediately following PRK, patients are able to blink normally and there is gradual visual improvement. Usually the bandage contact lens is removed after several days, and vision is often adequate for daily activities after a week.

Patient Initials _____

SECTION 3: PRK INDICATIONS, CONTRAINDICATIONS AND PERI-OPERATIVE CARE

- PRK is indicated for the treatment of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism.
- Candidates must be over 18 years of age.
- Candidates must have a stable refraction with no more than 0.50 diopter change within the previous year as the procedure will not change the natural growth or aging of the eye.
- Candidates must be aware that this is an elective procedure and that there are alternative forms of vision correction that are both non-surgical and surgical including eyeglasses, contact lenses, orthokeratology (ortho-K), radial keratotomy (RK), intracorneal ring segments (ICRS), automated lamellar keratoplasty (ALK), holmium laser thermokeratoplasty (LTK), conductive keratoplasty (CK), refractive phakic lens implants, or laser in situ keratomileusis (LASIK).
- Candidates must be free of certain eye diseases including keratoconus, glaucoma, cataracts and certain retinal and optic nerve diseases.
- Candidates must be free of certain health problems including uncontrolled diabetes, autoimmune or collagen vascular disease, any medication or condition which renders the patient immunocompromised.
- Candidates must make their surgeon aware of certain eye problems including amblyopia (lazy eye), strabismus (muscle imbalance), severe dry eyes, or any recurrent, residual or active eye condition which may affect healing.
- Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgery healing, back problems, claustrophobia or other psychological problems which may affect the surgery or recovery.
- Candidates must make their surgeon aware of implants including a cardiac pacemaker, insulin pump or other electronic implanted device.
- Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid any possible drug interactions and allergic reactions.
- The FDA considers pregnancy and nursing contraindications, although their effects on PRK are not certain. Female patients agree to disclose to their surgeon if they are pregnant, could potentially be pregnant or plan to become pregnant in the next six months.

PRE-PROCEDURE AND POST-PROCEDURE CARE

The screening examination is intended to assess your candidacy for refractive surgery based upon the corneal shape, thickness, prescription and other ocular and visual findings, but not to identify or treat eye disease. Ocular disease may be present prior to refractive surgery or may develop after the surgery, but it is unrelated to laser surgery. Refractive surgery will not treat ocular disease. You should have a complete eye exam with retinal evaluation prior to refractive surgery and annually thereafter to identify and treat ocular disease. In general, patients with higher degrees of myopia have a higher risk of retinal problems, and reducing the degree of myopia with laser vision correction does not lower the risk. Patients who wear contact lenses must discontinue their use prior to PRK to allow the cornea to return to its natural contour. Soft contacts must be removed *at least* three days prior to surgery. Candidates with rigid gas permeable lenses must discontinue their use for several weeks, and sometimes several months, prior to PRK.

Post-operative follow-up care with an eyecare professional is recommended for one year to monitor PRK healing, and yearly examinations are recommended thereafter. Occasionally an enhancement procedure (an attempt to refine the initial laser procedure) is requested, and usually this can be done at no additional charge in the first year. However if a later enhancement is required or if a complication occurs, the patient may incur a fee and may be required to travel to another laser center or be seen by another surgeon at the patient's own expense. The final clinical results are dependent, in part, upon properly following your post-operative care instructions.

Patient Initials _____

SECTION 4: PRESBYOPIA AND THE MONOVISION OPTION:

Presbyopia, the normal aging change of the internal near focusing structures of the eye, naturally causes people to need reading glasses for near vision and intermediate glasses for arm's length vision (computer screen) in their 40's or 50's. If you need bifocals or reading glasses now, and do not opt for monovision, you will still need reading glasses and/or intermediate glasses after PRK. If you do not wear reading glasses and/or intermediate glasses now, you will most likely need them as you age, whether or not you have PRK. PRK does not stop the natural aging process of the eye. Although farsighted patients usually improve their reading ability with PRK, it is possible that nearsighted patients may require reading glasses and/or intermediate glasses sooner than if they did not have PRK, often immediately after surgery.

One possible option is monovision. In monovision, the aim is to have the non-dominant eye a little under-corrected (i.e. not fully corrected for distance vision) in order to help reading and intermediate vision. This involves giving up a little distance sharpness. Glasses for night-time (i.e. driving) are more common with patients with monovision, and reading glasses and/or intermediate glasses may still be required for fine print or prolonged reading or computer work; HOWEVER, overall dependence upon glasses and contacts is usually reduced. Monovision helps with simple near tasks such as opening mail, reading price tags, or looking at one's wristwatch. Patients, who desire or require the best distance or night vision unaided, such as golfers or airline pilots, should avoid monovision. If you desire laser vision correction and are under the age of 40, monovision is not generally recommended.

