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Single-pass four-throw pupilloplasty

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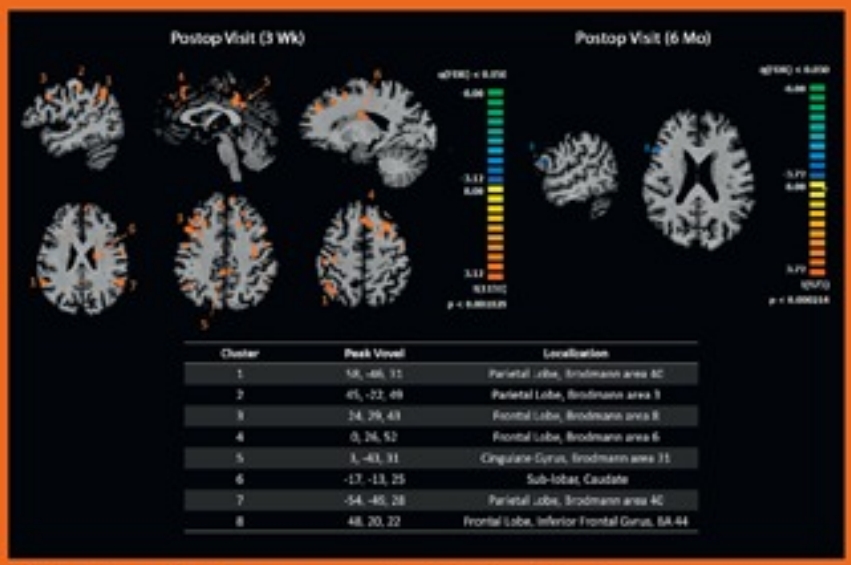


*Whole-brain analysis to assess neuroadaptation to multifocal intraocular lenses (see page 1287)*

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ARTICLE

# New pinhole sulcus implant for the correction of irregular corneal astigmatism

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**Purpose:** To evaluate the effect on visual acuity of the implantation of a new intraocular pinhole device (Xtrafocus) in cases of irregular corneal astigmatism with significant visual impairment.

**Setting:** University of São Paulo, São Paulo, Brazil.

**Design:** Prospective case series.

**Methods:** Pseudophakic eyes of patients with irregular corneal astigmatism were treated with the pinhole device. The causes of irregular corneal astigmatism were keratoconus, post radial keratotomy (RK), post-penetrating keratoplasty (PKP), and traumatic corneal laceration. The device was implanted in the ciliary sulcus in a piggyback configuration to minimize the effect of corneal aberrations. Preoperative and postoperative visual parameters were compared. The main outcome variables were manifest refraction, uncorrected and corrected distance and near visual acuities, subjective patient satisfaction, and intraoperative and postoperative adverse events and complications.

**Results:** Twenty-one patients (ages 35 to 85 years) were included. There was statistically significant improvement in uncorrected and corrected (CDVA) distance visual acuities. The median CDVA improved from 20/200 (range 20/800 to 20/60) preoperatively to 20/50 (range 20/200 to 20/20) in the first month postoperatively and remained stable over the following months. Manifest refraction remained unchanged, while a subjective visual performance questionnaire revealed perception of improvement in all the tested working distances. No major complication was observed. One case presented with decentration of the device, which required an additional surgical intervention.

**Conclusions:** The intraocular pinhole device performed well in patients with irregular astigmatism caused by keratoconus, RK, PKP, and traumatic corneal laceration. There was marked improvement in visual function, with high patient satisfaction.

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Online Video

Irregular corneal astigmatism significantly impairs visual function. It is induced by several corneal pathologies, including keratoconus, pellucid marginal degeneration, pterygium, and Salzmann nodules.[1] Irregular corneal astigmatism is also prevalent after corneal surgeries such as radial keratotomy (RK), eccentric excimer laser ablation, and penetrating keratoplasty (PKP) and is inevitably associated with a multitude of higher-order aberrations.[2]

Total ocular aberrations are known to become more unfavorable as pupil diameter increases,[1] whereas reducing the pupil aperture minimizes the effect of ocular aberrations because the paraxial light rays are less susceptible to imperfections of the optical system.[3] The use of miotic agents to reduce ocular aberrations is a common approach[4] because these agents promote an immediate and transient relief of glare and ghost images, 2 well-known disturbing optical phenomena associated with irregular corneal astigmatism. Ocular and systemic side effects represent the main disadvantages of these agents, including iris cysts, lacrimation, salivation, frontal headache, nausea, and bronchial spasm.[5] Additionally, a sustained contraction of the ciliary muscle may induce retinal detachment, especially in axial myopic and pseudophakic patients.[6] Poor long-term patient compliance also represents a drawback.

Although use of the small-aperture corneal inlay for depth of focus extension is an alternative presbyopia treatment,[7] the inlay should be implanted in only normal corneas, and therefore cases of irregular corneal astigmatism cannot benefit from the pinhole effect of such a device.

The Xtrafocus pinhole intraocular implant (Morcher GmbH) received a Conformité Européenne mark in July 2016 and was recently released in the European market. The purpose of this article was to evaluate the effect on

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visual acuity of implanting this pinhole device in cases of irregular corneal astigmatism with significant visual impairment.

## PATIENTS AND METHODS

Pseudophakic patients with irregular corneal astigmatism were treated with the pinhole device. The causes of irregular corneal astigmatism were keratoconus, post-RK, post-PKP, and traumatic corneal laceration.

The key inclusion criteria were age between 35 and 85 years, corrected distance visual acuity (CDVA) of 20/30 or less attributed to irregular corneal astigmatism, pseudophakia, anterior chamber depth greater than 3.5 mm with the presence of a monofocal intraocular lens (IOL) in the capsular bag, and central corneal transparency.

Exclusion criteria were presence of any vitreoretinal pathology detected at the initial evaluation, poorly controlled diabetes mellitus even with no retinopathy, uncontrolled glaucoma, history of uveitis or iritis, good rigid gas-permeable contact lens fitting and tolerance, and unwillingness to sign the informed consent.

