Correction of Myopia of 7 to 24 Diopters With the Artisan Phakic Intraocular Lens: Two-year Follow-up

Stefano Benedetti, MD; Virna Casamenti, MD; Lucio Marcaccio, MD; Carlo Brogioni, MD; Vincenzo Assetto, MD

ABSTRACT

PURPOSE: To evaluate the safety and efficacy of the iris claw phakic intraocular lens (Artisan; Ophtec BV, Groningen, The Netherlands) in patients with high myopia.

METHODS: Between May 1999 and July 2001, 93 Artisan phakic intraocular lenses (IOLs) were implanted in 60 patients affected by high myopia. All patients underwent 24-month follow-up. The power of the lenses ranged from −7.5 to −22.0 diopters (D). Patients were divided into two groups: group 1 (68 eyes), myopia −6.75 to −15.50 D (SE), and group 2 (25 eyes), myopia −16.0 to −23.0 D (SE). Pre- and postoperative patient evaluation included manifest and cycloplegic refractions, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), endothelial cell count, intraocular pressure, complication rate, safety, and efficacy.

RESULTS: At 4 months, 83.8% (57/68) (group 1, myopia −6.75 to −15.50 D) and 68% (17/25) (group 2, myopia −16.0 to −23.0 D) of eyes achieved UCVA of ≥20/40. The BSCVA remained the same or improved in 100% of eyes. After 4 months, 69.1% (47/68) of eyes in group 1 and 52% (13/25) of eyes in group 2 were within ±1.00 D of the desired refraction; the mean refraction was stable between 4 and 24 months. Of the intraoperative complications, 69.2% were observed in the first 25 lenses implanted; postoperative complications included iris atrophy in 11.8% (11/93), lens decentration in 5.4% (5/93), and night glare in 6.4% (6/93) of eyes. No IOLs were removed. Mean endothelial cell loss was 2.8% at 4 months, 3.9% at 12 months, and 5.4% at 24 months.

CONCLUSIONS: Our results regarding implantation of the Artisan phakic IOL confirm that these lenses are safe and effective for the correction of high myopia, with a stable refractive outcome but with a higher than normal rate of endothelial cell loss during 2-year follow-up. [J Refract Surg. 2005;21:xxx-xxx.]

More and more often people suffering from myopia, especially severe myopia, have expressed the desire or need to change their refractive status. Numerous treatment options are available; however, choosing the proper treatment depends on a series of factors relating to the individual characteristics of the patient’s myopia. Two important factors to consider when choosing the correct treatment are the anatomical structure and function of the treatable eye and the specific work and leisure requirements of the individual (eg, sports, driving, etc).

Developments and refinement of excimer laser technology have brought the corneal approach into the limelight. However, it has been found that correction instability, haze, loss of lines of best spectacle-corrected visual acuity (BSCVA), and corneal ectasia are potential complications that can result. Furthermore, current use of the confocal microscope permits a close-up study of cornea tissue characteristics, which could suggest potential problems thereby contraindicating laser treatment. Stromal microdots, Bowman’s or epithelial alterations, etc, reveal a poor cornea quality frequently observed in patients with high myopia especially after many years of contact lens use.

Implanting an intraocular lens in phakic eyes is one of the most satisfactory surgical procedures for the correction of high myopia. In the 1950s, Strampelli1,2 and Barraquer3 introduced phakic intraocular lenses (PIOLs) to correct refractive errors; since then, several PIOLs have been developed. Presently, three different major designs exist: posterior chamber PIOLs, anterior chamber angle-supported PIOLs, and anterior chamber iris-supported PIOLs.

The first iris claw lens was developed in 1978 for the correction of aphakia following cataract surgery.4 In 1986, it was modified into a biconcave design for the correction of myo-
in a convex-concave configuration. In 1997, a new model with a 6.0-mm optic was introduced to address potential night glare and halos.

