Pre–Excimer Laser and Post–Excimer Laser Refractive Surgery Measurements of Scotopic Pupil Diameter Using 2 Pupillometers

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Purpose: To compare a digital infrared pupillometer with a handheld light amplification pupillometer for measuring scotopic pupil size and to evaluate if the postoperative refractive changes of the cornea can influence pupil measurements.

Design: Prospective noncomparative interventional case series.

Participants: One hundred eyes, 50 myopic (mean spherical equivalent [SE] refraction [± standard deviation], −4.32±2.44 diopters [D]) and 50 hyperopic (mean SE refraction, +2.95±0.99 D), of 50 otherwise healthy subjects underwent photorefractive keratectomy or LASIK.

Intervention: The preoperative and postoperative scotopic pupil sizes were measured by 2 examiners (E1, E2) with both a handheld light amplification pupillometer (Colvard, Oasis Medical, Glendora, CA) and a digital infrared pupillometer (Eye World Pupillometer [EWP], Oculus Keratograph, Oculus Opikgeräte GmbH, Wetzlar, Germany). The agreement and interrater repeatability were determined using the comparison method described by Bland and Altman. The paired Student's *t* test was used to evaluate the difference between the preoperative and postoperative measurements.

Main Outcome Measures: Scotopic pupil diameter, topographic corneal refractive power, uncorrected visual acuity (VA), best spectacle-corrected VA, and manifest spectacle refraction.

Results: The preoperative mean scotopic pupil diameter was 6.12±0.90 mm with the EWP and 6.18±0.91 mm with the Colvard. After the surgery, mean SE refractions were −0.22±0.98 D (myopic patients) and +0.19±0.40 D (hyperopic patients). Postoperative mean scotopic pupil diameters were 6.12±0.89 mm (EWP) and 6.17±0.90 mm (Colvard). There was no statistically significant difference between preoperative and postoperative mean scotopic pupil sizes in either patient group. The limits of agreement between the 2 devices ranged from 2.24 mm (E1) to 2.12 mm (E2) preoperatively and from 2.27 mm (E1) to 2.08 mm (E2) postoperatively. The coefficient of interrater repeatability ranged from 0.56 mm (EWP) to 1.12 mm (Colvard) preoperatively and from 0.62 mm (EWP) to 1.14 mm (Colvard) postoperatively.

Conclusions: The digital infrared pupillometer showed better preoperative and postoperative repeatability than the handheld light amplification pupillometer. In the present study, a mean correction of <3 D of the corneal refractive power did not seem to modify the preoperative scotopic pupil size measurements. *Ophthalmology 2005;112:1003–1008 © 2005 by the American Academy of Ophthalmology.*

The accurate measurement of the pupil before photorefractive keratectomy (PRK) or LASIK represents an important and essential step when selecting refractive patients, increasing the safety of refractive surgery procedures and reducing subjective night vision disturbances. If the pupil enlarges beyond the optical zone created by the laser ablation, light rays could pass through the untreated cornea and through the edge of the treatment zone, disturbing vision with glare, halos, ghost images, and lower contrast sensitivity.[1–3]

At present, numerous pupillometers are available to measure the pupil size accurately. The measurements taken with these devices refer to a virtual image, magnified and displaced anteriorly in relation to the anatomical pupil, due to the optical effect produced by the cornea.[4] Theoretically, the refractive surgery, by changing the corneal refractive power, could modify the measurements of the patient's pupil. This could become a problem for those patients who complain of pupil-related night vision disturbances after surgery. An accurate postoperative measurement of pupil size in those cases becomes very useful.

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Table 1. Mean Scotopic Pupil Measurements of All Patients with the Eye World (EWP) and Colvard Pupillometers

Device/Examiner	Preoperative Pupil ± SD (mm)	Postoperative Pupil ± SD (mm)
EWP		
E1	6.10±0.93	6.10±0.91
E2	6.14±0.86	6.13±0.87
Mean	6.12±0.90	6.12±0.89
Colvard		
E1	6.23±0.93	6.19±0.93
E2	6.12±0.90	6.15±0.87
Mean	6.18±0.91	6.17±0.90

E1 = examiner 1; E2 = examiner 2; SD = standard deviation.

The objective of our study was to measure the scotopic pupil size using a digital infrared pupillometer and a handheld light amplification pupillometer, comparing the results and analyzing the pupil measurement changes secondary to the variations of corneal refractive power induced by excimer laser refractive surgery.

