

Chapter 44

Liability of Ophthalmologists

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INTRODUCTION

This chapter highlights principally liability issues pertaining to refractive eye surgery. In the three years since the last edition of this chapter, the utterly predictable has happened: technology has improved, rates of complication have fallen, and damage verdicts in litigation have rapidly escalated. A New York jury in 2005 awarded \$7.25 million to a plaintiff who proved liability and record-setting damages arising from inability to continue his high-paid work on Wall Street.¹ The award almost doubled the \$4 million we noted in the last edition as the highest then rendered.²

“Refractive eye surgery” (or just “refractive surgery”) is the general name for a variety of techniques, none more than about 35 years old, for correcting the corneal abnormalities at the root of refraction-related vision problems—myopia, hyperopia, and astigmatism. All of these surgical techniques involve reshaping the cornea so that (in the ideal case) eyeglasses or contact lenses are no longer necessary for bringing images into focus at the retina. Laser-assisted in situ keratomileusis (LASIK) is currently the dominant form of refractive eye surgery in the United States (accordingly, this chapter mainly covers LASIK). The LASIK surgeon employs a microkeratome (knife) to cut a flap on the surface of the cornea. With the flap pulled back on its hinge, the stroma is exposed. As in PRK, the surgeon then employs a laser to reshape the cornea by vaporizing, or ablating, small amounts of stromal tissue. Once that is finished, the flap is laid back in place.³

Because spectacles or contacts remain a fully adequate corrective for most people with refraction errors, any type of refractive surgery is almost always elective, with the election driven more by cosmetic and lifestyle considerations than the health benefits to be gained from surgery. For example, in *Stasack v. Capital Dist. Physicians Health Plan, Inc.*,⁴ the court held that an insurance plan properly denied coverage for refractive surgery on grounds that it was not medically necessary. Nonetheless, with millions of Americans exhibiting refraction errors, and with a surge in cosmetic procedures overall, there has been no shortage of patients willing to pay out of their own pockets.

There has also been no shortage of patients alleging *some* degree of adverseness in the result of their refractive surgeries. The American Academy of Ophthalmology, in a January 2002 assessment of the safety and efficacy of LASIK, concluded that “serious adverse complications leading to

significant visual loss . . . probably occur rarely in LASIK procedures,”⁵ but also that “annoying side effects such as dry eyes, night time starbursts, and/or reduced contrast sensitivity occur relatively frequently.”⁶ The assessment recognized that these “annoying side effects” can be severe, though some patients may be prone to overstating the annoyance “because their corrected visual acuity was most likely excellent before the procedure and because they elected to have surgery.”⁷ More recent evidence suggests that the rate of complications in LASIK has come down in recent years. “Technical advances, improved definition of the safe range of refractive errors for LASIK treatment, and experience with the management of complications have combined to enhance safety levels” since studies on the safety of LASIK were first conducted in the late 1990s.⁸ But, given the occurrence of the \$7 million and \$4 million verdicts noted above, lawsuits remain a significant concern.

RECOGNIZED COMPLICATIONS OF REFRACTIVE SURGERY

Peer-reviewed articles have noted a number of typical complications in connection with refractive surgery:

- Dry eyes: This is the most common complication of refractive surgery.⁹
- Visual perturbations such as glare, halos, and starbursts: The authors of one study concluded that “[t]here are a number of potential causes” of these and similar side effects: “irregular corneal topography”; “residual and surgically induced astigmatism”; “decentration of the treatment zone”; “large pupils”; “corneal surface microirregularities,” including surgery-associated folds in the flap; and “corneal haze,” including haze resulting from conditions at the interface between the flap and the stromal bed.¹⁰ A more recent study has identified three factors that appear to be associated with higher rates of perturbations: “increasing age, flatter preoperative minimum corneal curvature, and surgical enhancement [or reoperation following an earlier procedure].”¹¹ There is some evidence that aberrometry-guided LASIK can reduce the incidence of visual perturbations.¹²
- Reduced contrast sensitivity.¹³
- Errors in cutting the flap: Partial flaps and other flap-related complications occur in up to 14% of LASIKs (though various studies have reported different incidence

