

Position of Angle-Supported, Iris-Fixated, and Ciliary Sulcus-Implanted Myopic Phakic Intraocular Lenses Evaluated by Scheimpflug Photography

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- **PURPOSE:** To examine postoperative positional stability of myopic phakic intraocular lenses (IOLs).
- **DESIGN:** Prospective, nonrandomized clinical study.
- **METHODS:** The study included 46 eyes which received an anterior chamber angle-supported (Bausch & Lomb NuVita; 10 eyes), anterior chamber iris-fixated (Ophtec Artisan; 20 eyes) or ciliary sulcus-implanted phakic IOL (Staar ICL; 16 eyes). The distance between the phakic IOL and the crystalline lens and the cornea as well as rotation around the optical axis was evaluated using Scheimpflug photography at 1, 3 to 6, and 12 months postsurgery.
- **RESULTS:** The anterior chamber phakic IOLs showed no significant movement in anteroposterior direction. The posterior chamber phakic IOL showed a significant movement toward the crystalline lens between postoperative months 3 and 12. The median amount of rotation around the optical axis between the 3- and the 12-month evaluation was 1.9 degrees (range = 0.0–33.5 degrees) for the NuVita, 0.6 degrees (range = 0.0–3.5 degrees) for the Artisan, and 0.9 degrees (range = 0.2–2.3 degrees) for the ICL. Four NuVita IOLs rotated more than 10 degrees.
- **CONCLUSIONS:** The angle-supported anterior chamber phakic IOLs showed a generally stable position regarding distance to cornea and natural lens, but rotation was observed in four IOLs. The iris-fixated phakic IOL showed the highest overall stability. The posterior chamber phakic IOL was stable in terms of rotation but had a tendency to decrease in distance toward the crystalline lens. Intraocular lenses implanted in phakic eyes followed for 12 months

demonstrate stable IOL position overall. (Am J Ophthalmol 2004;138:723–731. © 2004 by Elsevier Inc. All rights reserved.)

IN THE LAST DECADE, REFRACTIVE SURGERY HAS gained widespread acceptance. Most procedures for the correction of ametropia are performed on the cornea, with laser-assisted in situ keratomileusis (LASIK) being the most common procedure. LASIK has shown its limitations, however. For the correction of higher myopic and hyperopic refractive errors, there are considerable undesired effects of the procedure, such as loss of contrast, glare, and decreased mesopic vision. Furthermore, excessive ablation of corneal tissue may cause iatrogenic keratectasia,¹ especially in eyes with a predisposition to keratoconus. Therefore, a variety of intraocular lenses (IOLs), known as phakic IOLs, have been designed to achieve full correction of high myopia and hyperopia without loss of accommodation. To prevent damage to intraocular tissues and achieve a stable refractive outcome, IOLs must retain their position after implantation. With several types of phakic IOLs, good results have been achieved in people with high myopia and hyperopia.

Up to now, only a few studies with long-term results of implantation with phakic IOLs have been published.^{2–5} The biocompatibility of IOLs depends in part on regularity of the surface. A previous study demonstrated excellent surface qualities of the phakic IOL models examined here.⁶ Another concern is postoperative movement of the phakic IOL. Because of the close proximity of the phakic IOL and intraocular structures, possible complications include endothelial cell loss resulting from contact between the IOL and cornea,⁷ pupil ovalization due to contact with the delicate iris tissue,⁸ and secondary glaucoma due to crowding of the anterior chamber angle or pupillary block.⁹ Posterior chamber IOLs can cause cataract due to contact with the crystalline lens and glaucoma due to dispersion of iris pigment and closure of the pupil opening.^{10–12} Further-

Accepted for publication June 3, 2004.

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Professor Kohnen is a consultant for scientific questions to Bausch & Lomb but has no financial interest in the products mentioned herein.

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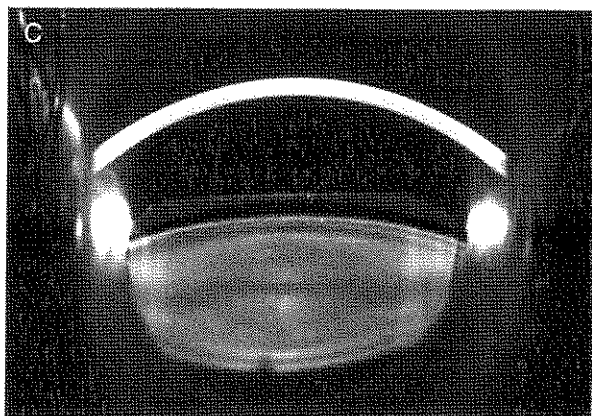
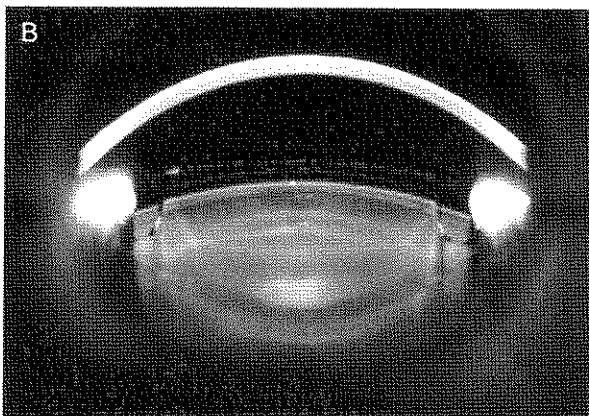
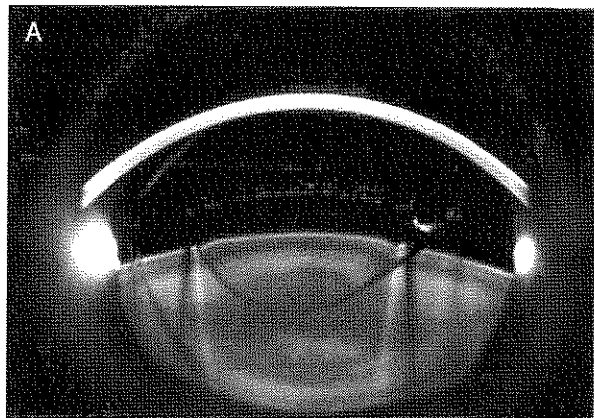


