



Visual acuity improvement in adult amblyopic eyes with an iris-fixated phakic intraocular lens: Long-term results

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PURPOSE: To evaluate the effect of implantation of iris-fixated phakic intraocular lenses (pIOLs) (Artisan) in adult amblyopic eyes.

SETTING: Optical Express, London, United Kingdom.

DESIGN: Retrospective case series.

METHODS: The study analyzed data from 5 years of follow-up of amblyopic eyes that were implanted with iris-fixated pIOLs and had a preoperative corrected distance visual acuity (CDVA) of 6/15 or worse. Visual acuity, refraction, endothelial cell count, and complications were assessed.

RESULTS: Data for 103 eyes were analyzed as 2 groups. Group 1 comprised 82 eyes with myopia or myopic astigmatism, and Group 2 contained 21 eyes with hyperopia or hyperopic astigmatism. The mean preoperative sphere in Group 1 was -13.42 diopters (D) ± 5.62 (SD) with a mean cylinder of -2.35 ± 1.75 D. In Group 2, the mean sphere and cylinder were $+6.77 \pm 1.91$ D and -2.63 ± 2.43 D, respectively. The mean CDVA improved from 0.51 ± 0.15 logMAR to 0.34 ± 0.16 logMAR ($P < .001$) in Group 1 and from 0.54 ± 0.17 logMAR to 0.46 ± 0.14 logMAR in Group 2 ($P < .005$). The safety index was 1.48 in Group 1 and 1.19 in Group 2. The efficacy index was 1.21 in Group 1 and 1.00 in Group 2. The mean gain in CDVA was statistically significantly greater in Group 1 (0.17 ± 0.14 logMAR) than in Group 2 (0.08 ± 0.11 logMAR). Two or more lines of CDVA were gained by 48.8% of eyes in Group 1 and by 19.0% of eyes in Group 2.

CONCLUSION: The iris-fixated pIOL was a safe and effective option for improving visual acuity in adult amblyopic eyes.

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Amblyopia affects approximately 3% of the population^{1,2} and carries a 1.2% projected lifetime risk for visual impairment to 6/12 or worse visual acuity.^{2,3} Treatment for amblyopia is effective, reducing the overall prevalence and severity of vision loss.^{2,4} Correcting refractive error alone significantly improves visual acuity, sometimes to the point where further amblyopia treatment is not required. Atropine penalization and patch occlusion are effective in treating amblyopia; however, treatment of amblyopia is typically effective only early in life. Adult amblyopia normally is corrected using spectacles or contact

lenses, which can be difficult in eyes with extreme refractive error or anisometropia.

Iris-fixated IOLs have been safely and successfully used to treat high myopia, hyperopia, and astigmatism.^{5–13} The use of pIOLs in pediatric amblyopic patients has also been described.^{14–16} To our knowledge, no study has evaluated solely the gain in visual acuity from implantation of pIOLs in adult amblyopic eyes. This retrospective study evaluated adult amblyopic eyes in which an Artisan iris-fixated phakic intraocular lens (pIOL) (Ophtec BV) was implanted. The 4 anterior chamber IOL (AC IOL) models used were

made of poly(methyl methacrylate) with ultraviolet filtration and had an overall diameter of 8.5 mm. Table 1 gives the optical zone diameters and power ranges for the 4 models. Model selection was based on preoperative refraction. The study evaluated the 5-year postoperative gain in corrected distance visual acuity (CDVA), safety, efficacy, refractive results, and complications in adult amblyopic eyes.

PATIENTS AND METHODS

Data for amblyopic eyes in which a pIOL was implanted from January 21, 2002, to March 3, 2008, were reviewed retrospectively. All patients provided written informed consent.

