

INFORMED CONSENT

PRK MONOVISION REVERSAL

INTRODUCTION

This document is provided to obtain your informed consent for laser vision correction retreatment to reverse monovision. This document contains important information detailing the risks and benefits as well as alternative treatments available. Laser vision correction is an elective procedure and you are choosing it because you want to, not because you must.

It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision.

INSTRUCTIONS

- You must review this entire document prior to treatment.
- Take as much time as needed to read and understand this document prior to signing.
- Your doctor is available to answer any questions or concerns you have regarding this consent.
- This document must be signed prior to any treatment.
- You will sign this document in-person at Laser Eye Institute.
- You may request a copy of this document at any time.

INFORMED CONSENT ADDENDUM FOR RETREATMENT / ENHANCEMENT

It is important to realize that even if you did not experience any difficulties with your original laser vision correction, that does not mean that you will not have any complications with retreatment. The only way a patient can avoid all surgical risks is by not proceeding with surgery. Each patient must balance the risks and benefits to determine whether to proceed with further surgery.

CONSIDERATIONS FOR RETREATMENTS

The surgeon alone can determine whether you are a candidate for retreatment and several factors determine eligibility. Eligibility and the choice of technique are determined primarily by the amount of time that has passed since original treatment, amount of healing that has taken place, and the corneal thickness. Retreatment can be performed once vision is stable, typically, one to four months.

The goal of retreatment is to achieve the best visual result with the safest method while reducing dependency on glasses. The degree of correction required determines both the rate of recovery and the initial accuracy of the treatment. Differences in healing can also greatly affect visual recovery and final visual outcome and are impossible to predict. After the initial treatment you may have some remaining nearsightedness, farsightedness, or astigmatism, if so, glasses or contact lenses may still be needed some or all of the time.

RISKS AND COMPLICATIONS

The risks associated with the original procedure apply to retreatment as well.

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your surgeon, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse. In giving my permission for treatment, I have received no guarantee as to the success of my particular case and understand that the following known risks:

Retreatment may result in overcorrection or under correction due to the 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 glasses or contact lenses or undergo additional treatment. Further treatment entails additional risk and is not guaranteed to provide an ideal visual outcome.

Depending upon the severity of the original prescription, the healing pattern of the patient, and other factors, regression may occur, causing the eyes to return to their original prescription, either partially or completely. Further retreatment may be performed when the eye is stable and if adequate corneal tissue is available and no medical contraindications exist.

In general, healing after retreatment is usually more rapid, but may follow the same course as the original healing pattern. The speed of the original healing pattern is usually based upon the severity of the original prescription and is typically slowest for patients treated for high degrees of farsightedness.

INFORMED CONSENT ADDENDUM FOR REVERSAL OF MONOVISION

A small percentage of patients are not satisfied with monovision. Most monovision treatments may be reversed. This is accomplished by treating the monovision eye fully for distance. **Once reversed both eyes will be corrected for distance and you will require reading glasses, just as you would had you not undergone monovision treatment.** Monovision may only be reversed after the initial treatment has stabilized and you have allowed a period of time to adjust to monovision correction. This time period will be determined by your surgeon, however is typically six months. **Reversal of monovision carries all of the risks of the original procedure.** Once reversed treatment is permanent and you will require reading glasses to correct your near vision.

Monovision reversal is performed on the near, or monovision eye. The surgeon will apply laser vision correction treatment to this eye to fully correct it for distance reversing monovision treatment. **The risks associated with the original procedure apply to reversal of monovision as well.**

ALTERNATIVES

There are several options to reversing monovision. Those include wearing bifocals or separate distance and reading glasses or contacts.

RISKS AND COMPLICATIONS

Reversal of monovision carries all of the risks of the original procedure, as you will undergo laser vision correction treatment.

Once reversed both eyes will be corrected for distance and you will require reading glasses, just as you would had you not undergone monovision treatment.

Once reversed, treatment is permanent.

NON-COVERED SERVICES DISCLOSURE

As outlined in the monovision consent, reversal of monovision is not covered under the original treatment fee and additional costs may apply.

INFORMED CONSENT FOR PRK / LASEK / ADVANCED SURFACE ABLATION FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS), HYPEROPIA (FARSIGHTEDNESS), AND ASTIGMATISM USING AN EXCIMER LASER.

