

CLINICAL INVESTIGATIONS

# Colvard Pupillometer Measurement of Scotopic Pupil Diameter in Emmetropes and Myopes

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**Purpose:** To prospectively compare the scotopic pupil size between emmetropes and myopes using a Colvard pupillometer.

**Methods:** The pupil diameters of 55 normal subjects and 55 healthy myopic subjects were measured with the Colvard pupillometer in a low-light situation that simulated the level of light encountered while driving at night.

**Results:** The mean ( $\pm$  SD) age of the emmetropic subjects was 30.78 years  $\pm$  10.03 (range, 18–54 years) and the mean ( $\pm$  SD) age of the myopic subjects was 27.35 years  $\pm$  8.43 (range, 21–52 years). The mean ( $\pm$  SD) scotopic pupil diameter was 6.46  $\pm$  0.90 mm (range, 4.5–8.0 mm) in the emmetropic group and 6.98  $\pm$  0.67 mm (5.5–8.5 mm) in the myopic group. The unpaired Student *t*-test showed that the difference in the scotopic pupil diameter between emmetropes and myopes was statistically significant (P = .0001).

**Conclusions:** The mean scotopic pupil diameter in myopes was larger than that in emmetropes. Therefore, a large ablation zone of the cornea or an appropriate optical size of the phakic intraocular lens should be considered in refractive surgery. Preoperative scotopic pupil measurements may be necessary in all refractive patients. **Jpn J Ophthalmol 2002;46:640–644** © 2002 Japanese Ophthalmological Society

Key Words: Colvard pupillometer, emmetrope, myope, scotopic pupil diameter.

## Introduction

Large pupil size under scotopic illumination is a limiting factor to a perfect outcome after keratore-fractive and phacorefractive surgery.<sup>1</sup>

Such annoying symptoms as halos, starbursts, and glare may develop after a small optical zone laser ablation or the implantation of a phakic intraocular lens in a patient with a widely dilating pupil.<sup>2–4</sup> Measurement of pupil size may be the most frequently neglected factor in refractive surgery evaluation. This is partly because measurement of pupil size has been difficult and unreliable with the old "coatpocket" pupil gauges, and partly because many surgeons have not appreciated the absolute necessity of

considering this parameter preoperatively. Meticulous measurement of pupil dilation in low-light situations should, therefore, be an essential part of the preoperative evaluation for refractive patients.<sup>5</sup>

Many devices have been used to measure pupil size in a scotopic condition. The use of a millimeter ruler and Rosenbaum pocket vision screen card may cause difficulties for clinicians in reliably predicting the level of a pupil in a room with low light.<sup>5</sup> Although the Rosenbaum pocket vision screen card is a commonly used device for the comparison method in many ongoing U.S. Food and Drug Administration clinical trials in refractive surgery,6 the Colvard pupillometer seems more reliable as a method of comparing pupil diameters in a scotopic condition.<sup>5</sup> With the Rosenbaum card, the pupil size could not be measured with confidence by the clinicians. When comparing two infrared pupillometers, the pupil measurements were more reliable with the Colvard pupillometer than with the Video Vision Analyzer (VIVA) pupillometer.<sup>1</sup>

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Pupil size is arguably the most important predictor of glare. To ascertain whether myopes have more pupil-related glare than emmetropes, we prospectively performed measurements and compared the scotopic pupil size between emmetropes and myopes using the Colvard pupillometer (Figure 1).

# **Materials and Methods**

# **Participants**

From May 2001 to August 2001, 110 volunteers participated in this prospective study. All participants provided written informed consent. They were divided into two groups according to the spherical equivalent: low myopia (6.00 diopters or less) and emmetropia. All participants had visual acuity correctable to 20/20 or better with spectacles or contact lens. Refractive astigmatism did not exceed 2.00 diopters in the low myopia group. Participants were excluded if they had a history of eye disease, eye surgery, eye trauma, diabetic mellitus, glaucoma, topical eyedrop use, systemic drug or alcohol abuse, or slit-lamp microscopic evidence of pupil or iris abnormalities.

# Device Description and Clinical Assessments Under Scotopic Illumination

The handheld Colvard pupillometer (Oasis Medical, Glendora, CA, USA), developed by Matthew Colvard, uses light amplification technology. A photo cathode is stimulated by low-light energy, which results in electron excitation. The electrons strike a phosphor screen and the image is intensified.