The current study evaluated our clinical and refractive results of the Artisan phakic IOL (Ophtec BV, Groningen, The Netherlands) for the correction of high myopia.

**PATIENTS AND METHODS**

**PATIENTS**

Between May 1999 and July 2001, 93 eyes of 60 patients (21 men and 39 women) underwent implantation of an Artisan PIOL by the same surgeon (S.B.) at Casa di Cura Villa Igea, Ancona, Italy. In 33 patients, both eyes were operated on. Patient age ranged from 22 to 52 years (mean: 35 ± 7 years) and the preoperative refractive error ranged from −6.75 to −15.50 D myopia (−6.75 diopters (D) to −23.0 D (mean: −13.7 ± 3.8 D). Fifty-eight (97%) patients wore contact lenses.

Patients were divided into two groups—group 1 included those patients with myopia −6.75 to −15.50 D (SE), and group 2 included patients with myopia measuring −16.0 to −23.0 D (SE). Lens model 204 (with 6.0-mm optical zone) was implanted in group 1 and model 206 (with 5.00-mm optic) was implanted in group 2.

The mean preoperative refractive error was −11.8 ± 2.4 D in group 1 and −18.9 ± 2.0 D in group 2. Preoperative uncorrected visual acuity (UCVA) was <20/20 in all eyes; preoperative BSCVA was ≥20/20 in 31 (45.6%) of 68 eyes in group 1 and in 2 (8%) of 25 eyes in group 2; the mean cylinder was −1.25 ± 0.93 D and −1.58 ± 0.95 D in groups 1 and 2, respectively. The mean endothelial cell count was 2658 ± 360 cells/mm².

TABLE 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral cases</td>
<td>33 (55)</td>
</tr>
<tr>
<td>Unilateral cases</td>
<td>27 (45)</td>
</tr>
<tr>
<td>Women</td>
<td>39 (65)</td>
</tr>
<tr>
<td>Men</td>
<td>21 (35)</td>
</tr>
<tr>
<td>Mean age (range) (y)</td>
<td>35 (22 to 52)</td>
</tr>
<tr>
<td>Group 1 (lens model 204)</td>
<td>68 eyes (73.1)</td>
</tr>
<tr>
<td>(−6.75 to −15.5 D myopia)</td>
<td></td>
</tr>
<tr>
<td>Group 2 (lens model 206)</td>
<td>25 eyes (26.9)</td>
</tr>
<tr>
<td>(−16.0 to −23.0 D myopia)</td>
<td></td>
</tr>
</tbody>
</table>

Demographics and refractive data of the 60 patients are summarized in Tables 1 and 2. Inclusion criteria was age >21 years with high myopia (>6.00 D), myopia with a variation in spherical equivalent refraction <−0.50 D in the 18 months before surgery, BSCVA of at least 20/200, central anterior chamber depth ≥3.00 mm, endothelial cell count ≥2000 cells/mm², problems with contact lens use or wearing spectacles, contraindication for laser in situ keratomileusis (LASIK) on the basis of pachymetric data or other corneal characteristics (revealed through confocal microscopy), no uveitis, and intraocular pressure <20 mmHg.

Exclusion criteria were systemic disease, previous corneal or intraocular surgery, anterior segment pathologic condition, glaucoma, and pre-existing macular degeneration or retinopathy.

The risks of this operation were explained, and written informed consent was obtained from all patients before surgery.

**PREOPERATIVE EXAMINATION**

Preoperative examination included UCVA and BSCVA, manifest and cycloplegic refraction, slit-lamp examination, tonometry (Topcon CT 80 computerized tonometer, Tokyo, Japan), keratometry (Nidek ARK-700), pupil diameter under low light conditions (Colvard pupillometer), white-to-white measurement of the limbus (Orbscan II, version 3.0; Bausch & Lomb, Rochester, NY), iris evaluation (vaulting, position, color, and thickness), and indirect ophthalmoscopy. Best spectacle-corrected visual acuity was measured under standard conditions using the Snellen chart; visual acuity was computed in decimal notation.

