



OMNI EYE SPECIALISTS

A Madison Street Company®

Proudly Owned by Employees

Specializing in Medical and Surgical Care of the Eye

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Patient Name _____

BACKGROUND INFORMATION AND INFORMED CONSENT FOR CATARACT SURGERY AND IMPLANTATION OF AN INTRAOCULAR LENS

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you need to make your decision about signing this informed consent document. You have the right to ask any questions you might have about the operation before agreeing to have cataract surgery.

A cataract operation is indicated when you cannot function adequately due to poor sight caused by the cataract, except in rare and unusual situations. After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation, based upon your own visual needs and medical considerations. You may decide not to have a cataract operation at this time. If you decide to have an operation, the surgeon will replace your natural lens with an intraocular lens (IOL) implant in order to restore your vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye. Eyeglasses may be required in addition to the IOL for best vision.

EXAMINATION PRIOR TO SURGERY

Before going forward with cataract surgery, you will have undergone an eye examination which includes microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated. You will have also undergone measurements of the curvature of your cornea (keratometry) and the length of your eye (axial length) which allow for intraocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted IOL.

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, the method used to calculate the power of the IOL, 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, in some cases, surgical replacement of the IOL may be considered. There are still cases where this may not be possible.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

As we age, we develop an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses or bifocals become necessary, typically after age 40, even for people who have had excellent distance and near vision without glasses in their youth. Presbyopic individuals require either bifocals or separate (different prescription) distance and reading glasses in order to see clearly both in the distance and at close range. Patients who have cataract surgery, have their human cataractous lens removed and an artificial lens (an IOL) implanted that also creates this presbyopic condition. There are several options available to you to achieve distance and near vision after cataract surgery.

- **GLASSES** You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses for near vision. Alternatively, though discouraged, you could have the IOL implanted for near vision and wear separate glasses for distance.
- **MONOVISION** Your surgeon could implant IOLs with two different targets, one for near vision, and other for distance vision. This combination of a distance eye and a reading eye is called monovision, and would allow you to see in the distance and read without glasses, though both with reduced depth perception. On occasion, it has been employed successfully in some prior contact lens and refractive surgery patients, yet not all patients are good candidates for this.
- **PRESBYOPIA-CORRECTING IOL** Your surgeon could implant a “multifocal” IOL. These Food and Drug Administration (FDA) approved IOLs, provide distance vision AND restore some or all of the near vision ability of the eye. Depending upon the technological features of the IOLs, they may be described as “accommodating” (Crystalens), “apodized diffractive” (ReSTOR) or “multifocal” (ReZoom). All of these lenses are “multifocal,” meaning they correct for both distance vision and other ranges, such as near or intermediate.

MORE INFORMATION ABOUT MONOVISION

For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for the same 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 with IOLs involving two targets.

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. 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 eye doctors may use different methods of testing. If considering monovision after cataract surgery, it is recommended 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 IOL targets during cataract surgery. If you have any doubts or uncertainty, surgery should be delayed. **Under no circumstances should you consider undertaking cataract 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.

MORE INFORMATION ON PRESBYOPIA-CORRECTING IOL'S

While a “multifocal” IOL can dramatically reduce dependency on glasses, you may still need to wear glasses or contact lenses after surgery to obtain your best vision. The refractive results of surgery cannot be guaranteed. Additional surgeries such as IOL exchange or refractive laser surgery may be considered for residual refractive error, though in some cases they cannot be performed. A “multifocal” IOL might result in overall less sharp vision than a monofocal IOL, which may be more problematic in dim light or fog. It may also contribute to some visual side effects such as rings or circles around lights. Driving at night may be affected. If you drive a considerable amount at night (for instance as for your profession) 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. Also, if complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a “multifocal” IOL despite your decision to have a “multifocal” IOL. It is possible that not all of the near (and intermediate) focusing ability of your eye will be restored.

ACKNOWLEDGEMENT OF FINANCIAL OBLIGATION FOR PRESBYOPIA-CORRECTING IOL IMPLANTATION

My care provider has informed me that “multifocal” IOL and the associated services for selection and optimization of the lens are **not covered** by Medicare and insurance companies. If I choose to have cataract surgery with implantation of this technology, I acknowledge that I am responsible for payment of the charge for the “multifocal” IOL and associated services that exceed the charge for insertion of a conventional, monofocal IOL following cataract surgery.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

Your surgeon or the anesthesia team will make your eye numb with either drops or an injection (local anesthesia). The anesthesia team provides for sedation during the procedure to make your experience comfortable.

An incision, or opening, is then made in the eye. This is at times self-sealing but it may require closure with very fine stitches on occasion (sutures). 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 the small incision into your eye. After your natural lens is removed, the IOL is placed inside your eye. In rare cases, 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 care providers. During the immediate recovery period, you will place drops in your eyes for several weeks. You should be able to resume most of your normal activities within 2 to 5 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 CATARACT SURGERY

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. Cataract surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain would be unusual and should be reported immediately to my surgeon.

As a result of the surgery and associated anesthesia, 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 cataract surgery is low.

