Long-term Results of Correction of High Myopia With an Iris Claw Phakic Intraocular Lens

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ABSTRACT

PURPOSE: Anterior chamber phakic intraocular lenses (PIOLs) are one of the modalities used to correct high myopia. We report the long-term results of our prospective study on the Artisan 5-mm optic myopia lens.

METHODS: We studied 67 eyes of 38 consecutive patients with preoperative myopia ranging from -5.38 to -28.00 D. All patients were operated by one surgeon. Mean follow-up was 35 months (24 months in 67 eyes and 36 months in 61 eyes).

RESULTS: In 45 eyes (67.2%), postoperative residual refraction was within ±1.00 D of emmetropia. The mean refraction was stable statistically during the entire follow-up period. Mean best spectacle-corrected visual acuity improved from 20/40 to 20/32. Mean endothelial cell loss at 6 months was 5.5% (range, -52.4% to +9.3%), at 12 months, 7.21% (range, -53.2% to +20.1%), at 24 months, 9.1% (range -43.6% to +13.6%), and at 36 months, 10.9% (range, -43.0% to +11.4%). The majority of eyes had an increase in best spectacle-corrected visual acuity; 5 eyes lost best spectacle-corrected visual acuity. We encountered no major complications.

CONCLUSION: Implanting the Artisan 5-mm optic myopia lens in high myopic eyes resulted in a stable and accurate refractive outcome. The apparent progressive corneal endothelial cell loss remains a matter of concern. [*J Refract Surg* 2000;16:310-316]

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Over the last few years, phakic anterior chamber lenses for correction of high myopia have been implanted with satisfactory refractive results.[1-4] In 1986, Worst and Fechner modified the existing iris claw lens for aphakia (used in cataract surgery) into a negatively biconcave lens, to be used in high myopic phakic eyes. This new Worst-Fechner lens had an optic diameter of 4.5 mm, and a few hundred of these lenses were implanted with good refractive results.[5-10] To increase the safety of this phakic intraocular lens (PIOL), the optical part was altered into a convex-concave shape in 1991 and the diameter of the optical part was increased to 5.0 mm, to reduce halos and glare. This new lens, called the Worst myopia claw lens, has been implanted successfully ever since.[11,12] In 1998, the name of the lens was changed to the Artisan myopia lens, without a change in lens design; it still has a convex-concave optical part. It is also available in 6-mm diameter for all powers up to -15.50 diopters (D). In 1995, we published the preliminary results of our prospective study on the implantation of the convex-concave 5-mm diameter Worst myopia claw lens in high myopes.[11] Because most of these patients have now been followed for 3 years, we present current results.

PATIENTS AND METHODS

Patients

This prospective study consists of consecutive cases operated in Stadskanaal, The Netherlands, by the same experienced surgeon (JGFW). Patients were sent to the Department of Ophthalmology at the University Clinic in Groningen for independent preoperative and postoperative examinations. Each patient was informed of the investigative nature of the procedure and received a detailed oral and written informed consent, in accordance with the

Table 1
Refraction in 67 Eyes Before Implantation of Artisan Anterior Chamber PIOL

No. Eyes (n=67)	Refraction (D)
15	-5.38 to -10.00
26	-10.12 to -15.00
19	-15.12 to -20.00
7	-20.12 to -28.00

Helsinki Declaration. The study was approved by the medical ethics board of Refaja Hospital in Stadskanaal.

A total of 73 eyes of 38 patients were operated, but for this report we excluded patients who were lost to follow-up early in the study. Therefore, the final study group was comprised of 67 eyes (92% of the original population) of 36 patients (95%; 20 men and 16 women). Patient age ranged from 17 to 52 years (mean, 35.4 ± 9.7 yr). Preoperative refraction ranged from -5.40 to -28.00 D, of which the majority had myopia between -10.12 and -20.00 D (Table 1). The follow-up period was 24 months in 67 eyes and 36 months in 61 eyes (86%).

