



Informed Consent for Cataract Surgery or Clear Lens Extraction with Implantation of an Intraocular Lens

Please read the following pages carefully, and initial and sign where indicated. Please do not sign any section that you have not read or do not understand.

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, even when you are wearing the best glasses or contact lenses that can be prescribed. 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. Alternatives to cataract surgery may potentially include: observation, glasses, contact lenses, or other forms of corrective eye surgery. If you decide to have an operation, your doctor 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. Most patients achieve an improvement in their vision after cataract surgery, though results vary and results cannot be guaranteed. Although your surgeon will try to give you good vision after cataract extraction without glasses, the goal of cataract surgery is to give you good vision with spectacle correction. Eyeglasses may be required in addition to the IOL for best vision.

NEED TO STOP WEARING 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 IOL that should be implanted. 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 two weeks. 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 may need to discontinue your contact lenses longer than two weeks for soft contact lenses and three weeks for rigid gas-permeable lenses.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

At about the age of 45, all people who have good distance vision begin to have difficulty seeing at near (presbyopia). If they require corrective lenses to see at distance, the same lenses do not produce good vision at near. This occurs because the optical system of the eye must change its power to change its point of focus. This is normally accomplished by changing the power of the lens inside the eye. As we age, the lens becomes stiff, so it cannot change the focal point of the eye from distance to near. Bifocal glasses have different powers in the top and bottom of the lens. The top of the lens focuses distant objects, and the bottom focuses near objects. If no correction is needed for clear distance vision, non-prescription reading glasses will correct near vision. There are several options available to help you see at distance and near without glasses, but none of them is without compromise and none will restore your eyes to the way they were when you were young and did not have cataracts.

- **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. This is a good choice if you don't mind wearing glasses be

- **MONOVISION** Your doctor 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. 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 impairs depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimal depth perception, it is best that you try monovision (with glasses or contact lenses) before opting for



monovision correction involving two IOLs. Also, it is possible that exact desired amount of correction may not be achieved.

- **ASTIGMATIC KERATOTOMY – AK**– Your doctor could choose astigmatism correction procedure at the time of cataract surgery.

- **LIMBAL RELAXING INCISION– LRI** – Depending on the shape of your cornea, your doctor may choose a procedure which allows the cornea to become more rounded when healed.

- **MULTIFOCAL IOL** A multifocal IOL is a newer type of IOL that focuses light from distant and near objects simultaneously, reducing dependence on glasses at all distances. Vision with these lenses is not perfect, however, because the portion of the lens that focuses near objects detracts from the quality of the image at distance. Similarly, the portion of the lens that focuses distant objects detracts from the quality of the near image. Thus, visual disturbances like halos, glare, and shadow images are more common with these lenses than they are with monofocal lenses. There is no guarantee that ALL the distance, near and intermediate vision will be restored. It could take 6–8 weeks for your brain to adapt to the images produced by these lenses. If you drive a lot at night or perform delicate, detailed, “up-close” work requiring perfect vision, a monofocal lens in conjunction with eyeglasses may be a better choice for you. Although multifocal lenses may represent one of your best options for reducing dependence on glasses, it is not possible to guarantee that glasses will never again be worn or that you will be happy with the quality of the images they produce. **ACCOMMODATING IOL** IOL’s that change the focal distance by moving in the eye typically avoid the compromise in image quality that is associated with multifocal lenses; however, they typically do not permit good vision as very close distances. They may be good choices for those who are not comfortable with any compromise in the quality of their vision and would be happy if their intermediate vision were better than it would be with a monofocal lens.

TORIC LENSES (IOLs)

Patients who have astigmatism see objects as skewed or distorted in one direction. This is caused by one or more parts of the eye (cornea or lens) having more of a “football” shape rather than a round shape. Standard cataract surgery does not correct the majority of astigmatism arising from the cornea, and patients still need to wear glasses full-time after surgery for distance and near tasks. **Toric IOLs** treat the astigmatism of an eye along with near- or



farsightedness. This could decrease your dependence on glasses for driving after cataract surgery.

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 or refractive surgery (like LASIK) might be considered. These procedures usually improve the situation.

