

# **Informed Consent for Lensectomy (either Refractive or for Cataract) with Implantation of the Multifocal ReSTOR® Intraocular Lens**

by Shawn R. Klein, MD

## **Introduction**

A cataract develops when the natural lens of the eye becomes cloudy, and causes vision to become blurred. Cataract surgery, via lensectomy, involves the removal of the cloudy natural lens. In most cases, the natural lens will be replaced with an artificial implant called an intra-ocular lens (IOL). This implant reduces or eliminates the need for strong eyeglasses after surgery.

Traditional intraocular lenses correct vision at one distance only: far or near (usually far vision is chosen), and glasses must be worn for other distances, such as computer vision or reading. Advanced lens designs may allow a patient to improve both far and reading vision. The advanced ReSTOR® multifocal lens is available at an extra cost.

At times, lensectomy can be performed for refractive purposes. This means that a similar surgery to cataract surgery is performed, but only for the purposes of reducing the need for glasses, not for cataract extraction.

## **Examination before surgery**

If you agree to have surgery using the advanced ReSTOR® multifocal IOL, a comprehensive eye examination is a pre-requisite. In addition, more extensive measurements of the eye are required including: measurement of the curvature of the cornea (keratometry); measurement of the length of the eye (axial length); and specific intra-ocular lens calculations (biometry) to determine the best estimate of the proper power of the implanted lens. As with any measurements, there is an associated degree of inaccuracy and, due to measurement and individual healing variability, there is no guarantee as to achieving the desired refractive (prescription) goal.

## **Procedure and post-operative care**

The surgery is performed using light sedation administered by an anesthesiologist while the eye is made numb by my surgeon with either anesthetic eye drops or a local anesthetic injection. The natural lens will then be removed by breaking it up into small pieces using an ultrasound probe and the pieces are gently vacuumed away. This type of surgery is called phacoemulsification. After the natural lens is removed, an artificial lens of the power determined during my pre-operative examination is placed inside my eye. In rare cases, it may not be possible to implant a lens. The incision required to perform this operation is usually self-sealing but it may require closure with very fine stitches. The surgery is usually

quite comfortable for the patient. Mild discomfort for the first 24 hours may occur but severe pain would be extremely unusual.

Several follow-up examinations are required after surgery. It is necessary to use prescribed eye drops to assist in healing during the immediate recovery period. Even though the goal is to reduce dependency on glasses or contacts, they may still be required for further improvement in my distance vision, reading vision, or both. I should be able to resume my normal activities within several days, and my vision will usually be stable within several weeks.

### **Benefits of Surgery**

Benefits to me should be clearer, more natural vision than I presently have. Using a standard implant with cataract surgery improves natural distance vision, but most patients require additional glasses for reading, and computer work.

If one desires to have uncorrected clear vision for both distant and near tasks, a multifocal implant is required. The ReSTOR® multifocal intra-ocular lens is an advanced design that makes it possible to focus both far and near simultaneously. Best results are obtained when used in both eyes, but it may be used in one eye only. In clinical studies, over 80% of ReSTOR® lens patients had no need for glasses at all once healed. The other 20% reported occasional use of corrective lenses. Depending on surgical considerations that Dr. Klein will discuss with you, it may sometimes be useful to put other types of multifocal (e.g. ReZoom®) lenses or a monofocal lens in your fellow eye.

### **Risks**

Risks of cataract surgery or refractive lensectomy include, but are not limited to:

1. Infection or bleeding, which if serious can lead to complete loss of vision.
2. Swelling in the central area of the retina (called "cystoid macular edema") which usually improves with time.
3. Clouding of the outer surface of the eye (corneal edema) that often improves with time, but can also be corrected with corneal transplant surgery if necessary.
4. Detachment of the retina (an increased risk in highly near-sighted eyes). A retinal detachment can usually be repaired if detected early.
5. Damage to the retina or nerve during the administration of the anesthesia but only if an injection is performed. This is very rare.
6. Inaccuracy of the intra-ocular lens power.
7. Decentration of the intra-ocular lens, which may provide unwanted images and increased glare.
8. Cloudiness of the membrane surrounding the lens implant ("posterior capsular opacification"), usually within the first year after surgery. This occurs in 40% of patients and can be treated by laser.
9. The risks of anesthesia, despite the fact that only mild sedation will be used.

