ARTICLE

Bilateral implantation of a supplementary intraocular pinhole

Bruno Lovaglio Cançado Trindade, MD, PhD, Fernando Cançado Trindade, MD, PhD, Claudio Lovaglio Cançado Trindade, MD, PhD

Purpose: To evaluate the safety and efficacy of bilateral implantation of a supplementary small-aperture device to treat irregular corneal astigmatism.

Setting: Private practice.

Design: Retrospective consecutive case series.

Methods: Patients with bilateral irregular corneal astigmatism secondary to multiple causes and consented for implantation of the XtraFocus intraocular pinhole (IOPH) were enrolled. The mean follow-up was 27 months (range 5 to 66 months). Patients were assessed in their scheduled follow-up visits and monocular and binocular uncorrected and corrected distance and near visual acuities were recorded. Assessment of darkening vision complaints was also performed after implantation in the first eye and repeated after second-eye surgery.

Results: Thirty-two eyes of 16 patients were analyzed. The mean monocular and binocular uncorrected distance visual acuities improved from logMAR 1.091 ± 0.208 and 1.078 ± 0.259 preoperatively to 0.342 ± 0.091 ($P < .001$) and 0.342 ± 0.147 ($P = .001$) 1 year postoperatively. Three patients were excluded because of darkening vision complaints after surgery in the first eye. No major complications were noted after implantation of the IOPH.

Conclusions: Bilateral implantation of the XtraFocus IOPH is a safe technique in a selected group of patients. There was improvement in visual acuity sustained over the analyzed period. Postoperative darkening vision complaints vary between individuals and can limit the application of this approach in certain patients.

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Small-aperture optics has been recently described by us and others as a new method for treating irregular corneal astigmatism.[1,2] The aberrant peripheral light rays are blocked by the reduced aperture, thus decreasing the circle of least confusion on the retina. Another benefit of these devices is the flattening effect on the defocus curve that allows increasing the depth of focus, improving the pseudophakia-induced presbyopia.[3] There are currently 2 commercially available intraocular small-aperture devices. The IC-8 intraocular lens (IOL) (AcuFocus) is a standard single-piece hydrophobic acrylic lens with a small-aperture mask embedded in its optic (Figure 1, A). The pinhole aperture is 1.36 mm, and the outer mask diameter is 3.23 mm. It was designed to be implanted in the capsular bag as a standard lens. The XtraFocus (Morcher, GmbH) is a supplementary intraocular pinhole (IOPH) with an occlusive mask of 6.0 mm and a central pinhole diameter of 1.3 mm (Figure 1, B). It has no refractive power and was designed to be implanted in the ciliary sulcus of pseudophakic eyes in a piggyback configuration. It is made of a special black hydrophobic foldable acrylic with very thin and polished haptics to avoid any uveal reaction.[4] This material has been shown to be opaque to visible light; however, it is totally transparent in the infrared range of the spectrum.[5] This allows retinal examination with infrared-operated equipment such as optical coherence tomography and scanning laser ophthalmoscopes.[6]

The use of small-aperture devices has been successfully demonstrated to improve vision in cases of different etiologies of irregular corneal astigmatism such as in post-radial keratotomy, post-penetrating keratoplasty or deep anterior lamellar keratoplasty, post-laser in situ keratomileusis ectasia, trauma, and others.[1,7,8] However, despite the improvement in image quality in cases of irregular corneas, small-aperture implants might reduce retinal luminance, and this might limit their use. Agarwal et al. reported a case that required explantation of the XtraFocus due to persistent dimmed vision 3 months after implantation.[9] For this reason, bilateral implantation of this device is usually not advised. Nevertheless, Artal et al. have shown that the reduction in perceived brightness

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From the Cançado Trindade Eye Institute, Belo Horizonte, Brazil (B.L.C. Trindade, F.C. Trindade, C.L.C. Trindade); Medical Sciences Medical School, FELUMA, Belo Horizonte, Brazil (B.L.C. Trindade); Medical Sciences Eye Institute, FELUMA, Belo Horizonte, Brazil (B.L.C. Trindade).

