Long-term Study of Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia

Ten-Year Follow-up Results

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Purpose: To determine the long-term performance of the Artisan phakic intraocular lens (PIOL) for the correction of myopia.

Design: Long-term (10 years) retrospective follow-up study.

Participants: Eighty-nine eyes of 49 patients who underwent Artisan PIOL implantation for the correction of myopia.

Methods: Comparisons were made between preoperative clinical data and the clinical data at 1, 6, and 10 years after surgery.

Main Outcome Measures: Refractive stability, refractive predictability, safety, efficacy, best-corrected visual acuity (BCVA), uncorrected visual acuity (UCVA), intraocular pressure, intraoperative problems, corneal endothelial cell density, corneal endothelial cell loss, and glare levels were evaluated.

Results: The mean spherical equivalent (SE) after 10 years was -0.70 ± 1.00 diopters (D; range, -4.00 to 2.00 D), with no significant change in mean SE between 1, 6, and 10 years. At 10 years, 68.8% of all eyes were within 1.0 D of the intended correction. At 10 years, 31.2% (n = 24) gained 1 or more Snellen lines of BCVA and 2.6% (n = 2) lost more than 2 Snellen lines of BCVA; 93.3% reached a BCVA of 20/40 or better, and 82.0% reached a UCVA of 20/40 or better. The mean intraocular pressure remained stable and was 15.5 ± 3.5 mmHg (range, 7–25 mmHg) at 10 years. The mean endothelial cell loss was $-8.86 \pm 16.01\%$ (range, -51.69% to 34.43%) at 10 years.

Conclusions: Long-term results demonstrate that the implantation of an Artisan PIOL for the correction of moderate to high myopia is a stable, predictable, and safe method when strict inclusion criteria for surgery are applied. There was no significant loss of corneal endothelial cells and no reports of long-term glare. *Ophthalmology 2007;114:1133–1142 © 2007 by the American Academy of Ophthalmology.*

To be able to evaluate the results of any corneal refractive surgical technique, it is essential to monitor the long-term refractive stability, refractive predictability, safety, and efficacy of that particular procedure. Several published clinical reports have demonstrated the excellent short-term performance of the Artisan phakic intraocular lens (PIOL) (Ophtec B.V., Groningen, The Netherlands).[1–10] When

evaluating surgical results of PIOL implantations, the assessment of corneal endothelial cell loss over time is an additional important factor in determining the long-term safety.

The long-term accuracy of excimer laser refractive surgery is known to decline with higher levels of myopia.[11–13] Additionally, secondary effects such as glare and halos are common downsides after excimer laser treatment for moderate to high myopia, because more corneal tissue is removed and the optical zone needs to be smaller to prevent excessively deep ablations.[14–16] The surgical implantation of PIOLs offers advantages in the correction of high myopia in that they provide the best chance of maintaining the best-corrected visual acuity (BCVA).[3,17] Specific concerns related to the implantation of PIOLs are the safety of the surgical procedure for the corneal endothelium, the stability of the refractive results, and the long-term biocompatibility with the ocular tissue.[7,10]

Implantations of PIOLs have been at the center of scientific interest for the surgical correction of moderate to

high myopia, for example, in patients who are intolerant to contact lenses, spectacles, or both. Of the 3 currently existing phakic lens models (iris fixated, angle supported, and posterior chamber), we evaluated the Artisan iris-fixated convex–concave PIOL.

Because PIOLs are implanted in healthy and phakic eyes, it is required that the implanted device provide a long-term tolerance by the ocular tissues. A lack of reports on the long-term stability and predictability of these types of refractive surgery procedures remains an important issue among eye surgeons. The implantation of the lens leading to chronic stress on the corneal endothelium with a concomitant corneal endothelial cell loss is of particular concern. Short-term clinical reports have demonstrated that corneal endothelial cell loss after Artisan PIOL implantation varies from 0.7% to 2.4% after 1 year and 0.7% to 11.7% after 3 years.[1–3,5,6,8–10]

The purpose of this study was to assess the long-term (10-year) performance of the Artisan PIOL for the correction of moderate to severe myopia. The Artisan PIOL is a lens with a fixed optical zone of 5.0 or 6.0 mm, depending on the dioptric power of the lens. The main outcome measures that were investigated included refractive stability, refractive predictability, safety, efficacy, BCVA, uncorrected visual acuity (UCVA), intraocular pressure, intraoperative problems, and corneal endothelial cell loss over a period of 10 years.

Patients and Methods

Patient Population and Study Design

Patients originally were identified and underwent surgery in 1991. The initial study group consisted of 177 eyes of 89 patients who had undergone surgical implantation of an Artisan PIOL for the correction of moderate to high myopia. Of the original group of 177 eyes of 89 patients, a group of 89 eyes of 49 patients were evaluated 1, 6, and 10 years after the surgical procedure. Data from the remaining 88 eyes were excluded from analyses in the study because of differing time points of clinical evaluation. Comparisons of preoperative and postoperative clinical data were made for all eyes. Institutional Review Board approval was obtained from the Academic Hospital Maastricht.

