

LAW OFFICE OF TODD J. KROUNER  
93 NORTH GREELEY AVENUE - SUITE 100  
CHAPPAQUA, NEW YORK 10514  
(914) 238-5800

TODD J. KROUNER\*

DOMINIQUE N. FERRERA  
STACEY M. RANCOURT

\*ADMITTED IN NY AND NJ

OF COUNSEL

EVELYN OCHMAN ROSEN

April 15, 2008

**VIA E-MAIL & FIRST CLASS MAIL**

Ms. Karen F. Warburton  
Executive Secretary to the  
Ophthalmic Device Panel  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: April 25, 2008 Hearing on Post-LASIK Results

Dear Ms. Warburton:

I represent LASIK patients in malpractice cases on a national basis. I am writing about recent media reports concerning the association between LASIK surgery and patient suicide. It is my opinion, based on extensive dealings with leaders in the LASIK field, that any study of this issue should not be entrusted to them, but rather to an independent panel whose members have no financial interest in the outcome.

Recently, I was retained by Amanda Campbell concerning the wrongful death of her late husband, Lawrence Campbell. Mr. Campbell committed suicide last month, on March 16, 2008. He left a suicide note that made explicit reference to his failed LASIK surgery as the reason for his having taken his life. At the time, Mr. Campbell had been employed as a police officer for 25 years in Brentwood, Tennessee, which is a suburb of Nashville. He is survived by his wife

and two children. According to his widow, Mr. Campbell had no history of mental illness or depression prior to his LASIK surgery.

Any doubt concerning the association between Mr. Campbell's suicide and his LASIK surgery was explicitly resolved by his suicide note. First, he wrote:

"No one knows what I am feeling."

Constant pain, blurred vision, stress that I never had before. If only DR. [ROBERT P.] SELKIN had done a pre-op and knew I was not a candidate for Lasik surgery.

No one understands truly my burden I carry. Dry eyes; cannot light a fire, cannot stand in front of air conditioning. Cannot cook without opening a window. Cannot spray deodorant. The list goes on and on... I just cannot burden my family for a poor decision (eye surgery), which Selkin knew was wrong, but only wanted money! AND I will not live on drugs (Zanax). I never used that drug wrong. A half a milligram at night and sparingly in the afternoon on a bad day. I am not a drug user! Never could I do this as it has ruined so many lives.

DO NOT HAVE LASIK SURGERY  
Tell the media!!!

(Emphasis in original).

Second, Mr. Campbell explicitly wrote in his note that the blame for his suicide was his LASIK surgeon: "To blame for this: Selkin Eye Surgery ... eye surgery has taken my life out of me. The pain - distorted vision chronic dry eye...is not bearable!!!" (Emphasis in original).

Clearly, LASIK surgery has the capacity to drive patients to suicide. To deny this in the face of Mr. Campbell's explicit suicide note defies reason.

In a March 25, 2008 article reported on the OSN SUPERSITE, Dr. Richard Lindstrom, who is President of ASCRS and OSN Chief Medical Editor, is quoted as asserting that there is no correlation between adverse LASIK outcomes and suicide. Presumably, Dr. Lindstrom did not have the benefit of having read Mr. Campbell's suicide note. Still, his visceral denial is not well reasoned.

First, no one should take comfort in the industry's patient satisfaction studies. Its surgeons notoriously under-report complications and unexpected results, even when they are required to do so by the FDA. Dr. Mark Speaker performed LASIK surgery on my client with a VISX laser that was in a trial phase. My client developed keratectasia as a result of the surgery. Dr. Speaker was aware of the unexpected outcome. Dr. Speaker had a duty to report this to FDA. Dr. Speaker never did. When someone of Dr. Speaker's stature fails to report, why should the FDA, consumers, patients and the public at large trust the LASIK industry's satisfaction numbers when the complication numbers are clearly under-reported?

Second, ask someone other than a LASIK surgeon if one's visual disability could lead to depression. The answer is obviously that it could. A study from the University of Miami involving cataract and glaucoma patients confirms this self-evident truth. See Ingrid U. Scott, M.D. et al., [Quality of Life in Low Vision Patients and the Impact of Low Vision Services](#), 128 American Journal of Ophthalmology 1 (1999). Anecdotally, virtually all of my clients who have post-LASIK complications suffer from clinical depression. Another article confirms this point:

The large differences in the scales that measure visual function (that is, Distance and Near Activities) and in the Mental Health and Role Difficulties are very informative. These indicate that keratoconus patients perceive a loss of function disproportionate to that reflected by clinical measures such as visual acuity. Most importantly, this loss of function may lead to a perceived impairment in the ability to perform social duties reflected in the mental health and role difficulty scores. The difference in self-generated general health between these groups of similar age and presumably similar in terms of other medical conditions, may reflect a perception of disability that extends beyond visual impairment...

Thus, clinicians who manage patients with keratoconus may be led erroneously into therapeutic complacency by good visual acuity achieved by contact lenses...

To function in our technological society, vision is arguably the most important of the five senses.

Steven M. Kymes, Ph.D., et al., Quality of Life in Keratoconus, 138 American Journal of Ophthalmology 4 (2004);

I read Abby Ellin's recent biographical story in the New York Times about her own LASIK eye surgery misfortune with keen interest. See Abby Ellin, LASIK Surgery: When the Fine Print Applies to You, N.Y. Times, March 13, 2008, at G3. It was a sad but refreshing counterbalance to the LASIK industry's infomercials that pass as news in other publications. Ms. Ellin confesses, "I'm not mad at my doctor. I'm mad at myself." She thinks she succumbed to her vanity. It is a classic victim's guilt. If she only knew.

