

Position of rigid and foldable iris-fixated myopic phakic intraocular lenses evaluated by Scheimpflug photography

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PURPOSE: To evaluate the postoperative intraocular positional stability of 1 rigid poly(methyl methacrylate) (PMMA) phakic intraocular lens (pIOL) model and 2 foldable polysilicone–PMMA iris-fixated pIOL models.

SETTING: Department of Ophthalmology, Johann Wolfgang Goethe-University Frankfurt am Main, Germany.

METHODS: One of 3 iris-fixated pIOL models (Artisan, Artiflex I, and Artiflex II, Ophtec BV) was implanted in 45 eyes of 26 patients with myopia or myopic astigmatism. The central distance between the pIOL and corneal endothelium and between the pIOL and anterior surface of the crystalline lens was evaluated using Scheimpflug photography 6 and 12 months after surgery.

RESULTS: The mean preoperative spherical equivalent was -9.32 diopters ± 1.78 (SD) (range -6.5 to -13.5 D). Each IOL model was implanted in 15 eyes. The median distance from the central corneal endothelium to the anterior surface of the pIOL at 6 months and 12 months was 2.65 mm and 2.64 mm, respectively, in the Artisan group, 2.47 mm and 2.50 mm, respectively, in the Artiflex I group, and 2.48 mm and 2.52 mm, respectively, in the Artiflex II group. The median distance between the posterior surface of the pIOL and the anterior surface of the crystalline lens at 6 months and 12 months was 0.40 mm and 0.48 mm, respectively, in the Artisan group, 0.53 mm and 0.55 mm, respectively, in the Artiflex I group, and 0.68 mm and 0.66 mm, respectively, in the Artiflex II group. At 12 months, the distance between the pIOL and crystalline lens was statistically significantly greater in the Artiflex II group than in the Artisan group ($P < .01$).

CONCLUSION: The intraocular position of rigid pIOLs and foldable silicone iris-supported pIOLs showed a difference between the 3 pIOL models in space to the crystalline lens and the corneal endothelium, which may affect long-term results in terms of IOL interaction with surrounding tissue.

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Phakic intraocular lenses (pIOLs) have been used for many years to correct refractive errors. The main indications for pIOL implantation are high myopic and hyperopic refractive errors and moderate refractive errors that cannot be corrected by corneal surgery because the cornea is too thin or the scotopic pupil too large, both of which are contraindications to corneal refractive surgery.¹

In 1978, Worst invented the iris-fixated pIOL (iris claw, Ophtec BV) for the correction of aphakia; this pIOL remains a feasible option for secondary implantation.² The iris-fixated pIOL for the correction of myopia was introduced in 1986 as a rigid single-piece poly(methyl methacrylate) (PMMA) model with a 5.0 or 6.0 mm optic; this pIOL (Artisan, Ophtec BV;

Verisyse, AMO, Inc.) has been implanted through a 5.0 to 6.0 mm incision for more than 20 years.^{3,4} The goal of reducing surgically induced astigmatism (SIA) was achieved in 2003 with the development of the foldable iris-fixated Artiflex model (Ophtec BV) (referred to here as Artiflex I). This pIOL model, with a foldable 6.0 mm polysilicone optic and PMMA haptics, can be implanted through a 3.2 mm incision. The close proximity of iris-fixated pIOLs to intraocular structures can lead to complications related to the iris and crystalline lens. These include anterior chamber inflammation, pIOL dislocation, iris injury, refractive changes, posterior synechias, and, potentially, cataract formation.^{5–7} When a patient of ours developed posterior synechias after Artiflex I implantation,

we determined that the haptic angle might have been too shallow. The manufacturer redesigned the Artiflex I pIOL and created a new configuration, the step-vaulted haptic. The Artiflex I pIOL was never marketed; thus, the changes were incorporated in the currently available Artiflex pIOL model (referred to here as Artiflex II).

We wondered whether the changes in pIOL design cause the silicone pIOLs (Artiflex I and II) to behave differently after implantation than their predecessor, the iris-fixated PMMA Artisan pIOL. Therefore, this study sought to determine the intraocular position and postoperative stability of the 3 iris-fixated pIOLs in relation to the central corneal endothelium and crystalline lens over 1 year using Scheimpflug photography.

