Long-term Results of Phakic Refractive Lens Implantation in Eyes With High Myopia

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ABSTRACT

PURPOSE: To evaluate the long-term results of phakic refractive lens (PRL; Carl Zeiss Meditec) implantation in eyes with high myopia.

METHODS: In this retrospective, noncomparative, interventional case series, 143 myopic eyes of 82 patients were treated for high myopia with the implantation of the silicone PRL in the posterior chamber.

RESULTS: Mean follow-up was 3.8±1.7 years (range: 1 to 6 years). Six years postoperatively (n=34), a statistically significant reduction was noted in the cycloplegic spherical equivalent from −14.08±4.00 diopters (D) (range: −24.88 to −4.75 D) before PRL implantation to −0.45±0.62 D (range: −1.00 to 1.00 D) ($P<.001$). At 6 years, 67.6% (23 eyes) and 91.2% (31 eyes) were within ±0.50 and ±1.00 D of target refraction, respectively. Mean logMAR uncorrected and corrected distance visual acuity improved significantly ($P<.001$) (counting fingers preoperatively in all eyes to 0.17±0.15 [range: 0.54 to −0.06] and 0.19±0.19 [1.00 to −0.08] to 0.07±0.10 [range: 0.30 to −0.10], respectively). Complications included anterior capsule damage (3 eyes), temporary intraocular pressure increase (14 eyes), pigment dispersion (1 eye), and PRL decentration (1 eye). No eyes presented any signs of cataract up to 6 years postoperatively.

CONCLUSIONS: Long-term results show that PRL implantation is an effective and safe method for treating high myopia. [*J Refract Surg.* 2011;27(11):787-791.]

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Phakic intraocular lenses (PIOL) have gained their place in intraocular refractive surgery as a relatively new, evolving technique for the correction of moderate to high refractive errors. In certain cases of high myopia and hyperopia, excimer laser treatment is not advised because of residual corneal stromal thickness concerns.[1,2] The main issue is to avoid the risk of postoperative ectasia, attributed mainly to LASIK,[2] in which the cornea progressively thins and steepens resulting in myopia, irregular astigmatism, and loss of corrected distance visual acuity (CDVA). Furthermore, it has been established that attempted corrections of high myopia/hyperopia induce more higher order aberrations, affecting vision quality and creating problems such as glare, halos, and ghost imaging.[3]

Phakic intraocular lens implantation does not affect the shape and central thickness of the cornea and has the advantage of being potentially reversible. In comparison to clear lens extraction, PIOL implantation preserves accommodation and, as a result, is a better solution for younger patients. Phakic intraocular lens implantation carries risks such as cataract formation, inflammation and infection, decentration, and retinal detachment especially when treating high myopia.[4]

Currently, three types of refractive lenses are used for correcting refractive errors: anterior chamber, iris-fixated, and posterior chamber. Two types of posterior chamber phakic refractive lenses are available for the correction of high myopia and hyperopia—Implantable Collamer Lens (Visian ICL; STAAR Surgical, Monrovia, California) and Phakic Refractive Lens (PRL; Carl Zeiss Meditec, Jena, Germany). The latter is made of silicone with a high refractive index (1.46), which allows its ultra-thin design. The PRL is not supported in the

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sulcus angle, but due to its hydrophobic material and aqueous fluid dynamics, it theoretically should avoid contact with the crystalline lens, even during accommodation. Because no true centration is achieved during implantation, minor rotation of the lens might occur during the follow-up period. One- and 2-year clinical results of PRL implantation suggest that it is efficient and predictable for the treatment of high myopia and hyperopia.[5-9] However, longer follow-up is mandatory to evaluate its safety and stability.

The purpose of our study was to evaluate the long-term efficacy, predictability, and safety of PRL implantation in highly myopic eyes. To our knowledge, this is the longest follow-up of PRL implantation to be reported in the literature.

PATIENTS AND METHODS

One hundred forty-three myopic eyes of 82 patients were treated with PRL implantation by the same surgeon (I.G.P.). Mean patient age was 28.7±6.1 years (range: 18 to 45 years). Preoperative evaluation included cycloplegic refraction in spherical equivalent, uncorrected distance visual acuity (UDVA), CDVA, intraocular pressure (IOP), slit-lamp microscopy, pupil size measurement under scotopic conditions, white-to-white corneal diameter measurement with the use of a caliper, dilated funduscopy, and A-scan ultrasonography (Axis-II; Quantel Medical, Clermont-Ferrand, France).

Exclusion criteria were age <18 years, previous intraocular surgery, anterior chamber depth <3 mm, glaucoma, cataract, and active ocular infection.

Each patient was informed about the nature of the procedure, possible outcomes and current clinical experience, and gave written consent according to the Declaration of Helsinki and institutional guidelines. Institutional review board/ethics committee (University of Crete) approval was obtained.

Lens power calculations were based on the preoperative cycloplegic spherical equivalent, average keratometric power, anterior chamber depth calculated with use of A-scan ultrasonography, and target postoperative refraction, and were based on the manufacturers' nomogram. The model of the myopic PRL implanted was based on the horizontal white-to-white diameter. The two PRL models available are the PRL 101, with a length of 11.3 mm for a white-to-white diameter >11.3 mm, and the PRL 100, with a length of 10.8 mm for a white-to-white diameter between 10.5 and 11.3 mm.

SURGICAL TECHNIQUE

One hour before surgery, cyclopentolate 1% and phenylephrine 5% were used every 15 minutes to dilate the pupil. Phakic refractive lenses were implanted under retrobulbar anesthesia through a 3.2-mm clear corneal temporal incision made with a diamond knife. The anterior chamber was filled with a low-viscosity viscoelastic agent.

Lenses were inserted with the use of special forceps. The haptics of the lens, one after the other, were placed under the iris. At the end of the procedure, a surgical iridectomy was performed with the use of a vitreotome in 76 eyes, whereas 2 YAG-laser iridotomies were performed 1 week before the procedure in 67 eyes.

Patients remained in the hospital on the day of surgery, as they were closely monitored during the first 24 hours for IOP increase. Acetazolamide was administered immediately after surgery. Patients were discharged the following day, and topical antibiotic-corticosteroid drops (tobramycin 0.3%-dexamethasone 0.1%, TobraDex; Alcon Laboratories Inc, Ft Worth, Texas) were prescribed four times daily for 15 days.

STATISTICAL ANALYSIS

Statistical analysis was performed using the paired Student *t* test and Wilcoxon signed rank non-parametric test (SPSS statistical software; SPSS Inc, Chicago, Illinois) in accordance with data normality test. Test for normality was performed using the Kolmogorov-Smirnov test. Results are presented as mean±standard deviation. *P* values <.05 were considered statistically significant.

RESULTS

Mean follow-up after PRL implantation was 3.8±1.7 years (range: 1 to 6 years). Approximately 68.5% of eyes (98/143) had ≥2 year follow-up after PRL implantation. The term "last follow-up" refers to the last reported examination for each eye in the entire cohort.

EFFICACY

Mean logMAR UDVA significantly improved from counting fingers preoperatively in all eyes to 0.13±0.87 (range: 0.70 to −0.18) at 2-year follow-up (n=62) to 0.17±0.15 (range: 0.54 to −0.06) at 6-year follow-up (n=34) (*P*<.001) (Fig 1).

SAFETY

Mean logMAR CDVA also improved from 0.19±0.19 (range: 1.00 to −0.08) to 0.07±0.10 (range: 0.30 to −0.10) at 6 years (*P*<.001). Compared to the preoperative value, 73.5% of eyes (25/34 eyes) gained 1 to 4 lines of CDVA at 6 years postoperatively. Also, compared to the preoperative value, at last follow-up, 57.3% of eyes (82/143 eyes) gained 1 to 4 lines of CDVA (Fig 2). Approximately 8% of eyes lost 1 or 2 lines of CDVA at last follow-up. This loss of lines is presumably not correlated to the PRL implanta-

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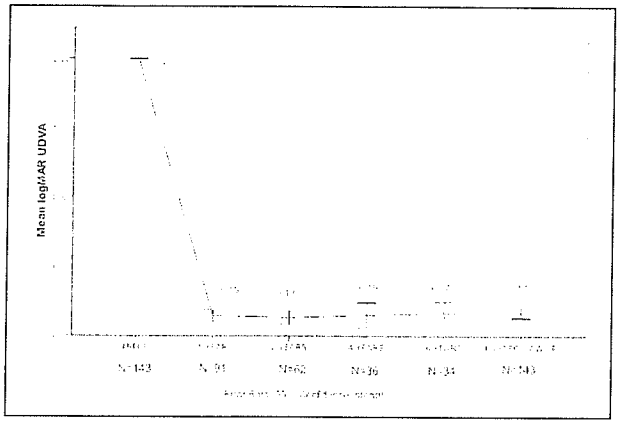

Figure 1. Efficacy. Uncorrected distance visual acuity (UDVA) in eyes that underwent PRL implantation.

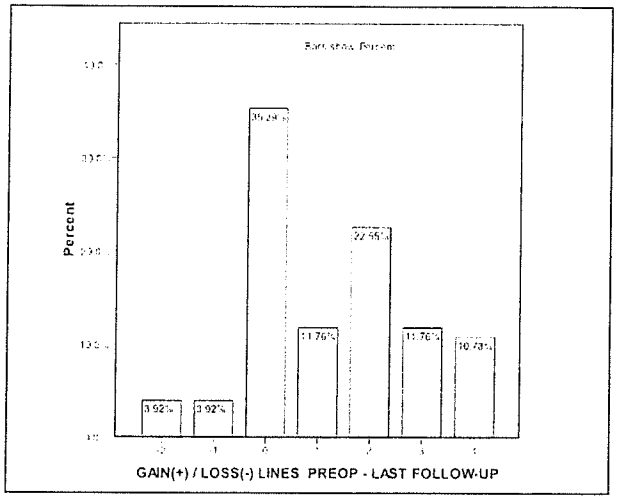

Figure 2. Safety. Change in corrected distance visual acuity in eyes that underwent PRL implantation.

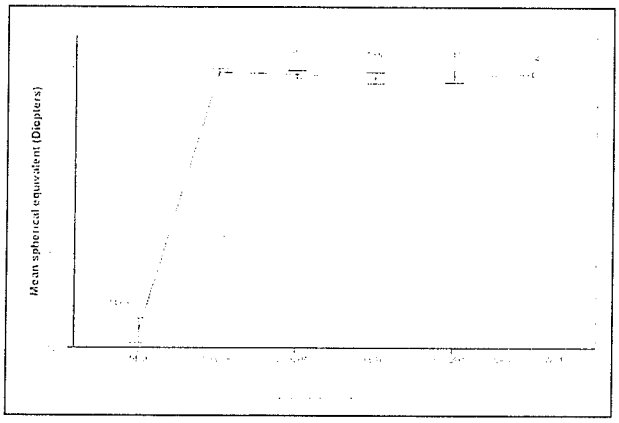

Figure 3. Stability of mean spherical equivalent refraction in eyes that underwent PRL implantation.

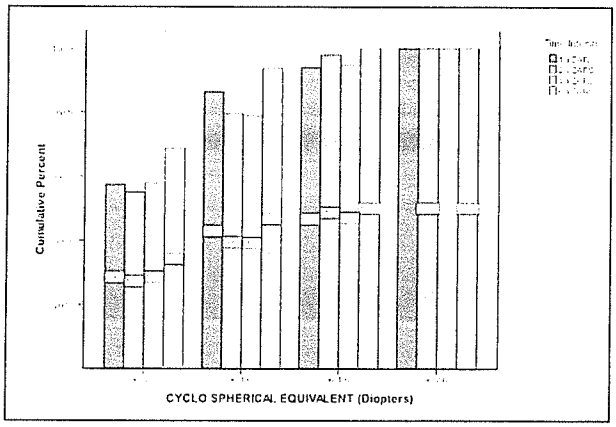

Figure 4. Predictability of cycloplegic spherical equivalent refraction in eyes that underwent PRL implantation.

tion, as those patients were high myopes who developed myopic retinopathy during the follow-up period, which resulted in deterioration of visual acuity.

STABILITY

Refractive results remained relatively stable, with a slight change from −0.35 at 2 years to −0.45 at 6 years (Fig 3).

PREDICTABILITY

A statistically significant reduction was noted in the cycloplegic spherical equivalent from −14.08±4.00 D (range: −24.88 to −4.75 D) preoperatively to −0.45±0.62 D (range: −1.00 to 1.00 D) 6 years postoperatively ($P<.001$). At 6 years, 67.6% (23/34) and 91.1% (31/34) of eyes were within ±0.50 and ±1.00 D of target refraction, respectively (Fig 4).

COMPLICATIONS

No eye presented signs of cataract over 6-year follow-up. During surgical iridectomy with the probe of a vitreotome, 3 eyes experienced damage of the anterior capsule of the crystalline lens with no further consequences. In 14 (~10%) eyes, a statistically significant increase in IOP was found during the first month postoperatively. Intraocular pressure returned to preoperative levels at 3 months (6 patients were corticosteroid responders). One eye had pigment dispersion, high IOP, and PRL extraction 3 years postoperatively due to reverse PRL implantation (ie, the lens was implanted upside down). One eye experienced severe PRL decentration and subsequent extraction 3 years postoperatively (Fig 5).

DISCUSSION

In the current study, we evaluated the long-term

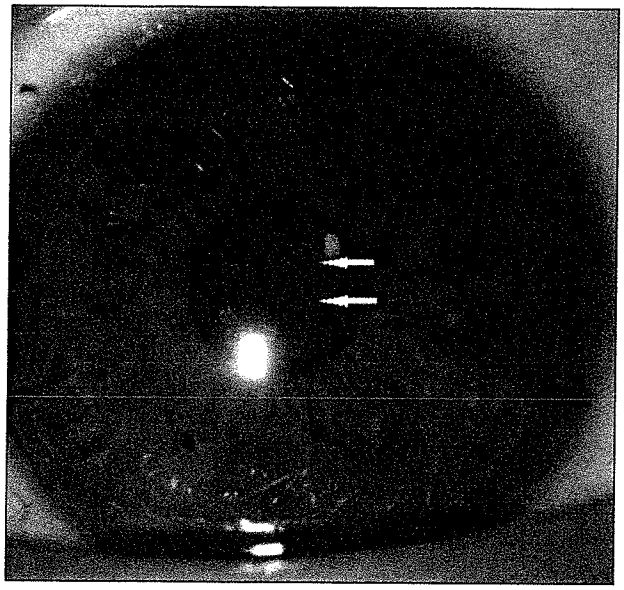

Figure 5. Slit-lamp photograph showing PRL decentration.

results of posterior chamber PRL implantation in highly myopic eyes. The PRL[10] design used in our study is an improved version of a 1987 Fyodorov[11] prototype made of silicone.

Six years postoperatively, efficacy, safety, stability, and predictability were adequately proven. At last follow-up, approximately 57% of eyes gained 1 to 4 lines of CDVA whereas mean UDVA improved significantly and mean cycloplegic spherical equivalent refraction was significantly reduced. Our results are similar in respect to other posterior chamber lenses.[12-18]

A slight difference is present in the predictability results of our patient series in comparison with the US Food and Drug Administration clinical trials of the ICL, as reported in the 2- and 3-year results.[17,18] Predictability results with the ICL seem better, but this may be mainly attributed to the difference in the preoperative spherical equivalent refraction in both groups. In our study, mean spherical equivalent refraction was approximately −14.00 D compared to −10.00 D in the ICL group. Because high myopes do not always provide accurate refractions, this might influence the final predictability result.

A small percentage (~8%) of our patients lost lines of CDVA at last follow-up (see Fig 2). This finding could be attributed to the myopic retinopathy that patients developed due to high myopia and is probably not correlated to the PRL implantation.

Regarding complications, those that were encountered in our study are similar to the complications included in the report of the American Academy of Ophthalmology.[19] In our study, only one PRL extraction 3 years after the original implantation was performed due to lens decentration and one was performed due to pigment dispersion and high IOP caused by reverse PRL implantation. The remaining complications, such as postoperative IOP increase, were managed without the need for further surgical intervention.

No eye experienced luxation in the vitreous. Dislocation of the PRL in the vitreous cavity is a potentially severe complication,[20-22] which can occur in high myopes, especially in cases with previous unrecognized ocular trauma or intraoperative manipulations resulting in spontaneous PRL decentration. The cases reported in the literature suggest that PRL rotation causes excess pressure against the zonules.[20-22] Pars plana vitrectomy and removal of the PRL are essential to manage this serious complication.

An important limitation of our study is the lack of information regarding endothelial cell loss after PRL implantation. Other studies mention inevitable endothelial cell loss during posterior chamber PIOL implantation, which varies between 2.1% and 7.6%.[23,24] After ICL implantation, a decrease of endothelial cells (12.3%) has been reported, but stability in size and morphology has been noted 4 years postoperatively.[25]

Long-term results suggest that PRL implantation is an effective, predictable, stable, and safe method for the treatment of high myopia.

AUTHOR CONTRIBUTIONS

Study concept and design (D.M.P., M.I.K.); data collection (S.I.P., M.A.G.); analysis and interpretation of data (G.D.K., I.G.P.); drafting of the manuscript (D.M.P., S.I.P., M.A.G.); critical revision of the manuscript (G.D.K., M.I.K., I.G.P.); statistical expertise (S.I.P.); supervision (G.D.K., M.I.K., I.G.P.)

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Phakic intraocular lenses

Part 2: Results and complications

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The second part of a review of phakic intraocular lenses (pIOLs) addresses results and complications with current pIOL models. Phakic IOLs demonstrate reversibility, high optical quality, potential gain in visual acuity in myopic patients due to retinal magnification; correction is not limited by corneal thickness or topography. With proper anatomical conditions, pIOLs also show good results in hyperopic patients. Toric pIOL designs enable spherocylindrical correction. Complications are rare and primarily related to pIOL position and type. The main complications of angle-supported anterior chamber pIOLs are glare and halos, pupil ovalization, and corneal endothelial cell loss; of iris-fixated anterior chamber pIOLs, chronic subclinical inflammation, corneal endothelial cell loss, and dislocation or pupillary block glaucoma; and of posterior chamber pIOLs, anterior subcapsular cataract formation, pigment dispersion, and luxation or pupillary block glaucoma. No causative relationship between pIOL implantation (of any pIOL type) and retinal detachment has been established.

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Implantation of intraocular lenses in the phakic eye (pIOL) is a relatively new technique to correct high ametropia. Time between the introduction of new pIOL designs is short; thus, experience with a new pIOL is short when the pIOL is implanted. New pIOLs are presented to overcome specific complications of older pIOLs. Currently, many studies with short follow-up and various case reports addressing results and complications of pIOLs have been published, but there are few long-term studies of pIOLs that have been on the market for some time. This second part of the pIOL review reassesses the published data about results and complications of currently available pIOLs. The results of pIOLs that have been withdrawn from the market are not discussed. As in Part 1,[1] results and complications are shown for each type of pIOL: angle-supported anterior chamber, iris-fixated anterior chamber, and posterior chamber.

Journal articles were considered for this review article after a thorough literature search. A Medline (National Library of Medicine, Bethesda, Maryland, USA) search from 1994 to 2009 was performed to identify all articles describing pIOLs. The terms *intraocular lens* and *intraocular lens implantation* from the Medical Subject Headings (MeSH) and the text word "phakic" were used for a broad and sensitive search. Five other searches were performed to look for additional articles (using the text words "phakic" and "lens," "phakic" and "IOL," "anterior chamber lens," "iris fixated lens," and "posterior chamber lens." All abstracts from the Medline search were read to identify articles that were pertinent to clinical results, surgical techniques, or complications of anterior chamber, iris-fixated, and posterior chamber pIOLs. Copies of the articles were obtained and the bibliographies searched manually for additional articles published in peer-reviewed journals. Complete articles were reviewed

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to identify those that reported original clinical data or complication(s) of pIOLs. Articles that covered previously published cases were included if they added new cases or up-to-date results.

FUNCTIONAL RESULTS OF pIOLs

To provide an overview, results of published data for the pIOL types are shown in Tables 1 to 3.

Results of Angle-Supported Anterior Chamber pIOLs

Visual acuity, predictability, efficacy, and safety of the Baikoff ZB5M (Domilens Corp.), Kelman Duet ZSAL-4 (Tekia, Inc.), I-Care (Corneal Laboratories, Inc.), Vivarte (Ioltech), and AcrySof Cachet (Alcon, Inc.) pIOL models are shown in Table 1.[2–11] For the Vivarte pIOL, results of only the refractive bifocal Vivarte pIOL are included.[10] At the time this review was written, no peer-reviewed studies of the ThinPhAc (Thin Opt-X) and Vision Membrane (Vision Membrane Technology) pIOLs had been published. Despite the long period in which anterior chamber pIOLs have been available, few long-term studies exist.[3,4] Anterior chamber pIOLs generally demonstrate good predictability, efficacy, and safety. However, there is a tendency toward undercorrection of the refractive error.

Results of Iris-Fixated Anterior Chamber pIOLs

Visual acuity, predictability, efficacy, and safety of the Artisan (Ophtec BV)/Verisyse (Abbott Medical Optics, Inc.), toric Artisan/Verisyse, and Artiflex/Veriflex iris-fixated anterior chamber pIOL models are shown in Table 2.[9,12–39] Several studies have long follow-up. The nontoric and toric models demonstrate good predictability, efficacy, and safety. With the toric pIOL models, larger amount of preoperative astigmatism can be managed successfully. Several studies address clinical outcome after toric pIOL implantation.[27,30,36,37,39] Recently, Güell et al.[27] reported a larger series with a mean follow-up of 3 years after implantation of the toric Artisan pIOL. The toric Artiflex is currently undergoing a multicenter clinical trial; it has shown excellent interim efficacy and safety results in the first 6 months of follow-up.

Results of Posterior Chamber pIOLs

Visual acuity, predictability, efficacy, and safety of the implantable Collamer Lens (ICL) (Staar Surgical Co.) and the Phakic Refractive Lens (PRL) (Carl Zeiss Meditec) posterior chamber pIOL models are shown in Table 3.[3,18,33,40–67] The safety and efficacy of these 2 pIOL models are good. In a United States Food and Drug Administration (FDA) study, the ICL pIOL showed good functional results with a low complication rate.[41] In a prospective study comparing matched populations of laser in situ keratomileusis (LASIK) and Visian ICL implantation, the ICL performed better than LASIK in almost all measures of safety, efficacy, predictability, and stability.[54] In a few case reports, results with the toric posterior chamber pIOL have been shown.[59,68,69] Schallhorn et al.[56] report better results with the toric ICL than with conventional photorefractive keratectomy in a randomized prospective comparison of safety, efficacy, predictability, and stability.

In summary, pIOLs show good refractive and clinical results. They demonstrate reversibility, high optical quality, potential gain in visual acuity in myopic patients due to retinal magnification, and correction is not limited by corneal thickness or topography. With proper anatomical conditions (especially sufficient anterior chamber depth [ACD]), pIOLs also show good refractive and clinical results in hyperopic patients.[70] Phakic IOLs preserve corneal architecture, asphericity, and accommodation. With recent innovations in the design of toric pIOLs, spherocylindrical correction is also feasible. However, pIOL implantation is not without complications. The spectrum of common and rare complications with each type of pIOL is presented in the following section.

COMPLICATIONS OF pIOLs

General Complications of Intraocular Surgery

With the increasing use of topical or parabulbar anesthesia, complications due to anesthesia such as retrobulbar hemorrhage, penetration of the globe, or life-threatening systemic side effects from accidental injection into the optic nerve are very rare. Because implantation of a pIOL is an intraocular procedure, it bears a potential risk for the development of postoperative endophthalmitis. The risk for this complication in general cataract surgery with implantation of a posterior chamber IOL is 0.1% to 0.7% with an optimal antiseptic perioperative treatment regimen.[71] Recently, a prospective randomized multicenter study by the European Society of Cataract and Refractive Surgeons[72] showed that an additional intracameral application of cefuroxime after cataract surgery significantly reduced the rate of postoperative endophthalmitis. Only one case of postoperative endophthalmitis after pIOL implantation has been reported.[73] In this case, endophthalmitis developed on the first day after anterior chamber pIOL implantation and was caused by β-hemolytic streptococci. Intraoperative sterility and meticulous postoperative follow-up examinations may help prevent this severe complication or enable early and aggressive treatment.

Table 1. Visual acuity, predictability, efficacy, and safety of angle-supported anterior chamber pIOLs.

					Efficacy				
Type of pIOL/Study*	Number of Eyes	Follow-up (Mo)	Mean Preop SE	Mean Postop SE	Postoperative ±0.5 D [%]	Postoperative ±1.0 D [%]	Postoperative UCVA ≥ 1.0 [%]	Postoperative UCVA ≥ 0.5 [%]	Efficacy Index
ZB5M									
Baikoff[2]	133	6–36	−12.5	−1.3	40	65	No data	No data	No data
Utine[3]	37	24–145	−17.45	−1.76	No data	No data	No data	No data	0.79
Javaloy[4]	225	12–144	−17.23	−1.80	No data	39.28	No data	34.69	1.26
ZSAL-4									
Pérez-Santoja[5]	23	24	−19.56	−0.55	56.5	82.6	0	54.5	1.12
Leccisotti[6]	12	12	−10.23 (keratoconus)	−1.31	67	100	0	100	0.77
Leccisotti[7]	190	12	−14.37	1.55	19	40	~7	~60	0.78
Kelman Duet									
Alió[8]	169	1–12	−14.26	−0.15	57.72	81.30	28.68	83.72	1.19
I-CARE									
Gierek-Ciacura[9]	20	12	−15.76	No data	85	100	No data	85	1.58
Vivarte Presbyopic									
Baikoff[10]	55	0.5–21	+1.8 (-5 to +5)	−0.12	No data	No data	No data	84 (≥ 0.6)	0.80
AcrySof									
Kohnen[11]	190	12	−10.38	−0.23	72.7	95.7	85.7	No data	1.04

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*First author

Angle-Supported Anterior Chamber pIOL Complications

Loss of Corneal Endothelial Cells The main concern with anterior chamber pIOLs is the loss of corneal endothelial cells or damage to the endothelial integrity (Figure 1). Excessive corneal endothelial cell loss was, along with pupil ovalization, the main reason for recalling several anterior chamber pIOLs from the market, as described in part 1. Exact preoperative examination should exclude patients with low corneal endothelial cell counts or with shallow anterior chambers because the risk to corneal endothelial cells increases as the distance between the pIOL and the endothelium decreases. In a 7-year follow-up study, Alió et al.[74] report an early postoperative loss of corneal endothelial cells of 3.8%, gradually decreasing to about 0.5% per year after the second postoperative year. In this study, the ZB5M/ZB5MF was evaluated for the full 7 years and the ZSAL-4, for only 4 years. The percentage of corneal endothelial cell loss over 7 years was 8.4%. Other studies have confirmed the initial significant corneal endothelial cell loss and the reduction of this tendency in the second postoperative year.[2,5,75] At 2 years, the corneal endothelial cell loss was 12% for the NuVita pIOL (Bausch & Lomb) and 4.2% for the ZSAL-4; at 3 years, it was 4.8% for the ZB5M. In a study of the reasons for pIOL explantation by Alió et al.,[76] corneal endothelial cell loss was the cause in 24%. In the study with the longest follow-up (up to 12 years) after pIOL implantation, Javaloy et al.[4] report an initial reduction in corneal endothelial cells of 10.6% in the first year followed by a mean annual decrease rate of 1.8% after ZB5M pIOL implantation. The mean corneal endothelial cell loss after implantation of an I-Care pIOL was 6.1% after 1 year, as reported by Gierek-Ciaciura et al.[9] All these anterior chamber pIOLs except the I-Care were poly (methyl methacrylate) (PMMA) rigid IOLs.

In a study of the new flexible anterior chamber pIOL by Baikoff et al.,[10] the corneal endothelial cell loss 1 year after implantation of the Vivarte pIOL was less than 5.0%, but there was a difference between the loss in myopic eyes (2.3%) and that in hyperopic eyes (5.4%). For the AcrySof foldable anterior chamber pIOL, the corneal endothelial cell loss was 4.8% after a 1-year follow-up.[11] In this context, a recent study by Kohnen and Klaproth[77] reports a stable adequate central clearance distance between the AcrySof pIOL and the corneal endothelium over a period of 3 years using Scheimpflug imaging. However, meticulous long-term follow-up of each patient with an anterior chamber pIOL is necessary to detect patients who have significant damage to the endothelium and explant the pIOL whenever clinically necessary.

Pupil Ovalization/Iris Retraction Ovalization of the pupil is a specific complication of anterior chamber pIOLs (Figure 2). The position of haptics in the

Table 1. (Cont.)

Safety					
Loss of 2 or More Lines of CDVA (%)	Loss of 1 Line of CDVA (%)	No Change in CDVA	Gain of 1 Line of CDVA (%)	Gain of 2 or More Lines of CDVA (%)	Saftey Index
No data	No data	No data	No data	No data	No data
3.2	No data	No data	No data	29.8	1.45
3.5	~7	~23	~21	~25	1.50
0	No data	82.6	No data	No data	1.45
0	0	40	50	10	1.18
0	0	~25	~25	~40	1.25
0	~5	~27	~11	56.20	1.37
0	0	5	25	70	No data
No data	No data	No data	No data	No data	0.94
0	1.2	44.7	31.1	23.0	1.25

sclerocorneal angle and their size might lead to mild deformation of the iridosclerocorneal architecture, resulting in iris retraction and pupil ovalization. Alió et al.[74] report mild deformation of pupil shape in 10.3%, which did not affect the refractive, cosmetic, or optical results of surgery.

Severe ovalization causes glare and is unacceptable from a cosmetic point of view. Alió et al.[74] observed this condition in 5.9% of the eyes; it led to pIOL explantation in 2 cases. Allemann et al.[75] report 8 oval pupils in a series of 21 eyes. Pérez-Santonja et al.[5] observed 4 cases in a series of 23 eyes. Leccisotti and Fields[78] report pupil ovalization not associated with any photic phenomena in 11% of eyes after ZSAL-4 anterior chamber pIOL implantation. Javaloy et al.[4] report a cumulative incidence of 34.7% of pupil ovalization after ZB5M implantation within 12 years of follow-up. In an analysis of a series of anterior chamber pIOL explantations (ZB5M pIOL) by Alió et. al.,[76] marked pupil ovalization extending beyond the edges of the pIOL was the reason for pIOL removal in 10% of cases. For the novel AcrySof anterior chamber pIOL implanted in 190 eyes, no case of pupil ovalization was reported.[11] Iris retraction with oval pupil deformation remains primarily a concern of anterior chamber pIOLs. This together with potential damage to endothelial cells are the major objections to the anterior chamber pIOL design.

Topical use of miotic agents should be considered in the early postoperative phase if pupil ovalization associated with glare is detected. Minor pupil ovalization requires observation only, but gross ovalization indicates entrapment of the iris root and ovalization may become irreversible if the pIOL is not explanted promptly.

Optical Quality, Glare, Halos One disadvantage of anterior chamber pIOLs is that they are positioned in front of the pupil, with edge effects a potential source of optical aberrations. Furthermore, the relationship between pupil size and the center of the pIOL optic is a crucial factor that should be evaluated and discussed preoperatively. Sometimes the anterior chamber pIOL optic center and the pupil center are not coincident. If the scotopic pupil size is significantly larger than the optic of the pIOL, one should be very cautious about implanting a pIOL because it will probably result in postoperative glare and subjective discomfort. The incidence of glare is dependent on the size and position of the optic, which varies in different IOL designs and generations. A study by Maroccos et al.[79] shows that all tested types of pIOLs, in particular posterior chamber pIOLs and anterior chamber pIOLs, lead to decreased nighttime visual performance due to glare and halos.

Topical use of miotic agents should be considered in the early postoperative period if the patient is disturbed by glare and halos. A study of the effects of pIOL implantation on contrast sensitivity showed

Table 2. Visual acuity, predictability, efficacy, and safety of iris-fixated anterior chamber pIOLs.

Type of pIOL/Study*	Number of Eyes	Follow-up (Mo)	Mean SE Preop	Efficacy					
				Postop	Postoperative ±0,5 D [%]	Postoperative ±1,0 D [%]	Postoperative UCVA ≥ 1.0 [%]	Postoperative UCVA ≥ 0.5 [%]	Efficacy Index
Artisan/Verisyse									
Alexander[12]	264	6	−12.76	−0.35	No data	No data	No data	100	No data
Budo[13]	249	6–36	−12.95	−0.6	57	79	34	76.8	1.03
Landesz[14]	67	6–36	−14.70	No data	No data	67	No data	40.9	No data
Landesz[15]	78	6–24	−17.00	−2.0	50	68	30	73	No data
Maloney[16]	155	0.5–6	−12.69	−0.54	55	90	26	83	No data
Malecaze[17]	25	12	−10.19	−0.95	24	60	No data	60	0.71
Menezo[18]	137	38–154	−16.17	−0.78	No data	No data	4	81	No data
Lifshitz[19]	31	3	−11.25	−0.50	67.8	96.8	93.5	No data	0.95
Benedetti[20]	68	4–24	−11.8	−0.91	44.1	69.1	25	83.8	0.84
Benedetti[20]	25	4–24	−18.9	−1.20	32	52	8	68	0.90
Senthil[21]	60	24	−12.5	No data	73.3	90	5	75	0.93
Coullet[22]	31	12	−10.3	−1.01	No data	58	No data	51.6	0.60
Moshirfar[23]	85	6–24	−12.2	−0.50	55	84	10	84	No data
Gierek-Ciacura[9]	20	12	−15.73	No data	65	95	No data	80	1.71
Tahzib[24]	89	60	−10.36	−0.70	43.8	68.8	No data		0.80
Stulting[25]	662	12–36	−12.3	No data	71.7	94.7	34.6	88	No data
Silva[26]	26	12–60	−12.30	−0.44	74	95	74	95	No data
Güell[27]	101	12–60	−19.8	−0.50	9.9	22.8	No data	14.8	0.86
Güell[27]	173	12–60	−11.27	−0.64	37.6	57.2	2.9	42.8	0.74
Fechner[28]	67	12–120	+9.98	0.07	No data	No data	~1.5	~35	No data
Alió[29]	29	12–24	+6.06	0.1	79.3	96.6	6.9	65.5	0.83
Alió[29]	28	12–24	+5.88	0.55	50	71.4	3.6	46.4	0.70
Dick[30]	22	6	+3.25	−0.24	50	100	18	96	No data
Saxena[31]	17	3–36	+6.8	−0.03	59	81	58.8	94	No data
Pop[32]	19	1–2	+5.89	−0.03	50	78	No data	89	No data
Güell[27]	41	12–60	+4.92	−0.02	34.8	64.2	0	42.8	0.9
Boxer Wachler[33]	31	3	−12.31	−0.78	58	68	55	90	No data
Coullet[22]	31	12	−9.50	−0.58	No data	83.9	No data	77.4	0.79
Dick[34]	290	24	−7.33	−0.15	75.2	94.3	No data	97.2	1.00
Toric Artisan/ Verisyse									
Tehrani[35]	29	6	−1.9	−0.56	No data	95	No data	~85	No data
Dick[30]	70	6	−3.74	−0.7	72	100	10	88.6	1.03
Güell[36]	27	12	−3.43	No data	62.9	96.2	No data	No data	No data
Alió[37]	8	6–12	Mixed astigmatism +3.6	+0.40	75	87.5	12.5	87.5	1.0
Alió[37]	8	6–12	Myopic astigmatism −8.6	−1.1	62.5	75	12.5	62.5	1.2
Alió[37]	9	6–12	Hyperopic astigmatism +5.9	+0.50	44.4	77.8	33.3	66.6	1.0
Güell[27]	84	12–48	−0.09	No data	66.6	81.3	7.1	65.4	0.93
Toric Artisan/Verisyse post keratoplasty									
Nujits[38]	16	3–18	−6.6	−1.42	0	31.25	0	50	No data
Toric Artisan in keratoconus									
Venter[39]	18	6–12	−4.64	−0.46	No data	78	22	100	No data

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*First author

Table 2. (Cont.)

