

Task Force Will Review Patient Satisfaction With LASIK

At an FDA hearing, patients called for a moratorium on LASIK, and surgeons defended its safety.

BY LEAH D. FARR, NEWS AND INDUSTRY EDITOR

Doctors and patients converged outside of Washington, DC, on April 25, to attend a highly publicized US Food and Drug Administration (FDA) hearing on post-LASIK quality-of-life issues. The hearing was prompted by more than 140 letters of complaint written to the FDA from patients who experienced poor outcomes after LASIK surgery, according to an FDA official.

Approximately 30 patients testified at the hearing and called upon the FDA to take immediate action—ranging from improved informed consent to a moratorium on the procedure until further study was completed on its safety and impact on quality of life. Much of the public comment was dominated by testimony from patients or family members who claimed that LASIK caused injury or psychological problems, such as severe depression.

“LASIK ruined my vision and my quality of life,” one patient testified to the panel. Another complained of deceit. “I had to pay out of pocket for medical expenses, lost wages, and daily suffering [because of complications after LASIK]. I do not know of any other procedure where hundreds of patients have created Web sites warning the public about the unpredictability and corruption of LASIK surgeons,” the patient said.

This tone was apparent in other consumer testimony at the FDA hearing, including that of a man who stated, “I come today at my own expense after 8 years of research to inform this panel that you have a serious problem on your

hands; [there are] very desperate, suicidal, angry patients who know that their LASIK doctors lied to them and who blame their LASIK doctors for ruining their precious lives.”

Ultimately, the panel decided that the hearing was less about the FDA’s role in informed consent or proving the safety of the device and more a “referendum on the performance of LASIK by some surgeons who should be doing a better job,” said Jayne Weiss, MD, Chair of the FDA panel.

In attempt to further examine LASIK’s impact on quality of life, the American Society of Cataract and Refractive Surgeons (ASCRS), the American Academy of Ophthalmology (AAO), and the FDA are developing and cofunding a prospective evaluation of LASIK (Joint LASIK Study Task Force) along with the National Eye Institute, to provide insight into the incidence of patient dissatisfaction, the causes of dissatisfaction, and possible treatments for unhappy LASIK patients.

Quality of life is not the same as safety or effectiveness, Richard L. Lindstrom, MD, of Minneapolis, Minnesota, Cochair of the Joint LASIK Study Task Force, said in a written statement to the FDA panel. “Unlike the latter parameter, quality of life is a subjective experience in which patients’ expectations and surgeons’ ability to communicate are important factors.”

The hope is that the LASIK quality-of-life study will not only enhance patient education and counseling but improve the selection of candidates and their treatment, therefore increasing satisfaction rates to a higher level, Dr. Lindstrom said.

The Joint LASIK Study Task Force will soon begin to study factors that might cause patients to be dissatisfied with their outcomes. Still in its preliminary stages, the \$1.2 million quality-of-life study will start by 2009, according to Daniel Schultz, Head of the FDA’s medical devices center. “Clearly there is a group [of patients] that aren’t satisfied and don’t

TAKE-HOME MESSAGE

- A Joint LASIK Study Task Force will examine the effect of LASIK on patients’ quality of life.
- A review of the literature on post-LASIK dry eye showed that most patients’ symptoms resolve within 2 to 4 weeks after LASIK.

COVER STORY

get the results they expect," Mr. Schultz said in an interview with Bloomberg News.¹ Studying these patients "is very high on the agency's priority list."

Dr. Lindstrom added that the recently formed task force has already (1) completed a global review of the literature, led by Cochair Kerry D. Solomon, MD, of Charleston, South Carolina, which found a 95.4% rate of satisfaction with LASIK, (2) requested the assistance of the US Department of Defense's Laser Vision Correction Warfighter Program in reviewing the results of LASIK, (3) started to develop a "validated, robust tool" to assess quality of life after LASIK, and (4) developed the protocol for the planned study.

The proposed large, prospective, multicenter evaluation is still being designed; however, its fundamentals are agreed upon, including determining (1) the level of satisfaction after LASIK, (2) the change in quality of life after LASIK, and (3) the factors associated with patients' level of satisfaction, particularly dissatisfaction, said Steven C. Schallhorn, MD, of San Diego, during his presentation to the FDA.

"Our goal is to make [the LASIK] procedure better," Dr. Schallhorn said. "We have done that over the years, and this is another effort to improve the procedure itself."

The task force will also evaluate the impact of postoperative dry eye, which is the No. 1 reason that patients are seen by eye care professionals, according to Eric D. Donnenfeld, MD, of Long Island, New York. In an effort to better understand dry eye, the Joint LASIK Study Task Force also conducted a world literature review on post-LASIK dry eye. Presented to the FDA panel were the preliminary results, collected from 113 peer-reviewed articles and 46 journal articles from 15 countries and representing more than 32,000 eyes. According to the analysis, most patients achieved complete resolution of dry eye symptoms 2 to 4 weeks postoperatively. Additionally, the study found that 32% of patients were diagnosed with dry eye before LASIK, and 35% of patients experienced dry eye symptoms postoperatively, Dr. Donnenfeld told the panel members.

The FDA panel also announced that changes will be made to the LASIK language on the FDA's Web site, including clarification on how often and severely some patients suffer from side effects of LASIK, as well as conditions that should disqualify someone from undergoing LASIK. The panel also recommended adding illustrations of side effects, such as glare and halos, to the Web site.

"It has been my experience that LASIK has a very positive, not negative, effect on the well-being of patients," Dr. Schallhorn, a member of the Joint LASIK Study Task Force, told *CRST Europe*. "Studies have shown that the quality of life, on average, is improved after LASIK." ■

1. Larkin C. LASIK study is a priority in US, will start by 2009. Bloomberg News. Available at: <http://www.bloomberg.com/apps/news?pid=20601124&refer=home&sid=aX6SKlIfKQvU>. Accessed on May 22, 2008.