

CONSENT FOR CATARACT SURGERY

INTRODUCTION

The natural crystalline lens can become cloudy due to aging, trauma, disease or medications. This condition is called a cataract. When cataracts become visually significant, surgery may be performed to replace the natural lens with an intra-ocular implant. Cataract surgery with implantation of a new intra-ocular lens (IOL) is designed to improve vision. The cataract procedure will often change the refractive error (glasses prescription) within the eye. Cataract surgery is almost always elective and should be performed when the patient is dissatisfied with their visual function. Ultimately, only the patient can make the decision as to when the potential benefits of surgery outweigh the risks.

EXAMINATION PRIOR TO SURGERY

Prior to surgery, a measurement of the curvature of the cornea (keratometry), length of the eye (axial length) and an intra-ocular lens calculation will be performed to determine the proper power of the implanted intra-ocular lens (IOL). As with any measurement, there is variable accuracy, and inaccuracy, associated with testing and intra-ocular lens (IOL) power calculations. There is no guarantee as to the ability of the surgery to achieve the attempted refractive goal. **I understand that after this procedure I may still need to wear glasses or contact lenses for all activities.**

THE PROCEDURE

The surgeons at Eye Doctors of Washington perform the procedure using two methods: (1) traditional cataract surgery and (2) laser assisted cataract surgery. Your surgeon and the staff have counseled you on these procedures. In both types of cataract surgery, an anesthesiologist administers light sedation at the onset of the procedure. The eye is anesthetized (made numb) with drops placed on the surface of the eye. In rare circumstances, an injection (local anesthesia) will be given. In the operating room, you will lie on your back throughout the procedure. A lid holder will be utilized to keep your eye from closing.

During traditional cataract surgery, a metal blade is used to create incisions in the surface of the eye to gain access to the internal components. A needle is used to create a round opening in the front surface of the natural crystalline lens. This is called a capsulotomy. This opening allows access for the ultrasound probe that breaks up and removes the cloudy lens material. After the natural lens (the cataract) is removed, the intra-ocular lens (IOL) of the selected power is inserted. The incision is usually self-sealing but it may require closure with fine sutures.

Laser Assisted Cataract Surgery (LACS) is performed with a femtosecond laser. EDOW surgeons were the first doctors in our region to perform the procedure in 2011. The LACS procedure replaces several of the steps traditionally done by hand held instruments with a precise, automated laser device. The femtosecond laser procedure is performed in a laser suite prior to entering the operating room. Prior to the procedure, you may be given a mild sedative. The procedure is usually performed in 2-3 minutes. You will lie on your back throughout the procedure. Anesthetic drops will be placed on the surface of each eye. A lid holder may be utilized to keep your eye open. A docking system will be applied using mild suction to stabilize your eye during the laser procedure. The laser delivery system will be lowered onto your eye. It is normal to feel mild pressure during this process; however, you should not feel substantial pain. The laser system will then be utilized to do all, or several, of the following steps:

1. Precise imaging of the eye structure especially the cornea and lens
2. Precise circular opening in the natural crystalline lens (Capsulotomy)
3. Softening of the dense lens material (Photolysis)
4. Incisions to reduce/eliminate astigmatism (Corneal Relaxing Incisions)

Once the laser has performed these tasks, you will be transported to the surgery suite. In the surgery suite, the remaining aspects of the cataract surgery will be completed as described above.

POSTOPERATIVE CARE

I have read and understood the contents of this page. _____ (Initials)

After the surgery, several follow-up examinations will be required. The usual sequence is one day, approximately one week, and approximately one month after the procedure. Depending upon your unique response to the procedure, more visits may be required. During the immediate recovery period, a number of eye drops will be used for 3-4 weeks. Most normal activities can be resumed the next day; however, there will be some limits upon physical activity. Post-operative care is described in separate documents and by the surgical center staff. Vision is often stable within 1-2 weeks; however, in some circumstances the recovery can be delayed for additional weeks or months. The prescription for new glasses is usually done after one month.

BENEFITS OF SURGERY

Patients with cataracts have a decrease in distance and/or near vision. Improved visual acuity is the most significant benefit expected with cataract surgery. Many individuals with cataracts also have visual disturbances such as glare and halos as well as a loss in the vibrancy of color vision. Cataract surgery will often improve these symptoms.

INTRAOCULAR LENS SELECTION

When the intra-ocular lens is inserted, there is a change in the refractive error (glasses prescription) of the eye. Intraocular lenses are available in a variety of types. Traditional IOLs are monofocal. Monofocal means the intraocular lens has one power throughout the lens. Monofocal IOLs can be selected to target uncorrected vision at distance or near. For example: A patient desiring good distance vision without glasses will have an IOL selected to focus light clearly at distance. This patient will require glasses to see clearly for near tasks such as reading, viewing a cellular phone, or working at a computer.

