Comparison of the Colvard, Procyon, and Neuroptics Pupillometers for Measuring Pupil Diameter Under Low Ambient Illumination

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ABSTRACT

PURPOSE: To compare three different pupillometers (Colvard, Procyon, and Neuroptics) for determining pupil diameter at 0.04 and 0.4 lux ambient illumination.

METHODS: In 92 eyes of 46 healthy volunteers, pupil diameter was measured at 0.04 and 0.4 lux. After dark adaptation for 2 minutes, measurements were performed with each device by two examiners. Interobserver agreement, instrument agreement, and repeatability were analyzed.

RESULTS: Mean pupil diameter was 6.63±0.68 mm, 6.24±0.11 mm, and 6.99±0.67 mm at 0.04 lux and 6.22±0.74, 4.64±1.04, and 6.73±0.72 mm at 0.4 lux with the Colvard, Procyon, and Neuroptics pupillometers, respectively. The interobserver disagreement ranged within narrower limits for the Colvard (0.04 lux: −1.0 to 0.5 mm; 0.4 lux: −0.75 to 1.0 mm) and Neuroptics (0.04 lux: −1.0 to 0.5 mm; 0.4 lux: −1.7 to 0.7 mm) than for the Procyon (0.04 lux: −0.74 to 1.14 mm; 0.4 lux: −1.82 to 2.4 mm) under both light conditions. Instrument agreement ranged within narrower limits for the Colvard versus Neuroptics (0.04 lux: −1.3 to 0.75 mm; 0.4 lux: −1.55 to 1.40 mm) than for the Neuroptics versus Procyon (0.04 lux: −1.06 to 2.69 mm; 0.4 lux: 0.18 to 3.69 mm) or Colvard versus Procyon (0.04 lux: −0.63 to 2.60 mm; 0.4 lux: −0.32 to 3.13 mm) at both light levels. At 0.04 lux, repeatability showed no measurement difference outside ±0.5 mm for the Colvard and Neuroptics; for the Procyon, 25% of consecutive measurements showed a difference >±0.5 mm. At 0.4 lux, 2.5% of consecutive measurements for the Colvard and 5% for the Neuroptics differed by >±0.5 mm; for the Procyon, 13% of measurements differed by more than this amount.

CONCLUSIONS: Pupil diameters under both light conditions were largest with the Neuroptics pupillometer and smallest with the Procyon. The most “examiner independent” Procyon pupillometer performed poorly. The underestimation of the pupil diameter might have severe consequences for refractive surgery patients. The Neuroptics pupillometer showed a high interobserver agreement and repeatability and therefore high safety.

PURPOSE: To determine if a patient is suitable for refractive surgery.1

Pupil diameter plays an important role because some postoperative complaints such as halos, glare, ghosting, poor contrast sensitivity, and monocular double vision are associated with large pupils.2 Under low ambient illumination, it is possible that pupil diameter becomes larger than the functional optical zone and light passes through the ametropic ring where the light is scattered by the cornea. Therefore, exact measurement of the pupil diameter is essential before refractive surgery to avoid such postoperative problems and to preoperatively determine if a patient is suitable for refractive surgery.3

Accurate measurement of pupil diameter can be difficult due to pupillary unrest (hippus), which occurs under all luminance levels, anisocoria, accommodation, level of activity of the sympathetic nervous system, and medical treatment.4 Dark iris color also makes it difficult to identify the border of the pupil. Different diagnostic devices use various techniques for accurate and reproducible measurements. The aim of this study was to compare the recently introduced Neuroptics digital monocular handheld pupillometer (Neuroptics Inc, San Clemente, Calif) and two commonly used pupillometers—Procyon (Procyon Instruments Ltd, London, United Kingdom) and Colvard (Oasis Medical, Glendora, Calif) under 0.04 and 0.4 lux ambient illumination.

PATIENTS AND METHODS

Ninety-two eyes of 46 healthy volunteers with a mean age of 25.7±5.75 years (range 18 to 45 years) were examined.

