Too Cautious Counsel On Pupil Size & LASIK?

Staff

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To the Editor:

It was with great interest that I read comments from prominent refractive surgeons in "Screening for LASIK: Tips and Techniques" (*July 2006*). In this generally helpful article, there is a section "Don't tell patients pupil size doesn't matter," in which the point is made that we need to be particularly careful to inform patients with large pupils that they are at increased risk of night vision problems after LASIK. In this section, it is pointed out that studies showing that night vision problems are, in fact, unrelated to pupil size were conducted using laser platforms not available in the United States (and therefore might not apply here) and that, from a practical standpoint, many patients with night vision problems note improvement with pharmacological constricting agents, proving the causative relationship of large pupils to night vision issues. The article cautions against surgery in large pupil patients and urges that, if surgery is done, heightened informed consent should be employed and surgery should only be performed one eye at a time.

It is certainly an appealing and intuitive assumption that, since large pupil patients have a scotopic pupil larger than the ablation area, night vision problems such as glare, halo, and haze might be more likely in these patients. Counter-intuitive as it may seem, however, careful review of the literature does not support the notion that laser vision correction is riskier in terms of night vision in these large pupil patients than in those with smaller pupils. A very elegant study on this topic was performed by Steve Schallhorn et. al. using the FDA-approved (and U.S.-available), VISX Star platform with conventional surgery on 100 consecutive patients.[1] These researchers. found that while the incidence of night glare, haze, and halo were initially higher in large pupil patients, pupil size had no impact on these night vision symptoms by six months. Rather than pupil size, risk factors related to long-term night vision symptoms included the level of treatment (preoperative myopia), preoperative contrast acuity,

postoperative UCVA, and residual cylinder.

Similarly, in a separate study using the Nidek EC-5000 excimer laser platform, Mihai Pop and Yves Payette studied 795 patients to ascertain risk factors for night vision complaints after conventional LASIK.[2] Attempted degree of spherical correction, age, optical zone, and postoperative spherical equivalent were major risk factors of night vision complaints throughout the first postoperative year, whereas pupil size was not associated with an increased risk of night vision problems.

Thus, in both of these large, excellent studies, pupil size simply was not a risk factor for night vision problems after laser vision correction. It is very helpful, however, to look at what were, in fact, risk factors for night vision problems. Close analysis reveals that the postoperative presence of new (compared to glasses or contact lens correction) aberration, either in the form of uncorrected residual lower order aberrations, or the induction of new higher-order aberrations, was correlated with subjective complaints of night vision problems after surgery. In both studies, residual refractive error clearly had an important role in night vision symptoms. Obviously, these residual lower order aberrations will affect night vision until corrected either with enhancement surgery or with glasses and contact lenses.

Interestingly, in both studies, however, the degree of preoperative myopic spherical correction attempted also was correlated with night vision problems. It is well established that conventional myopic surgery induces higher-order aberrations, particularly spherical aberration, in proportion to the degree of correction. The presence of the degree of correction as a risk factor tells us that the degree of induction of higher-order aberrations, not pupil size, is the critical risk factor for problems with night vision. In other words, a patient with a 9-mm scotopic pupil and 1 D of myopic correction probably has a lower chance of permanent night vision problems than a patient with a 6-mm scotopic pupil and 9 D of conventional myopic correction. It is not logical to inform large pupil patients of an increased risk of night symptoms based merely on their pupil size.

Also of relevance to night vision is the diameter of the ablation zone: smaller ablation zones have traditionally been associated with worse scotopic and mesopic vision. In fact, this appears as an independent risk factor for poor night vision in Pop's study. Previously, many have made the intuitively appealing, but unfounded, assumption that this was due to the pupil diameter enlarging beyond the ablation diameter under scotopic or mesopic conditions. The reason smaller ablation zones are associated with poorer night vision, however, again has to do with induction of aberrations—in this case at the transitional zone from ablated to unablated tissue in a region more optically significant based on

the predictions of the Stiles-Crawford effect. Independent of pupil size, the Stiles-Crawford effect predicts that aberrations are more visually significant the closer they occur to the optical axis of the visual system. Michael Endl and colleagues have elegantly demonstrated the increase in higher-order aberration based on wavefront testing in smaller ablation zone treatments compared to those employing larger zones.[3] Along these lines, Stephen Klyce has pointed out that the development of blending techniques at this critical transition zone help to minimize the severity of higher-order aberration induction, and, therefore, night vision complaints.[4] Thus, the night vision problems associated with smaller ablation zones really have nothing to do with a "mismatch" of pupil size to ablation size.

