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Informed Consent for Refractive Lens Exchange (Clear Lens Replacement)

This surgery involves the removal of the natural lens of my eye, even though it is not a cataract. The natural lens will be replaced with an artificial implant called an intraocular lens in order to attempt to correct my farsightedness, nearsightedness, presbyopia and/or astigmatism, to improve my unaided natural vision and thereby reduce my dependency on glasses or contact lenses to correct my vision.

In some cases, the lens may have an early cataract, a condition that does not significantly interfere with corrected vision and does not require surgical removal. The cost of the surgery, the surgeon's fee, anesthesia fee and the surgical center or hospital fee must be borne by the patient. Health insurance does not pay for removal of the clear or minimally cloudy natural lens of the eye for the purposes of correcting refractive error, or for removal of an early cataract that is not visually disabling.

I will undergo a complete eye examination should I decide to have the surgery. This complete examination will include analysis of my glasses prescription (refraction) often with and without dilating drops, measurement of my vision with and without glasses (visual acuity), measurement of the pressure inside my eye (tonometry), measurement of the curvature of my cornea (keratometry), measurement of the length of my eye (axial length), intraocular lens calculation 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 pupil dilated (ophthalmoscopy).

Should I decide to proceed with the surgery, I may opt for light sedation administered by a nurse anesthetist while my eye is made numb with either drops (topical) or local anesthesia, or I may elect to have the surgery with local or topical anesthesia without sedation. The natural lens in my eye will then be removed by gently breaking it into small pieces with a vibrating/aspirating probe (phacoemulsification) through a small incision in my eye. 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 2 lenses to obtain the optimum power needed. The incision required to perform this operation is usually self-sealing, but it may require closure with very fine stitches (sutures) which will either gradually dissolve over time or be removed by my physician. After the surgery, my surgeon will examine my eye usually the next day, then two weeks and 6 months later. During the immediate recovery period, I will place drops in my eyes for 2 to 4 weeks, according to my surgeion’s instructions. Glasses or contact lenses may still be required either for further improvement in my distance vision, reading vision, or both. I should be able to resume my normal activities within 2 or 3 days, and expect stable vision within 2 to 4 weeks, at which time glasses or contact lenses may be prescribed.

The expected benefit to me will be clearer vision than I presently have without spectacle or contact lens correction. The farsighted (hyperopic) eye is out of focus because the length of the eye is too short for the refracting power of the cornea and lens, therefore light rays focus behind the retina. The nearsighted (myopic) eye is out of focus

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because the length of the eye is too long for the refracting power of the cornea and lens, therefore light rays focus in front of the retina. The light rays can theoretically be brought to focus on the retina by substituting an artificial lens that has the proper power, thereby improving the focus of the eye. Although this can theoretically improve my unaided distance and/or near vision, I may still require additional glasses for reading, driving, and other activities.

Description of risks and side effects, foreseeable risks and discomforts:

Refractive Lens Exchange is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical, with severe pain being extremely unusual. Since this surgery is essentially the same as cataract surgery, the same risks apply. Complications of cataract surgery may include but are not limited to: infection (which if serious can lead to complete loss of vision); swelling in the central area of the retina (called cystoid macular edema which usually improves with time); clouding of the outer lens of the eye (corneal edema which can be corrected with a corneal transplant); detachment of the retina (an increased risk in highly near-sighted eyes even though the retinal detachment can usually be repaired); damage to the retina or nerve during the administration of the anesthesia if an injection is performed: increased astigmatism; inaccuracy of the intraocular lens power; decentration of the intraocular lens, which may provide unwanted images and increased glare; and development of increased pressure in the eye (glaucoma). Some or all of these complications can occur, however, their incidence following cataract surgery is exceptionally low.

In this procedure the front part of the capsule (membrane enclosing the lens) is opened and the natural lens is removed, with the back part of the capsule left in place to support the intraocular lens. Many months or even years after the surgery, this capsule remnant may become cloudy and cause blurry or poor vision. This cloudy remnant is called capsular opacity or posterior capsular fibrosis. The way to make vision clear again is with a posterior laser capsulotomy, which simply means making an opening in the back of the capsule with a laser. (When this occurs the laser procedure is performed as a medically necessary procedure and is generally covered by medical insurance.)

Although the accuracy of intraocular lens calculations is quite satisfactory for normal sized eyes, these calculations can be less accurate for unusually long or short eyes. The best available calculation formula will be used to evaluate the power of the lens to be implanted. In the event of a minor amount of residual myopia, hyperopia and/or astigmatism, the vision can usually be corrected by a glasses prescription, which should be considerably weaker than the patient's original prescription. A large amount of residual myopia, hyperopia, and/or astigmatism error may be corrected by a stronger pair of glasses, laser surgery, contact lenses, the exchange of the implant or the insertion of a second implant in another operation.

Since only one eye will undergo surgery at a time the patient may, depending on the refractive error, 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 prescription need for each eye, so the patient will either temporarily have to wear a contact lens in the non-operated eye or will have to function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within a few days once the first eye is stabilized.

MULTIFOCAL LENS IMPLANT:

The Array Multifocal lens implant is different from a monofocal lens implant. It is made of the same materials and basic design as many of the monofocal lenses, but in addition to providing clear vision at far distances, it also provides good focus for a range of near distances, such as the computer monitor and reading. Visual side effects may include halos and glare, which most patients report decrease in time and/or they grow accustomed to the symptom

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as time passes. Halos at night may persist indefinitely with some patients. You may also notice a loss of contrast, which can effect the quality of your vision at night and in low light conditions. FDA studies show that the contrast loss measured was insignificant.

