Abstract

**Purpose:** To evaluate the outcome of iris-claw phakic intraocular lens (PIOL) implantation for high myopia in a subspecialty training setting

**Methods:** Iris-claw phakic Artisan (Ophtec B.V., Groningen, The Netherlands) intraocular lens implanted patients were invited for an evaluation visit: 83 eyes had been operated on by a group of 10 cornea fellows under the supervision of nine anterior segment faculty members during 2005-2006. Postoperative time course ranged from four to 38 months. The outcome was assessed in those who participated in the evaluation visit (50 eyes collectively).

**Results:** Evaluation visit uncorrected visual acuity (UCVA) was equal to or better than preoperative best spectacle corrected visual acuity (BSCVA) in 68% of the eyes; mean BSCVA had improved significantly (equivalent to two Snellen lines; P<0.004). Residual spherical equivalent (SE) was within ±1.00 diopter (D) in 68% and ±2.00 D in 92%; eyes with longer postoperative time courses (>10 months) were on average 0.94 D more myopic (P=0.007). No eye had lost BSCVA. No major complication like retinal detachment or cataract had happened. Better UCVA was predictable by shorter postoperative time course, milder baseline myopia, and better baseline BSCVA (P<0.004).

**Conclusion:** Iris-claw PIOL implantation for high myopia was found efficacious and safe in subspecialty training. A noticeable myopic drift was observed, and refractive predictability was not as favorable as expected. Induced astigmatism, miscalculation, mislabeling/wrong refraction, and myopic progression could have been responsible for >2.00 D residual SE in four eyes.

**Keywords:** High Myopia, Iris-claw Phakic Intraocular Lens, Outcome Evaluation, Educational Setting
Introduction
Phakic intraocular lens (PIOL) implantation is gaining widespread acceptance as the standard surgical procedure for high myopia. They are grouped into three major subtypes: angle supported, iris-fixated, and posterior chamber PIOLs.

Alternative surgical approaches to PIOL implantation are laser refractive surgery and refractive lens exchange. Currently, most refractive surgeons refrain from performing laser ablation beyond myopia of 10.00 diopters (D) due to the risk of keratectasia and the inevitable degradation in the quality of vision. Refractive lens exchange poses the risk of posterior segment complications and abolishes the accommodative potential of the eye in the common age group of young myopic surgical candidates. Angle supported PIOLs are being abandoned in favor of other PIOL types as they are associated with high rates of iris and iridocorneal angle complications and corneal endothelial cell loss.

In this study, we aimed at assessing the outcome of non-toric iris-claw PIOL implantation as the most common surgical procedure in the management of high myopic young patients at our center. We also provided evidence on safety and efficacy of this procedure in subspecialty training and specifically focused on stability and predictability.

Methods
Study population and setting
The target sample was all eyes implanted with Artisan (Ophtec B.V., Groningen, The Netherlands) iris-claw PIOLs in a university affiliated eye hospital during 2005-2006 (or reoperated during the mentioned period). Patients were invited for an evaluation visit; 83 eyes had been operated on by a group of 10 cornea fellows under the supervision of nine anterior segment faculty members subspecialized in anterior segment of the eye.

Inclusion and exclusion criteria and the procedure routines
Highly myopic patients who were seeking for refractive surgery and had not been candidates for keratorefractive procedure [with spherical equivalent (SE) of −8.00 or higher and/or with an estimated risky residual stromal thickness] had been provided with this choice. A corrected anterior chamber depth of 2.5 mm and a central endothelial cell density of 2500/mm² or more had been the prerequisites. Patients with peripheral retina breaks and degenerations were excluded. The surgical procedures included: creation of a superior scleral tunnel, keratotomies at 2 and 10 o’clock, enclavation of haptics, performing a 12 o’clock surgical iridectomy, and suturing the wound. The procedures had been done under general anesthesia, and in case of bilateral implantation, on separate occasions. Either a dispersive or a cohesive viscoelastic agent had been used. The power of the PIOL had been calculated using the Van der Heijde formula.

Definitions and statistical analysis
Eyes were considered as the subjects; in case of bilateral implantation, age and gender were counted twice. Visual acuity (VA) data was converted to logMAR equivalents for statistical analyses; logMAR statistics were converted back into Snellen equivalents for the presentation of results.

To evaluate the generalizability of the outcomes to the study time frame, the study participants were compared with nonparticipants in terms of age, gender, baseline SE, follow-up interval, laterality, referral base, and reoperation rate distributions.