Artisan Myopia Claw Lens

The convex-concave Artisan myopia lens used in this study is made of one-piece clinical quality ultraviolet absorbing polymethylmethacrylate, and is manufactured by OPHTEC B.V. in Groningen, The Netherlands. For any amount of correction, the total length of the lens used in this study was 8.5 mm with an optic 5 mm in diameter. The vault height of the lens did not exceed 0.96 mm, regardless of its power. The lens power at the time the patients were operated ranged from -5.00 to -20.00 D and was manufactured in steps of 1.00 D. The two diametrically opposed haptics fixated the lens on the iris by enclavation of midperipheral iris stroma.

Surgical Technique and Medication

For more details about the surgical technique, we refer to a publication in 1998.[13] In short, the technique consisted of a corneoscleral incision of 6 mm at 12 o'clock. The anterior chamber was filled with a viscoelastic substance, sodium hyaluronate (Healon, Kabi Pharmacia, Stockholm, Sweden) before implanting the lens. The lens was inserted in the anterior chamber with a special implantation forceps and was then released. The lens was rotated into the horizontal position, bringing the enclavation sites to 3 and 9 o'clock. Small folds of iris tissue were enclavated with the iris "crochet" needle. Subsequently, a peripheral iridectomy was performed. All viscoelastic material was removed carefully with balanced salt solution, after which the incision was closed with 6 to 8 interrupted stainless steel sutures, the surgeon's (JGFW) preferred suture material.

Gentamicin 40 mg with betamethasone 4 mg was injected subconjunctivally immediately after surgery. Postoperatively, tropicamide 1% eye drops and acetazolamide 250 mg tablets were administered in the first two days, timolol 0.5%, and cyclopentolate 1% during the first week, and prednisolone, neomycin, and indomethacin topically during the first 5 weeks.

Clinical Examination

Preoperatively, all eyes were examined by slit-lamp microscopy and funduscopy to exclude any ocular disease, especially glaucoma and maculopathies. Patients with autoimmune disease were excluded. To determine the power of the PIOL, we measured the subjective refraction, the corneal curvature with the Zeiss keratometer, and the anterior chamber depth with ultrasound.

These three parameters were used in the Van der Heijde formula.[14] To determine the predictability of the refractive outcome we converted the Van der Heijde formula in such a way that we could calculate the expected correction for each implantation preoperatively. For measurement of visual acuity, we used the modified Bailey-Lovie chart, placed in a box with standardized direct illumination.[15] The visual acuity was expressed in the logarithm of the minimal angle of resolution (logMAR) and was converted into Snellen notation.

For examination of the corneal endothelium, we used a Zeiss non-contact specular microscope in 7 eyes and a Keeler Konan sp-3300 wide-field contact specular microscope in all other eyes, in combination with a video camera and a frame grabber. Because of technical difficulties later in the study, all eyes were examined with a noncontact autofocus camera, Konan Noncon Robo-ca sp 8000, from the beginning of 1995. We adjusted the outcome for the difference compared with the other cameras.[16] Three images were made of each eye during each session and were processed. The weighted average of the three processed images are presented as the mean endothelial cell density.

Follow-up examinations were done at 24 hours, 1 week, 2 to 4 weeks, 2 to 4 months, 6 months, and 12 months. After that, patients were examined annually. Patients with complications were examined more frequently. Specular microscopy was

Table 2
Refractive Outcome in 67 Eyes After Implantation of Artisan Anterior Chamber PIOL

Spherical Equivalent Refraction (D)	No. Eyes With Residual Refractive Error	No. Eyes With a Difference From Calculated Outcome
> +3.10	0	0
+2.12 to +3.00	1	0
+1.12 to +2.00	2	2
+1.00 to +0.62	1	9
+0.50 to +0.12	6	13
-0.50 to -0.00	26	9
-0.51 to -1.00	12	8
-1.12 to -2.00	8	9
-2.12 to -3.00	5	5
> -3.00	6	2

performed after 2 to 4 months, at 6 and 12 months, and then annually. Postoperative examinations included slit-lamp microscopy, applanation tonometry, manifest refraction, and best spectacle-corrected and uncorrected visual acuity.

All patients were asked to respond subjectively about satisfaction with their visual outcome. Statistical calculations were performed with SPSS 8.0 for Windows. A two-tailed probability of 0.05 or less was considered statistically significant.