As described by Salz,<sup>7</sup> the level of light typically encountered while driving on a suburban street at night can be reproduced by turning off all the lights in a windowless room and opening the door slightly



Figure 1. Colvard pupillometer.

by 1–2 inches to allow in some light from the hallway. This level of luminance usually ranges from 0.5–0.6 luxes.<sup>1</sup> This study used a Digital Lux Meter Model LX-50 (Sekonic Studio, Tokyo, Japan) to measure the amount of this light seen by the eyes.

The clinician used this device in a way that is similar to how a direct ophthalmoscope is used, by holding it 2-3 inches from the participant's eye. Then, light amplification was activated by pressing the ON/ OFF power button located on the instrument handle. As long as the ON/OFF button was held down, the bright-enhanced image was retained. The clinician looked through the eyepiece to visualize the iris and pupil. By moving the device slightly forward or backward, the image was brought into sharper focus. The participant was asked to fixate on a distant object with the eye that was not being measured. A reticule in the device superimposed a millimeter ruler over the image of the iris and pupil to allow for easy measurement of the pupil diameter. Each patient was measured three times by the examiner.

The Student *t*-test for unpaired groups was performed to prove the statistical significance of scotopic pupil diameter measurements between emmetropes and low myopes. A P value of .05 or less was considered significant. The relationship of scotopic pupil diameter, refractive error, and age were determined by multiple regression analysis.

## Results

The study population consisted of 55 emmetropic subjects and 55 myopic subjects with a mean ( $\pm$  SD) age of 30.78  $\pm$  10.03 years (range, 18–54 years) and 27.35  $\pm$  8.43 years (range, 21–52 years), respectively (Table 1).

There were no statistically significant differences in age between the emmetropic and myopic groups (P = .054). Each group also had no statistically significant differences in the scotopic pupil diameter between the right and left eyes (P = .739 and P =

Table 1. Comparison of Patient Data

Parameter	Emmetropes	Myopes	P-values
Age (v)	$30.78 \pm 10.03$	$27.35 \pm 8.43$	.054
Range (y)	18–54	21–52	
Sex			.124
Male	29	20	
Female	26	35	
Mean scotopic pupil			
diameter (mm)	$6.46\pm0.90$	$6.98\pm0.67$	.0001

.444 for the emmetropic group and the myopic group, respectively).

The mean ( $\pm$  SD) scotopic pupil diameter in the 110 subjects was 6.72  $\pm$  0.83 mm.

Figures 2 and 3 demonstrate the scotopic pupil diameter in emmetropes and myopes. The mean ( $\pm$  SD) scotopic pupil diameter in myopes (6.98  $\pm$  0.67 mm) was larger than that in emmetropes (6.46  $\pm$  0.90 mm). The Student *t* test for unpaired groups showed that the difference in the scotopic pupil diameter between emmetropes and myopes was statistically significant (*P* = .0001).

In emmetropic subjects, the scotopic pupil diameter was significantly correlated to the patient's age (P = .0001,  $\beta = -.513$ ), but not to sex and refractive error (P = .607,  $\beta = -.063$  and P = .820,  $\beta = .028$ , respectively) (Figure 2)).

In myopic subjects, the scotopic pupil diameter was significantly correlated to the patient's age and refractive error (P = .007,  $\beta = -.350$  and P = .027,  $\beta = -.285$ , respectively) but not to sex (P = .735,  $\beta = .042$ ) (Figure 3).

#### Discussion

Patients considering refractive surgery now commonly express concern over possible complications including glare, halos, or other bothersome symptoms.<sup>2–4,8–10</sup> These troublesome problems have been reported in 25–35% of the patients after photorefractive keratectomy (PRK)<sup>2,11</sup> and laser in situ keratomileusis (LASIK)<sup>12</sup> using a 6.0-mm ablation zone. These disturbances may be related to a large scotopic pupil diameter<sup>10,13,14</sup> and small ablation diameter.<sup>10,13</sup> Pupil/ablation-related night-vision disturbances are often preventable, because high-risk patients are identifiable, in particular those with the combination of a high prescription<sup>15</sup> and large scotopic pupil diameter.<sup>10,13,14</sup>

Pupil size is arguably the most important predictor of night-vision disturbances, but obtaining an accurate measurement is sometimes difficult. The pupil is a dynamic structure affected by pupillary hippus.<sup>16</sup> As pupil contractions will influence pupil measurement, clinicians should attempt to measure the largest pupil diameter in the hippus cycle. A common technique for measuring pupils involves a millimeter ruler or Rosenbaum Pocket Vision Screen card. However, infrared pupillometry is more accurate.<sup>6</sup> In this study, pupil measurement was performed with an infrared, light-amplification pupillometer.

