Artisan Phakic Iris Claw Intraocular Lens for High Primary and Secondary Hyperopia

Jorge L. Alió, MD, PhD; M. Emilia Mulet, MD, PhD; Ahmad M.M. Shalaby, MD

ABSTRACT

PURPOSE: To evaluate the efficacy, predictability, and safety of the Artisan iris claw phakic intraocular lens for the correction of high primary and secondary hyperopia.

METHODS: Fifty-seven eyes were divided into two groups: 29 eyes had primary hyperopia (mean refraction 6.06 ± 1.26 D, and 28 eyes had secondary hyperopia, (mean refraction 5.88 ± 1.88 D) induced or residual following a previous corneal refractive procedure. Consecutive implantation of the Artisan iris claw phakic intraocular lens was performed. Main outcome measures recorded were BSCVA, UCVA, refraction, and astigmatic change, intraocular inflammation, and endothelial cell loss.

RESULTS: Primary hyperopic group: Preoperatively, mean UCVA was 0.4 ± 0.7 and mean BSCVA was 0.2 ± 0.6. After implantation, mean UCVA was 0.3 ± 0.6 and BSCVA was 0.1 ± 0.6. Mean cycloplegic residual spherical refractive error after surgery was 0.10 ± 0.57 D (range -1 to +2 D). Mean surgically induced astigmatism was 1.48 ± 0.89 D. Safety index was 1.11. Efficacy index was 0.82. Secondary hyperopic group: Preoperatively, mean UCVA was 0.3 ± 0.7 and mean BSCVA was 0.2 ± 0.6. Postoperatively, mean UCVA was 0.4 ± 0.7 and mean BSCVA was 0.2 ± 0.6. Mean cycloplegic residual spherical refractive error was 0.55 ± 1.49 D. Mean surgically induced astigmatism was 1.85 ± 1.19 D. Safety index was 1.05. Efficacy index was 0.7. Postoperative iridocyclitis was observed in one eye (3.4%) in the primary group and in three eyes (10.7%) in the secondary group. Overall corneal endothelial cell loss at 1 year of follow-up was 9.4%.

CONCLUSION: The Artisan iris claw phakic intraocular lens was reasonably safe and predictable for correcting high hyperopia. [J Refract Surg 2002;18:697-707]

The surgical correction of hyperopia, especially for medium to high hyperopic errors, has been a continuous challenge in refractive surgery. Years ago, different techniques were described to steepen the central cornea, as with electrocoagulation to shrink peripheral corneal collagen or with paracentral hexagonal keratotomy. Such techniques had limited appeal because of their poor predictability, induction of astigmatism, loss of spectacle-corrected visual acuity, and many other complications. Another surgical technique, laser thermal keratoplasty (LTK) with the holmium laser, is not suitable in high hyperopia due to regression, especially in young patients. In addition, laser in situ keratomileusis (LASIK) results are good only in eyes with low to medium hyperopia. Refractive lensectomy mutilates the natural lens and does not preserve accommodation. Hence, high hyperopia, more than +5.00 diopters (D) of cycloplegic refraction, remains a consistent unsolved problem in refractive surgery.

The implantation of anterior or posterior chamber intraocular lenses in phakic eyes is an alternative that has good results in high myopia, and a low complication rate.

Improvements in instrumentation, surgical technique, and quality of the optical design of phakic intraocular lenses (PIOLs) have improved expectations in the use of intraocular lenses for the correction of high refractive errors. Worst and Fechner introduced the iris claw anterior chamber lens for the correction of high myopia in 1990, with initial satisfactory results.

To the best of our knowledge, there are no published reports on the results on iris-supported PIOL in hyperopic patients. Iris claw PIOL seems to be adequate for hyperopic eyes with more than +5.00 D
of cycloplegic refraction, provided they are located at the central part of the anterior chamber, without physical contact with the natural lens. Iris claw PIOL also avoids contact with the anterior chamber angle, frequently narrower with aging in high hyperopia.\textsuperscript{12}

We studied the predictability, safety, stability, and complications of the Artisan phakic iris claw intraocular lens for correction of high primary and secondary hyperopia (+6.00 D of cycloplegic spherical refraction) in two groups of hyperopic eyes.

