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U.S. Clinical investigation of the Artisan™ myopia lens for the correction of high myopia in phakic eyes

Report of the results of Phases 1 and 2, and Interim Phase 3

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Purpose: The purpose of this article is to present the results of the U.S. Clinical investigation of the Artisan™ anterior chamber iris fixed lens implant for the correction of myopia in phakic eyes.

Methods: A prospective, multi-center, FDA-supervised trial was designed and undertaken in the United States by Ophtec USA, Inc., Boca Raton, Florida to determine the safety and efficacy of the Artisan lens as a potential refractive treatment for patients with high myopia. During the trial, two different models of the Artisan lens were used: one with a 5-mm optical zone (model 206) and the other with a 6-mm optical zone (model 204).

Results: The data presented comprise 176 enrolled subjects and 264 implant procedures. The most frequently chosen Artisan lens power was – 13.00 D (average, – 12.76 D, SD, 3.24). The postoperative results at 6 months for all eyes ($n = 135$) showed 100% of patients were 20/40 or better best-corrected while 72% gained one or more lines and 22% gained two or more lines regardless of degree of astigmatism or postoperative goal. Through the course of the study, intraocular pressure maintained a level with a mean below 16 mmHg. In general, total reported complications in the patient cohort decreased over time, dropping from 39% at the initial visit to 10% at visit four and 0% at visit seven.

Conclusions: On the basis of the interim results of the U.S. Clinical Investigation of the Artisan Myopia Lens for the Correction of High Myopia in Phakic Eyes, the Artisan anterior chamber phakic IOL may offer an option for correction of high degrees of myopia. Refractive outcomes were exceptional and complications were minimal and amenable to treatment.

Key Words: Myopia, phakic eye, refractive treatment

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Refractive surgery is becoming a relatively common procedure, with Laser *in situ* keratomileusis (LASIK) appearing to take the lead. There are, however, limitations to laser-assisted refractive surgery, primarily in the zones of high refractive errors. The limitations and complications to LASIK are listed in Box 1. The primary complications of photorefractive keratectomy (PRK) involve corneal scarring and extended recovery times.

While improvements will undoubtedly be made in LASIK and other excimer procedures, currently phakic intraocular lenses may offer an alternative for high refractive errors while possibly eliminating the limitations and complications of LASIK refractive surgery. Certainly, phakic intraocular lenses (IOLs) have their own set of complications and limitations that are very dependent, in part, on lens design and surgeon experience. Reported complications of phakic IOLs include glaucoma and angle closure, retinal detachment, endophthalmitis, cataract, resultant pupillary anomalies, chronic subclinical inflammation, and corneal compromise and decompensation.[1-18]

The design of phakic intraocular lenses varies. Anterior chamber lenses include the NuVita lens from Bausch and Lomb Surgical and the Artisan™ lens from Ophtec USA, Inc. The NuVita is a Kelman-style lens and is relatively easy to insert using a standard technique.[19] Pupillary anomalies and fibrosis in the angle present potential complications.[19] Posterior chamber lenses include the Staar surgical lens, which is placed between the iris and anterior lens surface. The Staar lens is foldable, allowing insertion through a small incision. This lens may chafe the iris, creating pigment dispersion, and may compromise the capsule by physical contact creating the possibility of lenticular opacification.[14,15,20-22] The posterior

Some limitations and complications of LASIK refractive surgery[40-50]

Accuracy of LASIK more effective in low *versus* high myopia[40-42]
Corneal ectasia may occur in high myopia because of corneal thinning[43-45]
Glare is more common in high myopia[46]
Quality of vision is less in LASIK-corrected high myopia versus low myopia[47]
Irregular cuts, buttonholes, free cuts, incomplete cap, epithelial defects, flap dislocation, peripheral epithelial ingrowth, wrinkled flap, diffuse lamellar keratopathy, central corneal islands[46,48]
Loss of best-corrected visual acuity[50]

LASIK, Laser *in situ* keratomileusis.

Box 1

chamber lens does, however, minimize the risk for corneal endothelial chafing. Iris-supported anterior chamber lenses offer another possibility, but also carry the baggage of a tainted history. Early iris-fixated lenses for the correction of surgical aphakia attached to the mobile pupillary margin for the correction of aphakia carried an increased risk of cystoid macular edema and corneal decompensation.[23,24] The Artisan lens is a variation of the iris-supported phakic anterior chamber lens, used for refractive correction.

The Artisan lens for correction of high myopia evolved from the Iris Claw Lens, originally developed by Jan G.F. Worst, M.D. for the correction of surgical aphakia. The lens is compression molded and lathe cut from polymethylmethacrylate. The lens has been implanted in approximately 300,000 aphakic eyes worldwide, after being introduced in 1978. Phakic intraocular Worst lenses were first modified and used in 1986. In 1991, the configuration of the original biconcave lens was changed to a convex-concave design. In 1998, the Worst myopia claw lens was changed to the Artisan myopia lens. The Artisan haptics (fixation arms) attach to the midperipheral immobile iris stroma, allowing relatively unrestricted dilation and constriction of the pupil. The two opposed haptics allow stable fixation over the center of the pupil, with proper surgical technique.[15] The optic vaults approximately 0.87 mm anterior to the iris, allowing exceptional clearance from both the anterior lens capsule and the corneal endothelium. Long-term prospective studies have shown excellent refractive outcomes for the implantation of the Worst lens, with the caution that complications may occur necessitating careful patient followup.[6,11,25-27] A recent report extols the virtues of iris claw phakic intraocular lens implantation for high myopia, followed by LASIK for correction of any residual defect.[28]

A prospective, multicenter, FDA-supervised trial was designed and undertaken in the United States by Ophtec USA, Inc., Boca Raton, Florida, to determine the safety and efficacy of the Artisan lens as a potential refractive treatment for patients with high myopia. Maurice John, M.D. served as the Medical Monitor and Robert Maloney, M.D. served as a co-investigator in the Phase 1 trial. During the trial, two different models of the Artisan lens were used: one with a 5-mm optical zone (model 206) and the other with a 6-mm optical zone (model 204). In Phase 1, all 10 eyes were implanted with the 5-mm zone lens; in Phase 2, patients under – 15.00 D had the option of the 5-mm or 6-mm lens. The patients above – 15.00 D all received the 5-mm lens because the design of the lens dictated that the high error 6-mm lenses would position too close to the corneal endothelium. Lens power, available in 1.00 D steps, was calculated by inserting the spherical equivalent refraction, keratometry, and anterior chamber depth into the Van der Heijde formula.[29]

Materials and Methods

Clinical investigation of the Artisan lens was begun in October 1997 in the United States under FDA supervision. Phase 1 employed two investigational sites: the John-Kenyon Eye Center in Jeffersonville, Indiana and the Jules Stein Eye Institute in Los Angeles, California. Each site was allowed the enrollment of five subject eyes. Phase 1 was completed in March 1998. These subjects were followed for 6 months before requesting the approval of Phase 2. Phase 2 implantation began in June 1998 and was completed in March 1999. Ten total sites—including the John-Kenyon Eye Center—were allowed to enroll 10 subject eyes for implantation. A total of 110 subjects were enrolled through Phase 2. Phase 3 of the study began in April 1999, with a total of 22 sites allowed to enroll another 440 subject eyes to complete the total protocol enrollment of 550 subject eyes. Anticipated completion of Phase 3 is in the summer of 2000.

Characteristics of patients for Phase 1 included myopia from – 8.00 D to – 20.0 D and ages 21 to

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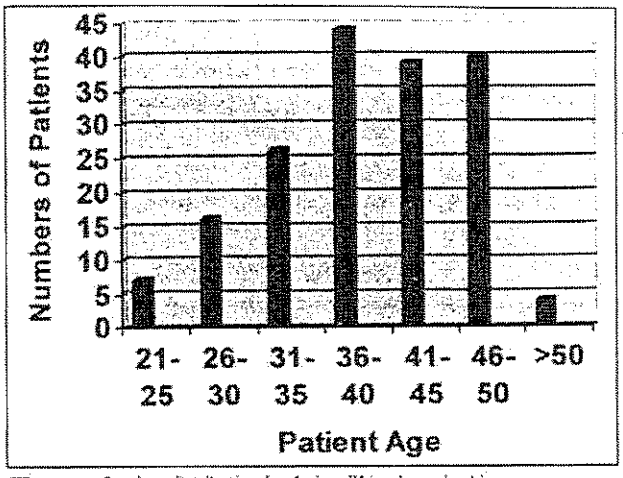

Figure 1 Age distribution for Artisan™-implanted subjects.

