

# Comparison of Iris-fixed Artisan Lens Implantation with Excimer Laser In Situ Keratomileusis in Correcting Myopia between $-9.00$ and $-19.50$ Diopters

## A Randomized Study

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**Objective:** To compare Artisan lens implantation with laser in situ keratomileusis (LASIK) for the correction of myopia between  $-9.00$  and  $-19.50$  diopters.

**Design:** Prospective randomized clinical trial.

**Participants:** Ninety eyes of 61 consecutive patients were enrolled in the study.

**Intervention:** Forty-five eyes (50%) received Artisan lens, and 45 eyes (50%) received LASIK; the procedure assigned to each eye was randomized. Eighteen patients (29.5%) received Artisan lens in one eye and LASIK in the other.

**Main Outcome Measures:** Slit-lamp microscopy, manifest refraction, uncorrected and spectacle-corrected visual acuity, contrast sensitivity, and specular microscopy were performed before surgery, and 1, 3, 6, and 12 months after surgery. Patient satisfaction and preference were assessed by a subjective questionnaire.

**Results:** At 1 year, 43 eyes (95.6%) from the Artisan group and 41 eyes (91.1%) from the LASIK group were examined, the mean spherical equivalent refraction was  $-0.64 \pm 0.8$  diopter in the Artisan eyes and  $-0.87 \pm 0.8$  in the LASIK eyes. The uncorrected visual acuity was 20/20 or better in 9 Artisan eyes (20.9%) and 5 LASIK eyes (12.2%) and 20/40 or better in 38 Artisan eyes (88.4%) and 24 LASIK eyes (58.5%); no Artisan eyes and 5 LASIK eyes (12.2%) lost 2 or more Snellen lines of spectacle-corrected visual acuity. One Artisan eye (2.3%) and six LASIK eyes (14.6%) reported severe night glare; the Artisan lens was exchanged with a larger optic diameter lens. Mean endothelial cell loss at 1 year was  $0.7 \pm 1.1$  cells/mm<sup>2</sup> in the Artisan eyes and  $0.3 \pm 0.9$  cells/mm<sup>2</sup> in the LASIK eyes. Contrast sensitivity curve decreased by 2 or more lines in two Artisan (4.7%) and six LASIK eyes (14.6%). Of the 18 patients who received both surgeries, one in each eye, 13 patients (72.2%) preferred the Artisan procedure because of the better quality of vision.

**Conclusions:** In this study, Artisan lens implantation and LASIK were found to be similarly effective, stable, and reasonably safe for the correction of myopia between  $-9.00$  and  $-19.50$  diopters. Better uncorrected and spectacle-corrected visual acuity and contrast sensitivity, a lower enhancement rate, and exchangeability are the main advantages of Artisan lens implantation. Thirteen (72.2%) of the 18 patients who received the Artisan lens in one eye and LASIK in the other preferred the Artisan lens to the LASIK, mainly because of the better quality of vision. *Ophthalmology* 2002;109:955-964 © 2002 by the American Academy of Ophthalmology.

Excimer laser in situ keratomileusis (LASIK) is by far the most commonly performed procedure for the correction of myopia. The efficacy, stability, and safety of LASIK has

been thoroughly studied.<sup>1-5</sup> The perception that LASIK can successfully treat a wide range of myopia, can achieve fast and painless return to excellent visual acuity, and can be adjusted in case of undercorrection has led many surgeons to adopt LASIK for the correction of low, moderate, and high amounts of myopia. However, the initial enthusiasm for this procedure has been tempered by more understanding of its potential complications, especially for high corrections in which small optic zone diameter and/or deep ablation are used. Iatrogenic keratectasia, optical aberrations, severe night glare, flap-related complications, and significant loss of spectacle-corrected visual acuity have recently been reported.<sup>6-9</sup>

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Since 1983, many phakic intraocular lens designs have emerged; today, the most commonly used designs are the anterior chamber, angle-fixated lens, originally introduced by Baikoff and Joly,<sup>10</sup> the iris-fixated lens introduced by Fechner and Worst,<sup>11</sup> and the posterior chamber, sulcus-fixated design introduced by Fyodorov<sup>12</sup> and modified by the Staar company.<sup>13</sup> However, the potential complications of intraocular surgery together with the relatively unknown long-term complications of most of these lenses are the major remaining obstacles to their popularity among refractive surgeons.

In this prospective randomized clinical trial we compared the efficacy, predictability, stability, and safety of the iris-fixated Artisan phakic intraocular lens (previously called the Worst myopia claw lens) and LASIK for the correction of myopia between  $-9.00$  and  $-19.50$  diopters (D). One year after surgery, patient satisfaction and preference were assessed subjectively by a questionnaire.

## Patients and Methods

### Study Design and Patient Population

Between April and November 1998, 90 eyes of 61 consecutive patients were enrolled in a prospective, randomized study. Forty-five eyes received the Artisan lens (Ophtec BV, Groningen, The Netherlands) and 45 eyes received LASIK. The procedure assigned to each eye was randomized, using a random number table. Patients selected for the study met inclusion criteria, including age of at least 21 years, documented stable refraction for 1 year, spherical equivalent refraction between 9.00 and 19.50 D of myopia, refractive astigmatism less than 3.00 D, spectacle-corrected visual acuity of 20/40 or better, corneal thickness permitting the surgeon to leave at least 250  $\mu\text{m}$  deep to the ablation, pupil size less than 6 mm at dim illumination for eyes with myopia of 15.50 D or less, and 5 mm for eyes with myopia greater than 15.50 D, and realistic expectations concerning the outcome. Exclusion criteria included previous refractive surgery, keratoconus or keratoconus suspect by videokeratography, active ocular disease, dry eyes, systemic disease likely to affect corneal wound healing (e.g., connective tissue disease), and inability to achieve the follow-up schedule given to the patients before surgery. There was no upper age limit in this trial. However, patients with presbyopia who preferred undercorrection of one eye (monovision) were not enrolled in the study, so emmetropia was the refractive goal in all eyes. All patients signed an informed consent in their native language as approved by Magrabi Hospital Research Committee. The Human Investigation Committee at Magrabi Eye and Ear Center, Abu Dhabi, UAE approved the study protocol.