FIGURE 1. Scheimpflug slit images taken of the examined phakic intraocular lenses. (A) Bausch & Lomb NuVita MA 20 angle supported anterior chamber phakic IOL. (B) Ophtec Artisan iris-fixated anterior chamber phakic IOL. (C) Staar ICL collamer posterior chamber phakic IOL. The vault between the phakic IOL and the crystalline lens is clearly visible.

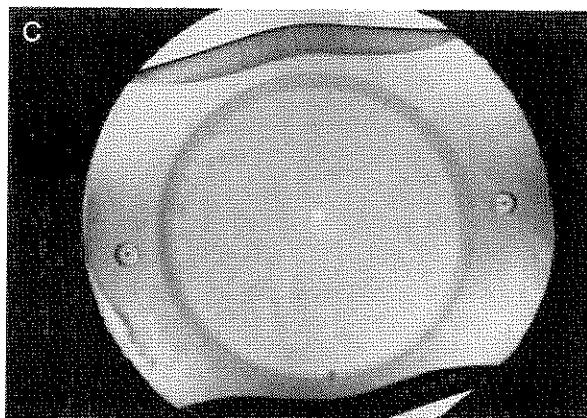
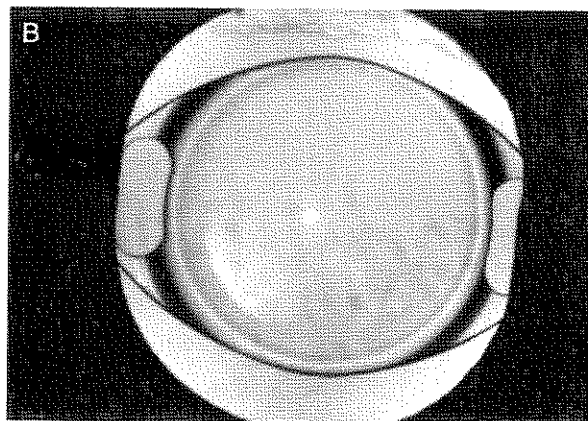
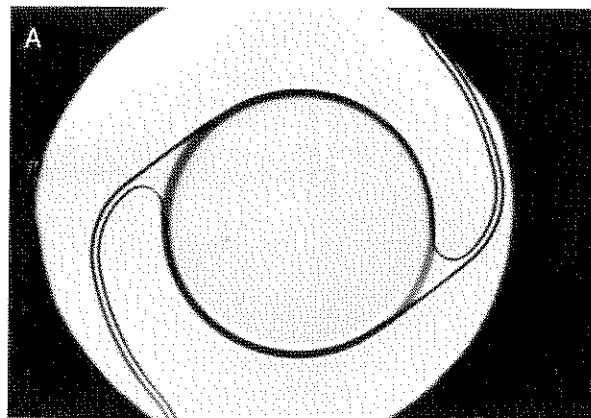


FIGURE 2. Infrared retroillumination images of the examined phakic intraocular lenses. (A) Bausch & Lomb NuVita MA 20. (B) Ophtec Artisan. (C) Staar ICL.

more, a well-centered and nontilted position of the optic is required to achieve good visual acuity, particularly for toric phakic IOLs. Therefore, positional stability of the phakic IOL is of great importance. The photography of the anterior eye segment according to Scheimpflug's principle provides reproducible noncontact slit-lamp images with

high depth of focus, which are appropriate for measurement of intraocular structures and long-term follow-up.¹³ Several studies have shown that Scheimpflug photography is useful for determining IOL position.¹⁴⁻¹⁶ The aim of this study was to determine the stability of the intraocular position for three types of phakic IOLs using Scheimpflug photography.