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ined for this study. Exclusion criteria were abnormalities of the pupil (e.g., synechia), history of eye disease, eye surgery, eye trauma, other morphological eye abnormalities, and use of topical eye drops or any systemic medication. In addition to the measurement of pupil diameter, an objective manifest refraction was performed with the RF303 autorefractor (Rodenstock GmbH, Munich, Germany). Mean sphere was \(-0.79 \pm 1.38\) diopters (D) and mean cylinder was \(-0.89 \pm 2.79\) D.

**Procyon Pupillometer**

The Procyon P3000 pupillometer is a digital infrared device for binocular simultaneous measurement of pupil diameter. The patient looks into the device and fixates on a black spot focused at a virtual distance of 10 m. Rubber eyecups prevent an influence of the pupil diameter by ambient light. Infrared light-emitting diodes illuminate the eye with invisible light that does not affect the pupil diameter but is recognized by the charge-coupled device camera in the system. Three illuminance levels can be set (0.04, 0.4, and 4 lux). At each level, a sequence of 10 images of both pupils is acquired simultaneously within 2 seconds. For evaluation, the PupilFit software (Procyon Instruments Ltd) fits a circle on the border of the pupil to determine diameter size. The images are stored on a computer and can be reviewed by the examiner. For each illuminance level, the mean, range, and standard deviation of the pupil diameter is evaluated by the software and displayed as a diagram. The operator is responsible for accurate centration and focus.

**Colvard Pupillometer**

The Colvard pupillometer is a handheld device with a built-in millimeter scale using infrared technology. By pressing the light amplification button, the image can be intensified. The examiner focuses the iris and the pupil by slight movements forward and backward. The patient is asked to fixate on an internal red light. The fellow eye may be covered by an eye shield to exclude convergence miosis. A horizontal millimeter ruler, with 0.5-mm precision, is superimposed by a reticle in the device, which allows direct measurement by the examiner. The examiner places his/her eye against the instrument as is done with a direct ophthalmoscope.

**Neuroptics Pupillometer**

The Neuroptics pupillometer is a new digital infrared handheld device for monocular measurement of pupil diameter. A dark, tight-fitting eyecup covers the patient’s eye during the examination. To exclude convergence miosis, an eye shield may cover the fellow eye. The pupillometer uses an autofocus digital camera to acquire a sequence of 14 images per second of the pupil over a period of 3 seconds. The eye of the patient is displayed on the LCD screen, and the examiner manually adjusts the pupil to a displayed horizontal spanning line in the center of the screen to ensure that the pupil is in focus. The device detects the largest pupil diameter of every image, and the software calculates the mean pupil diameter as well as the standard deviation of the acquired images and automatically discards images of outliers. If the number of adequate images is too low, the device indicates that a re-measurement is necessary.

**Measurements**

After a dark adaptation time of 2 minutes, the examinations were performed by two independent clinicians (M.S., V.B.), who were experienced in all three examination techniques. The Colvard pupillometer is the only device where the examiner measures the pupil diameter; therefore, examination with the Colvard was performed first to prevent the results of other tests from creating investigator bias. The order of the examiner and other devices was randomized by coin toss. Both examiners performed the measurements with one device and then with the next device. The right eye was tested first in each examination and all measurements were performed in the same examination room in which all light sources from other devices were excluded. To assess the repeatability of the measurements, two consecutive measurements were taken for each volunteer by one examiner (M.S.) after both examiners performed all tests once. The second mea-
The ambient light level in the examination room was 0.04 or 0.4 lux measured with a lux meter (Luxmeter MS-1500; Voltcraft, Hirschau, Germany) at eye height. These two light levels were chosen as these levels are preset on the Procyon pupillometer.

STATISTICAL ANALYSIS

To compare mean pupil diameter of the measurements, the paired t test was used. A P value of <.05 was considered statistically significant. To compare two devices, Bland-Altman plots were used. With this method, the differences in measurements were plotted against the mean to assess the measure of agreement between two devices. The limits of agreement were defined as the mean difference in measurements ±2 standard deviations. A smaller value indicates a better agreement. To assess the interobserver agreement, the limits of agreement were determined for measurements performed by both examiners with each pupillometer.

