Informed Consent

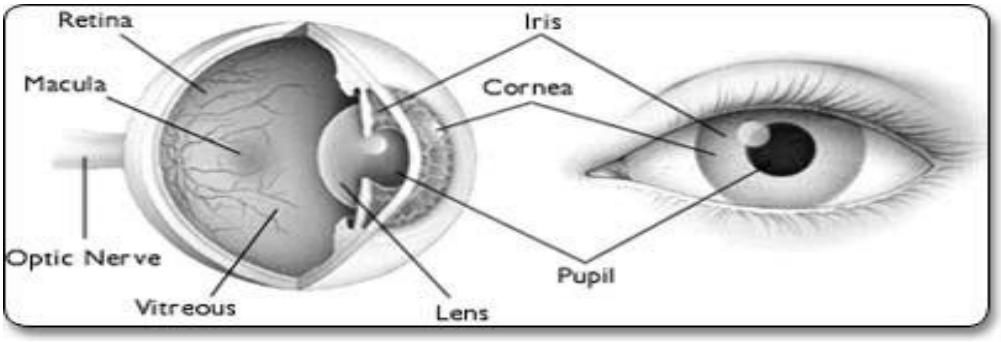
Implantation of Phakic Intraocular Lens

Introduction

Please read this document carefully and completely. If you require additional assistance, you may have this document read to you. If you have any questions, do not hesitate to ask your eye doctor. Do not sign this document unless you are satisfied that you understand what you are signing. Your decision should be based on your own visual needs following a thorough consultation with your eye doctor. You are under no obligation to undergo this surgery.

Procedure

The cornea is the clear, dome-shaped tissue that covers the front surface of your eye (Figure 1). Light rays enter your eye through the cornea, which is the main focusing element of the eye. The cornea bends the light rays through the pupil. A healthy cornea is clear and brings light into a sharp focus inside the eye on the retina.



Nearsightedness (myopia) is a condition of the eye where light is focused in front of the retina creating a distorted image. In the vast majority of cases, this condition is due to the eye being too long relative to the eye's optical focusing system. Your doctor believes the implantation of a phakic IOL may be useful to improve your vision. A phakic IOL is an implantable lens that does not require the removal of the natural lens.

EVO ICL Lenses

EVO ICL lenses are made from a soft plastic and natural collagen containing material called Collamer. It is similar to lenses that are placed in the eye (*intraocular lenses*) to correct vision after cataract surgery. EVO ICL lenses are similar to Visian ICL lenses that have been available in the US since 2005. When placed correctly, the EVO ICL lens focuses light properly on the back surface of your eye (*retina*). In EVO ICL lenses, a small hole (*central port*) has been added to the center of the lens. In previous Visian ICL lens models without

the central port, patients required another surgery between 2 to 3 weeks before ICL surgery to create a hole (*peripheral iridotomy*) in the extreme outer edge of the colored portion of the eye (*iris*). This additional surgery is not needed with the EVO ICL lens because it has a hole in the center of the optic.

Surgical Procedure

With the eye under topical or local anesthetic, the surgeon creates incisions in the eye, inserts the lens using specialized instruments, and fixes the lens in place. Following implantation, the lens is positioned over the natural lens of the eye. The surgeon may close the incision with sutures at the conclusion of the procedure.

Visits After Surgery

You will return to our office the next day for an evaluation and will start eye drops after the surgery. We recommend that you plan minimal activity for the day of the surgery and the next day, and arrange to have a driver bring you to the first day visit. You should notice an immediate improvement in your vision, but best vision will not be achieved for several weeks and is affected by the healing process of the eye. The doctors will examine you after surgery to follow your healing. Annual examinations by an eye care professional will still be recommended even though you have had surgery.

Risks or Discomforts

Any surgical procedure presents potential risks and it is possible that implanting the phakic IOL may make your vision worse. With increasing age there is a risk of cataract development (clouding of the natural lens of the eye), which may require removal of the phakic IOL, cataract removal, and the implantation of a suitable artificial intraocular lens.

Risks associated with the surgical procedure may include: hyphema (blood in the front chamber of the eye), iritis (inflammation of the colored part of the eye or iris), severe or chronic inflammation or infection of the tissues inside the eye, loss of cells on the back side of the cornea, swelling of the cornea, loss of corneal clarity, swelling or detachment of your retina, cataract formation, lowered or raised pressure inside the eye, drooping of the eyelid, decreased vision, surgically induced astigmatism, or wound leak following lens insertion requiring surgical repair. In some cases, complications may occur weeks, months, or even years later. These or other complications may occur and may result in poor vision, total loss of vision, or loss of your eye. Some complications could result in the need for further eye surgery. At some future time, the new lens may need to be surgically repositioned or removed.

Risks associated with the phakic IOL may also include: unequal refractive errors between

the two eyes, decrease in function of the iris, pupillary block (blockage of fluid flow through the pupil), decentered lens requiring surgical repositioning, removal or replacement of the lens if the desired results of surgery are not obtained (undercorrection or overcorrection), lens dislocation, double vision, decrease in best corrected visual acuity, and glare and/or halos in your vision. You may need to wear glasses or contact lenses to have useful vision following surgery.