RESULTS

Refraction and Visual Acuity

Mean spherical equivalent refraction was -14.70 ± 4.90 D preoperatively, -0.79 ± 2.20 D after 6 months, -0.92 ± 2.30 D after 12 months, -1.12 ± 2.10 D after 24 months, and -1.05 ± 2.20 D after 36 months. In Figure 1, we show individual refractive outcome in a scattergram. In 45 eyes (67.2%), postoperative spherical equivalent residual myopia was within ±1.00 D of emmetropia (Table 2). Undercorrection exceding 2.00 D occurred in 11 eyes (16.4 %); in 1 eye an overcorrection of more than 2.00 D was observed.

In Figure 2, we plotted the time course of the mean postoperative refraction. The analysis of variance (ANOVA) test did not show any significant differences over time ($P = .12$). In 7 eyes, the postoperative refraction changed by 1.00 D or more. In one eye, a severe change in refraction was due to the development of a nuclear cataract.

Figure 3 shows deviation of achieved correction from calculated correction for each eye. The mean deviation of refractive outcome was -0.16 D (range, -5.18 to +2.82 D). The difference around the calculated outcome was within ±1.00 D in 39 eyes (58.0%) (Table 2). The 95% confidence interval of deviation in predicted outcome was between -0.51 and +0.19 D.

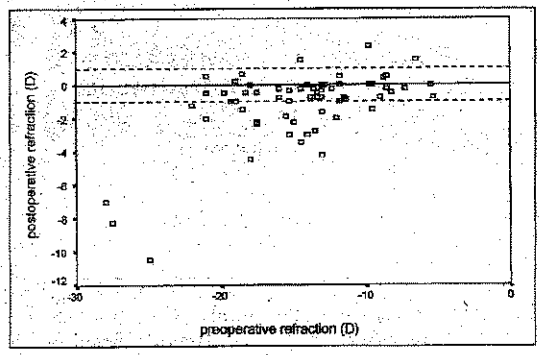

Figure 1. Postoperative refraction at the last follow-up examination after implantation of Artisan myopia PIOL. (X-axis orientation: numbers go from largest to smallest, left to right.)

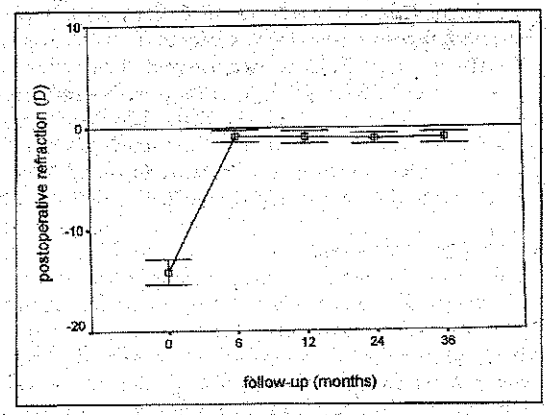

Figure 2. Time course of postoperative refraction over a 3-year follow-up period after implantation of Artisan myopia PIOL. (SD at 6 mo, 2.20 D; at 12 mo, 2.30 D; at 24 mo, 2.10 D; at 36 mo, 2.20 D.)

Mean spectacle-corrected visual acuity for all eyes improved from 20/40 preoperatively to 20/32 postoperatively. Mean postoperative uncorrected visual acuity was 20/50. The cumulative number of eyes with an uncorrected visual acuity of 20/20 or better was 8 (12.1%), 20/25 or better in 10 eyes (15.2%), 20/30 or better in 22 eyes (33.3%), and 20/40 or better in 27 eyes (40.9%). Spectacle-corrected visual acuity was 20/20 or better in 16 eyes (23.9%), 20/25 or better in 28 eyes (53.7%), 20/30 or better in 52 eyes (77.6%), and 20/40 or better in 55 eyes (82.1%).

Change in best spectacle-corrected visual acuity showed an increase of one Snellen line or more in

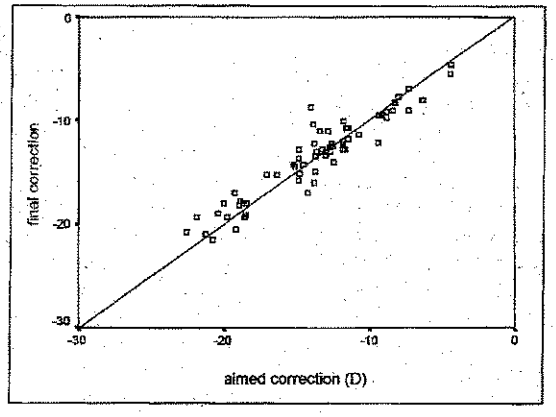

Figure 3. Deviation from attempted correction in eyes after implantation of Artisan myopia PIOL. (X-axis orientation: numbers go from largest to smallest, left to right.)