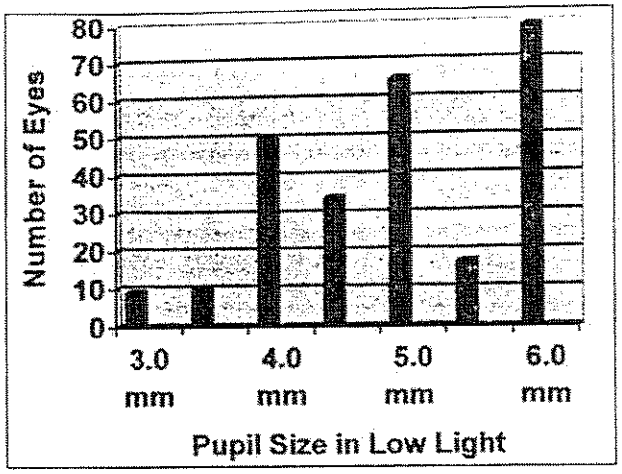

Figure 2 Preoperative "low-light pupil sizes" of subject eyes.

45 years. Other criteria included best spectacle-corrected acuity of 20/40 or better and stability of less than ±0.50 D at 1 month, contact lens or spectacle intolerance, and 2.50 D or less of refractive astigmatism, as measured by manual cycloplegic subjective refraction and projected Snellen acuity. Exclusion was also determined on the basis of current treatment for diabetes; history of retinal detachment or significant retinal pathology; abnormal pupil or iris; pupil under scotopic conditions greater than 6 mm (as measured in the dark with a blue penlight); significant corneal or anterior segment disease; cataract; endothelial cell count less than 2000 cells/mm^2; endothelial dystrophy; anterior chamber depth less than 3.2 mm (as measured by both the Orbscan Corneal Topographer and an A-scan ultrasound instrument); glaucoma or preoperative IOP of greater than 21 mmHg (as measured by applanation tonometry); and previous intraocular surgery. In Phases 2 and 3, the range of myopia was modified to include − 5.00 D to − 20.0 D, with ages extended to 21 to 50 years.

The pre-enrollment examination included a dry and cycloplegic refraction, corneal topography, a complete dilated eye health evaluation, and endothelial cell counts. The patient was then scheduled for implantation. Postoperative examinations were scheduled at 1 day, 2 to 3 weeks, 4 to 8 weeks, 4 to 6 months, 7 to 11 months, 12 to 18 months, and 19 to 24 months.

The patient was then prepared for surgery. A peripheral YAG iridotomy or surgical iridectomy was performed to minimize the postoperative risk of pupillary block glaucoma. A scleral tunnel, limbal-based incision or corneal incision was made—usually in the steep meridian—approximating the lens optic diameter. The lens was then inserted using viscoelastic and then rotated 90 degrees, with the axis of the lens perpendicular to the direction of insertion. The optic of the lens was grasped with the forceps, then a small knuckle of iris was drawn through the "claw" of each haptic with a disposable enclavation needle, striving for pupillary centration. Then the wound was manipulated to minimize postoperative astigmatism by (1) placement of the incision in the steep preoperative axis of astigmatism, by (2) adjustment of the suture tension intraoperatively, or by (3) selective suture removal postoperatively.

Results

Results were compiled for Phase 1, Phase 2, and interim Phase 3 of the FDA-supervised evaluation of the Artisan lens for high myopia. The data analysis was performed with Excel and SPSS for Windows. The data presented comprise 176 enrolled subjects and 264 implant procedures.

Characteristics of the patients follow: Right Eyes Implanted, 127 (48%) and Left Eyes Implanted, 137 (52%); Females, 108 (62%) and Males, 68 (38%); European Americans, 161 (91%), Asian Americans, 8 (5%), African Americans, 2 (1%), Hispanic Americans, 2 (1%), and Other, 3 (2%). Uncorrected visual acuity preoperatively was less than 20/400 in 98.1% of patients, 20/300 in 0.8% of patients, and 20/200 in 1.1% of patients. Best-corrected visual acuity preoperatively was 20/40 or better in 98.4% of subject eyes, but only 20/20 or better in 53.7% of subject eyes. The age distribution is shown in Figure 1 and peaked at ages 36 to 40 years. Patient preoperative pupil sizes in low light illumination are shown in Figure 2, with a high percentage in the 5.0 to 6.0 mm

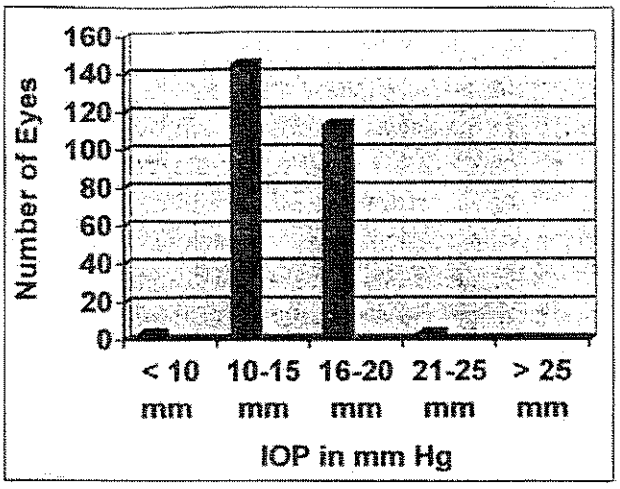

Figure 3 Preoperatie intraocular pressure in mmHg.

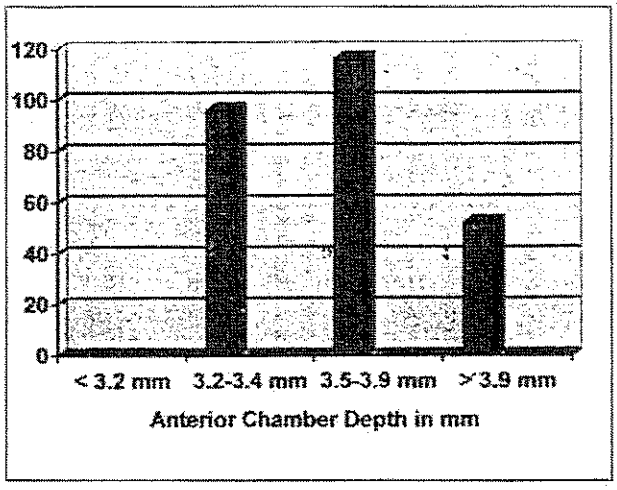

Figure 4 Preoperative anterior chamber depth in mm.

	N	Percentage
Peripheral Iris Procedure Performed		
*Iridectomy	77	29%
*Iridotomy	187	71%
Incision Size in mm		
*< 5.0 mm	0	0%
*5.0-5.4 mm	57	22%
*5.5-5.9 mm	45	17%
*6.0-6.4 mm	143	54%
*> 6.4 mm	19	7%
Incision Type		
*Corneal	84	31%
*Limbal	98	37%
*Scleral	82	32%
Surgical Difficulties		
*Minor	12	4%
*None	252	98%

Figure 5 Operative information within the study.

grouping. Figure 3 shows the preoperative IOP distribution in mmHg, with most eyes having preoperative pressures below 20 mmHg. Figure 4 represents the preoperative anterior chamber depth in mm, with the majority well above the study criteria of 3.2 mm.

