

Phakic Intraocular Lens Implantation for the Correction of Myopia

A Report by the American Academy of Ophthalmology

David Huang, MD, PhD, Steven C. Schallhorn, MD, Alan Sugar, MD, MS, Ayad A. Farjo, MD, Parag A. Majumdar, MD, William B. Trattler, MD, David J. Tanzer, MD

Objective: To review the published literature for evaluation of the safety and outcomes of phakic intraocular lens (pIOL) implantation for the correction of myopia and myopic astigmatism.

Methods: Literature searches of the PubMed and Cochrane Library databases were conducted on October 7, 2007, and July 14, 2008. The PubMed search was limited to the English language; the Cochrane Library was searched without language limitations. The searches retrieved 261 references. Of these, panel members chose 85 papers that they considered to be of high or medium clinical relevance to this assessment. The panel methodologist rated the articles according to the strength of evidence.

Results: Two pIOLs have been approved by the US Food and Drug Administration (FDA): one iris-fixated pIOL and one posterior-chamber IOL. In FDA trials of iris-fixated pIOLs, uncorrected visual acuity (UCVA) was $\geq 20/40$ in 84% and $\geq 20/20$ in 31% after 3 years. In FDA trials of posterior-chamber pIOLs, UCVA was $\geq 20/40$ in 81% and $\geq 20/20$ in 41%. Satisfaction with the quality of vision with both types of pIOLs was generally high. Toric anterior- and posterior-chamber pIOLs have shown improved clinical results in European trials compared with spherical pIOLs. Comparative studies showed pIOLs to provide better best spectacle-corrected visual acuity (BSCVA) and refractive predictability and stability compared with LASIK and photorefractive keratectomy and to have a lower risk of retinal detachment compared with refractive lens exchange. Reported complications and long-term safety concerns include endothelial cell loss, cataract formation, secondary glaucoma (pupillary block, pigment dispersion), iris atrophy (pupil ovalization), and traumatic dislocation.

Conclusions: Phakic IOL implantation is effective in the correction of myopia and myopic astigmatism. In cases of high myopia of -8 diopters or more, pIOLs may provide a better visual outcome than keratorefractive surgeries and better safety than refractive lens exchange. The short-term rates of complications and loss of BSCVA are acceptable. Comprehensive preoperative evaluation and long-term postoperative follow-up examinations are needed to monitor for and prevent serious complications, and to establish long-term safety.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references. *Ophthalmology* 2009;116:2244–2258 © 2009 by the American Academy of Ophthalmology.

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an assessment is to systematically review the available research for clinical evidence of efficacy and safety. After review by members of the Ophthalmic Technology Assessment Committee, other Academy committees, relevant subspecialty societies, and legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements.

Background

Keratorefractive surgeries, such as photorefractive keratectomy and LASIK, have limitations when used for the correction of high refractive errors.^{1–4} Wound healing and

biomechanical responses can occasionally lead to poor refractive predictability, prolonged visual recovery, instability of refraction, and loss of vision from corneal irregularity or scarring. Removing too much corneal tissue with the laser can induce progressive ectasia. Transient or permanent symptoms can occur, including night vision disturbances and dry eyes. As our understanding of these limitations has expanded, indications for corneal refractive surgery have narrowed.

Intraocular refractive procedures offer many potential advantages: a broader range of treatable ametropia, faster visual recovery, more stable refraction, and better visual quality.^{5–7} Two basic intraocular refractive procedures exist: phakic intraocular lens (pIOL) implantation and clear lens extraction with lens implantation, also called refractive lens exchange. Refractive lens exchange may increase the

risk for retinal detachment and is generally not considered in myopic pre-presbyopic patients who can still accommodate. Retinal detachment after refractive lens exchange for high myopia has been described to occur in 2% to 8% of patients.⁸

The risks and benefits of pIOL implantation in appropriate patients may be more favorable than other refractive surgery techniques. The pIOL is removable surgically, which makes the refractive result potentially reversible. Visual recovery is fast, and accommodation is preserved. Implantation of a pIOL utilizes operative techniques familiar to most cataract surgeons and does not require expensive or specialized devices, such as an excimer laser or microkeratome. However, it is important to realize that complications relating to pIOLs can be more disabling than those from keratorefractive surgery. Glaucoma, angle closure, cataract formation, corneal decompensation, pupil ovalization, uveitis, and endophthalmitis are potential complications after pIOL insertion. The purpose of this assessment was to review the safety and outcomes of pIOL implantation.

Types of Phakic Intraocular Lenses

Phakic intraocular lenses may be classified according to the site of implantation within the eye: anterior chamber or posterior chamber. Anterior-chamber pIOLs are further subdivided based on the method of fixation to the ocular structures: angle fixated or iris fixated.

The first pIOLs were designed to be placed into the anterior chamber and supported by the angle. Strampelli implanted the first pIOL in 1953 by placing a minus-powered lens into the anterior chamber to correct myopia.⁹ Use of this lens was associated with severe complications, including endothelial decompensation, pupillary ovalization, and angle fibrosis that were attributed to the coarse material of the pIOL, thick and poorly polished haptics, as well as inappropriate sizing that led to significant physical contact with iris and angle structures. Unfortunately, subsequent attempts at pIOL design by Barraquer as well as Choyce in the late 1950s met with similar setbacks.¹⁰ In fact, many of the pIOLs implanted during that period required explantation, and the idea of a pIOL was largely abandoned. It was nearly 30 years before pIOL design was revisited and >40 years before pIOLs became more widely accepted.¹¹

The pIOLs designed by Dvali and Baikoff in 1986 were significantly more advanced compared with their counterparts from the 1950s.¹⁰ Modern pIOL materials and haptic design, with thinner, more flexible, and highly polished haptics, allowed for rapid progress in the development of pIOLs. A number of pIOL designs were developed, starting with the Baikoff ZB lens, progressing to the ZB5M, the ZB5MF, and the NuVita lens. The ZB lens was an all-polymethylmethacrylate (PMMA) pIOL that had a Z-flex haptic design with four support points, haptic angulation of 25°, and a 4.5-mm optic.¹² In 1990, the pIOL was modified to the ZB5M, which had a smaller vaulting angle, thinner optic, and greater haptic flexibility. The ZB5MF added

fluorine plasma to the surface of the pIOL to increase biocompatibility. The final variant of the Baikoff pIOLs was the NuVita MA20, a single-piece PMMA pIOL with a 5.0-mm optical zone.¹³ This pIOL was associated with a number of pupillary and angle abnormalities, and it was eventually taken off the market in Europe owing to night vision problems.

A number of anterior-chamber, angle-supported pIOLs are or were available internationally. The ZSAL4 and ZSAL4-Plus (Morcher GmbH, Stuttgart, Germany) and the Phakic 6 IOL (Ophthalmic Innovations International, Inc., Ontario, CA) feature rigid optics and footplates. The ZSAL4 IOL, developed in 1994, avoided some of the complications of the Baikoff IOLs, but pupillary ovalization and decentration remained significant problems.^{14,15} It was a plano-concave, single piece PMMA IOL (overall length 12.5–13.0 mm) with a 3-sided-edge design optic (5.5 mm) that was thought to decrease glare and night vision problems.^{9,15–17} The z-shaped haptics, with an angulation of 19°, were made longer to decrease compressive forces against the angle structures. The pIOL is available from –6 to –20 diopters (D). The Phakic 6 is also an angle-supported pIOL with an optic diameter of 4.5 to 5.5 mm and an overall length of 11.5 to 13.0 mm.¹⁸ The size of the pIOL implanted is determined by the horizontal white-to-white corneal-diameter measurement. The Kelman Duet Implant Phakic IOL (Tekia, Inc., Irvine, CA) is another angle-supported IOL featuring rigid optic and haptics but with a unique 2-part design.¹⁹ This IOL features a separate optic and haptic, which can be implanted via a 2.5-mm incision. The PMMA haptic has 3 points of support and is available in 3 sizes: 12, 12.5, and 13 mm. The separate optic and haptics allow for exchangeability of the optic if the refraction changes or the haptic is sized inappropriately. Other angle-supported lens types include the GBR IOL (IOLtech Laboratoires Co., La Rochelle, France) and the Vivarte (CIBA Vision, Duluth, GA).^{12,20} These lenses feature a flexible optic and rigid haptics. The Vivarte is no longer marketed owing to concerns over endothelial cell loss. The ICARE IOL (Cornéal Laboratoires, Paris, France) has a flexible optic and haptics, and is a single-piece hydrophobic acrylic pIOL with an optic diameter of 5.75 mm and an overall diameter of 12 to 13.5 mm.²¹ Four haptics prevent rotation of the pIOL and minimize pressure against the angle structures. Another angle-supported pIOL with flexible optics and flexible haptics is the AcrySof pIOL (Alcon Laboratories, Inc., Fort Worth, TX). The AcrySof pIOL is manufactured in a 5.5- or 6.0-mm diameter meniscus optic with an overall length of 12.5 to 14.0 mm and a dioptric range of –6.00 to –16.50 D. The lens material is the same as for other AcrySof IOLs and has a long track record of excellent biocompatibility.^{22,23} This lens is undergoing US Food and Drug Administration (FDA) clinical investigation.

In the 1980s, as an increasing number of reports indicated complications from use of the angle-supported pIOLs, a new type of anterior-chamber pIOL was developed based on the 1977 design of Jan Worst's iris-fixated "iris-claw" lens.^{9,10,24} This pIOL had a biconcave optic design and was compression molded and lathe cut from PMMA. It was initially developed for the correction of aphakia. Anterior-

chamber, iris-fixated pIOLs have the advantages of “one size fits all” sizing, optimal distance from the crystalline lens and corneal endothelium, and excellent and stable lens centration. In addition, the integrity of the iris vascular supply is maintained, and there is relatively unrestricted pupil dilation. In 1986, the Worst-Fechner iris-claw pIOL was initially developed with a biconcave, PMMA optic, and in 1991 the design was modified to a 5-mm convex/concave optic with an overall length of 8.5 mm. In 1998, the design was modified to incorporate an 0.87-mm vault anterior to the iris, and the option of a 6-mm optic was added.²⁴ The name of the pIOL was changed to Artisan (Ophtec BV, Groningen, The Netherlands), and it became available in powers from -3 to -23.5 D. In 2004, the pIOL gained FDA approval under the name Verisyse Phakic IOL (Abbott Medical Optics, Inc., Santa Ana, CA), with powers from -5 to -20 D. A toric Artisan model is available in Europe with parameters similar to the Artisan, but with cylindrical powers up to 7.5 D.²⁵⁻²⁷ The Artiflex IOL was developed based on the Artisan platform, with a flexible, convex-concave, 6.0-mm silicone optic, PMMA haptics, and overall length of 8.5 mm.²⁸ The IOL is available in powers of -2 to -14.5 D, and it utilizes a small (3.2 mm), self-sealing incision, thereby allowing for more rapid recovery of visual acuity. The Artiflex has Conformité Européenne marking in the European Union and is undergoing FDA clinical trials as the Veriflex lens (Abbott Medical Optics, Inc.).