PATIENTS AND METHODS

In this retrospective nonrandomized study, the position of 3 iris-fixated phakic IOL models was depicted by Scheimpflug photography and evaluated. Forty-five eyes of 26 patients were enrolled in the study between December 2003 and September 2006. Each pIOL model was implanted in 15 eyes to correct myopia or myopic astigmatism.

Inclusion criteria were myopia of at least -5.0 diopters (D), age 18 years or older, and informed consent. Exclusion criteria were presbyopia, cataract, glaucoma, anterior chamber depth (ACD) less than 3.0 mm, endothelial cell count less than 2000 cells/mm², malformations of the globe or ocular adnexa, previous retinal detachment, macular edema, diabetic retinopathy, optic nerve atrophy, previous corneal or intraocular surgery, and significant inflammation of the anterior or posterior segment. The study was conducted in accordance with the tenets of the Helsinki agreement.

The following anterior chamber iris-fixated pIOL models, all with a 6.0 mm optic, were implanted (Figure 1):

1. Artisan 204, which has an overall length of 8.5 mm and a refractive power ranging from -5.0 to -15.5 D in

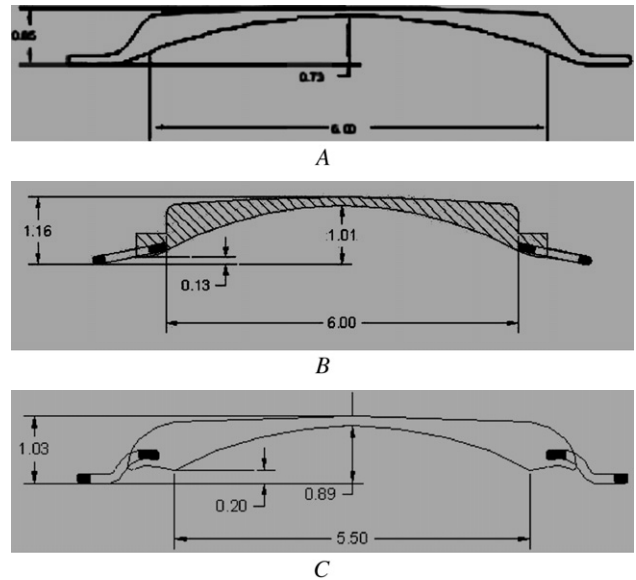


Figure 1. Drawing of the 3 iris-fixated pIOL models. A: Artisan. B: Artiflex I. C: Artiflex II.

0.5 D steps. The optic and haptics of this rigid pIOL are PMMA.

2. Artiflex I AC 401, which has an overall length of 8.5 mm and a refractive power ranging from -2.0 to -14.5 D in 0.5 D steps. The hydrophobic polysilicone optic of this foldable pIOL is attached to PMMA haptics. The highest point of optic curvature is 0.13 mm above the lowest point at the edge of the haptic. Clinical functionality of this pIOL model was assessed in a European multicenter study, in which our group participated (unpublished data).
3. Artiflex II AC 401, which has an overall length of 8.5 mm and a refractive power ranging from -2.0 to -14.5 D in 0.5 D steps. The hydrophobic polysilicone optic of this foldable pIOL, which is the currently available Artiflex model, is attached to PMMA haptics. The highest point of optic curvature is 0.20 mm above the lowest point at the edge of the haptic. The pIOL has a step-vaulted optic edge curvature.

All pIOLs were implanted by the same surgeon (T.K.). Which pIOL model to use was determined according to anterior chamber width and ACD from the corneal endothelium measured by Orbscan (Bausch & Lomb, Inc.) to ensure the anterior chamber was sufficiently deep. Intraocular lens power calculation was performed using the van der Heijde formula, taking into account the corneal curvature, ACD, and manifest spherical equivalent (SE) of the subjective manifest refraction. Artisan pIOLs were implanted through a 6.0 mm sclerocorneal tunnel incision and the Artiflex I and Artiflex II pIOLs, through a 3.2 mm posterior limbal tunnel incision.

