Evaluation of Pupil Dynamics After Implantation of Artisan Phakic Intraocular Lenses

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ABSTRACT

PURPOSE: To compare pre- and postoperative horizontal and vertical pupil diameters after horizontal Artisan phakic intraocular lens (PIOL) (Ophtec BV, Groningen, The Netherlands) implantation for correction of myopia.

METHODS: The pre- and postoperative scotopic pupil diameters measured by the Colvard pupillometer (Oasis Medical, Glendora, Calif) were compared in 71 eyes after Artisan PIOL implantation (Artisan Colvard group). Analysis of pupil shape (vertical vs horizontal diameter, V/H ratio) after horizontal Artisan PIOL implantation was performed with the Procyon pupillometer (Procyon Instruments Ltd, London, United Kingdom) in 121 eyes (Artisan Procyon group) under scotopic, mesopic-low, and mesopic-high conditions and compared to an age- and refraction-matched control group of 121 eyes of refractive surgery candidates (Procyon control group).

RESULTS: After horizontal Artisan PIOL implantation, the mean horizontal pupil diameter decreased from 6.23±0.70 mm preoperatively to 5.34±0.68 mm postoperatively in the Artisan Colvard group ($P<.01$). The mean horizontal scotopic diameter was 5.60±0.66 mm, the mesopic-low diameter was 4.94±0.71 mm, and the mesopic-high diameter was 3.98±0.54 mm for the Artisan Procyon group. The mean horizontal scotopic diameter was 6.29±0.91 mm, the mesopic-low diameter was 5.40±0.96 mm, and the mesopic-high diameter was 4.16±0.80 mm in the Procyon control group. A significant increase was noted in V/H ratio under scotopic, mesopic-low, and mesopic-high conditions from 1.02, 1.02, and 1.01, respectively, in the Procyon control group to 1.17, 1.12, and 1.06, respectively, in the Artisan Procyon group ($P<.01$).

CONCLUSIONS: Horizontal pupil size was significantly decreased after horizontal Artisan PIOL implantation and might be attributed to a mechanical restriction of the iris in the horizontal meridian. [*J Refract Surg*. 2006;22:367-371.]

Pupil size as an influential factor for the development of night vision complaints including halos, starbursts, and glare after corneal refractive surgery has been a recent topic of debate.[1] Although many authors suggest that a disparity between the pupil size measured under dim light conditions and the optical zone size of the laser ablation or the phakic intraocular lens (PIOL)[2] may be responsible for subjective night vision complaints, recent reports argue the role of pupil size in the pathophysiology of night vision complaints.[3-7] Implantation of Artisan myopia PIOLs (Ophtec BV, Groningen, The Netherlands) has proved to be a successful method for correction of moderate to high myopia over recent years.[8-13] Changes in pupil size, such as pupil ovalization after anterior chamber angle supported lens implantation, have not been described after implantation of the Artisan iris-fixated PIOL.[2,14] Recently, a change in pupil size has been described after iris-fixated toric PIOL implantation.[15] However, the effect of the Artisan iris-fixated PIOL on the pupil dynamics has not been evaluated.

Methods for measuring pupil size have included the use of pupil charts, photo cameras, and more recently, digital and handheld infrared pupillometers.[16-20] To study potential correlations between pupil size and night vision complaints, the measurement of the pupil size should reflect real-time situations and should be performed under standardized illumination conditions. The two most popular instruments for measuring pupil size under dim light conditions are currently the Colvard pupillometer (Oasis Medical, Glendora, Calif) and the Procyon pupillometer (Procyon Instruments Ltd, London, United Kingdom).[17,19,20] Measurements with the Colvard pu-

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pillometer are monocular and subject to fluctuations in room illumination whereas measurements with the Procyon pupillometer are binocular and the levels of illumination are prefixed and standardized. Therefore, Procyon pupillometer measurements may reflect true-life conditions (eg, driving at night) more realistically.[21]

The purpose of this study was to evaluate the effect of horizontal implantation of the Artisan PIOL on the size and shape of the pupil.

PATIENTS AND METHODS

The Artisan PIOL was designed by Professor J. Worst and was formerly known as the Worst-Fechner claw lens.[22] The lens has a convex-concave optic with either 6 mm (for intraocular lens powers up to −15.5 diopters [D]) or 5 mm (for intraocular lens powers from −16.0 up to −24.0 D) and is available in 0.50-D increments. This single-piece lens is composed of polymethylmethacrylate. The PIOL is iris claw-fixated.

Patients were enrolled at the Academic Centre for Refractive Surgery, University Hospital Maastricht, The Netherlands and were operated for myopia by the same surgeon (R.N.). The Artisan PIOL was enclavated at the 0 to 180° meridian in all patients.