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rates, some as low as 0.3%).¹⁴ A flap complication may not be an injury per se, but can lead to injurious complications, depending on the ophthalmologist's response. If surgery proceeds, a partial flap may interfere with ablation, and a decrease in the ablation zone "carries the risk of increased likelihood of visual symptoms after treatment."¹⁵ The surgeon's extension of the flap by hand "can induce irregular astigmatism and should be avoided."¹⁶

- Errors in replacing the flap: A correctly cut flap may be replaced incorrectly, causing folds in the flap that may affect visual acuity or contrast sensitivity.¹⁷ When the flap has been cut completely free of the cornea (a variety of poor keratectomy), the surgeon may continue with ablation and replace the flap.¹⁸
- Infection between the flap and the stromal bed.¹⁹
- Epithelial growth into the interface between the flap and the stromal bed.²⁰
- Disruption of fusion, leading to strabismus and diplopia:²¹ One authority suggests a connection between diplopia and irregular astigmatism and/or forme fruste keratoconus.²² "Until there is further information, we would suggest using caution in treating such patients and consider factors such as topographic power, thin corneas, topographical superior/inferior disparity, and decreased BCVA before treating."²³
- Distortion of the cornea due to thinning or kerectasia: According to one authority, "[t]here is increasing concern regarding the occurrence of kerectasia after LASIK, . . . but the cause and mechanism remain unknown."²⁴ Multiple retreatments are another possible risk factor for corneal scarring.²⁵
- Overcorrection and undercorrection, such that the patient will continue to require glasses or contacts (or additional surgery, which itself is a risk factor for complications), and may not achieve even the level of preoperative visual acuity.

THEORIES OF RECOVERY FOR INJURY-CAUSING COMPLICATIONS FROM REFRACTIVE SURGERY

Preoperative Negligence in Screening Patients for Refractive Surgery

Proper screening of surgical candidates has emerged as a key issue in refractive surgery lawsuits. In a number of recent cases resolved by verdicts or sizable settlements, there was evidence that the ophthalmologist was negligent in conducting a preoperative examination to determine whether the patient was a suitable candidate or a candidate who might face increased risk of an adverse result. This theory of recovery goes hand-in-glove with lack of informed consent, because an ophthalmologist cannot provide a meaningful explanation of the risks to a particular patient without conducting a proper preoperative screening. Where the evi-

dence shows that proper screening would have resulted in a better assessment of the patient's risk and, based on that assessment, the patient's decision to avoid the risk of an elective procedure, then the patient may have a claim for negligent screening *and* lack of informed consent. Thus, the plaintiff in the case that resulted in the \$7 million verdict alleged both medical malpractice in failing to detect keratoconus, which is often a contraindication for LASIK, and lack of informed consent for failing to apprise the patient of the keratoconus-related risk.²⁶ This section focuses, however, on the elements of a proper screening; the following section takes up the issue of informed consent.

Proper screening "consists of a comprehensive ophthalmologic examination and begins with a complete medical and ophthalmologic history."²⁷ With regard to a patient's general medical history, the following conditions are significant:

- Rheumatoid arthritis and other autoimmune or connective tissue diseases: "A history of uncontrolled connective tissue disease such as rheumatoid arthritis is considered a contraindication for LASIK."²⁸ There is recent evidence that LASIK may be performed safely on "patients who had inactive well-controlled stable-course rheumatic diseases."²⁹
 - Diabetes mellitus: It "represent[s] potential problems for the LASIK patient and need[s] to be discussed in advance."³⁰
 - Herpes simplex or zoster keratitis.³¹
- The ophthalmologic examination should include the following items:
- Pupil size, including scotopic pupil size: The medical literature has recognized pupil size as an important consideration:

*Pupil size measurement in low light conditions should be performed, because increasing pupil size may be correlated with increased postoperative vision disturbances such as halos and glare. Many surgeons consider that a pupil size greater than 7 mm in dim illumination increases the risk of corneal refractive surgery, especially in highly myopic or astigmatic eyes, although the allowable size may vary with the diameter of the treatment and blend zones of the laser ablation. The goal is to have an effective treatment zone at least as large as the scotopic pupil.*³²

The second-largest verdict in a LASIK case—\$4 million—involved a plaintiff who alleged that negligent presurgical screening failed to measure properly his pupil size in dim light; as a result, no one realized his higher risk for a complication that might have dissuaded him from surgery had it been disclosed (he worked as a commercial airline pilot).³³ A more recent study, however, has concluded that "the role of pupil size in postoperative [night vision complaints] has been overrated," and that "[t]he use of pupil size to predict . . . risks [of night vision complaints] is not justified."³⁴