Amblyopia was defined as having a CDVA of 6/15 or worse with no improvement using a pinhole occluder and having a history of reduced CDVA after age 7 in an ametropic but otherwise normal eye. All patients had at least 1 eye with refractive amblyopia. Nineteen patients (22.6%) had bilateral refractive isometric amblyopia with a CDVA of 6/15 or less in each eye. The remaining 65 patients (77.4%) had a fellow eye with a CDVA of 6/9 or better, and these patients were isometric (25 patients) or anisometric (40 patients) amblyopes. Fellow eyes also had iris-fixated pIOLs implanted, apart from 2 cases that qualified for excimer laser ablation. Study inclusion criteria were a stable refraction for 2 years before surgery, a minimum age of 21 years, an absence of ocular pathology, an endothelial cell count (ECC) of more than 2000 cells/mm², an anterior chamber depth (ACD) of more than 3.0 mm as measured from the anterior lens capsule to the endothelium, and a scotopic pupil size of 6.0 mm or less. A nontoric IOL was used in eyes with a refractive cylinder of 1.50 D or less (IOLs 1, 2, and 3) (Table 1), and a toric IOL was used in myopic and hyperopic eyes with a refractive cylinder over 1.50 D (IOL 4).

The eyes included in this study were not suitable for any form of excimer laser ablation. The patients elected to have refractive surgery because of contact lens intolerance, spectacle wear being considered a disability rather than an aesthetic drawback in their profession and daily life, or difficulty with spectacle correction in cases of anisometropia and high astigmatism. A short contact lens trial was performed if it was uncertain whether an eye would tolerate full correction of the refractive error or the effect of magnification and minification after surgery. Patients were thoroughly counseled about the risks and benefits of surgery, including the possibility that the surgery would reduce the ametropia but not improve the CDVA over the preoperative level because of the nature of amblyopia.

Preoperatively, uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, and cycloplegic refraction were measured and a slitlamp examination,

Table 1. Intraocular lenses used in the study.

IOL*	Optic (mm)	Power Range (D) [†]	Eyes (n)	
			Group 1	Group 2
1	5.0	+1.0, +12.0 [‡]	—	13
2	6.0	-1.0, -15.5	27	—
3	5.0	-1.0, -23.5	29	—
4	5.0	+12.0, -23.0 [§]	26	8

IOL = intraocular lens

*IOL 1 = Artisan Hyperopia 203; IOL 2 = Artisan Myopia 204; IOL 3 = Artisan Myopia 206; IOL 4 = Artisan Toric

[†]Available in 0.5 D increments

[‡]Used in hyperopic eyes

[§]With additional cylinder from 1.0 to 7.5 D

pupillometry (Colvard pupillometer, Oasis Medical, Inc.), autorefractometry and tonometry (Tonoref II, Nidek Co. Ltd.), ECC (SP 2000P Specular Microscope, Topcon Europe BV), corneal topography and pachymetry (Orbscan, Bausch & Lomb), optical biometry (IOLMaster, Carl Zeiss Meditec AG), and dilated fundus examination were performed. The power of the pIOL was calculated using the van der Heijde formula,¹⁷ which uses the mean corneal curvature, adjusted ACD (0.8 mm), and spherical equivalent (SE) of the eye's spectacle correction at a 12.0 mm vertex distance.

Surgical Technique

All procedures were performed by the same experienced surgeon (J.V.). In eyes with a toric IOL, a sterile disposable skin marker (Kendall Devon) was used to mark the enclavation sites on the cornea using a Mendez degree gauge (Duckworth & Kent Ltd) and with the patient sitting behind the slitlamp. Then, 1 drop of topical anesthetic was instilled, followed by delivery of sub-Tenon anesthesia. The surgical eye was prepared using a povidone-iodine solution, and the surgical field was isolated. Two paracenteses were made for instrument access, followed by instillation of acetylcholine chloride (Miochol) and an ophthalmic viscosurgical device (OVD). A 5.2 mm scleral tunnel incision was made for IOLs with a 5.0 mm optic zone (IOLs 1, 3, and 4) (Table 1), and a 6.2 mm incision was made for those with a 6.0 mm optic zone (IOL 2). After implantation in the anterior chamber using the holding forceps, the IOL was fixated on the iris using a disposable enclavation needle. Toric IOLs were first positioned on the correct axis using premarked reference points. After successful implantation, irrigation/aspiration was performed to remove the OVD and a surgical iridectomy was performed to prevent angle-closure glaucoma. Three single 10-0 polyglactin self-dissolving sutures (Vicryl) were used to obtain a watertight, sealing incision in all cases. Postoperatively, patients were instructed to instill 1 drop each of topical ofloxacin 0.3% (Exocin) and topical dexamethasone 0.1% (Maxidex) 4 times a day for 2 weeks.