Patients and Methods

Patients were enrolled in a prospective noncomparative case series between May 2003 and September 2003, after the local ethics committee approved the study protocol. Subjects with any contraindications to excimer laser refractive surgery were excluded from the study, as well as those affected by any pupillary alterations or under drug therapy influencing pupil dimensions and kinetics. One hundred consecutive eyes of 50 patients (22 male and 28 female; mean age [± standard deviation (SD)], 31.9±10.4 years [range, 19–70]) were selected after a complete ophthalmologic examination, including manifest and cycloplegic (subjective and objective) refraction, computerized videokeratography (Oculus Keratograph, Oculus Opikgeräte GmbH, Wetzlar, Germany), ultrasound corneal pachymetry (Sonogage, Corneo-Gage Plus, Cleveland, OH), and noncontact endothelial specular microscopy (SEED SP500, SEED Co. Ltd., Tokyo, Japan). Two independent examiners (E1, E2) performed the pupillometry after a period of dark adaptation of at least 1 minute under scotopic conditions. Ambient luminance at the subject's eyes, measured with the photometer Digital Lux Meter LM-20 (Pantec, Italy), was <0.1 lux. Each examiner used 2 different monocular devices for each patient, a handheld pupillometer (Colvard, Oasis Medical, Glendora, CA) and a dynamic computerized pupillometer (Eye World Pupillometer [EWP], Oculus Keratograph).

The handheld Colvard pupillometer has been described.[5] Briefly, the device uses light amplification technology. A photocathode is stimulated by a low level of light energy, so as not to influence the scotopic pupil size of the patient. The stimulated electrons strike a phosphor screen, and the image is thus intensified. The examiner is able to focus the iris and pupil of the examined eye moving the device slightly forward and back. A millimeter ruler is superimposed by reticule over the amplified fluorescent image, allowing direct measurement. The 2 examiners tried to estimate the pupil diameter with a precision of 0.5 mm.

The EWP is a software component of the Oculus Keratograph topographic system that utilizes an infrared light camera as an acquisition device. The system can examine the pupil diameter under different light conditions, using manual or automatic mode. The camera sends a continuous video signal to a personal computer, which uses software dedicated to recognizing the pupillary edge and to measuring the diameter variations during the examination. All subjects were examined by selecting the Pupillogram program, which consists of a cycle of 9.8 seconds of scotopic stimulus (0.1 lux) and 0.2 seconds of photopic stimulus (150 lux), repeated 5 times automatically. At the end of the examination, the software provides the maximum value (scotopic) and minimal value (photopic) of the pupil diameter and a diagram that represents graphically the behavior of the pupil to different luminous stimuli. The pupillometry is performed on both eyes of each patient, one at a time, by each examiner using first the Colvard and then the EWP.

The study was approved by the ethics committee of the School of Medicine, University of L'Aquila, and informed consent was obtained from all patients. Of the 50 patients selected, 25 were myopic, with a mean spherical equivalent (SE) refraction of −4.32±2.44 diopters (D) (range, −1 to −10.50), and 25 were hyperopic, with a mean SE refraction of +2.95±0.99 D (range, +1.25 to +5). Mean topographic corneal refractive powers were 43.09±1.20 D (myopic subjects) and 43.33±1.19 D (hyperopic subjects).

Thirty subjects underwent PRK (15 myopes, 15 hyperopes), and 20 subjects underwent LASIK (10 myopes, 10 hyperopes) using the MEL-70 excimer laser (Carl Zeiss Meditec, Jena, Germany) and, when required, the Hansatome microkeratome (Baush & Lomb, Dornach, Germany) using a 160-μm plate and a 9.5-mm suction ring. The laser settings were as follows: wavelength, 193 nm; frequency, 35 Hertz; fluence, 180 millijoules per square centimeter; and ablation rate, 0.25 μm. After PRK, a soft contact lens, topical antibiotic, and artificial teardrops were applied until reepithelialization was complete (from 4 to 8 days). In those patients who underwent LASIK and in the

Table 2. Scotopic Pupil Diameter in Myopic Patients Measured Preoperatively and Postoperatively