### Methods of Clinical Examination

All eyes had a comprehensive preoperative ophthalmic examination including slit-lamp microscopy, applanation tonometry, indirect ophthalmoscopy, ultrasonic pachymetry, contrast sensitivity, and specular microscopy. Manifest refraction was done by an independent ophthalmologist; the fogging (highest plus) technique was used for all manifest refractions. Contact lens overrefraction was performed for eyes assigned to receive the Artisan lens, and the spherical equivalent refraction at the corneal plane was calculated. Uncorrected and spectacle-corrected visual acuity were tested using the Nidek SCP-660 chart projector (20/10–20/400;

Nidek Co, Gamagori, Japan) with both tumbling E letters and Latin characters; the smallest line in which the patient could read the four letters correctly was recorded as the final visual acuity. Videokeratography (Computed Anatomy Topographic Modeling System, software version 1.51; Tomey Technology, New York, NY) was performed according to the manufacturer's instructions. Endothelial cell count was done using the contact EM-1000 specular microscope (Tomey Technology). Pupil diameter was measured at dim illumination with the Colvard pupillometer (Oasis, Glendora, CA). Contrast sensitivity was measured using the Vision Contrast Test System (VCTS–6000, Vistech Consultants, Inc. Dayton, OH) according to the manufacturer's instructions; the VCTS–6000 chart was clipped onto the phoropter at 16 inches. The test was performed under normal room lighting. Luminance of the chart was tested by the Vistech Consultants light meter. Each eye was tested separately using its appropriate far and/or near correction, and the patient was asked to identify the last seen patch on each row.

After surgery, all patients were examined at 1 day, 1 week, 1, 3, 6, and 12 months. We did slit-lamp microscopy, manifest refraction, and uncorrected and spectacle-corrected visual acuity at all examinations starting from the first month after surgery. Contrast sensitivity, videokeratography, and specular microscopy were done at the 1-, 6- and 12-month examinations.

### Surgical Technique

All operations were performed by one surgeon (MAD), who had previous experience with both Artisan lens implantation ( $>190$  cases) and LASIK ( $>7000$  cases).

The Artisan lens power was calculated based on the refraction at the corneal plane according to a customized clinical nomogram based on the manufacturer's instructions and our previous experience with the Artisan lens implantation. The lens was implanted under topical oxybuprocain hydrochloride (Benoxinate 0.4%; Dr. Thilo & Co. GmbH, Freiburg) and 0.2 ml intracameral lidocaine hydrochloride (Lidocaine 1%; Elkins-Sinn, Inc. Cherry Hill, NJ) in patients older than 40 years. Peribulbar anesthesia was used for younger patients. A 5-mm optic diameter lens was used for eyes with myopia greater than 15.50 D and a 6-mm lens for myopia of 15.50 D or less. A 3.00-mm clear corneal temporal incision was made with a diamond knife and viscoelastic was injected in the anterior chamber. The incision was then widened to be 0.5 mm larger than the optic diameter of the lens to be inserted. An Artisan lens of the calculated power was inserted into the anterior chamber with the Artisan lens holder, and two 10-0 nylon sutures were used to secure the wound. The lens was rotated in the vertical position with a microhook. A bimanual technique was used to enclavate a bite of the anterior and the posterior iris stroma in the claw mechanism of the lens haptic, using an enclavation needle and the Artisan lens holder. The lens was adjusted so the pupil was round and the center of the lens was over the center of the pupil. A small superior temporal peripheral iridectomy was done in all cases. The viscoelastic was irrigated from the anterior chamber. The wound was secured with one or two additional 10-0 nylon sutures. Vancomycin 0.2 mg (Abbot Laboratories, North Chicago, IL) was injected into the anterior chamber. Postoperative treatment included topical tobramycin, 0.3%, combined with dexamethasone, 0.1% (Tobradex; Alcon, Couvreur, Belgium), every 4 hours for 1 week, then tapered over 4 weeks. No astigmatic correction was attempted in the Artisan group.

The Nidek EC-5000 excimer laser (Nidek Co, Gamagori, Japan) was used for all LASIK eyes. The laser system parameters were as follows: wavelength, 193 nm; pulse repetition rate, 40 Hz; fluence, 140  $\text{mJ}/\text{cm}^2$ ; ablation depth, 0.26  $\mu\text{m}$  per scan in polymethyl methacrylate and 0.62  $\mu\text{m}$  per scan on the cornea; no

Table 1. Spherical Equivalent Refraction at Baseline and at 12 Months after Surgery

Spherical Equivalent (Diopter)	Baseline		12 Months	
	Artisan Eyes [No. of Eyes (%)]	Laser In Situ Keratomileusis Eyes [No. of Eyes (%)]	Artisan Eyes [No. of Eyes (%)]	Laser In Situ Keratomileusis Eyes [No. of Eyes (%)]
+2.00 to +1.10			1 (2.3)	0 (0.0)
+1.00 to +0.51			1 (2.3)	2 (4.9)
+0.50 to +0.10			7 (16.3)	2 (4.9)
0.00 to -0.50			11 (25.6)	10 (24.4)
-0.51 to -1.00			9 (20.9)	10 (24.4)
-1.10 to -2.00			14 (32.6)	15 (36.6)
-2.10 to -3.00			0 (0.0)	2 (4.9)
-9.10 to -11.00	8 (17.8)	12 (26.7)		
-11.10 to -13.00	9 (20.0)	8 (17.8)		
-13.10 to -15.00	12 (26.7)	13 (28.9)		
-15.10 to -17.00	8 (17.8)	7 (15.6)		
-17.10 to -19.50	8 (17.8)	5 (11.1)		
Total	45 (100)	45 (100)	43 (100)	41 (100)

aspiration air flow; mean ablation zone diameter,  $5.6 \pm 0.3$  mm (range, 5.0–6.0 mm); and transition zone 1 mm. A personal customized clinical nomogram was used in all LASIK procedures; this nomogram, based on the manifest refraction was previously published.<sup>14</sup> The laser system software (version 2.25 aHC) determined the number of scans needed to achieve the required ablation depth and profile to perform the correction entered in the laser computer. In cases with no refractive cylinder, the attempted correction was equal to the manifest refraction. In cases with spherocylindrical refraction, the spherical attempted correction was calculated by subtracting 20% of the numeric value of the refractive manifest cylinder from the spherical component of the refraction. The attempted cylindrical correction was equal to the manifest refractive cylinder. The axis entered into the laser system computer was that of the refractive minus cylinder. A Carriazo-Barraquer microkeratome with a manually advanced turbine motor head (Moria; Antony, France) was used for all LASIK procedures. The LASIK surgical technique was previously described in detail.<sup>3,14</sup> Briefly, three radial marks were applied to the cornea, suction of more than 65 mmHg was applied to the eye, a flap was created 8.5 to 9.0 mm in diameter and about 160  $\mu$ m thickness based on a superior hinge of approximately 1.0 mm width and 30° arc length, the laser beam was centered over the entrance pupil, the stromal bed was ablated, the stromal surface of the flap and the stromal bed were washed with sterile balanced salt solution, and the flap was repositioned using the radial marks as a guide. Postoperative treatment included topical tobramycin, 0.3%, combined with dexamethasone, 0.1% (Tobradex), every 6 hours for 1 week and tear substitute (Tears naturelle II; Alcon, Couvreur, Belgium) every 6 hours for 1 month.

We did all enhancement procedures between the fourth and the sixth months after the primary procedure. Criteria for enhancement were a residual refractive error of more than 1.00 D at the 3-month examination, with an improvement of 2 lines or more of visual acuity. Enhancement after Artisan lens implantation was done by performing a LASIK procedure, and LASIK enhancement was done by lifting the flap and ablating the stromal bed.