Statistical Analysis

The 103 study eyes were divided into 2 groups for statistical analysis: eyes with myopia or myopic astigmatism (Group 1) and eyes with hyperopia or hyperopic astigmatism (Group 2). Snellen visual acuity was converted into

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Table 2. Mean preoperative and 5-year postoperative measurements (N = 103).

Parameter	Group 1: Myopic/Myopic Astigmatism (n = 82)			Group 2: Hyperopic/Hyperopic Astigmatism (n = 21)		
	Preop	Postop	P Value	Preop	Postop	P Value
Sphere (D)						
Mean \pm SD	-13.42 \pm 5.62	+0.14 \pm 0.63	<.001	+6.77 \pm 1.91	+0.43 \pm 0.91	<.001
Range	-1.25, -24.00	-1.75, +1.75		+2.25, +10.0	-1.00, +2.25	
Cylinder (D)						
Mean \pm SD	-2.35 \pm 1.75	-0.86 \pm 0.66	<.001	-2.63 \pm 2.43	-1.20 \pm 0.78	.01
Range	0.00, -7.00	0.00, -2.75		0.00, -7.50	0.00, -2.50	
SE (D)						
Mean \pm SD	-14.57 \pm 5.29	-0.29 \pm 0.64	<.001	+5.46 \pm 2.41	-0.17 \pm 0.81	<.001
Range	-3.38, -24.00	-2.25, +1.63		+1.50, +9.75	-1.75, +1.38	
UDVA (logMAR)						
Mean \pm SD	1.49 \pm 0.09	0.43 \pm 0.20	<.001	1.35 \pm 0.28	0.54 \pm 0.14	<.001
Range	0.80, 1.50	0.10, 1.00		0.70, 1.50	0.20, 0.70	
CDVA (logMAR)						
Mean \pm SD	0.51 \pm 0.15	0.34 \pm 0.16	<.001	0.54 \pm 0.17	0.46 \pm 0.14	.005
Range	0.40, 1.00	0.00, 0.80		0.40, 1.00	0.20, 0.70	

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

logMAR units to calculate the means. The safety index (the mean postoperative CDVA divided by the mean preoperative CDVA) and efficacy index (the mean postoperative UDVA divided by the mean preoperative CDVA) were calculated for each group. The Student *t* test for paired data was used to compare preoperative and postoperative data. An independent-samples *t* test was used to compare the mean CDVA gain between Group 1 and Group 2. The ECC loss calculation was adjusted for the physiologic yearly loss, as described by Bourne et al.¹⁸ All data were analyzed using Excel 2007 software (Microsoft Corp.). A *P* value less than 0.05 was considered statistically significant.

RESULTS

Data for 103 amblyopic eyes of 84 patients were reviewed. The mean patient age was 36.9 years \pm 7.9 (SD) (range 21 to 50 years); 38 were women, and 46 were men. Group 1 contained 82 eyes of 63 patients and Group 2 included 21 eyes of 21 patients. Table 1 shows the distribution of the 4 IOL models in the 2 groups.

Table 2 shows the preoperative and 5-year postoperative mean values for sphere, cylinder, SE, UDVA, and CDVA in the study eyes. The decrease in the mean SE over the 5 years was statistically significant in Group 1 ($P < .001$) and Group 2 ($P < .001$). In each group, the decrease in refraction was also statistically significant when the spherical and the cylindrical components of refraction were analyzed separately (Table 2). Figure 1 plots the predictability of the SE. The postoperative SE in 73 eyes (89.0%) in Group 1 and in 17 eyes (81.0%) in Group 2 was within ± 1.0 D of emmetropia.

Figure 2 compares the preoperative CDVA with the postoperative UDVA. In both groups, all eyes had a preoperative CDVA of 0.4 logMAR (6/15) or worse. Postoperatively, 45 eyes (54.9%) in Group 1 and 5 eyes (23.8%) in Group 2 achieved a UDVA of 6/15 or better. The efficacy index was 1.21 in Group 1 and 1.00 in Group 2. The mean postoperative UDVA was 0.43 \pm 0.20 logMAR in Group 1 and 0.54 \pm 0.14 logMAR in Group 2.

