

Changes in Contrast Sensitivity after Artisan Lens Implantation for High Myopia

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Purpose: To determine the effects of Artisan lens implantation on contrast sensitivity.

Design: Prospective consecutive interventional case series.

Participants and Controls: Forty-nine eyes of 30 patients with myopia and myopia with astigmatism, who underwent implantation of the Artisan iris-fixated phakic intraocular lens. Preoperative testing served as the control.

Intervention: Implantation of the Artisan phakic intraocular lens to correct myopia.

Main Outcome Measures: Refractive predictability and Snellen visual acuity were evaluated preoperatively and at least 4 months postoperatively. Additionally, photopic and mesopic contrast sensitivities were measured at 1.5, 3, 6, 12, and 18 cycles per degree, with and without glare testing.

Results: The mean preoperative spherical equivalent (SE) was -12.16 diopters (D) (range, -6.88 to -18.00). The mean postoperative SE was -0.46 ± 0.58 D (range, $+0.50$ to -1.75). Ninety percent of eyes were within 1.00 D of the predicted result, and 39% gained ≥ 1 lines of best-corrected visual acuity (BCVA). When compared with preoperative measurements, postoperative contrast sensitivity was increased under photopic conditions and slightly decreased under mesopic conditions. Adverse events were one wound leak requiring resuturing in the immediate postoperative period and one subluxed lens after significant blunt trauma. No eyes lost ≥ 2 lines of BCVA.

Conclusions: Artisan implantation for the correction of high myopia seems to be a predictable procedure. Increases in photopic contrast sensitivity values after implantation of this phakic intraocular lens stand in distinction to the decreases in photopic contrast sensitivity previously reported after LASIK correction of this degree of myopia. *Ophthalmology* 2005;112:278–285 © 2005 by the American Academy of Ophthalmology.

The correction of the extremes of refractive errors poses special problems. Spectacle correction can generate significant magnification or minification of images. Visual aberrations and distortion of the visual field are introduced by the thicker lenses required for spectacle correction. Contact lenses often provide better vision than spectacles for higher corrections, but are not without their disadvantages and risks.¹ LASIK and photorefractive keratectomy (PRK) have a proven track record for successful correction of mild to moderate myopia with studies demonstrating good uncorrected postoperative visual acuity (VA).^{2,3} Several studies have demonstrated the relative loss of predictability and

stability as well as the risk of irregular astigmatism and ectasia with higher levels of myopic correction.^{4,5} Moreover, issues of higher order aberrations and contrast sensitivity affect the photorefractive outcomes of high myopes more than low to moderate myopes.^{6,7}

Given the limitations of the current options for correcting higher degrees of myopia, newer alternatives such as phakic intraocular lenses (IOLs) are being explored. Phakic IOLs have been used with good results in many preliminary studies, and may overcome some of the disadvantages of corneal refractive surgery for correcting extreme ametropia.^{8–10} One such lens is the Artisan implant, an anterior chamber iris-fixated phakic IOL manufactured by Ophtec (Groningen, The Netherlands). Several studies have demonstrated that implantation of the Artisan lens to correct high myopia results in a stable and fairly predictable refractive outcome.^{10–12} However, one of the real advantages to intraocular correction of high myopia may be that this type of correction maintains the prolate asphericity of the cornea and introduces fewer higher order aberrations than corneal photorefractive surgery. Contrast sensitivity has been a traditional way to examine these parameters of functional visual performance.^{13,14} In this study, we examine changes in both photopic and mesopic contrast sensitivity in patients undergoing Artisan lens implantation for high myopia.

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Materials and Methods

Forty-nine eyes of 30 patients underwent implantation of the Artisan lens for high myopia by 3 different surgeons (DRH, EAD, RLL) in one facility between June 1999 and July 2001. This group of patients represents a subset of the enrollment into the phase III Food and Drug Administration clinical trial and is the consecutive and total enrollment of patients receiving Artisan lenses during this time. There were 18 males and 12 females, and ages ranged from 20 to 50 years (mean \pm standard deviation [SD], 40 ± 7). The preoperative spherical equivalent (SE) ranged from -6.88 to -18.00 diopters (D) (-12.16 ± 2.32), and astigmatism ranged from 0.00 to $+2.50$ D ($+1.15 \pm 0.72$). The preoperative examination included uncorrected VA (UCVA), manifest and cycloplegic refraction, best-corrected VA (BCVA), intraocular pressure (IOP) measurement, undilated contrast sensitivity testing, slit-lamp evaluation, dilated fundus evaluation, corneal topography, and endothelial cell imaging. Endothelial cell density was calculated by identifying 50 cells on photomicrographs generated with a Noncon SP-9000 noncontact specular microscope (Konan, Hyogo, Japan). Reported densities are the mean of triplicate measurements. All patients gave informed consent, institutional review board/ethics committee approval was obtained, and the collection of data complied with the Health Insurance Portability and Accountability Act of 1996.