Several studies have demonstrated the measurement of a pupil diameter under scotopic light conditions (Table 2).When comparing measurements with the same device (Colvard pupillometer), Colvard<sup>5</sup> found a mean pupil size of 6.2 mm (3.0–9.0 mm) using his device under the same room illumination as described by Salz.<sup>7</sup> Schnitzler et al<sup>1</sup> showed that the mean scotopic pupil diameter was 6.08 mm (3.2–8.4 mm). In this present study, the mean ( $\pm$  SD) scotopic pupil diameter was 6.72  $\pm$  0.83 mm, which was slightly larger than in two previous studies,<sup>1,5</sup>



Pupil Diameter (mm)

Figure 2. Scotopic pupil diameter (mm) in emmetrope.



**Pupil Diameter (mm)** 

Figure 3. Scotopic pupil diameter (mm) in myopes.

even though the measurements were performed by the same clinician (WJ) in a windowless room with the door opened slightly by 1–2 inches to allow in some light from the hallway. The difference in the scotopic pupil diameter might be the result of a different iris color. All the subjects of this study had brown irises. Koch et al did not believe that the iris color might be an important factor in determining pupillary size and responsiveness.<sup>17</sup>

Pupil diameter was affected by emotional state,<sup>18</sup> systemic medication including antihistamine and opiates,<sup>19</sup> and age.<sup>20</sup> Loewenfeld<sup>20</sup> found that the pupil size tended to decrease with increasing age, which was supported by the results of this study. We also demonstrated that scotopic pupil diameter was not correlated to sex in both emmetropic and myopic subjects.

**Table 2.** Scotopic Pupil Diameter Measured with Various Devices

Devices	Scotopic Pupil Diameter (mm)*	Range of Scotopic Pupil Diameter (mm)
Colvard-infrared	$6.72 \pm 0.83$	4.0-8.5
Colvard-infrared <sup>1</sup>	$6.08 \pm 1.16$	3.2-8.4
Colvard-infrared <sup>5</sup>	6.20	3.0-9.0
VIVA-infrared <sup>1</sup>	$6.24 \pm 1.28$	3.5-9.0
IOWA-infrared <sup>6</sup>	$4.95 \pm 1.08$	_
Rosenbaum-comparison <sup>6</sup>	$5.40 \pm 1.10$	_
Photographs <sup>17</sup>	$5.60\pm0.91$	2.7-6.6

In this current study, comparing scotopic pupil size in both groups, there were no statistically significant differences based on age between the emmetropic and myopic groups. Interestingly, our study showed that the mean scotopic pupil diameter in low myopes was slightly larger than that in emmetropes. The mean scotopic pupil diameter in myopes was 6.98 mm. Considering corneal magnification of 14%,<sup>21</sup> the true pupil size was smaller than this measured value. The true value of pupil measurement was recalculated using this factor. The true mean pupil diameter in myopes was 6.00 mm. However, this magnification would also change because of the corneal refractive power and anterior chamber depth, which were not considered in this study.

Because the true and imaged pupils were optically conjugated, all light passing through the imaged pupil went through the true pupil and onto the retina. Consequently, if the functional optical zone was smaller than the imaged pupil, light could pass through a ring of undisturbed cornea, which would lead to night-vision disturbances.<sup>10</sup> Therefore, the ablation zone at the corneal plane or the optical size of a phakic intraocular lens should be larger than 6.00 mm, which was supported by the studies of O'Brart et al<sup>2</sup> and Boxer Wachler and Krueger.<sup>6</sup> However, patients who had large pupils at night did not always complain of significant night-time disturbances.<sup>2</sup> Martinez et al<sup>14</sup> reported that the patients who had a higher attempted correction for myopia would have a greater chance of night-vision problems.

Many studies of the relationship between pupil size, ablation zone, and quality of vision have been reported.<sup>4,5,22</sup> The results of this study agreed with Colvard's opinion<sup>5</sup> that the relationship between pupil size, quality of vision, and patient satisfaction was multifactorial.

In summary, this study demonstrated that the mean scotopic pupil diameter in myopes was larger than that in emmetropes. However, the sample size was relatively small. Larger sample sizes should be considered in future studies. Patients at high risk of developing night-vision disturbances might be better candidates for undergoing laser ablative correction (PRK/LASIK) with a large ablation diameter. In this study, an ablation diameter of at least 6.00 mm was recommended for simple myopic treatment.

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