Short-term Follow-up after Implantation of a Foldable Iris-Fixated Intraocular Lens in Phakic Eyes

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**Objective:** To evaluate efficiency, predictability, stability, complications, and patient satisfaction after implantation of a foldable iris-fixated phakic intraocular lens (PIOL) for the correction of myopia.

**Design:** Prospective, nonrandomized, comparative (self-controlled) trial.

**Participants:** Forty-one eyes of 22 myopic patients aged 18 to 56 years (mean, 36 years) with average sphere of \(-8.2\pm2.01\) diopters (D; range, \(-12.25\) to \(-3.75\) D) and average preoperative cylinder of \(-0.90\pm0.62\) D (range, \(-2.50\) to \(0.00\) D) were enrolled in this prospective study.

**Methods:** All eyes underwent implantation of a foldable iris-fixated PIOL with an optical zone of 6.0 mm. The follow-up was 6 months in all cases. Phakic intraocular lenses were available in powers ranging from \(-2.0\) to \(-12.0\) D.

**Main Outcome Measures:** The main parameters assessed were best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity, refraction, endothelial cell count, intraocular pressure, slit-lamp biomicroscopy, and indirect ophthalmoscopy.

**Results:** At 6 months' follow-up, no eyes experienced a loss in BSCVA and 78% gained 1 or more lines of their preoperative BSCVA. Uncorrected visual acuity was significantly improved, with 82% of eyes reaching 20/25 or better. There was a significant reduction in spherical errors in all patients after surgery. Ninety-one percent of eyes were within \(0.50\) D of target refraction. A slight loss of endothelial cells (2.3%) was observed 6 months after surgery. There were no intraoperative complications. In the postoperative follow-up, however, pigment precipitates were noted in 5 eyes of 4 patients.

**Conclusions:** At short-term follow-up, the implantation of the foldable iris-fixated PIOL proved to be effective and predictable for the correction of myopia in phakic eyes. However, longer follow-up with larger numbers of patients is necessary to evaluate long-term complications. Ophthalmology 2005;112:2189–2195 © 2005 by the American Academy of Ophthalmology.

Common surgical options for the correction of myopia are corneorefractive procedures like LASIK and photorefractive keratectomy. Keratorefractive techniques, especially in cases of high refractive error, can be associated with an increased risk of corneal ectasia and decreased visual quality. In recent years, intraocular procedures such as clear lens extraction or phakic lens implantation in the anterior or posterior chamber have gained increasing popularity. Clear lens extraction leads to a loss of accommodation, especially disadvantageous in young patients. In addition, the risk of retinal detachment is nearly doubled for patients with myopia of more than \(-10.0\) diopters (D) without surgery.

Phakic intraocular lenses (PIOLs) offer a promising alternative, particularly for high error correction up to 20 D. These lenses preserve accommodation, are potentially reversible, and, in contrast to keratorefractive procedures, maintain the original prolate shape of the cornea, thus not altering optical qualities of the cornea. Over the last few years, iris-fixated lenses have been implanted with success in phakic eyes for the correction of myopia, hyperopia, and astigmatism. In 1986, Fechner and Worst modified the early lens design into a negatively biconcave lens to correct high myopia. However, there was concern that the increased vault of the lens may not provide sufficient clearance from the corneal endothelium. In 1991, the lens was refined and the optic design was changed into a convex–concave shape, and the optic diameter was increased to 5 mm to reduce photic phenomena. This design, known as the Worst myopia claw lens, has been implanted successfully since then. The rigid polymethyl methacrylate model (Artisan, Ophtec, Groningen, The Netherlands; Verisyse, AMO, Santa Ana, CA) recently received Food and Drug Administration approval in the United States. The foldable model (Artiflex, Ophtec, Groningen, The Netherlands [CE approved]) is now under clinical investigation in selected clinical sites in Europe. This lens is a convex–concave 3-piece PIOL with a
silicone 6-mm optic and polymethyl methacrylate haptics. The total diameter is 8.5 mm. The PIOL currently is available from −2.0 D to −12.0 D power.

To our knowledge, there have been no previous reports on surgical outcome after implantation of the foldable iris-fixated lens in phakic eyes. This prospective study was designed to evaluate the clinical and refractive results of this new iris-fixated PIOL model for the correction of myopia.