Pupillometer	Procedure	Preoperative Pupil ± SD (mm)	Postoperative Pupil ± SD (mm)	*P* Value
E1-EWP	PRK	6.04±0.84	6.00±0.78	0.39
E1-EWP	LASIK	6.15±1.03	6.16±0.99	0.15
E2-EWP	PRK	6.18±0.77	6.16±0.80	0.41
E2-EWP	LASIK	6.06±0.91	6.01±0.89	0.15
E1-Colvard	PRK	6.35±0.72	6.28±0.77	0.25
E1-Colvard	LASIK	5.92±0.75	5.87±0.76	0.70
E2-Colvard	PRK	6.08±0.80	6.12±0.83	0.64
E2-Colvard	LASIK	6.07±0.80	6.10±0.84	0.79

E1 = examiner 1; E2 = examiner 2; EWP = Eye World Pupillometer; PRK = photorefractive keratectomy; SD = standard deviation.

Table 3. Scotopic Pupil Diameters in Hyperopic Patients Measured Preoperatively and Postoperatively

Pupillometer	Procedure	Preoperative Pupil ± SD (mm)	Postoperative Pupil ± SD (mm)	*P* Value
E1-EWP	PRK	5.91±1.13	5.94±1.13	0.26
E1-EWP	LASIK	6.44±0.51	6.46±0.52	0.16
E2-EWP	PRK	5.98±1.08	5.97±1.09	0.89
E2-EWP	LASIK	6.40±0.51	6.46±0.49	0.13
E1-Colvard	PRK	6.07±1.28	6.00±1.23	0.10
E1-Colvard	LASIK	6.62±0.52	6.65±0.54	0.20
E2-Colvard	PRK	5.90±1.13	6.00±1.05	0.14
E2-Colvard	LASIK	6.55±0.53	6.50±0.58	0.58

E1 = examiner 1; E2 = examiner 2; EWP = Eye World Pupillometer; PRK = photorefractive keratectomy; SD = standard deviation.

patients after reepithelialization, topical corticosteroid drops were administered for at least 1 month, and then, depending on the corneal haze and refractive outcome, the drops were tapered and titrated. Within 3 months from surgery, all patients stopped their medications.

All patients were evaluated by pupillometry before and 3 months after surgery, with both devices and with identical technical methods.

Data were analyzed according to the method described by Bland and Altman[6] using statistical analysis software.[7] This statistical method compares 2 measurement techniques by plotting their means against their differences. Agreement between the 2 pupillometers and interrater repeatability of each technique were evaluated. The limits of agreement were defined as the mean ± 1.96 SDs of the differences among the measurements taken by a single examiner with the 2 pupillometers, and by the 2 examiners with the same pupillometer. Within the limits of agreement are found 95% of the differences among the measurements. For each device, the coefficient of interrater repeatability was defined as twice the SD of the differences between both examiners' measurements. The lower values represent better repeatability. The analysis of repeatability has also included the intraclass correlation coefficient (*r*) between the measurements for each pupillometer.

The paired Student's *t* test was used to evaluate the difference between the mean preoperative and postoperative measurements of scotopic pupil diameter. A value of $P \leq 0.05$ was considered significant.

Results

All patients were treated once, and no intraoperative or postoperative complications developed. The uncorrected visual acuity (VA) of all subjects improved from a mean preoperative value of 0.83±0.54 logarithm of the minimum angle of resolution (logMAR) (range, 20/600–20/20) to a mean postoperative value of 0.06±0.14 logMAR (range, 20/100–20/20). The best spectacle-corrected VA had a mean preoperative value of 0.01±0.04 logMAR (range, 20/25–20/20) and a mean postoperative value of 0.01±0.02 logMAR (range, 20/25–20/20). After surgery, mean SE refractions were −0.22±0.98 D (range, −3.50 to +1) for myopic patients and +0.19±0.40 D (range, −1 to +1) for hyperopic patients. Forty-one of 50 myopic eyes (82%) obtained a final refraction within ±0.50 D of emmetropia, and 46 of 50 eyes (92%) were within ±1 D. Forty-three of 50 hyperopic eyes (86%) obtained a final refraction within 0.50 D of emmetropia, and all eyes (100%) were within 1 D. After the surgery, there was a reduction of the mean corneal refractive power in myopic patients equal to 2.77±1.29 D (range, 0.75–5.25) and an increase in hyperopic patients equal to 1.47±0.63 D (range, 0.32–2.29).