The Artisan implant is an all-polymethyl methacrylate iridifixed lens 8.5 mm in total length. The myopic lens is manufactured in 2 models, with optic diameters of 5 mm (model 206) and 6 mm (model 204). Each eye in this study received a model 204, which was available in powers -5 D to -15 D in 1-D increments. The IOL power was calculated from the spectacle refraction, keratometry values, and anterior chamber depth using van der Heijde tables.¹³ All eyes were targeted for emmetropia.

Surgical Technique

A neodymium:yttrium-aluminum-garnet laser peripheral iridotomy was created either the day before or the day of surgery. Preoperatively, the patients were treated with pilocarpine 1% to effect pupillary constriction. Under retrobulbar or peribulbar anesthesia, either a superior or an oblique shelved incision of 6.0 to 6.5 mm in length was fashioned. The decision on where to place the incision was based on preoperative corneal astigmatism—all had superior incisions, except one eye that had a corneal curvature that was steep on an oblique axis. This eye received an incision positioned on that oblique axis. Moreover, the anterior-posterior placement of the incision was based on preoperative keratometric astigmatism. The wounds were placed in the peripheral clear cornea for >2 D of astigmatism, at the limbus for 1 to 2 D of astigmatism, and in the sclera for <1 D of astigmatism. Standard peripheral paracentesis tracts, directed towards the peripheral iris, were fashioned to either side of this main incision for the purposes of access during lens enclavation to the iris.

Under the protection of a cohesive viscoelastic (Healon, Pharmacia Corp., Peapack, NJ), the lens was inserted and enclavated to the iris in such a way that the optic was centered over the pupil in all cases. The viscoelastic was removed, and the wound was closed with either a 10-0 nylon or a polygalactin suture placed in either an interrupted or a running configuration.

Postoperatively, the patients were placed on tobramycin/dexamethasone (TobraDex, Alcon Inc., Fort Worth, TX) and ketorolac (Acular, Allergan Inc., Irvine, CA) drops each 4 times a day, and these medicines were tapered and discontinued over 5 weeks. If high astigmatism persisted at 4 to 6 weeks, then sutures were cut to reduce astigmatism.

Contrast Sensitivity Testing

Monocular contrast sensitivity testing was performed with the Functional Acuity Contrast Test chart (Vision Sciences Research Corp., San Ramon, CA). The 2-dimensional charts (Fig 1) allow determination of contrast sensitivity values at spatial frequencies of 1.5, 3, 6, 12, and 18 cycles per degree of visual angle. The step size between the circular patches averages 0.30 log units, and the range of contrast sensitivity that the chart spans is 1.72 log units. Patients were asked to identify the orientation of the lines at each spatial frequency on 3 different versions of the charts. The number of correctly identified patches was averaged and translated to the corresponding contrast sensitivity value. The logarithms of contrast sensitivity values were used for statistical analysis.

Contrast sensitivity data were collected preoperatively and postoperatively at 3 m under 4 different lighting conditions—photopic, photopic with glare, mesopic, and mesopic with glare. Photopic conditions of 25 ± 3 foot lamberts were produced with a combination of overhead fluorescent and incandescent lights. Photopic glare conditions were produced under this lighting condition while viewing through the Brightness Acuity Tester (Mentor O & O Inc., Norwell, MA) set on medium. Mesopic conditions of 0.8 ± 0.1 foot lamberts were produced with dimmed overhead incandescent lights. Mesopic glare conditions were produced under this lighting condition with a 5-foot-candle light source set at eye level, 1 m and 30° away from the visual axis. Illuminances and luminances were confirmed before each examination with the handheld Photometer 1 (Quantum Instruments Inc., Garden City, NJ).