**PATIENTS AND METHODS**

**Patients**

In this prospective, consecutive study, we included 57 eyes (32 patients) consecutively implanted with the Artisan phakic anterior chamber iris claw intraocular lens (Ophtec BV, Groningen, The Netherlands). The mean age of the total group was 33.8 ± 5.6 years (range 19 to 54 yr). Patients were divided into two groups.

The primary hyperopia group included 29 eyes (16 patients) with primary hyperopia, with a mean cycloplegic spherical refractive error of 6.06 ± 1.26 D (range +3.00 to +9.00 D). Mean uncorrected visual acuity (UCVA) (logMAR) was 0.4 ± 0.7 (range count fingers to 0.2) and mean best spectacle-corrected visual acuity (BSCVA) was 0.2 ± 0.6 (range 1 to 0) (obtained with spectacles in all eyes in both groups). Mean anterior chamber depth in this group was 3.21 ± 0.26 mm (range 2.8 to 3.68 mm).

Some of the eyes with poor BSCVA were chosen for surgery as they were the fellow eyes of bilaterally high hyperopic patients with accommodative esotropia that required bilateral surgery to avoid residual accommodative esotropia after intraocular refractive surgery.

The secondary hyperopia group included 28 eyes (16 patients) with secondary hyperopia, with a mean cycloplegic spherical refractive error of 5.88 ± 1.88 D (range +3.50 to +9.50 D) induced by or residual after a previous corneal refractive surgical procedure. Preoperative mean UCVA (logMAR) was 0.5 ± 0.7 (range count fingers to 0.1) and mean BSCVA was 0.2 ± 0.6 (range count fingers to 0). Mean anterior chamber depth in this group was 3.05 ± 0.2 mm (range 2.8 to 3.4 mm).

In the secondary hyperopia group, hyperopia was induced by previous corneal refractive procedures: seven eyes after LASIK for myopia, eight eyes with hyperopic regression after LTK, five eyes with induced hyperopia after correction of irregular astigmatism with visokeratoplasty with excimer laser assisted by sodium hyaluronate (ELASHY\textsuperscript{13}), four eyes with induced hyperopia after radial keratotomy for myopia, and two eyes with induced hyperopia after LASIK for myopia treated by LTK, which further regressed.

**Methods**

The hyperopic model of the Artisan phakic iris claw lens (Ophtec BV, Groningen, The Netherlands) was used in all eyes, and consists of a biconvex optic of polymethylmethacrylate, with an overall length of 8.5 mm and optic zone of 5-mm-diameter, and a central thickness of 0.93 mm (Fig 1). The power of the lens was calculated by proprietary software based on the Van der Heyde formula (Ophtec BV).

The parameters used for calculation were anterior central chamber depth, keratometric power, and cycloplegic refraction. Anterior chamber depth was measured with an ultrasonic biometer (Ocuscan, Alcon, Ft. Worth, TX). Keratometric power was estimated from the tangential map of corneal topography (EyeSys Technologies, Houston, TX), measured at the 3-mm-diameter zone.

The decision to do intraocular lens surgery for hyperopia should satisfy certain medical requirements, such as patient desire not to use eyeglasses or contact lenses, and adequate comprehension of the medical implications of phakic IOL, evidenced by signing a written informed consent. A complete preoperative ocular examination was performed in all patients including complete clinical ocular examination, manifest and cycloplegic refraction, slit-lamp microscopy, gonioscopy, B-scan biometry (Ocuscan), keratometry, corneal topography (EyeSys), and vitreoretinal examination. Corneal
endothelial cell density (cells/square millimeter) was calculated automatically by the Cell Analyzer VER 4.00 (Konan Camera Research Institute, Inc., Hyogo, Japan) following a previously published protocol.  

