

Informed Consent For Refractive Lens Exchange (RLE) For the Correction of Hyperopia (Farsightedness) Or Myopia (Nearsightedness)

INTRODUCTION

This surgery, called a refractive lens exchange or RLE, involves the removal of the clear lens of your eye, even though there is no cataract. In some cases, the lens may have an early cataract which does not significantly interfere with corrected vision, and which would normally not require surgical removal. The eye surgeon, known as an ophthalmologist, surgically removes the natural lens of the eye and replaces it with an intraocular lens implant (IOL) in order to restore vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye.

BENEFITS OF RLE SURGERY

Benefits include better vision than you presently have without glasses. The farsighted (hyperopic) eye is out of focus because the length of the eye is too short for the curvature of the outer lens of the eye (cornea), which causes light rays to focus behind the retina. The nearsighted (myopic) eye is out of focus because the length of the eye is too long for the curvature of the outer lens of the eye (cornea), which causes light rays to focus in front of the retina. The light rays can theoretically be brought to a clearer focus on the retina by substituting an artificial IOL that has the proper power, thereby improving the natural focus of the eye. Although this can theoretically improve your natural distance vision if the calculations are accurate, you will lose the natural focusing power of the eye (accommodation). As a result, you will need to have near vision restored. Surgical alternatives for near vision correction are discussed later in this document.

NON-SURGICAL ALTERNATIVES TO RLE

Non-surgical alternatives to refractive lens exchange are to continue to wear spectacle lenses or contact lenses. Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its focusing power for near vision.

Although there are essentially no risks to wearing glasses, the quality of vision with strong farsighted or nearsighted glasses is not normal because of an enlarged image and a slight decrease in peripheral vision caused by the thickness of the lenses.

Although contact lenses provide higher quality and more normal vision, they have a slight risk of complications, especially if they are worn overnight. The risks of contact lenses include infection, which can rarely cause loss of vision if the infection involves the cornea; allergies called (giant papillary conjunctivitis, or GPC) which can make wearing the lenses difficult; mild irritation; and discomfort. There is also evidence that some damage occurs to the important internal layer of cells that are responsible for keeping the cornea clear. This damage could cause harm if the contact lenses are worn for many years. Whether this damage will eventually lead to serious long-term complications such as corneal clouding is unknown.

SURGICAL ALTERNATIVES TO RLE, INCLUDING LASER

I have read and understood this page. Patient's initials _____ Page 1 of 7

There are several other procedures for the correction of farsightedness and nearsightedness. The advantage of the procedures described below is that you retain your natural focusing power and do not require an incision into the inside of your eye, which is needed for RLE surgery. You may choose not to have this surgery at all and either continue wearing your glasses or contact lenses, or you may elect to have one of the other procedures discussed in this section.

1. Conductive keratoplasty (CK) is capable of reshaping the cornea, but is only indicated for low degrees of hyperopia.
2. The excimer laser can be used to correct low to moderate amounts of hyperopia (generally +1 to +5 D or diopters) and low to higher amounts of myopia (generally -1 D to -12D) through either PRK (photorefractive keratectomy) or LASIK (laser in situ keratomileusis). LASIK is an operation which combines the creation of a flap with the microkeratome or a laser and the removal of tissue with the excimer laser. PRK involves removing the surface cells on the cornea (“epithelium”) and using the excimer laser to remove tissue from the exposed tissue on the corneal surface. Both procedures have been found to be quite successful and relatively safe for the correction of moderate and high myopia up to about -12.00 D. Above 12 diopters, LASIK and PRK are less accurate and cause a high incidence of complications involving the quality of vision, especially at night. Many surgeons have stopped performing either procedure for these extremely nearsighted eyes.
3. In phakic implant surgery, an artificial intraocular lens is surgically placed inside your eye. The lens is made from material similar to the type used for the intraocular lenses currently being implanted in the eye to correct vision after cataract or refractive lens exchange surgery. The difference between phakic implant surgery and other intraocular lens implants is that your natural lens is not removed during phakic implant surgery. The phakic lens is inserted in front of your natural lens.

