Phakic intraocular lens implant surgery

Background

The phakic intraocular lens (IOL), which is also called an implantable contact lens (ICL), is a plastic lens that is permanently implanted in a patient’s eye to correct severe cases of nearsightedness, farsightedness, or astigmatism. It is called a phakic IOL because the eye still has its natural crystalline lens. The lens works by bending (refracting) light rays to allow them to focus on the retina, and it is surgically placed inside the eye between the cornea and the eye’s natural lens. If problems develop or the patient is dissatisfied with the results, the lens can be removed.

The phakic IOL is intended for use in patients who are between 21–60 years and have no significant systemic eye disease. It can be more advantageous than LASIK (laser-assisted in situ keratomileusis), which is currently the principle procedure in the United States for surgically correcting refractive conditions. LASIK surgery involves reshaping the cornea using a laser, and the procedure has its limitations. Approximately 20%–25% of patients who are interested in LASIK are not candidates for the procedure for one of the following reasons:

- The cornea is too thin to undergo LASIK
- The level of myopia or hyperopia is too high
- The corneal shape is too irregular

The phakic IOL implantation is a painless minor surgical procedure that takes about 15–30 minutes. While the patient is under local anesthesia, the eye surgeon inserts a plastic corrective lens through a tiny incision and places it in front of the eye’s natural lens between the cornea and iris. Once inserted, a phakic IOL works like any regular lens with the added benefit that it does not have to be continually removed, inserted, and cleaned. Ideally the lens can remain inside the wearer’s eye for life. Usually one eye is treated at a time.

The Verisyse™ Phakic IOL is the first lens of its kind to receive U.S. Food and Drug Administration (FDA) approval for use in patients with myopia. It is distributed by the Santa Ana, CA–based company Advanced Medical Optics (AMO) and has also been distributed under the name Artisan by Ophtec USA in Boca Raton, FL. Another phakic IOL, the Staar implantable lens, is manufactured and distributed by the Monrovia, CA–based STAAR Surgical Company and is also expected to receive FDA approval.
Involved specialties

Ophthalmologists

Positions of societies and academies

According to an article published in the September 2004 issue of *Ophthalmology*, the clinical journal of the American Academy of Ophthalmology (AAO), ICLs are safe, effective, and have predictable results for correcting moderate to high myopia. The article provided an update to the FDA’s long-term, follow-up multicenter STAAR Myopic ICL clinical investigation.

For the study, the STAAR myopic ICL was implanted in 526 eyes of nearly 294 patients whose myopia ranged from -3.0 to -20.0 diopters. The lens was inserted through a tiny incision and placed in front of the eye’s natural lens. The study found that at three years, nearly 60% of the patients had 20/20 or better visual acuity, and nearly 95% had 20/40 or better. Reports of symptoms such as glare halos, double vision, night vision, and difficulty driving at night either decreased or remained unchanged. Ninety-seven percent of patients said they would choose ICL implantation again. Less than 1% of patients said they were dissatisfied.

When compared with the refractive surgical procedure, LASIK, the ICL was found to be more effective for those with higher degrees of myopia. The study states that this data suggests that the ICL should be given serious consideration for use in eyes with -7 diopters of myopia or more.

“While LASIK is the best surgical option for many patients,” said AAO spokesperson Peter Kastl, MD, PhD, professor of ophthalmology and adjunct professor of biochemistry at Tulane University in New Orleans, “there can be more complications for patients with a higher range of myopia. ICLs may be a good option for those patients.”

Positions of other interested parties

The American Board of Ophthalmology (ABO) grants certification in ophthalmology. To obtain certification, candidates must meet the following requirements:

- Graduated from an allopathic or osteopathic medical school.

- Hold a valid and unrestricted license(s) to practice medicine in the United States, its territories, or a Canadian province in which the applicant’s practice of medicine is regularly
conducted and in each other place in which the person practices or has practiced medicine and has an unexpired license.

- Completed a postgraduate clinical year (PG-1) in a program in the United States accredited by the Accreditation Council for Graduate Medical Education (ACGME) or a program in Canada approved by the appropriate accrediting body in Canada. The PG-1 year must consist of training in which the resident is primarily responsible for patient care in fields such as internal medicine, neurology, pediatrics, surgery, family practice, or emergency medicine. As a minimum, six months of this year must consist of a broad experience in direct patient care.

- Satisfactorily completed a residency-training program in ophthalmology of at least 36 months duration, which is accredited by the ACGME in the United States or accredited by the Royal College of Physicians and Surgeons of Canada in Canada.

AOA

The American Osteopathic Association (AOA) grants certification in ophthalmology through the American Osteopathic Boards of Ophthalmology and Otolaryngology–Head and Neck Surgery. For these boards, the practice of ophthalmology is defined as consisting of the diagnosis and treatment of the disorders and diseases of the eye and its adnexa, including refraction.

