

Influence of anterior chamber morphometrics on endothelial cell changes after phakic intraocular lens implantation

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PURPOSE: To analyze the position of iris-fixated phakic intraocular lenses (pIOLs) using anterior segment optical coherence tomography (AS-OCT) and evaluate the effect of anterior chamber morphometrics on endothelial cell changes.

SETTING: Department of Ophthalmology, Academic Hospital Maastricht, The Netherlands.

METHODS: In this cross-sectional study, AS-OCT was used to measure the distances from the center and the edges of the pIOL to the corneal endothelium in 242 eyes with various models of myopic pIOLs. Endothelial cell measurements were performed preoperatively and at each follow-up examination.

RESULTS: The mean follow-up was 34.1 months \pm 24.7 (SD) (range 3 months to 7 years). The mean distance between the edge of the pIOL and the endothelium was 1.37 \pm 0.22 mm. Although this distance was smaller than the safety value of 1.50 mm in 68.6% of the eyes, no eye developed corneal decompensation. There was a significant endothelial cell density (ECD) loss of 1.28% \pm 8.46%, 3.25% \pm 8.24%, and 5.02% \pm 10.40% at 2 years, 5 years, and 7 years, respectively. Linear mixed-model analysis predicted a yearly ECD loss of 0.98% for a mean edge distance of 1.37 mm, 0.15% for an edge distance of 1.59 mm (mean plus 1 SD), and 1.80% for an edge distance of 1.15 mm (mean minus 1 SD).

CONCLUSIONS: A shorter distance between the edge of the pIOL and the endothelium was significantly associated with higher ECD loss. For safety reasons, the postoperative examination should include long-term evaluation of the anterior chamber morphometrics in addition to ECD counts.

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Iris-fixated phakic intraocular lenses (pIOLs) are used worldwide to correct high myopia, hyperopia, and astigmatism. In 1986, the first iris-fixated IOLs were implanted in phakic myopic eyes.¹ The original biconcave Worst myopia claw IOL was changed to a convex-concave shape in 1991, and the name of the lens

was changed to the Artisan (Ophtec BV) in 1998. More recently, the Artisan toric pIOL was introduced; this lens combines spherical and cylindrical correction. A foldable model of the myopic Artisan pIOL, the Artiflex (Ophtec BV), became available in 2003. This Artiflex pIOL may offer an advantage over the Artisan pIOL because it can be inserted through a smaller incision, which decreases surgically induced astigmatism and provides faster visual recovery.²

Several clinical studies^{3–8} show that visual results of the Artisan and Artiflex pIOLs are stable and predictable. However, the long-term effect of pIOLs on the corneal endothelium is a point of discussion. To evaluate the safety of iris-fixated pIOLs, clinical trials of endothelial cell changes after implantation have been performed. Pop et al.⁹ report no statistically significant change in mean endothelial cell loss rates up to 2 years after pIOL implantation. The percentage of hexagonal

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cells (an indicator of cell pleomorphism) remained stable and the coefficient of variation (an index of cell size variation) showed a significant decrease 1 year postoperatively. In contrast, Benedetti et al.¹⁰ found a significant change in mean endothelial cell loss of 3.5% after 12 months and 9.0% after 5 years. Saxena et al.¹¹ also report a significant loss in endothelial cell density (ECD) (12.6% after 7 years). In addition, they found a significant negative correlation between anterior chamber depth (ACD) and endothelial cell loss after 3 years of follow-up.

A recent study by Kohnen et al.² presents data on the position of the pIOL in the anterior chamber. The distance between the pIOL and the central corneal endothelium is measured using Scheimpflug photography. However, a myopic pIOL has a convex-concave shape, which means the edges of the pIOL are in closer proximity to the peripheral corneal endothelium. Baikoff et al.¹² state that the minimum distance between the edge of the optic and the endothelium measured by anterior segment optical coherence tomography (AS-OCT) must be 1.5 mm to minimize the risk for corneal decompensation. Anterior segment OCT allows a rapid noncontact examination, and the software includes a measuring system capable of calculating distances between 2 points. Several studies¹²⁻¹⁵ show that AS-OCT is useful for determining pIOL position.

In 2006, we began using the Visante OCT (Carl Zeiss Meditec Inc.) to visualize the pIOL in the anterior chamber. In this cross-sectional study, we analyzed the position of the iris-fixated Artisan pIOL and Artiflex pIOL in the anterior chamber using AS-OCT and evaluated the endothelial cell changes in relation to the anterior chamber morphometrics.

