

Opinion

LASIK Under Siege: A Battle Over Fact or Perception?

This spring, the FDA responded to the stack of letters it had received from patients who claimed uncorrectable visual disability and discomfort such as dry eye following LASIK. It convened an ophthalmic devices panel to review the evidence and hear testimony from patients. If you have been living in a cave or have been too busy to notice, you might not have heard how it went, so I refer you to Panel Chair Jayne Weiss' editorial on O.N.E.¹ (Her Guest Opinion follows.)

As medical scientists committed to the evidence basis for what we do, we point to the over 95 percent success rate reported in multiple studies, and the very low rate of serious vision-threatening complications, and we feel reassured. But the public tends to respond to a very different kind of "evidence." For many, anecdotes trump scientific validity; emotions trump logic. To these members of the public, we might say they are placing too much weight on individual patient stories. They might say in response that patient stories are real, but scientific studies are artificial and tend to overweight the averages.

The point here is that individuals assign different weights to the same evidence, and there is no way to predict the framework that a particular patient might be using. For some, the scientific evidence might hold sway; for others, it's the threat of a rare side effect. That is why, in addition to improving screening mechanisms to lower the percentage of

unhappy patients, we must be diligent and comprehensive about the informed consent process. In fact, the FDA panel recommended more stringent excimer laser labeling requirements for informed consent. But let's face it, while proper informed consent may offer liability protection for the physician, it does nothing to make a miserable patient any happier.

The panel also decided to recommend a prospective quality of life study for LASIK, examining patient perceptions as well as the clinical data. Unfortunately, public funds did not exist to support such a study. So the FDA asked the Academy and ASCRS to kick in \$500,000 each. The implication was that favorable study results might obviate further restrictions on the procedure. Others said it would be a disabling conflict of interest to allow foxes to finance a study to discover how happy the hens were. But ultimately, the Academy Board and ASCRS did the right thing and agreed to fund the study that would be designed by FDA and conducted by NEI.

But what to do about the penumbra of decreased demand for LASIK that is likely to follow the extensive press coverage of the hearings? The Academy is preparing a well-designed communications plan. An online patient resource "Is LASIK for Me?" and a commitment to ensure that prospective patients have access to reliable information through their ophthalmologist are key features of this plan. And EyeCare America is on the threshold of implementing a public

service initiative that will offer refractive surgery at no cost to quadriplegics and others who cannot take their glasses on and off without assistance. Volunteer ophthalmologists will take this program nationwide. Think of the many individuals—from war-injured veterans (the VA doesn't cover refractive surgery) to victims of motor vehicle accidents—who will benefit. Evidence-based though we are, as public perception hangs in the balance, we can always use a few good anecdotes.

Dr. Mills is chairman of EyeCare America and has a bias favoring public service.

1 one.aao.org/ce/lasikINFO.



RICHARD P. MILLS, MD, MPH
CHIEF MEDICAL EDITOR, EYENET