Figure 5 summarizes the operative information, including the type of peripheral iris procedure performed to minimize the risk of pupillary block, the incision size in mm, the incision type, and the surgical difficulties encountered. The majority of incisions were 6.0 to 6.4 mm and the distribution of corneal (31%), limbal (37%), or scleral (32%) incisions was almost identical among investigators. Peripheral YAG iridotomies (71%) or surgical iridectomies (29%) were performed on all eyes preoperatively to minimize the risk of IOP spikes due to pupillary block. Only 4% of patients experienced minor surgical difficulties. Figure 6 is a representation of the Artisan myopia lens power chosen for implantation in the 264 subject eyes. The most frequently chosen Artisan lens power was – 13.00 D, with the average at – 12.76 D (with a standard deviation of 3.24).

The postoperative results at 6 months for all eyes (n = 135) showed 100% of patients were 20/40 or better best-corrected, while 72% gained one or more lines and 22% gained two or more lines, regardless of degree of astigmatism or postoperative goal. A total of 83% of 93 eyes were 20/40 or better postoperative uncorrected at 6 months, regardless of degree of astigmatism or postoperative goal. If the postoperative goal was $\pm$0.5 D of emmetropia, monovision eyes were eliminated and postoperative cylinder was < 1.00 D (n = 77), 97% of 39 eyes were 20/40 or better uncorrected.

Figure 7 addresses preoperative versus postoperative best-corrected visual acuity at 6 months. When preoperative visual acuity was analyzed, uncorrected acuity was less than 20/400 in 98.1% of subject eyes, less than 20/300 in 0.8% of subject eyes, and 20/200

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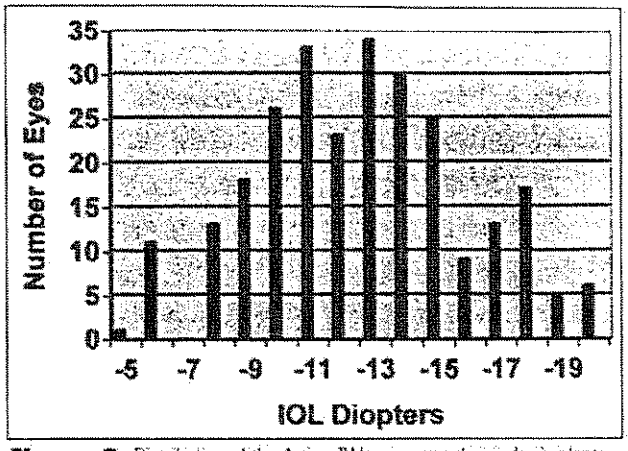

Figure 6 Distribution of the Artisan™ lens power chosen for implantation in the 264 subject eyes.

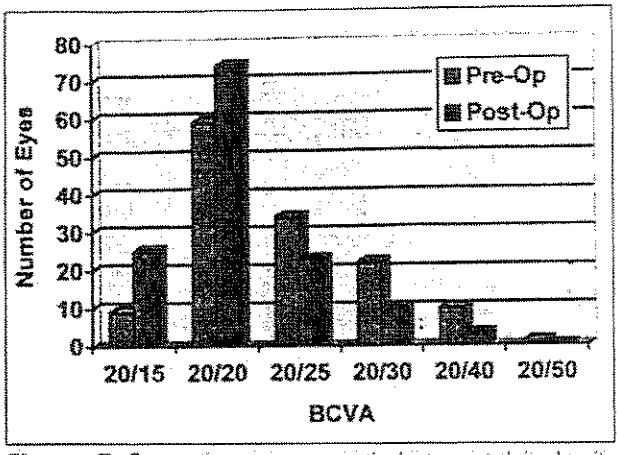

Figure 7 Preoperative *versus* postoperative best-corrected visual acuity at 6 months in all eyes (n = 135).

in 1.1% of subject eyes. Also, preoperative best-corrected visual acuity was 20/40 or better in 98.4% of subject eyes, but only 20/20 or better in 53.7% of those eyes. Figure 8 describes the lines of best-corrected visual acuity lost or gained at 6 months. Postoperative uncorrected acuity in the patient cohort demonstrated that 83% of subject eyes (n = 93) were 20/40 or better at 6 months, regardless of the degree of astigmatism. If the postoperative goal was ±0.50 D of emmetropia and cylinder was <1.00 D (n = 77), 97% of eyes were 20/40 or better. The postoperative best-corrected visual acuity at 6 months showed 100% of subject eyes (n = 135) were 20/40 or better, while 72% gained one or more lines of best-corrected acuity and 22% gained two or more lines of best-corrected acuity.

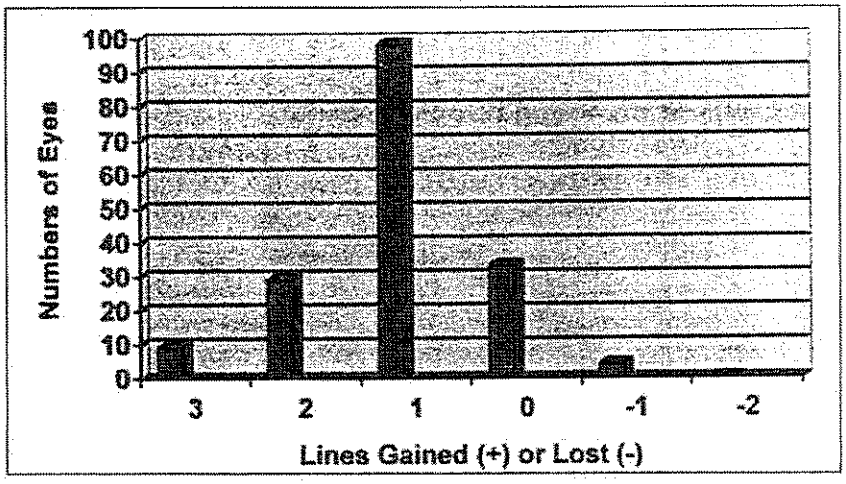

Figure 8 Lines of best-corrected visual acuity gained (+) or lost (–) at 6 months (n = 135).

Table 1. Spherical equivalent power preoperative versus postoperative—Mean versus ranges

Status	Mean	Range
Preoperative	-12.66 D	-22.75 D to -4.88 D
1 Day	-0.52 D	-4.25 D to +3.38 D
2 Week	-0.78 D	-5.00 D to +3.50 D
2 Month	-0.73 D	-4.00 D to +2.25 D
6 Month	-0.59 D	-2.88 D to +2.25 D
9 Month	-0.54 D	-2.63 D to +1.38 D
1 Year	-0.35 D	-1.50 D to +1.00 D

Figures 9 through 12 represent scatter plots of the results of Artisan lens implantation. In Figure 9, when predicted manifest spherical equivalents were addressed (of 129 subject eyes analyzed), 63% achieved correction within ±0.5 D of intended power and 90% achieved correction within ±1.00 D of intended power. In Figure 10, when predicted cycloplegic spherical equivalents were addressed (of 129 subject eyes analyzed), 61% achieved correction within ± 0.5 D of intended power and 82% achieved correction within ±1.00 D of intended power. In Figure 11, when actual manifest spherical equivalents were addressed (of 129 subject eyes analyzed), 53% achieved correction within ± 0.5 D of intended power and 78% achieved correction within ±1.00 D of intended power. In Figure 12, when actual cycloplegic spherical equivalents were addressed (of 129 subject eyes