Safety					
Loss of 2 or More Lines of CDVA (%)	Loss of 1 Line of CDVA (%)	No Change in CDVA	Gain of 1 Line of CDVA (%)	Gain of 2 or More Lines of CDVA (%)	Saftey Index
6	6	6	72	22	No data
1.2	2	53		44	1.31
2.5		97.5			No data
2.6	6.4	63		28	No data
0	9.5	78.5		12	No data
0	12	64		24	1.12
0	0	14	23	62	No data
0	0	35.5	64.5	41.9	1.29
0	0	35	11	22	1.12
0	0	3	4	18	1.39
0	11.6	88.3			1.19
6.4	6.4	29.0	19.4	25.8	1.13
0	7	31	43	19	No data
0	5	20	10	65	No data
2.6	3.9	62.3	31.2		1.10
1.8	6.6	38.6	40.4	13.6	No data
0	~4	~23	~56	~17	No data
No data	No data	No data	No data	No data	1.30
No data	No data	No data	No data	No data	1.04
0	~10	~73	~9	~8	No data
0	3.4	55.1	27.5	13.7	1.1
7.2	14.3	32.1	39.3	7.2	1.05
0	0	86		14	No data
0	17.6	82.4		0	No data
0	0	73.6	21	5.2	No data
No data	No data	No data	No data	No data	1.25
3	3	66	16	6	No data
9.7	0	29.0	22.6	25.8	1.12
0	9	51	33	7	1.09
No data	No data	No data	No data	No data	No data
0	0	35	65	0	1.25
0	11	19	70	0	1.40
0	0	4	2	2	1.3
0	1	0	1	6	1.6
2	1	3	1	2	1.3
No data	No data	No data	No data	No data	1.17
0	0	31.25	18.25	50	No data
0	0	28	39	33	No data

Table 3. Visual acuity, predictability, efficacy, and safety of posterior chamber pIOLs.

				Efficacy					
Type of pIOL/Study*	Number of Eyes	Follow-up (Mo)	Mean Preop SE	Mean Postop SE	Postoperative ±0,5 D [%]	Postoperative ±1,0 D [%] ≥	Postoperative UCVA ≥ 1.0 [%]	Postoperative UCVA ≥ 0.5 [%]	Efficacy Index
ICL									
Menezo[18]	21	11–21	−16.0	−1.60	No data	No data	0	76.2	No data
Sanders[40]	258	12	−10.05	−0.56	57.4	80.2	50.9	93.3	No data
Sanders[41]	369	36	−10.06	No data	67.5	88.8	40.8	81.3	No data
Uusitalo[42]	38	6–24	−15.1	−2.0	71.1	81.6	39.5	94.7	No data
Jimenez-Alfaro[43]	20	12–24	−14.1	−1.62	No data	20	No data	60	No data
Gonvers[44]	22	3–24	−11.5	−1.19	32	45	18	68	No data
Arne[45]	58	6–24	−13.85	−1.22	No data	56.9	No data	No data	0.84
Zaldivar[46]	124	1–36	−13.38	−0.78	44	69	2	68	No data
Rosen[47]	16	3	−9.28	−0.83	56.25	No data	25	56.25	No data
Rosen[47]	9	3	−15.4	0.3	88	No data	44.4	88.9	No data
Pineda-Fernandez[48]	18	12–36	−15.27	−0.62	No data	No data	5.5	44.4	No data
Lackner[49]	65	6–48	−16.23	−1.77	No data	42	No data	No data	No data
Pesando[50]	15	6–18	+7.77	0.02	69.25	92.3	0	46.15	No data
Davidorf[51]	24	1–18	+6.51	−0.39	58	79	8	63	No data
Lackner[49]	10	6–48	+7.88	0.44	No data	73	No data	No data	No data
Chang[52]	61	1–32	−14.53	−0.10	72.5	88.2	75	100	No data
Kamiya[53]	56	48	−9.83	−0.38	79	93	70	95	0.83
Sanders[54]	164	1–6	−6.01	−0.09	85	97	63	99	No data
Boxer Wachler[33]	30	3	−11.48	−0.40	88	100	67	100	No data
Rayner[55]	116	12	−8.83	No data	No data	100	78.5	100	No data
Rayner[55]	10	12	+4.25-8.88	No data	No data	100	78.5	100	No data
Toric ICL									
Schallhorn[56]	42	1–12	−8.04	−0.17	76	100	97	100	No data
Alfonso[57]	15	24	−7.08	−0.95	66.6	80	No data	46.6	1.02
Chang[58]	44	1–12	−12.81	No data	82.9	97.1	70.6	100	No data
Park[59]	30	1–18	−10.63	0.04	70	94	67	100	No data
PRL									
Pallilkaris[60]	34	12–24	−14.7	−0.61	44	79	No data	No data	No data
Hoyos[61]	17	12	−18.46	−0.22	53	82	No data	No data	No data
Verde[62]	90	12	−11.90	+0.04	68	80	~16	~92	0.98
Donoso[63]	53	8	−17.27	−0.23	No data	71.2	60	No data	1.0
Jongsareejit [64]	50	12	−12.54	−0.23	88	96	44	82	No data
Koivula[65]	14	24	−10.28	−0.38	79	100	50	100	0.98
Hoyos[61]	14	12	+7.77	−0.38	50	79	No data	No data	No data
Gil-Cazorla[66]	16	12	+5.65	+0.07	93.75	100	12.5	100	0.8
Koivula[65]	6	24	+5.67	−0.85	67	100	17	83	0.89
Koivula[67]	40	12	+5.90	−0.46	87.5	100	17.5	82.5	0.70
Fyodorov posterior chamber pIOL									
Utine[3]	14	24–132	−15.83	−0.71	No data	No data	No data	No data	1.0

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*First author

that in comparison to posterior chamber pIOLs, anterior chamber pIOLs and iris-fixated pIOLs led to improved contrast sensitivity at all frequencies.[80] With the AcrySof Cachet pIOL, no glare has been reported during a 1-year follow-up.[11]

Surgically Induced Astigmatism Surgically induced astigmatism (SIA) is significant because patients request acceptable uncorrected visual acuity. The surgeon needs to consider the preoperative amount and axis of astigmatism to decide whether to use a larger incision with a PMMA IOL or to implant a foldable pIOL such as the AcrySof Cachet through a small incision. If significant SIA is noted, further refractive surgical procedures might be

Table 3. (Cont.)

Safety					
Loss of 2 or More Lines of CDVA (%)	Loss of 1 Line of CDVA (%)	No Change in CDVA	Gain of 1 Line of CDVA (%)	Gain of 2 or More Lines of CDVA (%)	Saftey Index
0	0	9.5	19	71.4	No data
1.6	7.8	41.2	38.5	10.9	No data
0.8	No data	No data	No data	10.8	No data
0	6.3	18.8	31.3	40.6	No data
0	0	0	0	100	No data
0	0	9.1	90.9		No data
3	5	19	35	38	1.46
0.8	7	29	28	36	No data
0	6.25	50	37.5	6.25	No data
0	11.1	44.4	22.2	22.2	No data
5.5	0	55.5	5.5	33.3	No data
13.8		1.5	84.6		1.31
7.7	0	76.9	0	15.4	No data
4	0	33	29	8	No data
60		0	40		0.98
0	~3	~27	~62	~8	No data
0	9	32	46	13	1.19
0	4	52	41	3	No data
0	0	50	40	10	No data
0	0	38	62		No data
0	0	5	92	3	No data
0	0	54	13	33	1.58
0	2.2	58.2	31	8.6	No data
0	0	No data	No data	No data	No data
2.9	0	23.5	29.4	44.1	No data
0	0	35	47	18	No data
0	0	35	33	32	1.22
5.7	1.9	15.1	41.5	35.8	1.40
0	2	40	10	14	No data
0	No data	No data	No data	No data	1.18
0	7	86	7	0	No data
0	31.25	68.75	0	0	0.9
0	No data	No data	No data	No data	0.98
5.0	No data	No data	No data	0	0.89
9.1	No data	No data	No data	No data	1.21

considered. Irregular astigmatism due to large incisions too close to the corneal center should be avoided.[81]

Pigment Dispersion or Intraocular Lens Deposits Although no incidence of pigment dispersion or deposits on the IOL are reported, these conditions are seen in clinical practice (Figure 3). However, they do not usually negatively affect visual acuity and, thus, no further procedure is required. Besides pigment dispersion, intraoperative hemorrhage (Figure 4) may lead to erythrocyte deposits on the pIOL and intraocular pressure (IOP) elevation. Bleeding originates from vessels in the scleral tunnel or from the intraoperative iridectomy.

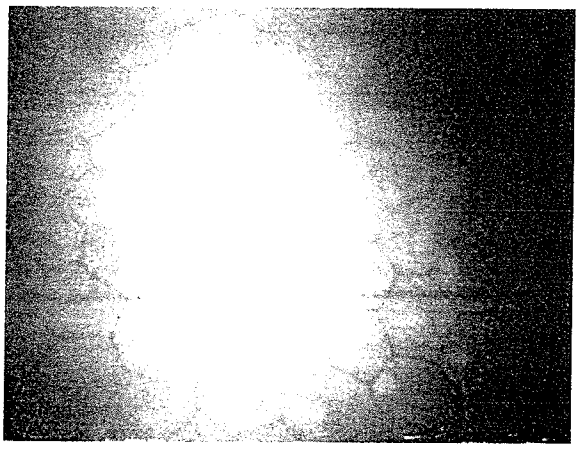


Figure 1. Confocal microscopic image of the endothelium showing endothelial cell loss after implantation of an anterior chamber pIOL (700 cells/mm^2).

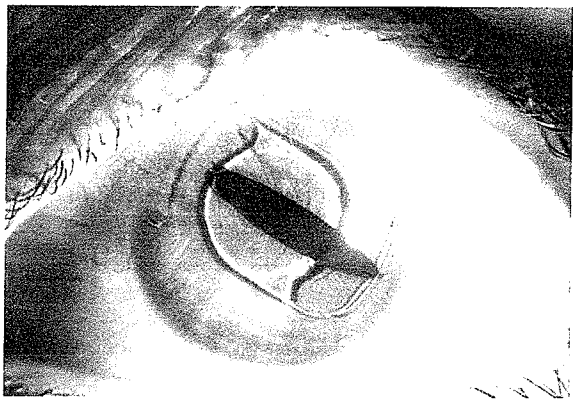


Figure 2. Severe cat-pupil ovalization following anterior chamber pIOL implantation (courtesy of J. Alió, Alicante, Spain).

Chronic Inflammation or Uveitis The first paper that described breakdown of the blood–ocular barrier was published by Alio et al. in 1993 after implantation of anterior chamber pIOLs.[82] As anterior chamber pIOLs are positioned directly in front of the iris, chronic inflammation and development of pigment dispersion is possible as pupil movement can induce some friction with the pIOL. Pérez-Santonja et al.[5] report a rate of 8.7% of eyes presenting with slight chronic inflammation during the first 6 months after ZSAL-4 IOL implantation. Allemann et al.[75] removed 1 of the 21 implanted pIOLs because of a chronic postoperative inflammatory response associated with ocular hypertension. Alió et al.[74] observed acute postoperative iritis in 4.6% of 263 anterior chamber pIOLs (ZSAL-4 and ZB5M). Leccisotti[7] reports an incidence of 3.1% of clinically significant iridocyclitis that appeared within 1 to 31 months of ZSAL-4 implantation. Van Cleynenbreugel[83] report one case of late intrapupillary membrane formation and chronic uveitis associated with corneal endothelial cell loss years after backward implantation of Vivarte anterior chamber pIOLs. Removal of the pIOL led to recovery of visual acuity. As with other complications, if conservative topical treatment does not succeed, removal of the pIOL should be considered to avoid long-term risks.

Intraocular Pressure Elevation/Pupillary Block Glaucoma The risk for acute pupillary block glaucoma is well known from aphakic anterior chamber IOLs; therefore, a peripheral iridectomy is recommended.

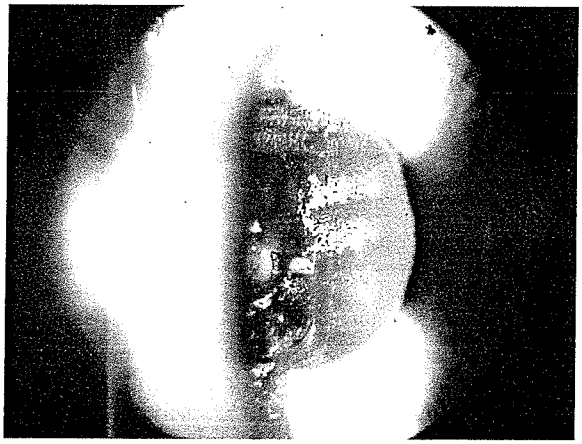


Figure 3. Protein deposits on an anterior chamber pIOL in a 34-year-old woman 1 month postoperatively.

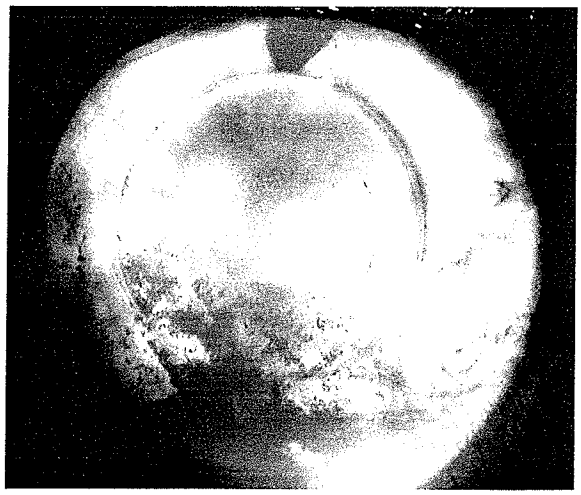


Figure 4. Anterior chamber hemorrhage after anterior chamber pIOL implantation (courtesy of E. Rosen, Manchester, United Kingdom).

Anterior chamber pIOLs have at least the same risk for acute glaucoma, primarily because the continuously growing crystalline lens is still inside the eye. Ardjomand et al.[84] observed one case of pupillary block after implantation of an anterior chamber pIOL that was successfully treated with a neodymium:YAG (Nd:YAG) iridotomy. Leccisotti and Fields[78] report a 3.0% rate of pupillary block 6 hours after anterior chamber pIOL implantation caused by incomplete iridectomy with uninterrupted pigment layer. Kohnen et al.[11] report no case of pupillary block after AcrySof foldable pIOL implantation. Moreover, increased IOP for a period of at least one month after surgery that required treatment was noted in only 3.2% of cases. Of note, iridotomy was only performed in 5 of 190 surgeries.

Two steps are recommended to prevent acute pupillary block glaucoma for angle-supported and other types of pIOLs. All the ophthalmic viscosurgical device (OVD) must be removed from the anterior segment at the end of surgery. In addition, a preoperative iridotomy using a laser or an intraoperative surgical iridectomy to forestall acute pupillary block glaucoma is mandatory. Particularly with foldable anterior chamber pIOLs, the need for a peripheral iridectomy has been discussed by experienced refractive intraocular surgeons. For the latest AcrySof pIOL, however, peripheral iridectomy does not seem to be mandatory, even though reports of acute angle-closure or pupillary block glaucoma have been published.[11] These cases might be attributed to incomplete OVD removal. Javaloy et al.[4] report a mean difference between preoperative and 12-year postoperative IOP of only 2 mm Hg. Prolonged therapy with antiglaucomatous medication was used in only 5 of 225 eyes during the complete follow-up in this study. Other factors of postoperative elevated IOP may be the steroid medication. Leccisotti and Fields[78] report steroid-related IOP elevation in 14% after ZSAL-4 implantation. Intraocular pressure elevation should be carefully observed and treated, with conversion to nonsteroidal antiinflammatory drugs and topical medication. Otherwise, if chronic IOP elevation develops, the anterior chamber angle should be examined to rule out synechiae formation and other pathologies. Removal of the pIOL should be considered, if necessary.

Phakic Intraocular Lens Rotation Rotation of an anterior chamber pIOL might occur because of undersizing. Allemann et al.[75] report that 80% of eyes showed greater than 15 degrees of rotation by 2 years; in 60% the rotation occurred between 1 year and 2 years, implying some instability in the anterior chamber. Pérez-Santonja et al.[5] observed rotation in 43.5% of 23 treated eyes. With the AcrySof pIOL, most eyes (71.1%) did not show an IOL rotation of more than 15 degrees but 28.9% did. However, IOL rotation was not associated with any clinical sequelae in these cases.[11]

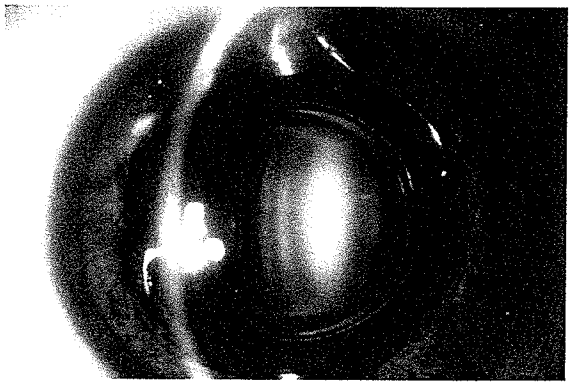


Figure 5. Nuclear cataract in an eye with an anterior chamber pIOL (courtesy of J. Alió, Alicante, Spain).

Cataractogenesis As the position of anterior chamber pIOLs is away from the lens, the formation of cataract is less significant than with a posterior chamber pIOL (Figure 5). Since cataract formation is more frequent in highly myopic patients than in the general population, discriminating between myopia-associated cataract formation and surgically triggered or hastened cataract is difficult. Alió et al.[74] report 9 cataract removals during a 7-year follow-up (3.4%). Cataracts were nuclear, and calculated survival curves for cataract development indicate that more than 90% of patients would be expected to remain free from cataract after 98 months. The same authors report that cataractogenesis seems to be increased in patients older than 40 years with an axial length longer than 29 mm.[85] A metaanalysis of cataract development after pIOL implantation reports that 15 of 1161 eyes developed new-onset cataract.[86] Of these, 9 were nuclear sclerotic, 3 were nonprogressive posterior subcapsular cataract, 2 were nonprogressive anterior subcapsular cataract, and 1 was both anterior and posterior subcapsular cataract. The total incidence of cataract formation for anterior chamber pIOLs was 1.3%. The incidence was 2.6% for the ZB5M anterior chamber pIOL and 0.6% for the ZSAL-4 anterior chamber pIOL; no cataracts were reported in eyes with the ZB, the Newlife/Vivarte Presbyopic, or the AMO multifocal prototype pIOLs.[86] With the novel AcrySof Cachet, the incidence of cataract formation was 2.6%. In 1.0% of the eyes, cataract formation was secondary to concurrent ophthalmic disease.[11] A recent study by Kohnen and Klaproth[77] using Scheimpflug imaging reports a stable distance between the AcrySof pIOL and the crystalline lens over a period of 3 years. Excessive postoperative

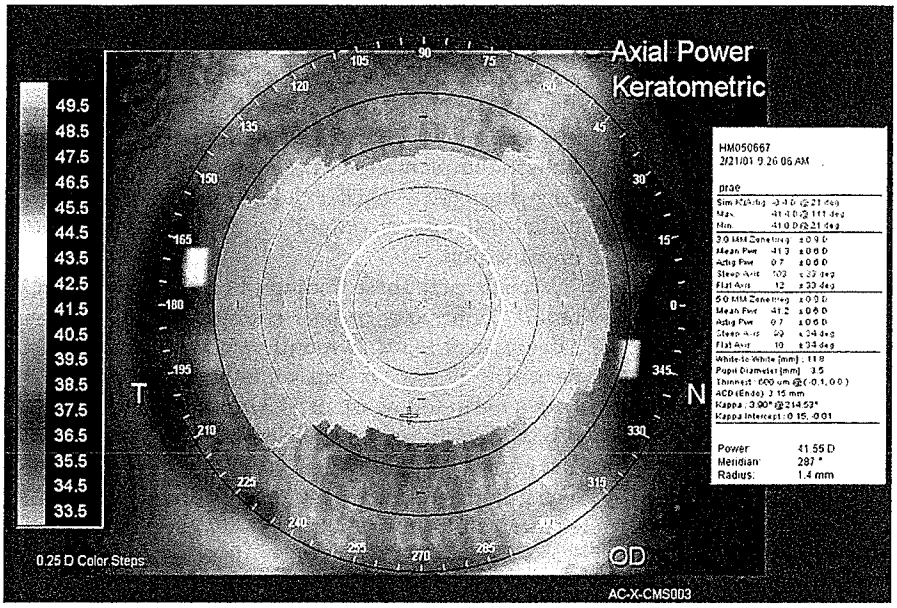
use of steroids should be avoided because of the potential risk for delayed cataract formation.[87]

Retinal Detachment Ruiz-Moreno et al.[88] report a retinal detachment (RD) rate of 4.8% 1 to 44 months after anterior chamber pIOL implantation (ZB5M and ZB5MF). In this study, no correlation between axial length and the incidence of RD was reported. The mean preoperative refraction was −18.6 diopters (D) and the mean axial length, 29.5 mm. Patients in this myopic range have been shown to have a 15 to 110 times higher risk generally than emmetropic patients for spontaneous RD.[89] Ruiz-Moreno et al.[88] also state that the time lapse between pIOL implantation and RD (mean 17.4 months) makes it difficult to infer that intraoperative hypotony with imbalance in premature degenerated vitreous structures played a role in the development of RD. In the study analyzing causes of anterior chamber pIOL explantation by Alió et al.,[76] one case of RD was noted and the pIOL had to be removed to enhance fundus visualization for retinal surgery. In a recent study reporting outcomes up to 12 years after ZB5M implantation by Javaloy et al.,[4] no case of RD was noted. For the novel AcrySof pIOL, no case of RD has been reported to date.[11]

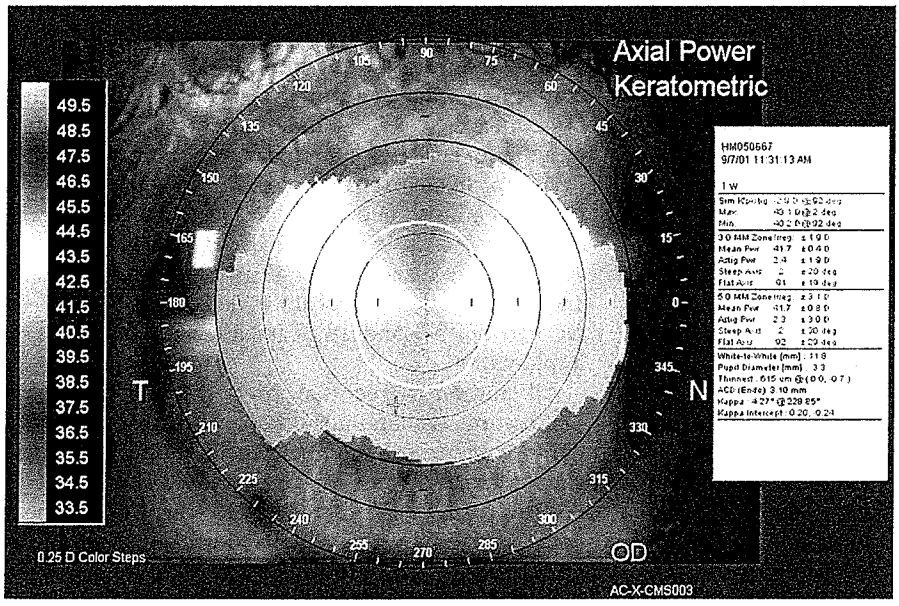
Oddities Urrets-Zavalia syndrome, fixed dilated pupil, iris ischemia, and IOP of 60 mm Hg despite a permeable surgical iridectomy after anterior chamber pIOL implantation were reported as a single case report by Yuzbasioglu et al.[90] in a 26-year-old highly myopic patient 1 day after surgery. In this case report, the type of pIOL is unfortunately not stated. Spontaneous macular hemorrhage has been reported in 2 eyes.[78] In these cases, repeat fluorescein and indocyanine angiography did not show a neovascular membrane and spontaneous improvement occurred. Also, incorrect power or upside-down placement is one possible complication that might cause secondary complications such as cataract formation. This complication is reported in 2 of 190 cases in the study by Kohnen et al.[11] after implantation of the AcrySof Cachet pIOL. A recent modification (marking) of this pIOL might prevent this complication in the future.

Iris-Fixated Anterior Chamber pIOL Complications

Optical Quality, Glare, Halos A pIOL can be implanted in eyes with large scotopic pupil diameters because of the mean age of preponderantly young patients. This can result in glare phenomena if the pupil is larger than the IOL optic. Glare and halos affect night vision and driving and are therefore important considerations in pIOL implantation. A study by Maroccos et al.[79] shows significantly less glare and halos with the Artisan pIOL than with other pIOLs (anterior chamber pIOL NuVita and posterior chamber pIOL ICL), especially the 6.0 mm optic. This was attributed to the larger optic (6.0 mm versus 5.0 mm) and the fixation of the IOL to the iris, which causes less pupil dilation. Therefore, the 6.0 mm optic iris-fixated pIOL seems to be preferable to the 5.0 mm optic. However, it is not always possible to implant this optic because of the greater thickness of the optic with higher corrections and the possible damage to the corneal endothelium in a given ACD. The power of the 6.0 mm optic has an upper limit of -15.5 D for myopia. The range of the 5.0 mm optic is +1.0 to +12.0 D for hyperopia. Menezo et al.[91] describe a case of permanent wide dilation of the pupil, causing decreased postoperative visual acuity because of glare. Landesz et al.[14] report 2 of 38 patients that required pilocarpine eyedrops because of halos after implantation of the 5.0 mm optic Artisan IOL. Maloney et al.[16] report mild to moderate glare in 18 eyes (13.8%) and severe glare in 1 eye (0.8%) of 130 eyes. In 3 eyes, an IOL with a 5.0 mm optic was exchanged for an IOL with a 6.0 mm optic, with no glare noticed afterward. Senthil et al.[21] report no glare and halos after implantation of the Artisan pIOL in 60 myopic eyes, probably because Indian eyes generally have smaller pupils than white eyes. Moshirfar et al.[23] report an incidence of 6.0% of glare and halos 1 month after Artisan/Verisyse implantation, which decreased to 2.7% at 2 years follow-up. In a recent study by Stulting et al.[25] analyzing the 3-year results of the Artisan/Verisyse pIOL, no contrast sensitivity decrease was seen. In this prospective study, patients with a mesopic pupil greater than the pIOL optic were not included; 80% of the pIOLs had a 6.0 mm optic and only 20% had a 5.0 mm optic. A study by Chung et al.[92] shows that Artisan pIOLs do not alter higher-order aberrations (HOAs) significantly, a finding comparable to that of Chandhrasri et al.,[93] who report a small increase in HOAs under photopic conditions after Verisyse pIOL implantation. One study investigating HOAs shows that after Artiflex pIOL implantation, postoperative trefoil increased and spherical aberration decreased.[94] The authors report a significant correlation between pIOL decentration and postoperative spherical aberration and coma. However, both trefoil and spherical aberration increased in the Artisan pIOL group postoperatively. Different incision sizes may explain differences in trefoil, whereas the different optic design of the two pIOLs seems to affect spherical aberration.[93,94] Bühren and Kohnen[81] report slightly increased HOAs after Artisan pIOL implantation,with induction of trefoil as a result of the incision and increase in spherical aberration from the pIOL. Cisneros-Lanuza et al.[95] report some degree of lenticular glistenings in 20% of the eyes



A



B

Figure 6. Induction of corneal SIA due to a 6.0 mm superior limbal incision (35-year-old man). *A*: Preoperative topography. *B*: Corneal topography 6 months postoperatively.

after Artiflex IOL implantation. Glistenings were noted from 6 days to 6 months after surgery, and neither decreased over time nor affected visual acuity or caused complaints.

Surgically Induced Astigmatism Because the PMMA iris-claw IOL (Artisan/Verisyse) is not foldable, it requires an incision that approximately equals the optic diameter (5.0 or 6.0 mm), which may induce SIA (Figure 6). According to the literature, SIA after the 5.0 to 6.0 mm incisions is less than one might expect. Menezo et al.[91] report no significant increase in postoperative astigmatism. Alió et al.[29] report a mean SIA of 1.48 D ± 0.89 (SD) for the hyperopic Artisan IOL with correction of primary hyperopia and 1.85 ± 1.19 D with correction of secondary hyperopia after corneal refractive surgery. Maloney et al.[16] report a mean decrease in astigmatism of 0.3 D after 6 months. Stulting et al.[25] report a change of more than 2.0 D cylinder in 3.5% of eyes 3 years after Artisan/Verisyse implantation and secondary refractive procedures had to be performed in 6.9% of eyes during the

follow-up. The foldable Artiflex/Veriflex further reduces SIA. In a prospective randomized study comparing the Artisan pIOL in one eye and the Artiflex pIOL in the other eye, the mean refractive cylinder power of the Artiflex pIOL was significantly lower than that of the Artisan pIOL, -0.56 ± 0.47 D and -1.02 ± 0.63 D, respectively.[22] The mean SIA was 0.29 ± 1.67 D and 0.73 ± 2.9 D, respectively, which was close to statistical significance ($P = .07$). In another study, SIA after Artiflex implantation was 0.42 D.[96] In a later report, the mean SIA 2 years after Artiflex pIOL implantation was only 0.33 D.[34]

Loss of Corneal Endothelial Cells Damage to the corneal endothelium may be due to direct contact between the pIOL and the inner surface of the cornea during implantation or from postoperative changes in pIOL position. Moreover, subclinical inflammation may cause direct toxicity to the endothelium and lead to further damage. In 1991, Fechner et al.[97] described the first results of this type of pIOL with a follow-up of more than 12 months: Five of 109 eyes experienced corneal endothelial cell loss by surgical trauma and 5 eyes showed progressive corneal endothelial cell loss that caused corneal edema in one eye. In a prospective study that included 111 eyes with a follow-up of 4 years, Menezo et al.[98] report that the largest percentage of corneal endothelial cell loss was noticed during the first 6 months after implantation and conclude that the main cause for corneal endothelial cell loss is surgical trauma. Corneal endothelial cell pleomorphism and polymegathism did not change significantly after surgery. One pIOL that was placed too superiorly caused corneal edema and had to be removed. Other studies have shown similar results.[14,29,99,100] Maloney et al.[16] report no difference in corneal endothelial cells between preoperatively and 6 months postoperatively. Budo et al.[13] report a corneal endothelial cell loss of 0.7% 3 years after Artisan/Verisyse implantation. Pop and Payette[32] report no significant change in corneal endothelial cells 2 years after Artisan implantation. Senthil et al.[21] did not find significant corneal endothelial cell loss 24 months after Artisan surgery. Moshirfar et al.[23] report a 6.2% decrease in corneal endothelial cells 2 years after Artisan/Versisyse implantation. A similar rate, 6.8%, was reported by Gierek-Ciaciura et al.[9] 1 year after Verisyse implantation. A recent study by Stulting et al.[25] shows a mean corneal endothelial cell change of 4.8% 3 years after surgery. Another recent study by Güell et al.[27] reports a significant decrease in corneal endothelial cells after myopic Verisyse implantation, whereas corneal endothelial cell loss was not significant in the hyperopic Verisyse and toric Verisyse groups 3 years after implantation. Overall, corneal endothelial cell loss in this study was 5.11% at 4 years. Natural loss of corneal endothelial cells is about 0.6% per year, as reported by Bourne et al.[101] One study has shown that corneal endothelial cell loss following combined pIOL explantation after Artisan implantation was only 3.5% 6 months after surgery.[102] Dick et al.[34] report corneal endothelial cell loss of only 1.1% 2 years after Artiflex implantation.

In contrast to these findings, Pérez-Santonja et al.[103] report continuous corneal endothelial cell loss with a decrease of 17.6% 24 months after surgery and Saxena et al.[104] report a corneal endothelial cell loss of 8.3% with a mean follow-up of 35.3 months. Saxena et al.[104] report a significant negative correlation between ACD and corneal endothelial cells. Benedetti et al.[105] report a continuous decrease in corneal endothelial cells after Artisan pIOL implantation; at 5 years, the decrease was 9.0%. Silva et al.[26] report a decrease of 14.05% corneal endothelial cells 5 years after Artisan implantation. In a recent study of factors leading to corneal endothelial cell loss after pIOL implantation,[106] the authors report a yearly corneal endothelial cell loss of 1.0% for a mean minimum distance of 1.43 mm between the edge of the pIOL and the corneal endothelium; the loss was 1.7% for a mean minimum distance of 1.20 mm and 0.2% for a mean minimum distance of 1.66 mm. In this study, according to a linear mixed model analysis, patients with preoperative corneal endothelial cells of 3000, 2500, or 2000 cells/mm^2 and an edge-distance of 1.43 mm, a critical corneal endothelial cell level of 1500 cells/mm^2 would be reached 56, 37, and 18 years after Artisan/Artiflex implantation.

All authors agree that preoperative endothelial microscopy is mandatory. Patients with endothelial damage or corneal endothelial cells below 2000/mm^2 should therefore not receive a pIOL. The height of the Artisan IOL and therefore the potential closeness to the cornea increases with its dioptric power. Therefore, a sufficient ACD for the calculated pIOL is necessary so the distance between the pIOL and the corneal endothelium is not less than 1.5 mm.[107,108]

Pigment Dispersion/Lens Deposits The optic of the iris-claw pIOL has an anterior vault to prevent iris chafing. Pop et al.[109,110] performed postoperative ultrasonic biomicroscopy of the haptics of myopic and hyperopic pIOLs and found no evidence of irritation of the iris pigment epithelium by the pIOL haptics during a follow-up of 24 to 371 days. Pigment cells are occasionally visible on the pIOL optic in the early postoperative period from surgical trauma. Figure 7 shows iris pigment defects at the site of enclavation as a possible source of pigment dispersion. Stulting et al.[25]

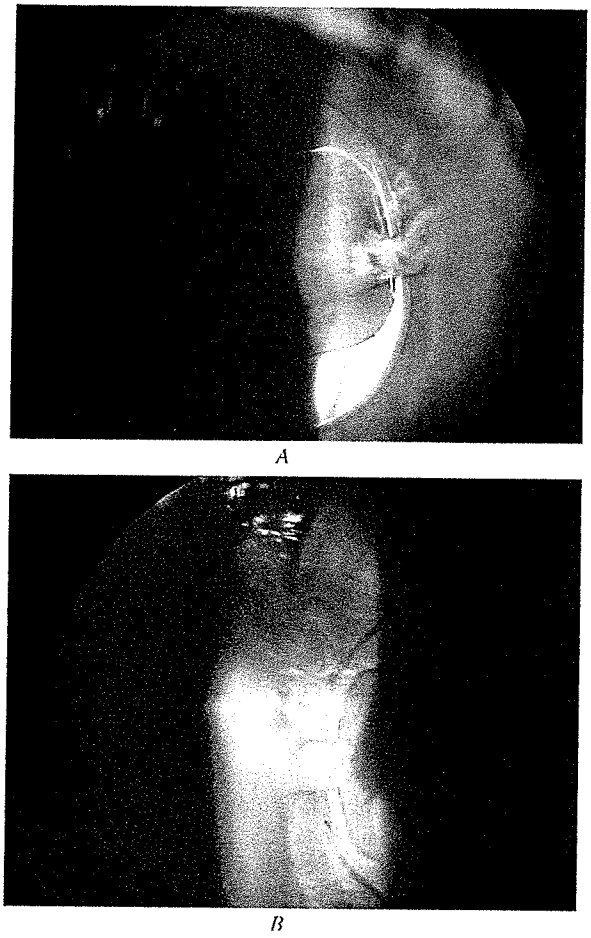


Figure 7. Iris pigment defects at the site of enclavation may be one source of dispersed iris pigment (30-year-old man [*A*] and 47-year-old woman [*B*]; both 3 months postoperatively).