Preoperative and postoperative contrast sensitivity testing was performed with the patient's best-corrected spectacle refraction in a trial frame. Pupil diameter was assessed under the above mesopic conditions with a pocket Rosenbaum card. Postoperative testing was performed at a single time point between 4 and 12 months after the surgery (mean \pm SD, 6.1 ± 2.3 months.). Statistical assessment of the data was performed with the assistance of Excel 2000 software (Microsoft, Redmond, WA). Preoperative and postoperative contrast sensitivity changes were compared using the paired *t* test, and statistical significance was established at the *P* = 0.05 level. Throughout the article, mean is reported with SD. Average VAs are calculated using the logarithm of the VA.

Results

Postoperative refractive results for all 49 eyes are presented in Figure 2. Forty-four eyes (90%) were within 1 D of the attempted correction, and 100% were within 1.71 D. Undercorrections were more common than overcorrections. Postoperative SE ranged from $+0.50$ to -1.75 D (mean, -0.46 ± 0.58 D), and astigmatism ranged from 0.00 to $+2.25$ D (mean, $+0.64 \pm 0.49$). At the time of contrast sensitivity testing, all the eyes saw 20/80 or better, uncorrected. Of particular note is the fact that 19 of the eyes (39%) gained ≥ 1 lines of BCVA after Artisan lens implantation. No eye lost more than 1 line of BCVA. Mean preoperative BCVA was 20/23 (range, 20/20–20/40). Mean postoperative UCVA was 20/30 (range, 20/20–20/80). Mean postoperative BCVA was 20/21 (range, 20/15–20/25).

Mean preoperative and postoperative contrast sensitivity values are displayed in Figure 3. Under photopic and photopic with glare conditions, the average contrast sensitivity value for all the tested frequencies increases after Artisan implantation. These changes are only statistically significant for 1.5 cycles per degree under photopic conditions, but are statistically significant at all tested frequencies for photopic with glare conditions (Fig 3A, B). Under mesopic and mesopic with glare conditions, contrast sensitivity

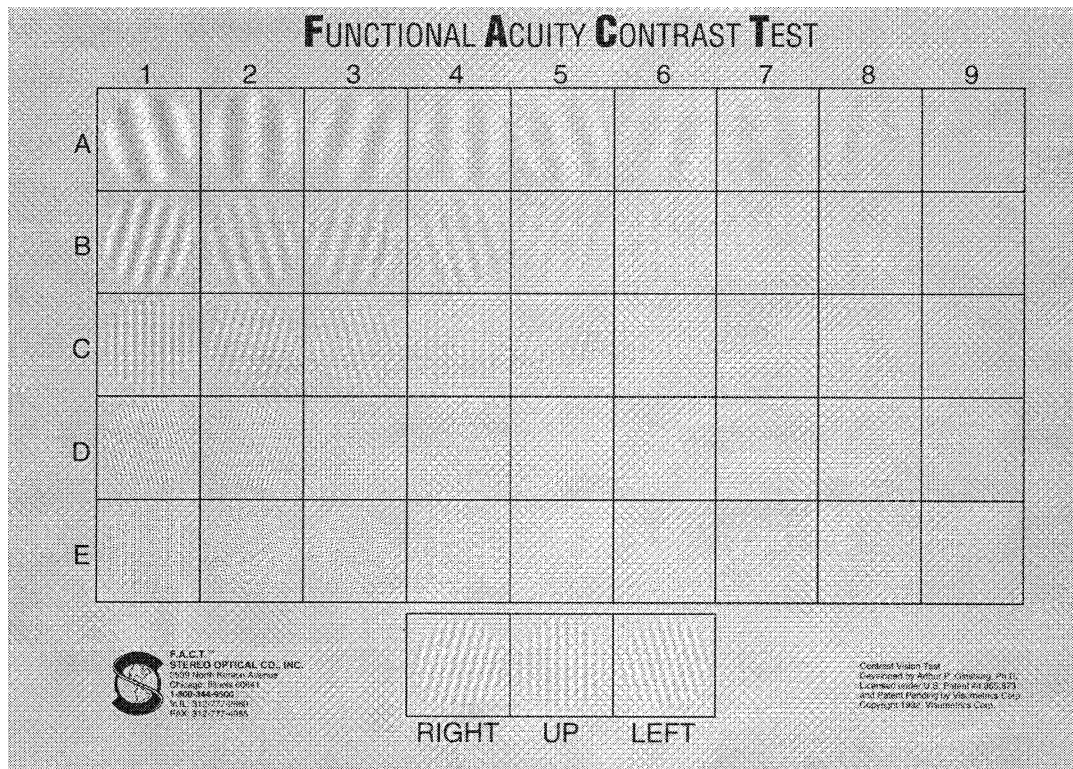


Figure 1. Functional Acuity Contrast Test chart for assessing contrast sensitivity. The sinusoidal gratings, present in each column except 9, vary in contrast within each row and vary in spatial frequency within each column. Reprinted with permission from Vision Sciences Research Corp. Copyright 2002. All rights reserved.

