Phakic intraocular lenses

Part 1: Historical overview, current models, selection criteria, and surgical techniques

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In this 2-part overview, the current status of phakic intraocular lens (pIOL) surgery to correct refractive errors is reviewed. Three types of pIOLs, categorized by their intraocular position, are included: angle-supported anterior chamber, iris-fixated anterior chamber, and posterior chamber (usually fixated in the ciliary sulcus). Part 1 reviews the main models of each pIOL type, the selection criteria, and the surgical techniques, with emphasis on currently available pIOLs. Bioptics, adjustable refractive surgery, and enhancements are addressed, and applications of the new anterior segment imaging techniques are reviewed.

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For the past 20 years, laser corneal refractive surgery has been used to correct a wide range of refractive errors and has proven to be effective and safe in most cases.[1] Various techniques have evolved, including photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK), laser-assisted subepithelial keratectomy, and epithelial laser in situ keratomileusis. Despite the use of highly optimized and customized laser treatments such as wavefront-guided, aspheric, and topography-guided ablations, the physical limitations of corneal thickness, curvature, and tissue remodeling limit the indications for a safe corneal refractive procedure.[2] Moreover, the optical quality of the outcomes may not be as good as desired, especially when treating high refractive errors that may require small optical zones, especially in patients with thin corneas and large mesopic pupil sizes.[3–5] In the case of hyperopic patients, although LASIK provides better predictability, less regression, and less corneal haze than PRK,[6] the choice of LASIK to correct hyperopia should be made cautiously as complications such as regression,[7] undercorrection,[7,8] epithelial ingrowth,[8] optical phenomena (eg, glare), and dry eye[9,10] are more common than with myopic ablations.

When keratorefractive surgery is not the appropriate approach in a determined patient, either phakic intraocular lens (pIOL) implantation or refractive lens exchange (RLE) with IOL implantation should be considered. Refractive lens exchange (or refractive lensectomy) with posterior chamber IOL implantation is safe and effective for the correction of moderate to severe myopia[11–17] and hyperopia,[18–24] especially in the presbyopic age group. One of the main concerns about RLE in highly myopic eyes is the increased risk for retinal detachment (RD), especially in younger patients (<50 years old) and in eyes with long axial lengths (>26 mm).[14] The incidence of RD after RLE ranges from 0% to 8%.[11,13,14,25–29] In the case of hyperopia, RD is not a concern and RLE can be performed in

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younger patients (45 to 55 years old). Because RLE causes loss of accommodation and neither multifocal IOLs nor accommodating IOLs can be considered universally valid, dynamic substitutes for the natural lens, RLE should be avoided when the natural lens is still functional.[30–34]

In the absence of contraindications, pIOL implantation is the best approach in young patients with moderate to high refractive errors and in those who have a contraindication to a corneal refractive procedure (eg, thin corneas).[35,36] The insertion of an IOL in a phakic eye should be simple, precise, and reproducible and should produce successful optical results.[37] Advantages are that pIOL implantation maintains accommodation[38] and is conceptually reversible.[39–41]

Phakic IOLs comprise 3 types that are reviewed in this article: angle-supported anterior chamber, iris-claw anterior chamber, and posterior chamber. Each design has its own features, selection criteria, surgical technique, results, and complications. Table 1 summarizes the main features of those that are U.S. Food and Drug Administration (FDA) approved or have CE marking.

ANGLE-SUPPORTED ANTERIOR CHAMBER pIOLs

Historical Overview

In 1953, Strampelli[42] implanted the first minus-power anterior chamber IOL in phakic eyes to correct myopia. In 1959, Barraquer[43] reported the results of 239 implantations. Although the first results were encouraging, many pIOLs had to be explanted owing to complications such as chronic loss of corneal endothelial cells, iris retraction and atrophy, peripheral anterior synechiae, subsequent pupil ovalization, and uveitis–glaucoma–hyphema syndrome.[44–46]

In the 1980s and the 1990s, technological progress in IOL manufacturing and surgical techniques was made. Several poly(methyl methacrylate) (PMMA) angle-supported anterior chamber pIOLs were developed, but all were subsequently phased out of the market because of unacceptable complication rates, including corneal endothelial cells loss, pupil ovalization, glare and halos, and chronic anterior uveitis. The most relevant designs included the ZB [47–49] and the ZB 5M (Domilens Corp.),[50–52] the NuVita MA 20 (Bausch & Lomb),[45,53–56] the ZSAL-4 (Morcher GmbH),[48,49,56] and the Safety Flex Phakic 6 H2 (Ophthalmic Innovations International).[57] The Vivarte/GBR (Ioltech) and the I-Care (Corneal Laboratories, Inc.) initially showed promising results, but they were withdrawn from the market in 2006 and 2008, respectively, because of safety concerns related to endothelial cell loss.[58] Lovisolo and Reinstein[59] provide a comprehensive review of these angle-supported anterior chamber pIOLs.

Current Models

Poly(methyl methacrylate) Angle-Supported Anterior Chamber pIOLs With the advent of foldable models, PMMA angle-supported pIOLs have been almost abandoned.

Foldable Angle-Supported Anterior Chamber pIOLs All the previously mentioned pIOLs require an incision that is at least the size of the optic (ie, 4.5 mm). Therefore, surgically induced astigmatism (SIA) may have an effect on the definitive refractive result and make visual recovery slower. To deal with the problem of SIA and in accord with the current tendency toward smaller incisions, foldable models of anterior chamber pIOLs have been developed. These pIOLs can be inserted through a 3.0 mm or smaller incision. Foldable IOLs and their haptics must be stiff enough to provide stability in the anterior chamber.

The Kelman Duet and the AcrySof IOLs have obtained the CE mark and are commercially available in Europe. The ThinPhAc and the Vision Membrane are in clinical trials in Europe and Russia.

Kelman Duet The Kelman Duet (Tekia, Inc.) consists of an independent Kelman tripod PMMA haptic with an overall diameter of 12.5, 13.0, or 13.5 mm and a 5.5 mm silicone optic with an ultraviolet (UV) absorber and a dioptric range of −8.0 to −20.0 D. The haptic is implanted first in the anterior chamber through an incision smaller than 2.5 mm; the optic is then inserted using an injector system; finally, the optic is fixated in the anterior chamber by the optic eyelets and haptic tabs using a Sinskey hook. If a calculation error in pIOL power or a refractive change occurs with time, the optic can be exchanged and assembled in the anterior chamber. If a haptic sizing error occurs, the haptics can be exchanged independently. The reported endothelial cell loss at 12 months is 5.43%,[60] but mid-term and long-term complication rates are not yet available.

AcrySof The AcrySof (Alcon, Inc.) is a single-piece, hydrophobic acrylic angle-supported pIOL manufactured as a 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 in 0.5 D increments (Figure 1, *A* and *C*). A multicenter study (United States, Canadian, and European arms) with a 1-year follow-up shows excellent results.[61]

ThinPhAc and Vision Membrane The microincision ThinPhAc (ThinOpt-X) and Vision Membrane (Vision Membrane Technology) are undergoing clinical trials and may be available in the future.[59]

Table 1. Phakic IOLs either FDA approved or with CE mark.

