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The truth about LASIK

FDA panel discusses patients' postoperative quality of life

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By: [Christina Phillis](#)

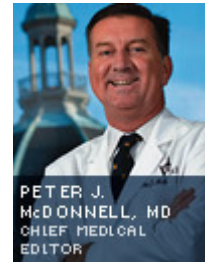
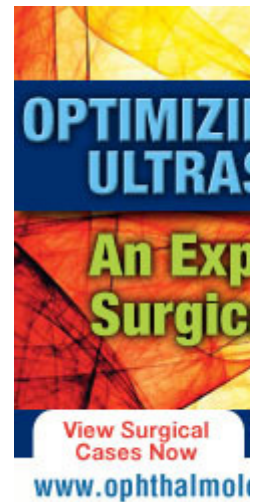
OPHTHALMOLOGY TIMES

Pages | [1](#) | [2](#) | [3](#) | [4](#) [More](#) →

Gaithersburg, MD—After hearing a variety of testimonies at the April 25 Ophthalmic Devices Panel Meeting to discuss the post-market experience of LASIK, advisers to the FDA determined that lasers need improved patient labeling information.

Stories from angry patients, which ranged from experiencing constant pain and discomfort to suicide in reaction to unfulfilled expectations from LASIK, brought to light the fact that patients might not be receiving important information, and, sometimes, even the correct information about the procedure.

"We need better screening, better information, and in some cases, perhaps better doctors for some of what was experienced here," said **Jayne S. Weiss, MD**, chairwoman of the ophthalmic devices panel and director of refractive surgery and ophthalmic pathology at the Kresge Eye Institute, Wayne State University, Detroit. "It's not that the device is bad, it's that [if] . . . you were not told that if you took off your glasses before surgery you wouldn't be able to have the same ability to read after surgery, that's lack of information, not a bad procedure."



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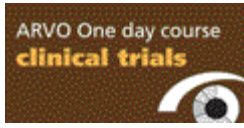
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Speaking on behalf of the International Society of Refractive Surgery and the American Academy of Ophthalmology (AAO) was *Ophthalmology Times*' chief medical editor, **Peter J. McDonnell, MD**. "About 700,000 Americans have LASIK surgery annually. More than 90% of people who undergo LASIK for nearsightedness achieve somewhere between 20/20 and 20/40 vision without glasses or contact lenses," said Dr. McDonnell, the William Holland Wilmer Professor of Ophthalmology and director of the Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore. "LASIK is the most studied elective ophthalmic procedure. A total of 7,830 patients representing 16,502 eyes participated in FDA clinical trials between 1993 and 2005."

According to FDA media spokesperson Pepper Long, the FDA hearing was held in response to consumer interest. In 2006, FDA staff reviewed data associated with LASIK due to consumer complaints and reports, including four citizen petitions. A total of 140 adverse event reports associated with LASIK—mandatory reports from manufacturers and user facilities as well as voluntary reports from individuals—were submitted to the agency.

Public response

Colin Dorian, who reportedly had such poor quality of life after LASIK that he committed suicide, was told by his doctor that his large pupil size might create a problem but that it would be no worse than what he experienced with contact lenses, according to his father, Gerry Dorian, who said he was speaking for his son at the meeting. Before his procedure, contact lenses were intolerable for Colin because of his dry eye; afterward, the senior Dorian stated, Colin experienced starbursts, triple overlapping images, ghosting, and a loss of contrast sensitivity.

Some recent consumer-oriented news reports have been covering the issue, putting a spin on the story that LASIK results may be linked to suicide. According to Jennifer Morse, MD, psychiatrist, San Diego, studies do not exist to support the claim that LASIK is a cause of postoperative depression.

"Depression is almost always not due to a single factor unless it is specifically related to a medical illness such as hypothyroidism," said Dr. Morse, who also spoke at the meeting in favor of LASIK and has conducted research on the psychologic effects of refractive surgery on U.S. Navy personnel. "You have to assume it is pre-existing and is already causing difficulty."

Factors that can contribute to depression after surgical complications are individual coping styles, defense mechanisms, and personality types, Dr. Morse said.

Although some hearing attendees reported not being able to cope psychologically, others provided insight into their physical trauma. Glenn Hogle spoke for Barry Elbasani, founder of Focus on Independence. Elbasani reportedly wore corrective lenses without a problem until a swimming pool accident left him a quadriplegic. Being completely paralyzed, he needed assistance with tasks as simple as pushing his glasses up his nose and wiping the lenses. After receiving LASIK, he now has 20/10 vision, which became extremely important after losing control of the rest of his body.



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"It's a gift I wanted available to other quadriplegics, so Dr. Daniel Durrie and I founded Focus on Independence. Funded by small personal donations, the organization helps quadriplegics like me get LASIK from doctors who donate their time and expenses."

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