Pinhole iris-fixated intraocular lens for dysphotopsia and photophobia

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We present the pinhole iris-fixated diaphragm intraocular lens (IOL), which is a 1-piece black polycarbonate IOL with rigid iris-fixated haptics, an 8.5 mm overall length, a 6.0 mm diameter optic, and a central opening, the pinhole. The IOL was implanted in a 36-year-old man who had a history of debilitating dysphotopsia (star burst, halos, glare, and ghosting) and severe light sensitivity in his right eye following several interventions for keratoconus. The diameter of the central opening of the pinhole IOL, 2.0 mm, was based on the patient's corneal aberration profile. Postoperatively, the dysphotopic symptoms and photophobia markedly improved. We recommend the use of the pinhole iris-fixated IOL in patients with severe photophobia or dysphotopsia refractory to other treatment modalities.

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Online Video

Visual complaints after refractive surgery such as dysphotopsia (halos, glare, star burst) and photophobia correlate with the induction of optical aberrations.[1] Several mechanisms may explain the increase in the amount of higher-order aberrations (HOAs) after excimer laser refractive procedures, including irregular astigmatism, a more oblate corneal shape after a myopic ablation, imperfect centration, and insufficient optical zone size. These adverse effects are particularly noticeable when the pupil is large.

We present an iris-claw intraocular lens (IOL) design that comprises a black diaphragm with a central aperture. The pinhole iris-fixated IOL can be used in cases of severe dysphotopsia and light sensitivity resistant to other treatment modalities. The IOL is designed around the principle of a pinhole to make use of paraxial rays, which are less affected by the abnormal refractive effects of corneal irregular astigmatism and HOAs.

Diaphragm IOLs are indicated for iris defects causing dysphotopsia, ghosting phenomenon, and light sensitivity.[2] However, these symptoms may also occur in eyes with a normal iris and pupil but significant corneal aberrations. The relationship between HOAs and pupil size shows a decrease in blur for a given value of HOAs if the pupil size is reduced.[3] The magnitude of HOAs is closely related to the pupil, and pupil size and HOAs are closely related to the depth of focus.

We designed and subsequently implanted a pinhole iris-claw IOL with a 2.0 mm diameter pupil in a patient with incapacitating photophobia and dysphotopsia due to irregular astigmatism and increased corneal HOAs. The case shows the effectiveness of the pinhole iris-fixated IOL in relieving the symptomatology associated with increased HOAs, including light sensitivity and ghosting. After a comprehensive literature search of PubMed and ISI Web of Science, we concluded that this is the first reported use of a pinhole

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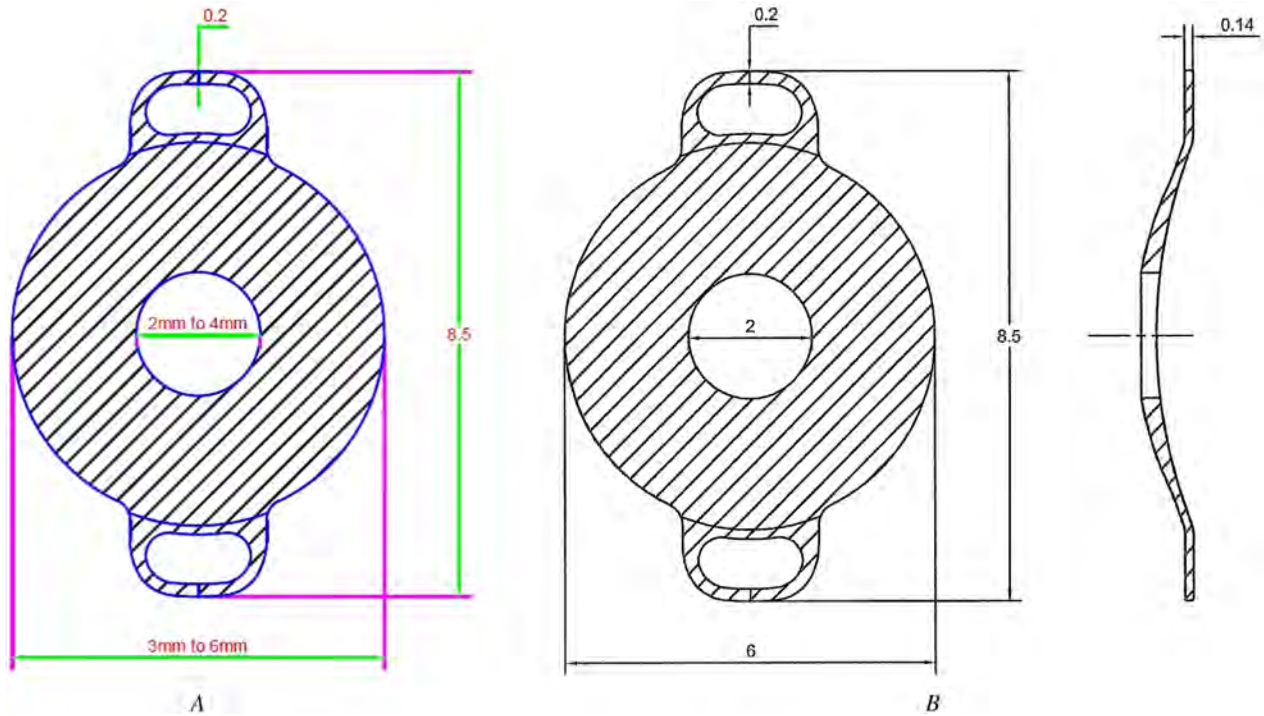