In Group 1, 65 eyes (79.3%) gained 1 or more lines of CDVA and 40 eyes (48.8%) gained 2 or more lines. In hyperopic eyes in Group 2, 12 (57.1%) gained 1 or more lines of CDVA and 4 (19.0%) gained 2 or more lines (Figure 3). Although the gain in CDVA was statistically significant when comparing preoperative and postoperative values in each group separately (Table 1), there was a statistically significantly higher gain in CDVA in Group 1 than in Group 2. The mean gain in CDVA in the myopic group was 0.17 \pm 0.14 logMAR and in the hyperopic group was 0.08 \pm 0.11 logMAR ($P = .006$). The safety index was 1.48 in Group 1 and 1.19 in Group 2. Figure 4 is a pair of scattergrams showing the preoperative to postoperative CDVA change in each eye.

Endothelial Cell Count

The mean ECC was 2859 \pm 396 cells/mm² (range 2176 to 3914 cells/mm²) in 103 eyes preoperatively, 2751 \pm 436 cells/mm² (range 1957 to 3658 cells/mm²) in 99 eyes at 1 year, and 2694 \pm 424 cells/mm² (range 1915 to 3699 cells/mm²) in 103 eyes at 5 years. When adjusted for 0.6% physiologic loss per year, the mean

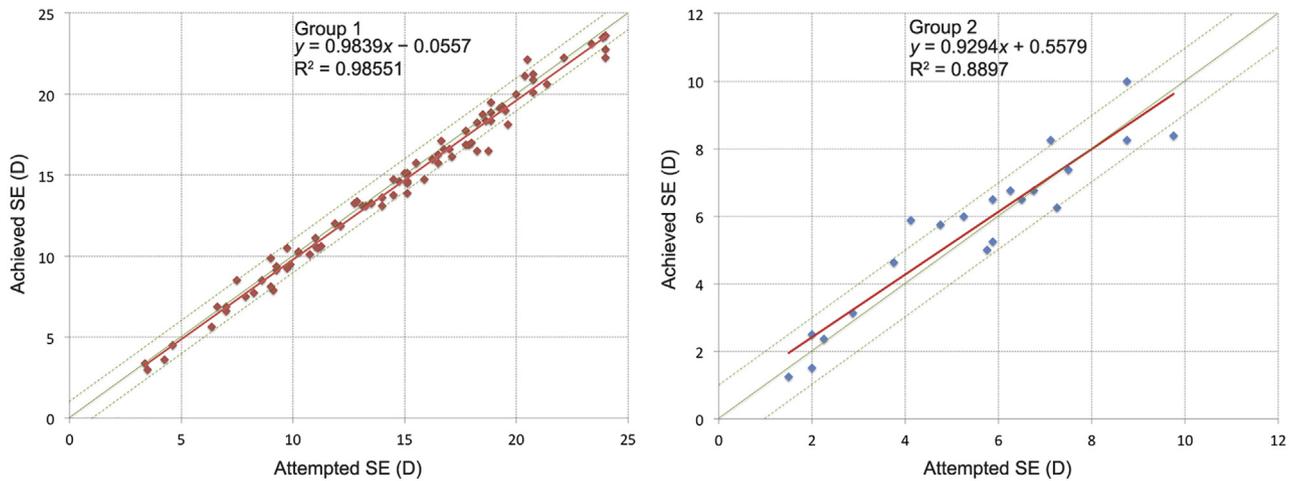


Figure 1. The predictability of the spherical equivalent (SE) in eyes in Group 1 and Group 2.

cell loss was $3.3\% \pm 8.2\%$ (range -33.6% to 18.1% ; $P < .001$) at 1 year and $1.4\% \pm 7.7\%$ (range -24.7% to 18.1% ; $P = .08$) at 5 years. The endothelial cell loss in Group 1 was 3.0% (range -33.6% to 7.7% , $P < .001$) at 1 year and 1.5% (-24.7% to 7.9% , $P < .001$) at 5 years. In Group 2, the cell loss was 5.0% (range -22.0% to 10.2% , $P = .03$) and 1.1% (range -13.0 to 7.3% , $P = .02$) at 1 year and 5 years, respectively. No eye required explantation of the iris-fixated pIOL due to unacceptable cell loss.

