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Dean Andrew Kantis
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Dear Mr. Kantis:

Here is my most recent perspective on the sad situation with LASIK-induced eye injuries. Figure 1 summarizes the percentage of LASIK patients that have eye pain, glare, halos, night-driving problems, and related vision problems for more than a year after surgery (~20 %) and corneal ectasia (~0.9 %).[1,2,3] Approximately 700,000 people will receive LASIK surgery in 2010 and 16 million have already received it. Therefore, about 140,000 LASIK injuries will occur this year and to date there have been approximately 3.2 million LASIK injuries. The precise severity of these injuries is unknown but they are sufficiently bothersome for patients to submit hundreds of injury reports to FDA.[4] Although the injuries are permanent some may be managed so they are tolerable but some not. Although LASIK improves visual acuity in ~95% of patients for about one year, a significant but unknown number of LASIK patients return to glasses or contact lenses within five years.

LASIK-induced eye injuries occur, in part, because FDA did not ensure that manufacturers have adequate design controls, fault tree analyses, and correction and prevention procedures, including, but not limited to, adverse event definitions, MDR reportable events, trend analysis, and root cause analyses. The agency also did not compare the safety and effectiveness of laser refractive correction outcomes with the safety and effectiveness of glasses and contact lenses so that consumers would have a context for comparison of risks and benefits. The Center did not conduct a formal risk analysis, or require the manufacturers to submit a formal risk analysis, e.g. sum the error rates due to corneal refraction, topography, thickness, eye length, algorithm accuracy, and the accuracy and precision of the microkeratome. Also FDA did not require worst-case clinical trials or clinical studies representative of clinical conditions of use of LASIK devices. Instead the clinical studies, except for the Kremer studies[5], were best-case studies of particular lasers with particular microkeratomes. Then these best-case results were erroneously assumed to be representative of the clinical use of the laser with any microkeratome. Moreover, the agency decided to regulate microkeratomes as Class II devices even though microkeratomes are clearly an accessory to a Class III device, the LASIK laser. The agency did not count patient reports of visual problems as primary safety measures, problems such as pain, glare, halo, and night driving problems, even

though reports showed consistent complaints across LASIK devices. The agency also did not to require labeling of LASIK devices that balanced risks and benefits so that consumers would be adequately informed about the risks of LASIK. The Center did not withdraw a PMA supplement even though the laser manufacturer reported many LASIK-induced injuries one month after FDA approval of the supplement[6]. Furthermore, the agency did not, still does not, use existing authority to reduce the number of LASIK injuries. For example, it continues to emphasize the benefits and de-emphasize the known risks of LASIK on its website[7] (Figure 3), does not enforce requirements that manufacturers and user facilities report adverse events, require manufacturers to revise labeling to provide consumers with more explicit information about risks of LASIK devices, require manufacturers to contract with their customers to provide the manufacturers with all adverse event data, issue public health advisories about the risks of visual problems beyond one year after LASIK surgery, or propose specific quality system requirements for LASIK manufacturers (lasers and microkeratomes).

