A surgeon in a blue surgical gown and mask is performing a procedure on a patient's eye. The surgeon is wearing a head-mounted microscope and is using a surgical instrument to insert a lens into the eye. The patient is lying on an operating table, and the scene is illuminated by bright surgical lights. The background is dark, and the overall atmosphere is clinical and focused.

Phakic Intraocular Lenses

*The New Focus in
Refractive Surgery*

G. Michael Morris and
Lee T. Nordan, M.D.

Phakic intraocular lenses represent the next major stage in the refractive surgery revolution. Building on the results obtained with LASIK and PRK, they offer the potential for customized wave-front correction, as well as correction of moderate to high ametropia, astigmatism and presbyopia. Thin, foldable and removable, these lenses can be inserted under local anesthetic as part of an outpatient procedure that is relatively easy to perform.

A vast revolution in eye care has occurred during the past two decades as excimer laser keratorefractive surgery has become an accepted and routine procedure. Just as the excimer laser greatly improved on the results of radial keratotomy (RK), the stage is now set for phakic intraocular lenses (IOLs) to build on the results obtained with LASIK and photorefractive keratectomy (PRK).

Although LASIK and PRK enhance visual function in most cases, both procedures have important limitations. The thinness of the cornea allows for an optical zone diameter only in the range of 6 mm—a situation that can induce significant optical aberrations at the junction of the optical zone and the untreated cornea. In LASIK and PRK patients, post-operative dry eye syndrome, fluctuating vision, increased light scattering and halos are not uncommon. In addition, surgeons cannot adequately treat presbyopia at the corneal level, because PRK and LASIK result in an unacceptable loss of contrast sensitivity. All these problems are worse in the higher versus lower ranges of preoperative ametropia.

A phakic IOL is essentially an implantable contact lens designed to work in conjunction with the patient's own image-forming elements, i.e., the cornea and natural crystalline lens (see Fig. 1). Phakic IOLs are advantageous because:

- they can be removed in case of complications;
- they can be less than 600 μm thick;
- their optic diameter can be more than 6 mm, which reduces the risk of halos and other optical distortions;

- they can be folded for insertion through a small incision 3 mm or less in length;
- they can be designed to correct any form of ametropia, astigmatism or presbyopia, as well as higher-order wave aberrations;
- they can be inserted during a relatively simple and inexpensive outpatient procedure that takes only a few minutes for the surgeon to perform.

Phakic lenses have been designed for placement in both the anterior chamber (between the cornea and the iris) and the posterior chamber (between the iris and

the natural crystalline lens). However, it is now generally accepted that the safest location for a phakic lens is in the anterior chamber because posterior-chamber phakic IOLs have a greater probability of inducing a cataract (an opacity or cloudiness of the crystalline lens). In this article, we will focus on five principal designs for phakic IOLs that are currently under investigation.

The STAAR ICL

The Staar Surgical Company (Monrovia, Calif.) has submitted for FDA pre-market approval the final module of its implantable contact lens (ICL) for correction of moderate to high myopia. The Starr ICL is a refractive lens designed to be implanted in the posterior chamber. The lens is made of a proprietary material called Collamer, a high-water-content hydrophilic copolymer of collagen and hydroxy-ethylmethacrylate (HEMA). It also contains a covalently bound ultraviolet (UV) chromophore. Flexible yet resilient, the foldable lens can be inserted through an incision as small as 2.8 mm. Produced in sizes that range from 11 to 13 mm long, the ICL is vaulted so that as it sits in the ciliary sulcus, the central optic arches over the crystalline lens.

