Five-Year Follow-up of 399 Phakic Artisan–Verisyse Implantation for Myopia, Hyperopia, and/or Astigmatism

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Purpose: To report long-term results of Artisan–Verisyse phakic intraocular lenses (PIOLs) to correct myopia, hyperopia, and/or astigmatism and the percentage of additional keratorefractive surgery to eliminate residual refractive errors.

Design: Retrospective, nonrandomized, interventional case series.

Participants: From January 1996 to January 2003, 399 Artisan–Verisyse PIOLs were consecutively implanted. To correct myopia, 101 5-mm optic Verisyse PIOLs (group 1) and 173 6-mm optic Verisyse PIOLs (group 2) were implanted. Forty-one were PIOLs for hyperopia (group 3), and 84 were toric (group 4).

Methods: Manifest refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), biomicroscopy, tonometry, funduscopy, and central endothelial cell count (ECC) were determined before surgery, at 3 months, and at yearly intervals up to 5 years.

Main Outcome Measures: Refraction, UCVA, BSCVA, efficacy and safety indexes, enhancements' rate with keratorefractive surgery, central ECC, and complications.

Results: Mean follow-up was 4.05 years. Mean preoperative spherical equivalent (SE) and that at last follow-up were, respectively, −19.8±3.23 and −0.5 ± 0.89 diopters (D) (group 1), −11.27±3.11 and −0.64±0.8 D (group 2), +4.92±1.7 and +0.02±0.51 D (group 3), and −6.82±8.69 and −0.09±0.64 D (group 4). Group 4 had a mean preoperative cylinder of −3.24±1.02 D, which decreased to −0.83±0.74 D postoperatively. Additional keratorefractive surgery was performed in 60.39% of eyes (group 1), 19.6% (group 2), 41.4% (group 3), and 5.95% (group 4). Mean preoperative central ECC and that at last follow-up were, respectively, 2836±398 and 2514±529 cells/mm^2 (group 1), 2755±362 and 2454±588 cells/mm^2 (group 2), 2735±355 and 2560±335 cells/mm^2 (group 3), and 2632±543 and 2537±615 cells/mm^2 (group 4). Main complications were 3 explantations due to an unacceptable drop in ECC, 3 lenses' repositioning (2 ocular trauma and 1 unappropriate iris capture), 3 lenses' exchange due to refractive errors, 1 macular hemorrhage, 1 retinal detachment, and 2 cataracts.

Conclusions: According to our experience, implantation of iris-claw PIOLs is a reversible, effective, stable, safe procedure in the first 5 years of follow-up. *Ophthalmology 2008;115:1002–1012 © 2008 by the American Academy of Ophthalmology.*

In recent years, the range of indications for LASIK, the most common refractive surgery procedure, has been narrowed. We are now aware of the long-term complications of LASIK in patients with high refractive errors.[1] Despite the latest approaches utilizing wavefront technology, patient selection is narrowed when we consider what we have learned of the cornea's biomechanical limits and LASIK's impact on optical performance.[2] A considerable number of patients who would have had LASIK 10 years ago are now being excluded from this procedure because of these concerns about quality of vision and safety. Moreover, it should be borne in mind that one of the main characteristics of laser corneal surgery is its irreversibility.

In presbyopic patients with high refractive errors, clear lens extraction is considered. However, this option is not apropriate for younger patients who can still accommodate. Moreover, all patients should be aware of the increased risk of retinal detachment (RD), which is higher in young myopic patients.[3–5]

The third option is to implant a phakic intraocular lens (PIOL). Compared to laser corneal surgery or crystalline lens exchange surgery, correcting moderate and high ammetropias with PIOLs not only allows maintenance of accommodation, but also offers a better quality of vision, some reversibility of the procedure, and easy management of postoperative residual error.[6–11]

Phakic intraocular lenses can be divided into 3 groups: angle-supported anterior chamber (AC) lenses, iris-fixated AC lenses, and posterior chamber (PC) lenses. Angle-supported PIOLs are most often used, probably because they are technically easier to insert. Although the design of these lenses has improved, they still cause a significant number of potentially serious complications, including chronic loss of endothelial cells, iris retraction, and subsequent pupil ovalization.[12,13] Peripheral pressure has been reduced to decrease the incidence of pupil ovalization. However, this leads to a higher incidence of rotation, which may result in chronic angle irritation and instability of toric correction. The latest prototypes seem to offer much better results, though they are still being evaluated.

Posterior chamber PIOLs fit in the space between the iris and the crystalline lens. There are different models available, and although their results in some case series have been outstanding, their implantation may be associated with serious complications, including anterior subcapsular cataracts, pigment dispersion, and secondary glaucoma.[14,15]

Finally, the iris-claw Artisan (Ophtec B.V., Groningen, Netherlands)–Verisyse (AMO, Santa Ana, CA) IOLs are available for the correction of myopia, hyperopia, and astigmatism, as well as for aphakia. Several long-term prospective studies of these lenses have shown good predictability and safety.[16–21] The phakic Artisan–Verisyse is a convex–concave nonfoldable polymethyl methacrylate (PMMA) AC iris-fixated lens. The 2 models for myopia have differing optic diameters but the same overall length of 8.5 mm. Model 206 has a 5.0-mm optic with power ranging from −3 to −23.5 diopters (D) in 0.5-D increments. Model 204 has a larger 6.0-mm optic and is consequently limited to a smaller range of powers because of its proximity to the endothelium: −3 to −15.5 D in 0.5-D increments. The optic vaults approximately 0.87 mm anterior to the iris, allowing for exceptional 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 mm depending on the dioptric power, AC anatomy, and diameter of the optic. For the correction of hyperopia, the model 203 incorporates a 5-mm optic with an overall length of 8.5 mm and is available in dioptric powers ranging from +1 to +12 D

in 0.5-D increments. The toric model has a 5-mm optical zone and is available in powers ranging from +12 to −23.5 D in 0.5-D increments, with additional cylinder from 1.0 to 7.0 D, also in 0.5-D increments. It has also proved to be a safe and predictable method for the correction of high astigmatism, including postkeratoplasty astigmatism.[22–24] For the last 2 years, we have been part of a multicenter group working with a foldable model, the Artiflex (Ophtec),[25,26] currently at a finished multicenter phase III trial and already in the European market. It is a hydrophobic polysiloxane foldable design with a 6.0-mm optic and powers ranging from −2 to −14.5 D in 0.5-D steps. The results of the work with these lenses are not included in this article.