The following complementary examinations were...
performed: videokeratography (Keratron, Optikon, Rome, Italy), elevation and curvature corneal maps (Orbscan II, version 3.0), central corneal ultrasound pachymetry (DGH-500), axial length and anterior chamber depth with ultrasonic biometer (Humphrey, model 820), color and contrast sensitivity (MAV-SIFI), confocal microscopy (Confoscan II, Nidek Technologies), and central endothelial cell count. Endothelial images were obtained using the SP8000 Noncontact Specular Microscope (Konan, Hyogo, Japan) and the cells were analyzed using the “dot method,” marking the centers of approximately 80 contiguous cells. From analyzed cells, the software gave values for the morphometric parameters including cell density, mean cell area, coefficient of variation (standard deviation of cell area/mean cell area), and the percentage of hexagonal cells.

**ARTISAN MYOPIA LENS**

The Artisan PIOLs used in the study (models 206 and 204) are convex-concave, iris fixated IOLs, designed by Jan Worst, MD, and manufactured by Ophtec BV, Groningen, The Netherlands. The biomaterial of this one-piece compression molded lens is CQ-UV absorbing polymethylmethacrylate. In both PIOL types, the overall length is 8.5 mm, whereas the thickness depends of the refractive power, increasing with the negative power of the IOL; lens model 204, available in powers from \(-3.00\) to \(-15.50\) D, has a 6.0-mm diameter optic, and lens model 206, available in powers from \(-3.00\) to \(-23.50\) D, has a 5.0-mm diameter optic.

Lens model 204 was implanted in group 1 (myopia \(-6.75\) to \(-15.50\) D) and model 206 in group 2 (myopia \(-16.0\) to \(-23.0\) D). The haptics of the Artisan PIOL consist of two diametrically opposed flexible arms, as an extension of the body of the lens; the two haptics fixate the lens on the iris by enclavation of midperipheral immobile iris stroma.

The power of the PIOL to be implanted was calculated using van der Heijde’s formula\(^7,8\) and based on the refractive power of the cornea (mean corneal curvature, K), adjusted anterior chamber depth (ACD, 0.8 mm), and the patient’s spherical equivalent refractive error (spectacle correction at a 12.0-mm vertex). The mean PIOL power implanted was \(13.5 \pm 3.2\) D (range: \(-7.5\) to \(-22.0\) D) (Fig 1).

**SURGICAL PROCEDURE**

Surgery was performed by the same surgeon (S.B.), and the surgical protocol was the same in all cases. Two days before surgery, norfloxacain 0.3%, dexamethasone 0.2%, diclofenac 0.1%, and gentamicin 0.3% were administered four times a day topically. To achieve stable intraoperative myosis, pilocarpine eye drops 2% were instilled twice a day the day before surgery and 30 minutes before surgery. All procedures were performed under pericocular anesthesia (6 mL of a proportional combination of lidocaine 2%, mepivacaine 1%, and mucopolisacaridase), except two cases performed under general anesthesia.

A scleral tunnel incision was made at 12 o’clock with a 5.5- or 6.5-mm width depending on the diameter of the lens, and two lateral paracenteses in the cornea were performed at 10 o’clock and 2 o’clock with a 1.5-mm width. The anterior chamber was washed with acetylcholine and filled with a viscoelastic substance (Healon). The lens was inserted from the 12 o’clock position and rotated into a horizontal position. The lens haptic enclavated a fold of midperipheral iris stroma using an enclavation needle at 3 and 9 o’clock meridians to achieve a perfect centration of the lens (Fig 2). A peripheral surgical iridectomy was performed at the 12 o’clock meridian to prevent pupillary block glaucoma. All viscoelastic material was carefully removed by manual irrigation to avoid postoperative ocular hypertension and the incision was closed with 10/0 nylon continuous suture.