PATIENTS AND METHODS

Patient Population and Study Design

From June 2006 to March 2008, 131 consecutive patients (242 eyes) were evaluated using Visante OCT to analyze anterior chamber morphometrics. All patients had Artisan or Artiflex pIOL implantation from May 1998 to September 2007 for the correction of moderate to high myopia and astigmatism. The study was conducted in accordance with the Declaration of Helsinki, and informed consent was obtained from all patients.

Criteria for pIOL implantation were a stable refractive error during the previous 2 years; an anterior chamber depth (ACD) of 2.8 mm or more (measured from the epithelium to the crystalline lens); a pupil (under mesopic light conditions) smaller than 6.0 mm; no corneal, pupil, or iris abnormalities; and no history of glaucoma and chronic or recurrent uveitis. Another safety criterion for pIOL implantation is an ECD count of 2000 cells/mm² or more. In this study, 8 patients wanted to have pIOL implantation despite an ECD less than 2000 cells/mm² and warnings about possible complications. These patients were included in the study and had the implantation because of complete contact lens

intolerance and the inability to continue their occupation with spectacle correction. Patients who had more than 1 operation in 1 eye were excluded from analysis after the second procedure.

Endothelial Cell Density

Endothelial cell density measurements were performed preoperatively and repeated 3 and 6 months and 1, 2, 3, 5, and 7 years after surgery. All ECD counts were performed by 2 independent observers using the Noncon Robo SP-9000 noncontact specular microscope (Konan Medical Inc.). During the investigation, 3 consecutive endothelial images of the central cornea were obtained. The images were analyzed using the dot method, in which the centers of approximately 50 contiguous cells are marked. The ECD data consisted of the mean of 3 measurements. The percentage of hexagonal cells and coefficient of variation were also evaluated. Endothelial cell density loss was defined as a decrease in cell density between the preoperative examination and postoperative examination.

Anterior Segment Optical Coherence Tomography

The position of the iris-fixated pIOL was analyzed once per eye using AS-OCT. All AS-OCT images were taken on the horizontal meridian in an unaccommodated state and under the same lighting conditions (50 lux). Cross-sectional images were taken using the anterior segment single scan. Enhanced images of the pIOL were taken using the high-resolution scan. One examiner (M.D.) analyzed the images. In the 2-dimensional anterior segment single scan, the distance between the anterior surface of the center of the pIOL and the corneal endothelium, the lens rise¹⁵ (the distance from the anterior surface of the crystalline lens to the horizontal line between the 2 angle recesses), and the distance between the posterior surface of the center of the pIOL and the anterior surface of the crystalline lens were measured using the calipers of the computer program provided by the manufacturer (Figure 1, A). Baikoff et al.¹⁵ describe a lens rise of 0.6 mm or more as a risk factor for pupillary pigment dispersion. Güell et al.¹⁶ report an arbitrary safety distance between the center of the pIOL and the endothelium of 2.0 mm. The distances between the edges of the pIOL and the corneal endothelium were measured in the high-resolution scan, also using the calipers (Figure 1, B). Baikoff¹² advises a distance of 1.5 mm between the edge of the pIOL and the endothelium. Of the 2 edge distances (nasal side and temporal side), the smallest distance was used for statistical analysis.

Due to the enhancement of the pIOL in the high-resolution scan, the central cornea is not captured in the image. When the central cornea is not pictured, the Visante device does not take the refractive index of the cornea into account. To obtain accurate measurements of the distances in this scan, a correction is necessary. In 22 eyes of 11 patients in this study, the distances from the edges of the pIOL to the corneal endothelium and the peripheral corneal thickness were measured in the high-resolution scan and the anterior segment single scan. Analysis of these results led to a mean correction factor of 1.31. In this report, all distances measured in the high-resolution scan were corrected with this factor before analysis.

Intraocular Lenses

The power of the implanted pIOL was calculated using the van der Heijde formula based on the mean corneal curve (K),