Inclusion Criteria

Included patients had a stable refraction during the previous 2 years; an anterior chamber depth of 3.0 mm or more; an endothelial cell density (ECD) count of 2000 cells/mm^2 or more; a normal pupil and iris configuration; no history of glaucoma; no preexistent corneal, lenticular, or retinal pathologic features likely to alter vision; and no history of chronic or recurrent uveitis.

Clinical Evaluation

Before and after surgery, subjective and objective refraction was determined by measurement of the Snellen UCVA and BCVA. Slit-lamp microscopy, Goldmann applanation tonometry, and fundus examination were performed. Pupil sizes were measured under mesopic conditions using the Goldmann visual field analyzer (Haag Streit, Bern, Switzerland).

Endothelial Cell Density

All ECD counts were performed by an independent employee. The ECD counts were determined by manual counting before and after surgery using a specular microscope (Topcon SP-1000 and SP-2000P Non-Contact Specular Microscope; Topcon Corp., Tokyo, Japan). During measurements, 3 consecutive endothelial images were obtained. The estimated ECD for each eye was measured using the mean value of the 3 consecutive ECD measurements. Any ECD loss was defined as the decrease in cell density between the preoperative examination and the postoperative (e.g., 1, 6, and 10 years) examination, expressed as a percentage of the preoperative ECD.

Surgical Procedure

All surgical treatments were performed by one surgeon (CJB) in a private clinic in Sint-Truiden, Belgium. The power of the PIOL was calculated using the Van der Heijde formula, which uses the mean corneal curvature (K), adjusted anterior chamber depth (ACD−0.8 mm), and spherical equivalent (SE) of the patient's spectacle correction at a 12.0-mm vertex.[18] The Artisan iris-fixated PIOL has a convex-concave polymethyl methacrylate optic that is available with an optic of either 6 mm (for intraocular lens powers up to −15.5 diopters [D]) or 5 mm (for intraocular lens powers from −16.0 D up to −24.0 D). For this study, only the Artisan myopia 5-mm optic lens (model 206) was used. The lens is 8.5 mm in overall length, has a vault of 0.8 mm, and is available in powers from −5.0 to −20.0 D. Before 1997, the lens was available in only 1.0-D power increments; since 1997, it has been available in 0.5-D increments. The Artisan PIOL is positioned in the anterior chamber and is held in place by fixation to the midperipheral iris stroma, creating a bridge over the optical axis.

For all patients, surgery was performed under general anesthesia. All eyes received identical surgical treatment. A 2-plane 6.3-mm corneoscleral incision was centered at 12 o'clock. Two paracenteses were placed at 2 and 10 o'clock and directed toward the enclavation sites. Miosis was achieved through preoperative instillation of pilocarpine (Isopto Carpine; Alcon, Fort Worth, TX) and a perioperative intracameral injection of acetylcholine 1.0% (Miochol-E; Bournonville Pharma, The Hague, The Netherlands) to prepare the iris for PIOL fixation, to reduce the risk of lens-touch during implantation, and to facilitate centration of the PIOL. A viscoelastic substance (Healon GV; Pharmacia, Uppsala, Sweden) was inserted through the paracenteses and primary incision to maintain sufficient anterior chamber depth, to protect the endothelium, and to facilitate adjusting the PIOL within the eye during fixation. The PIOL was introduced with a Budo forceps (Duckworth and Kent, Ltd., Baldock Herts, England). After subtle rotation of the PIOL, it was fixated in the horizontal axis with the use of a disposable enclavation needle (Ophtec). A slit iridotomy was performed at 12 o'clock to avoid pupillary block glaucoma. The viscoelastic substance was exchanged for balanced salt solution (Alcon). The wound was sutured with 3 to 5 interrupted 10-0 nylon sutures (Alcon). After surgery, topical tobramycin 0.3% combined with dexamethasone 0.1% (TobraDex; Alcon, Couvreur, Belgium) and ketorolac trometamol 0.5% (Acular; Westport Co., Mayo, Ireland) were used 4 times daily for 3 weeks in a tapered schedule and 3 times daily for 1 week, respectively.

Glare

Glare levels were assessed using a questionnaire that has been used previously for the evaluation of patient satisfaction after refractive surgery.[16,18–20] The instrument has proven to be reliable by a high level of internal consistency with Cronbach's α coefficients supe-

rior or equal to 0.83. Glare scale scores ranged from 1 (high glare levels) to 5 (no glare).

Statistical Analysis

Best-corrected visual acuity in logarithm of the minimum angle of resolution (logMAR) units was used for data reports, meaning the lower the value, the better the vision. Statistical analysis and comparisons between preoperative and postoperative data and between individual postoperative years were performed by paired Student's t tests ($P<0.05$ being significant; SPSS for Windows; SPSS Inc., Chicago, IL). All values in the text are mean±standard deviation (SD). Data from clinical evaluations at postoperative years 1, 6, and 10 were used for analysis. A linear decrease of 0.6% physiologic loss per year was applied for the preoperative ECD value, after which paired t tests were used to compare postoperative ECD values with the preoperative ECD values.