Here, we report the refractive results, efficacy and safety, incidence of enhancements with corneal refractive surgery to adjust residual refractive errors, and complications that have arisen over a 5-year follow-up period of 399 consecutive iris-claw PIOLs. To our knowledge, apart from an article by Tahzib et al[20] this is the longest follow-up reported on this kind of PIOL to date.

Subjects and Methods

Subjects

We retrospectively included 399 eyes that were consecutively implanted with iris-claw PIOLs to correct myopia, hyperopia, and/or astigmatism between January 1996 and January 2003. All patients were fully informed of the details and possible risks of the specific procedure, as well as of alternative refractive techniques and their respective benefits and risks. Written informed consent to perform the surgical procedure was obtained from all patients before surgery in accordance with the Declaration of Helsinki, and the study was approved by the ethics committee of our institution, Instituto de Microcirugia Ocular, and the Autonoma University of Barcelona. All the eyes were operated by the same surgeon (JLG).

For our study purposes, we divided the 399 eyes into 4 groups: (1) model 204, 5-mm optic for myopia (n = 101); (2) model 206, 6-mm optic for myopia (n = 173); (3) model 203, 5-mm optic for hyperopia (n = 41); and (4) toric model (n = 84).

Preoperative Examination

The patients underwent a complete preoperative ophthalmologic examination, including refraction; Snellen's uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA); applanation tonometry; ultrasound AC depth (ACD) measurement using Compuscan LT (Storz, St. Louis, MO); corneal topography using Orbscan (Bausch and Lomb, Rochester, NY); pachymetry using a DGH 500 Pachymeter (DGH Technology, Inc., Exton, PA); central endothelial cell count (ECC) using the

Table 1. Number (Percentage) of Eyes Examined at Each Follow-up Visit

	Group 1 (n = 101)		Group 2 (n = 173)		Group 3 (n = 41)		Group 4 (n = 84)	
	Expected	*Examined*	*Expected*	*Examined*	*Expected*	*Examined*	*Expected*	*Examined*
3 mos	101	101 (100)	173	173 (100)	41	41 (100)	84	84 (100)
1 yr	101	95 (94)	173	169 (97.7)	41	39 (95.1)	84	84 (100)
2 yrs	97	80 (82.5)	170	136 (80)	40	35 (87.5)	84	84 (100)
3 yrs	95	68 (71.6)	168	150 (94.9)	39	34 (87.2)	69	67 (97.1)
4 yrs	93	93 (100)	168	155 (92.3)	39	34 (87.2)	10	10 (100)
5 yrs	89	88 (98.9)	166	165 (99.4)	33	28 (84.8)	0	0 (100)

Table 2. Population Data and Baseline Characteristics

	Group 1	Group 2	Group 3	Group 4
Mean age (yrs)	34.43±5.73	32.39±4.23	32.64±3.67	36.29±7.20
No. of eyes/patients	101/61	173/89	41/23	84/42
Gender (male/female)	34/27	40/49	9/14	23/19
Eye (right/left)	43/58	92/81	18/23	42/42
Mean follow-up (yrs)	4.43±0.54	4.27±0.24	3.99±0.63	2.91±0.47
Mean preoperative SE (D)	−19.8±3.23	−11.27±3.11	+4.92±1.7	−6.82±8.69
Mean preoperative cylinder (D)	−1.71±0.11	−1.43±0.2	−1.15±1.07	−3.24±1.02
Mean preoperative BSCVA	20/50±20/150	20/30±20/90	20/35±20/90	20/30±20/100
Mean preoperative central ECC (cells/mm^2)	2836±398	2755±362	2735±355	2632±543

BSCVA = best spectacle-corrected visual acuity; D = diopters; ECC = endotelial cell count; SE = spherical equivalent.

specular microscope Noncon Robo-Ca (Konan Medical Inc., Fair Lawn, NJ); and a fundus examination.

Exclusion Criteria

Exclusion criteria were central ACD smaller than 3.2 mm, measured from the corneal epithelium to the anterior surface of the crystalline lens; central ECC < 2300 cells/mm^2; abnormal iris or abnormal pupil function; fixed pupil size > 4.5 mm; patients with a background of active disease in the anterior segment, recurrent or chronic uveitis, or any form of cataract; previous corneal or intraocular surgery; intraocular pressure > 21 mmHg; glaucoma; preexisting macular degeneration or macular pathology; abnormal retinal condition; and/or systemic diseases (e.g., autoimmune disorder, connective tissue disease, atopia, diabetes mellitus).

Lens Power Calculation

Lens power was calculated using Van der Heijde's formula,[27] which includes the patient's refraction, keratometry, and adjusted ultrasound central ACD.

Surgical Procedure

The surgical procedure (Videos 1–4 [available at http://aaojournal.org]) has been described by Güell et al.[9,28] In some cases, additional corneal refractive surgery (ACRS) such as LASIK, photorefractive keratectomy (PRK), conductive keratoplasty, or arcuate keratotomy (AK) was scheduled to adjust residual refractive errors. The largest possible optical zone in both the intraocular lens and stromal ablation was used to diminish glare, halos, and other common complaints under dim illumination.

Postoperative Follow-up

Postoperative follow-up visits were held 24 hours (n = 399), 3 months (n = 399), 1 year (n = 387), 2 years (n = 335), 3 years (n = 319), 4 years (n = 292), and 5 years (n = 281) after surgery. At each follow-up visit, manifest refraction, UCVA, BSCVA, slit-lamp examination, and applanation tonometry were determined or performed. The central ECC and fundus examination were performed only at yearly intervals.

Statistical Analysis

Excel (Microsoft, Redmond, WA) was used for data collection and to perform descriptive statistics. Continuous variables were described as means ± standard deviations (SDs).

Comparison of preoperative and postoperative data was performed by a paired *t* test (SPSS for Windows, SPSS Inc., Chicago, IL). A paired *t* test was performed at 3 months and at the last

follow-up visit for SE and cylinder and at 4 years for central ECC, except in group 4, where it was performed at 3 years. $P<0.05$ was considered statistically significant.

