Artisan Phakic Intraocular Lens for Myopia

Short-term Results of a Prospective, Multicenter Study

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The Artisan Lens Study Group

Purpose: To evaluate the safety and efficiency of the Artisan iris-supported phakic intraocular lens (Ophtec BV, Groningen, Netherlands) for the correction of high myopia.

Study Design: Nonrandomized, prospective, multicenter trial conducted under a United States Food and Drug Administration (FDA) Investigational Device Exemption.

Participants: One hundred fifty-five eyes of 155 patients with myopia from −5.5 to −22.5 diopters (D) underwent implantation of an Artisan lens, as part of a phase I, II, or III FDA trial.

Methods: Eyes were examined at 1 day (154 eyes), 2 weeks (142 eyes), 2 months (130 eyes), and 6 months (84 eyes). Intraocular pressure and presence of flare and cell on slit-lamp biomicroscopy were recorded at each visit.

Main Outcome Measures: Achieved correction, stability of spherical equivalent refraction, change in astigmatism, postoperative uncorrected vision, change in best spectacle-corrected acuity, and change in endothelial cell count.

Results: Mean spherical equivalent manifest refraction stabilized on postoperative day 1. Mean difference between attempted and achieved correction at 2 months was −0.32 ± 0.95 D (mean ± standard deviation; range, −4.42 to +2.2 D). At 6 months, 85% of eyes saw 20/40 or better uncorrected, and 90% of eyes were within 1 D of the attempted correction. Refractive astigmatism increased in 4.8% of eyes and decreased in 17% of eyes at 6 months. At 2 months, six eyes (4.8%) lost two or more lines of best spectacle-corrected visual acuity; by 6 months, no eyes lost two or more lines of best-corrected visual acuity. Endothelial cell count was unchanged at 6 months compared with the preoperative count. Nonprogressive lens opacities developed in four eyes as a result of surgical trauma. Chronic inflammation was not detected in any eye by slit-lamp biomicroscopy, nor did any eye develop angle closure or glaucoma.

Conclusions: Short-term results suggest that the Artisan lens is an accurate and safe method for the correction of high myopia. Surgical skill is important in avoiding lens opacities. Longer-term data are needed to assess the impact of the lens on the endothelium, the crystalline lens, and the iris. *Ophthalmology 2002;109: 1631–1641 © 2002 by the American Academy of Ophthalmology.*

Laser in situ keratomileusis for the correction of myopia of more than 6 diopters (D; "high myopia") is problematic. The accuracy of laser in situ keratomileusis is less for high myopia than for low myopia.[1,2] Glare and halos are common in high myopia because more tissue is removed and the optical zone needs to be smaller to prevent excessively deep ablations.[3] Corneal ectasia has been reported as the complication of laser in situ keratomileusis for high myopia, possibly because of excessive corneal thinning.[4–6] Finally, loss of spectacle-corrected acuity is more common in laser in situ keratomileusis for high myopia than for low myopia, as are other problems with quality of vision.[7–12]

Phakic intraocular lenses offer a promising alternative.[13–20] The lenses have the same optical quality as pseudophakic intraocular lenses[20] and minimize the risk of loss of spectacle-corrected acuity. Their refractive power is placed very close to the pupil, resulting in a better coverage of the night-dilated pupil than an equal diameter laser in situ keratomileusis ablation, theoretically minimizing the risk of halos.[21] Finally, because their refractive power is not dependent on corneal wound healing, phakic intraocular lenses have the potential of offering a more accurate refractive correction than laser in situ keratomileusis. However, phakic intraocular lenses are not without problems. Various models of these lenses have caused glaucoma, cataract, endophthalmitis, angle closure, corneal decompensation, and pupillary ovalization.[21–27]

Phakic intraocular lenses can be divided into three groups: posterior chamber lenses, anterior chamber lenses, and iris-fixated lenses. The anterior chamber lens is represented by the Nu Vita lens (Bausch & Lomb Surgical, St. Louis, MO). Invented by George Baikoff, this lens is a

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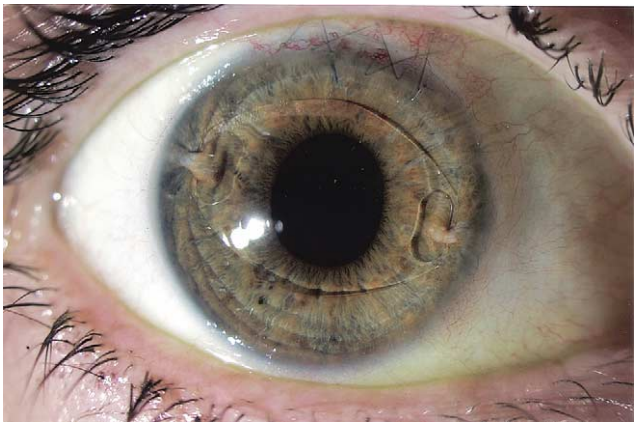

Figure 1. A highly myopic eye with an Artisan lens (Ophtec BV, Groningen, Netherlands) in the typical position overlying the pupil at postoperative week 2. The lens haptics form a small pincer, through which a knuckle of peripheral iris is drawn nasally and temporally to attach the lens. The fixation of the lens in the relatively immobile peripheral iris eliminates pseudophakodonesis and minimizes the risk of inflammation. This lens has a 6-mm diameter optic and was inserted through a 6-mm incision at the superior limbus, which is secured with a running 10-0 nylon suture.

