Public Comment on LASIK

Scathing or supportive, testimony before the FDA Ophthalmic Devices Advisory Panel was personal and often impassioned.

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At the April 25, 2008, meeting of the FDA Ophthalmic Devices Advisory Panel, the public had an opportunity to testify before representatives of the panel and Joint LASIK Study Task Force. Although some of the comments were in support of LASIK, much of the testimony by patients, their families, and advocates focused on postoperative debilitation that they argued led, in some cases, to depression and suicide. This article summarizes public comment at the panel meeting.

MICHAEL PATTERSON

Asserting that LASIK had ruined his vision and quality of life, Mr. Patterson stated that he was a victim of microkeratome failure, a reused blade, and scarring. He said that cutting a flap for LASIK is not safe when compared with the use of contact lenses or spectacles and that a LASIK failure rate of 5% or higher is not safe.

Mr. Patterson asked the FDA to control LASIK centers as ambulatory surgical facilities under the regulatory law. For quality-of-life studies, he said that qualified professionals who are completely independent of the LASIK industry should be involved versus those with a financial interest. He called for a moratorium on the devices used for LASIK and asked the panel to evaluate potential dry eye treatments.

DEAN KANTIS

Mr. Kantis testified that he has spent $30,000 during the past 9 years in an unsuccessful attempt to restore his post-LASIK vision. He said that doctors need to tell the truth about LASIK flaps and pupillary size. Mr. Kantis attested that he was told the LASIK flap would heal like a cut on his hand but that his did not, leaving his pupil permanently scarred. He stated that his pupils were 9 mm in diameter and that his surgeon told him that he was a perfect candidate for LASIK.

Mr. Kantis submitted to the panel a pamphlet that he created on the side effects of LASIK and asked the panel to make its use by refractive surgeons mandatory. Further, Mr. Kantis asked that informed consent include information on the timeframe during which patients can initiate legal action against a refractive surgeon that has performed the procedure incorrectly.

Mr. Kantis stated that a better definition of a successful LASIK procedure is needed. He said that, although he continues to experience double vision, halos, starbursts, fluctuating vision, and dry eye syndrome, his surgeon told him the procedure was a success. He requested that the panel establish a fund to help patients who are desperate and suicidal after LASIK obtain therapy.

DAVID HARTZOK, OD, AND BARBARA BERNEY

The comments of Dr. Hartzok and Ms. Berney were read by Glen Hagele, Executive Director of the Council for Refractive Surgery Quality Assurance (Sacramento, CA). Dr. Hartzok stated he is Executive Director of, and Ms. Berney stated she is President of the Vision Surgery Rehab Network (Rockford, IL), a nonprofit organization they said was established to help patients recover from any surgery that has altered the refractive status of the eye.

Dr. Hartzok and Ms. Berney asked the FDA to recognize and accept the definition of *refractive surgery syndrome* as

a complex, chronic, visual, psychological, and physiological combination of symptoms after surgery that affects the refraction of the eye. As an example, they said that post-LASIK dry eye is a physical symptom that may have physiological attributes relative to an inadequate tear film, which can create a psychological awareness of reduced vision.

Dr. Hartzok and Ms. Berney stated that post-LASIK complications disrupt patients' sense of normalcy and well-being and that their frustration is compounded when surgeons deny patients' feelings. Dr. Hartzok and Ms. Berney stated that aggressive marketing and inadequate informed consent exacerbate the psychological aspects of refractive surgery syndrome and can lead to depression and anxiety. They concluded by saying that any meaningful investigation into quality of life after LASIK must be impartial and that specialists in behavior and perception who do not have a vested interest in the study's outcomes should conduct it.

GERRY DORRIAN

Mr. Dorrian testified that his son Colin committed suicide because of post-LASIK complications. He said that his son had no signs of mental illness and was never diagnosed with depression before the procedure.

Mr. Dorrian said that his son decided to undergo LASIK, because dry eyes had rendered him intolerant of contact lenses. He testified that his son's surgeon had said Colin's pupils were large but that his dry eyes would be no worse than what he was experiencing with contact lenses. Mr. Dorrian testified that, postoperatively, his son saw three overlapping images and ghosting, had lost contrast sensitivity, and complained that dry eyes made it impossible for him to wear contact lenses. He read the letter that his son left his family before taking his own life. In it, Colin stated that he could not continue to endure his distorted vision.

Mr. Dorrian said, "I feel that people who are involved in corrective surgery need to take responsibility for the problems that they create—not just points of successes that they have. I don't think the patient satisfaction survey, no matter how you dress it up, really gives anyone any information about how people are suffering."