Complications

There were no intraoperative complications or late postoperative complications requiring surgical intervention. Early postoperative complications included 3 eyes with elevated intraocular pressure for up to 2

months and 2 complaints of glare from IOL edge reflection. Five patients chose to have laser eye surgery for residual refractive error.

DISCUSSION

Amblyopia treatment is mostly effective within the critical period of visual development, usually defined as up to 8 years of age. It is documented that at this stage, the earlier the treatment begins, the better the vision outcome.² Adults with amblyopia tend not to respond to conventional treatment. Preliminary studies using video display units and neurotraining methods to improve CDVA in adult amblyopic eyes show promising results¹⁹⁻²²; however, the sustainability of those outcomes is yet to be confirmed.

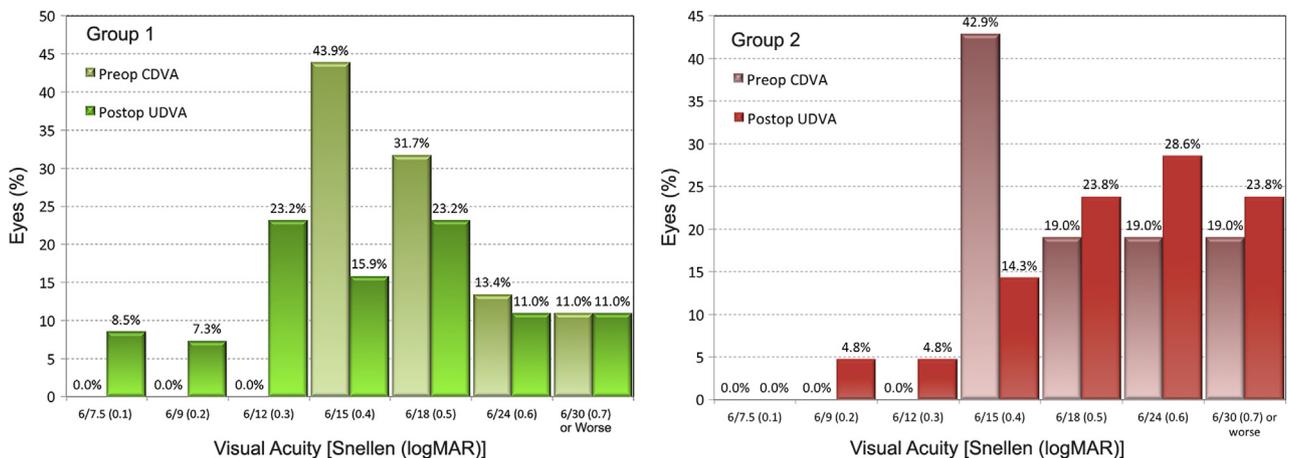


Figure 2. Comparison of the efficacy of preoperative CDVA and postoperative UDVA in Group 1 and Group 2 (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).

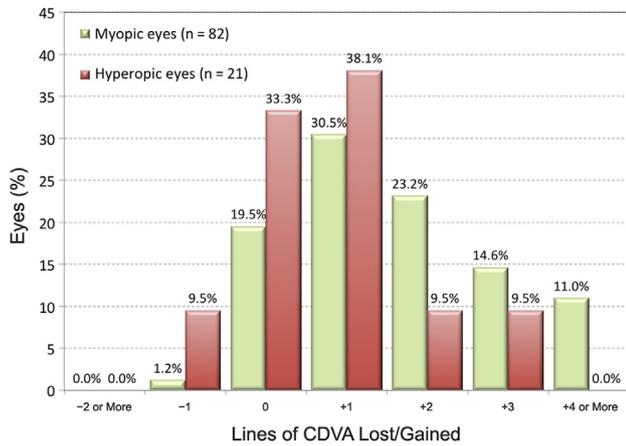


Figure 3. Comparison of the safety of preoperative and postoperative CDVA (CDVA = corrected distance visual acuity).