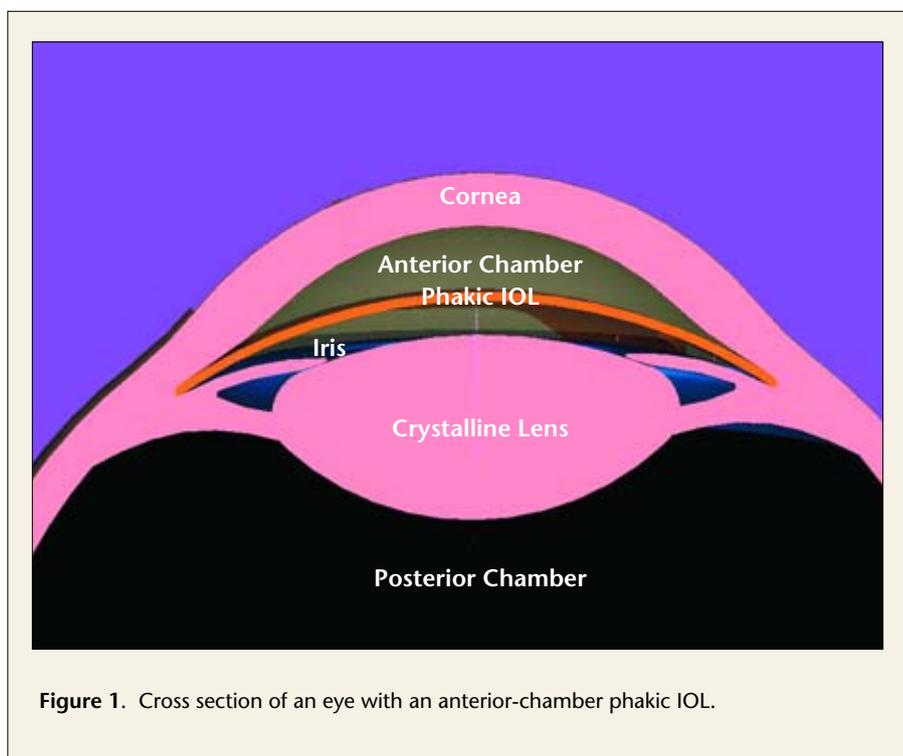


Figure 1. Cross section of an eye with an anterior-chamber phakic IOL.

Glossary

Ametropia. Any optical error (e.g., myopia); can be corrected with eyeglasses, contact lenses or refractive surgery.

Bimanual I/A. A method of removing material from the anterior chamber of the eye by use of two opposing cannulas about 1 mm in diameter.

Dry eye syndrome. Corneal and conjunctival dryness caused by deficient tear production. Can cause foreign body sensation, burning eyes, filamentary keratitis and erosion of conjunctival and corneal epithelium.

Endothelium. Single-cell layer of tissue lining the innermost surfaces of many organs, glands, blood vessels; also lines undersurface of the cornea, where it regulates corneal water content (hydration).

Haptic. Loop or foot of an intraocular lens implant that supports the lens against the iris.

Hyperopia, or farsightedness. Focusing defect created by an underpowered eye, one that is too short for its optical power. Light rays from a distant object enter the eye and strike the retina before they are fully focused (true focus would be "behind the retina.") Corrected with additional optical power supplied by a plus lens or refractive surgery.

Keratorefractive surgery. Any surgical procedure to alter the shape of the cornea so as to change the eye's refractive error. Can reduce or eliminate the need for eyeglass or contact lens correction.

LASIK. Laser assisted in situ keratomileusis. Method of reshaping the cornea to change its optical power. After a flap of cornea is cut with an automated microkeratome and folded back, a computer-programmed excimer laser reshapes (sculpts) the exposed surface of corneal tissue and the flap is replaced with suturing.

Miotic. Refers to small pupils.

Myopia, or nearsightedness. Focusing defect created by an overpowered eye, one that has too much optical power for its length. Light rays coming from a distant object are brought to a focus before reaching the retina. Corrected with a minus lens or refractive surgery.

Peripheral iridectomy. Removal of a full-thickness wedge of iris base near the corneal limbus. Permits aqueous to flow more easily from the posterior to the anterior chamber.

Phakic intraocular lens, or phakic IOL. Plastic lens that can be surgically implanted (either in front of or behind the iris) to work with the eye's natural crystalline lens to correct refractive errors.

Photorefractive keratectomy, or PRK. Use of a computer-controlled excimer laser to reshape the corneal curvature, changing its optical power, after the surface layer of the cornea (epithelium) is removed by gentle scraping.

Pseudophakic IOL. Plastic lens that is surgically implanted to replace the eye's natural crystalline lens.

Radial keratotomy (RK). Method of flattening the central cornea with 4-8 spoke-like (radial) incisions in the periphery to reduce its optical power. Corrects myopia.

Viscoelastic agent. Thick, elastic protective gel injected into the eyeball during corneal or cataract surgery. Helps maintain ocular structures in their normal position, keeps tissues moist and protects the back of the cornea (endothelium) from surgical damage.



The extended range of focus associated with some MOD lens designs is expected to be of particular benefit to the emerging presbyope.

