

Three-year Follow-up of the Artisan Phakic Intraocular Lens for Hypermetropia

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Purpose: We report the postoperative results of the Artisan Hyperopia phakic intraocular lens (IOL; model 203W; Ophtec, Groningen, The Netherlands).

Design: Prospective, nonrandomized trial.

Participants: Twenty-six eyes of 13 self-selected patients with refractive error ranging from +3.00 to +11.00 diopters (D).

Intervention: Patients with hypermetropia were implanted with the Artisan Hyperopia phakic IOL. Mean follow-up was 22.4 months (range, 3–36 months).

Main Outcome Measures: Predictability, stability, efficacy, loss of best spectacle-corrected visual acuity, and complications.

Results: At six months, 90.9% (20 of 22 eyes) were ± 1.00 D of intended correction and 81.8% (18 eyes) were ± 1.00 D of emmetropia. The mean spherical equivalent was stable within 0.25 D during the entire 3-year follow-up period. Twenty-four eyes (92.3%) had a postoperative best spectacle-corrected visual acuity of 0.50 or better at all of their individual follow-up examinations. No patient lost 2 or more lines after the procedure. There was a significant negative correlation between anterior chamber depth and endothelial cell loss. Two patients experienced posterior synechiae with pigment deposits in both eyes. One of these patients had convex irides and underwent implant removal within 2 years with a consequent clear lens extraction and posterior chamber lens implantation.

Conclusions: Implantation of the Artisan Hyperopic lens leads to accurate and stable refractive results with no significant loss of vision. More attention should be paid to convex irides and shallow anterior chambers during the preoperative screening to avoid unnecessary complications. *Ophthalmology* 2003;110:1391–1395 © 2003 by the American Academy of Ophthalmology.

High hyperopia has proven to be a challenge to correct. Procedures with the excimer laser have shown great potential, although many authors find that they are only safe in cases of low to moderate hyperopia.^{1–5} Thanks to the introduction of phakic intraocular lenses (IOL), however, correcting higher degrees of farsightedness has now become possible.

Phakic IOLs can be an attractive alternative to other types of refractive interventions, such as refractive keratectomy, LASIK, and photorefractive keratectomy. Studies on diverse phakic IOLs have demonstrated that visual results are stable and predictable.^{6–11} The Food and Drug Administration currently is undergoing clinical trials for several different types of hyperopic and myopic phakic IOLs (un-

published), although some of these lenses are already being used in clinical settings outside the United States.^{6–8,12}

One of these phakic IOLs is the Artisan Myopia lens (model 203W; Ophtec, Groningen, The Netherlands), first used clinically in 1986. The competency of this lens was scrutinized during the European multicenter study,⁶ with refractive errors ranging from -5.00 to -20.00 diopters (D). The authors concluded that the lens was safe, stable, efficacious and predictable. The first clinical implant of the Artisan Hyperopia lens took place in 1992. In this single-center investigation, we analyzed the predictability, stability, and visual acuity results of this phakic IOL, as well as its possible effect on the corneal endothelium and its rate of complications in hyperopic patients.

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Materials and Methods

Intraocular Lens

The Artisan Hyperopia lens is an iris-fixated anterior chamber implant made of ultraviolet-absorbing clinical quality polymethyl methacrylate, Perspex CQ-UV. The lens is vaulted to allow maximum clearance between itself and the cornea and the crystalline lens. It has a 5-mm diameter optic with a total length of 8.5 mm and an absolute height of 1.00 mm. It is available in half-diopter increments between +1.00 and +12.00 D.

Table 1. Preoperative and Postoperative Results of Refraction, Visual Acuity and Endothelial Cell Count

	Preoperative (n = 26)	1 Month (n = 26)	3 Months (n = 21)	4–6 Months (n = 22)	1 Year (n = 17)	2 Years (n = 15)	3 Years (n = 10)
Refraction (SE)	+6.80 ± 1.97	-0.16 ± 0.61	-0.04 ± 0.78	-0.08 ± 0.74	-0.03 ± 0.71	-0.15 ± 0.89	+0.10 ± 0.85
Range	+3.00 to +11.00 D	-1.25 to +1.25	-1.75 to +1.63	-1.50 to +1.38 D	-1.50 to +1.13 D	-2.00 to +1.00 D	-1.50 to +1.25 D
BSCVA	0.86 ± 0.59	0.86 ± 0.67	0.82 ± 0.65	0.87 ± 0.67	0.82 ± 0.27	0.82 ± 0.59	0.75 ± 0.52
UCVA	-NA-	0.73 ± 0.68	0.66 ± 0.67	0.65 ± 0.65	0.63 ± 0.62	0.59 ± 0.60	0.58 ± 0.57
BSCVA 0.5+	(92.3%)	92.3%	95.2%	95.5%	94.1%	93.3%	80.0%
Endothelial cell count	2749 ± 348	2946 ± 334	2804 ± 375	2858 ± 462	2965 ± 305	2611 ± 472	2471 ± 372

BSCVA = best spectacle-corrected visual acuity; SE = spherical equivalent; UCVA = uncorrected visual acuity.