TABLE 1. Patient Characteristics in a Study Comparing Three Designs of Phakic Intraocular Lenses (IOLs)

IOL Model	Eyes (N)	Mean SE \pm SD	Patients (N)	Sex	Mean Age \pm SD
NuVita	10	-13.39 \pm 4.62	6	0 M, 6 F	37 \pm 6
Artisan	20	-14.38 \pm 4.73	12	5 M, 7 F	34 \pm 11
ICL	16	-13.59 \pm 3.31	9	3 M, 6 F	44 \pm 6

F = female; M = male; SE = spherical equivalent.

TABLE 2. Distances (mm) Between the Cornea, the Phakic Intraocular Lenses (IOLs), and the Crystalline Lens Measured Along the Optical Axis at 1 month, 3 to 6 Months, and 12 Months After Implantation

IOL	Distance	1 Month		3-6 Months		12 Months	
		Median (range)	Mean \pm SD	Median (range)	Mean \pm SD	Median (range)	Mean \pm SD
NuVita	Cornea-IOL	2.08 (1.9-2.3)	2.06 \pm 0.16	2.15 (1.8-2.3)	2.01 \pm 0.15	2.01 (1.8-2.3)	2.04 \pm 0.16
	CL-IOL	0.79 (0.47-1.01)	0.81 \pm 0.16	0.69 (0.47-1.01)	0.74 \pm 0.22	0.79 (0.57-1.03)	0.80 \pm 0.14
Artisan	Cornea-IOL	—	—	2.57 (2.02-2.76)	2.48 \pm 0.25	2.52 (2.07-2.90)	2.51 \pm 0.18
	CL-IOL	—	—	0.42 (0.23-0.74)	0.46 \pm 0.15	0.37 (0.20-0.69)	0.41 \pm 0.12
ICL	Cornea-IOL	2.61 (1.97-3.02)	2.58 \pm 0.34	2.75 (1.94-3.11)	2.66 \pm 0.36	2.80 (2.23-3.08)	2.75 \pm 0.27
	CL-IOL	0.33 (0.0-0.8)	0.33 \pm 0.23	0.29 (0.0-0.6)	0.27 \pm 0.21	0.18 (0.0-0.5)	0.21 \pm 0.17

CL = crystalline lens.

METHODS

FIFTY EYES OF 29 CONSECUTIVE PATIENTS RECEIVED IMPLANTATION of a phakic IOL to correct myopia or myopic astigmatism. Inclusion criteria were informed consent, patient age of at least 18 years, and myopia of at least -5 diopters. Exclusion criteria were presbyopia, cataract, glaucoma, shallow anterior chamber (<2.8 mm), malformations of the globe or the ocular adnexa, previous retinal detachment, macular edema, diabetic retinopathy, optic nerve atrophy, previous corneal or intraocular surgery, and serious inflammation of the anterior or posterior segment. The study was conducted according to the tenets of the Helsinki agreement and was approved by the institutional review board of Frankfurt University.

For myopic corrections, the following phakic IOLs were implanted:

1. An anterior chamber angle-supported phakic IOL (Bausch & Lomb NuVita MA20). Material: poly (methyl)-methacrylate (PMMA); optic diameter: 4.5 to 5.5 mm; overall length: 11.5 to 13.0 mm; refractive power -7.0 to -20.0 diopters in 0.5-diopter increments; Figures 1, A, and 2, A).
2. An anterior chamber iris-supported phakic IOL (Ophtec Artisan). Material: PMMA. For model 204, optic diameter: 6.0 mm; overall length 8.5 mm; refractive power -5.0 to -15.5 diopters in 0.5-diopter increments. For model 206, optic diameter: 5.0 mm; overall length 8.5 mm; refractive

power -5.0 to -23.5 diopters in 0.5-diopter increments; Figure 1, B; 2, B).

3. A ciliary sulcus-implanted posterior chamber phakic IOL (Staar ICL V4). Material: Collamer, a copolymer of porcine collagen and 2-hydroxyethyl-methacrylate (HEMA); optic diameter: 4.5 to 5.5 mm; overall length 11.5 to 13.0 mm; dioptric power -3.0 to -20.0 diopters in 0.5-diopter increments; Figures 1, C; 2, C).

All phakic IOLs were implanted by the same surgeon (TK). The IOL size of the angle-supported IOL and the posterior chamber phakic IOL was determined according to white-to-white (WTW) measurements. For the anterior chamber angle-supported phakic IOL, 1 mm was added to the WTW measurement; for the ciliary sulcus implanted posterior chamber phakic IOL, 0.5 mm was added. Both anterior chamber phakic IOLs were implanted through a sclerocorneal tunnel incision; for the posterior chamber phakic IOL, a temporal clear cornea incision was used. Three of the eyes with an iris-supported anterior chamber phakic IOL received the model 206 with 5.0-mm optic diameter, and the other 17 eyes received model 204 with an optic diameter of 6.0 mm.