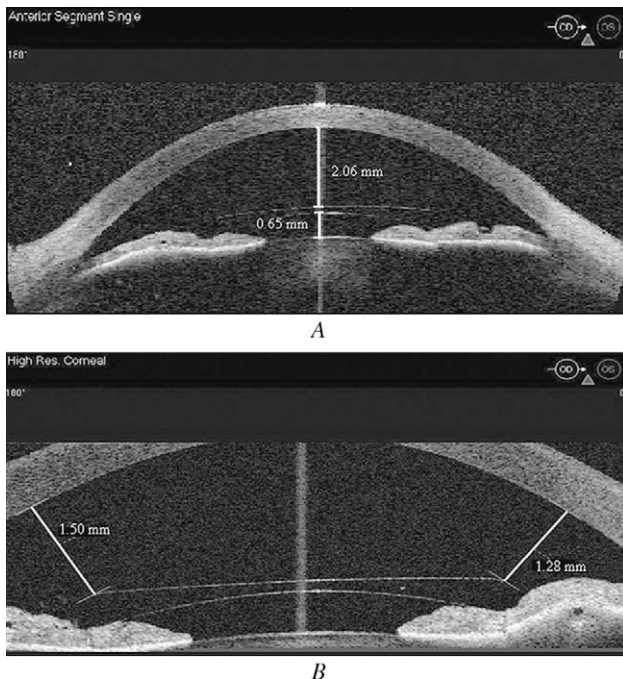


Figure 1. A: Anterior segment single scan with measured distance between the center of the pIOL and endothelium (2.06 mm) and distance between pIOL and crystalline lens (0.65 mm). B: High-resolution scan with measured distances between the edge of the pIOL and endothelium, 1.50 mm on the temporal side and 1.28 mm on the nasal side.

adjusted ACD (ACD – 0.8 mm), and spherical equivalent of the patient's spectacle correction at a 12.0 mm vertex.¹⁷ For the Artiflex pIOL, the adjusted ACD calculation was changed slightly by the manufacturer. The power of the IOL was chosen to obtain emmetropia. When the emmetropic pIOL was not available, a slight residual myopia was preferred.

The Artisan pIOL is convex-concave, has a 6.0 mm optic (for lens powers up to –15.5 diopters (D) or a 5.0 mm optic (for lens powers from –16.0 to –24.0 D) optic, and is available in increments of 0.5 D. This single-piece pIOL is made of polymethyl methacrylate (PMMA) and manufactured by compression-molding technology.

The PMMA Artisan toric pIOL has a convex-concave toric optic with a spherical anterior surface, a spherocylindrical posterior surface, and a 5.0 mm optical zone. The toric pIOL is available in dioptric powers of –2.0 to –23.0 for myopia and +2.0 to +12.0 for hyperopia, with a cylindrical correction of 1.0 to 7.5 D. The hyperopic toric pIOL was not used in this study.

The Artiflex pIOL is convex-concave and has a 6.0 mm optical zone. This 3-piece IOL has a flexible ultraviolet-absorbing silicone optic and 2 rigid PMMA haptics. It is available in dioptric powers of –2.0 to –14.5 D (in increments of 0.5 D). This study included 2 Artiflex types, Artiflex I and Artiflex II, which have different designs. The vault between the optic-haptic junction and the iris plane is 0.13 mm in the Artiflex I and 0.20 mm in the Artiflex II (Figure 2).

Surgical Technique

All surgical procedures were performed by the same surgeon (R.N.) between May 1998 and September 2007 at the

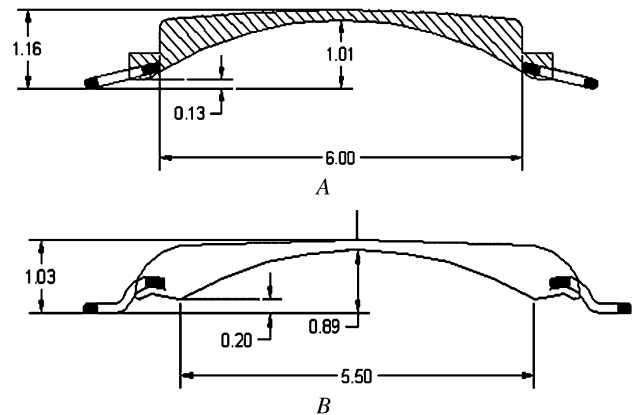


Figure 2. A: Cross-section of the Artiflex I –12.0 D pIOL. B: Cross-section of the Artiflex II –14.0 D pIOL. Cross-sections are from manufacturer drawings. Reported distances are in millimeters.

Academic Center for Refractive Surgery, University Eye Clinic of Maastricht. The surgical technique for Artisan pIOL implantation has been described.¹⁸ The method for Artisan toric pIOL implantation was identical to that for the Artisan myopia pIOL except that the haptics were aligned on the cylindrical axis (or perpendicular to the axis, depending on the pIOL used) according to the alignment marks on the cornea.

The Artiflex pIOL was inserted with a purpose-designed spatula that allows the surgeon to fold and insert the lens through an incision smaller than 3.4 mm. The incision was centered at 12 o'clock, similar to that for Artisan pIOL implantation. The wound was sutured with two 10-0 nylon sutures.

