Refractive Lens Exchange Versus Iris-claw Artisan Phakic Intraocular Lens for Hyperopia

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ABSTRACT

PURPOSE: To study a paired-match comparison between refractive lens exchange with pseudophakic IOL implant (RLE) and Artisan phakic IOL for high hyperopia.

METHODS: Nineteen eyes (12 patients, 20 to 41 years old) with an Artisan phakic IOL (Model 203: 1.00-D increment) for hyperopia from +2.75 to +9.25 D were matched to 19 eyes (15 patients, 26 to 46 yr) with hyperopia from +2.75 to +7.50 D, who had refractive lens exchange (pseudophakic IOL implantation; lenses: 0.50-D increment). Average paired-match difference was 1.13 D and 7.7 years of age.

RESULTS: At 1 month after surgery, 84% of refractive lens exchange/pseudophakic IOL eyes and 94% of Artisan phakic IOL eyes had a spherical equivalent refraction within ±1.00 D of emmetropia; 58% and 68% of eyes, respectively, were within ±0.50 D (*P*=.97). No eye lost lines of best spectacle-corrected visual acuity (BSCVA) and no significant changes in BSCVA were found in any eye at 1 month after surgery (*P*=.17). The percentage of eyes with uncorrected visual acuity (UCVA) of 20/40 or better improved from 79% to 89% of eyes at 1 to 2 months after phakic IOL; it remained at 89% to 82% of eyes from 1 to 2 months after refractive lens exchange/pseudophakic IOL. The coefficient of correlation showed statistically better accuracy (intended vs. achieved refraction; *P*=.035) for the Artisan phakic IOL (R = 0.83) than for refractive lens exchange/pseudophakic IOL (R = 0.50).

CONCLUSIONS: Spherical equivalent refraction outcome and BSCVA after surgery were similar for both procedures. The Artisan phakic IOL in carefully selected patients provided a better overall outcome for young patients with high hyperopia whose accommodation was preserved, as compared to refractive lens exchange. [*J Refract Surg* 2004: 20:20-24]

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Removal of the clear crystalline lens has been performed for high myopia[1,2] and hyperopia.[3,4] The concept of refractive lens exchange with pseudophakic lens implant (RLE) has been known for than 50 years. RLE resulted in stable and predictable visual acuity although the implant cannot be easily removed or replaced and accommodation is lost after RLE; risk of retinal detachment increases after RLE for the population with high myopia.[5,6] Therefore, RLE remains a controversial technique.[7,8]

Recent advances in lens design have provided an Artisan iris-claw phakic intraocular lens (IOL) for high myopia[9,10] as well as for hyperopia.[11] Although long-term results of these lenses are awaited, early results are promising. Furthermore, the Artisan phakic IOL can be removed, and does not involve RLE, for which loss of accommodation is problematic in the younger population.

The present study is a paired-match comparison of RLE and Artisan lens for high hyperopia.

PATIENTS AND METHODS

Eye Matching

Twelve patients (19 eyes; patient age 20 to 41 yr) had implantation of an Artisan phakic IOL for hyperopia of +2.75 to +9.25 diopters (D) from March 2000 to December 2001, and were matched to 15 patients (19 eyes; patient age 26 to 46 yr) with hyperopia from +2.75 to +7.50 D who had refractive lens exchange/pseudophakic lens implantation from September 1998 to March 2000. The maximum refractive difference between matched pairs was 2.25 D; the average difference was 1.13 D. The maximum age difference between matched pairs was 25 years; the average difference was 7.7 years.

Artisan Phakic IOL for High Hyperopia

All patients who had an Artisan phakic IOL implanted received approval by the Special Access Programme from the Therapeutic Product Medical

Devices Bureau of Health Canada. All patients signed a consent form, approved by the ethics review board prior to surgery. Exclusion criteria for this lens included high preoperative intraocular pressure (>21 mmHg), endothelial cell count lower than 2000 cells/mm^2, and a history of glaucoma, uveitis, diabetic retinopathy or iris atrophy, and pupil size greater than 6.5 mm. Gonioscopy and iris examination was performed before surgery; patients with abnormal angle were excluded.