The study followed the tenets of the Declaration of Helsinki, and approval of the Institutional Review Board/Ethics Committee of the University of São Paulo, Brazil, was obtained. All patients gave written informed consent before study enrollment.

### Pinhole Intraocular Implant

The pinhole device is a black opaque diaphragm with a 1.3 mm central opening and no refractive power (Figure 1). It is designed to be implanted in the ciliary sulcus of pseudophakic eyes in a piggyback configuration (Figure 2). The haptic is thin (250 µm), rounded, and well polished to prevent injury to the uveal tissue. The 14-degree angulation prevents iris chafing and pigment dispersion. The 6.0 mm occlusive part of the device has a concave–convex design to prevent contact with the primary IOL located in the capsular bag. The device is made of foldable hydrophobic acrylic and can be implanted through a 2.2 mm corneal incision (Video 1, available at http://jcrsjournal.org).

### Infrared Transparency

Because implantation of a pinhole device hinders indirect ophthalmoscopy, the material of this device has a unique feature to overcome this problem. The black acrylic is transparent to infrared (IR) light (Figure 3), enabling retinal examination after implantation with IR equipment such as optical coherent tomography (OCT) and the scanning laser ophthalmoscope. Anterior segment structures located behind the darker portion of the device (toric IOL marks, capsulorhexis edges, posterior capsulotomies, and Elschnig pearls) are also easily observed under IR imaging (Figure 4).

### Surgical Technique

Surgeries were performed by 2 experienced surgeons (C.C.T., F.C.T.) between November 2013 and April 2016. Surgery was performed under peribulbar block with lidocaine 2.0%, and pupil dilation was achieved with atropine 1.0%. The implantation was done with the Viscoject Bio injection system (Medicel AG) using an ophthalmic viscosurgical device (Provisc). A 2.2 mm clear corneal incision was created at the superonasal quadrant in left eyes and the superotemporal quadrant in right eyes. The device was implanted in the ciliary sulcus without a predetermined preference for meridional orientation of the haptics. Miosis was induced with intracameral carbachol to ensure proper centration.

### Primary Outcome Variables

Postoperative examinations were scheduled for 1 day; 1 and 2 weeks; and 1, 3, and 6 months. Additional visits were scheduled every 6 months. Primary outcome variables were manifest refraction, uncorrected distance visual acuity (UDVA), CDVA, and uncorrected (UNVA) and corrected (CNVA) near visual acuities, subjective patient satisfaction, and intraoperative and postoperative adverse events and complications. Centration of the pinhole device was subjectively assessed through slitlamp biomicroscopy in relation to the nondilated pupillary center. Further clinical assessments were performed in a subgroup of patients to evaluate the ability to perform posterior segment examination after implantation. A subjective test was also performed to evaluate induction of the Pulfrich effect by the pinhole device.

### Manifest Refraction and Visual Acuity

Visual acuity and manifest refraction were performed preoperatively and at each follow-up visit. Visual acuity measurements included monocular UDVA and CDVA at a simulated far distance of 20 feet and UNVA and CNVA at 16 inches.

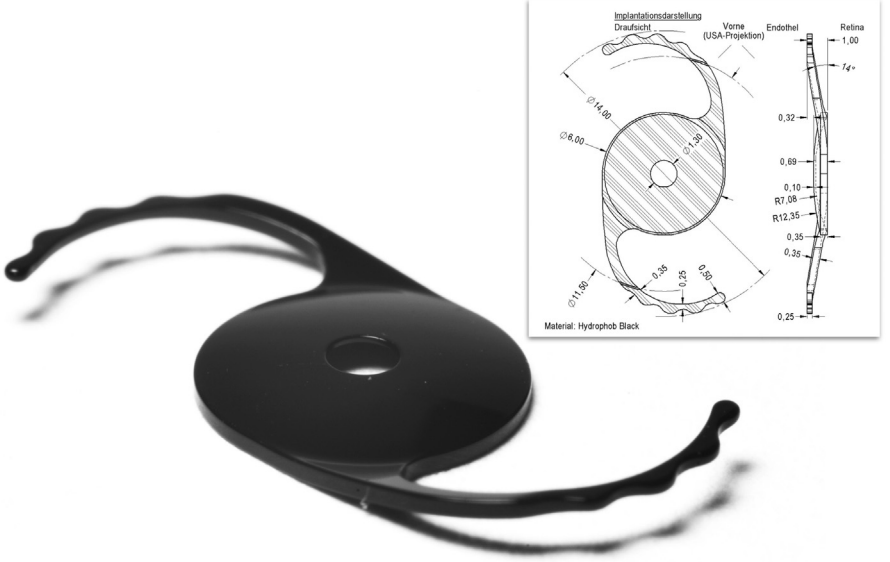


**Figure 1.** The pinhole has specific characteristics for sulcus implantation, such as larger overall diameter, angulated haptics with a thin and rounded profile, and a concave–convex occlusive portion.

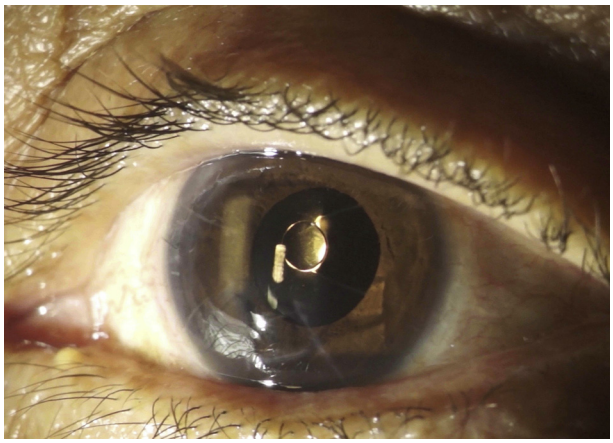

Figure 2. Detail of the pinhole device inside an eye with RK scars. The device aims to minimize the effect of corneal aberrations by reducing the size of the blur circle on the retina.


Figure 3. The black hydrophobic acrylic presents a window of transmission of IR light, enabling fundus examination with IR equipment.