- Cycloplegic refraction: "A cycloplegic refraction should be performed even if treatment may be based on the dry manifest refractive error."³⁵ According to Varley et al.,

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the purpose of such refraction is “[t]o uncover any latent hyperopia.”³⁶

- Degree and type of refractive error: Ophthalmologists should use “extreme caution . . . in treating eyes with high or extreme corrections . . .”³⁷ The safety cutoff for myopia is -10 or -12 diopters,³⁸ but only +4 or +5 for hyperopia,³⁹ and hyperopic correction is generally less predictable than myopic correction.⁴⁰ One set of authors has partly attributed recent declines in the rate of LASIK complications to ophthalmologists’ refusal to operate on eyes requiring high degrees of correction.⁴¹
- Periocular anatomy: It “may impact the ability to make a corneal flap,” and periocular abnormalities such as a chalazion may induce refractive changes.⁴²
- Ocular motility: “An unrecognized, minor strabismus controlled with a prism in glasses can be associated with an exacerbation of diplopic symptoms after LASIK surgery.”⁴³
- Ophthalmic pathologies, including Fuchs corneal endothelial dystrophy (which has been associated with decompensation of the cornea as well as poor flap adhesion), corneal epithelial basement membrane dystrophic changes (which have been associated with epithelial sloughing, epithelial growth into the interface between the flap and the stromal bed, and diffuse lamellar keratitis), significant blepharitis (which has been associated with postoperative infection and interface inflammation), and retinal tears.⁴⁴
- Preexisting dry eyes: Refractive surgery may aggravate the condition.⁴⁵
- Corneal topography: “[A]ssess[ing] corneal shape is a critical feature of the pre-LASIK evaluation.”⁴⁶ A careful topography can detect irregular astigmatism, keratoconus or asymmetrical steepening, inferior corneal steepening (forme fruste keratoconus), and flat corneas, all of which are associated at least to some extent with complications.⁴⁷ The authors of another study advised special caution in treating “[p]atients showing inferior steepening on topography, particularly if associated with steep keratometry,” and noted that such patients “may require more customized ablation, such as performing a spherical treatment of the steeper area of the cornea and careful patient counseling.”⁴⁸

We have already noted the role of undetected keratoconus in the outcome of *Schiffer v. Speaker*.⁴⁹ Undetected keratoconus underlay another high-damages case, *Cofsky v. Goosey*,⁵⁰ which settled for \$1.75 million. Cofsky had been a patient of Maltz, an optometrist, since 1988. In 1998, Cofsky consulted Maltz on LASIK. Maltz told Cofsky that he was a good candidate and referred him to Goosey, an ophthalmologist with whom Maltz shared fees. The surgical result was adverse, particularly to Cofsky’s left eye, where his vision deteriorated to 20/400. Two bilateral corneal transplants eventually restored his vision to useful levels. Cofsky alleged that Maltz erred in designating him a good candidate because he suffered from keratoconus and that Maltz should have known this from the corneal topographies he had performed in each of the five years preceding the referral to Goosey. He also alleged that Maltz failed to

provide the topographies to Goosey for review, and that Goosey was negligent in failing to detect the keratoconus in the topographies that Goosey himself ordered and reviewed prior to surgery. The defendants alleged that Cofsky’s keratoconus was, at all times prior to the original surgery, subclinical and beyond detection except by topography.

- Corneal thickness: Even absent the corneal thinning that may be associated with keratoconus, the cornea should be thick enough after ablation “to leave a central bed beneath the microkeratome flap that will allow corneal stability and prevent bulging or ectasia While the minimum safe bed thickness is not known with certainty, it is thought to be least 250 μm , and many surgeons recommend leaving 275 or 300 μm .”⁵¹ The authors of another study recommend that surgeons “always calculate the preoperative pachymetry even in low myopias, and based on present knowledge, attempt to leave 250 μm of stromal bed.”⁵²

Consequently, the surgeon must know how thick a flap the microkeratome will cut. This may not always be possible because “average flap thickness does not predictably follow the manufacturer’s label due to instrument variability and other operative factors,” and has varied an average of 16 to 30 μm , depending on the study.⁵³ Therefore, the surgeon must consider the variability of flap thickness in determining whether the patient will retain the recommended minimum of stromal bed.