The percentage of eyes with UCVA>20/20 and UCVA>20/40 and the percentage of eyes within ±1 D and ±0.5 D of emmetropia at each milestone of follow-up were also recorded.

The efficacy index is defined as the ratio between mean postoperative UCVA and mean preoperative BSCVA. The safety index is defined as the ratio between mean postoperative BSCVA and mean preoperative BSCVA. Efficacy and safety indexes were calculated for each postoperative interval.

Results

A total of 399 eyes were consecutively implanted with the Artisan–Verisyse PIOLs to correct myopia, hyperopia, and/or astigmatism between January 1996 and January 2003. All eyes were available for examination at 3 months, and 281 eyes (70.1%) were available for the 5-year follow-up visit. The mean follow-up period was 4.05 years (range, 0.25–5). Table 1 shows the number of patients of each group that attended follow-up visits. The last follow-up visit for group 4 was at 3 years postoperatively. Some of the patients who did not attend some of the visits came the following year. Table 2 shows baseline characteristics of each group.

Visual Acuity, Efficacy Index, and Safety Index

Figures 1 and 2 summarize the percentage of eyes with preoperative BSCVA and postoperative BSCVA and UCVA ≥ 20/40 and ≥ 20/20 for each group.
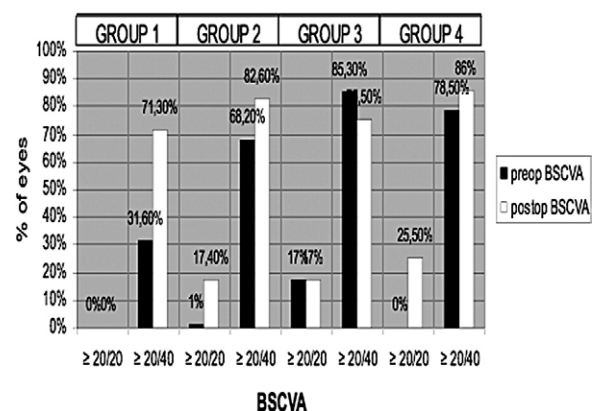

Figure 1. Percentage of eyes within a given range of best spectacle-corrected visual acuity (BSCVA) preoperatively (preop) and at last follow-up visit (safety).
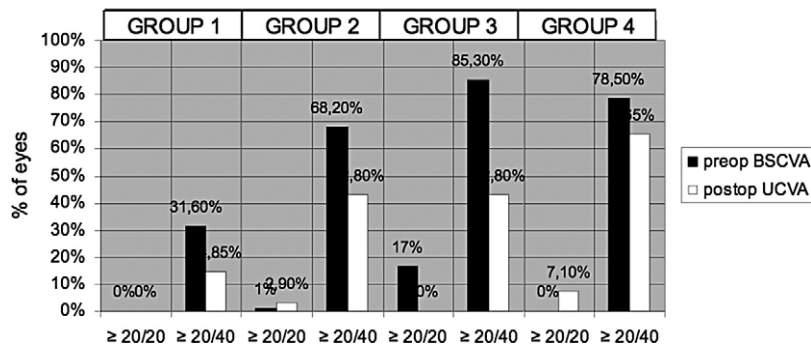
Figure 2. Percentage of eyes within a given range of preoperative (preop) best spectacle-corrected visual acuity (BSCVA) and of postoperative uncorrected visual acuity (UCVA) (efficacy).

Group 1: Model 204, 5-mm Optic for Myopia (n = 101). The mean preoperative BSCVA was 20/50±20/150 (range, 20/400–20/25). Preoperatively, none of the eyes of this group had BSCVA of 20/20 or better, and 32 eyes (31.6%) had BSCVA≥20/40. Three months postoperatively, 72 eyes (71.3%) had BSCVA≥20/40. Fifteen eyes (14.85%) had UCVA≥20/40. Efficacy indexes were 0.61, 1.157, 1.09, 1.11, 0.9, and 0.86 at 3 months and 1, 2, 3, 4, and 5 years, respectively. Safety indexes were 1.41, 1.40, 1.41, 1.40, 1.3, and 1.3.

Group 2: Model 206, 6-mm Optic for Myopia (n = 173). The mean preoperative BSCVA was 20/30±20/90 (range, 20/400–20/20). Preoperatively, 17 eyes (1%) had BSCVA≥20/20, and 118 eyes (68.2%) had BSCVA≥20/40. Three months postoperatively, 30 eyes (17.4%) had BSCVA≥20/20 and 142 eyes (82.6%) had BSCVA≥20/40. Five eyes (2.9%) had UCVA≥20/20

and 74 eyes (42.8%) had UCVA≥20/40. Efficacy indexes were 0.77, 0.95, 0.86, 0.81, 0.93, and 0.74 at 3 months and 1, 2, 3, 4, and 5 years, respectively. Safety indexes were 1.11, 1.17, 1.04, 0.99, 1.14, and 1.04.