Snellen chart UCVA and BCSCVA with and without cyclography were recorded preoperatively and postoperatively. Cycloplegic refraction was estimated 20 minutes after instillation of 1% cyclopentolate (Ciclopédico, Alcon-Cusi, Barcelona, Spain). Evaluation of the inflammatory response and corneal endothelial cell counts were performed at regular intervals during the follow-up at 1, 3, 6, and 12 months after surgery. Corneal astigmatic changes induced by the surgical procedure were analyzed by vector analysis of the topographic values measured at the 3-mm-diameter zone before and after surgery with cornea topography (EyeSys). 

We considered as contraindications for hyperopic IOL implantation previous history of iridocyclitis, glaucoma or intraocular pressure higher than 20 mmHg, cataracts, anterior or posterior synechiae, corneal dystrophy, central endothelial cell count lower than 2250 cells/mm², and anterior central chamber depth less than 2.8 mm, associated with normal anterior chamber angle configuration at gonioscopy (at least Grade 3 of Shaffer’s classification).  

Patients with corneal astigmatism >2.00 D or values between K1 and K2 >3.00 D were excluded. Eyes that had myopic pupil measurements larger than 6 mm were also excluded.

Follow-up examinations after surgery were performed at 24 hours, 7 and 21 days, monthly for 6 months, and at 1 year after surgery.

**Surgical Procedure**

The same surgeon (J.L.A.) performed all surgical procedures consecutively at the Instituto Oftalmológico de Alicante (Alicante, Spain) between 1998 and 1999. The surgical protocol was the same in all eyes. The surgical procedure was preceded by peribulbar anesthesia with 8 ml of Bupivacaine 0.75% and Lidocaine 2% with 1 cc of hyaluronidase. A Honan Balloon (Lebanon Corporation, Lebanon, IN) was used for at least 20 minutes before surgery. Pupillary miosis, using one drop of pilocarpine 2% (Isopto Carpine 2%; Alcon-Cusi, Barcelona, Spain), 30 minutes before surgery was used in all eyes.

With an astigmatic marker (Katena, Denville, NJ), we identified the horizontal 180° corneal axis, and two 1.5-mm stab incisions, 2 mm away from the limbus and directed toward the peripheral iris, were made at the 3 and 9 o'clock position using a 1.4-mm MVR blade (Sharpoint, Surgical Specialties Corporation, Reading, PA) (Fig 2). Then, the anterior chamber was filled with viscoelastic (Healon, Pharmacia, Stockholm, Sweden). A 6-mm incision was then made at the superior clear cornea just in front of the vascular arcades. This incision size was selected after finding difficulties in lenses with power higher than +5 through 5.5 mm. The peripheral iris was irrigated lightly with a solution of 1% acetylcholine (Alcon-Cusi, Barcelona, Spain). Then, the implant was inserted through an upper scleral corneal incision of 6 mm using a specially designed implantation forceps (Artisan lens forceps, Ophtec) (Fig 2) and then rotated to a horizontal position in the center into the anterior chamber with a Lester hook (Katena, Denville, NJ) (Fig 2). It was held in this position at the 12 o’clock position of the optic with Artisan lens forceps and the optic was centered on the pupil.

Then, through the stab incision using a specially designed iris forceps (Alíó iris forceps, ASICO, Westmont, IL) (Fig 2), a small fold of iris was caught and engaged in the claw of the implant. During these maneuvers, the optic of the lens was centered on the pupillary area (Fig 3). A peripheral iridotomy was always performed using specially designed iris scissors (Alíó iris scissors, ASICO) (Fig 2).

The incision was then sutured with a three-bite running nylon 10/0 suture (Alcon) (Fig 3). Before closing the knot, the cohesive viscoelastic was removed by careful washing with a 27-gauge cannula using a total of 10 cc of balanced salt solution (BSS, Alcon-Cusi, Barcelona, Spain). We found that automatic irrigation aspiration was not a safe...
Table 1
Visual Acuity (LogMar) Before and After Artisan Iris Claw PIOL Implantation for Hyperopia