To assess refractive stability, the refractive status of 26 eyes which had been operated earlier (with follow-ups>10 months) was compared with 24 eyes which were operated more recently. We were not able to provide a direct estimate of stability as we did not have the early postoperative refractive status of the eyes (to be compared with their follow-up refractive status in a paired fashion).

Mean visual acuities and postoperative and preoperative cylindrical errors were compared by paired T-test. To illustrate the predictability/accuracy of refractive outcome, scatter and box-whisker plots were used. These diagrams were explored to spot the outliers, for whom detailed case by case analysis is presented.

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Associations of age, follow-up interval, residual SE refractive error, baseline best spectacle corrected visual acuity (BSCVA), baseline SE, and uncorrected visual acuity (UCVA) were tested by Pearson correlation. Student T-test was used to compare residual SE refractive error in two groups of short vs. long term follow-up intervals. Linear regression model was built for the prediction of better postoperative UCVA.

Results

Baseline characteristics and comparability of participants and nonparticipants

Baseline characteristics are summarized in Table 1. The study population included 83 highly myopic eyes of 55 patients (55% bilateral). The age median was 25 years and 49% were female. Mean of the SE error was 13.75 (SD: 4.25) diopters. Thirty one cases (50 eyes) participated in the evaluation visit (60% of eyes). Participants were not significantly different from nonparticipants in terms of seven basic features (Table 1).

Efficacy

Postoperative UCVA was equal to or better than baseline BSCVA in 68% of the eyes (efficacy index: 0.68). The frequencies of a VA of 20/40 or better were 46%, 52%, and 86% for baseline BSCVA, postoperative UCVA, and postoperative BSCVA, respectively. Mean baseline BSCVA and postoperative UCVA were not significantly different (P=0.101), but mean BSCVA showed a remarkable improvement of 0.21 logMAR (equivalent to two Snellen lines; P<0.004). Snellen equivalent medians for baseline BSCVA, postoperative UCVA, and postoperative BSCVA were 20/50, 20/40, and 20/30, respectively (Figure 1).

Table 1. Characteristics of the study population and the comparability of evaluation visit participants to nonparticipants in terms of seven basic factors; P-values for comparability tests are shown in the right column.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median (Range)*</th>
<th>Mean±SD</th>
<th>Frequency</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>25 (19-51)</td>
<td>28±7.2</td>
<td>0.435</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td>49% female</td>
<td>0.180</td>
<td></td>
</tr>
<tr>
<td>Referral (Tehran vs. elsewhere)</td>
<td></td>
<td>28% vs. 72%</td>
<td>0.619</td>
<td></td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
<td>60% right</td>
<td>0.253</td>
<td></td>
</tr>
<tr>
<td>Spherical equivalent error (D)†</td>
<td>13.00 (5.75-25.00)</td>
<td>13.75±4.25</td>
<td>0.504</td>
<td></td>
</tr>
<tr>
<td>Cylindrical error (D)†</td>
<td>1.62 (0-4.00)</td>
<td>1.62±1.05</td>
<td>0.504</td>
<td></td>
</tr>
<tr>
<td>Cylindrical error ≥ 0.75 D</td>
<td></td>
<td>74%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline BSCVA</td>
<td>0.4 logMAR ~ 20/50 (20/100-20/25 plus)</td>
<td>0.504</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PIOL power (D)†</td>
<td>14.5 (8.5-21)</td>
<td>0.504</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PIOL type (204 vs. 206)</td>
<td></td>
<td>72% vs. 28%</td>
<td>0.606</td>
<td></td>
</tr>
<tr>
<td>Incision site (scleral vs. limbal/corneal)</td>
<td></td>
<td>74% vs. 26%</td>
<td>0.606</td>
<td></td>
</tr>
<tr>
<td>Secondary surgical procedure rate</td>
<td></td>
<td>11%</td>
<td>0.606</td>
<td></td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>11 (4-38)</td>
<td>0.606</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Only statistics which better describe the participants’ characteristics are shown.
† Minus sign is omitted.
BSCVA: Best spectacle corrected visual acuity
PIOL: Phakic intraocular lens
Predictability/Accuracy

Mean residual/postoperative SE was -0.31±1.25 D. Residual SE was within ±0.50 D in 38% of the eyes, ±1.00 D in 68%, and ±2.00 D in 92%. Figure 2 demonstrates the scatterplot of achieved correction against baseline SE error. The detailed features of the four eyes with poorer than expected residual refractive error (≥2.00 D) are summarized in table 2.