In the first part of the study, maximal horizontal pupil diameters were measured in 71 eyes of 37 patients (Artisan Colvard group) before and after horizontal Artisan PIOL implantation, using the handheld Colvard pupillometer. The second part of the study consisted of the pupil size measurements with the Procyon P2000 SA pupillometer in two populations: 1) 121 eyes of 62 patients (Artisan Procyon group) after horizontal Artisan PIOL implantation, and 2) 121 eyes of age- and refraction-matched refractive surgery candidates (Procyon control group). The Artisan Procyon and the Procyon control group were compared to evaluate differences in the horizontal and vertical pupil diameters.

Postoperative pupil diameters were obtained 3 months after surgery. Exclusion criteria included iris abnormalities and systemic diseases that might affect pupil function. Gonioscopy was used to exclude patients with a plateau iris or a convex iris configuration.

PUPIL SIZE MEASUREMENTS

The handheld Colvard pupillometer uses light amplification technology. The patient is asked to fixate on a red light, produced by an IR-LED inside the device, while the examiner is able to focus the iris and pupil by moving the pupillometer slightly forward and back. A millimeter ruler is superimposed by a reticule in the device over the image and allows direct measurement. The examiner was instructed to estimate the horizontal pupil diameter size with a precision of 0.25 mm, while covering the contralateral eye with the other hand.

The Procyon pupillometer is a digital infrared device for binocular simultaneous measurements of pupil diameter at three levels of luminance (scotopic [0.04 lux], mesopic-low [0.4 lux], and mesopic-high [4.0 lux]). Infrared light-emitting diodes illuminate the eyes with long-wave light that does not affect pupil size but is recognized by the charge-coupled device camera in the system. For both eyes, 10 images were acquired at each level of luminance and stored in a computer. The patient looks into the device and fixates on a black spot at a virtual distance of 10 m. Rubber eyecups prevent the illumination level to rise above the adjusted level. The examiner viewed the acquired images immediately and distorted images were removed. The mean and standard deviation and range of scotopic, mesopic-low, and mesopic-high pupil diameters were assessed by the software and displayed as a diagram.

Before each measurement, a 1-minute dark adaptation was taken into account. Surrounding room illumination was no more than 0.15 lux. Definitions on scotopic and mesopic levels of illumination were used according to the International Commission on Illumination as scotopic being <0.05 lux and mesopic between 0.05 and 50 lux (National Physical Laboratory, London, United Kingdom).[23] All Colvard and Procyon measurements were taken by one experienced examiner (F.E.)

Digital images from the Procyon measurements were converted to Adobe Photoshop 5.0 software program (1989-1998 Adobe Systems Inc, San Jose, Calif). Horizontal and vertical diameters were obtained using the measurement tool inside the program (Fig 1). The ratio between the vertical and horizontal pupil diameters, the so-called V/H ratio, was calculated from measurements with the Procyon device under all three light conditions. A ratio of 1.00 represents a perfect circular pupil shape.

In measuring the pupil size via the cornea and anterior chamber, it should be noted that the natural pupil is not being observed, but rather its image, which is called the entrance pupil. Because we are interested in comparing measured pupil sizes, it is appropriate to use the size of the entrance pupil. However, postoperatively the size of the entrance pupil is also changed by the Artisan PIOL, as the PIOL is positioned in front of the pupil entrance. Optically, the natural pupil is first imaged by the Artisan PIOL and secondly by the cornea/anterior chamber system. The distance from pupil to lens is given by the back surface sagittal depth called the vault by the manufacturer (0.799 mm for powers up to −15.5 D and 0.733 D for powers >−15.5 D). Because the Artisan PIOL is placed in the anterior chamber fluid (refractive index = 1.336) and is very close to the pupil, the object vergence is high compared to

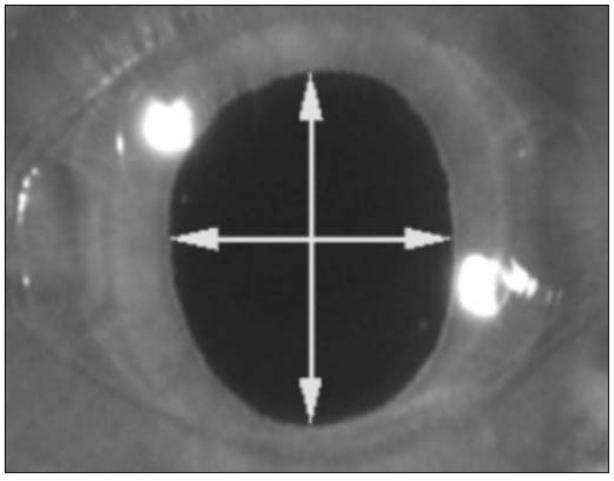

Figure 1. Oval shape of the pupil after Artisan PIOL implantation under mesopic low light conditions using Procyon pupillometry.