values are decreased after Artisan implantation. These changes are statistically significant at only 3 tested frequencies. The above analysis was also performed examining bilateral and unilateral surgeries separately. The results for the data assessed in this way are the same as when all the surgeries are considered together.

Another way to consider the changes in contrast sensitivity is to evaluate how many eyes gained or lost a standard increment in contrast sensitivity. This analysis can be carried out in much the same way as the analysis of gain or loss in Snellen lines of VA is carried out. With Snellen VA, there is a single value associated with each eye. However, with our contrast sensitivity study, there are 4 lighting conditions and 5 spatial frequencies to consider. To arrive at a global indicator of contrast sensitivity for each eye in the study, the contrast sensitivity values in all 4 lighting conditions and at all 5 spatial frequencies for each eye were averaged. This average contrast sensitivity value for each eye can then be compared preoperatively and postoperatively to determine whether each eye realizes a global increase or a decrease in contrast sensitivity after Artisan lens implantation (Fig 4). As indicated, 55% of the eyes had no change in contrast sensitivity, 18% lost 1 patch, 25% gained 1 patch, and 2% gained 2 patches. The average change in contrast sensitivity was 0.02 log units, which is equivalent to gaining <1 circular patch on the contrast sensitivity charts.

To investigate whether postoperative astigmatism was a factor in reducing contrast sensitivity, a separate post hoc analysis was undertaken in which the eyes were grouped into 2 groups based on their postoperative manifest astigmatism. The group of low astigmatism eyes included 26 eyes with a postoperative manifest cylinder of 0.29 D (range, 0–0.50), and the group of high astigmatic eyes included 23 eyes with a postoperative manifest cylinder of 1.03 D (range, 0.75–2.25). These 2 groups had statistically indistinguishable preoperative

contrast sensitivity values. When these 2 groups are compared from a postoperative standpoint, the contrast sensitivity values at all frequencies and across all lighting conditions did not statistically differ either. Thus, the contrast sensitivity changes observed here, after Artisan implantation, are not correlated with either preoperative or postoperative refractive astigmatism.

To assess whether pupil diameter could be correlated with the above changes in contrast sensitivity, the average photopic and mesopic contrast sensitivities were calculated for each eye. The changes after Artisan implantation were then evaluated with respect to that patient's pupil diameter in dim light. Mean mesopic pupil diameter ranged from 4 to 6 mm (mean ± SD, 5.2±0.6). Neither average photopic ($r^2 = 0.015$) nor average mesopic ($r^2 = 0.029$) changes could be significantly correlated to pupil diameter using a linear regression model. In fact, when only those mesopic changes that we measured to be statistically significant (mesopic at 12 cycles per degree and mesopic with glare at 12 and 18 cycles per degree) were considered in a separate analysis, contrast sensitivity changes still could not be correlated with pupil diameter ($r^2 = 0.042$).

Preoperative endothelial cell counts did not significantly differ when compared with the postoperative values. Preoperative endothelial cell density was 2741±358 cells per square millimeter (mean ± SD). Postoperatively, the density was 2704±388 cells per square millimeter ($P = 0.37$ by paired Student's *t* test). One patient had an incision wound leak that required resuturing on postoperative day 5. Another patient had one claw of the lens dislocated after being hit in the eye. This blow to the eye was severe enough to result in periorbital ecchymosis. No other damage to the eye, including persistent corneal edema, elevated IOP, or cataract, has resulted.

