

Informed Consent for Cataract and Lens Implant surgery

1. GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract surgery and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure.

2. AN OVERVIEW OF CATARACT AND LENS IMPLANT SURGERY

A cataract occurs when the natural lens of the eye becomes cloudy. The normal lens is clear and helps focus light on the retina in the back of the eye. As a cataract develops, it blocks and scatters light, reducing the quality of vision.

In cataract surgery, the cloudy natural lens of the eye is removed. In almost all cases, the cataract is replaced with a clear artificial lens call an **intraocular lens implant (IOL)**, which is placed permanently inside the eye at the same time the cataract is removed. IOLs are available in different sizes, powers, materials and designs and must be selected by the surgeon depending on the needs of the eye.

An IOL can be inserted later as a separate procedure after a cataract is removed. This may require a different type of IOL than is used if one is placed at the same time the cataract is removed.

3. RISKS AND CONTRAINDICATIONS:

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

- **Loss of Vision:** Cataract surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to problems such as infection, scarring, inflammation, or hemorrhage, and if severe can even cause partial or complete loss of vision or loss of the eye. Such severe complications are extremely rare, but can and do occur.
- **Visual Side-Effects:** Visual difficulties and conditions that can occur after cataract surgery include: differences in the power between the two eyes, differences in image size between the two eyes, double vision or ghost images, shadows in the peripheral vision, floaters or flashes of light, and halos or reflections from lights. These problems occur commonly after only one eye has cataract surgery, and may be relieved after both eyes are done.
- **Glasses or Contact Lenses:** Cataract surgery, even with an intraocular lens implant (IOL), does not eliminate the need for glasses. Most patients will have some residual nearsightedness, farsightedness, or astigmatism, and will need glasses for optimal distance and close vision after surgery. Often the glasses strength is fairly low, and some patients feel less dependent on glasses after surgery. However, other patients may find that they need glasses more afterwards. Typically, glasses will not be changed until several weeks after surgery.

The glasses power needed after surgery depends on a number of factors and can not be predicted with absolute accuracy. Some patients end up with more or less nearsightedness or farsightedness than expected, and may require stronger glasses or contact lenses. If there is a large unexpected difference in the glasses prescription, then a contact lens, exchange of the IOL, placement of an additional IOL, or an additional surgery to correct the vision may be required.

- **Surgical Complications:** Surgical complications can arise from anesthesia, the intraocular lens implant, or from surgery itself. In some cases, complications can occur weeks, months or even years later. Such complications may include bleeding, perforation of the eye, clouding of the cornea, retained pieces of cataract in the eye, infection, retinal detachment, droopy eyelid, glaucoma, dislocation of the IOL, or an uncomfortable or painful eye. Reactions to anesthesia can also occur.

If there is a complication at the time of surgery, the surgeon may decide not to implant an IOL in your eye, even though you may have given permission to do so.

- **Other Risks:** Cataract surgery may cause changes in the appearance of the eye, such as distortion of the pupil, or a reflection or shiny appearance in the pupil from the lens implant. Other eye conditions, such as macular degeneration, glaucoma or diabetic retinopathy may worsen following cataract surgery.
- **Risks of Not Undergoing Cataract Surgery:** If you do not undergo cataract surgery, your cataract will worsen with time. Although this does not generally cause other damage to the eye, your risks of falling and sustaining a hip fracture or other injury, or of being involved in a car accident if you drive, may be higher because of the cataract. The cataract may also become more difficult to remove, and the surgery more risky if the cataract grows too dense. In rare instances, the cataract can grow so much that it causes sudden severe glaucoma or inflammation leading to permanent damage to the eye and loss of vision.

Cautions: Extra caution may be required if cataract surgery is needed on patients with active inflammation in the eye, uncontrolled diabetes, severe glaucoma, who have taken certain medications such as Flomax or who have only one useful eye. If you know that you have any of these conditions, you should discuss them with your surgeon.

4. ALTERNATIVES TO CATARACT SURGERY

In the early stages, a change in glasses and attention to better lighting can sometimes improve the vision enough to delay surgery. Except in unusual circumstances, there is little danger to the eye from delaying cataract surgery, except that the vision will remain impaired until the cataract is removed. If delayed, surgery can usually be done later with a good chance of success. However, cataracts do not go away without surgery, and will get worse with time.

It is possible to remove the cataract and not insert an IOL. In this situation, strong glasses or a contact lens are usually required to focus. If glasses are used, the lenses may be very thick and can cause distorted or double vision or visual imbalance. Contact lenses may not be tolerated by some individuals and may be difficult to handle, insert and remove. Because of these problems, an IOL is recommended for almost all cataract surgery patients today.