### Questionnaire Forms

One year after surgery, a patient satisfaction questionnaire was given to the 18 patients (29.5%) who had Artisan lens in one eye and LASIK in the other eye. Four questions were asked:

1. “How satisfied are you with the quality of vision of each eye

without glasses or contact lenses?” (not satisfied, moderately satisfied, or very satisfied).

2. Which eye perceives more glare at night? (right eye or left eye).
3. “Based on your experience, which procedure do you prefer?” (right eye procedure or left eye procedure).
4. What is the most important reason for your preference? (less pain during surgery, faster recovery, better visual outcome, or other cause).

Every patient was asked to mark one of the choices provided, then to write a brief description of the experience during and after the surgery.

### Methods of Statistical Analysis

At baseline, two-sample *t* tests were used to compare the two groups randomly assigned to either LASIK and Artisan on variables such as spherical equivalent refraction and refractive cylinder. A repeated measures analysis of variance, with an unstructured covariance matrix for the repeated measures was used to test for treatment differences, differences over time (baseline, 1, 3, 6 months, and 1 year), and whether the differences over time varied for the different surgery groups (group by time interaction) with respect the variables: spherical equivalent refraction, refractive cylinder, and surgically induced cylinder. Robust asymptotic standard errors were used to ensure that inferences were robust to departures in the true covariance structure of the repeated measures. Post-hoc comparisons of the two treatment groups were made at each time point (1, 3, and 6 months, and 1 year), as well as the mean change from baseline to 1 year for all the variables. Unadjusted means and standard deviations are reported for these post-hoc comparisons; however, the *P* values are based on the results of the repeated measures analysis of variance, using a least squares means procedure. No adjustments were made to ensure an overall type 1 error rate for the post-hoc comparisons. Surgically induced cylinder was calculated using the 10-step method based on the oblique cross-cylinder solution described by Holladay and co-workers.<sup>15</sup> Repeated measures analysis of variance was used to analyze the difference in stability between procedures individually. A chi-square test of homogeneity was used to test whether the distribution of corrected and uncorrected visual acuity was similar between the two procedures at 1 year. A chi-square test was also used to test whether the distribution of the number of lines gained/lost was different between the two surgeries. Last, a Mann-

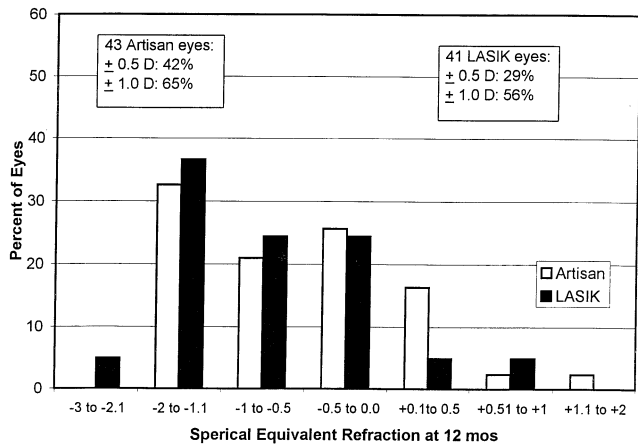


Figure 1. Distribution of spherical equivalent refraction of 43 Artisan eyes and 41 laser in situ keratomileusis eyes 12 months after operation.

Whitney test was used to test whether the average number of Snellen lines gained/lost from baseline to 1 year was similar for the two surgeries.

We have computed the statistical power for a sample size of 45 per surgery group to detect clinically important differences for a few primary outcomes. We have specified some clinically important differences for a few primary outcomes. This study has more than 80% power to detect changes in visual acuity as defined by the gain or loss of at least 2 Snellen lines for a two-sided hypothesis test with a 0.05 significance level. In addition, the study has more than 80% power to detect an endothelial loss of 5% for a two-sided hypothesis test with a 0.05 significance level.

## Results

Of the 90 eyes included in this trial, 45 eyes (50%) had Artisan lens implantation (Artisan eyes) and 45 eyes (50%) had LASIK (LASIK eyes). Patients ranged in age from 21 to 47 years (mean,  $33.7 \pm 7.1$  years). Of the 61 patients, 37 (60.7%) were female. Eighteen patients (29.5%) had Artisan lens in one eye and LASIK on the other (Artisan/LASIK subgroup), 5 patients (8.2%) had Artisan lens in both eyes, 6 patients (9.8%) had LASIK on both eyes, 17 patients (27.9%) had Artisan in one eye, and 15 patients (24.6%) had LASIK on one eye.

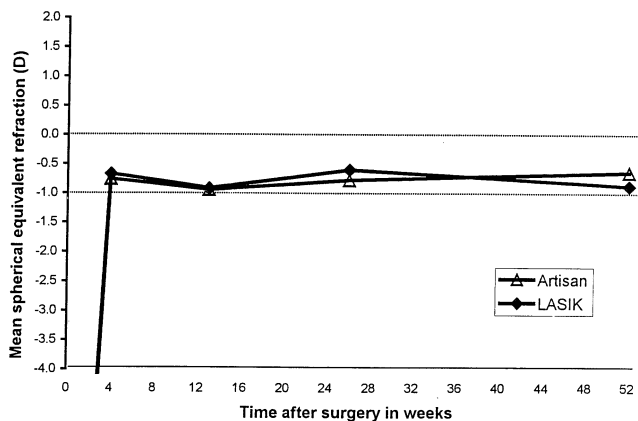
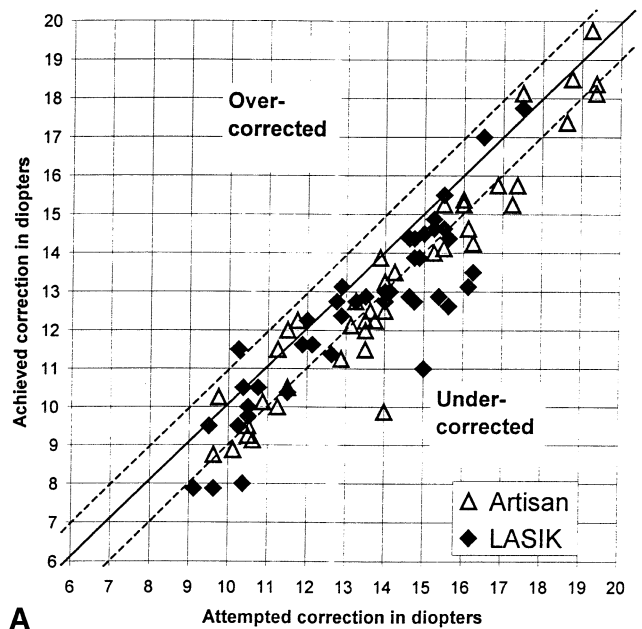
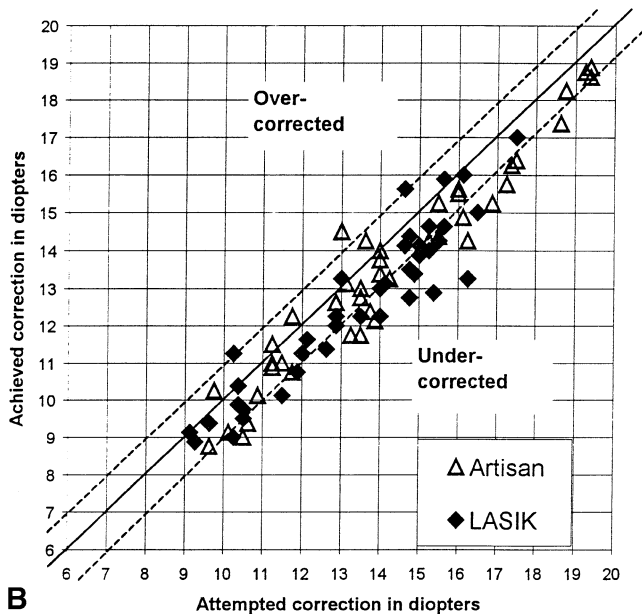


