Change in pupil size after implantation of an iris-fixated toric phakic intraocular lens

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Purpose: To evaluate the changes in pupil size after implantation of an iris-supported toric phakic intraocular lens (TPIOL) for correction of myopia and hyperopia with astigmatism.

Setting: Department of Ophthalmology, Johannes Gutenberg-University, Mainz, Germany.

Methods: Twenty-two myopic eyes and 9 hyperopic eyes were included in the study. The mean age of the 2 groups was 34 years and 40 years, respectively. The scotopic pupil size was measured with a handheld infrared pupillometer (Colvard, Oasis Medical) before and 6 months after implantation of the TPIOL. All examinations were performed under scotopic conditions after 2 minutes of dark adaptation with the fellow eye covered. Intraindividual comparisons were made between preoperative and postoperative pupil sizes. The relationship between implanted IOL power and postoperative pupil width in each group was studied to determine whether lens magnification could lead to misinterpretation of the results. The difference between horizontal and vertical postoperative pupil diameters was assessed in eyes with horizontally aligned IOLs to determine the potential mechanical effect of the TPIOL on pupil size.

Results: The mean scotopic pupil diameter decreased significantly from 4.7 mm (range 3.0 to 6.0 mm) preoperatively to 3.6 mm (range 2.0 to 5.0 mm) postoperatively in myopic eyes and from 5.0 mm (range 4.0 to 6.0 mm) to 4.0 mm (range 2.0 to 5.0 mm) in hyperopic eyes. No significant correlation between the power of the TPIOL and the postoperative pupil size diameter was found, confirming that the IOL did not distort measurements of pupil size. Comparing horizontal and vertical pupil diameters under medical mydriasis revealed reduced pupil size in the axis of enclavation.

Conclusions: The scotopic pupil diameter decreased by a mean of 1.1 mm in myopic eyes and 1.0 mm in hyperopic eyes after implantation of the iris-supported TPIOL. Postoperative pupil size was not related to IOL power, patients' emotional states, or other factors. The slightly smaller pupil diameter in the axis of enclavation suggests that this fixation method restricts pupil size under scotopic conditions, which could reduce the incidence of postoperative photic phenomena.

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Iris-supported toric phakic intraocular lenses (TPIOLs) offer a promising alternative to other types of refractive surgery for the treatment of severe ametropia and astigmatism.[1] Although reports of the benefits, adverse effects, and complications of these IOLs exist, no objective data on the changes in pupil size after IOL implantation have been published. The issue of pupil size is important because postoperative photic phenomena such as halos, starbursts, and glare can be provoked if the scotopic pupil diameter exceeds the optical zone of the IOL.[2,3] These side effects limit the outcomes of refractive lens surgery and make the problem clinically relevant.

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The fixation method of iris-supported TPIOLs involves enclavation of 2 diametrically opposite haptics on midperipheral iris stroma, which may affect iris mobility and thereby alter the pupil diameter. This could prevent excessive pupil dilation under scotopic conditions and avoid photic phenomena.

This study evaluated pupil size before and after insertion of a TPIOL and examined the influence of this fixation method on pupil size.

Patients and Methods

Patient Selection

Consecutive patients at the Department of Ophthalmology, Johannes Gutenberg-University, Mainz, Germany, were prospectively enrolled and implanted with the Verisyse TPIOL (Advanced Medical Optics) by the same surgeon between February 2000 and September 2001. The biomaterial of this 1-piece, compression-molded TPIOL consists of poly(methyl methacrylate). The optic diameter is 5.0 mm and the overall length, 8.5 mm. Total height values did not exceed 1.04 mm. The 2 diametrically opposed haptics fixated the IOL on the iris by needle enclavation of midperipheral iris stroma. Key exclusion criteria included iris abnormalities and systemic diseases that might affect pupil function.

Before surgery, patients were prepared as for standard cataract surgery but with the addition of miotic drops (pilocarpine 1%) on the day of surgery to prepare the iris for IOL fixation, reduce the risk for IOL touch during implantation, and facilitate centration of the IOL. The enclavation sites on the iris were not marked with an argon laser before surgery. Surgery was performed under general anesthesia.

Postoperative treatment consisted of topical prednisolone-21-acetate (Inflanefran forte) 3 times daily for 2 weeks, topical prednisolone-21-pivalate ointment (Ultracortenol) once daily for 2 weeks, and topical gentamicin (Gentamicin-POS) 3 times daily for 5 days. No postoperative pupil dilation was performed.

The research protocol followed the tenets of the Helsinki Declaration and was approved by the local ethics committee.