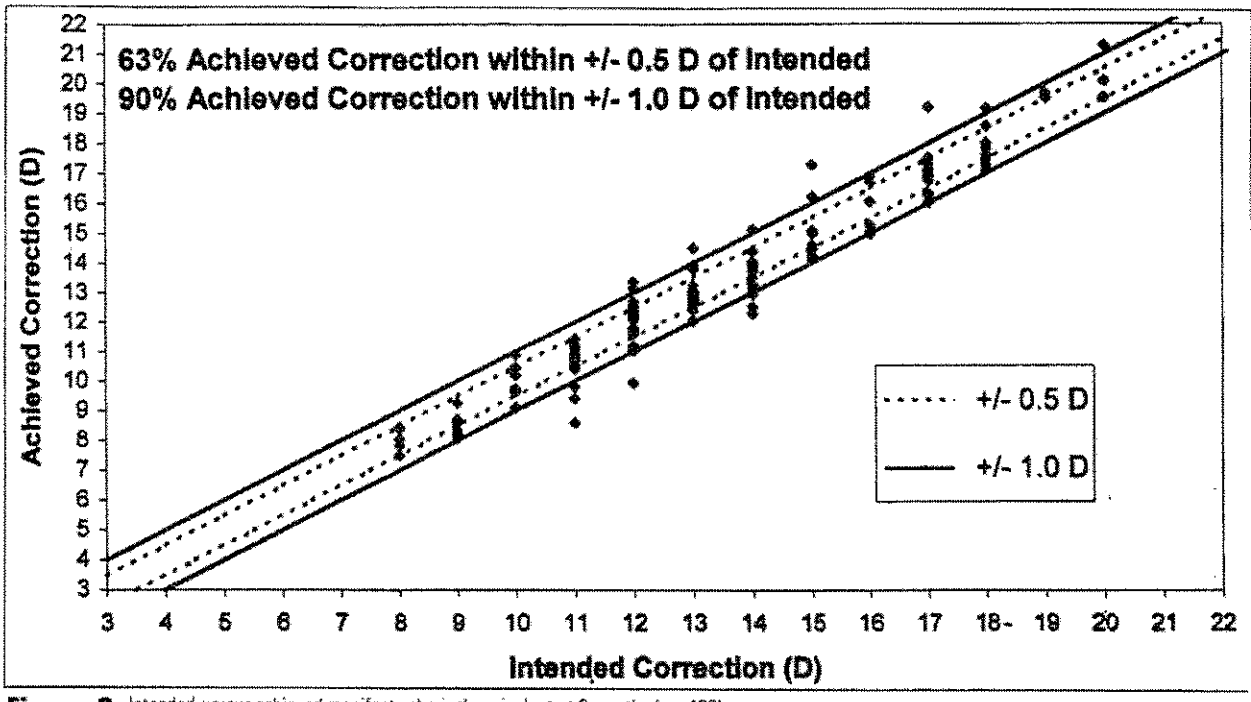

Figure 9 Intended *versus* achieved manifest spherical equivalent at 6 months (n = 129).

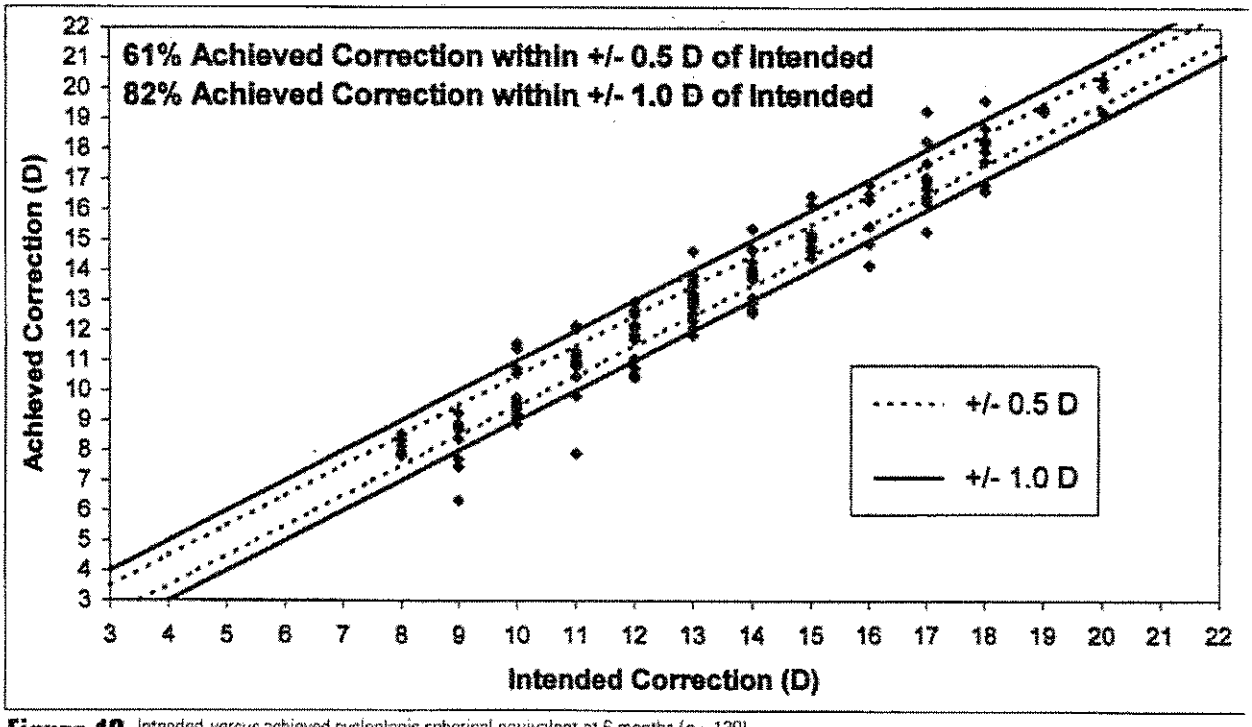

Figure 10 Intended *versus* achieved cycloplegic spherical equivalent at 6 months (n = 129).

analyzed), 51% achieved correction within ± 0.5 D of intended power and 84% achieved correction within ±1.00 D of intended power. Figure 13 demonstrates the mean spherical equivalent power preoperative versus mean spherical equivalent power postoperative of the Artisan subject eyes. Ranges for the spherical equivalent power throughout the study are presented in Table 1.

Figure 14 addresses the variability of the intraocular pressure, both preoperatively and

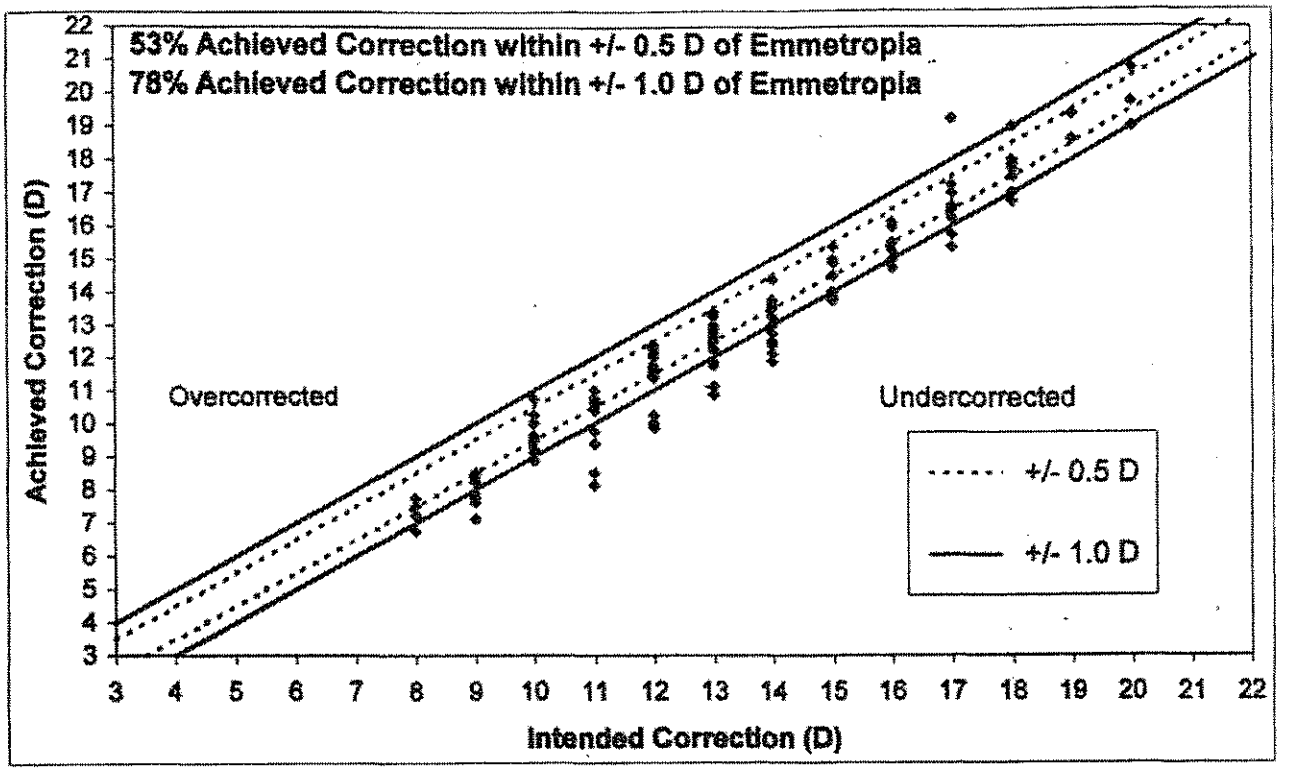

Figure 11 Actual manifest spherical equivalent at 6 months ($n = 129$).