- Recurrent corneal erosions: These patients “may do better with photorefractive keratectomy [PRK] than with LASIK.”⁵⁴
- Refractive stability: The patient should exhibit less than 0.5 diopters of change over at least one year “to help ensure that the correction will be appropriate in the future.”⁵⁵
- Previous refractive surgery: “[E]yes . . . undergoing multiple retreatments, particularly hyperopic retreatment after initial myopic or astigmatic PRK or LASIK,” face increased risk for “[s]erious complications such as scarring with ectasia”⁵⁶
- Contact lens-induced corneal warpage: “As a general guideline, spherical soft contact lenses should be discontinued for at least 1 week [before the preoperative examination], and toric soft lenses and rigid lenses should be discontinued until refractive and keratometric stability has been documented.”⁵⁷

Finally, the ophthalmologist must understand the patient’s occupational history and leisure-time activities:

- Does the patient’s job require perfect vision, including perfect night vision? The fact that the plaintiff in *Post* was a commercial airline pilot did not put him at greater risk for a complication than anyone else with large pupils. But the fact that he was an airline pilot did put him at greater risk for dire consequences resulting from the complication.
- Active participation in contact sports “in which blows to the face and eyes are a normal occurrence.”⁵⁸

The previous list of risk factors is not definitive, as researchers disclaim to have isolated all the risks that can be detected preoperatively for unsuccessful refractive surgery.

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According to one study published in 2000, “[w]e are unable to draw definite conclusions as to the avoidable factors for serious complications of LASIK and PRK based on this study.”⁵⁹ This situation complicates surgeons’ quest for a protocol of adequate, nonnegligent preoperative screening. It also complicates the task of plaintiff and defense counsel seeking, in any particular case, similar understandings of the appropriate standard of care and, thus, of the liability risk.

Lack of Informed Consent

Before a physician begins any invasive procedure, the process of informed consent must be complete. Informed consent is the patient’s agreement to a procedure after having had an opportunity to understand the risks of the procedure, the risks of not electing the procedure, and any alternative procedures and therapies. In the absence of informed consent, a patient having suffered an adverse surgical result can sue the physician for damages regardless of whether the physician was negligent; all the plaintiff has to prove is that a reasonable person would *not* have elected surgery if the risks of surgery had been adequately disclosed in the informed consent process. This may be difficult to prove in the case of surgery for life-threatening or serious conditions. The defense can often win by arguing persuasively that even if the risks of surgery had been adequately disclosed, the risks of not electing surgery were too great for a reasonable person not to elect surgery. Not so in the case of refractive eye surgery, where not electing the procedure generally entails no risks. Because all of the risks are on the side of having surgery, it is relatively easy for a damaged patient to claim that he or she would not have elected surgery if the risks had been adequately disclosed.⁶⁰

Another reason has contributed to making informed consent a most significant issue in litigation over the results of refractive surgery. Ophthalmologists often provide all of their surgery patients with the same informed consent documents instead of customized risk assessments based on the degree to which a specific patient presents any of the recognized risk factors. It is arguably inadequate to tell a patient that he or she faces a certain numerical risk of, *e.g.*, poor night vision, where the number reflects the average incidence of that result, without also telling the patient that he or she faces an above-average risk of that result because of a certain risk factor as determined in a preoperative assessment. Indeed, the average risk and the risk to a specific patient with a specific risk factor can vary immensely. Consequently, the process of obtaining informed consent must include discussion of the patient-specific risks, ideally in terms of percentages (based on current research) expressing the complications that may result from the identified risk factors. Otherwise, the patient’s consent is hardly meaningful.

