

# Surgeons Defend LASIK

Although the positive results of refractive surgery outweigh the negative, surgeons express compassion for patients whose quality of life decreases after LASIK.

BY SARA E. SMITH, SENIOR MANAGING EDITOR

**T**he FDA's Ophthalmic Devices Advisory Panel convened recently to discuss patients' post-LASIK quality-of-life issues. During testimony, many ophthalmologists from the Joint LASIK Study Task Force praised the procedure, while also showing empathy for those patients whose daily lives suffer due to unfavorable postoperative results. This article summarizes refractive surgeons' opinions about and data on LASIK and their thoughts on the many postoperative factors experienced by patients.



## RICHARD L. LINDSTROM, MD

In a written statement to *Cataract & Refractive Surgery Today*, Dr. Lindstrom, Co-Chair of the Joint LASIK Study Task Force, said that he fully understands that quality of life

is not the same as safety or effectiveness. Unlike the parameters, quality of life is a subjective experience in which patients' expectations and surgeons' ability to communicate are important factors.

Dr. Lindstrom has been involved in the development of laser refractive surgery since 1985 and has participated in several FDA Investigational Device Exemption clinical trials. He has performed LASIK on more than 10,000 patients, including three of his partners, six immediate family members, and numerous close friends.

He wrote, "While it is clear that LASIK is safe and effective, and that the vast majority of patients are satisfied with the outcome of their surgery, the dissatisfied patient is a real concern for the LASIK surgeon, organized ophthalmology as a whole, and the industry that supports the procedure. It is important for the dissatisfied LASIK patient to know that we, as LASIK surgeons, are listening, that we

hear them, that we care, and that we are responding in a tangible and constructive fashion."

"Quality of life is a subjective experience in which patients' expectations and surgeons' ability to communicate are important factors."

Dr. Lindstrom explained in his written statement that surgeons are working with the ASCRS, AAO, FDA, and National Eye Institute to plan, cofund, and conduct a Prospective Evaluation of LASIK Satisfaction study, which will provide important insight into the incidence of patients' dissatisfaction with modern LASIK, the causes, and possible treatments. He hopes the study will enhance patients' education and counseling, improve the selection of candidates and their treatment, and ultimately increase patients' satisfaction rates to a higher level.

"If a patient is unhappy, a surgeon is unhappy," Dr. Lindstrom stated. "... We surgeons, the patients' primary advocate, will not rest until we have raised LASIK satisfaction levels to the highest level possible."



## ERIC D. DONNENFELD, MD

Dr. Donnenfeld, an original FDA investigator of the excimer laser, has performed LASIK on more than 800 eye doctors and their families, with the majority of patients achieving postoperative vision equivalent to or better than what they saw with

their glasses or contact lenses. During his testimony before the FDA panel, he said that LASIK has always been a safe procedure and that it continues to improve with technological advances.

"As surgeons, we rejoice in our patients' success, and we understand the immense responsibility that comes with this [surgical] option," Dr. Donnenfeld said. "We are deeply committed to both the well-being of our patients and the safety and efficacy of LASIK." Furthermore, he commented that the majority of LASIK patients have less glare and fewer halos after LASIK than they did before the procedure. Nonetheless, refractive surgeons cannot be satisfied, he said, until all complications are eliminated.

"LASIK has always been a safe procedure ... [and] it continues to improve with technological advances."

Dr. Donnenfeld also addressed the issue of dry eye: "Dry eye is ... the number one medical reason patients are seen by an eye care professional." He stated that dry eye affects an estimated 55 million Americans; it impacts patients' quality of life, their level of comfort, and their ability to perform everyday activities. In an effort to better understand dry eye, the Joint LASIK Study Task Force reviewed the world literature following LASIK, and Dr. Donnenfeld presented the preliminary results for the first time at the FDA panel meeting. He explained that there are 113 peer-reviewed articles on dry eye following LASIK, and 46 articles published in 13 journals from 15 countries that contain reviewable data. The data represent more than 32,000 eyes. Thirty-two percent of patients were diagnosed with dry eye before LASIK. A similar 35% had dry eye postoperatively. The majority of patients achieve complete resolution of their dry eye symptoms during a 2- to 4-week period after surgery, according to Dr. Donnenfeld. He said that dry eye following LASIK is extremely rare.

"Modern thin-flap LASIK, advances in artificial tears, topical cyclosporine A, nutritional supplements, and the treatment of eyelid disease are improving outcomes," he testified. "Ophthalmology is committed to developing treatment options, and there are many exciting therapies currently undergoing FDA evaluation that offer great promise, not only for LASIK patients, but to the tens of millions of patients with dry eye disease who have not had LASIK."

To conclude, Dr. Donnenfeld stated, "LASIK improves patients' lives."