Figure 1 – Vision Problems After LASIK

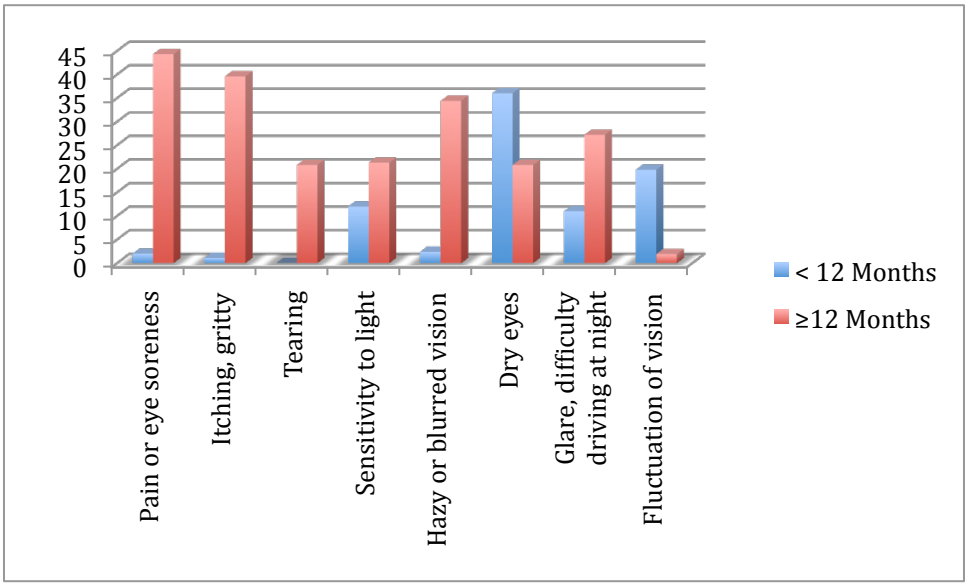
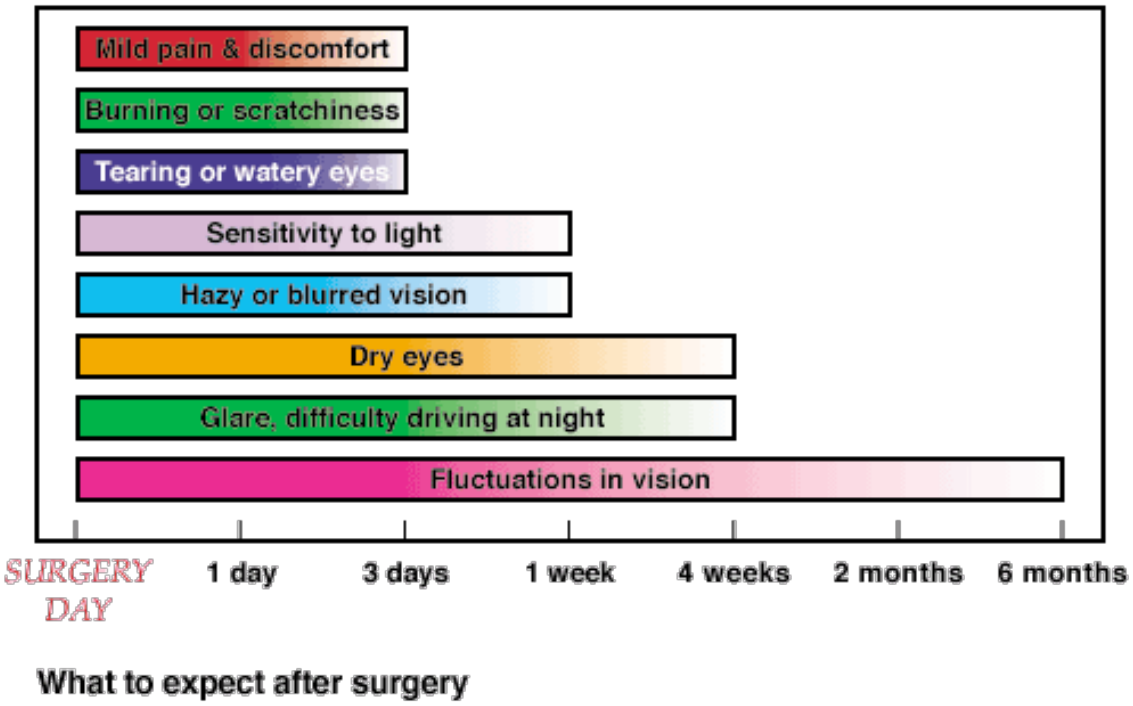


Figure 2 – FDA Depiction of Vision Problems After LASIK



[1] Melissa D. Bailey, OD, MS,1 G. Lynn Mitchell, MAS,1 Deepinder K. Dhaliwal, MD,2 Brian S. Boxer Wachler, MD,3,4 Karla Zadnik. Patient Satisfaction and Visual Symptoms after Laser in Situ Keratomileusis Ophthalmology, Volume 110, Number 7, July 2003 pp1371-1378.

[2] Schein OD. THE MEASUREMENT OF PATIENT-REPORTED OUTCOMES OF REFRACTIVE SURGERY: THE REFRACTIVESTATUS AND VISION PROFILE Tr Am Ophth Soc 2000;98:439-469

[3] Review Body for Interventional Procedures (ReBIP), Health Services Research Unit, University of Aberdeen. Alison Murray, Lisa Jones, Anne Milne, Cynthia Fraser, Tania Lourenço, Jennifer Burr. A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error. April 2005.

[4] Manufacturer and User Facility Device Experience Database (MAUDE) - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm

[5] P970005 – Kremer Laser System

[6] Morris Waxler, "LADAR6000 Injuries: Preliminary Report – Confidential – Privileged." June 24, 2009.

[7] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061270.htm

Please call me for clarification or for additional information. You will succeed.

Best regards,

Morris Waxler

Morris Waxler, Ph.D.
President