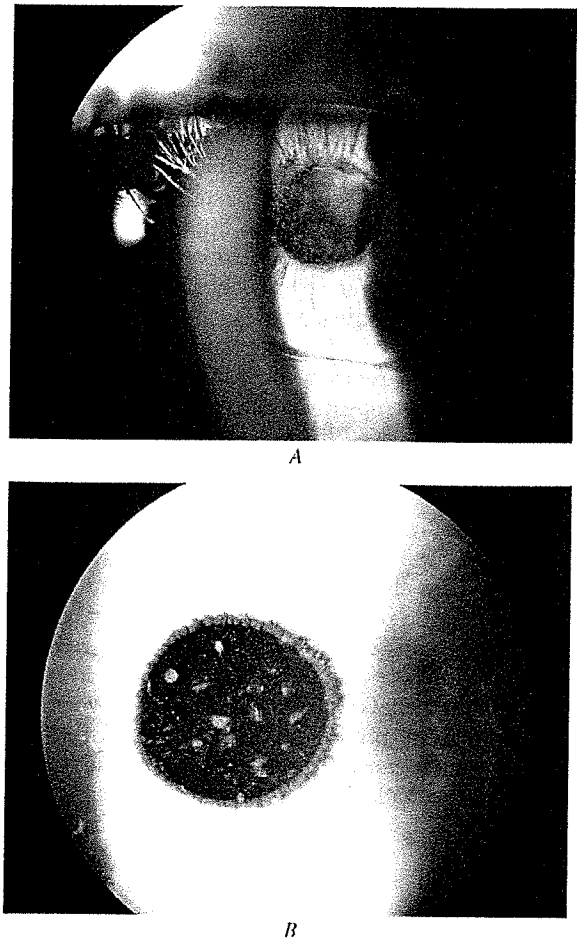


Figure 8. Inflammatory reaction after iris-claw IOL implantation. *A*: Dense fibrin coating on the pIOL 1 week postoperatively (34-year-old woman). *B*: Persistent deposits 3 months after implantation (37-year-old man).

report iris pigment precipitates with an incidence of 6.9% at 4 to 6 months follow-up and no case at the 3-year follow-up. Menezo et al.[18] report a long-term incidence of 6.6% pigment dispersion with the longest mean follow-up of 10 years after Artisan implantation. However, in the phase III trial for the hyperopic iris-claw pIOL, there are reports of 3 patients who had pigment dispersion or pupillary membrane formation due to iris touch.[111] Baikoff et al.[112] consider crystalline lens rise as a risk factor for developing pigment dispersion after iris-fixated pIOL implantation. In their study, 67% of eyes with a rise of more than 600 µm developed pupillary pigment dispersion after implantation of the Artisan pIOL. Nearly all eyes were hyperopic. For the Artiflex pIOL, pigment precipitates were reported in 4.8% of eyes, nonpigment precipitates in 1.4%, and synechiae formation in 1.4% 2 years after surgery.[34]

Chronic Inflammation/Uveitis Chronic inflammation has been a major concern with the iris-claw IOL because this pIOL is fixated directly to the iris tissue and causes pressure or shear forces when the eye is moving or patients rub their eyes (Figure 8). This may lead to injury or increased permeability of the iris vessels with breakdown of the blood–aqueous barrier and chronic release of inflammatory mediators. This has been repeatedly examined using different technologies. Two studies using iris angiography show no leakage of the iris vessels,[91,97] whereas studies conducted using a laser-flare cell meter show different results. Fechner et al.[97] report no elevated flare levels in 109 eyes with at least 12 months of follow-up. Pérez-Santonja et al. (Perez-Santonja JJ, Iradier MT, Benitez del Castillo JM, Serrano JM, Zato MA. Chronic subclinical inflammation in phakic eyes with intraocular lenses to correct myopia. J Cataract Refract Surg 1996;

22:183–187) report elevated flare levels in 30 eyes compared with the levels in a normal population at 12, 18, and 24 months after surgery. Groβ et al.[100] report no significantly elevated flare after 6 months in a study with 44 eyes. In all studies, clinically relevant inflammation could be detected in individual cases only. In a case report by Koss et al.,[113] posterior synechias developed 2 weeks after Artiflex implantation and required surgical reenclavation. However, 2 years after surgery, posterior synechiae did not change. A similar case report by Tahzib et al.[114] describes development of severe cell deposition 1 week after Artiflex implantation. After pIOL exchange, inflammation in the anterior chamber disappeared completely. Senthil et al.[21] report postoperative iritis in 3% of the eyes after Artisan implantation that resolved completely. Moshirfar et al.[23] report an incidence of 1.2% of cells and flare for 1 month after Artisan/Verisyse surgery. Moshirfar et al.[115] describe a case of toxic anterior segment syndrome (TASS), also known as sterile endophthalmitis, in a patient who presented with severe corneal edema 1 day after Verisyse pIOL surgery. The TASS resolved after a 2-month course of topical steroids. However, corneal endothelial cells decreased by 69% 1 year after surgery. Careful postoperative monitoring of inflammatory signs is generally necessary. If persistent intraocular inflammation occurs and is not sufficiently treatable with drugs, pIOL removal must be considered.

Pupil Ovalization/Iris Retraction Pupil ovalization or irregularity can occur if fixation of the pIOL haptics is performed asymmetrically. No progressive pupil ovalization has been reported. Maloney et al.[16] report pupil irregularities in 14.0% of eyes on the first day after surgery and 1.2% after 6 months. Moshirfar et al.[23] report a pupil ovalization incidence of 2.4% after Artisan/Verisyse implantation. Stulting et al.[25] report an incidence of 13.0% of asymptomatic oval pupil 1 day after Artisan/Verisyse pIOL implantation, which decreased to 0.4% at 3 years. As enclavation is performed in the peripheral iris, pupil dilation is limited after pIOL implantation. Artisan/Verisyse pIOLs are centered on the middle of the pupil. This can lead to difficulties if the pupil itself is decentered and the optical axis is not in the middle of the pupil (Figure 9). Postoperative decentration is possible if the enclavation is not sufficient. Menezo et al.[91] report an incidence of 13.5% decentration, but in only one case was a second intervention necessary because of double vision. Pérez-Santonja et al.[103] report a decentration greater than 0.5 mm in 43% of the examined eyes. Pérez-Torregrosa et al.[116] report a mean decentration of 0.47 with respect to the pupil center in 22 eyes using a digital imaging system. If the pIOL is fixated properly, no postoperative decentration or rotation of the optic should occur.

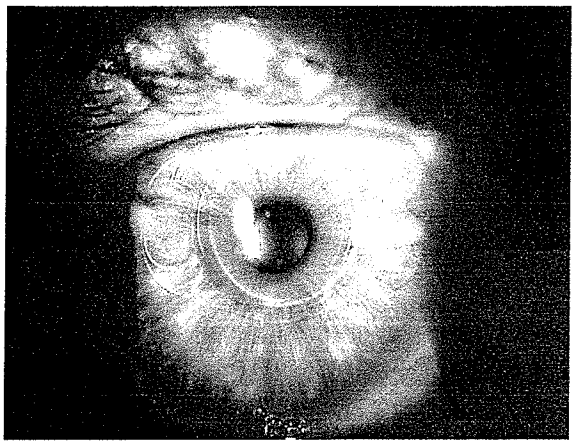


Figure 9. First generation iris-claw pIOL (Worst-Fechner) in an aphakic eye 11 years after implantation (61-year-old woman). Note slight decentration.

Intraocular Pressure Elevation The anterior chamber angle is not generally thought to be affected by the haptics of the iris-claw pIOL. Coullet et al.[22] report that within 1 year of surgery, IOP did not significantly change after Artisan or Artiflex pIOL implantation. However, Yamaguchi et al.[117] report that after implantation of an Artisan/Verisyse pIOL, partial narrowing of the anterior chamber angle of more than 5 degrees occurred in the area where the pIOL haptics pinched the iris. This did not affect IOP. A peripheral iridectomy or iridotomy is necessary to prevent acute pupillary block glaucoma. In several studies, cases of elevated IOP in the early postoperative period resolved without further damage and were probably related to retained OVD or steroid medication.[4,16,21,25,61,118,119]

Phakic Intraocular Lens Rotation Photographic analysis after implantation of toric Artisan pIOLs showed no rotation greater than 2 degrees at 6 months follow-up in a report by Tehrani et al.[35] Using Scheimpflug photography, Baumeister et al.[120] examined the postoperative stability of pIOLs and report that the iris-fixated pIOL had the best positional stability compared with anterior chamber and posterior chamber pIOLs. Therefore, the iris-fixated pIOL is particularly interesting for toric pIOL designs. However, spontaneous postoperative dislocations or dislocations due to blunt ocular trauma have been described (Figure 10).[16,91,103,121]

Cataractogenesis Formation of cataract due to the iris-claw pIOL is unlikely because the pIOL is inserted over a miotic pupil without contact with the crystalline lens. Menezo et al.[122] report a nuclear cataract rate of 3% after implantation of an iris-fixated pIOL. In this study, the implanted IOL was the older

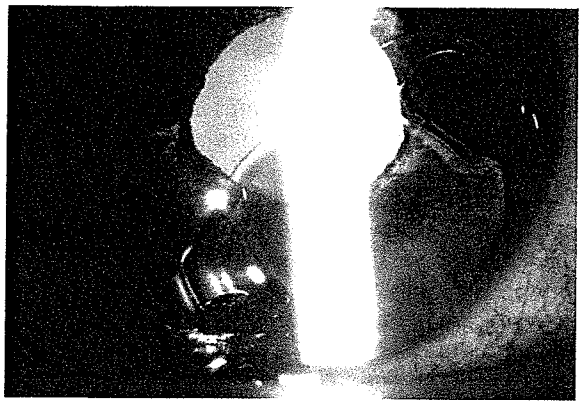


Figure 10. Traumatic dislocation of an iris-claw anterior chamber pIOL (courtesy of D. J. Annen, Winterthur, Switzerland).

Worst-Fechner pIOL. Patient age older than 40 years and axial length greater than 30.0 mm were factors related to nuclear cataract formation. However, new-onset nuclear cataracts were not ascribed to pIOL surgery. Clinically relevant cataract formation associated with the iris-claw IOL has also been reported by Stulting et al.[25] Most lens opacities were nuclear and unlikely to be related to the implanted pIOL. Lens opacities that required cataract extraction developed in 0.25% of patients. Very few were anterior subcapsular opacities, which were expected to be caused by surgical trauma. A metaanalysis of cataract development after pIOL surgery reported that 20 of 2781 eyes developed new-onset cataract.[86] Of these, 10 were nuclear sclerotic, 8 were cortical vacuoles, and 1 was anterior subcapsular cataract (data for 1 eye was not clear.) The incidence of cataract formation was 1.1% for the iris-fixated pIOL; it was 2.2% for the Worst-Fechner biconcave pIOL, 1.1% for the myopic Artisan/Verisyse pIOL, and 0.3% for the hyperopic Artisan/Verisyse pIOL. No cataracts have been reported to date with the Artiflex pIOL.[86] As for anterior chamber pIOLs, an excessive postoperative use of steroids should be avoided because of the potential long-term risk for cataract formation.[87]

Retinal Detachment Thorough examination of the posterior segment to rule out vitreoretinal pathologies is mandatory, although no vitreoretinal complications have been shown to be causally related to iris-fixated pIOL implantation to date. In the European multicenter study of the Artisan pIOL over 8 years, retinal detachment (RD) occurred in 2 eyes.[13] Stulting et al.[25] report an RD rate of 0.3% per year after Artisan/Verisyse implantation in eyes with a mean spherical equivalent between −11.50 D and −18.6 D. This is similar to RD rates that have been reported in the highly myopic population that did not have refractive surgery.[123–125] Güell et al.[27] report one case of RD in a series of 399 eyes with the Artisan/Verisyse pIOL. Retinal detachment was not thought to be related to the pIOL implantation. A recent report describes a bilateral giant tear RD following Artisan pIOL implantation in a 39-year-old patient with an axial length of 25.5 mm in the right eye and 25.8 mm in the left eye.[126] In this report, RD was attributed to a combination of inflammatory response and perioperative IOP fluctuations as a causative pathophysiological mechanism based on the time between the RD and the pIOL implantation.

Oddities Other complications of iris-fixated pIOL implantation are Urrets-Zavalia syndrome, early postoperative hyphema, and ischemic optic neuropathy.[127] Hyphema in the early postoperative phase from iris trauma is occasionally described.[14,16,91] Iris bleeding can also be caused by preoperative argon or Nd:YAG laser treatment of the iris to mark fixation points for pIOL enclavation. Iris perforation by the claw haptic of a pIOL is reported by Benedetti et al.[20] Another rare complication is implantation of a pIOL with incorrect power. Due to the aim of the surgery—to correct ametropia as precisely as possible—this complication should not occur with current formulas, as described in the first part of this review. Kohnen et al.[128] report a myopic shift of 4.0 D 10 days after Artisan pIOL implantation. They postulate that this event happened because of secondary movement of the ciliary body inwardly or forwardly or irritation of iris innervation by induction of ciliary body contraction.

Posterior Chamber pIOL Complications

The complication spectrum is similar for the ICL and PRL and is related to the position of the pIOL between the rear surface of the iris and the front surface of the crystalline lens. Differences in the incidence of most common complications such as cataractogenesis, pupillary block, and glaucoma are due to the different pIOL designs and materials.

Optical Quality, Glare, Halos Consequences of a small optic diameter (ICL up to 5.5 mm; PRL up to 5.0 mm) and decentration of posterior chamber pIOLs in relation to the pupil size are glare and halos, especially at night. Therefore, patients with larger pupils have increased difficulties driving at night, which, in extreme cases, may lead to an actual inability to drive at night. Menezo et al.[119] report a high incidence of visual disturbances after implantation of an ICL, which may be due to decentration of the posterior chamber pIOL and/or an optic diameter that is too small relative to the pupil size. Several studies report glare and diplopia in eyes with decentration of the ICL greater

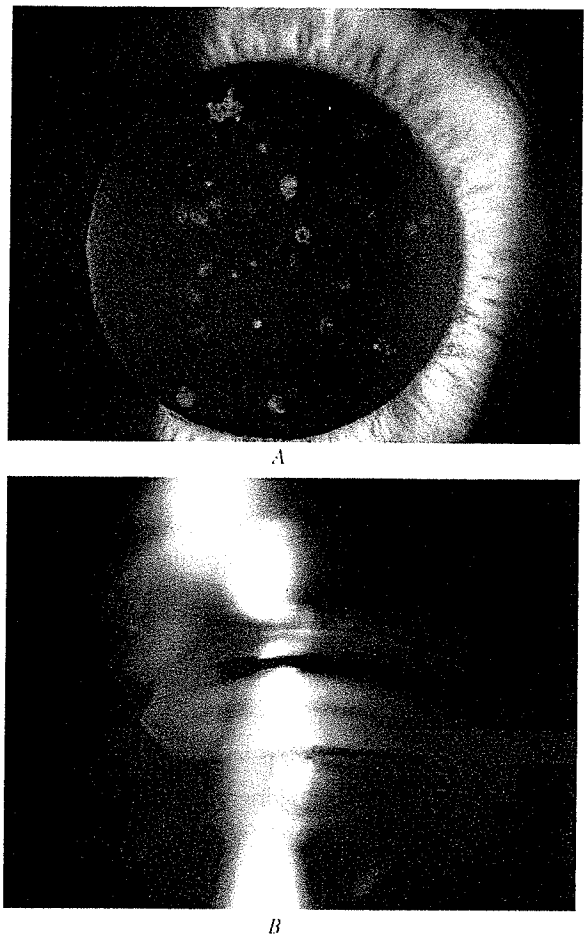
than 1.0 mm.[129,130] Maroccos et al.[79] report a greater increase in postoperative glare and halos after ICL implantation than after Artisan pIOL implantation in the anterior chamber. These findings were thought to be due to the edge effects of the small diameter of the whole ICL and the small optic diameter (4.5 to 5.5 mm) in relation to the pupil size (5.3 to 7.4 mm). With the PRL, which has an optic of 4.5 to 5.0 mm, glare and halos are also a concern. After PRL implantation, 25% of 31 patients reported halos and night glare.[61] To avoid this complication, a preoperative mesopic pupil larger than 5.0 mm should be considered a limitation. In large-pupil cases, a larger optic pIOL should be implanted. For example, an iris-fixated pIOL with a 6.0 mm optic should be used in patients with large scotopic pupils. In a study of the 3-year results of ICL implantation, patients were asked about their optical quality of vision. Improvement of glare and halos was reported in 11.9% of cases and 9.6% of cases, respectively, and worsening in 9.6% and 11.5%, respectively.[41] After PRL implantation, 26% to 28% of patients complained of glare and halos at night.[60,61] Some of the patients had scotopic pupils of 6.0 to 7.0 mm so the difference between the pupil size and the 5.0 mm PRL optic seemed responsible for the problems.[60] A recent report by Koivula and Zetterström[67] shows glare and halos after hyperopic PRL implantation in 2 of 40 eyes, requiring PRL explantation.

Surgically Induced Astigmatism Surgically induced astigmatism has not been reported to be a major concern of posterior chamber pIOLs because of the small-incision surgical procedure. In one study, the SIA after ICL implantation in 73 eyes through a 3.0 mm horizontal clear cornea incision was 0.45 D using a keratometer and 0.49 D using corneal topography.[53]

Loss of Corneal Endothelial Cells Loss of corneal endothelial cells can be divided into direct trauma loss caused by surgery and long-term loss. In various studies of the ICL, immediate corneal endothelial cell loss of 5.2% to 5.5% was documented after 12 months. However, the pace of corneal endothelial cell loss slowed down substantially from 1 year to 2 years (6.6% to 7.9%).[131,132] Researchers therefore considered surgery to be the cause of the early corneal endothelial cell loss. Four years postoperatively, corneal endothelial cell counts showed further decrease in cell density, which may be due to the implanted ICL, the learning curve of the surgeon, or natural cell loss, which is in the range of 0.5% in the normal population.[132] A recent study by Kamiya et al.[133] reports corneal endothelial cell loss of 3.7% 4 years after ICL implantation. Another study shows a cumulative corneal endothelial cell loss of 8.5% 3 years after surgery and 8.4% 4 years after surgery.[41,129] These figures also suggest that corneal endothelial cell density stabilizes over time. Alfonso et al.[57] show corneal endothelial cell loss of 8.1% 2 years after toric ICL implantation in eyes after penetrating keratoplasty. In a report by Koivula et al.,[65] no significant corneal endothelial cell loss was noted between 1 week and 1 or 2 years after implantation of a hyperopic PRL. In a report by Koivula and Zetterström,[67] corneal endothelial cell loss was 3.8% 1 year after hyperopic PRL implantation. Verde et al.[62] did not find a significant reduction in corneal endothelial cells 12 months after PRL implantation in 90 myopic eyes. Jongsareejit[64] reports corneal endothelial cell loss of 5.4% after a short follow-up of 6 months.

Pigment Dispersion/Intraocular Lens Deposits/Intraocular Pressure Elevation Using ultrasound biomicroscopy (UBM), contact between posterior chamber pIOLs (ICL, PRL) and the posterior surface of the iris has been shown.[131,134–137] Pigment dispersion and consecutive pigment accumulation in the anterior chamber angle is one possible consequence (Figure 11).[51,61,119,137] However, development of secondary glaucoma has not been observed. Nevertheless, eyes with pigment dispersion must be kept under observation to spot any increase in IOP. Menezo et al.[18] report a not statistically significant IOP increase of 1.5 mm Hg over 3 years after ICL implantation. Park et al.[59] did not find an IOP increase over 1 to 18 months after toric ICL implantation. In contrast, other studies of ICLs or PRLs have reported significantly increased IOP in rare cases 1 month after implantation. Kamiya et al.[133] did not find an increase of IOP 4 years after ICL implantation. Zaldivar et al.[46] report that 2 of 124 eyes showed IOL-related IOP spikes. One of these eyes with a decentered ICL had excessive pigment deposition on the pIOL surface. It remained unclear whether the pigment dispersion was related to the decentration or to the pIOL itself. In both eyes, the ICL had to be removed and phacoemulsification with capsular bag IOL implantation was performed. The IOP was subsequently well controlled without medication. Sanchez-Galeana et al.[138] report a case of refractory IOP increase due to pigment dispersion after ICL implantation. Despite medical therapy and ICL removal, this patient needed a trabeculotomy to control IOP.

Although Jiménez-Alfaro et al.[131] observed contact of the ICL and posterior iris with UBM in all cases, they did not find pigment dispersion. The authors suggest that the similarity between the Collamer and the anterior capsule of the crystalline lens could prevent mechanical pigment loss. Davidorf et al.[51] report that the pigment deposition on the pIOL surface remained stable over time in all eyes, with no occurrence of pigment dispersion glaucoma. They suggest that pigment



A

B

Figure 11. *A*: Pigment deposits on anterior surface of a PRL posterior chamber pIOL. *B*: Pigment dispersion in the anterior chamber angle after implantation of an ICL posterior chamber pIOL, gonioscopic view, 3 months after implantation (53-year-old man).

dispersion was probably surgically related. Hoyos et al.[61] report a case of window defects of the iris and increased angular pigmentation without increased IOP after PRL implantation in hyperopic eyes. They propose that a too shallow ACD of 2.8 mm was the cause and suggest a minimum ACD of 3.0 mm for posterior chamber pIOL implantation. Donoso and Castillo[63] report no change in IOP after PRL implantation with a mean follow-up of 8 months. Koivula and Zetterström[67] also report no change in IOP 1 year after PRL implantation. Verde et al.[62] report an increase in mean postoperative IOP compared with the preoperative values; the mean IOP was within normal limits in the follow-up. Only 1 of 90 eyes required antiglaucomatous medication. Some authors have reported incidents of secondary induced glaucoma due to the use of topical steroids. However, IOP normalized after a postoperative treatment regimen with steroids and

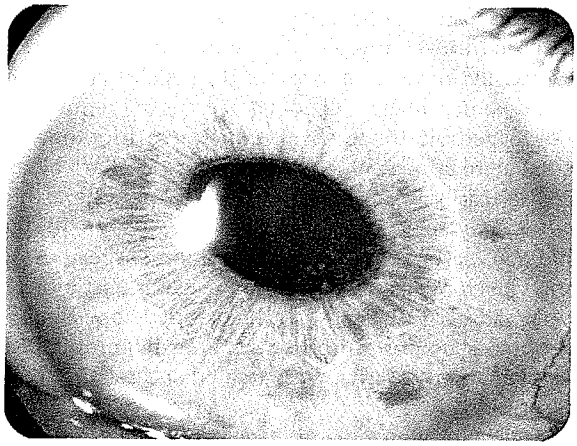


Figure 12. Pupil ovalization after PRL implantation.

was stopped in all eyes.[46,48,61,131] Davidorf et al.[51] report increasing vascularization of the anterior chamber angle and development of secondary glaucoma after ICL implantation in a hyperopic eye. Rosen and Gore[47] also report the development of secondary glaucoma after implantation of a hyperopic ICL. In both cases, the IOL had to be explanted as IOP could not be controlled by repeated iridotomy and topical medication.

Chronic Inflammation/Uveitis To detect intraocular inflammation, laser flare photometry was performed 6 months after ICL implantation. All eyes showed normal aqueous flare values.[42] Another study did not detect any long-term inflammation 2 to 3 years after ICL implantation.[139]

Pupil Ovalization/Iris Retraction In contrast to anterior chamber pIOLs, no cases of pupil ovalization or iris retraction have been reported to date with posterior chamber pIOLs. However, in our experience, they can still occur (Figure 12).

Pupillary Block/Malignant Glaucoma Due to the position of the posterior chamber pIOL, the iris may be pushed forward and cause acute pupillary block glaucoma, especially in hyperopic eyes.[46,50,51,131,140] The diameter of posterior chamber pIOLs is involved in this pathophysiological process. To prevent pupillary block glaucoma, preoperative or intraoperative iridotomies or iridectomies should be performed.[46,47,51] In some cases, preoperative iridotomies become nonpermeable over time because they are too small or the haptic of the posterior chamber pIOL blocks them. This may cause acute pupillary block glaucoma. A second iridotomy has to be performed in these cases.[129,141,142] In one case, pupillary block appeared 1.5 years after PRL implantation because the iridectomy was

obstructed by the PRL haptic.[61] After treatment with a second iridectomy, the IOP in all eyes normalized. Especially in the case of the PRL, which may rotate, 2 iridotomies in an angle of 90 degrees are required.[61] For hyperopic treatment, preoperative iridotomy is even more important to prevent early pupillary block. In such cases, it is necessary to make 2 peripheral and sufficiently sized iridotomies preoperatively with the Nd:YAG laser or during implantation surgery using the vitrectome or scissors.[51] In a recent report by Koivula and Zetterström,[67] 7 of 40 eyes developed pupillary block by a mean of 6 days after hyperopic PRL implantation. All eyes were treated successfully with laser iridotomy.

Malignant glaucoma after posterior chamber pIOL implantation is rare and has only been described by Kodjikian et al.[118] in a myopic eye that had an IOP of 54 mm Hg 3 days after ICL implantation. Both preoperatively performed laser iridotomies were patent and seemed large enough. The iris was not bowed forward, and the posterior segment did not show any pathology. Acute glaucoma due to pupillary block was ruled out. Despite medical treatment, the IOP remained 50 mm Hg; 5 days after implantation, ICL explantation had to be performed. Thereafter, IOP normalized without medical treatment and the corrected distance visual acuity was 20/25.

Decentration/Incorrect size /Phakic Intraocular Lens Rotation Preoperatively, it is mandatory to properly measure the white-to-white (WTW) distance to choose a pIOL with sufficient length to prevent decentration or rotation, even though limitations regarding the WTW distance relative to the sulcus diameter are well-known.[119,130] Although in few cases, Menezo et al.[119] report decentration with an adequate IOL length relative to the corneal diameter. The consequences of decentration are diplopia, glare, and pigment dispersion syndrome because of mechanical trauma.[46,51]

Trindade and Pereira[143] report the exchange of an ICL because of oversized length. Malpositioning with a very large vault and undercorrection occurred because the ICL was too long. The ICL was exchanged for a smaller ICL with higher power. This procedure was uneventful, and the patient was satisfied with the final visual outcome. In a study with a 12-month follow-up, UBM showed ICL rotation in 11% of eyes.[134] Although there was no decentration of the optic, the authors suggest that the diameter of the ICL was too small.[134] In another study,[61] decentration occurred after implantation of a PRL with a diameter that was too small. After the small PRL was exchanged for a newer generation PRL with a larger diameter, no decentration was observed. A recent study by Koivula et al.[65] showes a median PRL rotation 18.5 degrees during the first year after implantation and 0 degree during the second year. Centration of the PRL was good in all eyes for up to 1 year. Minor decentration of a PRL was observed in 5 of 90 eyes in a study by Verde et al.[62] The ICL length has to be calculated on the basis of the horizontal WTW diameter (addition of 0.5 mm to WTW measure). Baumeister et al.[144] report that a most accurate value of horizontal WTW diameter is determined by the IOLMaster (Carl Zeiss Meditec). In this study, the mean rotation of the ICL was 0.9 degrees. A recent study reports that postoperative rotation after toric ICL implantation was less than 5 degrees in 74% of eyes and less than 11% after 8 months.[59]

Cataractogenesis A metaanalysis of cataract development after posterior chamber pIOL surgery found that 223 of 1210 eyes developed new-onset cataract.[86] Of these, 195 were anterior subcapsular (Figure 13), 5 nuclear sclerotic, and 4 anterior subcapsular and cortical opacities. The overall incidence of cataract formation for posterior chamber pIOLs was 9.60%, which is significantly higher than the incidence for anterior chamber pIOLs and iris-fixated pIOLs. The incidence was 25.7% for the Adatomed pIOL, 8.5% for the ICL pIOL, and 3.6% for the PRL.[86] Because of this incidence, the Adatomed is no longer in use. Cataracts after ICL and PRL implantation often remain stable over a long period of time and rarely lead to a reduction in visual acuity. The most common type of cataract after posterior chamber pIOL implantation is anterior subcapsular.[145,146] Possible reasons are operative trauma, continuous or intermittent contact of the posterior chamber pIOL with the crystalline lens, insufficient nutrition through anterior chamber flow between the posterior chamber pIOL and the crystalline lens, or chronic subclinical inflammation with disruption of the blood–aqueous barrier due to friction between the pIOL and posterior iris or the haptic on the ciliary sulcus.[49,145,147] Studies with UBM and Scheimpflug-imaging techniques (Figure 14) have shown a central gap between the ICL and the crystalline lens but contact in the midperiphery.[131,134,137,143] Moreover, anteroposterior movement of the ICL during iris contraction or accommodation have led to intermittent central contact.[131,134] However, if the distance between the crystalline lens and posterior chamber pIOL is increased, the posterior chamber pIOL is closer to the iris with the consequent risk for pigment dispersion and development of pigment-induced secondary glaucoma.

In a study by Zaldivar et al.,[46] none of 124 eyes developed lens opacities due to ICL implantation. Nevertheless, one eye developed peripheral lens opacification at the position where Nd:YAG iridotomy

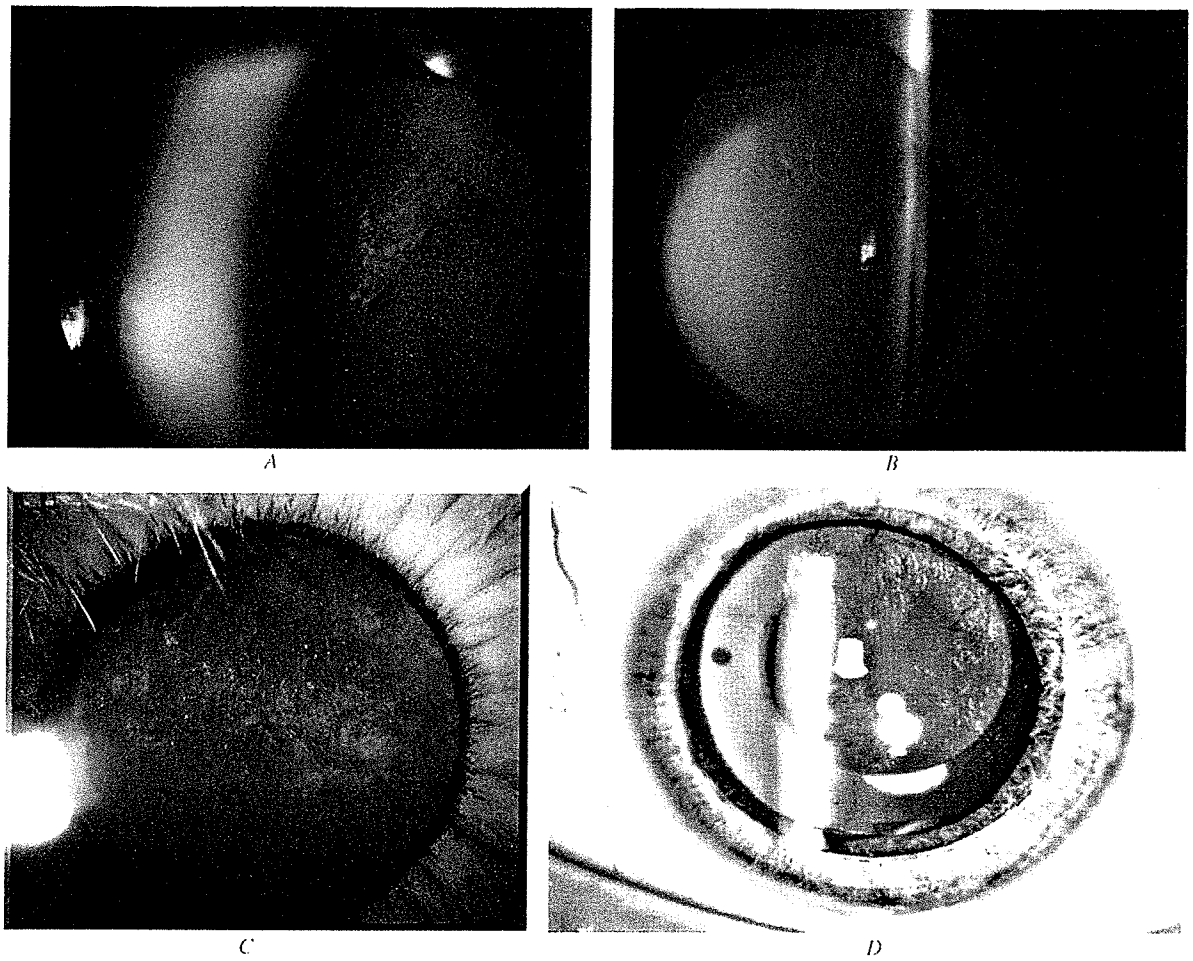


Figure 13. Cataract formation after implantation of posterior chamber pIOL. *A*: Faint anterior subcapsular opacities, 12 months after implantation (45-year-old woman). *B*: Same eye, retroillumination. *C*: Distinct anterior subcapsular cataract in an eye with posterior chamber pIOL. *D*: Retroillumination of anterior subcapsular cataract in an eye with posterior chamber pIOL (*C*: Courtesy of E. Rosen, Manchester, United Kingdom; *D*: Courtesy of J. Alió, Spain).

was performed preoperatively. Zadok and Chayet[148] report a case of focal lens opacification under the Nd:YAG laser iridotomy site, which did not enlarge after ICL implantation. Another study reports 2 eyes in one patient with anterior subcapsular cataractogenesis 1.5 years after ICL implantation.[42] Also, Trindade and Pereira[137] observed anterior subcapsular cataract formation in the eye of a 59-year-old patient 6 months after ICL implantation. The surgery was uneventful and atraumatic. With UBM, they were able to measure a central vault between the ICL and the natural lens, whereas contact was present in the midperiphery. Anterior subcapsular lens opacities developed in the noncontact area. Therefore, the authors surmised that both the proximity of the ICL to the natural lens, which may lead to metabolic disturbances, and pressure from the posterior chamber pIOL on the anterior surface of the crystalline lens could trigger cataract formation. In an FDA trial with a mean follow-up of 4.7 years, a cumulative probability estimate of 6% to 7% of anterior subcapsular opacities was found 7+ years after implantation of the Visian ICL.[149] However, only 1% to 2% progressed to a clinically significant cataract.