the effective power of the Artisan PIOL, resulting in a <1% change in pupil size. Nevertheless, we have adjusted our measured pupil size data for the influence of the Artisan PIOL using the following formula[24]:

> Corrected Entrance Pupil = ([1−(vault of Artisan PIOL in millimeters × Dioptric power of Artisan PIOL/1336)]) × Measured pupil size in millimeters

STATISTICAL ANALYSIS

All data were expressed as mean±standard deviation. Measured pupil diameters were distributed normally (Kolmogorov-Smirnov test). Independent and paired-samples *t* tests were used for analysis. Statistical significance was $P<.05$ (SPSS for Windows; SPSS Inc, Chicago, Ill).

RESULTS

The mean horizontal pupil diameter measured with the Colvard pupillometer (Artisan Colvard group) after horizontal Artisan PIOL implantation decreased from 6.23±0.70 mm preoperatively to 5.34±0.68 mm postoperatively ($P<.01$) (Table 1). This is a mean reduction of 13.8±10.6% in horizontal pupil diameter after implantation.

Horizontal pupil diameters measured with the Procyon device after horizontal Artisan PIOL implantation (Artisan Procyon group) were 5.60±0.66 mm (scotopic), 4.94±0.71 mm (mesopic-low), and 3.98±0.54 mm (mesopic-high). In the Procyon control group, the mean horizontal pupil diameter measured with the Procyon pupillometer was 6.29±0.91 mm (scotopic), 5.40±0.96 mm (mesopic-low), and 4.16±0.80 mm (mesopic-high) (Tables 1 and 2).

TABLE 1

Horizontal Pupil Diameter for All Three Groups

Group	Horizontal Diameter (mm)	V/H-ratio*
Artisan Colvard		
Before implantation	6.23±0.70	
After implantation	5.34±0.68	
Artisan Procyon		
After implantation	5.60±0.66	1.17
Procyon control	6.29±0.91	1.02

**Ratio between the vertical and horizontal pupil diameters*

A decrease in the horizontal pupil diameter was noted after horizontal Artisan PIOL implantation under all three light conditions ($P<.01$). In contrast, no change occurred in the vertical axis (Table 2). In the Procyon control group, the mean V/H ratio for scotopic, mesopic-low, and mesopic-high light conditions was 1.02, 1.02, and 1.01, respectively. After horizontal Artisan PIOL implantation (Artisan Procyon group), the mean V/H ratio significantly increased to 1.17, 1.12, and 1.06, respectively (Table 2, Fig 2).

DISCUSSION

Recently, the measurement of the scotopic pupil size and its relation to night vision complaints after refractive surgery has become an important topic in corneal and lenticular refractive surgery.[1] Although it is generally believed that a large scotopic pupil size may put patients at an increased risk for night vision complaints after refractive surgery,[25-28] more recent research argues the importance of the scotopic pupil size.[3-7] Most authors agree that a standardized measurement of pupil size under defined light conditions with good repeatability is useful when screening patients for refractive surgery.[20,23] In addition, the relevance of the binocular measured pupil size under well-defined illumination levels has to be related to illumination levels for specific activities in real life, eg, driving at night. Binocular measurements may imitate the patient's life conditions more realistically.[21] It has been shown that the digital Procyon pupillometer has a low variation in measuring pupil size and good inter-rater repeatability.[20] The variation in scotopic pupil size measured with different devices emphasizes the need for an objective measurement method. In addition, well-defined illumination conditions enhance comparison of future studies on pupillometry.

TABLE 2

Horizontal Versus Vertical Diameters (mm) Under Three Different Levels of Illumination After Artisan PIOL Implantation (Artisan Procyon Group) and in a Refractive Surgery Screening Group (Procyon Control Group)

	Scotopic			Mesopic-low			Mesopic-high		
Group	**Horizontal**	**Vertical**	**V/H-ratio***	**Horizontal**	**Vertical**	**V/H-ratio***	**Horizontal**	**Vertical**	**V/H-ratio***
Artisan Procyon	5.60±0.66	6.52±0.83	1.17±0.06	4.94±0.71	5.57±0.91	1.12±0.06	3.98±0.54	4.13±0.64	1.06±0.05
Procyon control	6.29±0.91	6.43±0.91	1.02±0.04	5.40±0.96	5.52±0.98	1.02±0.04	4.16±0.80	4.18±0.83	1.01±0.03
Significance (2-tailed)	$P<.01$	$P=.41$	$P<.01$	$P<.01$	$P=.72$	$P<.01$	$P<.01$	$P=.62$	$P<.01$