<table>
<thead>
<tr>
<th></th>
<th>UCVA* (range)</th>
<th>Preoperative BSCVA† (range)</th>
<th>Spherical Error (D) (range)</th>
<th>UCVA (range)</th>
<th>Postoperative BSCVA (range)</th>
<th>Spherical Error (D) (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Hyperopia Group (29 eyes)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.4 ± 0.7</td>
<td>0.2 ± 0.6</td>
<td>6.06 ± 1.26</td>
<td>0.3 ± 0.6</td>
<td>0.1 ± 0.6</td>
<td>0.10 ± 0.57</td>
</tr>
<tr>
<td></td>
<td>(CF§ to 0.2)</td>
<td>(1** to 0)</td>
<td>(+3.00 to +9.00)</td>
<td>(1** to 0)</td>
<td>(1** to 0)</td>
<td>(-1.00 to +2.00)</td>
</tr>
<tr>
<td><strong>Secondary Hyperopia Group (28 eyes)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.5 ± 0.7</td>
<td>0.2 ± 0.6</td>
<td>5.88 ± 1.88</td>
<td>0.4 ± 0.7</td>
<td>0.2 ± 0.6</td>
<td>0.55 ± 1.49</td>
</tr>
<tr>
<td></td>
<td>(CF to 0.1)</td>
<td>(CF** to 0)</td>
<td>(+3.50 to +9.50)</td>
<td>(CF** to 0)</td>
<td>(1 to 0)</td>
<td>(-1.50 to +5.00)</td>
</tr>
</tbody>
</table>

*Uncorrected visual acuity
†Best spectacle-corrected visual acuity
§Count fingers
**20/200 BSCVA corresponds to an amblyopic eye with previous strabismus

Figure 3. Artisan iris claw PIOL held in position with the Artisan lens forceps while a small fold of iris is engaged in the claw of the implant with the Alió iris forceps.

maneuver when performed in the anterior chamber of these eyes after PIOL implantation; it was easier and more controllable to wash out the cohesive viscous substance.

Postoperative care included instillation of cyclopleolate 1% (Alcon-Cusi, Barcelona, Spain) two drops immediately after surgery and then one drop per day for 5 days, to avoid development of posterior synechiae in the early postoperative period. Dexamethasone with polyoxymethyl N and neomycin (Maxitrol, Alcon-Cusi, Barcelona, Spain) drops four times at day for 15 days, and diclofenac drops (Voltaren, Ciba Vision, Barcelona, Spain) three times a day for 1 month were also used. An oral carbonic anhydrase inhibitor (Edemox, Chiese-Wasermann, Barcelona, Spain) was prescribed for the first 24 hours at a dose of 250 mg/8 h with potassium supplementation. For evaluation of postoperative inflammation, we used a clinical grading system, previously reported.15 The follow-up in this series was 14 ± 0.5 months (range 12 to 24 mo).

Statistical analysis of the results was performed with SPSS/8.0 for Windows; statistically significant differences between data sample means were determined. After verifying data normality, Student’s t-test was applied and differences were considered statistically significant when the probability value (P) was less than .05.

Data relative to standards for reporting the outcome of refractive surgery procedures, eg, safety, efficacy, and predictability, were analyzed, as previously described.16 The safety index is defined as the ratio [mean postoperative BSCVA / mean preoperative BSCVA]. The efficacy index is defined as the ratio [mean postoperative UCVA / mean preoperative BSCVA].

RESULTS

Visual Acuity and Refraction

Primary Hyperopia Group—After implantation of the Artisan iris claw phakic intraocular lens, mean UCVA (logMAR) improved to a mean 0.3 ± 0.6 (range 1 to 0.0) and mean BSCVA improved to 0.1 ± 0.6 (range 1 to 0.0). Mean cycloplegic spherical residual error after surgery was 0.10 ± 0.57 D (range -1.00 to +2.00 D) (Table 1). Change in BSCVA, UCVA, sphere, and spherical equivalent refraction were statistically significant with P = .001 for BSCVA and P < .0001 for each of the other parameters (Student’s t-test). Mean surgically induced astigmatism calculated by vector analysis was 1.48 ± 0.89 D (range 0 to +4.31 D).