Four eyes of three patients were excluded because of incomplete follow-up, and one Artisan IOL had to be repositioned because of insufficient enclavation during the follow-up period. There were no other intra- or postoperative complications and no occurrence of persistent elevated intraocular pressure (IOP) or pigment dispersion. Patient demographics (46 eyes of 27 patients) are as

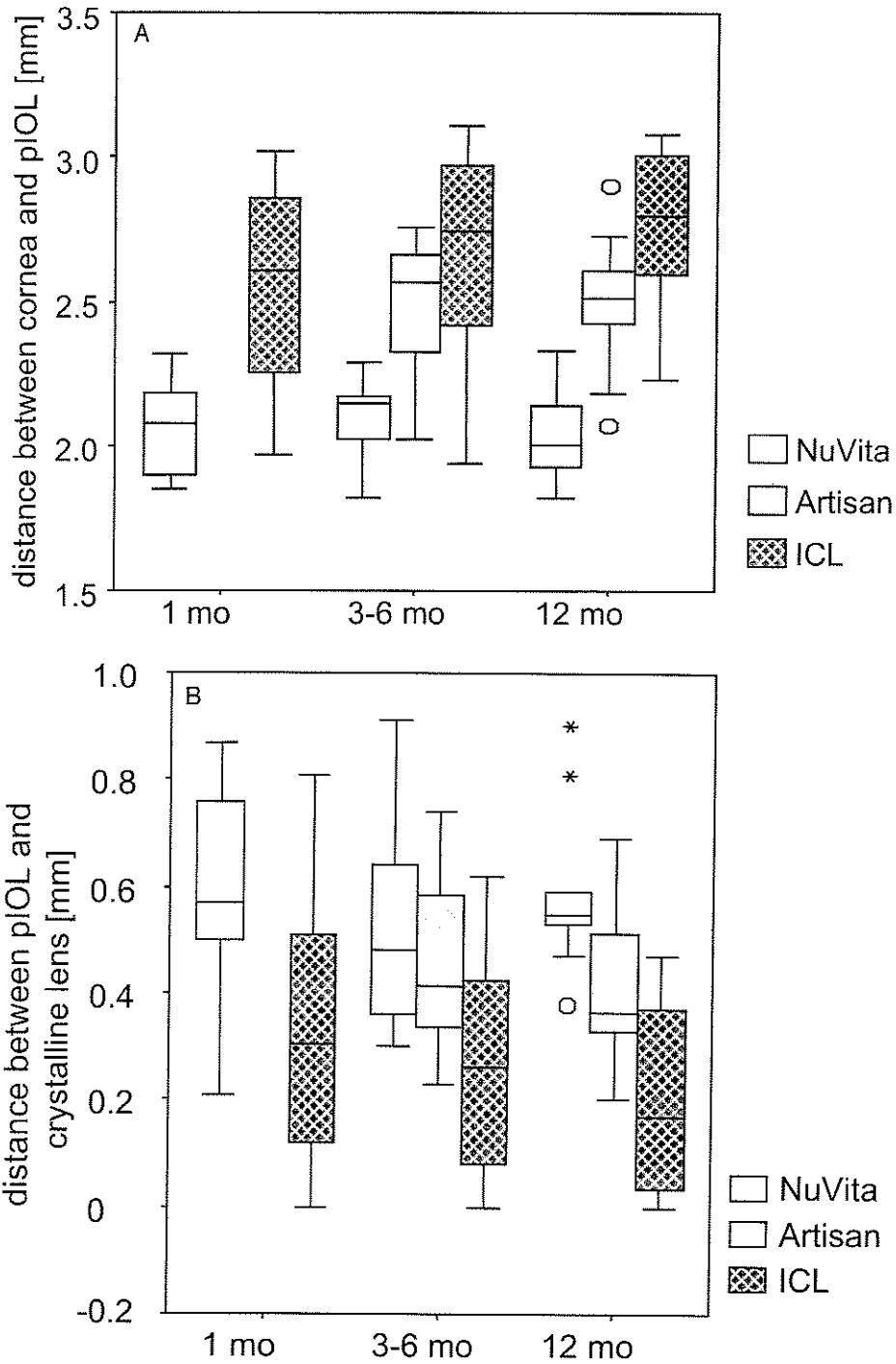


FIGURE 3. (A) Box plot diagram of the median distance between the examined phakic intraocular lenses (IOLs) and the cornea measured at different points of time postoperatively. There is a continuous increase of the distance between the cornea and the posterior chamber phakic IOL. (B) Box plot diagram of the median distance between the examined phakic IOLs and the crystalline lens. An apparent movement of the ICL toward the lens is visible. mo = months; pIOL = phakic IOL.

described in Table 1. Similar mean values \pm SD for the preoperative spherical equivalent were found for the different IOLs (Table 1). Because this was a nonrandomized study, there was a tendency to select older patients for the

implantation of the posterior chamber IOL because of possible iatrogenic cataract formation.