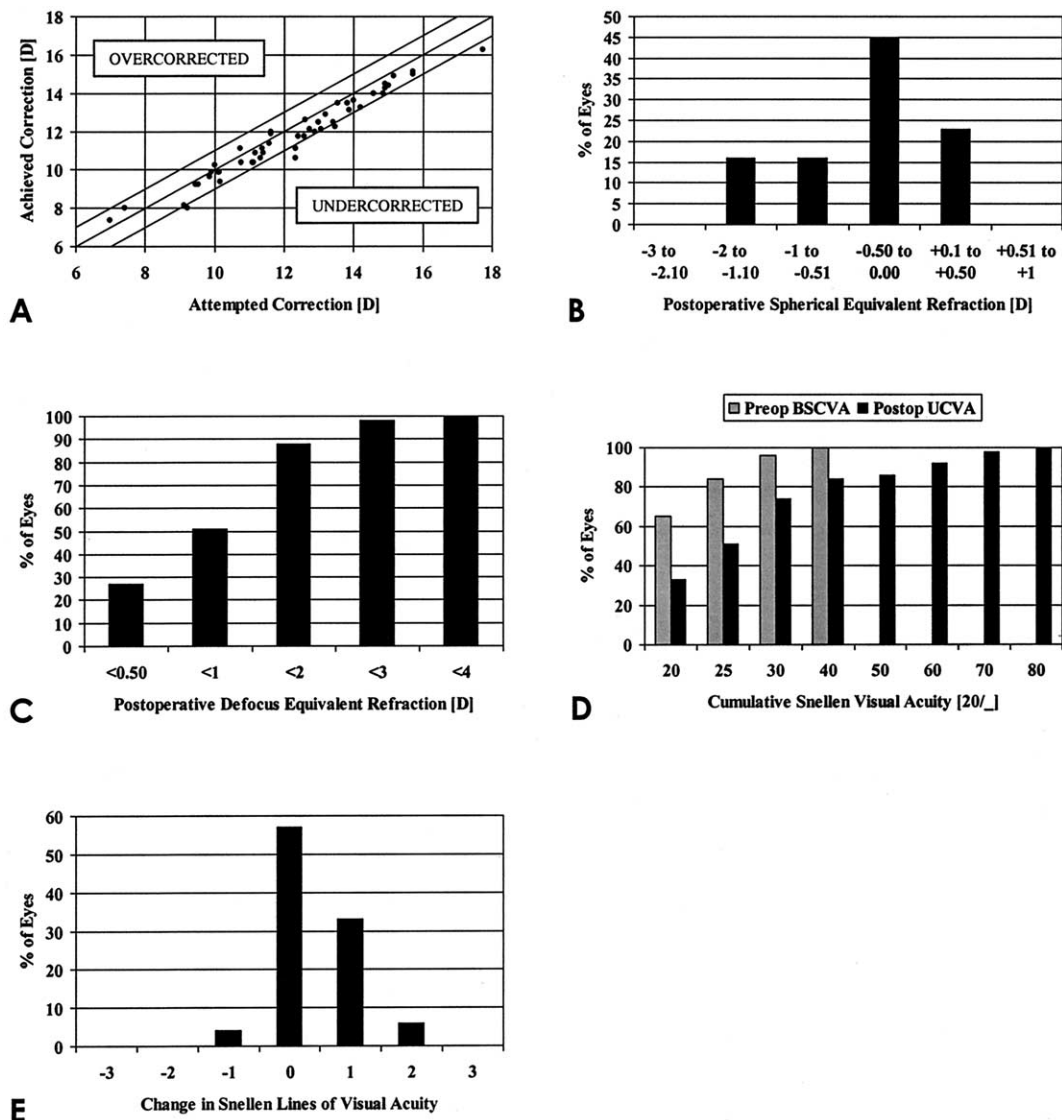


Figure 2. Standard graphs for reporting refractive surgery (n = 49 eyes). D = diopters. A, Scattergram of attempted versus achieved refraction. B, Spherical equivalent refractive outcome bar graph. C, Defocus equivalent bar graph. D, Uncorrected visual acuity (UCVA) bar graph. BSCVA = best spectacle-corrected visual acuity. E, Change in spectacle-corrected visual acuity bar graph.