Corresponding author: Bruno Lovaglio Cançado Trindade, MD, PhD, Cançado Trindade Eye Institute, Rua Manaus, 595, 30.150-350, Belo Horizonte, MG, Brazil. Email: bruno.trindade@ioct.org.

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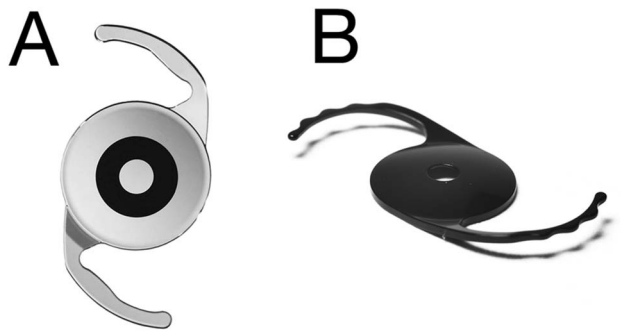

Figure 1. *A*: IC-8 IOL. This is a standard single-piece acrylic IOL with a pinhole mask embedded into the lens optic. *B*: XtraFocus intraocular pinhole. This is a supplementary device with no dioptric power intended to be implanted in pseudophakic eyes.

with small-aperture devices might be less than anticipated what would have been expected by the reduction in retinal luminance.[10] By using an experimental instrument, they showed that the perceived brightness was higher than anticipated by mathematical calculations taking into account the Styles-Crawford effect.[11]

The purpose of this study is to report clinical results of bilateral implantation of the XtraFocus IOPH in patients with irregular corneal astigmatism. To the authors' knowledge, this is the first report presenting results of this implant being used to treat binocular diseases causing irregular astigmatism.

METHODS

This is a retrospective study in which consecutive patients who had an IOPH implanted in both eyes to treat irregular corneal astigmatism from April 2014 to July 2020 were analyzed. The study followed the tenets of the Declaration of Helsinki and approval of the Institutional Review Board/Ethics Committee was obtained. The causes of irregular corneal astigmatism are listed in Table 1.

Indications for implantation of the IOPH were the following: older than 30 years; presence of irregular corneal astigmatism with corrected distance visual acuity worse than 20/50 in both eyes; contact lens intolerance or inability to wear them; no vitreoretinal pathology detected during a dilated fundus examination nor a history of vitreoretinal surgery; no glaucoma; no history of uveitis; agreement to sign the informed consent; for implantation in the second eye, no moderate or severe complaint of dimmed vision in mesopic/scotopic conditions after pinhole implantation in the first eye (see below).

In phakic patients, cataract or refractive lens exchange surgery was performed at the time of IOPH implantation.

Surgery was performed by 1 of 2 experienced surgeons (B.L.C.T., C.L.C.T.). In phakic patients, surgery consisted in phacoemulsification with cortical removal, followed by IOL implantation. Next, the IOPH was implanted and positioned in either the ciliary sulcus or the capsular bag according to the surgeon's preference. In pseudophakic patients, after filling the anterior chamber with cohesive ophthalmic viscosurgical device, the IOPH was implanted and positioned in the ciliary sulcus. In both cases (primary and secondary implantation), centration of the pinhole was aimed at the first Purkinje reflex.

After surgery was performed in the first eye, patients were evaluated in their routine postoperative visits with a complete ophthalmological examination. Patients were also specifically asked about darkening vision in mesopic/scotopic environments and were subjectively classified between 4 categories (Table 2). Those who had a moderate or severe complaint of dimmed vision were not considered for second-eye pinhole implantation. Those who were mildly or not symptomatic were scheduled for second-eye surgery.