All patients received a subconjuntival injection of betamethasone and gentamicin at the end of the procedure.
Postoperative treatment included topical betamethasone 0.2% and chloramphenicol 0.5% (Betabioptal; Farmila-Théa) every 4 hours for 1 week and tapered over 4 weeks.

**FOLLOW-UP**

All patients were examined on the first postoperative day, and at 1, 3, and 6 weeks after surgery; examination schedules were then continued at 4, 12, and 24 months.

Each postoperative examination included visual acuity, manifest and cycloplegic refractions, tonometry, slit-lamp examination, endothelial specular microscopy, and indirect ophthalmoscopy.

The visual acuity examination included the safety index (ratio of mean postoperative BSCVA over mean preoperative BSCVA) and the efficacy index (ratio of the mean postoperative UCVA to the mean preoperative BSCVA). A questionnaire was used at 4 months; all patients were asked to answer subjectively regarding satisfaction with visual outcome and vision characteristics.

**STATISTICAL METHODS**

Statistically significant differences between the means of the data samples were determined by three tests: paired-sample Student t test, independent-sample Student t test, and one-way analysis of variance (ANOVA). A probability value <.05 was considered statistically significant.

**RESULTS**

**VISUAL ACUITY**

Postoperative UCVA of the two groups is shown in Figure 3. Preoperative UCVA was <20/200 in all eyes. At 4 months, in group 1 (myopia −6.75 to −15.50 D), 17 (25%) eyes achieved UCVA of ≥20/20 and 57 (83.8%) eyes ≥20/40; in group 2 (myopia −16.0 to −23.0 D), 2 (8%) eyes achieved UCVA of ≥20/20 and 17 (68%) eyes ≥20/40; none achieved UCVA <20/200.

Pre- and postoperative BSCVA are shown in Figure 4. Preoperatively, 31 (45.6%) eyes in group 1 and 2 (8%) eyes in group 2 had BSCVA ≥20/20; at 4 months, 54 (79.4%) eyes in group 1 and 9 (36%) eyes in group 2 achieved this acuity.

In group 1, after 4 months, BSCVA ≥20/32 was achieved in 66 (97%) eyes and ≥20/50 in 68 (100%) eyes; in group 2, BSCVA ≥20/32 was achieved in 24 (96%) eyes and ≥20/50 in 25 (100%) eyes; none achieved BSCVA ≤20/60. Postoperative BSCVA was significantly better than preoperative values at all examinations (t test, P<0.05). No significant differences in UCVA or BSCVA were noted at any time after surgery, denoting the stability of visual acuity postoperatively.

Best spectacle-corrected visual acuity remained the same or improved in 100% of eyes (n=93) (Fig 5).

The efficacy index in group 1 was 0.79 at 4 months, 0.82 at 12 months, and 0.84 at 24 months, and 0.87 at 4 and 12 months and 0.90 at 24 months in group 2. The safety index in group 1 was 1.10 at 4 months, 1.09 at 12 months, and 1.12 at 24 months; in group 2, it was 1.40 at 4 months, 1.42 at 12 months, and 1.39 at 24 months.

**REFRACTION**

The mean preoperative spherical equivalent refraction was −11.89±2.4 D (range: −6.75 to −15.5 D) in group 1 and −18.92±2.04 D (range: −16.5 to −23.0 D) in group 2. The mean postoperative spherical equivalent refraction was −0.80±0.80 at 4 months, −0.89±0.77 at 12 months, and −0.91±0.77 at 24 months for group 1, and −1.07±0.94 at 4 months, −1.14±1.08 at 12 months, and −1.20±1.19 at 24 months for group 2. No statistically significant differences were noted among values after surgery (ANOVA, P=.6819 and P=.9126, respectively), confirming the stability of refraction in the postoperative time (Fig 6).