The posterior chamber phakic IOLs and the anterior chamber angle-supported phakic IOLs were examined at 1

TABLE 3. Anterior Chamber Depth Before and After Implantation of a Myopic Phakic Intraocular Lens (IOL, mm), Determined by Scheimpflug Photography

IOL	Preoperative		1 Month		3-6 Months		12 Months	
	Median (range)	Mean \pm SD	Median (range)	Mean \pm SD	Median (range)	Mean \pm SD	Median (range)	Mean \pm SD
NuVita	2.99 (2.83-3.51)	3.07 \pm 0.22	2.98 (2.79-3.48)	3.02 \pm 0.24	2.87 (2.72-3.50)	2.99 \pm 0.30	2.89 (2.70-3.44)	2.99 \pm 0.26
Artisan	3.14 (2.80-3.64)	3.15 \pm 0.20	—	—	3.18 (2.59-3.36)	3.14 \pm 0.19	3.18 (2.60-3.39)	3.11 \pm 0.19
ICL	3.15 (2.84-3.60)	3.18 \pm 0.23	3.07 (2.79-3.31)	3.05 \pm 0.19	3.04 (2.80-3.46)	3.07 \pm 0.19	3.16 (2.89-3.46)	3.16 \pm 0.19

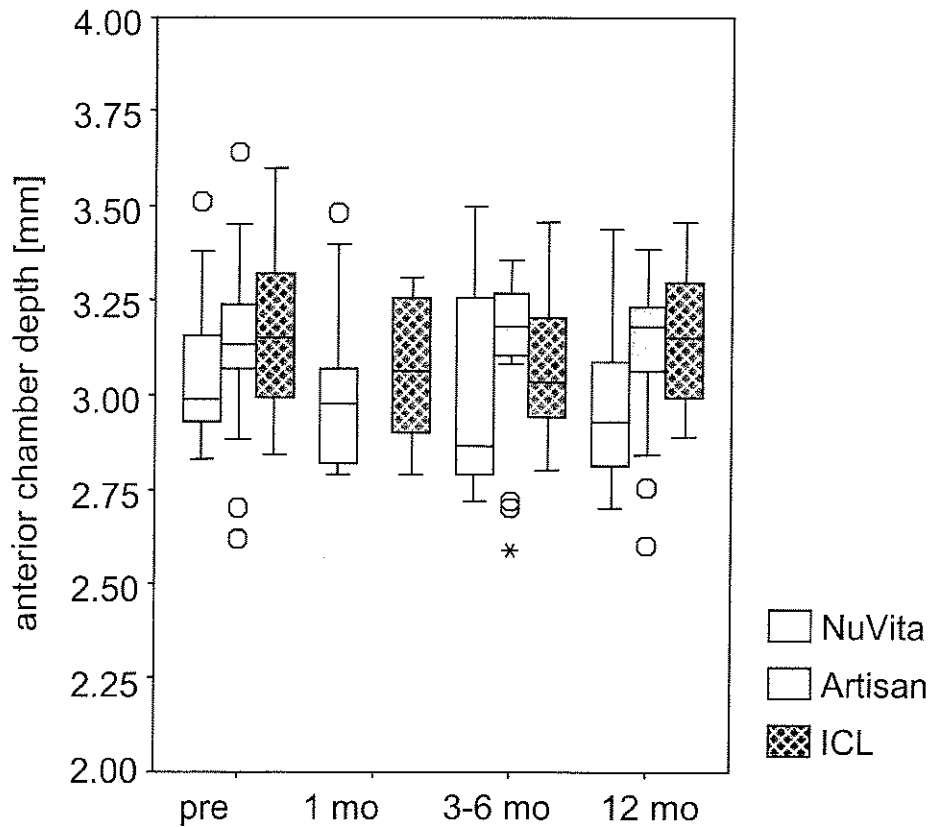


FIGURE 4. Box plot diagram of anterior chamber depth measurements before and after implantation of phakic intraocular lenses. There is a slight tendency toward a decrease of anterior chamber depth. mo = months.

month, 3 to 6 months, and 12 months postoperatively, and the iris-supported phakic IOLs were examined at 3 to 6 and 12 months postoperatively. All examinations were performed with Scheimpflug photography using the EAS-1000 anterior eye segment analysis system (Nidek, Gamagori, Japan). The measuring methods have been described previously by Sasaki and associates.¹⁴ In brief, a digital Scheimpflug slit image at 90 degrees slit position and an infrared retro illumination image of each eye were obtained, transferred to the computer, and stored on the hard disk for further evaluation. The subjects fixated a light source inside the device, and the reflection of the fixation light was centered in the pupil by the examiner to

ensure that the same section was obtained. The images were measured using the axial biometry function of the software provided by the manufacturer (version 2.23). All images were taken after pupil dilation with tropicamide 0.5% (Mydraticum, Stulln Pharma, Stulln, Germany) given twice with an interval of 10 minutes.

In all eyes, the distance between the cornea and the phakic IOL and the distance between the phakic IOL and the crystalline lens were measured.