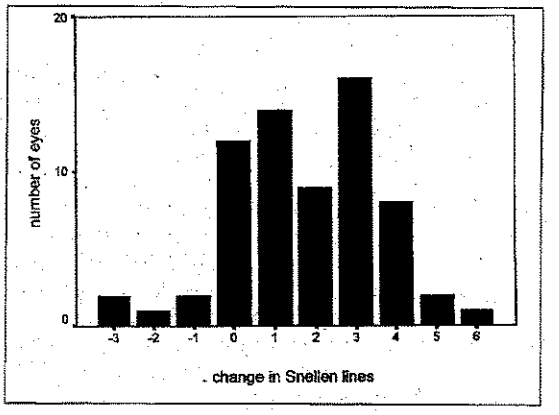

Figure 4. Change in best spectacle-corrected visual acuity after implantation of Artisan myopia PIOL.

the majority of the eyes (Fig 4). In 5 eyes, we observed a loss of best spectacle-corrected visual acuity by one line or more. In two eyes this was due to cataract formation. In the remaining eyes, we could not find a cause.

Corneal Endothelium

Figure 5 shows the mean corneal endothelial cell loss over the entire follow-up period. We corrected the measured cell loss with the predicted cell loss from aging—0.6% per year.[17] The mean cell loss in all 67 eyes was 5.5% at 6 months (range, -52.4% to +9.3%), 7.2% at 12 months (range, -53.2% to +20.1%), 9.1% at 24 months (range, -43.6% to +13.6%), and 10.9% at 36 months (range, -43.0% to +11.4%). The cell loss during the entire 3-year follow-up period is statistically significantly progressive (ANOVA, $P = .0001$).

The mean anterior chamber depth of these 67 eyes was 3.7 mm (range, 3.1 to 4.3 mm). We did not find any correlation between the anterior chamber depth and the amount of cell loss. Because 23 patients wore contact lenses previously, we tested to determine if the cell loss was significantly different. At 36 months, mean cell loss in contact lens wearers was 11.0% (range, -43.0 to +11.4%), and in non-contact lens wearers 9.9% (range, -24.7% to +5.1%), which was not significantly different (Student's t-test, $P = .63$).

Complications

Examination by slit-lamp microscopy revealed no apparent flare in the anterior chamber, nor did we see damage to the iris tissue. During surgery, we

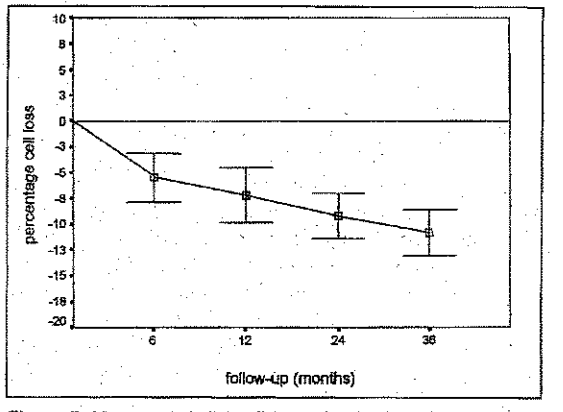

Figure 5. Mean endothelial cell loss after implantation of Artisan myopia PIOL, corrected for mean cell loss due to aging of 0.6% per year. (SD at 6 mo, 9.1%; at 12 mo, 10.2%; at 24 mo, 8.9%; at 36 mo, 8.6%.)

noticed corneal endothelial touch in one eye. The preoperative cell count was 2851 cells/mm^2 and the postoperative cell count was 1351 cells/mm^2 at 12 months, 1571 cells/mm^2 at 24 months, and 1569 cells/mm^2 at 36 months—a surgically induced and stable cell loss.

