

Informed Consent PRELEX Surgery Presbyopic Lens Exchange

Please read this consent form carefully and initial and sign where indicated.
Please do not sign any section that you have not read or do not understand.

Section 1. General Information:

It is our hope to fully inform you concerning the side effects, limitations and complications of Refractive Lensectomy. We continually strive to balance the benefits of the surgery with the known and unknown risks. It is important to understand that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent form in combination with the extensive educational materials provided and the entire consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both the surgical procedure and the healing process.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential complications. It is not our intention to frighten or dissuade someone from having refractive lensectomy surgery, as most of our patients will never encounter any serious complications, and the vast majority is thrilled with the improvement they achieve. It is our intention to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated or be better prepared to deal with any unexpected complication or side effects which may arise. Refractive Lensectomy or Clear Lens Extraction surgery is a purely elective procedure, and you may decide not to have this operation at all. The only way to avoid all surgical risk is by not proceeding with the surgery.

I have read and understand the information in Section 1.

Patient Initials: _____

Section 2. Background Information:

Refractive lensectomy is refractive surgery and is used as an alternative to other refractive surgical procedures including LASIK and PRK. Patients have refractive surgery to minimize their dependence on glasses and/or contact lenses. It is elective surgery and should be considered very carefully and should not be taken lightly. Presbyopic Lens Exchange is possible because of the miraculous advances in modern, state of the art cataract surgery. 2 Years ago we removed someone's cataract, leaving him or her with thick glass lenses. We eventually began using artificial lenses implanted into the eye. After many years of work, by thousands of eye surgeons, we can now predictably remove a cataract and replace it with an artificial lens that will allow a patient to see well with minimal dependence on glasses and/or contact lenses. We now call this refractive cataract surgery to acknowledge the importance of making the patient as independent of glasses and contact lenses as possible.



Presbyopic Lens Exchange is a very similar process to refractive cataract surgery. The primary difference between the two procedures is indication or the medical necessity for the surgery and who pays for the surgical procedure. Refractive lensectomy is elective surgery and is done primarily to decrease a patient's dependence on glasses and is not generally covered by any insurance plan. Refractive cataract surgery is done primarily to remove a cataract that is clouding the vision and is deemed medically necessary and is covered by insurance.

Both Cataract Refractive Surgery and Presbyopic Lens Exchange surgery are called intraocular surgery. By this we mean that the surgeon does surgery inside the eye and removes the natural lens and replaces it with an artificial plastic, or acrylic intraocular lens. The lens of your eye has prescription and the artificial lens needs to be carefully measured and calculated to achieve the best visual results. Our goal is to decrease dependence on glasses and/or contact lenses, but we do not guarantee total independence from either glasses or contacts. No guarantee can be made as to the outcome of any surgical procedure.

I have read and understand the information in Section 2.

Patient Initials: _____

Section 3. Indications for Refractive Lensectomy

Refractive lensectomy surgery is generally performed on persons over the age of 40 who are Hyperopic (farsighted) and would not be good candidates for LASIK SURGERY. LASIK is the preferred surgical procedure, but many people have prescriptions that are outside the current parameters of Excimer laser surgery. Many people in their fifties and sixties would like the option of refractive surgery but have early coloration changes to their natural lens and would likely need cataract surgery in less than 5 years. These people are better candidates for refractive lensectomy surgery because this will not only decrease their dependence on glasses and or contacts, but would also improve the quality of their vision.

Refractive Lensectomy surgery may have various goals including:

1. Setting both eyes for distance vision – You would see well at distance but would need reading glasses for near vision tasks.
2. Mono Vision – Setting one eye for distance and one eye for near vision. – Many people wear contacts with this type of prescription and prefer mono vision for most tasks. Most people who have mono vision have a pair of back up glasses for those times when both eyes are needed at distance or at near tasks.
3. Multifocal (Restor, Tecnis, Symphony) – This is a specialized intraocular lens that allows the patient to see at both distance and near. This lens will decrease your dependence on glasses and give you good vision at various focal lengths. The most common problem with this type of lens is halos around lights at night. Each person's lifestyle varies and many people are not bothered by these halos. If you have an exacting personality where vision must be perfect at all times this lens is not for you. If you would like good vision for most activities then this lens may be your first choice. Your surgeon and his/her staff will discuss the multifocal lens with you.

Each type of lens has pros and cons and your lifestyle and visual needs are very important in choosing the type of lens best suited to your activities.

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I have read and understand the information in Section 2.

Patient Initials: _____

Section 4. Risks of Intraocular Surgery:

All eye surgery has risks and benefits, Refractive Lensectomy is intraocular surgery and this type of surgery has inherent risks. We will minimize the risks to visual loss in every way possible, but we cannot eliminate all of the risks associated with this type of surgery.

1. Partial or total loss of vision – This is extremely rare and with the new types of surgical procedures and anesthesia much of the risk of visual loss has been minimalized.

2. Retinal Detachment – The retina detaches from the back of the eye and further surgery is necessary to restore vision. Retinal detachment can cause a permanent loss of vision and/or a decrease in your best vision. This also is a rare occurrence because of the newer techniques in intraocular surgery and anesthesia.

3. Macular edema – The central portion of your vision is focused on the macula. Rarely the macula becomes swollen and further medication treatments are necessary to decrease the inflammation. This swelling can temporarily or permanently decrease the vision in your eye.