Posterior-chamber pIOLs are cosmetically appealing because they are only visible by careful examination and are placed far from the anterior-chamber angle and the corneal endothelium.

The first posterior-chamber pIOLs were developed by Fyodorov in 1986.²⁹ They originally had a collar-button configuration with the optic in the anterior chamber and the haptics behind the iris. The Chiron Adatomed pIOL was designed as a rectangular, silicone-plate IOL with a length of 10.5 to 12.5 mm and a circular optical zone with a diameter of 5.5 mm.³⁰ Use of this pIOL resulted in a very high incidence of anterior-chamber inflammation and cataract, and so it was ultimately discontinued.⁹ The PRL Phakic Refractive Lens (CIBA Vision) is a nonfixated, 1-piece, hydrophobic silicone elastomer designed to “float” above the crystalline lens surface, with the haptics resting on the zonules.^{9,31-33} The IOL was available in 2 lengths in powers from -3 to -20 D. This pIOL was also discontinued due to a tendency to create zonular dehiscence and subluxation into the vitreous cavity.³⁴ The STAAR Surgical Co. (Monrovia, CA) Visian ICL is currently the only posterior-chamber pIOL approved for use in the United States.^{9,29,35,36} It, too, has undergone a number of modifications in design since 1993, culminating in the V4 (version 4) design in 1999 that increased the vaulting over the anterior lens capsule.³⁷ The IOL material is described as “collamer,” a copolymer of hydroxyethyl methacrylate and porcine collagen. The lens name was originally intended to be marketed as the “implantable contact lens.” However, the FDA advised against use of this phrase because of the potential for consumers to confuse it with corneal contact lenses, and the company changed the name to “implantable collamer lens.”⁹ The pIOL is approved for the correction of myopia ranging from

-3 to -15 D and for the reduction of myopia ranging from -15 to -20 D, with ≤ 2.5 D astigmatism at the spectacle plane. STAAR Surgical has submitted a Pre-Market Approval supplement to the FDA for the Visian Toric ICL, a toric implantable collamer lens, seeking an indication of -3 to -20 D of myopia with astigmatism of 1 to 4 D.

Food and Drug Administration Status

Although a number of pIOL designs and modifications have been implemented worldwide, currently only 2 pIOLs are approved by the FDA. The Verisyse Phakic IOL, marketed internationally as the Artisan lens by Ophtec and distributed in the United States by Advanced Medical Optics, Inc., was the first pIOL to gain approval by the FDA, in 2004. The Visian ICL, manufactured by STAAR Surgical Company, gained FDA approval in December 2005. Two pIOLs are currently undergoing FDA-approved phase 3 clinical trials: the iris-fixated Veriflex anterior-chamber pIOL (marketed internationally by Ophtec as the Artiflex lens) and the angle-supported ACRYSOF anterior-chamber pIOL. The ACRYSOF pIOL received European Union Conformité Européenne Marking in August 2008 based on clinical trial data involving 360 patients whose average preoperative refractive error was approximately -10.5 D.

This assessment focuses primarily on the pIOLs that are FDA approved or are in the process of gaining FDA approval. Other pIOL designs are briefly reviewed to gain insight on the design characteristics and how they relate to the complications that were encountered.

Table 1 lists the pIOLs that have been approved by the FDA for the correction of myopia. Table 2 lists the contraindications for the FDA-approved pIOLs. Table 3 lists the incidences of complications encountered in the FDA trials.

Preoperative Evaluation for Implantation

The preoperative evaluation of a patient for a pIOL is more comprehensive than is required for keratorefractive surgery. It consists of a complete ophthalmologic examination, including a medical and ophthalmologic history, as well as specialized testing to detect any pathology that may be a contraindication to using a pIOL.³⁸ As with every operative procedure, the surgeon should ensure that the patient receives proper informed consent.^{39,40} A manifest and, where appropriate, cycloplegic refraction should be performed to accurately determine the refractive state of the eye. For patients who wear contact lenses, especially rigid contact lenses, any evidence of corneal warpage requires that corneal stability be confirmed by serial measurements. As a general guideline,³⁸ spherical soft contact lenses should be discontinued for approximately 1 week.⁴¹ Toric soft contact lenses and rigid contact lenses should be discontinued for a longer period, because they are associated with a greater potential for corneal warpage and refractive instability. Documentation of refractive stability, usually <0.5 D of change over 6 months to 1 year or more, is also advised to help ensure that the correction will be appropriate in the future.

Table 1. Phakic Intraocular Lenses Approved by the US Food and Drug Administration for the Correction of Myopia

Model	Company	Indications
Visian ICL (Implantable Collamer Lens) (P030016; 12/22/05)	STAAR Surgical Co. (Monrovia, CA)	To correct myopia from -3 to -15 D and reduce myopia from -15 to -20 D with ≤ 2.5 D of astigmatism at the spectacle plane Age 21-45 years Anterior chamber depth 3.0 mm Refractive stability: within 0.5 D for 1 year before implantation
Artisan (Model 206 and 204) Phakic Intraocular Lens/Verisyse (VRSM5US and VRSM6US) Phakic Intraocular Lens (P030028; 9/10/04)	Ophtec BV (Groningen, The Netherlands)/Ophtec USA Inc. (Boca Raton, FL)	To correct myopia from -5 to -20 D with ≤ 2.5 D of astigmatism at the spectacle plane Age ≥ 21 years Anterior chamber depth 3.2 mm Refractive stability: within 0.5 D for 6 months before implantation

D = diopter.

Source: Available from <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>. Accessed December 5, 2008.

The preoperative examination includes best spectacle-corrected visual acuity (BSCVA), slit-lamp biomicroscopy, central corneal thickness measurement, endothelial cell count, keratometry, axial eye length measurement, tonometry, measurement of mesopic pupil diameter, and indirect ophthalmoscopy. A thorough peripheral retinal examination is necessary to rule out retinal tears, especially in highly myopic eyes. Because the refractive error and wound healing may be altered during pregnancy and lactation, these conditions are contraindications to pIOL implantation.

The anterior-chamber depth is a critical component to the safety of a pIOL procedure and should be assessed before surgery. A shallow anterior chamber can complicate the insertion and placement of the pIOL as well as increase the loss of endothelial cells. In a study of 318 eyes of 173 myopic patients treated with an iris-fixated pIOL, a significant correlation was found between lower anterior-chamber depth and endothelial cell loss.⁴² The minimum anterior-chamber depth for pIOL eligibility is generally between 3.0 and 3.2 mm as measured between the central anterior lens capsule and the endothelium. A variety of devices are available to assess anterior-chamber depth, including ultrasound imaging, the rotating Scheimpflug camera, scanning slit tomography, partial coherence interferometry, and optical

coherence tomography. All have shown reasonable interdevice agreement in comparative studies.⁴³⁻⁴⁶

An assessment of the anterior-chamber angle configuration is necessary for the placement of anterior-chamber lenses. Gonioscopy, ultrasound, or optical coherence tomography can be used for this evaluation. In addition, a careful examination of the iris should be a part of the preoperative workup.

An evaluation of the endothelium is a necessary part of the preoperative evaluation for pIOL patients, because pIOL insertion has the potential to reduce the number of viable endothelial cells.^{29,47} This can result in an immediate endothelial loss owing to surgical trauma and/or a chronic, and possibly progressive, reduction of cells as a result of the implanted pIOL. All FDA-approved pIOLs have a minimum preoperative endothelial cell count requirement related to patient age. This minimum provides added safety for long-term corneal clarity by accounting for the natural endothelial loss that occurs with age. This is especially important, because pIOLs are generally implanted in patients younger than the population with cataract. Thus, there is a need to preserve an adequate endothelial cell density (ECD) to accommodate aging. Accordingly, evaluation of the endothelium can be performed by manual specular,

Table 2. Contraindications for Implantation of Phakic Intraocular Lenses Approved by the US Food and Drug Administration

Contraindications	Visian Implantable Collamer Lens	Artisan (Model 206 and 204) Phakic Intraocular Lens/ Verisyse (VRSM5US and VRSM6US) Phakic Intraocular Lens
	Anterior chamber depth (mm)	<3.0
Anterior chamber angle	Less than grade II determined by gonioscopic examination	Any angle abnormalities
Pregnant or nursing	Yes	Yes
Endothelial density	Age-dependent minimum* (range 1900-3875 cells/mm ²)	Age-dependent minimum* (2000-3550 cells/mm ²)
Iris details	No	Abnormal iris, such as peaked pupil or elevated iris margin

Source: Available from <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>. Accessed December 5, 2008.

*The minimum endothelial cell density was determined by the upper 90% confidence interval of the average cell loss for eyes with a specified anterior-chamber depth in the FDA-authorized clinical trials. This was based on the minimum endothelial cell density criteria as a function of age that should result in ≥ 1000 cells/mm² at 75 years of age.

Table 3. Incidence of Complications with Phakic Intraocular Lenses in US Food and Drug Administration Submission

Model	No. of Eyes	Glare/Halos	HypHEMA	Mean Endothelial Cell Loss	Cataract	Iritis	IOP Elevation
Artisan (Model 206 And 204) Phakic Intraocular Lens/ Verisyse (VRSM5US and VRSM6US) Phakic Intraocular Lens (P030028; 9/10/04)	662	18.2% (n = 472)	0.2%	4.75% at 3 years (n = 353)	5.2% (12/232)	0.5%	0%
Visian ICL (Implantable Collamer Lens) (P030016; 12/22/05)[5-year specular microscopy data (2007)]	526	3 years glare: worse 9.7%; better 12.0% Halos worse 11.4%; better 9.1%	0%	Cumulative loss of 12.8% approaching stability at 5 years	Visually significant ASC 0.4%; NS 1.0%	NR	0.4% No cases of visual field loss or nerve damage

ASC = anterior subcapsular cataract; IOP = intraocular pressure; NR = not reported; NS = nuclear sclerosis.

