ARTICLE

Long-term safety of in-the-bag implantation of a supplementary intraocular pinhole

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Purpose: To evaluate the long-term effectiveness and safety of the XtraFocus intraocular pinhole (IOPH) when it is implanted inside the capsular bag.

Setting: Private practice.

Design: Retrospective consecutive case series.

Methods: Patients who had an IOPH implanted in the capsular bag together with the primary intraocular lens (IOL) to treat irregular corneal astigmatism secondary to multiple causes were enrolled. The mean follow-up was 16 months (range 7 to 48 months). Patients were assessed in their scheduled follow-up visits. The uncorrected and corrected distance visual acuities were recorded at each visit. An infrared slitlamp photograph was captured and analyzed to verify the presence of interlenticular membrane formation.

Results: Sixty eyes of 58 patients were analyzed. The mean uncorrected and corrected distance visual acuities improved from logarithm of the minimum angle of resolution 1.34 ± 0.338 and 0.57 ± 0.145 preoperatively to 0.14 ± 0.012 (P < .001) and 0.12 ± 0.008 (P = .001) at 1 year postoperatively, respectively. A mild pinhole decentration was noted in 5 eyes (8.3%). Interlenticular opacification (ILO) was not noted in any patient.

Conclusions: Implantation of the XtraFocus IOPH inside the capsular bag was a safe technique. Improvement observed in both uncorrected and corrected distance visual acuities was significant and sustained over time. ILO did not occur when this implant was positioned in the capsular bag together with a primary IOL.

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Irregular corneal astigmatism may be a challenging condition to treat, and it can be found in different scenarios, especially in keratoconus, post–penetrating keratoplasty, post–radial keratotomy (RK), post–laser in situ keratomileusis corneal ectasia, and trauma. Rigid contact lenses are the main treatment modality for these cases. However, there are patients in whom an adequate fitting is not achieved or there is no tolerance for their use. Multiple surgical approaches such as topography-guided excimer laser corneal ablation, intracorneal ring segments implantation, and lamellar or full-thickness keratoplasty have been proposed.[1–7]

More recently, the use of a small-aperture implant (XtraFocus. Morcher) has been published to address irregular corneal astigmatism.[8,9] Improvement was observed in both uncorrected and corrected distance visual acuities in patients with different degrees of corneal irregularity. This implant was designed to be supported in the ciliary sulcus of pseudophakic eyes. It is made of hydrophobic acrylic material, and it has a concave–convex design to avoid contact with the primary in-the-bag intraocular lens (IOL) and a longer overall length of 13.5 mm, which is compatible with sulcus dimensions. Its haptics are angulated, very thin, rounded, and well polished to minimize the risk of uveal tissue injury. It can be implanted primarily (at the time of cataract surgery) or secondarily (after cataract surgery), and this has been shown to be a very effective strategy to treat these patients. The nature of the XtraFocus implant material allows transmittance of infrared (IR) light through it.[9,10] This way, by using an IR-based equipment, we can examine the structures behind the implant.

However, sulcus-based implants might be more prone to decentrations, and these decentrations are especially critical to small-aperture implants.[11,12] We have shown that this implant can also be used inside the capsular bag as a sole implant or together with the primary IOL.[13,14] Despite

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having longer haptics, the XtraFocus implant can be easily maneuvered inside the eye and placed inside the capsular bag.

However, implantation of more than 1 IOL inside the capsular bag has been shown to be susceptible to interlenticular opacification (ILO).[15,16] This is a late complication of piggyback implantation in which lens material proliferates in between the implants and may degrade vision.[17–19] This is more of a concern when 2 hydrophobic acrylic IOLs with bioadhesive surfaces are used.[20]

The aim of this study was to investigate the safety of the implantation of the intraocular pinhole (IOPH) inside the capsular bag together with a regular IOL, especially regarding the formation of ILO. To the authors' knowledge, this is the first study to look into this potential complication.

METHODS

This is a retrospective study in which consecutive patients who had an IOPH implanted in the capsular bag at the time of cataract surgery together with a primary IOL from January 2015 to December 2018 were analyzed. The study followed the tenets of the Declaration of Helsinki, and approval of the Institutional Review Board/Ethics Committee was obtained. Multiple causes of irregular corneal astigmatism were included and are listed in Table 1.