## Patient Satisfaction

A self-administered customized questionnaire with 3 sections was used to evaluate visual performance and satisfaction at the 6-month follow-up. One section assessed visual performance at various distances, asking patients to rate their ability to perform daily activities—watch television, work on a computer, read a book—using a scale from 0 (severe problem) to 10 (no problem). A second section assessed undesirable optical phenomena, including glare and night-vision disturbance, using a scale from 0 (no problem) to 10 (severe problem). The third section determined patients' overall satisfaction with the procedure using a scale from 0 (extremely dissatisfied) to 10 (extremely satisfied). Thus, the best patient ratings would be 10 in the first section, 0 in the second section, and 10 in the third section.

## Fundus Examination

Although fundus examination was not a primary outcome variable, it was performed in a subgroup of 10 patients at the 6-month follow-up to evaluate the feasibility. The examination included indirect ophthalmoscopy with a 20-diopter (D) lens (Volk Optical, Inc.), fundus biomicroscopy with a small panretinal examination lens (Superpupil XL lens, Volk Optical, Inc.), OCT, and IR scanning laser ophthalmoscopy with a Spectralis HRA-OCT (Heidelberg Engineering GmbH). Two lenses were used to acquire wide-field IR images: a scanning laser ophthalmoscope contact retina lens (Staurenghi SLO 230, Ocular Instruments) and a noncontact ultra-wide-field lens (Spectralis, Heidelberg Engineering GmbH).

## Pulfrich Effect

The Pulfrich effect is an optical phenomenon characterized by a distorted perception of object motion induced by an interocular marked difference in retinal luminance. A simple pendulum swinging in a frontoparallel plane was held in front of the patient and the perception of the path evaluated. When this optical phenomenon is present, the path of the pendulum appears as an elliptical movement in depth rather than a lateral movement.

## Data Analysis

Distance visual acuity was recorded in Snellen fraction and converted to logarithm of the minimum angle of resolution (logMAR) notation using the formula

$$\text{logMAR} = -\log(\text{decimal visual acuity})$$

After statistical analysis, the logMAR values were reconverted to the final expression of visual acuity in Snellen notation, using the formula

$$\text{Snellen visual acuity denominator} = 20/\left(10^{-\text{logMAR}}\right)$$

Near visual acuity was recorded in the Jaeger (J) scale and converted to logMAR following a standardized conversion table for

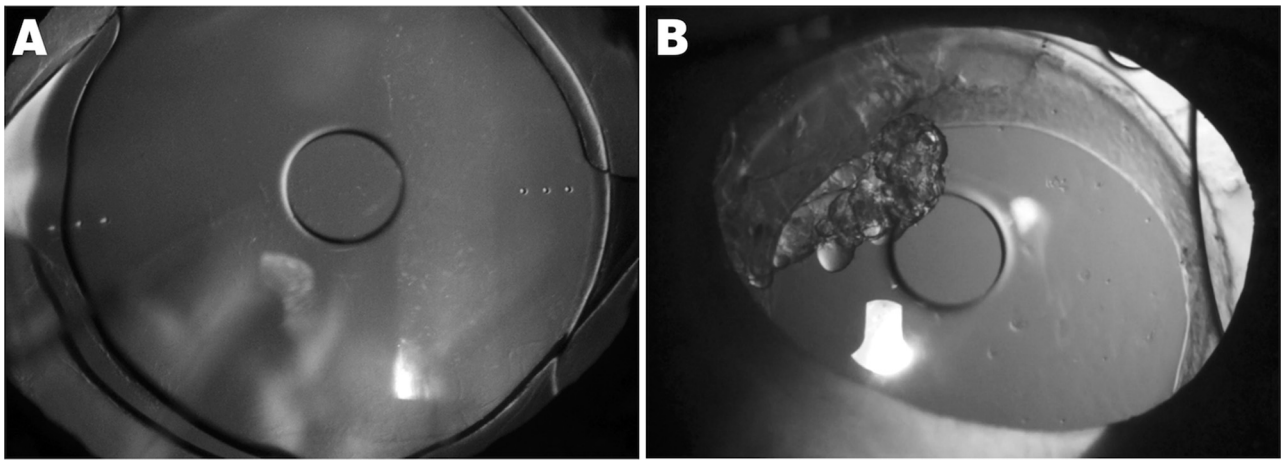


Figure 4. Toric marks (*A*) and Elschnig pearls (*B*) can be seen behind the black device with an IR slitlamp.

**Table 1. Patient demographics.**

| Demographic | Number of Patients (%) |
|---|---|
| Sex | |
| Female | 11 (46) |
| Male | 13 (54) |
| Eye | |
| Right | 14 (58) |
| Left | 10 (42) |
| Source of Irregular Astigmatism | |
| Keratoconus | 8 (33) |
| Post-RK | 8 (33) |
| Post-PKP | 7 (29) |
| Trauma | 1 (4) |
| Mean age (y) | 61.0 ± 12.0 |
| Mean follow-up (mo) | 22.1 ± 9.89 |
| Mean keratometry (D) | 44.18 ± 9.05 |
| Mean pupil size (mm) | 4.37 ± 1.72 |

PKP = penetrating keratoplasty; RK = radial keratotomy

visual acuity measurements.[8] After statistical analysis, logMAR notation was reconverted to the scale using the same table.

Normality was tested and rejected by the Kolmogorov-Smirnov test. Nonparametric variables were compared using the Friedman paired test. Variables were tested by comparing the preoperative data with each postoperative datapoint up to 12 months. Follow-up was limited to 12 months in the statistical analysis to avoid losing data from missing patients at the 18-, 24-, and 36-month points since every patient did not have that long of a follow-up. Multiple comparison analysis was performed to assess the difference between each 2 datapoints. Variables are expressed by their median and minimum and maximum. A $P$ value less than 0.05 was considered statistically significant. When multiple comparisons were made, Bonferroni correction was applied to correct the $\alpha$ error. All analyses were performed with SPSS Statistics software (version 22.0.0.0, IBM Corp.).