Figure 1. Specifications of the pinhole iris-fixated IOL. *A*: Minimum and maximum diameters of the optic and of the central hole. *B*: Specifications of the 2.0 mm central opening pinhole iris-fixated IOL.

iris-fixated IOL to treat debilitating photophobia and dysphotopsia.

TECHNIQUE

The pinhole diaphragm IOL (Ophtec BV) is a rigid concave–convex 1-piece black polycarbonate IOL with an 8.5 mm overall length, iris-claw haptics, and a central hole. Figure 1, *A*, shows the minimum and maximum specifications of the IOL. The central hole is variable between 2.0 mm and 4.0 mm, and the overall diameter is adjustable between 3.0 mm and 6.0 mm. The IOL is custom made based on the surgeon's specifications. The manufacturing process consists of compression molding of the material, milling, and subsequent polishing. Because the product is custom made, it is not Conformité Européenne certified.

Case Report

A 36-year-old man was referred to us because of severe subjective complaints of photophobia and debilitating ghosting, glare, and star-burst phenomena under mesopic and scotopic light conditions in his right eye, making routine daily-life activities very difficult. The medical history included several interventions for keratoconus performed in his right eye within the previous 6 years: intrastromal corneal ring segment implantation and removal, topography-guided photorefractive keratectomy, collagen cross-linking, deep anterior lamellar keratoplasty, wavefront-guided laser in situ keratomileusis, phacoemulsification with IOL implantation, and posterior neodymium:YAG laser capsulotomy. Examination of the right eye showed a corrected distance visual acuity of 20/20 with $0.25\ {-1.25} \times 90$ refraction, a clear corneal graft, normal iris, posterior chamber pseudophakia, posterior laser capsulotomy, intraocular pressure (IOP) of 13 mm Hg, and normal fundoscopy. The central pachymetry was 433 μm and the central corneal endothelial cell count (ECC), 2200 cells/mm^2. The pupil diameter was 3.0 mm under photopic conditions and 6.0 mm under mesopic conditions.

Symptomatology improved with the use of a pinhole on the spectacle frame, and the patient was started on diluted pilocarpine 0.2% eyedrops every 8 hours in the right eye, with subjective improvement of photophobia and dysphotopsia. However, the patient discontinued the use of pilocarpine because of headache and redness. The symptoms did not improve with the use of brimonidine eyedrops.

Scout software (version 5.1.0 for Windows, Optikon Ophthalmic Equipment) was used to compute corneal HOAs from Keratron (Optikon Ophthalmic Equipment) topographic data. Corneal videokeratographic data containing information about corneal elevation, curvature,

Table 1. Corneal aberrations, peak-to-valley difference in elevation map, and Strehl ratio for corneal diameters between 2.0 mm and 4.0 mm in 0.25 mm steps.

Diameter	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
Coma (μm)	0.025	0.030	0.043	0.066	0.102	0.141	0.188	0.243	0.303
SA (μm)	0.016	0.023	0.034	0.050	0.065	0.082	0.103	0.125	0.145
HOAs RMS	0.067	0.078	0.094	0.118	0.154	0.195	0.245	0.304	0.373
P-V (μm)	0.281	0.385	0.495	0.619	0.914	1.211	1.342	1.704	2.116
Strehl ratio	0.5913	0.4806	0.3215	0.1524	0.0939	0.0870	0.0645	0.0511	0.0367

HOA RMS = higher-order aberration root mean square; P-V = peak to valley difference; SA = spherical aberration

power, and position of the pupil were fitted with Zernike polynomials to determine aberration coefficients for pupil diameters between 2.0 mm and 4.0 mm in 0.25 mm steps (Table 1). Coma, spherical aberration, HOA root mean square (RMS), peak-to-valley elevation difference, and the Strehl ratio were measured.