Patients were assessed in their scheduled follow-up visits by subjecting to a complete ophthalmic examination with uncorrected distance and near photopic visual acuity testing, subjective refraction, biomicroscopy, tonometry, and fundoscopy with a high-powered lens (SuperPupil XL; Volk Optical Inc.). An IR slitlamp photograph was also obtained using a customized slitlamp. The IR images were then analyzed, looking for any signs of interlenticular membrane formation. The centration of the IOPH was verified by direct assessment and subjectively graded according to Table 2.

Surgery was performed by one of the experienced surgeons (B.L.C.T, C.L.C.T., or F.C.T.). Implantation of the IOPH was done at the same time of cataract surgery in all patients. An attempted 5.0 to 5.5 mm capsulorhexis was manually created, and after lens removal with phacoemulsification and cortical cleanup, the primary IOL was implanted in the capsular bag in the routine fashion. No particular effort was taken to polish the undersurface of the anterior capsule rim. If the primary IOL was a toric lens, meridional orientation was left slightly shy of the intended final position. An ophthalmic viscosurgical device (OVD) was then removed from behind the IOL with the irrigation/aspiration handpiece. Then, the OVD was injected over the IOL to reinflate the capsular bag, and the IOPH was implanted over the primary IOL. If the IOL was a toric lens, it was then rotated under the pinhole to the final desired axis. The pinhole was positioned with no specific meridional orientation and aligned to the first Purkinje reflex after complete OVD removal.

Visual acuity was recorded in all visits and converted from decimal values to logarithm of the minimum angle of resolution (logMAR) using the following formula:[21]

$$\text{logMAR} = -\log(\text{Decimal Acuity}).$$

Normality was tested and confirmed using the Shapiro-Wilks test. A paired *t*-test was used to compare uncorrected and corrected distance visual acuities preoperatively and at 1 year postoperatively.

RESULTS

The study included 60 eyes of 58 patients in which the IOPH was implanted inside the capsular bag together with a regular IOL. The mean age at the time of surgery was 52 ± 3.5 years. The causes of irregular astigmatism requiring surgery are listed in Table 1. Table 3 shows the models of the primary IOLs used, which are all manufactured from different hydrophobic acrylic materials. The mean follow-up was 16 months (range 7 to 48 months). No intraoperative complications were noted.

A dilated IR photography was performed in all patients, and IOPH and IOL structures were clearly visible. No signs of ILO were seen in any of the patients during the follow-up visits (Figure 1).

Visually significant posterior capsule opacification was noted in 8 eyes (13.3%). Nd:YAG laser posterior capsulotomy was performed in these patients with no additional technical difficulty introduced by the presence of the pinhole. There was a statistically significant sustained improvement of both uncorrected and corrected vision (Figure 2).

The mean uncorrected distance visual acuity improved from logMAR 1.34 ± 0.338 preoperatively to 0.14 ± 0.012

Table 1. Underlying pathologic conditions that required surgery.

Pathology	N
Keratoconus	38
Status post-PKP	12
Status post-RK	8
Others	2

PKP = penetrating keratoplasty; RK = radial keratotomy

Table 2. Pinhole centralization grading.

Pinhole Centralization	Grading
Well centered	0
Small decentration (no more than 10% of pinhole aperture obscured by iris)	1
Medium decentration (between 10% and 50% of pinhole aperture obscured by the iris)	2
Large decentration (more than 50% of pinhole aperture obscured by iris)	3

Table 3. Primary IOL model used during surgery.

Model	% (n)
J&J ZCB00	32 (19)
Alcon SN60WF	5 (3)
Bausch & Lomb MX60	27 (16)
Hoya 255	5 (3)
Alcon MA60MA	5 (3)
Alcon SN6ATx	18 (11)
J&J ZCTx	8 (5)

IOL = intraocular lens

Figure 1. Infrared photograph 2 years postoperatively: The pinhole is implanted in the capsular bag together with a toric intraocular lens (IOL). Note the early Soemmerring's ring formation superior to the IOL and the absence of any interlenticular membrane.

at 1 year postoperatively ($P < .001$). The mean corrected distance visual acuity improved from logMAR 0.57 ± 0.145 preoperatively to 0.12 ± 0.008 ($P = .001$) at 1 year postoperatively. The mean uncorrected near visual acuity showed the same trend as the distance acuity. It improved from logMAR 1.17 ± 0.346 preoperatively to logMAR 0.10 ± 0.007 ($P = .015$) at 1 year after implantation.