Group 3: Model 203, 5-mm Optic for Hyperopia (n = 41). The mean preoperative BSCVA was 20/35±20/90 (range, 20/60–20/20). Three months postoperatively, BSCVA was 20/30±20/90 and UCVA was 20/50±20/90. Preoperatively, 7 eyes (17%) had BSCVA≥20/20 and 35 eyes (85.3%) had BSCVA≥20/40. Three months postoperatively, 7 eyes (17%) had BSCVA≥20/20 and 31 eyes (75.5%) had BSCVA≥20/40. None of the eyes of this group had UCVA≥20/20, and 17 eyes (42.8%) had UCVA≥20/40. Efficacy indexes were 0.58, 0.79, 0.77, 0.81, 0.71, 0.74, and 0.9 at 3 months and 1, 2, 3, 4, and 5 years, respectively. Safety indexes were 0.86, 0.98, 0.94, 0.95, 0.92, 0.98, and 1.25.
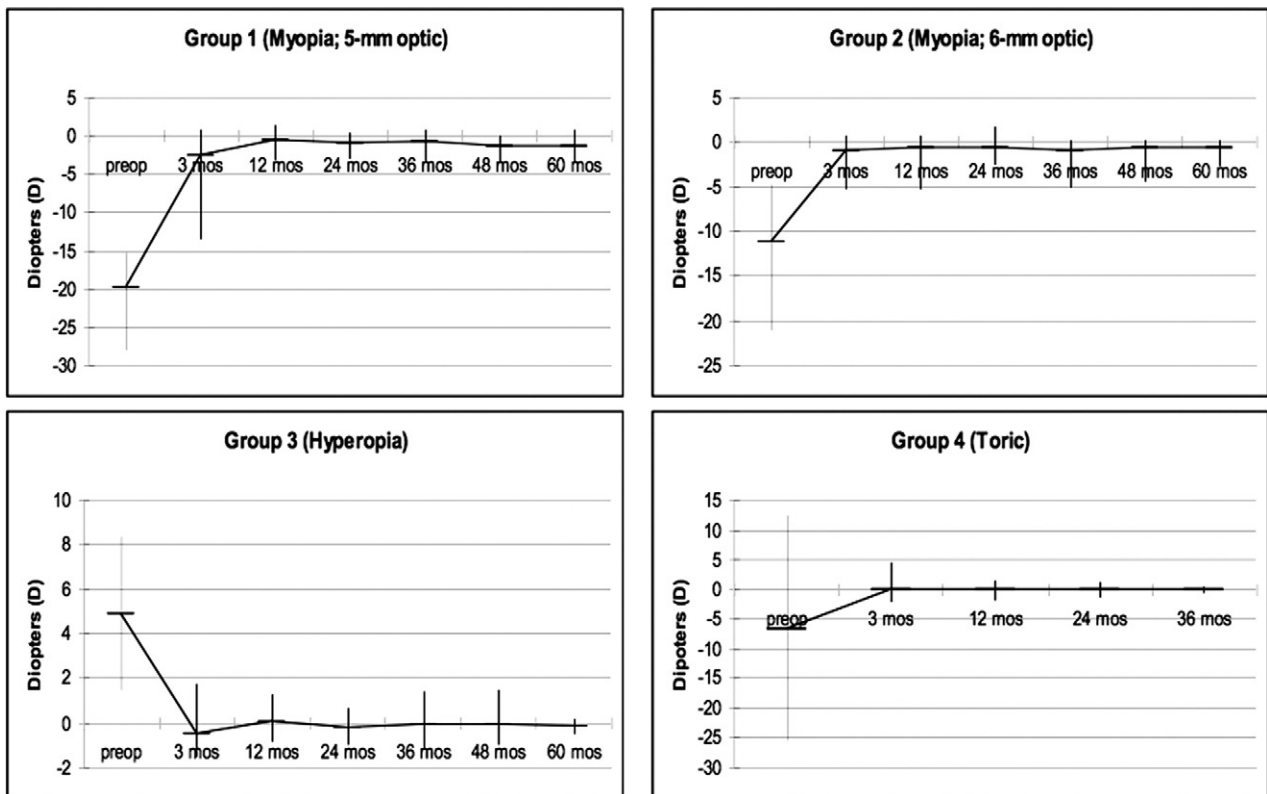

Figure 3. Graph demonstrating the stability of postoperative spherical equivalent after Verisyse phakic intraocular lens implantation. Mean and range (maximum–minimum values) are shown.
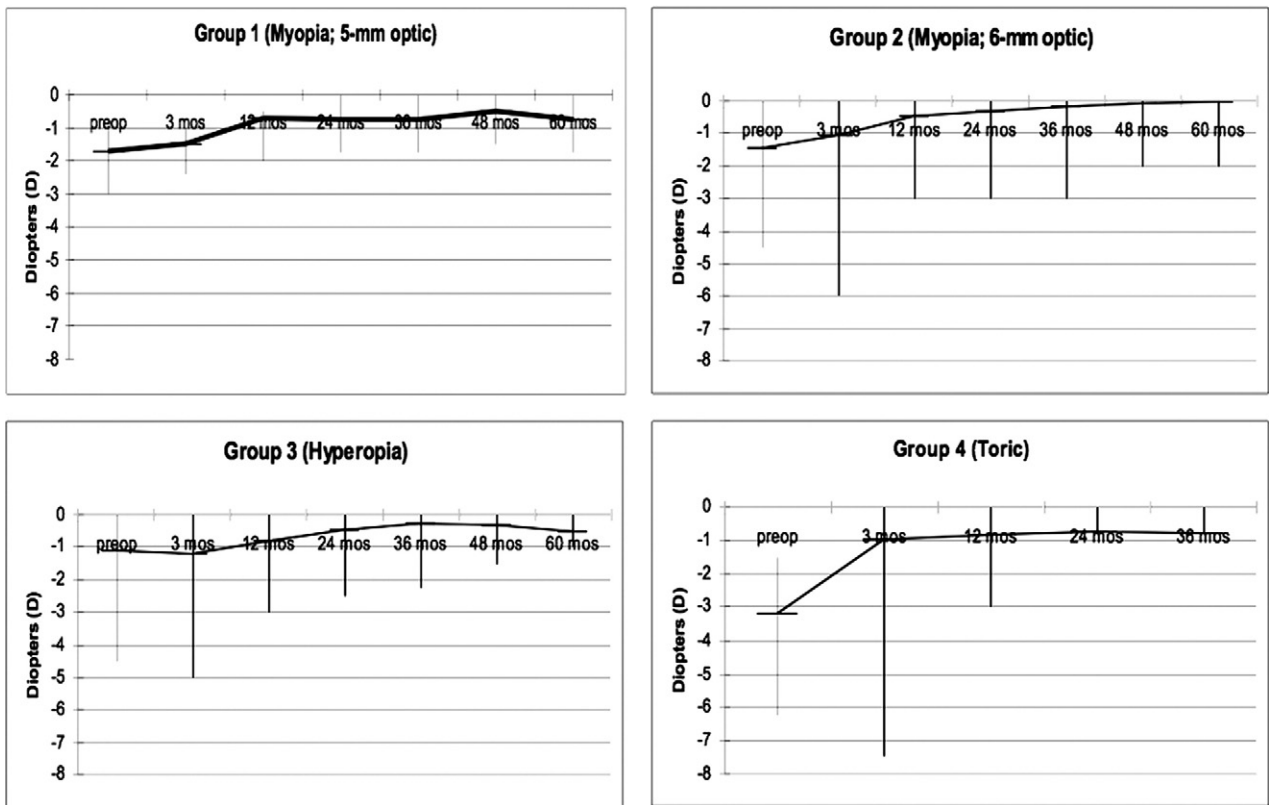
Figure 4. Graph demonstrating the stability of postoperative cylinder after Verisyse phakic intraocular lens implantation. Mean and range (maximum–minimum values) are shown.