The Phakic Refractive Lens

The Phakic Refractive Lens (PRL) is being developed by CIBA Vision (Duluth, Calif.).¹ It has been available in Europe in both a myopic and a hyperopic model since 2001. The myopic model is currently in Phase III FDA trials in the United States. The PRL is a posterior-chamber phakic IOL. It is composed of a proprietary silicone elastomer that renders it extremely flexible and pliable. Its surface curvature duplicates that of the crystalline lens. To aid in preserving the natural metabolism of the crystalline lens and preventing opacification, it is designed to maintain an aqueous fluid layer between its posterior surface and the crystalline lens. CIBA Vision has developed an injector delivery device that facilitates insertion of the IOL and may further reduce the risk of trauma to the corneal endothelium and anterior lens capsule.

The Verisyse (or Artisan) Phakic IOL

The Artisan lens (OPHTEC, Groningen, the Netherlands), a refractive lens designed for implantation in the anterior

chamber,² is currently available outside the United States. It will soon be distributed in the United States by Advanced Medical Optics Inc. (Santa Anna, Calif.) under the name Verisyse. This lens is sometimes referred to as the “iris claw” because it is placed in the anterior chamber and clips onto the iris so that it remains centered in the eye and cannot rotate. This means it can be used to correct astigmatism as well as extremely high degrees of myopia. Available in 1 diopter increments, the Verisyse phakic IOL is intended for treatment of myopia ranging from 5 to 23 diopters. It comes in two sizes: 5 mm for patients whose refractive error exceeds 15 diopters and 6 mm for individuals with lesser ametropias.

The Kelman Duet Implant

The Kelman Duet Implant is a two-piece, anterior-chamber phakic IOL³ developed by Charles Kelman, M.D., a clinical professor at New York Medical College and Tekia Inc. (Irvine, Calif.). Approved for sale in the European Union, the Kelman Duet is not available in the United States. The two-piece lens design is comprised of a poly-methylmethacrylate (PMMA) haptic (or optical mount) and a separate, foldable refractive optic. The surgeon first places the haptic in the anterior chamber, then injects the 6.3-mm lens optic and finally secures the optic to two tabs located on the haptics to create a tripod-shaped IOL. The standard lens package contains one optic and three haptics in sizes of 12, 12.5 and 13.5 mm to accommodate different anterior chamber sizes. This lens is currently designed for myopic correction. In the future, hyperopic, toric and multifocal designs will be available.

The Vision Membrane phakic IOL

We at Vision Membrane Technologies Inc. (Carlsbad, Calif.) and Apollo Optical Systems LLC (Rochester, N.Y.), together with engineers at Millennium Biomedical Inc. (Pomona, Calif.), are involved in the development of the Vision Membrane phakic IOL, which has the design flexibility to provide all the desirable features of a phakic lens listed above. The Vision Membrane silicone, anterior-chamber

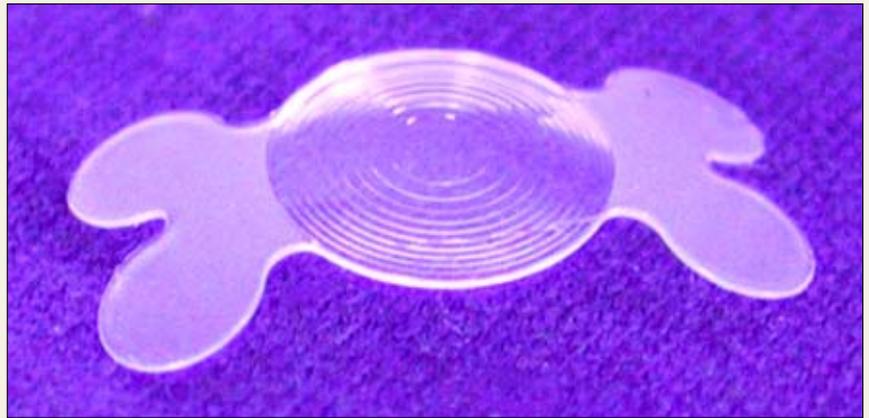


Figure 2. Vision Membrane phakic IOL. Its vaulted optic provides sufficient clearance from the corneal endothelium.

The principal feature of the MOD lens is that it brings the light associated with each of these high efficiency wavelengths to a common focal point; it is therefore capable of forming high quality white light images.

phakic IOL (see Fig. 2) uses a single, multi-order diffractive (MOD) lens to bring multiple wavelengths to a common focus with high diffraction efficiency. Since the lens is purely diffractive, it can be extremely thin (typically 200 to 600 μm), which makes it possible to fold it for insertion through a small incision measuring less than 3 mm. In addition, because it has no refractive power it is completely insensitive to changes in curvature of the substrate; for this reason, one design is capable of accommodating a wide range of anterior chamber sizes. Additional features of this design which are particularly interesting include: a type of “natural accommodation” effect, in which the MOD lens possesses a range of optical powers rather than a single power; and the ability to optimize for both photopic (daytime) and scotopic (nighttime) vision conditions.

