Pupillometry Using the Procyon Pupillometer

To the Editor:

I read with some surprise and was a little dismayed by the recent article by Schallenberg et al., which was published in the February 2010 issue of the Journal of Refractive Surgery, on the comparative performances of the Colvard (Oasis Medical, Glendora, California), Neuroptics (Neuroptics Inc, San Clemente, California), and Procyon (Procyon Instruments Ltd, London, United Kingdom) pupillometers. The article is very negative regarding the Procyon product, and the conclusions directly contradict previous studies and my own experience of using the device over many years.

The main thrust of this study appears to be concerned with a comparison of the pupillometer readings when the ambient illumination of the examination room is comparable to that incident at the cornea of the Procyon device. It should be pointed out that this type of comparison is fairly meaningless in the absence of any standardized examination room illumination and visual conditions. The variability between and within examination rooms is not addressed in any way, although this is likely to have the largest effect on pupil measurements. The study criticizes previous authors who compared Procyon pupillometry with alternatives for not attempting to set ambient illumination to be the same as the Procyon. One of the previous studies clearly stated that the intention was to compare the Procyon measurements with Colvard measurements taken under usual conditions at their institution.

The authors, in my opinion, have not taken full account of this effect and this puts a question mark over the conclusions of the paper. At least the Procyon device attempts to standardize visual conditions and gives information about the patient’s pupil size under various dim illumination intensities so clinicians can draw their own conclusions about the risks. There is also enough peer-reviewed literature to convince me the Procyon has set visual conditions appropriately and is the best device on the market today for refractive surgery.

Additionally, the fact that the above authors report significantly poorer repeatability of the Procyon compared to the alternatives seems tenuous at the very least. Previous studies have all concluded the repeatability of the Procyon is as certainly as good as or significantly better than the alternatives. Why is there such a large difference in the repeatability of the Procyon pupillometer in this new study compared with previous studies? No convincing explanation has been given.

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REFERENCES

Reply:

We thank Dr Rosen for his comments regarding our article. His critique addresses the absence of any standardized examination room illumination. In this context, we would like to point out that in our study the examination room illumination was standardized. As stated in the article, all measurements were performed in the same examination room under the same ambient light. All light sources from other devices were excluded. The ambient light level was 0.4 lux and 0.04 lux measured at eye height directly beside the right eye of the volunteer. Furthermore, we checked the ambient light level at several points within the examination room. Therefore, the examination room was standardized and the incident light at the cornea was comparable at all measurements.

In our opinion, the criticism of previous studies in which authors compared the Procyon pupillimeter (Procyon Instruments Ltd, London, United Kingdom) with alternatives ignoring the different ambient light level is justified.

Kohnen et al stated clearly that their intention was to compare the Procyon with the Colvard (Oasis Medical, Glendora, California) pupillometer under usual conditions at their institution. The only conclusion one can draw from this study is that the usual condi-

*The author has no proprietary interest in the materials presented herein.
tions at the authors’ institution are probably inadequate to assess the pupil diameter with the Colvard. In comparison to measurements under “usual” ambient light conditions, the Procyon might be more precise, but a general conclusion regarding which device is more accurate is not possible.

To compare several devices in general, it is necessary to standardize the conditions of measurement as much as technically possible. That is what we have done in our study.

In addition, Rosen stated that a convincing explanation for the poorer repeatability of the Procyon in our study is not given. We, too, were surprised by the fact that the Procyon performed so poorly with regard to repeatability. We discussed several possible explanations in the article. First, the “effective” internal illumination might be substantially higher than 0.04 lux or 0.4 lux. A second explanation might be the accommodative miosis when the volunteers fixate on the infrared-light emitting diode instead of the fixation target.

Furthermore, the mean pupil size measured with the Procyon was substantially smaller than we expected based on laboratory data using infrared photography. From this data, a mean pupil diameter of approximately 7.0 mm at less than 1 lux would be expected. The mean pupil diameter of the Procyon was 6.24 ± 1.01 mm at 0.04 lux and 4.64 ± 1.04 mm at 0.04 lux. Other studies of this device also showed smaller mean pupil diameters and larger differences between “scotopic” (0.04 lux) and “low mesopic” (0.4 lux) light levels with the Procyon pupillometer than one would expect from the slight difference in a state of retinal photoreceptor adaptation. The smaller pupil size might be another reason for the poorer repeatability of the Procyon because smaller pupils are able to show more pupillary unrest than pupils that are maximally dilated or constricted.