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision regarding LASEK (Laser Epithelial Keratomileusis) to reduce your nearsightedness, farsightedness, or astigmatism. LASEK treatment involves two steps. First, the epithelium (outer most layer of the eye) layer is removed using a diluted alcohol solution. Second, an excimer laser is used to remove thin layers of tissue from the cornea to reshape it, correcting vision. Finally, a bandage contact lens is placed over the eye, to promote healing of approximately 5 days.

ALTERNATIVES

All laser vision correction, including LASEK/PRK, SMILE and LASIK, are elective procedures: there is no emergency condition or other reason that requires or demands that you have it performed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have adequate vision. There are also other types of refractive vision correcting surgery, including ICL, clear lens exchange as well as other types of laser vision correction including LASEK/PRK, SMILE or LASIK.

RISKS AND COMPLICATIONS

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your surgeon, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse. In giving my permission for treatment, I have received no guarantee as to the success of my particular case and understand that the following known risks:

The laser could malfunction, requiring the procedure to be stopped or changed before completion. Depending on the type of malfunction, this may rarely be accompanied by visual loss.

Irregular healing could result in a distorted cornea. This means that glasses or contact lenses may not correct your vision to the level possible before undergoing treatment, with vision being worse than before treatment. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

Mild or severe infection is possible. 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 surgery or, if very severe, corneal transplantation or even loss of the eye.

Keratoconus, corneal warpage, could occur. Keratoconus is a degenerative corneal disease affecting vision. While there are tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative measurements. 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 or corneal crosslinking while mild keratoconus can be corrected by glasses or contact lenses.

Pain, irritation, foreign body sensation, or light sensitivity, particularly during the first 48 hours after treatment. Increased risk of eye irritation related to drying of the corneal (eye) surface following treatment. These symptoms may be temporary or, on rare occasions, chronic, and may require application of artificial tears and/or closure of the tear duct openings in the eyelid.

Vision after surgery will not be clear immediately and that I might not notice improvement for several days to several weeks. There may be a "balance" problem between my two eyes after treatment has been performed on one eye, but not the other. This may cause eyestrain and make judging distance or depth perception more difficult. I must not drive the day of surgery and should not drive until I am certain that my vision is adequate for driving.

Full correction may not occur from treatment (known as over-correction, or under-correction), causing me to become farsighted, nearsighted, or induce astigmatism; this could be treatable or untreatable. If untreatable, I may need to use glasses or contact lenses.

The improvement in vision I can expect may not be perfect. It is not realistic to expect that treatment will result in perfect vision, at all times, under all circumstances, for the rest of my life. Glasses, for distance vision, near vision, or both may be necessary while healing occurs, or even after healing which may require glasses or contact lenses to see clearly. This may occur soon after treatment or years later. Patients currently needing reading glasses, will still likely need reading glasses after treatment. The need for reading glasses may increase after treatment, even if a patient did not reading glasses prior to treatment. This is even more likely for patients over the age of 40.

Increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These conditions usually occur during the stabilization period of from one to three months, but they may also be permanent. Glare, starburst, 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. 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. 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 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.

Other very rare complications include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of floaters, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye are possible. There is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. Laser vision correction has been around since 1992, yet longer-term effects are unknown and that unforeseen complications or side effects could possibly occur. Since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete. The details of the treatment known as PRK/LASEK have been presented to me in detail in this document and explained to me.

ADDENDUM: USE OF MITOMYCIN-C (MMC) DURING LASEK/PRK TREATMENT

Excimer laser treatment is associated with a chance of developing corneal scarring or “haze.” This haze may develop years after the original procedure and can result in decreased vision. Laser vision correction has been associated with corneal haze in some patients. Since 1997, a medication called Mitomycin-C (MMC) has been used to treat corneal haze. Studies have shown that the use of MMC decreases the likelihood of developing haze after treatment. For this reason, MMC is used as a preventive measure during laser vision correction. MMC is most used during PRK/LASEK laser vision correction.

Although your planned treatment may not indicate the use of MMC it is possible that conditions arise during treatment requiring a change to LASEK/PRK requiring the use of MMC (*Review: Treatment Change Addendum*). It is important you review and consent to the use of MMC even if your planned treatment does not indicate its use. Different types of laser vision correction, (LASIK or SMILE) do not use MMC.

MMC is an antitumor antibiotic medication that has been used in the medical field for several decades. It is primarily used as an anti-cancer drug as it stops the 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. The use of MMC for the prevention of corneal haze during laser vision correction is a newer use of this medication. During treatment, a low dose of MMC is delivered to the eye by placing a small sponge on the eye for approximately 30 seconds. This technique minimizes but does not eliminate the chance of developing MMC-related complications as outlined below.