The phakic IOL is unique in that it can be placed into the eye without removing the natural lens. In most patients less than 40 years of age, the natural lens of the eye accommodates or changes power to allow focusing of both near and distant objects. Because the natural lens remains in the eye with the phakic IOL, accommodation is expected to be retained in those patients less than 40 years of age. After age 40, however, the ability of the eye to accommodate gradually diminishes; therefore, patients with the phakic IOL will eventually require bifocal or reading glasses to improve their near vision. It is possible that patients will require some corrective lenses to sharpen both near and distant vision.

After surgery, your eyes may potentially encounter such difficulties as retinal detachment or glaucoma, which are more common in abnormally shaped eyes (i.e., nearsighted, farsighted, or astigmatic eyes).

Complications due to anesthesia may occur, such as drug reactions or other factors. Such complications may involve other parts of your body, including the possibility of brain damage or even death. Since it is impossible to state every complication that may occur as a result of any surgery, this list of complications may be incomplete and there may be risks associated with this surgery that are currently unknown. Contact your doctor with any problems noticed after the surgery, such as an increase in pain, light sensitivity, loss of vision, or unusual mattering or discharge (other than tears) from the operative eye. Many complications are manageable if caught early. You are responsible for reporting any symptoms and making arrangements to be evaluated, and are also responsible for the associated fees.

Benefit

The potential benefit, which may be derived from surgery, is a reduction or correction of your refractive error. You may see well enough after surgery that you will not require any corrective lenses. Specific results cannot be guaranteed.

Alternative Treatments

You may elect to not undergo this procedure. People with moderate to extreme myopia have non-surgical and surgical treatment alternatives.

- **Spectacles (glasses) and contact lenses:** these have historically been used for the correction of myopia and require no surgery.

- **Laser vision correction: Laser In-Situ Keratomileusis** (LASIK) and Photo-Refractive Keratectomy (PRK) are surgical procedures performed with a laser wherein the surface of the cornea is altered.

These surgical treatment alternatives are generally approved for treatment of low to moderate levels of myopia and may not be alternatives for all people. There are risks associated with these procedures also.

- **Other phakic intraocular lenses:** several phakic intraocular lenses are currently being studied in the United States and worldwide, and may soon be commercially available. Like this lens, they are surgically placed in the eye with- out removing the natural lens, however, the design and placement of each lens is different.

- **Natural lens replacement:** a surgical procedure in which the natural lens is removed and replaced with a man- made lens to correct high levels of nearsightedness. This procedure is similar to cataract surgery.

"Off Label" Use

Using the Phakic IOL for your treatment may be "off label" if your treatment falls outside the Food and Drug Administration (FDA) approved use and ranges for the Phakic IOL. The following ranges are outside the indication for use and are not approved by the FDA. Any physician who accesses these uses/ranges does so as a practice of medicine. *VERISYSE Phakic IOL:* Sphere: -5.0 to -20.0 D, Cylinder: With up to 2.5 Diopters of Astigmatism. Use of the VERISYSE Phakic IOL on patients under the age of 21 is considered "off-label". Physicians are permitted to access these uses/ranges as a practice of medicine. A Patient Information Booklet that further outlines details of "off-label" use of the VERISYSE Phakic IOL or the VISIAN ICL as approved by the FDA is available upon request.

EVO ICL: Sphere: -3.0 to -20.0 D, Cylinder: Minor or no occurrence of Astigmatism. Use of the VISIAN ICL on patients under the age of 21 is considered "off-label". Physicians are permitted to access these uses/ranges as a practice of medicine.

Consent to Perform ICL Surgical Procedure

In signing this informed consent for implantation of phakic intraocular lens, also referred to as Implantable Collamer Lens (ICL), I am stating I have read all pages of this informed consent (or it has been read to me). I understand I am able to receive a copy of this consent form. I also understand that I have the right to choose "NO TREATMENT" at all. If I choose no treatment, my vision may stay the same or gradually become worse.

The basic procedures of this surgery, the reasons for the type of lens chosen for me, and the advantages, disadvantages, risks, and possible complications and alternative treatments have been explained to me by my ophthalmologist. Although it is impossible for the doctor to inform me of every possible complication that may occur, I have been given the opportunity to ask questions and the doctor and staff have satisfactorily answered all of my questions.

I hereby willingly give my consent to have this surgery performed on my:

RIGHT EYE / LEFT EYE (patient to circle one)

Patient Name (please print):_____Date: _____

Patient Signature:_____Time:_____:_____AM/PM

Witness Name (please print): _____

Witness Signature:_____Date: _____

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have Phakic IOL performed on the patient's

On____/_____/_____, this form was read to the patient by_____(First

and Last Name) who has the following relationship to the patient_____because

the patient was unable to read.