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REFERENCES

Reply:

This reply seeks to address issues raised by Rosen regarding the recently published article by Schallenberg et al. The article examined interobserver agreement for two observers, instrument agreement, and repeatability for three commercially available pupillometers—Procyon (Procyon Instruments Ltd, London, United Kingdom), Colvard (Oasis Medical, Glendora, California), and Neuroptics (Neuroptics Inc, San Clemente, California). Rosen has raised some issues regarding the results of this study, especially as it pertains to the Procyon device. Although it is impossible to determine the source of the deviations seen in the study, it is possible to rule out some causes.

Rosen suggests that the authors failed to standardize the ambient illumination and visual conditions. However, their article clearly states that each volunteer was dark-adapted for 2 minutes and the ambient illumination was measured with a lux meter. Furthermore, even if the ambient illumination was set incorrectly, this would still not account for the differences seen in the study. First, there is large variation in the Procyon readings for the interobserver comparisons of Figures 2C and 2F. Because the Procyon sets its own illumination and blocks the ambient illumination, any errors by the researchers in setting the room illumination would not show up in these measurements. Yet, there are still significant interobserver differences with the Procyon. A more interesting effect is the agreement between the two observers (see Fig 2C) for the Procyon device for pupils >6 mm, but the agreement seems to break down for pupils <6 mm. Again, this effect is independent of the ambient illumination. Second, if the authors had improperly assessed the ambient illumination, we would expect a constant offset in the Bland-Altman plots. In other words, improper setting of the room illumination would lead to, on average, a constant change in pupil size and not the variability that is seen in Figures 4C and 4F.

*The authors have no proprietary interest in the materials presented herein.*
The results of the study by Schallenberg et al\(^1\) clearly show some problems with the Procyon measurements. The array of literature on the performance of the Procyon device, as pointed out by Rosen, suggests that these measurement problems may not be inherent to the Procyon device in general, but may reflect specific problems with the device at the authors’ institution. Procyon should verify the calibration of this unit. However, it appears that the researchers are fully capable of measuring and controlling the ambient illumination, and that their study protocol is sound.

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Reply:
I reviewed the paper by Schallenberg et al\(^1\) exhaustively (twice). It had a number of strengths, specifically: 1) the authors themselves performed all testing, without delegation to technicians; 2) dark adaptation was well defined and ambient illumination was measured with an appropriate device; and 3) Colvard (Oasis Medical, Glendora, California) pupillometry was performed first to avoid investigator bias. The Neuroptics (Neuroptics Inc, San Clemente, California) and Colvard pupillometers showed much better inter-device agreement than the Procyon (Procyon Instruments Ltd, London, United Kingdom) compared to either pupillometer.

When considering the primary data, Rosen has two options. First, he can state that neither the Neuroptics nor the Colvard pupillometer were accurate and the fact that they show close agreement merely suggests that they were similarly inaccurate to a remarkable degree. Second, he can state that the Procyon pupillometer was either improperly calibrated or the investigators did not know how to use it.

Rosen’s claim that room illumination and viewing conditions were not standardized is false. His complaint that it is difficult to standardize illumination from one examination lane to another is not relevant to this article. Further, careful clinicians might perform all pupil testing in one specific room; but if not, it is quite possible to obtain a high degree of similarity of ambient illumination from lane to lane if one is meticulous.

In addition, the manufacturer of the Procyon device has never justified its use of an entirely artificial and unnatural viewing environment for pupil measurement. The claim that precisely controlling the flux at the corneal plane is somehow a better testing condition is unsupported. The simple fact that the Procyon gives such different results from two other pupillometers strongly suggests that the underlying premises for the device are incorrect.

I stand behind the authors’ work and my review of it.

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