Results

Patient Population

Thirty-four patients were women and 15 were men. The mean preoperative age for all patients was 38.3±10.5 years (range, 19–61 years). Population characteristics are listed in Table 1. The baseline parameters for all 89 eyes were a mean sphere of −9.78±4.43 D (range, −3.50 to −25.00 D), a mean refractive cylinder of −1.26±1.40 D (range, −6.75 to 0 D), and a mean baseline SE of −10.36±4.69 D (range, −3.75 to −25.25 D).

The mean baseline logMAR BCVA was 0.16±0.23 (range, 0–1). The mean anterior chamber depth was 3.30±0.28 mm (range, 3.00–4.20 mm), and the mean intraocular pressure was 14.7±2.8 mmHg (range, 8.0–19.0 mmHg). The mean baseline ECD was 2817±359 cells/mm² (range, 2100–3900 cells/mm²). The mean power of the implanted PIOL was −12.60±4.20 D (range, −7.0 to −20.0 D). The preoperative pupil size was 4.5±0.9 mm (range, 3.0–7.0 mm), with a pupil size larger than 5.0 mm in 9.5% of eyes.

Refractive Stability

After 1, 6, and 10 years, the mean SE was −0.70±0.97 D (range, −4.88 to 1.75 D), −0.71±0.99 D (range, −4.50 to 2.00 D), and

Table 1. Summary of Population Characteristics and Preoperative Data

Variable	Mean±Standard Deviation	Range
Mean patient age (yrs)	38.35±10.50	19–61
Number of females	34	
Number of eyes	89	
Right eyes	44	
Left eyes	45	
Sphere (D)	−9.78±4.43	−3.50 to −25.00
Cylinder (D)	−1.26±1.40	−6.75 to 0.00
SE (D)	−10.36±4.69	−3.75 to −25.25
ACD (mm)	3.30±0.28	3.00–4.20
IOP (mmHg)	14.7±2.8	8.0–19.0
ECD (cells/mm²)	2817±359	2100–3900
Implanted lens power (D)	−12.60±4.20	−7.00 to −20.0

ACD = anterior chamber depth; D = diopters; ECD = endothelial cell density; IOP = intraocular pressure; SE = spherical equivalent.

Table 2. Mean±Standard Deviation Spherical Equivalent before and after Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia

	Mean±Standard Deviation	Number of Eyes	Range	P Value*
Before surgery	−10.37±4.67	89	−25.25 to −3.75	
After surgery				
1 yr	−0.70±0.97	89	−4.88 to 1.75	
6 yrs	−0.71±0.99	89	−4.50 to 2.0	0.94
10 yrs	−0.70±1.00	89	−4.00 to 2.0	0.71

*Mean spherical equivalent value as compared with the mean value at 1 year after surgery.

−0.70±1.00 D (range, −4.00 to 2.00 D), respectively. No significant change in mean SE was found between 1 and 6 years after surgery and between 6 and 10 years after surgery ($P = 0.94$ and $P = 0.71$, respectively; Table 2, Fig 1).

Refractive Predictability

Spherical Equivalent. The deviation of the achieved SE correction from the calculated (intended) refractive SE correction was calculated. After 1, 6, and 10 years, 38.3% (n = 34), 50.5% (n = 45), and 43.8% (n = 39) of eyes were within ±0.5 D of the desired refraction, respectively. After 1, 6, and 10 years, 74.2% (n = 66), 65.1% (n = 58), and 68.8% (n = 61) of eyes were within ±1.0 D of the desired refraction, respectively. After 1, 6, and 10 years, 94.4% (n = 84), 93.3% (n = 83), and 93.3% (n = 83) of eyes were within ±2.0 D of the desired refraction, respectively (Table 3, Fig 2).

Astigmatic Correction. After 1, 6, and 10 years, the mean refractive cylinder was −1.02±0.85 D (range, −4.00 to 0 D; n = 89), −1.00±0.90 D (range, −4.00 to 0 D; n = 89), and −0.94±0.79 D (range, −4.00 to 0 D; n = 89), respectively. A postoperative refractive cylinder of more than 1.5 D was found in 15.7% (n = 14), 20.2% (n = 18), and 12.4% (n = 11) after 1, 6, and 10 years, respectively (Table 4).

Safety

The mean preoperative logMAR BCVA for all 89 eyes was 0.16±0.23 (range, 0–1). After 1, 6, and 10 years, the mean logMAR BCVA was 0.07±0.09 (range, −0.08 to 0.30), 0.12±0.17 (range, −0.08 to 1.30), and 0.12±0.21 (range, −0.08 to 1.30), respectively. A BCVA of 20/40 or better was found in 100%, 96.6%, and 93.3% of eyes after 1, 6, and 10 years, respectively. A BCVA of 20/20 or better was found in 70.8%, 50.6%, and 52.8% of eyes after 1, 6, and 10 years, respectively. After 1, 6, and 10 years, 40.3% (n = 31), 26.0% (n = 20), and 31.2% (n = 24) gained 1 or more Snellen lines of BCVA, respectively. After 1, 6, and 10 years, 1.3% (n = 1), 2.6% (n = 2), and 2.6% (n = 2) of eyes lost more than 2 Snellen lines of BCVA, respectively (Fig 3). The safety index (meaning the ratio of the mean postoperative BCVA to the mean preoperative BCVA) was 1.12, 1.10, and 1.10 after 1, 6, and 10 years, respectively.