Second-eye surgery followed the same technique as described earlier. The patients were also evaluated in their routine follow-up visits with monocular and binocular visual acuity measurement, subjective refraction, biomicroscopy, fundoscopy, and tonometry. One month after implantation in the second eye, patients were again classified between 4 categories in relation to their mesopic/scotopic vision (Table 2).

Visual acuity was recorded and converted from decimal values to logMAR using the following formula[12]:

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

Main outcome variables were monocular and binocular uncorrected and corrected distance and near visual acuities. Secondary outcome variable was dimmed vision complaints.

Normality was tested and rejected using Shapiro-Wilks test. Wilcoxon signed-rank test was used to compare distance and near visual acuities preoperatively and at 12 months postoperatively. For binocular visual acuity, the comparison was performed between preoperatively in the first eye and 12 months postoperatively in the second eye. A P value less than 0.05 was considered statistically significant.

RESULTS

Nineteen patients consented to bilateral IOPH implantation in the analyzed period. Three patients were excluded after implantation of the IOPH in the first eye because of moderate dimmed vision symptoms. Therefore, 32 eyes of 16 patients that had bilateral IOPH implantation were included. The mean age at surgery was 46.9 ± 8.6 years. The mean follow-up was 27 months (range 5 months to 5.5 years). In 7 eyes (22%), IOPH was performed secondarily as a standalone procedure. In the remaining 25 eyes (78%), pinhole implantation was performed at the same time as lens removal (cataract surgery or refractive lens exchange). In 12 eyes (37.5%), the XtraFocus was positioned in the ciliary sulcus, and in 20 eyes (62.5%), it was positioned inside the capsular bag together with the primary standard IOL (models listed in Table 3).

Figures 2 and 3 show distance and near visual acuity measurements during each postoperative interval. There was improvement in all measured visual acuities postoperatively. The improvement was stable over the analyzed postoperative course.

The mean monocular distant uncorrected visual acuity improved from logMAR 1.091 ± 0.208 preoperatively to 0.342 ± 0.091 1 year postoperatively ($P < .001$). Binocular uncorrected distance visual acuity improved from logMAR 1.078 ± 0.259 to 0.342 ± 0.147 12 months postoperatively ($P = .001$). Monocular corrected distance visual acuity improved from logMAR 0.495 ± 0.096 to 0.199 ± 0.021 ($P = .009$), and binocular corrected vision also improved from logMAR 0.481 ± 0.260 to 0.157 ± 0.058 1 year later ($P = .01$).

Despite improvement in mean values, uncorrected and corrected near vision did not show a statistically significant difference from preoperative to 1 year postoperative. The mean uncorrected monocular and binocular near visual acuity improved from logMAR 0.393 ± 0.233 and 0.383 ± 0.303 to 0.249 ± 0.071 and 0.210 ± 0.032 1 year later

Table 1. Underlying Pathology Causing Irregular Corneal Astigmatism.

Pathology, n (%)
Keratoconus, 17 (53)
Status post-RK, 10 (32)
Status post-LASIK ectasia, 2 (6)
Status post-PKP, 1 (3)
Other, 2 (6)

LASIK = laser in situ keratomileusis; PKP = penetrating keratoplasty; RK = radial keratotomy

(P = .082 and P = .115). The difference in corrected near acuity had even higher P values (with P = .125 and P = .176 for monocular and binocular, respectively).

Figure 4 shows the variation in the manifest refraction after pinhole implantation. There was a significant reduction in the manifest refraction spherical equivalent in the eyes that had combined lens surgery. This is due to the correction of the ametropia by the IOL. In eyes that were previously pseudophakic, there was no statistically significant change in the manifest refraction postoperatively.

