METROPOLITAN EYE CENTER

586-774-0393
www.metropolitaneyecenter.com

Refractive Surgery Informed Consent

The results of your comprehensive eye evaluation indicate that you are a candidate for refractive surgery. A great deal of information has been made available to you during your evaluation and discussions, as well as the opportunity to review printed materials and instructional videos. Our presentation of the benefits, as well as the risks and potential complications of refractive surgery, is designed to improve your understanding of the benefits, as well as the medical limitations of refractive surgery, and to initiate an open channel of communication between you and your eye doctor.

Certain terms or phrases have been used to describe your pre-procedure and post-procedure vision condition. These include the following:

- **Refractive error** — The specific power of a glass or contact lens prescription necessary to correct vision to the best possible level;
- **Best-corrected vision** — The very best vision recorded with glasses or contact lenses; not necessarily normal vision;
- **Uncorrected vision** — Vision recorded without glasses or contact lenses;
- **Normal vision** — Vision recorded as 20/40 or better and not necessarily perfect vision — vision good enough to pass a driver's license examination. People with normal vision most often require glasses to actually obtain best possible vision, although they find them unnecessary for most or all daily activities;
- **Perfect vision** — Vision recorded as 20/20 or better.

The condition and lens power of your refractive error and the fact that glasses and contact lenses are the most common method of correction for hyperopia, myopia and astigmatism have been explained to you. Glasses or contact lenses are acceptable and functional alternatives to refractive surgery for the correction of these vision abnormalities.

Refractive surgery is continually evolving and future refractive procedures may be available as an alternative to PRK, LASIK or LASEK. Be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies. Also, refractive surgery will create a permanent change in the shape of the cornea that is **not** reversible.

Refractive surgery is elective surgery. Your decision whether or not to have surgery of this type and at this time should be based on the information presented, conversations with other refractive patients, your own research and an understanding of the benefits, as well as the risks and potential complications.

It is important that you provide a complete and detailed medical and eye-care history. All decisions about the method of treatment, amount of correction needed or attainable, or whether refractive surgery is recommended at all will depend upon this information. Certain patients are not good surgery candidates because they may not achieve satisfactory results. For example, people with unstable or uncontrolled diabetes; keratoconus, a steepening of the cornea; progressive myopia; amblyopia, or lazy eye; or glaucoma. In addition, people who form keloid scars or have uncontrolled systemic vascular disease may not heal properly or predictably after procedures such as refractive surgery.

Patients who are pregnant or who have recently given birth and are nursing are

advised to consider postponing their surgery for several weeks following delivery or ceasing to nurse. This policy avoids unpredictable vision results due to fluctuations in vision during pregnancy, or potential harm to the unborn or recently born and nursing infant by medications that may be used.

At this time, PRK, LASIK and LASEK (methods using laser to correct vision) are the refractive surgery alternatives we recommend.

- **PRK** (Photorefractive Keratectomy, also known as laser vision correction): Computer-controlled excimer laser light energy is used to smoothly sculpt and alter the curvature of the corneal surface, changing the refractive power and improving uncorrected vision. PRK involves no knives or incisions.
- **LASIK** (A combination of IntraLase, or Automated Lamellar Keratectomy — ALK, — and PRK): In this technique, a flap or "cap" from the surface layer of the cornea is created and elevated, laser energy is applied directly to the middle layers of the cornea and the flap then repositioned over the reshaped cornea. The alterations to the corneal surface change the refractive power and improve uncorrected vision.
- **LASEK** Rather than cutting a flap, the very superficial surface tissue, the epithelium, is gently slid back from the center of the cornea and that center area is then treated with the laser as in PRK. Following treatment, this surface epithelium is then slid back over the cornea and a contact lens "bandage" is used until healed. Good for treatment to thinner corneas.

All of these treatment techniques will create a significant change in the refractive power of the cornea and improve uncorrected vision. No procedure is necessarily better than another but each is unique in its preparation for the laser application. Today, LASIK is the most often used procedure.

In all cases, surgery is performed without an injection, using only topical anesthetic eye drops for comfort. It is not necessary to administer a sedative (such as Valium) to achieve a painless and successful procedure.

Sometimes, a post-procedure bandage soft contact lens may be required for protection and added comfort. If such a contact lens is necessary, it can be worn continuously, even while you sleep, and will probably be removed at an early post-operative visit when the corneal surface layer — the epithelium — has healed satisfactorily — usually in one to four days.

Refractive surgery will not prevent the development of naturally occurring eye problems, such as glaucoma, cataract, retinal degeneration or detachment, or presbyopia (the need for reading glasses.)

The inability to read without glasses occurs naturally in people about 40 years of age. Refractive surgery normally corrects only distance vision abnormalities and will not routinely correct for the reading problems of presbyopia. However, vision correction treatment can be modified to leave, or make, one eye myopic (undercorrected, or nearsighted) creating monovision to forestall the need for reading glasses. With monovision (using one eye for distance and one eye for near), vision for distance or near is less than perfect but, in combination, provides a compromise that pleases many patients who elect this alternative treatment.