The retroillumination images were evaluated using the National Institutes of Health image software (version 1.62, Bethesda, MD). The angle between a horizontal line and a line drawn through the center of the IOL and the haptic

TABLE 4. Median Amount of Rotation (Degrees) Around the Optical Axis in Angle-Supported, Iris-Fixated, and Sulcus-Fixated Myopic Phakic Intraocular Lenses (IOLs)

IOL	1 Month/3 Months	3 Months/12 Months
NuVita	2.9 (0.6–14.0)	1.9 (0.0–33.5)
Artisan	—	0.6 (0.0–3.5)
ICL	0.6 (0.0–3.0)	0.9 (0.2–2.3)

TABLE 5. Evaluation of the Four Angle-Supported Anterior Chamber Phakic Intraocular Lenses (IOLs) That Showed Marked Rotation Around the Optical Axis

Eye	1 Month/ 3 Months (Degrees)	3 Months/ 12 Months (Degrees)	WTW (mm)	IOL Size (mm)
1	14.0	1.1	11	12.5
2	7.3	22.9	11	12.5
3	0.7	33.5	12.5	13.0
4	1.1	22.3	12.5	13.0

WTW = white-to-white measurement.

insertions was measured. The headrest and chinrest of the EAS 1000 camera ensured that the patient's head was in the same upright position for each follow-up examination.

Statistical evaluation was performed using the SPSS software (version 10.0.7, SPSS, Chicago, Illinois). For comparisons, within-group, repeated-measurements analysis of variance (ANOVA) was used. A *P* value < .05 was considered significant. Measurements are depicted as box plots. The length of the box marks the interquartile range, and the lines above and below the box indicate the extreme values. Outliers (values more than 1.5 box lengths above or below the box) are represented by asterisks.

RESULTS

THE MEDIAN AND MEAN VALUES AND RANGES FOR THE distance between the phakic IOLs and the cornea and lens, respectively, are presented in Table 2 and Figure 3, A and B. The anterior chamber phakic IOLs did not move significantly toward the cornea or the natural lens.

The posterior chamber phakic IOL showed a continuous decrease in the distance to the crystalline lens and a corresponding increase in distance to the cornea that was statistically significant (*P* = .011 and *P* = .003). One month after surgery, one eye had no vault between the IOL and the crystalline lens. In the 12-month examination, four eyes were found to have contact between the phakic IOL and the crystalline lens, determined with Scheimpflug photography.

In all eyes, the mean postoperative anterior chamber depth showed a slight decrease compared with the preoperative status, although the difference was not statistically significant (Table 3, Figure 4).

With exception of four angle-supported phakic IOLs, all examined IOL types were stable in terms of rotation around the optical axis (Figure 5). The median values are shown in Table 4. Although the angle-supported anterior chamber phakic IOL showed a stronger tendency to rotate than the other models in the evaluation of the retro illumination images, the difference was not significant. Four anterior chamber angle-supported IOLs of two patients rotated considerably (in one case, more than 30 degrees) (Figure 6). The measured angles of rotation of these IOLs are shown in Table 5.

DISCUSSION

PHAKIC INTRAOCULAR LENSES HAVE BEEN SHOWN TO BE A valid option for the treatment of high myopia with an optical quality that may be superior to corneal refractive surgery.¹⁷ Because of the rapid introduction of new phakic IOLs, however, there is no study comparing lenses, and few data exist about long-term results and complications. Each phakic IOL has its specific profile of possible complications that depends mostly on where it is implanted.

Phakic eyes are more crowded than aphakic eyes. Therefore, it is difficult to avoid touching sensitive intraocular tissues, especially the crystalline lens, during implantation. The postoperative stability of the IOL position is of equal importance. Implant movement and contact with the iris can cause pigment dispersion and a chronic inflammatory reaction. Contact with the crystalline lens may cause cataract, and contact with the inner surface of the cornea can lead to endothelial cell reduction and edema.

• **ANGLE-SUPPORTED ANTERIOR CHAMBER PHAKIC IOL:** The anterior chamber phakic IOL NuVita MA20 by Bausch & Lomb is generally described as an efficient treatment for high myopia.⁸ However, complications such as glare, endothelial cell loss, and pupil ovalization have been reported with angle-supported phakic IOLs, and these complications seem to increase over time.^{5,18,19} This study showed a marked rotation in four of the lenses despite following the manufacturer's recommended IOL size or using an even larger IOL. This could be related to the fact that the corneal diameter was measured by caliper, which has been shown to be less accurate than automated measurement methods.²⁰ In this study, the distance between the phakic IOL and the corneal endothelium remained constant for the 12-month follow-up period, but IOL rotation remains a major concern for this type of lens. The exertion of greater pressure on the anterior chamber angle in addition to the use of softer haptic materials may

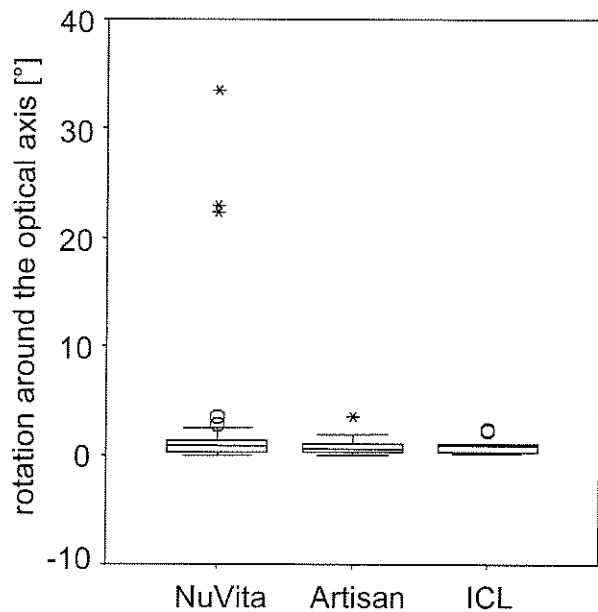


FIGURE 5. Median amount of rotation of the examined phakic intraocular lenses (IOLs) around the optical axis between the 3- and 12-month examinations. The asterisks above the NuVita box show the four outlying eyes that had high degrees of rotation.

