



Leaders in Eye Care

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## **Informed Consent For Clear Lensectomy** **With Premium Lens Implant**

### **Introduction**

This surgery involves the removal of the clear lens of my eye, even though it is not a cataract. The natural lens will be replaced with an artificial implant called an intra-ocular lens in order to attempt to correct my farsightedness or nearsightedness and my presbyopia (the inability to read due to the aging process), so that my natural vision will be improved, thereby reducing my dependency on glasses or contact lenses. In some cases, the lens may have an early cataract which does not significantly interfere with vision, and which would normally not require surgical removal. I understand that the Premium Implants will allow me to do 90-95% of my activities without glasses, but glasses may be necessary for some activities.

### **Examinations Prior To Surgery**

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

### **Anesthesia, Procedure, and Postoperative Care**

If I decide to proceed with the surgery, I may undergo light sedation administered by an anesthesiologist while my eye is made numb by my surgeon with either drops or an injection (local anesthesia) OR, I may have the surgery with local anesthesia only, without sedation. The natural lens in my eye will then be removed by breaking it up into small pieces with an ultrasound instrument. These pieces are then gently suctioned out of my eye. This type of surgery is called phacoemulsification. After my natural lens is removed, the artificial lens of the power determined during my pre-operative examination will then be placed inside my eye. In rare cases, it may be necessary to implant two lenses. The incision required to perform this operation is at times self-sealing but it may require closure with very fine stitches (sutures). After the surgery, my eye will be examined the next day, then at one week, and at 3 to 4 weeks. During the immediate recovery period, I will place drops in my eyes for 4 weeks. I should be able to resume my normal activities within 2 or 3 days, and my eye will usually be stable within 3 to 6 weeks. A few patients (5-10%) will require Laser Vision Correction with LASIK or PRK to fine tune vision at 6 weeks post-op, this fee is included in your procedure. 50% of patients will eventually require a YAG laser to open the capsule behind the implant if it becomes cloudy weeks, months or even years post-op. The YAG procedure is a separate procedure with a separate fee that is not included. If you have medical insurance, this usually will cover this procedure. Once the capsule is open, it remains open permanently to allow for clear vision.

Patient's Initials \_\_\_\_\_

## **Informed Consent for Clear Lensectomy con't.-**

### **Benefits of Surgery**

Benefits to me will be clearer, more natural vision than I presently have. 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. Presbyopia is what everyone develops after the age of 40-45, where the lens in the eye does not change shape as well when we try to focus to read requiring reading glasses or bifocals. The light rays can theoretically be brought to a clearer focus on the retina by substituting an artificial lens that has the proper power, thereby improving the natural focus of the eye, for both my distance and near vision.

### **Risks**

This type of surgery itself is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual. Since this surgery is essentially the same as cataract surgery, the same risks apply. These risks include, but are not limited to:

1. Infection, which if serious can lead to complete loss of vision. This is rare and is why it is important to use antibiotic drops pre and post operatively.
2. Swelling in the central area of the retina (called cystoid macular edema).
3. Clouding of the outer lens of the eye (corneal edema) which can be corrected with a corneal transplant.
4. Detachment of the retina (an increased risk in highly near-sighted eyes) even though the retinal detachment can usually be repaired, it may limit vision or cause loss of vision.
5. Damage to the retina or nerve during the administration of the anesthesia if an injection is performed. These injections are not used routinely.
6. Increased astigmatism.
7. Inaccuracy of the intra-ocular lens power requiring exchange of implant or laser vision correction.
8. Decentration of the intra-ocular lens, which may provide unwanted images and increased glare.
9. Development of increased pressure in the eye (glaucoma).
10. Hemorrhage (bleeding), double vision, and drooping of lid may also occur.

Although all of these complications can occur, their incidence following cataract surgery is exceptionally low.

### **Disadvantages of Surgery**

1. While most patients can perform 90-95% of their daily activities without glasses, we cannot guarantee complete spectacle freedom after surgery.
2. Since only one eye will undergo surgery at a time, the patient will 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 the patient will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance and near vision. In the absence of complications, surgery in the second eye can usually be accomplished within 1 to 2 weeks, once the first eye is stabilized.
3. In the FDA Study, 5% of patients 6 months post op will have significant halo and glare effect off of light sources usually with night driving. It is impossible to predict which patient will or will not experience halos and glare. The halos and glare will diminish with time but may not completely disappear. Some patients experience a period of adaptation to their vision after the surgery. Patients report mildly blurred or distorted vision that improves with time. This is considered normal post-operative recovery. Most of the patients in the FDA Study said they would have the same implant used if they were to have the surgery again.

**In giving your permission for a premium lens implant, it is very important that you understand the following information:**

1. Following surgery with implantation of an intraocular lens approximately 50% of all patients experience a 'clouding' of the posterior capsule (the membrane inside the eye that holds the intraocular lens in place). This 'clouding' results in a decrease in vision and can occur within months or years after the surgery. This is a naturally occurring condition in some patients and not the result of the surgery, the post-op care or anything done or not done by the patient or the doctor. This condition is resolved by the use of a YAG laser in a painless procedure performed on an outpatient basis. This condition and treatment is not part of, or included with, the surgery but is easily remedied with a short laser procedure. Your premium lens fee does not include the YAG laser procedure. The YAG laser procedure is not the LASIK procedure and involves separate fees. If you have medical insurance, this procedure is usually a covered expense but may require a deductible or copay. Should you experience a decrease in vision following your surgery, please consult your doctor.

