

INFORMED CONSENT

For the use of the Excimer Laser for LASIK (LASER IN-SITU KERATOMILEUSIS)

**Please read the following consent form very carefully. Please initial each page where indicated.
Do not sign this form unless you have read and understood each page.**

INTRODUCTION

It is our hope to fully inform you concerning the side effects, limitations and complications of LASIK surgery. This consent form in combination with the entire consultation process is designed to enhance your understanding of the potential for difficulties, which may be encountered during both the procedure and the healing process. It is not our intention to frighten or dissuade someone from pursuing LASIK surgery. The vast majority of patients will never encounter any serious complications and will be pleased with the visual 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 with surgery or be better prepared to deal with any unexpected complications or side effects. The only way in which a patient can avoid all surgical risks is by not proceeding with surgery.

BACKGROUND

The Excimer Laser is used to reshape the curvature of the eye in an effort to reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness). There are two ways the reshaping can be accomplished-on the corneal surface with PRK (Photorefractive Keratotomy) or beneath the corneal surface with LASIK. The surface of cells of the cornea are more reactive; in the PRK procedure, they may cause more pain for the first 1-3 days, and rarely infection or scarring. By going beneath the flap of tissue with the LASIK procedure, the risks associated with the reactivity of the surface cells are significantly reduced. However, the risks during surgery are greater with LASIK than with PRK alone. These intra-operative risks are associated with the device that creates the corneal flap known as a microkeratome.

The use of the automated microkeratome to treat myopia began in 1992 and is known as Automated Lamellar Keratoplasty (ALK). The combination of the use of ALK with Excimer Laser (LASIK) began in 1993.

With the LASIK technique, the microkeratome is used to create a very thin-hinged flap on the corneal surface. The microkeratome, a self-propelled instrument, is extremely fine and precise. It has delicate gears, which run within tracks of a suction ring. The corneal flap is approximately three hairs thick while the entire cornea is typically 11 hairs thick. A suction ring is placed on the eye, securing it for the microkeratome. When suction is applied, the vision will temporarily become dark gray. Patients cannot see or feel the incision. The suction ring is then removed, and the laser is focused on the eye. Most people state that they do not feel any pain, but rather pressure around the eye.

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The laser application is performed with the corneal bed instead of the corneal surface as with PRK. The laser application is associated with a clicking and snapping sound but no sensation is felt. The flap is hinged and replaced following the laser surgery. The flap is placed back into position through an almost immediate suction-type action with the cornea and by the protective layer of the cornea called the epithelial layer, which rapidly envelops the surface within days. In most cases no stitch is required. If a stitch is required, it is below the surface and usually removed in one day.

ALTERNATIVE TREATMENTS

Alternatives to LASIK include: no surgery, glasses, contact lenses, PRK alone and other refractive procedures such as radial keratotomy.

RECOVERY/RISKS

1. The risks of serious **infection** may be reduced from approximately 1 in 1000 with PRK to 1 in 5000 with LASIK, but it is not eliminated entirely.
2. The risk of moderate to severe post-operative pain for the first 1-3 days is reduced from approximately 1 in 10 with PRK to 1 in 50 with LASIK. It is common to feel as if an eyelash is in the eye and be light sensitive. The eye may be red or swollen and may tear. These symptoms usually last only a few days.
3. The risk of **scar tissue** or **corneal haze** is reduced approximately five to ten fold with LASIK compared to PRK. The risk of scar formation with current PRK is probably 1-2%, increasing in incidence with the degree of attempted correction. Scar tissue alone could develop on the surface of the eye with PRK and beneath the corneal flap with LASIK. Usually the haze effect would make you feel like you were looking through a dirty windshield.
4. **Night Glare** is common in nearsighted individuals even before any refractive procedure is performed, but increases almost immediately in the healing process. It is more common when only one eye has been treated. Typically, six months after both eyes have been treated, only 2% of patients will experience significant night glare that interferes with their night driving. Severe night glare can reduce vision in all reduced lighting conditions producing blurriness, ghosting or haloes. Patients with large pupils and severe myopia are at greater risk for night glare. Glare risks are similar for PRK and LASIK.
5. Almost all patients experience blurriness immediately following surgery. Some blurriness is common. With LASIK there is considerable improvement in vision within the first 24 to 48 hours. Approximately 80% of the visual recovery occurs within the first several days, with the last 20% of vision improving over 3 to 6 months. Patients experience a noticeable improvement of their vision within days, and then notice that the fine-tuning or sharpness of vision takes several weeks.