## RESULTS

The study cohort included 24 eyes of 21 patients. All patients completed the scheduled postoperative visits. The mean follow-up was 22.1 months (range 7 to 36 months). Table 1 shows the preoperative demographics. One implant had to be recentered. No explantation was performed.

Table 2 shows the visual acuity (UDVA, UNVA, CDVA, and CNVA) before and up to 12 months after implantation of the pinhole device. A significant difference between preoperative and postoperative results was found in the 4 variables.

### Efficacy

The mean spherical equivalent error changed from −0.82 ± 3.02 D preoperatively to −0.57 ± 2.32 D after 6 months ($P$ = .59) and remained statistically stable through the entire follow-up period (Figure 5). There were no statistically significant changes in the spherical and cylindrical components.

Figures 6 to 9 show the UDVA, UNVA, CDVA, and CNVA. They show initial improvement and long-term stabilization of the visual acuity (up to 36 months). Statistical analysis showed a significant increase initially (comparing preoperative and any postoperative period up to 12 months) but no statistically significant differences between postoperative periods.

### Safety and Complications

No implant had to be explanted during the follow-up period. Intraocular inflammation was limited to the first few postoperative days and controlled with the conventional antiinflammatory regimen. Intraocular pressure remained in the normal range in each patient, including the first week postoperatively. Slight variations in centration of the device were observed. In 1 eye, the device had to be recentered 3 weeks after implantation because of the subjective complaint of temporal darkening. Recentration was performed with a 27-gauge bent needle under topical anesthesia and resolved the symptom.

### Patient Satisfaction

**Subjective Visual Performance Score** The median score for performing 3 daily tasks at various distances improved from 4.67 (range 1.33 to 7.33) preoperatively to 8.50 (range 5.00 to 10.00) after 6 months ($P < .001$). Figure 10 shows the improvement in each task.

**Subjective Disturbing Optical Phenomena Score** The median score for the presence of undesirable optical phenomena improved from 5.00 (range 2.00 to 9.00) preoperatively to 2.00 (range 0.00 to 4.50) after 6 months ($P < .001$). One patient (4.2%) reported a minor complaint of dark vision in the operated eye when inside a very dark room. Two patients (8.3%) reported the presence of a faint circular halo around a light source.

**Overall Satisfaction** The median overall satisfaction with the procedure was 8.00 (range 3.00 to 10.00). A score of 8 or above was reported for 13 (54%) of the 24 eyes.

### Fundus Examination

Binocular indirect ophthalmoscopy with a 20.0 D lens was not possible after implantation of the device. Fundus biomicroscopy with a small panretinal examination lens was feasible, enabling stereoscopic examination of the posterior segment. However, the examination is challenging, requiring considerable examiner/patient stabilization and a short working distance (4.0 mm) between the lens and the cornea. The focusing process of macular OCT was time consuming because of the degradation of image quality caused by corneal irregularities and reflective light artifacts. The ultra-wide-field scanning laser ophthalmoscope IR images were of high quality. With the scanning laser ophthalmoscope contact lens, some anatomical details were obscured by reflective artifact from the pinhole device. These artifacts could be reduced by tilting the lens. With the noncontact wide-field lens, image acquisition was easier. Although a smaller number of reflective artifacts from the pinhole device were present, the reflections caused some loss of image quality. With both methods, a similar wide field of view of approximately 150 degrees could be scanned.

### Pulfrich Effect

After being asked to freely describe the movement of a swinging pendulum, all patients reported lateral movement of the bob. There was no spontaneous report of any

**Table 2. Monocular visual acuity.**

| Visual Acuity | Preoperative | Postoperative | | | | *P* Value |
|---|---|---|---|---|---|---|
| | | 1 Mo | 3 Mo | 6 Mo | 12 Mo | |
| UDVA | | | | | | |
| Median | 20/200 | 20/50 | 20/50 | 20/50 | 20/50 | <.001 |
| Range | 20/800, 20/60 | 20/200, 20/20 | 20/150, 20/20 | 20/200, 20/20 | 20/150, 20/20 | — |
| UNVA | | | | | | |
| Median | J7 | J2 | J2 | J2 | J2 | <.001 |
| Range | <J16, J2 | <J16, J1 | <J16, J1 | <J16, J1 | <J16, J1 | — |
| CDVA | | | | | | |
| Median | 20/60 | 20/40 | 20/40 | 20/30 | 20/40 | <.001 |
| Range | 20/400, 20/40 | 20/80, 20/20 | 20/80, 20/20 | 20/100, 20/20 | 20/80, 20/20 | — |
| CNVA | | | | | | |
| Median | J3 | J1 | J1 | J1 | J2 | <.001 |
| Range | J10, J1 | J7, J1 | J7, J1 | J7, J1 | J5, J1 | — |

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity, UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

distortion in the path. However, when asked whether they noticed an elliptical movement, 2 patients (8.3%) provided a positive response.

## DISCUSSION

The benefits of miosis in cases of irregular corneal astigmatism are well known.[4,9] Secondary sulcus piggyback IOL implantation is a common technique to correct unexpected refractive errors after cataract surgery and has a long record of safety.[10,11]

In this prospective study, implantation of the pinhole device in the ciliary sulcus was able to improve all outcome parameters, with statistical significance remaining stable for at least 1 year after surgery. The greatest improvement in visual acuity was observed in 4 cases with concurrent iris defects because of large pupillary areas. In those cases, traditional prosthetic iris devices could alleviate glare and other dysphotopic symptoms. However, the large aperture of these devices limits the improvement in visual acuity, making the pinhole device a more appropriate treatment option.

The subjective refraction data should be evaluated with caution. Because most of the patients had limited visual acuity (because of highly aberrated corneas), preoperative subjective refraction presented a low degree of reproducibility.