The mean interval between surgery in the first and second eye was 157.4 days (range 5 to 462 days). One eye had a significant postoperative inflammation after implantation of the IOPH on the second eye detected on the first postoperative visit. Anterior chamber cells and flare were noted during slitlamp examination. Visual acuity was limited to 20/200, and IOP was 12 mm Hg. In this case, an hourly use of topical dexamethasone acetate 0.1% (Maxidex, Alcon Laboratories, Inc.) together with 40 mg of daily systemic prednisone was prescribed. Five days later, the anterior chamber inflammation had improved significantly. Systemic steroids were ceased, and topical drops were tapered over 1 month. One month later, no signs of anterior chamber cells were noted. Uncorrected visual acuity improved to 20/50, with a corrected acuity of 20/30.

Posterior capsule opacification was noted in 2 eyes. In 1 patient, the opacification was noted 12 months postoperatively and, in the other, 16 months postoperatively. In these patients, Nd:YAG laser posterior capsulotomy was performed. A Peyman contact lens was used to improve focusing because of the irregular cornea. A capsular opening was attempted slightly larger than the central pinhole and was achievable by modifying patient's gaze during treatment. Vision improved in all cases that required capsulotomy.

Five patients had mild symptoms of dimmed vision before second-eye implantation. The other 11 patients were asymptomatic. After implantation of the pinhole in the second eye, 1 patient (6.2%) who was asymptomatic referred dimming of vision and was classified as mildly symptomatic. One other patient (6.2%) referred improvement of the dimmed vision after second-eye surgery and was classified as asymptomatic. All the other ones maintained their initial dimming vision symptoms. Table 4 shows darkening vision symptoms in all the subjects.

No postoperative hypertension was noted in any eyes. No relevant intraocular pressure difference was found between the eyes that had the IOPH placed in the capsular bag or the ones placed in the ciliary sulcus.

In 3 eyes (9.3%) of 3 patients, the IOPH had to be repositioned after implantation because of postoperative decentration. In all 3 cases, the pinhole aperture was partially obscured by the iris between 10% and 50% (moderate decentration). Recentration was performed under the surgical microscope using a Sinskey hook after filling the anterior chamber with cohesive ophthalmic viscosurgical device. This procedure was performed between 2 and 3 months after the initial surgery and, in all 3 patients, was suffice to warrant a better postoperative centration.

One patient (6.2%) referred glare and halos around light sources. The symptoms started after IOPH implantation in the first eye and maintained after second-eye surgery. However, the patient referred that the improvement of vision outweighed these symptoms and denied the explantation of the IOPHs.

DISCUSSION

Irregular corneal astigmatism is a challenging condition to treat and patients usually rely on RGPs to improve their vision. It can be present in many different conditions, and the use of small-aperture optics has recently been shown as an alternative surgical solution to these cases. We and others have demonstrated the safety and effectiveness of this approach to improve vision in different pathologies that cause irregular corneal astigmatism.[1,2] The reduction in aperture size decreases the impact of peripheral aberrant rays and improves visual acuity. There are currently 2 commercially available pinhole devices that have been shown effective in the treatment of irregular corneal astigmatism, the IC-8 IOL and the XtraFocus pinhole.

Table 2. Darkening Vision Complaints.

Complaint	Severity
No perception of darkening vision	No symptoms
Minor perception of darkening vision without compromise in the ability to see an object or navigate around poorly lit environments	Mild
Perception of darkening vision requiring some sort of extra illumination (such as a flashlight) to help seeing objects or navigate around poorly lit environments	Moderate
Important perception of darkening vision compromising the ability to see objects or navigate around moderately lit environments	Severe

Table 3. Primary IOL Model Used During Combined Lens Surgery.

IOL Model, n (%)
ZCB00, Johnson & Johnson Vision, 4 (21)
MX60, Bausch & Lomb, Inc., 4 (21)
255, Hoya Corp., 4 (21)
ZCTx, Johnson & Johnson Vision, 4 (21)
SN6ATx, Alcon Laboratories, Inc., 3 (16)

Although there is a third small-aperture device designed to be implanted in a corneal stromal pocket (Kamra, CorneaGen), it is not ideal to treat these complex eyes because many of them have a pathological cornea that would not be suited for inlay implantation.