Preoperative data included patients' demographics, ACD, and SE. The position of the pIOL was measured 6 and 12 months postoperatively by Scheimpflug photography (EAS-1000 anterior eye segment analysis system, Nidek Co.). The images were analyzed using the "axial biometry" function of the software (version 2.23) provided by the manufacturer. All images were taken after standard pupil dilation for retinal evaluation; pupils were dilated with

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tropicamide 0.5% (Mydraticum) administered twice at 10-minute intervals. Measurements of the distance between the pIOL and the cornea and between the pIOL and the crystalline lens were obtained in all eyes. The headrest and chinrest of the EAS-1000 camera ensured the patient's head was in the same upright position at each follow-up examination.

Statistical evaluation was performed using BIAS software (Windows version 8.2, Epsilon). In this retrospective study, no power calculation could be performed because of a maximum of 15 Artiflex I implantations. The David test showed the data evaluated were distributed nonparametrically. The Wilcoxon matched paired test was used to compare 2 time intervals in 1 pIOL group and the Kruskal-Wallis test, for comparisons between the 3 pIOL groups. A *P* value less than 0.01 was considered statistically significant in both groups.

RESULTS

Tables 1A and 1B show the patients' demographic data and refractive data, respectively. There was no statistically significant difference between groups in age, sex, ACD, or axial length. The Artisan group had a higher preoperative SE (median -10.75 D) than the Artiflex I (-8.50 D) and Artiflex II (-8.63 D) groups, although the difference was not statistically significant ($P > .48$, Kruskal-Wallis test).

The mean refractive stability 12 months after pIOL implantation was -0.18 ± 0.42 (SD) in the Artisan group, 0.02 ± 0.47 in the Artiflex I group, and -0.01 ± 0.04 in the Artiflex II group. The safety (best corrected visual acuity 12 months after surgery), efficacy (uncorrected visual acuity 12 months after surgery), and predictability were similar between the 3 groups.

Table 2A and Figure 2, A, show the median and mean distance between the corneal endothelium and anterior surface of the pIOL 6 and 12 months postoperatively in all 3 groups. There was no statistically significant difference in the measurements within each group over the 12 postoperative months (Wilcoxon matched pairs test). The distance between the pIOL and corneal endothelium at 12 months was statistically

significantly greater in the Artisan group than in the 2 Artiflex groups ($P < .01$, Kruskal Wallis test).

Table 2B and Figure 2, B, show the median and mean distance from the posterior surface of the pIOL to the anterior surface of the crystalline lens 6 and 12 months postoperatively in all 3 groups. The distance between the pIOL and crystalline lens at 12 months was statistically significantly greater in the Artiflex II group than in the Artisan and Artiflex I groups ($P < .01$, Kruskal-Wallis test).

DISCUSSION

Iris-fixated pIOLs are an option for the treatment of high myopia, hyperopia, and astigmatism, achieving a level of optical quality that may be higher than that of corneal refractive surgery.^{1,8-11} Predictability was high with all 3 models used in this study, as it is for iris-fixated pIOLs in general. Use of iris-fixated pIOLs gives the option of correcting lower residual refractive errors postoperatively by corneal excimer laser ablation (bioptic approach).¹² The Artiflex is the foldable version of the rigid PMMA iris-fixated pIOL model (ie, Artisan). It has a polysilicone optic and PMMA haptics and can be implanted through a 3.2 mm incision. The Artiflex pIOL was designed to result in less SIA than the PMMA Artisan model. Scheimpflug evaluation with a dilated pupil shows that iris-fixated pIOLs have better postoperative stability than angle-supported and sulcus-fixated pIOLs, which are more prone to postoperative rotation.¹³ Movement in the position of the latter 2 pIOL models results in minor changes in higher-order aberrations, whereas clinically significant changes due to pupil size can occur with iris-fixated pIOLs.¹⁴⁻¹⁶ Iris-fixated pIOLs should maintain their distance to the corneal endothelium and crystalline lens, reducing the risk for corneal endothelial cell loss and anterior subcapsular cataract.¹⁷

The intraocular position of the pIOL is important because enclavation that is too tight can cause the pIOL to rub on the iris, leading to occlusion of the pupillary aperture and thus to secondary angle-closure glaucoma, especially in hyperopic eyes.¹⁸ Tight enclavation can also induce refractive changes postoperatively.⁶ On the other hand, enclavation that is too loose may lead to pIOL dislocation and thus to endothelial cell loss, corneal decompensation, or secondary glaucoma as a result of mechanical trauma to angle structures.¹⁹ Postoperative complications of iris-fixated pIOLs include pigment dispersion and chronic anterior chamber inflammation, as reported for the rigid PMMA Artisan pIOL.²⁰ Baikoff et al.²¹ evaluated the hypothesis that the increasing thickness of the crystalline lens (defined by the distance between the crystalline lens' anterior pole and the horizontal plane

Table 1A. Patient demographics.

