Responding to LASIK's "Casualties"

The question is, how do we help these patients?

BY STEPHEN G. SLADE, MD

The FDA's Ophthalmic Devices Panel convened on April 25, 2008, in order to discuss quality of life after LASIK. The session was the result of the well-organized efforts over many years of a small, vocal group of individuals unhappy with the outcome of their refractive surgery. Calling themselves *casualties*, these patients have created Web sites, petitioned the FDA, and battled physicians and the LASIK industry. Since attending the meeting in Gaithersburg, Maryland, it is the casualties' stories and perspectives that I have thought about the most. How can we refractive surgeons help them?

A DIFFERENT LANGUAGE

At the panel meeting, several prominent ophthalmologists delivered scientific presentations on LASIK. They described success rates of 95%, testified that the rate of dry eye is essentially the same before and after LASIK, and shared how modern technology can provide patients with postoperative visual acuities that are even better than they had before surgery with glasses.

The casualties' presentations could not have been more different. Their testimony ranged from the sharing of profound personal experiences to the delivery of harsh threats. One of them was previously the chief financial officer of the LASIK center at a major university who underwent LASIK by that facility's surgeon. I heard moving testimony from a man who had retinopathy of prematurity, had a preoperative visual acuity of 20/50, and had barely been able to drive legally. Yet, he was enrolled in the FDA trial of an excimer laser. I will always remember his words: "I was never a candidate." A father spoke for his son, who committed suicide after LASIK. He related how his son had told him, "I'm rotting from the inside out." I heard alarming phrases such as *eyesight was robbed from them by an industry eager for money, it is not too much of a stretch to imagine someone's including the architect of their problems in their desperate rage, I have been lied to repeatedly by my own doctor*, and *it is ironic that my eyes had to be ruined by LASIK in order for me to see how corrupt this industry truly is.*

I remember listening to all of this testimony and only being able to think as a doctor. I wanted to see the medical chart on each patient. I wanted to try to diagnose and treat their problems. I did not understand. Why would a young man commit suicide over any LASIK outcome before trying a corneal transplant? How could he have given up on us so completely? Or, did we give up on him?

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SCIENCE IS NOT ENOUGH

When I started performing LASIK in 1991, we did not have eye trackers, wavefront-guided ablations, or femtosecond lasers. We did not have optical coherence tomography, advanced diagnostics, or Restasis (Allergan, Inc., Irvine, CA). We cut the cornea with metal blades. We tried to hold the eye as still as possible and aim as well as we could. We would only learn about post-LASIK ectasia years later.

Since LASIK's beginning, we have come a long way. Our science will continue to grow, but it is not a complete answer for the casualties. They are calling for a ban on one of the most studied procedures in medicine, a renunciation of dozens of premarket approvals, and the recall of hundreds of lasers. In addition, many of them believe that all forms of LASIK are bad all of the time but that PRK is just fine. How do we deal with these patients?

A new study, focused on quality of life after LASIK, will likely come out of the FDA panel meeting. This research is needed and will better our understanding of the LASIK

experience from the patient's perspective. I do not think, however, that this study will address the casualties. Our current technology is too good, and the doctors involved in the study will be among the best as will the criteria for patient selection. I do not think that the study—even with thousands of patients—is likely to yield one casualty.

WHERE DO WE GO FROM HERE?

How do we deal with LASIK's casualties—including those of the future, no matter how rare? Most of these people have completely broken ties with us, and it would be hard for me to overstate the anger they bear toward us.

I believe the FDA panel meeting was valuable for several reasons. For one thing, it provided a forum where these individuals could air their grievances. If nothing else, we came together, face to face, for the first time. From the doctors who gave presentations, I heard empathy for and commitment to the casualties in statements such as *we hear your concerns, and we care*; *we cannot be satisfied until all complications can be eliminated*; and *we surgeons are the patient's primary advocate and will not rest*. I hope the casualties heard those words.

The panel recommended making product labeling more descriptive, and I anticipate further refinement of our informed consents. Fortunately, we have become much better at screening patients' eyes for LASIK, but how can we better read their mental status? How do other factors in a patient's life interact with a poor surgical outcome? How do depression and LASIK combine? As I mention in my editorial on page 7, I believe improved doctor selection (meaning a better way for a patient to choose his surgeon) would help. If not us, then who will guide our efforts to help the casualties?

LASIK and PRK are amazing procedures. They are safer than contact lenses and provide patients with one of the highest levels of satisfaction of any surgical procedures ever studied, as noted in testimony at the FDA panel meeting. Refractive surgery can transform people's vision; often, patients see better than they ever did preoperatively with their best correction, 24 hours a day. What else can improve people's quality of life like that? Surely, the doctors and industry that created LASIK can come up with something to aid those casualties who are willing to let us help. ■

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