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Expert Analysis

LASIK Eye Surgery: Litigation Challenges and Issues

LASIK eye surgery is one of the most common forms of surgery in the United States. The overwhelming majority of patients are satisfied. However, for those who suffer complications, the resulting visual disability can be life altering. This article examines the common bases of liability in LASIK litigation.

Plaintiff verdicts from around the country confirm that the pain and suffering associated with poor quality vision, such as blurring, halos, double vision and impaired night vision have substantial seven-figure value. The hope among plaintiff lawyers is that such verdicts will influence high-volume LASIK surgeons to be less aggressive when dealing with borderline candidates for this elective surgery.

Complications

The surgical complication rate is disputed and underreported. The industry suggests this rate is below 1 percent. However, a recent article asserts that complications following LASIK surgery, such as halos, glares, dry eyes, and impaired night vision is approximately 20 percent.¹ The disparity occurs because LASIK surgeons do not count dry eyes and poor night vision, as well as other light phenomena, as “complications,” but rather as known and accepted risks of LASIK surgery.

One of the most serious complications from LASIK surgery is post-LASIK ectasia. Ectasia is the bulging of the cornea, which can result in the excessive thinning of the cornea, and compromise of its structural integrity. It can occur naturally, and when it does, it is referred to as keratoconus.² The term post-LASIK ectasia is used to refer to ectasia that was laser induced. Ectasia is progressive in nature, and usually will continue to worsen over time. In most cases, the ectasia will manifest within the first year following LASIK surgery. However, a leading

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article by J. Bradley Randleman, M.D., and others, from Emory University (the Randleman Study), teaches that post-LASIK ectasia may not develop until 45 months after the initial LASIK surgery.³ For claims arising in New Jersey, this is not a problem because the statute of limitations runs from discovery of the injury. By contrast, New York has no such discovery rule. Consequently, the delayed onset of symptoms can be fatal to a case, absent continuous treatment with the LASIK surgeon.

Keratoconus, and its early or sub-clinical predecessor, forme fruste keratoconus (FFK), are contraindications to LASIK surgery. The Randleman Study concluded that post-LASIK ectasia is most often caused by the clinician's failure in screening signs of keratoconus or FFK, or by surgical error in cutting the patients'

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cornea too thin, and breaching the structural integrity of the cornea. Recent studies suggest that 95 percent of the time ectasia occurs for known reasons, such as the surgeon missing pre-operative warning signs, or cutting the cornea too. Consequently, ectasia cases should be treated as evidence of presumptive malpractice.

In addition to cases involving contraindications and surgical negligence, some LASIK lawsuits arise with patients whose pupil size is larger than the optical zone of the surgery. In *Post v. University Physicians, Inc.*, 2002 WL 32832041 (Ariz. Super. 2002), the plaintiff, who was a pilot, was awarded a \$3.4 million verdict when the surgeon failed to recognize the plaintiff's large pupil size.

Other LASIK litigation involves lifting and creating the flap; maladministration of post-operative steroid drops giving rise to glaucoma; varying auto-immune disorders, thin corneas, corneal dystrophy, and central islands (discussed below) due to poor laser maintenance or product defect.

Product Defects

With today's laser technology, central islands are another injury, like ectasia, that rarely just happen for no known reason. The term is used to describe elevations in the central treatment zone of the cornea that can occur if the laser does not remove enough tissue in this area. The 'island' consists of a small mound of corneal tissue that can interfere with vision. Initially, central islands were an unfortunate complication of the early technology that resulted from the uneven application of the laser's energy. In recent years, this complication was thought to have been eradicated due to advances in laser technology. Today, if central islands occur, they can be assumed to be either a result of a product defect, or of the poor maintenance and cleaning of the laser itself. In September 2007, Alcon Laboratories recalled its LADAR 6000 surgical laser, because of reports that its laser created central islands.

Even though the Supreme Court has preempted product liability claims for medical devices in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), claims against product manufacturers can succeed under at least three theories. These include failure to manufacture the product in accordance with the specifications submitted to and approved by the Food and Drug Administration (FDA), failure to follow FDA protocols, and violations of parallel state law consumer fraud statutes. In March 2009, the Medical Device Safety Act was introduced to overturn *Riegel*, and reinstate injured patients' rights to recover for faulty medical devices.

In addition to Alcon's defective surgical laser, patients have developed central islands where a well-designed laser was not maintained properly. The laser needs to be tested and calibrated periodically. If this is not done, saline-like fluid has been known to splash on the laser optics and impair the even flow of the laser energy, and has also resulted in central islands. Central

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islands are one example of a corneal injury that, if severe enough, has no present cure or effective treatment.

Effects on Individuals

Vision has two components, acuity (quantity) and quality. Post-LASIK complications can distort the patient's vision, may impair visual acuity and will affect visual quality. Even if the patient can read the letters on the Snellen eye chart, often it is accompanied with double vision, blurring, ghosting, halos and various light phenomena including photosensitivity, difficulty with night vision, and starbursting.⁴

In addition, there are a small, but alarming, number of patients who have committed suicide allegedly due to LASIK complications. Although the industry asserts that suicide is a multi-factorial issue, and that no such association between LASIK and suicide can be demonstrated, there exists a clear correlation between visual impairment and depression.⁵ As other surgeons are required to assess a patient's mental health before surgery, at minimum, it would be prudent for LASIK surgeons to do the same.

