

May 5, 2008

Addressing Your LASIK Concerns on the Recent FDA Hearing

Whether you're a new or returning patient at our clinic, The UCSF Laser Vision Center would like to address your concerns over the recent public meeting held by the U.S. Food and Drug Administration (FDA) to discuss patient satisfaction with laser eye surgery. Dr. Stephen McLeod, one of the center's two surgeons and Chair of the UCSF Department of Ophthalmology, was requested to serve on the FDA panel as a consultant expert for this hearing.

Despite a recent study by the American Academy of Ophthalmology in which 95% of LASIK patients expressed satisfaction with the procedure, the FDA has been prompted to hold talks due to complaints received regarding side effects such as dry eye, blurred or double vision, and poor night time vision.

The number of complaints about LASIK outcomes reported to the FDA from 1998 through 2006 was 140. During this period, between 6 and 7 million patients underwent laser vision correction in the United States. Thus, the percentage of all LASIK cases resulting in a complaint to the FDA was only 0.002%, an extremely small fraction given the number of individuals who have undergone the procedure.

UCSF surgeons were among the first U.S. surgeons to perform PRK and LASIK surgery under FDA-sponsored clinical trial protocols. Since then, UCSF surgeons have safely and successfully treated thousands of patients, enabling them to reduce or eliminate their need for glasses or contact lenses. Our center's LASIK surgeons, Drs. Hwang and McLeod, are nationally recognized leaders in the field and have published extensively in both refractive surgery and corneal disease.

Drs. Hwang and McLeod will recommend surgery only after a very careful and comprehensive evaluation, which typically lasts from two to three hours. During the consultation process, the patient's eye will be examined and dilated, and specialized tests will be performed. The surgeon will discuss findings with the patient one-on-one and will formulate an individualized recommendation plan. Our goal is to identify appropriate candidates to refractive surgery, and to exclude those who are at a higher risk for surgical complications. During the consultation, the patient will also learn about how to prepare for surgery, the risks and benefits involved, as well as how to take care of their eyes after surgery.

Please call **415-353-2020** to learn more about LASIK at the UCSF Laser Vision Center. We aim to provide the very best in meticulous and safety-oriented care for all of our patients, and we welcome the opportunity to meet and speak with you.