Patients and Methods

Inclusion criteria were patients older than 18 years with a stable refraction for at least 1 year and myopia of more than 1.50 diopters (D) with a normal ophthalmologic examination. Exclusion criteria were anisometropia, anterior segment pathologic features, inadequate eyelid closure, endothelial cell count of <2000/mm², anterior chamber depth <3 mm, abnormal iris or abnormal pupil function, fixed pupil size >4.5 mm, recurrent or chronic uveitis, any form of cataract, previous corneal or intraocular surgery, intraocular pressure (IOP) >21 mmHg, glaucoma or family history of glaucoma, retinal detachment or family history of retinal detachment, preexisting macular degeneration or macular pathologic features, systemic diseases (e.g., autoimmune disorder, diabetes mellitus), chronic treatment with corticosteroids or any immunosuppressive treatment or state, and pregnancy.

All patients were fully informed about the details and possible risks inherent to this surgical procedure. Written informed consent was obtained from all patients before surgery in accordance with the Declaration of Helsinki, and the study was approved by the local ethics committee.

Preoperative and postoperative visits at 1 day, 2 weeks, 3 months, and 6 months included determination or calculation of uncorrected visual acuity (UCVA), determination of best spectacle-corrected visual acuity (BSCVA), computerized corneal topography (C-Scan; Technomed, Baesweiler, Germany), measurement of the pupil diameter under mesopic and scotopic conditions (Procyon; P2000, Albomed, Germany), manifest and cycloplegic refraction to calculate the spherical equivalent, applanation tonometry, evaluation of the central corneal endothelial cell count by using specular microscopy, measurement of the anterior chamber depth and axial length (measured by optical biometry; IOL-Master, Zeiss, Jena, Germany), and indirect ophthalmoscopy. All examinations were performed by the investigator or an optometrist trained and supervised by the clinical investigator. For the evaluation of the corneal endothelium, the photograph with the largest selectable region of interest for cell counting was selected.

Intraocular lens power calculation was performed using the van der Heijde formula, which uses the corneal curvature (K), adjusted anterior chamber depth, and manifest spherical equivalent of the patient’s subjective refractive error. Power calculations were performed by Ophtec, Groningen, Netherlands.

Although the surgical procedure is similar to the implantation of the rigid model, the foldability of this new lens allows a smaller, self-sealing 3.2- to 3.5-mm clear corneal incision. Before surgery, a laser iridotomy was performed at least 1 week before the procedure. Patients were prepared with miotic drops (pilocarpine 1% to 2%) to prepare the iris for lens fixation, to reduce the risk of lens touch during implantation, and to facilitate haptic enclavation. All surgeries were performed by the same surgeon (HBD) under general anesthesia. After the primary 3.2-mm clear corneal incision was made at 12 o’clock, 2 stab incisions were placed at 10 and 2 o’clock. Under viscoelastic protection (Healon; AMO), the lens was inserted into the anterior chamber using a specially designed implantation device. After PIOL positioning, the iris tissue was grasped and enclavated into the haptics. After removal of the viscoelastic, a watertight self-sealing tunnel incision without the need to suture finalized the procedure.

Statistical Analysis

Data were collected on standardized case-report forms and then entered into a central database for analysis. There were no missing data in the analysis. For statistical analysis, the logarithm of the minimum angle of resolution values of the visual acuity were converted into decimal notation, and vice versa.

Results

Forty-one eyes were enrolled in this prospective study between July, 2003, and November, 2004. All eyes were available for examination at 6 months. The mean preoperative sphere was −8.12±2.01 D (range, −12.25 to −3.75 D) and the mean preoperative cylinder was −0.90±0.62 D (range, −2.50 to 0.00 D).

The mean preoperative anterior chamber depth was 3.6 mm (range, 3.41–4.34 mm). Mean axial length was 26.3 mm (range, 24.47–29.89 mm). Demographic data are given in Table 1; age distribution is shown in Figure 1.

Safety

The mean preoperative BSCVA was 0.85±0.19 (range, 0.5–1.2). After 6 months, the mean BSCVA was 1.10±0.12 (range, 1–1.25). Seventy-eight percent of the eyes gained 1 or more lines of best-corrected visual acuity and 22% remained unchanged. The mean preoperative UCVA was 0.1±0.0. After 6 months, the mean UCVA was 0.89±0.18 (range, 0.5–1.25), with 82% of the eyes reaching 20/25 or better and 10% reaching 20/15 or better. Results are shown in Tables 2 and 3 and Figures 2 and 3.