For each device, repeatability was determined by comparing consecutive measurements. The coefficients
of intraobserver repeatability were defined as twice the standard deviation of the differences between consecutive measurements. Lower values indicate a better repeatability. A clinically acceptable disagreement defined as ±0.5 mm was assessed for interobserver agreement, instrument agreement, and repeatability.

RESULTS

Mean pupil diameter of both eyes measured by both examiners at 0.04 lux ambient light level was 6.99±0.67 mm (range: 5.30 to 8.60 mm) with the Neuroptics pupillometer, 6.63±0.68 mm (range: 5.00 to 8.00 mm) with the Colvard pupillometer, and 6.24±1.01 mm (range: 3.57 to 8.13 mm) with the Procyon pupillometer. At 0.4 lux, mean pupil diameters were 6.73±0.72 mm (range: 4.90 to 8.20 mm) with the Neuroptics, 6.22±0.74 mm (range: 4.25 to 8.25 mm) with Colvard, and 4.64±1.04 mm (range: 2.70 to 7.91 mm) with the Procyon. Pupil diameter as a function of duration of dark adaptation at 0.04 lux is shown in Figure 1. Interobserver comparisons for
INFLUENCE OF DURATION OF DARK ADAPTATION ON MEASUREMENTS

In a separate control study of 11 patients, we assessed the pupil diameter with the Colvard pupillometer after 1, 2, 5, 10, and 15 minutes’ duration of dark adaptation at 0.04 lux (Table 1). We found no significant change of pupil diameter after 2 minutes or more of dark adaptation (see Fig 1). Therefore, we were able to rule out that the time sequence of measurements influenced the results.

INTEROBSERVER AGREEMENT

The interobserver agreement for each test method is shown in Figure 2. At 0.04 lux ambient illumination, the measurements with each pupillometer showed a

Figure 4. Bland-Altman analysis of the interobserver repeatability. A) Repeatability of Colvard at 0.04 lux. B) Repeatability of Neuroptics at 0.04 lux. C) Repeatability of Procyon at 0.04 lux. D) Repeatability of Colvard at 0.4 lux. E) Repeatability of Neuroptics at 0.4 lux. F) Repeatability of Procyon at 0.4 lux. Solid lines = mean difference, dotted lines = mean ± 2 standard deviations, dashed lines = ±0.5 mm.
similar range of error within the limits of agreement using Bland-Altman analysis (Neuroptics: 1.48 and 1.12 for right and left eyes, respectively; Colvard: 1.44 and 1.44 for right and left eyes, respectively; and Procyon: 1.52 and 1.56 for right and left eyes, respectively). At 0.4 lux, the range of error within limits of agreement was smaller for Neuroptics (right eye 1.16, left eye 1.28) than for Colvard (right eye 1.72, left eye 1.84) and Procyon (right eye 2.76, left eye 2.52) (Table 2). No statistically significant difference between the right and left eyes with any devices at both ambient light levels was noted.

**INSTRUMENT AGREEMENT**

The mean differences and limits of agreement among the three pupillometers using Bland-Altman analysis are shown in Table 3. The instrument disagreement of the measurements at 0.04 lux ambient illumination ranged from −1.3 mm to 0.75 mm in Colvard versus Neuroptics; from −1.06 mm to 2.69 mm in Neuroptics versus Procyon; and from −0.63 mm to 2.60 mm in Colvard versus Procyon. The disagreement in Neuroptics versus Procyon and Colvard versus Procyon at 0.04 lux was greater at smaller pupil diameters.

At 0.4 lux ambient light condition, instrument disagreement of measurements ranged from −1.55 mm to 1.40 mm in Colvard versus Neuroptics; −0.18 mm to 3.69 mm in Neuroptics versus Procyon; and −0.32 mm to 3.13 mm in Colvard versus Procyon. The disagreement in Neuroptics versus Procyon and Colvard versus Procyon at 0.4 lux was greater over all pupil diameters. When considering clinically significant disagreement at 0.04 lux, 42.2% and 35.5% of measurement differences for examiners 1 and 2, respectively, fell outside ±0.5 mm for Colvard versus Neuroptics; 64.4% and 68.8% for examiners 1 and 2, respectively, for Neuroptics versus Procyon; and 26.0% and 45.6% for examiners 1 and 2, respectively, for Colvard versus Procyon. At 0.4 lux, 42.2% and 64.4% of measurement differences for examiners 1 and 2, respectively, fell outside ±0.5 mm for Colvard versus Neuroptics; 95.5% and 97.7% for examiners 1 and 2, respectively, for Neuroptics versus Procyon; and 89.1% and 89.1% for examiners 1 and 2, respectively, for Colvard versus Procyon (see Fig 3).