Discussion

In our prospective study, the Artisan lens was very effective and predictable (Fig 2). The procedure is safe from the standpoint of BCVA, and reversible complications occurred in only 4% of cases, with no loss of BCVA. No significant loss of endothelial cells occurred over the study period. These refractive and safety data are comparable with previously published refractive outcomes.¹⁰⁻¹²

LASIK is the most common surgical means by which myopic refractive errors are corrected. For low to moderate myopia, results from studies in the literature have shown that LASIK is effective and predictable in terms of obtaining very good to excellent UCVA, and that it is safe in terms of minimal loss of VA.⁵ For moderate to high myopia (greater than -6 D), the results are more variable and

generally correlate with the degree of preoperative myopia. An examination of recent retrospective and prospective studies of eyes undergoing LASIK for extreme myopia demonstrates reduced efficacy, predictability, and safety relative to the correction of lower degrees of myopia.¹⁵⁻²¹ When this group of studies on highly myopic eyes is assessed as a whole (1015 eyes), mean preoperative SE is -13.6 D, and 70% of the patients are within 1 D of the attempted correction. Seventy-one percent of the patients achieved UCVA of 20/40 or better, and 3% of patients lost ≥ 2 lines of Snellen VA. Our Artisan lens study seems to have superior refractive results in a comparable group of highly myopic patients (Fig 2).

The efficacy of refractive surgery is generally assessed by Snellen VA. This test is designed with high-contrast black letters on a white background. It does not provide a

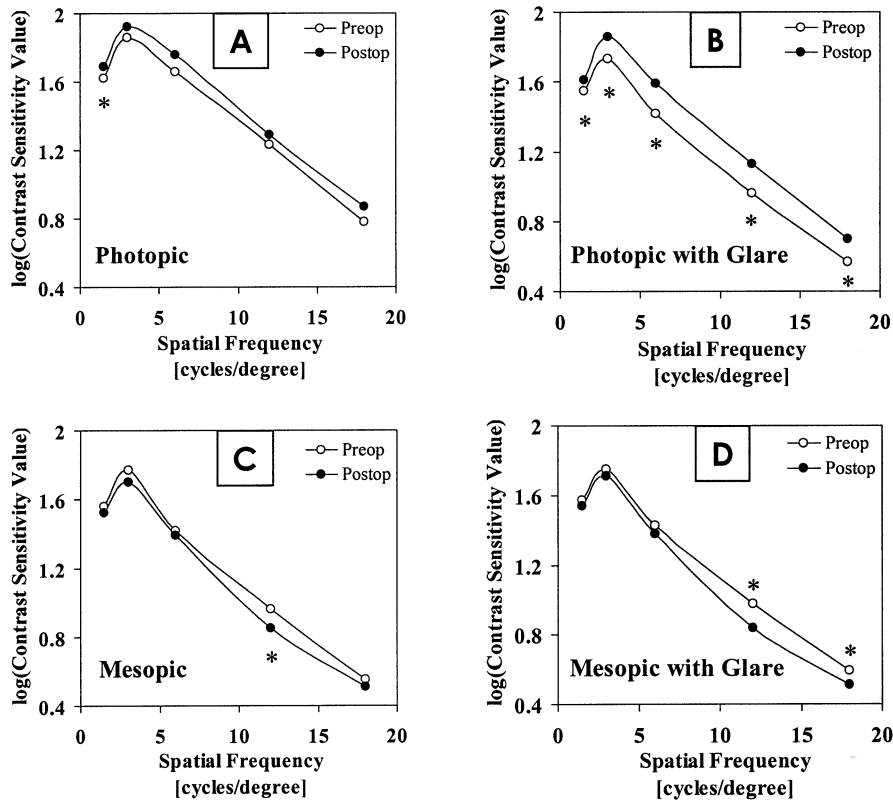


Figure 3. Contrast sensitivity results (n = 49 eyes). Testing conditions are described in detail in the text. Postop = postoperative; preop = preoperative. *Statistically significant differences using the paired t test ($P < 0.05$).

global measurement of vision, because it measures the capacity to distinguish small details (high spatial frequencies) in a high-contrast setting. Given that there are many spatial frequencies in our visual environment, it is of special importance to determine the quality of vision when refractive surgery results are evaluated, as patient satisfaction does not always correlate with the Snellen VA measurement in the office. It is generally accepted that contrast sensitivity testing provides a more sensitive and complete measure of visual function than VA based on Snellen charts.