5. CORRECTION OF ASTIGMATISM

Patients who have significant astigmatism affecting their vision will require glasses to correct the astigmatism following cataract surgery. Surgical treatment of astigmatism can significantly reduce the need for glasses and can be done at the time of cataract surgery. This procedure is known as **Limbal Relaxing Incision (LRI)** and is effective in reducing significant astigmatism.

The benefits of LRI are that it may significantly reduce the dependence on glasses for distance after cataract surgery such that you may only need glasses for near. With the new types of Multifocal lenses, reduction of astigmatism is necessary to allow distance and near focus without glasses. The risks of this procedure are rare and are similar to the risks present in standard cataract surgery without correction of astigmatism. The most common risk is persistent astigmatism although this may be further reduced with additional LRI or laser vision correction. The risks of LRI do not significantly increase the risks of cataract surgery including its risk of infection and loss of vision.

Patients who have significant astigmatism may benefit from a toric IOL. A toric IOL corrects astigmatism as well as nearsightedness and farsightedness. If you have a significant amount of astigmatism prior to cataract surgery, a toric IOL may reduce your need for glasses after surgery. The risks of this procedure are rare and are similar to the risks present in standard cataract surgery without correction of astigmatism. The most common risk is persistent astigmatism although this may be further reduced with additional LRI or laser vision correction. The risks of a toric IOL do not significantly increase the risks of cataract surgery including its risk of infection and loss of vision.

6. CORRECTION OF PRESBYOPIA

Most people develop a condition called **presbyopia** around age 40. Presbyopia is the loss of the eye's ability to change focus from distance to near, resulting in the need for reading glasses or bifocals. The standard lens implants used to replace the cataract in surgery have just one focus, so even if glasses are not needed for distance after surgery, correction will still be necessary for close vision. After cataract surgery, close vision can be corrected by:

- **Reading Glasses or Bifocals:** This is the standard approach chosen by most patients.
- **Premium IOLs:** Special IOLs, known as presbyopia-correcting or Multifocal IOLs can provide both distance and close vision from the same lens. Only certain patients are good candidates for this new technology. These IOLs typically need to be implanted in both eyes to work optimally. Some types of Premium IOLs can compromise the crispness of vision, especially in low light or poor contrast conditions and some patients may notice haloes or glare around lights with these implants. Other Premium IOLs are better at clarity of vision but are not able to be focused as well at near. Most patients with Premium IOLs are usually less dependent on glasses for distance and close vision than patients with standard IOLs. Many Premium IOL patients do not use glasses at all, although this can not be guaranteed. Extra services are required for use of a Premium IOL. Medical insurance generally does not cover the extra costs associated with these "premium" implants, so the patient is financially responsible for the cost difference between Premium IOL surgery and standard IOL surgery.

Your best options for correcting presbyopia will depend on many factors, including your pre-operative vision, visual preferences, occupational and lifestyle needs, shape and size of the eye, type of cataract, other eye and medical conditions, personality, age, and your tolerance for glasses and contacts lenses. Not all patients are good candidates for all options. Your surgeon can help determine the recommended options for your individual case. However, it is important to remember that regardless of the option chosen, it is impossible to guarantee a particularly visual result. Your final outcome and need for glasses may differ from the desired goal despite all reasonable efforts.

The overwhelming majority of patients receiving a Premium IOL implant do not have to wear glasses after surgery, but some still do. About 15% still wear eyeglasses, at least part-time; about 85% do not. The results of surgery can not be guaranteed. Selection of the proper IOL while based on 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 still need to wear eyeglasses or contact lenses after surgery to achieve your best vision. If you choose a Premium IOL, it is possible that not all of the near (intermediate) focusing ability of your eye will be restored. Up to 10% of patients may be candidates for laser vision correction to optimize their vision after cataract surgery. Laser surgery will be offered at a discount rate if the surgeon agrees with its suitability.

An occasional patient, perhaps 1 in 100, will not be able to adjust to the lens. In these cases, the lens may be removed and replaced with a standard Monofocal lens, after which eyeglasses may be needed. If you can not adjust to your lens and an exchange is necessary, there is neither a charge for the exchange nor a refund for the Multifocal lens.

