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May 7, 2010

Doyle Stulting, M.D., Ph.D.
Professor of Ophthalmology
President
American Society of Cataract and Refractive Surgeons

Dear Dr. Stulting:

You probably remember me. However, my resume is attached. I am Morris Waxler, Ph.D., a former Food and Drug Administration (FDA) official in charge of evaluating PRK and LASIK between 1996-2000.

The ASCRS Phase II keratectasia trial is unethical as described at http://www.ectasiaregistry.com/. Doctors in this study will operate on patients at high risk of post-surgical corneal failure, induce corneal thinning and bulging (keratectasia), and at the same time increase the likelihood of other permanent LASIK complications. Keractectasia is mostly caused by laser vision correction.

> "Keratectasia is a rare but serious complication of laser vision correction of any refractive errors. It occurs mostly after LASIK but was also described after surface excimer laser ablation (photorefractive keratectomy).14–16 It involves severe refractive changes mostly occurring several years after the surgery, which are caused by thinning and sagging of the corneal profile, similar to keratoconus."[1]

The ASCRS Phase II keratectasia trial proposes doctor-induced (iatrogenic) injury in vulnerable patients in order to study iatrogenic insult, instead of mitigating thinning and bulging of the cornea by not performing LASIK and by determining how to stabilize corneas already damaged by LASIK.

Keratectasia will occur in over 3,000 patients in 2010 (rate of 0.87[1] of about 700,000 LASIK surgeries expected to be performed). The benefit is ~60% chance of temporary

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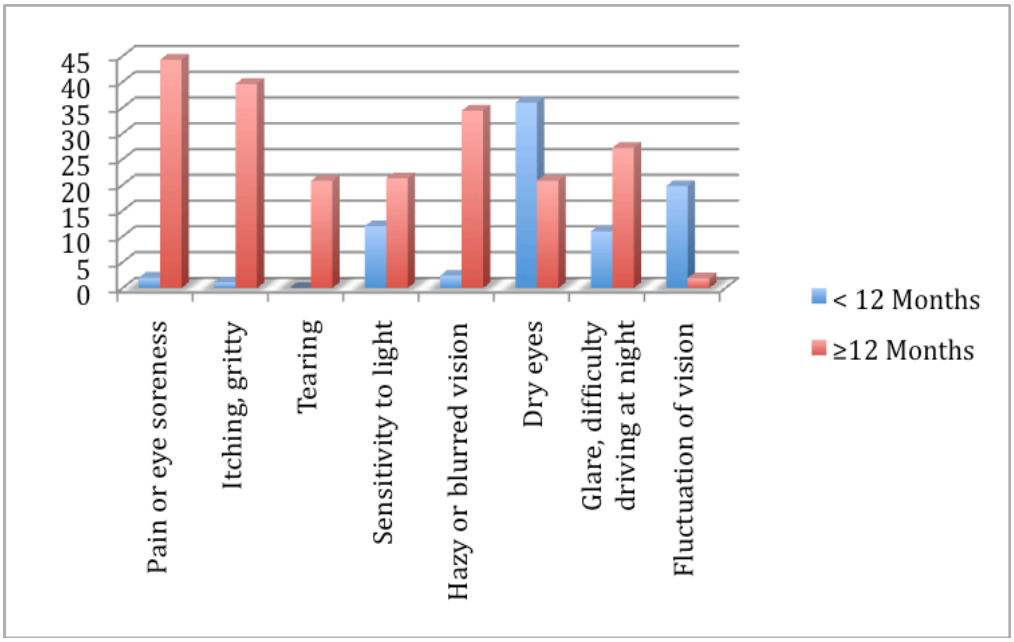
[1] Ezra Maguen, Yaron S. Rabinowitz, Lee Regev, Mehrnoosh Saghizadeh, , Takako Sasaki, and Alexander V. Ljubimov. Alterations of Extracellular Matrix Components and Proteinases in Human Corneal Buttons With INTACS for Post–Laser In Situ Keratomileusis Keratectasia and Keratoconus. Cornea. 2008 June; 27(5): 565–573.

reduction in dependence on glasses or contact lenses[2]. The ASCRS proposed Phase II study is a 'significant risk' study requiring an FDA-approved investigational device exemption and I will do everything I can to block approval of such a study.

In addition there is a high probability of many other permanent vision and ocular health problems. LASIK eye surgery complications are already a major public health problem. Hundreds of thousands of eyes are permanently injured each year for a 60% chance of a couple of years free from glasses and contact lenses, and a 40% chance of little or no freedom from spectacles or contact lenses at all. Fifteen to thirty percent of LASIK patients suffer from eye pain, glare, halos, dry eyes, night vision and other problems, even if their visual acuity is normal.[3] At least 1% of LASIK patients have keratectasia.[4] LASIK complications are more than 20 fold in excess of the 1% ceiling set for complications for these procedures by the FDA. Between 700,000 to 1,000,000 eyes will undergo LASIK surgery in 2010. Your sons, daughters, parents, and friends may be future victims, your grandchildren.

The FDA is complicit with LASIK manufacturers, ASCRS, and others in minimizing multiple permanent vision complications. The following figure summarizes some of the problems that the agency and refractive surgeons claim are minimal after 6 months. [4]



[2] P970053 Patient Information Booklet (p9 3rd bullet under #8) – This is a typical value for refractive lasers and better than some.

[3] Murray A, Jones L, Milne A, Fraser C, Lourenco T, and Burr, J. "A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error." Review Body for Interventional Procedures, April 2005.

[4] Pallikaris IG, Kymionis GD, Astyrakakis NI. Corneal ectasia induced by laser in situ keratomileusis. J Cataract Refract Surg 2001;27(11):1796-802.

Some of your colleagues already are aware of these facts because they treat LASIK-injured patients. Please join me in my effort to eliminate unnecessary LASIK. Join my voice for:

- Transparency regarding short-term "wow" effects versus reality of permanent eye injury

- Clear and complete informed consent documents comparing percentage risks and benefits of LASIK versus glasses or contact lenses

This summer I will publish an open letter to FDA Commissioner Hamburg in major newspapers in the United States urging specific actions by the agency to stem the tide of unnecessary LASIK eye injuries. Please contribute to this effort:

- Read the attached scientific literature, comment and pass it on to others
- Communicate this message to friends, loved ones, and colleagues
- Help develop a Proposed Public Health Advisory on LASIK (attached)

I speak with many LASIK-injured patients suffering silently with permanent vision problems. The rosy picture portrayed by LASIK providers and FDA quells many LASIK-injured patients' complaints. LASIK patients in their "wow" post-op phase cower LASIK-injured patients. Please make a heartfelt choice for visual health.

Regards,

Morris Waxler

Morris Waxler
President

Attachments:

1. Resume
2. Proposed Public Health Advisory

CC:
President Barack Obama
Kathleen Sibelius, Secretary, Health and Human Services
Erik K. Shinseki, Secretary, Department of Veteran Affairs
Robert Gates, Secretary, Department of Defense
Thomas Frieden, MD, M.P.H., Director, CDC
Jerry A. Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP)
Paul A. Sieving, M.D., Ph.D., Director, National Eye Institute
Margaret A. Hamburg, M.D., Commissioner, Food and Drug Administration
Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health
Christy Foreman (Acting), Director, Office of Device Evaluation
Malvina Eydelman, Director, Division of Neurologic, Ophthalmic, and ENT Devices