Providing the best possible correction of refractive error can improve the quality of life for adult amblyopic patients. Conventional correction of high ametropia using spectacles is safe but has drawbacks (eg, limiting visual field, aberrations, and cosmetic appearance and inconvenience, especially in cases involving high refractive error). Contact lenses are positioned closer to the nodal point of the eye and generally provide better quality of vision than spectacles, but some patients cannot tolerate them. Safety of long-term contact lens wear is also a concern. Surgical options include refractive lens exchange, excimer laser ablation, and implantation of a pIOL. Refractive lens exchange is not the best choice for younger patients because it does not preserve the eye's natural accommodation and is irreversible. Excimer laser ablation has been used in amblyopic eyes,^{23–25} but there is a

limit to how much refractive error can be corrected using a corneal procedure. Excimer laser ablation is generally used in eyes with refractive errors of +5.0 D to –10.0 D, and the higher the refractive error, the greater the possibility of it inducing higher-order aberrations, loss of contrast sensitivity, and regression. Several studies comparing excimer laser ablation and IOL implantation in eyes with high ametropia concluded that the outcome for the pIOL was better in terms of visual quality, contrast sensitivity, and gain in CDVA.^{26–28}

Three types of pIOL are currently available: angle-supported AC IOLs, iris-fixated AC IOLs, and posterior chamber IOLs. For adult amblyopic eyes, we aimed to maximize improvement in visual acuity and therefore chose iris-fixated pIOLs that are available in wide range of powers and that provide better pupil centration because of their fixation principle. Changing the location of the refractive correction from the spectacle plane to closer to the nodal point of the eye changes retinal magnification.²⁹ With pIOLs, the correction is nearer the entrance of the pupil than with spectacles and contact lenses. An increase in visual acuity from implantation of pIOLs in myopic eyes has been reported.³⁰ In hyperopic eyes, the refraction correction being closer to the nodal point of the eye creates a smaller image, possibly limiting the improvement in CDVA.

The present study evaluated 2 groups of amblyopic eyes: eyes with myopia or myopic astigmatism (Group 1) and eyes with hyperopia in hyperopic astigmatism (Group 2). A safety index in a particular group of greater than 1.0 yields an average gain in postoperative CDVA. The safety indices in this study were 1.48 in Group 1 and 1.19 in Group 2. In Group 1, 79.3% of

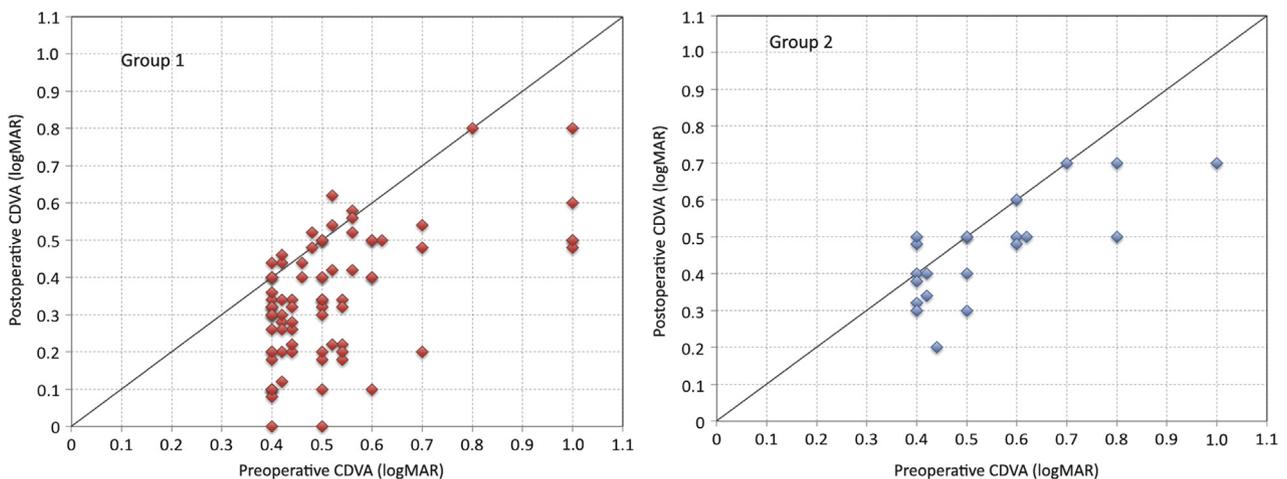


Figure 4. Preoperative versus postoperative CDVA for Group 1 and Group 2 (CDVA = corrected distance visual acuity).

eyes gained 1 or more lines of CDVA and 48.8% gained 2 or more lines. In Group 2, 57.1% gained 1 or more lines of CDVA and 19.0% gained 2 or more lines. Although both groups gained visual acuity, the CDVA gain in Group 1 was statistically significantly higher than in Group 2.