Figure 2. Mean spherical equivalent refraction weeks over time. Dotted lines indicate 0.0 to -1.0 diopter.



A



B

Figure 3. Attempted versus achieved correction at 3 months (A) and 12 months (B) after operation. Enhancement was performed on one Artisan and seven laser in situ keratomileusis eyes between the fourth and sixth months. Dotted lines indicate  $\pm 1.0$  diopter.

There was no statistically significant difference in the baseline manifest refraction or preoperative refractive cylinder between the eyes assigned for Artisan and the eyes assigned for LASIK. The mean preoperative spherical equivalent refraction was  $-13.93 \pm 2.9$  D (range,  $-9.50$  to  $-19.38$  D) in Artisan eyes and  $-13.24 \pm 2.3$  D (range,  $-9.13$  to  $-17.50$  D) in LASIK eyes ( $P > 0.20$ , two sample *t* test). The mean preoperative refractive cylinder was  $1.41 \pm 0.8$  D (range,  $0$ – $2.75$  D) in Artisan eyes and  $1.61 \pm 0.8$  D (range,  $0$ – $2.75$  D) in LASIK eyes ( $P > 0.20$ , two-sample *t* test). Seven Artisan eyes (15.6%) and five LASIK eyes (11.1%) had a refractive cylinder less than 1.00 D. Thirty Artisan eyes (66.7%) and 28 LASIK eyes (62.2%) had a refractive cylinder less than

Table 2. Uncorrected Visual Acuity at Different Postoperative Examinations

Time after Surgery	20/20 or Better		20/30 or Better		20/40 or Better		20/60 or Better		20/150 or Better	
	Artisan	Laser In Situ	Artisan	Laser In Situ	Artisan	Laser In Situ	Artisan	Laser In Situ	Artisan	Laser In Situ
	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]	[No. (%)]
1 mo	1 (2.2)	7 (17.5)	15 (33.3)	20 (50.0)	34 (75.6)	28 (70.0)	43 (95.6)	37 (92.5)	45 (100)	40 (100)
3 mos	3 (6.8)	6 (14.0)	23 (52.3)	24 (55.8)	38 (86.4)	30 (69.8)	43 (97.7)	39 (90.7)	44 (100)	43 (100)
6 mos	7 (16.3)	7 (16.7)	29 (67.4)	26 (61.9)	36 (83.7)	33 (78.6)	43 (100)	40 (95.2)	43 (100)	42 (100)
12 mos	9 (20.9)	5 (12.2)	30 (69.8)	19 (46.3)	38 (88.4)	24 (58.5)	43 (100)	39 (95.1)	43 (100)	41 (100)

2.00 D. The distribution of the baseline spherical equivalent refraction of all eyes is listed in Table 1. We implanted 6-mm optic diameter Artisan lenses in 32 eyes (71.1%) that had a baseline spherical equivalent refraction of  $-15.50$  D or less and 5-mm optic diameter lens in 13 eyes (28.9%) with baseline spherical equivalent refraction greater than  $-15.50$  D.

We examined 90 eyes (100%) at 1 day and 1 week (mean,  $1.2 \pm 0.3$  weeks), 45 Artisan (100%) and 40 LASIK eyes (88.9%) at 1 month (mean,  $4.2 \pm 0.6$  weeks), 44 Artisan (97.8%) and 43 LASIK eyes (95.6%) at 3 months (mean,  $11.3 \pm 0.6$  weeks), 43 Artisan (95.6%) and 42 LASIK eyes (93.3%) at 6 months (mean,  $25.3 \pm 1.9$  weeks), and 43 Artisan (95.6%) and 41 LASIK eyes (91.1%) at 12 months (mean,  $54.1 \pm 2.4$  weeks). The refractive data from baseline to 1 year were used in this study to assess differences between Artisan and LASIK surgeries.

**Slit-lamp Microscopy**

We measured the intraocular pressure in all Artisan eyes 3 hours after surgery. One eye had transient ocular hypertension (29 mmHg) caused by incomplete removal of visco elastic substance; this was treated with oral acetazolamide (250 mg tablets) every 8 hours for 48 hours; the intraocular pressure decreased to 18 mmHg in 12 hours. All LASIK eyes were examined 1 hour after the operation to ensure proper flap position.

On the first day after operation, 43 of the 45 (95.6%) Artisan eyes had clear cornea and two eyes (4.4%) had mild to moderate corneal edema that resolved within 1 week. All eyes had secure wounds, deep anterior chamber, round and reactive pupil, and good iris enclavation in the haptic's claw mechanism. Mean intraocular pressure was  $14.3 \pm 2.5$  mmHg (range, 10.0–20.0 mmHg). Forty-three of the 45 (95.6%) LASIK eyes showed a well-centered secure flap, and two eyes (4.4%) had a slight temporal decentration of the flap, with the nasal edge of the flap outside the edge the pupil at dim illumination. All flaps were clear and had intact central epithelium. Two eyes (4.4%) showed a small fiber in the interface outside the pupillary area. These fibers remained throughout all follow-up examinations with no effect on visual acuity.

By the end of the first week, all Artisan eyes were quiet, with no anterior chamber cells or flare. In 19 eyes (42.2%) the center of the lens coincided with the center of the entrance pupil; in 25 eyes (55.5%) the lens was decentered by 1 mm or less, with the whole pupil covered by the optic of the lens at dim illumination. In one eye (2.2%) the lens was decentered by more than 1 mm; the nasal edge of the pupil was outside the edge of the lens optic at dim illumination. The patient reported severe night glare, and the lens was exchanged at 6 months. The postoperative management of this case will be described later. All LASIK eyes had clear flaps with barely identifiable edges by the end of the first week.

All the sutures were removed from the Artisan eyes under topical anesthesia on the slit-lamp microscope between the second and third months after the operation.