- **Leave Both Eyes Nearsighted:** This is a good option for patients who are used to being nearsighted and for whom close vision is most important. A prescription will be needed for distance vision and a weaker more minimal prescription needed for close vision.
- **Leave One Eye Nearsighted (“Monovision” or “Blended Vision”):** Some patients prefer to have one eye focused for close and one for distance. This allows them to do many things without glasses. Depth perception at distance may be compromised but for patients who go back and forth from distance to close and don’t want to wear glasses, this is a popular option. This works especially well for patients who have successfully used Monovision with contact lenses in the past. Patients with Monovision often still need glasses for night-time driving or prolonged reading.
- **Contact Lenses:** Contact lenses are available with bifocals or can be fitted to produce Monovision with one eye focused for close. Contacts usually provide good vision but may be difficult to handle for some patients.
- **Refractive Surgery:** Various surgical procedures, such as Conductive Keratoplasty, PRK and LASIK can be used to correct close vision by creating nearsightedness in one eye. This is a form of Monovision. These procedures can be performed on one or both eyes after the eye has healed from cataract surgery. Medical insurance generally does not cover Refractive Surgery so the patient is financially responsible for the cost of these procedures. These costs are not included in the cost of cataract surgery.

7. THE PROCEDURE, PRE- AND POST-OPERATIVE CARE

Pre-Operative Care: Before surgery, an examination of your eyes and a general medical evaluation to determine your suitability for surgery are required. In addition, measurements of the size and shape of the eye are needed to determine the desired IOL power. You may be instructed to start drops in preparation for the procedure.

Surgery: Surgery is typically performed as an outpatient, using eyedrops and/or ointments for anesthesia. In the majority of cases, injections or stitches are not needed depending on how your eye responds before and during surgery.

Post-Operative Care: You will be given instructions on post-operative care. You will also be given a schedule for follow-up appointments. If you are unclear about any instructions, please ask. In most cases you will be able to resume most normal activities immediately, but should keep the eye clean and dry and avoid bumping or pushing on the eye during the initial healing. Time off work will vary depending on your job duties and speed of visual recovery. Some blurriness during healing is normal. Glasses, if needed, can be prescribed any time after surgery, but this is usually not done for 4-6 weeks.

YAG Laser Capsulotomy: After cataract surgery, it is very common to eventually develop some scar tissue behind the IOL. This scar tissue forms a film that can make the vision worsen again, much like when the cataract is present. This can happen a few months, or many years after cataract surgery depending on how quickly your body forms scar tissue and reacts to the IOL. When this scar tissue interferes with vision, it can be opened with a YAG laser. This procedure called a YAG Laser Capsulotomy, is usually done in the office, takes just a few minutes, is painless and usually restores the vision to the way it was initially after cataract surgery.

8. Treatment of Glaucoma (ECP)

During cataract surgery, laser treatment to reduce the need for glaucoma medication after surgery can be performed. This is known as Endocyclophotocoagulation (ECP). It works to reduce fluid production inside the eye and can lower eye pressure often allowing patients to use less glaucoma medications.

9. PATIENT CONSENT

I have reviewed all five (5) pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given and that my vision could become better or worse following surgery.

I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision or my surgery that they deem relevant in providing me with care.

Initial below if you wish to proceed with surgery:

_____ I wish to have cataract surgery with a lens implant on my RIGHT eye / LEFT eye.

_____ I wish to have a Limbal Relaxing Incision to reduce the astigmatism detected in my RIGHT / LEFT eye. I understand that this is not covered by insurance but the cost of the procedure is included in the cost of having a Multifocal IOL implanted if I chose this option. I understand that total reduction of astigmatism is not guaranteed but further surgery can be performed if my surgeon deems that it would be helpful.

Initial one of the choices below:

_____ I wish to have a Standard IOL implanted. I understand I will probably need glasses after surgery. About 70% of patients will wear glasses following surgery, at least part-time; about 30% do not.

_____ I wish to have a Multifocal IOL implanted. I understand that I will probably have less need for glasses after surgery, but this cannot be guaranteed.

_____ I wish to have a toric IOL implanted. I understand that I will probably have less need for glasses after surgery, but this cannot be guaranteed.

_____ I wish to have endocyclophotocoagulation (ECP). I am aware of the possible need for continuation of glaucoma medications after ECP.

Patient Name

Patient Signature

Date

Witness Name

Witness Signature

Date

Financial Information Initial below to proceed with surgery.

_____ I agree to be responsible for payment of all charges for surgery regardless of the amounts paid by my insurance carrier. I understand that there may be a deductible, co-insurance or other balance if not paid by my insurance for which I will be responsible. I also understand that in the event my insurance denies coverage for services, I will be responsible for payment in full. I understand that my portions are due the day of surgery unless prior arrangements have been made in writing with the office manager.

Patient Signature

Date

I have been notified by my physician that my insurance will deny payment for Limbal Relaxing Incision Surgery and Multifocal IOL implantation. I agree to be personally and fully responsible for payment with the amount as listed.

Procedure Type	Cost Due Patient Per Eye:
LRI only	\$499.00
Toric IOL	\$1100.00
Premium IOL LRI	
Multifocal IOL	\$2199.00
Crystalens	\$2399.00
Postoperative Refraction	\$ 35.00

Patient Signature

Date