reduce the risk of IOL rotation. Rotation of anterior chamber phakic IOLs has also been observed in other studies.^{5,19} With these IOLs, the danger is twofold: undersizing can result in rotation of the lens and oversizing can result in pupil ovalization. Future studies will determine whether these problems can be avoided with new anterior chamber phakic IOLs now available.

• IRIS-SUPPORTED ANTERIOR CHAMBER PHAKIC IOL:

The iris-supported IOL showed almost no rotation around the optical axis, as was expected because of the fixation in the iris tissue. There have been no reports of long-term changes in the position of iris-claw IOLs. Postoperative dislocations due to insufficient enclavation of iris tissue or blunt ocular trauma have been described.^{21,22} In a series of three cases, Pop and associates²³ examined iris-claw phakic IOLs by ultrasound biomicroscopy and found an IOL-cornea distance of 2.11 to 2.44 mm at the same follow-up interval. In our series of 20 eyes, the iris-claw phakic IOL showed an average central distance from the cornea of 2.51 mm (range = 2.07–2.90 mm).

• CILIARY SULCUS-FIXATED POSTERIOR CHAMBER PHAKIC IOL:

One of the most common complications with posterior chamber phakic IOLs is the development of anterior subcapsular cataract. In addition to surgical trauma (the primary cause of this complication), impairment of aqueous humor circulation by contact of the phakic IOL to the anterior lens surface has also been

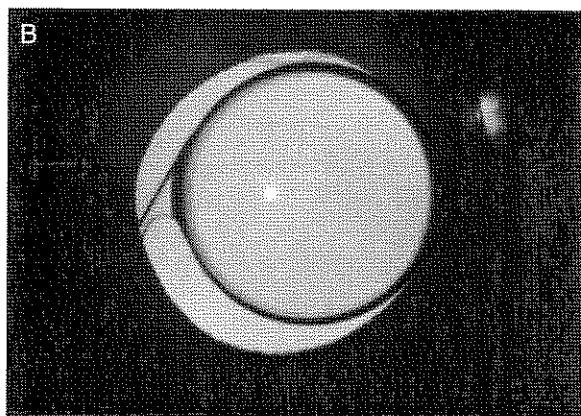
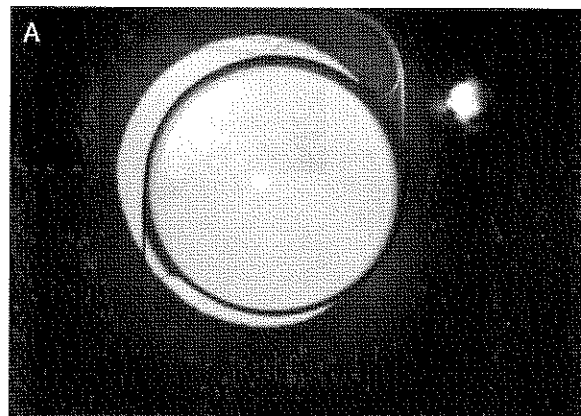


FIGURE 6. Retroillumination images of an angle-fixated anterior chamber phakic intraocular lenses (IOLs) showing rotation around the optical axis (A) 1 month after implantation and (B) 12 months after implantation. The rotation in respect to the neodymium:YAG iridotomy is clearly visible.

implicated. For this reason, the shape of the lens has been changed over the years to increase the vault between the phakic IOL and crystalline lens. Gonvers and associates⁴ examined 75 eyes with ICL models V3 and V4 and found a relationship between the degree of vaulting and anterior subcapsular cataract formation. They found a high risk of anterior subcapsular cataract when the vault was smaller than 0.09 mm and recommend a vault of 0.15 mm. In their study, the vault was determined by measurement of slit-lamp photographs 3 months and 12 to 21 months after implantation, and they saw only a slight decrease of the vaulting.