The intraocular Artisan phakic IOL, model 203 (Ophtec USA, Boca Raton, FL), measures 8.5 mm in length by 5.0 mm wide and has an optical zone of 5.0 mm. The IOL is available in 1.00-D increments from +3.00 to +12.00 D. The IOL is made of polymethylmethacrylate (PMMA) with a convex-concave shape of 1.0 mm total height. Each of the two haptics are composed of two arms with merging claws at their ends. The opening created by both of the merging claws of one haptic is 2.2 mm wide by 1.55 mm long. Each claw is necessary for iris entrapment to maintain IOL position on the iris. The lens power to be implanted was calculated with the Van Der Heijde formula.[12]

The lens is inserted in the anterior chamber filled with viscoelastics while the pupil is constricted. After insertion, the lens is rotated with haptics at 3 and 9 o'clock using a Sinskey-type IOL manipulating instrument. The lens is centered over the pupil. The iris entrapment is performed by holding a knuckle of iris with a disposable enclavation needle (Ophtec USA, Boca Raton, FL) while gently pressing the center of the haptic over the knuckle, thus grasping iris tissue with both claws. Both haptics are pinched into the iris. Enclavation needles were designed for the purpose of iris entrapment. After lens fixation, a manual peripheral iridectomy was peformed on all eyes. Viscoelastic was removed and the limbal incision at 12 o'clock was sutured with 10-0 nylon. Astigmatism was not managed through limbal relaxing incisions.

Refractive Lens Exchange/Pseudophakic Lens Implant

A contact ultrasonography technique was used to measure axial length with Ocuscan ultrasonography (Alcon, Ft. Worth, TX). Binkhorst II (1980), Colenbrander/Hoffer (1974), Holladay I (1988), SRK-T (1990), SRK-II (1980), and Hoffer Q (1983) formulas were used to predict the emmetropic lens power at the nearest 0.50 D. The best IOL power was then chosen by the surgeon based on his past postoperative results and experience. For this purpose, a personal analysis of coefficient of emmetropic predictions was performed using the axial length and the age of the patient. The analysis of coefficient predictions is individual to a specific surgeon, such as the calculation of the personal Hoffer coefficient, or the personal Holladay I coefficient.

Seventeen eyes with polyacrylic posterior chamber foldable IOLs (Acrysof, Alcon, Montreal, Canada) and two eyes with polymethylmethacrylate (PMMA) posterior chamber lenses (Pharmacia, Montreal, Canada) were implanted. PMMA lenses were chosen in order to avoid piggyback lens implantation due to very short axial length and unavailability of Acrysof lenses with power over 30 D. Astigmatism was not managed through limbal relaxing incisions.

Examination

Preoperative and postoperative examinations included manifest and cycloplegic refractions, Snellen best spectacle-corrected visual acuity (BSCVA) and uncorrected visual acuity (UCVA), corneal topography, and slit-lamp microscopy. Follow-up for the Artisan phakic IOL was performed at 1 day, 1 week, and 1, 2, 3, 6, 8, 12, and 24 months. Endothelial cell count was performed before and 6, 12, and 24 months after surgery for the Artisan lens only. All RLE follow-up was performed at 1 month after surgery; only five eyes had additional follow-up.

RESULTS

Figure 1 shows the target versus achieved spherical lens power for both RLE and phakic IOL eyes. Coefficient of correlation showed statistically better (P=.035) accuracy for the Artisan phakic IOL (R = 0.83) than for RLE (R = 0.50).

No significant change in BSCVA was shown for either procedure (P=.17), although RLE seemed to result in more gain of BSCVA lines earlier, at 1 month postoperative (P=.17) (Fig 2). However, preoperative eyes with BSCVA of 20/25 or better for the Artisan phakic IOL group was 84%, and only 68% for RLE. No eye lost lines of BSCVA after RLE or phakic IOL at 1 or 2 months postoperative.

At 1 month after RLE, 47% of eyes had UCVA of 20/25 or better, and after phakic IOL implantation, 63% of eyes achieved 20/25 or better (Table). This difference was not statistically significant (P =.76). At 1 month after RLE or phakic IOL, 84% and 94% of eyes, respectively, had a refractive outcome within ±1.00 D of emmetropia (Table); 58% and 68% of eyes, respectively, were within ±0.50 D of emmetropia, and these proportions were not

Table
Refractive Results for Eyes Before and After Artisan Phakic IOL or Refractive Lens Exchange With Pseudophakic IOL for High Hyperopia

	Refractive Lens Exchange With Pseudophakic IOL			Artisan Phakic IOL		
	Preop	1 mo	2 mo	Preop	1 mo	2 mo
No. of eyes	19	19	11	19	19	18
Mean spherical correction ± SD (D)	+4.76±1.41	-0.21±1.10	+0.18±0.71	+5.89±1.78	+0.12±0.78	-0.03±0.75
UCVA* 20/25 or better (% eyes)	0	63	64	0	47	67
UCVA 20/40 or better (% eyes)	0	89	82	0	79	89
Spherical equivalent refraction						
±0.50 D of emmetropia (% eyes)	0	32	55	0	37	50
±1.00 D of emmetropia (% eyes)	0	58	91	0	68	78
±2.00 D of emmetropia (% eyes)	0	84	100	0	94	100