Group 4: Toric Model (n = 84). The mean preoperative BSCVA was 20/30±20/100 (range, 20/200–20/27). Preoperatively, none of the eyes of this group had BSCVA≥20/20, and 66 eyes (78.5%) had BSCVA≥20/40. Three months postoperatively, 21 eyes (25.5%) had BSCVA≥20/20 and 72 eyes (86%) had BSCVA≥20/40. Six eyes (7.1%) had UCVA≥20/20 and 55 eyes (65.4%) had UCVA≥20/40. Efficacy indexes were 0.93, 0.96, 0.96, and 0.93 at 3 months and 1, 2, and 3 years, respectively. Safety indexes were 1.19, 1.26, 1.22, and 1.17 at 3 months and 1, 2, and 3 years.

Refractive Outcome

Figures 3 and 4 and Table 3 show preoperative and postoperative values for SE and cylinder in each group. Means ± SDs (*P* value resulting from paired *t* tests) are reported.

Table 4 shows the percent of eyes within ±1 D and ±0.5 D of emmetropia for each group.

Additional Refractive Surgery

Table 4 summarizes the number and type of additional keratorefractive procedures for each group, as well as the SE before and after the keratorefractive enhancement.

Group 1: Model 204, 5-mm Optic for Myopia (n = 101). Sixty-one eyes (60.39%) underwent ACRS. In 59 eyes, LASIK was performed, whereas 2 eyes underwent AK procedures. Fifty-eight LASIK procedures were performed between 3 and 6 months after the lens was implanted, whereas the other procedures (1 LASIK and 2 AKs) were performed between 12 and 18 months after implantation. It is also important to point out that, in 75% of cases, ACRS was scheduled before PIOL implantation to diminish

Table 3. Preoperative and Postoperative

	SE (D) (Mean ± SD)				
	Preoperative	*3 mos*	*1 yr*	*3 yrs*	*5 yrs*
Group 1	−19.8±3.23	−2.64±2.24 (*P*<0.001)	−1.32±1.01	−0.78±0.88	−0.5±0.89 (*P*<0.001)
Group 2	−11.27±3.11	−0.98±1.07 (*P*<0.001)	−0.58±0.75	−0.95±1.06	−0.64±0.8 (*P*<0.001)
Group 3	4.92±1.7	−0.51±0.85 (*P*<0.001)	0.2±0.48	−0.11±0.74	0.02±0.51 (*P*<0.001)
Group 4	−6.82±8.69	0.00±1.06 (*P*<0.001)	−0.02±0.63	−0.09±0.64 (*P*<0.001)	Not available

D = diopters; SD = standard deviation.
P value, paired *t* test (performed compared with baseline at 3 mos postoperatively and 5 yrs [groups 1–3] or 3 yrs [group 4]).

its height, due to either preoperative astigmatism or magnitude of the myopic sphere.

Group 2: Model 206, 6-mm Optic for Myopia (n = 173). Additional corneal refractive surgery was performed in 34 eyes (19.6%): 30 LASIK, 1 PRK, and 3 AK procedures. In 50% of the eyes, ACRS was scheduled before implantation. All refractive corneal surgery was performed between 3 and 6 months after lens implantation.

Group 3: Model 203, 5-mm Optic for Hyperopia (n = 41). Additional corneal refractive surgery was performed in 17 eyes (41.4%): 10 LASIK, 1 conductive keratoplasty, and 6 AK procedures. In 48.6% of the eyes, ACRS was scheduled before implantation. The time elapsed between implantation of the lens and ACRS was between 3 and 6 months in 11 eyes and between 12 and 18 months in 6 eyes.

Group 4: Toric Model (n = 84). Additional corneal refractive surgery was performed in 5 eyes (5.95%): 4 LASIK and 1 AK procedure. Additional corneal refractive surgery was scheduled before implantation in none (0%) of the eyes. Additional corneal refractive surgery was performed between 3 and 6 months after implantation in 3 eyes and between 6 and 12 months after implantation in the other 2 eyes.

Corneal Endothelial Cell Density and Endothelial Cell Loss

Table 5 shows central ECC and percentage of endothelial cell loss for each group and at each interval of follow-up. *P* values resulting from paired *t* tests at 4 years of follow-up (groups 1–3) and at 3 years of follow-up (group 4) are also reported.

Complications (Table 6)

Three lenses (0.75%) needed to be repositioned. In 2 eyes, the PIOL became dislocated due to an ocular contusion and the other moved spontaneously 1 year after the surgery, probably because a too small amount of iris had been grasped by the PIOL claw. There were no clinically significant sequelae in any of the 3 cases.

We also had to change lenses on 3 occasions (0.75%). One eye of group 3 had a residual refractive error of $+1.50-1.75 \times 160$ and UCVA of 20/60. As the cornea presented topographic signs of keratoconus, we chose to perform a PIOL exchange rather than to operate on the cornea. Six months after PIOL exchange, UCVA was 20/40 and refraction was $+0.5-0.5 \times 160$. The patient maintained the preoperative BSCVA of 20/40. However, central ECC decreased from 3012 cells/mm² preoperatively to 2700 cells/mm² after 5 years of follow-up. Another eye of group 3 had a residual refractive error of $+0.75-4.5 \times 35$. This patient had preoperative BSCVA of 20/40 and a refractive error of $+5.5-4.5 \times 40$. The hyperopic lens was finally replaced with a toric one. One year after PIOL exchange, UCVA was 20/50, BSCVA was 20/40, and the

residual refractive error was $+1.0-1.25 \times 80$. Up to now, there has been no decrease in central ECC (from 2889 cells/mm² preoperatively to 3324 cells/mm² after 3 years of follow-up). The third case occurred in group 4. Six months after surgery, the patient had a cylinder power value of -5.0 D, so the lens was replaced with another toric lens. We later learned that the problem stemmed from a manufacturing defect in the lens itself. One year after PIOL exchange, refraction was -1.00 at 180°. However, central ECC decreased from 2500 cells/mm² preoperatively to 2300 cells/mm² after 2 years of follow-up.