In one eye the PIOL had to be recentered 4 months after surgery because of distorted images. Unfortunately, we could not perform endothelial cell counting prior to the second surgical intervention, but the mean endothelial cell densities preoperatively and 36 months postoperatively were 3274 cells/mm^2 and 2441 cells/mm^2, respectively.

One patient had a blunt trauma to his left eye 4.5 months after surgery, without any obvious ocular damage. The endothelial cell counts in this eye

were 3751 cells/mm^2 preoperatively, 3385 cells/mm^2 after 6 months, 3332 cells/mm^2 after 12 months, 3190 cells/mm^2 after 24 months, and 3025 cells/mm^2 after 36 months.

In the left eye of another patient a severe inflammatory reaction in the anterior chamber was observed during the early postoperative period, which disappeared during the first week after medical treatment. The mean endothelial cell loss at 24 months in this patient was 19.2%. One patient had increased postoperative intraocular pressure in both eyes of 26 and 28 mmHg, which normalized after treatment and discontination of topical corticosteriods. One patient, 50 years old, developed a nuclear cataract 3 years after surgery in both eyes.

In total, 8 patients (22.2%) complained of seeing halos at night. Two of these patients were disturbed by this enough that they sometimes use pilocarpine 0.5 % at night. Only one patient complained of glare. In general, the patients were very satisfied with the results. On a scale of 1 to 10 (1—very poor, and 10—excellent), the mean satisfaction score for visual outcome in these patients was 7.9 (range, 5 to 10).

DISCUSSION

There are a variety of surgical procedures to treat high myopia. Sophisticated keratorefractive surgical techniques to correct high myopia, such as epikeratoplasty, keratomileusis, and excimer laser photorefractive keratectomy (PRK), have shown unpredictable results in refractive outcome, refractive regression, and even scar formation.[3,4] The results of LASIK seem promising[18-20], but correcting high myopia gives unsatisfactory results.[21] Clear lensectomy to correct high myopia is another surgical modality, but is still considered controversial[22,23], due to the increased incidence of retinal detachment in patients with high myopia. The incidence of retinal detachment in different studies on clear lens extraction varies between 1.9%[22] and 7.3%.[23] Another problem with this type of surgery is the development of posterior capsule opacification, which was described in 36.7%[23] of eyes, and the loss of accommodation in young patients.

The use of PIOLs in high myopia has a well-defined advantage over corneal procedures in terms of refractive outcome. The high percentage of achieved near-emmetropia, as well as accuracy, stability, and predictability of refractive outcome, confirm findings of other investigations on phakic anterior chamber lenses.[4-13] These results support the use of PIOLs for the correction of moderate to high refractive errors. However, the potential risks of these lenses need to be evaluated before using them on a large scale.

The surgeon (JGF Worst) in this study had much experience in implanting the claw lens in aphakia, the biconcave Worst-Fechner PIOL, and the Artisan myopia lens, so there was no learning curve that could influence the results on the effect on the corenal endothelium. In our population group the mean endothelial cell loss was 5.5% after 6 months, 7.12% after 1 year, 9.1% after 2 years, and 10.9% after 3 years. There seems to be progressive endothelial cell loss, therefore we want to follow these patients for a longer period of time to examine whether cell loss will stabilize after 3 years, as was seen in a long-term study on phacoemulsification.[24] However, because we were forced to use different techniques for endothelial cell counting, these results might not be as accurate. A study by Menezo and colleagues[25] on both the biconcave Worst-Fechner and the convex-concave Artisan myopia lenses together showed a cell loss of 7.9% at 1 year, 11.8% at 2 years, 13.4% at 3 years, 15.8% at 4 years, and 17.9% at 5 years. It is not clear whether the natural aging of the endothelium was taken into account in this study. In a study on the biconcave Worst-Fechner lens[8,9], severe endothelial cell loss was encountered in three eyes that subsequently required corneal transplantation. Certain studies on angle-supported phakic anterior chamber lenses reported a marked decrease in cell density after 1 year with a mean cell loss of 16.6%, ranging from 0 to 53.2%.[26,27] However, Baikoff and colleagues[21] observed a cell loss of 4.5% at 1 year and 5.5% at 3 years in patients with a newer type of angle-supported PIOL. Another study[29] on this type of lens showed a cell loss of 7.5% at 3 years with a progressive cell loss that varied between 0.3% to 0.6% yearly, up to 7 years postoperative.

