

INFORMED CONSENT FOR CATARACT SURGERY AND IMPLANTATION OF A MULTIFOCAL 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. You have the right to ask questions about any procedure before agreeing to have it.

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to poor sight produced by the cataract. You must remember that the natural lens within your own eye, even with a slight cataract, has some distinct advantages over any man-made lens.

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 on 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) in order to restore your vision. This is a small artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye. Objects are seen at their normal size. Conventional eyeglasses (not cataract or aphakic spectacles) may be required in addition to an intraocular lens for best vision.

Information about calculating the power of the intraocular lens

Prior to surgery, a number of examinations and measurements are done, one of which is called biometry, which calculates the power of the intraocular lens that will be implanted in the eye. While the method used to calculate the power of the IOL implant is very accurate in the vast majority of patients, some inaccuracy may occasionally occur. As the eye heals, the implant can shift very slightly toward the front or back of the eye. The amount of this shift is not the same in everyone, and may cause you to see differently than what may have been predicted by the measurements taken before surgery. Patients who are highly nearsighted or highly farsighted have the greatest risk of inaccuracies. Patients who have had LASIK or other refractive surgeries are especially difficult to measure precisely. It is rare, however, for the implant strength to be so inaccurate that surgical replacement is required. Fortunately, even in those rare instances, the lens replacement can usually be accomplished and the situation improved.

Presbyopia

Most patients who have cataract surgery also have, or will soon develop, an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses become necessary, typically in the mid-40's age range, even for people who have excellent unaided distance vision. Nearsighted individuals require bifocals or separate (different prescription) reading glasses once presbyopia develops in order to see clearly at close range. Until recently, the IOL implanted after cataract surgery corrected only distance vision, so conventional eyeglasses (not cataract or aphakic spectacles) were often required in addition to an intraocular lens for best vision after surgery. A few intraocular lenses with the potential to restore some or all of the focusing

(accommodating) ability of the eye have been approved by the Food and Drug Administration (FDA), providing ophthalmologists and their patients with expanded choices for cataract surgery. Depending upon the technological features of the lenses, they are described as “accommodating,” “apodized diffractive,” or “presbyopia-correcting.” All of these lens are “multifocal,” meaning they correct for both distance and other ranges, such as near or intermediate. Your surgeon has determined through a discussion with you that one of these lenses is the appropriate choice for you.

Alternatives to a Multifocal IOL

There are several other options available to cataract patients who are presbyopic. First, you can choose to have a monofocal (single focus) lens inserted for distance and wear separate reading glasses. A second option involves implanting lens with two different powers: the ophthalmologist deliberately corrects one of your eyes for close vision, which would allow you to read without glasses, even though this eye would then be nearsighted and require a corrective lens for distance vision. This combination of a distance eye and a reading eye is called monovision. It has been employed quite successfully in many contact lens patients. Your surgeon has discussed and demonstrated this option. Finally, a refractive procedure called NearVision CK uses radiofrequency energy to reshape the cornea.

Benefits and Possible Limitations of a Multifocal IOL

The goal of cataract surgery with a multifocal IOL is to restore some or all of the near (and intermediate, depending upon the lens) focusing ability of your eye.

- There is no guarantee that all of the near (and intermediate) focusing ability of your eye will be restored.
- Other factors affect the visual outcome of cataract surgery, including the power of the lens implant, your individual healing ability, and the function of the ciliary muscles in your eyes.
- 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 see 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 may be a better choice.
- The selection of the proper lens implant, while based upon sophisticated equipment and computer formulas, is not an exact science. An inaccurate power lens may be placed in your eye.
- If you have more than a small amount of astigmatism, your doctor may need to perform limbal relaxing incisions, or extra incisions in the cornea, to alleviate some of this astigmatism, in order for you to gain maximal benefit from the multifocal lens.
- Any residual refractive error after the surgery may need to be corrected with eyeglasses, refractive surgery (e.g. LASIK), or repositioning or replacement of the lens itself. This may have to wait until at least 3 months after your cataract surgery to allow for adequate healing.
- At the time of surgery, a monofocal IOL may need to be placed in your eye instead of a multifocal IOL, or your ophthalmologist may decide not to implant an intraocular lens at all.

These circumstances usually arise unexpectedly and only if there are problems with the lens 'capsule', or support structure of the lens in the eye.

Additional risks related to individual eye characteristics

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. 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.

Financial Implications of a Multifocal IOL

My ophthalmologist has informed me that if I have Medicare coverage for this cataract surgery, the "presbyopia-correcting" multifocal IOL device and associated services for fitting the lens are 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 IOL 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.

Complications of surgery to remove the cataract and insert the intraocular lens

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.

1. Complications of removing the cataract may include hemorrhage (bleeding), perforation of the eye, loss of corneal clarity, retained pieces of cataract in the eye, infection, detachment of the retina, uncomfortable or painful eye, droopy eyelid, glaucoma and/or double vision. These and other complications may occur whether or not a lens is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations.
2. Uncommon complications associated with the intraocular lens may include increased night glare and/or halo, double or ghost images, and dislocation of the lens. Multifocal lenses may increase the likelihood of these problems. In some instances, corrective lenses or surgical replacement of the intraocular lens may be necessary for adequate visual function following cataract surgery.
3. If an intraocular lens is implanted, it is done by surgery. It is intended that the small plastic, silicone, or acrylic lens will be left in your eye permanently.
4. At the time of surgery, your doctor may decide not to implant an intraocular lens in your eye even though you may have given prior permission to do so.
5. The results of surgery in any individual case cannot be guaranteed. Additional treatment and/or surgery may be necessary. You may need laser surgery to correct clouding of vision. At some future time, the lens implanted in you eye may have to be repositioned, removed surgically, or exchanged for another lens implant.
6. Cataract surgery and the calculations for intraocular implants are not "an exact science," as explained above. You might need to wear glasses or contact lenses subsequent to surgery to

obtain your best vision. There is also the possibility of the need for subsequent surgeries such as lens exchange, placement of an additional lens, or refractive laser surgery if you are not satisfied with your vision after cataract removal.

Consent for surgery

Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an intraocular lens to be implanted in my eye, I understand I must have cataract surgery performed either at the time of the lens implantation or before lens 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. 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 implantation of a multifocal intraocular lens, I am stating I have read this informed consent (or it has been read to me), I have been given a copy, and I fully understand it and the possible risks, complications, and benefits that can result from the surgery, as well as the financial implications of choosing a multifocal IOL.

1) I wish to have a cataract operation with a _____ intraocular lens implant (state name of implant) on my RIGHT / LEFT / BOTH (circle) eye(s).

OR

2) Since my cataract was previously removed and I have been informed that my eye is medically acceptable for lens implantation, I wish to have a _____ intraocular lens implant (state name of implant) inserted in my _____ RIGHT / LEFT / BOTH (circle) eye(s).

Patient (or person authorized to sign for patient)

Date

Patient's Name (print)

Witness's Signature

Date

Doctor's Signature

Date