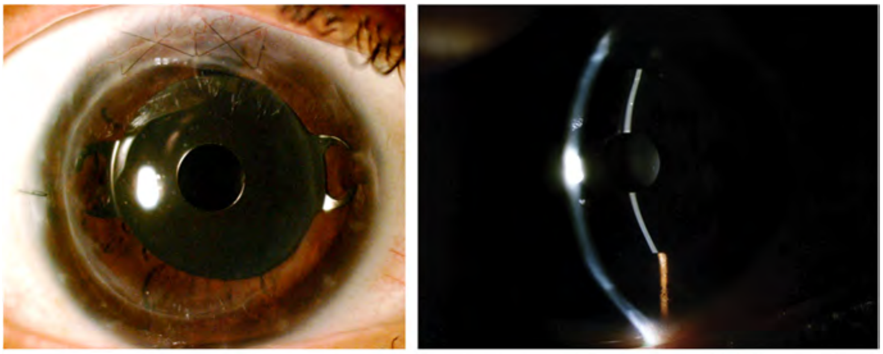
A 2.0 mm diameter central aperture pinhole iris-fixated IOL was implanted under peribulbar anesthesia through a 6.0 mm superior single-plane corneal incision. The central aperture of 2.0 mm (Figure 1, *B*) was used to minimize the effect of corneal HOAs as much as possible.

Two 1.0 mm stab incisions were created 180 degrees apart from each other at the horizontal axis. After acetylcholine was injected intracamerally, the pinhole IOL was introduced beneath sodium hyaluronate 1.0% and rotated to the 3 o'clock to 9 o'clock position and iris tissue was grasped to secure the IOL with a purpose-designed forceps (Ophtec BV). A slit iridotomy was performed, and a 10-0 nylon running suture was used to close the main incision. Postoperative treatment consisted of diclofenac sodium (Dicloabak) and a combination of dexamethasone and tobramycin (Tobradex). Both drugs were given 4 times daily during the first postoperative week and then slowly tapered.

Evaluations were performed 1 day, 1 week (Video 1, available at http://jcrsjournal.org), and 1, 3, 6, and 12 months after surgery (Figure 2). The patient presented marked improvement in all symptomatology including light sensitivity and ghosting at all follow-up visits. No serious complications occurred during the surgical procedure or follow-up. There was no acute or chronic IOP elevation, and there were no pigment deposits on the IOL surface. At the 12-month follow-up, the central ECC was 2020 cells/mm^2, an 8.2% loss. Visual field testing was performed with the Humphrey Field Analyzer II (model 745, Humphrey Systems) using the 30-2 SITA fast program with threshold strategy. The results were considered borderline with parameters very near normal values: visual field index 99%, median defect −2.68 decibels (dB) ($P<5\%$), and pattern standard deviation 1.94 dB. Fundus examination was possible using binocular indirect ophthalmoscopy or a contact Mainster wide-field lens with indentation. Retinal images of both eyes were obtained with an Optos P200 ultra-wide-field imaging system (Optos plc) (Figure 3).

DISCUSSION

A highly aberrated eye may lead to significant glare, photophobia, and impaired visual acuity.[1] Intraocular aberrations depend on the pupil size, with higher intraocular aberrations as the pupil size increases.[3] Reducing the pupil size with the pinhole iris-fixated IOL diminishes aberrations while reducing



A *B*

Figure 2. The pinhole iris-fixated IOL at the 1-month follow-up visit. *A*: Front view. *B*: Side view.

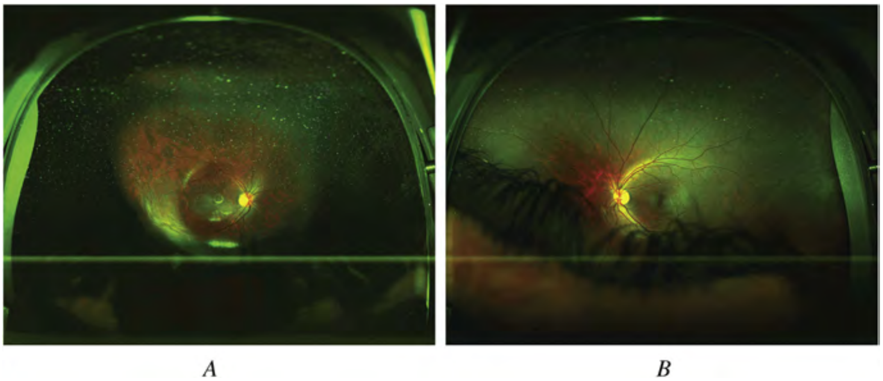


Figure 3. Retinal images obtained using an ultra-wide-field imaging system. *A*: Right eye through the pinhole iris-fixated IOL. *B*: Normal left eye.

incapacitating glare and photophobia. However, the magnitude of HOAs that will allow an acceptable visual quality and expand the depth of focus considering the influence of the pupil size has not been determined and may vary between patients.