Many patients present with bilateral disease and decreased visual acuity due to irregular corneal astigmatism. In these cases, it is important to assess the benefit of bilateral implantation of a small-aperture device.

Dick et al. published the results of 6 patients who received the IC-8 IOL bilaterally to treat presbyopia.[13] In that article, the authors mention that bilateral implantation yielded in better extended range of focus, with better intermediate and near vision. However, they reported that bilaterally implanted patients had a lower subjective satisfaction score and a higher incidence of photic phenomena such as halos when compared with the monocularly implanted controls. This difference was not statistically significant. In a different publication, Ang presented a prospective analysis of 10 patients who received the IC-8 IOL bilaterally to improve spectacle independence after cataract surgery.[14] In that article, the author shows an average of 0.2 log units reduction in contrast sensitivity in mesopic conditions compared with monofocal IOL implantation with no statistical significance. Subjective visual improvement was similar between the bilateral implantation group and the monocular-implanted subjects with slightly higher scores in the bilateral group without statistical significance. These 2 publications used a small-aperture device to treat presbyopia.

We presented the results of bilateral implantation of the XtraFocus pinhole implant in 16 patients with irregular corneal astigmatism. Seven eyes (22%) were already pseudophakic. Five eyes (15.6%) had a visually significant cataract, and 20 eyes (62.5%) had a clear crystalline lens. The XtraFocus device is different from the IC-8 IOL because it has no dioptric power and requires the presence of an IOL in the capsular bag. This device can be positioned either in the ciliary sulcus or inside the capsular bag together with the primary IOL.[8] There is a concern of implanting this device inside the capsular bag with another IOL because interlenticular membrane formation has been described when 2 or more implants are positioned within the capsular bag. We have demonstrated the safety of this approach with this specific implant.[8] We have hypothesized that the combination of a concave posterior optic surface, which minimizes contact with the primary lens, and the central hole, which allows the flow of aqueous in the interface, might prevent formation of these interlenticular membranes with the XtraFocus pinhole. In this series, the implantation of the XtraFocus device inside the capsular bag has been shown to be less prone to decentration postoperatively. Therefore, we tend to choose this approach when pinhole implantation is combined with lens removal surgery.

In this study, we showed a statistically significant improvement in distance vision after implantation of the pinhole both monocularly and binocularly. The improvement sustained over the follow-up period. This is consistent with previous published results in different patients using this same device. Near visual acuity was also improved monocularly and binocularly postoperatively although not statistically significant. This is caused by the flattening effect of the defocus curve induced by the pinhole. The combination of this flattening effect with a small residual myopic error and a multifocal irregular cornea is usually enough to warrant decent uncorrected acuity in these patients after implantation of a small-aperture optic device. There was no clinically relevant change in the manifest refraction after pinhole

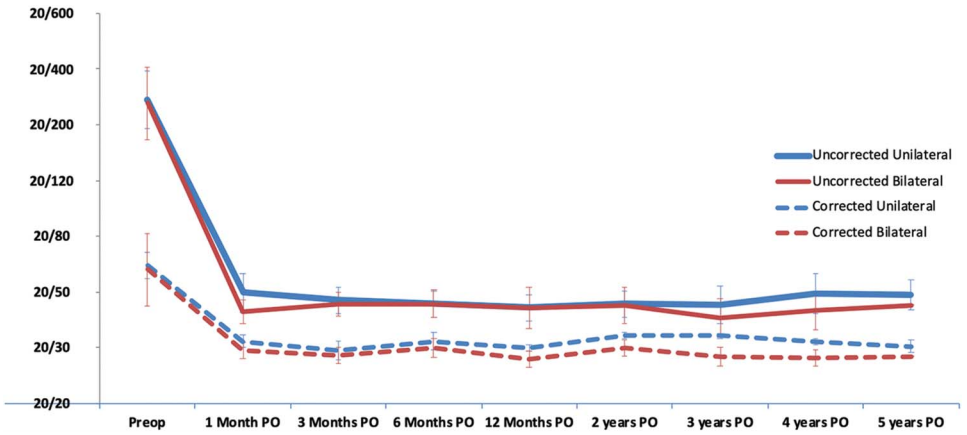

Figure 2. Distance visual acuity. There was a statistically significant improvement of the monocular and binocular uncorrected and corrected visual acuities. PO = postoperative; preop = preoperative