After surgery, all patients received topical tobramycin 0.3%-dexamethasone 0.1% (TobraDex) 4 times a day for 3 weeks on a tapered schedule and ketorolac trometamol 0.5% (Acular) 3 times a day for 1 week.

Statistical Analysis

All collected data were transferred to SPSS for Windows (version 15.0, SPSS Inc.) for data analysis. Continuous variables were described with mean, standard deviation, and range. One-way analysis of variance was used to evaluate differences between the 5 pIOL groups (Artisan 5.0 mm, Artisan 6.0 mm, Artisan toric, Artiflex I, and Artiflex II). When significant differences were observed, the Tukey least-significant-difference test was performed between all pairs of groups to identify pairs with and without significant differences. Comparisons between preoperative and postoperative data were performed by paired *t* tests.

To determine a relationship between ECD loss and the distance from the edge and the center of the pIOL to the corneal endothelium, the Pearson correlation coefficient (*r*) was used. A linear mixed model analysis was used to evaluate the association between ECD loss and the distance from the edge of the pIOL to the endothelium, correcting for the factor of patient age and assuming a random intercept per eye. This model allowed the use of all available ECD data. To look for possible differences in ECD loss for pIOLs with different distances between the edge of the pIOL and the corneal endothelium, an interaction term (Time × Edge pIOL–corneal endothelium distance) was also included

Table 1. Patient demographics.

Characteristic	Value
Age (y)	
Mean \pm SD	41.6 \pm 10.8
Range	18 to 62
Number of women (n)	171
Number of eyes (n)	242
Right eyes (n)	119
Left eyes (n)	123
Sphere (D)	
Mean \pm SD	-10.72 \pm 4.57
Range	0.00 to -28.00
Cylinder (D)	
Mean \pm SD	-1.20 \pm 0.99
Range	0.00 to -5.00
ACD (mm)	
Mean \pm SD	3.65 \pm 0.34
Range	2.83 to 4.73
Preoperative ECD (cells/mm ²)	
Mean \pm SD	2664 \pm 337
Range	1588 to 3753
Implanted IOL power (D)	
Mean \pm SD	-11.78 \pm 3.87
Range	-24.00 to -2.00
Type of IOL (n)	
Artisan 5.0 mm	32
Artisan 6.0 mm	129
Artisan toric	11
Artiflex I	20
Artiflex II	50

ACD = anterior chamber depth; ECD = endothelial cell density; IOL = intraocular lens

Furthermore, this analysis was used to determine significant changes in the coefficient of variation and the percentage of hexagonal cells during the study. A linear regression model was applied to evaluate the relationship between the distance from the anterior surface of the crystalline lens to the posterior surface of the pIOL and patient age. A *P* value less than 0.05 was considered significant.

RESULTS

Patient Population

One hundred thirty-one patients (242 eyes) were included in the study. The mean age was 41.6 \pm 10.8 years. Table 1 shows the patients' demographics. The mean follow-up was 34.12 \pm 24.72 months (range 3 months to 7 years).

Five eyes were excluded after they had lens exchange (*n* = 3) or reattachment of the haptics (*n* = 2). Lens exchange was necessary because of preoperative power calculation errors (*n* = 1) and pigment dispersion on the pIOL (*n* = 2). One eye required reenclavation of the nasal haptic due to trauma. The other needed reattachment of the haptic due to poor enclavation.

Distances Measured with Anterior Segment Optical Coherence Tomography

Table 2 shows the AS-OCT measurements. The Artisan 6.0 mm group had a significantly higher mean distance between the center of the pIOL and the endothelium than the other 4 groups (*P* < .001).

The mean edge distances for the Artisan 5.0 mm and Artisan 6.0 mm groups were significantly higher than the distances for the Artiflex I and Artiflex II groups (*P* = .001, *P* = .002, *P* = .004, and *P* = .007, respectively). The mean edge distance in the Artisan toric group differed significantly only from that in the Artiflex I group (*P* = .05).

There was no significant difference in lens rise between the 5 groups (*P* = .058). Furthermore, no pIOL was in contact with the crystalline lens (range 0.26 to 0.96 mm). Distances from the posterior surface of the pIOL to the crystalline lens were significantly shorter in the Artiflex II, Artisan 5.0 mm, and Artisan 6.0 mm group than in the Artiflex I group (*P* = .002, *P* = .001, and *P* = .030, respectively). In Figure 3, the distance between the posterior surface of the center of the pIOL and the anterior surface of the crystalline lens is plotted versus patient age. This distance was significantly smaller in older eyes (*r* = -0.247, *P* < .001). The mean linear decrease in the distance between the pIOL and the crystalline lens was 3.1 μ m \pm 0.8 (SE) per year. Furthermore, the distance from the edge of the pIOL to the endothelium was significantly smaller in eyes of older patients (*r* = -0.204, *P* = .001).