Patients

Twenty-six eyes of 13 patients (5 female and 8 male) were fitted with the Artisan Hyperopia lens implant between May 1996 and June 2000 at Erasmus MC in Rotterdam, The Netherlands. Patient age ranged from 28 to 59.5 years, the average being 43.6 years. Preoperative spherical refraction averaged $+6.80 \pm 1.97$ D (standard deviation; range, $+3.00$ – $+11.00$ D), with an astigmatism of -0.67 ± 0.52 D (range, -1.75 – 0.00 D). The mean best spectacle-corrected visual acuity (BSCVA) was 0.86 ± 0.59 and ranged between 0.1 and 1.5. Four amblyopic patients had a BSCVA of 0.5 and less in one eye each. The mean axial length was 21.22 ± 0.79 mm (range, 19.47–22.66 mm), and the anterior chamber depth average was 3.25 ± 0.25 mm (range, 2.87–3.69 mm). Four eyes (3 patients) had an anterior chamber depth of less than 3.00 mm.

All procedures were performed consecutively by the same surgeon (GL). Inclusion criteria for the intervention consisted of the following: age more than 18 years, absence of ocular pathologic features or abnormality, general good health, BSCVA more than 0.1, endothelial cell count more than 2000 cells/mm², anterior chamber depth more than 2.6 mm (first 15 months, eight patients) then 3.0 mm, fixed pupil size less than 5.0 mm, no surgical difficulty at the time of implantation that may increase the potential for complications.

Each patient was informed about the investigative nature of the procedure and signed a detailed informed consent form in accordance with the Helsinki Declaration.

Intervention

Preoperative examination included a complete slit-lamp examination, endothelial cell count (Topcon SP2000-P; Tokyo, Japan), keratometry, applanation tonometry (Haag Streit; Bern, Switzerland), and A-scan biometry (Alcon; Irvine, California, USA). The objective and subjective refractions were measured with and without cyclopentolate hydrochlorate 1.0% eye drops. Both the uncorrected visual acuity (UCVA) and the BSCVA were measured (Snellen). The IOL power calculations were determined using the Van der Heijde formula.⁶

One day before surgery, patients were requested to apply gentamicin (Genta Mytrex Tramedico, Weesp, The Netherlands) ointment in the eye. Each patient received an eyedrop of pilocarpine 4% on the morning of surgery and 30 minutes before surgery. The intervention was performed under complete anesthesia until mid June 1998 (both eyes of six patients). Thereafter, surgery was carried out with local retrobulbar anesthesia, using 5 ml of mepivacaine with hyaluronidase (Hyason) and applying pressure with the Honan balloon (Organon, Oss, The Netherlands) for a minimum of 10 minutes. The second lens implantation of each patient took place 2 to 4 weeks after the first.

Surgical procedure followed standard protocol. Corneoscleral beveled incisions of 5.5 mm were made at 12 o'clock and another two paracenteses were placed at 10 and 2 o'clock. The anterior chamber was opened and introduced with viscoelastic fluid (Healon) to maintain its depth. After implantation with the use of forceps (model D02-72, Ophtec, Groningen, The Netherlands), the lens was fixed onto the iris with an enclavation needle (model OD125, Ophtec). At the end of the operation, a slit-iridotomy was performed at 12 o'clock, the corneoscleral wounds were closed with a running suture (Ethilon 10.0), and the viscoelastic material was manually irrigated.

Follow-up examinations took place 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months after surgery, and on a yearly basis thereafter. Patients with complications were examined more frequently. To be included in this study, patients required a minimum 3-month follow-up. Patients were contacted by mail with an appointment date to ensure completeness of follow-up. One patient died after 2 years and thus was lost to follow-up.

For any given comparison of preoperative and postoperative data, the preoperative average included only the group of eyes depicted in the given postoperative period. To evaluate the stability of the procedure more precisely, we also separately analyzed eight eyes that were present at every examination for all 3 years.