Surgical Procedure

Pupil measurements were performed 2 weeks preoperatively and 6 months postoperatively using the Colvard pupillometer (Oasis Medical). This handheld device allows pupil size to be evaluated in refractive surgery patients in an office setting. The device uses light-amplification technology: Low levels of light energy stimulate a photo cathode, and provoked electron excitation strikes a phosphor screen, which intensifies the image of the anterior segment. The patient is asked to fixate on a red light; by moving the pupillometer slightly forward and backward, the image of the iris and pupil is brought into sharper focus. The examiner measures the pupil size using a millimeter ruler that is superimposed on the enhanced image of the anterior segment by a reticule in the device.

All examinations were conducted by 1 examiner under scotopic conditions after 2 minutes of dark adaptation with the fellow eye covered. The claw orientation of the phakic IOL was used for the ruler. After 3 consecutive measurements, the mean value was calculated and used for statistical analysis.

All eyes were photographed at 6 months after topical medical mydriasis (phenylephrine [Neosynephrin-POS] and tropicamide [Mydriaticum Stulln]) at retroillumination using slitlamp photography as well as the Scheimpflug system (SL-45 Scheimpflug camera, Topcon). Pupil diameter along the enclavation axis and perpendicular to enclavation (vertically) was measured using the photographs. The Scheimpflug principle allows precise evaluation of the anterior chamber to measure the distance between the IOL and the iris.[4]

Statistical Analysis

Descriptive analysis was based on overall and subgroup-stratified medians, quartiles, means, and standard deviations. Graphics were created based on nonparametric box plots. Intraindividual comparison of preoperative and postoperative time points was based on intraindividual differences; the statistical significance of postoperative changes was assessed by pairwise sign tests. Numerical analyses were done using SAS software (SAS Institute, Inc.), and graphs were generated using SPSS (release 7.5 for Windows, SPSS Inc.). A P value of 0.05 or less was considered an indicator of local statistical significance. Box plots were used for graphic presentation of data.

Results

The demographic and preoperative refractive characteristics of the 22 myopic eyes and 9 hyperopic eyes with astigmatic refractive errors are shown in Tables 1 and 2. The postoperative follow-up was 6 months. No intraoperative or postoperative complications were observed during the study. No eye had a window defect or detectable alterations of the iris. At 1 month, 7 eyes showed slight disturbances of pigment epithelium, with varying degrees of pigment deposition on the implanted TPIOL.

In myopic eyes, the mean scotopic pupil diameter decreased significantly from 4.7 mm preoperatively (range 3.0 to 6.0 mm) to 3.6 mm postoperatively (range 2.0 to 5.0 mm) ($P<.0001$) (Figure 1). In hyperopic

Table 1. Patient demographics.

Demographic	Myopic Group	Hyperopic Group
Eyes (number)	22	9
Sex (number)		
Male	13	3
Female	9	6
Mean age (y)	34	40
Age range (y)	32–49	21–47

eyes, it decreased significantly from 5.0 mm preoperatively (range 4.0 to 6.0 mm) to 4.0 mm postoperatively (range 2.0 to 5.0 mm) ($P<.05$) (Figure 2). The intraindividual changes in scotopic pupil size after TPIOL implantation in myopic and hyperopic eyes are shown in Figures 3 and 4, respectively. In myopic eyes, the mean pupil diameter decrease was 1.1 mm (range 2.0 to 1.0 mm) ($P<.05$). In hyperopic eyes, it was 1.0 mm (range 2.0 to 0.0 mm). Although the mean decrease was similar in both groups, the outliers' values were greater in myopic eyes.

There was no statistically significant correlation between postoperative scotopic pupil diameter and IOL power in myopic eyes ($P = .67$) or hyperopic eyes ($P = .70$). There was no statistically significant correlation between the preoperative pupil size and the quantity of change in pupil diameter ($P = .74$).

Computerized evaluation of differences between horizontal and vertical pupil diameters is presented in Figure 5. The comparison was performed under photic conditions and after topical medical mydriasis in eyes with horizontally aligned IOLs. Under photic conditions, horizontal and vertical pupil diameters were not significantly different. After pupil dilation, the vertical diameter was statistically significantly greater than the horizontal diameter ($P<.001$) (Figure 6).

Table 2. Preoperative refractive status.