Type/Trademark	FDA/CE	Material	Power (D)	Optic Diameter (mm)	Overall Diameter (mm)
Angle-supported AC					
Kelman Duet	−/+	PMMA haptic, silicone optic	−8 to −20	5.5	12.5 to 13.5
Acrysof	−/+	Hydrophobic acrylic, 1 piece	−6 to −16.5	6	12.5 to 14.0
Iris-Claw AC					
Verisyse/Artisan	−/+	PMMA, 1 piece	Myopia −3 to −15.5 Myopia −16 to −23.5 Hyperopia +1 to + 12 Toric +12 to −23.5, torus +1 to +7	6	8.5
Veriflex/Artiflex	−/+	PMMA haptics, polysiloxane optic	Myopia −2 to −14.5 Toric −1 to −13.5, torus −1 to −5	6	8.5
Posterior chamber					
ICL	+/+	Collamer	Myopia −3 to −23.0 Torus +1 to +6 Hyperopia +3 to +22	4.65 to 5.5* 5.5	11.5 to 13.0 11.0 to 12.5
PRL	−/+	Silicone	Myopia −3 to −20 Hyperopia +3 to +15	4.5 to 5.5* 4.5	10.8 and 11.3 10.6

AC = anterior chamber
*Depending on dioptric power

Selection Criteria

Preoperative Examination The preoperative workup for pIOL implantation is the same as the workup for any kind of refractive procedure and should include manifest refraction, cycloplegic refraction, Snellen uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), pupillometry, applanation tonometry, ultrasound anterior chamber depth (ACD) measurement, corneal topography, pachymetry, central endothelial cell count (ECC), and a fundus examination. New evaluation techniques are discussed later.

Inclusion and Exclusion Criteria Figure 2 summarizes inclusion and exclusion criteria specific to pIOL implantation. All the criteria except ACD apply to all pIOLs; ACD depends on the pIOL type. Figure 3 summarizes ACD requirements.

Surgical Technique

Intraocular Lens Power Calculation and Diameter Selection Van der Heijde[62] and Fechner et al.[63] proposed the theoretical basis of the power calculation for refractive phakic iris-claw IOLs. These principles are transferable to angle-supported IOLs. To calculate IOL power, the patient's refraction, keratometric dioptric power at the corneal apex, and adjusted ultrasound central ACD are used. Based on this formula, the manufacturers provide nomograms or software to calculate the required pIOL power.

The pIOL's overall diameter depends on the ACD and should provide perfect stability, with no unnecessary compression forces on the angle that could damage the angle structures or induce pupil ovalization. Before the development of anterior segment imaging techniques such as anterior segment optical coherence tomography (AS OCT), ultrasound biomicroscopy (UBM), and Scheimpflug imaging, it was not possible to determine the internal diameter of the anterior chamber, the angle-to-angle distance. This evaluation was approximate and was based on a white-to-white (WTW) measurement. The WTW distance can be measured manually (using the Holladay-Godwin gauge or a measuring caliper) or by automated technology (IOLMaster [Carl Zeiss Meditec], and Orbscan II topography system [Bausch & Lomb]). Automated measurement of the WTW distance provides more precise results than manual methods.[64] The diameter of angle-supported pIOLs is oversized 0.5 mm to 1.0 mm from the WTW measurement. Currently, with the advent of AS OCT and UBM, the angle-to-angle distance and anterior chamber angle can be measured precisely.[38] More information is included in the last section of this article.

Implantation of Foldable Angle-Supported pIOLs

Since PMMA angle-supported pIOLs are no longer available, the focus will be on surgical techniques used with currently available pIOLs.

Kelman Duet The Kelman Duet pIOL is not actually foldable but consists of 2 components, the optic and the haptic. These are sequentially inserted through a small incision and assembled in the anterior chamber. Two 1.0 mm clear cornea incisions are created at

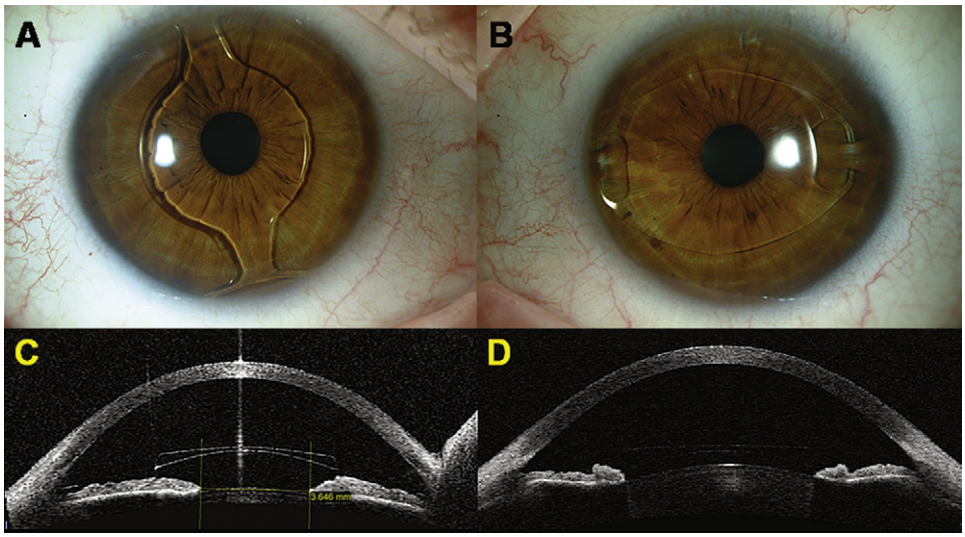

Figure 1. Clinical photographs and AS OCT images of AcrySof (*A* and *C*) and Verisyse (*B* and *D*) pIOLs 4 years after implantation.

3 o'clock and 9 o'clock and facilitate the manipulation of the components. The haptic is inserted first with forceps through one of the incisions and repositioned in the angle. The optic is then injected into the anterior chamber through a 3.0 mm incision. Two diametrically opposed tabs on the optic are fastened to corresponding "clips" on the haptic.[65]

AcrySof As with most foldable IOLs, implantation of the AcrySof pIOL can be performed under topical anesthesia. Some surgeons recommend preoperative instillation of pilocarpine 1.0%, whereas others prefer intracameral injection of acetylcholine intraoperatively. After an intracameral injection of OVD, the pIOL is introduced with a Monarch II or III IOL delivery system (Alcon, Inc.) and a B or P cartridge through a 3.2 mm or 2.6 mm incision usually centered on the 10:30 to 12:00 position. Placement of the haptic footplates can be confirmed by intraoperative gonioscopic examination. No peripheral iridotomy is required. Although the incision is usually water-tight, incisions larger than 3.0 mm can be sutured with a single 10-0 nylon, which can be removed 1 or 2 weeks postoperatively (Figure 4; Video 1, available at http://jcrsjournal.org).

Inclusion Criteria	Exclusion Criteria
• Age >21 years • Stable refraction at least 1 year • Ammetropia not correctable with excimer laser surgery • Unsatisfactory vision with/intolerance of contact lenses or spectacles • Irido-corneal angle ≥ 30º • cECC >2300 cells/mm^2: (>2500 cells/mm^2 if >21 years old, >2000 if >40 years old) • No anomaly of iris or pupil function • Mesopic pupil size <5.0–6.0 mm	• Background of active disease in the anterior segment • Recurrent or chronic uveitis • Any form of clinically significant cataract • Previous corneal or intraocular surgery (to be evaluated) • IOP >21 mm Hg or glaucoma • Preexisting macular degeneration or macular pathology • Abnormal retinal condition • Systemic diseases (eg, autoimmune disorder, connective tissue disease, atopia, diabetes mellitus)

Figure 2. Generally recommended inclusion and exclusion criteria for pIOL implantation.

ACD Requirements (Measured from Endothelium)
• AcrySof phakic: >2.7 mm
• Artisan-Verisyse/Artiflex-Veriflex: ≥2.7 mm
• ICL: ≥2.8 mm for myopia, ≥3.0 mm for hyperopia
• PRL: ≥2.5 mm

Figure 3. Anterior chamber depth requirements for pIOL implantation.

IRIS-FIXATED ANTERIOR CHAMBER pIOLs

Historical Overview

The iris-claw IOL was initially used in aphakic eyes after intracapsular cataract extraction. Starting in 1953, the first-generation models, such as the Binkhorst[66,67] and the Medallion IOLs,[68] were associated with cystoid macular edema, corneal decompensation, lens dislocation, uveitis, and glaucoma.[59]

In 1978, Worst designed the iris-claw or "lobster-claw" IOL, a coplanar single-piece PMMA IOL that was enclavated in a fold of midperipheral iris stroma, a relatively immobile portion of the iris. Many surgeons have used the iris-claw IOL after intracapsular cataract extraction or as secondary implantation in aphakia.[59,69–71] In 1986, Fechner and Worst implanted the IOL in the first sighted myopic phakic eye.[71] Follow-up showed good predictability but a progressive corneal endothelial cell loss of around 7%.[72–74] The currently available iris-claw model is basically the original IOL with few changes.