Source: Adapted with permission from the American Academy of Ophthalmology Basic and Clinical Science Course Subcommittee. Basic Clinical and Science Course. Refractive Surgery: Section 13, 2008–9. Table 8–3, p. 167. San Francisco, CA: American Academy of Ophthalmology, 2008.

automated contact and noncontact specular, and confocal microscopy.^{48–50}

Correct sizing of the pIOL is important to avoid postoperative complications such as spinning, decentration, and cataract formation (too little vault for a posterior-chamber pIOL). This typically involves measurement of the horizontal white-to-white corneal diameter using a caliper or topographic device.

An important element of the preoperative workup is the pIOL power calculation. The significant variables are refractive error, corneal curvature, and anterior-chamber depth. Of these three, the least accurately measured variable is anterior-chamber depth. This depth essentially accounts for the vertex distance of the lens. Newer techniques (such as optical coherence tomography) for measuring anterior-chamber depth may improve the overall refractive accuracy. Each manufacturer provides software to calculate the IOL optic power. This calculation is typically based on the formula developed by van der Heijde⁵¹:

Power = $n/(nk + P_s - d) - n/(nk - d)$ where n is the refractive index of the aqueous (1.336), d is the distance between the anterior corneal vertex and the principal plane of the IOL in meters (depth of the anterior chamber minus 0.8 mm), k is the dioptric power of the cornea, and P_s is the equivalent power of the eye's spectacle correction at the corneal plane.

Operative Technique

Laser or operative peripheral iridotomies are required before both anterior- and posterior-chamber pIOL implantations to prevent pupillary block.

For eyes undergoing implantation of anterior-chamber, iris-fixated pIOLs, the pupil is constricted with miotic drops and the procedure is performed under either topical, peribulbar, or retrobulbar anesthesia. Two paracenteses are created and the anterior chamber is filled with an ophthalmic viscosurgical device (OVD). A scleral tunnel, limbal incision, or corneal incision is made, usually in the steepest corneal meridian, which is approximately equal to the lens optic diameter. The pIOL is inserted and rotated into a

horizontal position. A fold of the peripheral iris is then captured by the pincherlike lens haptics in a process called enclavation. A peripheral surgical iridotomy can be performed. The incision is closed with an appropriate suture and the OVD is removed.

For eyes undergoing implantation of posterior-chamber pIOLs, the pupil is dilated with mydriatic drops and the procedure is performed under topical anesthesia. A 3.2-mm temporal clear corneal incision is created as well as 1 or 2 paracenteses. The anterior chamber is filled with an OVD. The pIOL is then injected into the anterior chamber, anterior and parallel to the iris plane, and allowed to unfold. Each corner of the footplates is gently tucked beneath the iris. Once the pIOL is well positioned, the OVD is removed and the corneal wound checked for integrity. Generally, the procedure on the other eye follows in 1 or 2 weeks.

Postoperative Management

Follow-up examinations are typically scheduled at 1 day, 1 week, 1 month, 2 months, 6 months, and 1 year after surgery and yearly thereafter. Postoperative examinations should include slit-lamp biomicroscopy, keratometry, applanation tonometry, subjective and objective refraction, and measurement of uncorrected visual acuity (UCVA), BSCVA, and ECD (beginning at 6 months after surgery). Within the first 6 postoperative weeks, the suture is cut or removed if it has created undesirable corneal astigmatism.

Resource Requirements

The implantation of a pIOL requires instruments commonly available for cataract surgery. In addition, a few special instruments are needed for the enclavation of the iris-fixated pIOL and the manipulation of the posterior-chamber pIOL. The preoperative and postoperative evaluation of pIOL patients requires standard equipment for refraction, vision testing, and slit-lamp biomicroscopy. In addition, specialized instruments are used for anterior-segment biometry and endothelial cell counting.

Question for Assessment

This assessment addresses the following question: What are the safety and outcomes of pIOL implantation for the correction of myopia and myopic astigmatism?

Description of Evidence

Literature searches of the PubMed and Cochrane Library databases were conducted on October 7, 2007, and July 14, 2008 using the MeSH terms *lenses, intraocular, myopia/prevention and control, myopia/rehabilitation, myopia/surgery, myopia/therapy, treatment outcome* and key words *phakic, refractive, angle-fixated, angle-supported, iris-fixated, toric, implantable contact lens, implantable Collamer lens, Baikoff ZBM5, NuVita, Visian, ICL, Artisan, Verisyse, Artiflex, Veriflex*. The PubMed search was limited to the English language; the Cochrane Library was searched without language limitations. The searches retrieved 261 references.

The first author reviewed the literature searches and selected 188 papers to review in full text to consider their relevance to the assessment question. Of these, panel members chose 85 papers that they considered to be of high or medium clinical relevance to this assessment. An additional 8 papers were identified during preparation of the assessment. The panel methodologist rated the articles according to the strength of evidence. A level I rating was assigned to well-designed and well-conducted randomized clinical trials; a level II rating was assigned to well-designed case-control and cohort studies and poor-quality randomized studies; and a level III rating was assigned to case series, case reports, and poor-quality cohort and case-control studies. Three studies^{29,52,53} described well-conducted randomized controlled trials with good follow-up, although all had relatively small numbers, and were rated as level I. Three studies were rated as level II; one was a small randomized trial with incomplete descriptions and 2 were cohort studies.^{54–56} The remainder of the literature, most of which described uncontrolled case series, was rated as level III.

Published Results

Visual Outcomes

Phakic IOLs can provide immediate improvement in UCVA, an increase in BSCVA, and preservation of accommodation, and they can correct higher levels of both myopia and hyperopia.⁵⁷ Because the FDA has approved only 2 of these, the Artisan/Verisyse IOL and the Visian ICL, discussion of visual acuity results are limited to these devices only. Initial results from clinical trials on the toric versions of these pIOLs are discussed later.

In general, best corrected and uncorrected visual acuities have not been reported to differ significantly between these 2 lenses, although 1 long-term study found slightly better visual results with the Artisan than with the Visian ICL lens.⁵⁸

Iris-fixated Phakic Intraocular Lenses. The Worst-Fechner lens has been implanted in patients with myopia

ranging from -5 to -31.75 D, with the majority of studies reporting on implantation in patients with at least -7 D.^{10,59–63} The IOL showed good postoperative visual acuity results, but high endothelial cell count loss led to discontinuation.^{10,59–63} The second iteration of the iris-claw IOL, the Worst myopia claw, altered the optical part of the IOL into a convex–concave model to reduce the degree of endothelial cell loss while maintaining visual acuity results.⁶⁴ In eyes with myopia ranging from -6 to -28 D (mean preoperative refractive error was -14.70 D), mean postoperative refraction was -0.93 D, with a high percentage of achieved near emmetropia, accuracy, stability, and predictability.⁶⁴

In FDA trials, preoperative refractive error in phase 1 ranged from -8 to -20 D, but it was expanded in the phase 2 and 3 trials to include -5 to -20 D.²⁴ In an interim report on 264 eyes, the overall preoperative UCVA was $<20/400$ in 98% of the subjects, with best-corrected visual acuity (BCVA) $\geq 20/20$ in only 54%.²⁴ At 6 months postoperatively, 100% of the eyes had $\geq 20/40$ BCVA, and 83% had $\geq 20/40$ UCVA, without regard to astigmatism. Further, 72% of the subjects gained ≥ 1 lines, with 22% gaining ≥ 2 lines; 90% were within 1 D of intended correction.²⁴ The FDA trial results concurred with earlier short-term study results.^{65,66} Longer term studies also found stable refraction, which increased both UCVA and BCVA.^{5,21,52,54,67–70} Longer term FDA clinical trial results found UCVA was $\geq 20/40$ in 84%, $\geq 20/25$ in 52%, and $\geq 20/20$ in 31% of the 3-year cohort ($n = 231$).⁴⁷ At 5 years postoperatively, UCVA was $\geq 20/40$ in 95% in 1 study,⁷¹ but it was only 65% in a second study.⁷² At 10 years, refraction was still stable, with 93.3% reaching a BCVA of $\geq 20/40$ and 82% achieving a UCVA of $\geq 20/40$ ($n = 89$).⁷³

When compared prospectively with LASIK for the correction of myopia between -8 and -12 D, the pIOL had a superior safety index and was preferred by more patients.⁷⁴ Neither the predictability of the refractive outcomes nor UCVA was significantly different between these 2 groups.

In a prospective, randomized trial with paired-eye control for the correction of myopia between -8 and -12 D, the Artisan-treated eye was found to be superior to LASIK in terms of the safety index (postoperative BCVA/preoperative BCVA; $P < 0.02$ at 1 year) and subjective preference (4/25 preferred LASIK, 11/25 preferred Artisan).⁷⁴ Predictability of refractive outcomes and UCVA did not differ significantly.