EXAMINATIONS PRIOR TO SURGERY

If you agree to have the surgery, you will undergo a complete eye examination by your surgeon. This will include an examination to determine your glasses prescription (refraction), measurement of your vision with and without glasses (visual acuity), measurement of the pressures inside your eye (tonometry), measurement of the curvature of your cornea (keratometry), ultrasonic measurement of the length of your eye (axial length), intraocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated.

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, the method used to calculate the power of the IOL (Intraocular lens), is very accurate in the majority of patients, the final result may be different from what was planned. As the eye heals, the IOL can shift very slightly toward the front or the back of the eye. The amount of this shift is not the same in everyone, and it may cause different vision than predicted. Patients who are highly nearsighted or highly farsighted have the greatest risk of differences between planned and actual outcomes. Patients who have had LASIK or other refractive surgeries are especially difficult to measure precisely. If the eye’s visual power after surgery is considerably different than what was planned, surgical replacement of the IOL might be considered. It is usually possible to replace the IOL and improve the situation if done within several weeks.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER RLE

Patients who have RLE surgery may have, or will eventually develop, an age-related condition known

as presbyopia. Presbyopia is the reason that reading glasses become necessary, typically after age 40, even for people who have excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate (different prescription) reading glasses in order to see clearly at close range. There are several other options available to you to achieve distance and near vision after RLE surgery.

- **GLASSES** You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses, or have an IOL implanted for near vision and wear separate glasses for distance.
- **MONOVISION** The ophthalmologist could implant IOLs with two different powers, one eye for near vision, and the other eye for distance vision. This combination of a distance eye and a reading eye is called monovision, and enables you to read without glasses. It has been employed quite successfully in many contact lens and refractive surgery patients. Your surgeon will discuss and demonstrate this option.
- **MULTIFOCAL IOL** The ophthalmologist could implant a “multifocal” IOL. These IOLs, more recently approved by the Food and Drug Administration (FDA), provide distance vision AND restore some or all of the focusing (accommodating) ability of the eye. Depending upon the technological features of the IOLs, they may be described as “accommodating,” “apodized diffractive,” or “presbyopia-correcting.” All of these lenses are “multifocal,” meaning they correct for both distance vision and other ranges, such as near or intermediate.
- **NEARVISION CK** A refractive procedure called NearVision CK uses radiofrequency energy to reshape the cornea in order to improve near vision. This procedure is typically performed in one eye so that the fellow eye remains corrected for distance. This is, therefore, another form of monovision correction.

I choose to have near vision after TLE surgery provided by the following method: _____Initials
_____ReSTOR lens _____Monovision _____Near Vision CK _____Glasses

MORE INFORMATION ABOUT MONOVISION

For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for distance. Eye care professionals refer to this as binocular vision. Monovision can impair depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is typically recommended that this option be tried with contact lenses (which are removable) prior to contemplating monovision correction involving two IOLs.

Ocular dominance, and choosing the ‘distance’ eye correctly: Ocular dominance is analogous to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant or preferred eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a particular person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near. While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant (rather analogous to being ambidextrous), and, in rare circumstances, a person may actually prefer using the dominant eye for near viewing.

The methods for testing and determining ocular dominance are not always 100% accurate: there is

some subjective component in the measurement process, and different eye doctors may use slightly different methods of testing. It is critical to determine through the use of contact lenses which combination is best for each person (right eye for distance, left for near, or vice versa) prior to undertaking surgical implantation of two different-powered IOLs during RLE. You can imagine how uncomfortable it might be if monovision were to be rendered “the wrong way around.” It might be compared to a right-handed person suddenly having to write, shave, apply make-up, etc., with the left hand. Be sure you understand this and have discussed with your surgeon which eye should be corrected for distance, and which for near. If you have any doubts or uncertainty whatsoever, surgery should be delayed until a very solid comfort level is attained through use of monovision contact lenses. **Under no circumstances should you consider undertaking RLE surgery with monovision correction before you are convinced it will be right for you.** Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.