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, iritis, scleral calcification, scleral melt, conjunctival irritation (redness of the eye), photophobia (sensitivity to light), and pain. Although the complications listed have been seen in various types of eye surgeries, complications using the low-dose technique for corneal haze prevention in refractive surgery are rare. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

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 administering MMC for treatment and prevention of corneal haze is considered an off-label use of an FDA-approved medication. 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 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.

ADDENDUM: HYPEROPIC (FARSIGHTED) TREATMENT

Hyperopic, or farsighted, treatments are complex in nature. A farsighted patient will need glasses to see close objects clearly. The amount your vision may shift (or regress) after treatment varies from patient to patient. Hyperopic patients will experience some regression or fluctuations in vision during approximately the first six months following treatment. This is normal and expected. The amount of fluctuation will vary for everyone in part due to their unique biology. Patients with larger amounts of astigmatism will experience greater fluctuations in vision after treatment, this is normal and expected.

Treatment parameters for hyperopic patients are selected based on historical clinical data and your surgeon’s clinical expertise. Even with this data there is no clinical method to determine the amount of regression (or change) that may occur after treatment. This may result in either an under-correction or over-correction that may require the use of corrective lenses or additional treatments to correct.

ADDENDUM: WAVEFRONT GUIDED (CUSTOMVUE) TREATMENT

Wavefront guided treatment is a specific type of laser vision correction that uses an imaging system known as a wavefront aberrometer to guide the laser to provide a more precise treatment profile. A wavefront aberrometer can detect subtle imperfections in a patient’s

vision that contribute to imperfect focusing of an image. These imperfections are known as higher-order-aberrations. A wavefront guided treatment, is commonly called CustomVue treatment, aims to address these imperfections by guiding the laser to correct higher-order-aberrations using the data captured from the wavefront aberrometer.

Data suggests that wavefront-guided treatments a higher percentage of patients achieve better vision, and a lower percentage have complaints, even at night. There is no guarantee that you will achieve these results, and the benefits of a wavefront guided treatment may be intangible as it cannot always be measured accurately. A wavefront guided treatment will remove more tissue from the eye when compared to a conventional (or non-wavefront) treatment, which may result in an increased chance of complications.

ADDENDUM: OFF-LABEL TREATMENT

When a drug, device, or procedure is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a label to explain its use. Once 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. This type of use is known as off-label use. The short- and long-term risks either now, or in the future, have not been studied by the FDA. The following sections describe off-label laser vision correction. I understand that having an off-label treatment poses additional short and long-term risks, now, or in the future that have not been studied by the FDA, nevertheless, I consent to treatment considered FDA off-label.

MYOPIA, HYPEROPIA, OR ASTIGMATISM GREATER THAN FDA INDICATION

Treatment amount may exceed the parameters indicated by the FDA. FDA approval for laser vision correction were based upon specific treatment constraints related to the amount of correction clinical trial participants. Treatment levels outside this range are considered off label and the short- and long-term risks, either now, or in the future have not been studied by the FDA.

Laser Name	FDA Indication
MEL80	Myopia: -7.00 D; Hyperopia: +5.00 D; Astigmatism: +3.00 D
STAR S4	Myopia: -11.00 D; Hyperopia: +4.00 D; Astigmatism: +3.50 D

LASEK/PRK (EPITHELIAL LASIK): USING WAVEFRONT GUIDED (CUSTOMVUE) LASER TREATMENT

The use of wavefront guided laser treatment during LASEK is considered off-label. The short- and long-term risks either now, or in the future, have not been studied by the FDA. *(Review: Addendum Wavefront Guided CustomVue Treatment)*

LASEK/PRK: USE OF MITOMYCIN-C (MMC) DURING TREATMENT

The use of mitomycin-c (MMC) during LASEK treatment is considered off-label. The short- and long-term risks either now, or in the future have not been studied by the FDA. *(Review: Addendum Use Of Mitomycin-C (MMC) During LASEK/PRK Treatment)*

ADDENDUM: CHANGE FROM PLANNED TREATMENT

During your laser vision correction treatment conditions may occur during which the surgeon may need to change either the specific treatment being performed (such as LASIK to LASEK), or the laser being utilized (Such as MEL80 to STAR S4). Because you will be given a sedative prior to treatment you will be unable to make an informed decision and must consent in advance to allow the surgeon to continue treatment. Typically, but not always, the surgeon will discuss any of these conditions and the proposed plan of treatment. These decisions will be made in the surgeon’s professional opinion in an attempt to result in a successful treatment. A change of procedure may pose different and additional risks or complications, in addition to the risks and complications of the originally planned procedure.