IF YOU HAVE HAD PREVIOUS CORNEAL SURGERY

Corneal refractive surgery changes the shape of the front of your eye. This usually decreases your need for glasses. Unfortunately, this shape change also affects the way testing devices determine the intraocular lens power that needs to be placed in your eye. This can lead to the insertion of implants with a power that does not match your eye well. With previous refractive surgery (RK, LASIK, PRK, epi-LASIK, corneal transplant), there is a likelihood that the desired outcome may not be achieved from this refractive lens implantation surgery alone. Options for correcting the remaining prescription after lens implant surgery may include any or all of the following:

1. Wearing contact lenses or glasses
2. Performing LASIK or other corneal refractive procedures to reduce the eye's prescription
3. Removing the implant and replacing it with one that more closely corrects the eye's prescription

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

Your doctor or the anesthesiologist/nurse 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.

The natural lens in your eye will be removed by a type of surgery called phacoemulsification, which uses a vibrating probe to remove the lens from your eye. The IOL is then inserted into the eye, in the same location as the natural lens that was removed. 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 doctor. 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 (without restrictions) within 7 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 so that the vision with glasses or contact lenses after surgery is better than the vision with glasses or contact lenses before surgery. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. There may be conditions not apparent before surgery that will limit your vision after surgery.

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. 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 covering of the eye (corneal edema), which may be corrected with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema), which may improve with time; retained pieces of lens in the eye, which may need to be removed surgically; infection; detachment of the retina, which is 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. Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and dislocation of the IOL. Multifocal IOLs increase the likelihood of glare, halo or “ghosting”. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following cataract surgery.

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, double vision, droopy eyelid, respiratory depression, hypotension, cardiac problems, and in extremely rare situations, brain damage or death.

4. If a monofocal IOL is implanted, either distance or reading glasses or contacts (or both) will be needed after cataract surgery for adequate vision.

5. Complications associated with monovision. Monovision may cause problems because it 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. 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, or your doctor may decide not to implant an IOL in your eye at the time of surgery.

7.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. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.

8.If your doctor 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.

9.If you have been informed 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.

10.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 spectacles because the marked difference in the prescriptions will cause double vision, so you 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 3 to 4 weeks, once the first eye has stabilized.

11.Other material risks of surgery include but are not limited to: death, cardiac arrest, brain damage, disfiguring scar, paraplegia or quadriplegia, paralysis or partial paralysis, loss or loss of function of any limb or organ, severe blood loss, allergic reaction and infection. There may be other risks not mentioned in this document.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

I have been informed that the “presbyopia-correcting” multifocal IOL and associated services for fitting the lens are not covered by medical insurance. I acknowledge that I am responsible for payment of charges 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 doctor and/or his staff have informed me about the coverage, deductible, and co-payment amounts of the cataract portion of the surgery if a medical 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 doctor and/or his staff. Monovision has been discussed with me, and my doctor 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.

I realize that, during the procedure, the physician/surgeon may become aware of conditions which were not apparent before the start of the procedure. I therefore consent to any additional or different operations or procedures the physician/surgeon considers necessary or appropriate to treat cure or diagnose such conditions.

Any tissue, organ, specimen, or member taken or severed in any operation or procedure may be retained, preserved, used for scientific or teaching purposes, or disposed of by Woolfson Eye Institute. I authorize observers to be present during the surgery or procedures. I further authorize the physician, or his/her designee, to photograph/videotape me before, during, or after this surgery or procedure, for purposes related to my care and treatment and/or purposes of



medical education. Patient has the right to request cessation of the production of the recording, films, or other images. Woolfson Eye Institute accommodates the patient's right to rescind consent before the recording, film, or image is used.

I understand that my medical records or personal information or data may be disclosed to a third party or outside source under certain rare circumstances as required by federal or state regulations. Examples of such situations are cases of elder abuse or reporting of certain diseases to the CDC.

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 _____
(print name)

CHOOSE ONE OF THESE OPTIONS AND CROSS OUT THE OTHERS:

1) Monofocal IOL/Glasses Option

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

2) Monovision with 2 IOLs Option

I wish to have a cataract operation with a monovision option.

I wish to have my _____ (write "right" or "left") eye corrected for near, and my _____ (write "right" or "left") eye corrected for distance.

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.



4)Accommodating IOL Option

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

5) Toric IOL

I wish to have a cataract operation with a toric IOL on my _____ (write "right" or
"left") eye .

Patient (or person authorized to sign for patient)

Date

Witness Signature

Date

Physician Signature

Date