FDA STATUS OF IOLs IMPLANTED DURING RLE (Considered “Off-Label”)

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 device/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. All IOLs were approved for use in patients with cataracts. Their use in patients having refractive lens exchange is considered an “off-label” use of the IOL.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

Either the ophthalmologist or the anesthesiologist/nurse anesthetist will make your eye numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist or nurse anesthetist, or elect to have the surgery with only local anesthesia.

A tiny incision, or opening, is then made in the eye. This is generally a self-sealing incision but it may occasionally require closure with very fine stitches (sutures) which will gradually dissolve over time. The natural lens in your eye will then be removed by a type of surgery called phacoemulsification, which uses a vibrating probe to break the lens up into small pieces. These pieces are gently suctioned out of your eye through a small, hollow tube inserted through a small incision into your eye. After your natural lens is removed, the IOL is placed inside your eye. In rare cases if complications occur at the time of surgery, it may not be possible to implant the IOL you have chosen, or any IOL at all.

After the surgery, your eye will be examined the next day, and then at intervals determined by your surgeon. During the immediate recovery period, you will place drops in your eyes for about 2 to 4 weeks, depending on your individual rate of healing. If you have chosen monovision or a multifocal IOL to reduce your dependency on glasses or contacts, they may still be required either for further improvement in your distance vision, reading vision, or both. You should be able to resume your normal activities within 2 or 3 days, and your eye will usually be stable within 3 to 6 weeks, at which time glasses or contact lenses could be prescribed if needed.

RISKS OF REFRACTIVE LENS EXCHANGE SURGERY

The goal of RLE surgery is to correct your hyperopia (farsightedness) or myopia (nearsightedness). Depending upon the type of IOL chosen, the goal may also be to restore some or all of the near (and intermediate, depending upon the lens) focusing ability of your eye or to reduce your dependency upon glasses or contact lenses. RLE surgery is usually quite comfortable. Mild discomfort or light

sensitivity for the first 24 hours is typical, but severe pain would be extremely unusual and should be reported immediately to your surgeon.

Since this surgery is essentially the same as cataract surgery, the same risks apply. As a result of the surgery and local anesthesia injections around the eye, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and, in rare cases, death. Although all of these complications can occur, their incidence following RLE surgery is exceptionally low.

These risks of RLE include, but are not limited to:

1. Complications of removing the natural lens may include hemorrhage (bleeding); rupture of the capsule that supports the IOL; perforation of the eye; clouding of the outer lens of the eye (corneal edema), which can usually be corrected with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema), which usually improves with time; retained pieces of cataract in the eye, which may need to be removed surgically; infection; detachment of the retina, which is definitely an increased risk for highly nearsighted patients, but which can usually be repaired; uncomfortable or painful eye; droopy eyelid; increased astigmatism; glaucoma; and double vision. These and other complications may occur whether or not an IOL is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations. **Additional surgery may be required to treat these complications.**
2. Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and dislocation of the lens. Multifocal IOLs may increase the likelihood of these problems. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following RLE surgery.
3. Complications associated with local anesthesia injections around the eye include perforation of the eye, destruction of the optic nerve, interference with the circulation of the retina, droopy eyelid, respiratory depression, hypotension, heart problems, and, in extremely rare situations, brain damage or even death.
4. If a monofocal IOL is implanted, either distance or reading glasses or contacts will be needed after RLE for adequate vision.
5. Complications associated with monovision. Monovision may result in problems with impaired depth perception. Choosing the wrong eye for distance correction may result in feeling that things are the “wrong way around.” Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.
6. Complications associated with multifocal IOLs (corrects for both distance and near in the same eye). While a multifocal IOL can reduce dependency on glasses for distance and near, it might result in less sharp vision, which may become worse in dim light or fog. It may also cause some visual side effects such as rings or circles around lights at night. It may be difficult to distinguish an object from a dark background, which will be more noticeable in areas with less light. Driving at night may be affected. If you drive a considerable amount at night, or perform delicate, detailed, “up-close” work requiring closer focus than just reading, a monofocal lens in conjunction with eyeglasses may be a better choice for you. If complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a multifocal IOL.
7. If an IOL is implanted, it is done by a surgical method. It is intended that the small plastic, silicone, or acrylic IOL will be left in the eye permanently.
8. If there are complications at the time of surgery, the doctor may decide not to implant an IOL in

your eye even though you may have given prior permission to do so.