Our measures of contrast sensitivity indicate improve-

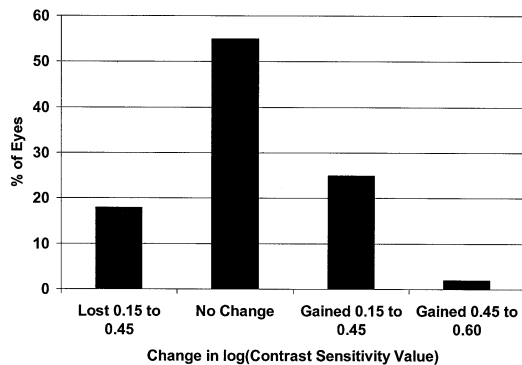


Figure 4. Changes in contrast sensitivity after Artisan lens implantation (n = 49 eyes). Changes in the total preoperative and postoperative contrast sensitivity values were examined as described in detail in the text.

ments under photopic conditions after phakic IOL implantation (Fig 3). Under mesopic conditions, contrast sensitivity is either unchanged or slightly decreased when compared with preoperative spectacle correction. Studying contrast sensitivity under different lighting conditions outlined in this study should help to understand the etiology of changes in contrast sensitivity after phakic IOL implantation. As well, it may help to understand the changes in contrast sensitivity after corneal excimer surgery.

Numerous reports have documented variable decreases in contrast sensitivity in the first few months after both PRK²²⁻²⁹ and LASIK.^{6,7,29-33} However, the persistence of the reduction of contrast sensitivity has varied, with some reporting a return in function over time to baseline preoperative levels, and other reports noting a sustained reduction for up to a year after surgery. Some of the recent major studies examining contrast sensitivity changes after refractive surgery for higher levels of myopia are summarized in Table 1. In all but 1 of the 18 studies involving only PRK and LASIK, decreases in contrast sensitivity were recorded. In 15 of these 18 studies, the changes were persistent over the study period. Regarding changes in contrast sensitivity after phakic IOL implantation, in all but our current study, implantation of a phakic IOL resulted in either stability of or improvements in contrast sensitivity relative to preoperative measurements. It should be noted that, in the 2 studies involving a bioptic approach of Artisan implantation and subsequent LASIK, the majority of the refractive error was

Table 1. Major Recent Studies Evaluating Contrast Sensitivity (CS) Changes after Refractive Surgery for High Refractive Errors

Study	Eyes (n)	Procedure	Preop SE (Range) (D)	Follow-up (mos)	Results
Ghaith*	24	RK	-4 (-2 to -6)	6	Significant decrease in photopic CS after RK and PRK.
	18	PRK	-4 (-2 to -6)	6	
Stevens†	198	PRK	(0 to -6)	12	Significant decrease in CS after PRK.
Bullimore‡	164	PRK	-4 (-1 to -8)	12	Significant decrease in photopic CS after PRK, worse when pupils dilated.
Tomidokoro§	79	PRK	NR	12	Significant decrease in photopic and mesopic CS after PRK.
Montés-Mico	49	PRK	-6 (-4 to -8)	6	Significant decrease in mesopic CS, but no change in photopic CS after PRK.
Niesen¶	46	PRK	-8 (-3 to -14)	12	Significant decrease in CS with and without glare after PRK.
Butuner#	32	PRK	-5 (-2 to -8)	12	Significant decrease in CS after PRK.
Verdon**	16	PRK	-5	12	Significant decrease in photopic CS after PRK.
Seiler††	15	PRK	-5 (-2 to -7)	3	Slight decrease in CS after PRK.
Ambrosio‡‡	6	PRK	-15 (-11 to -20)	6	Significant decrease in photopic intermediate frequency CS after PRK.
Montés-Mico§§	40	PRK	-6 (-4 to -8)	12	Temporary significant decrease in photopic CS after PRK and LASIK. Recovery at 6 mos.
	36	LASIK	-6 (-4 to -8)	12	
Mutyalal	49	LASIK	(-6 to -14)	3	Temporary decrease in high-frequency photopic CS after LASIK. Recovery at 1 mo.
Chan¶¶	41	LASIK	-6	12	Temporary decrease in photopic CS after LASIK. Recovery at 1 yr.
					Change in CS significantly correlated with refractive error.
Marcos###	22	LASIK	(-2 to -13)	6-12	Significant decrease in photopic CS after LASIK.
Holladay****	14	LASIK	-6 (-2 to -10)	6	Significant decrease in scotopic CS after LASIK.
					Temporary significant decrease in CS with glare after LASIK.
Nakamura†††	13	LASIK	(-6 to -14)	3	Significant decrease in photopic CS after LASIK.
Knorz‡‡‡	11	LASIK	(-10 to -15)	12	Decrease in mesopic CS with and without glare after LASIK.
Pérez-Santonja§§§	7	LASIK	(-10 to -20)	6	No significant change in photopic CS after LASIK.
Arne	58	Staar ICL	-14 (-8 to -19)	6	Significant increase in mesopic and photopic CS after phakic IOL.
Alfaro¶¶¶¶	20	Staar ICL	-14 (-9 to -20)	24	Significant increase in photopic CS after phakic IOL.
Güell####	26	Artisan then LASIK	-18 (-16 to -23), then -4 (-2 to -6)	24	No change in CS after either surgery.
Malecaze*****	25	LASIK	-9 (-8 to -12)	12	No change in CS after LASIK.
	25	Artisan	-10 (-8 to -12)	12	Increase in CS after phakic IOL.
Güell††††	8	Artisan then LASIK	-19 (-16 to -23), then -6 (-2 to -9)	16	No change in CS after either surgery.
Current	49	Artisan	-12 (-7 to -18)	6	Significant increase in photopic CS with glare and significant decrease in mesopic CS with glare after phakic IOL.