**R. DOYLE STULTING, MD, PhD**

Lt. Col. R. Scott Barnes read to the FDA panel a statement from Dr. Stulting, who was unable to attend the panel meeting.

Dr. Stulting represents the ASCRS and has practiced refractive surgery for more than 25 years. He participated in clinical trials of LASIK before the first excimer laser was approved for use in the US. He was also a member of the FDA's Ophthalmic Devices Advisory Panel for 10 years and was chairman for 3 years. During that time he helped to write the first FDA guidelines for the evaluation of excimer lasers for the correction of myopia. He was also a member of the panel when the first excimer laser was approved more than a decade ago.

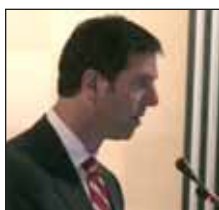
"A small group of individuals do not obtain the results that refractive surgeons have come to expect from LASIK."

Since the first clinical trials, Dr. Stulting said in his statement, he and his colleagues have worked to improve patients' quality of vision after LASIK. He testified that 20/20 vision is not the same for everyone. For example, functional night and driving vision may not be the same as the vision that was measured in the office. Dr. Stulting said that, today, most of the patients who undergo LASIK achieve 20/20 or better vision. In fact, 61% of patients achieved better than 20/20, according to a recent clinical trial. These patients also reported less glare, sensitivity to light, and difficulty driving at night than before surgery.

In his statement, Dr. Stulting acknowledged that a small group of individuals do not obtain the results that refractive surgeons have come to expect from LASIK. He said that surgeons are concerned about any disappointing outcomes. For that reason, Dr. Stulting and his colleagues have developed methods to evaluate the optical system in greater detail. They have also developed methods to correct abnormalities of the optical system, with treatments customized to address the unique needs of every patient. In addition, they have instituted a screening procedure to help identify patients who might have less-than-optimal outcomes after the procedure.

Dr. Stulting's goal is to ensure that the procedure meets the needs and expectations of each patient. He stated that he routinely tells patients that they are not candidates for LASIK eye surgery under any circumstances.

"The results of our collaboration with the AAO, the NEI, and FDA will allow us to refine our screening procedures even further," read Dr. Stulting's statement. "Our goal, like the goal of everyone here today, is to do everything possible to be sure that every patient achieves a result that is consistent with his or her individual needs and expectations."



#### KERRY SOLOMON, MD

One of the original investigators of LASIK, Dr. Solomon has performed the procedure for 13 years. He is a LASIK patient himself.

During the panel meeting, Dr. Solomon represented the

ASCRS, for which he has served as Chairman to the Liaison Committee for the past 4.5 years. He also serves as Co-Chair of the Joint LASIK Study Task Force.

"Based on the global scientific literature, more than 95% of patients worldwide are satisfied with the outcomes of their LASIK surgery."

Because of his position within the task force, and after meeting with members of the four agencies that compose the group, representatives from the ASCRS asked Dr. Solomon to perform an independent review of the global literature regarding LASIK patients' satisfaction for meta-analysis. Dr. Solomon, along with his colleagues, research students, faculty, and resident physicians (none of whom have consulting ties to any refractive surgery device manufacturer), helped with the study. The goal of the study is to identify patients' satisfaction and quality-of-life issues after LASIK. Nineteen of 309 articles identified, which signified a global distribution, specifically address patients' satisfaction and quality of life and represent surgeries from 1995 to 2003. He reported that, based on the global scientific literature, more than 95% of patients worldwide are satisfied with the outcomes of their LASIK surgery. These results are regardless of the ametropia treated, whether the surgery was performed at the inception of LASIK or recently, whether the surgery was performed in the US

or elsewhere, whether validated questionnaires were used or if they were submitted anonymously, and whether the question of satisfaction was asked within 6 months of the procedure.

Dr. Solomon explained that this level of satisfaction is one of the highest reported for an elective surgery. His review encompassed all articles from the inception of LASIK to the most recently published piece in 2008.



#### PETER J. McDONNELL, MD

Dr. McDonnell is a corneal surgeon who was involved in the early clinical and preclinical studies of excimer laser surgery. Two of his sisters underwent LASIK several years ago. He presented the following information to the FDA panel on behalf of the International Society of Refractive Surgeons (ISRS) and the AAO.

Approximately 700,000 Americans have LASIK surgery annually. More than 90% of those who underwent LASIK for nearsightedness achieved between 20/20 and 20/40 UCVA, Dr. McDonnell said. LASIK is the most studied elective ophthalmic procedure, according to Dr. McDonnell. Collectively, 7,830 patients (representing 16,502 eyes) participated in the FDA clinical trials between 1993 and 2005. Initial findings from the world review of the scientific literature, as Dr. Solomon had mentioned earlier, found an average rate of satisfaction of 95.4%.

