

Informed Consent for Presbyopia IOL Cataract Surgery

Introduction

Cataract surgery involves the removal of the cloudy lens of the eye. Usually the lens is replaced with an artificial implant called an intra-ocular lens (IOL). Traditional IOLs correct vision at one distance only. Usually corrected far vision is chosen but monovision, where the eyes are set at different distances, may be an option as well. Advanced presbyopic lenses (Restor, Tecnis, and Crystalens) allow you to select a correction that may improve far, intermediate and/or reading vision and make you less dependent on glasses. While some patients do not use glasses at all, there is no guarantee that you will not need glasses. Any surgery has inherent risks and you do have alternatives. Ultimately, only you, the patient, can make the decision that the potential benefits outweigh the risks.

Cataract surgery is performed under light sedation while the eye is made numb with topical anesthetic drops. Typically there is very little discomfort. The cloudy lens is removed by breaking it up into small pieces using ultrasound and the pieces are then gently vacuumed away. After the lens is removed, the IOL is placed inside your eye. The incision required to perform this operation is usually self-sealing but may require closure with very fine stitches.

Several follow-up examinations are required after surgery. You will need to use prescribed eye drops to assist the healing during the immediate recovery period. Most patients are able to resume normal activities within several days, and your vision will usually be stable within several weeks. The lenses do not address astigmatism so this might need to be dealt with separately in some patients; especially those with astigmatism before surgery. A laser treatment may be needed for the astigmatism or spherical correction to give the best, uncorrected vision. Even though the goal is to reduce dependency on glasses or contacts, glasses or contacts may still be required for further improvement in distance, reading, and/ or intermediate vision.

The Presbyopic Lenses

The **Restor** lens is an advanced, multifocal design that makes it possible to focus at far and near simultaneously. The lens may be used in both eyes, or it may be used in one eye only. In clinical studies, over 80% of Restor lens patients did not use glasses at all once healed. While the Restor lens is designed to give good uncorrected near and distance vision some patients still need glasses. Glare and halos as well as decreases in the quality of the vision (dysphotopsias) have also been reported with the Restor in a small percentage of patients.

The **Tecnis** lens is also an advanced, multifocal lens with the goal of providing you high-quality vision in any light condition. This lens is designed to focus at near, intermediate and far ranges. Glare and halos as well as decreases in the quality of the vision (dysphotopsias) have also been reported with the Tecnis in a small percentage of patients.

The **Crystalens** is the only lens approved by the FDA to accommodate or change focus like the human eye. It typically gives good distance and intermediate and may be a little weaker at near. The Crystalens cannot be implanted in every eye. Glare and halos are also possible.

Risks

Risks include, but are not limited to:

1. Infection, inflammation, bleeding or other complications can lead to a partial or complete loss of vision.
2. Swelling in the central area of the retina (called cystoid macular edema) can reduce your vision. The posterior capsule, the membrane of the lens may be broken at surgery increasing this risk. The vitreous can also be lost or disrupted, increasing the chances of CME.
3. Clouding of the outer surface of the eye (corneal edema) that may require a corneal transplant.
4. Detachment of the retina (an increased risk in highly near-sighted eyes).
5. Damage to the retina or nerve during the administration of the anesthesia but only if an injection is performed.
6. Inaccuracy of the intra-ocular lens power leading to the need to exchange the lens.
7. Decentration of the intra-ocular lens, which may provide unwanted images and increased glare.
8. Glare, haloes and starbursts, or problems with the quality of the vision (dysphotopsia).
9. The general risks of anesthesia, despite the fact that only mild sedation will be used.
10. There is also the risk that you may not be able to get the lens that was planned for before surgery or even a lens at all.
11. In many patients the posterior capsule of the lens, which is typically left in place, hazes over with time and will need to be opened.
12. Depending on your refraction before surgery and the accuracy of the lens calculations, an additional laser procedure may be needed to help you see your best.
13. There is no guarantee that you will not have to wear glasses after surgery.

NEED FOR GLASSES If a standard monofocal implant is used, some tasks such as close vision will usually remain blurred, requiring a separate pair of glasses for near and intermediate vision. In contrast, the advanced intra-ocular lens are intended to provide better near vision along with the distance correction although glasses may still be needed.

MONOVISION An alternative to an advanced lens, if both uncorrected distance and near vision is desired, is to deliberately correct one eye for distance and one for near or "monovision". With monovision one may require a corrective lens for best distance or near vision and one may have problems of depth perception.

ACCURACY OF THE LENS POWER If you choose to have surgery using the advanced lenses, extensive measurements of the eye are required to determine the best estimate of the proper power of the implanted lens. As with any measurement, there is an associated degree of accuracy and there is no guarantee as to achieving the desired refractive goal. If the result is too far from predicted values, a stronger pair of glasses, contact lenses, surgical exchange of the implant or the insertion of a second implant in another operation, or laser refractive surgery may be necessary.

ONE EYE AT A TIME 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.

MIX AND MATCH In many cases different lenses can be used in the eyes of the same patient. Patients may have two different types of advanced lenses or one advanced lens and one traditional lens. If you have had one cataract removed already and have a traditional lens, you may be a candidate for an advanced lens in your second eye. While this is the best option for many patients, you may notice differences between the two eyes.

NON-SURGICAL ALTERNATIVES

The only alternative to cataract surgery is to have stronger eyeglasses prescribed and to accept the vision blur. One may need to modify their life style as required by less acute vision. No medicine has been found to correct a cloudy cataract lens.

PATIENT RESPONSIBILITY FOR COSTS

You are responsible for the additional cost of the surgery using an advanced lens. Medicare (and any secondary coverage) does pay for removal of the cataract, but recognizes the extra expenses associated with use of the advanced implant as billable directly to the patient and not a covered Medicare benefit.

If you need a second surgical procedure, such as removal, replacement or repositioning of my intra-ocular lens, there may 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 you need additional refractive surgery such as LASIK to attain a more desirable refraction/prescription, there will be an additional fee not covered by insurance.

PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of advanced lenses for cataract surgery has been presented to me in this document, and explained to me by my eye doctor. I have had ample time to read this consent and ask questions, and my eye doctor has answered all my questions to my satisfaction. I therefore consent to undergoing cataract extraction with an advanced intraocular lens. I have been fully informed of my right to receive a copy of this signed and dated consent form.

Patient Name

Patient Signature

Date

Witness Signature

Date

Physician Signature

Date