Initial next to the statement that accurately describes your goal for vision correction:

I would like to correct my distance vision.

I may need to wear reading glasses and/or intermediate glasses after the age of 40.

I would like to have monovision.

Over the age of 40 whereby one eye is corrected for distance vision and one eye is corrected for near vision.

SECTION 5: LEGAL RESPONSIBILITIES

CONFIDENTIALITY

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Clear Advantage, Eyesight Ophthalmic Services, the excimer laser manufacturer and the government regulatory authorities. The data will be utilized for statistical analysis, record keeping, marketing, and quality control. Patient identity will be strictly confidential in any dissemination of data.

GOVERNING LAW / JURISDICTION

By initialing below, you agree that the relationship and resolution of any and all disputes between yourself, Clear Advantage, and your surgeon shall be governed by and construed in accordance with the laws of New Hampshire. You also acknowledge with your initials that courts of the state of New Hampshire shall have jurisdiction to entertain any complaint, demand, claim or cause of action whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in New Hampshire and you irrevocably submit to the exclusive jurisdiction of the courts of New Hampshire.

SECTION 6: RISKS AND COMPLICATIONS

As discussed earlier, all forms of surgery carry a certain degree of risk for adverse effects and complications. Problems can be related to the surgical component of PRK or the healing component. Most surgical problems are related to the preparation of the corneal surface for laser, and most healing problems develop within the first 3 months following PRK. Most complications improve or resolve within 6 – 12 months or with retreatment, but some

Patient initials _____

surgical or healing complications may result in permanent visual blurring, glare, discomfort or need for corrective contact lenses. The risk of a severe complication is not only dependent upon surgical technique but upon a number of other factors including the prescription, orbital structure, cornea shape, and healing characteristics of the individual treated. In general, there is a small risk in the range of 1 – 5 % of experiencing a complication and a very small risk, less than 1%, of a severe sight-threatening complication. Please read this section carefully for a better understanding and initial below

The risks of PRK revolve around 5 primary areas:

1. Post-operative Side Effects, Adverse Effects and Complications
2. Refractive Complications
3. Corneal Healing Complications
4. Corneal Ectasia
5. Other Miscellaneous Complications

1. Post-operative Side Effects, Adverse Effects and Complications

There are several adverse effects which may be encountered early in the post-operative period, which include foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dryness of the eyes, tearing and fluctuation in vision. Some degree of pain is common for the first 1 – 3 days following PRK, but is usually able to be managed effectively. However, progressively worsening pain may indicate a serious healing problem or possible infection and should be evaluated promptly by your doctor. Corneal infection following PRK is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases, infections can even result in blindness. Sterile corneal inflammation can sometimes develop, possibly causing corneal scarring and blurred vision. Treatment may involve topical steroids, other drops, or further surgery and may or may not restore vision fully. The most important long-term side effects are night glare, starbursts, haloes or simply reduced visual quality especially under low light conditions. It is very common to have night glare early during the recovery course and night glare is common when only one eye has been treated. Night visual disturbances may be more common in nearsighted patients with severe prescriptions and large pupils.

Some patients benefit from night driving glasses and most, but not all, patients improve substantially over 6 – 12 months. In a small percentage of patients night glare may be permanent and affect your night driving abilities.

2. Refractive Complications

Refractive problems that may be encountered include too much correction, too little correction, asymmetric correction, a prescription imbalance between eyes, aggravation of muscle imbalance problems or a loss of effect from regression. PRK may result in overcorrections and undercorrections due to variability in patient healing patterns and other surgical variables, leaving patients nearsighted, farsighted, or with astigmatism. This may or may not require patients to wear spectacles, contact lenses, or undergo further surgery. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is typically achieved. Patients may also heal differently between eyes, based upon differences between eyes in pre-operative prescriptions, corneal curvature, variation in healing or other surgical variables. Differences in refraction between eyes is termed anisometropia; this is most severe when only one eye is treated, and may result in a loss of depth perception, eyestrain, headache, double vision and the need for contact lenses. Both farsightedness and anisometropia may result in worsening of pre-existing muscle balance problems, causing an eye to wander more or produce eye fatigue. Lastly, depending upon the severity of the original prescription, the individual healing pattern of the patient and other surgical variables, regression may occur causing the eyes to return toward their original prescription, partially or very rarely, completely. Further enhancement surgery may be performed when medically stable if adequate corneal tissue is available and no other medical contraindications are present.