Current Models

Poly(methyl methacrylate) Iris-Claw Anterior Chamber pIOL The iris-claw Artisan (Ophtec BV)/Verisyse (Abbott Medical Optics, Inc.) is a single-piece nonfoldable IOL made of Perspex CQ-UV, a UV light–filtering PMMA material. It is available for the correction of myopia, hyperopia, and astigmatism, as well as for aphakia (Figure 1, *B* and *E*).

The optic vaults approximately 0.87 mm anterior to the iris, providing good clearance from both the anterior lens capsule and the corneal endothelium. The distance from the optic edge to the endothelium ranges from 1.5 to 2.0 mm depending on the dioptric power, anterior chamber anatomy, and optic diameter.

Two models to correct myopia are currently available: Model 206 has a 5.0 mm optic with power ranging from −3.0 to −23.5 D in 0.5 D increments. Model 204 has a 6.0 mm optic and is consequently limited to a smaller range of powers because of its greater proximity to the endothelium in the periphery of the IOL; the power ranges from −3.0 to −15.5 D in 0.5 D increments. For the correction of hyperopia, model 203 incorporates a 5.0 mm optic with power ranging from +1.0 to + 12.0 D in 0.5 D increments. Myopic pIOLs have thicker peripheral edges and therefore require more clearance than hyperopic pIOLs. The thickest part of the hyperopic IOL is central, where the ACD is greater. The toric model has a 5.0 mm optic and is available in powers ranging from +12.0 to −23.5 D in 0.5 D increments, with additional cylinder from +1.0 to +7.0 D in 0.5 D increments and oriented at 0 degree or at 90 degrees. Several long-term prospective studies of these IOLs, which will be reviewed in part 2, [35,75–93] have shown good predictability and safety.

The phakic Artisan/Verisyse has a fixed overall length of 8.5 mm (7.5 mm for pediatric implantations or small eyes), which is a great advantage to the surgeon who does not wish to deal with sizing measurements. Another major advantage of these pIOLs is that they can be properly centered over the pupil, even when the pupil is off center, a relatively common situation among people with high ametropia. Off-center pupils cannot be used as a reference for centration of symmetrical IOLs such as angle-supported and sulcus-fixated IOLs.[94] Moreover, the fixation system inhibits IOL movement,[95] which warrants the correction of astigmatism and may help to correct other vectorial or asymmetrical aberrations in the future (Figure 5, *B* and *C*).

Foldable Iris-Claw Anterior Chamber pIOL The foldable model of the iris-claw lens is the Artiflex (Ophtec BV).[38,96] It is a hydrophobic polysiloxane foldable design with a 6.0 mm optic and power ranging from –2.0 to –14.5 D in 0.5 D steps. The toric model of the Artiflex is also available in Europe (Figure 5, *A* and *D*).[97]

Selection Criteria

Selection criteria are shown in Figures 2 and 3.

Surgical Technique

Intraocular Lens Power Calculation The most commonly used method to calculate pIOL power is the van der Heijde[62] and Fechner et al.[63] formulas, which include the patient's refraction, keratometry, and adjusted

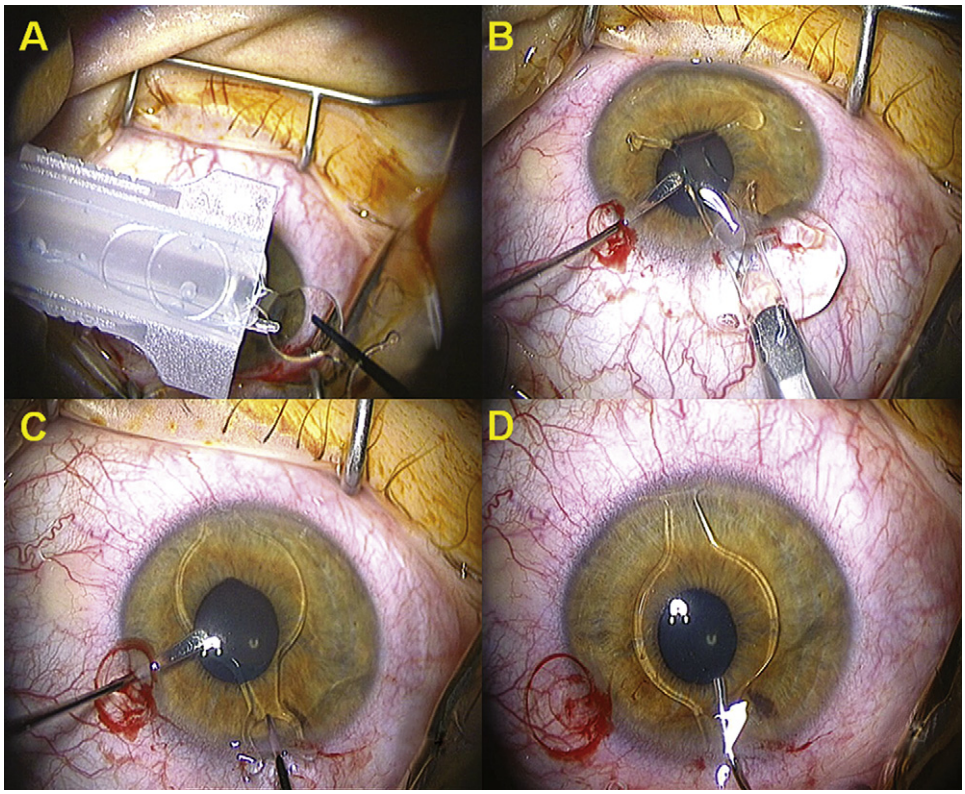

Figure 4. *A* and *B*: After intracameral injection of OVD, the pIOL is introduced with a delivery system through a 2.75 mm incision usually centered at 10:30 o'clock. *C* and *D*: The haptic footplates are placed in the anterior chamber angle using a blunt spatula.

ultrasound central ACD. The measurements are independent of the axial length. Moreover, the position in the anterior chamber defines the distance between the pIOL and the retina. Based on this formula, the manufacturers provide nomograms or software to calculate the required power.

The one-size-fits-all overall diameter of 8.5 mm prevents complications due to sizing errors that may occur with angle-supported or sulcus-supported pIOLs.

Poly(methyl methacrylate) Iris-Claw pIOL Depending on the surgeon's familarity with the technique, general, retrobulbar, peribulbar, or topical anesthesia can be used. For the Verisyse pIOL implantation procedure, retrobulbar or peribulbar anesthesia is generally recommended. According to our recommended technique, a 2-plane, 5.2 mm or 6.2 mm posterior corneal incision is centered at 12 o'clock and 2 vertical paracenteses directed toward the enclavation area are performed at 2 o'clock and 10 o'clock. Alternatively, a scleral incision can be used. Wound construction is important to minimize induced astigmatism or wound leaks. Some surgeons locate the incision on the steep corneal meridian.

The pupil should be constricted to protect the crystalline lens from contact with the pIOL or the instruments during surgery. This can be achieved by instilling pilocarpine 1.0% preoperatively or injecting acetylcholine (Myochol) in the anterior chamber at the beginning of the procedure. Taking advantage of the capability to locate this type of pIOL over the center of the pupil, the center should be marked preoperatively if using pilocarpine 1.0% or at the beginning of surgery if using intracameral acetylcholine to enable proper centration of the pIOL. After the anterior chamber is filled with a cohesive OVD, the IOL is introduced and rotated 90 degrees into a horizontal position. The pIOL is fixated with an enclavation needle that has a bent shaft and a bent tip that pushes the iris into both claws. The needle is introduced through one paracentesis and holds the fold of iris while the pIOL is slightly depressed with the implantation forceps so the claws will automatically grasp the iris. Hands are then switched, and the same maneuver is performed through the other paracentesis. Both fixation of the iris claws and proper centration of the pIOL over the pupil should be checked before the next step, which is one of the main advantages of this pIOL style. At the end of surgery, it is not unusual to have mild ovalization of the pupil due to the effect of the miotic agent. If the pIOL is not well centered, enclavation can be released by pushing in the central portion of the claw with the enclavation needle.