The deviation of the achieved correction from the intended refractive correction was calculated. In group 1, after 4 months 30 (44.1%) eyes were within ±0.5 D of the desired refraction, 47 (69.1%) eyes were within ±1.0 D, and 63 (92.6%) eyes were within ±2.0 D. In group 2, after 4 months 8 (32%) eyes were within ±0.5 D of the desired refraction, 13 (52%) eyes were within ±1.0 D, and 22 (88%) eyes were within ±2.0 D (Fig 7).

The mean preoperative astigmatism was −1.25±0.9 D in group 1 and −1.58±0.9 D in group 2; by 2 years postoperatively, mean astigmatism had decreased to −0.75±0.6 D in group 1 and −1.17±1.0 D in group 2. In group 1, mean astigmatism increased at the first postop-
erative visit and then decreased later in the postoperative period whereas in group 2, the surgical procedure did not significantly increase the preoperative astigmatism and no irregular astigmatism was induced (Fig 8).

**Complications**

Intraoperative problems and postoperative complications are summarized in Tables 3 and 4. In 72% of eyes (67/93), no intraoperative complications were noted. In 2 (2.1%) eyes, intraoperative bleeding in the anterior chamber due to the iridectomy occurred, but resolved the day after; in 18 (19.3%) eyes centering or enclavation of the PIOL was difficult, and iris prolapse occurred in the wound in 5 (5.4%) eyes; in 1 (1.1%) eye, the PIOL was damaged during the lens enclavation. Of the intraoperative complications, 62.5% occurred in the first 25 operated eyes. The PIOL was not replaced in any case.

No serious complications during follow-up were found. Four (4.3%) eyes developed pigment deposits, probably released from the iris, on the lens surface.

Mean intraocular pressure before surgery was 14.9±3.7 mmHg. Elevated intraocular pressure (>24 mmHg) that needed topical treatment complicated the early postoperative course in 7 (7.5%) eyes. At 4 months after surgery, mean intraocular pressure was 13.8±2.8 mmHg and was <22 mmHg in every eye.

Eleven (11.8%) eyes showed a persistent iris atrophy in the fixation area of one of the haptics (probably due to excessive iris manipulation to enclavate the lens). In 1 (1.1%) eye, the claw haptic perforated the iris, causing a slight decentration without subjective discomfort of the patient. A moderate IOL decentration was noted in 5 (5.4%) eyes, and glare/halos were reported by 4 patients (6 eyes, 6.4%); of these 6 eyes, 5 had 5-mm optic diameter lenses. Two eyes that had moderate preoperative lens opacities did not show any worsening in the postoperative period.

Corneal edema, wound leakage, Urrets-Zavalia syndrome, macular degeneration, or retinal detachment were not observed. No eye underwent surgical reintervention.

**Endothelial Cell Loss**

To evaluate the corneal endothelium, we measured the cell density. Preoperative mean endothelial cell density was 2658±360 cells/mm² and postoperative mean cell density decreased to 2583±361 cells/mm² at 4 months, 2554±322 cells/mm² at 12 months, and 2514±305 cells/mm² at 24 months. Mean endothelial cell density postoperatively was significantly lower than preoperatively (ANOVA, P=.0276); endothelial cell loss was 2.8% at 4 months, 3.9% at 12 months, and 5.4% at 24 months (Fig 9). No significant differences in endothelial cell loss were noted among the two groups (t test, P>.05).
Correction of High Myopia With the Artisan PIOL/Benedetti et al

**SUBJECTIVE RESPONSE**

All patients were very satisfied with the results. In 95%, patients reported a better quality of life, in most cases it was easier to read (87%), watch TV (89.2%), shop (80.6%), and play sports (87.1%). Eighty-eight percent reported a better day drive and 17.2% reported worse night driving. In 6.4% (6 of 93 eyes), patients reported halos and/or medium intensity nocturnal glare. Of the patients included in this study, 96.7% (58/60) would recommend the surgical procedure to a friend or relative.

