surgery. In our experience, many patients are found to have INR values that lie outside the normal therapeutic range. Although with an INR of <2 we still proceed with cataract surgery safely, this practice allows us to identify patients with an INR of >4, resulting in suitable modification of the dose of the anticoagulants preoperatively to achieve a therapeutic range, before elective cataract surgery. Such a practice inevitably adds an element of delay to the schedule of cataract surgery in patients on anticoagulants. From the data presented in Katz et al's study it is not clear whether the patients had their INR values checked preoperatively and whether patients who were asked to continue anticoagulant treatment had INR values strictly within the therapeutic range. We would appreciate the authors' comments on this aspect.

This study was conducted on patients using aspirin as the only antiplatelet drug. However, with the introduction of newer and more potent antiplatelet drugs such as clopidogrel etc., we need to be aware of potential risks for ocular hemorrhage during cataract surgery. Perhaps a similar study including the various available antiplatelet drugs is necessary to address this issue.

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Author reply

Dear Editor:
This study was part of a randomized trial to assess the impact of routine preoperative testing for cataract surgery on adverse medical outcomes. Physicians in the study were asked not to conduct tests that were not in the randomized battery unless there was a new or worsening condition that the physician felt required additional tests. Hence, international normalized ratio data were not routinely collected. We did record whether surgery was delayed and, if so, the reason for the delay. There was a total of 7 delays in surgery due to concerns related to international normalized ratio or prothrombin time test results. Given these small numbers, we think it unlikely that the key outcomes of our study would be affected. In our study we examined warfarin and aspirin, as these were the most common anticoagulants and antiplatelets used at the time the study was conducted. Hence, this study cannot provide any guidance regarding newer more potent antiplatelet drugs.

Joanne Katz, ScD
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Night Vision Complaints after LASIK

Dear Editor:
I read with interest the article by Drs Mihai Pop and Yves Payette[1] and the accompanying editorial by Dr Stephen Klyce on risk factors for night vision complaints (NVCs) after LASIK for myopia or myopic astigmatism. Pop and Payette analyzed the correlation between the self-reported severity of night-time halos, starbursts, and acuity distortion and the following factors: age, pupil diameter (PD), attempted spherical correction, attempted cylindrical correction, optical zone diameter, transition zone diameter, mean preoperative keratometry, the difference between the optical zone and the PD, and the difference between the transition zone and the PD. The authors performed an exhaustive statistical analysis and reported their findings meticulously. They concluded that "pupil size at any month postoperatively was not statistically predictive of postoperative NVCs in any differential model involving it."

One hazard of retrospective clinical studies is that it is impossible to create a robust experimental protocol post hoc. In this report the PD was a critical independent variable. "Patients and Methods" states that the preoperative "pupil size was measured in scotopic conditions using the Colvard pupillometer . . . to the nearest 0.5 mm," an experimental technique of notable imprecision. The measurement needed is the maximum physiologic dark-adapted PD. To elicit the DAPD,[2] the following conditions must be controlled: ambient illumination during dark adaptation, duration of dark adaptation, accommodation, patient alertness, and elimination of stray light sources.[3] If the investigators recorded the PD in increments of 0.5 mm, they must demonstrate that every individual who performed PD measurements was capable of this degree of accuracy using the specified equipment; it is insufficient simply to use a measuring device that contains a reticule with a 0.1-mm scale. Unless Drs Pop and Payette can assure readers that an appropriately designed and validated dark adaptation and PD measurement protocol was followed for every enrolled eye, we must reject this part of their analysis. It is careless of us to assume that the PD measurements were mostly correct and, therefore, conclude that the authors are probably right.

Unfortunately, the refractive surgery literature is filling up with clinical studies where great emphasis is placed on the statistics, and the experimental validity of the data set(s) is overlooked. This error is particularly egregious in studies involving pupil size,[4] most of which give one sentence or less to the protocol for PD measurement. Feeble methods of data collection on NVCs are also rife.[5] It is the responsibility of reviewers and editors to address this issue, because once such reports are in print, they gain the authority of peer review and the imprimatur of the journal that published them.

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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