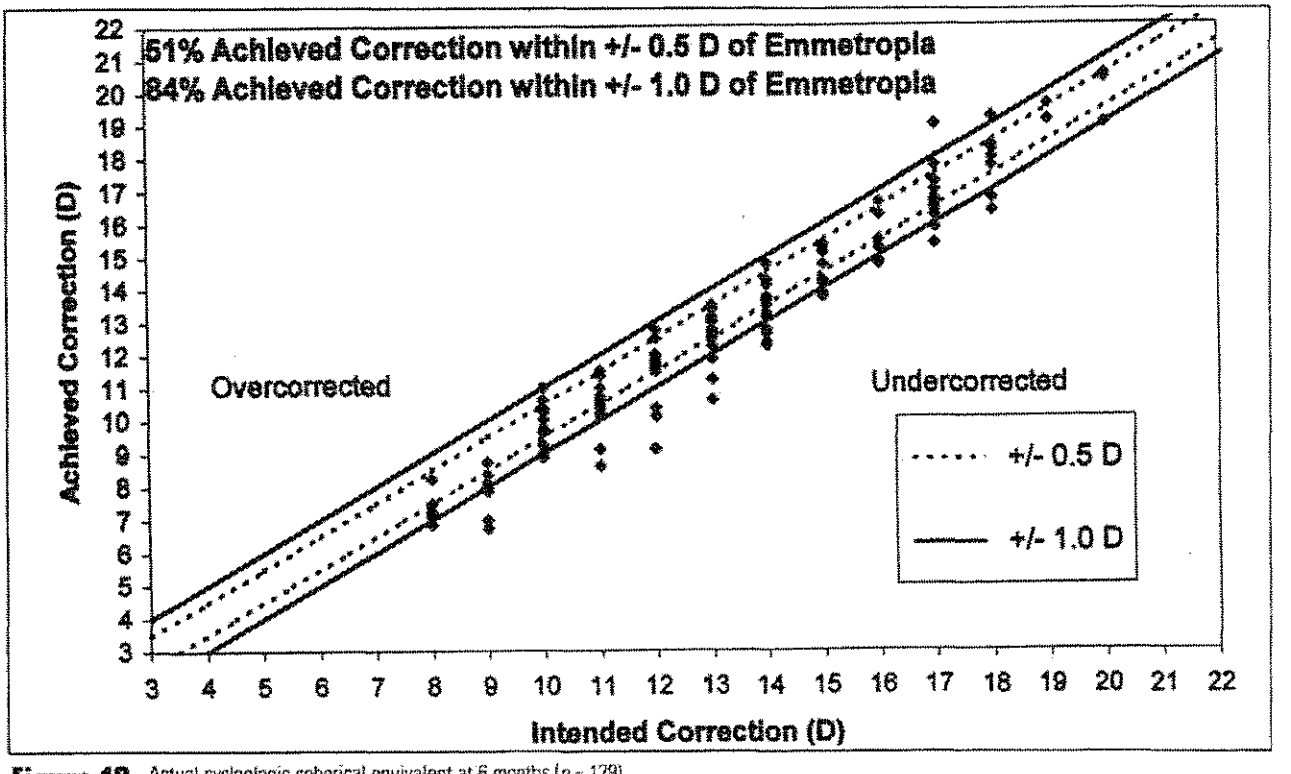

Figure 12 Actual cycloplegic spherical equivalent at 6 months ($n = 129$).

postoperatively. Through the course of the study, intraocular pressure maintained a level with a mean below 16 mmHg, ranging to an isolated high of 44 in the second postoperative week. Over the first postoperative year, there was no indication of a tendency toward a rising IOP.

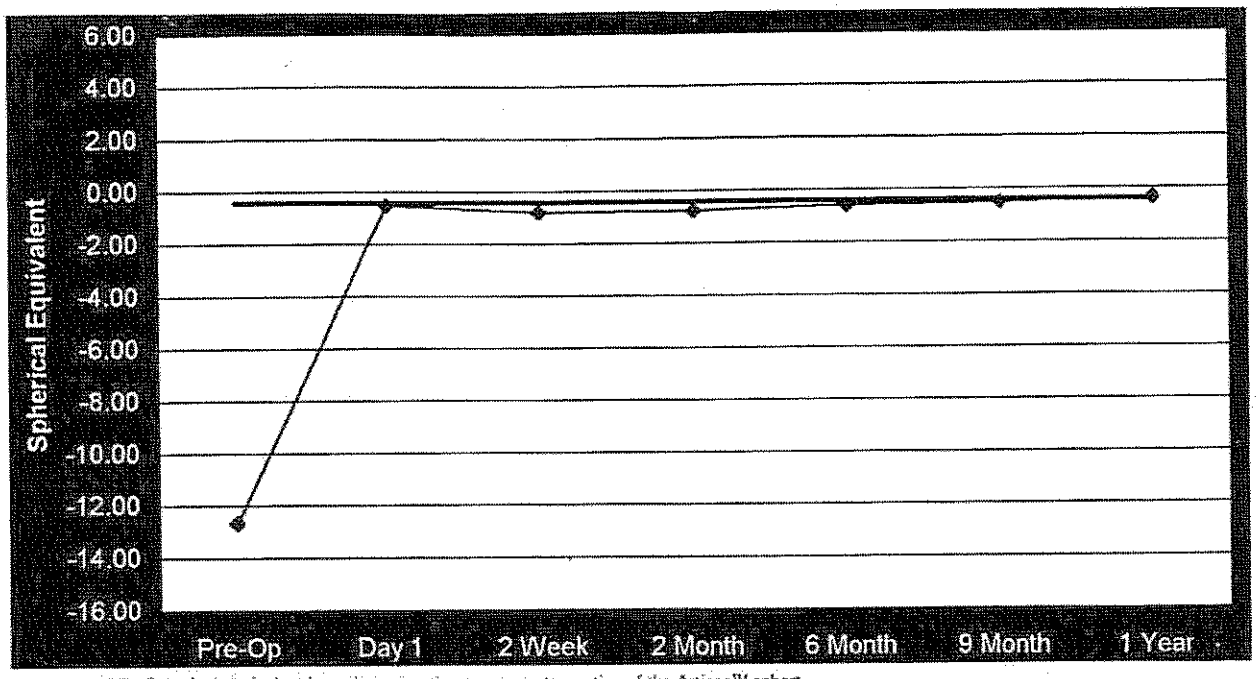

Figure 13 Spherical equivalent (mean) preoperative versus postoperative of the Artisan™ cohort.

Table 2. Variability of intraocular pressure in the Artisan™ lens cohort preoperatively versus postoperatively

Status	Mean	Range
Preoperative	14.94 mmHg	8 to 22 mmHg
1 Day	14.54 mmHg	0 to 42 mmHg
2 Week	16.01 mmHg	9 to 44 mmHg
2 Month	15.14 mmHg	9 to 32 mmHg
6 Month	14.34 mmHg	7 to 20 mmHg
9 Month	14.00 mmHg	8 to 20 mmHg
1 Year	13.76 mmHg	8 to 18 mmHg

Table 2 lists the ranges of intraocular pressures for the follow-up period.

