

ADDENDUM to the Informed Consent for Cataract Surgery with Intraocular Lens Implant

INTRODUCTION

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to decreased vision caused by the cataract. If you decide to have an operation, the surgeon will replace your natural lens with an intraocular lens implant (IOL) in order to restore your vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye.

NEED TO STOP WEARING CONTACT LENSES PRIOR TO SURGERY

If you wear contact lenses, you may be required to leave them out of the eyes for a period of time prior to having your preoperative eye examination and before your surgery. This is done because the contact lens rests on the cornea, distorting its shape, and this distortion will have an effect on the accuracy of the doctor's measurements of the power of surgical correction needed. Discontinuing contact lens use allows the corneas to return to their natural shape. Soft contact lens wearers are not required to discontinue lenses. Rigid (including gas permeable and standard hard lenses) contact lens wearers should leave lenses out of the eyes for at least four weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within four weeks, this process may take longer, and you will need to remain contact lens free until stabilization is complete.

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, 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. As the eye heals, 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 predict precisely. If the eye's visual power after surgery is considerably different than what was planned, surgical replacement of the IOL or laser vision correction might be considered. These treatments will usually improve the situation.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

Patients who have cataracts may have, or will eventually develop, an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses become necessary, typically after age 40, even for people who start out with excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate (different prescription) reading

glasses in order to see clearly at close range, both at near and at intermediate. There are several other options available to you to achieve distance and near vision after cataract surgery.

- **GLASSES** You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses, or have an IOL implanted for near vision and wear separate glasses for distance.
 - **MONOVISION** It is possible to implant IOLs with two different powers, one eye for near vision, and the other eye for distance vision. This combination of a distance eye and a reading eye is called monovision, and enables you to read without glasses. It has been employed quite successfully in many contact lens and refractive surgery patients.
 - **MULTIFOCAL IOL** It is possible to implant a “multifocal” IOL. These IOLs, more recently approved by the Food and Drug Administration (FDA), provide distance vision AND restore some or all of the focusing (accommodating) ability of the eye. Depending upon the technological features of the IOLs, they may be described as “accommodating,” “apodized diffractive,” or “presbyopia-correcting.” All of these lenses are “multifocal,” meaning they correct for both distance vision and other ranges, such as near or intermediate.
- **I choose to provide for near vision after cataract surgery by choosing:**

_____ Patient initials _____

(Please write “glasses,” “monovision IOLs,” or “multifocal IOLs”)

MORE INFORMATION ABOUT MONOVISION

For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for distance. Eye care professionals refer to this as binocular vision. Monovision can impair depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is typically recommended that this option be tried with contact lenses (which are removable) prior to contemplating monovision correction involving two IOLs.

Ocular dominance, and choosing the ‘distance’ eye correctly: Ocular dominance is analogous to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant or preferred eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a particular person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near. While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant (rather analogous to being ambidextrous), and, in rare circumstances, a person may actually prefer using the dominant eye for near viewing.

The methods for testing and determining ocular dominance are not always 100% accurate: there is some subjective component in the measurement process, and different eye doctors may use slightly different methods of testing. It is critical to determine through the use of contact lenses which combination is best for each person (right eye for distance, left for near, or vice versa) prior to undertaking surgical implantation of two different-powered IOLs during cataract surgery. You can imagine how uncomfortable it might be if monovision were to be rendered “the wrong way around.” It might be compared to a right-handed person suddenly having to write, shave, apply make-up, etc., with the left hand. Be sure you understand this and have

discussed with Dr. Jaben which eye should be corrected for distance, and which for near. If you have any doubts or uncertainty whatsoever, surgery should be delayed until a very solid comfort level is attained through use of monovision contact lenses. **Under no circumstances should you consider undertaking cataract surgery with monovision correction before you are convinced it will be right for you.** Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.

Complications associated with monovision: Monovision may result in problems with impaired depth perception. Choosing the wrong eye for distance correction may result in feeling that things are the “wrong way around.” Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.

MORE INFORMATION ABOUT MULTIFOCAL IMPLANTS

The multifocal IOLs are not perfect and will not totally reverse the loss of near vision function for reading and intermediate vision; however, approximately 90% of patients are free of dependence on corrective lenses. Most patients will function at a very high level quickly after surgery but the brain may take up to 3 to 6 months to continue to adapt to the new lens system.