Applicants for AOA certification in ophthalmology must meet the following requirements:

- Graduation from an AOA-accredited college of osteopathic medicine.

- Be licensed to practice in the state or territory where his or her practice is conducted.

- Show evidence of conformity to the standards set forth in the code of ethics of the AOA.

- Have been a member in good standing of the AOA or the Canadian Osteopathic Association for the two years immediately prior to the date of certification.

- Have satisfactorily completed a one-year AOA-approved internship.
- Have satisfactorily completed a minimum of three years of an AOA-approved residency-training program in ophthalmology. The training program must encompass all aspects of ophthalmology including adequate training in the basic medical sciences, with emphasis on the osteopathic principles as related to the specialty.

- Pass appropriate examinations.

According to Gregory J. Pamel, MD, a board-certified ophthalmologist at the New York City–based Manhattan Eye, Ear and Throat Hospital and principal investigator for the phase III FDA clinical trial for the treatment of high myopia and hyperopia, physicians who implant phakic IOLs should be ophthalmologists who have a track record in eye surgery so that a hospital knows they are competent. In addition, they should have completed an appropriate training course in implanting phakic lenses.

Cataract surgeons and cornea surgeons are already familiar with skills such as going into the eye and suturing it. “What they then need to learn in the phakic IOL training course,” says Pamel, “is the implant process, which includes creating the incision and attaching the lens to the mid-periphery of the iris. They also have to learn the indications for and the complications of the surgery.”

The AMO training course for implanting the Verisyse phakic IOL is a one-day program that includes a didactic session, a wet lab, and videos to teach this unique technique to the eye surgeons. In addition, the surgeons practice on cadaver eyes. Then when they return to their hospitals, they are proctored in their initial cases by refractive specialists from AMO or by AMO sales reps.

Pamel says that when eye surgeons have performed between five and 10 phakic IOL procedures, they usually feel comfortable with the technique. For continued competence, they should be able to demonstrate that they perform phakic IOL procedures each year. “It’s difficult to give a precise number because there’s such a variability among surgeons,” says Pamel. “But if people are going to do this procedure seriously, they should do at least 10 procedures a year if not more.”
**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

**Minimum threshold criteria for requesting core privileges in phakic IOL implant surgery**

- **Basic education:** MD or DO
- **Minimum formal training:** Applicants must have completed an ACGME/AOA-accredited training program in ophthalmology. In addition, applicants must complete a formal training course in phakic IOL implant surgery.
- **Required previous experience:** Applicants must be able to demonstrate that they have performed at least 10 phakic IOL surgery procedures in the past 12 months.

**References**

A letter of reference should come from the director of the applicant’s phakic IOL implant surgery training program. Alternatively, a letter of reference regarding competence should come from the chief of eye surgery at the institution where the applicant most recently practiced.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must be able to demonstrate that they have maintained competence by showing evidence that they have performed at least 10 phakic IOL implant surgery procedures annually over the reappointment cycle.

In addition, continuing education related to phakic IOL implant surgery should be required.

**For more information**

For more information regarding this procedure, contact:

Advanced Medical Optics
1700 East Saint Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162
Telephone: 714/247-8200
Fax: 714/247-8680
Web site: www.amo-inc.com
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American Academy of Ophthalmology
P.O. Box 7424
San Francisco, CA 94120-7424
Telephone: 415/561-8500
Fax: 415/561-8533
Web site: www.aao.org

American Board of Ophthalmology
111 Presidential Boulevard, Suite 241
Bala Cynwyd, PA 19004-1075
Telephone: 610/664-1175
Fax: 610/664-6503
Web site: www.abop.org

American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611
Telephone: 312/202-8000
Fax: 312/202-8200
Web site: www.aoa-net.org

Manhattan Eye, Ear and Throat Hospital
210 East 64th St,
New York, NY 10021
Telephone: 212/838-9200
Web site: www.lenoxhillhospital.org/services/meeth.jsp
Privilege request form
Phakic intraocular lens implant surgery

To be eligible to request clinical privileges in phakic IOL implant surgery, an applicant must meet the following minimum threshold criteria:

- Basic education: MD or DO

- Minimum formal training: Applicants must have completed an ACGME/AOA-accredited training program in ophthalmology. In addition, applicants must complete a formal training course in phakic IOL implant surgery.

- Required previous experience: Applicants must be able to demonstrate that they have performed at least 10 phakic IOL surgery procedures in the past 12 months.

- References: A letter of reference should come from the director of the applicant’s phakic IOL implant surgery training program. Alternatively, a letter of reference regarding competence should come from the chief of eye surgery at the institution where the applicant most recently practiced.

- Reappointment: Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must be able to demonstrate that they have maintained competence by showing evidence that they have performed at least 10 phakic IOL implant surgery procedures annually over the reappointment cycle.

In addition, continuing education related to phakic IOL implant surgery should be required.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ____________________________________________

Typed or printed name: ____________________________________________

Date: ___________________________________________________________
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