Efficacy

After 1, 6, and 10 years, the mean logMAR UCVA for all 89 eyes was 0.16±0.16 (range, −0.08 to 0.60), 0.24±0.23 (range, 0–1.30), and 0.27±0.29 (range, −0.08 to 1.30), respectively. A
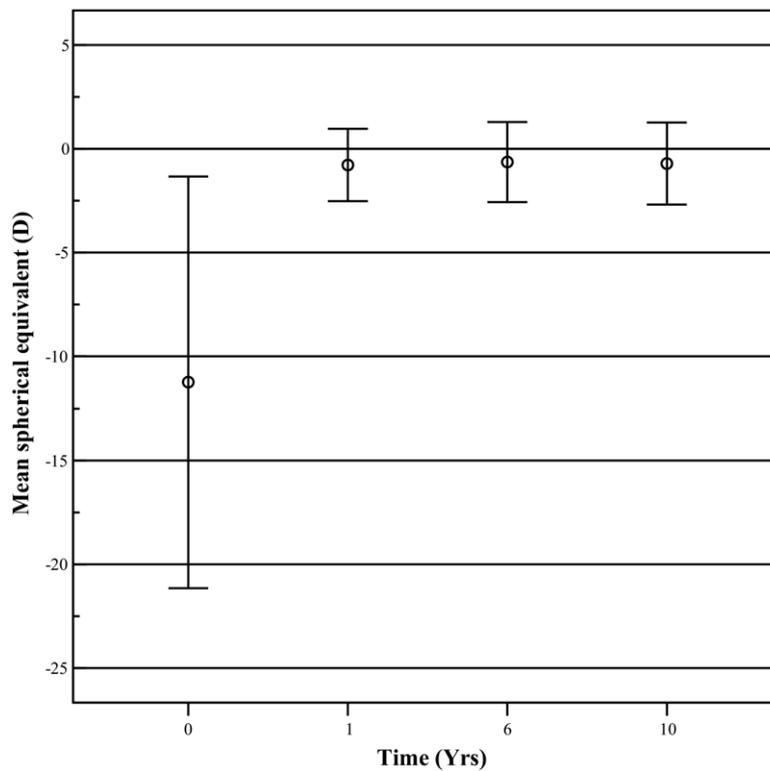
Figure 1. Graph demonstrating the stability of postoperative spherical equivalent after Artisan phakic intraocular lens implantation for the correction of moderate to high myopia. Mean ± standard deviation spherical equivalent before implantation (-10.36 ± 4.69; n = 89) and after 1 year (-0.70 ± 0.97; n = 89), 6 years (-0.71 ± 0.99; n = 89), and 10 years (-0.70 ± 1.02; n = 69) are demonstrated ($P>0.05$). D = diopters.

UCVA of 20/40 or better was found in 86.5%, 78.7%, and 82.0% of eyes after 1, 6, and 10 years, respectively. The efficacy index (meaning the mean postoperative UCVA to mean preoperative BCVA) was 0.96, 0.83, and 0.80 after 1, 6, and 10 years, respectively.

Intraocular Pressure

The mean preoperative intraocular pressure for all 89 eyes was 14.7 ± 2.8 mmHg (range, 8–19 mmHg) and changed to 15.3 ± 3.3 mmHg (range, 9–26 mmHg), 15.6 ± 3.8 mmHg (range, 9–24 mmHg), and 15.5 ± 3.5 mmHg (range, 7–25 mmHg) at 1, 6, and 10 years after surgery.

Endothelial Cell Density and Endothelial Cell Loss

After 1, 6, and 10 years, the mean±SD postoperative ECD was 2928 ± 351 cells/mm^2 (range, 2200–3900 cells/mm^2; n = 87),

Table 3. Overview of Refractive Predictability after Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia

Refractive Predictability	Year 1 No. of Eyes (%; n = 89)	Year 6 No. of Eyes (%; n = 89)	Year 10 No. of Eyes (%; n = 89)
±0.5 D	38.3 (32)	50.5 (45)	43.8 (39)
±1.0 D	74.2 (66)	65.1 (58)	68.8 (61)
±2.0 D	94.4 (84)	93.3 (83)	93.3 (83)

D = diopters.

2734 ± 360 cells/mm^2 (range, 2163–4500 cells/mm^2; n = 89), and 2800 ± 292 cells/mm^2 (range, 1849–3850 cells/mm^2; n = 89), respectively (Fig 4). To compare preoperative values with postoperative values, we assumed a linear decrease of 0.6% physiologic loss per year for the preoperative value. After this adjustment, we found a mean decrease of $-9.39\pm18.56\%$ (range, -57.47% to 17.36%; $P = 0.002$), $-3.26\pm18.96\%$ (range, -72.89% to 27.62%; $P = 0.494$), and $-8.86\pm16.01\%$ (range, -51.69% to 34.43%; $P = 0.001$) at 1, 6, and 10 years of follow-up, respectively (Tables 5, 6). For the relative SD, we found a within-subjects variation of 4%. The coefficient of repeatability was 344.[21–23] No significant correlation was found between the preoperative anterior chamber depth and endothelial cell changes after 10 years ($r = -0.050$; $P = 0.747$, respectively).