At 6 months, 12 Artisan eyes (27.9%) showed depigmentation of the iris stroma at the site of the enclavation. LASIK eyes had clear central corneas. The edge of the flap in 32 eyes (76.2%) was surrounded by a faint circular scar that was best seen with oblique illumination. In 10 LASIK eyes (23.8%) the flap could not be distinguished from the bed, even with oblique illumination. In all eyes, the interface was barely visible in slit illumination. In two (4.8%) a few superficial wrinkles were observed in the flap, with no effect on the visual acuity or the videokeratography. At 1 year, the clinical picture at slit-lamp microscopy was the same as at 6 months in all Artisan and LASIK eyes.

**Refractive Outcome**

At 1 month, the mean spherical equivalent refraction was  $-0.76 \pm 1.1$  D (range,  $-4.5$ – $1.75$  D) in Artisan eyes and  $-0.67 \pm 1.0$  D (range,  $-4.75$ – $1.25$  D) in LASIK eyes, which does not represent a statistically significant difference ( $P > 0.20$ , least squares). Eleven Artisan eyes (24.4%) and 14 LASIK eyes (35.0%) had a spherical equivalent refraction between plano and  $-0.50$  D; 28 Artisan eyes (62.2%) and 30 LASIK eyes (75.0%) were within  $\pm 1.00$  D; and 42 Artisan eyes (93.3%) and 37 LASIK eyes (92.5%) were within  $\pm 2.00$  D. Three Artisan eyes (6.7%) and three LASIK eyes (7.5%) were undercorrected by more than 2.00 D.

At 3 months, the mean spherical equivalent refraction was  $-0.89 \pm 0.9$  D (range,  $-4.13$ – $0.63$  D) in Artisan eyes and  $0.94 \pm 1.1$  D (range,  $-4.00$ – $1.25$  D) in LASIK eyes, which does not represent a statistically significant difference ( $P > 0.20$ , least squares). Ten Artisan eyes (22.7%) and 13 LASIK eyes (30.2%) had a spherical equivalent refraction between plano and  $-0.50$  D; 29 Artisan eyes (65.9%) and 27 LASIK eyes (62.8%) were within  $\pm 1.00$  D; and 43 Artisan eyes (97.7%) and 37 LASIK eyes (86.0%) were within  $\pm 2.00$  D. One Artisan eye (2.3%) and six LASIK eyes (14.0%) were undercorrected by more than 2.00 D.

Between the third and sixth months, one Artisan eye (2.3%) and seven LASIK eyes (16.3%) had enhancement procedures.

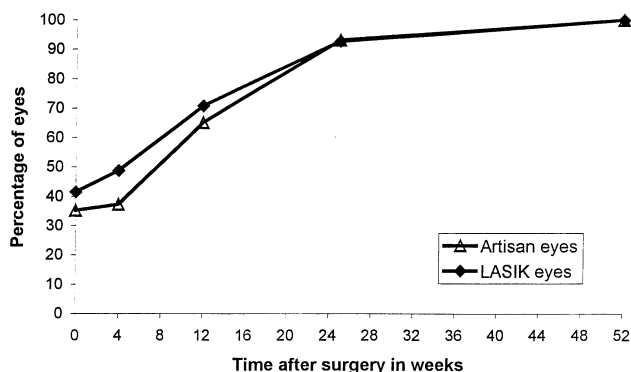


Figure 4. Visual recovery. Percent of eyes achieving their final uncorrected visual acuity at each examination after surgery.

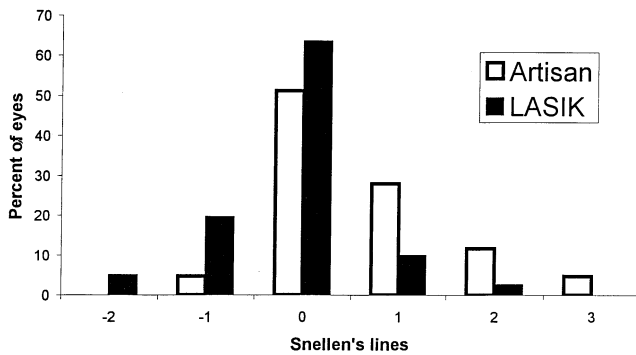


Figure 5. Loss or gain of spectacle-corrected visual acuity of 43 Artisan and 41 laser in situ keratomileusis eyes 12 months after operation.

At 1 year, the mean spherical equivalent refraction was  $-0.64 \pm 0.8$  D (range,  $-2.00$ – $-1.50$  D) in Artisan eyes and  $-0.87 \pm 0.8$  D (range,  $-3.00$ – $-1.00$  D) in LASIK eyes, which does not represent a statistically significant difference ( $P > 0.20$ , least squares) between the means. Eleven Artisan eyes (25.6%) and 10 LASIK eyes (24.4%) had a spherical equivalent refraction between plano and  $-0.50$  D; and 28 Artisan eyes (65.1%) and 24 LASIK eyes (58.5%) were within  $\pm 1.00$  D. All Artisan eyes and 39 LASIK eyes (95.1%) were within  $\pm 2.00$  D of emmetropia. Two LASIK eyes were between  $-2.10$  and  $-3.00$  D. The distribution of the 1-year refractive outcome of all eyes is shown in Table 1 and Figure 1. Figure 2 shows the mean spherical equivalent refraction at each examination.

At 1 year, the mean refractive cylinder was  $0.83 \pm 0.6$  D (range,  $0$ – $2.00$  D) in Artisan eyes and  $0.41 \pm 0.3$  D (range,  $0$ – $1.25$ ) in LASIK eyes ( $P < 0.001$ , least squares); 23 Artisan eyes (53.5%) and 38 LASIK eyes (92.7%) had a refractive cylinder less than  $1.00$  D. All eyes in either group had a refractive cylinder less than  $2.00$  D. The average change in mean refractive cylinder between baseline and 1 year is  $0.60 \pm 0.81$  in the Artisan group and  $1.2 \pm 0.87$  for the LASIK group. This difference was statistically significant ( $P < 0.001$ , least squares). In addition, there was a statistically significant difference in the mean surgically induced refractive cylinder 1 year after operation between the Artisan group ( $1.2 \pm 0.6$  D, range,  $0.25$ – $0.23$  D) and the LASIK group ( $1.8 \pm 0.8$  D; range,  $0$ – $3.2$  D,  $P = 0.001$ , least squares).

The predictability of the two procedures was assessed by examining the achieved correction at 3 months. There was no statis-

tically significant difference between the mean change in spherical equivalent refraction at 3 months from baseline after the two procedures. In Artisan eyes the mean change from baseline was  $13.06 \pm 2.92$  D (range,  $8.75$ – $19.75$  D), whereas in LASIK eyes it was  $12.47 \pm 2.22$  D (range,  $7.88$ – $17.75$  D), which represents a difference in the mean effect of  $0.59$  (95% confidence interval,  $-0.52$ ,  $1.7$ ;  $P > 0.20$ , least squares). The attempted versus achieved correction of the spherical equivalent refraction in 44 Artisan eyes and 43 LASIK eyes 3 months after the two procedures is shown in Figure 3a.