Safe implantation of any intraocular implant in the ciliary sulcus requires specific design and material features. Complications have been reported with sulcus implantation; the most significant of these are pigmentary dispersion, glaucoma, hyphema, uveitis, interlenticular opacification (ILO), and vitreous hemorrhage.[12–14] Other undesirable

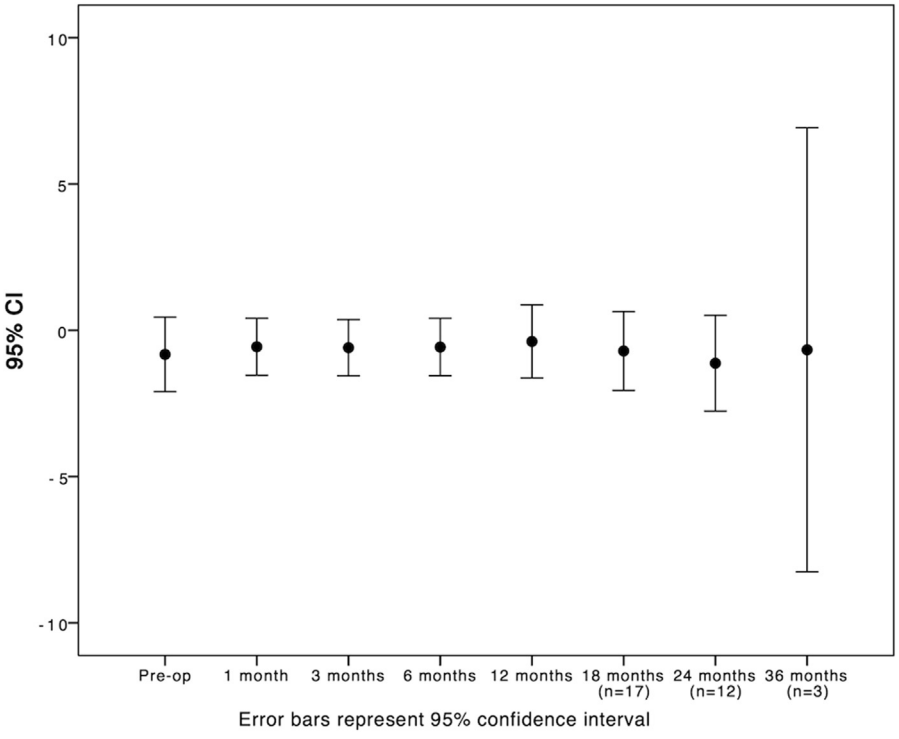


**Figure 5.** The mean spherical equivalent subjective refractive error (CI = confidence interval).

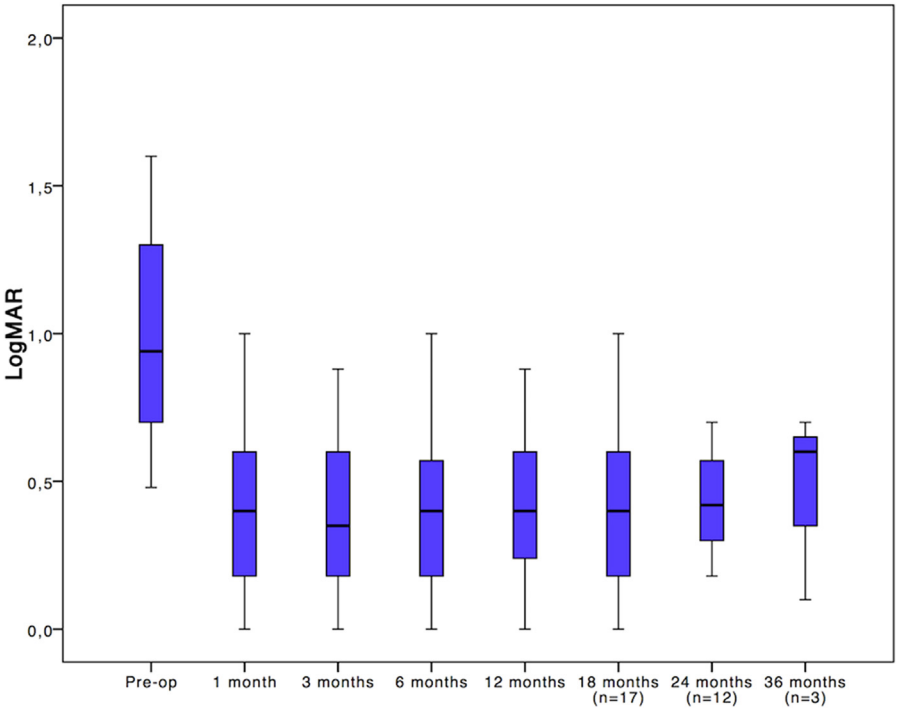


**Figure 6.** Monocular UDVA (LogMAR = logarithm of the minimum angle of resolution).

optical phenomena, such as monocular diplopia and a hyperopic shift, have also been associated with piggyback IOL implantation.[15] The design of the pinhole device has several features that prevent these complications. The haptics have a thin, rounded profile to prevent pigmentary dispersion and damage to the uveal tissue. The overall diameter is slightly larger (14.0 mm) than most IOLs intended for in-the-bag implantation. This prevents decentration of the device because the diameter of the sulcus is larger than the equatorial diameter of the capsular bag (Figure 11).[16] Lateral movement of the device in the sulcus is undesirable because it may chafe the surrounding uveal tissue. Even 3-piece IOLs with poly(methyl methacrylate) haptics have been associated with iris pigment dispersion when implanted in the ciliary sulcus.[17] The cause was contact between the sharp edges of the optic and the posterior surface of the iris, leading to transillumination defects. To prevent this complication, this pinhole device has a