Pupil Diameter

Preoperative mean scotopic pupil diameters were 6.12±0.90 mm (evaluated by the EWP) and 6.18±0.91 mm (Colvard pupillometer). Postoperative mean scotopic pupil diameters were 6.12±0.89 mm (EWP) and 6.17±0.90 mm (Colvard) (Table 1). Mean scotopic pupil diameters of myopic subjects are shown in Table 2, and those of hyperopic subjects in Table 3. No statistically significant difference was observed in preoperative and postoperative pupil diameters in either group.

Mean differences between measurements taken preoperatively by E1 and E2, with the EWP and the Colvard pupillometer, are shown in Table 4 and Figure 1. Mean differences between measurements taken postoperatively by E1 and E2, with the EWP and the Colvard, are shown in Table 5 and Figure 2.

Agreement

Figures 1A, B and 2A, B and Tables 4 and 5 show the limits of agreement of the measurements taken preoperatively and postoperatively by the 2 examiners with both pupillometers. Agreements between the EWP and the Colvard were similar for both examiners, with limits of agreement ranging from 2.24 mm (E1) to 2.12 mm (E2). Postoperatively, the limits of agreement between the 2 pupillometers did not change significantly, ranging from 2.27 mm (E1) to 2.08 mm (E2).

Repeatability

Figures 1C, D and 2C, D and Tables 4 and 5 show the limits of agreement of the measurements taken preoperatively and postoperatively by the 2 examiners with each pupillometer. The preoperative coefficient of interrater repeatability was smaller for the EWP (0.56 mm) than for the Colvard pupillometer (1.12 mm). Intraclass correlation coefficients were 0.95 ($P<0.0001$; 95% con-

Table 4. Limits of Agreement in Preoperative Measurements

Comparison	Mean Difference ± SD (mm)	Limits of Agreement* (mm)	Range (mm)
EWP–Colvard (E1)	−0.13±0.57	−1.25–0.99	2.24
EWP–Colvard (E2)	0.02±0.54	−1.04–1.08	2.12
E1–E2 (EWP)	−0.04±0.28	−0.59–0.52	1.11
E1–E2 (Colvard)	0.12±0.56	−0.98–1.21	2.19

E1 = examiner 1; E2 = examiner 2; EWP = Eye World Pupillometer; SD = standard deviation.
*Mean difference ± 1.96 SDs of the difference between measurements.