The “ear-like” structures on the side of the lens are the haptics, which are seated in the angle of the anterior chamber. The Vision Membrane phakic IOL is the first anterior-chamber IOL to possess a vaulted optic that provides enough clearance from the corneal endothelium to

accommodate an optic of greater than 6 mm in diameter. This larger optic is critical to avoiding the risk of halos that has been inherent in other phakic IOL designs. Moreover, the vaulted optic precludes the need for a peripheral iridectomy to prevent papillary block and angle-closure glaucoma. Clinical trials of the Vision Membrane phakic IOL are being conducted in Mexico and are expected to begin in the United States and Europe in the next three to six months.

Multi-order diffractive (MOD) lenses

The basic structure of the MOD lens used in the Vision Membrane phakic IOL is illustrated in Fig. 3. The MOD lens consists of concentric annular Fresnel zones with zone radii denoted by r_j . The step height at each zone boundary is designed to produce a phase change of $2\pi p$, where p is an integer greater than 1. Design details for MOD lenses can be found in Refs. 4 and 5.

To illustrate its operation, consider the case of a MOD lens operating in the visible wavelength range with $p = 10$.

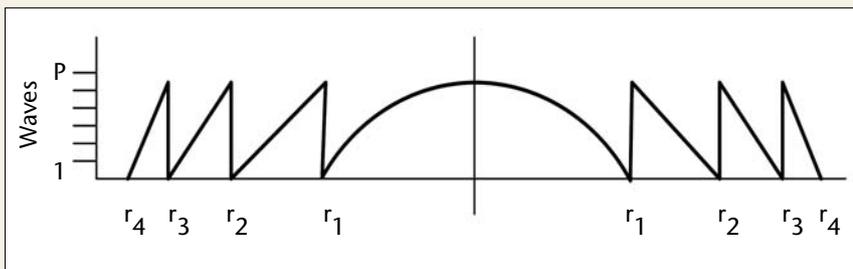


Figure 3. Schematic of a multi-order diffractive (MOD) lens.

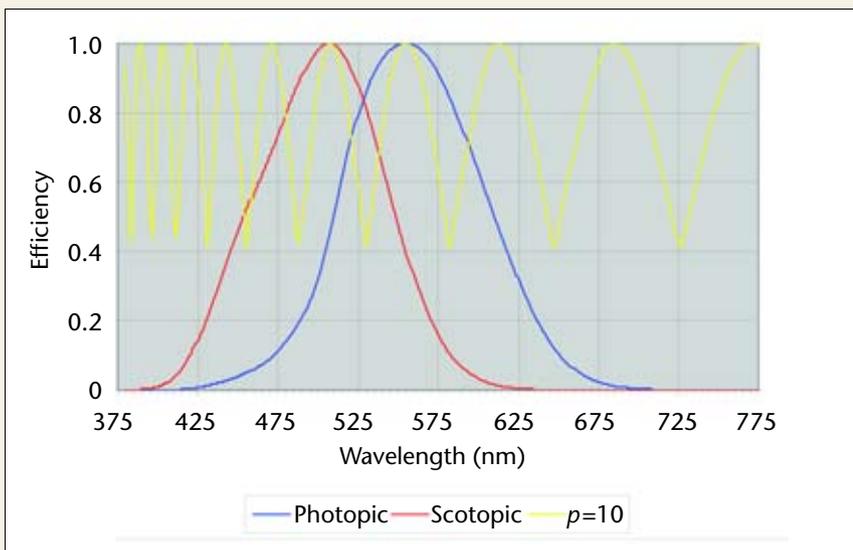


Figure 4. Diffraction efficiency versus wavelength for a $p = 10$ MOD lens.

