

Informed Consent for Cataract Surgery and Implantation of an Intraocular Lens



INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. You have the right to ask any questions you might have about the operation before or after agreeing to have it.

A cataract operation is necessary only when you cannot function satisfactorily due to decreased vision caused by the cataract. After Dr. Proulx has told you that you have a cataract, you and he are the only ones who can determine if or when you should have a cataract operation. You may decide not to have a cataract operation at this time. If you decide to have an operation, Dr. Proulx will replace your natural lens with an intraocular lens implant (IOL) in order to restore your vision. This is an artificial lens, made of 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. This will include measurement of your vision (visual acuity), measurement of the pressures inside your eye (tonometry), microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina with your pupils dilated. Furthermore, approximately 1-2 weeks prior to your surgery you will be required to attend a preadmission visit at the hospital. At this visit, measurements of the curvature of your cornea (keratometry) & the length of your eye (axial length), & intraocular lens calculation (biometry) will be performed to determine the best estimate of the proper power of the implanted IOL. You general health will also be reviewed with one of our physicians as well as the medications you are currently taking.

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While 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. The way you eye heals is somewhat unpredictable, and 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. Although it is very rare to require a second procedure, it is usually possible to replace the IOL and improve the situation.

IOL Master

Biometry must be done with accuracy to calculate the appropriate power of IOL to implant into your eye. Two different technologies are available to perform biometry – a conventional method that uses a high-resolution ultrasound device, and a newer technique known as the IOL Master that uses a laser device.

The IOL Master is a high-precision instrument that offers theoretical advantages over the conventional ultrasound method. Because it uses laser light to measure axial length instead of longer ultrasound waves, its accuracy is about three times that of ultrasound devices. No local anesthesia is required and there is no risk associated with taking the measurements. Further, the risk of confusing right and left eye measurements is eliminated with this technology because the IOL Master automatically detects the right or left eye while taking the measurement. Lastly, measuring the eye with the IOL Master takes less time than using ultrasound.

At the time of your consultation, you will be given a choice to have your biometry performed with either the ultrasound or IOL Master technique. As of this time, biometry performed by conventional ultrasound is an OHIP-covered benefit and there is no cost to you for this service. Biometry done with the IOL Master is currently not a covered service, and the cost is therefore billable to you. Some private insurance plans will cover this cost – if you have private medical insurance you should contact your provider to inquire about coverage for this service. A portion of the cost is remitted to the hospital for purchase and maintenance of the IOL Master device. It is important to recognize that although IOL Master measurements are more accurate than ultrasound ones, this does not guarantee the desired visual outcome after surgery. As mentioned in the previous section, IOL shifting during the healing period may affect the final visual outcome. Use of the IOL Master is meant to maximize the accuracy of the biometry measurement only.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

Before surgery, your eye will be made numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthetist, or have the surgery with only local anesthesia.

A very small incision, or opening, is then made in the eye. This is usually self-sealing but it may require closure with very fine stitches (sutures). The natural lens in your eye will then be removed using a vibrating ultrasound probe to break the lens up into small pieces. Laser equipment is not used during the actual removal of the lens. 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, or any IOL at all.

After the surgery, your eye will be examined either at the end of the surgical day or the next day, and then at intervals determined by Dr. Proulx. 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. 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 by your optometrist.

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.

Cataract surgery is the most frequently performed operation in all of medicine. Greater than 95% of all patients of all patients who undergo cataract surgery, and who have healthy eyes before the operation, will achieve satisfactory vision after the operation. Although very safe, complications can occur in very small minority of cases. Luckily, most complications are managed readily by medical means (e.g. drops, etc.) As a result of the surgery and associated anesthesia, there is a very slim possibility 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 very rare situations. Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and, in very rare cases, death. Although all of these complications can occur, their incidence following cataract surgery is extremely 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; 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 an increased risk for highly nearsighted patients), but which can usually be repaired; uncomfortable or painful eye; droopy eyelid; increased astigmatism; glaucoma; 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. <u>Complications associated with the IOL</u> may include increased night glare and/or halo, double or ghost images, and dislocation of the IOL. 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, droopy eyelid, respiratory depression, hypotension, cardiac problems, and in rare situations, brain damage or death. Local anaesthesia injection around the eye is only rarely used during cataract surgery in virtually all cases, only eye drops are used to numb the eye surface.
- 4. Either distance or reading glasses or contacts are normally needed after cataract surgery for adequate vision.
- 5. 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.
- 6. 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.
- 7. 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. <u>Additional surgeries such as IOL exchange,</u> placement of an additional IOL, or refractive laser surgery rarely may be needed if you are not satisfied with your vision after cataract surgery.

8. If 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.

Although a highly successful operation, the results of cataract surgery cannot be guaranteed. This list of potential complications is not intended to make you fearful, but rather to provide you with the information you need to make an informed decision. Recall that the incidence of complications is very low.

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 a few weeks, once the first eye has stabilized.

PATIENT CONSENT

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 Dr. Proulx to inform me of every possible complication that may occur, he 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.

Patient or substitute decision maker	Witness
Dat	re