SANDY KELLER

Mr. Hagele read the comments of Ms. Keller. She said that she had dry eyes before undergoing LASIK surgery in late 1999 and that preoperative topography illustrated corneal warping due to her use of hard contact lenses for 25 years. She stated that her pupillary diameter was larger than 8 mm but that she was treated with an elliptical 6-mm ablation zone. She stated that less than half of her dioptric gap was corrected with the laser and that her surgeon ignored these issues.

During surgery, she said, the microkeratome blade left a ridge within her scotopic pupil. She testified that infiltration of her right cornea started within 28 hours of her surgery but that her optometrist did not diagnose diffuse lamellar keratitis. She said that, upon referral back to her surgeon, he blamed her optometrist for the advanced stage of diffuse lamellar keratitis. At 8 weeks postoperatively, she had 6.00 D of hyperopia. She stated that her refractive surgeon performed a 4.70 D treatment with 5.90-mm zone, which further reduced her effective optical zone. She said the second treatment made her myopic and caused her to see multiple images.

Ms. Keller stated that seven additional surgeries have failed at removing the wrinkle in her cornea. She said she is able to discern at least 19 images when viewing a point of light. She testified that a psychiatrist diagnosed her with depression and posttraumatic stress disorder but that she still thinks of ending her life after several months of psychiatric care.

DOM MORGAN

Mr. Morgan testified that he is legally blind due to his surgeon's improper use of an investigational laser. He stated that he has retinopathy of prematurity and that he had a visual acuity of 20/50 and was barely legal to drive when he underwent LASIK. Mr. Morgan said he was never a candidate for the procedure and that his permanent postoperative problems cannot be addressed by a contact lens.

Mr. Morgan created a Web site about his experience and stated that he has received hundreds of e-mail messages in the past year from other post-LASIK patients seeking help. He said that many are depressed and some have told him they want to commit suicide. "I believe they are just ordinary people caught in unusual circumstances," he testified.

Mr. Morgan stated that the FDA has been ineffective in its oversight of investigational studies, its enforcement of the policies mandated for the LASIK industry, and its protection of patients. He called on the agency to conduct an independent, unbiased study without funding from the LASIK industry. He concluded by advocating a moratorium on advertisements by LASIK surgeons and the creation of a Web site that lists refractive surgeons' qualifications.

DAVID SHELL

Mr. Shell testified that constant eye pain from LASIK for hyperopia in October 1998 had transformed him from "a healthy, happy, physically active, skilled engineer" to a man "who now has difficulty reading due to double vision, who can no longer view a TV or computer monitor comfortably and clearly, who is reluctant to drive at night, and … who has been diagnosed with clinical depression." Mr. Shell stated that, preoperatively, his vision was crisp and clear with glasses.

"Since LASIK, I am visually handicapped by double vision, starbursts, glare, fluctuating vision, floaters, and impaired vision in dim light, and that's with my glasses or rigid contact lenses," he testified.

Mr. Shell stated that no treatment for his LASIK-induced dry eye had been successful. He testified that he had never suffered from depression until he underwent LASIK.

Mr. Shell asked the FDA to conduct an investigation of LASIK independently of individuals and organizations with a financial interest in the procedure. He also asked the agency to reclassify LASIK-induced dry eye and visual-quality issues as serious complications of the procedure rather than symptoms or side effects.

BARRY ELBASANI

Mr. Elbasani's comments were read by Mr. Hagele. Mr. Elbasani stated that he had tolerated his glasses until the summer of 2002, when an accident left him paralyzed from the chest down with limited mobility of his arms. He said that LASIK had freed him of his glasses and left him with 20/10 vision and a desire to share this gift of independence with other quadriplegics. He said he cofounded the nonprofit Focus on Independence with Daniel Durrie, MD. Funded by small personal donations, the organization links quadriplegic patients with surgeons who donate their time and waive their expenses, according to Mr. Elbasani. More than 4 dozen patients have been helped thus far, he said.

GLEN HAGELE

Mr. Hagele said he works for the nonprofit organization USAEyes.org. He stated that the nonprofit's research indicated that the primary factor in the success or failure of a LASIK procedure is the patient's expectations. He described a recently developed survey, in which the group is retrospectively soliciting patients' opinions as to whether the outcome of their refractive surgery (including LASIK and IOLs) met, failed to meet, or exceeded their expectations. He said that the anonymous, multicenter survey had been sent to 1,800 individuals by April 16, 2008, and that the organization had received 550 (31%) responses.