Some examples include loss of vacuum pressure during LASIK, patient’s inability to focus on a laser’s fixation light, or inability to complete LASIK or SMILE requiring a change to PRK/LASEK. While not common these types of conditions are considered routine. Because a change in treatment method may pose a different set of risks, side effects, or complications; it is important that you read, understand, and consent to all parts of this informed consent document; including treatment methods that may not apply to your planned treatment.

LASER VISION CORRECTION FINANCIAL AGREEMENT**FOLLOW UP CARE, TRAUMA, AND NON-COVERED SERVICES**

Laser vision correction includes a follow-up period of two-years from treatment date. During this time, any visits directly related to treatment, most typically post-operative check-ups, are included at no charge. As much as you try to avoid eye injury, it may occur. If you experience eye trauma, during, or after your post-op period, it is important to schedule an exam immediately to ensure your eyes are healthy. Exams related to eye trauma are not included in your treatment fee. During your post-operative care we may encounter pathology (eye disease) not related to your vision correction treatment. Examples of this include but are not limited to eye trauma, stye, or allergies. It is our obligation to inform and offer treatment or refer you to have appropriate treatment. Under most circumstances this treatment is billable to your medical insurance.

ANNUAL EYE EXAMS

After your included post-operative care period ends it is important to maintain annual eye exams (once per year) to ensure your treatment is stable and check the overall health of your eyes. Annual exams are billable and may be covered by insurance. If it is not practical to follow up at Laser Eye Institute, please inform us of your local ophthalmologist so we may transfer relevant medical records and properly coordinate your care with your local ophthalmologist.

INFORMATION REGARDING REFERRALS

Under some circumstances it may be necessary to refer you to an additional specialist that may be either related, or un-related to your procedure. There are many different parts of the eye and our facility specializes in only vision correction. Referrals are made at the discretion of your surgeon and you are under no obligation to see the specialist we recommend. Any treatment by an outside physician is not included in your vision correction fee, and we have no financial interest with any parties we refer to for additional care.

MEDICATIONS

Medications are required both before and after treatment. These medications reduce the chance of infection as well as promote rapid healing. It is important to follow medication instructions provided. Typically, these medications are covered by insurance, however you are responsible for any costs associated with these medications.

RETREATMENT AND ENHANCEMENT POLICY

After treatment you may result in an under- or over-correction, requiring additional treatment, while rare, this typically appears within the first three to six months following treatment. This differs from a shift or change in your vision due to aging or other biological factors, such as pregnancy. Eligibility for treatment of an under- or over-correction will be determined by your surgeon. Generally, you must wait at least three months between treatment to allow adequate healing, have stable vision, and your vision should be worse than 20/30 when measured. Retreatment involves the same risks as the original procedure. During your two-year post-operative period surgeon fees are waived for retreatments, however a facility fee to cover the costs of supplies may apply. If your original treatment did not include wavefront guided (CustomVue) treatment and a wavefront guided retreatment is required, an additional fee may apply. Changes or shifts in vision due to aging or other biological factors are not covered by this retreatment policy.

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 7 pages of this document have been given to me in its entirety. I have been given this document in advance of being asked to sign it.

All of my questions regarding treatment have been answered to my satisfaction allowing me to give my informed consent.

I have read, understand, and hereby consent to: *Monovision Reversal*

I understand that during the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion. These additional procedures may carry additional risks in addition to the risks outlined above.

I understand that no warranty or guarantee has been made to me regarding the result, cure, or safety.

I give my permission for Laser Eye Institute to videotape or photograph my procedure for purposes of documentation, education, research, or training. Additionally, I give my permission for Laser Eye Institute to use data about my treatment to advance the field of laser vision correction. I understand that my name, or any other personally identifiable information will remain confidential unless I give subsequent written permission for my identity to be disclosed.

MY SIGNATURE BELOW FURTHER CERTIFIES:

TO THE BEST OF MY KNOWLEDGE I AM NOT CURRENTLY PREGNANT.

I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT OR MY ABILITY TO UNDERSTAND THIS CONSENT.

I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT. ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S).

Patient Name	Patient MRN	Date

Patient Email Address	Surgical Coordinator

Patient Signature