	Myopic Group		Hyperopic Group	
Refraction	Mean ± SD (D)	Range (D)	Mean ± SD (D)	Range (D)
Spherical equivalent	9.1 ± 4.9	21.25–2.50	3.8 ± 1.50	1.50–6.25
Sphere	7.5 ± 4.9	19.00–0.50	5.5 ± 1.50	3.25–8.00
Cylinder	3.6 ± 1.1	5.50–1.75	3.5 ± 0.75	4.25–2.00

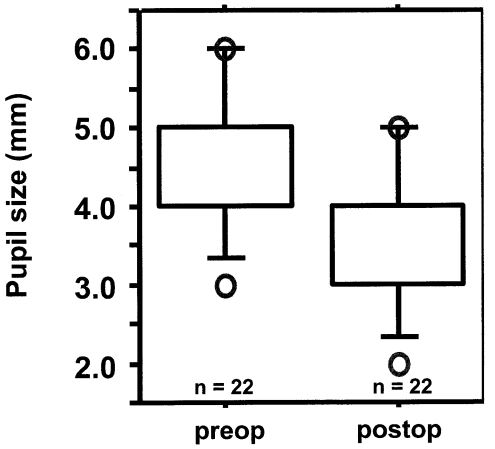

Figure 1. Box plots of pupil size in myopic eyes before (median 5.0 mm) and 6 months after (median 3.0 mm) implantation of a TPIOL (horizontal lines = medians and 1st/3rd quartiles; vertical lines = minimum/maximum; circles = outlier values). The difference in pupil size was significant ($P<.0001$).

The Scheimpflug photographs showed no evident distance between the TPIOL and the iris.

Discussion

The precise measurement of scotopic and mesopic pupil diameters has become an essential part of preoperative evaluation and an important criterion of suitability for refractive surgery.[5] If pupil size exceeds the optical zone diameter, higher-order aberrations could be markedly increased.[3] Glare phenomena, halos, and poor contrast sensitivity, frequently observed postoperatively in scotopic conditions, render night vision extremely difficult for some patients. Modern

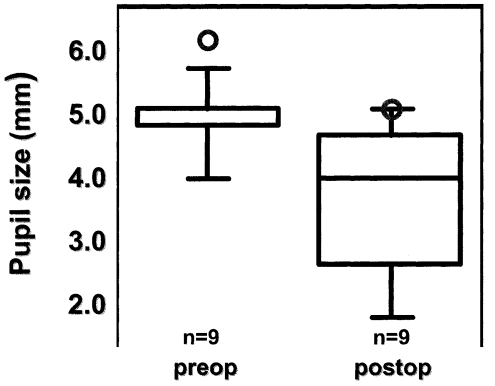

Figure 2. Box plots of pupil size in hyperopic eyes before (median 5.0 mm) and 6 months after (median 4.0 mm) implantation of a TPIOL (horizontal lines = medians and 1st/3rd quartiles; vertical lines = minimum/maximum; circles = outlier values).

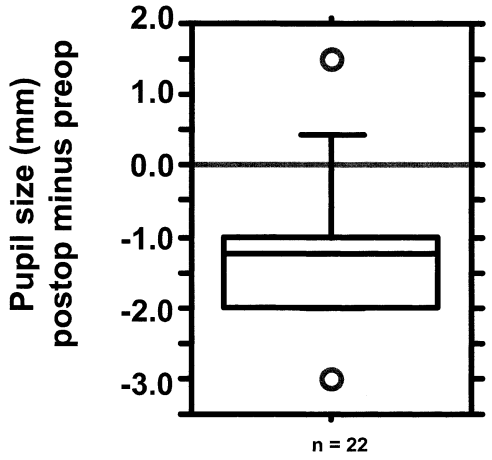

Figure 3. Box plots of intraindividual changes in pupil diameter in myopic eyes.

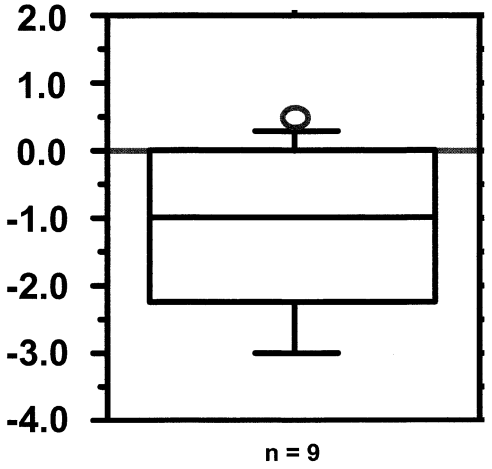

Figure 4. Box plots of intraindividual changes in pupil diameter in hyperopic eyes.

keratorefractive procedures aim to adjust the postoperative optical zone to the scotopic pupil diameter to preclude these undesirable adverse events.[6,7] In IOL surgery, this practice is limited by the TPIOL optic size of 5.0 mm. Patients whose pupils enlarge beyond this in dim-light conditions may be subject to photic symptoms.