Postoperative examinations included slit-lamp biomicroscopy, applanation tonometry, manifest refraction, UCVA, and BSCVA. Postoperative specular microscopy was performed at every follow-up after 3 months. All data were collected prospectively from patient charts during follow-up examinations by the ophthalmologists (GL and ML) and their assistants.

Both eyes of each patient were analyzed separately. We performed regression analysis and *t* tests ($P = 0.05$) using the SPSS statistical program. To analyze BSCVA and UCVA results, Snellen visual acuity was first converted into logarithm of the minimum angle of resolution notation to calculate the mean and then transformed back into Snellen visual acuity.

Results

Mean follow-up was 22.4 months per patient. All 26 eyes were followed-up for 1 month, 21 eyes for 3 months, 22 for 6 months, 17 for 1 year, 15 for 2 years, and 10 for 3 years (Table 1). Eight eyes with a 3-year follow-up attended every examination.

Average preoperative measurements are noted in Table 1, along with postoperative spherical equivalent, BSCVA, UCVA, and endothelial cell counts.

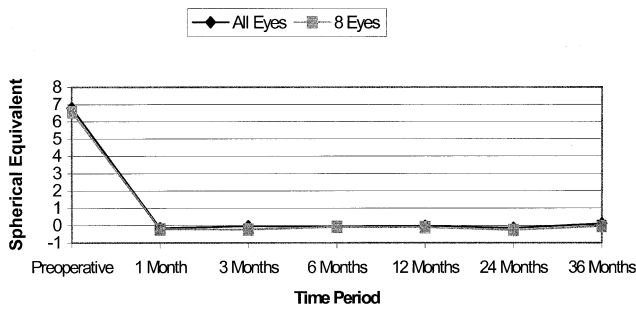


Figure 1. Stability in 3-year period postoperative refraction over a 3-year period (n = 21 at 3 months, n = 22 at 6 months, n = 17 at 12 months, n = 15 at 24 months, n = 10 at 36 months).

Refraction

The preoperative subjective spherical equivalent ranged from +3.00 to +11.00 D, with a mean of +6.80 ± 1.97 D (standard deviation). The average spherical equivalent was -0.16 ± 0.61 at 1 month after surgery, -0.04 ± 0.78 D at 3 months, and -0.08 ± 0.74 at 6 months. At 1, 2, and 3 years after surgery, the averages were -0.03 ± 0.71 D, -0.15 ± 0.89 D, and +0.10 ± 0.85 D, respectively (Fig 1 and Table 1). One eye with no evidence of cataract or other pathologic features changed more than 1.00 D in refraction between 1 month and 3 years.

At 6 months, 13 eyes (59.1%) were ± 0.50 D of intended correction and 19 eyes (86.4%) were within ± 1.00 D (Fig 2). There was a significant correlation between intended and achieved correction ($R = 0.87$; $P < 0.0005$). Thirteen eyes (59.1%) were corrected within ± 0.50 D of emmetropia, and 18 eyes (81.8%) were corrected within ± 1.00 D. All eyes were within ± 2.00 D of intended correction and emmetropia throughout the investigation. Four eyes required lenses stronger than what was available (from +12.50 to +14.70 D). Five other eyes would have benefited from half-diopter incremented lenses, which were not being manufactured at the time of surgery, so that the intended refraction of 2 eyes was -0.50 D and the intended refraction of 3 eyes was +0.50 D. Three eyes whose preoperative refraction was more than +12.00 D achieved a final refraction of more than +1.00 D. There were no correlations between predictability and the following: preoperative refraction, axial length, anterior chamber depth, and endothelial cell counts.

The spherical refraction of the four patients who attended every check-up averaged -0.22 ± 0.76 after 1 month, -0.23 ± 0.86 D at 3 months, -0.09 ± 0.72 D at 6 months, -0.11 ± 0.72 D at 1

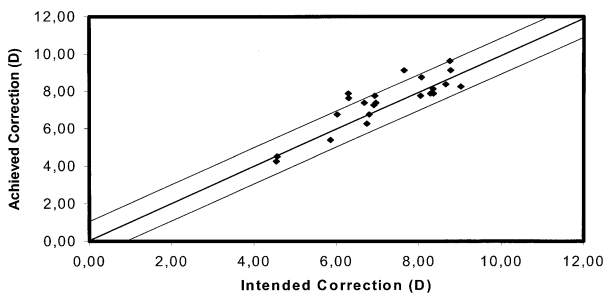


Figure 2. Intended versus achieved correction 6 months after deviation from attempted correction in 22 eyes after the implantation of the Artisan Hyperopia phakic intraocular lens (model 203W; Ophtec, Groningen, The Netherlands).