**DISCUSSION**

The implantation of PIOLs has been shown to be an interesting alternative to corneal surgery for the correction of high refractive errors. Presently, the third-generation PIOL has excellent surface quality and high biocompatibility,11,12 which provides a minimal risk of intraocular inflammation.

Posterior chamber PIOLs provide satisfactory refractive results but with the potential problem of cataract induction,13 endothelial cell loss,14 problems due to smaller optical zone, and centration.12

The implantation of an anterior chamber iris supported PIOL to correct severe myopia has a long history.1-6,8 It offers more advantages than other refractive techniques, such as stability, surgical reproducibility, better quality vision, accommodation preservation, absence of a clear lens contact, and potential reversibility.
Correction of High Myopia With the Artisan PIOL/Benedetti et al

Anterior chamber angle-supported PIOLs have more risk of endothelial cell damage,\(^{15}\) can cause pupil ovalization,\(^{16-20}\) iris retraction,\(^{19-21}\) and atrophy\(^{17,18}\) because of ischemic iridopathy probably induced by haptic compression of the blood vessels of the iris.\(^{18}\) Other complications of angle-supported PIOLs, such as chronic elevation of intraocular pressure,\(^{18}\) cataract development,\(^{18}\) retinal detachment,\(^{18,21-23}\) halos and glare,\(^{18-21}\) and implant displacement\(^{20,21}\) are described in the literature. Moreover, sizing is a crucial point for this type of lens because a lens with a small diameter makes dislocation possible with potential endothelial cell damage; on the other hand, a wide lens could interfere with iris blood circulation causing iris depigmentation, iris distortion, and ciliary body inflammation.

Finally, angle-supported PIOLs must be placed on the geometrical center, not considering the real pupil area; this could be a limiting factor in those patients with decentered nasal pupil and large pupil diameter at night. The advantage regarding these lenses is that they are easier to implant.

The Artisan lens offers the advantages of anterior chamber IOLs and can be positioned on the pupil cen-

![Figure 6. A) Change over time of spherical equivalent manifest refraction of group 1 (myopia \(\leq -15.5\) D). B) Change over time of spherical equivalent manifest refraction of group 2 (myopia \(-16.0\) to 23.0 D). Error bars indicate standard deviation.](image1)

![Figure 7. Attempted versus achieved spherical equivalent refraction (minus power) of 93 eyes that underwent Artisan PIOL implantation.](image2)

![Figure 8. Changes in mean refractive cylinder power measured in diopters over time. Error bars indicate standard deviation.](image3)

### TABLE 3

<table>
<thead>
<tr>
<th>Intraoperative Complications in 93 Eyes (60 Patients) that Underwent Iris Claw Phakic Intraocular Lens (IOL) Implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>Bleeding</td>
</tr>
<tr>
<td>Difficult IOL centering or enclavation</td>
</tr>
<tr>
<td>Iris prolapse</td>
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<tr>
<td>IOL damage</td>
</tr>
</tbody>
</table>
The Artisan lens can be used in young patients with anisometric amblyopia with restricted treatment options.24,25

As appears in Figure 1, the mean anterior chamber iris supported PIOL power implanted was $-13.6 \pm 3.3$ D (range: $-7.5$ to $-22.0$ D); in 24 (25.8%) eyes, we implanted lenses $<-11.0$ D. In these eyes, laser treatment (photorefractive keratectomy or LASIK) was contraindicated because of corneal thickness (attempted residual stromal bed $<250$ µm), final corneal dioptric power $<34$ to $35$ D, or corneal sublayer abnormalities evidenced by confocal microscope examination.