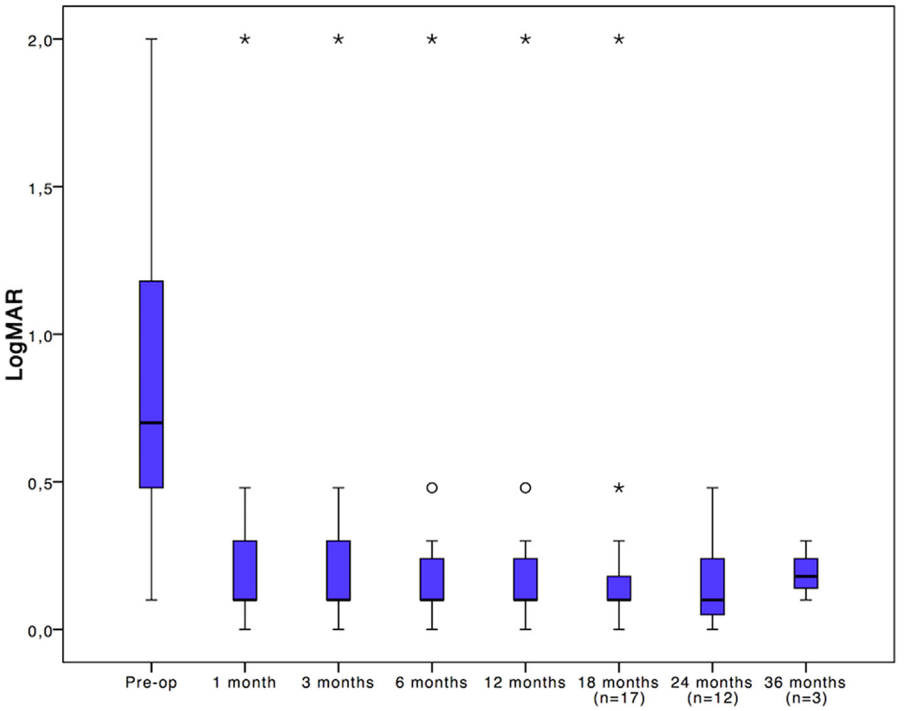


**Figure 7.** Monocular UNVA (LogMAR = logarithm of the minimum angle of resolution).

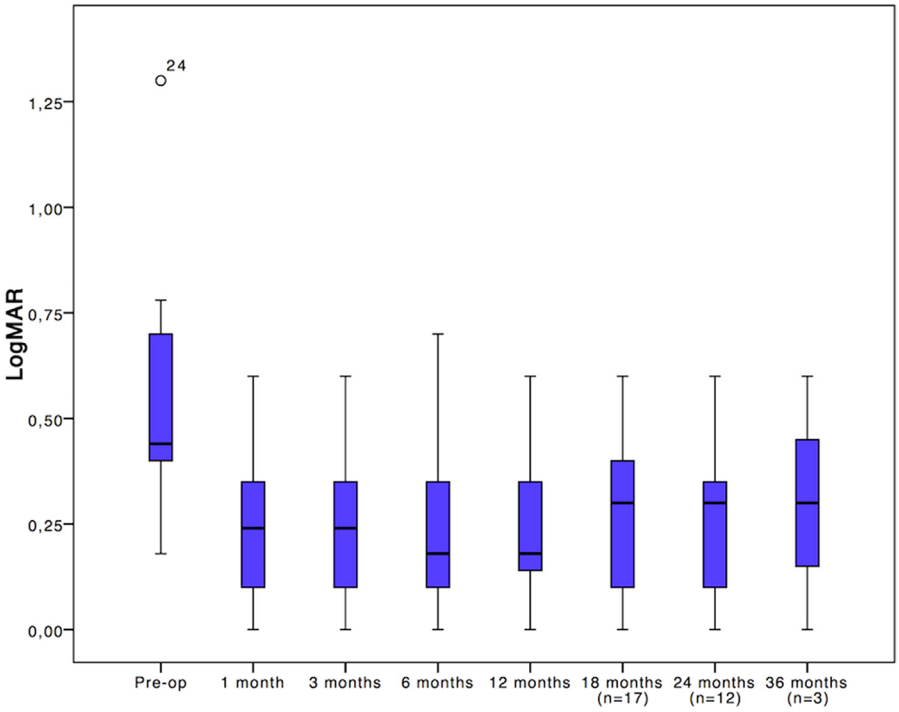


**Figure 8.** Monocular CDVA (with spectacles) (LogMAR = logarithm of the minimum angle of resolution).

well-polished and rounded optic edge and 14-degree angulation of the haptics (Figure 12).

Some studies of cadaver eyes have attempted to determine the actual size of the ciliary sulcus. Apple et al.[18] estimated the sulcus to be approximately 11.0 mm ± 0.5 (SD), and Davis et al.[19] reported 11.32 ± 0.29 mm and 11.00 ± 0.37 mm for the vertical axis and horizontal axis, respectively. Assia et al.[20] reported the average diameter of the ciliary sulcus to be 11.10 mm. Blum et al.[21] reported age-related anatomical variations of the sulcus, with a tendency toward progressive shrinkage of the sulcus and ovalization of the ciliary processes. Studies using ultrasound biomicroscopy (UBM) report slightly larger sulcus diameters.[16,22] The difference between the 2 methods of measurement was probably because of the tissue shrinkage observed during formalin fixation of postmortem eyes. Because of the anatomical variations, it is helpful to perform UBM measurements of the sulcus-to-sulcus diameter in

