Eye Doctors OF WASHINGTON

Informed Consent Form
Cataract Surgery

INTRODUCTION

With aging, or due to trauma, disease or medications, the natural crystalline lens becomes cloudy. This condition is called a cataract. When cataracts become visually significant, surgery can be performed to replace the natural lens with an intra-ocular implant. This intra-ocular lens (IOL) will improve vision as well as change the refractive error 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 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 (biometry) will be performed to determine the best estimate for the proper power of the implanted lens. As with any measurement, there is a variable accuracy, and inaccuracy, associated with testing. There is no guarantee as to ability of the surgery to achieve the attempted refractive goal. I understand that even after this procedure that I may still need to wear glasses or contact lenses.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

At the onset of the procedure, an anesthesiologist administers light sedation. The eye is made numb with either drops or an injection (local anesthesia). During surgery, the natural lens is removed by breaking it up into small pieces with a vibrating needle (phaco-emulsification) or pulses of water (Aqua-Lase®). These pieces are gently suctioned out through a small, hollow tube inserted through a small incision in the eye. After the natural lens is removed, the intra-ocular lens (IOL) of the selected power is inserted. The incision required to perform this operation is at times self-sealing but it may require closure with very fine stitches (sutures). After the surgery, several follow-up examinations will be required. During the immediate recovery period, 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. Usually, visual correction is stable within 3-4 weeks; however, in some circumstances the recovery can be delayed for additional weeks or months.

In rare cases, it may not be possible to implant a lens or an alternative lens type may be inserted. For individuals selecting a presbyopia-correcting IOL such as ReSTOR® and ReZOOM®, it is possible that an alternative standard IOL or no IOL will be inserted. This would preclude the patient from the benefits of presbyopia correction. For individuals selecting an astigmatism correcting 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.

BENEFITS OF SURGERY

Improved visual acuity is the most significant benefit of cataract surgery. Patients with cataracts have a decrease in either distance and/or near visual function. While decreased acuity is the most common complaint, many individuals also have visual disturbances such as glare and halos. Color vision may also become less vibrant. Cataract surgery can help improve these complaints as well.

When the intra-ocular lens is inserted, it changes the natural refractive error of the eye. Intraocular lenses are now available in a variety of types. Traditional IOLs are monofocal. Monofocal means the intraocular lenses has one power throughout the lens. This lens power can be set to attempt to give good uncorrected vision at distance, near, or to be similar to the other eye. Monofocal lenses or incisions in the cornea can be utilized to correct astigmatism. Patients electing these lenses or corneal incisions will also need to read and sign the supplemental consent.

The ReSTOR® and ReZOOM® IOLs are advanced design intra-ocular lenses that have a dual focus, far and near, simultaneously. Best results are obtained when used in both eyes, but these lenses can be used in one eye only. In clinical studies, about 80% of ReSTOR lens patients had no need for glasses at all, once the eyes had healed. The other 20% reported occasional use of glasses or contact lens. Patients electing these lenses will also need to read and sign the supplemental consent.

I have read and understood this page. Patient's Initials _____

RISKS

Cataract surgery is one of the most frequently performed procedures in the United States, with well over a million successful procedures performed each year. The surgery itself is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical, but severe pain would be unusual. The risks 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 macular edema). Cystoid macular edema usually improves with time. It is possible that the edema will not subside and vision may be limited or require further treatment. For patients with diabetic retinopathy, progression of the 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.
4. Development of increased intraocular pressure. This condition, know as glaucoma, may require medical or surgical intervention. If not controlled, glaucoma may cause a partial or total loss of vision.
5. Detachment of the retina. Patients who are highly near-sighted are at an increased risk of retinal detachment compared with the general population. This risk of retinal detachment is increased by intraocular surgery. Most retinal detachments can be repaired; however there is a small but not insignificant risk of partial or total loss of vision.
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. Posterior capsular opacification. During cataract surgery, the outer coating of the natural crystalline lens (the capsular bag) is retained within the eye to support the implanted intraocular lens. With time, the back surface of the capsular bag can get cloudy (opacified). This may cause a reduction in vision. The capsule can opened with a simple, painless procedure known as an Nd: YAG laser capsulotomy. This procedure is safe, takes only several minutes, and has a rapid effect. Patients can immediately return to normal activities, usually without the need for new medications.
8. Lid droop (ptosis) can occur from surgery or due to the postoperative use of corticosteroids drops or anesthesia. Usually, the lid droop resolves within 6 months; however, permanent lid abnormalities may occur. These 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. Decentration 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. Up to 20% of the patients with the ReSTOR® and ReZOOM® lenses describe some visual disturbances. The incidence of this complication is rare.
12. The general risks of anesthesia and surgery despite the fact that only mild sedation will be used.

Although all of these problems and complications can occur, their incidence with cataract surgery is low. Also, it is not possible to inform and educate on all possible complications pertaining to refractive lens exchange and cataract surgery.

CONSIDERATIONS OF CATARACT SURGERY

1 If a standard monofocal implant is used, 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 IOL calculation targeted to correct the eye's distance vision, close vision will usually remain blurred, requiring a separate pair of glasses for close and intermediate vision. By contrast, the ReSTOR® and ReZOOM® intra-ocular lenses have a dual focus system intended to provide some near vision along with the distance correction. Even so, reading glasses may be needed after these dual focus IOL implants. Further, intermediate (computer) vision is not fully aided by the ReSTOR® and ReZOOM® IOLs.

2 An alternative implant strategy is to deliberately correct one of the eyes for close vision and the other eye for distance vision. This would allow the patient to read with one eye 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 reading eye is called planned multi-vision or monovision. It has been employed successfully in many contact lens and cataract surgery patients.