Parameter	Phakic IOL Model		
	Artisan	Artiflex I	Artiflex II
Eyes (n)	15	15	15
Patients (n)	9	8	9
Sex, m/f	2/7	1/7	3/6
Age (y)			
Mean \pm SD	32 \pm 10	34 \pm 10	35 \pm 6
Median	29	33	34
Range	23-56	23-47	26-47

IOL = intraocular lens

Table 1B. Refractive results.

Parameter	Phakic IOL Model		
	Artisan	Artiflex I	Artiflex II
ACD (mm)			
Mean ± SD	3.35 ± 0.24	3.11 ± 0.24	3.34 ± 0.24
Median	3.26	3.14	3.29
Range	3.04 to 3.83	3.0 to 3.53	3.01 to 3.89
Preop SE (D)			
Mean ± SD	-10.23 ± 1.92	-8.78 ± 1.56	-8.7 ± 0.92
Median	-10.75	-8.5	-8.63
Range	-6.50 to -12.50	-7.00 to -11.50	-7.25 to -10.13
Mean SE (D) ± SD 12 mo postop; ie, stability	-0.18 ± 0.42	-0.02 ± 0.47	-0.01 ± 0.04
Change in lines BCVA (optotypes) 12 mo postop; ie, safety (%)			
Loss	13	0	10
Unchanged	40	13	30
Gain 1 line	27	13	60
Gain ≥ lines	20	34	
UCVA 12 mo postop; ie, efficacy (%)			
1.2	0	33	20
1.0	47	47	80
0.8	27	20	0
≤0.6	27	0	0
Final visual acuity 12 mo postop; ie, predictability (%)			
Within ±0.5 D of target	93	80	100
Within ±1.0 D of target	7	20	—

ACD = anterior chamber depth; BCVA = best corrected visual acuity; SE = spherical equivalent; UCVA = uncorrected visual acuity

joining the opposite iridocorneal recesses) over time might lead to a sandwiching effect of the iris; that is, the iris could be squeezed between the pIOL and crystalline lens. This complication may be more frequent in hyperopic eyes, and the assumption was that there is little or no risk for pigment dispersion if the vault is below 600 μm.²¹ Nevertheless, we believe this

complication is negligible as hyperopia is not a major indication for pIOL correction. Recently, we reported a patient with posterior synechias after Artiflex I implantation that resulted in pIOL re-enclavation and intensified application of steroids to ease anterior chamber inflammation.⁷ During management of this case, it was presumed that the distance between the optic curve and haptics (0.13 mm) was insufficient and the angle too shallow with the Artiflex I. This is in contrast to the Artisan, the rigid PMMA Artisan model, for which the optic curve-haptic distance is 0.20 mm. Ophtec redesigned the Artiflex I pIOL and increased the distance between the PMMA haptic and the silicone optic from 0.13 to 0.20 mm, resulting in the step-vaulted haptic design of the Artiflex II model. The Artiflex I pIOL was never marketed, and the changes were incorporated in the currently available Artiflex II pIOL.

In this study, we compared the postoperative central distances between the 3 pIOL models and the cornea and crystalline lens using Scheimpflug photography. An advantage of the Scheimpflug technique is the fast noncontact acquisition of data for the anterior chamber. One disadvantage is that it works on an optical basis only, requiring clear optical media, and

Table 2A. Distance between the anterior surface of the pIOL and the corneal endothelium (dilated pupil).

