

letters were not properly reported to the FDA and that more patients were recruited for the study than were authorized by the FDA.

3. Performing surgery on the right eye when the left eye sustained a loss of best corrected visual acuity from 20/40 -2 to 20/70. On 4/27/02 the clinical notes state that the patient "feels vision is weaker since Fri. and night time is a problem." The refraction was $-0.25 -0.75 \times 80 = 20/70$ (the target for this eye was monovision for the left eye of about -2). Thus the patient had a significant over response to the laser, had complaints about the quality of his vision and his night vision, and had lost at least 2 lines of best-corrected visual acuity.

Despite these problems, Dr. Nevyas impression was that he was "doing well" and recommended and performed LASIK surgery on the dominant right eye on 4/30/98. The imbalance between the two eyes that the patient experienced should have been corrected with a contact lens or glasses in the right eye while the situation in the left eye was evaluated. The left eye eventually regressed to about -1.25 so it may actually have been possible for him to continue simply wearing glasses and a contact lens may not have been necessary. This is especially true since the patient had a previous history of strabismus surgery and he may not have had true stereopsis so the anisometropia may have been easily tolerated and surgery on the right eye could have been deferred indefinitely.

4. Comment: Mr. Morgan has been examined by several highly qualified experts since his LASIK surgery in an attempt to explain the decrease in his best-corrected visual acuity. The possible mechanisms include retinal damage, optic nerve damage, a combination of both; optical problems related to positive angle kappa and an ablation centered over the pupil, and early cataract changes. Based on my examination and records review, I attribute his loss of vision and visual complaints to a combination of all except the cataract. I do not feel the minimal lens opacity is sufficient to explain his loss of vision. This would not explain why his vision became worse immediately after the surgery in both eyes. Dr. Guyton suggested the minimal cataracts as a possible explanation in June of 2000 and suggested that if the cataracts were at fault we would expect to see progression in the lens changes and further decrease in his visual acuity. It is almost 2 years since that exam and today, his visual acuity was better than the 20/125 recorded by Dr. Guyton and the lens changes are still minimal so this goes against the thought that the cataracts are at fault.

Within a reasonable degree of medical certainty, it is my opinion that LASIK caused all the problems discussed above and in my report to occur. LASIK surgery usually does not provide a patient with vision better than his or her best corrected vision with spectacles or contact lenses. Although common, this surgery is not without risk, and the practice is not to perform surgery on patients who already have compromised vision secondary to severe eye conditions. By avoiding patients whose vision is already compromised to this degree we leave the patient a "safety net" in case the procedure leaves them with less than