Table 3 lists the incidence of complications in the study cohort. The majority of complications occurred within the first two postoperative visits and could be considered surgically related. These complications were dominated by anterior chamber reactions and glare. At the first day postoperative, 131 complications were noted (39%). The most common noteworthy observation was an 18% rate of cell/flare. Three reports of elevated IOP (3%) were related to residual viscoelastic. Irregular pupils seemed to resolve with time, as did the majority of complications. Asymptomatic vacuoles (1%), seen in some of our patients, also appeared to either not progress or to resolve with time. It was thought that the vacuoles were the result of inadvertent touch of the implant to the lens or to rapid instillation of the viscoelastic. At the second postoperative visit, the residual cells/flare had reduced to 5%, while 12% reported glare or halos. In general, total reported complications in the patient cohort decreased over time, dropping from 39% at the initial visit to 10% at visit four and 0% at visit seven.

Table 4 is a compilation of endothelial cell counts, both preoperatively and postoperatively. The data represent three separate patient groups reported by postoperative elapsed time. In the 6-month group (n = 135), endothelial cell counts actually improved by 0.3%. Within the 12-month group (n = 25), cell counts decreased 2.4% in the first 6 months, then increased 2.4% over the next 6 months, to give a 0% net change. The data on the 24-month group (n = 6) demonstrated a 7.8% cell loss over the time span.

Box 2 provides a summary of eight adverse events that occurred in the study. Halos due to large pupil size dominated the events, while the other five events created no untoward effects. Adverse events encountered in the reported patient cohort were all resolved without complication.

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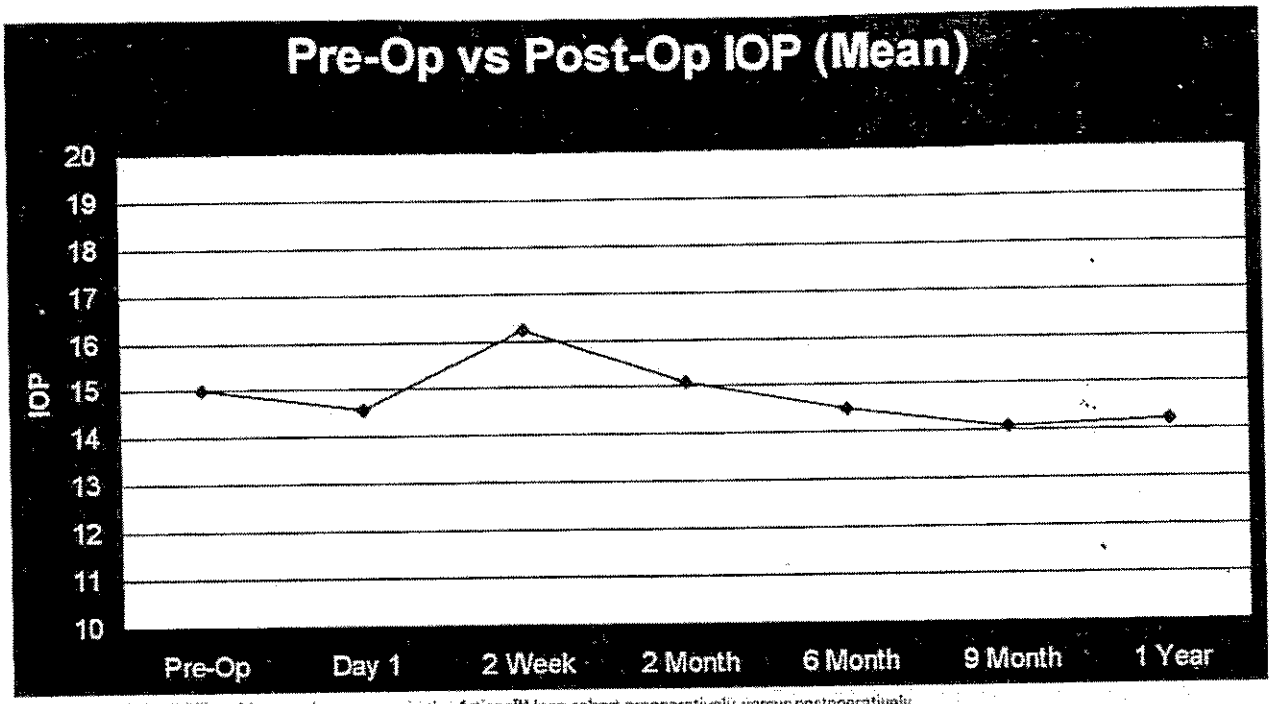

Figure 14 Variability of intraocular pressure in the Artisan™ lens cohort preoperatively *versus* postoperatively.

Adverse events encountered in the Artisan™ lens high myopia study

- One (1) lens exchanged due to operating room error—resolved without complication.
- Three (3) lenses exchanged due to halos due to pupil size—resolved with 6-mm optic lens replacement without complication.
- One (1) lens repositioned due to improper positioning during initial surgery—resolved without complication.
- One (1) elevated IOP due to steroid response—resolved without complication.
- One (1) response to general anesthesia—resolved without complication.
- One (1) lens removal in patient who expressed anxiety of having lens in eye—resolved without complication.

IOP, Intraocular pressure.

Box 2

Discussion

Refractive surgery has become a major clinical and economic force in the provision of eye care to Americans. LASIK has supplanted radial keratectomy as the refractive surgery of choice because of a combination of better predictability, patient post-surgical comfort, minimal drift, and ocular stability. There are, however exceptions to the successful application of LASIK—most notably in patients with thin corneas, flat keratometric readings, and high refractive errors (refer to Box 1). Phakic lens implantation and clear lensectomy has gained recent interest for the patient with exceptions to the criteria for use of LASIK, PRK, or RK.

This interim report describes the results of an FDA-supervised study of the implantation of the Artisan lens into phakic eyes of patients ages 21 to 50 years with refractive errors of - 5.00 D to - 20.0 D. Patients were required to meet specific criteria as outlined in the section on materials and methods. This report addresses 264 of the total 550 eyes to be enrolled in the study at completion. Of the 13 centers involved in the implantation at the time of this report, John-Kenyon Eye Center implanted 44 subject eyes—17% of all subject eyes. The next-highest implantation rate was by the Jules Stein Eye Institute, reporting 29 subject eyes (or 11% of all eyes).

Table 3. Incidence of complications in the study cohort for the high myopia Artisan™ lens

		Visit (no. of eyes)						
		1 (258)	2 (222)	3 (201)	4 (135)	5 (70)	6 (25)	7 (6)
Cells/flare	Mild	47 (18%)	12 (5%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
	Moderate	14 (5%)	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Corneal edema	Mild	11 (4%)	3 (1%)	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Moderate	5 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Glare/halos	Mild	5 (2%)	19 (9%)	14 (9%)	6 (4%)	3 (4%)	2 (8%)	0 (0%)
	Moderate	0 (0%)	6 (3%)	6 (3%)	2 (1%)	1 (1%)	0 (0%)	0 (0%)
	Severe	0 (0%)	1 (0%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hyphema		3 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Transient rise of IOP		7 (3%)	5 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Nonpigmented precipitates		2 (1%)	6 (3%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Iris pigment precipitates		0 (0%)	11 (5%)	6 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Wound leak		10 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Diplopia		1 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Irregular pupil		23 (9%)	6 (3%)	4 (2%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)
Asymptomatic vacuoles on crystalline lens		3 (1%)	4 (2%)	4 (2%)	2 (1%)	0 (0%)	1 (4%)	0 (0%)
Total complications reported/ no. of subject eyes		131/100 eyes (39%)	73/61 eyes (27%)	37/32 eyes (16%)	14/14 eyes (10%)	4/4 eyes (6%)	3/3 eyes (12%)	0/0 eyes (0%)

IOP, Intraocular pressure.