Examination	Distance from pIOL to Corneal Endothelium (mm)		
	Artisan	Artiflex I	Artiflex II
6 months			
Median	2.65*	2.47	2.48
Range	2.59-2.85	2.19-2.66	2.31-2.59
Mean ± SD	2.67 ± 0.08	2.45 ± 0.15	2.48 ± 0.10
12 months			
Median	2.64	2.50	2.52
Range	2.45-2.90	2.14-2.66	2.28-2.66
Mean ± SD	2.63 ± 0.11	2.44 ± 0.19	2.48 ± 0.10

IOL = intraocular lens

*Eleven of 15 eyes available for evaluation

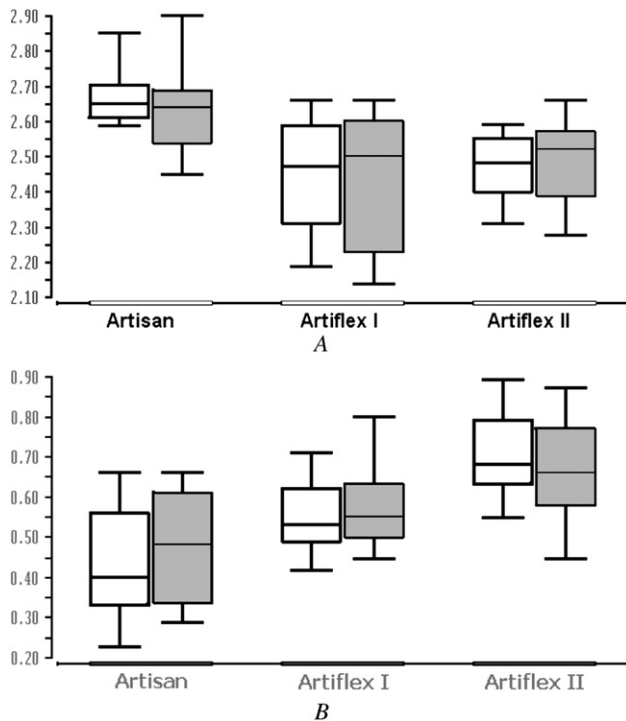


Figure 2. A: Box-plot diagram of the median distance between the pIOLs and cornea measured with dilated pupil 6 months (white boxes) and 12 months (gray boxes) postoperatively. At 6 months, 11 of 15 Artisan eyes were available for evaluation. B: Box-plot diagram of the median distance between the pIOLs and the crystalline lens measured with a dilated pupil 6 months (white boxes) and 12 months (gray boxes) postoperatively. The length of the box indicates the interquartile range and the lines above and below, the extreme values.

cannot be used to examine peripheral structures behind the undilated iris, as can be done with ultrasonography. We did not measure the peripheral distance between the pIOL and iris, although the measurement is of great value because of the imprecise depiction of iris tissue due to light scattering in the

Scheimpflug camera. The central distance was measured according to the methodology used in previous studies that examined this distance, which is important in terms of the possible squeezing effects between the pIOL, iris, and crystalline lens.¹³ Pupil dilation was achieved in the same manner in all our patients (2 applications of tropicamide 0.5% eyedrops at 10-minute intervals). The potential effect of mild partial cycloplegia, which has been described after 60 minutes of tropicamide 1%,²² was unlikely in our study. The main shortcoming of this study was the low number of cases. Unfortunately, we had data on only 15 eyes with the Artiflex I pIOL; thus, we could not perform a sample-size calculation before the study. However, the development of new pIOL designs is rapid and to our knowledge, there is no published study comparing the stability of the postoperative distance, in particular between the pIOL and the crystalline lens, with these 2 consecutively developed iris-fixated pIOL models (Artiflex I and Artiflex II).

Tehrani and Dick²³ recently used Scheimpflug photography to examine the intraocular distance between foldable iris-fixated pIOLs and the corneal endothelium and crystalline lens in 17 myopic eyes. They reported a mean distance to the corneal endothelium of 2.01 ± 0.26 mm and a mean distance to the crystalline lens of 0.73 ± 0.09 mm. Our study found a median distance from the Artiflex II to the crystalline lens of 0.68 mm (mean 0.7 ± 0.1 mm) and 0.66 mm (mean 0.7 ± 0.1 mm) 6 months and 12 months, respectively, after implantation. The distance remained stable over the 12-month follow-up. The distance between the Artiflex II pIOL and crystalline lens was statistically significantly greater than the vault between the Artisan pIOL and crystalline lens (median 0.40 mm and 0.48 mm after 6 months and 12 months, respectively) ($P < .001$). The median distance between the Artiflex I pIOL and crystalline lens was 0.53 mm at 6 months and 0.55 mm at 12 months, which was statistically significantly different than the distance between the Artisan pIOL and crystalline lens during the same time periods. At 12 months, there was no statistically significant difference between the Artiflex I and II models, although on average the Artiflex II pIOL was farther from the crystalline lens than the Artiflex I pIOL was.