Patient satisfaction with visual acuity results has also been highly favorable, even when fewer patients achieve $\geq 20/40$ UCVA.⁷⁵ The Artisan IOL has been shown to increase contrast sensitivity after implantation.⁵⁵ Using LASIK as an enhancement treatment for residual refractive error after IOL implantation was found to be an effective treatment for patients with myopia greater than -15 D.⁷⁶

The Veriflex/Artiflex IOLs differ from the Verisyse/Artisan IOLs in that the former are foldable pIOLs made from flexible hydrophobic polysiloxane material, and the latter are not foldable and made from rigid PMMA material. European clinical trials on the foldable version indicate that it can provide a faster visual recovery and better UCVA

Table 4. Complications Associated with Anterior-Chamber

Study	IOL	No. of Eyes	No. of Patients	Follow-up (mos)	Loss of BSCVA >2 Lines (%)	ECD Loss (%)	Increased IOP (%)
Alio et al ¹⁹	Kelman Duet	169	110	12	None	5.43 ± 11.19	Yes for first 3 mos
Allemann et al ¹³	NuVita	21	12	24	None	12 [at 2 yrs]	NR
Javaloy et al ¹²	ZB5M	225	146	12–144	3.50	30.31 [at 12 yrs]	2.2 [required prolonged treatment]
Leccisotti and Fields ¹⁵	ZSAL-4	190	115	12–24	None	6.2 [at 1 yr]	0.5 [required prolonged treatment]
Perez-Santonja et al ¹⁴	ZSAL-4	23	16	24	None	4.18 [at 2 yrs]	13 [first month]

BSCVA = best spectacle-corrected visual acuity; ECD = endothelial cell density; IOL = intraocular lens; IOP = intraocular pressure; NR = not rated.

than the rigid lens, with overall efficacious and predictable results.^{28,77–79}

Posterior Chamber Phakic Intraocular Lenses. The current STAAR model available in the United States is the Visian ICL. Studies on all versions of this pIOL have included patients with myopia from -5.0 to -24.75 D^{37,80} and hyperopia up to $+11.75$ D,^{81,82} with the majority including patients between -9.00 and -20.00 D.^{29,35,36,61,83,84} European studies on the various STAAR lenses have included patients with myopia of at least -5.0 D⁸⁰ and hyperopia up to $+11.75$ D.^{81,82} The majority of studies have included patients whose myopia was between -9.00 and -20.00 D,^{29,35,36,61,83,84} but 1 study included eyes with myopic errors up to -24.75 D.³⁷

European studies on the earlier iterations of the collamer lens had excellent visual results, although complications did exist. Three studies published results on more than 1 version of the collamer lens, with a UCVA of $\geq 20/40$ in 76% of eyes at 18 months,⁵⁸ $\geq 20/40$ in 72% of eyes at 1 month,⁸² and $\geq 20/40$ in 75% of the eyes.⁸⁵ One study compared 2 versions of the lens; 6 eyes were implanted with the V3 and 12 with the V4.⁸³ The combined UCVA results found that 8 eyes (44%) were $\geq 20/40$ at ≥ 1 year postoperatively. Other studies do not specify which version of the pIOL was used, but results are similar.^{29,36,80,81,84}

In the United States, the clinical trial for FDA approval reported on 526 eyes of 294 subjects implanted with the V4 to treat preoperative myopia ranging from -3.0 to -20.0 D, and 3-year results were reported on 369 eyes examined.⁸⁶ The mean preoperative refractive error in this cohort was

-10.06 ± 3.74 D. Uncorrected visual acuity was $\geq 20/20$ in 41% of eyes and $\geq 20/40$ in 81%. Overall, UCVA was better in those with lower levels of preoperative myopia: 97% had a UCVA of $\geq 20/40$ if preoperative myopia was no more than -7 D, compared with 70% of eyes with preoperative myopia more than -10 D.

Fifteen eyes (3%) required an additional refractive procedure. Patient satisfaction with visual outcomes study was favorable, with 92% claiming to be “very satisfied” or “extremely satisfied.” Those in the highest myopic preoperative group were less satisfied than the mid- or low-myopic groups; 1% (2 eyes) in the highest preoperative myopic group was dissatisfied, compared with none in the other 2 groups.

In terms of contrast sensitivity, the ICL fares well, with no loss reported in the FDA study at any spatial frequency. Overall complications were minor and occurred in the group with the highest preoperative myopia levels. These are discussed later.

Results in highly myopic Asian eyes are similar to those in the FDA study, without initial overcorrection or gradual regression of myopia. Modifying the horizontal white-to-white corneal diameter measurement nomogram in these smaller Asian eyes increased the likelihood of success.³⁷

When compared with visual outcomes of LASIK in myopes up to -12.00 D, the ICL offered better safety, efficacy, predictability, and stability.^{6,86–88} At 1 year, 90% of those implanted with the V4 IOL (n = 184) during an FDA study had a BCVA of 20/20, compared with 82% (n = 94) of those who had undergone LASIK. There were 96

Table 5. Complications Associated with Anterior-Chamber

Study	IOL	No. of Eyes	No. of Patients	Follow-up (mos)	Loss of BSCVA >2 Lines (%)	ECD Loss (%)	Increased IOP (%)
Benedetti et al ⁶⁷	Artisan	93	60	24	0	5.4 [at 24 mos]	4.30
Budo et al ⁵⁴	Artisan	518	335	6–36	1.2	0.7 [at 36 mos]	NR
Dick et al ²⁶	Artisan-toric	70	53	6	0	4.5 [at 6 mos]	0
Landesz et al ⁶⁸	Artisan	67	36	NR	2.99	10.9 [at 36 mos]	2.99 (early postoperatively)
Landesz et al ⁶⁵	Artisan	78	39	6–24	2.56	Inconsistent results	NR
Menezo et al ⁶¹	Worst-Fechner	94	62	36–72	0	17.9 [at 60 mos]	5.3 (early postoperatively)
Perez-Santonja et al ⁶³	Worst-Fechner	32	19	6–24	0	17.6 [at 24 mos]	15.6 (early postoperatively)
Silva et al ⁷¹	Artisan	26	15	6–60	0	14.05 [at 60 mos]	0
Stulting et al ⁴⁷	Artisan	684	684	35 [at 36 mos]	0	4.76 [at 36 mos]	None after 1 month
Tahzib et al ⁷³	Artisan	89	49	120	2.6	8.86 [at 120 mos]	0
Tehrani and Dick ²⁸	Artiflex	41	22	6	0	2.3 [at 6 mos]	Short term

BSCVA = best spectacle-corrected visual acuity; ECD = endothelial cell density; IOL = intraocular lens; IOP = intraocular pressure; NR = not rated.

Angle-Supported IOLs Reported in Clinical Trials

Uveitis (%)	Pupil Ovalization (%)	Iris Synechiae (%)	Decentration (%)	Night Halos/Glare (%)	Cataract (%)	Reoperations (%)
0.59	11.24	0.59	6.51	1.18 [at 12 mos]	None	7.1
NR	40	NR	NR	20 "moderate"	None	4.8
1.33	34.7	NR	NR	NR	10.7	6.41
1	11	NR	NR	18	NR	1
8.7 [early postoperatively]	17.4	NR	4.30	26.1	None	NR

patients (52%, n = 185) who attained 20/20 UCVA at 1 year with the ICL, compared with 36 patients (36%, n = 100) in the LASIK group.⁸⁸ Similar results were found for low myopes when compared with LASIK outcomes as well.⁸⁷ The pIOL also performed better than photorefractive keratectomy in terms of safety, efficacy, predictability, and stability.⁷

Outcomes of Toric Lenses and Other Adjunctive Procedures for Astigmatism

Spherical pIOLs are approved by the FDA for use in the United States, and they have been proven to be efficacious in the reduction or elimination of myopia. One major difficulty with currently approved technology is that astigmatic refractive error, present in nearly every ametropic eye, is not improved by a spherical pIOL. The patient's inability to tolerate astigmatic blur after spherical pIOL insertion requires the surgeon to address it by prescribing eyeglasses or contact lenses, or by following up with additional operative procedures such as limbal relaxing incisions, astigmatic keratotomy, or the more popular application of the excimer laser through either photorefractive keratectomy (PRK) or LASIK.

The concept of bioptics was first reported by Zaldivar in 1998 to describe using LASIK in combination with posterior-chamber pIOLs for high levels of myopia and astigmatism.³⁶ This concept was further elucidated in the literature by Guell in 1998 and again in 2001 when he described the concept of adjustable refractive surgery, com-

binning iris-fixated pIOLs and LASIK.⁷⁶ In 2003, Munoz et al described combining angle-supported pIOLs and LASIK for the correction of high myopia.⁸⁹

The Artisan/Verisyse toric pIOL is being studied in Europe and the United States. The pIOL's firm fixation to the iris stroma reduces the likelihood of rotation.⁹ The first published report on the results of the surgical implantation of a toric pIOL came from the European Multicenter Study published by Dick et al in 2003.²⁶ Safety, efficacy, predictability, stability, complications, and patient satisfaction were reported after implantation of iris-fixated pIOLs for myopia and hyperopia with astigmatism. Forty-eight myopic eyes with a mean spherical equivalent of -8.90 D and 22 hyperopic eyes with a mean spherical equivalent of +3.25 D were included. Mean sphere and cylinder corrected in the myopic group were -7.03±4.65 D (range, -19.0 to 1.75) and -3.74±1.09 D (range, -7.25 to -1.75), respectively, and in the hyperopic group they were +5.2±1.93 D (range, +2 to +8) and -3.7±1.05 D (range, -6 to -1.5 D), respectively. By 6 months postoperatively, no eye in either group experienced a loss of BSCVA, and 46 eyes gained ≥1 lines of BSCVA from their preoperative level. Uncorrected visual acuity was ≥20/40 in 85.4% of myopic and 95.5% of hyperopic eyes, respectively. All eyes were within ±1.00 D of intended refraction and 83.3% of myopic and 50% of hyperopic eyes were within ±0.50 D of intended correction. There was a 4.5% decrease in mean endothelial cell count by 6 months after implantation; otherwise, no serious complications were re-

Iris-Supported IOLs Reported in Clinical Trials

Uveitis/Hyphema (%)	Pupil Ovalization (%)	Iris Synechiae/Atrophy (%)	Decentration (%)	Night Halos/Glare (%)	Cataract (%)	Reoperations (%)
NR	NR	11.8	NR	6.4	NR	0
1.6	0	0.4	8.8	13.66	2.4	8.8
0	0	0	NR	1.4	0	3.77
1.49 (early postoperatively)	0	0	1.49	22.2	2.99	1.49
3.85 (early postoperatively)	NR	NR	NR	12.8	2.56	5.13
3.2 (early postoperatively)	NR	4.24	3.2	23.4	NR	3.2
9.3 (generally early postoperatively)	NR	90.63	15.63	56.25	0	3.13
NR	0	0	NR	3.85	3.85	7.69
None after 3 mos	1.7	NR	NR	NR	NR	3.48
NR	NR	NR	NR	4.49	2.25	3.37
Short term	NR	NR	NR	NR	0	NR

Table 6. Complications Associated with

Study	IOL	No. of Eyes	No. of Patients	Follow-up (mos)	Loss of BSCVA >2 Lines (%)	ECD Loss (%)	Increased IOP (%)
Chang and Meau ³⁷	Visian ICL	61	40	1–32	0	NR	0 [at 3 mos]
Donoso and Castillo ³⁴	PRL	53	39	8±9.4 (SD)	1.89	NR	0
Jimenez-Alfaro et al ²⁹	ICL	20	10	12–24	0	6.57 [at 24 mos]	0 [at 3 mos]
Jongsareejit ³¹	PRL	50	31	NR	0	NR	2 (angle closure)
Koivula et al ³²	PRL	20	20	24	0	7.7 [at 24 mos]	Early postoperatively only
Lackner et al ⁸⁰	Visian ICL	76	46	36	0	6.4–26.1 [at 36 mos*]	NR
Sanders et al ⁸⁸	Toric ICL	210	124	1 week–12 mos	0.50	NR	NR
Verde et al ³³	PRL	90	51	12	0	Not significant at 12 mos	Increased up to 1 year