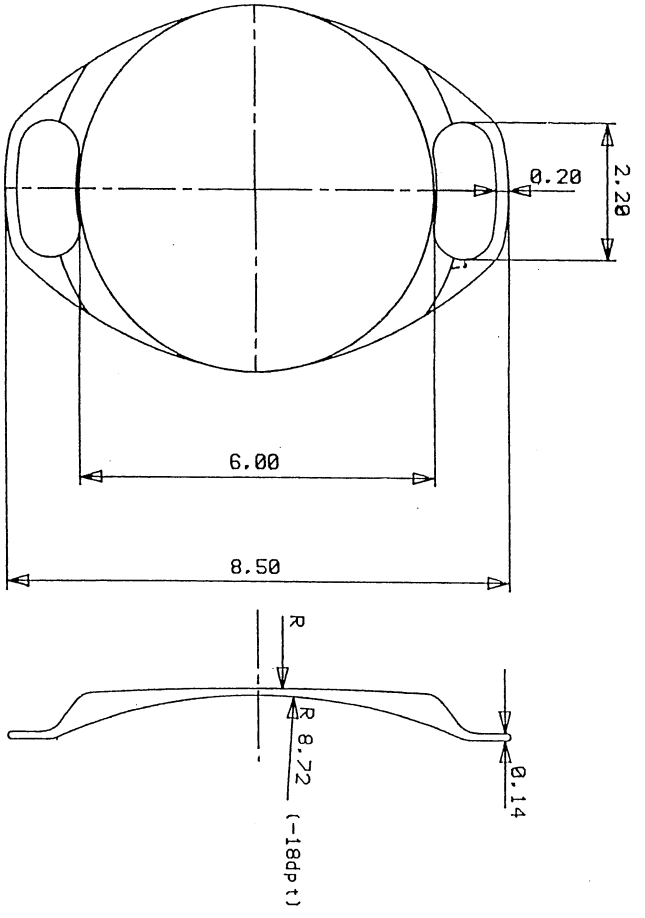

Figure 2. Diagram of the 6-mm Artisan lens (Ophtec BV, Groningen, Netherlands) with relevant dimensions. The haptics lie in the pupillary plane, whereas the optic vaults anterior to the pupil to prevent iris chafing. The anterior surface of the optic of a −12-diopter lens lies approximately 1.71 mm from the endothelium in a myopic eye with an anterior chamber depth of 3.2 mm.

Kelman-style anterior chamber lens. Advantages include ease of insertion using a technique with which most cataract surgeons are familiar. Potential disadvantages include pupillary ovalization from fibrosis around the footplate in the anterior chamber angle and the potential for chronic compromise of the anterior chamber angle, leading to glaucoma.[25–26] Posterior chamber phakic intraocular lenses fit in the space between the iris and the crystalline lens.[13–19,23,24] One representative model is the Intraocular Contact Lens (Staar Surgical, Monrovia, CA). These lenses are foldable, offering the advantage of insertion through a small incision. They are cosmetically appealing because they are not visible to the naked eye and are placed far from the anterior chamber angle and the corneal endothelium. Potential disadvantages include angle closure from forward displacement of the iris, pigment dispersion from chafing, and cataract because of contact with the crystalline lens.[23,24]

The third category of phakic intraocular lens includes those that are iris supported. The only such lens that is commercially available is the Artisan lens (Ophtec BV, Groningen, Netherlands). It was designed by Jan Worst and was formerly known as the Worst-Fechner Claw Lens.[28–44] This lens attaches to the peripheral iris (Fig 1). It has two pincer-like haptics through which a small knuckle of iris is drawn during implantation in a process called *enclavation*. These knuckles of iris secure the lens so that the optic lies immediately anterior to the plane of the iris. The first such lens was implanted in a phakic eye in 1986[29,37]; a similar iris-fixated design has been used as a pseudophakic lens since 1980.

Iris-fixated intraocular lenses have had a checkered history. These were among the earliest pseudophakic intraocular lenses used. Early iris-fixated designs include the Binkhorst lens and the Medallion lens. They were inserted in an aphakic eye after intracapsular cataract extraction, where no posterior capsular support was present. Eyes with these lenses did well initially, but years later developed cystoid macular edema and corneal decompensation.[21] Because of this early experience, similar potential concerns have been raised about the Artisan lens. All of these early iris-fixated lenses were secured to the iris at the pupillary margin, which resulted in significant phacodonesis. In contrast, the Artisan lens is fixated to the peripheral iris and has no visible movement within the eye. Several long-term prospective studies of this lens have shown good predictability and safety.[28,31,41–44] A 2-year prospective, multicenter, Food and Drug Administration-supervised trial was undertaken to determine the safety and efficacy of the Artisan lens as a treatment for high myopia. Data for the first 6 months of the trial is reported here.

Patients and Methods

Study Population

Patients aged 21 to 45 were prospectively enrolled in phase I (10 eyes of 10 patients), phase II (100 eyes of 100 patients), or phase

Table 1. Eligible Eyes at Each Follow-up Interval with Attendance

	Eligible Eyes	Eyes Examined (% of Eligible Eyes)
1 day	155	154 (99%)
2 wks	146	142 (97%)
2 mos	139	130 (94%)
6 mos	89	84 (94%)

III (45 eyes of 45 patients) of a Food and Drug Administration-authorized trial. In phase I, patient age from 21 to 45 years and intraocular lens powers from −8 to −20 D were permitted. Depending on anterior chamber depth, myopia up to −22 D can be treated with a −20-D Artisan lens. In phases II and III, patient age from 21 to 50 years and lens powers from −5 to −20 D were permitted. Otherwise, inclusion and exclusion criteria were the same for all phases. Other inclusion criteria in the enrolled eye included 2.5 D or less of refractive astigmatism and best spectacle-corrected visual acuity of 20/40 or better. Exclusion criteria for the enrolled eye included retinal detachment or significant retinal pathologic features, an abnormal pupil or iris, significant corneal or anterior segment disease, cataract, endothelial cell count less than 2000 cells/mm^2 or endothelial dystrophy, an anterior chamber depth less than 3.2 mm, glaucoma, preoperative intraocular pressure more than 21 mmHg, or prior intraocular surgery. Patients with diabetes mellitus were excluded. All sites obtained investigational review board approval.