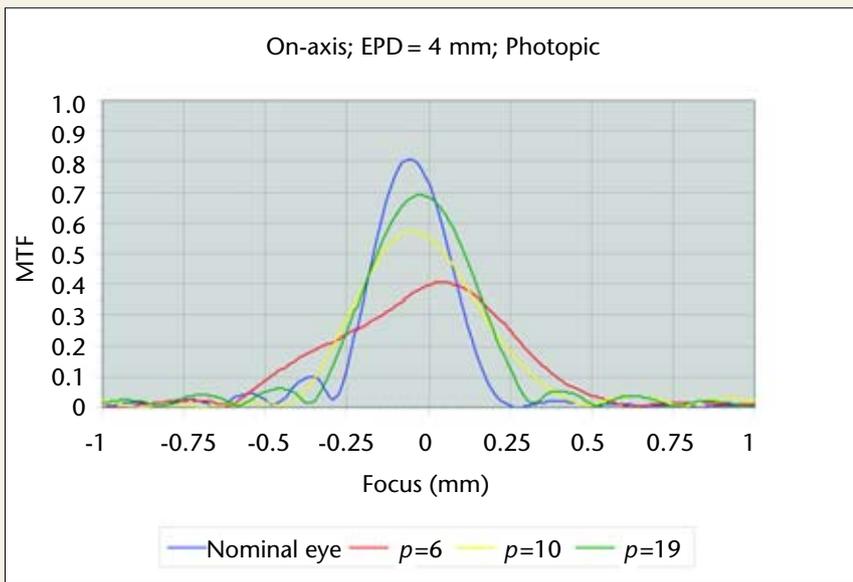


Figure 5. Through-focus, polychromatic MTF at 10 cycles per degree for three different MOD lens designs ($p = 6, 10$ and 19), together with an MTF for a nominal eye.

Figure 4 illustrates the wavelength dependence of the diffraction efficiency (with material dispersion neglected). Note that several wavelengths within the visible spectrum exhibit 100 percent diffraction efficiency. The principal feature of the MOD lens is that it brings the light associated with each of these high efficiency wavelengths to a common focal point; it is therefore capable of forming high quality white light images. For reference, the photopic and scotopic visual sensitivity curves are also plotted in Fig. 3. Note that with the $p = 10$ design, high diffraction efficiencies occur near the peak of both visual sensitivity curves.

In Fig. 5, we illustrate the on-axis, through-focus, polychromatic modulation transfer function (MTF) at 10 cycles per degree with a 4-mm entrance pupil diameter for three different MOD lens designs ($p = 6, 10$ and 19), together with the MTF for a “nominal eye.” Note that both the $p = 10$ and $p = 19$ MOD lens designs yield acceptable values for the in-focus Strehl ratio and also exhibit an extended range of focus compared to a nominal eye. This extended range of focus feature is expected to be of particular benefit for the emerging presbyope (typical ages: 40 to 50 years old).

Surgical implantation

Foldable phakic IOLs can be implanted by means of an injector through a clear corneal incision typically less than 3 mm in length. The implantation technique for this lens is similar to that used for a posterior-chamber pseudophakic IOL after cataract extraction. Preoperatively, a topically instilled 1 percent pilocarpine solution is used to create a miotic pupil. The surgeon leads the phakic IOL into the lubricated injector cartridge, creates a sideport incision and injects a viscoelastic agent into the anterior chamber. The IOL is injected into the anterior chamber through the corneal incision [see Fig. 6(5)]. The surgeon engages the inferior haptics of the IOL into the inferior angle before removing the cartridge tip from the anterior chamber. Bimanual I/A removes all viscoelastic from the anterior chamber and the surgeon uses the I/A instruments to adjust the position of the lens if necessary. The anterior chamber is inflated to a normal pressure

with BSS⁶ and the incision is checked. Finally, the surgeon places a bandage contact lens and a drop of ZYMAR⁷ on the eye. The entire procedure takes a few minutes only and can be performed using topical anesthesia in an outpatient setting.

Explantation

The surgeon can explant a phakic IOL by grasping its superior haptic with forceps through a small incision and externalizing the entire IOL by means of gentle traction. The incision will remain watertight whether or not the surgeon implants a new lens, so sutures are not required.

Potential concerns

Several issues need to be addressed as phakic IOLs make their way through the FDA and European Union approval processes.

Endothelial cell loss has been identified as a potential risk factor for younger patients: guidelines on the minimum age for recipients of phakic IOLs will have to be established because there is concern about the cumulative impact of endothelial cell loss on young recipients, who could have the lenses for 40 years or more.

Another issue that must be evaluated is the risk of surgery-induced cataract formation associated with the various designs. For example, anterior-chamber phakic IOLs have been found to carry a much lower risk of inducing cataract formation than posterior-chamber IOLs.

So far, there have not been significant reports of chronic inflammation or progressive elevation of intraocular pressure after phakic IOL implantation.