Post-procedure follow-up care will necessarily include several visits with either your surgeon or your referring optometrist and the routine depends on the type of treatment you have undergone.

Antibiotic and anti-inflammatory (steroid) eye medications will be prescribed and their precise dose schedule **must** be followed to assure best possible visual results. Typically, antibiotic eye drops are used for the first few days following the procedure. Steroid drops required initially *may* be required for several additional weeks post-treatment to regulate the healing response when PRK or LASEK has been performed.

The typical schedule for return visits is Day 1, 2-4 weeks, Month 3, Month 6 and one

year after treatment. More frequent visits may be required for patients requiring a bandage contact lens, those who have an abnormal healing response or those who require a retreatment. Thereafter, yearly examinations are recommended. If the patient follows these recommendations, we offer an unlimited time frame should an enhancement be considered appropriate.

Risks and other considerations

Refractive surgery, as with all other types of eye surgery, is **NOT risk free**. It is not possible to discuss all potential risks and complications involved, as some may even be unknown at this time.

The following list includes the most likely risks, discomforts or inconvenience that might be encountered with refractive surgery:

1. Loss of best-corrected visual acuity. Refractive surgery may result in making your vision worse. Some patients have lost one to three lines of visual acuity on the eye chart in comparison to their pre-procedure best corrected vision.

   This vision loss most commonly occurs as the result of microscopic corneal surface irregularities; decentration of the treatment zone as a result of significant eye movement or loss of fixation during the treatment (small amounts of eye movement will not affect the outcome); infection that could not be controlled with antibiotics or other means; or by the development of severe haze or scarring in the optical zone.

   It might be necessary to wear glasses or contact lenses after treatment to achieve best vision and possibly this may not restore full vision.

2. Discomfort. Mild discomfort or irritation is usual for several days following treatment. Although individual patient reactions range from none to moderate discomfort, most patients describe their discomfort as the sensation of having sand or an eyelash in their eye.

3. Blurry Vision. After treatment, vision can range from quite clear to blurry. Vision improves steadily as the eye heals. However, vision can remain blurry after a number of weeks, depending on the individual circumstance. For most patients, stable vision is achieved within three to four months, but can take six months or longer in extreme cases.

4. Corneal haze. When corneal haze occurs, it is most often associated with the PRK or LASEK procedure and is usually not visually significant and only detectable with a special microscope. The haze is first noticed after 1 or 2 months following treatment and then gradually subsides during the next 6 to 12 months with little or no long-term effect on vision. If haze develops there may be extended use of anti-inflammatory medication. Very few patients experience excessive haze or scarring. Retreatment or enhancement generally corrects this problem.

5. Halo and glare. Some patients experience a halo effect, particularly noticeable in dim light which may interfere with night driving. Unusual glare sensitivity may also be noticed, most often disappearing within a few weeks after treatment.

6. Starbursts and double vision. Starburst-like images around lights, image size differences and double vision may occur, which may adversely affect the ability to drive and judge distances comfortably.

7. Vision fluctuation. Early on, patients may have variable or unstable vision from day to night or from day to day. Temporary glasses may seem necessary but are difficult to prescribe because of the variations in vision. Depending on the procedure, vision usually stabilizes within two to four months.

8. Increased eye pressure. Although glaucoma may not have been present prior to treatment, elevated intraocular pressure can occur in some patients who

use topical steroid eye drops. Typically, once treatment ceases, pressure returns to normal with no long-term ill effects.

However, if intraocular eye pressure is elevated on a long-term basis, permanent loss of vision can result. This is one of the important reasons that post-treatment progress **must** be monitored during the prescribed follow-up period.

9. Slow healing of the epithelium. The surface layer of the cornea — the epithelium — may be removed or disturbed during treatment and usually requires two to four days to heal.

   Occasionally, epithelial healing is slower than expected and, in such cases, the risk of increased discomfort and infection is greater. Such protracted healing may necessitate the prolonged use of a bandage contact lens and antibiotic eyedrops.

10. Under- or over-correction. Patients may under- or over-react to the refractive treatment, creating residual myopia (nearsightedness) or hyperopia (farsightedness). The goal of surgery is to achieve 20/40 or better uncorrected vision and more than 90 percent of patients achieve that goal. There is no guarantee in refractive surgery that a patient will be successful in achieving the desired vision correction. In some, but not all, cases, significant under- or over-correction can be retreated (or enhanced). Retreatment may be delayed for six months or more, depending on individual circumstance.

11. Regression. Initial vision correction may diminish over several months after treatment, most commonly in patients who are very nearsighted or farsighted, or with high astigmatism. In most cases, retreatment helps to remedy the effect of regression.

12. Inconvenience between procedures. In the event that refractive treatment is performed on one eye at a time, the two eyes may not work well together in the interval between surgeries. This condition may hamper your ability to drive or work effectively.

    Usually, a temporary pair of glasses or the continued use of a contact lens in the unoperated eye adjusts for the difference in refraction between the eyes.

13. Dry Eye. For reasons that are, at this time, not easy to explain, some patients experience a period of relative dryness and require frequent use of artificial tear lubrication. For most patients, this dry condition subsides, like most of the other discomforts and inconveniences, within the first several months after the procedure. However, for an occasional patient, the problem of dryness persists for prolonged periods and treatment may extend to temporary or permanent tear duct plugs to help retain natural tears to combat dryness.