There was no statistically significant difference between the mean change in spherical equivalent refraction from baseline to 1 year after the two procedures (enhancements included;  $P = 0.08$  least squares). In Artisan eyes the mean change was  $13.5 \pm 2.72$  D (range,  $8.75$ – $18.88$  D), whereas in LASIK eyes it was  $12.6 \pm 2.1$  (range,  $8.88$ – $17.00$  D), which represents a difference in the mean effect of  $0.87$  (95% confidence interval,  $-0.19$ ,  $1.9$ ) between the two procedures. The attempted versus achieved correction of the spherical equivalent refraction in 43 Artisan and 41 LASIK eyes 12 months after the surgery is shown in Figure 3b.

We assessed the stability of the refractive correction throughout the first year after the two procedures by comparing the spherical equivalent refraction at the 1-month, 3-month, 6-month, and 12-month examinations after excluding the eyes that received enhancement in either group. In the Artisan eyes, the highest change was between the 1-month and 3-month examinations (mean,  $-0.21 \pm 0.9$  D; range,  $-1.88$ – $1.50$  D). In LASIK eyes, the highest change was between the 6-month and 12-month examinations (mean,  $-0.22 \pm 0.5$  D; range,  $-1.50$ – $0.75$  D). The mean change between all examinations in either group was less than  $1.00$  D. A repeated measures analysis of variance showed that there was no significant difference over time for either Artisan ( $P = 0.36$ ) or LASIK ( $P = 0.77$ ) eyes.

### Visual Outcome

The uncorrected visual acuity at baseline was 20/400 or worse in 43 Artisan eyes (95.6%) and 44 LASIK eyes (97.8%); and 20/200 in two Artisan eyes (4.4%) and one LASIK eye (2.2%). There was no statistically significant difference between the preoperative uncorrected visual acuity of either group ( $P > 0.2$ , chi-square). On the first day after surgery, three Artisan eyes (6.6%) and five LASIK eyes (11.1%) could see 20/20 or better without correction; 12 Artisan eyes (26.7%) and 16 LASIK eyes (35.6%) could see

Table 3. Comparison of Refractive Outcome of Laser In Situ Keratomileusis

Technique	Reference	Attempted Correction (Diopters) [Mean (Range)]	Follow-up Time (mos)	No. of Eyes	Mean Deviation from Target Refraction (Diopters)
Angle-fixated lens	Baikoff <sup>13</sup>	12.5 (7.0 to 18.8)	35.8	133	<1.0
Posterior chamber lens	Zaldivar <sup>14</sup>	13.4 (8.5 to 18.6)	11	124	-0.8
Posterior chamber lens	Pensando <sup>15</sup>	16.7 (8.1 to 21.3)	12	19	-1.5
Iris-fixated lens	Landesz <sup>12</sup>	14.7 (5.4 to 28.0)	35	67	-0.2
Iris-fixated lens	Current study	13.9 (9.5 to 19.4)	12	45	-0.7
Keracor 116 LASIK	Guell <sup>4</sup>	9.3 (7.0 to 12.0)	6	21	-0.8
Keracor 116 LASIK	Guell <sup>4</sup>	14.9 (12.3 to 18.5)	6	22	-1.8
Nidek LASIK	Zaldivar <sup>21</sup>	8.57 (5.5 to 11.5)	4.5	84	-0.6
Nidek LASIK	Current study	13.24 (9.13 to 17.5)	12	45	-0.7

\*Not reported.

20/30 or better, and 39 Artisan eyes (86.7%) and 40 LASIK eyes (88.9%) could see 20/50 or better.

At 1 month, one Artisan eye (2.2%) and seven LASIK eyes (17.5%) could see 20/20 or better without correction; 15 Artisan eyes (33.3%) and 20 LASIK eyes (50%) could see 20/30 or better; 40 Artisan eyes (88.9%) and 35 LASIK eyes (87.5%) could see 20/50 or better; and 44 Artisan eyes (97.8%) and 39 LASIK eyes (97.5%) could see 20/80 or better. One Artisan eye that had an intraocular lens miscalculation had an uncorrected visual acuity of 20/150, and one LASIK eye had an uncorrected visual acuity of 20/200 with a manifest refraction of -4.75 D. At 1 month the proportion of eyes that had uncorrected visual acuities of 20/20, 20/30, 20/40, and >20/40 between the LASIK and Artisan eyes was not statistically significant ( $P = 0.07$ , chi-square).

At 1 year, the uncorrected visual acuity was 20/20 or better in nine Artisan eyes (20.9%) and five LASIK eyes (12.2%); 20/30 or better in 30 Artisan eyes (69.8%) and 19 LASIK eyes (46.3%), and 20/40 or better in 38 Artisan eyes (88.4%) and 24 LASIK eyes (58.5%). All Artisan eyes and 39 LASIK eyes (95.1%) could see 20/60 or better. Two LASIK eyes (4.9%) had an uncorrected visual acuity of 20/80. There was a statistically significant difference in the final uncorrected visual acuity after the two procedures at 1 year ( $P < 0.01$ , chi-square). The uncorrected visual acuity of the two groups at different points in time is shown in Table 2.

To compare the visual recovery after both procedures, the number of eyes at each postoperative examination that had achieved their final uncorrected visual acuity was calculated and is shown in Figure 4. This showed no statistically significant difference in the visual recovery after both procedures.

Baseline spectacle-corrected visual acuity was 20/20 in 11 Artisan eyes (24.4%) and 13 LASIK eyes (28.9%) and 20/40 or better in all eyes. There was no statistically significant difference between the baseline spectacle-corrected visual acuity of either group. At 1 year, the spectacle-corrected visual acuity was 20/20 or better in 18 Artisan eyes (41.9%) and seven LASIK eyes (17.1%), 20/30 or better in 36 Artisan eyes (83.7%) and 31 LASIK eyes (75.6%), and 20/40 or better in all Artisan eyes and 38 LASIK eyes (92.7%). Three LASIK eyes had spectacle-corrected visual acuity of 20/50 or worse. The difference between the corrected visual acuity 1 year after both procedures was statistically significant ( $P = 0.02$ , chi-square test).

No Artisan eyes and five LASIK eyes (12.2%) lost two or more lines of Snellen visual acuity. Seven Artisan eyes (16.3%) and one LASIK eye (2.4%) gained two or more lines. Figure 5 shows the loss and gain of Snellen lines at 1 year in all eyes ( $P < 0.01$ ,

chi-square test). In addition, a Mann-Whitney test was used to compare the average number of Snellen lines gained/lost ( $0.49 \pm 0.98$  for Artisan and  $-0.30 \pm 0.98$  for LASIK,  $P < 0.001$ ).