The future

Phakic IOLs will most likely become the dominant form of refractive surgery worldwide in the next five to eight years. Although keratorefractive surgery will continue to be practiced, phakic IOLs are expected to play a growing role, especially in the correction of moderate to high ametropia and presbyopia. The high optical quality and accurate, stable correction of refractive errors associated with phakic IOLs will attract cataract surgeons to the technology, particularly since the surgical implantation techniques are already

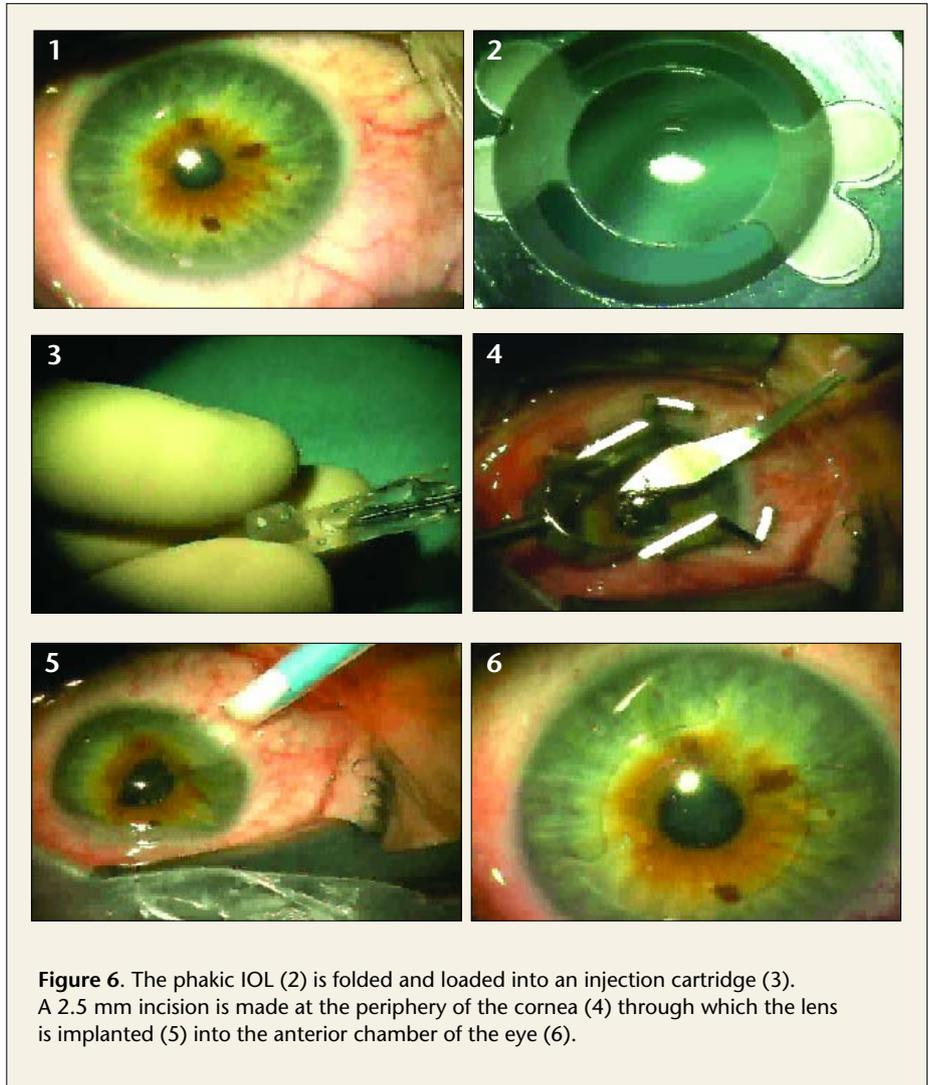


Figure 6. The phakic IOL (2) is folded and loaded into an injection cartridge (3). A 2.5 mm incision is made at the periphery of the cornea (4) through which the lens is implanted (5) into the anterior chamber of the eye (6).

familiar to them and the cost of the instruments is only a few thousand dollars, as opposed to the large capital expenditures associated with LASIK and PRK. It is highly likely that the typical cataract surgeon's practice will quickly transition into a refractive practice as well.

LASIK and PRK will be used to "fine tune" small amounts of refractive error that develop after phakic IOL implantation.

As the market for phakic IOLs develops, manufacturers will have to keep in mind the fact that there are two customers for the product: the patient and the surgeon. The size of the incision, the simplicity of packaging and handling and the ease of insertion and removal are issues that will be of interest primarily to

the surgeon. The patient will of course be the judge as to the quality of the optic.

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