**UCVA = uncorrected visual acuity*

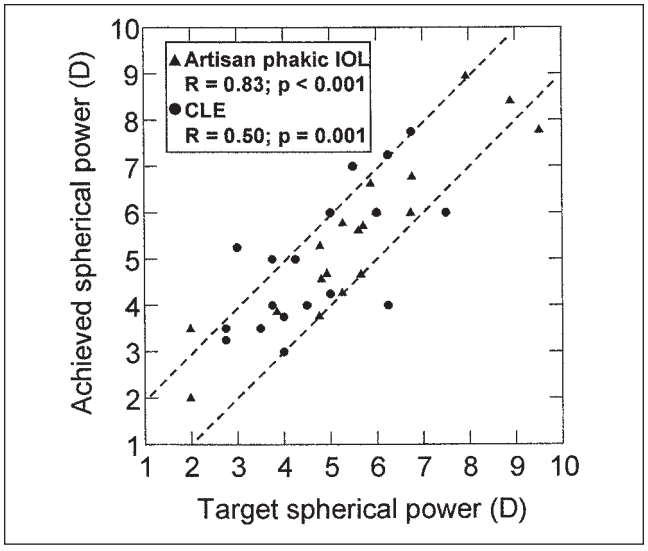

Figure 1. Target versus achieved spherical lens power for refractive lens exchange with pseudophakic IOL implant (CLE) and Artisan phakic IOL for hyperopia at 1 month after surgery. Back vertex distance is 12.5 mm. Dotted lines indicate ±1.00 D of target.

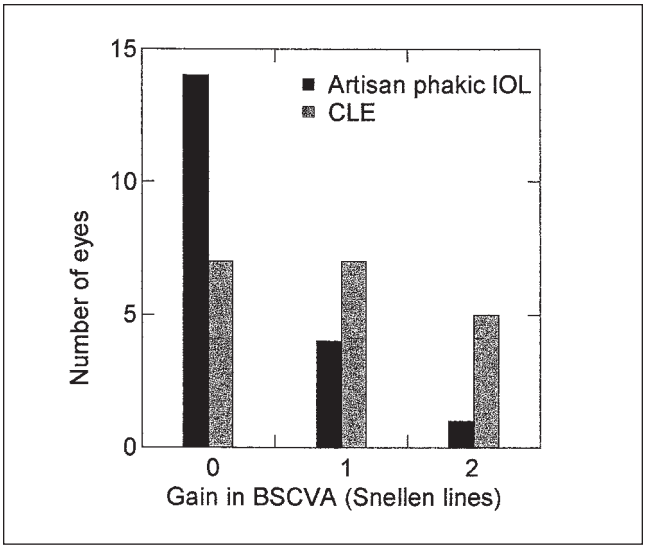

Figure 2. Early comparison of best spectacle-corrected visual acuity (BSCVA) lines gained for refractive lens exchange with pseudophakic IOL implant (CLE) and Artisan phakic IOL for hyperopia at 1 month after surgery; no eye lost lines of BSCVA after either procedure. Before surgery, 84% of eyes in the Artisan phakic IOL group and only 68% of eyes in the CLE group had BSCVA of 20/25 or better.

statistically different (P=.97). From 1 to 2 months postoperative, mean refractive outcome did not significantly change for either procedure (P>0.3) (Table). However, two eyes that had RLE and one eye that had phakic IOL were overcorrected by more than +0.50 D up to +2.25 D at 1 month after surgery.

The percentage of eyes with UCVA of 20/40 or better improved from 79% at 1 month (Fig 3) to 89% at 2 months after phakic IOL (Table). UCVA of 20/40 or better for RLE remained at 89% to 82% of eyes from 1 to 2 months after surgery. The last recorded Artisan phakic IOL UCVA resulted in 74% of eyes at 20/25 or better and 89% of eyes at 20/40 or better (mean follow-up time 5.4 mo).

All but two eyes with the Artisan phakic IOL had J1+ near visual acuity 1 month after surgery; the two eyes (two patients) had J2 and J7 Jaeger near visual acuity. The J2 eye had UCVA of 20/50 with

-1.25 -2.25 x 77° at 1 month postoperative but had BSCVA of 20/30 before surgery; the J7 eye had UCVA of 20/50 and +1.00 D at 1 month postoperative but had BSCVA of 20/40 before surgery.

Postoperative analysis of endothelial cell count for the Artisan phakic IOL was performed in 12 eyes at 6 months postoperative. Data showed a decrease of cell density by -73 cells/mm^2 for -2.3% total change. Three-quarters of eyes had decreased endothelial cell count (range -1% to -7%); the remaining eyes had an increase in cell density (range +1% to +7%). The difference between preoperative and postoperative endothelial cell counts was not statistically significative (non-parametric sign test: *P*=.15).

No incidence of retinal detachment was observed in any eye in the study.