With various generations of the ICL, appearance of cataract formation is different. The less vaulted model V3 caused a higher incidence of cataract formation than the newer V4 and V5 models.[119] With the V4 model, the recently published FDA study showed an incidence of 2.1% anterior subcapsular opacities.[150] To prevent cataract formation, a sufficient vault between the posterior chamber pIOL and the lens seems to be important. With UBM, it was possible to measure central vault after implantation of ICL; in

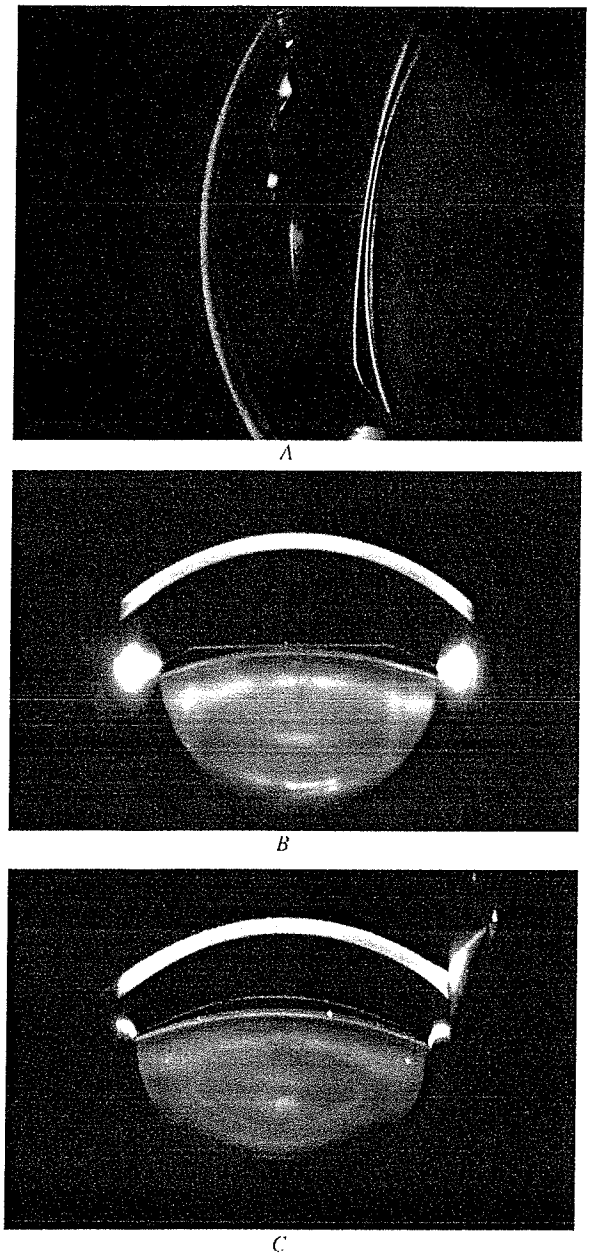


Figure 14. Contact between posterior chamber pIOL and crystalline lens. *A*: Myopic ICL, slitlamp image. Note delicate opacities in the lower hemisphere (40-year-old man). *B*: Myopic ICL, Scheimpflug image. *C*: Hyperopic ICL, Scheimpflug image.

the midperiphery, lens–IOL contact existed in most cases.[131,134,137] Also, size changes, the loss of the central vault, as well as changes in the location and extension of the contact zone were measured (Figure 14).[131,134] These findings would indicate anteroposterior shifts in the position of the ICL. Such shifts may be due to the flexibility of the pIOL material,

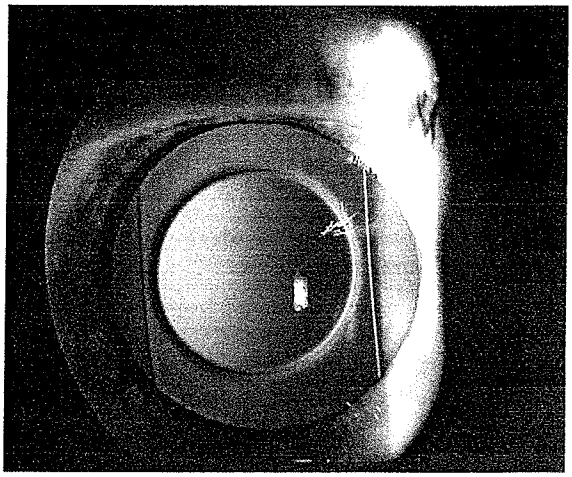


Figure 15. Residual OVD substance between a hyperopic ICL and the crystalline lens 1 week postoperatively (23-year-old woman).

which would allow the ICL to become deformed, perhaps while iris movements or accommodation occurred. Nevertheless, lens opacities did not effect visual acuity in any examined eye. One study evaluated the dynamics of the PRL in myopic and hyperopic eyes during accommodation with Visante OCT.[151] The PRL moved forward during accommodation in all eyes, with preserved distance between the anterior surface of the crystalline lens and the smaller PRL 100 model. However, with other PRL models, 101 in myopic eyes and 200 in hyperopic eyes, this distance decreased significantly. The authors conclude that this finding combined with the floating design of the PRL could permit aqueous humor circulation to the anterior surface of the crystalline lens, resulting in a less cataractogenic effect than with the ICL. After PRL implantation, Hoyos et al.[61] observed anterior cortical opacification in the immediate postoperative examination in one eye. This opacification remained stable up to 2 years of follow-up. The authors suggest that the touch of the natural lens during surgery was the trigger. Koivula and Zetterström[67] report no case of cataract formation one year after hyperopic PRL implantation. Other risk factors are experience of the surgeon, older patient age, and preexisting lens opacities.[49] As a differential diagnosis of lens opacities, residues of OVD substances (Figure 15) should be considered, particularly if the opacity is seen in the early postoperative period. If cataract formation progresses and leads to a decrease in visual acuity, posterior chamber pIOL explantation, phacoemulsification, and posterior chamber IOL implantation are indicated.[137,152]

Administration of pilocarpine in eyes with posterior chamber pIOLs should be considered carefully since

a case report demonstrated posterior chamber flattening and resulting crystalline lens opacification after instillation of pilocarpine eyedrops in a 46-year-old hyperopic patient who had ICL implantation.[153] As for all pIOLs, one should also consider that excessive use of steroids postoperatively is a potential cause of cataract formation.[87]

Retinal Detachment As for all intraocular surgeries, implantation of a posterior chamber pIOL carries a potential risk for vitreoretinal complications and RD. Most implantations of posterior chamber pIOLs are performed in patients with high myopia and long axial length, who therefore have a predisposition for spontaneous RD, as discussed previously. Thorough preoperative and postoperative fundoscopic investigation is mandatory to rule out retinal changes and to perform prophylactic laser photocoagulation, if required. Zaldivar et al.[46] report a single case of RD after implantation of a posterior chamber pIOL in 124 eyes. In this myopic patient, no causal relationship to pIOL surgery was noted. Panozzo and Parolini[154] describe 4 cases of RD after posterior chamber pIOL implantation in a consecutive case series. Two of the 4 cases had giant retinal tears. One case of bilateral giant retinal tear was reported 4 months after posterior chamber pIOL implantation. The patient had a history of RD.[155] Another case of RD as a late postoperative complication was reported after PRL implantation.[63] In a prospective study comprising 61 eyes, one eye developed RD 15 months after Visian ICL implantation.[52] This case was attributed to the pre-existing axial length of 31.0 mm and not to the pIOL surgery. The largest clinical trial reporting results in 526 eyes after Visian PIOL implantation found only 3 RDs.[41] The largest series of RD after posterior chamber pIOL surgery was published by Martőnez-Castillo et al.[156] and included 16 eyes after ICL implantation (ICMV2, ICMV3, and ICMV4). In this retrospective study, RD occurred from 1 to 70 months after lens surgery (mean 29 months) and no giant retinal tear or retinal dialysis was noted. As mean axial length of the 16 eyes was 30.1 mm, the authors conclude that these RDs were part of the natural history of RD in high myopia.

Oddity: Zonular Dehiscence There are some reports of serious complication with PRL luxation into the vitreous cavity. Eleftheriadis et al.[157] report a spontaneous dislocation of PRL 2 months after uneventful implantation into the vitreous cavity. Luxation was attributed to preexsisting zonular defect in the highly myopic eye and unrecognized ocular trauma. In a case report by Martőnez-Castillo et al.,[158] 2 patients had PRL luxation into the vitreous cavity after normal surgery, 4 and 22 months postoperatively. Hoyos et al.[159] report 2 cases of zonular dehiscence 2 years after PRL implantation in highly myopic eyes. Donoso and Castillo[63] report 2 cases of subluxation of PRL inferotemporally through the zonules with no predisposing factors. The authors speculate that an altered position and rotation of this type of pIOL and/or preoperative or undetected intraoperative trauma might contribute to this rare but potentially severe complication. For posterior chamber pIOL implantation, selection of a pIOL with an incorrect power is an avoidable complication that should not occur using current biometric formulas.

In summary, the main complications of anterior chamber pIOLs are glare and halos, pupil ovalization, and corneal endothelial cell loss; the main complications of iris-fixated pIOLs are chronic subclinical inflammation, corneal endothelial cell loss, dislocation or pupillary block glaucoma; and the main complications of posterior chamber pIOLs are anterior subcapsular cataract formation, pigment dispersion, pupillary block glaucoma, or luxation of pIOL (PRL). For all types of pIOLs, there is no established direct relationship between pIOL and RD.

DISCUSSION

According to Charles Kelman,[160] learning from complications of former and current pIOL models, a pIOL to be developed should fit the following requirements: The haptics should not damage the anterior chamber angle and haptics should not be in touch with peripheral corneal endothelium; the pIOL should not be in contact with any part of the iris that moves during pupillomotoric reflexes; the pIOL should be flexible if the assumed internal diameter might be smaller than the diameter of the pIOL; the pIOL should be placed in the largest diameter of the eye to avoid rotation; and the edges of pIOL should be smooth. Additionally, there should be sufficient space between the pIOL and the corneal endothelium and between the pIOL and the crystalline lens.

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Epicrystalline intraocular lens: «From a challenging start to a promising present»

INTRODUCTION

As we all know, phakic intraocular lens (PIOL) experienced a very challenging naissance. Early prototypes suffered many changes in search of a more physiological design and ensured biocompatibility, which could address the high rate of postoperative complications associated with the first procedures. The surgical techniques were difficult to master, presenting long learning curves, and there was an obvious need for significant improvement in the IOL sizing and power calculation formulas, in hopes of improving the precision of the initial refractive outcomes. Regardless of all, the posterior chamber phakic lens (PC PIOL) coined ICL™, became the most popular PC PIOL, registering a significant penetration in the PIOL's global market share. So, how can we explain the fact that if their early adoption experienced so many drawbacks, ICLs represent close to 55% of the phakic IOLs implanted currently, 80% between Spain and Latin America, as well as registering an annual growth rate of 35%?

A HISTORICAL REVIEW

Numerous events have occurred leading up to the ICL's successful present. Its development started in Russia, with **Svyatoslav Nikolayevich Fyodorov, MD**[1]; who created the first phakic mushroom-shaped IOL in the mid 80's, followed by Fetchner's modifications of the original design; and its evolution has continued ever since, allowing for its gradual and widespread acceptance. During the early 90's, **STAAR Surgical AG**[2] decided to explore the Russian idea and soon afterwards they acquired the legal rights to obtain the materials and designs including sketches and drawings, in order to develop them in the western hemisphere. In 1991, I was invited to Moscow where I was able to observe these IOLs, their surgical implantation technique, as well as witness their impressive refractive outcomes; considering that these IOLs were implanted unfolded in the absence of iridectomies, and while using permanent infusion. Also, the quick post-operative recovery period was quite note-worthy for those times.

Meanwhile, in the western hemisphere other silicone-elastomer PC PIOLs were being developed based on Fechner and Ertuck's modifications of Fydorov's original prototypes such as Chiron's Adatomed boat-shaped plate lens. The Adatomed lens preceded the ICL, but after several years of clinical trials its use was abandoned in 1997, due to its high rate of cataract induction. Another PIOL, the phakic refractive lens (PRLTM) was a US-designed silicone lens whose origin traced back to the first Russian models. International Vision Inc. of North Olmstead Ohio (IVI Medennium Inc. Irvine, California) originally designed this PC PIOL, which was later marketed by IOLTech/Carl Zeiss AG, and consequently by Ciba/Vision. Although the PRL came after the ICL, it was commercially unsuccessful in the long run.

PERSONAL EXPERIENCE

After having initiated in 1987 my learning curve with the Baikoff's anterior chamber PIOL dubbed «ZB», I began my PC PIOL experience with the Russian model on May 27, 1989 together with **Albert Neumann, MD**[3] who had obtained a special permit to implant these PIOLs in the US. That day, we operated using not only a Fyodorov PIOL model, but also a ZB and a Japanese PC PIOL model designed by Momose that never achieved worldwide promotion. Upon my return to Argentina, I implanted my first Fyodorov-

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designed PIOL (1991) and two years afterwards (1993) we implanted the first manufactured ICLs (20/20) in the western hemisphere, simultaneously with European experience led by Christian Skorpic in Austria, Vicenzo Assetto, Paolo Pesando and Stefano Benedetti in Italy. Since then, their development has been non-stop due to several milestones that should be taken under consideration and which I have highlighted as follows:

– In 1993, after having implanted several unfolded ICLs, we introduced the first folded PC PIOL technique using the newly designed Staar cartridge, which reduced the size of the incision considerably. Another issue back in those days was the high incidence of pupillary block, since the original Russian technique did not include the use of routine iridectomies. So we decided to perform a laser iridectomy with the aid of an Argon and a Nd:YAG laser delivery systems. These iridectomies became the first important step forward in addressing safety. They proved to be the key success factor in patients with shallow or narrow anterior chambers such as moderate to high hyperopic patients where I was honored by being the first surgeon to implant a Hyperopic ICL. Another advancement was the use of Metilcellulose instead of Sodium Hialuronate, which minimized the risk of hypertensive spikes in the immediate postoperative period caused by the obstruction of either the trabecular meshwork or the iridectomy itself, by the presence of viscoelastic substance.

– In 1994, my main concern focused on finding a way to avoid the iridectomies all together, and therefore and I proposed to STAAR the creation of a central drilling in the lens in order to balance the pressure between the posterior and anterior chamber. With the aid of **Vladimir Feingold**[4], I proceeded to implant 30 newly designed lenses with a central hole. Although STAAR Surgical patented the idea in 1996, the model was discontinued shortly afterwards, due to manufacturing restrictions. During the same period, while the company was working hard on obtaining the European Community Mark (CE) approval there were still some points to improve in the lens' design, since rotation and consequent decentration of the ICL were still a weakness and a very frequent drawback. Therefore suggested to re-design the haptics, which now resembled «handles» in order to avoid lens rotation, and fortunately enough our goal was achieved. Moreover, I encouraged changing their angulation so the haptics would lie in the sulcus.

– In 1996, STAAR also decided to decrease the ICL's posterior curvature in order to avoid pupillary block, but this change increased considerably the incidence of anterior subcapsular cataracts and it was probably the darkest period in STAAR's history as a company. Something interesting to point out is that the incidence of subcapsular cataracts in my own practice back in those days was considerably lower than those registered in patients of the same ethnic group in Europe (Caucasian). After verifying our clinical data with STAAR, we realized that the average size of the implanted lens in Europe was quite lower than the ones I was using in Argentina. This discovery contributed to explain not only Europe's higher incidence, but also the true importance of the need of privileging the space between the crystalline lens and the ICL. By the end of the decade we finally understood the critical role this space played; which by the way, Dr. **Michael Deitz, MD**[5] (medical monitor of the ICL clinical trials) had called VAULT back in the early 90's, without foreseeing its great importance evidenced only many years later. There were also other achievements which really enhanced ICL's global success like the use of topical anesthesia during its implantation or its combination with LASIK, a procedure I coined «Bioptics» back in February 1996 during a meeting in Aspen, and published in 1999. Bioptics allowed for overarching all those clinical cases that presented extreme refractive errors, and that were at loss with the use of only one procedure. Therefore, ICLs could be used in extreme cases of myopes and hyperopes with or without pre-existing astigmatisms, since the correction of the total refractive error was divided between the corneal (LASIK) and lenticular plane (ICL), Thus the advantages of both procedures were maximized while at the same time, their disadvantages as sole procedures in these types of clinical cases minimized.

– The next revolution came with the incorporation of the concept of IOL toricity at the beginning of the year 2000. This represented another important step forward, allowing not only the correction of higher degrees of astigmatism (≥ 1.50 D), but also enabling

the treatment of «suspicious corneas» safely, without decreasing patient's visual quality and by preserving their tear film. Another milestone that took place during that same period was our «obsessive» focus on improving the preciseness of our outcomes. New measuring methods such as the use of high frequency ultrasound and optical coherence tomography (OCT) allowed for precise readings of the sulcus-to-sulcus, white-to-white, vaults, and AC/PC distances and angles and consequently the right selection of the ICL's sizing. The 2000's were also a breakthrough regarding the visual quality of the human eye. For the first time, Ophthalmologists started thinking about «how good is my patient really seeing» instead of «how much is he seeing». This new paradigm was also feasible thanks to the technological evolution witnessed in diagnostic imagery, where new devices improved significantly not only the selection criteria for the sizing of the ICLs, the preciseness of its postoperative monitoring, but the patient's final optical quality too. Personally, I consider this milestone as one of the most impressive contributions that conferred true competitive advantages to the ICL, when compared with other refractive solutions. The visual quality achieved by patients with ICLs was distinctly superior, which was clearly demonstrated by measuring and comparing their visual acuity with optical performance tools such as modulation transfer function (MTF), Strehl Ratio, and OSI (objective scattering index) registered with OQAS (Visiometrics, Spain).

Nonetheless, there are still two critical points that are waiting for a more refined solution: how to avoid performing iridectomies that cause disphotopic phenomena, and most importantly, how to choose the sizing of the lens in order to achieve adequate vaulting. Regarding the first point, the new ICL model V4C has created new market expectations because it resembles our original 1994 prototype where a central drill (Aquaflow) was designed to prevent an IOP spike by increasing the central flow. Just like in the past, my current cases using the new Aquaflow ICL have all presented a normotensive postoperative period, and our experiences with the V4c so far, have been very encouraging and auspicious. In regards to adequate ICL sizing, further studies will be required to prove the efficacy of the new diagnostic technology.

In conclusion, if we were to define an ideal PC PIOL, it should be similar in design and present the same biocompatible material and conditions as the current Visian ICL. Future research should continue focusing on improving imagery diagnostic tools in order to achieve more precise and user-friendly methods for determining IOL sizing for sophisticated designed PC PIOLs, which would allow for a simpler and more efficient way of control vaulting of these lens, consequently ensuring long-term visual quality and safety outcomes.

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Posterior chamber phakic intraocular lenses: a comparative study between ICL and PRL models. Choosing/selection criteria

Lentes intraoculares fáquicas de cámara posterior. Estudio comparativo entre los modelos PRL e ICL. Criterios de elección

The objective of this letter is to establish comparative similarities and differences between the two posterior chamber phakic pre-lens for correcting myopy and hypermetropy. These are ICL (Staar) and PRL (Ioltech-Zeiss/CibaVision). The comparison is based on the information provided by the manufacturers as well as from the PubMed review of literature, summarized in tables I and II.

The most relevant similarities between both are: 1) *Convenience of two prophylactic iridotomies.* These must be broad and are separated at 90° to avoid possible obstruction of the pupil and consequently acute glaucoma, particularly in hypermetropes. 2) *Optic zone diameter.* Similar, slightly smaller in PRL, between 4.5 and 5.5 mm depending on the power of the lens. Accordingly, to similar percentage of luminous halos and night blindness is foreseeable. 3) *Choice of lens size.* Also similar, adding all .5 mm to the white-white corneal diameter. 4) *Biometric calculation through the lenses.* Not altered, i.e., once implanted none artifacts the measure of the axial axis of the ocular globe, and this is particularly relevant for the subsequent calculation of intra-ocular lens in case of to subsequent cataract surgery, the long-term prevalence of which could be increased (1,2). 5) *Secondary implant.* In both, the possibility of being utilized as to secondary implant in pseudophakic patients for correcting residual emmetropies. 6) *Similar range of commercial power.* Although, as we shall see later on, the patient dioptre correction range is very different. In myopia from -3 to -20 for PRL and from–3 to –23 for ICL. In hypermetropy, from +2 to + 15 for PRL and +3 to + 21,5 for ICL. 7) *Very similar refraction index.* 1,46 for PRL, 1,45 for ICL. 8) *Similar cost.* Approx. 800 euros.

The most relevant differences between both are: 1) *Size.* Only one hypermetropic PRL lens of 10.6 mm, compared to 4 sizes for ICL from 11.0 to 12.5 mm. Two myopia PRL lenses of 10.8 and 11.3 mm against 4 ICL sizes from 11.5 to 13.0 mm. +++2) *Possibility of correcting myopic a astigmatism.* From 1 to 6 dioptres (with the axis in positive powers). Exclusively with the ICL lens. 3) *Different material.* Water-repellant purified silicone for PRL against copolymer collage for ICL. 4) *Different injection technique.* Through 3.2 mm micro incision, utilizing pliers for PRL lens, and injector for ICL. 5) *Distance between lens and the phakic lens.* A lot longer in the central area of the ICL lens than in the PRL, but a lot shorter and therefore greater possibility of cataratogenic contact with the lens in the periphery of the ICL lens than in the PRL lens. 6) *Point of support.* Verified with ultrasound biomicroscopy. Most ICL lenses are supported in sulcus and most of the PRL ones on the zonule. This explains why only a few cases of dislocation to the

Table I. Similarities and differences between posterior chamber phakic lenses

	ICL	PR
Hypermetropy sizes	11.0, 11.5, 12.0, 12.5	10.6
Myopia sizes	11.5, 12.0, 12.5, 13. 0	11. 3-10. 8
Correction in astigmatism	From 1 to 6 dioptres	No
Commerical range in myopia	-3 to -23	-3 to -20
Commercial range in hypermetropy	+ 3 to + 21,5	+ 3 to + 15
Optic zone	4. 65-5.5	4.5-5.0
Material	Copolymer collagen	Purified silicon
Refraction index	1.45	1.46
Recommendable to enlarge incision	No	Yes
Injection method	Injector (cartridge)	Pliers
Distance from central to lens	Longer	Shorter
Distance to lens in periphery	Shorter	Longer
Peripheral support	Sulcus	Zonule
Company	Staar	Ioltech-Zeiss/Ciba V
National distributor	Bloss Group	Imex

vitreous have been published in relation to the PRL lens and not of the ICL between two months and two years after the implant (3-5).

The most important point, from the clinical viewpoint, are two practical facts (table II and fig. 1): 1) *The ICL/ PRL lenses with similar power correct a very different number of dioptres.* By changing the power of the lens for the same case when using either PRL or ICL, with the difference being between 1 to 9 dioptres, depending on the number thereof to be corrected and the type of defect. In addition, said difference is increased with the increase of the number of dioptres to be corrected. For example, to correct -6 dioptres of myopia, a PRL lens of -5 must be implanted but -8.5 if it is ICL.

To correct –10 dioptres of myopia, the PRL to implant is–8 and the ICL of –13.5. And to correct a myopia of -18, the PRL is of –14 and the ICL of –22. In hypermetropy, to correct +2 dioptres a PRL of +2 must be implanted or an ICL +3.20. And to correct +6, the PRL to implant is +6 and ICL +10; and to correct +11 we should use a PRL of +12 but an ICL of +21. 2) Some refractive defects can only be corrected with a specific ICL or PRL lens, without alternatives to choose from. For myopic patients from–2 to –3.25 it is possible to implant only an ICL lens, because there is no alternative with PRL. This is important in refractive surgery post-Lasik cases in which it is not possible to repeat laser treatments of the residual defect (flat or thin cornea) or against moderate regressions, or in cases where the first refractive option is intraocular surgery (keratocones, etc.). The same occurs in cases of myopia over -22, where we only have PRL lenses for correcting that refractive defect, and in hypermetrope patients from +11 to +13 where it is only possible to implant a PRL lens.

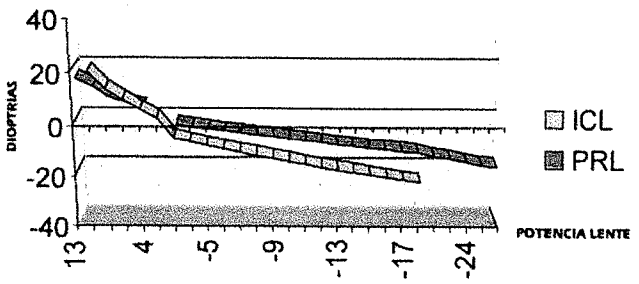

Fig. 1: Differential graph for ICL and PRL lenses for the same refraction.

We consider the above to be relevant for choosing the best refractive option in the cases requiring intraocular phakic surgery.

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Table II. Equivalences between ICL and PRL posterior chamber phakic lenses based on patient refraction to be corrected (*)

	Refractive spherical equivalent in hypermetropy					
	+2.00	+4.00	+6.00	+8.00	+11.00	+13.00
ICL Power	+3.20	+6.64	+10.36	+14.38	+21.08	—
PRL Power	+2.00	+4.00	+6.00	+8.00	+12.00	+15.00
Diff. ICL-PRL	1.20	2.64	4.36	6.38	9.08	—

	Refractive spherical equivalent in myopia											
	-2.00	-3.00	-4.00	-6.00	-8.00	-10.00	-12.00	-16.00	-19.00	-20.00	-22.00-24.00	-27.00
ICL Power	-3.12	-4.59	-6.02	-8.74	-11.28	-13.66	-15.90	-19.99	-22.78	—	— —	—
PRL Power	—	—	-3.56	-5.23	-6.82	-8.36	-9.84	-11.27	-14.65	-15.30	-16.57-17.81	-19.62
Diff. ICL-PRL	—	—	2.46	3.51	4.46	5.30	6.07	7.34	8.13	—	— —	—

* Established for to theoretical calculation with mean corneal dioptres of Ks 42.5, anterior chamber depth 3mm and corneal pachymetry 560 microns.

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Phakic Refractive Lens (Medennium) for Correction of +4.00 to +6.00 Diopters: 1-year Follow-Up

Raquel Gil-Cazorla, DOO; Miguel A. Teus, MD, PhD; Esther Arranz-Marquez, MD, PhD; Celeste Marina-Verde, DOO

ABSTRACT

PURPOSE: To study the efficacy and safety of phakic refractive lens (PRL) implantation to correct high hyperopia.

METHODS: Inclusion criteria for this prospective, observer-masked, interventional study were spherical equivalent ≥+4.00 diopters (D) of cycloplegic hyperopia, best spectacle-corrected visual acuity (BSCVA) ≥0.5, anterior chamber depth ≥3 mm, and mesopic pupil size ≤6 mm. Lenses were implanted in all cases under regional anesthesia using forceps.

RESULTS: Sixteen eyes of nine patients were included in the study. Mean preoperative spherical equivalent refraction was +5.65±1.41 D (range: +3.25 to +5.75 D). Mean 1-year postoperative spherical equivalent refraction was +0.07±0.43 D (range: −0.50 to 0.75 D). Fifteen (93.75%) eyes were within ±0.50 D of emmetropia, and 16 (100%) eyes were within ±1.00 D of emmetropia. Safety and efficacy indexes were 0.9 and 0.8, respectively. Eight (50%) eyes needed LASIK to correct residual astigmatism. Five (31.25%) eyes lost one line of BSCVA; no eye lost two or more lines of BSCVA. The BSCVA did not increase in any eye. No significant intraocular complications developed.

CONCLUSIONS: Phakic refractive lens implantation to correct high hyperopia seems to be a safe and accurate procedure. A mild but significant loss in BSCVA can be anticipated. [*J Refract Surg.* 2008;24:350-354.]

Hyperopia is a common refractive error, yet its management is much more controversial than that of myopia. Several corneal refractive procedures such as automated lamellar keratoplasty, holmium:YAG laser thermal keratoplasty, photorefractive keratectomy (PRK), conductive keratoplasty, and hyperopic LASIK are being performed, but none is completely satisfactory to treat hyperopia greater than 5.00 diopters (D).[1] The visual outcomes obtained in patients with hyperopia using these corneal techniques are not as favorable as those obtained for treatment of myopia because of the large ablation zones required and the small optical zones achieved together with flap-related complications.

Refractive lensectomy provides rapid ocular rehabilitation with good quality of vision, but the loss of accommodation limits its use in young patients. Phakic intraocular lenses (PIOLs) are gaining popularity because they offer a wide range of correction, stability, reversibility, and preservation of accommodation; however, both anterior and posterior phakic refractive lenses have been associated with corneal decompensation, pupil deformation, uveitis, glaucoma, and crystalline lens opacification. Hyperopic eyes usually have shallow anterior chambers,[2-5] which becomes more evident with increasing age. This makes hyperopic eyes prone to possible contact with the corneal endothelium in the periphery and extreme narrowing of the anterior chamber angle in patients implanted with angle-supported intraocular lenses (IOLs) and PIOLs, respectively.

The Phakic Refractive Lens (PRL)[3-5] (Medennium Inc, Irvine, Calif) is a posterior chamber refractive lens. Its single-piece plate is made of medical-grade silicone. The IOL has an over-

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The authors have no proprietary interest in the materials presented herein.

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all length of 10.6 mm with an optical zone of 4.5 mm, a refractive index of 1.46, lens powers ranging from +3.00 to +15.00 D in 0.50-D increments, and an optical thickness based on the dioptric power (maximum of 0.6 mm). The PRL seems to float over the crystalline lens without coming into contact with either the anterior capsule[6] or the ciliary body, which may reduce the risk of crystalline opacification and postoperative inflammatory reactions.

Although a few studies have reported short-term optical results with the PRL that are excellent and stable in a myopic population, the sample sizes of these studies are small[6-8]; moreover, there are even fewer published reports dealing with the use of the PRL to correct hyperopia.[6,9,10] In addition, because hyperopic eyes usually have shallow anterior chambers,[2] these eyes could be prone to complications such as extreme narrowing of the anterior chamber angle and pigment dispersion caused by chronic abrasion of the posterior iris on the anterior surface of the implant[11] in cases of posterior chamber PIOLs. For these reasons, we analyzed the 1-year results of PRL implantation in patients with high hyperopia.

PATIENTS AND METHODS

PATIENT POPULATION

This prospective, observational, non-comparative study included consecutive patients recruited at the Vissum Hospital Oftalmológico de Madrid, Madrid, Spain, who fulfilled the inclusion criteria and agreed to participate. The nature and purpose of the study were explained in detail to all participants, who provided informed consent before entering the study.

In this study, PRL implantation was indicated in patients with a cycloplegic spherical equivalent refractive error between +4.00 D and +11.50 D who desired refractive surgery and in whom laser refractive surgery was contraindicated. Other inclusion criteria were age between 20 and 45 years; a normal anterior segment with an anterior chamber depth of at least 3 mm; mesopic pupil size ≤6 mm; endothelial cell density ≥2500 cell/mm^2; white-to-white corneal diameter measurement of 11.5 to 12 mm measured using a caliper; intraocular pressure (IOP) <20 mmHg; and no uveitis, cataract, or other ocular disease.

PREOPERATIVE EXAMINATION

The preoperative examination included measurement of best spectacle-corrected (BSCVA) and uncorrected visual acuity (UCVA), manifest and cycloplegic refractions, corneal topography using EyeSys (EyeSys Technologies, Houston, Tex), ultrasound pachymetry using the DGH 5100 (DGH Technology Inc, Exton, Pa), endothelial cell counts with a specular microscope (SP-2000P; Topcon, Tokyo, Japan), slit-lamp microscopy, mesopic pupil size measured with the Colvard OftalTech pupillometer (Oasis Medical, Glendora, Calif), white-to-white corneal diameter measured using a caliper, Goldmann applanation tonometry, and dilated funduscopy. Keratometry was performed using an autorefractometer to evaluate the preoperative corneal curvature. Ultrasound measurements (OcuScan, version 3.02; Alcon Laboratories Inc, Ft Worth, Tex) of the axial length by applanation and the anterior chamber depth (defined as the distance from the corneal epithelium to the crystalline lens) also were obtained.

LENS IMPLANTATION

One surgeon (M.A.T.) implanted the PRL in all cases under regional anesthesia through a clear cornea temporal incision. The anterior chamber was filled with a low-viscosity viscoelastic agent (hydroxymethyl methyl cellulose 2%; Alcon Laboratories Inc), and the lens was inserted using forceps. Three laser Nd:YAG iridectomies (at the 10-, 12-, and 2-o'clock positions) were performed at least 1 week preoperatively. The required lens power was calculated using a nomogram provided by Ciba Vision (Apollo Beach, Fla) that was based on the refraction, keratometry, anterior chamber depth, horizontal white-to-white value, and desired postoperative target refraction (emmetropia in all eyes).

POSTOPERATIVE PERIOD

Postoperatively, patients received 250-mg tablets of acetazolamide to be taken three times during the first postoperative day. Antibiotic-steroid (dexamethasone) combination drops were prescribed four times daily for 1 week, followed by tapered doses of fluorometholone for 3 weeks.

Patients were examined 1 day, 1 week, and 1, 3, and 12 months postoperatively. Patients underwent a complete ophthalmologic examination including manifest refraction, slit-lamp microscopy, applanation tonometry, endothelial cell count, and Snellen visual acuity (decimal notation). Visual acuity was converted to logMAR units for statistical analysis.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statview SE + Graphics (Abacus Concepts Inc, Berkeley, Calif) software on a Macintosh personal computer (Apple Computer Inc, Cupertino, Calif). The Mann-Whitney *U* and Wilcoxon signed rank tests were used for comparison when appropriate. Data are expressed as the

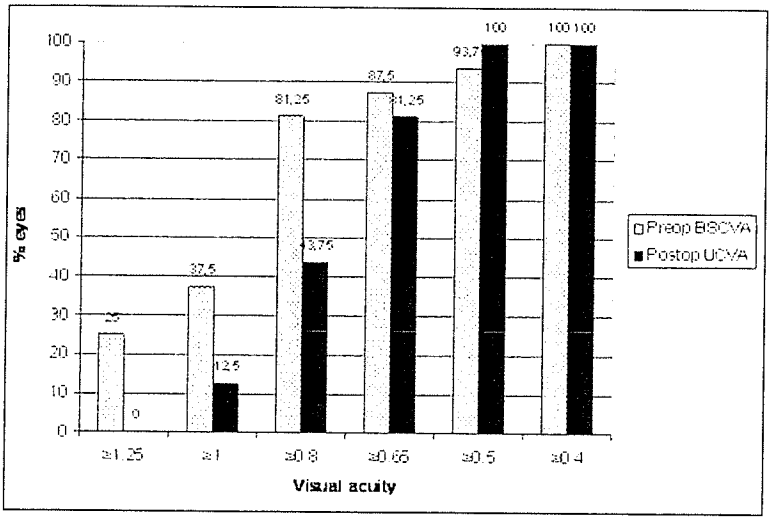

Figure 1. Preoperative best spectacle-corrected visual acuity (BSCVA) and postoperative uncorrected visual acuity (UCVA) in 16 eyes that underwent PRL implantation.

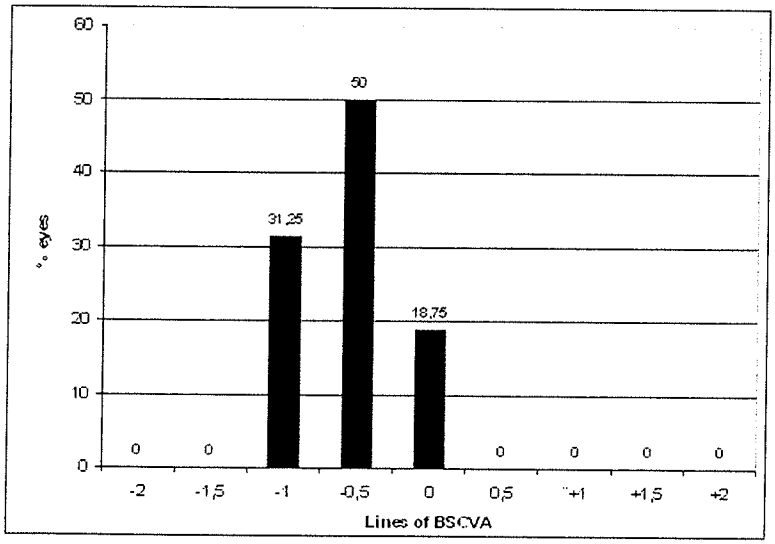

Figure 2. Percentage of eyes that gained and lost lines of best spectacle-corrected visual acuity (BSCVA) 1 year after PRL implantation.

average±standard deviation. The exact *P* value is expressed for each comparison. A *P* value <.05 was considered significant.

RESULTS

Sixteen eyes of nine patients (two women and seven men) were included in the study. Mean patient age was 34 years (range: 25 to 43 years). All patients were available for 1-year follow-up examinations. Mean preoperative anterior chamber depth was 3.10±0.20 mm (range: 3.00 to 3.50 mm).

EFFICACY

Mean Snellen UCVA improved from 0.2±0.3 (range: 0.05 to 0.3) preoperatively to 0.7±0.1 (range: 0.5 to 1) 1 year after PRL implantation. The efficacy index (postoperative UCVA/preoperative BSCVA) was 0.8 (Fig 1).

SAFETY

Mean BSCVA was 0.9±0.2 (range: 0.5 to 1.25) preoperatively and 0.8±0.1 (range: 0.5 to 1) 1 year postoperatively (*P*<.007). Figure 2 summarizes the change in preoperative and 1-year postoperative BSCVA. The safety

index (postoperative BSCVA/preoperative BSCVA) was 0.9.

One year after PRL implantation, eight (50%) eyes lost half a line of BSCVA, and five (31.25%) eyes lost one line of BSCVA. No eye lost two or more lines of BSCVA. The BSCVA did not increase in any eye.

PREDICTABILITY

Mean spherical equivalent measurements showed a significant change from +5.65±1.65 D (range: +4.25 to +7.75 D) preoperatively to 0.07±0.43 D (range: −0.50 to 0.75 D) 1 year postoperatively. The mean 1-year postoperative sphere and cylinder values were 0.17±0.40 D (range: −0.20 to −1.25 D) and −0.60±0.60 D (range: 0 to −1.50 D), respectively.

Fifteen (93.75%) eyes were within ±0.50 D and 16 (100%) eyes were within ±1.00 D of the target refraction at 1-year follow-up. Eight (50%) eyes needed LASIK retreatment to correct residual astigmatism.