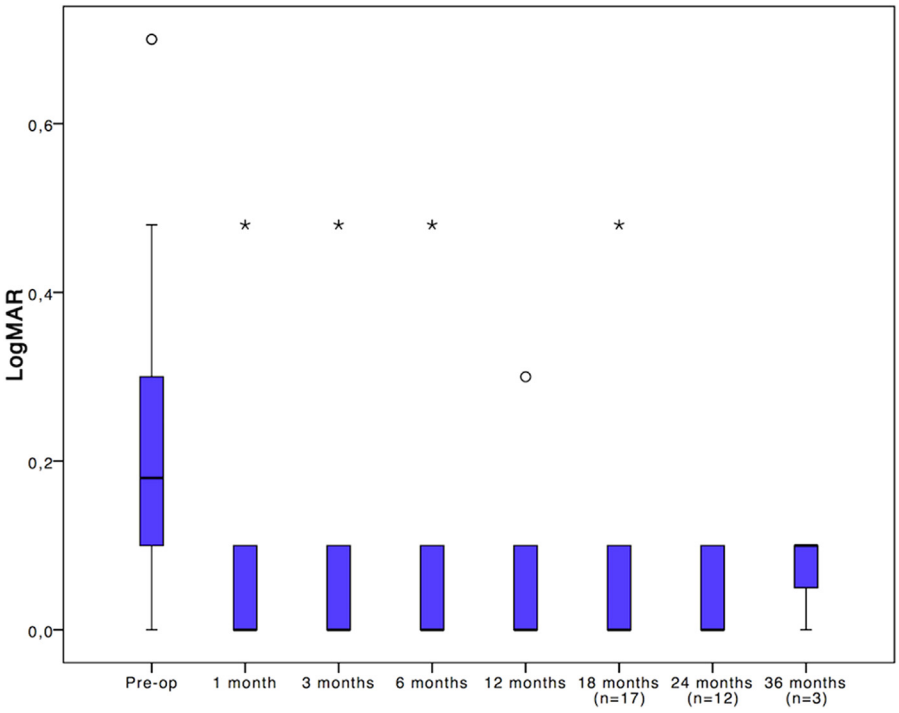


**Figure 9.** Monocular CNVA (with spectacles) (LogMAR = logarithm of the minimum angle of resolution).

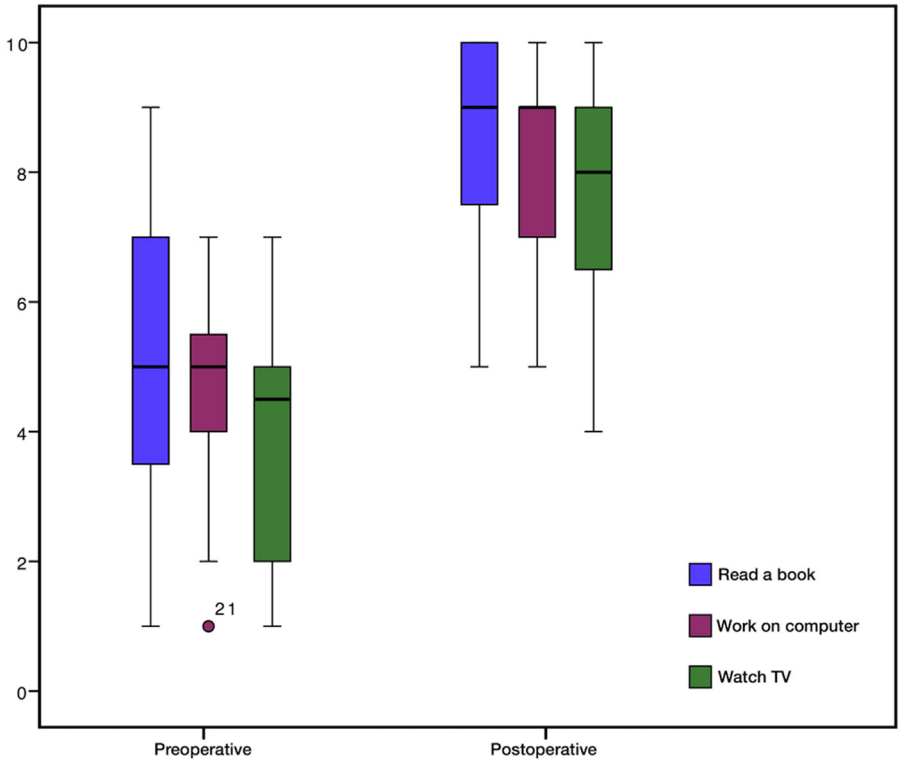


**Figure 10.** Subjective visual performance evaluation showed improvement in different working distances.

different meridians. This information can then be used to select the optimal haptic orientation.

The 6.0 mm occlusive portion of the device, which includes the central 1.3 mm pinhole, can cover the entire optic of most IOL designs. To prevent contact between the device and the underlying IOL, with consequent flattening of the optic and hyperopic shift, the occlusive portion has a concave–convex design. This design also prevents ILO, a condition associated with contact of multiple IOLs.[23]

Because the entrance of light into the eye is reduced by the pinhole device, it was expected that patients would complain of reduced visual acuity under low-light conditions. However, only 1 patient (4.2%) reported this, with a minor impact on daily activities. Our explanation for this unexpected tolerance to low light is the Stiles-Crawford effect. This principle[24] states that the pupil luminance is not proportional to the pupillary area. Therefore, to match the apparent brightness of light entering through a 30.0 $mm^2$ pupil, the luminance of light entering through a 10.0 $mm^2$ pupil must be increased by a factor of 2, instead of the expected factor of 3. Ultimately, dilated pupils achieve a lower degree of visual response per unit of light energy than contracted pupils.

One important consideration when using small-aperture optics is the effect on the visual field. In this study, we did not perform perimetric tests because all the patients had limited preoperative visual acuity, which would have

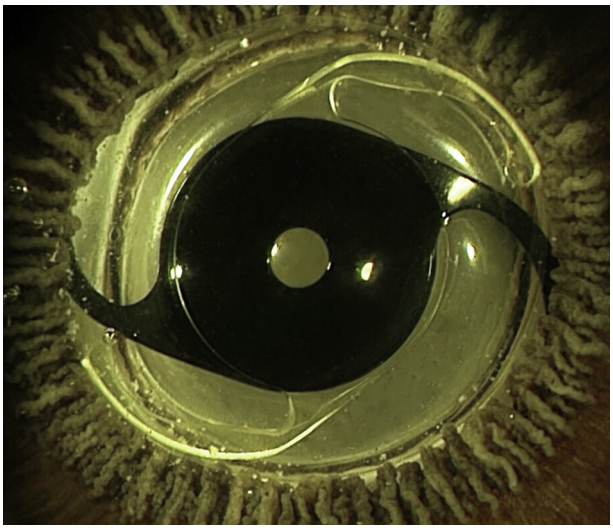

**Figure 11.** Miyake-Apple view of the pinhole implant in the ciliary sulcus of a cadaver eye shows proper centration.

**Figure 12.** Comparison of the pinhole device and a 1-piece acrylic IOL. The pinhole device has thin, polished, and angulated haptics and a larger overall diameter.

compromised the reliability of the subjective perimetric tests. In a study of a small-aperture corneal inlay for presbyopia correction, Seyeddain et al.[25] reported a reduction in the mean deviation from 0.50 ± 1.03 dB preoperatively to 0.46 ± 1.10 dB after 36 months ($P < .0001$). The mean pattern SD was 1.39 ± 0.18 dB preoperatively and 1.41 ± 0.26 dB after 36 months ($P = .0003$). None of the changes were clinically significant, which is in agreement with our findings. In our study, only 1 patient, who presented with relevant temporal decentration of the device, reported the disturbing presence of a dark crescent in the temporal field of view. The symptom resolved after the device was surgically repositioned.