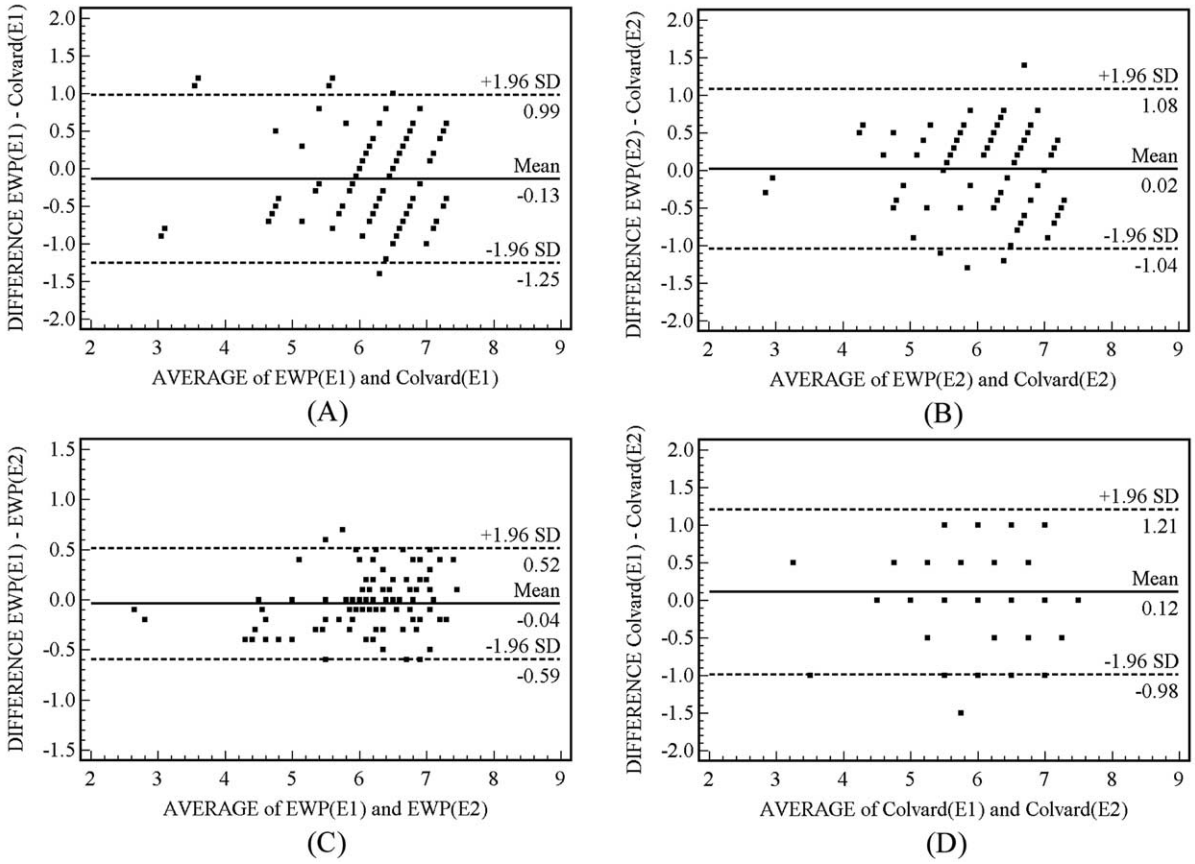

Figure 1. Preoperative pupil measurements. **A**, Agreement of the Eye World (EWP) and Colvard pupillometers for measurements taken by examiner 1 (E1). **B**, Agreement of the EWP and the Colvard pupillometer for measurements taken by examiner 2 (E2). **C**, Interrater repeatability for the EWP. **D**, Interrater repeatability for the Colvard pupillometer. All values are in millimeters. SD = standard deviation.

fidence interval [CI], 0.93–0.97) for the EWP and 0.81 ($P<0.0001$; 95% CI, 0.74–0.87) for the Colvard. Postoperatively, coefficients of interrater repeatability were 0.62 mm (EWP) and 1.14 mm (Colvard). Intraclass correlation coefficients were 0.94 ($P<0.0001$; 95% CI, 0.92–0.96) (EWP) and 0.79 ($P<0.0001$; 95% CI, 0.70–0.85) (Colvard). This finding indicates better preoperative and postoperative repeatability for the EWP device.

Discussion

Photorefractive keratectomy and LASIK are standard techniques in the refractive surgery field due to proven efficacy and high safety in the correction of medium to low myopia and hyperopia. However, there are some patients who, after surgery, complain of visual problems such as halos, glare, and ghost images, especially at night. Patients with larger pupil diameters report these disturbances more frequently.[1–3] Therefore, the accurate measurement of the scotopic pupil diameter has become an essential part of the preoperative evaluation of each patient. The pupil diameter can be affected by numerous factors, such as illumination, adaptation to light, drugs, emotional state, and age.[8,9] In addition, pupillary unrest, a phenomenon known as hippus, causes continuous changes in the pupil diameter at all levels of illumination.[10]

Table 5. Limits of Agreement in Postoperative Measurements

Comparison	Mean Difference ± SD (mm)	Limits of Agreement* (mm)	Range (mm)
EWP–Colvard (E1)	−0.09±0.58	−1.22–1.05	2.27
EWP–Colvard (E2)	−0.02±0.53	−1.06–1.02	2.08
E1–E2 (EWP)	−0.03±0.31	−0.63–0.57	1.20
E1–E2 (Colvard)	0.04±0.57	−1.12–1.19	2.31

E1 = examiner 1; E2 = examiner 2; EWP = Eye World Pupillometer; SD = standard deviation.
*Mean difference ± 1.96 SDs of the difference between measurements.