The distance between the center of the pIOL and the endothelium was smaller than the recommended 2.0 mm in 63 eyes (27.3%). Furthermore, the distance between the edge of the pIOL and the endothelium was less than the advised 1.5 mm in 166 eyes (68.6%). Despite the high number of eyes not meeting the safety criteria, all corneas remained clear during follow-up. Nineteen eyes (8.1%) had a lens rise of more than 0.6 mm; 11 (57.9%) of these eyes developed pigment dispersion on the pIOL.

Endothelial Cell Changes

Table 3 shows the ECD loss from 6 months to 7 years postoperatively. Preoperatively, the mean ECD count was 2664 \pm 337 cells/mm². There was a significant mean ECD loss from preoperatively to 2 years postoperatively that continued up to 7 years after implantation.

Table 4 shows the coefficient of variation and the percentage of hexagonal cells. Preoperatively, the mean coefficient of variation in cell size was 32.7 \pm 7.0. After 6 months, there was a significant decrease in the coefficient of variation compared with preoperative values. The significant decrease continued up to 5 years postoperatively. Linear mixed-model analysis

Table 2. Anterior chamber OCT measurements.

pIOL Type (n)	Distance (mm)			
	Endothelium–Center pIOL	Endothelium–Edge pIOL	Crystalline Lens–pIOL	Lens Rise
Artisan 5.0 mm (32)				
Mean \pm SD	2.07 \pm 0.26	1.45 \pm 0.25	0.65 \pm 0.14	0.34 \pm 0.24
Range	1.40 to 2.50	0.70 to 1.91	0.33 to 0.96	0.00 to 0.75
Artisan 6.0 mm (129)				
Mean \pm SD	2.28 \pm 0.23	1.41 \pm 0.21	0.62 \pm 0.14	0.21 \pm 0.25
Range	1.70 to 2.70	0.78 to 1.98	0.26 to 0.92	–0.35 to 0.81
Artisan toric (11)				
Mean \pm SD	1.94 \pm 0.18	1.40 \pm 0.19	0.65 \pm 0.08	0.29 \pm 0.10
Range	1.70 to 2.20	0.99 to 1.69	0.51 to 0.76	0.06 to 0.39
Artiflex I (20)				
Mean \pm SD	1.99 \pm 0.14	1.25 \pm 0.15	0.73 \pm 0.14	0.27 \pm 0.17
Range	1.60 to 2.20	0.99 to 1.52	0.37 to 0.92	0.00 to 0.65
Artiflex II (50)				
Mean \pm SD	2.10 \pm 0.27	1.31 \pm 0.22	0.62 \pm 0.11	0.28 \pm 0.23
Range	1.70 to 2.80	0.89 to 1.89	0.39 to 0.84	–0.10 to 0.67
Total (242)				
Mean \pm SD	2.18 \pm 0.26	1.37 \pm 0.22	0.64 \pm 0.14	0.25 \pm 0.24
Range	1.40 to 2.80	0.70 to 1.98	0.26 to 0.96	–0.35 to 0.81
P value*	<.001	.001	.017	.058

pIOL = phakic intraocular lens

*ANOVA between the 5 pIOL groups

showed a yearly decrease in the coefficient of variation of 0.027 ($P = .001$).

The mean percentage of hexagonal cells increased over the study, although the difference between preoperative and postoperative hexagonal cells was only significant after 6 months and 1 year. Linear mixed-model analysis showed no significant differences in

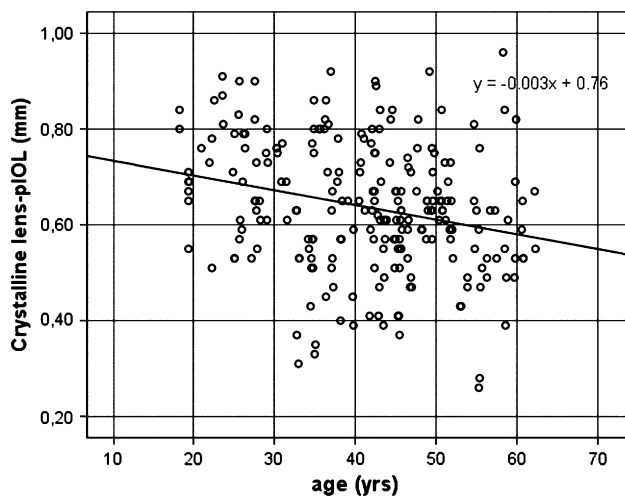


Figure 3. Relationship between patient age and the distance between the pIOL and the crystalline lens per eye ($n = 242$; $P < .001$, $r = -0.247$) (pIOL = phakic intraocular lens).

the percentage of hexagonal cells over the course of the study.