The attachment method of iris-fixated TPIOLs may restrict the range of pupil dilation. To better understand this potential mechanical effect, we took preoperative and postoperative measurements of pupil diameters. To our knowledge, this is the first data on pupil size changes after implantation of an iris-fixated TPIOL.

Our results revealed a decrease in pupil size after TPIOL implantation. The changes were similar in the myopic and hyperopic groups. The mean postoperative pupil diameter in myopic eyes was 1.1 mm smaller than preoperatively. In hyperopic eyes, it was 1.0 mm smaller.

Keuch and Bleckmann[8] report an unexpected decrease in pupil diameter 2 weeks after implantation of a phakic posterior chamber implantable contact lens (ICL). They suggest that the anterior vault design of the ICL may play a role in mechanical irritation of pupil constriction and redilation, thus explaining the results.

To confirm our hypothesis of a potential mechanical effect of iris-supported IOLs on pupil changes, we first tried to exclude other possible causes of pupil size reduction. The influence of the patient's emotional state on measurement outcomes was excluded since all

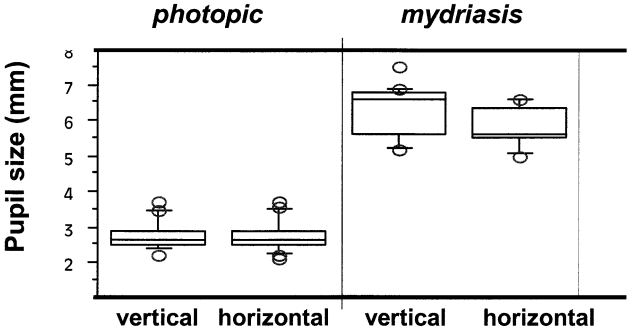

Figure 5. Comparison of horizontal and vertical pupil diameters under photopic conditions and under topical medical mydriasis 6 months after TPIOL implantation.

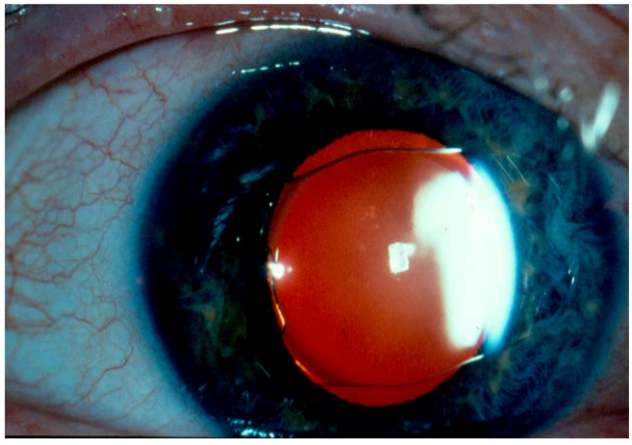

Figure 6. Photograph of an eye implanted with a TPIOL under medical mydriasis. The pupil diameter is greater vertically than horizontally.

examinations were performed 2 weeks before and 6 months after surgery. The sympathetic activity of patients at these times was considered within normal limits.

We were aware that the position of the phakic IOL in the anterior chamber may induce optical effects and lead to miscalculation of pupil size. Therefore, photographic documentation of all eyes implanted with the TPIOL was performed using retroillumination and Scheimpflug photography after topical mydriasis. Image analysis revealed no evident distance between the refractive IOL and the iris, indicating that the pupil as an optic object is very close to the inserted IOL. Magnification power reduces as the distance between object and IOL reduces, and we therefore considered it unlikely that the phakic IOL would lead to inaccurate pupil size measurements. To confirm this assumption, we compared postoperative change in the scotopic pupil size in myopic and hyperopic eyes. Assuming the different powers of implanted diverging and converging IOLs, there should be a notable difference in postsurgical pupil diameter between the groups. Our results showed no statistically significant difference. Therefore, the TPIOLs did not distort measurement of the pupil or cause misinterpretation of the data.

Chronic inflammation and atrophic iris changes are known to induce pupil deformation.[9,10] After anterior chamber IOL implantation in phakic eyes, an intense and chronic traction of the haptic at the midperipheral iris might induce ischemic or inflammatory changes with consecutive iris retraction and pupil ovalization. The mechanical fixation of iris-fixated IOLs usually does not predict compression or traction on the iris root. As for postsurgical inflammatory complications, Pérez-Santonja et al.[11] report a subclinical inflammation between 1 year and 2 years after iris-claw IOL implantation. We did not observe this inflammation in our patients; however, laser flare measurements were not performed. There were no signs of pupil reaction alterations. Pupil size was reduced (compared with preoperative pupil size) only under scotopic conditions or medical mydriasis.

