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Author reply

Dear Editor:

I welcome this opportunity to respond to Drs Brown and Khanani. Although results may be contrary to certain beliefs within the medical practice concerning the role of pupil size in night vision complaints (NVCs) after refractive surgery, I believe that good scientific interpretation of data should lead to better objective conclusions.

First, a retrospective cohort study is a robust protocol for exploratory data mining, which is different than a confirmative cohort study through long-term investigation. The use of a retrospective cohort study also differs from that of a case–control study; such a study could not investigate risk factors within matched criteria between controls and disease. For example, if controls and NVC patients had been matched by pupil size, because the ratio of control to NVC would have been 1, it would have been impossible to detect the role of pupil size in NVCs. Therefore, a retrospective cohort study was chosen to consider a broad analysis of the phenomenon, because clinical data on NVCs were sparse, and the phenomenon is not clearly understood.

Before this study, assessment of pupil size measurement protocol was published[1] and cited in our "Discussion." This study reflected general practice of pupil size measurement in a clinical setting using a good and proper standard-of-care protocol.

As stated in our "Discussion," "even if measured more precisely, pupil size may not be the most important clinical predictor of postoperative NVCs, because other variables demonstrated a high degree of statistical significance." In this study, the odds ratio (OR) for pupil size greater than 7 mm was 0.92 ($P = 0.82$). If pupil size was to surpass spherical correction of >5 diopters as a risk factor, it would have to exceed a 2.8 OR ($P = 0.002$).

Although Schallhorn et al's results[2] differed slightly from those of the present study, their conclusion was that "most of the variability in visual quality could not be explained by preoperative or clinical outcome measures, including pupil size." The present study differs in its conclusions, as preoperative spherical correction, age, optical zone, and postoperative spherical equivalent were predictive of NVCs. However, as in the study by Schallhorn et al, the direct implication of pupil size was a negligible factor in the prediction of the long-term quality of vision after LASIK.

In our study, criticism suggesting greater emphasis on statistics is not reasonable. I believe that statistical analysis is merely an objective tool to gain knowledge of a phenomenon. Too often, studies contain too little or inappropriate statistical analysis.[3,4] The present study used the best statistical tools available to assess ORs of NVCs after LASIK while exploring bilaterality among patients.[5] As medical knowledge grows, so do statistical tools used to scrutinize its results.

The present study discussing 12-month findings in over 750 eyes took 2 years to complete. There was an additional 2-year period for the review and revision process, during which time valuable comments from 5 reviewers were received and considered. I do not believe the credibility of the Journal or the peer review process has been undermined.

In this study, the rating of NVCs was subjective; to measure NVCs objectively may even prove to be harder. I sincerely hope the present article will help point to new directions for future studies.

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Dear Editor:

In the January 2004 issue, Drs Pop and Payette have attempted to analyze the importance of pupil size in determining potential night vision problems after LASIK.[1] Although they did find an early correlation with night vision complaints (NVCs) and pupil size at 3 months, by 6 months they were unable to statistically validate an association.

The conclusions in this study are in marked contrast to Dr Pop's earlier opinion, where he stated that "patients with refractive errors greater than -4D and scotopic pupils 8 mm or larger are contraindicated for 6-mm-zone excimer surgery."[2] Optical zones (OZs) of 5.5 to 6.5 mm with blend zones up to 8.0 mm were used in the current study. We feel it is unlikely that the simple addition of a blend zone would completely eliminate NVCs in patients with large pupils.

We caution refractive surgeons not to interpret Pop and Payette's study as meaning we no longer have to measure scotopic pupil size and discuss the potential implications of large pupils during preoperative patient examinations. The original Visx PRK training manual, multiple presentations at meetings, and textbooks on corneal laser surgery all stress the potential importance of pupil size as a possible predictor

of nighttime symptoms. All of us have postoperative patients with varying amounts of preoperative myopia in our practices with scotopic pupils of >6.5 mm, treated with modern lasers, 6.5-mm ablations, and blend zones. Although it is true that many of them do well, a few are truly miserable because of their NVCs.