Intraoperative Problems and Adverse Events

There were no intraoperative problems. Throughout all follow-up years, a total of 5 eyes of 3 patients demonstrated a loss of more than 2 Snellen lines of BCVA. For follow-up year 1 (n = 1), the loss was caused by the development of a myopic maculopathy. For follow-up year 6 (n = 2) and year 10 (n = 2), the loss in Snellen lines was the result of the development of a cornea guttata dystrophy and of a visually significant cataract and were the same eyes in both years.

Glare

After 10 years' follow-up, the scores for 3 optical side effects for all 49 patients were assessed. The mean scores for perception of stars around lights, distortion of details, and double outline of images were 4.49 ± 0.65, 4.69 ± 0.59, 4.69 ± 0.62, respectively (Table 7).
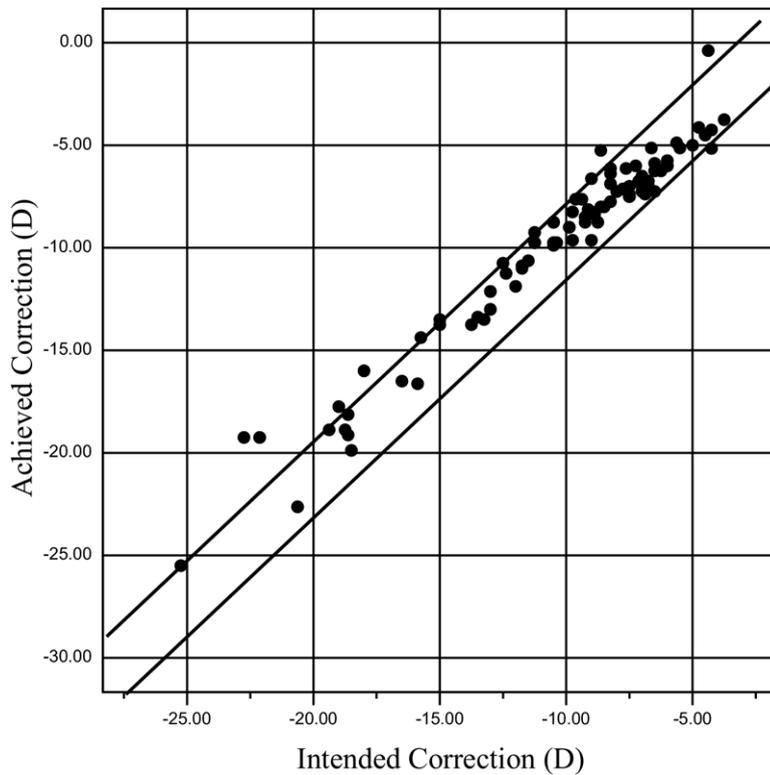
Figure 2. Scatterplot demonstrating the refractive predictability of the spherical equivalent 10 years after Artisan phakic intraocular lens implantation for the correction of moderate to high myopia; 65.2% (n = 45) were within ±1.0 diopter (D) of the desired refraction.

Secondary Surgical Intervention

To correct a significant postoperative undercorrection, 1 eye underwent an uneventful additional excimer photorefractive keratectomy procedure 4 months after the surgical implantation. Because of a visually significant age-related cataract that developed 6 years after surgery, 2 eyes underwent explantation of the Artisan PIOL with subsequent phacoemulsification and the implantation of a posterior chamber intraocular lens.

Discussion

The purpose of this retrospective study was to evaluate the long-term (10 years) refractive stability, refractive predictability, safety, and efficacy of the Artisan PIOL for the correction of moderate to high myopia and to monitor changes in corneal ECD over time. A potential drawback of

Table 4. Overview of Refractive Cylinder Values (Diopters) after Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia

	Mean±Standard Deviation	Range	No. of Eyes
Before surgery	−1.26±1.40	−6.75 to 0.0	89
After surgery			
Year 1	−1.02±0.85	−4.0 to 0.0	89
Year 6	−1.0±0.90	−4.0 to 0.0	89
Year 10	−0.94±0.79	−4.0 to 0.0	89

long-term studies in the field of refractive surgery is the variation in follow-up time. In our study, of the 177 eyes of 89 patients who initially had undergone Artisan PIOL implantation, we were able to include 89 eyes of 49 patients in the study to perform a paired comparative analysis between
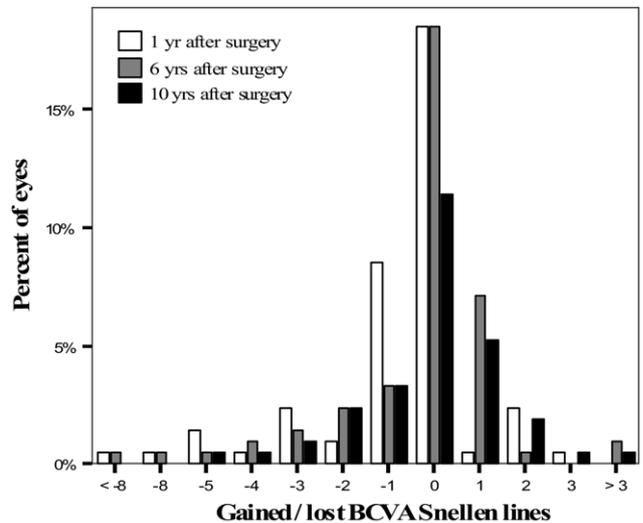

