

FDA Data Confirms Safety and Effectiveness of LASIK Surgery

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Results reported by the Food & Drug Administration (FDA) on a long-awaited comprehensive prospective, multi-center study on the safety and efficacy of LASIK were well-received by refractive surgeons in attendance at the recent American Academy of Ophthalmology (AAO) meeting held in Chicago, according to eye surgeon Lance Kugler, MD, president of the Refractive Surgery Alliance.



Lance Kugler, MD, President, Refractive Surgery Alliance: "The FDA data confirm what patients and their refractive surgeons have known for many years: That LASIK is a safe and effective treatment for the correction of myopia, hyperopia and astigmatism." (Photo: Business Wire)

The study surveyed patients regarding their visual symptoms and quality of life before and three months after LASIK surgery. The FDA report confirms that over 95% of the survey respondents achieved 20/20 or better binocular vision. The study also indicated that the prevalence of symptoms such as ghosting, glare, halos, and starburst did not increase postoperatively after LASIK. "In fact, patients with ghosting actually decreased from 33% before surgery to 6% after surgery," said Dr. Kugler.

"We're obviously extremely pleased with the favorable results reported by the FDA in the extensive study," said Dr. Kugler, who indicated this was the most comprehensive study of patient-reported outcomes after LASIK ever conducted. "This report will provide reassurance to potential LASIK patients who may be hesitant to have their vision corrected due to fear or concerns about safety or results." Malvina B. Eydelman, MD, Director, Division of Ophthalmic Device Evaluation, FDA, reported the results as part of the LASIK Quality of Life Collaboration Project (LQOLCP), a partnership with the Department of Defense (DOD) and the National Eye Institute (NEI), incorporating data from questionnaires PROWL-1 and PROWL-2 (Patient reported outcomes with LASIK).

"The Refractive Surgery Alliance (RSA) is grateful to the FDA, NIH, and DOD for conducting this comprehensive study," said Dr. Kugler. "The data confirm what patients and their refractive surgeons have known for many years: That LASIK is a safe and effective treatment for the correction of myopia, hyperopia and astigmatism."

Incoming RSA president Greg Parkhurst, MD said his colleagues will use this data to continue refining laser vision correction techniques. "Our goal with LASIK is to continually enhance our pre-operative diagnostics and surgical techniques to provide patients a higher quality of vision than is possible with corrective eyewear," he said. "The Refractive Surgery Alliance puts high value on studies of LASIK outcomes. We will continue to address the small percentage of patients who are not fully satisfied with their outcomes."

Leading refractive industry expert Dan Durrie, MD, who served as investigator at one of the five centers in the FDA study, was also impressed by the FDA report. "The key positives in the study were that it showed the procedure was extremely safe and that ghosting, glare, halos and starburst went down after surgery. Overall, patients experienced improved symptoms after surgery and an

extremely high satisfaction rate.” Dr. Durrie is the founder and medical director of Durrie Vision in Kansas City, Mo.

Approximately 16,000,000 LASIK procedures have been performed in the United States over the past two decades. “The collective experience of the RSA surgeon members suggests that results continue to improve beyond three months,” said Dr. Kugler. “Satisfaction is expected to be even higher over time. By six months, the vast majority of dry eye symptoms, i.e. feeling dryness, foreign body sensation and night-vision difficulty, will abate.”

Kugler cautioned that “Occasional complications can occur after LASIK. Fortunately, most are transient. The RSA and many LASIK surgeons around the world are continually striving to make the results better and to eliminate all complications. This report confirms that those efforts are having an impact.”

Source: <http://www.refractivealliance.com/>