Risks of cataract surgery include, but are not limited to:

1. **Infection** that is vision threatening occurs in less than 1/1000.
2. **Bleeding** in and around the eye can occur as a result of the surgery or as a result of the anesthetic shot that may be used to numb the eye. The chance of bleeding sufficiently to result in a decrease in your vision is less than 1/1000.
3. **Corneal clouding** (corneal edema), which if permanent may require correction with a corneal transplant is required less than 1/1000.
4. **Rupture of capsule support membranes** that typically hold the IOL in place. In some circumstances, a rupture of capsule support membranes may result in the need for an alternate lens design where the IOL is supported by your iris. Your surgeon may elect, rarely, to withhold placing a lens in your eye until a later date. Loss of capsule support requiring an alternate lens design or no lens implantation occurs less than 1/1000.
5. **Cystoid macular edema** or swelling in the central area of the retina results from a microscopic amount of fluid accumulating in the retina in the back of the eye. This usually resolves on its own or with medications. The chance of this condition causing a noticeable decrease in your vision is about 1/500.
6. **Retained lens material** in the eye may or may not need to be removed surgically. This occurs in less than 1/1000.
7. **Retinal Detachment** is a separation of the light-sensitive nerve layer in the back of the eye from the back of the eye that requires surgical intervention for repair. Its rate of occurrence is about 1/500. There is a higher risk in highly nearsighted patients.
8. **Droopy eyelid** may occur after cataract surgery. Needing surgery to repair this occurs in about 1/700.
9. **Glaucoma** (associated with an elevation in the pressure of the eye) can compromise peripheral and central vision in its latter stages. The use of drops and other means of controlling the pressure may be required. This occurs in less than 1/1000.
10. **Double vision** may occur because of injury to the muscles that move the eyeball such that there is difficulty using both eyes together. This usually goes away on its own but if it is persistent, may be able to be corrected with prisms though in some cases may require eye muscle surgery. The risk for this surgery induced double vision is about 1/500.
11. **Irregular Pupil:** The pupil is the black hole in the brown or blue part of your eye. The chance of this becoming irregular is about 1/500. The chance of this irregularity affecting your visual outcome is less than 1/1000.
12. **Secondary/After Cataract:** There is a fine clear transparent membrane that is left behind at the time of surgery. This membrane can become cloudy in about 1 in 10 patients between an average of 2 months to 2 years after surgery. If this were to blur your vision, a 5 minute

- YAG laser procedure would be performed to create an opening in the membrane and improve your vision. There are rare complications associated with the use of the YAG laser.
13. **Iritis** is an inflammation in the eye that may require chronic steroid eye drops or shots to control. This occurs in about 1/700.
 14. **Wound leak** requiring an operation to repair the wound occurs in about 1/700.
 15. **Diabetic Eye Disease** may progress after surgery even if not evident before surgery. While this may have occurred even if surgery was not performed, the likelihood of this progressing depends on the duration of diabetes and to what extent your eye has been affected by diabetes.
 16. **Cyst formation** that develops after surgery on the white of the eye may lead to eye irritation enough to require minor surgery to remove it in 1/1000.
 17. **Removal of the intraocular lens** is rarely required after surgery and the chance of needing this and not replacing it with another IOL is less than 1/1000.
 18. **Complete loss of vision or vision worse than prior to surgery** is a risk with cataract surgery. As stated above, this is very rare, about 1/1000. The risk of lost or worse vision is low, but it is not zero.
 19. **Anisometropia** (unequal refractive errors in the two eyes). Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes. This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so you may temporarily have to wear a contact lens in the non-operated eye or function with only one clear eye for distance vision. Surgery in the second eye can usually be done within 4 weeks, once the first eye is stabilized.

Patient Name

PATIENT CONSENT

Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an IOL to be implanted in my eye, I understand I must have cataract surgery performed either at the time of the IOL implantation or before IOL implantation.

The basic procedures of cataract surgery, the reasons for the type of IOL chosen for me, and the advantages and disadvantages, risks, and possible complications of cataract surgery have been explained to me by my eye care provider. 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.

I recognize that, during the course of the operation, additional or different procedures other than those described above may be necessary. I authorize such procedures as are in my surgeon’s professional judgment desirable to my health, including attempts to remedy any conditions that are not known at the time the operation has begun.

In signing this informed consent for cataract operation and/or implantation of an IOL, I am stating that I understand that a copy of this consent is available to me and I fully understand the possible risks, benefits, and complications of cataract surgery.

- **I have read this informed consent _____ (patient initials)**

CHOOSE ONE OF THESE OPTIONS

1) Monofocal (single vision) IOL/Glasses Option

I wish to have an intraocular lens implanted in my _____ (state “right” or “left”) eye whose focus will be for (Distance), (Nearsighted), (Farsighted)

2) Monovision with 2 IOL Option

I wish to have a cataract operation with two different-powered IOL implanted in an attempt 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.

3) Presbyopia-Correcting IOL Option

I wish to have a cataract operation with a _____ (state name of implant) IOL implant on my _____ (state “right” or “left”) eye.

Patient (or person authorized to sign for patient)

Date

Witness Signature

Date

Physician Signature

Date

Patient Name

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Patient (or person authorized to sign for patient)

Date

Witness Signature

Date

Physician Signature

Date

CONSENT FOR COMANAGEMENT CARE

I, _____, understand that my referring optometrist is licensed and capable of performing my post-operative follow-up care. I understand that I have been given the option of being seen by my referring optometrist or having the staff doctors at Omni Eye Specialists complete my post operative care. Should I choose to have my optometrist do the follow-up care, I understand that at ANY time during my post operative period, I can consult with the doctors at Omni Eye Specialists.

I elect to have my post-operative care provided by:

MY REFERRING OPTOMETRIST: Dr. _____

I understand that if my referring optometrist is not contracted with my insurance, I will be responsible for post-operative care charges.

OMNI EYE SPECIALISTS

Patient/Guardian Signature _____ Date _____

Witness Signature _____ Date _____