The correction of primary hyperopia with the Artisan PIOL was a safe and effective procedure.
Table 2

<table>
<thead>
<tr>
<th></th>
<th>Primary Hyperopia Group (29 eyes)</th>
<th>Secondary Hyperopia Group (28 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild* N Eyes (%)</td>
<td>Moderate* N Eyes (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glare</td>
<td>--</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Halos</td>
<td>--</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Pupillary block</td>
<td>1 (3.45)</td>
<td>2 (7.14)</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>--</td>
<td>2 (7.14)</td>
</tr>
<tr>
<td>Iridocyclitis</td>
<td>--</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Lens displacement</td>
<td>1 (3.45)</td>
<td>1 (3.57)</td>
</tr>
</tbody>
</table>

*Mild: low complication, with minimal or no subjective report by patient
Moderate: more important objective and symptomatic complication
(Severe: important objective complication with severe patient disability; not present in any eye in this series)

Only one eye (3.4%) lost one line of BSCVA. No eye lost two or more lines of BSCVA. The safety index of the procedure was 1.1 (Figs 4A, 4B). Preoperatively, nine eyes (31%) had an UCVA of 0.3 or better and no eye had an UCVA of 0. Postoperatively, 19 eyes (65.5%) had an UCVA of 0.3 or better and two eyes (6.9%) had an UCVA of 0. The efficacy index for this patient group was 0.83 (Figs 5A, 5B). Concerning predictability, 23 eyes (79.3%) were within ±0.50 D of intended spherical correction, 27 eyes (96.6%) were within the ±1.00 D, and 29 eyes (100%) were within ±2.00 D (Figs 6A, 6B).

Secondary Hyperopia Group—Postoperatively, mean UCVA (logMAR) was 0.4 ± 0.7 (range 0) and mean BSCVA was 0.2 ± 0.6 (range 1 to 0) with a cycloplegic spherical residual error of 0.55 ± 1.49 D (range -1.50 to +5.00 D). Change in UCVA, sphere, and spherical equivalent refraction were statistically significant with \( P = 0.013 \) for UCVA, and \( P < 0.001 \) for each of the other parameters (Student’s t-test). Change in BSCVA was not statistically significant (\( P = 0.364 \), Student’s t-test). Mean surgically induced astigmatism calculated by vector analysis was 1.85 ± 1.19 D (range 0 to 4.49 D). Concerning safety of the procedure, one eye (3.6%) lost three lines of BSCVA, one eye (3.6%) lost two lines, and four eyes (14.3%) lost one line. The safety index was 1.05 (Figs 7A, 7B). Regarding efficacy, 13 eyes (46.4%) had a postoperative UCVA of 0.3 or better and one eye (3.6%) had a postoperative UCVA of 0. Preoperatively, seven eyes (25%) had an UCVA of 0.3 or better and none had an UCVA of 0.0. The efficacy index was 0.7 (Figs 8A, 8B). Concerning predictability, 14 eyes (50%) were within ±0.50 D of the intended spherical correction, 20 eyes (71.4%) were within ±1.00 D, and 25 eyes (89.3%) were within ±2.00 D (Figs 9A, 9B). In this group using linear regression, there was no correlation between preoperative and postoperative outcomes.

Intraocular Pressure

After surgery, none of the eyes developed increased intraocular pressure to more than 21 mmHg. Pupillary block syndrome did not develop in any eye. Mean IOP at last follow-up was 14.03 ± 2.04 mmHg (range 10 to 16 mmHg). No statistically significant differences were found concerning preoperative IOP values in either group (\( P > 0.05 \), independent sample t-test).

Postoperative Inflammation

In most eyes, postoperative inflammation was within normal limits (Grade 1 ± 2 of the Uveitis Scoring System). In six eyes (10.53%), inflammation was identified as an increase in the level of flare and cell count equal or above Grade 3 of the grading scale. At the first postoperative week, an acute anterior iridocyclitis was observed in three other eyes (5.26%). In these eyes, inflammation was associated with the development of fibrin membrane formation with a small sterile hypopyon and absence of cilary injection and/or pain without elevation of intraocular pressure above 21 mmHg. This acute anterior iridocyclitis was controlled with an increase in the use of topical corticosteroids (0.1% dexamethasone alcohol, Maxidex, Alcon) and cyclopiaegia. None of these eyes developed any other complication or suffered a decrease in endothelial cell count higher than average. In all these eyes, synechiae formation and precipitate deposits over the IOL surface were present at the end of the follow-up (Fig 10).