The size of the diaphragm of the eye can be modified by several methods, including pharmacological (pilocarpine, brimonidine), extraocular (contact lenses), corneal (tattooing, intrastromal implants), and intraocular (iris suturing, diaphragm IOLs, artificial iris) techniques. Our patient had previously shown intolerance to pilocarpine and contact lenses. Corneal tattooing is a noninvasive treatment but disadvantages include a fixed pupil size that does not vary consensually with ambient light conditions and the effect of parallax as the artificial pupil is not in the pupillary plane. An artificial iris behind the pupillary plane and iris suturing were considered potentially more aggressive in this patient and more difficult to revert if necessary. Intraocular lenses comprising a black diaphragm with a transparent optic have been used in eyes with iris defects.[2,4] The advantage of this IOL is that it provides a functional pupil in the correct anatomic plane. Most IOL diaphragm models are designed for transscleral fixation in the presence of compromised capsule support in posttraumatic eyes or for capsular bag fixation in cases of aniridia.[2,4]

In our patient, the pinhole diameter of 2.0 mm was chosen to minimize the impact of corneal HOAs on the quality of the retinal image as much as possible. Smaller diameters were not considered for 2 main reasons. First, diffraction would deteriorate the retinal image quality for very small pinhole diameters. Second, the peripheral retinal evaluation would be extremely difficult.

Corneal or total ocular aberrometry are useful tools in choosing an appropriate diameter for the pinhole. Table 1 shows the variation in aberrometry from 2.0 mm to 4.0 mm in the patient's right eye. These results can be used to select the most adequate pinhole-type pupil size. The Keratron Scout software and other available topography software can calculate the corneal aberrations and the Strehl ratio for different pupil diameters. In the case we present, a pupil diameter of 2.0 mm showed a Strehl ratio of 0.5913 in comparison with 0.0939 for a 3.0 mm diameter. The HOAs RMS decreased from 0.154 μm to 0.067 μm when comparing 3.0 mm and 2.0 mm pupil diameters.

Advantages of decreasing the pupil size with the pinhole iris-fixated IOL include increasing the depth of focus, reducing intraocular HOAs, and reducing subjective complaints of dysphotopsia and photophobia. However, there are potential drawbacks that should be considered. First, the small pupil aperture may hinder posterior segment visualization and treatment, if needed. In our patient, visualization of the retinal periphery close to the equatorial region was possible using binocular indirect ophthalmoscopy or a Mainster wide-field lens with indentation. Wide-field imaging systems such as the Optos P200 or a similar system can also be useful, as shown in Figure 3, *A*. Second, the pinhole IOL may limit visual quality under mesopic or scotopic conditions by reducing available light and may also affect visual field results. Third, the IOL may amplify the adverse effects of diffraction. Finally, the anterior chamber pinhole IOL may lead to progressive damage of the corneal endothelium. In our case, the ECC loss of 8.2% is similar to the reported mean ECC loss in large series, which is around 10.0% for the first year.[5] The postoperative endothelial cell loss value is also similar to the values reported by the U.S. Food and Drug Administration Artisan evaluation.[6]

In summary, the pinhole iris-fixated IOL may represent an alternative for severe dysphotopsia and light sensitivity due to corneal irregular astigmatism and increased HOAs refractory to other treatment modalities. A larger number of patients are needed to ascertain the safety of the procedure.

WHAT WAS KNOWN

- Dysphotopsia and photophobia after corneal refractive surgery correlate with the induction of optical aberrations.
- These adverse effects are particularly noticeable when the pupil is large.

WHAT THIS PAPER ADDS

- We present the pinhole iris-claw IOL, which comprises a black diaphragm with a central hole. The IOL is designed around the principle of a pinhole to make use of paraxial rays, which are less affected by the abnormal refractive effects of corneal irregular astigmatism and HOAs.
- This new IOL design may be used in cases of severe dysphotopsia and light sensitivity resistant to other modalities of treatment.

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