Explantation due to unacceptable endothelial cell loss was necessary in 3 eyes (0.75%), all of them belonging to group 1, and the cell loss was possibly associated with eye rubbing in all 3 cases. Five years after surgery, 1 eye suffered a drop in ECC from a preoperative value of 3813 cells/mm² to 1856 cells/mm², and the lens was explanted without any complications. Two and 3 years after PIOL explantation, central ECC was 1300 cells/mm². Three years after surgery, 2 eyes of one patient presented a drop in ECC from preoperative values of 2382 cells/mm² in the right eye and 2064 cells/mm² in the left eye to 1805 cells/mm² and 723 cells/mm², respectively. Uneventful PIOL explantation and cataract surgery were performed in both eyes. The cornea remains clear in all cases, and central ECC remains stable. Nevertheless, close monitoring of central ECC is being performed in all these patients.

A 46-year-old patient of group 1 developed nuclear cataracts in both eyes (0.5%) 3 years after lens implantation. This patient's BSCVA had declined from 20/25 in both eyes 1 year after surgery to 20/60 in the right eye and 20/40 in the left eye 3 years after surgery. Uneventful cataract surgery was performed, and patients' BSCVA increased to the values before cataracts developed (20/25).

One eye (0.25%) of group 1 presented a macular hemorrhage 4 months after surgery, and another one (0.25%) of the same group presented an RD 3 years after surgery. Our vitreoretinal specialists do not believe these situations were related in any way to the implanted lens, and both cases were successfully treated.

Discussion

The use of spectacles to correct high ammetropias involves minimal risk, though the visual quality achieved is generally deficient, as aberrations, minification, and limitation of the visual field are often produced. Apart from that, functional and aesthetic drawbacks may also be present. Contact lenses give users greater visual acuity and quality of vision.[29] Even though the availability of highly oxygen-permeable contact lenses has increased the tolerance and safety of extended contact lens wear, their use may be associated with poten-

Spherical Equivalent (SE) and Cylinder

	Cylinder (D) (Mean ± SD)			
Preoperative	*3 mos*	*1 yr*	*3 yrs*	*5 yrs*
−1.71±0.11	−1.48±0.94 (P = 0.016)	−0.71±0.26	−0.75±0.3	−0.75±0.27 (P<0.001)
−1.43±0.2	−1.09±0.15 (P = 0.016)	−0.49±0.67	−0.18±0.51	−0.06±0.26 (P<0.001)
−1.15±1.07	−1.25±1.22 (P = 0.616)	−0.81±0.89	−0.27±0.57	−0.55±0.43 (P<0.001)
−3.24±1.02	−0.99±1.23 (P<0.001)	−0.77±0.45	−0.83±0.74 (P<0.001)	Not available

Table 4. Additional Corneal Refractive Surgery (ACRS)

	Group 1	Group 2	Group 3	Group 4
No. (%) of eyes within ±1 D of emmetropia	23 (22.8)	99 (57.2)	26 (64.2)	68 (81.3),*53 (62.7)[†]
No. (%) of eyes within ±0.5 D of emmetropia	10 (9.9)	65 (37.6)	14 (34.8)	56 (66.6),*29 (34.8)[†]
No. (%) of eyes undergoing ACRS	61 (60.39)	34 (19.6)	17 (41.4)	5 (5.95)
No. (%) of eyes with ACRS scheduled before PIOL	46 (75)	17 (50)	8 (48)	0 (0)
Type of ACRS	59 LASIK, 2 AK	30 LASIK, 3 AK, 1 PRK	10 LASIK, 6 AK, 1 CK	4 LASIK, 1 AK
Time between procedures (no. of eyes)	3–6 mos (58), 12–18 mos (3)	3–6 mos (34)	3–6 mos (11), 12–18 mos (6)	3–6 mos (3), 6–12 mos (2)
SE before ACRS	−2.64±2.239 (0.8 to −13.5)	−0.98±1.07 (0.75 to −5.3)	−0.51±0.85 (0.8 to −2.0)	0.0±1.06 (4.5 to −2.2)
SE after ACRS	−0.5±0.89 (1.5 to −3.25)	−0.64±0.80 (0.2 to −2.75)	−0.1±0.67 (0.4 to −1.0)	−0.09±0.64 (1.5 to −1.8)

ACRS = additional corneal refractive surgery; AK = arcuate keratotomy; CK = conductive keratoplasty; D = diopters; PIOL = phakic intraocular lens; PRK = photorefractive keratectomy; SE = spherical equivalent.
*Spherical equivalent.
[†]Cylinder.

tially serious complications, especially among chronic users, which may lead to severe vision loss.[30–32]

Implantation of iris-claw Artisan/Verisyse PIOLs offers a good alternative to spectacles and contact lenses, especially for patients under 50 with high refractive errors who have not lost accommodation, provided they meet the anatomical requirements outlined in "Subjects and Methods." Implantation of these lenses has proved effective, stable, and very safe,[16–24,26] despite a report by Muñoz et al,[33] who reported that one third of their patients lost 1 line of BSCVA after implantation of the Artisan lens and then recovered it after LASIK was performed to correct the residual refractive error, which is something quite difficult to understand. Benedetti et al[21] obtained the same or better BSCVA values after implantation of the Artisan/Verisyse PIOLs in 100% of cases, which coincides with our own results and with those of prospective multicenter clinical trials.[17–19]

Several authors have compared the effectiveness and safety of LASIK with those of Artisan/Verisyse PIOLs in moderate and high myopia. Malecaze et al[8] reported similar predictabilities for both procedures, but BSCVA values and patients' subjective evaluation of quality of vision were better in the PIOL group. Nio et al[10] reported better UCVA

values, predictability, and contrast sensitivity in the Artisan group.