A peripheral iridectomy should be performed to prevent pupillary block. Alternatively, a neodymium:YAG

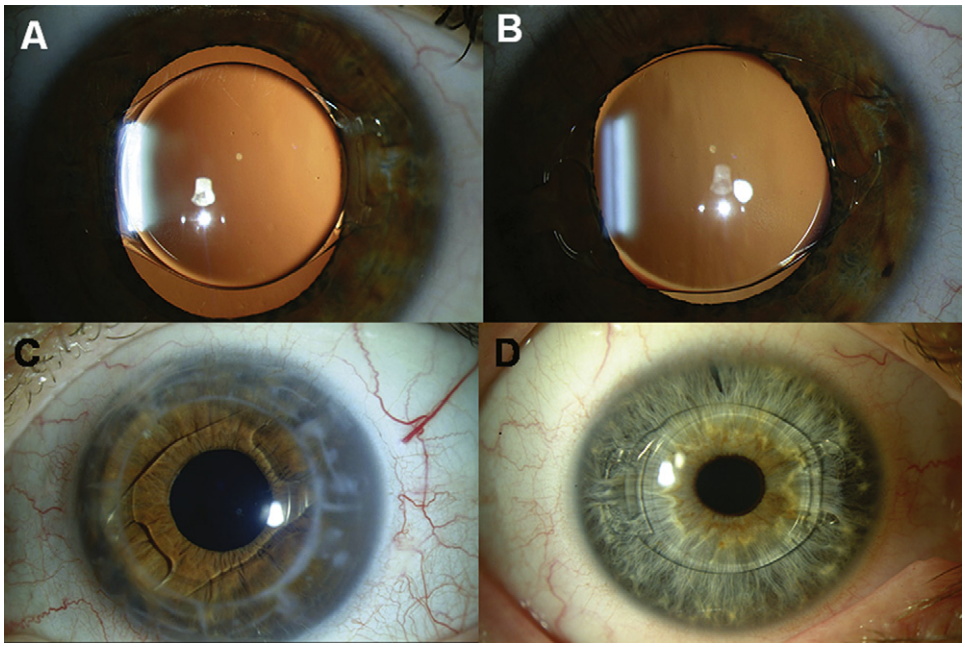

Figure 5. *A*: Pharmacological mydriasis after Veriflex pIOL implantation. *B*: Pharmacological mydriasis after Verisyse pIOL implantation. In both cases, exploration of the retina can be easily performed. *C*: Verisyse toric pIOL implantation to correct residual myopic astigmatism after penetrating keratoplasty. *D*: Veriflex pIOL 2 years after implantation. Notice the superior slit iridotomy. No pupil ovalization is seen.

(Nd:YAG) laser can be used preoperatively to create 1 or 2 small iridotomies 90 degrees apart. The corneal wound is then sutured with 5 interrupted 10-0 nylon sutures and the scleral incison with 1 running (cross or mattress) suture. Proper tension of the sutures is checked with a standard qualitative Maloney keratoscope. Beginning at week 4 and over a period of 3 months, sutures are selectively removed, depending on the patient's refractive and topographic astigmatism. Some other surgical approaches have been published and may be reviewed on basis of the reference section (Video 2, available at http://jcrsjournal.org).

Toric Verisyse implantation requires careful preoperative marking of the implantation axis. Marking should be performed at the slitlamp or the argon laser to avoid implantation errors due to cyclotorsion and/or positional changes induced by the retrobulbar or peribulbar anesthetic injection. Two models of toric Verisyse are available—one with torus at 0 degree and the other with torus at 90 degrees. Therefore, implantation is always performed close to the horizontal or vertical axis, depending on the individual surgeon's preference (Figure 6).

Foldable Iris-Claw pIOL Implantation of the foldable model requires a 3.1 mm incision, which corresponds to the width of the PMMA haptics. The Artiflex pIOL is inserted using a specially designed spatula. The enclavation process is the same as for the PMMA pIOL except that the pIOL is grasped with the implantation forceps at the base of the haptic instead of at the edge of the optic. The incision is usually watertight, but a 10-0 nylon suture may be preferred by some surgeons (Figure 7; Video 3, available at http://jcrsjournal.org).

POSTERIOR CHAMBER pIOLs

Historical Overview

Complications that have arose from anterior chamber angle-supported pIOLs led to movement toward the posterior chamber. This location theoretically induces a lower incidence of halos and glare as the margins of the pupil cover the border of the optical zones. The risk for corneal endothelial damage is also theoretically minimized because of the greater distance between the IOL and the corneal endothelium. However, a higher rate of cataract formation and pigment dispersion remains as a clear disadvantage of posterior chamber pIOLs.

One of the first posterior chamber pIOL designs, the "collar-button" or "mushroom" configuration, is attributed to Fyodorov in 1986.[98] He developed a single-piece silicone pIOL with a 3.2 mm optic and a concave anterior surface that projected anteriorly through the pupil. The pIOL was fixated behind the iris plane by 2 haptics and had a total length of 8.0 mm. Initial complications included corneal touch, decentration, pupillary block glaucoma, iridocyclitis, and cataract formation.[59]

Since the Fyodorov pIOL, evolution in design and materials has led to the emergence of several models. The Adatomed pIOL (Chiron Ophthalmics, Inc.) was a 5.5 mm optic ellastomer model with an overall length up to 12.5 mm and dioptric power up to −25.0 D. However, cortical opacities and decentration frequently occurred after surgery and use of this pIOL declined.[9–107]

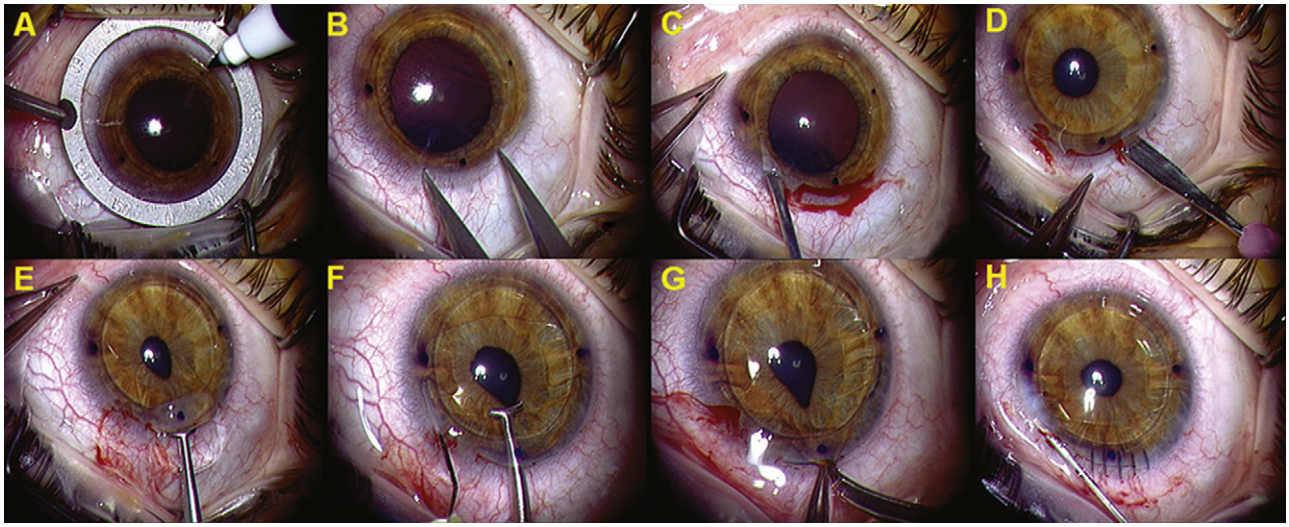

Figure 6. Toric Verisyse pIOL implantation. *A*: Preoperative marking of the axis of implantation. *B*: Surgical caliper measuring 5.2 mm incision. *C*: Two vertical paracenteses directed toward the site of enclavation are performed. *D*: A 2-plane 5.2 mm posterior corneal incision is centered 90 degrees from the axis of implantation. *E*: Pupil constriction is achieved by injecting acetylcholine into the anterior chamber. The anterior chamber is filled with a cohesive OVD, and the IOL is introduced using a special forceps and rotated 90 degrees into a horizontal position. *F*: Enclavation process. The enclavation needle is introduced through one of the paracenteses and holds the fold of iris; the claws automatically grasp the iris. *G*: A peripheral iridectomy using scissors is performed to prevent pupil block. *H*: The wound is then sutured with 5 interrupted 10-0 nylon sutures.

