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# MEDICAL MALPRACTICE

# Screening Lasik Cases

## The rapid acceptance of laser eye surgery has led to a proliferation of malpractice claims

**By Abbott S. Brown**

Laser Assisted In Situ Keratomileusis, or lasik surgery, has become one of the most frequently performed operations in the United States. More than three million lasik procedures have been performed in the United States since the procedure was approved by the FDA in 1995, and over one million lasik procedures will be performed this year. The rapid acceptance of lasik surgery has led to a significant increase in medical malpractice claims.

The best estimates are that 3 percent of lasik patients, or more than 30,000 people this year, will experience significant complications from this surgery. An example of the increase in lasik malpractice cases was provided in 2004 when one New Jersey surgeon settled a dozen lasik cases. See, "Med-Mal Insurer Must Pay $15M in Arbitrated Awards," *New Jersey Law Journal*, Feb. 21, 2005 [179 N.J.L.J. 737]. The recoveries ranged from $3.5 million to $50,000, and the average recovery was in excess of one million dollars. Medical malpractice attorneys should be prepared to screen these cases.

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### What Is Lasik Surgery?

The cornea is the clear front part of the eyeball that refracts and focuses light onto the retina. The retina is a layer of sensory tissue that transforms the images into electrical signals, and sends the signals to the brain. When the cornea is "out of focus," the vision of that person will be adversely impacted in predictable ways. Persons with myopia, or nearsightedness, have difficulty seeing objects in the distance. Persons with hyperopia, or farsightedness, have difficulty seeing objects that are close. Persons with astigmatism, or irregularities in the cornea, experience distorted vision.

In most cases, these errors of refraction can be corrected by the use of glasses or contact lenses. Lasik surgery utilizes a laser to ablate, or vaporize, part of the cornea, correcting these common errors of refraction. The portion of the cornea to be ablated is determined by computerized mapping of the cornea. Since the changes in the cornea are permanent, lasik surgery promises a permanent fix for these visual problems.

### Presurgical Screening

Most studies have demonstrated that between 25 percent and 33 percent of all patients are not good candidates for lasik surgery. Many lasik malpractice cases involve allegations of negligent screening of the patient prior to surgery. The standard of care requires that the surgeon perform a complete eye examination before the operation, including, at a minimum, the following tests:

1. Measurement of the pupils. The normal size of a person's pupil is 4 to 6 millimeters. Lasik surgery may cause permanent visual disturbances, described as ghosting, shadowing, starbursts or halos, in persons with larger pupils.

2. Measurement of corneal thickness. Lasik surgery is contraindicated for those with thin corneas. The presurgical cornea generally ranges from 450 to 650 microns in thickness. The FDA recommends that the cornea be at least 410 microns thick after lasik surgery. Lasik surgery should not be performed if the amount of cornea to be ablated will result in a residual thin cornea.

3. Corneal mapping. The surgeon must check for irregularities in the cornea, including ectasia, a steep area of the cornea, or keratoconus, a bulging cornea. Both of these conditions are absolute contraindications for lasik surgery.

4. Slit lamp examination. The sur-

geon must also check for irregularities in the membrane of the cornea which are contraindications for lasik surgery

5. Performance of a tear test for dry eyes. The surgeon must check for dry eyes, which may be exacerbated by lasik surgery. Dry eyes are not only very uncomfortable, but can reduce visual acuity. Pre-existing dry eye syndrome is a contraindication for lasik surgery.

6. Measurement of visual acuity. The surgeon must not only check visual acuity but also measure for astigmatism, which causes visual distortions. Additionally, the surgeon must check for presbyopia, the condition which often requires persons over 40 to use reading glasses. Persons with presbyopia will still need reading glasses after lasik surgery.

7. Assessment of refractive stability. Persons who have experienced a change in prescription in the year prior to surgery may have conditions which make them poor candidates for lasik surgery. It is essential that refractive stability be confirmed before performance of lasik surgery.

8. Screening for pre-existing medical conditions. Patients who have certain medical conditions, such as glaucoma, diabetes, cataracts and other conditions, are not good candidates for lasik surgery.

Additionally, the standard of care requires cessation of soft contact lens use for at least three days to two weeks prior to lasik surgery. Rigid contacts must be discontinued at least four weeks before the surgery. Contact lenses can temporarily alter the shape of the cornea for several weeks after using them. If the cornea has not assumed its natural shape before surgery, the computer programs which operate the laser will use inaccurate measurements to determine how much corneal tissue to remove, most likely resulting in poor vision after surgery.