Patient's Initials \_\_\_\_\_

Informed Consent for Clear Lensectomy con't.-

2. *Complications of surgery in general:*

As with all types of surgery, there is the possibility of other complications due to anesthesia, drug reactions or other factors that may involve other parts of your body, including a possibility of brain damage or even death. Since it is impossible to state every complication that may occur as a result of surgery, the list of complications included in this form is incomplete.

3. Following the implantation of the clear lens, a prescription for spectacles or contact lenses is occasionally necessary. The prescription may include a spectacle or contact lens correction for your near vision and for your distance vision. In some cases, a distance correction will not be necessary but we cannot predict nor guarantee, in any fashion, that you will not need glasses (for near or distance vision) following surgery. Fees generated by the purchase of glasses and/or contact lenses are not included in your clear lens implantation fee.
4. Following your surgical procedure, several examinations will be necessary to monitor the health of your eyes and the healing process. We may suggest to patients that they return to their optometrist or to an optometrist affiliated with our clinic at some point during this process for appropriate post-operative examinations. We are fully confident in the post-operative care delivered by optometrists affiliated with our office and believe this to be very convenient for most patients. We have full confidence in the clinical competence of your optometrist and monitor this competence on an on-going basis. Post-procedure exams are recommended for one day, one week, 3 weeks and four months following your procedure. Any unacceptable risks or complications during your surgery may result in modifications to our recommended post-operative care. Although we recommended the care provided by our affiliated doctors, should you wish to receive your post-operative care at our office we will be happy to accommodate your request.

## **Patient Statement**

**The basic procedures of clear lensectomy, the advantages and disadvantages, risks and possible complications and alternative treatments have been explained to me by my doctor. Although it is impossible for my doctor to inform me of every possible complication that may occur, the doctor has answered all of my questions to my satisfaction.**

## **NON-SURGICAL ALTERNATIVES**

Non-surgical alternatives to clear lens extraction are to continue to wear spectacle lenses or contact lenses. 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 (giant papillary conjunctivitis, GPC) which can make wearing the lenses difficult; mild irritation; and discomfort.

## **SURGICAL ALTERNATIVES, INCLUDING LASER**

There are several other procedures for the correction of farsightedness and nearsightedness.

1. The excimer laser is capable of reshaping the cornea. The excimer laser can be used to correct low to moderate amounts of hyperopia (generally +1 to +4 D) through either PRK (Photorefractive keratectomy) or LASIK (laser in situ keratomileusis) and low to higher amounts of myopia (generally -1 D to -12D).
2. LASIK is an operation that combines the creation of a flap with the microkeratome and the removal of tissue with the excimer laser. LASIK has been found to be quite successful and relatively safe for the correction of moderate and high myopia up to about -10.00. Above 10 diopters, LASIK has been found to be complicated by problems with accuracy and by a high incidence of complications involving the quality of vision, especially at night, and many surgeons have stopped performing LASIK for these extremely near-sighted eyes.

The advantage of all the above procedures is that they retain the patient's natural focusing power and do not require an incision into the inside of the eye as does clear lens extraction. I understand that I may choose not to have this surgery at all and either continue wearing my glasses or contact lenses or I may elect to have one of the other procedures discussed in this section.

Patient's Initials\_\_\_\_\_

Informed Consent for Clear Lensectomy  
**Surgical Alternatives, Including Laser con't -**

**Patient Responsibility For Costs**

I understand that I am responsible for the cost of the surgery, both the surgeon's fee, anesthesiologist's fee if any, and the surgical center's or hospital's fee must be borne by the patient. 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 which is not visually disabling.

I understand that I will be responsible for the costs of the 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 the premium lens implantation, 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.

If I need a second surgical procedure, such as replacement or repositioning of my intra-ocular lens, 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.

I understand if I need additional surgery for the correction of a residual distance prescription, at my doctor's option, depending on the health of my eye(s), a subsequent procedure (Lasik, PRK or additional refractive surgery) will be provided at no charge.

**Patient's Statement Of Acceptance And Understanding**

The details of the clear lensectomy have been presented to me in detail in this document and explained to me by my doctor or my doctor's representative. Although it impossible for my doctor to inform my of every possible complication that may occur, my doctor or my doctor's representative has answered all my questions to my satisfaction. I, therefore, consent to undergoing premium lens implantation (refractive lensectomy). I have been fully informed of my right to receive a copy of this signed and dated consent form.

I give my permission for medical data concerning my operation and subsequent treatment to be submitted to the intraocular lens manufacturer. In signing this informed consent for a premium lens, I am stating that I have read this informed consent (or it has been read to me). I fully understand the consent I am giving, the possible risks, complications and benefits that can result from surgery. Please circle one below.

**OD Right Eye**

**OS Left Eye**

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date