Study Examinations

The preoperative evaluation of the enrolled eye included manifest and cycloplegic refraction, a complete eye examination, uncorrected and best spectacle-corrected distance visual acuity in both eyes, and endothelial cell count. Postoperative examinations were scheduled at the following intervals: 1 to 6 days ("1 day"), 2 to 3 weeks ("2 weeks"), 4 to 8 weeks ("2 months"), and 4 to 6 months ("6 months"). At each postoperative examination, the following were recorded: uncorrected distance acuity, manifest refraction, slit-lamp examination results, uncorrected near acuity, any subjective complaints, and any complications or adverse reactions that had occurred. Endothelial cell counts were repeated at the 6-month visit. Each center measured endothelial cell count using its customary device. The follow-up protocol was the same for all phases.

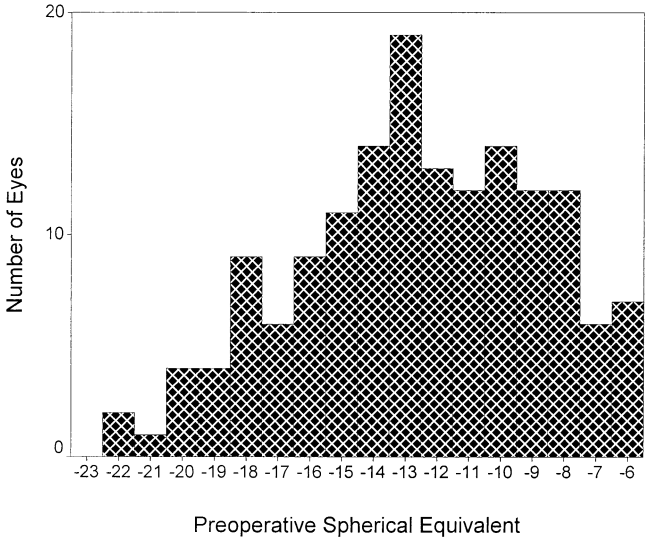

Figure 3. Distribution of preoperative myopia. Mean myopia was −12.69 ± 3.80 diopters (D), with a range −5.5 D to −22.5 D.

Table 2. Comparison of Mean Preoperative Variables of Study Population for Each Phase of Study

	Phase I	Phase II	Phase III
Number of eyes	10	50	95
Age (yrs)	39	39	39
Preoperative spherical equivalent (diopters)	−17.1	−12.6	−12.3
Preoperative astigmatism (diopters)	1.60	1.17	1.05
LogMAR best-corrected acuity	20/15	20/17	20/17
Intraocular pressure (mmHg)	16.2	14.4	15.5
Endothelial cell count (cells/mm^2)	2775	2676	2597
Anterior chamber depth (mm)	3.77	3.69	3.68

Artisan Lens

The Artisan lens is lathe cut from a Perspex CQ ultraviolet polymethyl methacrylate blank. The lens is designed so that the two haptics lie in the plane of the iris, and the optic vaults 0.69 mm anterior to the iris. The design is intended to prevent chafing of the pupillary margin during pupillary movement. During the trial, two different models of the Artisan lens were used. One has an optical zone of 5 mm (model 206), whereas the other has an optical zone of 6 mm (model 204). The 6-mm lens (Fig 2) has the potential to reduce nighttime glare, but increases the risk of induced astigmatism because it is inserted through a slightly larger incision. The higher power Artisan lenses have a greater optic thickness and come closer to the corneal endothelium. For this reason, the manufacturer has elected not to make the lenses with power more extreme than −15 D in the 6-mm diameter lens. In phase I, all 10 eyes received 5-mm lenses. In phases II and III, patients who needed a lens power of −15 D or milder had a choice of lenses. This choice was made in consultation with the surgeon, and generally the larger-diameter lens was chosen to minimize the risk of halos. Eyes requiring a lens power more extreme than −15 D in power received the 5-mm lens.

The lens power needed for emmetropia was calculated before surgery by inserting spherical equivalent refraction, keratometry, and anterior chamber depth into the Van der Heijde formula.[39,44] The lenses used in this study were available in power increments of 1 D. The surgeon chose a lens power close to the power needed for emmetropia.

Table 3. Comparison of Mean Preoperative Variables of Eyes Examined at 6 Months with Those Not Examined

	Eyes Examined	Eyes Not Examined
Number of eyes	84	71
Age (years)	39	39
Preoperative spherical equivalent (diopters)	−13.0	−12.3
Preoperative astigmatism (diopters)	1.15	1.09
LogMAR best-corrected visual acuity	20/17	20/17
Intraocular pressure (mmHg)	15.1	15.3
Endothelial cell count (cells/mm^2)	2631	2637
Anterior chamber depth (mm)	3.69	3.68

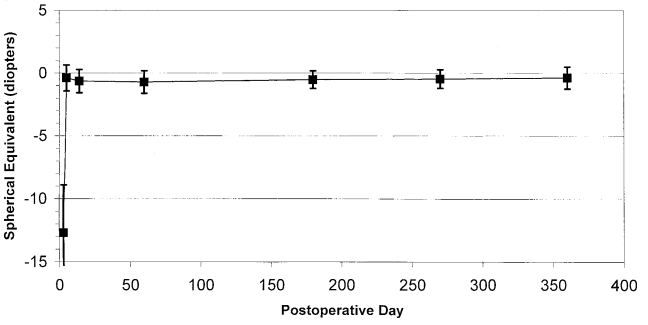

Figure 4. Mean spherical equivalent manifest refraction over time. Mean spherical equivalent refraction stabilized at postoperative day 1. The error bars show 1 standard deviation.

Surgical Procedure

The surgical procedure is as described by van der Pol and Worst,[33] Menezo et al,[34] and Perez-Satonja et al.[35] A scleral tunnel, limbal incision, or corneal incision is made that is approximately equal to the lens optic diameter, usually in steep corneal meridian. The pupil is constricted pharmacologically. Two stab incisions are made on either side of the main incision. The lens is inserted into the anterior chamber under an ocular viscoelastic device. It is rotated 90° so that the axis of the lens lies perpendicular to the direction of insertion. The surgeon then grasps the optic of the lens with a Budo forceps (Duckworth and Kent, Ltd, Baldock Herts, England). A small knuckle of iris is then drawn through the pincer of each haptic with a disposable enclavation needle (Ophtec BV, Groningen, Netherlands). A peripheral iridectomy or iridotomy is performed. The viscoelastic is removed and the wound is closed with sutures.