Table 2. Four eyes with refractive mishaps (≥2.00 D residual spherical equivalent; in 50 eyes)

<table>
<thead>
<tr>
<th>Eye</th>
<th>Age</th>
<th>Presbyopic Error</th>
<th>Baseline BSCVA</th>
<th>PIOL Power Label</th>
<th>Postoperative Refraction</th>
<th>Postoperative UCVA</th>
<th>Postoperative BSCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right eye of a 24-year-old male</td>
<td>24</td>
<td>-15.00 sph -2.00 cyl x 80</td>
<td>20/50</td>
<td>-16.50</td>
<td>-2.25 sph -0.50 x 30</td>
<td>20/80</td>
<td>20/30</td>
</tr>
<tr>
<td>Right eye of a 27-year-old male</td>
<td>27</td>
<td>-20.00 sph -3.00 cyl x 60</td>
<td>20/100</td>
<td>-21.00</td>
<td>+5.50 sph -2.50 x 55</td>
<td>20/30</td>
<td>20/25</td>
</tr>
<tr>
<td>Right eye of a 31-year-old female (operated bilaterally)</td>
<td>31</td>
<td>-25.00 sph -0.5 cyl x 60</td>
<td>20/100</td>
<td>-19.50</td>
<td>-3.50 sph -2.00 cyl x 80</td>
<td>20/200</td>
<td>20/70</td>
</tr>
<tr>
<td>Left eye of the abovementioned participant</td>
<td>24</td>
<td>-24.00 sph -0.5 cyl x 110</td>
<td>20/100</td>
<td>-17.00</td>
<td>-1.75 sph -1.75 cyl x 105</td>
<td>20/200</td>
<td>20/200</td>
</tr>
</tbody>
</table>
Figure 2. Scatter plot depicting predictability of refractive outcome. Linear regression with 95% individual prediction interval is shown (spherical equivalent correction=0.65+0.93 * baseline spherical equivalent error; R-square=0.91). The inset box-whisker plot illustrates accuracy; two outliers were identified which are the counterparts of the two points that lied outside of the prediction interval in the scatterplot (minus figures are hyperopic) [see Table 2].

**Stability**
Eyes with longer follow-up intervals (>10 months) on average had a residual myopia of 0.94 D more than the eyes with shorter follow-up intervals (P=0.007); residual SE and follow-up time were correlated (r=0.48, P=0.001), i.e. at the time of evaluation visit, eyes which had been operated earlier had more residual myopia than those which had been operated more recently (even when controlling for the effect of baseline myopia severity [partial correlation]). Age and residual SE were not correlated (P=0.606).

**Safety**
Not a single eye had lost any line of BSCVA postoperatively which translates to a safety index of 1. Mean postoperative cylindrical error showed a marginally significant improvement/reduction of 0.25 D (P=0.079). Ten reoperation procedures had been performed on nine eyes (of 83); readjustment of centration (two eyes), refixation due to subluxation/dislocation (three eyes), resuturing due to shallow anterior chamber and/or bleb formation (four eyes), and surgical iridectomy (one eye). Night glare/halo was reported in four eyes. Severely decentered PIOL was seen in one eye. Moderate iris atrophy at enclavation sites was observed in four eyes; two eyes with mild to moderate pupil ovalization were seen; two IOLs had moderate pigment dusting on both optic sides. Postoperative course of one eye was complicated by sterile endophthalmitis severe enough to necessitate inpatient observation, but it had resolved without surgical intervention. Steroid induced ocular hypertension and surgical site bleb formation, each were documented in one eye which resolved spontaneously.

**UCVA determinants**
Better postoperative UCVA was correlated with shorter follow-up intervals, lower myopia, and better baseline BSCVA. The associations were maintained in the linear regression model (Table 3). The PIOL type (6 mm vs. 5 mm optic) was not associated with postoperative UCVA, BSCVA, SE, and cylindrical error (all P>0.05).
Table 3. Determinants of postoperative UCVA

<table>
<thead>
<tr>
<th>Determinant</th>
<th>Univariate r</th>
<th>P-value</th>
<th>Linear regression model</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>R-square: 0.5, P&lt;0.004</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Standardized coefficients</td>
</tr>
<tr>
<td>Follow-up time</td>
<td>0.36</td>
<td>0.01</td>
<td>0.27</td>
</tr>
<tr>
<td>Baseline spherical equivalent</td>
<td>0.57</td>
<td>&lt;0.004</td>
<td>0.24</td>
</tr>
<tr>
<td>Baseline BSCVA</td>
<td>0.63</td>
<td>&lt;0.004</td>
<td>0.49</td>
</tr>
</tbody>
</table>