Zaldivar et al[34,35] introduced the term *bioptics* to describe LASIK after PIOL implantation in patients with SE of ≥−18.0 D, patients with high levels of astigmatism (≥−2.0D), and, initially, patients for whom lens power availability was a problem. Similarly, with the aim to improve the quality of vision and to diminish glare, halos, and other common complaints under dim illumination in highly myopic subjects (>−15.0 D), we developed the idea of adjustable refractive surgery, in which we combined implantation of a 6-mm optic Verisyse PIOL and a 6.5-mm optical zone LASIK procedure.[9,28] Adjustable refractive surgery proved to be predictable and safe in our series of 26 patients, with all of them (100%) achieving ±1 D of emmetropia and 21 eyes (80.70%) achieving ±0.05 D of emmetropia.

Nevertheless, the potential risks of these implantations should be borne in mind, especially the loss of corneal endothelial cells. Several studies have examined changes in ECC after implantation of the Verisyse/Artisan PIOL. Although some of them have found a significant decrease of endothelial cell density,[36,37] data from the European Multicenter Study of the Artisan PIOL[19] and the United States Food and Drug Administration Ophtec Study[38] show that

Table 5. Preoperative and Postoperative Central Endothelial Cell Count (ECC) and Percent of Endothelial Cell Loss

	Central ECC (Cells/mm²) [Mean ± Standard Deviation (% of Endothelial Cell Loss from Baseline)]					
	Preoperative	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
Group 1	2836±398	2598±350 (8.4)	2548±398 (10.1)	2625±447 (7.4)	2791±246 (1.5), P = 0.004	2514±529 (11.3)
Group 2	2755±362	2643±414 (4.06)	2614±469 (5.11)	2519±372 (8.57)	2698±576 (2.07), P = 0.002	2454±588 (10.9)
Group 3	2735±355	2600±442 (4.93)	2587±551 (5.4)	2505±508 (8.4)	2560±335 (6.4%), P = 0.123	Not available
Group 4	2632±543	2673±439 (1.56*)	2483±339 (5.66)	2537±615 (3.6), P = 0.069	Not available	Not available

P values, paired t tests were performed compared to baseline.
*Central ECC increased.

Table 6. Complications

Complication	No. of Eyes (%)
PIOL reposition	
Ocular trauma	2 (0.50)
Unappropriate iris capture	1 (0.25)
PIOL exchange (postoperative refractive error)	3 (0.75)
Endothelial cell loss	3 (0.75)
Cataracts	2 (0.50)
Macular hemorrhage	1 (0.25)
Retinal detachment	1 (0.25)

PIOL = phakic intraocular lens.

implantation of the Artisan iris-claw PIOL did not result in a significant loss of endothelial cell density at up to 2 years postoperatively. In our study, the decrease in central ECC was statistically significant for the 5-mm and 6-mm optic Verisyse PIOL for myopia ($P = 0.004$ and $P = 0.002$, respectively), whereas it was not statistically significant for the hyperopia and toric groups ($P = 0.123$ and $P = 0.069$, respectively). The overall percentage of loss of corneal endothelial cells at 4 years after implantation was 5.11% ($P<0.001$), which was smaller than those found in previous studies (13.4%[36] and 15.8%[37]). Tahzib et al[20] have recently reported a mean endothelial cell relative gain of 8.86%±16.01% at 10 years that has been attributed to several factors, including the discontinuation of contact lenses, recovery capability of the corneal endothelium after surgical trauma, or variability of specular microscopy measurements. More-

over, preoperative central ECC values were adjusted for a linear decrease of 0.6% physiologic loss per year.[39] Interpretations of the clinical significance of data for endothelial cell loss after ocular surgical procedures should also take into account the effect of natural age-related cell loss.

Central ECC comparing LASIK and Verisyse/Artisan PIOL implantation has been previously assessed. Malecaze et al[8] reported that endothelial cell losses were 0.21% at 3 months and 0.42% at 1 year postoperatively in the LASIK-treated eyes and 0.96% at 3 months and 1.76% at 1 year postoperatively in the Artisan-implanted eyes. Those differences did not statistically differ at either 3 months ($P = 0.73$) or 1 year ($P = 0.60$) postoperatively. Similarly, El Danasoury et al[40] reported that there was no statistically significant difference between the endothelial cell loss in both groups at 1 year postoperatively (0.3% in the LASIK group and 0.7% in the Artisan group). A longer follow-up of those same patients would be very useful to determine the PIOL-related endothelial cell loss in the long term. Despite all the concerns in endothelial cell loss, provided the patient is checked regularly, which must be an absolute prerequisite for this kind of surgery, the loss of endothelial cells is a foreseeable complication and may be corrected before more serious advanced complications may occur. This is not the case with the possible cataracts, pigmentary glaucoma associated with PC phakic lenses,[14,15] or pupil ovalization associated with angle-supported lenses[12,13]: they can be neither stopped nor reversed.

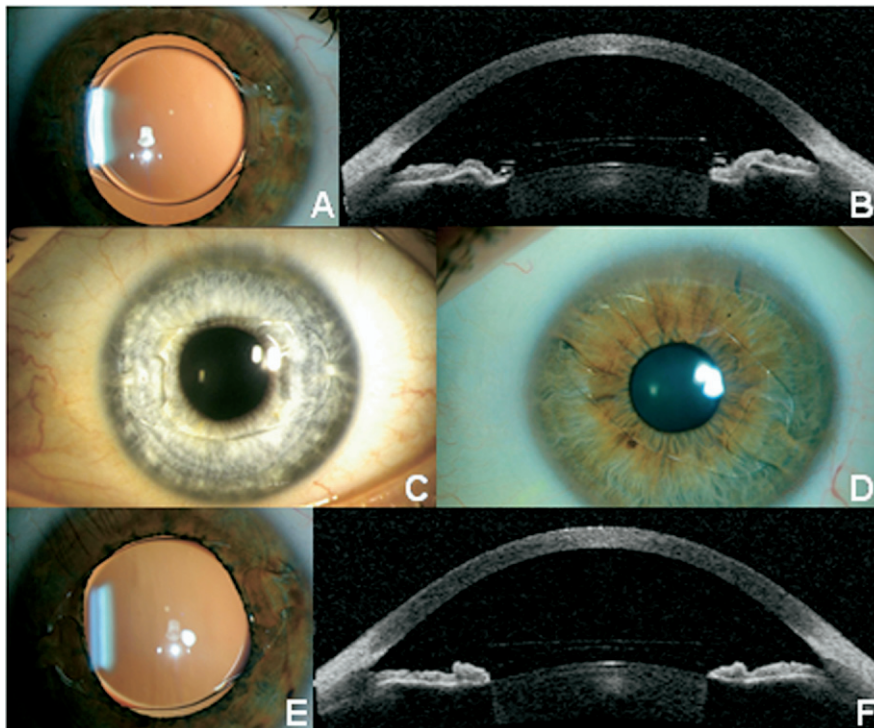In our series, 3 lenses (0.75%) of 2 patients had to be explanted due to severe endothelial cell loss. This acceler-