BSCVA = best spectacle-corrected visual acuity; ECD = endothelial cell density; IOL = intraocular lens; IOP = intraocular pressure; NR = not rated; *The loss of ECD was 6.4% in those with clear lens and 26.1% in those with lens opacification.

ported. Overall patient satisfaction was very high.²⁶ Similar results were found in other studies for the correction of myopia.²⁵

This landmark study was followed by the report from Guell et al that discussed 5-year follow-up of 399 iris-fixated pIOLs, including 84 toric pIOLs.⁷² Preoperative mean spherical equivalent of -6.82 D was reduced to -0.09 D by the final examination and preoperative cylinder of -3.24 D was reduced to -0.83 D. Endothelial cell count was reduced 3.6% by the final examination.⁷²

Quality of vision was specifically addressed in an article published by Dick et al in 2004 evaluating the change in contrast sensitivity with glare after the implantation of iris-fixated toric pIOLs.²⁷ Using the CVS-1000 HGT (VectorVision, Greenville, OH), which tests 4 separate spatial frequencies with sine wave gratings, the investigators determined that 3 months after implantation of iris-fixated toric pIOLs for myopia and astigmatism, the mean contrast sensitivity improved at all spatial frequencies tested and the extent of improvement was statistically significant at the 6 and 12 cycle per degree frequencies.²⁷

Bartels et al²⁵ acknowledged the effect of incision-induced astigmatism as a significant variable for the accuracy of toric pIOL implantation, especially in the iris-fixated device, which currently requires a larger corneal-scleral wound for implantation. The authors recommended a systematic undercorrection of 0.50 D for attempted cylindrical outcome to account for the induced astigmatism associated with a 5.5-mm incision.²⁵

A toric model of the Visian ICL for spherocylindrical correction is also in trials.^{9,88} The clinical outcomes of the FDA trial evaluating efficacy of the posterior-chamber toric pIOL for moderate to high myopic astigmatism were reported by Sanders et al in 2007.⁸⁸ This was a prospective clinical trial involving 210 eyes followed for 12 months. By 12 months postoperatively, 83% of eyes had a UCVA of $\geq 20/20$ and 96% were $\geq 20/40$. Seventy-six percent of eyes had postoperative UCVA better than or equal to their preoperative BSCVA. Mean spherical equivalent was reduced from -9.36 D preoperatively to 0.05 D postoperatively. Astigmatism was reduced by 74%, from a mean of 1.93 D preoperatively to 0.51 D postoperatively. As a measure of accuracy, 97% of eyes were within ± 1.0 D and 77% were within ± 0.50 D of intended refraction by the 12-month

postoperative examination. There was a mean improvement in BSCVA of 0.88 lines, a 2% incidence of eyes losing ≥ 2 lines of BSCVA, and a 19% incidence of eyes gaining ≥ 2 lines of BSCVA from the preoperative to 12-month postoperative examination. Additionally, BCVA of $\geq 20/12.5$ was achieved in 38% of patients, and 99% were $\geq 20/20$. Three toric pIOLs were removed without significant loss of BSCVA, and 1 clinically significant lens opacity was observed and treated with no loss in BSCVA. This important study concluded that the treatment of moderate to high myopic astigmatism supported efficacy and predictability of the posterior-chamber toric pIOL, with no significant safety concerns identified.⁸⁸ As of this writing, no toric pIOL is approved for use in the United States, and the FDA is continuing to evaluate the results of this clinical trial.

Safety

Although multiple factors influence the side effect profiles of pIOLs, the majority of complications can generally be predicted by the design and location of the pIOL within the anterior segment. The closer the pIOL comes to the corneal endothelium, angle structures, or crystalline lens, the greater the risk of endothelial cell loss, iris complications, and cataract, respectively. In addition to the inherent problems from pIOL designs, appropriate sizing of the pIOL, surgeon inexperience, and surgical trauma as well as other patient-specific factors can contribute to intraoperative and postoperative complications. A comprehensive review and grouped analysis of pIOL complications and possible causes can be found elsewhere.⁹

The most significant, and suspected, concerns with anterior-chamber pIOLs are elevated intraocular pressure and endothelial cell loss. This is in contrast with posterior-chamber pIOLs, where cataract formation and lens subluxation are greater concerns. Given the risk of pupillary block, peripheral iridectomies or iridotomies are placed preventatively in all pIOL patients, yet this, too, may lead to complications including secondary images, hyphema, localized cataract, and iris synechiae. With modern pIOL designs, increased IOP seems to be relatively uncommon after 3 months postoperatively and is typically thought to be related to corticosteroid response.⁵⁹ However, there have been case reports of malignant glaucoma⁹⁰ and intractable elevation of

Posterior-Chamber IOLs

Uveitis/Hyphema (%)	Pupil Ovalization (%)	Iris Synecchia/Atrophy (%)	Subluxation (%)	Night Halos/Glare (%)	Cataract (%)	Reoperations (%)
NR	NR	NR	NR	1.6 [at 6 mos]	1.60	3.28
NR	NR	NR	3.77	NR	NR	NR
NR	NR	NR	NR	NR	NR	NR
NR	NR	NR	NR	46 ("mild")	2	NR
NR	5	5	NR	NR	NR	5
NR	NR	NR	NR	NR	14.47	3.95
Transient uveitis only	NR	NR	NR	NR	2.90	2.40
NR	NR	NR	0	NR	0	0

SD = standard deviation.

IOP requiring filtration surgery.⁹¹ Similarly, late angle-closure glaucoma can occur owing to pupillary block with or without⁹⁰ closure of the original iridotomy.

Angle-supported pIOLs may be more prone to endothelial cell loss, because they are more difficult to size appropriately and are more prone to postoperative rotation than iris-fixated pIOLs. However, 1 study with older versions of this style found the opposite.⁹² In initial FDA studies of the Artisan lens, endothelial cell loss was not found to be marked,⁶⁶ but ECD measurement was not standardized across each study center. A post hoc analysis of the FDA study for the Artisan lens⁴⁷ performed the ECD analysis in a more standardized fashion from 12 of 25 sites incorporating 353 eyes of 684 recruited and did not find marked cell loss at 3 years postoperatively. However, 1 center from the same FDA study found significant and progressive cell loss at 5 years postoperatively.⁷¹ A separate report also noted progressive loss of ECD at 5 years.⁵²

Given the proximity of pIOLs to the iris, uveitis has been a concern, but it does not seem to be a significant long-term complication with modern designs. However, 1 group has found low-grade subclinical inflammation by laser flare cell meter relative to controls as long as 2 years postoperatively with an iris-fixated and angle-supported anterior chamber pIOL.^{56,63} Increased flare has also been found after the implantation of a posterior chamber pIOL.²⁹ One group has found an association between increased ECD loss and lens opacification 3 years after posterior-chamber pIOL implantation, and attributed it to chronic inflammation.⁸⁰ There is a need to study uveitis in a systematic and standardized fashion after pIOL implantation.

The influence of operative technique and the surgeon's ability on complication rates is also difficult to ascertain, but there seems to be a typical learning curve. With iris-fixated pIOLs, difficulty with enclavation of the iris can lead to iris atrophy and decentration of the implant. Surgical trauma during implantation of posterior-chamber pIOLs may lead to cataract formation, typically of the anterior subcapsular variety. Alternatively, chronic trauma from contact of the IOL with the crystalline lens can also result in cataract formation.⁸² Similarly, chronic zonular trauma can lead to mild IOL decentration or to complete subluxation of the IOL into the posterior segment.³⁴ Blunt external trauma in eyes with pIOLs has been reported to cause IOL dislocation

and cataract.^{49,93} Although these cases are anecdotal, it seems reasonable to presume that the presence of the pIOL will lead to more intraocular damage than if it were not there. Although intraocular damage from significant blunt trauma is expected, it is possible that even lesser trauma, such as eye rubbing, leads to complications such as endothelial cell loss, particularly in eyes with anterior-chamber pIOLs.⁷²

Retinal detachment, a complication of note given the degree of high myopia that patients had in these studies, seems to be uncommon.^{94,95} One report showed that the risk of retinal detachment in pIOL cases was lower than in clear lens extraction cases.⁹⁶ One case of endophthalmitis had been associated with the implantation of a pIOL.⁹⁷

Rates for other situations requiring reoperation, including explantation for any reason, recentration, reenclavation, and/or cataract surgery were <8% in most published studies. There are no clear differences in the reoperation or complication rates based on IOL type, but limited data on paired eye comparison studies among pIOLs are available. Of the paired eye studies among pIOLs, one found that Artisan and Artiflex pIOLs have similar complication rates,⁷⁷ whereas another found greater lens decentration and cataract formation in Adatomed posterior-chamber pIOLs compared with various models of the STAAR ICL.⁸⁵ Table 3 lists the incidence of complications with pIOLs in the FDA submissions. Tables 4, 5, and 6 list complications reported in clinical trials.

Anatomic Fit

Proper sizing of pIOLs is critical because of the limited space for implantation and the sensitive structures surrounding the implanted IOL. The development of cross-sectional imaging modalities such as optical coherence tomography, the Scheimpflug camera, and ultrasound imaging has made detailed anatomic measurement possible. The use of imaging to improve the fit and safety of pIOLs is needed in future clinical trials.

For angle-fixated pIOLs, the length of the lens is the critical dimension. A lens that is too long presses on the iris root and can lead to sectoral iris atrophy and pupil ovalization. A lens that is too small can cause decentration and iritis owing to movement. The current fitting strategy is based on white-to-white angle measurement. This may not corre-

spond well with internal anterior-chamber width. Direct measurement of the anterior-chamber width from recess to recess using optical coherence tomography^{98,99} or ultrasound imaging¹⁰⁰ may improve the fit of the lens. Three-dimensional imaging of the anterior chamber can determine the widest meridian and help to determine the most stable orientation for IOL implantation.⁹⁸ Later generations of angle-fixated pIOLs that use more flexible haptic architecture or material may further improve the fit and safety of the IOL.