Correlation of Endothelial Cell Loss and Optical Coherence Tomography Measurements

The relationship between ECD loss and the distance from the edge of the pIOL to the endothelium 1 and 5 years postoperatively is shown in Figure 4 and Figure 5, respectively. After 1 year, there was a statistically significant negative correlation between ECD loss and the distance from the edge of the pIOL to the corneal endothelium ($r = -0.216$, $P = .012$). This relationship continued up to 5 years postoperatively ($r = -0.322$, $P = .029$).

Linear mixed-model analysis showed a statistically significant effect of the interaction term time and the distance from the edge of the pIOL to the endothelium on ECD loss. A shorter distance from the edge of the pIOL to the endothelium was associated with higher ECD loss. The mean distance from the edge of the pIOL to the endothelium was 1.37 mm. Using this mean distance in the linear model, the model predicted a yearly ECD loss of 0.98%. However, when a distance between the edge of the pIOL and the endothelium of 1.15 mm was used (ie, mean edge distance minus 1 standard deviation), the model predicted an ECD loss of 1.8% per year. An edge distance of 1.59 mm

Table 3. Endothelial cell density counts before and after pIOL implantation.

Period	Eyes (n)	Mean \pm SD		P Value*	Yearly Rate (%)
		ECD (Cells/mm ²)	ECD Change (%)		
Preoperative	242	2664 \pm 337	NA	NA	NA
Postoperative					
6 mo	157	2663 \pm 351	-0.06 \pm 9.81	.934	-0.12
1 y	136	2636 \pm 350	-0.18 \pm 9.58	.468	-0.18
2 y	134	2637 \pm 346	-1.28 \pm 8.46	.020	-0.64
3 y	66	2548 \pm 343	-4.35 \pm 10.86	<.001	-1.45
5 y	46	2594 \pm 325	-3.25 \pm 8.24	.005	-0.65
7 y	18	2426 \pm 286	-5.02 \pm 10.40	.045	-0.72

ECD = endothelial cell density; NA = not applicable

*Paired *t* test between postoperative and preoperative ECDs

(ie, mean distance plus 1 standard deviation) resulted in an ECD loss of 0.15% per year. The distance from the edge of the pIOL to the endothelium and the distance from the center of the pIOL to the endothelium were highly correlated ($r = 0.790$, $P < .001$). Linear mixed-model analysis of the distance between the center of the pIOL and the endothelium showed the same association with ECD loss. The Pearson correlation coefficient did not show a significant relationship between the center distance and ECD loss.

The coefficient of variation and the percentage of hexagonal cells were not correlated with the distance between the edge of the pIOL and the endothelium.

DISCUSSION

The purpose of this cross-sectional study was to evaluate the position of various iris-fixated pIOL models in the anterior chamber and the effect of this position on the corneal endothelium. Our most important finding was the relationship between ECD loss and the

distance from the edge of the pIOL to the endothelium. A shorter distance between the edge of the pIOL and the endothelium was associated with higher ECD loss. We applied a linear-mixed model analysis, which is an extremely useful test as it uses all available ECD data to fit the best linear model. The model predicted a yearly ECD loss of 0.98% for an edge distance of 1.37 mm, which was the mean distance from the edge of the pIOL to the endothelium in our study population. We believe that an endothelial cell loss rate of 0.98% per year is acceptable when compared with the natural yearly endothelial cell loss of $0.6\% \pm 0.5\%$.¹⁹

Several studies have evaluated endothelial changes after pIOL implantation. Short-term studies^{3,5,9-11,20} found that corneal endothelial cell changes after pIOL implantation vary postoperatively, from gains of 0.5% to losses of 6.6% at 1 year and losses of 0.7% to 11.7% at 3 years. Studies of long-term endothelial cell loss^{7,11} describe losses of 2.9% to 9.1% 6 years after pIOL implantation. To our knowledge, there is only 1 study of ECD loss 10 years after Artisan pIOL

Table 4. Coefficient of variation and percentage of hexagonal cells before and after pIOL implantation.