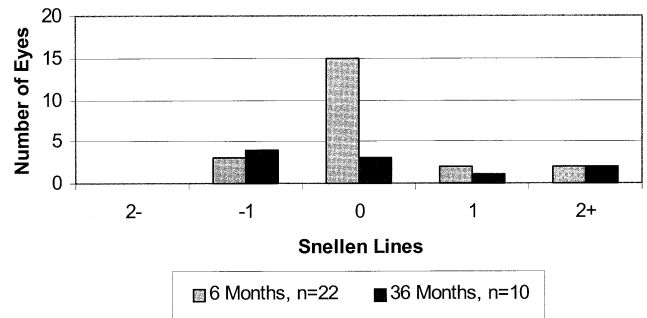


Figure 3. Gain and loss of Snellen lines change in best spectacle-corrected visual acuity after implantation of the Artisan phakic intraocular lens (model 203W; Ophtec, Groningen, The Netherlands). There were no significant loss of Snellen lines (loss of two or more lines) throughout the investigation.

year, -0.27 ± 0.99 at 2 years, and -0.05 ± 0.85 D at 3 years (Fig 1).

Visual Acuity

Mean preoperative BSCVA was 0.86 ± 0.59. After surgery, the average BSCVAs were 0.86 ± 0.67 at 1 month, 0.82 ± 0.65 at 3 months, 0.87 ± 0.67 6 months, 0.82 ± 0.27 at 1 year, 0.82 ± 0.59 2 years, and 0.75 ± 0.52 at 3 years (Table 1). There were no significant differences between the preoperative and postoperative BSCVAs.

Postoperative BSCVA was unchanged or better in 80.8% of the eyes (21 eyes) at 1 month, 85.7% (18 eyes) at 3 months, 86.4% (19 eyes) at 6 months, 82.4% (14 eyes) at 1 year, 80.0% (12 eyes) at 2 years, and 50.0% (5 eyes) at 3 years. Figure 3 shows the number of Snellen lines gained and lost at 6 months and 3 years after surgery. No eyes lost 2 or more lines throughout our investigation.

A BSCVA of 0.50 or better was achieved by 92.3% of the eyes (24 eyes) at 1 month, 95.2% (20 eyes) at 3 months, 95.5% (21 eyes) at 6 months, and 94.1% (16 eyes) at 1 year. In the second year, 93.3% (14 eyes) could see equal to or better than 0.50, and 80.0% (8 eyes) could see equal to or better than 0.50 in the third year (Table 1). A BSCVA of 1.00 or better was achieved by 73.1% of the eyes (19 eyes) at 1 month, 57.1% (12 eyes) at 3 months, 50% (11 eyes) at 6 months, 58.8% (10 eyes) at 1 year, 60.0% (9 eyes) at 2 years, and 40.0% (4 eyes) at 3 years.

The average UCVA was 0.73 ± 0.68 at 1 month, 0.66 ± 0.66 at 3 months, 0.65 ± 0.65 D at 6 months, 0.63 ± 0.62 at 1 year, 0.59 ± 0.60 at 2 years, and 0.58 ± 0.57 at 3 years. There were no significant differences in UCVA among the different time periods (Table 1).

Six months after surgery, 20 eyes (90.9%) could see 0.50 or better uncorrected, and 5 eyes (22.7%) could see 1.00 or better.

Endothelium

Up to and including the first year after the procedure, we noted gains in the postoperative corneal endothelial counts ranging from 1.0% to 3.8%. After 2 years, there was a decrease of 8.5% from the mean preoperative cell count, and there was a decrease of 11.7% after 3 years. There was a significant loss of endothelial cells between the 3-year postoperative endothelial cell count and 1-month and 1-year postoperative cell counts, even when we corrected for different patient groups ($P < 0.05$). However, there were no significant differences between the preoperative and any of the postoperative results. We found a significant negative cor-