The cause of NVCs is no doubt multifactorial, involving the amount of correction, ablation zone diameter, quality of the ablation and blend zone, patient healing response, and the individual patient's subjective neural processing of his or her new vision. To deny that a large entrance pupil is not *potentially* an important risk factor in at least some patients is not consistent with our clinical experience.

When symptomatic patients have their pupil size reduced pharmacologically and report a dramatic decrease in symptoms, it is obvious that pupil size is related to their symptoms. In many patients, the reduction of both the pupil size and NVCs can be correlated with a dramatic decrease in the magnitude of wavefront higher order aberrations such as coma and spherical aberration.[3]

We now address several aspects of the current study:

1. The decrease in subjective complaints about halos and other nighttime glare problems is similar to the experience with multifocal intraocular lenses (especially the ARRAY). Although the halos do not actually disappear, the patients become more tolerant, and the unwanted images are less noticeable due to the neural adaptation of the brain.
2. A significant flaw in this study and in the Schallhorn et al study[4] is that NVCs need to be analyzed and compared in high-risk versus low-risk groups. The former is the group with higher myopia (>6 diopters [D]) *and* a larger pupil (>7 mm), and the latter group is everyone else. Usually 20% of the population having LASIK meet the criteria for being high risk. Pupil size alone often will not be a statistically significant factor, because the 20% of the group where it does matter (high risk) unfortunately get lost in the larger 80% with average to small pupils (low risk).
3. Another problem relates to the OZ size. Studies by Holladay and Janes[5] and Boxer Wachler et al[6] have shown that with increasing levels of myopic correction, the OZ becomes smaller and spherical aberrations increase. In the Pop and Payette study, the *manufacturer's specified* OZ was used, not the *effective* OZ that is related to the amount of treatment. As a result, −1-D and −10-D treatments with the manufacturer's OZ of 6.5 mm are considered equal, even though our studies have shown that the effective OZ is 25% less in the larger treatment. The result is that the pupil size–OZ size disparity is no longer accurate because the actual achieved OZ sizes are not correct. Without adjusting for the effective OZs, the analysis looking at the differential pupil size is flawed.
4. We do not know the reasons for choosing a 5.5-mm OZ versus a 6.0-mm OZ versus a 6.5-mm OZ or selecting a transition zone (TZ), which varied from 6.0 mm to 8.5 mm. Of course—in this article—all patients, according to "Patients and Methods," had a "gradual change in postoperative curve . . . from the limit of OZs to the limit of TZs." Thus, the TZ was a progressive change with this laser. Therefore, the findings in this study would not be applicable to patients treated with the VISX laser, which has a 1-D TZ that does not increase with increasing degrees of myopic correction.
5. The NVCs were purely subjective, and it is generally observed that patients can adapt to these symptoms with time, as many of them did in this study and the Schallhorn study. An objective measurement, such as with the Seipser Glarometer, would have been very helpful to determine the actual level of starbursts for each patient.

Hopefully with more studies such as this one we will come to a better understanding of the relationship between NVCs, pupils, ablation zones, amount of correction, aberrometry measurements, and the role of wavefront-based treatments. Because we have no accurate pretest to predict which patients will be able to adapt to their postlaser night vision, we urge all refractive surgeons to continue accurately to measure scotopic pupil size and inform patients with large pupils, especially in combination with higher degrees of myopia, that they are potentially at more risk of NVCs than are those with average to small pupils. This is the reason that some of us use large OZs (6.5–8.0 mm) in such high-risk patients.

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Author reply

Dear Editor:

I believe Dr Salz et al's comments reflect the general attitude of some refractive surgeons who consider preoperative scotopic pupil size measurement important for assessing the risk of night vision complaints (NVCs) after LASIK.