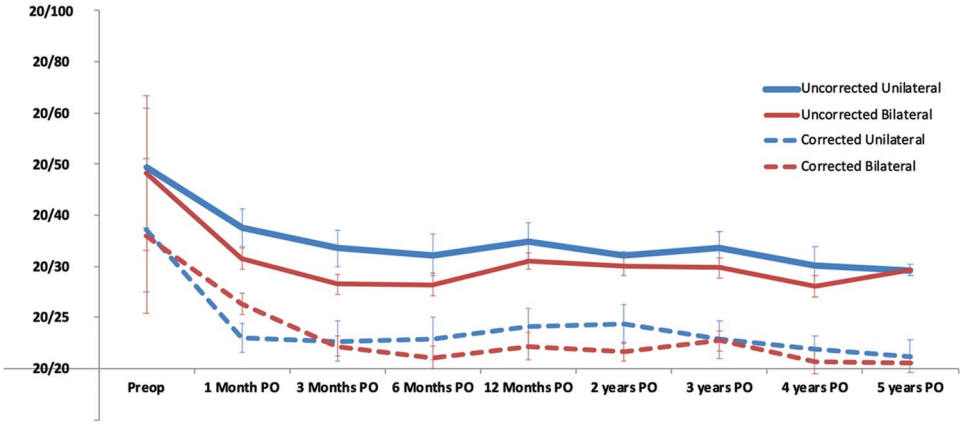

Figure 3. Near visual acuity. Despite an improvement of the monocular and binocular near vision, this difference was not statistically significant. PO = postoperative; preop = preoperative

implantation in the eyes that were pseudophakic. In the ones that the IOPH was implanted at the same time of lens surgery, there was a reduction of the manifest refraction spherical equivalent because of the power adjustment of the IOL. It is worth mentioning that, because of the increase in depth of focus, subjective refraction after small-aperture implantation might be confusing with a wide range of corrections yielding the same vision. We considered the final refractive error the one in which the spherical equivalent was closer to plano.

Toric IOLs can sometimes be used in cases of irregular corneal astigmatism. They are mainly reserved for patients who have a reasonable corrected acuity and who are not contact lens wearer. In this study, a toric implant was used in 7 eyes (21.8%). The correction of the regular component of the corneal astigmatism with a toric lens can improve the outcome when using a small-aperture implant. We have recently published a case in which this aspect is thoroughly discussed.[15] A trial can be made to assess the benefit of a toric implant under the IOPH in cases of no cataract. With the pinhole occluder on top of the best manifest refraction, one can alternate between the spherical equivalent and the full cylindrical correction. In cases where there is a significant benefit in vision with the cylindrical correction, a toric IOL can be considered.

In 2 eyes, posterior capsule opacification had to be treated with Nd:YAG laser capsulotomy, and this procedure was performed uneventfully in both patients with notably improvement of vision on the follow-up visit. It is worth mentioning that Nd:YAG laser is an infrared laser; thus, it is even possible to shoot this laser through the occlusive portion of the XtraFocus because of the characteristic infrared transmittance property of the implant material.[5] This is not required because the capsular opening can be extended beyond the central pinhole by modifying patient's gaze.