Data Analysis

The intended postoperative spherical equivalent refraction (refractive goal) was calculated as the difference between the lens power needed for emmetropia and the actual lens power used. Intended correction was calculated as the difference between the refractive goal and the preoperative spherical equivalent manifest refraction. Achieved correction was calculated as the difference between the postoperative spherical equivalent manifest refraction and preoperative spherical equivalent manifest refraction. A high percentage of patients returned for each follow-up visit, but not all required data were recorded for each eye on the case report forms. As a result, the total eyes shown in Tables 4 through 11 is slightly less than the totals shown in Table 1. The number of eyes with recorded data were taken as the denominator for all percentages given. Data analysis was performed with Excel (Microsoft, Redmond, WA) and SPSS for Windows (SPSS Inc., Chicago, IL). All averages given in the text are mean ± standard deviation. Mean Snellen acuity was calculated by converting the arithmetic average of log MAR acuity.

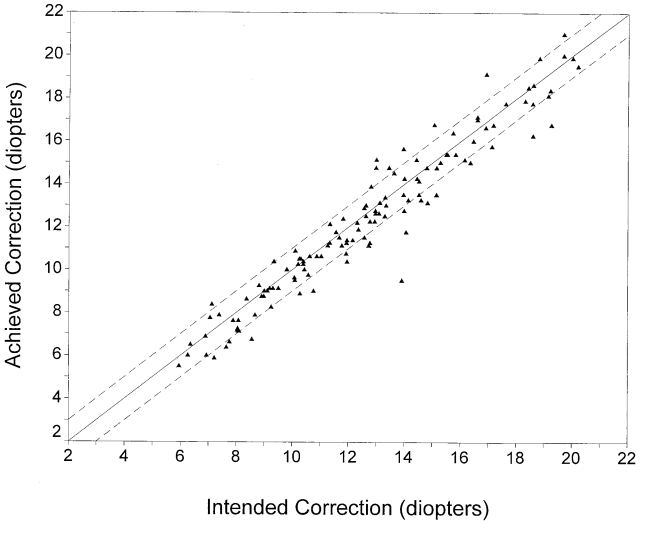

Figure 5. Scattergram of intended versus achieved spherical equivalent refractive change at 2 months. The diagonal lines show equality and overcorrection and undercorrection by 1 diopter.

Table 4. Comparison of Intended and Achieved Spherical Equivalent Correction at Each Visit, Expressed as Number of Eyes (Percentage)

	1 Day	2 Weeks	2 Months	6 Months
Within 0.5 D of intended correction	73 (51%)	68 (50%)	62 (49%)	46 (55%)
Within 1.0 D of attempted correction	106 (74%)	103 (76%)	90 (71%)	76 (90%)
Total number of eyes	143 (100%)	135 (100%)	126 (100%)	84 (100%)

D = diopters.

Results

One hundred fifty-five eyes of 155 patients were enrolled between October 1997 and July 1999. Mean preoperative spherical equivalent myopia was −12.69 ± 3.80 D (range, −5.5 D to −22.5 D; Fig 3). Patient enrollment was continuing up to the time of the data analysis for this report. This report is a cross-sectional view of all eyes enrolled as of August 1, 1999. Eyes that were enrolled in phase III had a significantly shorter follow-up interval than eyes enrolled in phase II, which were followed up for less time than eyes in phase I (Table 1). Because follow-up intervals were different for the eyes in each phase, the data presented here could in theory be skewed if the eyes in various phases had different characteristics. Table 2 gives the preoperative characteristics of the eyes in each phase of the study. The eyes enrolled are comparable, except that the degree of myopia in phase I was higher than in later phases. These more highly myopic eyes may be expected to have a less accurate refractive result and may be more likely to develop complications such as nighttime glare. Long-term results for the entire population of eyes therefore may be expected to be comparable with or superior to the long-term results presented here, which include a disproportionately high number of phase I eyes. Table 3 compares the preoperative characteristics of eyes that had a 6-month follow-up visit with those that did not. As expected, preoperative myopia is higher in the group with 6 months of follow-up, although the difference is not significant ($P = 0.26$, t test). The other preoperative characteristics are virtually identical for both groups, suggesting that the cross-sectional results presented here are representative of the entire study population.

Mean spherical equivalent refraction stabilized at postoperative day 1 (Fig 4), changing from −0.39 ± 1.04 D at day 1 to −0.54 ± 0.70 D at month 6. The slightly myopic mean outcome resulted

Table 5. Comparison of Intended to Achieved Spherical Equivalent Correction for Spherical Equivalent Myopia of 10 Diopters or Less, Expressed as Number of Eyes (Percentage)

	1 Day	2 Weeks	2 Months	6 Months
Within 0.5 D of intended correction	27 (68%)	16 (46%)	17 (53%)	14 (74%)
Within 1.0 D of intended correction	35 (88%)	30 (86%)	26 (81%)	19 (100%)
Total number of eyes	40 (100%)	35 (100%)	32 (100%)	19 (100%)

D = diopters.