INTRAOCULAR PRESSURE

Mean preoperative IOP was 13.07±2.78 mmHg (range: 8 to 17 mmHg). After PRL implantation, mean IOP values were 14.93±2.67 mmHg (range: 11 to 20 mmHg) 1 week postoperatively, 14.57±2.82 mmHg (range: 11 to 20 mmHg) 1 month postoperatively, 14.07±2.05 mmHg (range: 10 to 18 mmHg) 3 months postoperatively, and 11.44±2.55 mmHg (range: 8 to 16 mmHg) 1 year postoperatively.

POSTOPERATIVE COMPLICATIONS

No horizontal iris transillumination defects (ie, pigment deposits on the anterior surface of the PRL), pupillary block, flare, cataract, decentration of the intraocular implant, or other major complications developed after 1 year of follow-up.

Mean preoperative endothelial cell density was 2620±300 cells/mm^2 and 2587±332 cells/mm^2 1 year after the procedure. There was no significant difference between the preoperative and the 1-year postoperative values (P=.2).

DISCUSSION

The surgical treatment of moderate to high hyperopia continues to generate controversy. Photorefractive keratectomy is effective for hyperopia up to +4.00 D but is unpredictable for treating high levels of hyperopia.[12] Furthermore, PRK has been associated with substantial undercorrection and regression,[13,14] and has the added risk of a greater incidence of persistent subepithelial scarring. Laser in situ keratomileusis is used to treat a wide range of hyperopia, but in eyes with hyperopia +6.00 D or greater, the results are less effective and less predictable.[13,15,16]

On the other hand, intraocular procedures, such as clear lens extraction, can be used to treat moderate to high hyperopia. However, they are associated with loss of accommodation and risk of intraocular complications, which are at least potentially more severe than those that may occur after laser ablations.

Implantation of PRLs in patients with high myopia and hyperopia recently has generated renewed interest because it could become one of the most satisfactory surgical techniques for high amounts of ametropia. The results we obtained are in agreement with those reported previously[6,10] in terms of safety and predictability, but the number of patients with hyperopia in those studies were smaller than in the current study.

In the current study, no complications developed at any follow-up. This is in contrast with previous studies,[6,10] in which cataract formation, lens decentration, lens dislocation to the vitreous, horizontal iris transillumination, pupillary block, increased IOP, and PRL extraction were reported. Our good results might be due to the use of a new-generation PRL, good preoperative evaluation (ie, selecting eyes with anterior chamber depths of at least 3 mm), and a correct surgical technique (including the performance of three laser iridotomies preoperatively). These factors seem to be essential for improving the safety with PIOLs.

The fact that no eye gained lines of BSCVA in the current study probably is the result of a loss of image magnification and increments of optical aberration. We believe patients with moderate to high hyperopia should be advised preoperatively that BSCVA could decrease up to one line and never be regained. In contrast, significant improvements in UCVA and BSCVA have been associated with PRL implantation to correct high myopia and appear to be secondary to image magnification.[6,10]

Our results indicate PRL implantation to correct moderate to high hyperopia appears to be a safe, predictable, and stable procedure. More studies are needed with a larger number of eyes and longer follow-up to further elucidate the changes in BSCVA and the long-term efficacy and safety of PRL implantation to correct moderate to high hyperopia.

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LONG-TERM SAFETY AND EFFICACY OF THE PHAKIC REFRACTIVE LENS (PRL)

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Financial Interest: [1] Research is fully or partially funded by Carl Zeiss Meditec Co. that makes/develops/provides the PRL. Travel expenses have been reimbursed, paid in full or subsidized by Carl Zeiss Meditec Co.; that makes/develops/provides the PRL. [2, 3, 4, 5, 6, 7, 8] No financial interest.

INTRODUCTION

The Phakic Refractive Lens (PRL) (Carl Zeiss Meditec, Jena/Germany) is a posterior chamber phakic IOL for the correction of high-grade myopia (-3 to -27 D) and hyperopia (+3 to +15 D). The PRL is an ultrathin, flexible, hydrophobic silicone lens with a refractive index of 1.46. There are three types of PRL available: PRL100 with a total length of 10.8 mm and PRL101 with a total length of 11.3 mm for myopic eyes and PRL200 with a total length of 10.6 mm for hyperopic eyes. Pre-requisite for the implantation of the PRL is an anterior chamber depth (including corneal thickness) of 3.0 mm. Eyes with retinal detachment, iritis, corneal transplantation, chronic miosis, diabetic retinopathy, glaucoma, damaged zonules, uveitis, Marfan syndrome, history of ocular trauma and Pseudoexfoliation syndrome should be excluded from implantation. The PRL is implanted via a 3.0 mm corneal incision with the Dementiev-folding forceps or via injector. One or two irido-tomies/iridectomies are mandatory (either performed preoperatively with the Neodym:YAG laser or intraoperatively). The lens floats in the posterior chamber between iris and cristalline lens.

Surgery can be performed in topical, retro- or parabulbar or general anaesthesia.

The purpose of this study was to evaluate the safety and efficacy of the PRL implantation in myopic eyes.

The PRL is not approved in the United States (off-label-use). It is approved in Europe (CE-Mark).

METHODS

This is a retrospective, non-randomized, multicenter, multi-country European study. The charts of all eyes with PRL implantation in eight European centers were reviewed (Northern Europe: 3 centers in Germany, Southern Europe: 5 centers in Italy, Spain and Portugal). Only eyes with at least one postoperative control in the surgical center were included in the evaluation. Surgeries had been performed between April 30, 2001 and April 17, 2008. To guarantee the anonymity of the patients, sex and age were not noted. That is the reason, why we cannot tell the number of patients – only the number of eyes. The following data were taken from the charts: white-to-white, anterior chamber depth, axial eye length, keratometry, UCVA, BCVA, manifest and cycloplegic refraction, endothelial cell counts and eye pressure before and after surgery. Intraoperative data were incision length, PRL power and model, anaesthetic procedure, instrument for IOL insertion and intraoperative complications. Additionally, postoperative complaints or complications were recorded.

All retrieved data were transferred from the forms into the program STATISTICA Version 6 (StatSoft Inc., Hamburg/Germany). Before evaluation, the data were tested for plausibility using the minimum/maximum method.

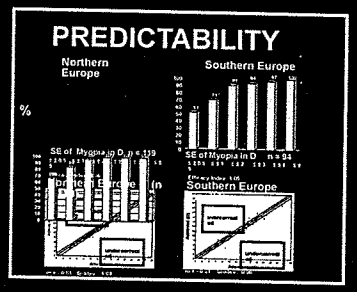
• Outcome Measures

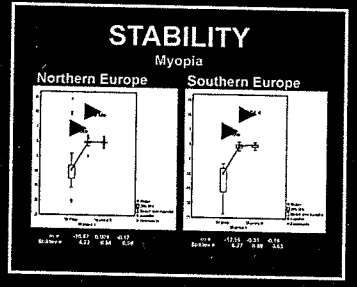
The primary outcome measure was efficacy and safety as measured with the visual acuity.

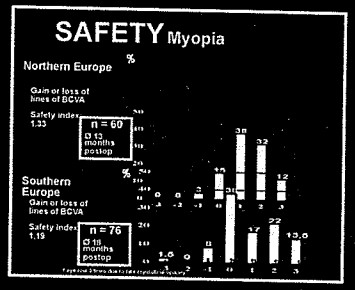
Secondary outcome measures were predictability, stability, change of intraocular pressure, course of endothelial cell count and complications.

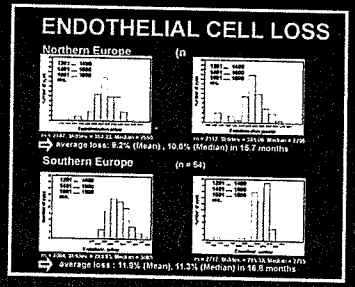
RESULTS

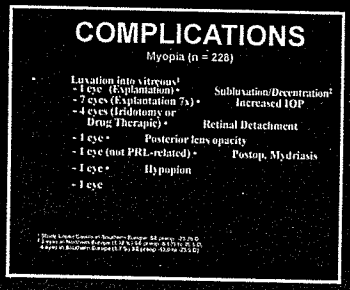
- Data evaluation of 228 myopic eyes
- Follow-up median 12.0 months (m = 14.49 ± 16.01 months, maximum 60 months)
- Preoperative refraction m -11.56 ± 5.22 D
- Power of implanted PRLs -3.0 to -20.0 D
- Predictability: Target refraction was reached ± 1.0 D in 82 %, ± 0.5 D in 63 %
- Efficacy index 1.05 to 1.06
- Safety index 1.19 to 1.33

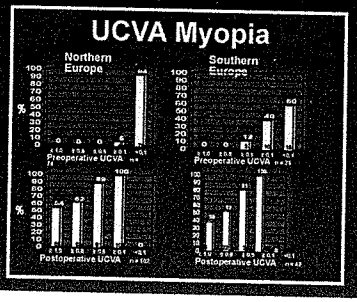


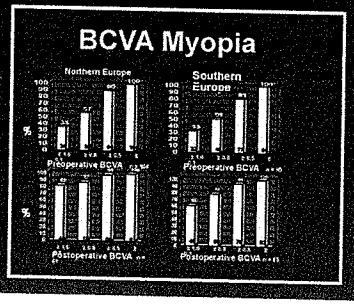












- The PRL implantation resulted in a reduction of the spherical equivalent of the myopic eyes from -11.56 ± 5.22 D to -0.12 ± 0.84 D.
- UCVA increased from preoperatively 0.07 ± 0.12 (0.38 ± 0.51 LogMAR) to postoperatively 0.79 ± 0.29 (0.15 ± 0.24 LogMAR).
- BCVA increased from preoperatively 0.74 ± 0.26 (0.17 ± 0.20 LogMAR) to postoperatively 0.92 ± 0.24 (0.06 ± 0.16 LogMAR).
- Only one eye lost more than 1 line (due to posterior cataract, not PRL-related).
- Main complication was decentration/luxation. The reason for one case of hypopyon could not be found out.

DISCUSSION AND CONCLUSIONS

The PRL implantation is an effective and safe method for the correction of myopia of more than -3.0 D. Safety and efficacy index compare well with the ICL and are better than with LASIK corrections.

Predictability and stability are excellent.

The endothelial cell loss does not exceed what is known from cataract surgery.

The complication rate is low. Cataract is not a concern of PRL implantation. Main concern is decentration/subluxation/luxation that required explantation in 8 eyes. None of the explanted eyes lost visual acuity. The cause for the decentrations is not yet clear. Zonula damage is a prerequisite for the decentration and subluxation. It could be pre-existing in high myopic eyes (no subluxation in eyes of less than -10.0 D). Zonula damage could also be caused during surgery or after surgery. Further research is needed.

Increase of intraocular pressure only happend in four eyes and was due to inadvertent pre- or intraoperative iridotomies.

The limitations of the retrospective design of the study are also valid for this study. But the results of the study are in agreement with the previous published data on the PRL.

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ESASO Bali 2008

Phakic Refractive Lens: Two-year Results

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ABSTRACT

PURPOSE: To evaluate the surgical outcome and adverse events associated with correction of myopia and hyperopia with a phakic refractive lens (PRL), and to determine the random errors of the analytical methods used in the trial.

METHODS: In this prospective clinical study, 14 myopic and 6 hyperopic PRLs were implanted in 20 eyes of 20 patients from April to November 2002. Follow-up included evaluation of the PRL rotation with retroillumination photography, the distance between the PRL and crystalline lens with Scheimpflug images, laser flare meter, endothelial cell count, uncorrected (UCVA) and best spectacle-corrected visual acuity (BSCVA), refraction, intraocular pressure, and induced cataract. The random errors of the measurements with laser flare meter were 17%, with Scheimpflug images 10%, and with endothelial cell count 2.8%.

RESULTS: Postoperatively, 25% of eyes gained 2 or more lines and no eye lost 2 or more lines of BSCVA. Mean UCVA was 0.89±0.34. Laser flare values returned to baseline at 3 months and had no changes at 1 or 2 years ($P>.05$). The PRL rotated less during the second year than the first year. The distance between the PRL and crystalline lens was less at 1 year than at baseline ($P<.05$) but had no change during the second year. No statistically significant endothelial cell loss was noted between 1 week and 1 or 2 years postoperatively ($P>.05$). Two (10%) eyes developed pupillary block, one (5%) hyperopic eye showed unexpected postoperative myopia, and in another hyperopic eye (5%) the horizontal iris transillumination defects were noticed at 1 year combined with slight pupil ovalization at 2 years. No induced cataract, glaucoma, or inflammation was observed.

CONCLUSIONS: Safety and efficacy indexes were high at 2-year follow-up. The distance between the PRL and crystalline lens decreased by 59% during the first year but seemed to stabilize thereafter. The PRL rotated in only a few eyes after the first year. [*J Refract Surg.* 2008;24:507-515.]

Since the mid 1990s, LASIK has been the dominant refractive surgery followed by other corneal refractive surgeries.[1] Laser in situ keratomileusis continues to be the preferred surgical procedure for patients with refractive errors ranging from +3.00 to −8.00 diopters (D).[1] But for high myopes and hyperopes with >+3.00 D the interest in phakic intraocular lenses (PIOLs) is increasing. Even for eyes with ≤−7.00 D of myopia, a PIOL should be considered.[2] The optical consequences of corneal refractive surgery are well known and limit its clinical indications. On the other hand, PIOL implants respect the cornea, have predictable behavior,[3] and are reversible. However, some concerns have to be addressed prior to PIOL implantation. Anterior chamber implants can compromise the well-being of corneal endothelium in the form of long-term endothelial cell loss, especially in hyperopic eyes with convex irides.[3] For posterior chamber IOLs, the main risk for complications is related to compromising the transparency of the crystalline lens, which has been shown in many studies on the Implantable Collamer Lens (ICL; STAAR Surgical, Monrovia, Calif).[2,4-9] The silicone phakic refractive lens (PRL; Medennium Inc, Irvine, Calif), the other commercially available model of a posterior chamber PIOL, has a similar plate design to the ICL. However, the PRL rests on the zonulas and floats in the posterior chamber whereas the ICL is fixated and supported in

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This study was presented at the 9th ESCRS Winter Refractive Surgery Meeting, February 4-6, 2005, Rome, Italy; and ASCRS Annual Symposium & Congress, April 16-20, 2005, Washington, DC.

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TABLE 1

Preoperative Data for Patients With PRL Implantation

Variable	Myopia	Hyperopia
No. of patients	14	6
No. of eyes	14	6
Mean age (y) (range)	32 (24 to 39)	29 (23 to 39)
Right eyes	6	4
No. of females	10	1
Mean SE±SD (D)	−10.28±3.37	+5.67±2.05
Median SE (range) (D)	−9.19 (−6.88 to −17.63)	+6.13 (+3.38 to +8.63)

SE = spherical equivalent refraction, SD = standard deviation

the sulcus angle. Cataract formation is less frequently reported with the PRL[10-12]; however, long-term follow-up studies have yet to be performed.

With this in mind, we designed a prospective, single-center study to evaluate the surgical outcome and adverse events associated with PRL implantation for myopia and hyperopia. A parallel sub-study was designed to evaluate the precision of the analytical methods used in the main study.

PATIENTS AND METHODS

STUDY CRITERIA

Inclusion criteria were patient age between 20 and 45 years, uncorrected visual acuity (UCVA) 0.5 (20/40) or worse, best spectacle-corrected visual acuity (BSCVA) in the fellow eye 0.1 (20/200) or better, stable myopia between −3.50 and −27.00 D or hyperopia between +3.00 and +11.50 D corresponding to available PRL power, normal anterior segment with an anterior chamber depth at least 3.0 mm including the cornea, endothelial cell density >2500 cells/mm², and intraocular pressure (IOP) <20 mmHg.

Patients were excluded if they had regular astigmatism ≥3.00 D, cataract, corneal pathology, narrow angle or glaucoma, history of anterior or posterior segment inflammation, diabetes, infections, or retinal problems.

Only one eye of each patient was included in the study. The local ethical committee provided approval for the study. Patients were informed and consent was obtained. Preoperative data of 20 eyes of 20 patients in the main study group are shown in Table 1. In the sub-study of the analysis of the follow-up methods, 20 additional eyes were included. These eyes met the inclusion criteria stated above and had undergone PRL surgery.

PHAKIC REFRACTIVE LENS

The PRL is a non-fixated, one-piece posterior chamber PIOL. It is made of a hydrophobic silicone elastomer, with a refractive index of 1.46. The optical portion is biconcave or concave–convex. The haptics are spherical and flexible, and the overall lens shape is designed to conform to the natural shape of the posterior chamber of the human eye.

The hyperopic PRL model 200 (Medennium Inc) has an overall length of 10.6 mm. The myopic PRL is available in two models depending on the white-to-white (WTW) diameter of the cornea. The myopic PRL model 100 (Medennium Inc) is 10.8-mm long designed for eyes with WTW between 10.5 and 11.3 mm, and model 101 is 11.3-mm long for WTW >11.3 mm. The refractive range of the myopic implant is −3.00 to −20.00 D and that of the hyperopic design is +3.00 to +15.00 D. Both are available in increments of 0.50 D.

The clinical department of Ciba Vision Surgical AG calculated the PRL power using the following data: refraction, keratometry, anterior chamber depth, WTW diameter, and desired target postoperative refraction. For evaluation of change in spherical equivalent refraction over time, the PRL Calculation Chart was used to find the PRL power needed corresponding to the preoperative refraction and to estimate the deviation in the spherical equivalent correction in myopic eyes. The goal of PRL surgery was to neutralize the spherical correction because the PRL does not correct astigmatism.

SURGICAL TECHNIQUE

A detailed description of the surgical technique has been described previously.[11] Two peripheral neodymium:YAG laser iridotomies were performed superiorly 2 weeks before surgery. Fifteen (75%) surgical procedures were performed under subtenonal anesthesia and 5 (25%) under general anesthesia. Following the placement of sodium hyaluronate 1.34% (Biocorneal; Corneal, Paris, France), the PRL was introduced into the anterior chamber through a 3.2-mm clear corneal self-sealing incision using implantation forceps. Lens haptics were placed underneath the iris with a lens manipulator. The pupil was closed with acetylcholine chloride (Miochol; Novartis Pharma Stein AG, Stein, Switzerland) injection. The remaining viscoelastic was irrigated out of the anterior chamber. At the end of the surgery, 1 mg of cefuroxime sodium (Zinacef; Baxter Healthcare Corp, Deerfield, Ill) was injected into the anterior chamber. Postoperatively, topical dexamethasone 0.1% was prescribed 3 times daily for 1 week with tapered doses for 3 weeks and tropicamid 0.5% 2 times daily for 2 days.

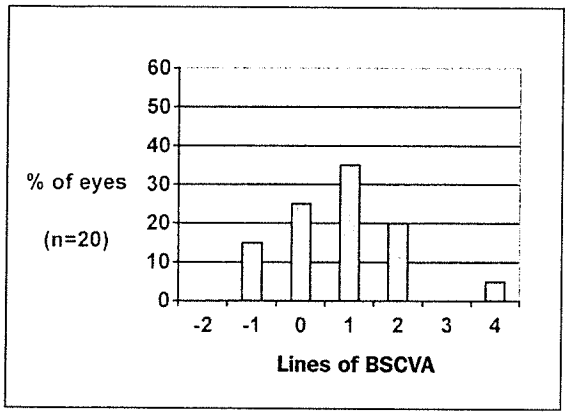

Figure 1. Percentage of eyes gaining and losing lines of BSCVA at 2 years. No eyes lost two or more lines.

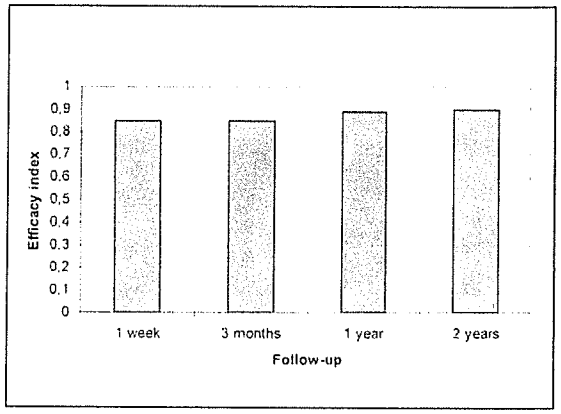

Figure 2. Efficacy index at follow-up.

POSTOPERATIVE FOLLOW-UP

All patients were scheduled for follow-up at 1 day, 1 week, 3 months, 1 year, and 2 years; follow-up was completed in all cases. The visits involved a detailed ophthalmologic examination including manifest refraction, slit-lamp microscopy, applanation tonometry, laser flare measurement, Scheimpflug slit images in dilatation, retroillumination photographs, and endothelial cell count. The crystalline lens was examined with clinical assessment by slit-lamp, retroillumination photographs, and Scheimpflug images to analyze lens transparency. Retroillumination photographs were taken after pupil dilatation with tropicamid 0.5% to illuminate at least one edge of the PRL for comparison. Endothelial cell density was measured preoperatively, at 1 week, 1 year, and 2 years. Visual acuity was tested with the Early Treatment of Diabetic Retinopathy Study (ETDRS) acuity charts. Safety was evaluated by the BSCVA. A safety index was defined as the ratio of the mean postoperative BSCVA over the mean preoperative BSCVA, and an efficacy index as the ratio of the mean postoperative UCVA over the mean preoperative BSCVA.[13]

ANALYSIS OF THE FOLLOW-UP METHODS

Anterior chamber flare was measured using the Kowa FM-500 laser flare (Kowa Co Ltd, Tokyo, Japan). All eyes had dilated pupils during measurements. Ten sequential scans were averaged. Flare values were expressed as photon counts per millisecond.

The Topcon SP-1000 specular microscope and IMAGEnet systems (Topcon, Tokyo, Japan) were used for measuring corneal endothelial cell density. On the basis of approximately 100 identified cells taken from the recorded picture of the endothelium, the computer traced the cellular outlines while the investigator corrected false readings (semiautomated method). The software performed the final calculation and the values were expressed as cells per square millimeter.

Images of the anterior segment were made using a NIDEK EAS-1000 Anterior Eye Segment Analysis System (NIDEK Co Ltd, Gamagori, Japan) in a dilated pupil. After the photographic procedure, the measurement of the distance (in millimeters) between the posterior surface of the PRL and the anterior lens surface was repeated three times and averaged to obtain final results for distance.

To evaluate the precision of the analytical methods used, double independent measurements of laser flare meter, endothelial cell count, and determination of the distance between the PRL and the crystalline lens with Scheimpflug images were performed on 20 eyes after PRL surgery and they were not included in the main study. All measurements were done by the same investigator (M.T.).

STATISTICAL ANALYSIS

Statistical analysis was performed by Friedman two-way analysis of variance (ANOVA) by ranks with multiple comparisons.[14] The level of significance was $P<.05$.

RESULTS

SAFETY

At 2 years, 80% of eyes had BSCVA 1.0 (20/20) or better (93% of myopic and 50% of hyperopic eyes), an improvement over the baseline level of 65%. The change in BSCVA is summarized in Figure 1. Five (25%) eyes gained two or more lines and no eyes lost

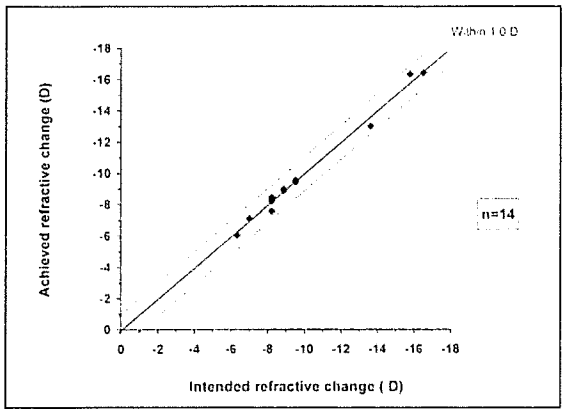

Figure 3. Change in spherical equivalent refraction over 2 years in 14 myopic eyes. Eleven (79%) eyes were within ±0.50 D of desired refraction and 14 (100%) were within ±1.00 D.

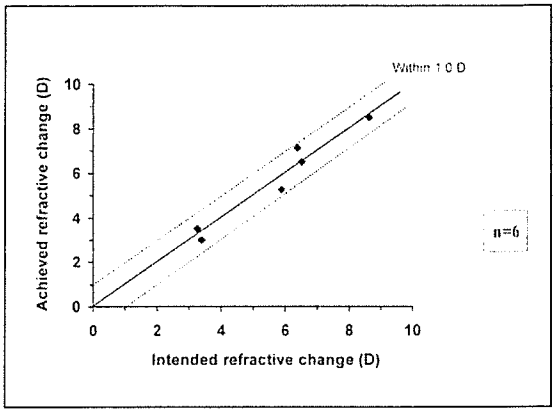

Figure 4. Change in spherical equivalent refraction over 2 years in 6 hyperopic eyes. Four (67%) eyes were within ±0.50 D of the desired refraction and 6 (100%) eyes were within ±1.00 D.

TABLE 2

Mean Distance Between the Posterior Surface of the PRL and the Anterior Lens Surface With 95% Confidence Intervals for the Means at Follow-up

	Mean Distance (mm)				
Eyes	1 Day	1 Week	3 Months	1 Year	2 Years
Myopic	0.66±0.09	0.52±0.11	0.45±0.11	0.26±0.06	0.26±0.08
Hyperopic	0.69±0.33	0.62±0.30	0.52±0.25	0.30±0.12	0.31±0.13
All	0.64±0.13	0.55±0.12	0.47±0.11	0.26±0.06	0.27±0.06

two or more lines of BSCVA. The mean BSCVA was 0.98 preoperatively, 1.11 at 1 year, and 1.18 at 2 years. The safety index was 1.2 (ie, 1.18/0.98) at 2 years.

EFFICACY

Regarding the uncorrected visual results, it should be noted that only 65% of eyes had BSCVA of 1.0 (20/20) or better preoperatively. At 2 years, the mean UCVA was 0.89 and the efficacy index 0.91 (ie, 0.89/0.98). Figure 2 shows the efficacy index over time. For the entire study group, UCVA was 1.0 (20/20) or better in 8 (40%) eyes and 0.5 (20/40) or better in 19 (95%) eyes. Of myopic eyes, 50% had UCVA of 1.0 (20/20) or better and 100% had 0.5 (20/40) or better. Of hyperopic eyes, 17% had 1.0 (20/20) or better and 83% 0.5 (20/40) or better. One hyperopic eye had postoperative UCVA 0.2 (20/100), ie, worse than 0.5 (20/40). The refraction was +7.00 −2.25 × 70° preoperatively and 0 −3.00 × 85° postoperatively. After 2-year refractive data inclusion was completed, the eye underwent laser epithelial keratomileusis[15,16] (LADARVision4000; Alcon Laboratories Inc, Ft Worth, Tex) for astigmatism. The eye resulted in UCVA of 0.8 (20/25), which was the same as the preoperative BSCVA.

PREDICTABILITY

Fifteen (75%) eyes were within ±0.50 D of the desired refraction and all (100%) eyes were within ±1.00 D. The change in spherical equivalent refraction is shown for myopic eyes in Figure 3 and for hyperopic eyes in Figure 4. The mean spherical equivalent refraction in myopic eyes was −0.35 D (range: +0.63 to −1.63 D) at 1 year and −0.38 D (range: 0 to −1.25 D) at 2 years. In hyperopic eyes, the mean spherical equivalent refraction was −0.60 D (range: +0.125 to −1.75 D) at 1 year and −0.85 D (range: −0.25 to −1.75 D) at 2 years. If the mean spherical component is studied separately, it was +0.04 D at 1 year and +0.02 D at 2 years in myopic eyes. The mean spherical correction in hyperopic eyes was +0.13 D at 1 year and −0.13 D at 2 years.

DISTANCE BETWEEN THE PRL AND CRYSTALLINE LENS

Table 2 shows the central distance between the posterior surface of the PRL and anterior lens surface over time. In myopic and hyperopic eyes, the gap decreased

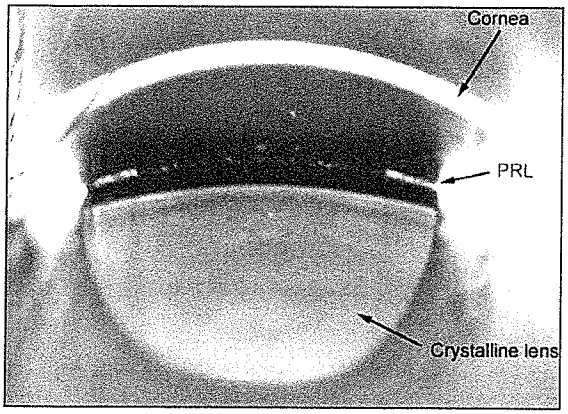

Figure 5. Scheimpflug image of a hyperopic eye showing 0.74-mm distance between the posterior surface of the PRL and the anterior lens surface.

TABLE 3

Median PRL Rotation Between Follow-up Examinations

Eyes	PRL Rotation (Range) (°)			
	1 Day to 1 Week	1 Week to 3 Months	3 Months to 1 Year	1 Year to 2 Years
Myopic	5 (1 to 58)	2 (1 to 72)	1 (0 to 87)	0 (0-11)
Hyperopic	7 (2 to 15)	2 (0 to 98)	3 (0 to 39)	0 (0 to 55)
All	5 (1 to 58)	2 (0 to 98)	1 (0 to 87)	0 (0 to 55)

during the first year after surgery without changes during the second year. Friedman two-way ANOVA showed a statistically significant difference in distance when comparing 1- and 2-year distance with distance 1 day after surgery ($P<.05$). No statistically significant change was noted between 1 day and 1 week, 1 week and 3 months,

TABLE 4

PRL Rotation in All Eyes at Various Follow-Up Examinations

Patient No.	PRL Rotation (°) Follow-up			
	1 Day – 1 Week	1 Week – 3 Months	3 Months – 1 Year	1 Year – 2 Years
1	15	0	2	55
2	2	2	7	0
3	13	0	3	0
4	—	—	10	11
5	11	98	2	0
6	1	2	21	4
7	27	5	1	0
8	1	1	87	4
9	1	2	0	0
10	58	2	1	5
11	2	2	0	0
12	—	72	1	0
13	3	6	39	22
14	8	2	0	3
15	36	3	2	0
16	4	52	1	0
17	10	1	9	0
18	2	3	0	4
19	2	0	0	0
20	5	3	0	0

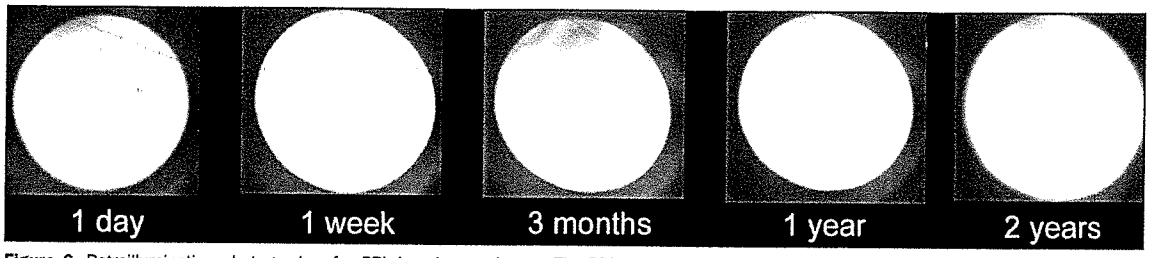

Figure 6. Retroillumination photographs of a PRL in a hyperopic eye. The PRL rotated 15° between 1 day and 1 week and 55° between 1 and 2 years.

TABLE 5

Mean Endothelial Cell Density With 95% Confidence Interval Over Time and Percentage Change From Preoperative Values

	Endothelial Cell Density (cells/mm²) (%)		
	All Eyes (n=20)	Myopic Eyes (n=14)	Hyperopic Eyes (n=6)
Preoperative	3051±145	2989±151	3198±322
Postoperative			
1 week	2804±232 (8.4)	2752±267 (8.1)	2925±483 (9.3)
1 year	2849±223 (7.1)	2771±224 (7.4)	3031±539 (6.2)
2 years	2823±209 (7.7)	2753±238 (8.0)	2986±427 (7.1)

or 1 year and 2 years. Figure 5 illustrates an example of Scheimpflug images used for evaluation of distance.

PRL Rotation

The median rotation (18.5° during the first year and 0° during the second year) with range is presented in Table 3. Fifteen (75%) PRLs during the first follow-up year and three (15%) PRLs between 1 and 2 years rotated 10° or more (Table 4). In two eyes, the edges of the PRL could not be evaluated at the beginning of the study because of compromised pupil dilatation and corneal edema. The centralization of the PRL was good in all eyes. Figure 6 illustrates PRL rotation in a hyperopic eye over time.

Endothelial Cell Change

Measurements 1 week after surgery showed 8.4% endothelial cell loss with slight recovery at 1 year without significant changes at 2 years (Table 5). Friedman two-way ANOVA showed statistical significance between visits preoperatively and all postoperative visits ($P<.05$). However, no statistically significant change was noted in endothelial cell density between 1 week and 1 year or 2 years after surgery.

Laser Flare

Laser flare measurements are presented in Figure 7. The highest average flare count was 15.6 photons/ms at 1 day after surgery compared with mean 3.8 photons/ms before surgery. The mean laser flare returned to the preoperative level at 3 months and had no significant change at 1 year or 2 years after surgery ($P>.05$).

Result of the Analysis of the Follow-up Methods in the Sub-study Group

The random error for laser flare was 17%, endothelial cell count 2.8%, and distance measurement 10%.

Intraocular Pressure

The mean IOP was 16 mmHg (range: 13 to 21 mmHg) preoperatively, 15 mmHg (range: 10 to 27 mmHg) 1 day after surgery, 20 mmHg (range: 15 to 49 mmHg) at 1 week, 15 mmHg (range: 11 to 21 mmHg) at 3 months, 16 mmHg (range: 13 to 20 mmHg) at 1 year, and 16 mmHg (range: 10 to 22 mmHg) at 2 years.

A myopic eye developed corticosteroid-induced high IOP of 49 mmHg 1 week postoperatively that resolved after discontinuation of the steroid drops.

Complications

Complications are reported in Table 6. No cataract formation was observed at any time. Two eyes, one hyperopic and one myopic, developed pupillary block 2 and 4 days after surgery, respectively. In both cases, IOP was normalized with complementary YAG-iridotomies and topical cycloplegic agents. A hyperopic

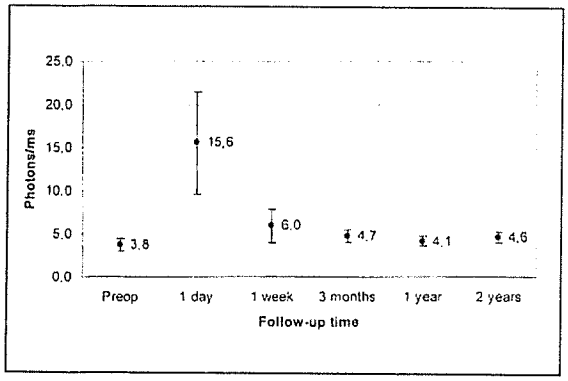

Figure 7. Mean laser flare measurement at various follow-up examinations. The error bars indicate 95% confidence intervals for the means.