Currently, 2 posterior chamber pIOLs are available, the Implantable Collamer Lens (ICL) (Staar Surgical Co.) and the Phakic Refractive Lens (PRL) (Carl Zeiss Meditec).

Current Models

Implantable Collamer Lens The ICL is currently the most widely used posterior chamber pIOL. It incorporates material with increased biocompatibility known as Collamer (0.2% collagen and 60% hydroxylethyl methacrylate copolymer). This material attracts deposition of a monolayer of fibronectin on the IOL surface that inhibits aqueous protein binding and makes the IOL invisible to the immune system.[59,108]

The ICL's design and materials were refined through a series of prototypes in different clinical trials. For models V (Version) 2 and V3, the reported complications were small percentages of pupillary block and pigmentary dispersion glaucoma.[109,110] However, late anterior subcapsular opacities of the crystalline lens occurred in 5% to 30% of cases after 1 to 3 years of follow-up (9.2% of the FDA V3 study)[105,111] and are attributed to intermittent contact between the ICL and the crystalline lens.[112]

The current model, the Visian ICL V4, is a rectangular single-piece IOL, 7.5 to 8.0 mm wide, available in 4 overall lengths: 11.5 to 13.0 mm in 0.5 mm steps for myopic correction and 11.0 to 12.5 mm in 0.5 mm steps for hyperopic correction. The optic diameter ranges from 4.65 to 5.5 mm in myopic ICLs, depending on the dioptric power. It is always 5.5 mm in hyperopic ICLs. The available power ranges from −3.0 to −23.0 D for myopic IOLs, from +3.0 to +22.0 D for hyperopic ICLs, and with an added positive cylinder of +1.0 to +6.0 D for toric ICLs correcting myopia (Figure 8, *B*).[113] The ICL can be inserted through a 3.0 mm incision using a microinjector. It has orientation markings on its haptics, allowing control during the unfolding maneuver. The thickness is less than 50 µm in the optic zone, 500 to 600 µm in the haptic zone, and 100 µm in the haptic footplates, which are theoretically positioned in the cilliary sulcus using a spatula specially designed for the ICL (Figure 9).[114]

The basic design change of the ICL V4 addresses the vaulting. This model has an additional 0.13 to 0.21 mm anterior vault due to the steeper radius of curvature of the base curve, which depends on the dioptric power. The higher vault provides a greater space between the posterior surface of the ICL and the anterior surface of the crystalline lens,[111] which allows fluid change of nutrients and prevents contact between the ICL and the crystalline lens.[115]

Numerous studies have shown that ICL pIOLs are predictable, stable, and safe for the correction of refractive errors.[36,100,101,116–123] However, the risk for cataractogenesis, pigment dispersion, and glaucoma should not be overlooked.[124,125] An endothelial loss of 12.3% at 4 years has been reported,[126] although other authors report no endothelial cell loss.[127] Longer follow-up studies will clarify this question.

Phakic Refractive Lens The PRL for the correction of myopia and hyperopia is made of ultrathin, highly

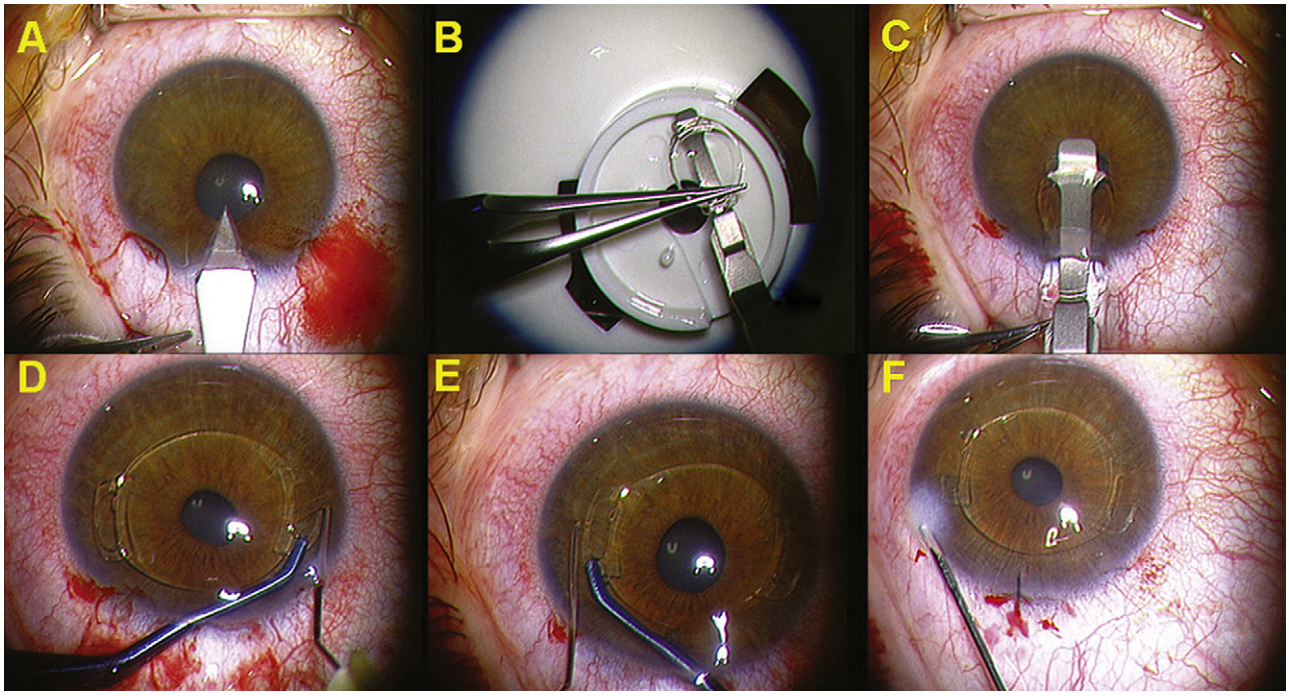

Figure 7. Implantation of the Artiflex/Veriflex pIOL *A*: A 3.1 mm incision is required. *B* and *C*: The Artiflex IOL is inserted using a specially designed spatula. *D*: The enclavation needle is introduced through one of the paracenteses and holds the fold of iris while the IOL is grasped with the implantation forceps at the base of the haptic. *E*: The surgeon's hands are switched, and the same maneuver is repeated to enclavate the other claw. *F*: The incision is sutured with a 10-0 nylon suture.

purified, optically clear silicone and has a concave posterior base curve with a 10.0 mm radius that mimics the anterior curvature of the crystalline lens. The central thickness is less than 0.5 mm and is constant in myopic PRLs but varies in hyperopic PRLs. Edge thickness is less than 0.2 mm and is constant in hyperopic PRLs and varies in myopic ones.