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3 The accuracy of the intra-ocular lens calculations is quite satisfactory for normal sized eyes. In eyes that are highly near or farsighted, these calculations can be less accurate. Further, the majority of the IOLs used do not correct pre-existing astigmatism. 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 by a stronger pair of glasses, contact lenses, or 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 by a stronger pair of glasses, contact lenses, or 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 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 2 to 4 weeks, once the first eye is stabilized.

NON-SURGICAL ALTERNATIVES

There are no medical treatments for cataracts. Non-surgical alternatives to cataract surgery are to continue to wear spectacle lenses or contact lenses.

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 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, there will be an additional fee for services not covered by insurance.

I have read and understood this page. Patient's Initials _____

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 staff. I have had ample time to read this document and to ask questions. My ophthalmologist and their 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.

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Patient Name

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date

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Physician Signature Date

I have read and understood this page. Patient's Initials _____

Supplemental Informed Consent – ReSTOR® & ReZOOM®

Traditional intraocular lens implants correct vision at one distance only, either far or near (usually far vision is chosen). Advanced lens designs allow a patient to elect a correction that improves both far and reading vision. The advanced ReSTOR® and ReZOOM® IOLs multifocal lens are available at an extra cost.

If you decide to have surgery using the advanced multifocal IOL, extensive measurements of the eye will be required including: measurement of the curvature of the cornea (keratometry); a measurement of the length of the eye (axial length); and specific intra-ocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens. As with any measurements, there is an associated degree of accuracy and, due to measurement and individual healing variability, there is no guarantee as to achieving the desired refractive (prescription) goal.

I understand that I am eligible to have the advanced design lens alternative. Further, I understand that any surgery has inherent risks. Ultimately, only I can make the decision that, for me, the potential benefits outweigh the risks.

I understand that implantation of the advanced multifocal IOL is designed to decrease my dependency on eyeglasses or contact lenses, BUT that I may still need to wear glasses or contact lenses after surgery.

I understand that there are inherent differences with the ReSTOR® and ReZOOM® IOLs compared with standard lens implants. While the majority of patients are satisfied with the result, in the U.S. FDA clinical trials, a higher incidence in visual disturbances were reported with these lenses when compared with traditional monofocal lenses. I also understand that events during surgery may make it impossible to implant the ReSTOR® and ReZOOM® IOL. I will leave this decision to the surgeon's discretion.

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the additional cost of the surgery using ReSTOR® or ReZOOM® lens. Medicare (and any secondary coverage) reimburses for removal of the cataract, but stipulates that the extra expenses associated with use of the advanced implant are billable directly to the patient and is not a covered benefit.

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 if one is required, although these are usually covered by health insurance. If I need additional refractive surgery such as LASIK or PRK or an intraocular lens exchange to attain a more desirable refraction / prescription, there will be an additional fee for services not covered by insurance.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of advanced ReSTOR® and ReZOOM® IOLs use for cataract surgery has been presented to me in this document, and explained to me by my ophthalmologist and the staff. I have had ample time to read this document and ask questions. My ophthalmologist has answered all 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

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Patient Name

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Patient Signature Date

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Witness Signature Date

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Physician Signature Date

I have read and understood this page. Patient's Initials _____

Supplemental Informed Consent – Astigmatism Correcting Intraocular Lenses (Toric IOL)

In some individuals, the cornea is not perfectly round. It has two distinct curvatures as is shaped more like tshape a football than that of a basketball, i.e., one flatter curvature and one steeper curvature. The result is that objects are not focused into a single image. Traditional intraocular lens implants do not correct astigmatism in that they have only one curvature ("spherical IOL"). An astigmatism correcting intraocular lens, called a "Toric IOL" is now available. Alternatives to the use of a Toric IOL include, among others, eyeglasses, contact lenses, and other refractive surgical procedures such as corneal relaxing incisions, LASIK, and PRK.

If you decide to have surgery using the toric IOL, extensive measurements of the eye will be required including: measurement of the curvature of the cornea (keratometry); a measurement of the length of the eye (axial length); and specific intra-ocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens. As with any measurements, there is an associated degree of accuracy and, due to measurement and individual healing variability, there is no guarantee as to achieving the desired refractive (prescription) goal.

I understand that I am eligible to have the Toric IOL. Further, I understand that any surgery has inherent risks. Ultimately, only I can make the decision that, for me, the potential benefits outweigh the risks.

I understand that implantation of the Toric IOL is designed to decrease my dependency on eyeglasses and contact lenses, BUT that I may still need to wear glasses or contact lenses after surgery.

I understand that there are inherent differences with the Toric IOLs compared with standard lens implants. While the majority of patients are satisfied with the result, in the U.S. FDA clinical trials, a higher incidence in visual disturbances were reported with these lenses when compared with traditional monofocal lenses. I also understand that events during surgery may make it impossible to implant theToric IOL. I will leave this decision to the surgeon's discretion.

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the additional cost of the surgery using a Toric intraocular lens. Medicare (and any secondary coverage) reimburses for removal of the cataract, but stipulates that the extra expenses associated with use of the advanced implant are billable directly to the patient and is not a covered benefit.

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, although these are usually covered by health insurance. If I need additional refractive surgery such as LASIK or PRK or an intraocular lens exchange to attain a more desirable refraction / prescription, there will be an additional fee for any services not covered by insurance.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of Toric IOL use for cataract surgery has been presented to me in this document, and explained to me by my ophthalmologist and the staff. I have had ample time to read this document and ask questions. My ophthalmologist has answered all 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

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Patient Name

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Patient Signature Date

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Witness Signature Date

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Physician Signature Date

I have read and understood this page. Patient's Initials _____