We believe the position of the pinhole device in the ciliary sulcus near the iris plane (and the eye's nodal point) is more physiological, with less impact on the visual field, than the position of the corneal inlay.

The small pinhole hinders fundus examination after implantation. Binocular indirect ophthalmoscopy is not feasible, and fundus biomicroscopy is dependent on the accessory lens with particular small-pupil capabilities. However, the black material of the device has a unique feature that facilitates a distinct imaging method for examination of the retina. Light spectroscopy shows a sudden increase in light transmittance through the device's material in the near IR spectrum (Figure 13). Therefore, IR examination of the posterior segment is feasible with IR-based imaging equipment such as OCTs and scanning laser ophthalmoscopes.[26] With special lenses (a scanning laser ophthalmoscope contact lens or a noncontact ultra-wide-field lens), the field of view can be expanded to 150 degrees.[27] A noncontact lens minimizes light reflection artifacts, which are more intense in a contact lens system. Although studies have suggested that the scanning laser ophthalmoscope contact lens is well tolerated for retinal imaging,[28] use of this lens requires local anesthetic instillation and has a higher risk for discomfort and corneal injuries. Because of these limitations, we suggest the use of the ultra-wide-field noncontact lens for wide-field IR imaging. However, this gives only a 2-dimensional view of the posterior segment and the field of view is not as wide as in regular indirect ophthalmoscopy. Therefore, it is mandatory to perform a thorough posterior segment examination, including binocular indirect ophthalmoscopy with scleral indentation, before implantation of the device.

Any retinal pathology should be treated before implantation and risk factors for retinal disease (especially those conditions that affect the peripheral retina) should be considered in the preoperative evaluation. If any vitreoretinal treatment is needed after implantation, the device would have to be explanted. The near IR window of transmittance observed in the pinhole device might extend the possibility of development of an IR indirect ophthalmoscope, which would provide a stereoscopic view of the posterior segment with a wider field of view.

The Pulfrich effect is an optical phenomenon caused by interocular differences in retinal luminance. Its best-known effect is the way it distorts the apparent path of a simple swinging pendulum so the pendulum bob appears to follow an elliptical path in depth rather than a lateral path. In theory, patients who experience this effect may have difficulties during activities involving moving objects, such as driving.[29] Clinically, it has been described in cases of unilateral cataract and in cases of marked anisocoria.[30] In our study, there was no report of this phenomenon. We believe that the interocular difference in retinal luminance induced by the pinhole device was not high enough to produce the effect. Another possible explanation is that the effect requires a minimal level of optical quality to occur, which was not reached by our patients (because of the high levels of corneal aberrations).

One important advantage of a piggyback approach is reversibility, as the device can be easily explanted, if needed. However, caution is necessary because sulcus–haptic contact may lead to the formation of uveal bridges and excessive traction of those adherent areas may cause bleeding in case of explantation.

In conclusion, the Xtrafocus pinhole device is an alternative for the treatment of challenging cases of irregular corneal astigmatism. In this study, the device performed well in patients with irregular astigmatism caused by keratoconus, RK, PKP, and traumatic corneal laceration. Although the device is indicated for cases of normal iris anatomy, patients with irregular corneal astigmatism and concurrent iris defect, and thus with a large pupillary area, are especially suitable for this approach. There was a marked improvement in visual function, with high patient satisfaction. Despite the expected reduction in the light entrance, the apparent brightness perceived by the patients was not proportionally impaired. A longer follow-up is necessary to evaluate long-term performance and continued patient satisfaction.

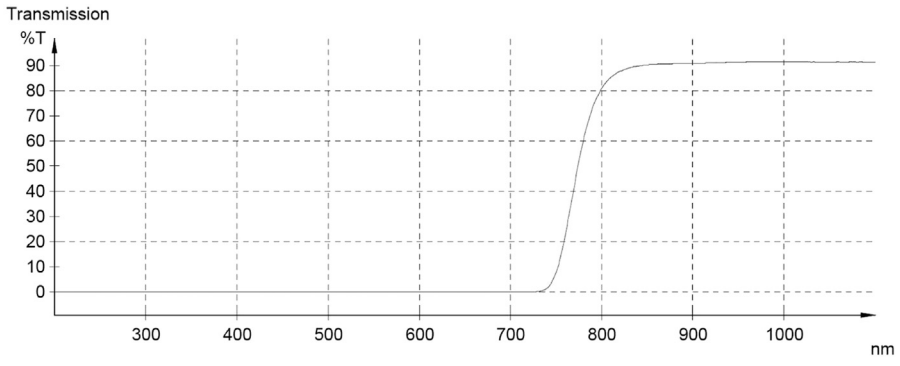


**Figure 13.** Spectroscopic analysis shows a window of transmittance in the near IR portion of the light spectrum.

### WHAT WAS KNOWN

- A small pupil diameter yields better visual acuity in cases of irregular corneal astigmatism.

### WHAT THIS PAPER ADDS

- Implantation of the sulcus pinhole device in a piggyback configuration is a new treatment option for irregular corneal astigmatism and other higher-order aberrations.
- The black occlusive material of the device showed a window of transmittance of IR light, enabling examination of structures behind the device, including the retina.

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