Corneal astigmatism is when the curvature of the cornea is more like a football than a soccer ball. Traditional monofocal IOLs do not correct astigmatism. Astigmatism may be reduced or eliminated by two methods (1) laser assisted cataract surgery, which creates precise incisions in the cornea and/or (2) special IOLs called toric lenses. **Patients electing these options will also need to read and sign a supplemental consent.**

The multifocal IOLs use an advanced design to provide dual focal points, focusing light simultaneously for distance and near vision. Best results are obtained when these advanced lenses are used in both eyes; however, in rare circumstances, multifocal IOLs can be implanted only in one eye. The Crystalens and Trulign are advanced intra-ocular lens designed to move or flex inside the eye to focus on near, intermediate, and distance objects. **Patients electing any of these lenses will also need to read and sign a supplemental consent.**

NON-SURGICAL ALTERNATIVES

There are no medical treatments for cataracts. Non-surgical alternatives to cataract surgery are to delay surgery and continue to function without glasses or wear spectacle lenses or contact lenses, if necessary. In almost all instances, deferring cataract surgery to a later date does not increase the risks of the future procedure or prolong the convalescence.

RISKS

Cataract surgery is one of the most frequently performed procedures in the United States. Over a million successful procedures are completed each year; however, as with all surgical procedures there are risks including permanent partial or total loss of vision. The risks of cataract surgery include, but are not limited to:

1. Infection, which if serious, can lead to partial or complete loss of vision
2. Swelling of the retina (called macula edema). Macula edema usually improves with time. It is possible that the edema will not subside and vision may be limited or require further treatment.

- a. Patients with diabetic retinopathy are at higher risk for developing retinal edema after surgery and progression of retinopathy may occur after intraocular surgery.
3. Swelling of the cornea. This condition, known as corneal edema, usually resolves with time. It is possible that the edema will not subside and vision may be limited or require a corneal transplant.
 - a. Patients with endothelial disorders such as Fuchs corneal dystrophy or who have had previous corneal transplants are at a higher risk of developing prolonged or permanent corneal edema
4. Development of increased intraocular pressure. This condition, known as glaucoma, may require medical or surgical intervention. If not controlled, glaucoma may cause a partial or total loss of vision.
 - a. Patients with pre-existing glaucoma or a family history of glaucoma are at a higher risk
5. Tears or detachment of the retina. This risk of retinal detachment is increased by intraocular surgery, even when performed successfully. Most retinal detachments can be repaired; however there is a small but not insignificant risk of partial or total loss of vision.
 - a. Patients who are highly near-sighted (myopic) are at an increased risk of retinal tears or detachment compared with the general population.
6. Damage to the retina, eye muscles, or optic nerve from anesthetic block. During the administration of anesthesia to the eye region, the needle can inadvertently injure the eye. Such damage may lead to partial or total loss of vision or double vision. This condition is very unusual because most surgeries are performed **without** a local injection or the local injection is performed with a peri-bulbar block.
7. A common occurrence after cataract surgery is the development of posterior capsular opacification. During cataract surgery, the outer coating of the natural crystalline lens (the capsular bag) is retained to support the implanted intraocular lens. The back surface of the retained capsular bag will often get cloudy (opacified) over months to years. This opacification process may cause a reduction in vision. The opacified capsule can be opened by a brief and painless procedure known as a YAG laser capsulotomy. This procedure has a rapid effect. Patients can immediately return to normal activities.
8. Lid droop (ptosis) may occur from surgery or the use of the corticosteroids drops. Lid droop usually resolves within 6 months; however, permanent lid abnormalities may infrequently occur. Permanent ptosis can usually be remedied by further surgical intervention
9. Inaccuracy of the intra-ocular lens power selection, necessitating the need for glasses, contacts, or further surgical intervention (intraocular lens exchange, LASIK, PRK, etc.).
10. De-centration of the intra-ocular lens that may provide unwanted images and glare.
11. Significant visual disturbances described as glare, haloes and starbursts have been reported by a small percentage of patients who have standard lens implants. Patients with multifocal IOLs, such as the ReSTOR® and Tecnis lenses, describe visual disturbances at a higher incidence than monofocal IOLs.
12. The general risks of anesthesia and surgery despite the fact that only mild sedation will be used.
13. Rarely, if the cataract is difficult or if the tissue is weak, a piece of the cataract, or the entire cataract, could fall to the back of the eye. If this event occurs, then a second surgery, performed by a retinal specialist, may be required
14. Laser Assisted Cataract Surgery has been associated with an increased risk of small red spots on the surface of the eye called a sub-conjunctival hemorrhage. These will not affect vision and are transient, usually resolving in 1-2 weeks.
15. Laser Assisted Cataract Surgery and traditional cataract surgery have not been demonstrated to be safe for exposure to an embryo, fetus, or infant, therefore pregnant women or nursing mothers may not participate.
16. Although all of these problems and complications can occur, their incidence with cataract surgery is low. In addition, it is not possible to inform and educate on all possible complications pertaining to cataract surgery or refractive lens exchange, extremely rare or unexpected complications can occur.