Figure 3. Bar graph demonstrating the lost and gained Snellen lines of best-corrected visual acuity (BCVA) after Artisan phakic intraocular lens implantation for the correction of moderate to high myopia. After 1, 6, and 10 years, 1.3% (n = 1), 2.6% (n = 2), and 3.6% (n = 2) of eyes lost more than 2 Snellen lines of BCVA, respectively.
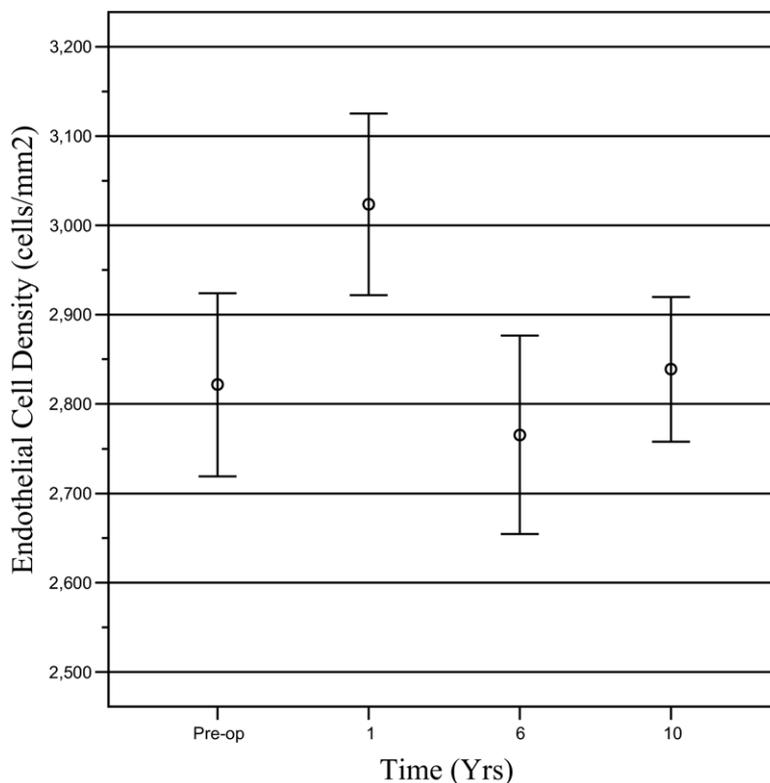
Figure 4. Graph demonstrating the mean±standard deviation endothelial cell density before Artisan phakic intraocular lens implantation for the correction of moderate to high myopia (2817±359; n = 89) and after 1 year (2928±351; n = 89), 6 years (2734±360; n = 89), and 10 years (2776±321; n = 69).

the individual follow-up years 1, 6, and 10. Data from the excluded 88 eyes were measured at different time points, and therefore were not suitable for the intended comparative analysis. However, none of these eyes had lost 2 or more lines of BCVA at their last follow-up visit.

Long-term Refractive Stability

The short-term results of Artisan PIOL implantation have been demonstrated in several clinical reports with a follow-up time of up to 4 years.[1,3–7,9,10,24] These reports demonstrate that stabilization of the postoperative refraction occurs within the first few years after surgery with more than 90% of eyes that achieve a refraction within 1 D of the intended correction and a high safety index.

The long-term data demonstrated in this study showed comparable results to the above-mentioned short-term studies on refractive stability. Ten years after Artisan PIOL implantation for the correction of moderate to high myopia, the mean SE (±SD) was −0.70±1.00 D (range, −4.00 to 2.00 D) and remained stable over time. This finding is in accordance with the short-term literature, which demonstrated stabilization of the postoperative refraction within the first few years after surgery (see above). The mean SE values of −0.7 D after 1, 6, and 10 years indicate a slight average undercorrection. The SE was aimed at slight myopia, because the lens was available in only 1.0-D power increments before 1997 (since 1997, the lens has been available in 0.5-D increments), and care was taken to avoid a postoperative hyperopic overcorrection that certainly

Table 5. Mean±Standard Deviation Endothelial Cell Density Counts before and after Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia

	No. of Eyes	Endothelial Cell Density±Standard Deviation (Range), cells/mm^2	Range	Endothelial Cell Density Loss±Standard Deviation (%)	P Value*
Before surgery	89	2817±359	2100–3900		
After surgery					
1 year	89	2928±351	2200–3900	−9.39±18.56	0.002
6 years	89	2734±360	2163–4500	−3.26±18.96	0.494
10 years	89	2800±292	1849–3850	−8.86±16.01	0.001

*Mean postoperative endothelial cell loss as compared with the mean preoperative value.