The survey is ongoing, but Mr. Hagele shared some preliminary data. He reported that, of the 462 patients with eligible responses, 99% stated that their quality of life postoperatively (at least 6 months from the date of surgery) was as they expected, better, or much better. Only 0.9% reported a worse quality of life than they expected, he said. According to Mr. Hagele, 91% reported either that they had experienced no complications or that their complications had been resolved. Seven percent responded that they have complications but that they are seldom problematic, and 91% of these individuals stated that they would undergo the surgery again, he testified.

DIANA ZUCKERMAN, PHD

Dr. Zuckerman testified that she is the president of the National Research Center for Women and Families, a nonprofit organization she said is focused on using research to improve programs and policies that affect the health and safety of adults and children, with an emphasis on FDA issues. She also stated that she is a fellow at the Center for Bioethics at the University of Pennsylvania and that she was trained in epidemiology at Yale University.

Dr. Zuckerman stated that neither the FDA's Web site and patient booklets nor product labeling is an effective means of communicating information to patients. She asserted that the language used in the booklets is not accessible to laypeople.

In addition, Dr. Zuckerman testified that recent research shows that half of patients have adverse reactions such as dry eye during the first week after LASIK surgery but that the problems persist for 20% at 6 months. She said that the complications were more likely to affect women and patients who received high corrections. Dr. Zuckerman testified that ocular pain, whether associated with dry eye or another cause, is debilitating and should be addressed by the panel. In addition, Dr. Zuckerman stated that the need for additional surgery after LASIK should be studied appropriately. She cited a recent study in which 28% of eyes treated with LASIK required a retreatment within 10 years due to undercorrection, overcorrection, or regression.[1] She also called for objective, scientific research on the possibility of a higher suicide rate among LASIK patients.

TESTIMONY FROM TODD KROUNER, ESQ

My name is Todd J. Krouner. I am a plaintiff's medical malpractice attorney in Chappaqua, New York. I am here at my own expense today. I represent victims of LASIK and related eye malpractice on a national basis. Most of my cases involve high-volume LASIK facilities that failed to screen properly for keratoconus or other contraindications to surgery. I am not here to criticize the safety of LASIK. I am not here to criticize ophthalmologists generally or LASIK surgeons in particular. I am here to encourage the FDA to do whatever it can to prevent the conversion of eyes to commodities by doing four things: first, encouraging the effective and safe training of LASIK surgeons; second, encouraging the reporting of adverse outcomes by the industry; third, commissioning an independent study of LASIK patient satisfaction; and, fourth, reporting on its findings and making its data available on a timely basis.

The LASIK industry does not police itself effectively. Many doctors have completed rigorous training with corneal fellowships. However, many LASIK surgeons have not. The surgery itself is not that complex, however the screening process can be. More time, skill, and care need to be invested to ensure unsuitable LASIK candidates are screened out. The LASIK industry underreports adverse outcomes. Even doctors with the duty to report have failed to do so. Voluntary reporting should be encouraged. Mandatory reporting failures should be enforced with meaningful sanctions. If the LASIK community truly believes that patient satisfaction runs at upwards of 95%, then I suggest it should welcome with open arms an independent study to prove this. Patient satisfaction must be measured by both qualitative and quantitative measures. It is not enough to say the patient has good visual acuity. My client Mark Schiffer had good visual acuity. He had poor visual quality. When his eye doctor saw this iTrace (Tracey Technologies, Bellaire, TX) result and focused on the top right quadrant, where there's an E, which depicted how the patient saw an E on the eye chart, the doctor scheduled his corneal transplant. When Ross Martinez in Virginia Beach complained of poor visual quality, her optometrist used this Nidek technology (Nidek, Inc., Fremont, CA) to demonstrate how poor her vision was, even though her LASIK surgeon boasted of 20/30 corrected visual acuity and 20/40 uncorrected visual acuity.