CONSIDERATIONS OF CATARACT SURGERY

1. The main rationale for cataract surgery is to improve the quality of vision, **not reduce or eliminate glasses**. It is possible that even after successful cataract surgery, glasses will be required for some, or all, visual tasks. If a standard monofocal implant is targeted for distance vision, a side effect of having the cataract surgery is the loss of the near focusing power of the eye (accommodation). In this case, it must be clearly understood that even with successful surgery and an accurate monofocal IOL calculation targeted to distance vision, close vision will usually remain blurred. A pair of glasses for close and intermediate vision will usually be required. By contrast, multifocal IOLs have a dual focus system intended to provide near vision along with the distance correction. Even so, distance or reading glasses may be needed for some, or all, visual tasks.
2. An alternative implant strategy is to deliberately correct one eye for close vision and the other eye for distance vision. This combination of a distance eye and reading eye is usually called monovision. Monovision allows

the patient to read with one eye without glasses and use the other eye for distance tasks. This near eye will be blurred at distance and the patient may require a corrective lenses for certain, or all, distance visual tasks. It has been employed successfully in many contact lens, LASIK, and cataract surgery patients; however, monovision is associated with a higher incidence of visual disturbances.

3. The accuracy of the intra-ocular lens calculations is quite satisfactory for normal sized eyes. In eyes that are highly near or farsighted (myopic or hyperopic), these calculations are less accurate. In the event of a minor residual refractive error, vision can usually be corrected by an eyeglass prescription or contact lenses. This prescription will usually be considerably weaker than the patient's original prescription. In the event of a significant residual refractive error, vision can usually be corrected by a stronger pair of glasses, contact lenses, surgical procedures such as an exchange of the implant, insertion of a second implant, or laser vision correction (LASIK or PRK)
4. Certain patients are more difficult to accurately measure for the correct intraocular lens power. This includes, but is not limited, to patients who have undergone previous refractive surgery (LASIK, PRK, RK, etc.) as well as patients who have had previous procedures such as corneal transplants. In the event of a minor residual refractive error, vision can usually be corrected by an eyeglass prescription or contact lenses. This prescription will usually be considerably weaker than the patient's original prescription. In the event of a major residual refractive error, vision can usually be corrected with a stronger pair of glasses, with contact lenses, or through surgical procedures such as an exchange of the implant, insertion of a second implant, or laser vision correction (LASIK or PRK).
5. Since only one eye will undergo surgery at a time, the patient may experience a period of imbalance between the two eyes (anisometropia). This cannot be corrected with spectacles if there is a marked difference in the prescriptions. The patient will either temporarily have to wear a contact lens in the non-operated eye or function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 2 to 4 weeks, once the first eye is stabilized.
6. Rarely, due to complications in surgery, it may not be possible to implant an IOL or an alternative lens type may be inserted. For individuals selecting a multifocal IOL, it is possible that an alternative standard IOL, or no IOL will be inserted. This would preclude a patient from the benefits of presbyopia correction. For individuals selecting an astigmatism correcting toric IOL, it is possible that an alternative standard IOL or no IOL will be inserted. In this rare circumstance, corneal relaxing incision can usually be performed to reduce or eliminate the naturally occurring astigmatism.

PATIENT RESPONSIBILITY FOR COSTS

Surgery involves services by the surgeon & anesthesiologist, as well as facility fees for the surgical center and the intra-ocular lens. I understand that the surgeon, anesthesiologist, and facility will make all reasonable efforts to obtain pre-authorization and collect the appropriate reimbursements from my insurers; however, I am ultimately responsible for the costs incurred.

If I need a second surgical procedure, such as removal, replacement or repositioning of my intra-ocular lens, I understand that there will be additional fees from the surgeon, the surgery center, and the anesthesiologist. These costs are usually covered by health insurance.

I understand that I will be responsible for the costs of surgery-related injuries and medication. I also understand that no compensation is being offered to me in the event of an injury or complication. If I need additional refractive surgery, such as LASIK or intraocular lens exchange, to attain a more desirable refraction (prescription), then there will be an additional fee for services not covered by insurance.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of cataract surgery have been presented to me in detail in this document and explained to me by my ophthalmologist and his/ her associated staff. I have had ample time to read this document and to ask

I have read and understood the contents of this page. _____ (Initials)

questions. My ophthalmologist and their associated staff have answered all of my questions to my satisfaction. I therefore consent to undergoing cataract surgery and understand that all procedures have risks as well as benefits. I have been fully informed of the right to receive a copy of this signed and dated consent form.