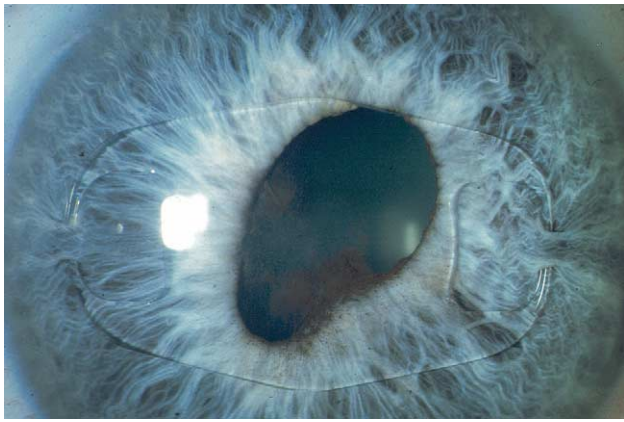


Figure 4. A dilated pupil with pigment dispersion on the crystalline lens and posterior synechiae from 4 o'clock to 5 o'clock and again from 7 o'clock to 11 o'clock.

relation between endothelial cell loss and the depth of the anterior chamber at 3 months ($P < 0.05$) and 2 years ($P < 0.01$). Although a trend toward this was also present in the other time periods, results were not significant. Before surgery, there was no correlation between the endothelial cell count and anterior chamber depth ($P = 0.45$).

Complications

Two patients experienced posterior synechiae and pigment cell deposits on the crystalline lens of both eyes 2 weeks after surgery. Patient 1, 49 years of age, experienced no clinical symptoms and remained stable all 3 years (Fig 4). Patient 2, 59.5 years of age, experienced posterior synechiae at nearly all clock hours with a fixed pupil size of 2.5 mm. She described her vision as "like looking through a pinhole," although her BSCVA remained at 1.00 (Fig 5). She chose to have the lenses removed, and underwent clear lens extractions in both eyes; the first eye 4 months after the initial intervention, and the second after 2 years.

None of the 13 patients reported halos or glare in either eye.

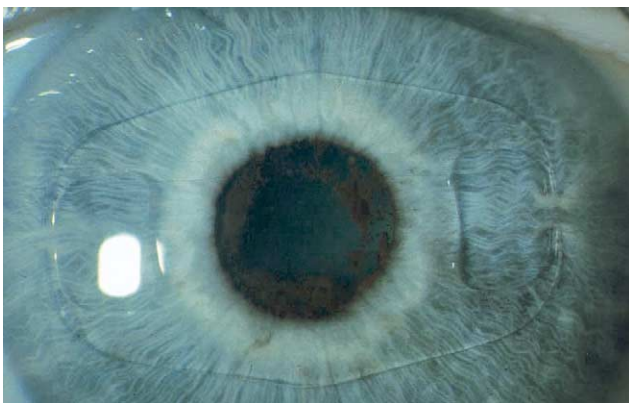


Figure 5. Pigment dispersion on the crystalline lens and posterior synechiae encircling the pupil. This patient subsequently underwent implant removal and a clear lens extraction and thereafter, a posterior chamber lens implantation in both eyes.

Discussion

We achieved a predictability of 88.5% (23 of 26 eyes) within 1.00 D of intended correction. Only 2 eyes of a patient (1.79 D and 1.45 D of overcorrection) and a single eye of another patient (1.49 D of overcorrection) were not within ± 1.00 D of intended correction. The individual overcorrected in both eyes did have the longest axial length and the third deepest anterior chamber from all the patients; however, neither of these factors nor a ratio thereof showed a correlation with predictability. We believe, therefore, that other yet unknown factors may play an important role in determining the postoperative refractive outcome.

Compromises in correction are a general problem encountered with all lens implants. In our case, the Artisan lens is produced minimally in half-diopter increments and up to a maximum of +12.00 D. Nine of 26 eyes were not fitted with lenses that would have ideally corrected their vision. The 4 eyes that required lenses stronger than that available were the most undercorrected (postoperative spherical refraction between +0.63 and +1.38 D). Patients requiring corrections of smaller increments had to settle for a minor overcorrection or undercorrection. Nonetheless, at 6 months, 20 of the 22 eyes (90.9%) requiring lenses up to +12.00 D saw within ± 1.00 D of emmetropia.

The mean spherical equivalent remained within 0.25 D during the 3 years of follow-up. However, because not all patients were present at each of the examinations and their follow-up was not of equal length, we decided to examine 8 eyes of 4 patients who were present at every follow-up examination. The greatest difference we found among this group was 0.22 D between years 2 and 3. Three of the 8 eyes (3 of 4 patients) increased in refraction (two from -1.00 to -0.50 D and one from emmetropia to +0.75 D). One of these patients, however, did not experience a reduction in visual acuity in the same time frame. A longer follow-up may be required to determine the cause of this change.