To assess the effectiveness of refractive surgery, UCVA is the main criterion used.20,26 In our study, at 4 months, 19 (20.4%) eyes had UCVA $20/20$ and 74 (79.6%) eyes had UCVA $20/40$; 38 (40.9%) eyes had a refraction within $0.50$ D and 60 (64.5%) eyes were within $1.00$ D, and the refractive results were stable for 2 years. These data reflect good predictability, even if the refractive accuracy was slightly better for lower levels of myopia, with 69.1% (group 1) and 52% (group 2) within $1.00$ D at 4 months.

The efficacy index (0.84 and 0.90 in the two groups, respectively, 2 years after surgery) was lower than in unoperated eyes, with an endothelial cell loss of 2.8% at 4 months, 3.9% at 12 months, and 5.4% at 24 months. In fact, Bourne et al25 reported a mean cell loss of $0.6\% \pm 0.5\%$ per year over 10 years in a longitudinal study in normal unoperated eyes, correlating with the values found in previous studies33-35 conducted over shorter periods.

Several studies concerning Artisan iris claw lens implantation reported endothelial damage and cell loss. Pérez-Santonja et al15 reported a significantly greater endothelial cell loss than in cataract surgery36 of 13% and 17.6% at 12 and 24 months after surgery, respectively. Menezo et al28 reported a mean postoperative cell loss of 3.85% at 6 months, 6.59% at 12 months, 9.22% at 2 years, 11.68% at 3 years, and 13.42% at 4 years. Landesz et al6 found a mean endothelial cell loss of 5.3% after 6 months and 8.9% after 12 months.

Our results show that the last generation of Artisan PIOLs induces a lower mean endothelial cell loss than previously reported; however, we believe that mean endothelial cell loss alone does not reflect the functional damage of corneal endothelium. The coefficient of variation in cell size, measure of cell size variation (polymegatism), the percentage of hexagonal cells, and measure of cell pleomorphism are values independent of cell density, but offer a more sensitive indication of

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**TABLE 4**

**Postoperative Complications in 93 Eyes (60 Patients) that Underwent Iris Claw Phakic Intraocular Lens (IOL) Implantation**

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. Eyes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iris atrophy</td>
<td>11 (11.8)</td>
</tr>
<tr>
<td>Iris pigment precipitates</td>
<td>4 (4.3)</td>
</tr>
<tr>
<td>Raised intraocular pressure</td>
<td>4 (4.3)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>IOL non centered</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>Diplopia</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Glare/halos</td>
<td>6 (6.4)</td>
</tr>
<tr>
<td>Iris perforation</td>
<td>1 (1.1)</td>
</tr>
</tbody>
</table>

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These data are similar to those of Budo et al27 who reported a safety index of 1.31 in a multicenter study of the Artisan PIOL.

Our data demonstrate an increase in both UCVA and BSCVA after Artisan PIOL implantation, and show stability in visual acuity and refractive results 2 years after surgery.

Concerning the endothelium, our study shows a continual decrease in cell density after lens implantation significantly greater than in unoperated eyes, with an endothelial cell loss of 2.8% at 4 months, 3.9% at 12 months, and 5.4% at 24 months. In fact, Bourne et al25 reported a mean cell loss of $0.6\% \pm 0.5\%$ per year over 10 years in a longitudinal study in normal unoperated eyes, correlating with the values found in previous studies33-35 conducted over shorter periods.

#### Figure 9

Mean endothelial cell density over 2 years. Error bars indicate standard deviation.
endothelial cell damage and functional reserve than cell density alone. Therefore, the corneal endothelium would be evaluated for several years, until endothelium has obtained an equilibrated level after cell loss, to determine the stability of endothelial cell density. Evaluation of the endothelium should be standardized.

Despite the difficult surgical procedure, intraoperative complications, such as bleeding, iris prolapse, difficult enclavation, or IOL centering, were minimal especially when the surgical technique was improved; in no case was the IOL removed or exchanged.