Predictability

Ninety-one percent of eyes were within ±0.5 D of desired refraction (Fig 4). The change in refraction (spherical equivalent) and

| Table 1. Summary of Preoperative Data for Patients Undergoing Implantation of a Foldable Iris-Fixated Lens |
|-----------------|-----------------|
| Variable        | Data            |
| Total no. of eyes | 41              |
| Average age (yrs) | 36              |
| Range of age (yrs) | 18–56     |
| No. female (eyes) | 23              |
| No. male (eyes)  | 18              |
| No. right eyes   | 21              |
| No. left eyes    | 20              |
| Mean spherical equivalent±SD (D) | −8.57±2.06 |
| Range of SE (D)  | −12.3 to −4.0  |
| Mean sphere±SD (D) | −8.2±2.01  |
| Range of sphere (D) | −12.25 to −3.75 |
| Mean cylinder±SD (D) | −0.90±0.62  |
| Range of cylinder (D) | −2.5 to 0.0   |
| Range of anterior chamber depth (mm) | 3.41–4.34 |
| Range of axial length (mm) | 24.47–28.89 |
| Implant power (D) | −5.0 to −11.5 |
| Range of preoperative scoptopic pupil size (mm) | 4.98–7.08 |
| Range of preoperative mesopic pupil size (mm) | 3.1–4.87 |

D = diopter; SD = standard deviation; SE = spherical equivalent.
subjective refraction remained almost stable during the postoperative follow-up between the third and the sixth months, as shown in Figure 5. Uncorrected visual acuity and BSCVA stabilized after 3 months with little or no changes in the follow-up period.

**Endothelial Cell Count**

The mean preoperative endothelial cell count was 2863 ± 286 cells/mm² (range, 2226–3323 cells/mm²). One day after surgery, a negligible cell loss of 0.3% was observed (2857 cells/mm²). At the 2-week and 3-month postoperative examination, the overall cell loss reached 1.8% and 5.1%, respectively. Differences in cell density are illustrated in Figure 6. After 6 months, the average cell loss was 2.3% (range +15.0% to −10.3%).

Box plots for overall efficacy index are illustrated in Figure 7.

**Complication and Secondary Intervention**

During the 6-month follow-up, no cataract formation, uveitis, permanent IOP increase (Fig 8), or development of glaucoma were observed. All surgeries were uncomplicated. One week after surgery, a patient experienced a cellular reaction on the anterior surface of the PIOL because of premature cessation of his prescribed antibiotic and steroid local medication. After intense local steroid medication (1% prednisolone acetate eye drops 5 times daily for 1 week), the cellular reaction was completely eradicated. Postoperative PIOL dislocation and persistent corneal edema or dystrophy could not be detected. No eyes required a secondary intervention or lost a line of best-corrected visual acuity.

Five eyes of 4 patients had pigment cells on the posterior intraocular lens (IOL) surface after surgery. Four eyes had a mild pigment layer on the posterior IOL side at the 2-week follow-up, which did not increase. One patient had a moderate pigment cell layer with no IOP increase. The cause is unknown at this time; however, we assume that mechanical forces may have induced the pigment cell dispersion. The rigid haptics are connected with the foldable silicone optic with a slight step within the implant. This irregularity may lead to iris pigment abrasion during pupillary movement. To address these concerns, modifications in the design of the foldable model have been initiated that will allow more distance between the posterior side of the lens and the iris stroma.

Halos and glare commonly are associated with poor centration or a larger scotopic pupil than the optic diameter of the lens. If poor centration or fixation were observed during surgery, the lens was reenclavated for accurate centration and sufficient iris tissue enclavation. By using the dynamic pupilometry (Procyon), mesopic and scotopic pupil diameters were evaluated before surgery, thus excluding patients with much larger pupil size than the optic diameter of the lens under mesopic conditions. This was a major caution that prevented cases of disturbing halo and glare in our cohort of patients. Although retinal complications have been reported to be as high as 3% in phakic IOL implantation, no retinal problems were observed after surgery in the current study.