According to Dr. McDonnell, the ISRS and AAO support efforts to further improve LASIK techniques and technology as well as to better identify patients who might not respond well to the procedure or who have characteristics that might make them poor candidates for surgery.

"[We] are dedicated to doing everything possible to make the LASIK procedure better for all of our patients."

"In summary, the ISRS and AAO agree that the safety and efficacy of the LASIK procedure has been well studied and documented in hundreds of publications," Dr. McDonnell said. "Millions of patients have benefited from this procedure. No surgery is without risk, but the physician members of the organizations I represent are dedicated to doing everything possible to make the LASIK procedure even better for all of our patients."



**STEVEN C. SCHALLHORN, MD**

Dr. Schallhorn serves on numerous committees of the AAO, the members of which, he said, are committed to responding compassionately and ethically to patients' needs and advancing the

highest standards of eye care. Dr. Schallhorn recently retired from the US Navy after nearly 30 years as the head and founder of the Navy Refractive Surgery program. He said he has performed thousands of LASIK procedures and conducted numerous clinical trials of laser vision correction.

“Physicians are dedicated to doing everything in their power to make the LASIK procedure better for all patients.”

During his testimony to the FDA panel on behalf of the AAO, Dr. Schallhorn explained that the effectiveness and safety of LASIK is documented in numerous studies conducted with thousands of patients over the past 15 years. He said that patients' satisfaction is high following the procedure and higher than with other types of elective procedures. There are a small number of patients, however, whose outcomes are not reflected in their levels of satisfaction. He stated that, “While we can identify several reasons for dissatisfaction, sometimes we cannot do this, which points to other factors for consideration.”

Dr. Schallhorn stated that physicians are dedicated to doing everything in their power to make the LASIK procedure better for all patients. He said that the AAO believes that the knowledge gained from the Prospective Evaluation of LASIK Satisfaction study will benefit both patients and physicians. An enhanced understanding of preoperative factors associated with dissatisfaction will allow surgeons to better select candidates for the procedure and better meet the patients' expectation. “The goal of the study is to further improve our understanding of LASIK to ensure that the significant benefits are realized by all patients who undergo the procedure.”



**LT. COL. SCOTT BARNES, MD**

Dr. Barnes addressed the importance of LASIK to the military. He explained that military members, especially those involved in the Special Operations command,

want to be able to see without relying on glasses or contact lenses. When troops are in combat situations, it is a serious problem if they cannot see others as well as they can be seen. “The word from the guys who are out there standing in harm's way, whose lives depend on their ability to see to do their job, are asking that you please do not take this away,” Dr. Barnes said.

“Military members, especially those involved in the Special Operations command, want to be able to see without relying on glasses or contact lenses.”

After reading Dr. Stulting's statement to the FDA panel earlier, Dr. Barnes added some comments of his own. He spoke of a young captain who was leading 21 men in his military company when they were ambushed. During the ensuing firefight, the captain could not locate his glasses but was able to make his way back to his Humvee. He instructed an 18-year-old corporal to drive them to safety. As soon as that military company returned home, the captain came to Dr. Barnes' office asking for LASIK so that he would never put himself or his men in that kind of position again.

While serving in the military, Dr. Barnes himself underwent laser vision correction and was so impressed with his results that he decided to become an eye surgeon. He is currently Chief of the Warfighter Refractive Eye Surgery Program at Fort Bragg, North Carolina. ■

*Lt. Col. Scott Barnes, MD, is Chief of the Warfighter Refractive Eye Surgery Program in Fort Bragg, North Carolina. Dr. Barnes may be reached at (910) 907-7921; scott.d.barnes@us.army.mil.*

*Eric D. Donnerfeld, MD, is a trustee of Dartmouth Medical School in Hanover, New Hampshire, and is a partner in Ophthalmic Consultants of Long Island in Rockville Centre, New York. He is a consultant to Advanced Medical Optics, Inc.; Alcon Laboratories, Inc.; Allergan, Inc.; Bausch & Lomb. Dr. Donnerfeld may be reached at (516) 766-2519; eddoph@aol.com.*

*Richard L. Lindstrom, MD, is Founder and Attending Surgeon at Minnesota Eye Consultants, PA, in Bloomington, Minnesota, and he is the immediate past president of the ASCRS. He is also on the board of directors at and co-medical director for TLCVision. He is a paid consultant to Advanced Medical Optics, Inc.; Alcon Laboratories, Inc.; and Bausch & Lomb. Dr. Lindstrom may be reached at (612) 813-3600; rllindstrom@mneye.com.*

## TAKE-HOME MESSAGES FROM THE MEETING OF THE FDA'S OPHTHALMIC DEVICES ADVISORY PANEL ON LASIK

By Stephen G. Slade, MD; Peter J. McDonnell, MD; Steven C. Schallhorn, MD; and John A. Vukich, MD

Cataract & Refractive Surgery Today asked several surgeons who attended the panel meeting to share their reactions.