### Informed Consent

Lasik surgery has been associated with numerous complications, most of which are preventable. Since lasik surgery is by definition elective surgery in virtually all cases, prior to the surgery the surgeon is obligated to explain the risks, possible complications, and potential side effects, including the pros and cons of having one or both eyes done on the same day, as well as the nonsurgical alternatives to lasik surgery. See, e.g., *Largey v. Rothman*, 110 N.J. 204 (1988). See also, *Caputa v. Antiles*, 296 N.J. Super. 123 (App. Div. 1996), where the court held that since the standard for disclosure is imposed by law, a patient is entitled to a directed verdict on liability when a physician admits that the patient was not informed about the material risks of a proposed course of treatment.

Some of the risks and possible complications of lasik surgery include:

1. Over-correction or under-correction. Under-correction may be improved with glasses, contact lenses and additional surgery, but over-correction may not be correctable.

2. Corneal scarring or irregular astigmatism (warping of the cornea), resulting in an inability to wear contact lenses.

3. Infection, which could lead to the loss of the cornea or the eye itself. This complication is rare, but must be diagnosed early and treated aggressively.

4. Decrease or loss of visual contrast, sensitivity or sharpness.

5. Corneal flap disorders, including: irregular flaps, incomplete flaps, free flaps, i.e., separated entirely from the eye, and growth of cells under the flap, resulting in discomfort or pain.

6. Hazy, double or blurry vision; dry eyes, glare; haloes or starbursts around lights, poor night vision and sensitivity to light.

7. Striae, or wrinkles in the corneal flap. Striae must be treated as soon as they are discovered, or they may cause permanently distorted vision. Striae are usually treated by lifting and smoothing the flap.

8. Diffuse Lamellar Keratitis, often called the "Shifting Sands of Sahara." This condition results in inflammation and irritation of the corneal interface, without a bacterial cause. Treatment consists of steroids and lifting and cleaning of the corneal flap.

9. Decentered ablation, resulting in the significant loss of best corrected visual acuity, even with the use of glasses or contacts, and severe visual distortions. A significant decentered ablation is almost always the result of malpractice or an equipment failure, invoking the *Anderson v. Somberg*, doctrine. See *Anderson v. Somberg*, 67 N.J. 291 (1975), cert. denied, 423 U.S. 929 (1975), and *Chin v. St. Barnabas Medical Center*, 160 N.J. 454 (1999). The largest award in the series of cases against the northern New Jersey surgeon mentioned at the beginning of this article was $3.5 million and involved a case of severe bilateral decentered ablation.

Additionally, since lasik is a relatively new medical procedure, the long-term safety and effectiveness of lasik surgery has not been studied and is not currently known.

It should be remembered that unlike many malpractice cases, the lasik patient does not have a pre-exiting condition that could cause harm, which would create the need to allocate damages between the pre-exiting condition and the surgery. In most lasik malpractice cases, the patient could see quite well, albeit with glasses or contacts, before the lasik surgery, but suffered from severely diminished or no vision after the operation. Thus, in most lasik malpractice cases, there is no need to reduce the damages as required by *Scafidi v. Seiler*, 119 N.J. 93 (1990), and its progeny.

### Sources of Lasik Information

The FDA maintains a Web site which describes lasik surgery at: http://www.fda.gov/cdrh/lasik. The FDA also maintains a list of approved lasers, with links to data about the lasers. See: http://www.fda.gov/cdrh/LASIK/lasers.htm. This FDA Web page lists a summary of the "safety and effectiveness" of each laser, and provides labeling information for each laser, including the Physician's Booklet, which in most cases will establish the standard of care for use of that laser. See *Brambley v. McGrath*, 347 N.J. Super. 1 (App. Div. 2002).

For example, the FDA Web page will direct you to http://www.fda.gov/cdrh/PDF/p970043s015c.pdf which is the Alcon's LadarVision 4000 Custom Cornea Patient's Information Book, followed by Alcon's Physician's Information Book, both of which state "LASIK is contraindicated in patients with signs of keratoconus." Id. at 12.

The American Society of Cataract and Refractive Surgery's Web site contains much helpful technical information and is found at www.ascrs.org. See also, for patient oriented Web sites: Surgical Eyes, at http://www.surgicaleyes.org, the LasikInfoCenter at http://www.lasikinfocenter.net; and an Emedicine article at http://www.emedicine.com/oph/topic666.htm.

Lasik malpractice cases, like most medical malpractice cases, are challenging. However, a careful review of the patient's medical records, the medical literature and the manufacturer's physician information booklet or operating manual will allow attorneys to readily identify valid cases of lasik malpractice. ■