The measurement of the pupil diameter and, particularly, the scotopic pupil diameter is performed using pupillometers that function according to different principles. Methods of comparative measurements, such as the Rosenbaum pupillometer, have proved unreliable,[11] as well as photopic measurements taken using videokeratography, which underestimates the pupil diameter due to the bright luminance of the Placido rings.[12]

Pupillometers such as the Colvard, which use light amplification technology, and infrared devices, such as the EWP, produce the most reliable results.[10–15] These instruments are able to function under dim conditions without

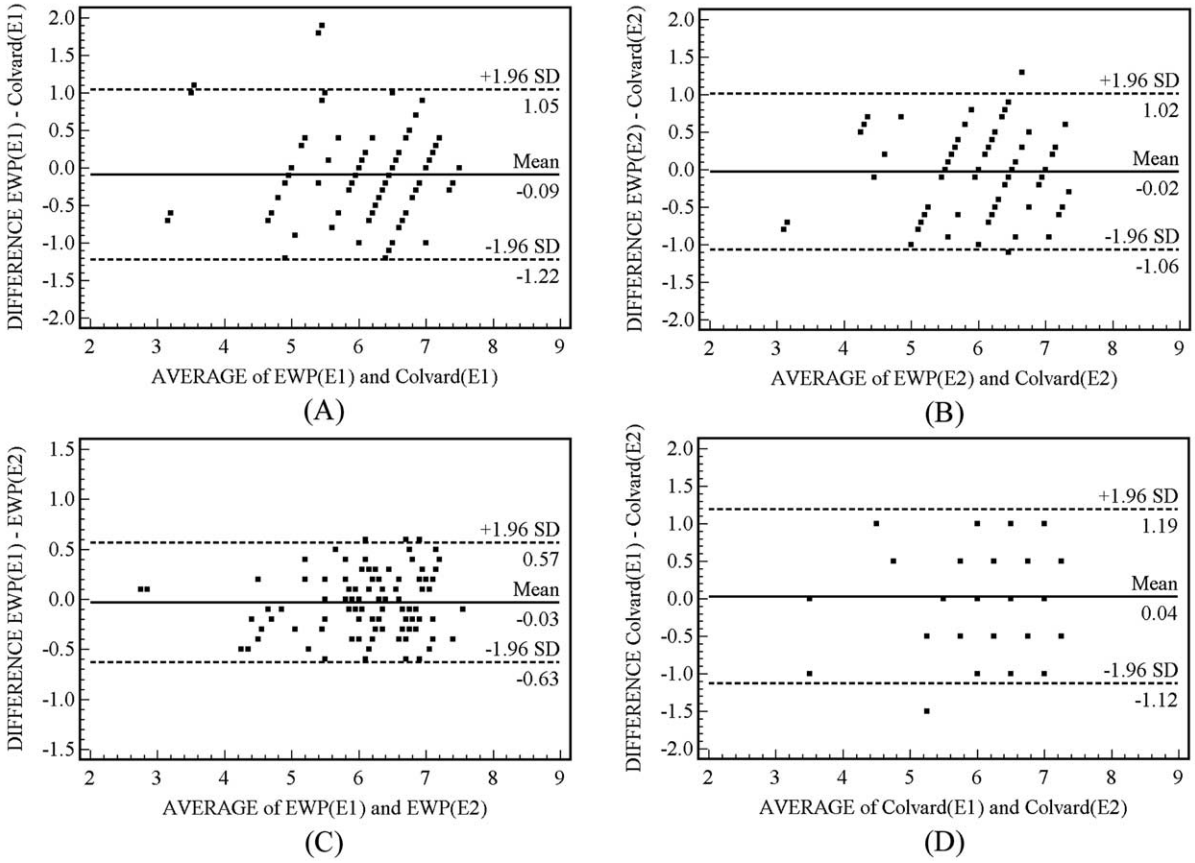

Figure 2. Postoperative pupil measurements. **A**, Agreement of the Eye World (EWP) and Colvard pupillometers for measurements taken by examiner 1 (E1). **B**, Agreement of the EWP and the Colvard pupillometer for measurements taken by examiner 2 (E2). **C**, Interrater repeatability for the EWP. **D**, Interrater repeatability for the Colvard pupillometer. All values are in millimeters. SD = standard deviation.

interfering with patients' mydriasis. The major limitation of the Colvard pupillometer is its dependence on subjective estimation. Therefore, measurement errors can easily occur because a 1-mm scale is used; this problem may be aggravated by a distortion of the pupil image, which can occur when the instrument is not positioned at the correct distance and perpendicular to the patient's eye. This source of error could explain the lower interrater repeatability of the Colvard device relative to the EWP. The Colvard's coefficients of interrater repeatability were 1.12 mm before and 1.14 mm after surgery, pointing to a high variability of measures. Several authors have investigated the Colvard's validity, reporting a range of coefficients of interrater repeatability between 0.59 and 1.20 mm.[13,15–18] Despite the poor evidence of its statistical validity, the Colvard is still considered the most used pupillometer in practice.[19]

Digital pupillometers, such as the EWP, allow a dynamic analysis of the pupil during a period of time and under different and standardized lighting conditions. In this way, it is possible to notice even very fast changes in the pupil diameter, such as hippus. The EWP management software allows the examiner to acquire objective measurements with a precision of 0.1 mm, to check the results, and to correct the errors easily, if necessary.