Complications associated with multifocal IOLs:

- (1) While multifocal IOLs can reduce dependency on glasses, it might result in less sharp vision, which may become worse in dim light or fog.
- (2) Most patients will notice visual side effects such as halos or rings around lights at night. Driving at night may be affected.
- (3) If you drive a considerable amount at night, or perform delicate, detailed, “up-close” work requiring closer focus than just reading, a monofocal lens in conjunction with eyeglasses may be a better choice for you.
- (4) If complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a multifocal IOL.
- (5) “Matched” IOL technology with ReSTOR IOLs in both eyes may result in having to hold reading materials closer than usual (10 to 14”) and less glare symptoms. Intermediate vision activities may be less clear and require low power reading glasses.
- (6) “Mixed” IOL technology such as ReSTOR in one eye and ReZOOM in the other eye may result in a difference in the two eyes when comparing; ReSTOR may provide better vision for reading up close and ReZOOM may provide better vision at intermediate distance, but, when teamed together, brain adaptation to the new lens system will usually overcome any imbalance and result in a more complete range of near and intermediate vision activities. Dr. Jaben will assist you in deciding which lens choices are best for you.
- (7) Glasses for close vision may be needed for such activities as reading for prolonged periods of time such as novels or for intermediate distances such as working on a computer.
- (8) In approximately 5% of patients, corrective lenses may still be needed after multifocal IOL surgery; it is possible that additional surgery such as IOL exchange, piggyback IOLs, corneal incisions or laser vision correction may be helpful; if needed, these procedures are not covered in the original fees. Often it is best to wait for 1 to 3 months before considering other surgery.

MORE INFORMATION ABOUT COMPLICATIONS FOR CATARACT SURGERY

1. If there are complications 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.

2. 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. Additional surgeries such as IOL exchange, placement of an additional IOL, or laser vision correction surgery may be needed if you are not satisfied with your vision after cataract surgery.
3. The results of surgery cannot be guaranteed. If you chose a multifocal IOL, it is possible that not all of the near (and intermediate) focusing ability of your eye will be restored. Additional treatment and/or surgery may be necessary. Regardless of the IOL chosen, you may need laser surgery (called YAG laser capsulotomy) to correct clouding of vision due to a secondary cataract. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.
4. 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 1 to 4 weeks, once the first eye is stabilized.
5. If there is significant astigmatism present, additional procedures may be required to enhance the chances of needing no corrective lenses after surgery. For pre-existent astigmatism, surgical incisions called Limbal Relaxing Incisions (LRIs) may be performed at the time of the surgery to decrease the astigmatism. For postoperative residual astigmatism, additional procedures may include LRIs or laser vision correction surgery.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

Dr. Jaben has informed me that if I have Medicare coverage for this cataract surgery, the “presbyopia-correcting” multifocal IOL and associated services for fitting the lens are only considered partially covered. I acknowledge that I am responsible for payment of that portion of the charge for the “presbyopia-correcting” multifocal IOL and associated services that exceed the charge for insertion of a conventional, monofocal, IOL or monovision following cataract surgery. Dr. Jaben and/or his staff have informed me about the coverage, deductible, and copayment amounts if a private insurance company is paying for this procedure. I also understand that if additional surgery, such as IOL exchange or laser vision correction, is required, the original fees for the cataract surgery do not cover these surgeries.

Patient initials _____

PATIENT CONSENT

The basic procedures of cataract surgery, the reasons for the type of IOL chosen for me, and the advantages and disadvantages, risks, possible complications and alternative treatments have been explained to me by Dr. Jaben. Although it is impossible for the doctor to inform me of every possible complication that may occur, Dr. Jaben and his staff have answered all my questions to my satisfaction.

In signing this informed consent for cataract surgery and IOL implantation, I am stating that I have been offered a copy of this consent and I fully understand the possible risks, benefits, and complications of cataract surgery and

- I have read this informed consent _____ **(patient initials)**
- The consent form was read to me by _____ **(name)**.

CHOOSE ONE OF THESE OPTIONS

YES() NO() MONOFOCAL IOLS / READING GLASSES OPTION

I wish to have CATARACT SURGERY with a monofocal IOL implant in **BOTH** of my eyes for distance vision and wear glasses for near vision.

YES() NO() MONOFOCAL IOLS / DISTANCE GLASSES OPTION

I wish to have CATARACT SURGERY with a monofocal IOL implant in **BOTH** of my eyes for near vision and wear glasses for distance vision.

YES() NO() MONOFOCAL IOLS / MONOVISION OPTION

I wish to have CATARACT SURGERY with two different-powered monofocal IOL implants inserted in each eye to achieve monovision.

I wish to have my _____ eye (state "right" or "left") corrected for **DISTANCE** vision.

I wish to have my _____ eye (state "right" or "left") corrected for **NEAR** vision.

YES() NO() MULTIFOCAL IOL OPTION

I wish to have CATARACT SURGERY with a _____ (state either ReSTOR or ReZOOM) multifocal IOL implant in my **RIGHT** eye.

I wish to have CATARACT SURGERY with a _____ (state either ReSTOR or ReZOOM) multifocal IOL implant in my **LEFT** eye.

SIGNATURES

Patient (or person authorized to sign for patient)

Date

Witness

Date

Physician Signature

Date

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