

INFORMED CONSENT

LASER VISION CORRECTION SMILE

INTRODUCTION

This document is provided to obtain your informed consent for laser vision correction using a treatment method known as SMILE. It 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 FOR SMILE (SMALL INCISION LENTICULE EXTRACTION) FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS) AND ASTIGMATISM USING A FEMTOSECOND LASER.

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision about SMILE (small incision lenticule extraction) to reduce your nearsighted, or astigmatism. SMILE treatment involves three steps. First, a femtosecond laser creates a thin disk-shaped sliver of tissue slightly below the surface of the eye (called a lenticule). Second, the laser creates a small incision to allow the surgeon to remove the lenticule. Third, the surgeon removes the lenticule through the small incision, thereby correcting vision.

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 corneal crosslinking or a corneal transplant, 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.

The whites of my eyes may temporarily appear pink or red for several days to several weeks after surgery.

Vision after surgery will not be perfectly 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 under-correction or over-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.

The lenticule may be difficult to remove and may result in tissue damage. If additional treatment is needed after SMILE it may only be possible to perform a LASEK/PRK retreatment.

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 SMILE have been presented to me in detail in this document and explained to me.

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: BILATERAL SIMULTANEOUS TREATMENT

During laser vision correction many patients chose to have both eyes treated at the same time. The benefits to having both eyes treated at the same time include: lower cost, increased convenience, faster overall recovery, less post-operative visits. There are risks associated with simultaneous treatment that are not present when eyes are treated on different days. If you chose to have treatment on both eyes at the same time you should understand the additional risks outlined below:

During laser vision correction many patients chose to have both eyes treated at the same time, however, there are risks associated with simultaneous treatment that are not present when eyes are treated on different days. If you chose to have treatment on both eyes at the same time you should understand the additional risks outlined below:

The risk of infection, severe inflammation, clouding of the cornea, corneal scarring, or internal bleeding, are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should these complications occur you could experience significant loss of vision or blindness. By choosing to have both eyes treated at the same time, the risk of having any of these complications, in both eyes, is increased.

The risk of an under-correction or over-correction in both eyes, requiring additional treatment or the use of glasses or contact lenses is increased. Having each eye treated on different days allows your surgeon to monitor the healing process in one eye and make the appropriate modifications to the treatment plan for the other eye. By correcting both eyes simultaneously there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Most patients experience rapid visual recovery, but some may experience symptoms such as blurred vision, night glare, or ghost images that can result in prolonged recovery of normal vision. This may continue for several weeks, which could make daily tasks difficult or dangerous. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the other eye while the first eye fully recovers.

Both eyes tend to experience similar side effects. If you experience undesirable side effects in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the procedure has produced satisfactory visual results without loss of vision or other undesirable side effects. If you have presbyopia (use reading glasses), you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision to fully correct your other eye to maintain some amount of close vision without the need for glasses (known as a monovision treatment).

There may be additional risks, benefits, or complications that can result from a bilateral simultaneous (both eyes) treatment. I understand these risks and wish to have both of my eyes treated at the same time if my surgeon determines that treatment in the first eye appeared to be technically satisfactory.

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)*

SMILE OR WAVEFRONT GUIDED (CUSTOMVUE) TREATMENT FOR PATIENTS UNDER THE AGE OF 21

Although the FDA has approved SMILE and wavefront guided (CustomVue) treatment for patients over the 18, clinical trials did not contain enough patients under the age of 21. Therefore, treatment of patients under the age of twenty-one (21) is considered off-label. The short- and long-term risks either now, or in the future have not been studied by the FDA.

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.

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 use of MMC it is possible that conditions arise during treatment requiring a change to LASEK/PRK which uses MMC (Review: Addendum Change From Planned Treatment). It is important you review and consent to use of MMC even if your planned treatment does not indicate use. Different types of laser vision correction, (LASIK, 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.

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 6 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: *SMILE*

I have read, understand, and hereby consent to addendums: *Bilateral Simultaneous Treatment, Hyperopic (Farsighted) Treatment, Wavefront Guided CustomVue Treatment, Change From Planned Treatment, Off-Label Treatment, Use Of Mitomycin-C (MMC) During LASEK/PRK Treatment*

I have read, understand, and hereby consent to *Laser Vision Correction Financial Agreement*. I understand that all or part of my procedure may not be covered by insurance and accept responsibility for all out-of-pocket expenses.

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