MONOFOCAL LENS IMPLANT:

One definite disadvantage of having the clear lens removed, especially in a patient less than 40 years of age, is the loss of the near focusing power of the eye (accommodation). Thus, it must be clearly understood that even with a successful surgery and an accurate intraocular lens calculation targeted to correct the eye's distance vision, close vision without spectacles will be blurred, and will require spectacles for close and intermediate vision. It may be possible to deliberately correct one eye for close vision instead of distance. This would allow the patient to read without glasses, even though the eye would then be nearsighted and require a corrective lens for distance vision. This combination of a distance eye with a reading eye is called monovision. It has been employed quite successfully in many contact lens patients and this option can be demonstrated with contact lenses if desired.

Non-surgical alternatives:

Non-surgical alternatives to refractive lens exchange is 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 or minified 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, or GPC which can make wearing the lenses impossible); mild irritation and discomfort. There is also evidence that some damage may occur to the important internal layer of cells that are responsible for keeping the cornea clear. This damage may cause harm if the contact lenses are worn for many years and it is unknown whether this damage will eventually lead to serious long-term complications such as corneal clouding. Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription and also allows the eye to retain its focusing power for near vision before age 45.

Surgical alternatives (including lasers):

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

The excimer and holmium lasers are capable of reshaping the cornea. The excimer laser can be used to correct low to moderate amounts of hyperopia, myopia and astigmatism through PRK (photorefractive keratectomy) or LASIK (laser insitu keratomileusis) procedures. The holmium laser is indicated for low degrees of hyperopia only.

Conductive Keratoplasty (CK) uses radiofrequency energy, instead of a laser, to reshape the cornea. CK is indicated for low degrees of hyperopia only.

LASIK, the most commonly performed of these alternatives, 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 –12.00 diopters. LASIK is complicated by problems with accuracy and the quality of vision, especially at night, above -12 diopters. Many surgeons have stopped performing LASIK for extremely near-sighted eyes.

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The advantage to all the above procedures is retaining the under 45 year old patient's natural near focusing power and no incision into the inside of the eye. I understand that I may choose not to have this surgery and continue wearing my glasses or contact lenses or I may elect to have one of the other procedures discussed in this section.

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 from refractive lens exchange, 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, I understand that I will be responsible for any uncovered costs.

Should a second surgical procedure be required within the one-year follow-up period, i.e. replacement or repositioning of my intraocular lens, I understand that my surgeon will not charge me a surgical fee, although there will be additional fees from the surgery center and from an anesthetist if required.

Should a second surgical procedure be required after the one-year follow-up period, i.e. YAG laser capsulotomy, I understand there will be additional fees from my surgeon and the surgery center.

I consent to the photographing or televising of the operation(s) or procedure to be performed for medical, scientific or educational purposes, provided that my identity is not revealed.

I consent to the admittance of observers to the operating room for purposes of advancing medical education.

I acknowledge that no quarantee has been given by anyone as to the results of the procedure.

I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur and therefore, any unforeseen risks.

I have carefully read and understand the information presented in this form and consent to have refractive lens exchange (clear lens replacement) performed. I have had the opportunity to ask questions and have had them answered to my satisfaction. I have been fully informed of my right to receive a copy of this signed and dated consent form.

I am making an informed decision in giving my permission to have Refractive Lens Exchange surgery performed on my_____right eye _____left eye _____both eyes.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date

_____ _____

Physician Signature Date

07/25/02

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Refractive Lens Exchange and Laser Capsulotomy

A Refractive Lens Exchange is removing the natural lens of the eye surgically by the method called "extracapsular" lens extraction. In this procedure, the front part of the capsule (membrane enclosing the lens) is opened and the natural lens is removed; the back part of the capsule is left in place to support the IOL. Many months or even years after the surgery, this capsule remnant may become cloudy and cause blurry or poor vision. This cloudy remnant is called capsular opacity or posterior capsular fibrosis.

The way to make vision clear again is with a posterior laser capsulotomy, which simply means making an opening in the back of the capsule with a laser.

The YAG Laser

Lasers are high-tech devices that produce very high-energy light beams. Lasers have many practical uses, from scanning bar codes at supermarket checkout counters to cutting tissue in certain types of surgery.

A YAG is a type of laser used to make the small opening in the capsule remnant. (The name comes from the three substances from which it derives its light energy: yttrium, aluminum, and garnet.) The YAG laser has significant advantages over a scalpel, because it makes more precise cuts and make them inside the eye without needing an incision through the outside of the eye. In addition, it can cut behind the IOL without damaging the IOL. There is less risk of an ocular infection and no problems related to wound healing.

Laser Capsulotomy Surgery

Laser capsulotomy surgery is an outpatient procedure that does not require hospitalization or general anesthesia.

You will be comfortably seated in front of the laser instrument. It is helpful for you to stay calm and not move during the treatment, so you may be steadied by the doctor's assistant. The surface of the eye may be numbed with anesthetic eye drops and you may also be given a drop to keep the eye pressure from increasing after the procedure.

The doctor directs the laser beam by looking through a slit lamp (clinical microscope) at the area being treated. Each time the laser is "fired," you will see a flash of colored light and hear a quick tapping sound.

Risks and Prognosis

The chance of obtaining a successful result with laser capsulotomy is excellent. Vision is typically improved, but sometimes the improvement is only minimal. Vision, although very rare, may worsen. Laser surgery, as with any surgery, is not without risk. Bleeding, increased pressure and retinal tears are all possible, but rare, and are temporary and/or treatable for the most part. YAG capsulotomy is a highly effective procedure and the risks are very low.

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