Possible Treatments

Treatment is difficult for patients of LASIK malpractice. Glasses do not help. Contact lens therapy is thwarted by dry eyes. Intacs offer another hope in stabilizing vision. Intacs are artificial lenses implanted into the cornea in an attempt to reshape the cornea. In the worse case, a corneal transplant surgery is necessary. Recently, the FDA has approved an experimental protocol to arrest, but not cure, post-LASIK ectasia. It involves riboflavin drops and ultraviolet (UV) light. The hope is that the combination of riboflavin and UV light will, on a microscopic level, increase the levels of collagen in the cornea to strengthen the cornea and prevent further deterioration.

Jury Verdict Data

Juries in New York, and around the country, are recognizing the substantial value associated with loss or impairment of vision. At the same time, it is difficult to explain to a jury how problems with visual quality can ruin a patient's life, when the patient retains a reasonable visual acuity. Pictures of these qualitative complaints, from the patient's eye doctor, or from the patient's environment can be quite helpful.

In July 2005, a Manhattan jury awarded an investment banker \$7.25 million in *Schiffer v. Speaker*, where the author represented the plaintiff. The doctor was found negligent in screening the patient, who had pre-operative FFK. The pain and suffering award alone was \$3 million. The award was affirmed in *Schiffer v. Speaker*, 36 A.D.3d 520 (1st Dept 2007). Last month, in a case where the author represented the plaintiff, a Manhattan jury returned a verdict of approximately \$5.6 million in another ectasia case. The pain and suffering component in that case was also \$3 million. *Devadas v. Niksarli*, Index No. 107637/07 (N.Y. Sup. Ct.) The post-trial

process is at an early stage.

In 2006, a jury in Nassau County returned a pain and suffering award of \$3 million (which was reduced to \$2.1 million post-trial). *Gropack v. Donnenfeld*, Index No. 8476/02 (Sup. Ct. Nassau Co. 2007) (J. Mahon). No meaningful claim for loss of income was reflected in that verdict.

Prior to the *Schiffer* case, a pilot was awarded \$3.4 million for post-LASIK visual complaints. *Post v. University Physicians, Inc.*, 2002 WL 32832041 (Ariz. Super. 2002). Last year, a \$2.1 million settlement was reported in a LASIK malpractice case in New Jersey, against Dr. Joseph Dello Russo. Russell Ben-Ali, "Lasik patient received \$2.1M: Eye surgeon settles suit, does not admit fault," *The Star Ledger*, 07/08/08.

In *Crawford v. City of New York*, 198 A.D.2d 48 (1st Dept. 1993), the plaintiff was awarded \$1 million for pain and suffering for an injury to only one eye. In *Cofsky v. Goosey*, 2002 WL 32119471 (Texas Dist. 2002), the plaintiff received a settlement of \$1.75 million. In *Johnson v. LCA Vision, Inc.*, 285 A.D.2d 971 (1st Dept. 2001), the New York Appellate Division held that a \$1 million award for future pain and suffering for post-LASIK visual impairment in only one eye was reasonable.

Multimillion-dollar verdicts have made LASIK surgeons less aggressive in operating on patients whose screening is suspicious for FFK. In 2005, in response to the *Schiffer v. Speaker* verdict,

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several ophthalmologists wrote and published an article in an attempt to reset the standard of care. Binder, P, Lindstrom, R, et al., "Keratoconus and Corneal Ectasia After LASIK," *Journal of Refractive Surgery*, Nov/Dec 2005, p. 749.

Retaliation

Finding a LASIK surgeon who is willing to testify on behalf of an injured patient is almost impossible. Yet, without a reputable LASIK surgeon, the case cannot proceed. One of the most significant impediments to retaining a LASIK expert to testify is retaliation. In *Post*, supra, TLC's founder, Jeffrey Machat, M.D., testified in favor of the patient.⁶ As a result, his refractive surgeon colleagues retaliated against him, cursed him, verbally assaulted him, and he was forced to resign from TLC's advisory board. In other cases, experts have had invitations to present at professional conferences revoked and been threatened with baseless ethics complaints.

Consequently, extraordinary efforts must be made to protect the identity of the few

well-credentialed experts who are willing to testify on behalf of plaintiffs. Protective orders should be considered to insulate experts from retaliation.

FDA Advisory Panel Hearings

In April 2008, the FDA convened hearings in response to patient requests for a review of the safety and effectiveness of LASIK surgery. As there have been increasing complaints of dissatisfaction and suicide in connection with LASIK surgery, the FDA assembled members for the Ophthalmic Device Panel to hear from various constituents. In response, the FDA has commissioned a LASIK Study Task Force to evaluate quality of life after LASIK. To date, there has been no report. Incidentally, all of the ophthalmologists on the Advisory Panel wore glasses.

Contrary to the Supreme Court's view in *Riegel*, supra, the FDA is ineffective. The recalled LADAR 6000 surgical laser was approved without input from its Ophthalmic Device Panel. State licensing agencies are indifferent to complaints of serial wrongdoers. A LASIK surgeon in Chicago has been sued 43 times, and the Illinois Medical Disciplinary Board has seen no merit to patient complaints. Governmental oversight is myopic.

1. Bailey M.D., Zadnik K. "Outcomes of LASIK for myopia with FDA-approved lasers," *Cornea*. 2007 Apr; 26(3):246-54.

2. For the purposes of this article, the terms "keratoconus" and "post-LASIK ectasia" will be referred to by the term "ectasia."

3. Randleman JB, et al. "Risk Factors and Prognosis for Corneal Ectasia after LASIK," *Ophthalmology*. 2003;110:267-275 at 269.

4. See, e.g., Abby Ellin, "LASIK Surgery: When the Fine Print Applies to You," *N.Y. Times*, March 13, 2008.

5. 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).

6. TLC is a national provider of laser facilities. It is a public company whose shares trade on the NASDAQ. Tiger Woods is one of their celebrity spokesmen. TLC was also a co-defendant in the *Schiffer* case.

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