

Is the Assault on LASIK Justified?

A former FDA Official refers to the procedure as “an epidemic.”

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Morris Waxler, PhD, was the head of the US Food and Drug Administration (FDA) branch responsible for reviewing data on LASIK between 1996 and 2000. LASIK was approved for use with multiple devices during his time in that position. Recently, Dr. Waxler told the media that the FDA's approval of the procedure was a mistake. He stated that he plans to file a citizen's petition urging the agency to take steps to stop what he calls “the epidemic of permanent vision problems” caused by LASIK.¹ His petition will reportedly implore the FDA to issue a public health advisory about the dangers associated with LASIK and to implement stricter controls over LASIK device manufacturers and practitioners. CRST Europe invited two US and three European surgeons to share their opinions of Dr. Waxler's statements and actions. For more information, read the original newsnote in the October 2010 issue of CRST Europe.

ARTHUR B. CUMMINGS, MB CHB, FCS(SA), MMED(OPHTH), FRCS(ED)

LASIK is probably the most successful procedure that an ophthalmologist can offer patients—it surpasses even the safety of cataract surgery. Although no procedure is without risk, Dr. Waxler errs on a number of fronts. First, he compares LASIK with doing nothing, which is hardly appropriate because the patient must do something in order to see better. If he were to compare LASIK to contact lenses, LASIK would come out on top in terms of sight-threatening complications. Would Dr. Waxler also want to ban the use of contact lenses? Second, LASIK techniques and technology have continued to evolve; LASIK is different now compared with the period in which he reviewed data. Would safety standards for automobiles in 1996 be acceptable today? Perhaps not. Third, new technology such as excimer lasers, microkeratomes, femtosecond lasers, ablation profiles, and standards of care for preoperative evaluation have provided LASIK practitioners with the ability to improve patients' vision to levels that were not attainable preoperatively with spectacles. The safety profile has never been better. Finally, most of the serious complications with LASIK are not a result of the procedure being flawed or unsafe. Rather, they are a result of the commodification of LASIK and the trivialization of the procedure with inappropriately trained examiners making clinical decisions about patients' suitability for LASIK. When LASIK is performed by experienced surgeons and on appropriate patients, it is probably the safest procedure in ophthalmology. Therefore, I do agree with Dr. Waxler that there is a need for stricter control and regula-

tion of the laser refractive industry. However, it would be greatly unjust for one person's misdirected efforts to harm the public perception of what can only be described as the most miraculous surgery to come of age in the recent past.

JOSE L. GÜELL, MD

LASIK is possibly the most common elective surgical procedure worldwide and, for the same reason, the most extensively studied. The procedure has successfully obtained more than 25 approvals by the FDA and a similar number of examinations in Europe or Japan. In 2010, the European Society of Cataract and Refractive Surgeons (ESCRS) celebrated the 20th anniversary of LASIK. In addition to various activities commemorating this anniversary, refractive surgery professionals from the ESCRS launched an awareness campaign to inform the general European population about the safety of LASIK when patient selection and treatment are executed properly.

I do not think that Dr. Waxler's statement makes sense from any point of view, especially considering the rate of complications and biomechanical problems associated with contact lenses—the most common nonsurgical vision correction option worldwide—compared with LASIK. The positive thing that we all share with him is our interest in doing the best for our patients by constantly improving our surgical and medical care.

ROBERT K. MALONEY, MD

LASIK was approved by the FDA under Dr. Waxler only after the procedure fulfilled all of the agency's safety protocols and guidance documents. Now, Dr. Waxler is discussing

the safety of LASIK based on his recollection of data that he reviewed 10 to 15 years ago. These data do not reflect the improvements that have developed as a result of 15 years of technological advances. Since Dr. Waxler left the FDA, his successors have authorized an additional 28 LASIK approvals and clearances upon thorough review of studies involving thousands of eyes. It is fair to say that few procedures in medicine have received as careful scrutiny or as many approvals by the FDA as LASIK. Additionally, Dr. Waxler has confused the discussion by combining severe, safety-related problems and subjective complaints such as dry eye under the general heading *injuries*. This use of subjective complaints to inflate the number of overall complaints results in a disservice not only to the millions of patients whose lives were changed for the better by LASIK but also to the relatively few patients with problems who deserve to have their conditions clearly understood and effectively treated.

JAY S. PEPOSE, MD, PhD

LASIK is the most commonly performed elective surgery in medicine and arguably the most studied. A recent meta-analysis of the world literature by Solomon et al² showed that LASIK is associated with a higher level of patient satisfaction when compared with other elective procedures. This review included studies dating as far back as 1988. There may be even higher levels of satisfaction now, as iterative, substantive advances have further improved patient safety and the predictability of outcomes with LASIK. These include customized laser vision correction, pupil tracking and adjustment for pupil centroid shift, personalized nomograms, and more precise microkeratomes and femtosecond lasers. There are few fields that advance at the pace of laser refractive surgery, although it is sad to see that many newer innovations and clinical trials are now located outside the United States due to the type of draconian thinking expressed by Dr. Waxler.

When I was a resident at Johns Hopkins University years ago, A. Edward Maumenee, MD, counseled me with tongue in cheek that his one surefire method to guarantee no complications and no dissatisfied patients was never to operate. Dr. Waxler, it seems, would like to actually implement this plan and impose a moratorium on the most frequently performed elective procedure associated with the highest level of patient satisfaction. Those of us who are involved in advancing ophthalmology through clinical trials know that there is some level of complaint from patients associated with every lens implant, with every drug and placebo, and even with unoperated control eyes. All of us await and applaud further improvements to an already refined procedure, but if Dr. Waxler's criteria for the approval of surgical devices were widely applied, cataract surgery would no longer be performed today, no

one would benefit from an IOL, and Sir Harold Ridley would likely be posthumously stripped of his knighthood.

KJELL U. SANDVIG, MD, PhD

It may be that LASIK should have been introduced more slowly and less widespread until more long-term results had been obtained. But the LASIK of today is a very different method. I stopped doing LASIK 5 years ago because I was more satisfied with the safety and the results of anterior surface ablation. However, both methods have high levels of safety and efficacy and are still improving. In my practice, refractive patients are in general equally or even more satisfied than cataract patients. Regarding LASIK complications, there are few compared with the amount of contact lens complications that I see almost every day. All treatments of refractive errors have pros and cons. To ban LASIK, or excimer laser surgery in general, would be a mistake and unfair to the huge majority of patients who can benefit from these surgeries. ■

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1. Carollo K. Could LASIK lead to permanent vision problems? *ABC News*. September 22, 2010. <http://abcnews.go.com/Health/EyeHealth/lasik-advocate-files-petition-criticizing-procedure/story?id=11689793>. Accessed October 8, 2010.
2. Solomon KD, Fernández de Castro LE, Sandoval HP, et al. LASIK world literature review: quality of life and patient satisfaction. *Ophthalmology*. 2009;116(4):691-701.