Table 6. Comparison between Previous Studies and the Current Study

	Menezo et al[9]	Budo et al[1]	El Danasoury et al[3]	Pop and Payette[10]	Current Study
No. of eyes	111	518	43	765	89
Follow-up (mos)	6–48	6–36	12	6–24	12–144
Mean patient age (yrs)	34.9	36.4	NA	NA	38.3
Lens power (D)	−8.0 to −20.0	−5.0 to −20.0	−9.0 to −19.0	−5.0 to −24.0	−7.0 to −20.0
ECD change (%)					
1 year follow-up	6.59±2.93	2.4±1.0	0.7±1.1	−0.87±16.35	−9.39±18.56
3 years follow-up	11.68±4.18	0.7±1.0	NA	NA	−8.86±16.01*

D = diopters; ECD = endothelial cell density; NA = not applicable.
*Long-term (10-year) data mentioned for the current study.

would decrease patient satisfaction in our highly myopic group of patients. In addition, we believe that a mean postoperative SE of −0.7 D in this highly myopic group with a preoperative SE of −10.36 is an acceptable result.

At 10 years after surgery, 65.2% and 92.8% of eyes were within ±1.0 D and ±2.0 D of the desired refraction with an excellent stability of the postoperative refractive cylinder, the mean±SD refractive cylinder being −0.99±0.81 D (range, −4.00 to 0 D) at 10 years.

Visual Outcome and Visual Complications

Short-term data showed that after Artisan PIOL implantation, more than 85% of eyes demonstrated a BCVA of 20/40 or better and more than 60% of eyes gained 2 or more Snellen lines of BCVA.[1,3–7,9,10,24]

Our long-term data show great similarity to the short-term data. After 10 years, patients reached a BCVA of 20/40 or better in 92.5% of eyes and a UCVA of 20/40 or better in 79.7% of eyes. With respect to safety, we showed that after 10 years, 3.6% (n = 2) of eyes lost more than 2 Snellen lines of BCVA. Throughout all follow-up years, 5 eyes in total demonstrated a loss of more than 2 Snellen lines of BCVA. For year 1 (n = 1), the loss was caused by the development of a myopic maculopathy. For follow-up years 6 (n = 2) and 10 (n = 2), the loss in one eye of the same patient was the result of the development of a cornea guttata dystrophy without preexistent signs of cornea guttata or a low endothelial cell count, and in the eye of a another patient the result of a visually significant cataract. We believe that the loss of visual acuity was not related to the implantation of the PIOL, but rather to the nature of myopic eye disease and earlier development of cataract in myopia.

Table 7. Glare Scores 10 Years after Artisan Phakic Intraocular Lens Implantation for the Correction of Moderate to High Myopia (n = 49)

	Mean±Standard Deviation*	Range
Perception of stars around lights	4.49±0.65	3–5
Distortion of details	4.69±0.59	3–5
Double outline of images	4.69±0.62	3–5

*Scores of 0 to 5 (0 = high glare levels, 5 = no glare).

In the eye with cornea guttata, it is unclear whether the cornea guttata had developed in the 6 years after the surgical procedure, or whether it was actually present at the time of patient inclusion and escaped diagnosis. Endothelial cell counts of more than 2000 cells/mm^2 may be possible in patients with cornea guttata because of the variations in regional endothelial cell density.[25]

From 1 to 10 years after surgery, there was a slight decrease in the safety index and a larger decrease in the efficacy index of the Artisan procedure. After 10 years, we found a safety index of 1.10 as compared with 1.12 at 1 year. The efficacy index decreased from 0.96 at 1 year to 0.80 after 10 years. We believe that this decrease is not related to the surgical procedure, but to the development of age- and high myopia-related changes, like earlier development of lens opacities and maculopathy in this group of highly myopic patients whose average patient age after 10 years was 48.3 years.[1,5,26–28] It can be expected that a sample size of approximately 100 cases can detect unanticipated severe adverse events to occur approximately 3% of the time. Our study sample demonstrated unanticipated severe adverse events to occur at a rate of less than 5%.

Long-term Endothelial Cell Loss

Several short-term studies evaluated corneal ECD after Artisan PIOL implantation (Table 6).[1,3–10,24,29] In 1998, Menezo et al[9] showed data from 111 eyes with an Artisan PIOL with subsequent ECD loss of 11.7% at 3 years of follow-up. In 2000, Budo et al[1] reported 3-year follow-up data from 518 patients that demonstrated a relatively low amount of ECD loss and stabilization over time (2.4% after 1 year and 0.7% after 3 years). In 2004, Pop and Payette[10] reported data that did not show any statistically significant postoperative endothelial cell loss for up to 2 years after Artisan PIOL implantation. No strong evidence can be found in the literature for concerns on the long-term safety of the current Artisan PIOL design. In 2000, an experimental study used scanning electron microscopy to analyze the surface quality of the Artisan lens.[30] The study stated that the surface quality of this lens is excellent and that no contraindications related to surface quality could be found for the implantation of these lenses into phakic eyes. In addition, reports that have studied changes in ECD in healthy emmetropic eyes demonstrate a correlation between patient age and ECD. With age, the number of cells de-