In March 2008, in a biographical story in *The New York Times*, Abby Ellin described her own LASIK surgery regret.[1] She described her doctor's false measure of success based solely on her good visual acuity. However, it is only half of one's vision. Visual quality comprises the other half. For an impeccably credentialed LASIK surgeon to say that surgery was successful because the patient has good visual acuity is, frankly, dishonest. Of the homemaker from West Virginia, who took her cat's medication while her cat took her thyroid medication for 3 days due to blurred vision; of the surgical assistant in Virginia Beach who cut the patient instead of the surgical thread due to poor contrast sensitivity and impaired depth perception; and of the executive in New Jersey whose son asks, "Daddy, why don't you play with me anymore?" due to photosensitivity and irritation from the elements, including the wind, dust, and sand. If just 1% of LASIK patients have a bad outcome, depending on one's numbers, that may mean upwards of 10,000 patients per year will suffer potentially serious visual disability. It is reported that the overwhelming majority of such cases are avoidable or, in my view, constitute presumptive evidence of medical malpractice. Studies indicate that these cases are a result of either the doctor's failure to screen properly or missing warning signs such as keratoconus, or the surgeon cutting the cornea too thin, giving rise to post-LASIK ectasia. The likelihood of serious visual disability in this patient population is high. As visual learners, 85% of what we perceive comes through our eyes. Consequently, the likelihood of clinical depression in this visually disabled population is high. The incidence of suicide in this population, while exceedingly rare, is not hard to fathom.

Editor's note: this testimony is presented verbatim.

1. Ellin A. LASIK surgery: when the fine print applies to you. *The New York Times.* March 13, 2008. Available online at: http://www.nytimes.com/2008/03/13/fashion/13SKIN.html. Accessed: May 25, 2008.

LAUREN BIRCH, PHD

Dr. Birch testified that she has been a medical researcher for more than 20 years. She stated that she is trained to design, conduct, and review medical research studies. She stipulated that the proposed task force to examine post-LASIK quality-of-life issues is composed of individuals with conflicts of interest.

"If there were no serious concerns about the safety and effectiveness of LASIK, we wouldn't be here today," she said. Dr. Birch testified that the ophthalmic literature contains growing evidence that "today's happy 20/20 LASIK patients are also today's most dangerous drivers on the highway at night due to LASIK-induced loss of contrast sensitivity and may ultimately experience debilitating, late-onset complications of LASIK."

MATT KOTSOVOLOS

Mr. Kotsovolos said that his LASIK procedure in 2006 with the IntraLase FS laser (Advanced Medical Optics, Inc., Santa Ana, CA) was considered successful, because it left him with 20/20 vision. He testified, however, that he has experienced debilitating, unremitting eye pain for 2 years.

Mr. Kotsovolos asserted that the rate of complications is much higher than reported and that the FDA allows manufacturers to hide complications such as dry eyes and impaired nighttime vision by categorizing them as symptoms. Mr. Kotsovolos cited a report from the Ohio State University College of Optometry that reviewed data from the summaries of safety and effectiveness for the 12 lasers approved by the FDA for LASIK for myopia or myopic astigmatism. According to Mr. Kotsovolos, the researchers found that, 6 months postoperatively, roughly 20% of patients experienced worse or significantly worse dry eye and/or night vision disturbances.[2]

Mr. Kotsovolos stipulated that the high rate of patients' satisfaction reported by the industry is not indicative of a low rate of complications. He testified that a patient might be happy with his result despite problems with nighttime vision that could affect his and other motorists' safety. He testified that he knew many patients whose complications led to clinical depression and, subsequently, suicidal ideation.

Mr. Kotsovolos urged the FDA to place a moratorium on LASIK until a proper comprehensive study of long-term LASIK complications, including clinical depression, can be completed. He also asked the agency to change the labeling for excimer lasers so that it categorizes dry eye and night vision disturbances as complications rather than symptoms.

Mr. Kotsovolos concluded by asserting that the FDA is controlled by the LASIK industry, surgeons, and manufacturers. As evidence, he cited a press release from the ASCRS dated April 7, 2008: "In that press release, the FDA stated that LASIK is safe and effective. Clearly the fix is in."

BETH KOTSOVOLOS

Mrs. Kotsovolos testified that the post-LASIK symptoms of severe dry eye and unremitting eye pain experienced by Matt, her husband, almost destroyed their family. She said that he has suffered from depression, suicidal ideation, and posttraumatic stress disorder since undergoing surgery.

"As I look upon the panel today, I see that many of you are LASIK surgeons or have close ties to LASIK surgeons," Mrs. Kotsovolos said. "I truly hope that you can put any bias aside and be objective … and listen to the people who have walked in the shoes of LASIK failure."

Mrs. Kotsovolos related stories of other patients who contemplated suicide due to poor LASIK outcomes.

We use our eyes every second of the day," Mrs. Kotsovolos said. "When you permanently damage someone's previously healthy eyes, that person's physical and emotional state will be significantly impacted."

Mrs. Kotsovolos asked the FDA to begin an investigation on post-LASIK suicidal ideation.