Two models of myopic PRLs are available: The PRL 100 has an overall diameter of 10.8 mm and the PRL 101, an overall diameter of 11.3 mm. The diameter of the optic is 4.5 to 5.5 mm, depending on the PRL power, which ranges from −3.0 to −20.0 D (maximum correction at the spectacle plane of −28.0 D). The hyperopic PRL (PRL 200) has an overall diameter of 10.6 mm, a 4.5 mm optic, and power ranging from +3.0 to +15.0 D.

This foldable pIOL can be inserted through a 3.2 mm incision and theoretically floats on a layer of aqueous humor inside the posterior chamber, exerting no pressure on the ciliary structures and having no contact with the anterior capsule of the crystalline lens.[128] Because this type of pIOL lacks fixation, stability of centration and rotation are concerns. Thus, this pIOL is unsuitable for the correction of astigmatism. Ultrasound biomicroscopy studies document that the PRL is located on the zonules in most cases and that contact between the PRL and the crystalline lens occurs in some cases.[129,130] Moreover, reports of PRL dislocation into the vitreous cavity have raised doubts about the safety of these IOLs.[131]

Selection Criteria

Selection criteria are shown in Figures 2 and 3. For the PRL, the manufacturer suggests an ECC of at least 2000 cells/mm^2 and a central ACD of at least 2.5 mm. For the ICL, an ACD, measured from the endothelium to the anterior surface of the crystalline lens, of at least 2.8 mm for myopia and at least 3.0 mm for hyperopia is required.

Surgical Technique

Intraocular Lens Power Calculation and Diameter Selection For calculating pIOL power, most users employ the formula proposed by Olsen et al.,[132,133] which uses the patient's refraction at the 12.0 mm spectacle plane or the vertex refraction, the corneal keratometric dioptric power at its apex, and adjusted ultrasound central ACD, also known as the effective lens position.[59]

The ICL overall diameter depends on the ciliary sulcus diameter and should provide perfect stability with no excess of compression forces to the sulcus and allow correct vaulting. Excessive vaulting (>750 μm) due to an ICL that is too long may cause angle-closure, pupillary block glaucoma, or pigmentary dispersion glaucoma. Insufficient vaulting (<250 μm) due to an ICL

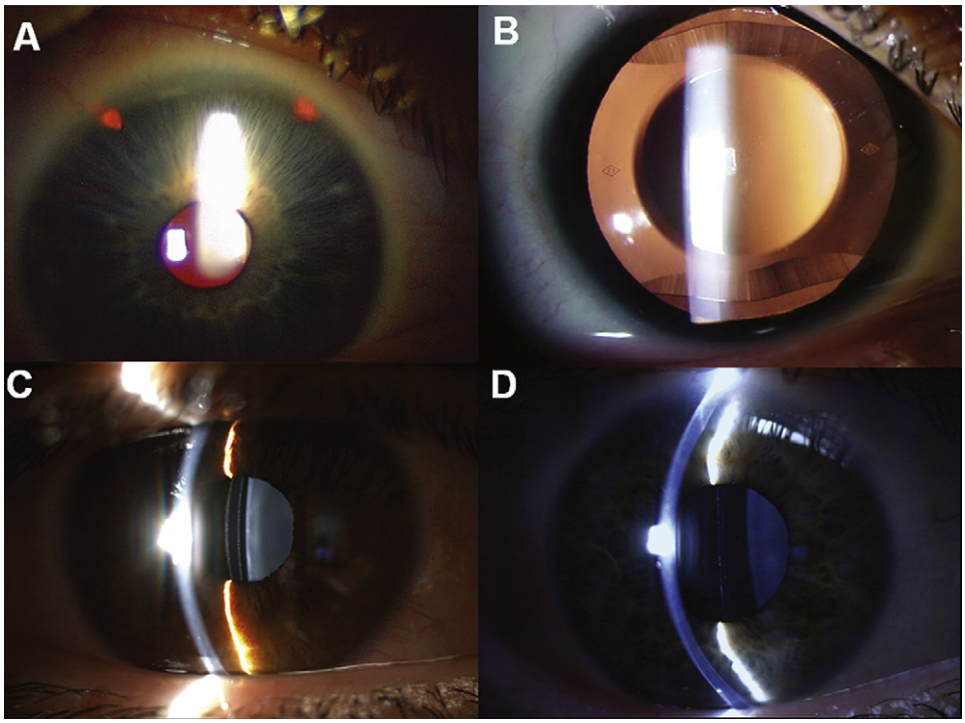

Figure 8. *A*: Clinical photograph of ICL pIOL. Notice the 2 superior Nd:YAG laser iridotomies 90 degrees apart to prevent pupillary block. *B*: The toric ICL has 2 orientation marks that must fit the selected axis of implantation. *C*: Slightly insufficient vaulting (<250 µm) probably due to an ICL that is too short. *D*: Excessive vaulting (>750 µm) due to an ICL that is too long. Both ICLs were selected according to the WTW distance plus 0.5 mm rule. Sizing errors highlight the need for more accurate measurements of the sulcus diameter.

that is too short increases the risk for cataractogenesis due to the contact between the posterior surface of the ICL and the anterior surface of the crystalline lens (Figure 8, *C* and *D*).[36,59,100,110,111,115,120] Before the development of UBM, no system that allowed determination of the internal diameter of the ciliary sulcus existed. This evaluation was approximated and depended on a WTW measurement. The ICL's diameter is oversized 0.5 to 1.0 mm from the WTW measurement in myopic eyes and the same length or oversized 0.5 mm in hyperopic eyes. However, recent studies demonstrate that there is no anatomical correspondence between external measurements and internal dimensions.[40,114,134,135] Therefore, WTW distance alone may not predict angle or sulcus size, causing some of the problems experienced with anterior chamber angle-supported or posterior chamber pIOLs. New imaging techniques are discussed later in this article.

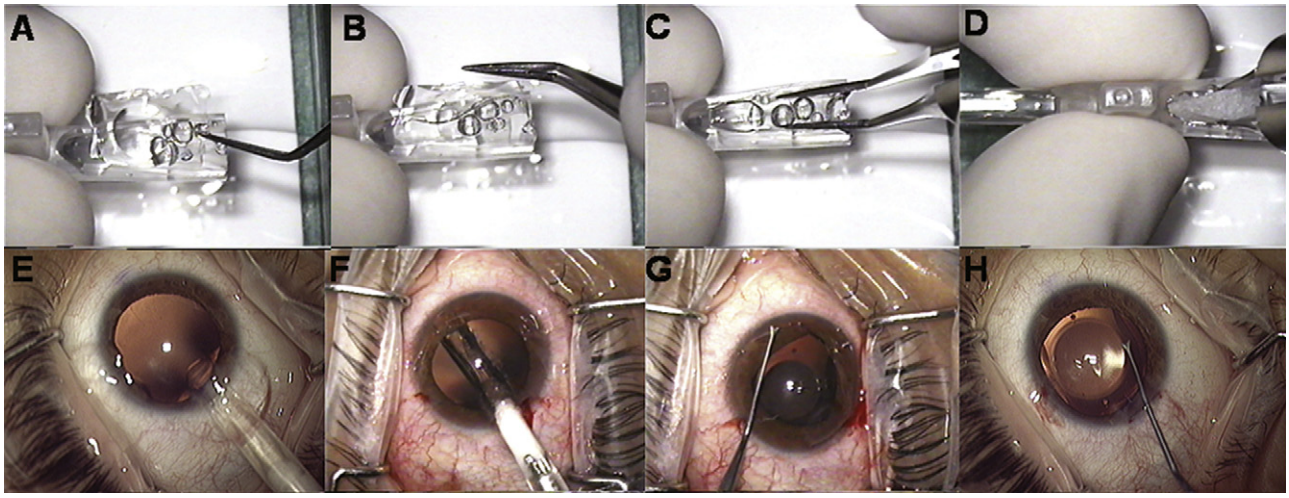

Figure 9. Loading the ICL in the cartridge. *A*: Using a modified McPherson forceps, the ICL is checked under the operating microscope. The 2 tiny holes on the footplates must be oriented distal right and proximal left. *B* and *C*: The ICL is loaded with the dome up. *D*: A piece of soft material, the Staar Foam-tip, is positioned to protect the ICL from contact with the plunger of the shooter. *E*: Broad pharmacological mydriasis is essential for implantation. The anterior chamber is filled with a cohesive OVD and the cartridge inserted bevel down. *F*: The ICL is carefully injected. *G* and *H*: The haptics are gently pushed under the iris with a blunt spatula. (Courtesy of Dani Elies, MD, IMO, Barcelona, Spain.)

