Repeatability of the Procyon P3000 Pupilometer

To the Editor:

The results from the study by Schallenberg et al., which was published in the February 2010 issue of the Journal of Refractive Surgery, seem at odds with previous publications. The coefficient of inter-rater repeatability (CIR) may be defined as twice the standard deviation of the differences between two examiners’ measurements. For the P2000 pupilimeter (Procyon Instruments Ltd., London, United Kingdom), the mean difference is reported to be ~0.1 mm, with a standard deviation (SD) of 0.32 mm, and thus a CIR of 0.64 mm.

I have analyzed P3000 (Procyon Instruments Ltd) repeatability data from 52 eyes of 26 normal individuals, mean age 29 years. Each individual was dark adapted at 1 lux for 2 minutes before being positioned in the P3000 with the illumination set at 0.04 lux (scotopic). The pupil diameter of each eye was recorded simultaneously at 5 frames per second over 20 seconds, to yield 100 frames. The individual was then exposed to normal room lighting for several seconds before being re-dark adapted and the measurement process repeated. To simulate the “normal” Procyon method used in refractive surgery (10 measurements over 2 seconds at 5 frames per second), I put a 10-measurement moving average filter over the data to create 20 measurement epochs. Each epoch from the first measurement sequence was compared with every epoch from the second measurement for each eye. The most common differences and most extreme differences (outside the 95th percentile) between the two measurements were analyzed.

The mean scotopic pupil size was 6.5 mm. The mean of the most common difference measurements was 0.03 mm (SD=0.16 mm, CIR=0.32 mm). At the extremes, the difference was 0.28 mm (SD=0.25 mm, CIR=0.50 mm). The P3000, therefore, appears to outperform its predecessor.

Although the importance of pupil size as a cause of night vision complaints has been questioned, there continues to be great interest in its measurement. A correlation exists between the ambient light level and the pupil diameter measured. Many examination rooms will be brighter than cited in Schallenberg et al’s article, and thus yield smaller mean pupil sizes with measuring devices that do not occlude external light and provide a fixed light level, such as the P2000 and P3000.

Schallenberg et al suggest that the smaller pupil sizes and poor repeatability may be due to instability of accommodation caused by patients fixating the infrared sources, rather than the correct target. I am concerned that no mention is made of what the correct fixation target looks like and that the machine they describe sounds more like a P2000 vis-à-vis the rubber eye caps. Previous work has shown that monocular measurements of pupil diameter followed by binocular measurements of the same patients, with the same instrument, may give rise to a significantly larger monocular diameter.

I am concerned that the results reported are based on flawed methodology for the Procyon instrument, and are potentially misleading. Suggesting that high interobserver agreement and repeatability equates with high safety is a false reassurance if the measurement is not accurate. My results suggest that the P3000 repeatability is even better than the Procyon P2000, an instrument that has been widely tested and accepted in the refractive surgery community.

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Reply:

We thank Mr Smith for his comment regarding our article. His main criticism addresses the higher coefficient of interrater repeatability (CIR) of the Procyon pupillometer (Procyon Instruments Ltd., London, United Kingdom). He assumes a methodology flaw and he misses a convincing explanation for the poorer performance of the Procyon with regard to repeatability. The Procyon P3000 with the “rubber foam” eye caps was used strictly according to the manufacturer’s guidelines and the examiners were well experienced in pupillometry with the Procyon.
In our paper, we discussed several possible explanations for the smaller pupil diameter and the poorer repeatability measured with the Procyon. First, there might be a convergence miosis when the patients try to fixate to the fixating target, but fixate to the infrared-light emitting diode instead. Second, an explanation for the poorer repeatability might be the smaller pupil diameter measured with the Procyon because smaller pupils are able to show more pupillary unrest than pupils that are maximally dilated or constricted.

Smith notes that many examination rooms are brighter than cited in the paper and therefore there is an advantage to occlude external light during the measurement and provide fixed light levels, which the Procyon device is capable of doing. In our study, we controlled the ambient light level with the luxmeter at eye height and at several points within the examination room to guarantee stable settings. However, the mean pupil size measured with the Procyon was substantially smaller than we expected based on data using infrared photography. Previous studies showed the same results. Therefore, the “effective” internal illumination might be substantially higher than 0.04 lux or 0.4 lux. A clinically important distinction exists between internal illumination and ambient room illumination. The labeled 0.04 lux or 0.4 lux might cause more photoreceptor saturation than the same value measured with a luxmeter under open viewing conditions. Thus, to occlude external light during the measurement and provide fixed light levels might be a disadvantage.

According to Smith, Kurz et al showed that monocular measurements of pupil diameter followed by binocular measurements may give rise to a significant larger monocular diameter. The study design of Kurz et al is confusing and the methodology seems inaccurate. The authors used different types of dark-adaptation protocols in the pilot and in the main study. It is not clearly defined whether the adaptation to daylight is also used between the different illumination conditions in the main study. In addition, there is no information about the exact ambient light condition in the examination room.

Moreover, one simple explanation may exist that monocular measurements of pupil diameter followed by binocular measurements give rise to a significantly larger monocular diameter. Kurz et al covered one eye with a black eyeshield during monocular measurement, which leads to complete dark-adaptation of this eye. After removing this eyeshield, the rods of this eye were at least partially bleached and the pupils were constricted. Therefore, the differences between monocular and binocular measurements were higher under low mesopic and mesopic conditions than under scotopic conditions.

For exact pupillometry, it is essential that the rod system is in a steady state because the pupil dark response is controlled by the rod system.

Smith made the same error in his own study. The patients were dark-adapted to 1 lux but Smith measured the scotopic pupil diameter with the Procyon P3000 at 0.04 lux. The whole dark-adaptation protocol is imprecise. There is no information about the “normal” room lighting and a precise value as to how long the patients were exposed to normal room light between first and second measurement. The presented data are limited and cannot be generalized to other clinical conditions.

In addition to a high interobserver agreement and repeatability, it is most important that the results of the measurements are in accordance with laboratory data using infrared photography, which is the most exact method currently. These three points together ensure safe measurements and avoid later complaints such as halos, glare, ghosting, and monocular double vision.

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