Preoperative agreements between the 2 devices were similar for both examiners (E1, 2.24 mm; E2, 2.12 mm). The limits of agreement are similar to those shown by other authors who have compared the Colvard with other digital infrared pupillometers, such as the Procyon (Procyon Instruments Ltd., London, United Kingdom).[15] The above values seem too high to claim that the 2 pupillometers are clinically interchangeable. However, it is known that the repeatability of each of the 2 instruments can affect the degree of agreement between them. A new method, even if highly reliable, will not agree with an old method if the latter is highly variable.[6]

The anatomical pupil is not the same as the pupil clinically measured, the entrance pupil (EP), because the latter is a virtual image, magnified and displaced anteriorly with respect to the real plane.[4] The relation of the real pupil (RP) and the EP is described by the equation $RP = EP\,(1 - AK/1.3375)$,[20] where A is the depth of the anterior chamber expressed in meters, K is the central corneal refractive power, and 1.3375 is the corneal standard refraction index. Applying this equation to a hypothetical patient with a measured pupil of 6.0 mm, central K of 44 D, and A of 4.0 mm, we find that his RP has a diameter of only 5.21 mm, a much smaller value.

The theoretical possibility that the postoperative change of the corneal power could influence the pupil measure-

ments was investigated by analyzing the scotopic pupil diameters taken with both pupillometers before and after surgery. We thought that the EWP would be more suitable than the Colvard pupillometer for this purpose, due to its better repeatability and higher precision.

Despite relative mydriasis after PRK having been reported,[21] in our study it was assumed that the patient's RPs were unchanged by the surgical procedures used. According to the above equation, by decreasing the value of K, as with myopic treatments, or by increasing it, as with hyperopic treatments, the clinically measured pupil diameter should decrease or increase, respectively. The measurements performed by both examiners, with both Colvard and EWP devices, before and after surgery did not differ significantly in either myopic or hyperopic patients. Moreover, the limits of agreement of the postoperative measurements were very similar to the preoperative ones; the agreement between instruments and the interrater repeatability of each pupillometer showed no significant changes after surgery.

Actually, according to the equation, after 3-D correction of the corneal refractive power, the increase or reduction of the preoperative measurement of the pupil diameter would be approximately 1%, constituting a too small variation to be measured with the EWP, and would be even more difficult to measure with the Colvard. A possible limitation of this study could be the small change of the mean corneal refractive power registered in patients after the intervention, -2.77 ± 1.29 D (myopic patients) and $+1.24 \pm 0.91$ D (hyperopic patients). It would be interesting to evaluate the difference between pupillometries performed before and after the surgery in subjects with greater refractive defects. However, the best indication for corneal excimer laser refractive surgery is medium to low refractive errors. It is possible that even the most sophisticated pupillometer available nowadays has technical limitations that will not allow a study of the effect of refractive changes on pupil size.

In conclusion, it is necessary to emphasize the importance of accurately measuring the scotopic pupil diameter during the evaluation of patients before refractive surgery. Thanks to pupillometry, more information is available to surgeons for planning the laser ablation zones, allowing them to appropriately advise against surgery in cases where the risk of compromising the visual quality of the patient is too high. The Colvard pupillometer and the EWP are both valid tools for measuring scotopic pupil diameters in a clinical setting. It was predictable that the EWP would be more reliable than the Colvard, due to its better repeatability rate and greater precision, as well as the possibility to save dynamic, objective, and standardized measurements.

Significant statistical differences have not been observed between the measurements of the pupil before and after surgery. However, this finding could have been influenced by a very small postoperative change in the mean corneal refractive power registered in our patients. Although the precision of the EWP is high, perhaps it is just not enough to measure such small changes.

To allow proper treatment of patients with postoperative pupil-related night vision disturbances, further studies on the effect of refractive surgery on pupil measurement are needed.

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