Patient initials _____

3. Corneal Healing Complication

After PRK, significant healing is still required which can affect the quality and vision of the final result. Corneal healing problems with PRK are more likely to be experienced by patients corrected for higher degrees of nearsightedness, farsightedness and astigmatism, which may potentially slow visual recovery and increase the need for enhancement procedures for over- and under-corrections. Mild corneal haze is common during the healing following PRK, but rarely, more severe corneal scarring may be produced with PRK. The most important aspect of corneal healing following PRK or any other form of refractive surgery is the development of corneal irregularities that may permanently affect the quality, crispness and sharpness of the final visual result. Corneal irregularities or irregular astigmatism is produced when the cornea heals in an irregular pattern. Corneal irregularity may also be produced from abnormalities and complications of the laser treatment, including central islands and decentrations, that may produce blurring, shadowing, glare, and doubling of vision. Some corneal irregularity is commonly expected for the first several weeks following an uncomplicated PRK; however, if it persists beyond six months it is considered abnormal and may be permanent. Most corneal irregularity improves over 6 – 12 months and some causes of corneal irregularity may be surgically managed but other causes are permanent.

The limitation of healing problems are that further surgical intervention does not guarantee better healing and may, in fact, result in a further reduction in visual quality.

Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that a patient may be unable to read the bottom few lines of the eye chart even with spectacle or contact lens correction. Specifically, the best vision a patient measures after surgery even with lens correction may not be as good as the patient enjoyed before refractive surgery. In some cases, patients will actually gain best corrected vision.

In certain cases, the vision may be severely impaired and affect the ability of a patient to drive legally. This is most important in patients who already have reduced visual acuity from other causes. PRK is not intended to increase the visual potential of a patient and many candidates with high prescriptions often are unable to read 20/20 before surgery and should not expect to read 20/20 after surgery. Furthermore, a patient who is best corrected before surgery to 20/40 is already borderline for legally driving and any loss of best corrected vision from healing or surgical complications may prevent legal driving.

4. Corneal Ectasia

It is possible that the thinning of a cornea with PRK may lead to gradual bulging of the tissue, or ‘ectasia.’ Mild corneal ectasia may have minimal impact on a person’s vision other than leading to a return of mild myopia. More significant corneal ectasia may result in progressive distortion of vision and, in severe cases, may require corneal transplant surgery. People with higher myopic prescriptions and naturally thinner corneas are felt to be at a higher risk for developing post-PRK ectasia. Pre-operatively, surgeons calculate the presumed residual corneal thickness following PRK to estimate the risk of future corneal ectasia. However, we do not fully understand all the factors that place someone at risk for ectasia. What we currently feel is a “safe” residual thickness may later be determined to be inadequate to prevent ectasia. There have been reports of corneal ectasia following PRK. However, it should be noted that the overwhelming majority of PRK patients already treated have not subsequently demonstrated corneal ectasia.

5. Other Miscellaneous Complications

It is important to note that it is impossible to list every conceivable complication that is not listed above. Risks and complications that are considered to be unforeseeable, remote or not commonly known are not discussed. In addition, there may be long term effects not yet known or anticipated at the present time. The most severe possible complications would necessitate more invasive or repeated corneal surgery, including corneal transplantation and could potentially produce partial or complete loss of vision.

Patient initials _____

SECTION 7: EXPECTATIONS OF THE PROCEDURE

The goal of PRK is to achieve the best visual result the safest way. The goal is not to eliminate glasses and contacts completely but to dramatically reduce your dependence upon them in an attempt to help improve your quality of life. Night driving glasses and reading glasses may always be needed even when an excellent visual result is achieved. It is also important to recognize that even 90% clarity of vision is still 10% blurry and glasses may still be needed for certain activities that require fine or detailed vision.

Enhancement procedures can be performed when a patient's healing appears stable, unless medically unwise or unsafe.

Typically patients considered for an enhancement procedure should have at least 1.00 diopter of residual hyperopia, myopia, or astigmatism or unaided vision of 20/40 or worse. Enhancement procedures are usually not performed until after 3 months, once adequate corneal healing and stability is achieved. Enhancement procedures are typically performed in a similar fashion as the original procedure, but may be technically more difficult. There are always risks which must be balanced against the benefits of performing further surgery.

Complications are an inherent part of surgery and despite our best efforts, training and skill, we recognize that some patients will experience problems. It is simply our hope to educate you as to what those problems may be so that you can make an informed decision whether or not to proceed.