The distance between the 3 pIOLs and the corneal endothelium was generally stable over 12 months; the greatest vault was found with the all-PMMA Artisan pIOL. This is consistent with biomicroscopic findings of Pop et al.,²⁴ who evaluated the distance between rigid Artisan pIOLs and the corneal endothelium. These findings are comparable to the results in our patients with the foldable IOL with the new design. Our study indicates that both foldable pIOL models (Artiflex I and Artiflex II) guarantee a safe

Table 2B. Distance between the posterior surface of the pIOL and the crystalline lens (dilated pupil).

Examination	Distance from pIOL to Crystalline Lens (mm)		
	Artisan	Artiflex I	Artiflex II
6 months			
Median	0.40*	0.53	0.68
Range	0.23–0.66	0.42–0.71	0.55–0.89
Mean \pm SD	0.43 ± 0.13	0.55 ± 0.10	0.70 ± 0.10
12 months			
Median	0.48	0.55	0.66
Range	0.29–0.66	0.45–0.80	0.45–0.87
Mean \pm SD	0.46 ± 0.13	0.57 ± 0.10	0.67 ± 0.12

IOL = intraocular lens

*Eleven of 15 eyes available for evaluation

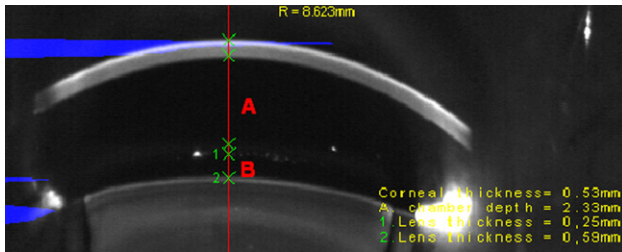


Figure 3. Scheimpflug images of an Artiflex II pIOL. A: Distance between the corneal endothelium and anterior surface of the pIOL. B: Distance between the posterior surface of the pIOL and anterior surface of the crystalline lens.

distance to the corneal endothelium and to the crystalline lens. Slitlamp examination and careful consideration of several anatomical parameters (eg, ACD, endothelial cell count, pupil size before pIOL implantation) remain essential, however. Additional data, such as dynamic central and peripheral intraocular distance changes, should be acquired in the future using anterior segment optical coherence tomography or digital Scheimpflug techniques (Figure 3).

The biocompatibility of IOLs also plays a decisive role and depends partly on the regularity of the surface. For PMMA models, a smooth and homogenous surface quality has been confirmed by scanning electron microscopy.²⁵ Thus, unlike the known qualities of the Artisan's PMMA material, the silicone-PMMA of Artiflex pIOLs may trigger anterior chamber inflammation. In 2006, Tahzib et al.²⁶ reported a case of large-cell deposits on the haptics and silicone optic of an Artiflex I pIOL, which indicates that inflammatory cells may adhere to the silicone optic. Nine months after uneventful implantation, the Artiflex I pIOL was explanted due to recurrent anterior chamber inflammation with subsequent cell and pigment deposits on the posterior surface of the pIOL. We reviewed our cases and the literature for reports of large-cell deposition on iris-fixated PMMA pIOLs and found no clear correlation to this complication. To our knowledge, this is the first time silicone has been used for iris-fixated pIOLs after the excellent experiences with various other foldable pIOL types (collagen-hydroxyethyl methacrylate implantable contact lens; silicone pIOL).

The development of new pIOL models will continue, and special attention must be paid to potential causes of anterior chamber inflammation. Further basic and clinical studies are warranted as pIOL design and material continue to evolve.^{27,28}

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