There was a significant decrease in the spherical equivalent subjective refraction error (Figure 3). It varied from −7.29 ± 2.563 diopters (D) preoperatively to −0.67 ± 0.053 D ($P = .001$) at 1 year postoperatively.

Intraocular pinhole decentration was graded as 0 in 55 eyes (91.7%) and as 1 in 5 eyes (8.3%). No eyes showed a decentration of grade 2 or 3. No additional procedure to recenter the pinhole was needed.

DISCUSSION

Recently, small-aperture implants are drawing global attention because they can increase the depth of focus and improve pseudophakic presbyopia.[22] Moreover, they have been shown to be particularly helpful when dealing with irregular corneal astigmatism caused by keratoconus, post-RK, post–penetrating keratoplasty, and others.[9,23] These cases are usually challenging, and patients are often left with no alternative other than a corneal transplant.

The XtraFocus implant was introduced as a sulcus-based small-aperture diaphragm to treat irregular corneal astigmatism. It has been shown to be effective in numerous conditions and can be implanted primarily or secondarily in pseudophakic eyes.

Although there are other small-aperture devices commercially available, we believe that the XtraFocus pinhole has potential advantages, especially in cases of irregular corneal astigmatism. The Kamra corneal inlay (CorneaGen) is a small-aperture polyvinylidene fluoride mask designed to be implanted in a stromal corneal pocket. The IC-8 IOL (Acufocus) is a hydrophobic single-piece IOL with a small-aperture mask embedded in its optic. Both of these implants were developed to overcome presbyopia. When dealing with an irregular cornea, a corneal inlay may not be the best alternative. Regarding the IC-8 IOL, the constraints in the current dioptric power range (+15.50 D to 27.50 D) limit its use in these patients. In cases of steep corneas (such as in keratoconus), a lower-power IOL is often needed. In cases of flat corneas (such as in status post-RK), a higher dioptric power is required. Moreover, small-aperture optics may compensate for small cylindrical errors; however, the correction of high astigmatism (>3 D) is paramount for successful treatment. This way, a toric IOL may be of a great benefit in some cases, and currently, there is no toric version of the IC-8 implant. By contrast, the XtraFocus pinhole implant can be used with any IOL model currently available.

We have shown that in-the-bag implantation of the XtraFocus can be easily achieved with minimal additional intraocular manipulation. Positioning this implant inside the capsular bag may warrant better short- and long-term centrations. This is especially useful in these implants in which a small decentration may lead to visual degradation and visual field disturbances caused by partial or total covering of the pinhole by the iris. Postoperative asymmetric capsular bag contraction may cause implant decentration and degrade vision.[11] However, in this article, we showed that implantation of the IOPH inside the capsular bag was effective in achieving and maintaining a good centration over time. A small decentration (with the pinhole being obscured by the iris by no more than 10%) was seen in 8.3% of the eyes. In all these cases, the decentration was noted in the early postoperative period (within the first 3 months), and there was no increase in the decentration over time. We believe that this small decentration was caused by a misalignment between the pupillary axis and the capsular bag center. Recentering of the IOPH was not required in any of the patients. As a comparison, in our own series of sulcus implantation of this same device, a secondary procedure to recenter the IOPH was needed in 9% of the cases with a mean of 2.3 ± 0.15 months after the initial operation (unpublished data).

Piggyback implantation of 2 IOLs has been proposed as a mean to achieve a higher dioptric power required to

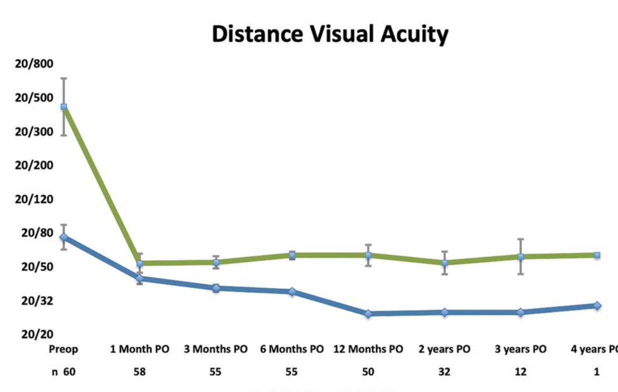

Figure 2. UDVA and CDVA values measured at the follow-up visits (CDVA = corrected distance visual acuity; PO = postoperatively; UDVA = uncorrected distance visual acuity).