Implantable Collamer Lens Correct loading of the ICL in the cartridge and the injector is essential for correct and easy implantation. Using a modified McPherson forceps with long, blunt, curved tips, the ICL is grasped and checked under the operating microscope. The ICL has 2 tiny holes on the footplates (distal right and proximal left) that allow correct anterior–posterior orientation. The cartridge is filled with OVD. The ICL is loaded with dome up, being especially careful of the haptic positions to avoid rupturing them. A piece of soft material, the Staar foam tip, is positioned to protect the ICL from contact with the plunger of the shooter. Some surgeons also recommend inserting the tip of a wet surgical microsponge between the foam tip and the ICL to further protect the optic and haptics.

Broad pharmacological mydriasis is essential for uneventful implantation. The ICL can be inserted through a sub-3.0 mm incision. One side-port incision of about 1.0 mm and 90 degrees from the main incision is created. Some surgeons prefer 2 paracenteses to enable easier implantation of the haptics in the ciliary sulcus. The anterior chamber is filled with a cohesive low-viscous OVD to protect the corneal endothelium and crystalline lens from surgical trauma. The cartridge is inserted bevel down, and the ICL is carefully injected. It is essential to control IOL unfolding to twist the bevel right or left to ensure correct orientation of the lens. Finally, the haptics are gently pushed under the iris with a blunt spatula. While centration of the ICL and position of the haptics in the ciliary sulcus are checked, acetylcholine is injected into the anterior chamber to induce pupil constriction. Complete extraction of the OVD, as in any intraocular surgery, is mandatory to prevent postoperative ocular hypertension. A peripheral iridectomy should be performed with scissors or using a vitrectome to prevent pupillary block (Figure 9).[123] Alternatively, 2 Nd:YAG laser iridotomies, located 90 degrees apart superiorly, are performed in the peripheral iris 1 week preoperatively (Figure 8, *A*). Finally, the wound is hydrated (Video 4, available at http://jcrsjournal.org).

Phakic Refractive Lens The implantation procedure for the PRL is almost the same as for the ICL. Two opposed paracentesis ports are created on either side of a 3.2 mm clear corneal incision. The PRL is inserted with a specially designed forceps (Dementiev implantation forceps) or with an injector system. Once the PRL unfolds slowly in the anterior chamber, its haptics initially lie anterior to the dilated iris. Each haptic corner is gently placed behind the iris through the pupil with a long spatula or an intraocular hook. When proper horizontal lens orientation is verified, a miotic agent is injected. As spontaneus rotation of the PRL can easily occur, 2 peripheral iridotomies, 90 degrees apart, are mandatory to prevent pupillary block (Video 5, available at http://jcrsjournal.org).

BIOPTICS, ADJUSTABLE REFRACTIVE SURGERY, AND ENHANCEMENTS

The main goal of any refractive surgery is to achieve maximum UDVA by correcting the refractive error as close to emmetropia as possible. Zaldivar et al.[136–138] introduced the term *bioptics* to describe the combination of LASIK following pIOL implantation in patients with a spherical equivalent of more than −18.0 D, patients with high levels of astigmatism (≥ −2.0 D), and patients for whom lens power availability was a problem.

Similarly, to improve the quality of vision and diminish glare, halos, and other common complaints under dim illumination in highly myopic patients (greater than −15.0 D), Güell et al.[86,139,140] developed adjustable refractive surgery (ARS), which combines implantation of a 6.0 mm optic Verisyse pIOL and a 6.5 mm optical zone LASIK procedure. The ARS proved to be predictable and safe in 26 patients, with all achieving ±1.0 D of emmetropia and 21 eyes (80.70%) achieving ±0.5 D of emmetropia.

Several other investigators have used this combined approach, which allows fine-tuning of the refractive results, especially in patients with high refractive errors and/or astigmatism.[141–144]

ANTERIOR SEGMENT IMAGING AND pIOLs

Until the recent development of new anterior segment imaging techniques, monitoring the anatomic relationship of pIOLs with anterior chamber structures was primarily done at the slitlamp. This limited accuracy of the measurement of distances between the pIOL and the corneal endothelium or the anterior capsule of the crystalline lens, as well as the internal diameters of the anterior chamber or the sulcus. In addition, the dynamic relations during accommodation or pupil light reflex were difficult to assess.

Ultrasound biomicroscopy, AS OCT, and Scheimpflug photography have been used to provide measurements and verify the intraocular position of pIOLs within the anterior chamber.[145] Table 2 summarizes the main features of each anterior segment imaging technique.

Measuring Angle-to–Angle Distance

The overall diameter of angle-supported pIOLs should be selected according to the anterior chamber diameter. A main source of complications with anterior chamber angle-supported pIOLs is an IOL sizing error. A pIOL that is too short will be unstable and may move freely in the anterior chamber, thus

contacting the corneal endothelium. A pIOL that is too long will have a high vault that will approximate the optic of the pIOL to the endothelium, increasing the risk for corneal decompensation. Additionaly, it may excessively compress the angle, thereby damaging angle structures and provoking pupil ovalization.

Before the development of anterior imaging techniques, anterior chamber diameter evaluation depended on WTW measurement. The WTW distance can be measured manually (using the Holladay-Godwin gauge or a measuring caliper) or by automated technology (Zeiss IOLMaster and Orbscan II topography system). Automated measurement of the WTW distance provides more precise results than manual measurements.[64] An angle-supported pIOL diameter is oversized 0.5 to 1.0 mm with WTW measurement. However, WTW distance does not always correspond to anterior chamber diameter.[146–149] The internal horizontal diameter of the anterior chamber is usually larger than the horizontal corneal diameter determined by automated WTW measurements.[146]

Currently, with the advent of AS OCT, the anterior chamber angle can be precisely measured. Ultrasound biomicroscopy may also be useful, but it requires image reconstruction to allow angle-to-angle measurement. In addition, it requires immersion of the eye in a water-bath solution, which can lead to slight anterior segment distortion through external compression. Use of miotic eyedrops or stimulation of the fellow eye is required to perform dynamic studies of accommodation. Studying the anterior segment under these conditions is often a long, uncomfortable process.[38,150] Although Scheimpflug imaging allows fast noncontact acquisition of data, it requires clear optical media; iris tissue is imprecisely depicted because light scattering and anterior chamber angle structures cannot be properly captured.[38,95]

Anterior Segment Optical Coherence Tomography: Anterior Chamber Biometry and Accommodation Studies Anterior segment OCT (Visante OCT, Carl Zeiss Meditec Inc.) is a noncontact high-resolution cross-sectional imaging technique that uses low coherence interferometry to provide in vivo cross-sectional images of ocular structures with a spatial resolution of 10 µm to 20 µm. Using a 1310 nm infrared wavelength allows increased penetration in scattering tissues, such as the sclera and iris, while simultaneously permitting sufficient illumination power to be used to enable high-speed imaging (up to 4000 axial scans per second).[151] The Visante OCT is designed to image the shape, size, and position of the structures of the anterior segment and make precise measurements of the distances between them, including corneal thickness and surface profile, anterior segment biometry (ACD, angle-to-angle distance, angle size in degrees), pupil diameter, and thickness and radii of curvature of the crystalline lens. It has also proved useful in determining pIOL position and relation to the crystalline lens (Figure 10).[147,152–154] The equipment has a target that can be defocused with positive or negative lenses. By focusing and defocusing the target with positive or negative lenses, it is possible to relax or stimulate the patient's accommodation in a natural way. Thus, both static and dynamic (accommodation-induced changes) analysis can be performed.[147,152–154]

Table 2. Main features of new anterior segment imaging techniques.