LASIK is a huge business. The application of the surgical laser to the cornea actually takes less than 60 seconds. A corneal or refractive surgeon can schedule ten patients in 15-minute blocks, and at \$5,000 per patient, generate \$50,000 of revenue in just 2.5 hours.

The surgery is not complex. Most errors occur in the screening with the doctors who are too busy running the conveyor belt to notice warning signs of unsuitable LASIK candidates.

Post-LASIK ectasia is an avoidable, surgically-induced thinning of the cornea, which causes severe problems with visual quality: blurring, double vision, halos, glare, star-bursting, ghosting, photosensitivity and impaired night vision. Its onset can be almost immediate. I had a client's vision deteriorate to legally blind, 20/200, in about two weeks. Other cases are time bombs with a long fuse, which can take as long as five years to explode (well after New York's 2.5 year statute of limitation for medical malpractice will likely have expired).

However, most often, when it happens, it is due to the surgeon's malpractice. The incidence of post-LASIK ectasia is reported at less than 1%. However, when it occurs, the overwhelming majority of the time, retrospective studies demonstrate it is a result of the LASIK

surgeon's error. See, J. Bradley Randleman, M.D., et al., Risk Factors and Prognosis for Corneal Ectasia After Laser In Situ Keratomileusis, 110 *Ophthalmology* 267, 269 (2003).

The industry makes it difficult to prove these cases of presumptive malpractice by intimidating colleagues from testifying against one another, and by retaliating against those who do. Titans in the LASIK industry wear their willingness to commit perjury on behalf of their colleagues like a badge of honor. At the same time, I've yet to have a case where a doctor who had an obligation to report a bad result, or unexpected outcome, ever did. One doctor in the metropolitan New York region has reportedly spent over \$1 million in advertising his LASIK services, been sued, and paid upwards of 20 patients for his alleged malpractice. Yet, he continues to practice with seeming impunity from his colleagues and licensing authorities.

Then there is the equipment. If it is not properly calibrated by the laser facility pre-operatively, bad things will happen. If the doctor uses it in a way in which the FDA and manufacturer did not intend it, bad things will happen.<sup>1</sup> If it is not well-manufactured, like the Alcon LADARVISION 6000, and enough bad things happen, it may be recalled by the FDA.<sup>2</sup>

Finally, Ms. Ellin describes the false success of good visual acuity. It is only half of one's vision. Visual quality comprises the other half. For an impeccably-credentialed LASIK surgeon to say the surgery was successful because the patient has good visual acuity is dishonest.

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<sup>1</sup>I have one case, where a LASIK surgeon used a NIDEK laser to treat hyperopia, or farsightedness. However, the laser was neither approved by the FDA, nor in clinical trials for this indication, at the time of treatment. To the best of my knowledge, to date, no laser has been approved in the United States to treat this particular patient's degree of hyperopia.

<sup>2</sup> On July 24, 2007, my office sent a FOIA request to the FDA regarding the Alcon LADARVISION 6000. Nine months later, with the statute of limitations approaching, there has still been no response from the FDA. The FDA should address its own internal procedures that constitute an impediment to the public's right to obtain information, and injured patients' rights to investigate and pursue their claims.

I hear it often: 1) of the homemaker who took her cat's medication, while the cat took her thyroid medication for three days due to blurred vision; 2) of the surgical assistant who cut the patient instead of the surgical thread due to poor contrast sensitivity and impaired depth perception; and 3) of the executive whose son asks, "Daddy, why don't you play with me anymore?", due to photosensitivity and irritation from wind, dust, and sand.

Most of my LASIK clients are clinically depressed. Few had prior mental health issues. One world-class photographer says, "I spent \$5,000 to acquire a visual disability." Another client says his visual disability, notwithstanding his fine visual acuity, is worse than cancer. He explains, "During the Super Bowl, a cancer patient can at least watch the game and forget about his troubles for two hours. I'm reminded of mine every waking minute."

After LASIK, reportedly about 1 million people wake up per year and can read their clock without glasses. If, according to the LASIK industry's rosy satisfaction numbers, just one percent of those patients have bad outcomes, that means 10,000 people wake up and cannot read their clocks. But that's just the beginning of their daily misery, as a result of an entirely elective procedure which their LASIK surgeons sold them.

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Given the self-interest of the LASIK industry and its surgeons, it is respectfully submitted that any review of LASIK safety, satisfaction, or study of correlation between bad LASIK outcomes and suicide, should not be delegated exclusively to those who have a vested interest in the conclusion.

There are well-credentialed corneal surgeons who explicitly disavow FDA guidelines and manufacturer protocols. In one case of mine, a defense expert testified that a LASIK surgeon has no responsibility for checking the calibration of the excimer surgical laser. Coincidentally,

this expert is working on the FDA clinical trials involving riboflavin treatment for keratoconus.

Others have published articles that purport to define the standard of care, when in fact, their publications are not driven by the sound and prudent practice of medicine, but rather by the clinicians' "considerable anxiety" concerning litigation avoidance. See, e.g., Yaron S. Rabinowitz, M.D., *Ectasia after laser in situ keratomileusis*, 17 Curr. Opin. Ophthalmol., 421, 421 (2006).

Clearly, it is treacherous, and imperils the public health and welfare, to rely on an industry whose leaders behave in such fashion. The LASIK industry has demonstrated it lacks the ability to police itself. Independent studies are required concerning LASIK safety, patient satisfaction, and the grave association with patient suicide.

I look forward to the privilege of addressing the Panel on April 25, 2008.

Respectfully submitted,

A handwritten signature in black ink that reads "Todd J. Krouner". The signature is written in a cursive, flowing style.

Todd J. Krouner