One year after surgery, we compared the contrast sensitivity curve of each eye with its baseline curve; two Artisan eyes (4.7%) and six LASIK eyes (14.6%) lost two or more lines, three Artisan eyes (7.0%) and nine LASIK eyes (22.0%) lost one line, four Artisan eyes (9.3%) and no LASIK eyes gained two or more lines, and seven Artisan eyes (16.3%) and five LASIK eyes (12.2%) gained one line. The contrast sensitivity did not change in 27 Artisan eyes (62.8%) and 21 LASIK eyes (51.2%). Mean endothelial cell count at baseline was  $2859.3 \pm 116.1$  cells/mm<sup>2</sup> (range, 3250–2450 cells/mm<sup>2</sup>) in the Artisan group and  $2738.8 \pm 197.6$  cells/mm<sup>2</sup> (range, 3150–2550 cells/mm<sup>2</sup>) in the LASIK group. At 1 year, there was no statistically significant difference between the endothelial cell loss in both groups (mean,  $0.7\% \pm 1.1\%$ ; range, -3.1%–1.7% in the Artisan group and mean  $0.3\% \pm 0.9\%$ ; range, -1.9–1.8% in the LASIK group).

### Patient Assessment

One year after surgery, the questionnaire given to the 18 patients of the Artisan/LASIK subgroup showed that 14 patients (77.8%) were very satisfied with their Artisan eye and 10 patients (55.6%) were very satisfied with their LASIK eye. In addition, four patients (22.2%) were moderately satisfied with their Artisan eye and six patients (33.3%) were moderately satisfied with their LASIK eye. Two patients (11.1%) were not satisfied with their LASIK eye ( $P = 0.16$ ).

Eleven patients (61.1%) experienced more night glare or halos with their LASIK eye, three patients (16.7%) had more night glare with their Artisan eye, one patient (5.6%) reported equal glare in both eyes, and three patients (16.7%) said that they had no glare with either eye ( $P = 0.001$ ).

Thirteen patients (72.2%) preferred the Artisan procedure; the cause of their preference was the better quality of vision. Four patients (22.2%) preferred the LASIK; the first cause of this preference was the less invasive nature of the procedure (3 patients, 16.7%) and the second cause was cosmetic; one patient (5.6%) was bothered by the Artisan lens shining in her eye at certain positions of gaze. One patient (5.6%) said that, in his opinion, there was no difference between the two procedures. The results of the questionnaire showed that although the difference in patient satisfaction 1 year after the two procedures is not statistically significant, patient preference for Artisan lens implantation is

and Phakic Lenses for Myopia of Approximately -6 to -28 Diopters

Eyes within ± 1.00 Diopters [No. (%)]	Eyes within ± 0.50 Diopters [No. (%)]	Eyes with Uncorrected Visual Acuity of 20/20 or Better [No. (%)]	Eyes with Uncorrected Visual Acuity of 20/40 or Better [No. (%)]	Eyes Gained 2 or More Lines of Spectacle-corrected Visual Acuity [No. (%)]	Eyes lost 2 or More Lines of Spectacle-corrected Visual Acuity [No. (%)]	Intraocular Lens Extraction/Exchange
78 (58.8)	43 (42.4)	*	14 (47.8)	13 (36.2)	4 (11.1)	8 (6.0)
86 (69.0)	55 (44.0)	3 (2.0)	84 (68.0)	45 (36.0)	1 (0.8)	8 (6.5)
8 (42.1)	4 (21.1)	0 (0)	12 (63.2)	9 (47.4)	0 (0)	0 (0)
45 (67.2)	38 (56.7)	8 (12.1)	27 (40.9)	*	*	0 (0)
28 (65.0)	18 (41.9)	9 (20.9)	38 (88.4)	13 (30.2)	0 (0)	1 (2.3)
18 (85.7)	11 (52.0)	0 (0)	15 (71.4)	2 (9.5)	0 (0)	
3 (13.6)	9 (40.9)	0 (0)	1 (4.5)	0 (0)	0 (0)	
70 (83.0)	47 (56.0)	18 (22.0)	65 (77.0)	11 (14.0)	1 (1.3)	
24 (58.5)	12 (29.3)	7 (17.5)	35 (87.5)	1 (2.4)	2 (4.9)	

significantly higher than LASIK ( $P = 0.0001$ ), mainly because of the better quality of vision.

## Complications

One eye (2.2%) that had a preoperative refraction of  $-13.25 -1.50$  axis 170, a spectacle-corrected visual acuity of 20/25, and an uneventful implantation of an Artisan lens had a significant undercorrection that was manifest the first day after the operation; uncorrected visual acuity was 20/150, corrected to 20/30 with  $-4.00 -0.50$  axis 85. Review of the preoperative and operative data showed a miscalculation of the lens power. The required power for this eye was  $-14.50$  D, whereas the miscalculated lens power used was  $-10.50$  D. Three months after the operation, the manifest refraction was  $-3.75 -0.75$  axis 175. At 5 months, LASIK was performed uneventfully, and at the 1-year examination, the uncorrected visual acuity of this eye was 20/25 corrected to 20/20 with  $-0.50 -0.25$  axis 180. Another eye (2.2%) that had a baseline manifest refraction of  $-15.50 -1.50$  axis 10, and a 5-mm pupil at dim illumination, and had received a  $-16.00$  D, 5-mm Artisan lens, experienced severe night glare after the operation. The night glare was severe enough to affect his night driving. The lens was removed and exchanged with a  $-15.5$  D, 6-mm Artisan lens 6 months after the primary operation. At 1 year, the manifest refraction of this patient was  $-1.25 -0.75$  axis 20. Uncorrected visual acuity was 20/40 corrected to 20/20. The night glare was no longer a complaint. Five eyes (11.6%) had symptomatic mild-to-moderate night glare, not affecting night driving. Of these five eyes, four (80.0%) had 5-mm optic diameter lenses. Two eyes (4.4%) had transient ocular hypertension; both responded to topical levobunolol hydrochloride, 0.5% (Betagan; Allergan, Mayo, Ireland). The intraocular pressure went down to the preoperative level after discontinuation of the topical steroids.

At 3 months, 13 (LASIK) eyes (30.2%) were undercorrected by more than 1.00 D. Of these, seven eyes (16.3%) had enhancement between the third and the sixth months. The mean spherical equivalent refraction of these seven eyes was  $-13.79 \pm 2.8$  D (range,  $-9.13$  to  $-16.13$  D) at baseline,  $-2.38 \pm 1.0$  D (range,  $-1.25$  to  $-4.00$  D) at 3 months; and  $-0.11 \pm 0.68$  D (range,  $-1.00$ – $1.00$  D) at 1 year. At the 1-year examination, seven eyes (17.1%) had symptomatic night glare that was mild to moderate, and six eyes (14.6%) had severe night glare that affected night driving. One eye (2.2%) had developed deep lamellar keratitis 3 days after an uneventful LASIK and received topical dexamethasone, 0.1%, combined with tobramycin 0.3% (Tobradex) every 3 hours. The inflammation resolved completely in less than 1 week.

