Is LASIK Safe?

R. Doyle Stulting, MD, PhD Responds to Claims Made by Morris Waxler, PhD

Background

Morris Waxler, PhD, a former member of the FDA panel that helped promote LASIK in 1995, recently criticized LASIK in a ABC Television New Story (Hindsight 20/20: LASIK Surgery Now Unsafe?). Previously, he was featured in an article entitled "While Listening to Industry, CDRH Flexes Muscle," by Jim Dickinson, published in the July 2010 on-line edition of MDDI and had also sent a letter critical of LASIK to Dr. R. Doyle Stulting, MD, Phd, the current President of the American Society of Cataract and Refractive Surgeons (ASCRS).

Dr. Stulting responded to Dr. Waxler's allegations in a letter dated September 2010.

About Dr. R. Doyle Stulting

Dr. Stulting was the Chair of the Ophthalmic Advisor Panel for three years during Dr. Waxler's tenure on the FDA to approve LASIK He participated in the first physician-sponsored clinical investigation of LASIK prior to the refractive laser's FDA approval in the United States. Over his 30 year professional career, Dr. Stulton has authored of over 200 publications and countless other articles based on his extensive clinical research concerning LASIK, corneal transplants, and cataract surgery as well as other areas in ophthalmology.

Dr. Stulting's Response

Below are relevant excerpts* copied from Dr. Stulting's letter concerning the safety and satisfaction of LASIK in response to Dr. Waxler's allegations:

> "During my 10 years of service as a member of the FDA's Ophthalmic Devices Committee and three years as its Chairman, I came to know and respect you for your professionalism, knowledge, and dedication during your tenure with the FDA. However, your current view of LASIK is misinformed, unsupported by evidence, and lacking in balance and perspective.
>
> In your letter to me, you wrote that the U.S. Food and Drug Administration (FDA), is "complicit" with LASIK manufacturers [manufacturers of ophthalmic excimer lasers], and the American Society of Cataract and Refractive Surgery (ASCRS) in trivializing complications. Nothing could be further from the truth.
>
> LASIK was first approved by the FDA on your watch, following all the required FDA protocols and guidance documents created to measure safety and effectiveness. In fact, laser vision correction is one of the most studied elective surgical procedures, with 7,830 patients representing 16,502 eyes in US FDA clinical trials from 1993 to 2005–not to mention more recent submissions to the FDA and thousands of other patients reported in the published literature. The FDA review process is more stringent than that of any other country in the world.
> Concerning LASIK, Dr. Waxler, you further wrote, "The benefit is ~60% chance of temporary reduction in dependence on glasses or contact lenses" To support this claim, you cite "P970053 Patient Information Booklet (p9 3rd bullet under #8)" and state, "This is a typical value for refractive lasers and better than some."

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First, it should be noted that the document you reference describes the results of treatment with a laser designed more than 20 years ago, tested more than 15 years ago, and approved by the FDA 12 years ago—a laser that is not commonly used in the United States today and one that does not incorporate numerous technological advances that have occurred in the last two decades. Second, the document you cite pertains to PRK, rather than LASIK. Finally, the actual statement you reference states, "PRK may reduce or eliminate dependency upon contact lenses or glasses (60.6% could see 20/20 or better without glasses or contacts at 6 months)." Clearly, the document that you reference bears no resemblance to what you wrote in your letter.

Dr. Waxler, you also state, "This is a typical value for refractive lasers and better than some." That statement is simply false. For example, 93.4 percent of patients achieved 20/20 or better vision at 6 months post-operatively with the WaveLight ALLEGRETTO WAVE™ Excimer Laser System (see FDA- P020050/S004, page 34, Table 7, Study Cohort, Summary of Key Efficacy Variables Over Time), which was approved in 2003 (Appendix 4).

Your letter to me also contains a graph, which you claim was taken from an article published by Pallikaris in 2001, showing what he says are visual complaints expressed by patients who have undergone LASIK. There are two major problems with this claim. First, the article you reference does not contain the chart you included in your letter to me. Second, it is important to show that the incidence of visual complaints after LASIK is higher than it was before LASIK, in order to conclude that LASIK caused them. Omitting the preoperative symptoms and claiming that LASIK is the cause of postoperative symptoms is misleading because many people notice visual symptoms with their glasses and contact lenses.