We performed a computerized evaluation using photographs to compare horizontal and vertical pupil diameters with and without pharmacologic dilation. We enrolled only eyes with horizontal alignment of the torus axis to determine whether fixation plane influences pupil size changes. The scotopic pupil diameter was smaller in the enclavation axis after surgery, suggesting the iris-fixated TPIOL mechanically restricts pupil size changes under low-light conditions.

Koch et al.[12] found that pupil size after phacoemulsification can be changed by surgery alone, independent of the attachment of the IOL. In their study, pupil size got both smaller and larger.[12]

The smaller postoperative pupil size can be regarded as a side effect with unknown clinical relevance. Vitreoretinal procedures as well as postoperative ophthalmoscopy of the peripheral posterior segment of the eye might be complicated by a smaller postoperative pupil. The 6-month follow-up was short, and the pupil size might change over a longer period of time.

Conclusions

Although pupil size seems to be much less critical in keratorefractive surgery than previously supposed,[13–15] in phakic IOL implantation, smaller optical diameters coupled with larger pupil size seems to be a dominant factor in night-vision disability. Because pupil size after phakic IOL implantation seems to play a more crucial role in these adverse events,[16] the significant reduction in pupil size 6 months after iris-claw phakic IOL implantation under low-light conditions may help reduce postoperative mesopic phenomena.

References

1. Dick HB, Alió J, Bianchetti M, et al. Toric phakic intraocular lens; European multicenter study. Ophthalmology 2003; 110:150–162
2. Rosen E, Gore C. Staar Collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia. J Cataract Refract Surg 1998; 24:596–606
3. Schmitz S, Krummenauer F, Henn S, Dick HB. Comparison of three different technologies for pupil diameter measurement. Graefes Arch Clin Exp Ophthalmol 2003; 241:472–477
4. Wegener A, Laser H. Optische Schnittbild-Vermessung des vorderen Augenabschnittes nach Scheimpflug: Möglichkeiten und Grenzen—und Übersicht. Klin Monatsbl Augenheilkd 2001; 218:67–77
5. Colvard M. Preoperative measurement of scotopic pupil dilation using an office pupillometer. J Cataract Refract Surg 1998; 24:1594–1597
6. O'Brart DPS, Corbett MC, Lohmann CP, et al. The effects of ablation diameter on the outcome of excimer laser photorefractive keratectomy; a prospective,

randomized, double-blind study. Arch Ophthalmol 1995; 113:438–443
7. Nixon WS. Pupil size in refractive surgery [letter]. J Cataract Refract Surg 1997; 23:1435–1436
8. Keuch RJ, Bleckmann H. Pupil diameter changes and reaction after posterior chamber phakic intraocular lens implantation. J Cataract Refract Surg 2002; 28:2170–2172
9. Pérez-Santonja JJ, Alió JL, Jiménez-Alfaro I, Zato MA. Surgical correction of severe myopia with an angle-supported phakic intraocular lens. J Cataract Refract Surg 2000; 26:1288–1302
10. Alió JL, de la Hoz F, Pérez-Santonja JJ, et al. Phakic anterior chamber lenses for the correction of myopia; a 7-year cumulative analysis of complications in 263 cases. Ophthalmology 1999; 106:458–466
11. Pérez-Santonja JJ, Iradier MT, Benítez del Castillo JM, et al. Chronic subclinical inflammation in phakic eyes with intraocular lenses to correct myopia. J Cataract Refract Surg 1996; 22:183–187
12. Koch DD, Samuelson SW, Villarreal VR, et al. Changes in pupil size induced by phacoemulsification and posterior chamber lens implantation: consequences for multifocal lenses. J Cataract Refract Surg 1996; 22:579–584
13. Pop M, Payette Y. Risk factors for night vision complaints after LASIK for myopia. Ophthalmology 2004; 111:3–10
14. Lee Y-C, Hu F-R, Wang I-J. Quality of vision after laser in situ keratomileusis; influence of dioptric correction and pupil size on visual function. J Cataract Refract Surg 2003; 29:769–777
15. Haw WW, Manche EE. Effect of preoperative pupil measurements on glare, halos, and visual function after photoastigmatic refractive keratectomy. J Cataract Refract Surg 2001; 27:907–916
16. Aslam TM, Dhillon B. Principles of pseudophakic photic phenomena. Ophthalmologica 2004; 218:4–13

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