Assuming proper disclosure of risks, the defendant should prevail. For example, in *Lehrer v. McClure*,⁶¹ the plaintiff’s preoperative best uncorrected vision was 20/400; after surgery, his best uncorrected vision was 20/40 and he alleged that he could not read as well as before, had

problems with nighttime driving, and also experienced halos and blurry vision. The jury found that the three-page informed consent document adequately disclosed these risks and issued a verdict for the defense. Similarly, in *Bawa v. Garabet*,⁶² the microkeratome cut the flap completely free of the cornea. Following the standard of care, the surgeon proceeded to ablation, then resealed the corneal flap and bandaged it with a contact lens, with instructions to the patient not to remove the lens or rub the eye and to return for a follow-up examination. When the plaintiff returned, the contact lens bandage and the corneal flap were both gone, so the physician performed a lamellar keratoplasty. The plaintiff claimed that his particular complication was the cause of uncorrected vision of 20/60 in the affected eye and was an undisclosed material risk. The defendant argued that the informed consent material provided to the plaintiff disclosed the risk of free flaps and, in any event, was irrelevant because the plaintiff testified that he did not read the material or view a companion videotape. The jury rendered a verdict for the defense.

Counsel involved in an informed consent case must review the informed consent documents to determine whether the complication at issue was disclosed.

Surgical Negligence

The federal Food and Drug Administration approves lasers for specific types of refractive treatment (LASIK, PRK, etc.) of patients with refraction errors falling within certain parameters. For example, a certain laser may be approved for LASIK correction of myopia of less than -9.0 diopters (but not any degree of hyperopia), with or without astigmatism of -0.5 to -3.0 diopters. The same laser might be approved for PRK correction of myopia up to -10.0 diopters (but not any degree of hyperopia) with or without astigmatism of up to -4.0 diopters. Another laser may be approved only for LASIK or PRK correction of certain degrees of hyperopia. The investigation of any adverse outcome should consider whether the surgeon used the equipment to treat a condition beyond its licensed specifications. The FDA’s list of approved lasers, and the indications for which each has been approved, is available on its website.⁶³ (The FDA has not approved any laser for LASIK on a minor.⁶⁴) In January 2001, the FDA reached a settlement with a company and four of its executives for \$1.5 million (the executives were held personally liable for a third of the amount) on claims that the company sold software that allowed ophthalmologists to program lasers for treatments exceeding the terms of their FDA licenses.⁶⁵

While it may seem that the obvious claim to make in the case of misused equipment is that of negligence, the issue may be presented as one of informed consent. In *Anonymous v. Anonymous*,⁶⁶ the plaintiff obtained a \$1.03 million settlement after LASIK for mild hyperopia (20/70 and 20/50) left him with severely degraded vision (20/200 and 20/400). The evidence would have shown, allegedly, that the defendant had not informed the patient that, at the time of surgery in 1996, the FDA had not approved any laser for LASIK correction of hyperopia.⁶⁷

The technician and surgeon should check the surgical equipment—the laser, suction ring, microkeratome, and blade—before a procedure.⁶⁸ A \$1.7 million LASIK verdict involved negligent setup of the equipment.⁶⁹ Tonya Oliver underwent a generally successful LASIK for myopia in her left eye, and about 6 months later a second procedure to fix an astigmatism in the same eye. The second surgery, however, increased Oliver's astigmatism. The plaintiff's theory of the case was that the ophthalmologist transposed her refraction, with the result that he programmed the laser to make corrections to the wrong axis of her eye. Preoperative notes supported the transposition theory, as did medical testimony that the observed damage to Oliver's vision was exactly what would be expected from corrections made along the wrong axis. Oliver also had testimony from one of the ophthalmologist's former employees, who allegedly heard Oliver say after the surgery that "the prescription didn't add up." The surgeon scheduled Oliver for enhancement surgery only one week later. (This in itself was problematic: enhancement surgery "can be performed once the refraction is stable for at least 1 month after surgery, but generally is not performed before 3 months."⁷⁰) After that and a fourth surgery, and then a corneal transplant, Oliver remained legally blind in her left eye.

Other equipment-related problems that have turned into lawsuits include:

- Placing the microkeratome upside down, which caused shredding of the corneal flap.⁷¹
- During retreatment to correct halos and double vision in one eye, failure to lock the depth plate, as a result of which the laser perforated the cornea and iris, ruptured the globe, and penetrated into the anterior chamber, leaving plaintiff with vision of 20/400.⁷²
- Keeping the laser on for too long and gouging a hole beneath the corneal flap, causing the patient to require a lamellar keratoplasty, which restored his uncorrected vision to presurgical levels.⁷³
- Failing to seat the spacing plate into the keratome machine, as a result of which the keratome removed approximately 70% of the iris in the patient's right eye.⁷⁴