Although all of these complications can occur, their incidence following cataract surgery is exceptionally low.

Risks specific to the ReSTOR® intraocular lens include, but are not limited to:

1. Vision disturbances of glare, haloes and starbursts, which may be severe in up to 5% of patients.
2. Scotomas - which can be shadows (often ring-like) in the sides of the visual field.
3. Patients may still require some correction with glasses for certain tasks.
4. Patients may need to hold reading material closer than they currently do.
5. Patients may have less vision in the intermediate range and may need to get closer to objects to see them clearly. This may improve with time.
6. Patients may notice that their vision improves with time as there is an adaptation period.
7. Patients may require more light in order to read clearly.

I understand that I have alternatives and that any surgery has inherent risks.

Ultimately, only I can make the decision that the potential benefits of surgery outweigh the risks.

### **Surgical alternatives and shortcomings**

If a standard monofocal intra-ocular lens implant (not a ReSTOR® lens) is used, near (reading) and intermediate (computer) vision will usually remain blurred, requiring a separate pair of glasses. In contrast, the ReSTOR® intra-ocular lens has a multi-focus system intended to provide near vision along with the distance correction. However, there is no guarantee that reading glasses may not be needed for certain tasks even with the ReSTOR® lens.

An alternative to a multifocal lens is to use "monovision." In monovision, a standard monofocal lens is implanted in both eyes, but one eye (the non-dominant eye) is left deliberately nearsighted. Many people successfully use monovision with contact lenses, but for some patients, the disadvantage is that the monovision eye may require a corrective lens for best distance vision (such as night driving) and one may have problems of depth perception.

The latest lens measurement techniques and formulas are used before surgery to predict the power of the lens to be implanted. In the event that a patient's individual healing results in the prescription being other than predicted, the vision can usually be corrected by an eyeglass prescription. If the result is further from predicted values, a stronger pair of glasses, contact lenses, surgical exchange of the implant, the insertion of a second implant with another operation, or laser refractive surgery may be necessary for an optimal outcome.

Since only one eye will undergo surgery at a time, one may experience a period of imbalance between the two eyes (anisometropia). One may need to function with only one clear eye for vision until the second eye is operated. In the absence of

complications, surgery in the second eye can usually be accomplished within a few weeks.

**Non-Surgical Alternatives**

Patients having surgery for purely refractive reasons, might opt for contact lens monovision. The only alternative to cataract surgery is to have stronger eyeglasses prescribed and to accept the associated vision blur. One may need to modify their lifestyle as required due to the less acute vision. No medicine or eye drops are available to correct a cloudy cataractous lens.

**Patient Responsibility For Costs**

My insurance company (Medicare or other private insurance) will cover the expenses associated with standard cataract removal and insertion of a standard monofocal (not ReSTOR®) lens, but will not pay for the additional costs of implanting the ReSTOR® lens. Medicare and private insurance companies recognize the extra expenses associated with use of the advanced implant as billable directly to the patient and not a covered Medicare or Insurance benefit. I understand that I am responsible for the additional cost of the surgery using a ReSTOR® lens. The additional cost includes special testing, including topography, before and after surgery, and any "touch-up" procedures that might be necessary in order to help you improve your ultimate visual outcome, including LASIK surgery, astigmatic keratotomy, and/or contact lens fitting. It does NOT include YAG laser posterior capsulotomy or other procedures which are part of the normal healing process after cataract surgery.

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.

**Patient's Statement Of Acceptance And Understanding**

The details of refractive lensectomy, cataract, cataract surgery and the use of the advanced ReSTOR® multifocal lens use have been presented to me in detail in this document, and explained to me by my ophthalmologist. I have had ample time to read this and ask questions, and my ophthalmologist has answered all my questions to my satisfaction. I therefore consent to undergoing cataract surgery using the ReSTOR® multifocal lens. 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

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Date

Patient Initials \_\_\_\_\_

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Witness Signature

Date

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Physician Signature

Date

Patient Initials \_\_\_\_\_