For iris-fixated pIOLs, the crystalline lens rise—the axial distance between the crystalline lens apex and the line joining the 2 opposite angles—has been found to be another important anatomic parameter to consider, in addition to the anterior-chamber depth. A crystalline lens rise of >0.6 mm has been found to cause a high incidence of pigment dispersion.¹⁰¹ The crystalline lens rise can be measured by cross-sectional imaging modalities such as optical coherence tomography, the Scheimpflug camera, and ultrasound. Using the cross-sectional images, lens implantation can be simulated and the resulting clearance from the cornea and the crystalline lens can be measured.¹⁰²

For angle-fixated and iris-fixated pIOLs, the most likely site of endothelium–IOL touch may be at the periphery of the optic, where the negatively powered lens is thickest. Thus, safety assessment may be improved by using a cross-sectional imaging modality to model the corneal clearance of the peripheral optic preoperatively and measure it postoperatively. Because the loss of corneal endothelial cells may occur primarily in the periphery, central endothelial cell count may not detect progressive loss until several years later.¹³ Peripheral endothelial cell counting may be able to detect progressive loss earlier. Case reports of corneal decompensation despite uncomplicated pIOL implantation,¹⁰³ sometimes many years later,¹⁰⁴ suggest that long-term monitoring of corneal clearance and endothelial cell count are prudent.

For posterior-chamber pIOLs, the size of the lens relative to the distance between opposite ciliary sulci determines the vault of the IOL and clearance over the crystalline lens. Ultrasound imaging to directly measure the sulcus-to-sulcus width may improve the predictability of the crystalline lens vault and reduce the incidence of cataract from inadequate clearance and pigment dispersion from too much vault.

Aging changes are a concern for the long-term safety of pIOLs. The human crystalline lens increases in thickness with age, with corresponding shallowing of the anterior chamber.^{105,106} Thus, a pIOL that has adequate clearance over the crystalline lens may come into contact with it when the patient reaches an older age. The sulcus-to-sulcus width of the posterior chamber also narrows with age^{107,108}; thus, the vault of a posterior-chamber pIOL may increase with age and eventually cause pigment dispersion. The effect of these aging changes on the tolerance of pIOLs deserves further study.

In conclusion, phakic IOL surgery is an efficacious technique for correcting refractive error in patients who would otherwise be poor candidates for corneal refractive surgery owing to high myopia. The designs of pIOLs have evolved over many years. Most early designs have been abandoned because of high rates of complications. At present, 1 iris-

fixated pIOL and 1 posterior-chamber pIOL have received FDA approval in the United States, but several other lenses are undergoing trials. The newer designs aim to improve the ease of implantation and to correct astigmatism.

Visual outcomes are, in the aggregate, very encouraging. By retrospective comparison, pIOL surgery seems to offer distinct predictability and stability advantages over LASIK for patients with high and perhaps even moderate myopia. A relatively high percentage of patients had increased BSCVA and increased contrast sensitivity. Satisfaction with the quality of vision was generally high. Residual refractive error has been successfully addressed with a bioptics approach involving secondary LASIK¹⁰⁹ or PRK.¹¹⁰

The main concerns with pIOL implantation relate to its safety. In addition to the rare catastrophic risks of intraocular surgery, such as endophthalmitis and hemorrhage (risks that are absent in LASIK and with contact lens or eyeglass correction), there are potential long-term risks with pIOLs. Chief among safety concerns are long-term endothelial cell loss and cataract formation. Although the FDA-approved pIOLs have acceptable rates of complications and loss of BSCVA through the 3- to 5-year duration of the trials, longer term problems cannot be ruled out. There is evidence that endothelial cell loss continues at a higher than normal rate even beyond 5 years for pIOLs located in the anterior chamber, potentially leading to corneal edema that requires keratoplasty. The rate of cataract formation may become higher as patients age.

Secondary glaucoma (pupillary block, pigment dispersion), iris atrophy (pupil ovalization), and traumatic dislocation are also concerns. Patients should be informed of these long-term risks before surgery and be advised to maintain regular follow-up after the surgery. Endothelial cell count and intraocular pressure should be measured regularly. Routine slit-lamp biomicroscopy should be performed to detect possible corneal edema, pigment dispersion, pupil ovalization, closure of peripheral iridotomy, lens dislocation, and cataract formation. Regular dilated fundus examinations are also needed to screen for retinal breaks and detachment in these highly myopic patients.

Despite the risks of pIOL implantation for high myopia, it remains an attractive method compared with alternative operative treatments. LASIK and PRK for high myopia are less predictable and stable than keratorefractive surgery for lower degrees of myopia. Both LASIK and PRK can induce higher order aberrations that decrease the quality of vision. Post-LASIK ectasia and post-PRK haze are also significant risks for high-diopter laser treatments. Another alternative is refractive lens exchange, which carries an increased risk of retinal detachment. The reasonable alternatives for each patient depend on the degree of myopia, corneal thickness, anatomy, and other individual factors. The surgeon must advise patients on the pros and cons of the various reasonable operative alternatives to eyeglass or contact lens wear, and help them to make the proper choice consistent with their visual goals and occupational needs.

The information in this assessment is current as of the date it was prepared, but we expect new data to become available rapidly in this area of active research on pIOLs. Furthermore, there may be new pIOLs under development

that were not yet in clinical trials and thus not included in this assessment. Interested readers are advised to update searches to remain current with developments in this field.

Future Research

Future research should be directed at prospective and retrospective studies of the long-term (≥ 10 years) efficacy and complications of pIOLs, imaging studies to evaluate the sizing and anatomic fit of pIOLs before surgery and assess the results after surgery, and randomized, controlled clinical trials on the merits of different lens models and types.

References

- American Academy of Ophthalmology. Excimer laser photorefractive keratectomy (PRK) for myopia and astigmatism. *Ophthalmology* 1999;106:422–37.
- Schallhorn SC, Farjo AA, Huang D, et al. Ophthalmic Technology Assessment Committee Refractive Management/Intervention Panel. Wavefront-guided LASIK for the correction of primary myopia and astigmatism: a report by the American Academy of Ophthalmology. *Ophthalmology* 2008;115:1249–61.
- Sugar A, Rapuano CJ, Culbertson WW, et al. Ophthalmic Technology Assessment Committee 2000–2001 Refractive Surgery Panel. Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. *Ophthalmology* 2002;109:175–87.
- Varley GA, Huang D, Rapuano CJ, et al. Ophthalmic Technology Assessment Committee Refractive Surgery Panel. LASIK for hyperopia, hyperopic astigmatism, and mixed astigmatism: a report by the American Academy of Ophthalmology. *Ophthalmology* 2004;111:1604–17.
- El Danasoury MA, El Maghraby A, Gamali TO. Comparison of iris-fixed Artisan lens implantation with excimer laser in situ keratomileusis in correcting myopia between -9.00 and -19.50 diopters: a randomized study. *Ophthalmology* 2002;109:955–64.
- Sanders DR. Matched population comparison of the Visian implantable collamer lens and standard LASIK for myopia of -3.00 to -7.88 diopters. *J Refract Surg* 2007;23:537–53.
- Schallhorn S, Tanzer D, Sanders DR, Sanders ML. Randomized prospective comparison of Visian toric implantable collamer lens and conventional photorefractive keratectomy for moderate to high myopic astigmatism. *J Refract Surg* 2007;23:853–67.
- Colin J, Robinet A, Cochener B. Retinal detachment after clear lens extraction for high myopia: seven-year follow-up. *Ophthalmology* 1999;106:2281–4; discussion 85.
- Chen LJ, Chang YJ, Kuo JC, et al. Metaanalysis of cataract development after phakic intraocular lens surgery. *J Cataract Refract Surg* 2008;34:1181–200.
- Fechner PU, Strobel J, Wichmann W. Correction of myopia by implantation of a concave Worst-iris claw lens into phakic eyes. *Refract Corneal Surg* 1991;7:286–98.
- Praeger DL, Momose A, Muroff LL. Thirty-six month follow-up of a contemporary phakic intraocular lens for the surgical correction of myopia. *Ann Ophthalmol* 1991;23:6–10.
- Javaloy J, Alio JL, Iradier MT, et al. Outcomes of ZB5M angle-supported anterior chamber phakic intraocular lenses at 12 years. *J Refract Surg* 2007;23:147–58.
- Allemann N, Chamon W, Tanaka HM, et al. Myopic angle-supported intraocular lenses: two-year follow-up. *Ophthalmology* 2000;107:1549–54.
- Perez-Santonja JJ, Alio JL, Jimenez-Alfaro I, Zato MA. Surgical correction of severe myopia with an angle-supported phakic intraocular lens. *J Cataract Refract Surg* 2000;26:1288–302.
- Leccisotti A, Fields SV. Clinical results of ZSAL-4 angle-supported phakic intraocular lenses in 190 myopic eyes. *J Cataract Refract Surg* 2005;31:318–23.
- Jimenez-Alfaro I, Garcia-Feijoo J, Perez-Santonja JJ, Cuina R. Ultrasound biomicroscopy of ZSAL-4 anterior chamber phakic intraocular lens for high myopia. *J Cataract Refract Surg* 2001;27:1567–73.
- Leccisotti A. Bioptics by angle-supported phakic lenses and photorefractive keratectomy. *Eur J Ophthalmol* 2005;15:1–7.
- Yu A, Wang Q, Xue A, et al. Comparison of contrast sensitivity after angle-supported, iris-fixated and posterior chamber phakic intraocular lens implantation for high myopia. *Ophthalmologica* 2008;222:53–7.
- Alio JL, Pinero D, Bernabeu G, et al. The Kelman Duet phakic intraocular lens: 1-year results. *J Refract Surg* 2007;23:868–79.
- Van Cleynenbreugel H. Late postoperative complications of backward implantation of a Vivarte phakic intraocular lens. *J Cataract Refract Surg* 2007;33:1474–6.
- Gierek-Ciaciura S, Gierek-Lapinska A, Ochalik K, Mrukwa-Kominek E. Correction of high myopia with different phakic anterior chamber intraocular lenses: ICARE angle-supported lens and Verisyse iris-claw lens. *Graefes Arch Clin Exp Ophthalmol* 2007;245:1–7.
- Oshika T, Nagata T, Ishii Y. Adhesion of lens capsule to intraocular lenses of polymethylmethacrylate, silicone, and acrylic foldable materials: an experimental study. *Br J Ophthalmol* 1998;82:549–53.
- Linnola RJ, Sund M, Ylonen R, Pihlajaniemi T. Adhesion of soluble fibronectin, laminin, and collagen type IV to intraocular lens materials. *J Cataract Refract Surg* 1999;25:1486–91.
- Alexander L, John M, Cobb L, et al. U.S. clinical investigation of the Artisan myopia lens for the correction of high myopia in phakic eyes: report of the results of phases 1 and 2, and interim phase 3. *Optometry* 2000;71:630–42.
- Bartels MC, Saxena R, van den Berg TJ, et al. The influence of incision-induced astigmatism and axial lens position on the correction of myopic astigmatism with the Artisan toric phakic intraocular lens. *Ophthalmology* 2006;113:1110–7.
- Dick HB, Alio J, Bianchetti M, et al. Toric phakic intraocular lens: European multicenter study. *Ophthalmology* 2003;110:150–62.
- Dick HB, Tehrani M, Aliyeva S. Contrast sensitivity after implantation of toric iris-claw lenses in phakic eyes. *J Cataract Refract Surg* 2004;30:2284–9.
- Tehrani M, Dick HB. Short-term follow-up after implantation of a foldable iris-fixated intraocular lens in phakic eyes. *Ophthalmology* 2005;112:2189–95.
- Jimenez-Alfaro I, Benitez del Castillo JM, Garcia-Feijoo J, et al. Safety of posterior chamber phakic intraocular lenses for the correction of high myopia: anterior segment changes after posterior chamber phakic intraocular lens implantation. *Ophthalmology* 2001;108:90–9.