With respect to surgical technique, refractive surgery (the laser-assisted varieties) generally involves topical anesthetic of the operative eye, placement of a speculum to hold the lids open, marking the cornea to assist in aligning the flap after ablation, placement of a suction ring on the eye to induce intraocular pressure of greater than 65 to 70 mmHg, creation and reflection of the flap, ablation, repositioning of the flap and verification of alignment, removal of the speculum, and then reexamination of the flap about 30 minutes later to verify alignment.⁷⁵

A mistake can occur at any stage, particularly in creating the flap and in repositioning and aligning the flap after ablation (see *supra* text accompanying notes 14–18). When a partial or otherwise problematic flap has been created, the standard-of-care recommendation has been to replace the flap and give the cornea some 3 months to heal before reattempting LASIK.⁷⁶ But in a recent case study, the authors describe extending partial flaps by making a second pass with the microkeratome (versus manual extension)

and completing surgery without further complications.⁷⁷ They also suggest that an intraoperative second pass may be safer than reoperation at a later date, which would disturb scar tissue that forms after the first surgery. They note, however, that in all five eyes involved in their case study, the microkeratome stopped prematurely because of an obstruction (usually an eyelid), not a mechanical problem, and that the resulting flaps were, other than being partial, of good quality.

Postoperative Negligence

Ophthalmologists should advise patients to refrain from rubbing their eyes for several weeks after surgery, should prescribe antibiotics and corticosteroids and advise patients to use eye drops frequently for lubrication, and should schedule follow-up visits on the day after surgery, one week after surgery, and thereafter as needed.⁷⁸ One study has examined the use of soft contact lenses as bandages and concluded that they offer no measurable benefit, except possibly for "males with a history of good contact lenses tolerance and Schirmer II values over 16 mm."⁷⁹ Follow-up surgery should not be attempted until the patient's refraction has stabilized,⁸⁰ and there is some emerging evidence suggesting that correction of post-LASIK hyperopia (with or without astigmatism) should be in the form of conductive keratoplasty rather than another session of LASIK.⁸¹

CONCLUSION

Better technology, more surgical experience, and greater care in patient selection offer hope that some adverse results previously experienced by surgical patients can be avoided, and *perhaps* that some adverse results suffered by patients can be ameliorated (if their corneas are not too scarred or ectatic for retreatment). Greater care in patient selection entails exercising caution at two junctures where litigation has proven ophthalmologists most vulnerable: in conducting preoperative screenings in a nonnegligent manner; and in communicating to their patients, in the process of obtaining informed consent, a realistic assessment of patient-specific risks with reference to the results of preoperative screenings.

Endnotes

1. Natalie White, *Laser Eye Surgery Verdict Nearly Doubles Previous Record: Breaks New Ground with Damages for Pain and Suffering*, Lawyers Weekly USA (Aug. 15, 2005), at 1.
2. Dianna Digges, *\$4M Award over Laser-Eye Surgery Breaks New Ground*, Lawyers Weekly USA (May 27, 2002), at 1. The verdict was overturned but subsequently reinstated. *\$4M Verdict in LASIK Suit Reinstated*, LAWYERS WEEKLY USA (Mar 1, 2004), at 2.
3. Gary A. Varley et al., *LASIK for Hyperopia, Hyperopic Astigmatism, and Mixed Astigmatism*, 111 *Ophthalmology* 1604, 1604–05 (2004).
4. 736 N.Y.S. 2d 764 (N.Y. App. Div. 2002).
5. Alan Sugar et al., *Laser In Situ Keratomileusis for Myopia and Astigmatism: Safety and Efficacy*, 109 *Ophthalmology* 175, 181 (2002).