Table 6. Comparison of Intended to Achieved Spherical Equivalent Correction for Spherical Equivalent Myopia of More than 10 and No More than 15 Diopters, Expressed as Number of Eyes (Percentage)

	1 Day	2 Weeks	2 Months	6 Months
Within 0.5 D of intended correction	35 (52%)	35 (55%)	30 (50%)	27 (63%)
Within 1.0 D of intended correction	47 (70%)	49 (77%)	43 (72%)	39 (91%)
Total number of eyes	67 (100%)	64 (100%)	60 (100%)	43 (100%)

D = diopters.

from two factors. First, six eyes were targeted for monovision. Second, the surgeons in this study tended to be conservative, choosing a lens power that would leave the patient mildly myopic rather than hyperopic; the mean intended postoperative spherical equivalent was −0.34 D. The mean difference between the intended and achieved correction at 2 months was −0.32 ± 0.95 D (range, −4.4 D to +2.2 D; Fig 5). At 2 months, the achieved correction was within 0.5 D of the intended correction in 49% of eyes and within 1 D in 71% of eyes (Table 4). Percentage accuracy was calculated for each eye by dividing the achieved correction (difference between the postoperative and preoperative spherical equivalent) by the intended correction (difference between the postoperative goal and the preoperative spherical equivalent). The mean percentage accuracy was 97% ± 7.7% of the intended correction at 2 months.

Refractive accuracy with the Artisan lens was slightly better for lower levels of myopia, with 26 of 32 eyes (81%) with myopia less than 10 D corrected to within 1 D of emmetropia at 2 months (Tables 5, 6, and 7), whereas 21 of 34 eyes (62%) with myopia of more than 15 D were similarly corrected. In contrast to laser in situ keratomileusis,[1,2] the decline in accuracy of the Artisan lens for higher degrees of myopia is relatively small (Fig 5).

The Artisan lens is not foldable, and consequently it requires a corneal, limbal, or scleral incision approximately equal to the diameter of the optic. This has the potential to induce astigmatism either from tight suturing of the wound or from relaxation of the cornea in the axis of the incision. The surgeon generally attempted to manipulate the wound to minimize postoperative astigmatism, using one or more of three methods: by placement of the incision in the steep preoperative axis of astigmatism, by adjustment of suture tension during surgery, or by selective suture removal after surgery. Mean astigmatism increased at the first postoperative visit and then decreased later in the postoperative period. By 6 months after surgery, mean astigmatism had decreased to 0.82 ± 0.62 D from its preoperative value of 1.12 ± 0.80 D (Table 8). Wound manipulation by the surgeon led to variable results, but eyes with higher levels of preoperative astigmatism tended to have a reduction in astigmatism (Fig 6). At 6 months, 79% of eyes had refractive astigmatism within 1 D of preoperative astigmatism, 17% of eyes had a decrease of more than 1 D of preoperative refractive astigmatism, whereas 4.8% of eyes had an increase of more than 1 D of astigmatism (Table 8).

Uncorrected visual acuity was 20/25 or better in 44% of eyes and 20/20 in 23% of eyes at 2 months after surgery (Table 9). Preoperative best-corrected vision was 20/20 or better in only 52% of eyes. Thirty-eight of 84 eyes (45%) had a postoperative uncorrected vision equal to or better than their preoperative best-spectacle corrected acuity at the 6-month follow-up.

Best spectacle-corrected visual acuity was either unchanged or improved in 92% of eyes at 2 months after surgery (Table 10). Five eyes (4.0%) lost two lines and one eye (0.8%) lost three lines of best spectacle-corrected visual acuity at 2 months. Five of the six eyes with a two-line or more loss of best spectacle-corrected visual acuity had recovered to within one line of preoperative acuity by the 6-month visit; the sixth eye had not yet been seen for the 6-month visit at the time of data analysis. By 6 months after surgery, no eye in the study had lost two or more lines of best spectacle-corrected visual acuity.

Endothelial cell density was measured before surgery and at 6 months after surgery. In 80 eyes with 6-month endothelial cell counts, the preoperative endothelial cell count averaged 2635 ± 523 cells/mm^2. At 6 months after surgery, mean cell density in these eyes was 2641 ± 515 cells/mm^2, a mean increase of 6 ± 526 cells/mm^2 (P = ns, paired t test). Twenty percent of these eyes had an endothelial cell loss of 10% or more, whereas 25% of eyes gained 10% or more at 6 months (Fig 7).

Complications are listed in Table 11. Most complications occurred in the immediate postoperative period. In four eyes, new lens vacuoles were noted after surgery. These vacuoles likely were caused either by inadvertent contact with the crystalline lens during surgery or by overly aggressive use of an ocular viscoelastic device. Two of these four eyes were followed up for 2 years, whereas the other two eyes were followed up for 9 months to 1 year. In all four eyes at the last follow-up visit, the lens opacities were nonprogressive, and best spectacle-corrected visual acuity had improved by one or more lines compared with preoperative best-corrected visual acuity. In one eye, a lens of the wrong power was inserted during surgery, the result of a nurse's error. The error was identified at the completion of surgery. The surgical wound was reopened, and the incorrect lens was removed and replaced with the correct lens. The eye did well without sequelae. Other

Table 7. Comparison of Intended to Achieved Spherical Equivalent Correction for Spherical Equivalent Myopia of More than 15 Diopters, Expressed as Number of Eyes (Percentage)

	1 Day	2 Weeks	2 Months	6 Months
Within 0.5 D of intended correction	11 (31%)	16 (44%)	15 (44%)	6 (27%)
Within 1.0 D of intended correction	24 (67%)	24 (67%)	21 (62%)	18 (82%)
Total number of eyes	36 (100%)	36 (100%)	34 (100%)	22 (100%)

D = diopters.

Table 8. Refractive Astigmatism at Each Visit, Expressed as Number of Eyes (Percentage)

	Preoperative	1 Day	2 Weeks	2 Months	6 Months
Mean (SD)	1.12 (0.80)	1.73 (2.18)	1.13 (1.05)	1.11 (1.68)	0.82 (0.62)
Within 1 D of preoperative measurement		93 (65%)	105 (78%)	99 (79%)	66 (79%)
Increase of >1 D from preoperative measurement		35 (24%)	14 (10%)	9 (7%)	4 (5%)
Decrease of >1 D from preoperative measurement		15 (10%)	16 (12%)	18 (14%)	14 (17%)
Total number of eyes	155 (100%)	143 (100%)	135 (100%)	126 (100%)	84 (100%)

SD = standard deviation.

intraoperative complications included aspiration pneumonia caused by general anesthesia in one patient that resolved without sequelae. Four eyes (3.1%) had an irregular pupil at the 2-month visit. This occurs when the iris is enclavated unevenly in the lens haptics. In each of these eyes, the irregular pupil was present at last follow-up. Progression of irregularity was not seen in any eyes.