creases, with a physiologic rate of 0.6% per year after age 18.[31] This means that after 10 years, a loss of approximately 6% could be found. In the present study, however, we could not find an endothelial cell loss of this magnitude. Our data demonstrated that there was no long-term corneal endothelial cell loss over time, with a relative gain in ECD after 1 year (gain of 8.73±18.45%) and 10 years (gain of 3.62±16.97%) of follow-up. No correlation was found between endothelial cell loss at 10 years and the preoperative anterior chamber depth, which supports the hypothesis that an anterior chamber depth of at least 3.0 mm is an adequate safety measure for the implantation of the Artisan PIOL.[10] Previous studies also have attempted to explain the gain in ECD after Artisan PIOL implantation, among which a large variation in cell density measurements and small sample sizes enabled the large variations.[4,5] Specular microscopy measurements have been reported to be reproducible within 7%, of which approximately one third is the result of the precision of the technique and the remaining two thirds is the result of the variance of the ECD population within each eye.[10,31,32] Another report stated that ECD assessment may be considered less valid when evaluating corneal endothelial cell loss caused by a surgical technique.[33] In the present study, ECD was measured with the Topcon SP-1000 specular microscope until 2002, after which measurements were taken with the Topcon SP-2000P. The Topcon SP-1000 has been mentioned in several studies,[33–36] although no studies have compared this specular microscope with the newer Topcon SP-2000P. A small comparative study in our department showed a high correlation for ECD between the 2 microscopes (unpublished data). Therefore, we do not expect that the switch in these instruments significantly contributed to a bias in ECD measurements.

Another explanation for a relative gain in ECD after implantation could be that the recovery capability of the corneal endothelium after intraocular surgery may be higher than previously assumed. A recent report by Whikehart et al[37] suggested that cells in the corneal endothelium may be renewed by stem cells located in a niche at the posterior limbus and that increased cell renewal may occur after mechanical trauma, such as intraocular surgery. Data reported by Konomi et al[38] indicated that both central and peripheral corneal endothelial cells are capable of dividing and that age had a greater influence on proliferative capacity than on the relative position of the cells. Data by Amann et al[25] demonstrated that the ECD in the peripheral cornea is significantly higher than in the central cornea, which plays an important role in the wound healing response of the corneal endothelium after PIOL implantation, because the peripheral cornea provides a physiologic reserve for endothelial cells. Published data of a clinical study using a different type of PIOL (Implantable Contact Lens, STAAR Surgical AG, Nidau, Switzerland) suggested that corneal endothelial cell loss between the first and third postoperative years is explained by prolonged corneal ECD remodeling after the surgical procedure rather than ongoing cell loss.[39]

Finally, a trend toward improvement and recovery of the corneal endothelial cell morphologic features after discontinuation of contact lens wear has been reported previously,[40] including an improvement in endothelial morphologic parameters after photorefractive keratectomy[41,42] and LASIK.[43,44] This improvement was attributed to the discontinuation of contact lens, switching to spectacle wear, or both. This may be another explanation for the relative gain in ECD after the implantation in our study, because many of our patients were long-term contact lens wearers before the implantation and many discontinued wearing their contact lenses after surgery. Unfortunately, because of insufficient data, we were not able to analyze the relation between preoperative contact lens or spectacle use and postoperative endothelial cell values.

Comparison with Other Long-term Studies of Refractive Surgery

Recently, a study was published on the long-term (12-year) results of patients who underwent myopic photorefractive keratectomy for the correction of myopia. The range of the preoperative SE was −1.5 to −17.5 D. Seventy-five percent of patients who underwent a −2-D correction and 65% of patients who received a −3-D correction were within 1 D of intended correction at 12 years. Fifty-seven percent of the −4-D group and 50% of the −5-D group were within 1 D, and this was reduced further to 25% and 22% in the −6-D and −7-D groups, respectively. In our study of Artisan PIOL implantation, 65.2% and 92.8% of patients were within ±1.0 D and ±2.0 D of the desired refraction after 10 years. The photorefractive keratectomy study demonstrated that after 12 years, 94% had a BCVA better than or equal to the preoperative BCVA. A loss of 1 Snellen line of BCVA was shown in 4.0% and of 2 Snellen lines of BCVA in 1.4% of patients. Our data at 10 years showed a BCVA of 20/40 or better in 92.5% of patients and a loss of more than 2 Snellen lines of BCVA in 3.6%.[13]

Late Complications

No intraoperative or postoperative complications occurred in the patient group. Previous studies on Artisan PIOL implantation have discussed intraoperative and postoperative complications.[1,5,9,24] These studies demonstrated that intraoperative problems that can occur usually are minimal and typically are related to the learning curve required to master the special implantation technique for the Artisan lens. We believe that the 2 eyes in which a visually significant cataract developed 6 years after surgery were related to age and high myopia and were not caused by the surgical implantation of the Artisan PIOL.

Glare

Glare levels were evaluated after 10 years' follow-up. For this purpose, a validated questionnaire was applied that represented the quantification of glare levels after the surgical procedure.[16,18,19] The results demonstrated that glare levels after the Artisan PIOL implantation procedure were low and showed results comparable with those of previous PIOL studies.[1,20]

In conclusion, this study has demonstrated that after the implantation of Artisan PIOLs for the treatment of moderate to high myopia, refractive stability was maintained for up to 10 years. There was no evidence of late-onset complications or long-term endothelial cell loss. However, to achieve these results, a meticulous surgical technique of PIOL implantation by an adequately trained surgeon is needed and strict inclusion criteria must be applied.

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