Informed Consent for Multifocal Lens Implant Surgery
(ReSTOR Lens Implantation)

INTRODUCTION

This surgery involves the removal of the lens of my eye. The natural lens will be replaced with an artificial implant called an intra-ocular lens. This surgery is entirely elective, and I understand that I have alternatives such as wearing eyeglasses and that any surgery has inherent risks. Ultimately, only I can make the decision that the potential benefits outweigh the risks.

EXAMINATIONS PRIOR TO SURGERY

If I agree to have the surgery, I will need a measurement of the curvature of my cornea (keratometry), a measurement of the length of my eye (axial length) and intra-ocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens. As with any measurement, there is a degree of accuracy and inaccuracy associated with measurement and there is no guarantee as to achieving the desired or stated refractive goal.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE

If I decide to proceed with the surgery I may undergo sight sedation administered by an anesthesiologist while my eye is made numb by my surgeon with either drops or an injection (local anesthesia) or I may elect to have the surgery with local anesthesia only, without sedation. The natural lens in my eye will then be removed by breaking it up into small pieces with a vibrating needle (ultrasound). These pieces are gently suctioned out of my eye through a small, hollow tube inserted through a small incision into my eye. This type of surgery is called phacoemulsification. After my natural lens is removed, the artificial lens of the power determined during my pre-operative examination will then be placed inside my eye. In rare cases, it may not be possible to implant a lens. I understand that even though I have given my permission to implant the ReSTOR lens, the surgeon may decide during surgery not to implant the ReSTOR lens. The incision required to perform this operation is self-sealing in most cases, but rarely may require fine stitches (sutures). During the immediate recovery period, I will place drops in my eyes for 4 to 6 weeks, depending on my individual rate of healing. EVEN THOUGH THE GOAL IS TO REDUCE DEPENDENCY ON GLASSES OR CONTACTS, THEY MAY STILL BE REQUIRED EITHER FOR FURTHER IMPROVEMENT IN MY DISTANCE VISION, READING VISION, OR BOTH. I should be able to resume my normal activities within 2 or 3 days, and my eye will usually be stable within 3 to 6 weeks.

BENEFITS OF SURGERY

Benefits to me will be clearer vision than I presently have. The ReSTOR lens is a very advanced design intra-ocular lens that has a dual focus, far and near, simultaneously. Best results are obtained when the lens is implanted in both eyes (binocular), but the lens can be used in only one eye (monocular). In clinical studies, about 80% of ReSTOR lens patients had no need for glasses at all once fully healed. The other 20% reported occasional use of glasses or contact lenses. In most cases this group could also have another surgical procedure such as LASIK to further reduce dependency on glasses. In this event, there would be an additional charge.

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

RISKS

This type of surgery itself is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical. Severe pain is extremely unusual. The risks include but are not limited to:

1. Infection, which if serious can lead to complete loss of vision or loss of the eye.
2. Swelling in the central area of the retina (cystoid macular edema) which usually improves with time.
3. Clouding of the outer surface of the eye (corneal edema) which can be corrected with corneal transplant.
4. Detachment of the retina (definitely increased risk in highly near-sighted eyes), which can often be repaired by retinal surgery.
5. Damage to the retina or nerve during the administration of the anesthesia if an injection is performed.
6. Increased astigmatism.
7. Inaccuracy of the intra-ocular lens power which may require the use of stronger then desired glasses, contact lens, surgical exchange of the lens, or another surgery like LASIK to correct the error in lens power.
8. Decentration of the intra-ocular lens, which may provided unwanted images and increased glare.
9. Development of increased pressure in the eye (glaucoma),
10. Significant glare, halos, and starbursts, which have been reported by 5% of patients who have the ReSTOR lens.
11. The general risks of anesthesia despite the fact that only mild sedation will be used.
12. Other unlisted complications.

Although all of these complications can occur, their incidence is low.

DISADVANTAGES

The ReSTOR intra-ocular lens has a dual focus system intended to provide some near vision along with the distance correction. Even so, there is no guarantee that reading and or distance glasses will not be needed. Further, intermediate (computer) vision is not fully aided by the ReSTOR lens. For best results it may be necessary to implant the ReSTOR lens in both eyes, even if the vision in the first eye is not completely satisfactory. Another alternative is to deliberately correct one of the eyes for close vision instead of distance, which would allow the patient to read without glasses, even though this eye would then be nearsighted and would require a corrective lens for distance vision. This combination of a distance eye and a reading eye is called planned multi-vision or mono-vision. It has been employed quite successfully in many contact lens patients. Intra-ocular lens calculations is quite satisfactory for normal sized eyes, these calculations can be less accurate for unusually long or short eyes (highly near-sighted and highly far-sighted). Lens calculations can be particularly inaccurate in eyes that have had previous refractive surgery such as PRK, LASIK, or RFC. In the event of a minor error in the calculation, the vision can usually be corrected by a glasses prescription. A large error in the lens calculation could be corrected by a stronger pair of glasses, contact lenses, exchange of the implant lens or insertion of a second implant lens, or possibly laser surgery. If laser surgery is required there will be an additional fee.

ALTERNATIVES

The alternative to the ReSTOR dual focus intra-ocular lens is a lens that focuses at only one distance (mono-focal intra-ocular lens). Mono-focal lenses, if calculated to focus clearly at distance, require patients to wear glasses for reading. Other types of multiple focus intraocular lenses such as the ReZoom lens are another alternative.

I have read and understood this page. Patient's initials_____

FEES

Medicare and most commercial insurance companies will not cover the additional fees related of the correction of presbyopia. In order to achieve the maximum level of visual acuity, additional tests and procedures will be necessary. The fees for both the lens as well the additional procedures will be charged to you.

Pay to Surgical Suites (Eye Facility Center) --The Cost of ReSTOR Len /One eye

Professional Services Fee per Eye:

1) Astigmatism Keratotomy (at the time of Cataract Surgery)
2) Professional Fee to DR Ming Chen for using RESTOR Len

TOTAL Fee per Eye: $

Should you not be satisfied with your distance vision, LASIK surgery may be necessary to refine the refractive error. Typically, the fee for LASIK surgery is $2,000 per eye. If required, the fee for your LASIK surgery will be reduced to $500 per eye.

If you have any questions regarding these non-covered fees, please feel free to direct them to either the surgeon or any one of our staff members.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the ReSTOR lens have been presented to me in this document and explained to me by my surgeon --DR Ming Chen and staff, I have had ample time to read this document and ask questions, and DR Ming Chen has answered all of my questions to my satisfaction. I therefore consent to undergoing ReSTOR lens implantation both eyes. I understand implantation of the ReSTOR lens in <u>both</u> eyes may be needed for best results. I understand that there is no guarantee of the results in my particular case and that I may have to wear glasses following ReSTOR lens surgery. 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

I have read and understood this page. Patient's initials_____