West Michigan Ophthalmology
Informed Consent For Cataract Surgery
And/Or Implantation of an Intraocular Lens

INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish 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 it.

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to decreased vision caused by the cataract. 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 implant (IOL) 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.

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 IOL, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated.

NEED TO STOP WEARING RIGID CONTACT LENSES PRIOR TO SURGERY

If you wear contact lenses, you will be required to leave them out of the eyes for a period of time prior to having your preoperative eye examination and before your surgery. This is done because the contact lens rests on the cornea, distorting its shape, and this distortion will have an effect on the accuracy of the doctor's measurements of the power of surgical correction needed. Discontinuing contact lens use allows the corneas to return to their natural shape. Soft contact lens wearers should leave lenses out of the eyes for at least one week. Rigid (including gas permeable and standard hard lenses) contact lens wearers should leave lenses out of the eyes for at least three weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within three weeks, this process may take longer, and you will need to remain contact lens free until stabilization is complete.

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, surgical replacement of the IOL might be considered. It is usually possible to replace the IOL and improve the situation.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

Patients who have cataracts 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 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, or have the IOL implanted for near vision and wear separate glasses for distance.
- ☐ MONOVISION The ophthalmologist could implant IOLs with two different powers, 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 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, while the other eye remains corrected for distance. It is, therefore, another form of monovision correction.
- ☐ **I choose to have near vision after cataract surgery provided by** _____ Patient initials _____

(**Please write** "glasses," "monovision," "NearVision CK," or "multifocal IOL.")

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 cataract surgery. 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 the use of monovision contact lenses. **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.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

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.

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 (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, 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.

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 extremely unusual and should be reported immediately to the 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. 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 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 lens 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. 2. Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and dislocation of the IOL. 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 cataract surgery.
3. 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, cardiac problems, and in rare situations, brain damage or death.
4. 4. If a monofocal IOL is implanted, either distance or reading glasses or contacts will be needed after cataract surgery for adequate vision.
5. 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. 6. Complications associated with multifocal IOLs. While a multifocal IOL can reduce dependency on glasses, 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. 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. 8. If complications occur 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. 9. Other factors may affect the visual outcome of cataract surgery, including other eye diseases such as glaucoma, diabetic retinopathy, 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. 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 cataract surgery.
11. 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. 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. 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 usually be repaired but may lead to vision loss or blindness.
14. 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 has stabilized.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

My ophthalmologist has informed me that if I have Medicare coverage for this cataract surgery,

the "presbyopia-correcting" multifocal IOL and associated services for fitting the lens are only considered **partially covered**. I acknowledge that I am responsible for payment of that portion of the charge for the "presbyopia-correcting" multifocal IOL and associated services that exceed the charge for insertion of a conventional, monofocal, IOL or monovision following cataract surgery. My ophthalmologist has informed me about the coverage, deductible, and copayment amounts if a private insurance company is paying for this procedure.

Patient initials _____

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. If my cataract was previously removed, I have been informed that my eye is medically acceptable for 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 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 cataract operation and/or implantation of an IOL, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of cataract 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

1) Monofocal IOL/Glasses Option

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

2) Monovision with 2 IOLs Option

I wish to have a cataract 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.

3) Multifocal IOL Option

I wish to have a cataract 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
Witness Signature	Date
Physician Signature	Date

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