#### STEPHEN G. SLADE, MD

We refractive surgeons need to try our best to assist LASIK's casualties, as they call themselves (*see Dr. Slade's article on page 43*). These patients' efforts were the impetus for the FDA panel meeting.

After listening to all of the presentations, I felt that LASIK was an even better procedure than I had thought, and I was impressed by how well our societies (the ASCRS and AAO) worked together on this issue. I was proud of all the ophthalmologists who testified. I believe the meeting was of considerable value for every ophthalmologist.

#### PETER J. McDONNELL, MD

LASIK is probably the most carefully studied elective procedure in ophthalmology and possibly all of medicine. It has been proven safe and effective. Nevertheless, complications (although rarely serious, fortunately) can and do occur. For this reason, patients need to see well-trained ophthalmologists who can fully evaluate them and determine their candidacy for the procedure.

#### STEVEN C. SCHALLHORN, MD

LASIK is safe and effective, as demonstrated by numerous studies involving thousands of patients that have been conducted during the last 15 years. Patients' satisfaction after LASIK is excellent and higher than that reported for other forms of elective surgery. The procedure has benefited millions of patients.

Quality of life is the next area where we need to focus, and it is not the same as the safety and effectiveness. Although published studies demonstrate an overall improvement in patients' quality of life after LASIK, this research could not make a complete assessment of those individuals who were dissatisfied with their outcomes. In addition, there is a small number of patients whose outcomes are not reflected by their degree of satisfaction.

The Joint LASIK Study Task Force will evaluate underlying factors that impact satisfaction and quality of life after LASIK. A large number of subjects will be necessary if the

study is to have statistical validity, given the very low percentage of dissatisfied patients. Results from the study will benefit both patients and physicians and could provide an incremental breakthrough in the former group's level of satisfaction with the procedure.

#### JOHN A. VUKICH, MD

The FDA Ophthalmic Devices Advisory Panel is obligated to monitor the postapproval safety of devices on the US market. The April 25th meeting was designed to gather input from individuals whose lives have been touched by laser refractive surgery as well as other interested parties. Individual accounts of difficulties related to LASIK were compelling. This testimony was balanced by the thoughtful and well-prepared analysis of the world literature by Kerry Solomon, MD, as well as the US military experience, as reported by David Tanzer, MD.

The important points of the meeting were that LASIK surgery is a safe and effective procedure with a high rate of satisfaction on the part of patients. Less-than-perfect outcomes, however, leave certain individuals with real problems. We surgeons must continue to try to do better.

*Peter J. McDonnell, MD, is Director of the Wilmer Eye Institute of the Johns Hopkins University School of Medicine in Baltimore. He is a member of the Alcon Scientific Advisory Board. Dr. McDonnell may be reached at (443) 287-1511; pmcdonn1@jhmi.edu.*

*Steven C. Schallhorn, MD, is in private practice in San Diego. He is a consultant to Advanced Medical Optics, Inc., and AcuFocus, Inc. Dr. Schallhorn may be reached at (858) 695-3849; scschallhorn@yahoo.com.*

*Stephen G. Slade, MD, is the surgeon at Slade and Baker Vision in Houston. Dr. Slade may be reached at (713) 626-5544; sgs@visiontexas.com.*

*John A. Vukich, MD, is Assistant Clinical Professor at the University of Wisconsin, Madison. Dr. Vukich may be reached at (608) 282-2002; javukich@facstaff.wisc.edu.*

*Peter J. McDonnell, MD, is Director of the Wilmer Eye Institute of the Johns Hopkins University School of Medicine in Baltimore. He is a member of the Alcon Laboratories, Inc., Scientific Advisory Board. Dr. McDonnell may be reached at (443) 287-1511; pmcdonn1@jhmi.edu.*

*Steven C. Schallhorn, MD, is in private practice in San Diego. He is a consultant to AcuFocus, Inc., and Advanced Medical Optics, Inc. Dr. Schallhorn may be reached at scschallhorn@yahoo.com.*

*Kerry Solomon, MD, is Professor of Ophthalmology and Medical Director, Magill Laser Center, Medical University of South Carolina in Charleston. He is a consultant to Alcon Laboratories, Inc. Dr. Solomon may be reached at (843) 792-8854; solomonk@muscd.edu.*

*R. Doyle Stulting, MD, PhD, is Professor of Ophthalmology and Director of Cornea and Refractive Surgery at Emory University in Atlanta. He is a consultant to Advanced Medical Optics, Inc. Dr. Stulting may be reached at (404) 778-6166; ophtrds@emory.edu.*