**Ratio between the vertical and horizontal pupil diameters*

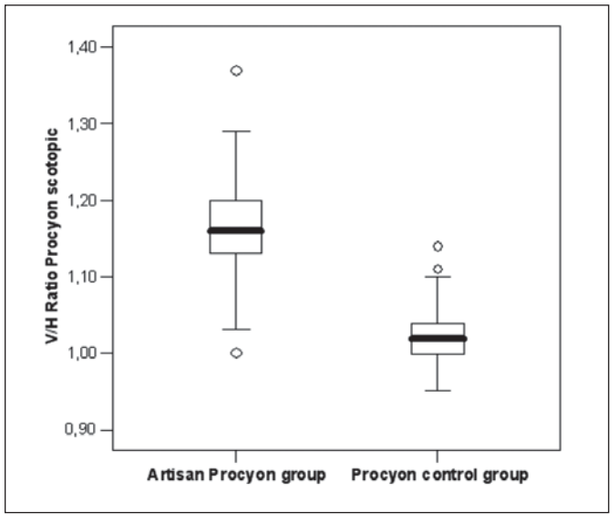

Figure 2. Box-plot showing the range of vertical/horizontal (V/H) ratios measured in the Artisan PIOL implantation group (Artisan Procyon group) and the refractive surgery screening group (Procyon control group) under scotopic condition (N = 121 eyes for both groups). The difference between the groups is significant ($P<.01$).

After implantation of PIOLs, especially with anterior chamber angle fixated lenses, progressive changes such as pupil ovalization and atrophy of iris stroma due to infarction of iris vessels in the chamber angle have been reported.[2,14,29] It has been suggested that the Artisan PIOL has no influence on pupil dynamics because of the enclavation of the haptics in the mid-periphery of the iris, far away from the vulnerable chamber angle structures.[30] Consequently, the implantation of iris-fixated PIOLs has become increasingly popular and has been proven successful for the correction of moderate to high refractive errors. For Artisan PIOLs with a 6-mm optical zone, the manufacturer prefers that the lenses not be implanted in eyes with a scotopic pupil size >6 mm. This is stated because of the presumed correlation between night vision complaints, including contrast sensitivity loss, glare, and halos, and a disparity of the optical lens zone with the pupil diameter. However, we do not know the methods and illumination levels that have been used by the manufacturer to formulate this recommendation.

To evaluate the effect of the iris fixation mechanism of the Artisan lens on pupil dynamics, we measured the horizontal scotopic pupil size with the Colvard device before and after horizontal Artisan PIOL implantation. In addition, we calculated the ratio between the vertical and horizontal pupil diameter after horizontal Artisan lens implantation (V/H ratio). After horizontal implantation, the horizontal pupil diameter decreased on average by 13.8%. The relationship between individual vertical and horizontal pupil diameters in normal subjects was recently investigated and provided comparable results to our findings, ie, a ratio of 1.01 to 1.03.[31] Dick et al[15] described a change in pupil size after implantation of toric PIOLs using pharmacological mydriasis and flash slit-lamp photography. Our study demonstrates a restriction in the dilation of pupils in the horizontal axis after horizontal Artisan myopia PIOL implantation under physiological light conditions. A possible explanation for this restriction could be the mechanically induced prevention of pupil dilatation by the iris claw. It seems unlikely that the function of the dilator pupillae muscle is impaired by the induction of ischemia by the enclavation of the iris claw itself, as this has not been supported by fluorescein angiography studies in the past.[30]

The main finding of this study was the decreased horizontal meridian of the pupil after horizontal Artisan PIOL implantation as compared to the vertical

meridian at all three levels of illuminance, ie, scotopic, mesopic-low, and mesopic-high. The postoperative constriction in the horizontal axis and subsequent smaller scotopic pupil diameter may have implications for the inclusion criteria for implantation as a relatively larger proportion of patients would fit the currently formulated inclusion criteria where the optical zones should be at least as large as the scotopic pupil size.

In summary, horizontal pupil size is diminished after horizontal Artisan PIOL implantation and a significant change in V/H ratio was measured under three levels of illumination leading to a vertical oval shape of the pupil. The decrease in the postoperative pupil area could be beneficial for reduction of aberrations, thereby diminishing the incidence of night vision disturbances. A digital infrared pupillometer is not only advantageous for standardized measurement of the horizontal pupil diameter but also may provide insight into the mechanical effects of PIOLs on pupillary dynamics. In addition, a decreased horizontal pupil diameter could be the result of the enclavation points exceeding the 8.5 mm of the haptic distance and, thereby, pulling the iris more central in the horizontal plane.

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