4. Infection – This is called endophthalmitis or infection inside the eye. This is a severe problem and all care is taken to prevent infection inside the eye. It is important that you follow all postoperative instructions and take your medication as directed. The most common occurrence of infection is when patients do not use their medications or use them improperly. Endophthalmitis can cause permanent loss of vision if not treated immediately. If you experience pain or decreased vision after surgery, you must call our office immediately.

5. Lens Power Problems – We constantly strive to improve the technology that measures your eye for the intraocular lens power. Very rarely the lens power implanted does not correct all of your prescription, and if this occurs, the lens can be exchanged for a different power or LASIK can be done after the lensectomy surgery heals to further correct the prescription. Our most common problem with lens powers is how the lens sits inside the eye. The lens is placed into the natural tissue that surrounded your lens. If this tissue shrinks around the new lens and moves the lens even 1 millimeter, the prescription can be incorrect. This is why we must wait at least one week between surgeries to ensure that the lens is in the proper position and that there are no problems with the lens power.

6. Opacified Posterior Capsule – This is the outside layer of tissue that surrounds your natural lens and now surrounds your new artificial lens. This tissue may cloud in the future and require a procedure called Yag Laser Capsulotomy. This is a medically covered procedure and is done in our office on an outpatient basis. There is no down time from this procedure and many people can resume normal activities within an hour after the procedure.

7. No guarantee can be made as to the outcome of any refractive surgery or intraocular surgery. We strive to achieve the best results possible with the best technologies available. We continuously review our statistics to ensure good results, but every patient and every eye is different. You may need glasses and/or contact lenses to achieve your best possible vision after refractive lensectomy surgery.

I have read and understand the information in Section 4.

Patient Initials: _____

Section 5. Contraindications to Surgery

You are NOT a candidate for Refractive Lensectomy surgery if you have the following conditions.

You are under 21 years of age

You have unstable or uncontrolled diabetes. All diabetics must have testing before surgery to ensure that the diabetes is stable.

Any active ocular infection

Any autoimmune disease that would prevent healing or medication for autoimmune disorders that compromises the body's ability to heal and fight infection.

Candidates must be free of certain eye viruses including herpes simples, and herpes zoster.

*****IF YOU ROUTINELY HAVE HERPES BREAKOUTS i.e. cold sore, shingles, etc.**

YOU MUST BE ON ORAL ANTIVIRALS PRIOR TO SURGERY.

Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgical healing, back problems, claustrophobia or psychological problems, which may affect the surgery or recovery

Candidates must be free of certain eye diseases including, keratoconus, cataracts, uncontrolled glaucoma and certain retinal and optic nerve diseases.

Candidates must make their surgeon aware of certain eye problems including amblyopia (lazy eye), strabismus (muscle imbalance), severe dry eyes, or any recurrent residual or active eye condition, which may affect healing.

Female candidates must advise the surgeon if they are pregnant, nursing or plan to become pregnant in the near future.

Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid potential drug interactions and allergic reactions.

I have read and understand the information in Section 5.

Patient Initials: _____

Section 6. Pre Procedure and Post Procedure Care

The screening examination performed by your eye doctor is intended to assess candidacy for Refractive surgery based upon the prescription, corneal shape, corneal thickness and other ocular and visual findings. Ocular disease may be present prior to refractive surgery or may develop after surgery, but it is unrelated to refractive surgery. Refractive surgery will not treat ocular disease. Your preoperative examination is a comprehensive examination and you should continue to have annual eye examinations. Patients who wear contact lenses must discontinue their use prior to any refractive surgery to allow the cornea to resume its natural shape. Soft contact lens wearers must remove their contacts at least one week prior to their examination and a minimum of three days prior to their surgery. Hard or Gas Permeable contact lenses wearers may have to discontinue the use of their contacts for one to three months prior to their pre operative examination. Postoperative care with an eye professional is required for 6 months after refractive surgery. All patients need to carefully follow all postoperative instructions and take their medications as prescribed to prevent complications. The final postoperative results are dependent upon properly following your postoperative care instructions.

I have read and understand the information in Section 6.

Patient Initials: _____

Section 7. Legal Responsibilities and Disclosures

Confidentiality

I give permission for the medical data concerning my surgery and subsequent treatment to be submitted to the Intraocular Lens Manufacturers and government regulatory authorities. This data will be used for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Governing Law / Jurisdiction

I agree that the relationship and resolution of any and all disputes between the surgeon and myself shall be governed by and construed in accordance with the laws of the State of Texas. I also acknowledge that the courts of the State of Texas shall have jurisdiction to entertain any complaint, demand, claim or cause of actions, whether based on alleged breach of contract or alleged negligence arising out of treatment. I agree that I will commence any such legal proceedings in the State of Texas and Irrevocably submit to the exclusive jurisdiction of the courts of the state of Texas.

Financial Interest of Some Doctors

I acknowledge that I am aware that some Advanced Laser Vision and Surgical Institute medical doctors have a financial interest in this facility and may indirectly benefit financially from the laser vision correction service performed at this facility.

I have read and understand the information in Section 7.

Patient Initials: _____



I wish to have Refractive Lensectomy surgery performed on my:

Right Eye Date _____ Initial _____
Left Eye Date _____ Initial _____

**Please Write the Following Paragraph in
Your Own Handwriting and Sign.**

I have read this consent form and all of my questions pertaining to Refractive Lensectomy Surgery have been answered to my satisfaction. I understand that all surgery has risks and benefits and no guarantee can be made as to the outcome of this surgery. I also understand that glasses and or contacts may be necessary to obtain my best vision after surgery.

Handwriting area with six horizontal lines.

Signed by _____ Date _____

Patient Name Printed _____ ID# _____

Witnessed by _____ Date _____

Comments: _____