**REPEATABILITY**

Table 4 shows the measurement repeatability of the three pupillometers using Bland-Altman analysis. The coefficient of intraobserver repeatability was smaller for the Colvard pupillometer (0.28) than for the Neuroptics (0.40) and Procyon (1.06). A low coefficient of intraobserver repeatability indicates a better repeatability of sequential measurements. The Colvard pupillometer can be affected by observer bias. At 0.4 lux ambient illumination, the coefficient of intraobserver repeatability was also smaller in Colvard (0.52) and Neuroptics (0.52) than in Procyon (0.68) pupillometry.

The disagreement of two consecutive measurements at 0.04 lux ambient illumination ranged from −0.25 to 0.5 mm with Colvard, from −0.4 to 0.4 mm with Neuroptics, and from −1.46 to 1.26 mm with Procyon. For Colvard and Neuroptics pupillometers, no measurement fell outside ±0.5 mm; for the Procyon, 25% of measurements fell outside ±0.5 mm (see Fig 4). At 0.4 lux ambient light condition, disagreement of two consecutive measurements ranged from −1.0 to 0.5 mm with Colvard, −0.9 to 0.9 mm with Neuroptics, and −1.28 to 0.25 mm with Procyon. For Colvard and Neuroptics, 2.5% and 5%, respectively, of the measurements fell outside ±0.5 mm and 13% of the measurements for Procyon fell outside ±0.5 mm.

**DISCUSSION**

Although numerous articles compare various pupillometers using different techniques, most are difficult to interpret because most investigators failed to properly measure ambient illumination, did not use a consistent and adequate dark adaptation protocol, did not use the same light levels for each pupillometer, or used data compiled from clinical records of refractive surgery patients in which numerous individuals performed the testing. In our study, the ambient light levels of all measurements were controlled by lux meter measurement, a rational dark adaptation protocol was used, and we
compared three different pupillometers under 0.04- and 0.4-lux ambient illumination. Furthermore, we used two different analysis concepts—the commonly used Bland-Altman analysis and a protocol that uses coefficients focused on clinically unacceptable imprecision and inaccuracy.

The Colvard was the first commercially available pupillometer. It has limited precision because the in-built reticule is marked in 0.5-mm integers. Therefore, measurements in 0.1-mm steps are not possible and readings are clustered to integer values (eg, 5.0, 5.25, 5.5, and 5.75 mm) even by experienced examiners. This clustering is seen in the graphs (ie, Figs 2A and 2D) by straight lines of data points. It underlines the subjective observer-based measurement of Colvard pupillometry. Therefore, the Colvard is prone to user bias unless the examiner is skillful and careful. The Colvard has a variable learning curve depending on the examiner.14

On the other hand, from an economic point of view, the Colvard pupillometer is an attractive alternative to digital pupillometers, and an experienced examiner can also follow the dynamic pupil process, such as hippus, to assess the largest pupil diameter.

The second commercially available pupillometer is the Procyon. The Procyon pupillometer offered some advantages such as objective measurement, simultaneous binocular measurement, dynamic multiple measurement, and perfect fixed illuminance levels (0.04, 0.4, and 4 lux), which is hard to ensure under general clinic conditions.

Some authors suggest that binocular measurements with the Procyon pupillimeter imitate the patient’s life conditions more realistically than monocular measurements.9 Our data indicate that monocular pupillometry either with the Neuroptics or Colvard pupillometer is at least as accurate as using the Procyon. These findings are similar to the studies of Kohnen et al11 and Michel et al.15

Another problem of the Procyon P3000 is the lack of automated outlier recognition, which makes it neces-
sary to check every measurement to select appropriate frames to be analyzed.