In the patient cohort, 63% of eyes achieved intended correction within ±0.50 D and 90% within ±1.00 D on manifest spherical equivalent at 6 months. Under cycloplegia, 61% were within ±0.50 D and 82% within ±1.00 D (refer to Figures 9 and 10). On evaluation of actual manifest spherical equivalent at 6 months, 53% achieved correction within ±0.50 D and 78% were within ±1.00 D. Under cycloplegia, 51% were within ±0.50 D and 84% within ±1.00 D (refer to Figures 11 and 12). While the mean preoperative spherical refraction was − 12.56 D, the mean postoperative spherical refraction was − 0.53 D at 6 months, − 0.35 D at 12 months, and − 0.42 D at 24 months. In a previous study, the postoperative results with the posterior chamber Starr Collamer lens indicated 97.1% of patients achieved 20/40 or better at 4 to 6 months. At 6 months, 4.7% of patients required YAG capsulotomy.[30] In another (more recent) study of the posterior chamber lens—involving 19 myopic eyes with a mean followup of 12 months—uncorrected visual acuity was 20/40 or better in 63.15% of eyes. In that patient cohort, postoperative refraction withi ±0.50 D occurred in 21.5% of eyes and withi ±1.00 D occurred in 42.1% of eyes. In this sam study, a severe pupillary block developed 13.33% of eyes.[31]

In past reports, complications from rece implantation of angle-supported rather tha iris-supported phakic anterior chamber IO (Domilens) included a 4.8% incidence of retin detachment, averaging 17+ months post-impla tation,[18] as well as pupil distortion.[32] With t implantation of silicone posterior chamber lens in phakic, highly myopic eyes, anterior subca sular cataract formation and nuclear scleros were observed in 52.9% of 17 eyes, and, wh considering patients with a followup of only years, the rate rose to 81.9%.[20,33] Another rep cited the occurrence of an opacity of the anteri capsule in a posterior chamber implantation at t site of the laser peripheral iridotomy,[34] while another addressed the complication of corn decompensation 1 year after implantation

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Table 4. Endothelial cell analysis preoperative versus postoperative in the Artisan™ subject eyes

	Preop. count	6-mo. count	6-mo. change from preop.	12-mo. count	12-mo. change from 6-mo.	24-mo. count	24-mo. change from 12-mo.	Cumulative change (%)
N = 135 @ 6 months	2615/mm² Range, 2000 to 4200/m² 517 SD	2622/mm² 489 SD	0.3%	—	—	—	—	0.3%
N = 25 @ 12 months	2770/mm² Range, 2100 to 4000/mm² 461 SD	2703/mm² Range, 1649 to 3800/mm² 539 SD	- 2.4%	2768/mm² Range, 2100 to 3721/mm² 475 SD	2.4%	—	—	0.0%
N = 6 @ 24 months	2717/mm² Range, 2100 to 3200/mm² 406 SD	2667/mm² Range, 1900 to 3500/mm² 525 SD	- 1.8%	2529/mm² Range, 2100 to 3105/mm² 388 SD	-5.2%	2508/mm² Range, 2000 to 3058/mm² 369 SD	- 0.8%	- 7.8%

Preop., Preoperative; ***SD***, standard deviation.

Two other recent reports imply significant potential problems with the collamer posterior chamber phakic IOLs. Design concerns are apparent and IOL–iris touch, IOL–crystalline lens touch, and anterior chamber shallowing are all potential problems that loom to create complications with the posterior chamber lens.[36,37]

Complications in the current Artisan cohort are transient and are not of catastrophic nature, especially when compared with previous reports of anterior chamber and posterior chamber phakic IOLs for the correction of high myopia. The *caveat* associated with this report is that it covers a limited period of time.

Endothelial cell loss continues to be a concern of anterior chamber refractive lens implantations. In an earlier report, routine uncomplicated phacoemulsification surgery created a 9% endothelial cell loss 1 year postoperatively, while there have been reports of a 16% average endothelial cell loss cited after phakic Anterior Chamber (AC)-IOL surgery. Over the long term, it is reported that the loss for AC–IOL is about 20%, as compared to 12% for uncomplicated cataract surgery.[38] A more recent report addressed endothelial loss in a 4-year followup of the iris-claw aphakic lens. In 111 phakic eyes implanted with the Worst iris-claw lens, mean endothelial cell loss was 3.85% at 6 months, 6.59% at 12 months, 9.22% at 24 months, 11.68% at 36 months, and 13.42% at 48 months. It was noted, however, that morphometric changes recovered and were close to preoperative levels.[39] The current study demonstrated lower endothelial cell loss than past anterior chamber phakic IOL reports and compared favorably with the reported 9% cell loss at 1 year postoperative in uncomplicated phacoemulsification. The latest report cites the results of a mean follow-up period of 35 months in Artisan implanted eyes. In 67.2% of the eyes, postoperative refraction was within ±1.00 D of emmetropia. Mean best-corrected acuity improved from 20/40 to 20/32. No major complications were encountered. There did appear to be, however, a progressive endothelial cell loss over time. At 6 months, mean endothelial cell loss was 5.5%, at 12 months 7.21%, at 24 months 9.1% (current study at 7.8%), and at 36 months 10.9%.[26]

Conclusion

The interim results of the U.S. Clinical Investigation of the Artisan Myopia Lens for the Correction of High Myopia in Phakic Eyes support a reasonable option in the management of patients with high degrees of myopia. Glare appeared to be the primary reported complica-

tion. Isolated postoperative spikes in intraocular pressure occurred in the patient cohort, but corneal compromise was not an issue. Endothelial cell loss in the study was comparable to uncomplicated phacoemulsification procedures previously reported and certainly consistent with earlier reports. Adverse events were dominated by halos and surgical procedure occurrences and all were resolved without complication. Complications over the short term were minimal and resolvable and were far-less ominous than alternative phakic IOL solutions to high myopia. The complications were primarily associated with the standard anterior chamber postoperative events—such as cells and flare—and all decreased over time.

Refractive and visual acuity outcomes are extremely good. Postoperative uncorrected visual acuity was 20/40 or better in 83% of subject eyes at 6 months, without regard to astigmatism. Postoperative best-corrected visual acuity at 6 months showed 100% of eyes were 20/40 or better, while 72% gained one or more lines of acuity. Twenty-two percent of the cohort gained two or more lines of best-corrected acuity. The actual gain in best-corrected acuity was the strongest positive event in the study. The mean preoperative spherical refraction was – 12.56 D, while the mean postoperative spherical correction was – 0.42 D at 24 months. Intended correction within ±0.50 D occurred in 63% of eyes and within ±1.00 D in 90% of eyes. Manifest spherical equivalents at 6 months within ±0.50 D occurred in 58% of eyes and within ±1.00 D in 78% of eyes.

Based on the interim results of the U.S. Clinical Investigation of the Artisan Myopia Lens for the Correction of High Myopia in Phakic Eyes, the Artisan anterior chamber phakic IOL may offer an option for correction of high degrees of myopia. The reader must recognize, however, the fact that the Artisan™ myopia lens for the correction of myopia is in the developmental phase and long-term recommendations regarding routine implantation must be tempered.

Disclaimer

This is to acknowledge that none of the authors or contributors to the article has any affiliation or association with the devices or products mentioned within the article.