Period	Eyes (n)	Mean \pm SD			Mean \pm SD		
		CV	CV Change	P Value*	Hex Cells (%)	Hex Cell Change (%)	P Value*
Preop	221	32.73 \pm 6.99	NA	NA	56.01 \pm 8.03	NA	NA
Postop							
6 mo	156	31.35 \pm 4.53	-1.95 \pm 7.49	.002	57.43 \pm 7.88	1.88 \pm 8.67	.009
1 y	136	31.27 \pm 4.78	-2.26 \pm 6.49	<.001	57.81 \pm 9.01	1.61 \pm 8.49	.039
2 y	134	30.95 \pm 4.99	-1.85 \pm 7.29	.005	57.06 \pm 7.81	1.04 \pm 9.31	.213
3 y	66	31.57 \pm 5.50	-3.96 \pm 8.05	.001	56.00 \pm 7.54	1.33 \pm 9.46	.306
5 y	46	30.50 \pm 3.99	-5.15 \pm 5.47	<.001	58.62 \pm 8.97	3.45 \pm 11.00	.081
7 y	18	29.11 \pm 3.88	-4.94 \pm 7.35	.160	56.70 \pm 9.72	7.33 \pm 13.25	.233

CV = coefficient of variation; Hex = hexagonal; NA = not applicable

*Paired *t* test between postoperative and preoperative measurements

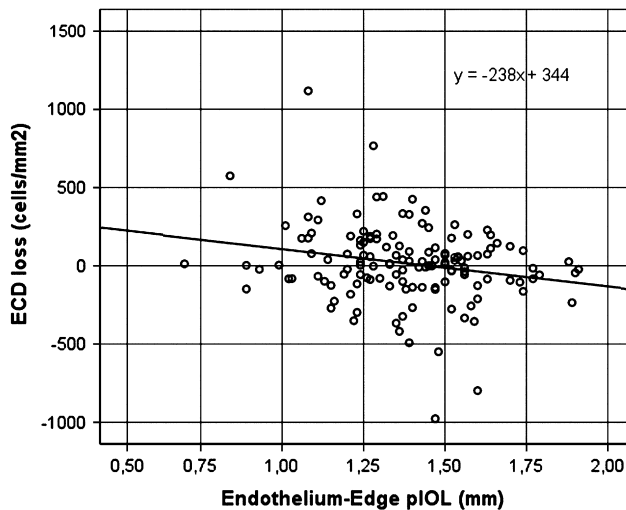


Figure 4. Relationship between ECD loss (preoperative ECD – postoperative ECD) and the distance between the edge of the pIOL and the endothelium per eye 1 year postoperatively ($n = 136$; $P = .012$, $r = -0.216$) (ECD = endothelial cell density; pIOL = phakic intraocular lens).

implantation.⁷ In that study, Tahzib et al. found a mean ECD loss of 0.6% at 10 years. In our study, there was a significant ECD loss of 1.28% at 2 years, 4.35% at 3 years, 3.25% at 5 years, and 5.02% at 7 years. Furthermore, we evaluated the changes in the coefficient of variation and percentage of hexagonal cells. An increase in the coefficient of variation may be an early sign of continuing ECD loss.²¹ In our study, a significant decrease in the coefficient of variation was observed, meaning that the stability of the corneal

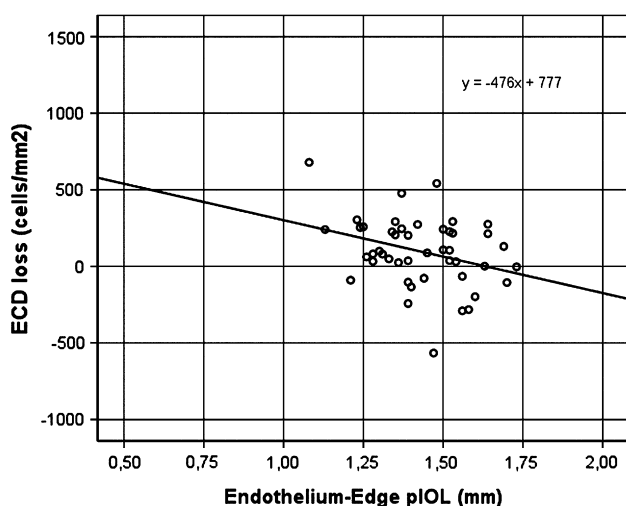


Figure 5. Relationship between ECD loss (preoperative ECD – postoperative ECD) and the distance between the edge of the pIOL and the endothelium per eye 5 years postoperatively ($n = 46$; $P = .029$, $r = -0.322$) (ECD = endothelial cell density; pIOL = phakic intraocular lens).

