COMPREHENSIVE INVESTIGATION OF WORLDWIDE LASIK RESEARCH CONFIRMS SAFETY, EFFICACY AND PATIENT SATISFACTION WITH VISION CORRECTION AND HAS IMPROVED OVER TIME

Fairfax, Va. and DALLAS, Sept. 15, 2016 — Findings from a scientific literature review of more than 4,400 peer-reviewed clinical studies of LASIK vision correction safety and performance published worldwide over a 7-year period show the procedure, using modern technology and techniques, is among the safest and most effective elective procedures available today. The study, “Modern Laser in Situ Keratomileusis Outcomes,” reporting a global patient satisfaction rate of more than 98 percent, was published in the current issue of the Journal of Cataract and Refractive Surgery.

The significant research undertaking updates and improves upon the work published in 2009, “LASIK World Literature Review – Quality of Life and Patient Satisfaction,” which reviewed available LASIK clinical research published between 1988-2008 totaling more than 2,900 articles. The current study reviewed high quality LASIK literature published between January 2008 and August 2015. This involved examining whether modern LASIK – using the latest technologies and techniques - is safe and effective, if patients are getting the results they desire, and if the results have improved over time.

“The study was designed to compare recent procedure outcomes with those from earlier forms of LASIK. We knew from our earlier work, LASIK has, from its inception, an excellent record for safety and effectiveness,” said Kerry Solomon, M.D., current president of the American Society for Cataract and Refractive Surgery, director of the Carolina Eyecare Research Center and lead study author. “The good news is with the introduction and utilization of new technologies including wavefront guidance, modern treatment profiles and femtosecond laser keratomes, we are seeing even better results and patients are even more satisfied. In fact, the studies providing data on patient satisfaction found only 1.2 percent of patients were dissatisfied.”

Key clinical findings related to LASIK efficacy and safety were extracted from the relevant studies and determined:

• 20/20 or better was achieved in 90.8% of the 56,000 eyes that reported data
• 99.5% of patients were 20/40 or better

• Overall, 90.9% of patients were within 0.5 diopter of target correction, and 98% were within 1 diopter

• Less than 1 percent, .61%, of patients lost 2 lines (of the eye chart) of best corrected visual acuity of the 58,653 procedures reporting data. As a point for reference, the U.S. Food and Drug Administration threshold for safety is less than 5 percent, confirming LASIK far surpasses the standard for safety.

The literature review began by analyzing the 4,474 articles found via PubMed search yielding 2,189 related to LASIK, 2007 related to the term “laser in situ keratomileusis” and 269 related to “laser vision correction.” Subsequent abstract evaluation reduced the relevant references to 97 articles representing 67,893 eyes (procedures). These studies identified and included 30 different laser systems and were further evaluated for industry bias with no significant finding.

“Literature review isn’t the most popular research approach, but it is scientifically necessary in order to evaluate the growing body of evidence for any treatment modality,” said Dr. Solomon. “Importantly, our work underscores the fact there is a tremendous amount of research both supporting and advancing the science of LASIK; there is simply no questioning its excellence from a clinical perspective. We were impressed with how good the data was, and that it was consistently good across multiple articles.”

In the final analysis, “Modern Laser in Situ Keratomileusis Outcomes,” found patients are experiencing better visual outcomes than ever before. However, from a practical standpoint, LASIK is not for everyone. It’s important for those considering LASIK to choose a good surgeon and clearly understand the risks and benefits of the procedure. But, for those patients who are looking to be less dependent on their glasses or contacts, the preponderance of clinical research shows LASIK technologies and outcomes are better than they’ve ever been and support the procedure as a safe and effective vision correction option.

“This review of the impact of the years of research and development in the field of LASIK confirms that modern LASIK improves patient visual outcomes,” concluded Solomon. “The data clearly show LASIK results have only improved with innovation and better patient screening protocols. For those considering LASIK, the good news from all of this research is LASIK is and has been a very safe and effective vision correction procedure that has only gotten better over time.”
The study was supported by the American Society of Cataract and Refractive Surgery and the American Refractive Surgery Council.

**About the American Refractive Surgery Council**

ARSC is a working group of industry representatives and medical professionals with expertise in developing, researching and using the technologies and techniques behind advanced refractive – or vision correcting – surgical procedures. Millions of people have benefited from refractive procedures. Many more could benefit if they more fully understood the procedures available and the clinical research behind them, the lifestyle benefits of excellent vision, and the factors that make people good candidates for refractive procedures.

Through its educational efforts, ARSC serves as a resource for people to make informed, unbiased decisions about their vision correction surgery options.

**About the American Society of Cataract and Refractive Surgery**

The American Society of Cataract and Refractive Surgery is an international, educational society with more than 9,000 members. Its mission is to advance the art and science of ophthalmic surgery and the knowledge and skills of ophthalmic surgeons by providing clinical and practice management education and by working with patients, government, and the medical community to promote the delivery and advancement of high-quality eye care.

Since its founding in 1974, ASCRS has led the field through significant advances in technology and clinical science through its educational programs, publications and on-line resources. ASCRS has become the surgeons' primary source of up-to-date clinical information, published research, and regulatory information affecting the practice of medicine.

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