In 3 eyes (9.3%), the IOPH had to be repositioned after implantation due to decentration. All these eyes had the IOPH implanted in the ciliary sulcus, and repositioning was performed 2 to 3 months after implantation. No further decentration was noted, and only 1 repositioning procedure was necessary in these eyes. None of the in-the-bag implanted IOPH had a clinically significant decentration that required a recentering procedure. If we consider only the ciliary sulcus fixated implants (n = 12), the incidence of IOPH decentration was 25%, which is higher than our personal experience with this implant. In our entire series of implantation of this device, the overall incidence of ciliary sulcus-fixated implants decentration is 9% of 99 eyes (unpublished data). This contrasts with the

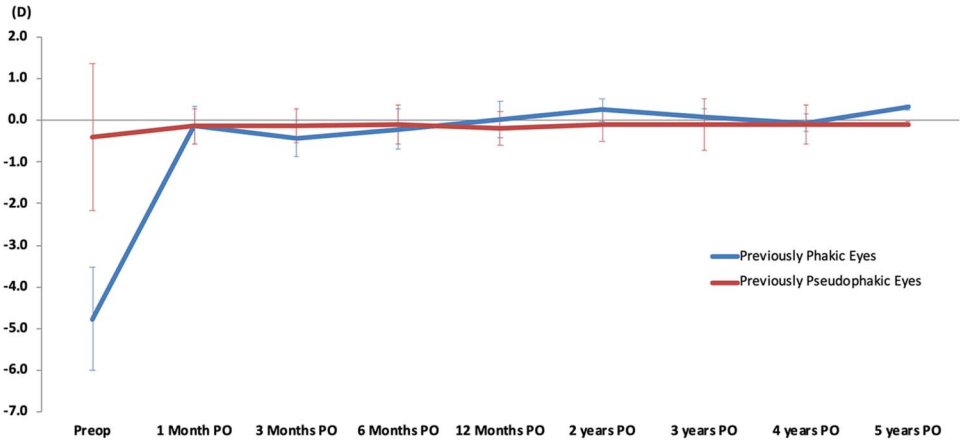

Figure 4. Manifest refraction spherical equivalent. Despite no significant change was noted in pseudophakic eyes, a statistically significant reduction of the manifest refraction was observed in the eyes in which lens surgery was performed, caused by the correction of the refractive error by the IOL implanted. PO = postoperative; preop = preoperative

Table 4. Darkening Vision Symptoms.

Patient no.	Postop first eye	Postop second eye
1	No symptoms	No symptoms
2	Mild	Mild
3	No symptoms	No symptoms
4	No symptoms	Mild
5	No symptoms	No symptoms
6	Mild	Mild
7	No symptoms	No symptoms
8	No symptoms	No symptoms
9	Mild	No symptoms
10	No symptoms	No symptoms
11	No symptoms	No symptoms
12	Mild	Mild
13	No symptoms	No symptoms
14	Mild	Mild
15	No symptoms	No symptoms
16	No symptoms	No symptoms

postop = postoperative

absence of clinically significant decentration seen when it is positioned inside the capsular bag. The ciliary sulcus anatomy is not symmetrical and minor variations in sulcus size might be responsible for postoperative implant decentration.

Contrast sensitivity has been shown to decrease in eyes with a small-aperture implant.[3] This is more pronounced in lower frequencies and in mesopic conditions, and in many series, it is not a statistically significant finding.[16] In cases of normal corneas in which a small-aperture device is used to treat presbyopia, the impact of such reduction in contrast sensitivity might be more recognized and significant than in cases of irregular corneal astigmatism. Patients with irregular corneas have a very poor optical system with aberrations degrading visual quality in a level that is more important than in a patient with normal cornea. After implantation of a small-aperture device, the impact of a small decrease in contrast sensitivity is usually outweighed by the improvement in visual acuity. It is important to notice that contrast sensitivity is a subjective test to evaluate subtle decreases in visual performances. To properly measure contrast sensitivity, patients must have adequate visual acuity to be able to detect the faint contrast patterns. We did not study contrast sensitivity in our patients because the final visual acuity, although greatly improved when compared with preoperative values, was not consistent, and this would compromise the analysis of this test.