TABLE 6

Complications in 20 eyes That Received PRL

Complication	No. of Eyes (%)	Comment
Pupillary block	2 (10)	YAG-iridotomy and medical treatment
Unexpected postoperative myopia	1 (5)	PRL exchange
Iris transillumination defect with pupil ovalization	1 (5)	Continuous clinical follow-up

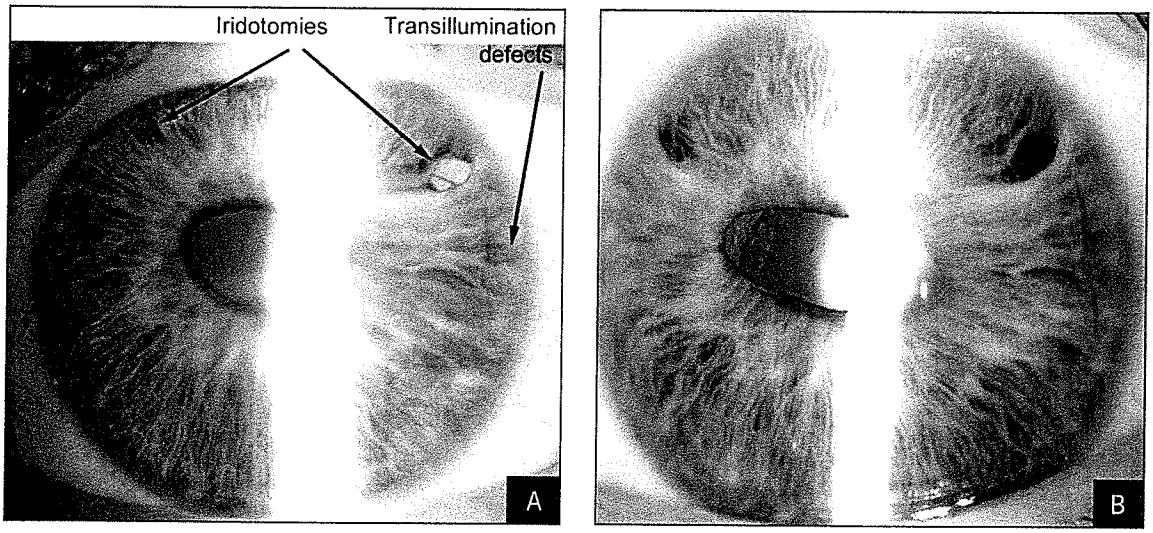

Figure 8. A) Transillumination defects in an iris in a hyperopic eye at 1 year with **B)** pupil ovalization at 2 years.

eye with preoperative refraction +3.75 −1.00 × 20° showed unexpected myopia (−1.50 −0.75 × 45°) after PRL (+4.50 D) implantation. Exchange of the PRL for +3.50 D changed the postoperative refraction to +0.25 −1.00 × 45°.

Horizontal iris transillumination defects were noted in a hyperopic eye at 1 year combined with pupil ovalization at 2 years (Fig 8). No pigment deposits on the anterior surface of the PRL or Krukenberg spindles were noted. A 360° gonioscopic examination did not show trabecular pigmentation or anterior synechias. Ultrasound biomicroscopy (UBM) revealed haptics in contact with the peripheral iris on both sides with capture nasally. At 2 years, the distance between the posterior surface of the PRL and anterior lens surface was 0.55 mm (mean for all eyes 0.27 mm). The PRL rotated slightly during the first year without rotation thereafter. The laser flare was below the mean values and the IOP was <16 mmHg during follow up. The patient had no complaint of glare or halos.

DISCUSSION

The evaluation of the precision of the laser flare meter and Scheimpflug method showed relatively high random errors, 17% and 10%, respectively. The results in an earlier laser flare study showed within-subject variability in aqueous flare of 12% in normal eyes.[17] To achieve more reliable laser flare and Scheimpflug results, double, or even triple, independent measurements could be used. The endothelial cell count, how-

ever, showed low random error (2.8%) and is a reliable indicator for evaluation of corneal endothelium. This result is confirmed in another study that used the same system.[18]

Visual acuity outcome showed excellent results. A total 95% of eyes had UCVA 0.5 (20/40) or better even though the PRL with its floating design can not provide correction of astigmatism. In astigmatism with significant effect on visual outcome, other options exist which are complementary to PRL. One is bioptics, in which a PIOL is combined with a corneal laser procedure.[19,20] For myopic eyes with astigmatism, the toric ICL is a potential option as it remains rotationally stable after surgery.[21] Unfortunately, no toric hyperopic posterior chamber PIOL exists. In our hyperopic case with marked astigmatism, bioptics was chosen and the eye gained 6 lines in UCVA. Complementary treatment was delayed until the study was completed. However, our results indicate stabilizing of refraction at 3 months postoperatively, which could be seen as a recommendation for timing of the bioptics procedure for residual astigmatism.

For residual refractive error in the form of pure spherical ametropia after PRL surgery, the easiest option is to exchange the PRL for the correct power, as we did in one case in the present study. After replacement of the PRL in a hyperopic eye, all eyes were within ±1.00 D and 75% were within ±0.50 D of the desired refraction. These results are better compared with other studies of posterior chamber lenses, most of which used the ICL.[4,10,12,13,20]

The primary concern with any posterior chamber PIOL is cataractogenesis, which was not found in our study. The floating design of the PRL could be a protecting factor for the crystalline lens. During the first year, the distance between the posterior surface of the PRL and anterior lens surface decreased considerably but stabilized without changes during the second year. We did not investigate the possible influence of accommodation in the distance. In their case report with anterior chamber optical coherence tomography (OCT), Baikoff et al[22] showed that the posterior surface of the PRL touched the anterior lens surface in accommodation. However, further dynamic studies are essential to demonstrate the impact of the distance between the IOL and the lens capsule for lens metabolism and in cataractogenesis. With its high resolution capacity, the anterior chamber OCT can have better precision than Scheimpflug images.

The PRL seems to rotate in the posterior chamber even though the rotation is much less during the second year. Garcia-Feijoo et al[23,24] reported in some cases the PRL had rotated from the original implantation position and both haptics were on the zonules, which could indicate this position facilitates mobility of the PRL in the posterior chamber. However, there are some reports of serious complications with PRL luxation into the vitreous cavity, suggesting PRL rotation causes excess pressure against zonules.[25-27] Our study can not confirm this theory. Some degree of rotation is shown in the majority of the eyes but mostly just once between different visits. The absence of decentration of the PRL in the study can be seen as an indication for correct lens sizing. Two study parameters, the rotation of the PRL and distance measurements, indicate stabilization of the PRL position in the posterior chamber 1 year after implantation.

After initial endothelial cell loss induced by surgical trauma as reported in our earlier study,[11] there was no ongoing cell loss induced by the PRL. The laser flare values were also low without influence of the PRL and without changes since our earlier reports.[11] The most severe complication in our study was iris transillumination defects in a hyperopic eye noted 1 year postoperatively[11] with progress of pupil ovalization at 2 years. The two factors, UBM result of iris capture and the anterior convexity of the PRL, indicated poor fit of the PRL in the posterior chamber.

This study demonstrates excellent visual outcome in myopic and hyperopic eyes with PRL implantation without serious intra- or postoperative complications. No PRL-induced lens opacification was seen. These clinical outcomes are better or comparable to existing refractive surgery alternatives. However, further follow-up with a larger study-group is needed to review the long-term characteristics of the PRL.

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LONG-TERM RESULTS OF PHAKIC REFRACTIVE LENSES FOR CORRECTION OF MYOPIA AND HYPEROPIA

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To my Marko and our Anton and Edvin

ABSTRACT

The phakic refractive lens (PRL) is a silicone lens implanted into the posterior chamber to correct myopia and hyperopia. At the beginning of 2002, when the PRL was introduced at St. Erik Eye Hospital, there had been no reports published on this lens model and therefore the pilot studies of myopic and hyperopic eyes were conducted to investigate the surgical outcome.

In the first study, the first 20 consecutive cases with PRL implantation were followed for 1 year after surgery. The visual acuity results were comparable to other refractive methods and demonstrated high safety and efficacy indexes. The mean distance between the posterior surface of the PRL and the anterior lens surface decreased significantly in all eyes during the 1-year follow-up. The retroillumination photographs revealed slight rotation of the PRL in most eyes. The endothelial cell count decreased significantly 1 week after surgery without changes thereafter indicating that the difference in cell density was caused by surgical trauma and not the PRL. Few complications were observed. Increased intraocular pressure (IOP) related to pupillary block developed in two eyes (1 myopic and 1 hyperopic) during the first postoperative days. A myopic eye developed corticosteroid-induced high IOP 1 week postoperatively, which resolved after discontinuation of the steroid drops. One hyperopic eye unexpectedly developed myopia after PRL implantation. The PRL was exchanged with success. Iris transillumination defects were noticed in a hyperopic eye 1 year postoperatively. No ongoing inflammation, lens opacification or glaucoma was found.

The second study was a prospective 2-year follow-up study of the same myopic and hyperopic population as in the first study. A parallel substudy was designed to evaluate the precision of the analytical methods used in the main study. Ninety-five percent of eyes had an uncorrected visual acuity (UCVA) of 0.5 or better even though the PRL with its floating design did not correct astigmatism. In 65 % of cases the best-corrected visual acuity (BCVA) improved over the preoperative level. Fifteen eyes (75%) were within ±0.5 diopter (D) of the desired refraction and all eyes (100%) were within ±1.0 D. During the first year, the distance between the PRL and the anterior lens surface decreased 59% but stabilized without changes during the second year. Fifteen PRLs (75%) rotated 10 degrees or more during the first follow-up year and three PRLs (15%) between 1 and 2 years. These study parameters, the rotation of the PRL and distance measurements, indicated stabilization of the PRL position in the posterior chamber 1 year after implantation. Endothelial cell count measurements 1 week after surgery showed 8.4% endothelial cell loss with slight recovery at 1 year without significant changes at 2 years. No PRL-induced lens opacification or inflammation was seen. The study showed excellent visual outcomes in myopic and hyperopic eyes with PRL implantation without serious intra- or postoperative complications.

Evaluation of the precision of the laser flare meter and Scheimpflug method showed relatively high random errors, 17% and 10%, respectively. The endothelial cell

count, however, showed low random error (2.8%) and indicated that this method is a reliable indicator for evaluation of the corneal endothelium.

In the third study, the movement of the PRL was evaluated in relation to the behavior of the crystalline lens and the pupil during accommodation in three groups: eyes with PRL 101, PRL 100, and PRL 200. The effect of accommodation was studied with optical coherence tomography (OCT). To evaluate the precision of Visante OCT, we conducted a double-independent measurement study, which showed a random error of 5% in the measurements between the PRL and the anterior lens surface. This result indicated that Visante OCT is sufficiently accurate and reliable to allow an analysis of distances in the anterior segment. Fifty-two patients were examined at least 1 year after PRL implantation using the Visante OCT. During accommodation, significant forward movement of the anterior lens surface and the PRL was observed in each group. Although the PRL moved anteriorly with accommodation with all three lens models, the space between the PRL and the crystalline lens was preserved only with PRL 100, and the space decreased significantly with the other two models. With the PRL 101, the baseline distance between the PRL and the anterior lens surface was significantly smaller in older eyes, indicating a decreased posterior chamber depth with aging of the lens. In three myopic cases, the PRL touched the anterior lens surface at baseline and two of them developed lens opacification. Both eyes had PRL 101 model. During accommodation, an additional implant in the PRL 101 and in the PRL 100 groups came in contact with the crystalline lens. In hyperopic eyes, there was no contact with the crystalline lens at baseline. During accommodation, the PRL 200 was in contact in three cases. This study showed that the PRL and the anterior lens surface moved forward during accommodation, and in most cases there was no mechanical contact with the anterior lens surface during accommodation.

The fourth study was conducted to evaluate the surgical outcome and adverse events associated with PRL implantation in hyperopic eyes. The results showed excellent predictability with all eyes within ±1.0 D of the attempted refraction. There was no gain in BCVA and three eyes (7.5%) lost two lines of corrected visual acuity. The initial endothelial cell loss postoperatively was -4.6% and remained stable thereafter. The mean IOP remained unchanged during the entire follow-up period. The most frequent complication was development of postoperative pupillary block in seven eyes (17.5%). Two eyes with severe glare and one eye with unexpected myopia and discomfort underwent PRL explantation. Unexpected postoperative myopia was treated with PRL exchange in two eyes and with laser epithelial keratomileusis (LASEK) in one eye. No PRL-induced glaucoma or cataract developed. The study showed high refractive stability and predictability at the 1-year follow-up. There was no gain in corrected visual acuity. Despite two iridotomies performed 2 weeks preoperatively, the main complication was early pupillary block.

LIST OF PUBLICATIONS

I. **Koivula A**, Petrelius A, Zetterström C.
Clinical outcomes of PRL in myopic and hyperopic eyes: one-year results.
Journal of Cataract & Refractive Surgery, 2005, 31:1145-1152.

II. **Koivula A**, Taube M, Zetterström C.
Phakic Refractive Lens: Two-year Results.
Journal of Refractive Surgery (In press)

III. **Koivula A**, Kugelberg M.
Optical Coherence Tomography of the Anterior Segment in Eyes with Phakic Refractive Lenses.
Ophthalmology [Epub ahead of print].

IV. **Koivula A**, Zetterström C.
Phakic Refractive Lens for Correction of Hyperopia.
(Submitted)

CONTENTS

LIST OF ABBREVIATIONS

AC	Anterior chamber
AC PIOL	Anterior chamber phakic intraocular lens
ALS	Anterior lens surface
AS-PRL	Anterior surface of the phakic refractive lens
BCVA	Best-corrected visual acuity
D	Diopter
ETDRS	Early Treatment of Diabetic Retinopathy Study
ICL	Implantable contact lens
IOL	Intraocular lens
IOP	Intraocular pressure
LASEK	Laser epithelial keratomileusis
LASIK	Laser in situ keratomileusis
logMAR	Logarithm of the minimum angle of resolution
Nd:YAG	Neodymium-yttrium aluminium garnet
OCT	Optical coherence tomography
OVD	Ophthalmic viscosurgical device
PC	Posterior chamber
PC PIOL	Posterior chamber phakic intraocular lens
PIOL	Phakic intraocular lens
PMMA	Polymethyl methacrylate
PRK	Photorefractive keratectomy
PRL	Phakic refractive lens
PS-PRL	Posterior surface of the phakic refractive lens
SE	Spherical equivalent
UBM	Ultrasound microscopy
UCVA	Uncorrected visual acuity
WTW	White to white (corneal diameter)

1 INTRODUCTION

1.1 BACKGROUND

Almost 10 years ago, Tobias Neuhann wrote in his *Journal of Refractive Surgery* editorial: "Excimer lasers are used today practically all over the world to treat refractive errors. This provides us with a wealth of data and findings that must be analyzed, presented, interpreted, and discussed. One major finding is already certain: the absolute and indisputable necessity of refractive surgery. Even those who are skeptical about refractive surgery must accept this. Patients simply do not care about the ethical or other misgivings of ophthalmologists. People who suffer from refractive errors seek and desire a treatment. By definition, they are patients and not clients. We should not ignore this, but rather accept it; in fact, they are calling on us to help them."(Neuhann 1998)

Refractive surgery, as all branches of medicine and surgery, is a dynamic process with advancement of knowledge leading to constant improvement in standards of care. Refractive surgery continues to evolve: it remains one of the fastest changing fields in medicine. Over the years, refractive surgeons have experienced a significant change in every aspect of refractive surgery, including patient selection, diagnostic tools, microkeratomes, refractive lasers, and refractive lenses. Patient selection has changed from correction of only myopia to include hyperopia, astigmatism, and presbyopia.

1.1.1 Prevalence of refractive errors

Mild-to-moderate hyperopia can be overcome by accommodation in youth and early adulthood, with the result that low degrees of hyperopia often are unnoticed until the onset of presbyopia in mid-adulthood. Myopia results in blurred vision at all ages. Blurred vision from refractive error can be relived in most cases by neutralizing the refractive error with spectacles, contact lenses, or refractive surgery (Figure 1).

Figure 1. Spectacle correction in hyperopia and myopia.

hyperopia

myopia

In Scandinavia, Fledelius estimated that the frequency of myopia in the general population was between 25% and 30% and about in 25% of cases myopia begins during adulthood (Fledelius 2000). The cause of this type of myopia is unclear, although some evidence supports an environmental influence linked to a greater amount of near work.

Comparison of prevalence rates of refractive errors among young (20-25 years) and middle-aged (40-45 years) adults in Norway showed that most subjects in both age groups were emmetropic: 51.8% of young and 52.3% of middle-aged adults. The prevalence of myopia (defined as spherical equivalent [SE] $\leq$ -0.5 D) was 35.0% in the young adult group and 30.3% in the middle-aged adult group. The proportion of people with high myopia (<-5.0 D) was similar in both age groups, with 2.8% among young and 3.3% among middle-aged adults. Hyperopia (defined as SE $\geq$ +0.50 D) increased significantly with age from 13.2% among young adults to 17.4% among the middle-aged (Midelfart et al. 2002).

In the Western European population of persons 40 years and older for the year 2000, an estimated 11.6% had hyperopia of ≥+3.0 D (21.6 million persons), 26.6% had myopia of ≤-1 D (49.6 million persons), and 4.6% (8.5 million persons; 17.1% of all persons with myopia) had myopia of ≤-5.0 D (Kempen et al. 2004). The prevalence of hyperopia was observed to be progressively higher with increasing age and the prevalence of myopia of -1 D or less tended to be substantially lower for individuals older than the younger age groups. Similarly, myopia of -5.0 D or less was strongly associated with age, with the highest prevalence in the youngest strata (ages 40-49 years) (Kempen et al. 2004).

1.1.2 Refractive surgery

Why would somebody undergo refractive surgery? Many individuals are uncomfortable with their refractive error and poor uncorrected visual acuity (UCVA). Although external aids in the form of spectacles or contact lenses are acceptable to many, several factors are instrumental in the search for a permanent solution to refractive errors. The most frequently claimed reason in people with high myopia is that with spectacle correction the viewed objects are minified, and with high myopia and hyperopia the peripheral fields are severely distorted by spectacles. In addition, contact lens intolerance, occupational requirements, sporting and other leisure interests, physical problems wearing glasses, and a psychological (self-image) desire to achieve visual freedom are the other reasons patients cite for wanting to undergo refractive surgery (Rosen and Gore 1998).

Currently, there are three general approaches to correct a refractive defect:

1. corneal refractive surgery
2. crystalline lens surgery
3. implantation of an intraocular lens (IOL) in the anterior (AC) or the posterior chamber (PC).

In any case, the main goal of refractive surgery is the attainment of the smallest residual refractive error that preserves vision quality with the same visual capacity.

1.1.2.1 Corneal refractive surgery

Corneal refractive surgery might be divided into three types:

1. Incisional and thermal corneal surgery
2. Corneal ablation surgery
    a. Surface ablation
    b. Lamellar laser refractive surgery
3. Additive refractive keratoplasty

Corneal refractive surgery, except for intracorneal lenses, attempts to modify the anterior curvature of the cornea to obtain its effect. Radial keratotomy was the keystone of corneal refractive surgery to correct myopia (Fyodorov and Durnev 1979) but resulted in instability of the corneal dome (Waring et al. 1991). In thermal corneal surgery, the anterior corneal curvature is modified by thermal induced shrinkage of collagen fibers in the cornea, and the collagen shrinkage steepens the cornea. The method should be reserved for mild hyperopia in patients over 40 years (Sher 2001).

The first prototypic excimer laser system was debuted at the American Academy of Ophthalmology (AAO) in 1987 and it generated great interest in alternatives to radial keratotomy. In 1988, McDonald and colleagues (Waring et al. 1991) performed the first successful excimer laser photorefractive keratectomy (PRK) on a seeing human eye with myopia. In the early 1990s, Pallikaris and colleagues (Pallikaris et al. 1990) and Buratto and colleagues (Buratto et al. 1993) independently described a technique that combined two existing technologies: the microkeratome and the excimer laser. Pallikaris coined the term laser in situ keratomileusis (LASIK) for this new technique, which has become a widely used refractive technique worldwide.

Three methods of surface ablation are currently in use: PRK (Tengroth et al. 1993, Hamberg-Nystrom et al. 1996), laser epithelial keratomileusis (LASEK) (Claringbold 2002, Camellin 2003) and epi-LASIK ablation (Pallikaris et al. 2003, Pallikaris et al. 2005). These methods differ in the manner in which the epithelial layer is handled. However, the ablation of the most anterior portion of the corneal stroma is the same for all procedures. The ablation in particular, through Bowman's layer leads to a wound-healing response that might result in stromal haze and scarring (Fagerholm 2000). Recovery after surface ablation is both slower and more painful than after LASIK (Tomas-Barberan and Fagerholm 1999, Shortt and Allan 2006, O'Doherty et al. 2007).

LASIK is a lamellar laser refractive surgery in which the excimer laser ablation is done under a partial-thickness lamellar corneal flap. Until recently, the lamellar flap could only be made with a microkeratome that cut the lamellar flap to depths of 100 to 200 μm. A femtosecond laser provides more accuracy in flap thickness (Kezirian and Stonecipher 2004) and flap creation is less dependent on the corneal curvature. Compared with surface ablation, LASIK results in earlier and faster improvement of UCVA, and results in no haze and less postoperative discomfort (Kato et al. 2007). With LASIK, however, the risks of flap-related complications and corneal thickness limitations may be associated with the creation of the lamellar flap (Fagerholm et al. 2004, Rao et al. 2004).

It is easier to flatten the cornea permanently for myopia than to steepen it centrally for hyperopia. In contrast to myopic excimer laser surgery, a hyperopic ablanation profile is a peripheral annular ablation around the central optical zone, which produces steepening (Haw and Manche 2000). This requires larger ablation diameter than for myopic corrections. Centration is more critical and decentration are less forgiving in hyperopic ablanations, whether PRK or LASIK. Decentrations may be induced by smaller corneas of hyperopic eyes and larger ablanations (O'Brart 1999).

Additive refractive keratoplasty refers to a procedure in which a foreign material, either biological or synthetic, is added to the corneal tissue to modify the ocular refractive condition. Intracorneal ring segments and inlays are reversible methods that are under development. One of the important advantages over corneal laser procedures is that intracorneal ring segments spare the visual axis. There is essentially no risk of the development of central corneal haze or scarring. No corneal tissue is removed. However, intracorneal ring segments cannot correct more than -4 D of myopia without substantially increasing ocular spherical aberration (Malecaze et al. 2002). Synthetic stromal inlays or intracorneal implants are implanted within the cornea at a depth between 36% and 60% of the corneal thickness to correct hyperopia. However, a variety of complications occurring postoperatively following implantation of the implant has limited its use in refractive surgery (Alio 2004).

1.1.2.2 Crystalline lens surgery

Clear lens extraction has been recognized since 1708, when Boerhave described the possible good results of lens extraction in myopic patients (Seiler 1999). One hundred fifty-five years later, Von Graefe warned about the increased risk of retinal detachment with this type of procedure. After the invention of sterilization in 1889, Fukala reported lens extractions through a discission of the anterior capsule in myopic eyes and has been considered the creator of clear lens extraction (Seiler 1999).

This procedure has been called clear lens extraction by some and refractive lensectomy by others. The current approach is the substitution of the natural lens with an IOL of proper dioptric power. The predictability and stability of the results, comparable to those observed after IOL implantation at the time of cataract surgery, are the main advantages of this technique (Packer et al. 2002, Leyland and Zinicola 2003). Conversely, this technique to correct refractive error must be considered with caution because it might increase the risk of retinal detachment in patients with moderate and high levels of myopia, among other complications (Colin et al. 1999). For some hyperopic patients, while retinal detachment is not a major concern, they often have a shallow anterior segment with little room in the anterior or the posterior chamber for a phakic lens, and refractive lensectomy may be the only surgical alternative (Kolahdouz-Isfahani et al. 1999). However, young patients undergoing this procedure must be aware of the consequent loss of accommodation (Fink et al. 2000). In fact, the current use of multifocal IOLs and the emergence of early accommodative IOLs as refractive surgical techniques now are directed to presbyopia (Fernandez-Vega et al. 2007).

1.1.2.3 Phakic intraocular lens surgery

The third general approach in refractive surgery is placing an intraocular lens in the phakic eye. This definition includes any lens located between the cornea and the anterior surface of the crystalline lens, which is left undisturbed inside the eye. Corneal procedures have the advantage of preserving the human lens but there are limits to the range of correction at the corneal plane. With the most popular refractive surgical procedure, LASIK (Duffey and Leaming 2005), keratectasia is a significant issue and provides a certain myopic limit (Seiler et al. 1998, Pallikaris et al. 2001), whereas the difficulty in producing added corneal power creates a limit on the hyperopic side (Zadok et al. 2003, Varley et al. 2004).

Phakic IOLs (PIOLs) allow correction outside the limits of the corneal refractive surgery (Sanders and Vukich 2003). The insertion of an implant in a phakic eye preserves accommodation and is reversible. Current IOL choices include AC PIOLs, angle-supported or iris-fixated models, and PC PIOLs, sulcus-fixated or free-floating models.

Historically, the idea of curing refractive problems by means of built-in or integrated additional optics (built-in glasses or contact lenses) sounds logical; however, even the great surgeons of our time failed initially with this approach that dates back to the late 1950s. Despite the well-known setbacks of Strambelli (Strambelli 1954), Barraquer (Barraquer 1959), and Choyce (Choyce 1966), individual scientists never allowed the idea of PIOL implantation to die. Three different scientists pursued three different anatomic concepts for PIOLs at roughly the same time: Baikoff saw a solution in the angle-supported anterior chamber lens (Baikoff and Joly 1990); Fechner

developed another solution in the modification of Worst's iris fixated lobster claw IOL (Fechner et al. 1989, Fechner and Worst 1989); and Fyodorov implanted a silicone lens into the posterior chamber (Fyodorov et al. 1991) (Figure 2).

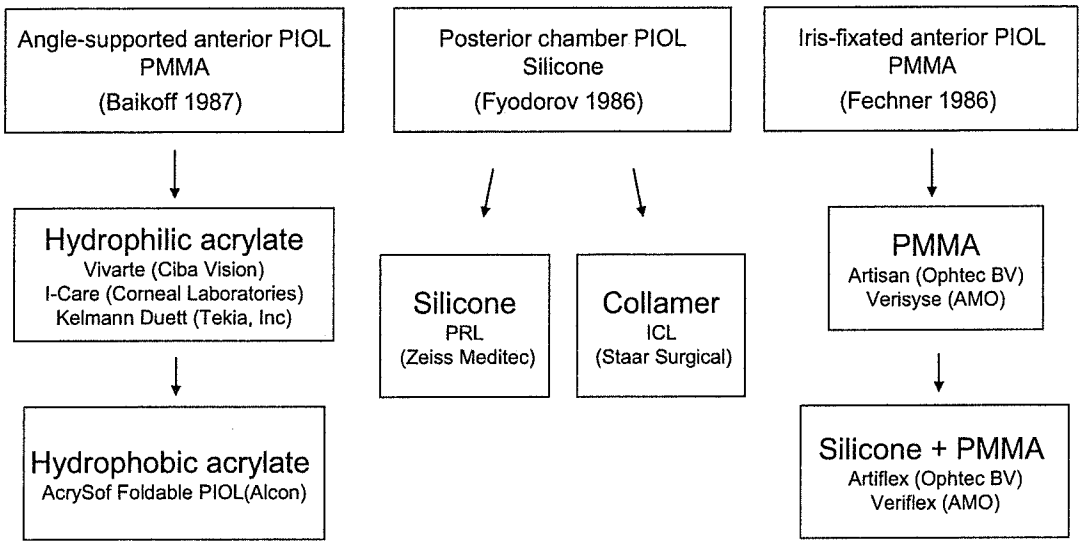


Figure 2. Three different concepts for phakic intraocular lenses (PIOL) and currently available models and materials.

The Baikoff design, angle-supported PIOLs evolved from 4-point fixation poly(methyl methacrylate) (PMMA) versions (Baikoff and Joly 1990) to three-point PMMA versions, and then to foldable IOLs to decrease induced astigmatism. The PMMA versions failed basically due to endothelial cell loss, pupil ovalization, and induced astigmatism. To overcome these problems, the material was changed from PMMA to hydrophilic acrylate or hydrophobic acrylate. However, severe complications such as endothelial decompensation (Coullet et al. 2007) and pupil ovalization (Leccisotti 2005) after implantation of an anterior PIOL have resulted in several European countries having recalled these lenses for the correction of refractive errors (Kohnen 2007).

The iris-fixated PIOL for the correction of myopia was introduced in 1986 as a rigid single-piece PMMA model with a 5.0- or 6.0-mm optic (Fechner et al. 1989, Fechner and Worst 1989). The iris-fixated PIOL has been implanted for more than 20 years through a 5.0- to 6.0-mm incision. The goal of reducing surgically induced astigmatism was achieved with the development of the foldable iris-fixated model with silicone optic and PMMA haptics introduced in 2003. The foldable design makes implantation possible through a 3.2-mm incision. However, this PIOL may be associated occasionally with recurrent intraocular inflammation (Tahzib et al. 2006), enhanced iris dispersion with posterior synechiae (Koss et al. 2007), and lenticular glistering (Cisneros-Lanuza et al. 2007).

The posterior chamber PIOLs to correct myopia was introduced first by Fyodorov in 1986 (Fyodorov et al. 1991). The first-generation Fyodorov PC PIOL was a one-piece silicon lens fixated by a haptic in the PC. In 1990, this lens was replaced by a second-generation model. Using

knowledge of the early model of silicon posterior PIOL designs as a basis, two manufacturers, i.e., Medennium Inc., Irvine, CA, USA and Staar Surgical Co, Monrovia,CA, USA, currently are researching and marketing posterior PIOL designs (Figure 3).

The implantable contact lens (ICL) (Staar Surgical Co) has undergone many modifications in design since 1993 (Assetto et al. 1996). The latest model, V 4, developed in 1999, made significant improvement in the amount of vaulting over the anterior lens capsule from the previous model (Sanders and Vukich 2002).
The lens has a one-piece plate design with a rectangular shape, 7.5 to 8.0 mm wide, available in four standard overall lengths: 11.5 to 13.5 mm for myopic lenses and 11.0 to 13.0 mm for hyperopic lenses to adapt to eyes of different sizes. The diameter of the optic zone is 4.65 to 5.5 mm in the myopic lenses, based on the desired dioptric power, and 5.5 mm for hyperopic ICLs. Available powers for myopic lenses range from -3.0 to -22.0 D and from +3.0 to +20.0 D for hyperopic lenses (Lackner et al. 2003).

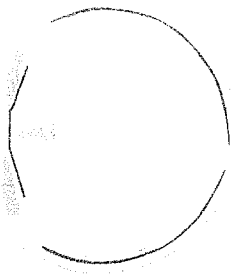


Figure 3. Schematic picture of a posterior phakic IOL.

The lens is introduced by means of a Staar microinjector. The proximity of the ICL to the crystalline lens, a dynamic phenomenon, has been postulated to be a risk factor for cataract development, which has been the main problem with this lens, and a greater vault would be expected to decrease ICL-crystalline lens contact (Sanders and Vukich 2002, Lackner et al. 2003, Sanders et al. 2003, Sarikkola et al. 2005). However, it is also possible that interference with lens nutrition instead of IOL contact of the crystalline lens may be the cause of cataract (Olson et al. 2005).

The main differences between the ICL and the phakic refractive lens (PRL) are the lens material and lens dynamics. The ICL is made of a collamer; which is hydrophilic acrylic with some cross-linked porcine collagen (Olson et al. 2005). The PRL is made of hydrophobic silicone and rests on the zonulas and floats in the PC, whereas the ICL is fixated and supported in the ciliary sulcus. Cataract formation has been reported less frequently with the PRL (Hoyos et al. 2002, Pallikaris et al. 2004). However, rotation of the PRL in the PC excludes the possibility for cylinder compound whereas the ICL has the toric alternative for myopic eyes (Sanders et al. 2007).

1.2 PRL

1.2.1 History

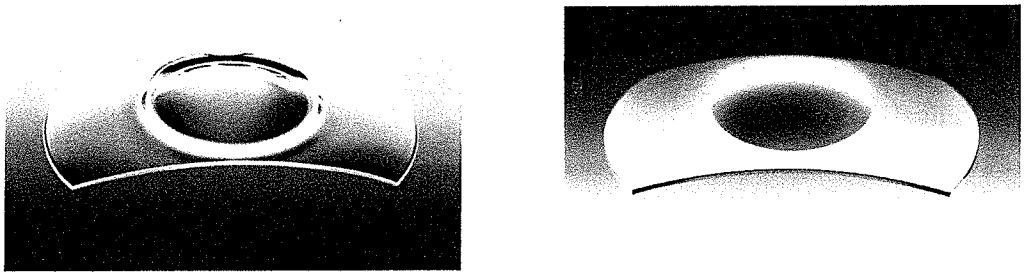
To reduce the incidence of potential problems with phakic AC lenses, especially such sequelae as lens contact with the corneal endothelium and pupil ovalization, Fyodorov and co-workers (Fyodorov et al. 1991, Fyodorov et al. 1993) introduced a PC PIOL made of silicone to be inserted between the iris and the crystalline lens. Fyodorov performed the first implantation of this silicone design IOL in a phakic eye to correct high-degree myopia in August 1986. The first models were pupil-fixated lenses (mushroom lenses) that were implanted in the former Soviet Union until 1990 (Wiechens et al. 1997). These lenses were designed to be fixated in the ciliary sulcus, but because the optic had the shape of a collar-button with a small diameter (3.2 mm in the

first model) and protruded into the AC, the pupil could not constrict anterior to the lens optic. The optic and haptics were connected by a bridge through the pupillary opening.

This Fyodorov IOL was modified to correct high myopia (Fechner et al. 1996). The modified IOL, the Chiron-Adatomed silicone lens, had a single-piece plate design with plano haptics, and also was made of silicone. With a wide range of powers (up to -25.0 D), the characteristic features were the long overall length (up to 12.5 mm) and a larger optic diameter (5.5 mm) (Erturk and Ozcetin 1995). In some dioptric ranges, the optic edge around its circumference was very thick (up to 1.1 mm). This lens was withdrawn from the market because of anterior lens fibrotic opacities in the contact zones with the thick edges of the IOL (Marinho et al. 1997, Brauweiler et al. 1999, Fechner 1999, Menezo et al. 2001).

The latest version of these lenses is the PRL (Figure 4), now marketed by Zeiss-Meditec (Jena, Germany), formerly by Ciba Vision (Salt Lake City, UT, USA) and IOLTech (La Rochelle, France), after the commercial rights were purchased in 2000 from the developer, Medennium International Vision (Cincinnati, OH, USA) (Lovisolo and Reinstein 2005).
The current design has been manufactured since 1995 worldwide, and sold on the European market since 2000. The clinical department of the PRL distributor estimates that more than 5500 PRLs have been implanted worldwide until 2004 and thereafter more than 2800 PRLs have been sold in Europe only. The current data are incomplete and do not reflect the actual number of implants worldwide (Fresnais Laetita, Product Manager, Zeiss-Meditec, personal communication, October 2007).

Figure 4. The PRL for myopic and hyperopic eyes.



Myopic model Hyperopic model

1.2.2 PRL design

The PRL is available in myopic and hyperopic models and is manufactured by Medennium Inc. Irvine, California, USA. According to the manufacturer, it is made from a highly purified, optically clear silicon elastomer, with a refractive index of 1.46 and a specific gravity of 0.99.

The overall lens shape is designed to conform to the natural shape of the PC of the human eye. A major feature of this lens is reported to be the hydrophobic nature of its material, which, in association with aqueous fluid dynamics, should prevent contact of the lens with the AC of the crystalline lens: The IOL would "float" on the natural lens, and no contact with this ocular structure would be observed even during accommodation. Because no real fixation is achieved

with this lens, rotation and lens positioning at different meridians during the postoperative period can be expected to occur.

The PRL has spherical, thin, flexible haptics, which are frosted to reduce the incidence of postoperative halos or glare (Figure 5). The haptics rest on the zonulas.

The refractive range of the myopic implant is -3.0 to -20.0 D and that of the hyperopic design is +3.0 D to +15.0 D. Both are available in increments of 0.5 D. There are two different sizes of myopic PRL depending on the white-to-white (WTW) diameter of the cornea: model PRL 101 with a length of 11.3 mm for WTW over 11.3 mm and model PRL 100 with a length of 10.8 mm for WTW between 10.5 to 11.3 mm. Hyperopic PRL is manufactured only in one size with an overall length of 10.6 mm (model PRL 200). The central optic zone is biconcave or concave convex. The optic size of the hyperopic PRL is 4.5 mm and for the myopic models 4.5 to 5.0 mm depending on the dioptric power.

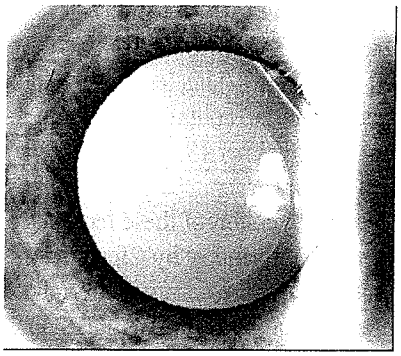


Figure 5. The hyperopic phakic refractive lens with frosted haptics to reduce the incidence of halos or glare.