In PRK, vision is very blurred, like looking through glasses smeared with grease for at least 3 days and sometimes several weeks. Usually vision is very good with a small blur, within 1-2 weeks. By one month, vision with PRK or LASIK is usually the same.

In 98-99% of patients, remaining blur, if any, is resolved over 6 to 8 months. However, approximately 1-2% of patients, independent of the procedure performed, will develop corneal irregularities reducing the sharpness, crispness and clarity of their vision even with glasses. In these rare instances, contacts may be used or another surgery may be attempted to restore their vision, but permanent blurriness may persist. There is no way to predict or predetermine which patients will be in the 1-2% who will have some degree of permanent blurriness.

6. Corneal Flap Complications: The corneal flap portion of the LASIK procedure, performed with the microkeratome, takes approximately 2 seconds. There is a 1% risk that the eye will experience a complication during this part of the surgery. The corneal flap may be too thin or short, which may result in postponement of the laser procedure for three months or temporary blurred vision. Another potential flap complication is a free flap, which may increase the potential for a prolonged visual recovery, blurred vision, and epithelial in-growth (discussed later). The most dangerous complication is the incision is too deep, which would result in perforation of the eye. This is exceedingly rare. To decrease the risk of this serious complication, a plate in the microkeratome is present as a safeguard. The plate and microkeratome assembly is checked before each and every procedure and the unit is tested for proper functioning.

If your surgeon determines at the time of surgery that the shape of your eye and socket makes the microkeratome process less likely to succeed, he or she will change the treatment plan from LASIK to PRK. In signing this consent, you agree to fully grant this discretion to your surgeon.

7. Epithelial In-growth: During the first 24 hours the epithelial protective layer grows over the corneal flap. There is a 1-2% risk that epithelial cells may grow underneath the flap. Treatment involves lifting the flap and removing the cells. Un-treated epithelial in-growth may distort vision and may damage the flap if severe and progressive. Small in-growths do not usually present any visual problems and need only to be monitored. In rare cases, the epithelial in-growth returns and causes permanent vision impairment.

Other complications

You should recognize that any surgical procedure presents potential risks and that it is possible that this surgery may make your vision worse.

Additional risks associated with LASIK include corneal perforations, corneal scarring, cataract formation, intra-ocular infection, over-correction of vision, under-correction of vision and glare. You should understand that this list of complications might be incomplete and that because LASIK is a relatively new procedure, there may be risks associated with this surgery that are currently unknown.

LASIK carries a higher risk of intra-operative complications than PRK, but a lower risk of post-operative complications including pain, infection and scarring.

EXPECTATIONS

The goal of LASIK is to achieve the best visual result with the safest method while dramatically reducing one’s dependency on glasses or contacts. Night driving glasses and reading glasses may always be needed.

The degree of correction required determines both the rate of recovery and the initial accuracy of the procedure. Severe degrees of nearsightedness may require two procedures. Patient’s differences in healing can also greatly affect visual recovery and final visual outcome and are impossible to predict.

After the initial procedure and even if further procedures are performed, you may have some remaining nearsightedness, farsightedness, or astigmatism. If so, glasses and/or contact lenses may still be needed, some or all the time.

Even 90% clarity of vision is 10% blurry. Subsequent enhancement surgeries can be performed when vision becomes stable UNLESS unwise or unsafe, but success can never be guaranteed 100%. Typically, if greater than 1.0 diopters of nearsightedness or vision worse than 20/40 persists, an enhancement procedure may be performed. But, generally this is performed no sooner than 3 months.

Enhancement surgery may consist of creating another flap with the microkeratome, lifting the original flap with specialized techniques or performing Astigmatic Keratotomy incisions. Another alternative is to perform PRK over the LASIK flap. If there is inadequate tissue remaining after the original procedure, it may not be possible to perform an enhancement with the laser. An assessment and consultation will be held with the surgeon to discuss the benefits and risks of any enhancement surgery.

FUTURE COMPLICATIONS

You should be aware that there are other complications that could occur that have not been reported before the creation of this consent form as LASIK surgery has been performed only since early 1990’s and longer-term results may reveal additional risks and complications.

VOLUNTARY CONSENT

In signing this Informed Consent Form, I certify that I have read the preceding information and understand the contents. The potential advantages and disadvantages have been review with me during the educational consultation. Any questions I have concerning this consent form have been fully answered. I fully understand the possible risks, complications and benefits that can result from LASIK. My decision to proceed with LASIK has been voluntarily and freely given.

Patient Name (Signature)

Date:

Patient Name (Printed)

Date:

Witness Name (Signature)

Date:

Surgeon Name (Signature)

Date:

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