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6. *Id.* The study also noted the difficulty in distinguishing between “a complication compared to a minor nuisance or annoying side effect.” *Id.*
7. *Id.*
8. Stephanie L. Watson et al., *Improved Safety in Contemporary LASIK*, 112 *Ophthalmology* 1375, 1375 (2005).
9. Sugar, *supra* note 5, at 181.
10. Peter S. Hersh et al., *Photorefractive Keratectomy versus Laser In Situ Keratomileusis: Comparison of Optical Side Effects*, 107 *Ophthalmology* 925, 931–32 (2000).
11. Melissa D. Bailey et al., *Patient Satisfaction and Visual Symptoms after Laser in Situ Keratomileusis*, 110 *Ophthalmology* 1371, 1371 (2003). See also Mihai Pop & Yves Payette, *Risk Factors for Night Vision Complaints after LASIK for Myopia*, 111 *Ophthalmology* 3, 8 (2004) (“[p]atient age showed significant importance in predicting [night vision complaints]”).
12. Keith P. Thompson et al., *Using InterWave Aberrometry to Measure and Improve the Quality of Vision in LASIK Surgery*, 111 *Ophthalmology* 1368, 1378 (2004).
13. Sugar, *supra* note 5, at 181.
14. Vikentia J. Katsanevaki et al., *Intraoperative Management of Partial Flap during LASIK*, 112 *Ophthalmology* 1710.e1, 1710.e1 (2005).
15. *Id.*
16. *Id.*
17. Sugar, *supra* note 5, at 181. E.g., in *Wilger v. Faulkner*, No. A9800710, 2001 WL 718554 (Ohio Ct. C.P. Apr. 19, 2001), the surgeon performing automated lamellar keratoplasty replaced the patient’s flap inverted and upside down; the jury awarded \$325,000.
18. Sugar, *supra* note 5, at 181.
19. *Id.*
20. *Id.*
21. *Id.*
22. Simon P. Holland et al., *Avoiding Serious Corneal Complications of Laser Assisted in Situ Keratomileusis and Photorefractive Keratectomy*, 107 *Ophthalmology* 640, 651 (2000).
23. *Id.* at 650.
24. *Id.* at 646.
25. *Id.* at 651 (“[c]aution is also advisable before performing a third or fourth retreatment for under- or overcorrection”).
26. *Schiffer v. Speaker*, No. 0101191/2003 (N.Y. Sup. Ct. Dec. 16, 2004) (order denying motions for summary judgment). The case went to trial; for a report of the verdict, see *Lawyers Weekly USA*, (Aug. 15, 2005), at 1 (N.Y. Sup. Ct. July 27, 2005). The case settled for an undisclosed sum during the post-trial phase. *Schiffer v. Speaker*, No. 0101193/2003 (N.Y. Sup. Ct. Oct. 5, 2005) (order permitting withdrawal of post-trial motion based on settlement).
27. Varley, *supra* note 3, at 1605.
28. *Id.* See also Sugar, *supra* note 5, at 176 (systemic autoimmune disease “has been associated with corneal melting after PRK and may therefore increase LASIK risks, although the peer reviewed literature on this topic is sparse”).
29. Jorge L. Alio et al., *LASIK in Patients with Rheumatic Diseases*, 112 *Ophthalmology* 1948, 1953 (2005).
30. *Id.*
31. *Id.*
32. Sugar, *supra* note 5, at 176; see also Varley et al., *supra* note 3, at 1605; Hersh, *supra* note 10, at 932 (“[i]n low illumination, a disparity between the dilated pupil size and treatment zone may allow unfocused noise light into the eye”).
33. *Post v. University Physicians, Inc.*, 22 No. 6 Verdicts, Settlements & Tactics 248 (Ariz. Dist. Ct. May 9, 2002).
34. Pop, *supra* note 11, at 9.
35. Sugar, *supra* note 5, at 176.
36. Varley, *supra* note 3, at 1605.
37. Holland, *supra* note 22, at 646.
38. Watson, *supra* note 8, at 1376; Alio, *supra* note 29, at 1948.
39. Varley, *supra* note 3, at 1610.
40. Philip D. Jaycock et al., *5-Year Follow-up of LASIK for Hyperopia*, 112 *Ophthalmology* 191, 197 (2005).
41. Watson, *supra* note 8, at 1378.
42. Varley, *supra* note 3, at 1605.
43. *Id.*
44. Sugar, *supra* note 5, at 176; see also Varley, *supra* note 3, at 1605–06.
45. Sugar, *id.*; see also Varley, *id.* at 1606.
46. Sugar, *id.*; see also Varley, *id.*
47. Sugar, *id.*; see also Varley, *id.*
48. Holland, *supra* note 22, at 651 (emphasis added).
49. See *supra* text accompanying note 26.
50. 22 No. 7 Verdicts, Settlements & Tactics 297 (Texas Dist. Ct. Apr. 30, 2002).
51. Sugar, *supra* note 5, at 176 (footnotes omitted).
52. Holland, *supra* note 22, at 646; see also Varley, *supra* note 3, at 1606.
53. Sugar, *supra* note 5, at 177.
54. Varley, *supra* note 3, at 1605.
55. Sugar, *supra* note 5, at 176; see also Varley, *supra* note 3, at 1605.
56. Holland, *supra* note 22, at 651.
57. Varley, *supra* note 3, at 1605; see also Sugar, *supra* note 5, at 176.
58. When is LASIK Not for Me?, <http://www.fda.gov/cdrh/LASIK/when.htm> (last visited Dec. 20, 2005).
59. Holland, *supra* note 22, at 651.
60. “[A]ny potentially vision-threatening complication is of great importance in such an elective procedure, with readily available alternatives for correcting the refractive error.” *Id.* at 640.
61. No. 01-CC-02195, 2002 WL 1918295 (Cal. Super. Ct. May 17, 2002).
62. No. BC-238080, 2001 WL 1849087 (Cal. Super. Ct. Sept. 26, 2001).
63. FDA-Approved Lasers for LASIK, <http://www.fda.gov/cdrh/LASIK/lasers.htm> (last visited Dec. 12, 2005).
64. When is LASIK Not for Me?, <http://www.fda.gov/cdrh/LASIK/when.htm> (last visited Dec. 20, 2005).
65. Diana Digges, *Laser Eye Surgery Settlement Sends Warning That Feds Are Watching*, *Lawyers Weekly USA* (Feb. 19, 2001), at B1.
66. 21 No. 7 Verdicts, Settlements & Tactics 302 (N.C. Dist. Ct. Apr. 23, 2001).
67. See also *Cody v. Garabet*, No. BC-196910, 1999 WL 1069219 (Cal. Super. Ct. Sept. 27, 1999) (jury awarded \$48,000; plaintiff alleged that surgeon never told patient that equipment was not FDA-approved).
68. Sugar, *supra* note 5, at 177; see also Varley, *supra* note 3, at 1606.
69. *Oliver v. Abell*, No. 99-CI-1816 (Ky. Cir. Ct. Nov. 1, 2001). The facts presented here are drawn from Elizabeth Amon, *The View is Clear: More Laser Lawsuits*, *Nat’l Law J.* (Dec. 10, 2001), at 4. The verdict was later overturned because of the fact, undisclosed to the litigants prior to trial, that the trial judge’s husband occasionally worked on cases with the law firm that represented the plaintiff. *\$1.7M Award over LASIK Overturned*, *Lawyers Weekly USA* (Apr. 14, 2003), at 2.
70. Sugar, *supra* note 5, at 177.