One day after surgery, mild cell and flare were evident in 19% of eyes and moderate cell and flare were evident in 3.9%. By the 2-month postoperative visit, no eyes had anterior chamber inflammation visible on slit-lamp biomicroscopy (Table 11).

Mild to moderate glare was noted in 18 eyes (13.8%) at the 2-month postoperative visit, whereas severe glare was noted in one eye (0.8%; Table 11). In three eyes of three patients who reported postoperative glare, a lens with the 5.0-mm optic was exchanged for the lens with the 6.0-mm optic, after which these patients noted no glare in the eye.

Mean intraocular pressure before surgery was 15.2 ±2.8 mmHg. A rise in intraocular pressure to more than 40 mmHg was observed in one eye at the 1-day postoperative visit. Intraocular pressure was less than 30 mmHg in all eyes by the 2-month visit. By 6 months after surgery, mean intraocular pressure was 14.9 ±2.7 mmHg. At 6 months, intraocular pressure was less than 21 mmHg in every eye.

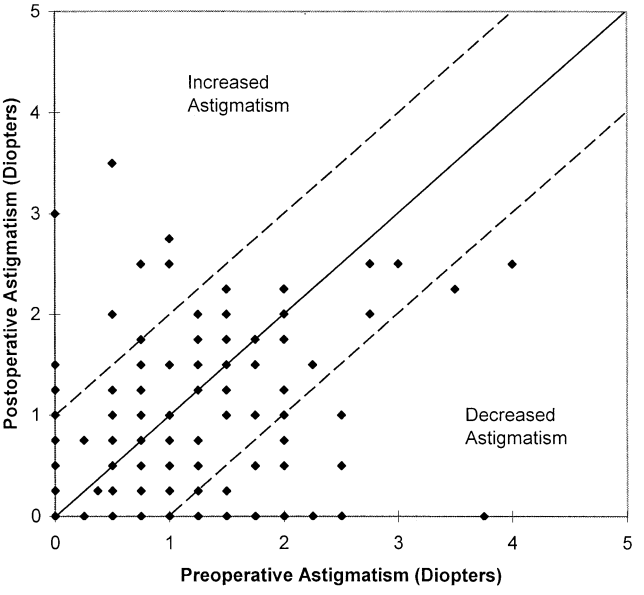

Figure 6. Scattergram of preoperative versus postoperative refractive astigmatism at 2 months. The solid diagonal line indicates no change in astigmatism, whereas the dashed lines indicate an increase or decrease of 1 diopter (D). All eyes with more than 2 D of preoperative astigmatism had a decrease in astigmatism, which resulted from wound manipulation by the surgeon.

Discussion

The Artisan lens corrected an average of 97% of the intended correction at the 2-month visit, with a standard deviation of 7.7%. The standard deviation is a measure of the variability in refractive outcome. The standard deviation for the Artisan lens is considerably less than the 13% that Hersh et al[3] found for the correction of high myopia by laser in situ keratomileusis. The reduced variability of this phakic intraocular lens in comparison with laser in situ keratomileusis is not surprising. Eyes undergoing laser in situ keratomileusis are significantly affected by corneal wound healing and variability in the performance of the excimer laser. Phakic intraocular lenses can be fabricated with near perfect refractive accuracy. The major limitation in refractive accuracy is power calculation. In contrast to pseudophakic intraocular lenses, power calculation for phakic intraocular lenses depends only on corneal curvature and anterior chamber depth. Corneal curvature can be measured accurately with keratometry. Anterior chamber depth is measured less accurately, but has much less impact on intraocular lens power than axial length does for pseudophakic lenses because anterior chamber depth in essence affects only the vertex distance of the phakic intraocular lens.[45] Eyes with a phakic intraocular lens can undergo laser in situ keratomileusis enhancement if necessary for a small residual refractive error.[46,47] Laser in situ keratomileusis is less likely to induce significant glare, loss of spectacle-corrected visual acuity, or corneal ectasia in eyes with a low residual refractive error compared with laser in situ keratomileusis for high myopia.

Spectacle-corrected visual acuity is expected to improve after surgical correction of high myopia because elimination of the spectacle correction creates a relative magnification, making the letters on the chosen eye chart easier to see.[46,48] Indeed, in this study, spectacle-corrected visual acuity was the same or improved in 90% of eyes and declined two lines in no eyes at 6 months. This is in contrast to laser in situ keratomileusis, where 3% to 5% of highly myopic eyes typically lose two or more lines of best spectacle-corrected visual acuity at 6 months.[1,3] The good preservation of spectacle-corrected visual acuity with the Artisan lens may be attributed to the high optical quality of phakic intraocular lenses in general and the undisturbed corneal optics. In contrast, laser in situ keratomileusis commonly reduces the quality of the corneal optics by inducing irregular astigmatism, central islands, and other topographic abnormalities.[46,49,50]

Table 9. Uncorrected Visual Acuity at Each Visit with Comparison with Preoperative Best-corrected Visual Acuity, Expressed as Number of Eyes (Percentage)

Visual Acuity	Preoperative Best Spectacle-corrected Visual Acuity	1 Day	2 Weeks	2 Months	6 Months
20/20 or better	80 (52%)	20 (13%)	27 (20%)	29 (23%)	22 (26%)
20/25 or better	118 (76%)	45 (29%)	55 (40%)	56 (44%)	43 (51%)
20/40 or better	153 (99%)	94 (61%)	104 (76%)	100 (78%)	70 (83%)
Total number of eyes	155	153	137	128	84

The superior optics of the Artisan lens and its better refractive accuracy in comparison with laser in situ keratomileusis are reasons to recommend it over laser in situ keratomileusis for the correction of myopia of more than 10 D. However, these advantages must be counterbalanced against the relatively greater risk of an intraocular procedure. No eye in this study had serious intraocular complications as a result of the procedure.