Table A (available at <http://jcrsjournal.org>) summarizes the literature reporting gains in visual acuity in long-term studies of Artisan iris-fixated IOLs with a follow-up of up to 10 years.⁵⁻¹² Although those studies did not concentrate on amblyopic eyes, the preoperative CDVA values indicate some eyes had some degree of amblyopia. All reported safety indices were above 1.0. The safety index for myopic studies ranged from 1.04 to 1.31 and for hyperopic studies ranged from 1.06 to 1.25. The Budo et al.⁵ multicenter study showed that the higher the degree of preoperative myopia, the greater the gain in postoperative CDVA. In that study, 23.5% of eyes with -5.0 D to -10.0 D of myopia and 63.3% with -15.0 D to -20.0 D of myopia gained 2 or more lines of CDVA. The Güell et al.⁷ study of 399 eyes with 5 years of follow-up also showed this relationship, with a safety index of 1.30 in the high myopia group and 1.04 in the moderate myopia group.

There have been fewer studies of the use of iris-fixated IOLs in hyperopic eyes, and the patient cohort in such studies is usually smaller than in studies of myopic eyes, but hyperopic eyes^{7,11,12} and eyes with hyperopic or mixed astigmatism^{9,10} also tend to gain some lines of CDVA. Because hyperopic eyes tend to have a shallower ACD, more long-term studies are needed to evaluate the safety of the use of an iris-fixated IOL.

In Table A, the reported loss of 2 or more lines of CDVA with iris-fixated IOLs ranged from 0% to 2.6%. Most CDVA loss in these studies was related not to the pIOL surgery but rather to the nature of high ametropia; eg, the development of myopic maculopathy, nuclear cataract, or retinal detachment in myopic eyes. However, the incidence of retinal detachment in eyes with high myopia was the same as in the myopic population without pIOL surgery. In the present study, no eye lost 2 lines of CDVA, but the tendency to lose 1 line was higher for hyperopic eyes (9.5%) than for myopic eyes (1.2%).

Despite the excellent safety of iris-fixated IOLs in our study and other studies,⁵⁻¹² there are some concerns about their long-term use. One of the most discussed topics related to the safety of pIOLs is potential chronic endothelial cell loss. There is a wide variation in reported cell loss in the literature, ranging from a loss of 13.4% 4 years postoperatively¹³ to a potential cell gain at 10 years.⁶ Such variation might be attributable to the measurement techniques

used, repeatability of measurements, and perhaps the accuracy of the ECCs in retrospective studies. In the present study, the cell loss of 1.4% at 5 years was not statistically significant. Ongoing monitoring of the corneal endothelium is necessary with any pIOL. Drawbacks of implanting iris-fixated IOLs are the steep learning curve for mastering the implantation technique for these rigid IOLs and the longer vision recovery period caused by the large incision and use of sutures. No late-onset complications occurred in this study, confirming the long-term safety of iris-fixated IOLs.

In conclusion, in our cohort of adult amblyopic eyes, the iris-fixated pIOL proved to be safe, effective, and predictable 5 years postoperatively. Both the myopic group and the hyperopic group gained CDVA. The advantages of implanting an iris-fixated IOL in adults are increased visual acuity, better convenience and aesthetics than with spectacles and contact lenses, and its theoretical reversibility.

WHAT WAS KNOWN

- Achieving the best possible correction of the refractive error in adult amblyopic eyes can improve the quality of life of this population, but treatment options are limited.

WHAT THIS PAPER ADDS

- Iris-fixated IOLs were safe for the correction of refractive error in amblyopic eyes with a CDVA of 6/15 or worse.
- After 5 years of follow-up, there was a significant improvement in CDVA in both myopic and hyperopic amblyopic eyes in which an iris-fixated IOL was implanted.

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