Low light-adapted pupil diameter is strongly influenced by age. The average age of our patient cohort was 25.7 years (range: 18 to 45 years). Based on laboratory data using infrared photography, we would expect a mean pupil diameter of approximately 7.0 mm at less than 1 lux. The Colvard and Neuroptics pupillometer results were generally in agreement with the laboratory standards. The mean pupil diameter of the Colvard (6.63 ± 0.68 mm) was slightly smaller than expected. The Neuroptics pupillometer was best in agreement with laboratory values. The Procyon pupillometer showed a significantly smaller pupil diameter, especially at 0.4 lux ambient illumination.

Other studies of this device also showed larger differences between “scotopic” (0.04 lux) and “low mesopic” (0.4 lux) light level with the Procyon pupillometer than one would expect from the minimal difference in the state of retinal photoreceptor adaptation. The mean pupil diameter value at 0.4 lux (4.64 ± 1.04 mm) was so small that it can be concluded that the “effective” internal illumination of the Procyon is substantially higher than 0.4 lux whereby the rod photoreceptors were significantly saturated.

The smaller pupil diameter may also be an effect of accommodative miosis when the patient fixates on the infrared-LED in the device instead of the fixation target.

To avoid patient complaints such as halos, glare, ghosting, monocular double vision, and loss of con-

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**TABLE 3**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Mean Difference ± SD (mm)</th>
<th>Limits of Agreement (mm)</th>
<th>Range of error (mm)</th>
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<tr>
<td>0.04 lux</td>
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<td></td>
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<tr>
<td>Colvard vs Neuroptics</td>
<td>−0.41 ± 0.41</td>
<td>−1.23, 0.41</td>
<td>1.64</td>
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<tr>
<td>Neuroptics vs Procyon</td>
<td>0.76 ± 0.68</td>
<td>−0.60, 2.12</td>
<td>2.72</td>
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<tr>
<td>Colvard vs Procyon</td>
<td>0.38 ± 0.67</td>
<td>−0.96, 1.72</td>
<td>2.68</td>
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<tr>
<td>0.4 lux</td>
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<td></td>
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<tr>
<td>Colvard vs Neuroptics</td>
<td>−0.50 ± 0.49</td>
<td>−1.48, 0.48</td>
<td>1.96</td>
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<tr>
<td>Neuroptics vs Procyon</td>
<td>2.08 ± 0.81</td>
<td>0.46, 3.70</td>
<td>3.24</td>
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<tr>
<td>Colvard vs Procyon</td>
<td>1.57 ± 0.81</td>
<td>−0.05, 3.19</td>
<td>3.24</td>
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</table>

*Limits of agreement is defined as mean difference ±2 standard deviations.
†Range of error is defined as range of the limits of agreement.

**TABLE 4**

<table>
<thead>
<tr>
<th>Device</th>
<th>Mean Difference ± SD (mm)</th>
<th>Limits of Agreement (mm)</th>
<th>Coefficient of Intraobserver Repeatability†</th>
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<tr>
<td>0.04 lux</td>
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<td></td>
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<tr>
<td>Colvard</td>
<td>0.01 ± 0.14</td>
<td>−0.27, 0.29</td>
<td>0.28</td>
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<td>Neuroptics</td>
<td>−0.02 ± 0.20</td>
<td>−0.42, 0.38</td>
<td>0.40</td>
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<tr>
<td>Procyon</td>
<td>−0.02 ± 0.53</td>
<td>−1.08, 1.04</td>
<td>1.06</td>
</tr>
<tr>
<td>0.4 lux</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colvard</td>
<td>−0.01 ± 0.26</td>
<td>−0.53, 0.51</td>
<td>0.52</td>
</tr>
<tr>
<td>Neuroptics</td>
<td>0.00 ± 0.26</td>
<td>−0.52, 0.52</td>
<td>0.52</td>
</tr>
<tr>
<td>Procyon</td>
<td>−0.23 ± 0.35</td>
<td>−0.93, 0.47</td>
<td>0.70</td>
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</tbody>
</table>

*Limits of agreement is defined as mean difference ±2 standard deviations.
†A lower coefficient of intraobserver repeatability indicates a better repeatability.
Comparison of Three Pupillometers/Schallenberg et al

contrast sensitivity, the exact measurement of pupil size is essential prior to refractive surgery. Measurements with a negative bias (pupil diameter is measured smaller than actual) have a greater surgical risk for a patient than measurements with a positive bias (pupil diameter is measured larger than actual). In a young, fully dark-adapted cohort such as ours, very few patients should have a pupil diameter smaller than 6.0 mm at 0.04 lux. At 0.04 lux, 7.8% of eyes measured with the Neuroptics and 9.2% of eyes measured with the Colvard had a pupil diameter <6.0 mm, whereas 31.5% had a pupil diameter <6.0 mm with the Procyon. This indicates a strong negative bias in Procyon pupillometry.