Historically, iris-fixated intraocular lenses were associated with corneal decompensation.[21,51] The iris-fixated lenses that were associated with corneal decompensation were pupillary fixated aphakic lenses. Propelled by the vitreous, these lenses underwent dramatic contre-coups movements each time the eye moved. The source of endothelial cell trauma was likely contact between the endothelium and the edge of these lenses. In contrast, the Artisan lens is secured to the peripheral iris. The peripheral iris is relatively immobile and provides a more stable anchor than the pupillary margin. In addition, the lens–iris diaphragm is intact in the phakic eye, so that the vitreous does not propel movements of the lens. As a consequence, the Artisan is stable in the eye, with no visible movement relative to the eye when the Purkinje images are examined.[52]

The impact of the Artisan lens on the corneal endothelium has been examined in a large study by Menezo et al[53] of 111 eyes followed up for 4 years. The mean cell loss was 3.9% at 6 months, 6.6% at 1 year, 9.2% at 2 years, 11.7% at 3 years, and 13.4% at 4 years. At 2 years, the hexagonality and coefficient variation in cell size were close to the preoperative levels. The authors suggested that endothelial damage might have occurred during the surgical procedure. Similar results were found in others studies.[44,54] This loss is higher than the natural rate of endothelial cell loss of 0.6% per year.[55,56] In contrast, the present study found no significant change in mean endothelial cell count at the 6-month visit. In some eyes, large decreases in measured cell counts occurred, but in other eyes, large increases took place (Fig 7). The normal distribution of changes in cell count, without skewing, suggests that the reduction in cell count in some eyes was a normally distributed statistical fluctuation, rather than intraoperative trauma or damage to the corneal endothelium in the early postoperative period. The unchanged mean endothelial cell count of this study compares favorably with the endothelial cell loss with phacoemulsification of 7% to 10% in the first 6 months, a procedure whose rate of endothelial cell loss is generally considered acceptable.[55–58] Most high myopes wear contact lenses, and discontinuance of lens wear may improve central endothelial cell counts.[59] A short-term improvement in cell count from the discontinuance of lens wear may mask a decrease in cell count induced by trauma from the Artisan lens procedure, so longer-term follow-up will be necessary to determine if there is progressive cell loss.

Iris-fixated pseudophakic intraocular lenses also have been associated with chronic inflammation and cystoid macular edema occurring years after surgery. No inflammation was noted by slit-lamp examination in the eyes in the present study after the 2-month postoperative visit. The preservation of spectacle-corrected visual acuity argues against significant cystoid macular edema. In the present study, more sensitive indicators of intraocular inflammation, such as iris angiography or a flare-cell meter, were not used. Fechner et al[32] studied 109 eyes with the Artisan lens with at least 1 year of follow-up and found no inflammation

Table 10. Change in Best Spectacle-corrected Visual Acuity at Each Visit, Expressed as Number of Eyes (Percentage)

	1 Day	2 Weeks	2 Months	6 Months
Gain 2 lines	9 (6.3%)	16 (12%)	21 (17%)	10 (12%)
Gain 1 line	33 (23%)	38 (28%)	41 (33%)	39 (46%)
No change	54 (38%)	56 (41%)	52 (42%)	27 (32%)
Lost 1 line	24 (17%)	19 (14%)	5 (4.0%)	8 (9.5%)
Lost 2 lines	8 (5.6%)	4 (2.9%)	5 (4.0%)	0 (0.0%)
Lost 3 lines	9 (6.3%)	1 (0.7%)	1 (0.8%)	0 (0.0%)
Lost 4 lines	3 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lost 5 lines	3 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lost 6 lines	1 (0.7%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Lost 7 lines	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total number of eyes	144	135	125	84

Percentages were limited to two significant digits or less to avoid giving an inaccurate impression of the precision.

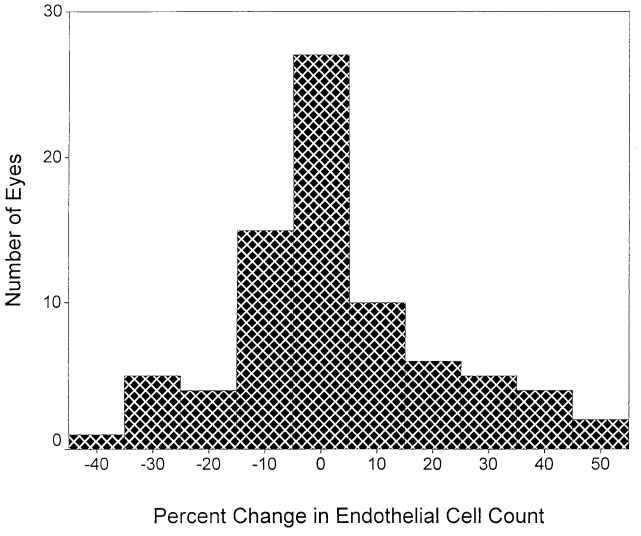

Figure 7. Histogram of percent change in endothelial cell density at 6 months compared with preoperative readings. Mean cell density increased by 6 ± 526 cells/mm^2 at 6 months, a statistically insignificant change. Eyes were equally likely to experience an increase or a decrease in cell count, suggesting that variability in measurement rather than surgical trauma was the cause of the decrease in those eyes that experienced a decrease in cell count.

using a flare-cell meter. Another study used fluorometry and found inflammation of the same magnitude as that seen after cataract surgery with in-the-bag lens implantation at 6 months after surgery.[35] Conversely, Perez-Santonja et al[60] found evidences of chronic subclinical inflammation between 1 and 2 years after implantation of both Worst-Fechner and Baikoff intraocular lens types using a laser flare-cell meter. Further study will be required to resolve this issue.