71. *Anonymous 38 Year Old Female v. Anonymous Eye Surgeon*, 2001 WL 1854266 (Va. Cir. Ct. 2001) (settled for \$235,000).
72. *McLeod v. York*, No. SC-059561, 2000 WL 33800665 (Cal. Super. Ct. Dec. 1, 2000) (settled for \$275,000).
73. *Doe v. Dr. Roe*, 2000 WL 33143769 (Cal. Super. Ct. Nov. 14, 2000) (structured settlement with present-day cash value of \$350,000).
74. *Scott v. Wong*, No. 99-07375, 2000 WL 33719626 (Texas Dist. Ct. Nov. 6, 2000) (settled for \$200,000).
75. Sugar, *supra* note 5, at 177.
76. Holland, *supra* note 22, at 651 (footnote omitted). See also Vivien M.-B. Tham et al., *Microkeratome Complications of Laser In Situ Keratomileusis*, 107 *Ophthalmology* 920, 922 (2000) (“making another microkeratome pass after 3 months and attempting to complete the LASIK procedure is generally safe”).
77. Katsanevaki, *supra* note 14, at 1710.e3.
78. Varley, *supra* note 3, at 1607.
79. Walter Sekundo, M.D., et al., *Benefits and Side Effects of Bandage Soft Contact Lens Application after LASIK*, 112 *Ophthalmology* 2180, 2183 (2005).
80. Varley et al, *supra* note 3, at 1607 (noting that for hyperopes, refractive stabilization may not occur until 3 to 6 months after surgery).
81. Peter S. Hersh et al., *Conductive Keratoplasty to Treat Complications of LASIK and Photorefractive Keratectomy*, 112 *Ophthalmology* 1941 (2005).

