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## The truth about LASIK

### FDA panel discusses patients' postoperative quality of life

May 15, 2008

By: [Christina Phillis](#)

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#### On the horizon

Beside improving the patient labeling and information provided by FDA Web sites to help future LASIK patients, another matter is the evaluation of patients who are not satisfied with LASIK surgery results. Dr. Schallhorn will be leading a quality-of-life study, which is being supported by the FDA, the National Eye Institute (NEI), the American Society of Cataract and Refractive Surgery (ASCRS), and the AAO.

"The quality of life really represents the next area where we need to focus. It is important to appreciate that quality of life is not the same as safety and effectiveness, Dr. Schallhorn said. "Published studies looking at quality of life using a validated questionnaire have shown an overall improvement in quality of life after LASIK. But because the satisfaction was so high after LASIK, the previous studies could not reassess the quality of life in those patients who were dissatisfied."

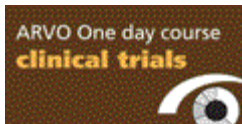
According to Dr. Schallhorn, there are a very small number of patients whose outcomes are not reflected in their level of satisfaction. "While



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normally we can identify several reasons for their dissatisfaction ,sometimes we can't, which points to other factors. That in a nutshell is why the FDA, NEI, ASCRS, AAO are committed to participating in a study," Dr. Schallhorn told *Ophthalmology Times*.

To ensure that the study has statistical validity, it will have to be a large multicenter study to compensate for the fact that LASIK satisfaction is so high, he noted.

"Our objectives are to determine the change in quality of life after LASIK and understand the factors associated with satisfaction and dissatisfaction," Dr. Schallhorn said. "Greater knowledge of how LASIK affects the quality of life will provide an opportunity to understand, anticipate, and eliminate potential issues related to patient satisfaction. This is something we have done for every ophthalmic procedure, and we will continue to refine and improve LASIK."

Richard L. Lindstrom, MD, former president of ASCRS, attending surgeon of Minnesota Eye Consultants, and professor at the University of Minnesota Department of Ophthalmology, Minneapolis, has been involved in the development of laser refractive surgery since 1985 and performed LASIK on more than 10,000 patients.

"An overwhelming majority of patients—95%—are satisfied, yet a small percentage feel they have not experienced the same satisfaction. For those patients, I want to be clear," Dr. Lindstrom said. "We hear your concerns, we care, and we respond in a tangible and constructive manner.

"The goal of any elective medical procedure is to ensure all patients are satisfied. While the satisfaction rate for LASIK is higher than for any other elective procedure, there is always room for improvement," Dr. Lindstrom concluded. "In this case that means learning about why some patients are dissatisfied."

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