30. Marinho A, Neves MC, Pinto MC, Vaz F. Posterior chamber silicone phakic intraocular lens. *J Refract Surg* 1997; 13:219–22.
31. Jongsareejit A. Clinical results with the Medennium phakic refractive lens for the correction of high myopia. *J Refract Surg* 2006;22:890–7.
32. Koivula A, Taube M, Zetterstrom C. Phakic refractive lens: two-year results. *J Refract Surg* 2008;24:507–15.
33. Verde CM, Teus MA, Arranz-Marquez E, Cazorla RG. Medennium posterior chamber phakic refractive lens to correct high myopia. *J Refract Surg* 2007;23:900–4.
34. Donoso R, Castillo P. Correction of high myopia with the PRL phakic intraocular lens. *J Cataract Refract Surg* 2006; 32:1296–300.
35. Jimenez-Alfaro I, Gomez-Telleria G, Bueno JL, Puy P. Contrast sensitivity after posterior chamber phakic intraocular lens implantation for high myopia. *J Refract Surg* 2001;17: 641–5.
36. Zaldivar R, Davidorf JM, Oscherow S. Posterior chamber phakic intraocular lens for myopia of –8 to –19 diopters. *J Refract Surg* 1998;14:294–305.
37. Chang JS, Meau AY. Visian collamer phakic intraocular lens in high myopic Asian eyes. *J Refract Surg* 2007;23:17–25.
38. American Academy of Ophthalmology Refractive Management/Intervention Panel. Preferred Practice Pattern. Refractive Errors and Refractive Surgery. San Francisco: American Academy of Ophthalmology; 2007:10. Available at: <http://one.aao.org/CE/PracticeGuidelines/PPP.aspx?p=1>. Accessed December 16, 2008.
39. American Academy of Ophthalmology. Policy Statement. Pretreatment assessment: responsibilities of the ophthalmologist. San Francisco: American Academy of Ophthalmology; 2006. Available at: http://one.aao.org/CE/PracticeGuidelines/ClinicalStatements_Content.aspx?cid=0b059383-f91a-4f23-9e16-09c05bcdff11b. Accessed December 16, 2008.
40. American Academy of Ophthalmology. Policy Statement. An ophthalmologist's duties concerning postoperative care. San Francisco: American Academy of Ophthalmology; 2006. Available at: http://one.aao.org/CE/PracticeGuidelines/ClinicalStatements_Content.aspx?cid=219fce14-3bee-499b-aeaa-b740c637e534. Accessed December 16, 2008.
41. Nourouzi H, Rajavi J, Okhovatpour MA. Time to resolution of corneal edema after long-term contact lens wear. *Am J Ophthalmol* 2006;142:671–3.
42. Saxena R, Boekhoorn SS, Mulder PG, et al. Long-term follow-up of endothelial cell change after Artisan phakic intraocular lens implantation. *Ophthalmology* 2008;115: 608–13.
43. Frisch IB, Rabsilber TM, Becker KA, et al. Comparison of anterior chamber depth measurements using Orbscan II and IOLMaster. *Eur J Ophthalmol* 2007;17:327–31.
44. Rabsilber TM, Becker KA, Frisch IB, Auffarth GU. Anterior chamber depth in relation to refractive status measured with the Orbscan II topography system. *J Cataract Refract Surg* 2003;29:2115–21.
45. Lavanya R, Teo L, Friedman DS, et al. Comparison of anterior chamber depth measurements using the IOLMaster, scanning peripheral anterior chamber depth analyser, and anterior segment optical coherence tomography. *Br J Ophthalmol* 2007;91:1023–6.
46. Dada T, Sihota R, Gadia R, et al. Comparison of anterior segment optical coherence tomography and ultrasound biomicroscopy for assessment of the anterior segment. *J Cataract Refract Surg* 2007;33:837–40.
47. Stulting RD, John ME, Maloney RK, et al. U.S. Verisyse Study Group. Three-year results of Artisan/Verisyse phakic intraocular lens implantation: results of the United States Food and Drug Administration clinical trial. *Ophthalmology* 2008;115:464–72.
48. Modis L Jr, Langenbucher A, Seitz B. Corneal endothelial cell density and pachymetry measured by contact and non-contact specular microscopy. *J Cataract Refract Surg* 2002; 28:1763–9.
49. de Sanctis U, Machetta F, Razzano L, et al. Corneal endothelium evaluation with 2 noncontact specular microscopes and their semiautomated methods of analysis. *Cornea* 2006; 25:501–6.
50. Kitzmann AS, Winter EJ, Nau CB, et al. Comparison of corneal endothelial cell images from a noncontact specular microscope and a scanning confocal microscope. *Cornea* 2005;24:980–4.
51. van der Heijde GL. Some optical aspects of implantation of an IOL in a myopic eye. *Eur J Implant Refract Surg* 1989; 1:245–8.
52. Benedetti S, Casamenti V, Benedetti M. Long-term endothelial changes in phakic eyes after Artisan intraocular lens implantation to correct myopia: five-year study. *J Cataract Refract Surg* 2007;33:784–90.
53. Tahzib NG, Eggink FA, Frederik PM, Nuijts RM. Recurrent intraocular inflammation after implantation of the Artiflex phakic intraocular lens for the correction of high myopia. *J Cataract Refract Surg* 2006;32:1388–91.
54. Budo C, Hessloehl JC, Izak M, et al. Multicenter study of the Artisan phakic intraocular lens. *J Cataract Refract Surg* 2000; 26:1163–71.
55. Lombardo AJ, Hardten DR, McCulloch AG, et al. Changes in contrast sensitivity after Artisan lens implantation for high myopia. *Ophthalmology* 2005;112:278–85.
56. Perez-Santonja JJ, Iradier MT, Benitez del Castillo JM, et al. Chronic subclinical inflammation in phakic eyes with intraocular lenses to correct myopia. *J Cataract Refract Surg* 1996;22:183–7.
57. Kohnen T. Searching for the perfect phakic intraocular lens. *J Cataract Refract Surg* 2000;26:1261–2.
58. Menezo JL, Peris-Martinez C, Cisneros AL, Martinez-Costa R. Phakic intraocular lenses to correct high myopia: Adatomed, Staar, and Artisan. *J Cataract Refract Surg* 2004; 30:33–44.
59. Aguilar-Valenzuela L, Lleo-Perez A, Alonso-Munoz L, et al. Intraocular pressure in myopic patients after Worst-Fechner anterior chamber phakic intraocular lens implantation. *J Refract Surg* 2003;19:131–6.
60. Fechner PU, Haubitz I, Wichmann W, Wulff K. Worst-Fechner biconcave minus power phakic iris-claw lens. *J Refract Surg* 1999;15:93–105.
61. Menezo JL, Avino JA, Cisneros A, et al. Iris claw phakic intraocular lens for high myopia. *J Refract Surg* 1997;13: 545–55.
62. Menezo JL, Cisneros A, Hueso JR, Harto M. Long-term results of surgical treatment of high myopia with Worst-Fechner intraocular lenses. *J Cataract Refract Surg* 1995;21: 93–8.
63. Perez-Santonja JJ, Bueno JL, Zato MA. Surgical correction of high myopia in phakic eyes with Worst-Fechner myopia intraocular lenses. *J Refract Surg* 1997;13:268–81; discussion 81–4.
64. Landesz M, Worst JG, Siertsema JV, van Rij G. Correction of high myopia with the Worst myopia claw intraocular lens. *J Refract Surg* 1995;11:16–25.
65. Landesz M, van Rij G, Luyten G. Iris-claw phakic intraocular lens for high myopia. *J Refract Surg* 2001;17:634–40.