All but a single patient had a postoperative BSCVA 0.5 or higher until the third year of the investigation, when the BSCVA of another patient dropped from 0.5 to 0.4 (from a preoperative 0.5). The one patient who remained at less than 0.5 throughout the investigation was amblyopic. Her preoperative BSCVA was 0.1 and improved to 0.2 after phakic IOL implantation.

The mean postoperative BSCVA at every examination period was better than the mean preoperative BSCVA, indicating that, on average, the Artisan Hyperopia phakic IOL improved the BSCVA. Comparing the mean postoperative UCVA to the preoperative BSCVA led to less positive results and indicated that many patients still benefited from glasses or contact lenses after acquiring the implant. As mentioned before, ideal corrections were hampered by the availability of the lens of the exact corrective error. More importantly, however, is that hyperopic patients experience a smaller image size when their refraction is corrected, thereby limiting postoperative BSCVA improvement. This may explain why patients implanted with the Artisan lens for myopia saw, on average, better without correction after

surgery than they did before surgery with correction and that the hyperopic patients did not.⁶⁻⁸

The Artisan lens maintains a relatively favorable position in the eye. As long as the anterior chamber is deep enough, the lens keeps a healthy distance from the corneal endothelium and avoids the posterior chamber completely. Still, anterior chamber implants do run the risk of damaging the corneal endothelial layer, mostly through intraoperative trauma or through rubbing of the eyes. There were no significant differences between preoperative and postoperative endothelial cell counts in our study, even after correcting for different groups of patients. Nevertheless, our investigation did indicate a loss of 11.7% after 3 years. Even after correcting for a naturally occurring decrease of 0.6% a year, endothelial cell loss remained high (10.1% after 3 years), indicating that endothelial cell loss remains a cause for concern. Also, we found a significant negative correlation between endothelial cell loss and the anterior chamber depth at 3 and 24 months, although not at any other period. The increased loss of cells in shallower anterior chambers may have been the result of the endothelium undergoing more trauma during the implantation process and thereafter, although the inconsistencies among the different periods and in the endothelial counts themselves indicate that further investigation is required. Nevertheless, we propose that a minimum anterior chamber depth of 3.00 mm be incorporated in the inclusion criteria, instead of the current 2.6 mm recommended by the manufacturer. Fechner et al¹¹ made same recommendation when studying a similar iris-fixed lens and further suggested a minimum anterior chamber depth of 3.5 mm in younger patients, considering that the depth decreases with increasing age.¹⁴ This may prevent endothelial damage during surgery and the complications mentioned above.

The most serious complication we encountered was the appearance of pigment deposits on the crystalline lens of both eyes of two patients, along with posterior synechiae. We found that the asymptomatic patient, patient 1, had convex irides. The constant contact of the lens with the iris could have created the complication. We could not find a satisfactory explanation for the synechiae of patient 2 because ophthalmologic examination showed no further abnormalities and surgery had proceeded without any complications. The anterior chamber depths and axial lengths of their eyes were at neither extremes of the ranges measured within our group of patients. Patient 1 had an anterior chamber depth of 3.30 mm in both eyes and an axial length of 20.60 and 21.20 mm in the left and right eye, respectively. Patient 2 had an anterior chamber depth of 3.00 mm in both eyes with axial lengths measuring 21.10 and 21.40 mm in the respective left and right eyes. The only common factor between the 2 patients is that they were both operated under general anesthesia; however, four other patients with the same form of anesthesia did not experience this complication. During the American Food and Drug Administration trials of the same lens, 2 of the 14 eyes taking part in the study experienced analogous problems. Furthermore, an eye had a fibrin pupillary membrane 6 weeks after surgery. These complications were ascribed mainly to the implantation procedure (unpublished). These findings emphasize

that special care should be taken to avoid disturbing the internal structures of the eye during surgery and that careful preoperative screening is required with hyperopic eyes, which tend to be smaller, have shallow anterior chambers, and have a higher frequency of convex irides. After we began regarding convex irides as a contraindication, we no longer encountered such complications. We also advise that iris abnormalities, such as convex irides, likewise be considered contraindications for anterior chamber lenses in general.

Conclusions

The Artisan Hyperopic phakic IOL provides predictable, stable, and efficacious results in patients with high degrees of refractive error, with minimal loss of BSCVA. Strict patient screening is necessary to prevent complications. Further study on long-term complications, endothelial cell loss, and stability with a greater number of eyes is required.

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