endothelium increased. A decrease in the percentage of hexagonal cells indicates some form of endothelial injury.²¹ During this study, the percentage of hexagonal cells showed a slight but insignificant increase, indicating the stability of the endothelial monolayer. These changes in the percentage of hexagonal cells and coefficient of variation are in accordance with results in other studies.^{3,9,10,22}

Recently, new imaging devices became available that have enabled us to visualize the pIOL in the anterior chamber. Several studies have analyzed anterior chamber morphometrics in eyes with iris-fixated pIOLs. Baumeister et al.²³ investigated the position of Artisan pIOLs in 20 eyes using Scheimpflug photography. They report distances of 2.51 ± 0.18 mm and 0.41 ± 0.12 mm from the center of the pIOL to the endothelium and the pIOL to the crystalline lens, respectively, 1 year after implantation. Güell et al.¹⁶ studied 11 eyes implanted with an Artiflex pIOL using anterior chamber OCT. They report a mean distance of 2.41 ± 0.16 mm from the center of the pIOL to the endothelium and a mean distance of 0.74 ± 0.05 mm between the pIOL and the crystalline lens. Tehrani et al.²⁴ evaluated 17 myopic eyes implanted with a foldable iris-fixated pIOL using Scheimpflug photography. They report a mean distance of 2.01 ± 0.26 mm and 1.34 ± 0.21 mm from the center and the edge of the pIOL to the endothelium, respectively. The mean distance between the pIOL and the crystalline lens was 0.73 ± 0.09 mm. In our study, the mean distance between the edge of the pIOL and the endothelium was 1.37 ± 0.22 mm. The mean central distance to the endothelium was 2.18 ± 0.26 mm. These measurements are comparable to the distances reported by Tehrani et al.²⁴

When evaluating the differences between the various pIOL types, we found a significantly higher mean distance between the center of the pIOL and the endothelium in the Artisan 6.0 mm group than in the other 4 groups (Artisan 5.0 mm, Artisan toric, Artiflex I, and Artiflex II). This difference was also detected by Kohnen et al.,² who found that the mean distance between the center of the pIOL and the endothelium was significantly higher in the Artisan 6.0 mm group than in the Artiflex I and Artiflex II groups. The central lens thickness provided by the manufacturer is variable for Artiflex pIOLs, ranging from 0.14 to 0.52 mm depending on the dioptric power of the lens. The Artisan pIOLs show a constant central thickness of 0.14 mm. This might explain the significant difference between the Artisan pIOLs and the Artiflex pIOLs in the distance from the center of the pIOL to the endothelium.

The mean edge distances for the Artisan 5.0 and 6.0 mm pIOLs were significantly higher than the distances for the Artiflex I and Artiflex II pIOLs. The

flexible optic of the Artiflex pIOL is of ultraviolet-absorbing silicone, which has a refractive index of 1.43. In contrast, the PMMA optic of the Artisan pIOL has a refractive index of 1.49. This higher refractive index leads to a safer distance from the edge to the endothelium for the Artisan pIOL than for the Artiflex pIOL. New materials with higher refractive indices would decrease the height of the optic edge.

In our study, the distance between the pIOL and the crystalline lens decreased with increasing patient age. A linear decrease of 3.1 μm per year was found. This relationship was also reported by Koivula et al.,²⁵ who analyzed the position of posterior chamber pIOLs using AS-OCT. In recent studies, a yearly 20 μm forward progression of the anterior pole of the crystalline lens due to aging is described, which is much higher than the decrease in distance from the pIOL to the crystalline lens that we found.^{15,26} However, a stable distance between the pIOL and the crystalline lens during accommodation was reported by Güell et al.,¹⁶ which might suggest that the iris and crystalline lens act as a unit and move forward. This movement as a unit could be an explanation for the minimal decrease in the distance from the pIOL to the crystalline lens. However, if the iris and the crystalline lens move forward with an iris-fixated pIOL, the distance from the edges of the pIOL to the endothelium might decrease with increasing patient age. In the future, this effect should be monitored during long-term follow-up.

In conclusion, ECD measurements are mandatory before and after pIOL implantation to monitor the long-term effect of the pIOL on the endothelium. In addition to ECD counts, anterior chamber morphometrics should be analyzed during long-term follow-up to evaluate the safety of pIOLs. A potential decrease in the distance from the edge of the pIOL to the endothelium due to age-related changes of the crystalline lens should be carefully monitored.

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