Corneal Endothelium

Preoperative mean cell density of the central cornea was 3205 ± 296.47 cells/mm². Six months after surgery, the percentage of endothelial cell loss was 6.8% with a mean of 2988 ± 243.23 cells/mm². The follow-up at 1 year showed a mean endothelial cell density of 2905 ± 0.35 cells/mm² (9.4% loss from
baseline). Differences in mean cell density at all consecutive examinations were statistically significant ($P < .05$; analysis of variance [ANOVA], Scheffé test) at 1 year.

As mentioned, there was no relationship between endothelial cell loss and postoperative complications, such as postoperative acute iritis (Table 2).

**Halos and Glare**

Fixation of the lens is achieved when a fold of the iris is pulled through the slit in each claw. This placement allows the pupil to move freely with the PIOL in place. Spontaneously reported halos and glare at night were present in four eyes (7.02%), one in the primary hyperopia group (3.45%) and three in the secondary hyperopia group (10.74%) (Table 2). No instances of halos or glare in daylight conditions were found.

**Pupil Deformation and PIOL Decentration**

Pupil deformation was present in small degrees in three eyes (5.26%). Two eyes (3.51%) showed minor degrees of decentration of the PIOL optic of less than 1 mm from the pupillary center. None of these eyes were symptomatic (Table 2).

**Loss of Best Spectacle-corrected Visual Acuity**

In the primary hyperopia group, only one eye lost one line of BSCVA (3.4%) at 1 year. This eye showed postoperative acute iritis that left clinically relevant lens deposits at 1 year of follow-up. No eye lost two or more lines of BSCVA in this group.

In the secondary hyperopia group, there were six eyes that showed a decrease in BSCVA (21.4%). In three of them (10.7% of the total series), this was associated with an increase in irregular corneal astigmatism. These eyes also showed the highest
Artisan PIOL for High Primary and Secondary Hyperopia/Alio et al

Figure 6. A) Achieved correction in primary hyperopia eyes treated with the Artisan iris claw PIOL. B) Comparison of intended and achieved correction shows clustering around equality with a similar number of eyes overcorrected and undercorrected.

Figure 7. A) Change in lines of best spectacle-corrected visual acuity (BSCVA) at the end of follow-up in secondary hyperopia eyes after implantation of Artisan iris claw PIOL. B) Comparison of preoperative and postoperative BSCVA indicates that eyes either maintained or gained visual acuity.

Figure 8. A) Uncorrected visual acuity in secondary hyperopia eyes after implantation of Artisan iris claw PIOL shows a spread of values, with a shift toward improvement. B) Efficacy of the Artisan lens in secondary hyperopia.
astigmatism on the tangential corneal topography map and with vector analysis. In the other three eyes (10.7%), the decrease in BSCVA was related to acute iritis with development of a fibrin membrane and lens pigment deposits present on the surface (Fig 10).

**DISCUSSION**

Our results indicate that the Artisan iris claw PIOL can be used successfully in highly hyperopic patients. As it has no angular support, it reduces the possibility of peripheral contact with the corneal endothelium.\(^\text{17}\) This PIOL should perform well in patients who have a shallow anterior chamber and a narrow angle such as in high hyperopia.\(^\text{12}\) This anterior chamber lens had high rates of efficacy, predictability and safety in the correction of high hyperopia. With this technique, good optical and functional results were obtained in high hyperopic eyes, and provided a more stable visual quality than for other published corneal refractive procedures for high hyperopia.\(^\text{17-21}\)

For many years, a safe, efficient, and predictable refractive surgical technique has been sought as a solution for patients with high hyperopia or induced hyperopia from previously unsuccessful refractive corneal surgery.\(^\text{20}\) For high hyperopia correction, the surgeon can increase the refractive power of the eye in four ways: increase the axial length of the eye, modify the curves of corneal surface, modify the intraocular refraction index, or add a new optical system to the eye. The latter seems to be the only successful alternative.