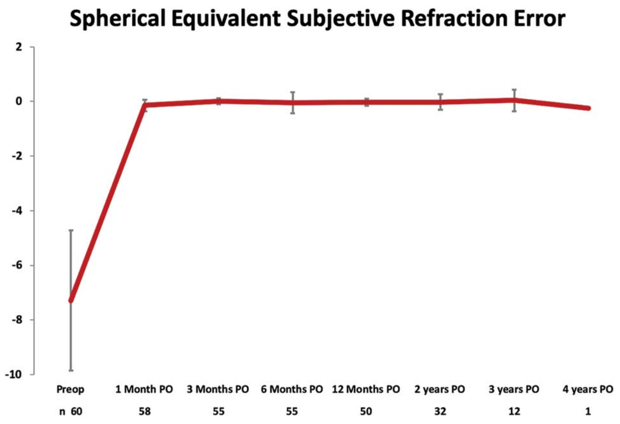

Figure 3. Spherical equivalent subjective refraction error values at the follow-up visits (PO = postoperatively).

correct highly hyperopic eyes.[24–27] However, in-the-bag implantation of 2 acrylic devices can lead to the formation of ILO.[15,16,18,20,28] This is a late complication of polypseudophakia that has been reported especially when 2 hydrophobic acrylic IOLs are placed together inside the capsular bag.[20] It usually presents 1 to 2 years postoperatively. It is thought to be caused by the proliferation of lens epithelial cells in the space between the 2 implants after anterior capsule sealing of the capsular bag compartment.[19] The formation of an interlenticular membrane between 2 IOLs can cause visual deterioration, late hyperopic shift, and firm adhesions between the implants.[28] The tackiness of some hydrophobic acrylics has been incriminated as a contributor of the process, and this explains the much higher incidence of this complication when using lenses of this material. The Nd:YAG laser applied to the interlenticular space has been proposed as a treatment for this condition.[29] However, IOL explantation is sometimes required.

In our study, despite having 2 hydrophobic acrylic implants in the capsular bag, we could not notice any signs of ILO formation in all patients in the follow-up period of up to 48 months. We hypothesize that the meniscus shape of the occlusive portion of the pinhole vaults over the primary IOL with no direct contact in between them. In addition, the central pinhole may allow aqueous flow between the implants and contribute to the elimination of any proliferating cells in that space.

Although in our study we used a modified IR slitlamp to assess the structures behind the black pinhole, there are many commercially available devices that can give the same IR-retroillumination images. These include OCTs, autorefractors, wavefront aberration equipments, and optical biometers, among others.

The mean subjective refraction spherical equivalent reduced significantly postoperatively. It is important to highlight that the flattening effect of the defocus curve induced by the pinhole optics associated with the irregular cornea makes small variations in the postoperative refraction imperceptible to the patient. This way, the smallest refraction error that could give the corrected vision was the one considered. Moreover, there was no significant variation in the spherical equivalent of the subjective refraction in the postoperative period. The implantation of the IOPH inside the capsular bag did not cause any significant hyperopic shift. More importantly, there was a statistically significant sustained improvement in vision in the included patients with no major postoperative complication.

Posterior capsule opacification occurred in 13.3% of the cases. It was possible to perform Nd:YAG laser capsulotomy in all these cases. Corneal irregularity compromises aiming of the laser beam and a contact lens, such as a Peyman lens, may facilitate this. The IOPH permits opening of the central part of the posterior capsule with no additional technical difficulty. By modifying gaze, it is possible to even extend the capsule opening farther than the pinhole margins, although this is usually not required.

Although the IR transparency characteristic of the XtraFocus material might allow fundus visualization, one major drawback of this technology is the impossibility to perform retinal treatment with this implant. If argon laser treatment or vitreoretinal surgery is required, this implant has to be removed. This is very important to be informed in the consent process.

One important limitation of this study is the fact that it is a retrospective series. To further validate our findings, a prospective controlled trial might be needed.

The IOPH can improve vision in cases of irregular corneal astigmatism. Implantation of this device in the capsular bag can be safely performed. Interlenticular opacification does not seem to occur with this implant when used together with a conventional IOL.

WHAT WAS KNOWN

- Intraocular pinhole implantation can improve vision in cases of irregular corneal astigmatism.
- This supplementary pinhole device can be implanted in the cilliary sulcus or in the capsular bag.

WHAT THIS PAPER ADDS

- Implantation of the supplementary pinhole device in the capsular bag together with a primary intraocular lens is an effective and safe technique.
- Interlenticular opacification does not seem to occur with this specific implant.

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