[T]he Summary of Safety and Effectiveness published by the FDA for the WaveLight Allegretto Wave Excimer Laser System, which was approved on October 7, 2003, states, "Patient reports of glare from bright lights, light sensitivity, night driving glare and visual fluctuations all improved after LASIK. The percent of subjects reporting "none" or "mild" of these symptoms improved after treatment" (Appendix 4). If these and other objective data from FDA-supervised clinical trials of modern excimer lasers had been reviewed by you, Dr. Waxler, you should have concluded that modern LASIK does not increase the incidence of visual symptoms.

In summary, your letter is filled with false statements, incorrect citations of the published literature, references that do not fairly represent the existing literature, mischaracterization of a study protocol you have never seen, incorrect reference to outcomes of PRK as if they were for LASIK, citation of results for a laser designed two decades ago as if were representative of modern lasers, mischaracterization of results from older lasers as "better than most," reference of a graph that does not exist in the reference you cite, and misrepresentations of the actual performance of modern excimer lasers for the correction of refractive errors.

A recent review of the world's literature on LASIK led to the conclusion that it is safe and effective, with outstanding results in the vast majority of patients.(1) Complex, visually demanding activities like night firing range performance and military helicopter piloting is as good or better without glasses in soldiers who have had refractive surgery as it is with glasses before surgery. (3,4) In fact, laser refractive surgery is now commonly performed on our military personnel, including aviators and members of Special Forces units, whose lives, performance, and operation of multi-million dollar equipment depends on their ability to identify accurately and

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target the enemy in unfriendly environmental conditions. Based on this positive real-life military experience over the past decade, NASA approved LASIK for astronauts.

LASIK has been shown to be a safe and effective procedure for the correction of refractive errors by numerous studies around the world.(1,2) It has a low complication rate that is acceptable to many patients and comparable to that of contact lenses over a lifetime. It serves to reduce or eliminate dependency on glasses and contact lenses for millions of patients around the world and has been found by the US government to be acceptable for use by military personnel and astronauts. Advances in technology and techniques based on scientifically based studies have allowed the profession continually to improve the safety of LASIK. This is clearly a procedure that should be made available to patients who are properly informed about its risks and benefits.

Complications of LASIK still exist, and even their low rate is a concern to surgeons and ASCRS. The literature clearly shows that efforts of excimer laser manufacturers, physicians, ASCRS, and the FDA have improved LASIK outcomes over the years. We continue to work to produce better results for our patients and will not be satisfied until the complication rate for this procedure is effectively zero."

Sincerely,

/s/ R. Doyle Stulting
R. Doyle Stulting, MD, PhD
President
American Society of Cataract and Refractive Surgery

*****Those portions of this letter that contained Dr. Stulting's responses to Dr. Waxler's allegations concerning keratectasia (a specific condition of the cornea) have been omitted.

References:

(1) Solomon KD, Fernnandez de Castro LE, Sandoval HP,et al. LASIK world literature review: quality of life and patient satisfaction. Ophthalmology. 2009: 116: 691-701.

(2) Schallhorn SC, Farjo AA, Huang D, Boxer Wachler BS, Trattler WB, Tanzer DJ, Majmudar PA, Sugar A. Wavefront-guided LASIK for the correction of primary myopia and astigmatism: a report by the American Academy of Ophthalmolgy (Ophthalmic Technology Assestment). Ophthalmolgoy 2008; 115: 1249-1261.

(3) Bower KS, Burka JM, Subramanian PS, Stutzman RD, Mines MJ, Rabin JC. Night firing range performance following photorefractive keratectomy and laser in situ keratomileusis. Mil Med 2006; 171:468–471.

(4) Van de pol C., Greg JC,Estrada A, Bissetet GM, Bower KS: Visual flight performance recovery after PRK or LASIK in helicoptor pilots Aviat Space Environ Med; 2007: 78 542-553.