References

1. Pesando PM, Ghiringhello MP, Tagliavacche P. Posterior chamber collamer phakic intraocular lens for myopia and hyperopia. *J Refract Surg* 1999;15:415-23.
2. Sanders DR, Martin RG, Brown DC, et al. Posterior chamber phakic intraocular lens for hyperopia. *J Refract Surg* 1999;15:309-15.
3. Baikoff G, Arne JL, Bokobza Y, et al. Angle-fixated anterior chamber phakic intraocular lens for myopia of –7 to –19 diopters. *J Refract Surg* 1998;14:282-93.
4. Fechner PU. The correction of myopia by lens implantation into phakic eyes. *Am J Ophthalmol* 1989;107:659-63.
5. Fechner PU, Strobel J, Wichman W. Correction of myopia by implantation of a concave Worst-iris claw lens into phakic eyes. *Refract Corneal Surg* 1991;7:286-98.
6. Perez-Santonja JJ, Bueno JL, Zato MA. Surgical correction of high myopia in phakic eyes with Worst-Fechner myopia IOLS. *J Refract Surg* 1997;13:268-81.
7. Perez-Santonja JJ, Ruiz-Moreno JM, de la Hoz F, et al. Endophthalmitis after phakic intraocular lens implantation to correct myopia. *J Cataract Refract Surg* 1999;25: 1295-8.
8. Perez-Santonja JJ, Iradier MT, Betinez del Castillo JM, et al. Chronic subclinical inflammation in phakic eyes with IOLs to correct myopia. *J Cataract Refract Surg* 1996;22: 183-7.
9. Menezo JL, Avino JA, Cisneros A, et al. Iris claw intraocular lens for high myopia. *J Refract Surg* 1997;13:545-55.
10. Assetto V, Benedetti S, Pesando P. Collamer intraocular contact lens to correct high myopia. *J Cataract Refract Surg* 1996;22:551-6.
11. Fechner PU, Singh D, Wulff K. Iris-claw lens in phakic eyes to correct hyperopia: preliminary study. *J Cataract Refract Surg* 1998;24:48-56.
12. Baikoff G. Phakic anterior chamber intraocular lenses. *Int Ophthalmol Clin* 1991;31:75-86.
13. Fyodorov SN, Zuyev VK, Tumanian ER, et al. Analysis of long-term clinical and functional results of intraocular correction of high myopia. *Ophthalmosurgery* 1990;2:3-6.
14. Fyodorov SN, Zuyev VK, Aznabayev BM. Intraocular correction of high myopia with negative posterior chamber lens. *Ophthalmosurgery* 1991;3:57-8.
15. Worst JFG, Van der Veen G, Los LL. Refractive surgery for high myopia: the Worst-Fechner biconcave iris claw lens. *Documenta Ophthalmologica* 1990;75:335-41.
16. Landesz M, Worst JGF, Siertsema JV, et al. Negative implant. A retrospective study. *Documenta Ophthalmologica* 1993;83:261-70.
17. Stulting RD, Thompson KP, Waring GO III, et al. The effect of photorefractive keratectomy on the corneal endothelium. *Ophthalmology* 1996;103:1357-65.
18. Ruiz-Moreno JM, Alio JL, Perez-Santonja JJ, et al. Retinal detachment in phakic eyes with anterior chamber intraocular lenses to correct severe myopia. *Am J Ophthalmol* 1999;127:270-5.
19. Baikoff G. Refractive phakic intraocular lenses. In: Elander R, Rich LF, Robin JB, eds. *Principles and practice of refractive surgery.* Philadelphia: WB Saunders Company, 1997:435-47.
20. Brauweiler PH, Wehler T, Busin M. High incidence of cataract formation after implantation of a silicone posterior chamber lens in phakic, highly myopic eyes. *Ophthalmology* 1999;106:1651-5.
21. Trindade F, Pereira F. Cataract formation after posterior chamber phakic intraocular lens implantation. *J Cataract Refract Surg* 1998;24:1661-3.

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22. Fechner PU. Cataract formation with a phakic IOL (letter). *J Cataract Refract Surg* 1999;25:461-2.
23. Waltman SR. Corneal changes from intraocular surgery. In: Kaufman HE, Barron, VA, McDonald MB, et al., eds. *The cornea*. New York: Churchill Livingstone, 1988:911-33.
24. Mimouni F, Colin J, Koffi V, et al. Damage to the corneal endothelium from anterior chamber intraocular lenses in phakic myopic eyes. *Refract Corneal Surg* 1991;7:277-81.
25. Menezo JL, Avino JA, Cisneros A, et al. Iris claw phakic intraocular lens for high myopia. *J Refract Surg* 1997; 13:545-55.
26. Landesz M, Worst JG, van Rij G. Long-term results of correction of high myopia with an iris claw phakic intraocular lens. *J Refract Surg* 2000;16:310-6.
27. Alio JL, de la Hoz F, Perez-Santonja JJ, et al. Phakic anterior chamber lenses for the correction of myopia: a 7-year cumulative analysis of complications in 263 cases. *Ophthalmology* 1999;106:458-66.
28. Guell JL, Vazquez M, Gris O, et al. Combined surgery to correct high myopia: iris claw phakic intraocular lens and laser *in situ* keratomileusis. *J Refract Surg* 1999;15:529-37.
29. Van der Heijde GL. Some optical aspects of implantation of an IOL in a myopic eye. *Eur J Implant Ref Surg* 1989; 1:245-8.
30. Brown DC, Grabow HB, Martin RG, et al. Staar Collamer intraocular lens: clinical results from the phase I FDA core study. *J Cataract Refract Surg* 1998;24:1032-8.
31. Pesando PM, Ghiringhello MP, Tagliavacche P. Posterior chamber collamer phakic intraocular lens for myopia and hyperopia. *J Refract Surg* 1999;15:415-23.
32. Saragoussi JJ, Pucch M, Assouline M, et al. Ultrasound biomicroscopy of Baikoff anterior chamber phakic intraocular lenses. *J Refract Surg* 1997;13:135-41.
33. Wiechens B, Winter M, Haigis W, et al. Bilateral cataract after phakic posterior chamber top hat-style silicone intraocular lens. *J Refract Surg* 1997;13:392-7.
34. Zadok D, Chayet A. Lens opacity after neodymium: YAG laser iridotomy for phakic intraocular lens implantation. *J Cataract Refract Surg* 1999;25:592-3.
35. Marcon GB, Galan A, Rappo G, et al. Edematous decompensation of the cornea after silicaon implant of the posterior chamber in phakic eyes in myopia. *J Fr Ophthalmol* 1996;19:149-52.
36. Visessook N, Peng Q, Apple DJ, et al. Pathological examination of an explanted phakic posterior chamber intraocular lens. *J Cataract Refract Surg* 1999;25:216-22.
37. Trindade F, Pereira F, Cronemberger S. Ultrasound biomicroscopic imaging of posterior chamber phakic intraocular lens. *J Refract Surg* 1998;14:497-503.
38. Werblin TP. Long-term endothelial cell loss following phacoemulsification: model for evaluating endothelial damage after intraocular surgery. *Refract Corneal Surg* 1993; 9:29-35.
39. Menezo JL, Cisneros AL, Rodriguez-Salvador V. Endothelial study of iris-claw phakic lens: four-year followup. *J Cataract Refract Surg* 1998;24:1039-49.
40. Knorz MC, Wiesinger B, Liermann A, et al. Laser in situ keratomileusis for moderate and high myopia and myopic astigmatism. *Ophthalmology* 1998;105:932-40.
41. Gimbel HV, van Westenbrugge JA, Penno EE, et al. Simultaneous bilateral laser *in situ* keratomileusis: safety and efficacy. *Ophthalmology* 1999;106:1461-7.
42. Knorz MC, Jendritza B, Liermann A, et al. LASIK for myopia correction. 2-year followup. *Ophthalmologe* 1998;95:494-8.
43. Speicher L, Gottinger W. Progressive corneal ectasia after laser in situ keratomileusis. *Klin Monatsbl Augenheilkd* 1998;213:247-51.
44. Seiler T, Quurke AW. Iatrogenic keratectasia after LASIK in a case of forme fruste keratoconus. *J Cataract Refract Surg* 1998;24:1007-9.
45. Geggel HS, Talley AR. Delayed onset keratectasia following laser in situ keratomileusis. *J Cataract Refract Surg* 1999;25:582-6.
46. Hersh PS, Brint SF, Maloney RK, et al. Photorefractive keratectomy *versus* laser in situ keratomileusis for moderate to high myopia. A randomized prospective study. *Ophthalmology* 1998;105:1512-22.
47. Perez-Santonja JJ, Bellot J, Claramonte P, et al. Laser *in situ* keratomileusis to correct high myopia. *J Cataract Refract Surg* 1997;23:372-85.
48. Knorz MC, Jendritza B, Hugger P, et al. Complications of laser *in situ* keratomileusis. *Ophthalmologe* 1999;96:503-8.
49. Gimbel HV. Flap complications of lamellar refractive surgery. *Am J Ophthalmol* 1999;127:202-4.
50. Stulting RD, Carr JD, Thompson KP, et al. Complications of laser *in situ* keratomileusis for the correction of myopia. *Ophthalmology* 1999;106:13-20.

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