Many postoperative complications have been described after iris claw lens implantation.\textsuperscript{5,6,27-34,37-45} Fechner et al\textsuperscript{39} found no evidence of iris atrophy in the fixation area; on the other hand, Menezo et al\textsuperscript{30} observed iris atrophy in the fixation area of one of the haptics in 12.8\% of eyes and both haptics in 10.6\% of eyes. In our series, evident iris atrophy was found in 11.8\% of eyes in which the surgery was particularly difficult and required excessive iris manipulation to enclavate the lens correctly (Fig 10).

Menezo et al\textsuperscript{30} reported an iris perforation caused by the lens haptic in three (3.2\%) eyes, which required reintervention in one eye due to lens luxation. Mertens and Tassignon\textsuperscript{46} described a detachment of iris claw haptic. In the present study, iris perforation was observed in one eye, determining a slight decentration without subjective discomfort of the patient and no reintervention (Fig 11). A correct enclavation, with at least 1.5 mm of folded iris inside the claw, is important to avoid this complication; moreover a correct surgical technique performed by expert hands is fundamental to obtain correct lens implantation and good centration.

Perez-Santonja et al\textsuperscript{29} reported corneal pigment deposition in 18.7\% of eyes; in our study, pigment deposition was found in 4.3\% of eyes and was not significantly significant.

Perez-Torregrosa et al\textsuperscript{47} performed a digital system measurement of the iris claw decentration and reported a mean decentration of the IOL from the pupil center of $0.47 \pm 0.29$ mm; in our study, a clinically insignificant lens decentration was measured at slit-lamp examination in five (5.9\%) eyes.

Glare/halos were found in 6.4\% (6/93) of eyes; of these 6 eyes, 5 had 5-mm optic diameter lenses. Budo et al\textsuperscript{27} reported glare in 6\% and halos in 8.8\% of 249 eyes at 3-year follow-up; they exclusively used the Artisan model 206 with a 5.00-mm optic. El Danasoury et al\textsuperscript{48} exchanged one 5-mm Artisan lens for a 6-mm lens with a lower power in one patient who reported severe night glare, which affected night driving.

Perez-Santonja et al\textsuperscript{29} observed inflammatory reac-
tions in 9.3% of eyes; in our study, no eye examination by slit-lamp biomicroscopy revealed evident flare in the anterior chamber. In another study, the same authors described increased flare using cell flare photometry in both angle-supported and iris-claw PIOLs in eyes without clinically inflammatory reactions.

Menezo et al. and Fechner et al. did not describe lens opacities after iris-claw implantation. Budo et al. found age-related cataract in 2.4% of eyes and Pérez-Santonja et al. reported cataract development in 3%. Maloney et al. described the development of nonprogressive lens opacities in 3.1% as a result of surgical trauma. In our study, no eyes developed lens opacities. The two eyes that had a moderate preoperative lens opacification did not show any progression in the postoperative period, and we are following their possible evolution.

Other complications reported in the literature such as corneal edema, iridocyclitis, wound leakage, cystic wounds, Ureits-Zavalia syndrome, retinal detachment, ischemic optic neuropathy, vitreous hemorrhage, and choroidal neovascularization were not found in our study.

Recently, PIOL implantation has been considered a satisfactory surgical procedure to correct high myopia. Some potential advantages include optical improvement, preservation of accommodation, and potential reversibility; some disadvantages that could limit their use include long-term complications to the corneal endothelium and anterior chamber structures especially for angle-supported lenses or possible cataract development for posterior chamber IOLs.

Our results with Artisan PIOL implantation to correct high myopia show an increase in both UCVA and BSCVA and demonstrate stability in visual acuity and refractive results 2 years after surgery.

Although it is a difficult surgical procedure, our experience over 2 years demonstrated minimal intraoperative and postoperative complications. When the procedure is performed correctly by an experienced surgeon, it represents a safe and repeatable surgical technique. As previously commented on by other authors, further follow-up is necessary to confirm these data and to monitor potential long-term complications.

REFERENCES
Correction of High Myopia With the Artisan PIOL/Benedetti et al

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