## Discussion

A high follow-up examination rate (mean, 94.0%) was achieved throughout the first year. This is explained by the enrollment of only those patients who said that they could follow the postoperative examination schedule given to them before surgery.

### Patients and Procedures Selection

A prospective bilateral randomized study on consecutive eyes may be the strongest design to compare two procedures, especially when subjective measures are considered. Our study was prospective and randomized on consecutive eyes; we did not aim at bilaterality, because we knew it would be practically difficult to perform two completely

different procedures on two eyes of a statistically significant number of patients. One procedure is an intraocular surgery with lens implantation, and the other is extraocular with laser ablation. Also, for 31 (50.8%) of 61 patients enrolled in the study, only one eye met the inclusion criteria. However 18 patients (29.5%) received an Artisan lens in one eye and LASIK in the other. We used this subgroup in comparing subjective measures such as severity of night glare, patient satisfaction, and preference, whereas we used all eyes to compare objective measures such as visual acuity, manifest refraction, endothelial cell count, and contrast sensitivity.

Contact lens overrefraction was performed on eyes assigned to the Artisan group and not to the eyes assigned to receive LASIK because the nomogram used to calculate the Artisan lens power was based on the refraction at the corneal plane, whereas the LASIK nomogram used in this series was based on manifest refraction.

LASIK has the known advantage of correcting astigmatism, whereas commercially available Artisan lenses have only spherical powers. That is why we only included eyes with a refractive cylinder less than 3.00 D. In LASIK procedures, we used a toric ablation profile to correct the compound myopic astigmatism, whereas in the Artisan group, we intended to correct the spherical equivalent refraction; this explains the statistically significant difference in the surgically induced cylinder between the two groups 1 year after the operation. In the near future when a "toric" Artisan lens will be made available, it would be interesting to compare the efficacy of both procedures on higher amounts of cylinder.

### Refractive and Visual Outcome

The significantly better uncorrected and corrected visual acuity in the Artisan group 1 year after the surgery was not consistent with the statistically insignificant difference between the final refractive outcome of either group. This can be explained at least partly by the magnification of the retinal image and the preservation of the corneal asphericity after Artisan implantation. On the other hand, every eye that receives LASIK ends with an oblate cornea that increases the optical aberrations.<sup>9,16</sup> Magnification of the retinal image may also explain the significant gain of spectacle-corrected visual acuity in the Artisan group. Improvement of spectacle-corrected visual acuity with phakic intraocular lenses was also reported by other authors.<sup>13,17–20</sup>

The better uncorrected visual acuity in the Artisan group may also explain the lower rate of enhancement (2.2% in the Artisan group, 25.6% in the LASIK group) despite the statistically insignificant difference in the refractive outcome of the two groups.

Comparison of our refractive results to those reported by other authors in correcting a similar amount of myopia is shown in Table 3.

One patient (2 eyes) who had Artisan lenses in both eyes did not show up for the 1-year examination because he had to move out of the country for unforeseen reasons. This patient was last examined 6 months after the operation; his spherical equivalent refraction was  $-0.75$  and  $-0.50$  axis 20 for his right and left eyes, respectively. Four of 45 eyes



(three patients) from the LASIK group dropped out at the 12-month examination for unknown reasons. At their last examination, 6 months after the surgery, their visual and refractive results were not different from the other subjects of the group. Their uncorrected visual acuities were 20/25, 20/25, 20/30, and 20/40; spectacle-corrected visual acuities were 20/20, 20/25, 20/25, and 20/30; and their spherical equivalent refractions were  $-0.50$ ,  $-0.50$ ,  $0.50$ , and  $-0.75$  D, respectively.

The mean endothelial cell loss in our Artisan group was  $0.7\% \pm 1.1\%$  at 1 year; this is similar to that reported by Krumeich et al<sup>20</sup> ( $1.2\%$ ). Landesz and co-workers<sup>17</sup> reported a significantly higher mean endothelial cell loss ( $7.2\%$ ); this, in their opinion, may be due to the use of different techniques for endothelial cell counting that might not be accurate. However, a long-term study on a larger group of patients is needed to assess the effect of the Artisan lens on corneal endothelium.

### Surgeon Assessment

The protocol of this study did not include a formal prospective measurement of the intraoperative difficulties encountered by the surgeon, but because all the surgeries were done by one surgeon, his overall experience was that the LASIK procedure was easier and less technically demanding, whereas the Artisan implantation was more complex and more strenuous for both the surgeon and the patient. Patient tolerance during and immediately after the surgery was generally better with the LASIK procedures.

The most difficult step of the operation was the enclavation of a sufficient amount of iris tissue in the haptic's claw, because the surgeon has, at the same time, to maintain the lens centered over the pupil to avoid touching the corneal endothelium and the crystalline lens. When we started Artisan lens implantation in 1993 and during our learning curve, we used to mark the iris at the desired sites of enclavation with the argon laser; however, after gaining enough experience (about 30 cases), we found that marking the iris is unnecessary.

### Complications

Severe night glare in one eye ( $2.2\%$ ) of the Artisan group and seven eyes ( $14.6\%$ ) of the LASIK group was the most prominent complication in our study. We exchanged one 5-mm Artisan lens for a 6-mm lens with a lower power. After the exchange, the patient was satisfied, although he had a residual myopia of  $-1.25$  D, because the night glare was significantly reduced. He is now ready to receive LASIK as a secondary procedure to correct the residual myopia. On the other hand, we have little, if anything, to offer for those patients who developed severe night glare after LASIK. This points to the advantages of exchangeability that are possible with phakic lenses but not with LASIK.

The percentage of patients ( $14\%$ ) who had symptomatic night glare in our study was significantly less than previously published by Landesz and colleagues,<sup>17</sup> who reported night glare in  $25\%$  of their patients. This may be due to the

use, in our study, of a larger optic zone diameter ( $6$  mm) in eyes with myopia of  $15.5$  D or less ( $32$  eyes,  $71.1\%$ ) compared with the  $5$ -mm lens used in Landesz series.

We performed LASIK on one eye that received a miscalculated Artisan lens; the LASIK procedure was uneventful with no evidence of touch between the Artisan lens and the endothelium during or after the surgery either clinically or by specular microscopy. However, a formal prospective study is needed to assess the possible effect of dissecting a corneal flap with a microkeratome of an eye with an Artisan lens. Combining LASIK with phakic intraocular lenses can provide an alternative to lens exchange in treating under-correction after phakic intraocular lens implantation; it can also give the surgeon the opportunity to maximize the effective optic zone diameter, to improve the predictability of the refractive outcome, and to minimize the potential optic aberrations.<sup>22,23</sup>

Altogether, we can say that using the techniques described, both Artisan lens implantation and LASIK are reasonably safe and have similar efficacy and final refractive outcome in correcting myopia greater than  $9.00$  D. Better uncorrected and corrected visual acuity, contrast sensitivity, quality of vision, and exchangeability are the main advantages of Artisan lens implantation.

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