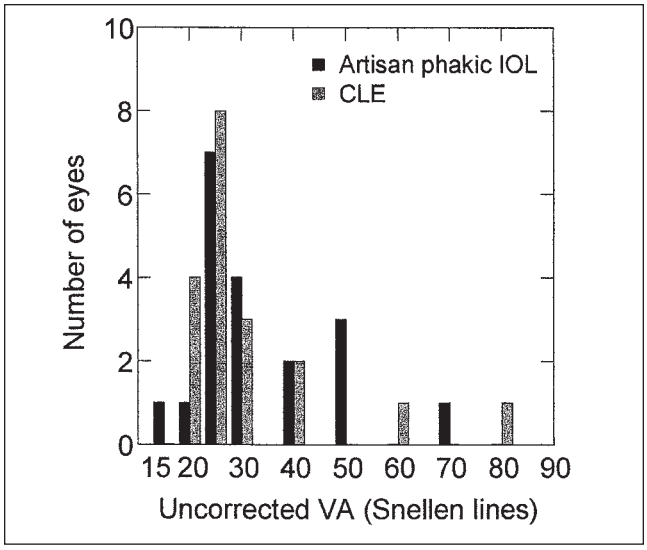

Figure 3. Uncorrected visual acuity after refractive lens exchange plus pseudophakic IOL implant (CLE) and Artisan phakic IOL for hyperopia at 1 month after surgery. At 1 month after CLE or phakic IOL implantation, 47% and 63% of eyes, respectively, had UCVA of 20/25 or better (*P*=.76).

DISCUSSION

No differences were noted in refractive stability at 1 month after surgery for patients between 20 and 46 years old. At 1 month postoperative, UCVA of RLE patients was slightly better than after Artisan phakic IOL. However, at 2 months postoperative, UCVA of Artisan phakic IOL patients was slightly better than after RLE; UCVA of Artisan phakic IOL patients seemed slower to improve than RLE patients. It is possible that slower UCVA recovery might have been related to the larger incision and suturing during surgery. None of these differences were statistically significant.

In this study of patients less than 50 years old, prediction of Artisan phakic IOL lens power seemed to be more accurate than for RLE. The phakic IOL was available only in 1.00-D increments; better lens power prediction for the Artisan lens resulted in similar refractive results compared to RLE. When available, increased phakic IOL lens power increments may result in better refractive outcome. However, newer methods of calculating lens power for RLE, such as the Holladay 2 formula[13], and use of immersion ultrasonography or partial coherence interferometry, eg, as in the IOLMaster (Alcon, Ft. Worth, TX)[14], may also improve lens power calculation and accuracy. We think that these study results are representative of current practice with RLE in a standard clinical setting from 1998 to 2000.

Mean endothelial cell loss after phacoemulsification was estimated to be between 8% to 10% at 1 year after surgery.[15,16] Endothelial cell counts of Artisan phakic IOL for hyperopia showed 2.3% cell loss at 6 months postoperative. Change in preoperative to postoperative cell counts was not statistically significant, hence additional study may be appropriate to assess long-term results of endothelial cell count using the present hyperopic Artisan lens model.

The incidence of retinal detachment has been studied. Data from 1116 patients yield a normal retinal detachment incidence of 0.014% inhabitants in an urban area.[17] Reports estimate a 2.4% rate of retinal detachment over a 2-year period after cataract extraction in highly myopic eyes.[18] Retinal detachment occurred in 2 of 311 patients (0.6%) after cataract surgery over a 7-year study period[6]; another study reported 4 of 49 eyes (8.1%) with retinal detachment during the same time period for refractive lens exchange for high myopia.[5] Up to June 2003, no retinal detachment has been related to Artisan phakic IOL for hyperopia for a total of 129 eyes included in the US FDA study (Ophtec USA, personal communication, January 13, 2003). Six retinal detachments for the myopic Artisan model, five of which were reported to be inevitably related to high myopia itself, were recorded for a total prevalence of 0.4% within the US phase III FDA study (Ophtec USA, personal communication, January 13, 2003). No retinal detachment was observed for eyes within the present study's small sample. Consequently, reports on retinal detachment incidence with the Artisan lens for hyperopia might be premature, without long-term follow-up and a larger sample size—as in the US FDA trial of the Artisan lens for hyperopia.

Preliminary investigation of near visual acuity after Artisan phakic lens showed that accommodation was preserved, whereas it was expected to change after RLE. Some pseudo-accommodation may be preserved after RLE.[19] We did not evaluate the efficacy of multifocal or accommodatable lenses available for patients older than 46 years old versus Artisan lens implantation.

The Artisan phakic IOL is a reversible procedure, since the iris-claw lens can be detached easily and explanted through the limbal incision. Therefore, it is perceived that the Artisan phakic IOL might be a more practical solution than RLE for young patients with high hyperopia, whose accommodation should be preserved and whose risk of retinal detachment should be minimized.

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