One eye had a significant postoperative inflammation that was treated with increased topical and systemic steroids. The inflammation subsetted a week after treatment, and steroids were gradually tapered.

Dimmed vision after pinhole implantation can happen. This is a well-known complication of reduction of pupil size and has been long described with the use of miotics for the treatment of glaucoma.[17] There has even been a report of a case that required explantation of the XtraFocus pinhole because of dimmed vision after implantation.[9] However, Artal et al. have shown that the reduction in retinal luminance with small-aperture devices is smaller than it can be predicted by theoretical calculations even when including the Stiles-Crawford effect.[10] This represents a brighter perceived image than expected and might explain our clinical observation of multiple patients referring no difference in visual luminance after pinhole implantation. We noticed a large individual variability in the intensity of postoperative dimmed vision-related complaints after pinhole implantation with symptoms varying between none to moderate. To date, it has not yet been determined which variables might predict an intensely symptomatic outcome, and further studies are required to screen these patients preoperatively. This way, we advise that this potential complication should be always mentioned during the consent process. In this study, there were 3 patients (15.8%) who were initially consented for bilateral implantation but did not receive the XtraFocus implant in the second eye because of dimmed vision symptoms postoperatively in the first eye. One patient (6.3%) who was asymptomatic after implantation in the first eye referred mildly dimmed vision after implantation of the pinhole in the second eye and was classified as mildly symptomatic. Another patient (6.3%), on the other hand, referred improvement of dimmed vision after second-eye surgery.

Halos around light sources can occur after pinhole implantation. In this series, 1 patient referred these symptoms postoperatively. Although noticeable, these symptoms were not enough to request a pinhole explantation. This complication has been published using small-aperture devices to treat presbyopia in normal eyes.[3,18] We believe that, in eyes with normal corneas, these symptoms might be more pronounced and can become problematic in certain situations such as driving at night.

One important point to be emphasized is the necessity of a clear central cornea to consider the implantation of small-aperture devices. In this study, all patients had a transparent central region of the cornea. Central corneal opacities might be present in many cases of irregular corneal astigmatism and the presence of central haze or scars will compromise the final visual result after pinhole implantation. This is true even in cases that show an improvement of vision with a preoperative pinhole occluder test. These patients might be preferably treated with a corneal graft to restore corneal transparency and decrease irregularity.

Vitreoretinal complications might occur after implantation of a small-aperture device. Careful preoperative screening is mandatory, and proper counseling should mention the necessity of postoperative follow-up using infrared operating equipment such as an optical coherence tomography. However, if any posterior segment surgical procedure becomes necessary after implantation, this pinhole implant has to be explanted.

Further studies are still required to compare this approach with the more traditional one using a corneal graft in cases of irregular corneal astigmatism. However, in this study, we showed that bilateral implantation of this

supplementary IOPH was safe and reliable to improve vision in these challenging cases.

CONCLUSION

Bilateral implantation of the XtraFocus IOPH is safe in cases of irregular corneal astigmatism. It provides sustained improvement of uncorrected and corrected visual acuities. This approach can be considered in patients with bilateral disease that cannot tolerate contact lenses. Dimming vision in poorly lit environments can limit the application of this technology in some patients, and proper preoperative counseling should include this discussion.

WHAT WAS KNOWN

- Small-aperture implants are effective in treating irregular corneal astigmatism.
- Dimmed vision can happen after implantation of a small-aperture device.

WHAT THIS PAPER ADDS

- Bilateral implantation of the XtraFocus pinhole is safe and effective in selected cases of irregular corneal astigmatism.
- Proper patient selection is important to warrant success in this approach.

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First author:
Bruno Lovaglio Cançado Trindade, MD, PhD

Cançado Trindade Eye Institute, Belo Horizonte, Brazil