Many years ago, techniques were described to steepen the central cornea by shrinking peripheral corneal collagen with electrocauterization.\(^\text{21}\) Hexagonal keratotomy to decouple the central cornea biomechanically from the periphery had limited applicability because of its reduced predictability, induction of astigmatism, and high complication rate.\(^\text{1,2}\) Other surgical techniques such as keratoplasty, keratomileusis, and epikeratoplasty were quickly abandoned due to technical difficulties or complications. Fyodorov\(^\text{22-24}\) proposed radial thermal keratoplasty, but had unpredictable results. The use of thermal keratoplasty either with Holmium laser (LTK), diode laser, or conductive keratoplasty needle are not suitable for hyperopia of more than -3.00 D, and usually are not effective in young patients as they are affected by regression.\(^\text{3,4,20}\) In addition, LASIK results are adequate only in eyes with low hyperopia.\(^\text{19,21}\) Since the 1950s, the concept of correcting ametropia by implantation
of an anterior chamber lens in a phakic eye has evolved. Implantation of anterior or posterior chamber intraocular lenses in phakic eyes is feasible and safe in high myopia.\textsuperscript{7,11,24} Other alternatives, such as clear lens extraction for the treatment of high hyperopia,\textsuperscript{6} causes loss of accommodation and is not indicated in young patients with good accommodative functions.

The development of new intraocular surgical techniques including corneal incisions, new biomaterials, and sutures, has resulted in new and better intraocular lenses that have favorably changed expectations for intraocular lenses in the correction of high refractive errors.

The Artisan PIOL, used in this study for high hyperopic patients, is a modified model of the iris-claw Fechner Worst phakic lens for the correction of myopia.\textsuperscript{25} Its lack of angular support reduces the possibility of peripheral contact with the corneal endothelium. This PIOL works well in patients who have an anterior chamber less than 3.4 mm or a narrow angle, as it is placed at the central anterior chamber without interfering with the anterior chamber angle, allowing an intact accommodation mechanism.\textsuperscript{26} This is especially important when we consider previous reports that hyperopia greater than +6.00 D shows a shallower anterior chamber when compared with the emmetropic or low myope, a tendency that becomes even more evident with increase in age.\textsuperscript{12} This fact makes it even more compelling to have a PIOL placed at the central area of the anterior chamber, where this space will be better maintained over time.

Using the Artisan iris claw PIOL in the primary hyperopia group, only one eye lost one line of BSCVA (3.4%). On the other hand, 12 eyes had better BSCVA than preoperatively. Four eyes (13.8%) gained one line, seven eyes (24.1%) gained two lines, and one eye (3.4%) gained three lines. In the second group (secondary hyperopia), six eyes lost lines of BSCVA: one eye lost one line (3.6%) and five eyes lost two or more lines (17.9%). On the other hand, 13 eyes gained lines of BSCVA (46.4%): seven eyes (25%) gained two lines and six eyes (21.4%) gained one line.

This favorable result indicates that the minification of the retinal image that should be expected in eyes with hyperopia corrected by intraocular refractive surgery (contrary to the magnification obtained in myopic eyes)\textsuperscript{27} does not affect significantly the BSCVA of the operated eye. However, a significantly lower predictability and efficacy were observed in the secondary hyperopia group. The reason for this is probably based on the imprecise refraction obtained in many eyes already operated by other corneal refractive procedures and the irregular change in the keratometric power values, already modified by the previous corneal refractive procedures. All these factors could alter the power of the Artisan PIOL to be implanted. This finding is relevant, as many patients operated by previous procedures who later regressed or were overcorrected are waiting for an improved solution for their refractive problem.