**Table 2. Gains and Losses of Best Spectacle-Corrected Visual Acuity 3 Months and 6 Months after Implantation of a Foldable Iris-Fixated Lens**

<table>
<thead>
<tr>
<th>Best Spectacle-Corrected Visual Acuity</th>
<th>3 Months (n = 41)</th>
<th>6 Months (n = 41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost of line</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No change</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Gained 1 line</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Gained 2 lines</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Gained 2 or more lines</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 3. Preoperative and 6-Month Postoperative Uncorrected Visual Acuity after Implantation of a Foldable Iris-Fixated Lens**

<table>
<thead>
<tr>
<th>Uncorrected Visual Acuity</th>
<th>20/20 or Better</th>
<th>20/25</th>
<th>20/30</th>
<th>20/40</th>
<th>20/50 or Worse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>56%</td>
<td>26%</td>
<td>13%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Discussion

To our knowledge, this is the first report describing the performance of a foldable iris-fixated lens for the correction of myopia in phakic eyes. After 6 months’ follow-up, our results show that implantation of this lens is a predictable, stable, and efficient surgical option for the correction of myopia. When considering predictability, 91% of the eyes were within the ±0.50 D of the desired correction. Postoperative optical performance also was significantly enhanced. In all eyes, postoperative UCVA was improved, with 82% of the eyes achieving 20/25 or better. No eye lost a line of UCVA. Seventy-eight percent of the eyes gained 1 or 2 lines of best-corrected visual acuity. No transient or permanent IOP increase was observed.

Efficacy of iris-fixated lenses for the treatment of myopia has been reported previously by our group (Dick et al9) and others10,11 using the rigid model. In a clinical study investigating the Artisan IOL for the correction of high myopia in 264 phakic eyes, Alexander et al10 reported a significant improvement of BCVA with 100% of patients reaching 20/40 or better; 72% gained 1 or more lines and 22% gained 2 or more lines. Refractive outcomes were convincing and complications were minimal. Landesz et al7,8 also demonstrated, in 2 independent studies, that implantation of the Artisan IOL in a highly myopic population resulted in a stable and accurate refractive outcome. Similarly, Budo et al12 reported safe and predictable outcomes with the Artisan IOL for the correction of myopia up to −20 D. In this prospective clinical study involving 518 eyes, a postoperative best-corrected visual acuity of 20/40 or better was observed in 93% of the eyes and a UCVA of 20/40 or better was reached in 77% of the patients.

Figure 2. Bar graph showing the change in best spectacle-corrected visual acuity (BSCVA) after implantation of foldable iris-fixated lens. preop = preoperative.

Figure 3. Bar graph change in uncorrected visual acuity (UCVA) after implantation of foldable iris-fixated lens. pre op = preoperative.
Progressive endothelial cell loss has been a major concern with anterior chamber IOLs. Eyes with a shallow anterior chamber, extensive eye rubbing, or IOL dislocation resulting from insufficient iris enclavation are among the various factors that may induce significant endothelial cell loss. Several studies have addressed potential midterm and long-term complications associated with this type of refractive correction with controversial data. Landesz et al reported a progressive endothelial cell loss of 5.5% at 6 months, 7.21% at 12 months, and 9.1% at 2 years after surgery. In contrast, Pop and Payette did not observe a loss of endothelial cell density up to 2 years after implantation of the myopic model in 765 eyes. A similar conclusion was reported by Maloney et al at the 6-month postoperative visit. Consistent with these data, we did not detect significant endothelial cell loss during our 6 months’ follow-up. In a longer-term follow-up study by Menezo et al, the hexagonality and coefficient variation in cell size at 2 years were close to the preoperative levels. These morphologic changes recovered to reach nearly preoperative levels, suggesting that endothelial damage occurred primarily during the surgical procedure. Interestingly, a correlation was found between the anterior chamber depth, the implant power, the amount of endothelial cell loss, or a combination thereof: the higher the IOL power (IOL thickness) or the shallower the anterior chamber depth (or both), the higher the risk of corneal endothelial cell loss over time. This finding, however, was not confirmed by others.