D = diopters; IOL = intraocular lens; NR = not recorded; PRK = photorefractive keratectomy; RK = radial keratotomy; SE = spherical equivalent. *Ghaith AA, Daniel J, Stulting RD, et al. Constant sensitivity and glare disability after radial keratotomy and photorefractive keratectomy. *Arch Ophthalmol* 1998;116:12-8.

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(continues)

Table 1. (Continued.)

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corrected with the phakic IOL surgery. Subsequent LASIK surgery corrected the residual refractive error and averaged -5.65 D in Güell et al.³⁴ and -3.65 D in Güell et al.³⁵ All the contrast sensitivity studies performed with phakic IOLs,^{34–38} including ours, have reported data at only one time point. The differences in the changes in contrast sensitivity after photorefractive surgery and phakic IOL surgery should be even more striking, given the level of myopia addressed with each surgery.

The causes of a decrease in contrast sensitivity function after excimer laser treatment are not clearly understood and probably represent a complex interplay of factors. Forward light scatter is related to the haze in corneas after PRK and is correlated with a reduction in contrast sensitivity.^{39,40} Alternative explanations that could account for changes in visual function after LASIK when haze is presumably not an issue include changes in the normal physiologic cell structure and extracellular matrix.²³ Intracellular vacuole formation, proteoglycan content, and irregular spacing of collagen fibers have all been implicated as contributing to irregular corneal optical quality and decreased visual function. Furthermore, optical aberrations due to surface irregularity or inclusion of the excimer ablation zone edge within the entrance pupil might all degrade the retinal image and lead to decreased contrast sensitivity function and visual perturbations.⁷ Much has been written on the alteration of the normal prolate shape of the cornea with photorefractive surgery. Until recently, all the excimer lasers used for photorefractive surgery increased the spherical aberrations of the cornea by producing oblate corneas with positive spherical aberration. This higher order aberration decreases contrast sensitivity most prominently under mesopic conditions when the pupil is dilated. Correction of high myopia with phakic IOLs avoids all of these potential sources, and increasing numbers of visual function studies such as ours are beginning to be performed on phakic IOL eyes.⁴¹

The results of our study, in the context of previous studies, are consistent with the following hypotheses. With phakic IOL correction of high myopia, photopic contrast

sensitivity is largely determined by the central cornea and optic of the phakic IOL. The improvements in contrast sensitivity that are seen are consistent with improvements in the central optics of phakic IOLs over spectacle lens correction. Moreover, the prolate shape of the cornea is maintained. Effects from reduction of image minification may also improve contrast sensitivity results. Under mesopic conditions, the pupil dilates, making the edge of the phakic IOL optic more likely to scatter light and cause aberrations that decrease contrast sensitivity. Our difficulty in establishing a close correlation between pupil diameter and mesopic contrast sensitivity probably relates to the imprecision by which the pupils were measured with a Rosenbaum card, and the limited range of pupil diameters among this cohort of patients. Furthermore, each lens was regarded as clinically centered by postoperative slit-lamp examination; however, detailed imaging of the anterior segment under mesopic conditions was not performed. This may reveal small decentrations that could contribute to decreases in mesopic contrast sensitivity. This postulated mechanism of slight decentration would be largely independent of pupillary diameter.

Further wavefront studies of phakic IOL eyes—with careful attention to pupillary diameter, optic diameter, and lens centration—may further refine these theories. Larger phakic IOL optics or lessons from pseudophakic IOLs regarding treatment of IOL edges may be beneficial in decreasing mesopic glare after phakic IOL implantation.

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