Night halos and glare were not frequent in our study. Displacement, ovalization, and pupillary deformation were minimal and occurred in only a limited number of eyes. A meticulous technique of positioning the iris claw at the right place with the adequate amount of iris tissue could guarantee that pupillary movement is conserved, diminishing the symptoms of glare. On the other hand, other complications such as postoperative acute inflammation were observed in a significant number of eyes (15.8%), but were well controlled with an increase in topical corticosteroids. The potential causes for the postoperative iritis are not clear. Trauma to the iris at the moment of engagement of the iris to the claw and intraocular manipulations probably play a major role. It also seems possible albeit speculative that racial pigmentation and iris color could be predisposing factors involved in its pathogenesis. Other likely causes for iritis include implanting a lens in an eye with an abnormal iris, which bulges and creates excessive chronic iris touch in the pupillary margin (a condition that seems to be more prevalent in short eyes), taking too much iris into the claw mechanism, therefore causing the lens optic to exert excessive posterior pressure on the adjacent pupillary iris margin, placement of the claw too close to the iris root, or creating excessive tension on the iris from the claw mechanism, significantly decentered placement of the lens, or vertical placement of the lens in a small white-to-white eye, which may cause excessive lens-iris touch. This was not the case in this study. In a previous publication\textsuperscript{7,28} we reported the finding of subclinical inflammation following implantation of the iris claw lens, a finding that we now consider as probably an artifact of measurement with the flare cell meter. However, in some of these eyes, the excessive tension of the iris from the claw mechanism could explain the incidence of iridocyclitis found in this study.

Careful preoperative examinations are recommended to avoid or decrease the incidence of this complication, such as preoperative gonioscopy to
evaluate the iris, excluding eyes where the iris is abnormal or where the anterior chamber is too shallow, or associated with a narrow angle configuration, lower than Grade 3 of Shaffer's classification⁴, to avoid placing excessive iris tissue into the claw, minimizing trauma to the iris during lens implantation, reducing intraocular pressure preoperatively either digitally or with a compressing device, and assuring that lens centration and claw positioning are not too close to the iris root. Most likely patients with short white-to-white measurements (less than 11 mm) may not be good candidates, because of correlation with shallower anterior chamber configuration.¹²

The induction of irregular astigmatism in some of our study eyes, especially in the secondary hyperopic group, is related to the incision size for implantation of the model of Artisan lenses used in this study. The presence of unstable corneas, as in some eyes in the secondary hyperopic group, and which in some cases were operated after corneal procedures such as radial keratotomy, explain the higher incidence of complications in this group. A foldable lens implanted through a small incision size would improve results.

For assessment of efficacy, we did not take into account the astigmatic refractive error, but only spherical error. This is because the lens was spherical, and we were not attempting to modify the astigmatic component of the refractive error when selecting the power of the lens. Hence, we studied the predictability of the achieved spherical correction only. We preferred to perform a separate analysis of spherical outcome and to evaluate the surgically induced astigmatism separately as well with vector analysis. However, we must emphasize that only 50% of eyes were within ±0.50 D of emmetropia. This indicates that either the IOL calculation formula needs further adjustment or surgeon factors should be considered, as in pseudophakic formulas. The data do not provide information about any trends (Fig 7) that could be adjusted in future cases to improve refractive outcome.

Endothelial cell loss was similar to that reported in previous studies with anterior chamber PIOLs.⁹ This is noteworthy, especially because previous reports on the Artisan lens in myopic eyes have shown larger endothelial cell losses and a trend toward chronic endothelial cell loss.⁷,⁹,¹¹,¹⁷,²⁹ This may reflect important differences in our surgical technique compared to standard or more aggressive surgical manipulation that can lead to corneal endothelial cell trauma. Our data do not seem to indicate the presence of high endothelial cell loss as a trend, although individual eyes with complications at surgery or shallow angles should be investigated further.

The hyperopic Artisan PIOL seems to be an adequate lens to correct high hyperopia; further improvement in predictability and implantation technique, using a foldable model, will enhance its application for correction of hyperopia. We advocate its use in hyperopia higher than +5.00 to +6.00 D, or in eyes in which central corneal steepening induced by corneal surgery will be higher than 50 D, a limit frequently associated with night vision disability and loss in BSCVA.

REFERENCES


706 Journal of Refractive Surgery Volume 18 November/December 2002