Figure 5. **A, B,** Clinical photograph and Visante optical coherence tomography (OCT) of a Veriflex phakic intraocular lens (PIOL) 12 months postoperatively. **C,** Clinical photograph of a Verisyse 5-mm optic PIOL 5 years after its implantation. **D,** Verisyse toric PIOL 3 years after its implantation. **E, F,** Clinical photograph and Visante OCT of a Verisyse 6-mm optic PIOL 4 years after its implantation.
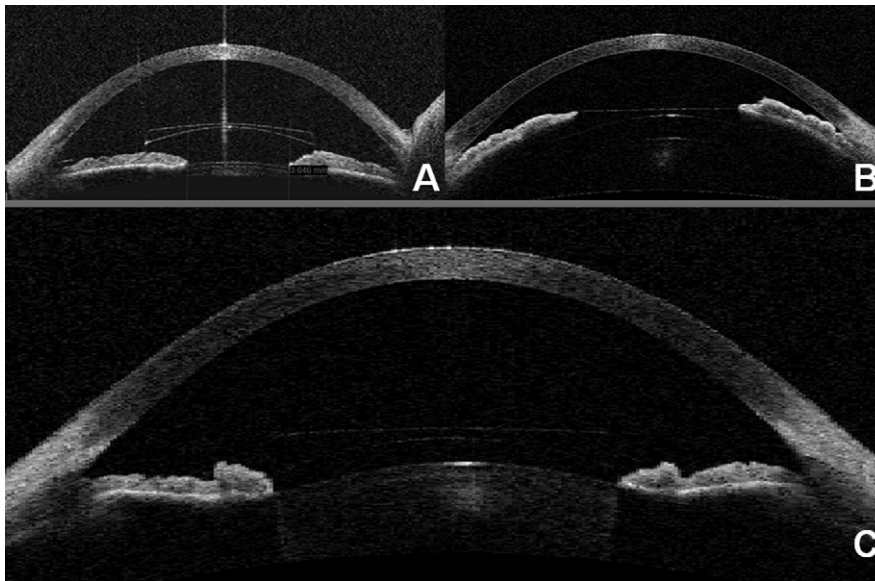
Figure 6. Visante optical coherence tomography of 3 different PIOLs: (**A**) angle-supported anterior chamber (AC) phakic intraocular lens (PIOL), (**B**) sulcus-supported posterior chamber (PC) PIOL, and (**C**) Verisyse AC PIOL. Observe the difference in clearance between each PIOL and the corneal endothelium and crystalline lens: the angle-supported PIOL is the closest to the endothelium, and the sulcus-supported PC PIOL is the closest to the crystalline lens.

ated loss of endothelial cells may be caused by both patients rubbing their eyes very often, though they did not present any sign of chronic allergic conjunctivitis. In fact, since then we consider eye rubbing an absolute contraindication for this surgery and one of the issues that must be discussed preoperatively with our patients.

A far as trauma to the iris is concerned, it is actually minimal, provided the lens is properly and carefully fixed to the iris. On the other hand, angle-supported lenses may cause a greater trauma to the iris, which is manifested as ovalization with anterior synechia and iris atrophy, both of which are irreversible situations that did not appear in any case of our study. However, only longer-term follow-up studies will clarify this and other issues.

Besides the possible complications outlined above, the surgical technique of implanting an iris-claw lens has 2 additional disadvantages. First, it requires a steep learning curve, given that the technique is more difficult than the procedure involved in implanting either angle-supported lenses or PC PIOLs. Second, the 5.2- or 6.2-mm incision required for the implantation of this rigid PMMA lens can extend postoperative visual recovery. Large corneal incisions are reported to induce high astigmatism in the first postoperative weeks,[41,42] although they may behave like astigmatically neutral incisions in the medium and long term, depending on the incision design.[43] Experience has allowed us to achieve incisions that, in the majority of cases, do not cause astigmatism by 12 weeks after surgery, as has been shown in this series of patients. Other surgeons prefer a scleral incision or a temporal approach, rather than a superior one, which may result in varying degrees of astigmatism during the immediately postoperative period. The problem of astigmatism in the immediately postoperative period has probably been resolved with the Artiflex or Veriflex (AMO) foldable models, which can be inserted through 3-mm incisions that do not induce significant astigmatism (Fig 5A, B).[25,26]

Despite this drawback and the potential chronic loss of endothelial cells, our extensive experience shows that these lenses provide a number of advantages over other PIOLs' designs. In comparison with most angle-supported lenses, they neither occupy nor change the AC angle structures, and they are located further away from the endothelium, deeper in the AC. Moreover, they are also farther away from the crystalline lens than PC PIOLs and do not touch the pigmentary epithelium of the iris (Figs 5, 6).[44–47] Another major advantage of these lenses is that they can always be properly centered over the pupil, even when it is off center, a relatively common situation among people with high ammetropias. Off-center pupils cannot be used as a reference for centration with symmetrical implants, such as angle-supported and sulcus-fixated IOL implants.[48] Moreover, the fixation system inhibits implant movement,[45] which warrants the correction of astigmatism and may help to correct other vectorial or assimetrical aberrations in the future.

In conclusion, this series of 399 eyes shows that implantation of iris-claw Verisyse/Artisan PIOLs is a reversible, effective, stable, safe procedure in the first 5 years of follow-up. However, data arising from retrospective studies should always be taken with caution, especially data related to safety concerns, as the sample size may be statistically insufficient to detect rare complications. Significant differences with longer follow-up studies would probably not be expected, although, obviously, such studies will be mandatory to properly evaluate Verisyse/Artisan PIOLs' safety in the long term.

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