Although we did not detect flare in our patients by microscopy, anterior chamber lenses may lead to important blood-aqueous-barrier changes due to the fixation on the iris or pressure of the footplates on the iris root. This can produce subclinical uveitis, which may cause chronic endothelial cell loss.[30] Nonetheless, a retrospective study[31] on the protein and the cell concentrations in the anterior chamber of eyes with a biconcave Worst-Fechner lens did not show a significantly raised protein concentration or elevated concentrations of cells. Iris angiography on a subgroup of patients with an Artisan myopia lens[12] did not show any leakage in the anterior chamber. Because we could not perform laser flare photometry, the concern about an ongoing

inflammatory response creating chronic progressive endothelial cell loss in these phakic anterior chamber lenses[30,32] can only be excluded in our patient population by a long-term study on the endothelium.

Damage to the iris has been described in both iris-fixated and angle-supported PIOLs. In our study, we have not noticed any sign of iris atrophy or other abnormalities at the enclavation sites. However, others[25] reported iris damage in 4.2% of 94 eyes. Several authors[26,29] have described specific complications in patients with an angle-supported lens, such as inflammatory reactions, pupillary deformations, iris atrophy, iris perforation, and adherence of the iris to the footplate. Complications that have been described in iris-fixated PIOLs are early postoperative iritis, iridocyclitis, cystic wounds, temporary increased intraocular pressure, and Urrets-Zavalia syndrome.[4,8,9] An early postoperative inflammatory reaction happened in only one eye of our series. None of the other problems described above have occurred in our patient group. The use of an iridectomy or iridotomy in this type of lens is highly recommended.

Elevated intraocular pressure and pupillary block due to the configuration of the different PIOLS are other possible complications. Only one patient in our study had transient raised intraocular pressure in both eyes in the immediate postoperative period that normalized after discontinuation of topical corticosteroids. The percentage of raised intraocular pressure in other studies was 5.3%[25] and 16%.[8] Studies on the angle-supported and posterior chamber PIOL describe increased intraocular pressure in 7.2%[29] and pupillary block in 4.8%[33] of cases.

We do not think that the nuclear cataract that developed in one patient after 3 years can be ascribed to the PIOL itself, because there was no opacification of the anterior capsule, nor did we see cataract formation in the other eyes. One can imagine that during implantation, the anterior capsule of the crystalline lens might have been touched by the intraocular lens. In a study by Menezo and colleagues[21] on the Artisan myopia lens, no cataract formation was noticed.

High myopia may cause blinding complications, even when these eyes are not operated. One of the serious complications that has been related to phakic anterior chamber lenses is retinal detachment; the exact incidence and prevalence of retinal detachment is unknown. An incidence up to 0.8%[8,9] was reported when using the iris-fixated type of PIOL. With other models of PIOLs, retinal detachment has been reported in 0.8%[31], and 0.6%[4] of cases. An expectation of 4.5% of retinal detachment in angle-supported lenses at 79 months was described in another study.[29] In our group of 67 eyes, we have not encountered a retinal detachment in 3 years, nor did Menezo and coworkers[25] in their study of 94 eyes up to 72 months postoperative.

Night halos and glare were reported in 25% of our patients. Only three patients (8.3%) were significantly hindered by halos, and two of these patients use pilocarpine on occasion. A perfect lens centration of the Artisan myopia lens is technically difficult because it involves good enclavation of the iris on both sides. We think that when the lens is slightly decentered toward 12 o'clock, patients experience more halos or glare. Also, large pupil sizes can be responsible for these visual effects at night. To diminish these problems, the optical part of the lens has been enlarged to 6 mm in diameter for lenses up to a power of -15.00 D, since 1998.

Our study supports the satisfactory refractive outcome of phakic anterior chamber lenses in terms of predictability and stability. Of course, the main study subject of this procedure is its safety. The technique remains an intraocular surgical procedure with potential risks. In our series, no major complication occurred, nor did we have to explant any of the lenses. Patients will be followed as long as possible and we hope to report 5-year data.

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