Iris-fixated IOLs have been associated with various other complications such as cataract, glaucoma, chronic subclinical inflammation, and pupil ovalization. Menezo et al reported late nuclear cataract in 3.04% of the eyes implanted with the Artisan IOL. This potential complication, however, remains very rare. A few cases of nonprogressive lens

Figure 4. Bar graph showing the predictability of refraction after implantation of foldable iris-fixated lens. m = months; w = weeks.

Figure 5. Graph showing the change in refraction (spherical equivalent) during the follow-up period. postop = postoperative; preop = preoperative.
Vacuoles also have been observed by Maloney et al after the Artisan IOL implantation. In fact, this type of complication is the result of surgical trauma that may be induced by overinflation of the anterior chamber with ocular viscoelastics, by intraoperative contact of the IOL lens with the crystalline lens, or by both.

Pupillary block also can occur in patients with anterior chamber IOLs, either by direct blocking of the pupil by the optic or by the development of adhesions between the vitreous and the posterior iris. Failure to relieve the pupillary block can lead to the development of chronic angle-closure glaucoma and glaucomatous optic neuropathy. Phakic IOLs also can induce glaucoma by compromising the anterior chamber angle. In the present study, all eyes underwent a preventive peripheral laser iridotomy before surgery, and no evidence of IOP rise was observed during the 6 months’ follow-up. Also, because the lens used in this study does not involve the anterior chamber angle, no long-term effect on IOP is expected.

Pupil ovalization also can be a complication of anterior chamber IOLs, either by direct blocking of the pupil by the optic or by the development of adhesions between the vitreous and the posterior iris. Failure to relieve the pupillary block can lead to the development of chronic angle-closure glaucoma and glaucomatous optic neuropathy. Phakic IOLs also can induce glaucoma by compromising the anterior chamber angle. In the present study, all eyes underwent a preventive peripheral laser iridotomy before surgery, and no evidence of IOP rise was observed during the 6 months’ follow-up. Also, because the lens used in this study does not involve the anterior chamber angle, no long-term effect on IOP is expected.

Figure 6. Box plot showing the endothelial cell counts before and after surgery.

Figure 7. Box plots showing the overall efficacy index (mean postoperative uncorrected visual acuity [UCVA] divided by mean preoperative best-corrected visual acuity [BCVA]) at the latest visit. Horizontal lines indicate medians and first and third quartiles, vertical extensions indicate minimum/maximum values.

Complications and side effects in general are minimal with iris-fixed IOLs. In fact, as reported by Budo et al, intraoperative complications can be avoided when a short learning curve, required to master the special iris-fixed implantation technique, is applied. Strict preoperative exclusion criteria also are mandatory. In particular, high-precision measurements, such as evaluation of peripheral anterior chamber depth with Scheimpflug imaging or dynamic pupil size evaluation under scotopic and mesopic conditions, contribute to excellent postoperative outcomes and minimize potential complications.

The foldability of the new iris-claw lens represents a promising benefit. The rigid material has been modified into a foldable silicone optic connected with rigid polymethyl methacrylate haptics. A specially designed implantation spatula (Ophtec, Groningen, Netherlands) enables the surgeon to hook and fixate the PIOL. The PIOL then can be inserted through an unenlarged 3.2-mm clear corneal incision without the need for sutures. The foldable PIOL model allows a self-sealing small incision, which may lead to less surgically induced astigmatism if compared with the prior 5.5- to 6.5-mm sutured incisions needed for the rigid model insertion. Postoperative intraocular cell reaction on day 1 was lower in our patients after foldable PIOL insertion when compared with our patients with rigid PIOL insertion; thus, the foldable material seems to be a progress toward faster visual recovery.

In our 6 months’ follow-up after implantation of a foldable iris-fixed lens, we could demonstrate good refractive results with excellent predictability and efficacy. None of
the patients experienced permanent IOP increase, corneal decompensation, synechia, iris atrophy, chronic inflammation, or pupil ovalization. Progressive endothelial cell loss could not be detected, but remains a concern especially in cases of, for example, high-power IOL. Pigment precipitates with no IOP increase were observed in 5 eyes after surgery. Some irregularity in the design of the current lens might have led to iris pigment abrasion during pupillary movement. Continued monitoring of our patients will establish the long-term safety of this type of lens.

References


Figure 8. Graph showing the intraocular pressure (IOP) before and after implantation of foldable iris-fixated lens.