Interestingly, both Dr. Schallhorn's and Dr. Pop's studies were performed using conventional surgery. Wavefront surgery should be expected to produce even fewer night vision problems since there is less induction of higher-order aberrations and since most platforms use large optical zones and blend zones in their ablation profiles. As a sort of ironic confirmation of this, although one prominent surgeon in the Review article mentions that he performs all of his large pupil surgery one eye at a time, all of his large pupil patients treated with wavefront surgery (even the one he discusses with a 9.7-mm pupil) elected to have their second eye done.

Perhaps an even more powerful demonstration of the value of wavefront correction to night vision is the FDA clinical data used to approve the VISX CustomVue system.[5] In the FDA clinical trials, patients were given questionnaires about their night vision satisfaction both with correction before surgery, and without correction after surgery. Once healing had finished, four times as many patients were likely to have the highest level of satisfaction with their night vision after surgery compared to before surgery. Interestingly, if the data was separated based on pupil size, there was no indication that larger pupils had any negative impact on night vision satisfaction. In fact, large pupil patients were actually more likely to notice an improvement in their night vision quality (compared to preoperative night vision) than smaller pupil patients. In this way, large pupil patients were actually better, not worse, candidates for wavefront laser vision correction.

Finally, this article on LASIK screening proposes the notion that large pupil patients are at greater risk for night vision problems after laser vision correction since there are anecdotal reports of patients who do have night vision problems and report improvement with pupil constricting agents such as pilocarpine or Alphagan. While we have all seen such cases, it is faulty logic to deduce that large pupil patients are therefore, a priori, at greater risk from surgery in the first place. Again, regardless of pupil

size, it is the induction of aberrations, particularly higher-order aberrations, which leads to night vision problems after laser vision correction.

It is true, as the article points out, regardless of pupil size being referenced, higher-order aberrations typically increase in cumulative effect as pupil size increases. In a patient who now has a more aberrated cornea due to laser vision correction problems, certainly it is worth trying to constrict the pupil at night as this is often helps by decreasing overall aberrations. It should be noted, however, that this would be equally true for a symptomatic patient with a 9-mm scotopic pupil as it would for a symptomatic patient with a 6-mm scotopic pupil. In no way does this concept apply preferentially to large pupil patients only. The fact that aberrated patients sometimes find relief with pupil constriction only proves that, in these patients, a smaller pupil sometimes helps. It does not mean that large pupil patients are somehow more likely to have an induction of symptomatic aberration.

As an interesting correlation, I have published a case in which a patient had severe night vision problems after having undergone conventional LASIK surgery elsewhere for approximately 5 D of myopic correction (Ocular Surgery News, March 15, 2004, p 30-32.) He had large, 7.5-mm, scotopic pupils but experienced only minimal improvement with night time Alphagan or with glasses. Wavefront testing revealed post-LASIK elevated RMS scores of 0.54 OD and 0.67 OS (6-mm pupil measured OU), characterized by high degrees of spherical aberration. Therapeutic wavefront correction of each eye was performed with complete resolution of the patient's night vision problems. Clearly, since wavefront correction worked far better than Alphagan, the culprit was induced higher-order aberrations, not the patient's pupil size.

Despite the intuitive assumptions that larger pupils are associated with greater risk of night vision problems after LASIK, the data simply does not support this. If, out of well intentioned cautious impulse we dissuade large pupil patients from undergoing laser vision correction, we may be unfairly limiting this group of people from enjoying its benefits. In fact, based on the Visx CustomVue clinical trials, we have to ask ourselves if we are not unfairly pushing away the very patients we could best help. Certainly caution is always a virtue, but, given the potential for both medical and medical-legal misuse, it should be based on solid data.

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