66. Maloney RK, Nguyen LH, John ME. Artisan phakic intraocular lens for myopia: short-term results of a prospective, multicenter study. *Ophthalmology* 2002;109:1631–41.
67. Benedetti S, Casamenti V, Marcaccio L, et al. Correction of myopia of 7 to 24 diopters with the Artisan phakic intraocular lens: two-year follow-up. *J Refract Surg* 2005;21:116–26.
68. Landesz M, Worst JG, van Rij G. Long-term results of correction of high myopia with an iris claw phakic intraocular lens. *J Refract Surg* 2000;16:310–6.
69. Lifshitz T, Levy J, Aizenman I, et al. Artisan phakic intraocular lens for correcting high myopia. *Int Ophthalmol* 2004;25:233–8.
70. Senthil S, Reddy KP. A retrospective analysis of the first Indian experience on Artisan phakic intraocular lens. *Indian J Ophthalmol* 2006;54:251–5.
71. Silva RA, Jain A, Manche EE. Prospective long-term evaluation of the efficacy, safety, and stability of the phakic intraocular lens for high myopia. *Arch Ophthalmol* 2008;126:775–81.
72. Guell JL, Morral M, Gris O, et al. Five-year follow-up of 399 phakic Artisan-Verisyse implantation for myopia, hyperopia, and/or astigmatism. *Ophthalmology* 2008;115:1002–12.
73. Tahzib NG, Nuijts RM, Wu WY, Budo CJ. Long-term study of Artisan phakic intraocular lens implantation for the correction of moderate to high myopia: ten-year follow-up results. *Ophthalmology* 2007;114:1133–42.
74. Malecaze FJ, Hulin H, Bierer P, et al. A randomized paired eye comparison of two techniques for treating moderately high myopia: LASIK and Artisan phakic lens. *Ophthalmology* 2002;109:1622–30.
75. Tahzib NG, Bootsma SJ, Eggink FA, Nuijts RM. Functional outcome and patient satisfaction after Artisan phakic intraocular lens implantation for the correction of myopia. *Am J Ophthalmol* 2006;142:31–9.
76. Guell JL, Vazquez M, Gris O. Adjustable refractive surgery: 6-mm Artisan lens plus laser in situ keratomileusis for the correction of high myopia. *Ophthalmology* 2001;108:945–52.
77. Couillet J, Guell JL, Fournie P, et al. Iris-supported phakic lenses (rigid vs foldable version) for treating moderately high myopia: randomized paired eye comparison. *Am J Ophthalmol* 2006;142:909–16.
78. Guell JL, Morral M, Gris O, et al. Evaluation of Verisyse and Artiflex phakic intraocular lenses during accommodation using Visante optical coherence tomography. *J Cataract Refract Surg* 2007;33:1398–404.
79. Koss MJ, Cichocki M, Kohonen T. Posterior synechias following implantation of a foldable silicone iris-fixated phakic intraocular lens for the correction of myopia. *J Cataract Refract Surg* 2007;33:905–9.
80. Lackner B, Pieh S, Schmidinger G, et al. Long-term results of implantation of phakic posterior chamber intraocular lenses. *J Cataract Refract Surg* 2004;30:2269–76.
81. Pesando PM, Ghiringhello MP, Tagliavacche P. Posterior chamber collamer phakic intraocular lens for myopia and hyperopia. *J Refract Surg* 1999;15:415–23.
82. Sarikkola AU, Sen HN, Uusitalo RJ, Laatikainen L. Traumatic cataract and other adverse events with the implantable contact lens. *J Cataract Refract Surg* 2005;31:511–24.
83. Pineda-Fernandez A, Jaramillo J, Vargas J, et al. Phakic posterior chamber intraocular lens for high myopia. *J Cataract Refract Surg* 2004;30:2277–83.
84. Rosen E, Gore C. Staar Collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia. *J Cataract Refract Surg* 1998;24:596–606.
85. Menezes JL, Peris-Martinez C, Cisneros A, Martinez-Costa R. Posterior chamber phakic intraocular lenses to correct high myopia: a comparative study between Staar and Adatomed models. *J Refract Surg* 2001;17:32–42.
86. ICL in Treatment of Myopia (ITM) Study Group. United States Food and Drug Administration clinical trial of the implantable collamer lens (ICL) for moderate to high myopia: three-year follow-up. *Ophthalmology* 2004;111:1683–92.
87. Sanders D, Vukich JA. Comparison of implantable collamer lens (ICL) and laser-assisted in situ keratomileusis (LASIK) for low myopia. *Cornea* 2006;25:1139–46.
88. Sanders DR, Schneider D, Martin R, et al. Toric implantable collamer lens for moderate to high myopic astigmatism. *Ophthalmology* 2007;114:54–61.
89. Munoz G, Alio JL, Montes-Mico R, Belda JI. Angle-supported phakic intraocular lenses followed by laser-assisted in situ keratomileusis for the correction of high myopia. *Am J Ophthalmol* 2003;136:490–9.
90. Kodjikian L, Gain P, Donate D, et al. Malignant glaucoma induced by a phakic posterior chamber intraocular lens for myopia. *J Cataract Refract Surg* 2002;28:2217–21.
91. Sanchez-Galeana CA, Zadok D, Montes M, et al. Refractory intraocular pressure increase after phakic posterior chamber intraocular lens implantation. *Am J Ophthalmol* 2002;134:121–3.
92. Perez-Santonja JJ, Iradier MT, Sanz-Iglesias L, et al. Endothelial changes in phakic eyes with anterior chamber intraocular lenses to correct high myopia. *J Cataract Refract Surg* 1996;22:1017–22.
93. Munoz G, Montes-Mico R, Belda JI, Alio JL. Cataract after minor trauma in a young patient with an iris-fixated intraocular lens for high myopia. *Am J Ophthalmol* 2003;135:890–1.
94. Ruiz-Moreno JM, Alio JL, Perez-Santonja JJ, de la Hoz F. Retinal detachment in phakic eyes with anterior chamber intraocular lenses to correct severe myopia. *Am J Ophthalmol* 1999;127:270–5.
95. Martinez-Castillo V, Boixadera A, Verdugo A, et al. Rhegmatogenous retinal detachment in phakic eyes after posterior chamber phakic intraocular lens implantation for severe myopia. *Ophthalmology* 2005;112:580–5.
96. Arne JL. Phakic intraocular lens implantation versus clear lens extraction in highly myopic eyes of 30- to 50-year-old patients. *J Cataract Refract Surg* 2004;30:2092–6.
97. Perez-Santonja JJ, Ruiz-Moreno JM, de la Hoz F, et al. Endophthalmitis after phakic intraocular lens implantation to correct high myopia. *J Cataract Refract Surg* 1999;25:1295–8.
98. Baikoff G, Jodai HJ, Bourgeon G. Measurement of the internal diameter and depth of the anterior chamber: IOL-Master versus anterior chamber optical coherence tomographer. *J Cataract Refract Surg* 2005;31:1722–8.
99. Goldsmith JA, Li Y, Chalita MR, et al. Anterior chamber width measurement by high-speed optical coherence tomography. *Ophthalmology* 2005;112:238–44.
100. Lee JY, Kim JH, Kim HM, Song JS. Comparison of anterior chamber depth measurement between Orbscan IIz and ultrasound biomicroscopy. *J Refract Surg* 2007;23:487–91.
101. Baikoff G, Bourgeon G, Jodai HJ, et al. Pigment dispersion and Artisan phakic intraocular lenses: crystalline lens rise as a safety criterion. *J Cataract Refract Surg* 2005;31:674–80.
102. Baikoff G, Lutun E, Wei J, Ferraz C. Contact between 3 phakic intraocular lens models and the crystalline lens: an anterior chamber optical coherence tomography study. *J Cataract Refract Surg* 2004;30:2007–12.

103. Couillet J, Mahieu L, Malecaze F, et al. Severe endothelial cell loss following uneventful angle-supported phakic intraocular lens implantation for high myopia. *J Cataract Refract Surg* 2007;33:1477–81.
104. Alio JL, Abdelrahman AM, Javaloy J, et al. Angle-supported anterior chamber phakic intraocular lens explantation causes and outcome. *Ophthalmology* 2006;113:2213–20.
105. Baikoff G, Lutun E, Ferraz C, Wei J. Static and dynamic analysis of the anterior segment with optical coherence tomography. *J Cataract Refract Surg* 2004;30:1843–50.
106. Koretz JE, Strenk SA, Strenk LM, Semmlow JL. Scheimpflug and high-resolution magnetic resonance imaging of the anterior segment: a comparative study. *J Opt Soc Am A Opt Image Sci Vis* 2004;21:346–54.
107. Strenk SA, Semmlow JL, Strenk LM, et al. Age-related changes in human ciliary muscle and lens: a magnetic resonance imaging study. *Invest Ophthalmol Vis Sci* 1999;40:1162–9.
108. Strenk SA, Strenk LM, Guo S. Magnetic resonance imaging of aging, accommodating, phakic, and pseudophakic ciliary muscle diameters. *J Cataract Refract Surg* 2006;32:1792–8.
109. Zaldivar R, Davidorf JM, Oscherow S, et al. Combined posterior chamber phakic intraocular lens and laser in situ keratomileusis: bioptics for extreme myopia. *J Refract Surg* 1999;15:299–308.
110. Sanchez-Galeana CA, Smith RJ, Rodriguez X, et al. Laser in situ keratomileusis and photorefractive keratectomy for residual refractive error after phakic intraocular lens implantation. *J Refract Surg* 2001;17:299–304.

Footnotes and Financial Disclosures

Originally received: June 17, 2009.

Accepted: August 11, 2009.

Manuscript no. 2009-829.

Prepared by the Ophthalmic Technology Assessment Committee Refractive Management/Intervention Panel and approved by the American Academy of Ophthalmology's Board of Trustees February 21, 2009.

Financial Disclosure(s):

The authors have made the following disclosures:

David Huang – Consultant – Ophthalmic Systems, Optovue, Inc.; Lecture Fees/Equity Owner – Optovue, Inc.; Patents/Royalties – Carl Zeiss Meditec/Optovue, Inc.; Grant Support – Optovue, Inc./Vistakon Johnson & Johnson Visioncare, Inc.

Steven C. Schallhorn – Consultant/Advisor – Acufocus, Inc./Advanced Medical Optics

Alan Sugar – Consultant/Advisor – Lux Biosciences; Grant Support – Lux Biosciences/National Eye Institute.

Parag A. Majmudar – Consultant/Advisor – Advanced Medical Optics/

Inspire; Lecture Fees – Advanced Medical Optics/Alcon Laboratories, Inc./Allergan, Inc./Bausch & Lomb Surgical/Inspire.

William B. Trattler – Consultant/Advisor – Allergan Inc./Inspire Pharmaceuticals, Inc./Ista Pharmaceuticals, Inc./Sirion/Vistakon/Wavetec; Lecture Fees – Advanced Medical Optics/Allergan, Inc./Inspire Pharmaceuticals, Inc./Sirion; Equity Owner – AskLasikDocs.com; Grant Support – Advanced Medical Optics/Allergan, Inc./Glaukos Corporation/Inspire Pharmaceutical, Inc./Ista Pharmaceutical/Lenstec, Inc./QLT Phototherapeutics, Inc./Rapid Pathogen Screenings/Sirion/Vistakon/Wavetec.

Funded without commercial support by the American Academy of Ophthalmology.

Correspondence:

Ms. Nancy Collins, Guidelines and Assessment Manager, American Academy of Ophthalmology, The Eye MD Association, PO Box 7424, San Francisco, CA 94120-7424. E-mail: ncollins@aao.org.