I am having surgery on my (check one): RIGHT EYE LEFT EYE

(Patient's full name)

(Patient's signature)

(Witness's signature)

(Date of signature)

(Date of signature)

Supplemental Informed Consent – Astigmatism Correction with Laser Assisted Cataract Surgery and/or Toric IOL

In some individuals, the cornea is not perfectly round. The result of this condition, known as astigmatism, is that objects are not focused into a single, clear, image. Traditional intraocular lens implants do not correct astigmatism. There are two available options for correcting corneal astigmatism:

1. Laser Assisted Cataract Surgery (LACS) can be used to make 1 or 2 precise incisions in the cornea
2. An astigmatism correcting intraocular lens called a “Toric IOL”

If you decide to have surgery to correct astigmatism using LenSx and/or the Toric IOL, then extensive measurements of the eye will be required. As with any measurement, there is a high, but variable degree of accuracy. Due to measurement and individual healing variability, there is no guarantee as to achieving the desired refractive (glasses prescription) goal.

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the additional costs of surgery using Laser Assisted Cataract Surgery and/or a toric intraocular lens. Medicare (and any secondary coverage) reimburses the removal of the cataract but stipulates that the extra expenses associated with the use of advanced implants are billable directly to the patient and are not covered benefits.

If I need a second surgical procedure, such as removal, replacement, or repositioning of my intraocular lens, then I understand that there will be additional fees from my surgeon, the surgery center, and the anesthesiologist, although these are usually covered by health insurance.

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If I need additional refractive surgery such as LASIK, PRK, and/ or an intraocular lens exchange to attain a more desirable refraction (glasses prescription), then there will be an additional fee for any services that are not covered by insurance – it is important to note that these services are not usually covered by insurance.

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PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I understand that I am making a decision for myself, such that I feel the potential benefits of this procedure outweigh the potential risks. I understand that despite all reasonable efforts there is a chance that I may still need to wear glasses and/ or contact lenses after surgery for all activities. I have had ample time to read this document and ask questions. My ophthalmologist their associated staff have answered all questions to my satisfaction. I, therefore, consent to undergoing cataract **surgery with laser assisted cataract surgery and/or a toric IOL.** I have been fully informed of my right to receive a copy of this signed and dated consent form.

(Patient’s full name)

(Patient’s signature)

(Witness’s signature)

(Date of signature)

(Date of signature)

Supplemental Consent - Presbyopic Reduction Surgery using Tecnis and ReSTOR Multifocal IOLs or Crystalens/Trulign IOLs

Advanced multifocal IOL designs as well as Crystalens IOLs allow for a patient to elect a correction that improves both far and near vision. Multifocal intraocular lenses (Tecnis and ReSTOR) and Crystalens are capable of providing an improved range of vision without glasses. I understand that there are inherent difference between multifocal or Crystalens/Trulign lens and standard monofocal lens implants. While the majority of patients are satisfied with the results of having multifocal IOLs, a higher incidence in visual disturbances were reported with multifocal lens when compared with traditional monofocal (standard) lenses in clinical trials. I also understand events during surgery may make it impossible to implant the Tecnis Multifocal lens, ReSTOR® lens or Crystalens/Trulign lens. I will leave this decision to the surgeon's discretion

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the additional costs of the surgery using the ReSTOR® and Tecnis multifocal lens, or Crystalens/Trulign lens. Medicare (and any secondary coverage) reimburses the removal of the cataract but stipulates that the extra expenses associated with the use of advanced implant are billable directly to the patient and are not covered benefits.

If I need a second surgical procedure, such as removal, replacement, or repositioning of my intraocular lens, then I understand that there will be additional fees from my surgeon, the surgery center, and the anesthesiologist, although these are usually covered by health insurance.

_____ (Initial here)

If I need additional refractive surgery such as LASIK, PRK, and/ or an intraocular lens exchange to attain a more desirable refraction (glasses prescription), then there will be an additional fee for any services that are not covered by insurance – it is important to note that these services are not usually covered by insurance.

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PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I understand that I am making a decision for myself, such that I feel the potential benefits of this procedure outweigh the potential risks. I understand that the implantation of the advanced multifocal IOL is designed to decrease my dependency on eyeglasses and/ or contact lens but I still may need to wear glasses and/ or contact lens after my surgery. I have had ample time to read this document and ask questions. My ophthalmologist and his/her associated have answered all of my questions to my satisfaction. I, therefore, consent to undergoing cataract **surgery with this special lens implant.** I have been fully informed of my right to receive a copy of this signed and dated consent form.

(Patient's full name)

(Patient's signature)

(Witness's signature)

(Date of signature)

(Date of signature)

I have read and understood the contents of this page. _____ (Initials)