Our results show that the Neuroptics pupillometer had the best interobserver agreement at both ambient light levels. The interobserver agreement between two skilled examiners using the Colvard pupillometer was not as good as Neuroptics but better than Procyon, even though this device supposedly has the least possibility of the tester introducing error.

Using the range of interobserver disagreement as an indicator of the worse case scenario, the range was larger with Procyon at both light levels. This indicates a higher risk that the measurements of two examiners vary.

The instrument agreement was best between Colvard and Neuroptics at both light levels using Bland-Altman analysis. These results agree with the range of instrument disagreement, which showed a smaller range in Colvard versus Neuroptics than in the others at 0.04- and 0.4-lux ambient light condition. But even in Colvard versus Neuroptics, approximately 40% and 60% of the measurement differences fell outside ±0.5 mm at 0.04 lux and 0.4 lux, respectively. A measurement difference of ±0.5 mm can be defined as a coefficient of clinically acceptable difference between two devices. These findings underline that even the devices with best instrument agreement showed results with clinically unacceptable differences. Most of the published studies comparing different pupillometers showed similar or worse results when re-evaluating the figures with regard to the coefficient of clinically acceptable difference. The Procyon showed poor agreement with the other two devices at both illumination levels.

Analyzing the repeatability of two consecutive measurements, our results showed that the repeatability was worse with Procyon using Bland-Altman analysis as well as the coefficient of the clinically acceptable difference. The repeatability of Neuroptics and Colvard was comparable with a smaller coefficient of intraobserver repeatability for the Colvard at 0.04 lux. On one hand, the Colvard pupillometer can be affected by observer bias, but on the other the readings are clustered to integer values (e.g., 5.0, 5.25, 5.5, and 5.75 mm); therefore, fewer values showed differences between the first and second reading.

To our knowledge this is the first detailed study with the newly introduced Neuroptics pupillometer, a fully automated portable handheld device for monocular measurements. It offers multiple measurements of the pupil diameter for a relatively modest price, but it lacks a fixed illumination level. A disadvantage of the Neuroptics device is that it sometimes failed in assessing large pupils (>8 mm) and in cases of patients with dark iris because of missed recognition of the pupil edge.

Michel et al15 performed a study comparing the Procyon and Neuroptics pupillometers and found a high level of repeatability and agreement of pupil diameter at 0.04 lux light condition for repeated measurements and between the two devices, but this study has two important limitations—study size (only 21 volunteers) and mean age (71 years; range: 57 to 87 years). In our opinion, this average age is not appropriate in a study comparing different pupillometers, which are normally used to assess pupil diameters before refractive surgery.

The newly introduced Neuroptics pupillometer represents an observer independent, digital, multiple measurement device, which showed a higher inter- and intraobserver repeatability and a larger pupil diameter than the other two devices.

Considering our data in current clinical practice, the Neuroptics pupillometer is superior to the Procyon pupillometer and is preferable to the Colvard pupillometer. However, it is a surgeon’s decision to perceive the best parameter for an individual case to avoid complaints such as halos, glare, ghosting, and monocular double vision. Therefore, reliable data as presented are necessary.

AUTHOR CONTRIBUTIONS
Study concept and design (M.S., J.M.S.); data collection (M.S., V.B.); analysis and interpretation of data (M.S., V.B., K.S., S.K., J.M.S.); drafting of the manuscript (M.S.); critical revision of the manuscript (V.B., K.S., S.K., J.M.S.); statistical expertise (M.S., J.M.S.); administrative, technical, or material support (K.S., S.K., J.M.S.)

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