The PRL neutralizes only the spherical compound and not the cylinder and the surgical goal is to neutralize the spherical correction. The clinical department of the PRL distributor calculates the PRL power needed corresponding to the preoperative refraction using the following data: refraction, keratometry, AC depth, WTW diameter, and desired target postoperative refraction.

1.3 PRL IMPLANTATION

1.3.1 Indications

The PRL is designed for the surgical correction of moderate to high myopia between -3.5 to -27.0 D and hyperopia between +3.0 to +11.5 D corresponding to available PRL power. Phakic IOL implantation is generally performed in patients older than 20 years who have stable refraction; the refraction might not be stable in younger patients. The upper age limit might be pre-presbyopic, although this could be seen as a relative recommendation. Especially in highly myopic eyes with increased risk for retinal complications in intraocular surgery, PRL implantation can be considered before clear lens extraction if the crystalline lens is clear (Sanders 2003). To maintain the safety of the corneal endothelium, the AC depth should be at least 3.0 mm including the cornea and endothelial cell density greater than 2000 cells/mm^2. Increased intraocular pressure (IOP) may imply insufficient aqueous flow and therefore the preoperative IOP should not exceed 25 mmHg.

1.3.2 Contraindications

A general contraindication to PRL implantation is a history of ocular pathology, including nanaophthalmos, conditions associated with impaired corneal endothelium, glaucoma and pigment dispersion syndromes, pseudoexfoliation of the lens capsule, ocular manifestations of diabetes, the presence of lens opacities (or early cataract formation in a previously operated fellow

eye), and history of uveitis. Dystrophies causing abnormal corneal shape (e.g., keratoconus) are not corrected by a PRL. Pupil size is a critical factor in refractive surgery. However, the impact of large pupils in dim light as a reason for halos and glare is debated (Pop and Payette 2004, Villa et al. 2007). In general, PRLs are best avoided in patients who have large pupils in dim light.

1.3.3 Preoperative evaluation

Before PRL implantation, a general preoperative examination should include assessment of the UCVA, spectacle-corrected visual acuity with manifest refraction and cycloplegic refraction in hyperopic eyes, keratometry, corneal topography, slit-lamp microscopy, applanation tonometry, dilated funduscopy, and biometry. In eyes with pathological myopia, a posterior segment evaluation should be performed to document and treat if necessary any retinal pathology that may lead to retinal detachment.

Patient lifestyle, vocation, and hobbies also might affect the selection for surgery, and the choice of vision correction modality. Considering the limitations of the surgery, patients who can tolerate zero risk to vision or need perfect stereopsis (and who presently have good vision and stereovision with other forms of correction) for their jobs or hobbies might not be good candidates for refractive procedures.

In eyes with pre-existing astigmatism, an arcuate keratotomy can be performed at least 1 month before PRL implantation. The keratotomies are placed on the steep axis of the corneal astigmatism (Lindstrom et al. 1994).

Before PRL implantation, two neodymium-yttrium aluminium garnet (Nd:YAG) laser iridotomies, placed 90 degrees apart, are performed in the peripheral iris (single burst 3-10 mJ) to avoid the possibility of pupil block after PRL implantation. These generally measure 250 to 500 μm in diameter and are located superiorly in order to be covered by the upper eyelid (Figure 6). Iridotomies should be performed at least 1 to 2 weeks preoperatively. One surgical, peripheral iridectomy also can be performed intraoperatively. The choice of anesthesia can vary from general anesthesia to sub-Tenon's and topical anesthesia.

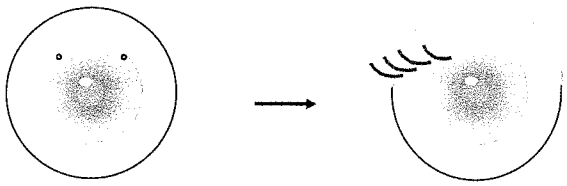


Figure 6. Two iridotomies in the superior iris covered by the upper eyelid.

1.3.4 Surgical procedure

A combination of cyclopentolate 0.75% and phenylephrine 2.5% is applied 3 times 30 minutes before surgery or 150 μl of cyklopentolate 0.1%, phenylephrine 1.5%, and lidocaine 1% is administered intracamerally (Lundberg and Behndig 2003, Behndig and Eriksson 2004) at the beginning of the procedure to obtain good pupil dilation. The incision for implantation of a PRL

can be a self-sealing, clear corneal tunnel of 3.2 x 1.5 mm. Intraoperatively, care is taken to prevent the surgical instruments from touching anatomic structures such as the corneal endothelium, the crystalline lens capsule, or the iris diaphragm. The use of an ophthalmic viscosurgical device (OVD) is important for protecting adjacent tissues and allowing the lens to unfold in a controlled manner (in our case injection of an OVD that is not too heavy; sodium hyaluronate 1.34% [Biocorneal®, Corneal, Paris, France]).

The PRL is inserted with a forceps specially designed for this lens (Dementiev implantation forceps, Figure 7). Once the lens unfolds slowly in the AC, the haptics initially lie anterior to the dilated pupil. Each haptic corner then is placed gently behind the iris through the pupil with a long spatula or an intraocular hook without placing pressure on the crystalline lens and without decentering the optic.

Figure 7. The PRL implantation forceps to insert the PRL into the anterior chamber through 3.2 mm incision. After the PRL has introduced into the anterior chamber, it unfolds and the PRL lies anterior to the dilated pupil.

When proper horizontal PRL orientation is verified, a miotic agent, acetylcholine chloride (Miochol®, Novartis Pharma Stein AG, Stein, Switzerland) is injected that causes the pupil to constrict and traps the lens in the PC. The remaining OVD then is irrigated out of the AC. At the end of surgery, 1 mg of cefuroxime sodium (Zinacef®, Baxter Healthcare Corporation, Deerfield, IL) is injected into the AC (Montan et al. 2002). Corneal wounds can be closed by stromal hydration without using a suture.
The suggested postoperative treatment includes 0.1% topical dexamethasone eye drops three times daily for 1 week with dose tapering over 3 weeks. Cyclopentolate 1.0% is prescribed twice daily for 2 days to prevent elevated IOP related to retained OVD.

1.3.5 Complications

The PC PIOL is a potentially reversible procedure but one in which the possibilities of complicating cataract formation, pigment dispersion, and pupil block glaucoma coexist. Like all refractive surgical procedures, whether corneal or lenticular, it is invasive and therefore carries small but definable general risks such as inflammation and infection.

1.3.5.1 Cataract formation

The possibility of crystalline lens damage and cataracts formation is probably the most controversial issue of PC PIOL implantation (Werner et al. 2001). The anterior subcapsular opacification (Figure 8) has been described as typical form of an posterior PIOL-induced cataract (Fink et al. 1999, Arne and Lesueur 2000, Gonvers et al. 2003, Sanchez-Galeana et al. 2003). In the normal, undisturbed lens, the epithelium is confined to the anterior surface and to the equatorial region and equatorial lens bow (Blumenthal et al. 1991). The epithelium of the crystalline lens consists of a sheet of anterior epithelial cells (A-cells) that are in continuity with

the cells of the equatorial lens bow (E-cells). The primary type of response of these A-cells to any stimulus is to proliferate and form fibrous (Font and Brownstein 1974). The A-cells lining the anterior capsule are the cells of origin of anterior subcapsular cataract (Apple 2000). The second zone is a continuation of the anterior lens cells around the equator, forming the equatorial lens bow (E-cells). In sharp contrast to their precursors (A-cells), mitoses, cell division, and multiplication in this region are quite common. New lens fibers are continuously produced in this zone throughout life (Apple 2000).

A primary risk factor for lens opacification seems to be direct mechanical contact with the anterior lens surface (Sanders and Vukich 2002, Gonvers et al. 2003). Therefore, the distance between the posterior PIOL and crystalline lens seems to be important when evaluating different models of PIOLs (Baikoff et al. 2004). In accommodation, the anterior lens surface moves forward and assumes a more rounded shape (Brown 1973). Fechner and colleagues suggested that pressure from the posterior PIOL on the anterior surface of the crystalline lens may be caused by constant or intermittent contact from increased crystalline lens curvature during accommodation (Fechner 1990, Fechner 1999). It can be assumed that in eyes with an implanted PC PIOL, the PIOL moves closer to the crystalline lens during accommodation, especially in nonpresbyopic eyes (Baikoff et al. 2004), since with increasing age the maximum possible change in lens movement declines (Koretz et al. 1997). However, the crystalline lens grows throughout life approximately at the same rate as the AC depth decreases, i.e., 13 μm annually (Koretz et al. 1997). Such growth may be responsible for reduction of the space between the crystalline lens and the phakic IOL.

Nevertheless, other factors may be involved in cataractogenesis. The crystalline lens ideally should not be touched at all during phakic IOL implantation. However, accidental contact with the anterior lens capsule can occur during injection of OVD, phakic IOL injection or insertion, haptics placement behind the iris, and IOL rotation (Pallikaris et al. 2004, Sarikkola et al. 2005). Pressure applied on the phakic lens should be reduced to a minimum, if necessary, for IOL positioning. Anterior capsule trauma, even when unnoticed, can lead to proliferation of epithelial subcapsular cells (A-cells), which can provoke crystalline lens opacities months later. A possible effect of the Nd:YAG laser used to make iridotomies in the preoperative or postoperative period cannot be ignored , although this therapy is not directly related to the surgical procedure.

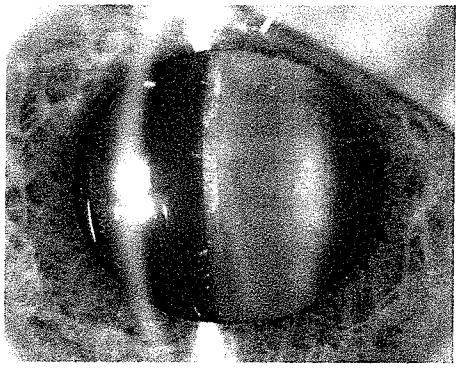


Figure 8. The placement in the posterior chamber close to the crystalline lens makes cataract formation a primary complication of posterior PIOL implantation. This eye with the ICL has a typical anterior subcapsular cataract.

Additionally, contact between the IOL and the crystalline lens in the midperiphery may block normal circulation of the aqueous humor. A pool of aqueous stagnation can cause in part metabolic changes and alteration of crystalline lens nutrition. To clarify the cause of secondary cataract after ICL implantation, Fujisawa et al studied aqueous circulation in the space between the ICL and crystalline lens in porcine eyes (Fujisawa et al. 2006). When an ICL similar to the human eye was inserted into porcine eyes, anterior subcapsular opacities developed in all cases during the 3-month follow-up. No direct contact was observed between the ICL and crystalline lens at any time. The results suggest that the ICL altered

the circulatory dynamics of the aqueous humor, probably because of poor circulation on the anterior surface of the crystalline lens, and resulted in cataract. There are structural and functional differences between human and porcine eyes, and results cannot be extrapolated directly to human eyes. However, the findings are interesting and could partly explain the difference in cataract incidence between ICL and PRL.

1.3.5.2 Inflammation

Like all intraocular procedures, posterior PIOL implantation carries general risks such as inflammation and infection. The study of Jimenez-Alfaro and associates showed a constantly elevated flare at all time points, which indicates continuous disruption of the blood-aqueous barrier and subclinical inflammation of the anterior segment. After phacoemulsification with IOL implantation, anterior segment inflammation measured with the laser flare meter usually returns to preoperative values 1 year postoperatively. Therefore, the constantly elevated flare values in these patients can reasonably be attributed to the presence of the phakic lens (Jimenez-Alfaro et al. 2001). The mechanisms may include constant friction between the posterior iris surface and the phakic lens or between the haptic and the ciliary sulcus. The flare values observed with iris-fixated or angle-supported AC PIOLs were more elevated than the values observed with the ICL in the study of Jimenez-Alfaro and associates. The subclinical inflammation may have repercussions not only on the crystalline transmittance but also on the corneal endothelium. Subclinical inflammation may cause metabolic disturbances of the crystalline lens, resulting in cataract formation.

1.3.5.3 Pupillary block glaucoma

Complications also can include pupillary block glaucoma (Figure 9) owing to functional closure of the laser iridotomies (Rosen and Gore 1998, Pesando et al. 1999, Sarikkola et al. 2005). The IOP can increase in the immediate postoperative period because of residual OVD, postoperative inflammation, and steroid drug treatment (Hoyos et al. 2002, Pallikaris et al. 2004).

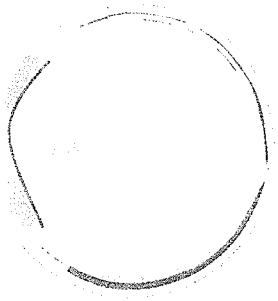


Figure 9. A schematic representation of an eye that shows pupillary block induced by a posterior PIOL. If the iridotomies do not facilitate sufficient aqueous outflow, the pupil is occluded by the posterior PIOL with a large volume of aqueous trapped between the PIOL and the crystalline lens.

1.3.5.4 Pigment deposits

Fine pigment deposits can be seen on the lens surface in the postoperative period. This seems to be more frequent when Nd:YAG laser iridotomies are performed. Pigment deposition did not seem to impair the image quality of the lens (Jimenez-Alfaro et al. 2001). Another concern is

possible pigmentary dispersion syndrome resulting from contact between the iris and the posterior PIOL (Brandt et al. 2001). This syndrome is characterized by deposition of pigment in the trabecular meshwork on the corneal endothelium (forming the Krukenberg spindle) and on the anterior lens capsule, as well as radial, slit-like, transilluminating defects of the iris (Abela-Formanek et al. 2001). Although all patients in the series of Jimenez-Alfaro and coworkers had contact between the ICL and the posterior surface of the iris, no patient had pigmentary dispersion (Jimenez-Alfaro et al. 2001). Davidorf and associates believe that pigment dispersion on the ICL surface is surgically related, because the amount of pigment in that series appeared not to progress (Davidorf et al. 1998).

1.3.5.5 Glare and halos

Subjective edge glare and halos have been reported by many surgeons. Because the optic size of the posterior PIOLs varies between 4.5 to 5.5 mm, patients whose pupils enlarge beyond that size in dim light may be subject to minor halos or night glare, phenomena that would also trouble a patient if the lens optics were decentered. Some surgeons do not consider implanting phakic lenses if the pupillary diameter in dim conditions is 7 mm or larger. Night halos appear to be less frequent than might be expected with PC PIOLs, possibly because the lenses are behind the pupil, thus increasing the effective optic zone (Werner et al. 2001).
Even large iridectomies can increase the risk of light scattering through the iridectomy and cause glare, especially if the iridotectomy is visible and not covered by the upper eyelid.

1.3.5.6 PIOL decentration and luxation in the vitreous

A decentered posterior PIOL generally arises from an inadequate lens length. Decentration may also lead to monocular diplopia. There are some reports of serious complications with PRL dislocations into the vitreous cavity and subluxation, suggesting that PRL rotation causes excess pressure against the zonules (Eleftheriadis et al. 2004, Martinez-Castillo et al. 2004, Hoyos et al. 2005, Donoso and Castillo 2006). The distributor of the PRL has reported problems in Italy and Spain with 11 PRL luxations into the vitreous cavity up to 2004 and three cases from 2004 to the present (2 cases in 2005 and 1 in 2006, all in Italy) (Fresnais Laetita, Product Manager, Zeiss-Meditec, personal communication, October 2007).

1.3.5.7 Retinal detachment

The patient population undergoing refractive surgery is largely myopic and as such is particularly vulnerable to posterior segment pathology. PIOL implantation in myopic eyes is associated with the risk of retinal detachment that ranges from 0.8% to 4.8 % (Ruiz-Moreno et al. 2006). A dilated fundus examination is an integral part of optimum clinical care in patients who undergo refractive surgery, and shared preoperative assessment by a retinal specialist is advisable in those with a predisposing retinal pathology (Brady et al. 2007).

1.3.6 Surgery in hyperopic eyes

Preoperative UCVA plays a significant role in the motivation to undergo refractive surgery; a 30-year old myopic patient is more likely to seek corrective surgery than a 30-year old patient with hyperopia. Since refractive surgery is performed less frequently in hyperopic eyes compared with

myopic, the surgical outcome and adverse effects of PIOLs in hyperopic eyes are not that well documented in the literature (Sher 2001).

Hyperopic eyes often have relatively smaller anterior segments, which may require more careful IOL insertion to avoid contact with the corneal endothelium (Davidorf et al. 1998). Hyperopic eyes with a central AC depth of 3.0 mm or less are an important contraindication to PIOL implantation to avoid postoperative pupillary block and to maintain a safe distance from the corneal endothelium. In addition, Davidorf and colleagues reported that the incidence of pupillary block glaucoma in hyperopic eyes was more than double the incidence of pupillary block they observed in a previous series of ICL implantations in myopic eyes (Zaldivar et al. 1998). Pupillary block glaucoma, related to functional closure of the iridotomies or retention of an OVD, seems to be particularly important with hyperopic eyes (Pesando et al. 1999).

According to Rosen and Gore (Rosen and Gore 1998), an intraoperative surgical iridectomy at a location away from possible occlusion by the PIOL is important to minimize the risk of pupillary block, particularly in small eyes with hyperopia and eyes with brown irides.

Pesando and coworkers implanted ICLs in 59 hyperopic eyes with a follow-up of 6 to 10 years. The postoperative refraction was within ±1.00 D in 96% of the eyes. According to those authors, the refractive predictability appeared better for hyperopia than for myopia using the ICL (Pesando et al. 1999, Pesando et al. 2007).

1.4 METHODS

1.4.1 Visual acuity

The visual acuity was tested using the Early Treatment of Diabetic Retinopathy Study (ETDRS) acuity charts in all the studies with modification in the study IV, in which the ETDRS logarithm of the minimum angle of resolution (logMAR) acuity charts was used.
The safety index was defined as the ratio of the mean postoperative BCVA over the mean preoperative BCVA and the efficacy index as the ratio of the mean postoperative UCVA over the mean preoperative BCVA, respectively (Koch et al. 1998).

1.4.2 Intraocular pressure

Goldman applanation tonometry was used to measure IOP at the follow-up visits.

1.4.3 Laser flare meter

The protein concentration in the AC flare was measured using the Kowa FM-500 laser flare meter (Figure 10). The laser flare meter measures indirectly aqueous protein concentrations in the AC by measuring light scattered from protein (Sawa et al. 1988). All eyes had pupils dilated with topical 0.5% tropicamide. Ten sequential scans were averaged. Flare values were expressed as photon counts per millisecond (ms).

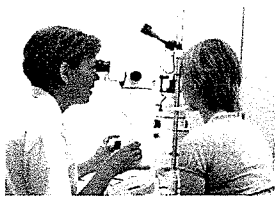


Figure 10. Examination with Kowa-500 laser flare meter.

1.4.4 Corneal endothelial cell count

The Topcon SP 1000 specular microscope and IMAGEnet systems were used for counting corneal endothelial cell density (Figure 11). Cell morphologic indices were not studied. On the basis of about 100 identified cells taken from the recorded picture of the endothelium, the computer traced the cellular outlines while the investigator corrected false readings (semiautomated method). The software performed the final calculation and the values were expressed as cells/square millimeter (cells/mm^2).

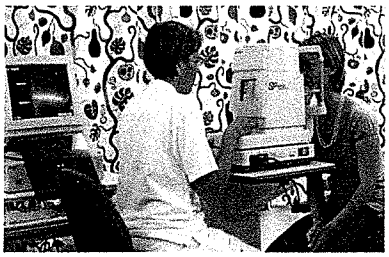


Figure 11. Taking endothelial cell photograph with Topcon SP 1000.

1.4.5 Scheimpflug images

Images of the anterior segment were made using a Nidek EAS-1000 Anterior Eye Segment Analysis System through a dilated pupil. After the photography, the measurement of the distance (in millimeters) between the posterior surface of the PRL (PS-PRL) and the anterior lens surface was repeated three times and averaged to obtain final results for distance (Figure 12). The disadvantage of the Scheimpflug method is the need for pupil dilation to obtain images of the entire surface of the crystalline lens and stimulation of the fellow eye to study accommodation of the eye under observation.

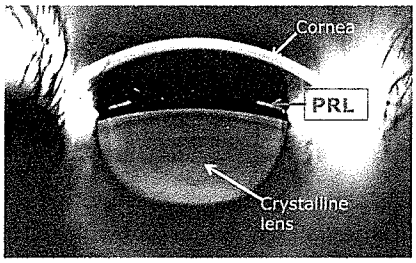


Figure 12. The Scheimpflug image of the PRL in a dilated pupil. The method was used to estimate the distance between the PRL and the anterior lens surface.

1.4.6 Retroillumination photographs

The retroillumination photographs were taken after pupil dilatation with tropicamide 0.5% to illuminate at least one edge of the PRL for comparison between the different follow-up examinations. The edges of the PRL were projected over each other to determinate possible degrees of rotation (Figure 13).

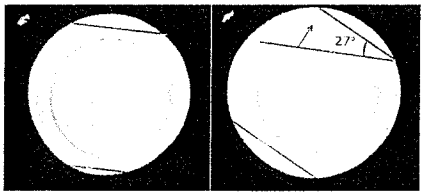


Figure 13. A retroillumination photograph of the PRL with rotation of 27 degrees between 1 day and 1 week.

1.4.7 Optical coherence tomography

Optical coherence tomography (OCT) uses low-coherence interferometry to provide in vivo cross-sectional images of tissue structures. OCT was developed initially for retinal imaging, using a near-infrared 800-nm wavelength (Hee et al. 1998). For anterior segment imaging, a longer

wavelength of 1300 nm allows greater penetration through high light-scattering tissues, such as the limbus and sclera, and makes it possible to visualize angle structures (Radhakrishnan et al. 2001). The technique works by splitting the light source into a reference and a measurement beam. The measurement beam from the ocular structures interacts with the reference light reflected from the reference mirror causing interference.

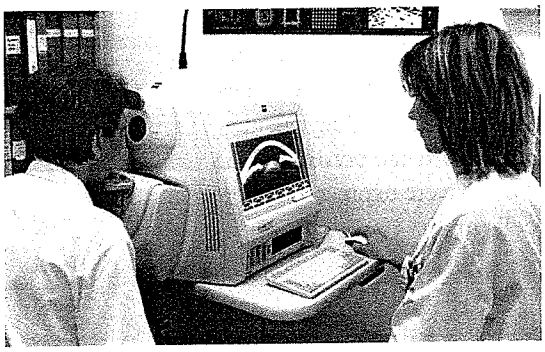


Figure 14. Scanning with Visante OCT. The patient is asked to focus on a central target internal to the OCT device. After the scanning in the non-accommodated state the eye is stimulated with negative lenses to achieve accommodation. The eye can be scanned several times at different degrees of accommodation.

In study III, evaluation of different distances in the anterior segment and the horizontal diameter of the pupil was performed with Visante OCT (Zeiss, Jena, Germany). The patient fixates on a target that is adjustable with positive or negative lenses, which are located within the OCT device, allowing compensation for spherical ametropia (Figure 14). It is also possible to defocus the target with negative lenses to induce physiologic accommodation in the examined eye.

After acquiring the scan, software in Visante OCT automatically finds the anterior and posterior corneal surfaces. The investigator may apply additional measurement overlays for analysis (Figure 15).

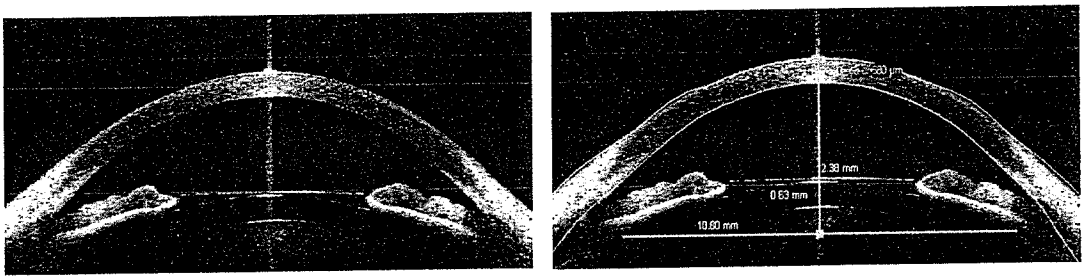


Figure 15. Visante OCT image of a myopic PRL before and after the measurement overlays are applied for analysis.

2 AIMS

1. To evaluate the surgical outcome and adverse events associated with correction of myopia and hyperopia with a PRL (I, II, IV).
2. To investigate the dynamics of the PRL in relation to the behavior of the crystalline lens and the pupil (I, II, III).
3. To determine the random errors and evaluate the precision of the analytical methods used in the trials (II, III).

3 MATERIAL AND METHODS

3.1 PATIENTS AND METHODS (I)

3.1.1 Patients

Twenty eyes of 20 patients (11 women, 9 men) with a median age of 31 years (range, 23-43 years) were included. Fourteen eyes were myopic with a median spherical equivalent (SE) refraction of -9.19 D (range, -6.88 to -17.63) and six eyes were hyperopic with a median SE of +6.13 D (range +3.25 to +8.63 D). The local ethics committee provided approval of the study protocol. The patients were informed about the details of the study and they provided informed consent.

3.1.2 Inclusion criteria

The inclusion criteria were patient age between 20 and 45 years, UCVA less than 0.5 in Snellen visual acuity, BCVA of the fellow eye better than 0.1, stable myopia between −3.5 and −27.0 D or hyperopia between +3.0 and +11.5 D corresponding to the available PRL power, a normal anterior segment with an AC depth of at least 3.0 mm including the cornea, endothelial cell density greater than 2500 cells/mm^2, and an IOP less than 20 mm Hg. Only one eye of each patient was included in the study to avoid bias.

3.1.3 Exclusion criteria

Patients were excluded if they had regular astigmatism of 3.0 D or higher, cataract, corneal pathology, a narrow angle or glaucoma, a history of anterior or posterior segment inflammation, diabetes, infections, or retinal pathologies.

3.1.4 Follow-up

All patients were scheduled for follow-up visits on 1 day, 1 week, 3 months, and 1 year postoperatively. The follow-up examinations were completed in all cases. The visits involved a detailed ophthalmologic examination including manifest refraction, slit-lamp microscopy, applanation tonometry, laser flare measurement, Scheimpflug slit images through a dilated pupil to evaluate the distance between the PRL and the crystalline lens, and retroillumination photographs to evaluate the PRL rotation in the PC. The endothelial cell density was measured preoperatively, and at 1 week and 1 year postoperatively. Safety and efficacy indexes were evaluated based on the UCVA and the BCVA.

3.1.5 Statistical analysis

Statistical analysis was performed using Friedman 2-way analysis of variance (ANOVA) by ranks with multiple comparisons (Siegel S. 1988). The level of significance was $P<0.05$.

3.2 PATIENTS AND METHODS (II)

3.2.1 Patients

In the primary study, the study population and the inclusion and exclusion criteria were the same as in study I. In the parallel sub-study "analysis of the follow-up methods", 20 eyes other than

those in the primary study were included. These eyes met the inclusion criteria as in the primary study and they also had undergone surgery to implant a PRL.

3.2.2 Follow-up

The patients were scheduled for a follow-up visit 2 years after PRL implantation and the follow-up was completed in all cases. The visit involved a detailed ophthalmologic examination including manifest refraction, slit-lamp microscopy, applanation tonometry, laser flare measurement, Scheimpflug slit images in dilatation, retro-illumination photographs, and endothelial cell count. The crystalline lens was clinically assessed by slit-lamp, retro-illumination photographs, and Scheimpflug images to analyze lens transparency. Safety and efficacy indexes were evaluated in the same manner as in study I.

3.2.3 Analysis of the follow-up methods

To evaluate the precision of the analytical methods used, double-independent measurements of laser flare meter, endothelial cell count, and determination of the distance between the PRL and the crystalline lens with Scheimpflug images were performed on 20 eyes after PRL implantation and they were not included in the primary study. All the measurements were done by the same investigator (M.T.).

3.2.4 Statistical analysis

Statistical analysis was performed by Friedman 2-way ANOVA by ranks with multiple comparisons. The level of significance was $P < 0.05$.

3.3 PATIENTS AND METHODS (III)

3.3.1 Study design

The study population included 52 patients (52 eyes) with myopia and hyperopia. The PRLs were implanted between April 2002 and May 2005. The inclusion criteria included a minimum of 1 year after PRL implantation. Only one eye of each patient was enrolled in the study to avoid bias. An eye was excluded if any refractive surgery was combined with PRL implantation. The study had a cross-sectional design in which all patients were scanned with the Visante OCT only once without follow-up and the association between the distance PRL-anterior lens surface and lens opacification was investigated. The local ethics committee approved the study. All patients were provided with written and oral explanations of the study, and they all provided their consent.

3.3.2 Visante OCT as an analytical method

To evaluate the precision of Visante OCT, a double-independent measurement study was conducted. Twenty-two eyes of 12 patients underwent scanning of the anterior segment; the scans were repeated after an interval of 5 minutes. The investigator evaluated the distances from the PS-PRL to the anterior lens surface and from the anterior surface of the PRL (AS-PRL) to the posterior corneal surface before the patient underwent a new scan. The second scan was analyzed later without knowledge of the results of the first scan.

3.3.3 Main outcome measures

Manifest refraction was tested before the OCT scans were performed to compensate for spherical ametropia during scanning. After scanning, the crystalline lens was examined after the pupils were dilated using tropicamide 0.5% to determine the presence of lens opacification.
Baseline measurements were performed in the non-accommodated state at the horizontal meridian. All examinations were performed in a room with dim illumination.
The eye was stimulated with negative lenses to achieve accommodation. The target was slowly defocused in -0.25 D increments until it was subjectively blurred and could no longer be focused (push-up method). The mean lens power added before blurred vision was achieved was -4.6 D (range, -1.25 to -13.0 D).

3.3.4 Statistical analysis

Confidence intervals, based on the t-distribution, were calculated for differences in mean results. The differences were statistically significant when the confidence intervals did not include zero. Results are expressed as mean ± 95% confidence interval based on a significance level of $P<0.05$. Regression analysis was used to determine regression equations.

3.4 PATIENTS AND METHODS (IV)

3.4.1 Patients

The study population included 40 consecutive eyes of 25 patients with hyperopia independent of the degree of astigmatism. A certain degree of amblyopia was observed in 12 eyes (30%). The local ethics committee approved the study. All patients provided informed consent after the study was explained fully.

3.4.2 Inclusion criteria

The inclusion criteria were patient age between 20 to 45 years, hyperopia corresponding to an available PRL power, a normal anterior segment with an AC depth of at least 3.0 mm including the cornea, an endothelial cell density greater than 2000 cells/mm^2, and IOP below 25 mmHg.

3.4.3 Exclusion criteria

Patients were excluded if they had a narrow angle or glaucoma, infections, and a history of anterior or posterior segment inflammation. In addition, those who did not undergo one of the postoperative follow-up visits were excluded.

3.4.4 Arcuate keratotomy

The PRL with its floating design cannot correct astigmatism. In cases of astigmatism of 2 D or greater with a substantial effect on visual outcome, an arcuate keratotomy with a 7-mm-diameter clear zone (Lindstrom et al. 1994) was performed preoperatively in nine eyes (22.5%). The mean time between the relaxing keratotomies and the PRL surgery was 2.4 months (range, 1.0-4.6 months). Only a moderate effect was gained in eyes with lower hyperopia and no effect in eyes with hyperopia over 10 D.

3.4.5 Follow-up

The patients were scheduled for follow-up visits at 3 months and 1 year postoperatively. The first six patients (six eyes) had the first postoperative examination at 1 week instead of 3 months. The visits involved a detailed ophthalmologic examination including manifest refraction, slit-lamp microscopy, applanation tonometry, and measurement of the endothelial cell count.

3.4.6 Statistical analysis

Each patient was the subject in the statistical analysis and not the eye because in some cases both eyes were included in the analysis. Statistical analysis was performed by a mixed effects model. The level of significance was less than 5% ($P<0.05$). Statistical analyses were performed by SAS 9.1.3 Proc Mixed (Cary, NC).

4 RESULTS AND DISCUSSION

4.1 VISUAL OUTCOME (I, II, IV)

4.1.1 Safety

Safety was evaluated by measurement of the BCVA. The safety index (I, II) was 1.13 at 1 year and 1.2 at 2 years. At 1 year, 3 eyes (15%) and at 2 years five eyes (25%) gained two or more lines of BCVA. All eyes were myopic. No eye lost two or more lines of BCVA (Figure 16).

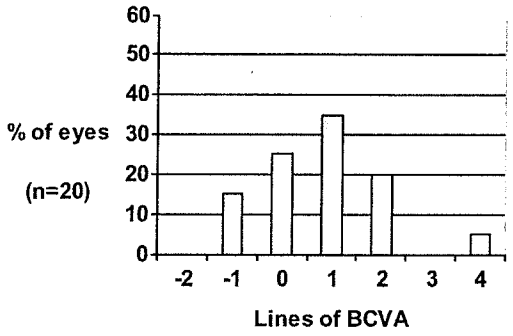


Figure 16. Percentage of eyes gaining and losing lines of BCVA 2 years postoperatively (study II).

At 1 and 2 years, 80 % of eyes had a BCVA of 1.0 or better (93% of myopic and 50% of hyperopic eyes), an improvement over the baseline level in myopic eyes. There was no change in the hyperopic eyes. All the eyes had a BCVA of 0.5 or better at 1 year that did not change at 2 years.

The 1-year follow-up in 40 hyperopic eyes showed a safety index 0.89. No eyes gained two or more lines. Two eyes (5.0%) lost two lines of BCVA. The mean BCVA decreased from 1.03 preoperatively to 0.93 at 3 months ($P<0.05$) without a change at 1 year ($P>0.05$). At 1 year, 17.5% of eyes had a BCVA of 1.0 or better and 65% had 0.5 or better.

The BCVA increased significantly in myopic eyes with excellent visual outcome and safety results. However, in the hyperopic eyes, the BCVA decreased postoperatively, and even though the clinical relevance of this decrease can be discussed, the result showed no postoperative gain in BCVA in hyperopic eyes. Limited improvement in BCVA also has been reported in studies with other hyperopic PIOLs (Davidorf et al. 1998, Bartels et al. 2006). This could be explained by a smaller image size with corrected refraction closer to the nodal point of the eye and elimination of the spectacle-induced magnification experienced by patients with hyperopia preoperatively. In high myopia, the spectacle correction minifies the image, which is eliminated after refractive surgery resulting in gains of lines of vision (Langenbucher et al. 2007). Preoperative contact lens-corrected visual acuity compared with postoperative spectacle–corrected visual acuity might provide a more realistic evaluation of the safety index and a comparison between hyperopic and myopic eyes (MacRae 1998).

4.1.2 Efficacy

The efficacy index (I and II) was 0.89 at 1 year and 0.91 at 2 years (Figure 17).
The UCVA was 1.0 or better in 50% of eyes (64% of myopic and 17% of hyperopic) at 1 year and in 40% (50% of myopic and 17% of hyperopic) at 2 years. All myopic eyes had an UCVA of 0.5 or better. In hyperopic eyes, the UCVA was 0.5 or better in 67% of eyes at 1 year and 83% of eyes at 2 years.

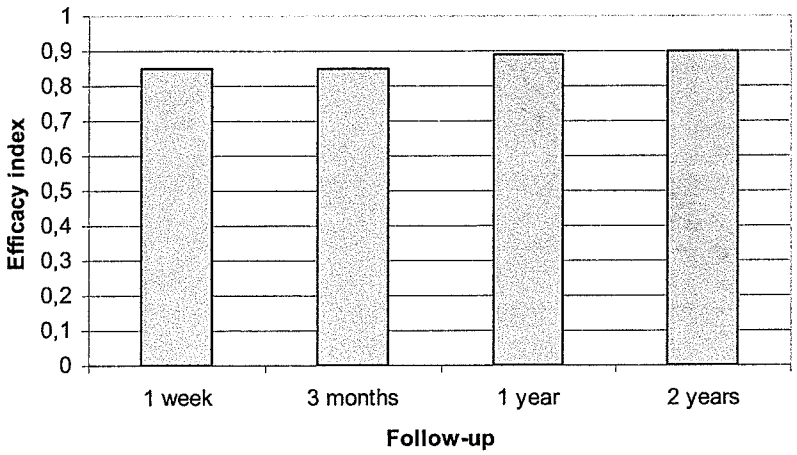


Figure 17. The efficacy index during the 2-year follow-up period.