Feature	Imaging Technique		
	AS OCT	UBM	Scheimpflug
Image source	Optical	Ultrasound	Optical
Axial resolution (µm)	18	25 (50 MHz)	N/A
Contact	—	Immersion fluid	—
Operator skills	+	++++	++
Accommodation studies	+	+*	+*
Topography	—	—	+
Pachymetry	+	+	+
Angle visualization	+	+	—
ATA distance masurement	+ Direct	+ Image reconstruction	—
Ciliary sulcus visualization	—	+	—
Opaque media	+	+	—

+ = yes; — = no; AS OCT = anterior segment optical coherence tomography; ATA = angle-to-angle distance; N/A = not applicable; UBM: ultrasound biomicroscopy; N/A: not applicable
*Accommodation studies performed using myotic agents or contralateral eye stimulation

Biometric modifications of the anterior segment with accommodation and age using anterior chamber OCT have been performed by Baikoff et al.[155] and confirm the Helmholtz theory of accommodation. Moreover, accommodation studies of pIOL implantation have also been performed.[38] With every diopter of accommodation, the anterior pole of the crystalline lens moves 30 µm forward.[156] This could affect the relationship between intraocular structures and the pIOL; ie, a decrease in the distance between the posterior surface of the ICL and the anterior surface of the crystalline lens has been documented. Even intermittent contact between the ICL and the crystalline lens may exist, which may be the cause of cataract formation.[95,152,157] With iris-claw pIOLs, the distance between the pIOL and the crystalline lens remains stable during accommodation,[38] although one report

observed a decrease in the space between the posterior surface of an iris-claw pIOL and the natural crystalline lens during accommodation in a patient with 5.0 D of hyperopia.[152]

Morphologic changes of the crystalline lens with aging may also affect its relationship with pIOLs.[155] Baikoff et al.'s[155,157] observations of aging showed that along with thickening of the crystalline lens, there is forward movement of the crystalline lens' anterior pole, even when the eye is at rest. This is accompanied by a reduction in ACD. Considering that the crystalline lens thickens with age, with 18 to 20 µm of forward movement of the anterior pole each year, the distance that remains between the CLR and a 600 µm theoretical safety level allows calculation of how long a pIOL can theoretically remain safely in the eye.[153,154]

The distance between the anterior pIOL surface and the corneal endothelium is also modified during the accommodation process. A decrease in the pIOL–endothelium distance is reported in some studies.[38,95,152,154,155] This is specially important with anterior chamber angle-supported and iris-claw pIOLs as it may be a factor in endothelial cell loss with age and underscores the importance of monitoring the ECC in these patients throughout their lifetime.[35,38]

Rotating Scheimpflug Imaging: Pentacam Scheimpflug The Pentacam Scheimpflug is a noncontact optical system that was specifically designed to image the anterior segment of the eye. It has a rotating Scheimpflug camera that takes up to 50 slit images of the anterior segment in less than 2 seconds. Software is then used to construct a 3-dimensional (3-D) image. It calculates data for corneal topography (anterior and posterior surface), corneal thickness, and corneal

Figure 10. The Visante OCT is capable of making precise measurements of anterior chamber structures, including corneal thickness, ACD, angle-to-angle distance, and angle size in degrees. It can also determine the pIOL's location and relationship to the corneal endothelium and crystalline lens.

wavefront, ACD, lens opacification, and lens thickness.[95,145,158] The ACD is an important parameter to consider before pIOL implantation.

A new version, the Pentacam RH, has recently become available. In addition to a higher resolution camera, it has pIOL software that simulates the position of the proposed lens.[145] However, this device has certain limitations for evaluating pIOLs as it cannot capture the anterior chamber angle structures or the sulcus.[38]

Measuring Sulcus-to-Sulcus Distance

As with angle-supported pIOLs and anterior chamber diameter, posterior chamber sulcus-supported pIOLs' overall length should be selected according to sulcus-to-sulcus distance. Sizing error is the main source of complications after ICL implantation, increasing the risk for angle-closure and pigmentary dispersion glaucoma if the ICL is too long or the risk for cataract if the ICL is too short.

Before the development of UBM, no system allowed determination of the internal diameter of the ciliary sulcus. This evaluation was approximated and depended on WTW measurement. The ICL's diameter is oversized 0.5 to 1.0 mm from the WTW measurement in myopic eyes, and same-length or oversized 0.5 mm in hyperopic eyes. However, recent studies demonstrate no anatomical correspondence between external measurements and internal dimensons.[40,114,134,135,159,160] The posterior chamber appears to have a vertically oval shape, and the WTW technique is thus inaccurate in predicting the horizontal diameter of the ciliary sulcus because sulcus-to-sulcus distance is generally smaller than the anterior chamber diameter.[135,160] In the ICL FDA study, which adopted the WTW measurement protocol, the replacement rate due to symptomatic over-undersizing issues was 1.5%.[111] Moreover, ICL length determined by the UBM method achieved significantly a more ideal ICL vault than with the conventional WTW method. The UBM method is superior to the conventional method in terms of predicting sulcus-to-sulcus horizontal diameter for ICL length determination.[161]

High-Resolution Ultrasound Biomicroscopy: Artemis and Paradigm P60 Images of ciliary sulcus can only be obtained with high-resolution ultrasound devices that use very-high-frequency waves in the 50 MHz range. Ophthalmic ultrasound imaging is based on the emission of an acoustic pulse and reception of the pulse after it has been reflected by ocular tissues.[145]

The Paradigm P60 (Paradigm Medical Industries, Inc.) offers flexibility in its clinical use by incorporating 4 different probes with different frequencies of 12.5, 20.0, 35.0, and 50.0 MHz. The best image quality and resolution is obtained by the 50.0 MHz probe, but

the scan field is limited to a 5 × 5 mm square.[145] Therefore, angle and sulcus dimensions cannot be measured in one scan sweep.[59] Ultrasound biomicroscopy provides high-resolution images with an axial resolution of about 25 μm and transverse resolution of about 50 μm. In contrast to optical systems, UBM is able to scan through opaque media. However, image acquisition requires the eye to be immersed in a fluid with an eyecup, which is uncomfortable for both patient and examiner and may potentially distort the eye anatomy and angle configuration.[162–165]

The Artemis 2 system (Ultralink L.L.C.) uses a 50 MHz transducer that is swept in an arc matching the curvature of the anterior of the eye. In addition, the Artemis uses a more sophisticated system for data acquisition, storing the actual echo data (from which images are formed) instead of the image itself. An optical system for eye fixation and alignment allows direct visualization to confirm the exact position where measurements are taken. Then a computer-controlled scan along multiple clock hours permits a 3-D biometric mapping of the eye.[61,166]

CONCLUSIONS

In conclusion, depending on the site of implantation, there are 3 types of pIOLs: angle-supported anterior chamber; iris-fixated anterior chamber; and posterior chamber, which are usually fixated in the ciliary sulcus. The implantation of pIOLs has been demonstrated to be an effective, safe, predictable, and stable procedure to correct moderate and high refractive errors. Complications are rare and are primarily related to the site of implantation. However, longer follow-up studies are needed to establish the long-term safety of these pIOLs.

The development of new anterior segment imaging devices is changing preoperative and postoperative management of pIOLs, increasing safety profiles, and allowing more accurate follow-up. Moreover, exact measurements of ACD and ciliary sulcus diameter are improving the pIOLs selection and thus decreasing the risk for unwanted complications. The potential clinical applications and the range of information they may yield are being continuously explored and further developed. These issues, which are addressed in part 2, will finally improve safety and anatomical and functional outcomes of pIOLs.

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