Another potential concern with phakic intraocular lenses is cataract. Four patients in this study experienced nonprogressive lens vacuoles. These may have been caused by intraoperative contact with the crystalline lens or by overinflation of the anterior chamber with the ocular viscoelastic device. Either cause could be related to surgeon inexperience. Visually significant opacities in the immediate postoperative period are rare with the Artisan lens, in contrast to posterior chamber phakic intraocular lenses.[23–25] This may be the result of surgical technique: the Artisan lens is inserted over a miotic pupil, whereas posterior chamber phakic intraocular lenses are inserted in direct contact with the crystalline lens behind a widely dilated pupil. Late development of cataract also has been associated with posterior chamber phakic intraocular lenses.[22–24] This may be because of chronic contact with the anterior capsule or impairment of aqueous nourishment of the lens epithelial cells. An increased incidence of late cataract has not been reported with the Artisan lens.[28–31] Longer follow-up of the eyes in this study will be needed to determine if late cataracts develop more frequently than would be expected.

Phakic intraocular lenses could induce glaucoma, either by causing pupillary block or by compromising the anterior chamber angle. Peripheral iridectomy or iridotomy was performed routinely in this study, and no eye developed pupillary block. In no eyes did the Artisan lens implant cause a sustained increase in intraocular pressure. Because the Artisan lens does not involve the anterior chamber angle, no long-term effect on intraocular pressure is anticipated.

Another possible complication is pupillary ovalization. This can occur with the Artisan lens if enclavation of the haptics into the peripheral iris is performed asymmetrically. In this study, an oval or irregular pupil developed in 2.9% of eyes and was noted at the 2-month visit. Progressive pupillary ovalization has been reported with Baikoff-style ante-

Table 11. Incidence of Complications at Each Visit, Expressed as Number of Eyes (Percentage)

Complication	Visit			
	1 Day	*2 Weeks*	*2 Months*	*6 Months*
Total number of eyes	151	141	130	84
Cell flare				
Mild	29 (19%)	9 (6.4%)	0 (0.0%)	0 (0.0%)
Moderate	6 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal edema				
Mild	9 (6.0%)	2 (1.4%)	1 (0.8%)	0 (0.0%)
Moderate	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Glare and halo				
Mild	3 (2.0%)	15 (11%)	12 (9.2%)	5 (6.0%)
Moderate	0 (0.0%)	5 (3.5%)	6 (4.6%)	2 (2.4%)
Severe	0 (0.0%)	1 (0.7%)	1 (0.8%)	0 (0%)
Hyphema	3 (2.0%)	0 (0%)	0 (0%)	0 (0%)
IOP > 21 mmHg	4 (2.6%)	2 (1.4%)	0 (0%)	0 (0%)
Wound leak	6 (4.0%)	0 (0%)	0 (0%)	0 (0%)
Pupil irregular	14 (9.3%)	5 (3.5%)	4 (3.1%)	1 (1.2%)
Asymptomatic vacuoles on crystalline lens	2 (1.3%)	3 (2.1%)	4 (3.1%)	2 (2.4%)

Percentages were limited to two significant digits or less to avoid giving an inaccurate impression of the precision.

rior chamber phakic intraocular lenses that are anchored with haptics in the anterior chamber angle.[20,37] No eye in this study developed progressive pupillary ovalization.

Clear lens extraction offers an alternative means of surgical correction of high myopia. It carries the risk of inducing retinal detachment and cystoid macular edema. Retinal detachment is more common in high myopes and may occur with a lifetime incidence of 5% to 10% in highly myopic pseudophakes.[61] Clear lens extraction also causes a complete loss of accommodation, which is especially problematic in younger eyes.

In addition, refractive accuracy may be worse for lens extraction in high myopes because axial length measurements are difficult to perform accurately in the presence of a posterior staphyloma. In contrast, phakic intraocular lens power calculation in a highly myopic individual does not depend on axial length, but only on keratometry and anterior chamber depth.

One of the weaknesses of the present study was the varying lengths of follow-up. The varying lengths of follow-up create a risk of survivorship bias, where the long-term results may look better than they should if complications occurred more frequently in eyes enrolled later in the study. We believe this is not the case, for several reasons. First, the comparability of the preoperative characteristics of the eyes seen for a 6-month visit with those not seen at 6 months (Table 3) suggests that the results presented here are representative of the entire study population. Second, except for glare and halo, the complications listed in Table 11 develop in the early postoperative period and may resolve with time, so the 1-day and 1-week data provide an upper bound on the risk of these complications at any time during the study. Complications occurred relatively rarely even at 1 day and 1 week. Third, the risk of complications should decrease with surgeon experience. For example, two of the four eyes with asymptomatic crystalline lens vacuoles were the first two eyes enrolled in the study. Survivorship bias will make long-term complications appear to be more frequent than they actually are.

Survivorship bias also may affect the reported refractive results. If, for example, the eyes initially enrolled in the study were relatively easier corrections than eyes treated later in the study, the long-term refractive results may appear more accurate than is warranted. In this study, the eyes enrolled in phase I had higher levels of myopia and astigmatism than eyes enrolled later (Table 2). Because implantation of the Artisan lens, like other refractive procedures, is less accurate at higher levels of myopia (Fig 5), it is possible for the long-term results for refractive accuracy in this report to appear worse than they will be when follow-up is complete because of survivorship bias. Similarly, reported mean astigmatism (Table 8) may be higher at 6 months than it will be when all enrolled eyes have been followed up for 6 months. Again, because preoperative spherical equivalent and preoperative astigmatism were not significantly different in those eyes examined at 6 months in comparison with those eyes not examined (Table 3), this is likely not to be the case. We will continue to report on the results of Artisan lens implantation as longer-term follow-up on these eyes becomes available. Until then, the results presented here should be interpreted with caution.

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