In 40 hyperopic eyes (IV), the efficacy index was 0.70 at 1 year. The UCVA was 1.0 or better in seven eyes (17.5%), 0.50 or better in 26 eyes (65%), and less than 0.5 in seven eyes (17.5%). In the last group, the mean preoperative BCVA was 0.6±0.19 (range, 0.32-0.8). The mean astigmatism was -1.9±0.61 D (range, -1.0 to -2.5 D) compared with the astigmatism in the other eyes -0.96±0.65 (range, ±0.0 to -2.5 D).

The efficacy index showed slight undercorrection corresponding to uncorrected astigmatism. However, UCVA showed excellent outcomes especially in myopic eyes in which all eyes had an UCVA of 0.5 or better even though the PRL with its floating design cannot correct astigmatism. In cases of astigmatism with a substantial effect on visual outcome, there are other options complementary to PRL. One of these is bioptics in which the PIOL is combined with a corneal laser procedure (Zaldivar et al. 1999, Sanchez-Galeana et al. 2001). PRL implantation followed by LASIK or LASEK enhancement could provide more precise results and produce the parallel treatment of preexisting and surgically induced astigmatism. However, combining corneal and intraocular surgeries exposes patients to complications from both techniques. The toric ICL can solve some problems in the myopic eyes, because it remains rotationally stable after surgery (Gimbel and Ziemba 2002). Unfortunately, there is no toric hyperopic PC PIOL currently commercially available.

In the study of 40 hyperopic eyes, the fact that 30% of eyes had different levels of amblyopia certainly had a substantial effect on the postoperative visual outcomes.

4.2 PREDICTABILITY (I, II, IV)

The change in SE refraction in studies I and II showed that 15 eyes (75%) were within ±0.5 D of the desired refraction and all eyes (100%) were within ±1.0 D at the 1- and 2-year visits. Eighteen eyes (90%) were within ±1.0 D of emmetropia at 1 and 2 years postoperatively.
The study population of 40 hyperopic eyes showed even more precious predictability (Figure 18).

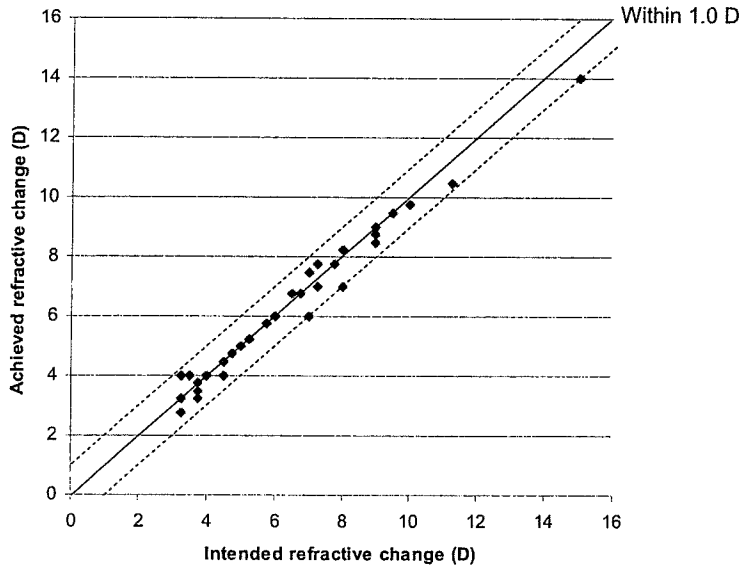


Figure 18. Distribution of achieved refraction versus intended refraction in diopters (D) in hyperopic eyes shows that all the eyes were within ± 1.0 D of the desired refraction 1 year postoperatively.

Thirty-five eyes (87.5%) were within ±0.5 D of the desired refraction and all eyes (100%) were within ±1.0 D. At 1 year postoperatively, 87.5% (35 eyes) were within ±1.0 D of emmetropia.

The current standard-of-care precision in refractive surgery is ±1.0 D from the attempted refraction (Lovisolo and Reinstein 2005). In cases of residual refractive error in the form of pure spherical ametropia after PRL implantation, the PRL was exchanged for the right power as we did in two hyperopic cases with primary overcorrection postoperatively. After replacement of the PRL in these eyes, all cases were within ± 1.0 D of the desired refraction and the refraction remained stable during the follow-up period. These results are better compared with other studies of the PRL and the ICL (Davidorf et al. 1998, Fink et al. 1999, Hoyos et al. 2002, Pallikaris et al. 2004, Sarikkola et al. 2005).

4.3 INTRAOCULAR PRESSURE (I, II, IV)

In the mixed myopic and hyperopic study population (I, II), the mean IOP was 16±1.8 mmHg (range, 13-21 mmHg) preoperatively, 16±2.0 mmHg (range, 13-20 mmHg) at 1 year and 16±3.0 mmHg (10-22 mmHg) at 2 years.

One hyperopic and one myopic eye developed pupillary block 2 and 4 days after surgery, respectively. In both cases the IOP was normalized with complementary Nd:YAG-iridotomies and medication. A myopic eye developed corticosteroid-induced high IOP of 49 mmHg 1 week postoperatively that resolved after discontinuation of the steroid drops.

In the hyperopic study population, there was no difference in the mean IOP values between visits (P>0.05). The mean IOP was 15.5±3.2 mmHg (range, 8-24 mmHg) preoperatively and 15±3.3 mmHg (range, 8-26 mmHg) at 1 year. Seven eyes (17.5%) developed pupillary block by a mean of 6 days postoperatively (range, 1-15 days) and were treated successfully with Nd:YAG-iridotomies and medication.

The IOP was stable and no long-term changes or glaucoma was observed, which confirms the results in the other PRL studies (Pallikaris et al. 2004, Donoso and Castillo 2006). However, the most frequent complication was early postoperative pupillary block in one myopic and seven hyperopic eyes. This is discussed further in the chapter 4.9 on complications.

4.4 ENDOTHELIAL CELL DENSITY (I, II, IV)

The mean changes in endothelial cell count (studies I and II) were -247 cells/mm^2 (range, -1288 – 160 cells/mm^2) (-8.4 %) 1 week after surgery, -203 cells/mm^2 (range, -767 – 176 cells/mm^2) (-7.1%) 1 year postoperatively, and -228 cells/mm^2 (range, -899 – 173 cells/mm^2) (-7.7%) 2 years postoperatively. Friedman 2-way ANOVA showed statistical significance between visits preoperatively and at all postoperative visits (P<0.05). However, there was no change in the endothelial cell density between 1 week and 1 year or 2 years postoperatively (P>0.05).

In 40 hyperopic eyes, the mean change in the endothelial cell count at 3 months was -139 cells/mm^2 (range, -911 to +328 cells/mm^2) (-4.6%) and at 1 year -115 cells/mm^2 (range, -847 to +183 cells/mm^2) (-3.8%) as shown in Figure 19. The endothelial cell densities at 3 months and 1 year were significantly lower than preoperatively (P<0.01). Between 3 months and 1 year postoperatively, the cell count increased by a mean of 25 cells/mm^2 (1.1%), a difference that did not reach significance (P>0.05).

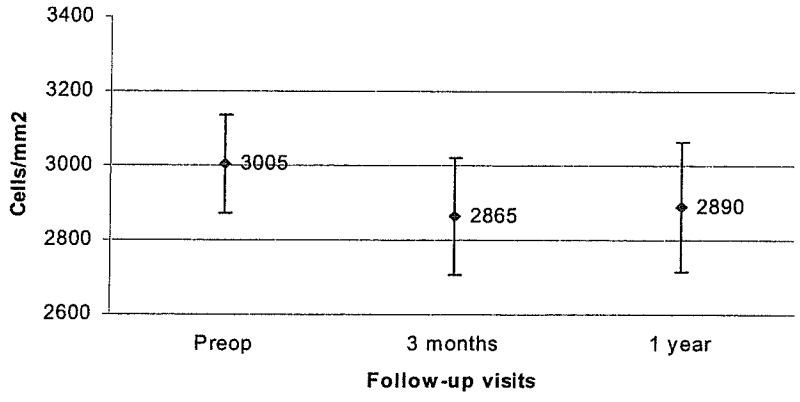


Figure 19. The mean endothelial cell density in hyperopic eyes. The error bars indicate 95% confidence intervals. Endothelial cell loss was -4.6% at 3 months without a significant change at 1 year.

Surprisingly, hyperopic eyes (study IV) had lower endothelial cell loss compared with the myopic eyes. The results in hyperopic eyes were comparable to the hyperopic ICL implantations that had a -4.7% endothelial cell loss postoperatively and remaining unchanged throughout the 10-year follow-up (Pesando et al. 2007). Evaluation of the endothelial cell density in 78 myopic eyes with PRL implantation showed a -7.1% cell loss at 3 months and a -6.3% cell loss at 1 year (Koivula et al, Poster presentation, ESCRS Winter Meeting, Athens, Greece, 2007), which confirms the results in the studies I and II with most myopic eyes.

However, the myopic ICL implantations have shown another pattern. The low initial endothelial cell change after surgery (-1.8 to -2.1% at 3 months) was followed by continuous cell loss -5.7 to -7.9% at 2 years and -8.9 to -12.9% at 3 years (Dejaco-Ruhswurm et al. 2002, Edelhauser et al. 2004). With a mean cell density of 3000 cells/mm^2 at 20 years of age, physiologic endothelial cell loss is reported to be approximately 0.6% per year (Bourne et al. 1997), indicating that continuous cell loss after ICL implantation is more than the result of aging. According to the authors, one explanation could be endothelial cell remodeling. The compensatory changes that occur in the endothelium during recovery from surgical trauma, such as the migration of cells from the central cornea to the area where the surgical trauma occurred, may account for the significant central cell loss over the first postoperative years (Dejaco-Ruhswurm et al. 2002, Edelhauser et al. 2004). In our studies, there was no continuous cell loss after 3 months, indicating that the initial loss mainly results from the surgical procedure and is not induced by the PRL.

Although the surgical maneuvers are identical in myopic and hyperopic PRL eyes, the hyperopic eyes with shallower ACs may have increased risk for contact with the corneal endothelium intraoperatively. However, the myopic cases still had increased cell loss. Can the difference in the PRL design with biconcave optics in myopic eyes increase the risk of damage to the corneal endothelium in myopic eyes at the time of surgery?

4.5 INFLAMMATION (I, II)

The highest average flare count was 15.6 photons/ms at 1 day after surgery compared with the mean 3.8 photons/ms before surgery. The mean laser flare returned to the preoperative level at 3 months and did not change at 1 or 2 years after surgery (P>0.05). Laser flare was not influenced by PRL rotation.

The laser flare measurements were as expected at the highest level 1 day postoperatively due to surgical trauma. Similar results have been found in eyes implanted with an ICL (Sarikkola et al. 2005). The laser flare findings in eyes with an ICL were compared with the control group that did not undergo surgery during 2 years. The results showed that laser flare values after ICL implantation were well within the range of normal values (Sanders 2003).

4.6 PRL ROTATION (I, II)

Fifteen PRLs (75%) rotated 10 degrees or more during the first follow-up year and three PRLs (15%) between 1 and 2 years. The centration of the PRL was good in all eyes. Figure 20 illustrates PRL rotation in a hyperopic eye over time.

The rotation of the PRL may indicate aqueous exchange behind the PRL. Therefore, the floating design of the PRL could be a protective factor for the crystalline lens. The retroillumination photographs showed that the PRL rotated in the PC even though the rotation was much less after the first follow-up year. In addition, the findings from the other PRL studies with ultrasound biomicroscopy (UBM) suggested that PRL rotation could indicate the right haptic position on the zonules without capturing in the sulcus (Garcia-Feijoo et al. 2003, Garcia-Feijoo et al. 2003).

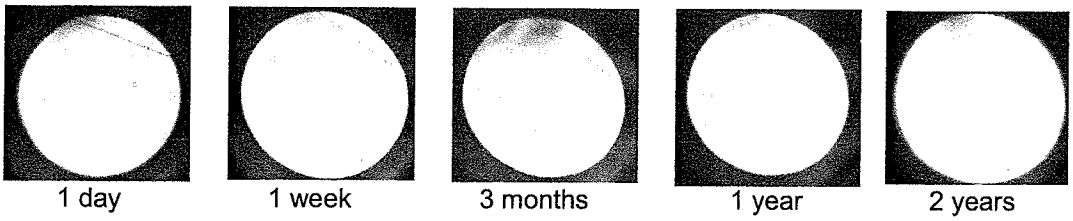


Figure 20. Retroillumination photographs of a hyperopic eye during the 2-year follow-up period. The PRL rotated 15 degrees between 1 day and 1 week and 55 degrees between 1 and 2 years.

However, there have been some reports of serious complications with PRL luxation into the vitreous cavity, suggesting that PRL rotation causes excess pressure against the zonules (Eleftheriadis et al. 2004, Martinez-Castillo et al. 2004, Hoyos et al. 2005). Results in studies I and II cannot confirm this hypothesis. Some degree of rotation was shown in most eyes but in most cases just once between different visits. The absence of PRL decentration can be seen as an indication for right lens sizing.

4.7 DISTANCE BETWEEN THE PRL AND THE ANTERIOR LENS SURFACE (I, II, III)

Figure 21 shows the central distance between the PS-PRL and the anterior lens surface over time (I, II) measured with the Scheimpflug technique. In both myopic and hyperopic eyes, the gap decreased during the first year after surgery. The mean distance was 0.26±0.14 mm (range, 0.0 – 0.46 mm) at 1 year and 0.27±0.15 (range, 0.0 – 0.56 mm) at 2 years. A significant difference was found when comparing the 1-year and 2-year distances with 1-day distance ($P < 0.05$). The possible effect of accommodation was not investigated. The disadvantage of the Scheimpflug method is the need for pupil dilatation to obtain images of the entire surface of the crystalline lens and stimulation of the fellow eye to study accommodation of the eye under observation (Koretz et al. 2002).

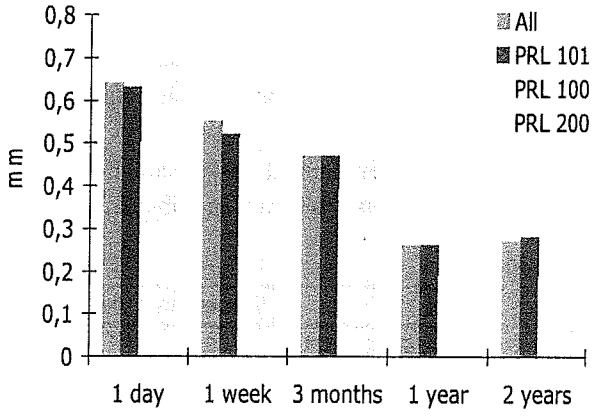
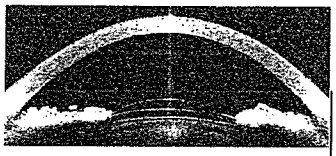


Figure 21. Mean distance between the posterior surface of the PRL and the anterior lens surface at follow-up.

However, the impact of accommodation seems to be essential for distance evaluation. Baikoff and coauthors

(Baikoff et al. 2004) showed in a case report with AC OCT that the PS-PRL touched the anterior lens surface during accommodation. Our distance measurements with OCT showed the mean baseline distance 0.35±0.18 mm (range, 0.0 – 0.80 mm) and during accommodation 0.28±0.24 mm (range, 0.0 – 0.94 mm). All eyes in the OCT study were investigated at least 1 year after PRL implantation.

The study population was divided into the groups according to the lens model. There was no significant difference in the initial PS-PRL and the anterior lens surface distance between the eyes that received the PRL 101, PRL 100, and PRL 200. During accommodation, with the PRL 200 and the PRL 101, there was a mean 84-μm decrease in the distance between the PRL and crystalline lens. The distance between the PRL 100 and crystalline lens did not change during accommodation (Table 1). The changes in the distances between the posterior corneal surface and the anterior lens surface and the posterior corneal surface and the AS-PRL were significant with all PRL models ($P<0.05$).

	 Baseline	 Accommodation	Difference
PRL 101 (n=31)	0.38	0.29	-0.084±0.044*
PRL 100 (n=10)	0.30	0.31	0.002±0.100
PRL 200 (n=11)	0.32	0.23	-0.083 ±0.074*

* p<0.05

Table 1. Mean distance between the posterior surface of the PRL and the anterior lens surface with 95% confidence interval at baseline and during accommodation.

The contact between the PRL and the anterior lens surface at baseline and during accommodation in different PRL types is shown in Table 2.

	Baseline	Accommodation	Cataract
PRL 101	2	3 (2+1)	2
PRL 100	1	2 (1+1)	0
PRL 200	0	3 (0+3)	0

Table 2. The number of PRLs in contact with the anterior lens surface at baseline and in accommodation in the different PRL models. The last column shows the distribution of cases with lens opacification between the PRL models.

All cases with contact between the PRL and the anterior lens surface at baseline had continuous contact during accommodation. Of these three eyes (5.8%), two (3.8%) developed lens opacities. In a total of five cases (9.6%), the PRL touched the crystalline lens during accommodation without contact at baseline. None of these eyes developed a cataract.

In Figure 22, the distance between the PS-PRL and the anterior lens surface at baseline is plotted against patient age. The initial distance was significantly lower in older eyes implanted with the PRL 101 ($r = -0.36$; $P<0.05$). There was no significant trend in eyes implanted with the PRL 100 and the PRL 200 ($rs = -0.12$ and 0.14, respectively; $P>0.05$).

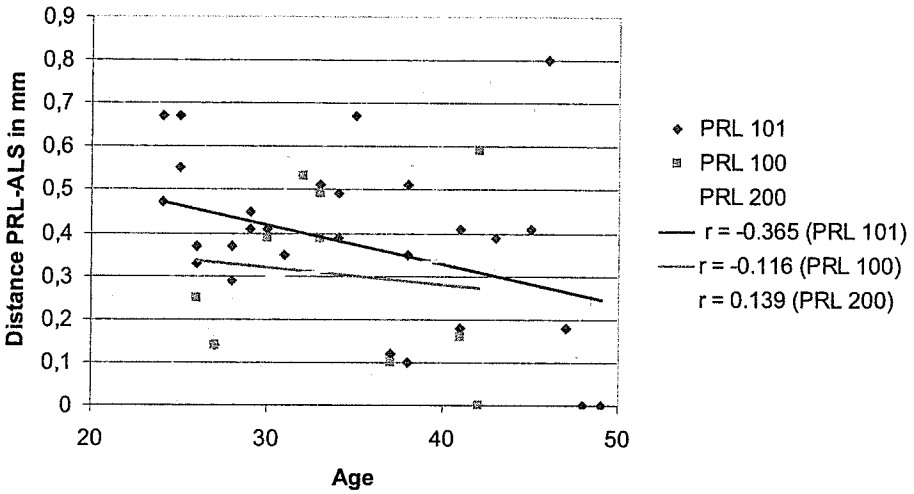


Figure 22. Significant correlation between age and distance to the crystalline lens in PRL 101 ($P<0.05$) but not in PRL 100 and 200.

In the development of the posterior PIOL design, a great effort has been directed toward proper vaulting of the implant because a flat design was shown to produce most of the cataracts (Sanders and Vukich 2002). Therefore, the evaluation of the distance between the posterior PIOL and the crystalline lens seems to be important when comparing different PIOL models.

The distance measurements with the Scheimpflug method showed a significant decrease in the distance between the AS-PRL and the anterior lens surface during the first follow-up year without changes at the 2-year visit, indicating a time-related interaction. This result was confirmed in a study with the ICL (Baumeister et al. 2004). The distances measured with the Scheimpflug method showed comparable results with distances during accommodation investigated with Visante OCT. However, the baseline measurements evaluated with OCT showed an increased distance between the PS-PRL and the anterior lens surface compared with the Scheimpflug technique. This finding is important because it reveals a good average safety distance between the PRL and the crystalline lens evaluated with a more precise method than the Scheimpflug method.

During accommodation, the anterior lens surface moves forward and assumes a more rounded shape (Brown 1973). We found a significant forward movement of the anterior lens surface and PRL in each group. Although the PRL moved anteriorly with accommodation with all three lens models, the space between the PRL and crystalline lens was preserved only with the PRL 100,

and the space decreased with the other two models. The smaller size and weight of the PRL 100 may account for the difference in response to accommodation.

Lens thickening with age did not decrease the baseline distance between the PRL and crystalline lens in eyes with the PRL 100 and PRL 200. However, with the PRL 101 the initial gap decreased significantly with increasing age, indicating a smaller PC depth with aging of the lens.
The measurements with the Scheimpflug method revealed contact between the PRL and the crystalline lens in two cases without lens opacifications. In the OCT study, three cases had contact at baseline and two of them had lens opacifications. No eyes with PRL touch only during accommodation had lens opacities.

4.8 CHANGE IN PUPIL SIZE (III)

Another force that pushes the posterior surface of the artificial lens toward the anterior surface of the crystalline lens is pupil constriction resulting from light as reported by Petternel et al (Petternel et al. 2004) who found a significantly reduced distance between the ICL and crystalline lens under photopic conditions with pupil constriction.

The reduction in pupil diameter during accommodation was found in all models ($P<0.05$). There was a correlation between the reduction in pupil diameter and the reduction in the distance between the PS-PRL and the anterior lens surface during accommodation in eyes with the PRL 200 ($r = 0.67$; $P<0.05$) but not in eyes with the PRL 101 and PRL 100 ($rs = 0.20$ and -0.41, respectively). In hyperopic eyes, this correlation confirmed the results from the study of Petternel et al., although the number of hyperopic cases was rather small. However, pupil constriction in myopic eyes, as part of the accommodative process with lens changes, did not have the same effect as pupil constriction induced by light. Even if the pupil closed in front of the PRL, it did not push the myopic PRL backward to the crystalline lens.

4.9 COMPLICATIONS

4.9.1 Lens opacification (I, II, III, IV)

Anterior subcapsular opacification was observed in two myopic eyes. No PRL removal or cataract extraction has been performed due to lens opacities.
In the first case, the mean follow-up time after the onset of lens opacification was over 3 years. The eye had gained two lines of vision over the preoperative BCVA without loss thereafter and had stable opacification. The other eye had progressive opacification and lost one line from the preoperative value during 6 months of follow-up (Figure 23).
Both cases had central contact between the PRL and the crystalline lens. However, the higher age of these patients (48 and 49, respectively), extremely high myopia (SE -17.0 and -20.25 D, respectively), and the problematic PRL exchange in the case with stable opacification cannot be overlooked. The results

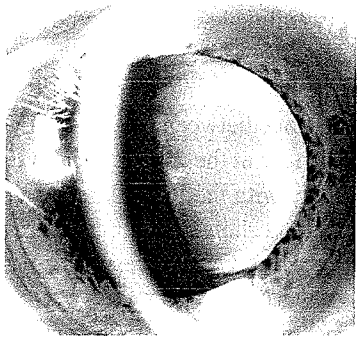


Figure 23. Anterior subcapsular opacification in a myopic eye of 49-year-old man 2 years after PRL implantation detected at the time of OCT scanning.

from ICL studies indicated that mechanical contact, presbyopic age, and intraoperative trauma are associated with an elevated incidence of crystalline lens opacification (Gonvers et al. 2003, Lackner et al. 2004, Sarikkola et al. 2005). High myopia itself increases the risk for earlier cataract formation compared with emmetropic, low myopic, and hyperopic eyes (Sarikkola et al. 2005).

A 34-year-old hyperopic patient developed anterior lens vacuoles initially after surgery. The lens was clear at the 3-month follow-up visit without further complications. The obvious reason for the transient vacuoles was intraoperative trauma to the crystalline lens. In hyperopic eyes with a shallow AC, the risk of accidental contact of the anterior capsule during surgery is increased and extra care should be taken during implantation to avoid contact with the lens capsule and corneal endothelium.

4.9.2 Pupillary block (I, II ,IV)

The most frequent complication was early postoperative pupillary block in one myopic and seven hyperopic eyes despite two iridotomies performed 2 weeks preoperatively. Residual OVD in the posterior chamber or incomplete iridotomies were reported to be the most common reasons for increased IOP postoperatively (Jimenez-Alfaro et al. 2001, Hoyos et al. 2002, Sarikkola et al. 2005). Pupillary block itself was reported to be the most important complication in the earlier studies with the hyperopic ICL (Rosen and Gore 1998, Pesando et al. 1999). But in recently published ICL study, this was not a problem if double peripheral Nd:YAG laser iridotomies or a classic 12 o'clock iridectomy was performed (Pesando et al. 2007).

However, ICL implantation in 61 Asian eyes with myopia showed transient rise in IOP in 26% of eyes within the 2 months postoperatively (Chang and Meau 2007). Compared to myopic Caucasian eyes, the Asian eyes have smaller WTW diameter and shallower anterior chamber, which can cause problem with ICL sizing because the recommended protocol is based on Caucasian populations. The myopic Asian eyes can be compared with Caucasian hyperopic eyes, which also have narrow iridocorneal angles. The presence of an implant can have long-term effects on the redirection of the aqueous flow. In contrary to results of Chang and Meau, our findings suggest that the risk for angle-closure glaucoma seems to increase during the first 2 weeks after surgery. Identifying eyes with a narrow iridocorneal angle could determine those needing extreme care in the creation of sufficiently large laser iridotomies or surgical iridectomy.

The difference between the PRL and the ICL is in the dynamics of the implant. The PRL floats in the posterior chamber, whereas the ICL is fixated and supported in the sulcus angle. The floating design of the PRL makes rotating the implant possible. Even if the PRL is most often implanted in the horizontal meridian (at the 3 to 9 o'clock meridian), it can easily change the meridian after the implantation and thus occlude one of the iridotomies at the superior part of the iris or even both of them if they are too close together (Hoyos et al. 2002). Even though the rotation mechanism of the PRL is the same in myopic and hyperopic eyes, the risk of pupillary block in hyperopic eyes seems to be more prominent.

Our findings suggest that if there is any doubt of penetration through the all iris layers with the initial Nd:YAG-iridotomy treatment, the patient should return for complementary treatment so that absolutely reliable iridotomies are performed before PRL implantation, particularly in small

eyes and eyes with brown irides. The distance between the iridotomies should be over 6.0 mm, which is the width of the PRL. If the laser treatment fails, the Nd:YAG-iridotomies should be combined with an intraoperative surgical iridectomy.

4.9.3 Iris transillumination defect (I, II, IV)

No pigment dispersion was found in any case even though the posterior iris surface seems to touch the anterior PRL surface. However, horizontal iris transillumination defects (Figure 24) were observed in a hyperopic eye 1 year after PRL implantation combined with pupil ovalization at 2 years and no other complications. The same kind of iris atrophy has been reported in another PRL study (Hoyos et al. 2002) as well as in myopic eyes with ICLs (Brandt et al. 2001).
UBM showed iris capture and the anterior convexity of the PRL, indicating poor fit of the PRL in the posterior chamber. The patient had no complaint of glare or halos. Since the hyperopic PRL is manufactured in only one size, exchanging it for a smaller model was impossible. The patient is followed on a regular basis.

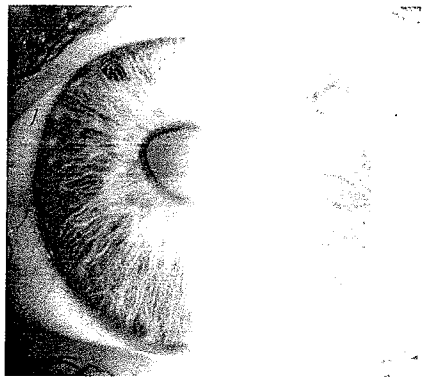


Figure 24. Transillumination defects in the iris in a hyperopic eye. The PRL has signs for oversizing for the actual posterior chamber. The patient was satisfied with the visual outcome and did not require PRL explantation.

4.9.4 Overcorrection of hyperopia (I, II, IV)

Unexpected postoperative myopia with a mean postoperative SE of -1.35 D (range, -1.35 to -1.75 D) was found in four hyperopic eyes (studies I, II and IV) with a mean preoperative SE +5.53 D (range, +3.25 - +8.75). The PRL was exchanged in two cases and in one case a LASEK enhancement was performed. These procedures changed the mean SE to -0.08 D (range, ±0.0 to -0.25 D).
In the fourth case, the patient did not desire PRL exchange or LASEK enhancement but wanted PRL explantation, after which the patient returned to spectacle use without loss in BCVA.

The refraction of a hyperopic eye can be challenging. Young hyperopes can transiently accommodate without correction while reading an eye chart but cannot maintain accommodation without asthenopic symptoms. Accommodation affects the manifest refraction, which should be combined with cycloplegic refraction before surgery, because the theoretical approach to calculating the lens power is as important as the proper surgical technique. Additionally,

preoperative contact lens-corrected visual acuity and refraction may provide more accurate results for PRL power calculation in high myopia and hyperopia than the traditional spectacle-corrected visual acuity and refraction.
In hyperopic eyes, slight postoperative hyperopia seems to be more acceptable than myopia, which must be considered in the power calculation. Young patients are used to accommodate and prefer that after surgery rather than vice versa. In the hyperopic study population, the mean patient age was comparable with that in the studies of myopic eyes. However, hyperopia becomes increasingly problematic with advancing age and patients treated for hyperopia might on average be older than myopic patients. Therefore, hyperopes approaching presbyopia do not gain any benefits if the surgery leaves them hyperopic.

4.9.5 Halos and glare (I, II, IV)

Two hyperopic eyes had severe glare and halos in dim light and night. The PRL was removed 17 and 24 months postoperatively, which resulted in symptom relief in both cases.
In the study of Hoyos and associates, night halos and glare were reported in 26% of eyes, although the PRLs were well centered (Hoyos et al. 2002). The study of Pallikaris and coworkers confirmed this result: 28.5% of high myopic eyes had minor glare and halos at night. In most cases the pupil diameter was greater than 7 mm. However, these symptoms decreased 6 months after implantation (Pallikaris et al. 2004).
Because the optic size of the PRL is 4.5 to 5.0 mm, patients whose pupils dilate beyond that size in dim light may be subject to halos or night glare, phenomena that also would be problematic for a patient if the lens optics were decentered.

4.10 ANALYSIS OF FOLLOW-UP METHODS (II, III)

In the assessment of any new instrument, an estimate of the reproducibility is essential before further data analysis can be performed. To evaluate the precision of the instruments used in the main trials, double-independent measurement studies were conducted.
Evaluation of the precision of the laser flare meter showed a random error of 17%, which was higher compared with the 12% within-subject variability in aqueous flare in normal eyes (Shah et al. 1991). The endothelial cell count, however, showed a low random error (2.8%) as a reliable indicator for the evaluation of corneal endothelium. The result was confirmed in another study with the same system as ours (Vecchi et al. 1996).
The random error using the Scheimpflug method (with the EAS-1000 system in the evaluation of the distance between the PRL and the anterior lens surface) was 10%. For Visante OCT, the same study design using double-independent measurements, repeated after 5 minutes, showed a random error of 5% in the measurements between the PRL and crystalline lens and 1.25% in the measurements between the PRL and the posterior corneal surface. This result indicated that Visante OCT is sufficiently accurate and reliable to allow an analysis of distances in the anterior segment and confirmed the results of a study with Visante OCT in measurements of the AC (Koch et al. 1998). Because the PRL does not change thickness during accommodation, the mean central thickness of the PRL in each group at baseline and during maximum accommodation served as an internal control. The results were comparable to the error analysis and confirmed the accuracy of the measurements. With its high-resolution capacity, AC OCT is more precise than Scheimpflug images.

5 CONCLUSIONS

Treating high myopia and hyperopia is a more challenging task than treating patients with low ametropia. The clinical outcomes of PRL implantation are better or comparable to existing refractive surgery alternatives. PRL implantation meets the high expectations of refractive surgery and provides excellent quality of vision and corrects myopia and hyperopia with good predictability and refractive stability. The lens has a biocompatible design and material that do not induce ongoing endothelial cell loss and only induce subtle iris or lens damage resulting in less cataractogenesis than that seen with other PC PIOL models. The lens is foldable and can be implanted through a small, self-sealing incision. It is adjustable and can be exchanged. In addition, the method is reversible in contrast to techniques that permanently alter corneal tissue.

However, the PRL does not have all the ideal qualities of a PIOL. The future implant could be improved with a 7-mm diameter functional optic, which might decrease the risk for edge effects, glare, and halos. Lens design should better guarantee the free flow of aqueous and minimize the risk of pupillary block. The lens should be easy to implant to facilitate the development of fewer intraoperative complications and decrease the psychologic stress for the surgeon, which results from reports of luxation of the PRL. The ideal PIOL should not be manufactured only in negative and positive powers but also have a spherocylindrical alternative for eyes with astigmatism. In the best of worlds, the PIOL would even correct presbyopia without reducing the quality of vision. This would provide an implant with a solution for virtually every refractive problem and would be tolerated by the patient for decades, perhaps for life. The method therefore has to be refined further and studied carefully.

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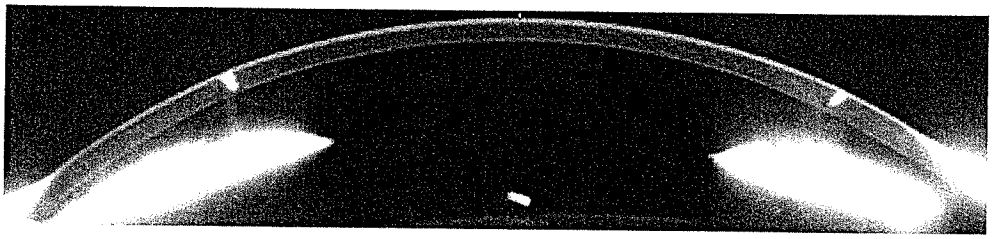
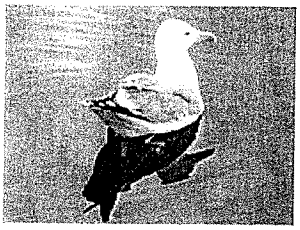
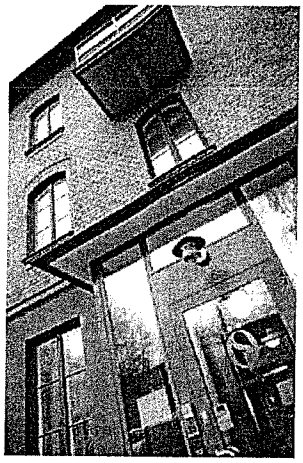




Questions & Answers

- Cataracts
- Refractive surgery
  - Common questions about ICL/PRL
  - Common questions about RLE/multifocal surgery
- Glaucoma screening
- Eyelid surgery
- Finance

Common questions about ICL/PRL



Will the result be permanent?
Serious short-sightedness can arise later in life, and you may require weak spectacles or contact lenses to see clearly at a distance. You may need reading glasses after 45 years of age, as all short-sighted persons may.

How long does it take to acquire good vision after the procedure?
It is usual to see rather well as early as the next day.

How can I manage in the period after treating the first eye, and before treating the second?
It will be necessary to try to cope with having only one good eye, or to use a contact lens on the eye that has not yet been corrected.

How long will it be before the second eye can be treated?
It is usual to treat both eyes on the same occasion, but it is also possible to wait a week or a few weeks.

How soon can normal life begin again?
You should avoid rubbing your eyes the first week, and you should not go swimming. You may have to take the first week after surgery off work.

What are the risks?
We work in extremely sterile conditions, and the risk for infection is thus very low (less than 1 in 2,000). There is, however, a slightly increased risk (1 in 100) of developing a cataract. This arises when the eye's own lens becomes cloudy during the surgery, or under the influence of pressure from the lens. If this occurs, the lens must be surgically removed and an artificial lens inserted.

Short-sightedness can also be cured in this case by choosing a lens with a suitable power. This method is sometimes used to correct severe short-sightedness (see the section dealing with RLE). It will, however, be necessary to use spectacles for reading and other tasks requiring near vision, and thus this method is normally used for those over 45 years old.