9. Other factors may affect the visual outcome of RLE surgery, including eye diseases such as glaucoma, diabetic retinopathy, and age-related macular degeneration; the power of the IOL; your individual healing ability; and, if certain IOLs are implanted, the function of the ciliary (focusing) muscles in your eyes.
10. The selection of the proper IOL, while based upon sophisticated equipment and computer formulas, is not an exact science. After your eye heals, its visual power may be different from what was predicted by preoperative testing. You may need to wear glasses or contact lenses after surgery to obtain your best vision. Additional surgeries such as IOL exchange, placement of an additional IOL, or refractive laser surgery may be needed if you are not satisfied with your vision after RLE.
11. The results of surgery cannot be guaranteed. If you chose a multifocal IOL, it is possible that not all of the near (and intermediate) focusing ability of your eye will be restored. Additional treatment and/or surgery may be necessary. Regardless of the IOL chosen, you may need laser surgery to correct clouding of vision. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.
12. If your ophthalmologist has informed you that you have a high degree of hyperopia (farsightedness) and/or that the axial length of your eye is short, your risk for a complication known as nanophthalmic choroidal effusion is increased. This complication could result in difficulties completing the surgery and implanting a lens, or even loss of the eye.
13. If your ophthalmologist has informed you that you have a high degree of myopia (nearsightedness) and/or that the axial length of your eye is long, your risk for a complication called a retinal detachment is increased. Retinal detachments can lead to vision loss or blindness. Most retinal detachments can be surgically repaired.
14. Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes (anisometropia). This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so you will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 3 to 4 weeks, once the first eye is stabilized.

FINANCIAL IMPLICATIONS OF RLE SURGERY

I understand that I am responsible for the cost of the surgery and the IOL, including the surgeon's fee, the anesthesiologist's fee, if any, and the surgical center's or hospital's fee. This is because health insurance does not pay for removal of the clear lens of the eye for the purposes of correcting natural vision or for removal of an early cataract that is not visually disabling.

I understand that I will be responsible for the costs of any surgery-related injuries. I also understand that no compensation is being offered to me in the event of an injury or complication. In the event of a complication for RLE, it might be possible that other surgery, eye drops, or even hospitalization may be required. Although some or even all of these costs may be covered by my health insurance policy, if they are not, I understand that I will be responsible for these costs as well.

If I need a second surgical procedure, such as replacement or repositioning of my IOL, I understand that although my surgeon will not charge me a surgical fee, there will be additional fees from the surgery center and from the anesthesiologist, if one is required.

Patient initials _____

PATIENT CONSENT

The basic procedures of RLE surgery, the reasons for the type of IOL chosen for me, and the advantages, disadvantages, risks, and possible complications of alternative treatments have been explained to me by my ophthalmologist. Monovision has been discussed with me and my ophthalmologist has either demonstrated it to me with glasses or contact lenses, or offered to do so. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction.

In signing this informed consent for RLE surgery and implantation of an IOL, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of RLE surgery and

- I have read this informed consent _____ (patient initials)
- The consent form was read to me by _____ (name).

CHOOSE ONE OF THESE OPTIONS AND CROSS OUT THE OTHER TWO

- **Monofocal IOL/Reading Glasses Option**

I wish to have a RLE operation with a monofocal (distance) IOL on my _____ (state "right" or "left" eye) and wear reading glasses for near.

- **Monovision with 2 IOLs Option**

I wish to have a RLE operation with two different-powered IOLs implanted to achieve monovision.

I wish to have my _____ (state "right" or "left") eye corrected for **distance** vision.

I wish to have my _____ (state "right" or "left") eye corrected for **near** vision.

- **Multifocal IOL Option**

I wish to have a RLE operation with a _____ multifocal IOL implant (state name of implant) on my _____ (state "right" or "left") eye.

Patient (or person authorized to sign for patient)

Date

Physician Signature

Date

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