In our study, the posterior chamber phakic IOLs show an apparent continuous movement toward the crystalline lens (Figure 7), the average distance being reduced from 0.33 mm 1 month after surgery to 0.21 mm 12 months after surgery. This could be related to actual movement of the phakic IOL, or it may be a consequence of an increasing thickness of the crystalline lens. Undersizing of the IOL is a possible cause of movement. Erosion into the sulcus may also be an explanation, but this has not been described in

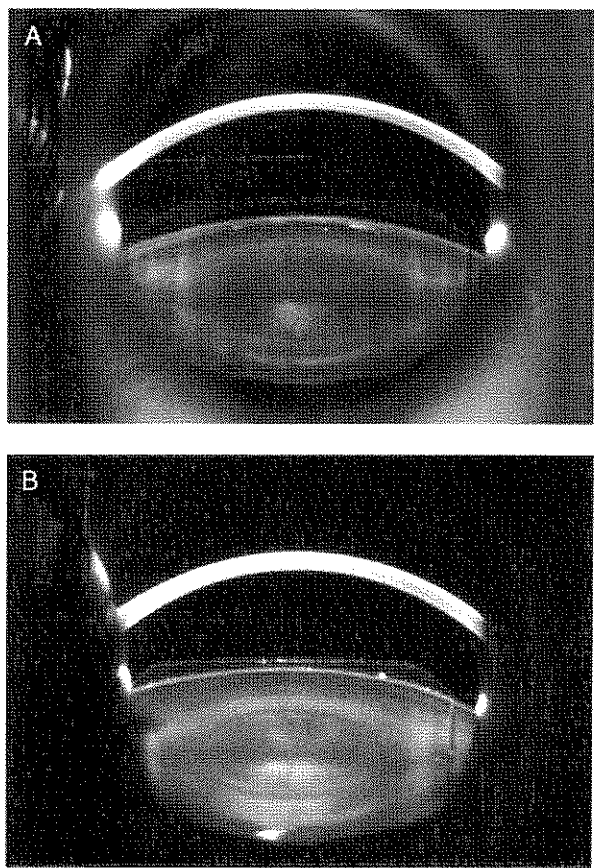


FIGURE 7. Scheimpflug slit image of a sulcus-fixated posterior chamber phakic intraocular lenses (IOLs) showing decrease of the vault between IOL and crystalline lens (A) 1 month after implantation and (B) 12 months after implantation.

the literature thus far. Clinical signs such as IOP or pupil shape changes were not detected. Although we have not yet seen cataract formation, the descriptions of cataract in the literature occur after more than 12 months of observation time. Fechner²⁴ suggested adding another 0.25 mm to the 0.5-mm addition to the corneal diameter to determine the length of the phakic IOL to be implanted. However, the data published by Pop and associates²⁵ suggest that the white-to-white diameter is not related to the sulcus diameter. The use of extremely thin posterior chamber phakic IOLs that float in the aqueous humor, which would ensure that the crystalline lens is always surrounded by aqueous, could help to minimize the risk of cataract formation.

As stated earlier, the average age of the patients receiving an ICL was higher than that of the other groups. According to a Scheimpflug photographic study by Dubbelman and associates,²⁶ lens thickness increases approximately 0.024 mm per year between the ages of 16 and 65 years. There is no evidence that this increase in lens thickness accelerates with age. The effects on cataract formation of an increasing lens thickness and of shape

changes during accommodation after implantation of a posterior chamber phakic IOL have yet to be studied.

In this study, rotation of the sulcus-implanted phakic IOL of more than three degrees was not observed. Garcia-Feijoo and associates²⁷ examined the position of the Staar posterior chamber phakic IOL by ultrasound biomicroscopy and found rotation in 2 of 18 cases.²⁷

Scheimpflug photography has been used repeatedly for the evaluation of phakic IOLs.^{4,28,29} Ferreira de Souza and associates²⁹ found no significant difference between Scheimpflug photography and ultrasound biomicroscopy for measurement of the central distance between anterior chamber angle-supported phakic IOLs and the corneal endothelium.

An advantage of the Scheimpflug photography technique is the fast noncontact acquisition of data. One of the major disadvantages is that it is a purely optical technique requiring clear optical media and is thus unable to examine structures behind the iris, which ultrasonography can accomplish. The distance between the anterior chamber IOL and the iris was not measured because of the imprecise depiction of the iris tissue resulting from light scattering; for monitoring changes in anteroposterior direction, the central measurement is sufficient, however. Pupil dilation before Scheimpflug photography was necessary primarily for better visualization of the posterior chamber phakic IOLs, but also to maintain a similar pupil size at all measurements. We note that pupil dilation with mydriatic drugs is a nonphysiologic condition, and thus it cannot be ruled out that changes in IOL position under mydriatic conditions may occur. This topic should be addressed in a separate study.

The main limitation of this study is the comparatively low number of cases. However, there is no other study to date in which all three IOL designs were studied with a 12-month follow-up. In a previous study, no statistically significant changes within 6 months could be observed in a smaller number of cases.²⁸ After 12 months, these trends become clearer.

In this study, the iris-supported phakic intraocular lens demonstrated the best positional stability of the three types of phakic IOLs examined. It maintains a safe distance to the corneal endothelium and crystalline lens and does not rotate inside the eye. This design is especially suitable for toric phakic IOLs. The risk of inflammation by continuous irritation of iris tissue, breakdown of the blood-aqueous barrier, and liberation of inflammatory mediators remains, however, although clinically relevant inflammation has only been shown in individual cases and chronic subclinical inflammation also occurs with other phakic IOLs.^{3,30,31}

The development of new phakic IOL designs continues and must be followed carefully. It is likely that the best possible design for refractive implants in the phakic eye has not been determined.³²

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