14. Other risks. Unforeseen complications, such as corneal ulcer formation, endothelial cell loss, epithelial healing defects, corneal thinning or scarring causing irregular corneal astigmatism which may not be correctable, ptosis (droopy eye lid), corneal swelling, retinal detachment or hemorrhage are all possible. Complications could also arise requiring further corrective procedures, including either a partial or full-thickness corneal transplant using a donor cornea. These might include loss of, or damage to the corneal flap or flap decentration occurring during LASIK surgery, or severe corneal scarring. Sutures may also be required which could induce significant astigmatism. It is possible that the microkeratome or the excimer laser could malfunction and the procedure would be interrupted as a result. Unanticipated adverse reactions to medications could also occur.

15. Future complications. *Because it is impossible to state all potential risks of any surgery, this discussion is incomplete.* Refractive surgery began with RK in the

United States in the late 1970s and Laser Vision Correction since the late 1980s. Longer term results may reveal additional risks and complications not experienced thus far.

Possible benefits

In most cases, refractive surgery results in a comfortable reduced dependence on eyeglasses and contact lenses. In 90 percent of patients who undergo these procedures, 20/40 vision or better is achieved — enough to pass your driver's license exam without glasses. There often are psychological benefits for patients who feel that they look better, participate in sports or leisure activities more proficiently, or simply function better without glasses or contact lenses.

Consent to Refractive Surgery

In giving my permission for surgery, I declare the following:

1. I have read this Consent Form.
2. I have discussed treatment with my doctor and have been given ample opportunity to ask questions, all of which have been answered to my satisfaction. I understand how the refractive surgery procedure is performed and many of the risks and complications that are associated with this treatment.
3. I understand refractive surgery is an elective procedure and that there is no health or medical reason why I need to have the procedure performed.
4. I understand that there are alternatives to refractive surgery, including eye glasses and contact lenses, to achieve good vision.
5. I understand refractive surgery is not risk-free and that no guarantee of a specific visual result or complete freedom from glasses has been offered. It is possible to incur complications, such as corneal vascularization or corneal ulcer formation, epithelial healing defects, endothelial cell loss, corneal thinning, irregular or lack of permanent corneal curvature change, double vision, endophthalmitis (infection inside the eye), blindness and even loss of the eye, as well as other unforeseen complications.
6. I understand that enhancement or retreatment may be necessary to achieve the desired surgical result and there is no guarantee that retreatment will be successful or that the desired change in refractive error can be obtained, even though a considerable improvement in uncorrected vision may have occurred.
7. I understand it is important for me to follow the instructions from my eye doctor and attend the regular follow-up visits.
8. My decision to undergo refractive surgery has been my own. I understand that if at any time prior to my procedure, I decide that I do not want to go forward with surgery, I may withdraw my consent and this choice will not affect the commitment of my eye doctor to continue to provide me with care.
9. I authorize the eye doctors involved in performing my refractive surgery procedure and in providing my pre- and post-procedure care to share with one another any relevant medical information relating to my health, vision or treatment.
10. I understand that any recordings of, or information gathered about my surgical treatment and my pre- and post-procedure care or condition may be released to physicians and others with a "need-to-know" in studying refractive surgery. My medical records and/or recordings may be published in journals or presented at professional, scientific, educational, promotional or similar meetings, so long as my name is not revealed.

11. I understand that, prior to surgery, hard or gas-permeable contact lenses are not to be worn for three weeks; soft contact lenses must not be worn for three days to one week.
12. Testing for HIV and/or HBV may be required if any health professional or employee sustains a percutaneous, mucous membrane or open wound exposure to my blood or other body fluids.
13. When applicable, I must inform my doctor of the possibility that I may be, or am pregnant, or that I have recently given birth, so that the procedure can be rescheduled, if necessary.
14. I understand that refractive surgery may not be covered by insurance. If insurance coverage changes or there is no insurance coverage, I accept full personal financial responsibility for payment of all fees related to my refractive surgery procedure, including the procedure itself, necessary medications, eyeglasses or contact lenses required after treatment, and expenses connected with my travel to and from the surgery site or office.

— — — — — — — — — — — — — — — — — — — —

To assure that I understand the information presented to me, the following statement has been handwritten by me:

"I understand the information presented and am willing to accept the fact that I may need glasses, contact lenses or further surgery following my refractive surgery treatment to achieve my best possible level of vision."

_____

_____

_____

_____

_____

In signing this form, I am stating that I have read this consent and, although it contains medical terms which I may not completely understand, I have had the opportunity to ask questions and had them answered to my satisfaction.

I am making an informed decision in giving my permission to have _____ _____ surgery performed on my ❑ right ❑ left ❑ both eye(s).

I have elected to have my ❑ right ❑ left eye specially-corrected in an attempt to create monovision which may forestall my need for reading glasses. ❑ Yes ❑ No

Patient name: _____

Patient signature: _____ Date _____

Witness signature: _____ Date _____

Surgeon signature: _____ Date _____