UCVA: Uncorrected visual acuity
BSCVA: Best spectacle corrected visual acuity

Discussion
Our study replicates the efficacy and safety of Artisan PIOL implantation for the surgical management of high myopia in an educational setting (efficacy index: ~ 0.7 and safety index: 1) in short term (in congruence with expert surgeon series); postoperative BSCVA showed significant improvement equivalent to two Snellen lines. Postoperative UCVA was highly predictable by better baseline BSCVA, shorter follow-up intervals, and lower myopia in a descending order.

Refractive predictability and stability were less than optimal as 32% of the eyes had a residual refractive error of more than 1.00 D and a noticeable myopic drift was suggested. As defined in the methods section, stability could only be evaluated indirectly; we compared the refractive status of the eyes which had been operated earlier with eyes which were operated more recently; former eyes were on average about 1.00 D more myopic.

A refractive outcome within ±1.00 D was variably reported to be achieved in 55.5%, 60%, 68%, 70%, 82%, 90%, 94% (in an FDA trial) of the eyes.

Four eyes with unsatisfying refractive outcome are presented in Table 2; one case was attributable to miscalculation as our recalculation revealed 3.00 D disparity. In one case, lens mislabeling and/or refraction error was surmised. In still another eye, myopic progression was hypothesized. Two of the four eyes also had experienced remarkable induced astigmatism which was due to positioning the reoperation incision anterior to the previous scleral incision into the clear cornea (Table 2).

Myopia can progress after puberty and it is believed that very high axial myopia may not stop from progressing (albeit at a lower rate), hence the term progressive myopia. But PIOL studies generally have reported a stable refractive status in these highly myopic eyes. An ethnic difference in the nature of pathologic myopia may be considered for our observation as ethnicity has been shown to be a determinant in myopia progression. In our study, as mentioned, myopic progression is suggested: longer follow-up (but not age and baseline myopia) was associated with a higher myopia at evaluation visit. This observation warrants further studies.

Our study findings emphasize the importance of adopting a highly formal refractive approach for PIOL candidates. When PIOL power calculation was less certain, adopting a bioptic approach in the form of PIOL implantation followed by laser refractive surgery was recommended, and variously named as combined or adjustable refractive surgery. Holladay recommended retinoscopy over a (myopic) soft contact lens of about 90% of the power of the eye prescription to determine baseline refraction and eliminate the source of error due to vertex distance, which is specially relevant in the case of extremely high refractive errors. It also seems advisable that
the PIOL power calculation be performed by two independent examiners.

No major complication like retinal detachment was noted in these 83 eyes, but the reoperation rate of 11% seems higher than that reported previously. This could safely be imputed to the educational setting, surgeon mix, and the outcome nature of the study; it is noteworthy that almost all of the cases were due to wound revision or PIOL readjustment/refixation.

At our institute, specular microscopy is routinely performed for patient selection and a central endothelial cell density of 2500/mm² or more is a prerequisite. Unfortunately, these data had not been suitably documented and we could not provide safety data in terms of corneal endothelium status where controversy still exists and reports are conflicting. It would be ideal if we had a formal regular follow-up data for our study. Participation rate in the current cross sectional study was less than optimal either; as 40% of the eligible eyes were not examined. To address this limitation, we compared participants vs. nonparticipants in seven basic factors – including follow-up – and did not observe a significant difference (Table 1).

Future studies on iris-claw PIOLs should focus on photic phenomena, contrast sensitivity function, higher order aberration (and vision quality), patient satisfaction (through quality of life questionnaires), and long-term biocompatibility and positional stability (in terms of endothelium safety, cataractogenesis, iris atrophy and ischemia, and long-term decentration).

**Conclusion**

In conclusion, iris-claw PIOL implantation in the management of high myopia was found efficacious and safe in subspecialty training setting; and the outcome was more desirable in those with relatively milder baseline myopia and better baseline visual potential. Adopting a strict refractive approach is recommended through soft contact lens over refraction, double checking the PIOL power calculation, inclining to overcorrection (due to the likelihood for myopic progression), choosing an astigmatically neutral incision (even for reoperations), and addressing cylindrical errors by planned relaxing incisions or implantation of toric PIOLs. Patients should be informed that enhancements may be needed because myopic progression is likely and the refractive accuracy might be less than optimal.

**Acknowledgments**

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**References**