No one ever believes that they will be in the small percentage of people that develops a significant complication, so it is important for all candidates to appreciate that there are truly no guarantees. The laser manufacturer also has a Patient Information Booklet that is available to patients at Clear Advantage and Eyesight Ophthalmic Services which describes, among other things, the results of clinical trials for the laser.

SECTION 8: TREATMENT OF ONE OR BOTH EYES

There are both advantages and disadvantages of having PRK on both eyes on the same day. The benefits of surgery on both eyes the same session begin with the simple fact that patients often prefer this option as it is more convenient with respect to either work or home life. Patients may also find that their vision feels more balanced, with improved depth perception, and night glare may dissipate more rapidly. Some patients find they have less anxiety, while others prefer the safety of treating only one eye at a time to allow visual recovery of the first eye prior to proceeding with the second eye.

The primary risks of treating both eyes on the same day are related to unrecognized surgical complications or, more commonly, unexpected healing complications, which can produce either temporary or permanent visual blurring. Adequate visual recovery from laser vision correction for activities such as driving as well as returning to work, may take 1 week or even longer in patients who respond abnormally, whether one or both eyes are treated. If both eyes are treated, then visual recovery may be prolonged and there is no way to predict who will take longer to heal. There is also no opportunity to learn from the healing pattern of the first eye. If there is an undercorrection or overcorrection in one eye, this is likely to occur in both eyes and both eyes will require treatment. Other healing complications may also affect both eyes, most importantly the risk of infection may result in severe scarring, corneal transplantation and even complete loss of vision in both eyes.

Please FILL IN the blank below with the appropriate response to indicate the treatment you choose to have:

I would like to have my RIGHT LEFT BOTH eye(s) treated

Patient initials _____

SECTION 9: WRITTEN CONFIRMATION

PLEASE WRITE IN THE FOLLOWING TWO STATEMENTS to confirm that you have understood and accept that PRK is an elective surgical procedure and, as with all surgical procedures, the result cannot be guaranteed; that you acknowledge that although vision-threatening complications are quite rare, it is possible that partial or complete loss of vision may be produced as a result of a surgical or healing complication; that the procedure may eliminate all of your myopia, hyperopia, or astigmatism and that additional correction with glasses, contact lenses or further surgery may be required.

“I understand that there are risks and no guarantees.”

“I understand that I may still need to wear glasses.”

SECTION 10: VOLUNTARY CONSENT

Please sign below indicating that you have carefully reviewed this informed consent document and that you have had an opportunity to ask any questions. By signing below you also indicate that you are aware that LASIK is an elective procedure, that you do not need to have this procedure, and that you understand your other surgical and non-surgical alternatives for vision correction.

Patient Full Name (print): _____

Patient Signature: _____

Witness Full Name (print): _____

Witness Signature: _____

Surgeon Name: N. Timothy Peters, M.D. or Jennifer Ling, MD

Surgeon Signature: _____

Date of Procedure: _____



Informed Consent for the use of Mitomycin-C

Background:

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

In 1997, a practice pioneered the use of a medication called mitomycin-C (MMC) to treat patients who developed this visually debilitating condition. Since that time, we have also begun using MMC prophylactically (as a preventative measure) to decrease the possibility that corneal haze will develop after Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), Crosslinking (CXL) and with inlays. 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 only very rare complications have been reported following our technique, as we have described, for corneal haze removal and prevention. Our technique uses a low dose (0.02%) of MMC delivered to the central cornea for less than 1 minute. This technique minimizes the chance of complications (compared to the types of surgeries in which MMC has been associated with such complications).

Additionally, the majority of internationally renowned eye surgeons from around the world have embraced this technique and reported good results at national meetings. The possibility does exist, that over longer periods of time, corneal haze and/or unforeseen toxicity may develop in the future, but the use of MMC can minimize that risk.

Consent:

My surgeon has indicated to me that either I have corneal haze, or that I may be more likely to develop corneal haze following PRK, Crosslinking or an inlay procedure. 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 effects may develop.

I give my informed consent to my surgeon (indicated below), and/or his assistants to use MMC on my

RIGHT LEFT BOTH EYE(S)

as described above.

Patient's Name (printed)	Signature	Date
--------------------------	-----------	------

Witness' Name (printed)	Signature	Date
-------------------------	-----------	------

N. Timothy Peters, M.D.

Jennifer Ling, MD

Surgeon's Name	Signature	Date
----------------	-----------	------