TERRY LYNN F. BANKAS, MD

Dr. Bankas testified that she was a volunteer physician counselor for several LASIK support group meetings held throughout the Tampa Bay area, Florida, between 2001 and 2004. Dr. Bankas said the meetings consisted of 10 to 30 patients who had all experienced visual problems following refractive surgery. She said that attendees complained of decreased contrast sensitivity, visual aberrations in scotopic conditions, difficulty driving at night, problems reading, and concerns about losing their jobs due to postoperative visual symptoms. She stated that the patients described a variety of emotional responses, including depression, anxiety, difficulty sleeping, panic attacks, suicidal ideation, and rage.

"I fail to understand how the ophthalmic community can defend continuing to perform a surgery with life-altering complications," Dr. Bankas said.

MICHAEL MULLERY, MD, MBA

Dr. Mullery stated that he is a graduate of the University of Notre Dame and the Pennsylvania State University College of

Medicine. He said he is a board-certified medical specialist with a secondary interest in psychiatry. Dr. Mullery asserted that the refractive surgery industry has known since its inception that LASIK surgery carries a risk of depression and suicide and that poor outcomes are not rare. He testified that he has interviewed nearly 75 people who developed suicidal ideation as a result of LASIK and that few of them had a history of depression or other psychiatric problems.

Dr. Mullery said that allowing eye associations to conduct the studies of quality of life after LASIK "defies common sense and the scientific method." He stated that the study of the procedure's psychological consequences should be carried out by mental health professionals who "lack any financial interest in the outcome."

COURTNEY HENRICHS

Ms. Henrichs testified that LASIK significantly improved her quality of life after a skiing accident left her a quadriplegic and forced her to give up her contact lenses. Limited use of her hands and fingers, she said, made her rely on others to put her glasses on her and to keep them clean and dry in inclement weather. She testified that LASIK provided her with 20/15 vision and that she no longer needs to wear her glasses. She said surgery was a positive step toward regaining some of the independence she lost after her accident.

AMANDA CAMPBELL

Ms. Campbell's comments were read by Attorney Krouner. She stated that she is the widow of a police officer from Brentwood, Tennessee, who committed suicide earlier this year. She said that, in a note he left, he expressed regret that he had undergone LASIK and described chronic dry eye as a source of stress that affected his ability to perform everyday activities. According to Mrs. Campbell, her husband had no history of mental illness prior to undergoing LASIK.

ROGER DAVIS, PHD

Dr. Davis stated that he has a doctoral degree in clinical psychology and that he has served as Director of the Vision Surgery Rehab Network (Rockford, IL).

"Patients respond emotionally to their total situation, not simply to their eyes," Dr. Davis said. "With minor complications, they develop various adjustment disorders. With severe complications, however, they develop what I term *refractive surgery shock syndrome*, which includes major depression, suicidal ideation, and posttraumatic stress."

Dr. Davis stated that, in his experience, no preexisting psychology is necessary for patients to develop suicidal ideation after LASIK. He said that decades of psychological research has shown that catastrophic injuries of all kinds produce a period of prolonged psychological crisis and adjustment.

JOANN WILLS

Ms. Wills stated that her husband underwent LASIK with a laser that was not yet FDA approved. She said he underwent seven procedures to correct additional problems. She testified that her husband suffers from ghosting, starbursts, and multiple images (triple in one eye and quadruple in the other). She asked the FDA to police refractive surgeons better.

EDWARD BOSHNICK, OD

Dr. Boshnick stated that he has been in private practice for over 37 years. He testified that a major portion of his practice is devoted to the nonsurgical treatment of patients who have lost quality vision due to ocular trauma, disease, and refractive surgery, including LASIK. Dr. Boshnick testified that most of the patients he has seen who have undergone the procedure are depressed and that many are taking antidepressants. He said that LASIK represents a significant public health crisis.

REBECCA PETRIS

Ms. Petris testified that she founded a nonprofit organization several years ago to help patients who were suffering from painful dry eyes after LASIK.

"Few people understand that dry eye pain after LASIK can drive people crazy," she testified. "I can't tell you how many people I know who are on short- or long-term disability because of this kind of pain."

She said, if the LASIK industry is interested in helping, it needs to rally around the consumer groups that are seeking help. Ms. Petris stated that practical solutions are needed, because the currently available drugs and punctal plugs are not working." ■

1. Alió JL, Muftuoglu O, Ortiz D, et al. Ten-year follow-up of laser in situ keratomileusis for high myopia. *Am J Ophthalmol.* 2008;145:55-64.
2. Bailey MD, Zadnik K. Outcomes of LASIK for myopia with FDA-approved lasers. *Cornea.* 2007;26:246-254.