

THE LASIK REPORT

A Call for the Discontinuation of a Harmful Procedure

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LASIK is one of the most commonly performed elective surgeries in the United States today. The public perception of LASIK is based largely on advertising, which is intended to entice patients to have surgery without disclosing risks, side effects and contraindications.

The perceived benefits of LASIK surgery are obvious, whereas risks and adverse effects are not widely known by the general public. It is unwise to assume that a surgeon who has a financial interest in a patient's decision to have LASIK will provide adequate informed consent.

LASIK is irreversible and may result in long-term, debilitating complications. There are permanent adverse effects of LASIK in 100% of cases, even in the absence of clinically significant complications. This is unacceptable in the context of an elective surgery when safer alternatives such as glasses or contact lenses exist.

I. BACKGROUND

When the first laser received FDA approval for LASIK, little was known about complications and long-term safety of the procedure. Early clinical trials did not thoroughly examine adverse effects of LASIK.

Since that time, numerous medical studies have examined the risks of LASIK. It is now widely reported in ophthalmic medical journals that complications such as dry eye and visual disturbances in low light are common, and that creation of the corneal flap permanently compromises tensile strength and biomechanical integrity of the cornea.

In 1999 during the initial boom in popularity of LASIK, Marguerite B. McDonald, noted refractive surgeon and then-Chief Medical Editor of *EyeWorld* magazine, stated in an editorial:

"We are only starting to ride the enormous growth curve of LASIK in this country. There will be more than enough surgeries for everyone to benefit if we keep our heads by sharing information openly and honestly and by resisting the temptation to criticize the work of our colleagues when we are offering a second opinion to a patient with a suboptimal result. Who was it who said, 'When the tide comes in, all the boats in the harbor go up?'"

Today some prominent refractive surgeons are finding superior outcomes and better safety profiles with surface ablations such as PRK and LASEK, which avoid creation of a corneal flap. Yet LASIK continues to be the most common refractive surgical procedure performed.

II. DRY EYE

A report by the American Academy of Ophthalmology published in 2002 states that dry eye is the most common complication of LASIK surgery.¹ Refractive surgeons are aware that LASIK induces dry eye, yet patients are not fully informed as to the etiology, chronic nature and severity of this condition.

“My LASIK dry eye is not a minor problem, as downplayed by some ophthalmologists. It's a disability. I estimate that I am blind approximately 10 percent of the time due to my eyes being closed because of the pain. At the time of my surgery, I was told only a small number of patients experience a complication from this procedure. There is substantial evidence that shows this crippling side effect to be relatively common.”

LASIK patient David Shell, testifying before the FDA Ophthalmic Devices Panel in August, 2002.

Persistent Dry Eye and Quality of Life after LASIK

Patients elect to undergo LASIK surgery with the expectation of improved quality of life. Instead, many are living with chronic pain from LASIK-induced dry eye. The FDA website states that dry eyes after LASIK may be permanent (<http://www.fda.gov/cdrh/LASIK/risks.htm>).

Patients should be informed that LASIK surgery severs corneal nerves that play a crucial role in tear production, and that these nerves do not return to normal. Inability to sense and respond to dryness may lead to ocular surface damage.

Medical Research on Duration and Severity of Dry Eye

Dry eye disease is a painful, chronic condition for some patients after LASIK surgery. In 2001, Hovanesian, Shah, and Maloney found that 48% of LASIK patients reported symptoms of dryness at least 6 months after surgery, including soreness, sharp pain and eyelid sticking to the eyeball.²

A Mayo Clinic study published in 2004 demonstrates that 3 years after LASIK, corneal nerves are less than 60% of preoperative densities.³

In 2006, researchers at Baylor College of Medicine reported the incidence of dry eyes six months after LASIK at 36% overall and 41% in eyes with superior-hinges.⁴ These findings were based on objective medical tests rather than patient questionnaires, which is significant as patients with nerve damage may not be capable of sensing dryness.

The scientific literature is replete with case reports and studies of LASIK-induced dry eye. This complication is widely recognized in the industry as the most common complaint of LASIK patients, yet the problem is downplayed in the informed consent process. Most dry eye therapies provide only marginally effective symptomatic relief. There is no cure for LASIK-induced dry eye. Internet bulletin boards with forums devoted to post-LASIK dry eye are a testament to this widespread, debilitating condition.

III. NIGHT VISION IMPAIRMENT

Millions of LASIK surgeries have been performed in the United States in the past decade. Many patients now suffer from visual impairment at night. Some patients, especially those with large pupils, are unsafe to drive at night and can no longer live normal, independent lives.

“When I drive to work every day, fighting the DC traffic I hear lots of great advertisements including the advertisements from the center that did my surgery talking about 95, 98 percent, whatever the percentage is of their patients who achieve 20/20 or 20/40 or better vision, and they consider that a success. I am considered a success by that criteria as well. However, in anything but extremely bright daylight I am visually impaired by starbursts, halos, multiple ghost images because of LASIK done on my 8-millimeter pupils...

FDA approval of devices should include not only approval within a certain range of myopia or astigmatism or hyperopia but within a range of pupil sizes such that any use of that device outside of that pupil size should be considered against the FDA approval of that device....”

LASIK patient, Mitch Ferro, testifying before the FDA Ophthalmic Devices Panel in July, 1999.

Unfortunately the FDA turned a deaf ear on this recommendation and did not place a pupil size limit on the approval, nor did it include large pupils in the list of LASIK contraindications. Instead, the FDA approved lasers for LASIK with watered-down cautionary language in the labeling regarding large pupils. Dissemination of this labeling to patients was mandated by the FDA but not enforced, which violated the right to fully informed consent for many patients with large pupils.

Reduced visual quality in dim light is frequently reported by LASIK patients.¹ Patients with pupils that dilate larger than the effective optical zone of the LASIK treatment are at increased risk for debilitating visual aberrations and loss of contrast sensitivity.⁵ Even patients with normal pupil sizes are at risk, as the laser loses efficiency on the slope of the cornea resulting in an effective optical zone that is smaller than intended.⁶ Newer laser technologies attempt to compensate by applying more laser energy in the periphery of the ablation, but this technique removes more corneal tissue, increasing the risk of surgically-induced keratectasia.⁷

In a study published in 2004, dark-adapted pupil sizes of candidates for refractive surgery were found to range from 4.3 to 8.9 mm with a mean diameter of 6.5 mm.⁸ This finding explains why many patients had severe nighttime visual aberrations in the early days of photorefractive keratectomy when optical zones as small as 4 mm were used. In an attempt to overcome pupil size/optical zone mismatch, the standard treatment zone was increased incrementally over several years. However, even the 6.5 mm optical zone commonly used today does not prevent aberrations in many patients with large pupils, or high corrections and associated small effective optical zones.

Image degradation and visual aberrations in low light after LASIK were predictable. These problems had been widely recognized and reported with previous refractive surgeries such as radial keratotomy (RK) and photorefractive keratectomy (PRK), and were related to pupil size.⁹ If corneal refractive power is not consistent across the entire diameter of the pupil, visual aberrations and loss of contrast sensitivity result. After cataract surgery or refractive lens exchange, patients also report poor vision at night when the pupil dilates. As phakic intraocular lenses begin to replace LASIK for

high myopia due to safety concerns, the pattern of patients with large pupils experiencing night vision disturbances is consistent.

Public Health Concerns Following LASIK Surgery

Dr. Leo Maguire forewarned of the threat to public health posed by impaired night vision following refractive surgery.¹⁰ The following is an excerpt from an editorial published in the March, 1994 edition of American Journal of Ophthalmology:

“I hope the reader will now understand how a patient may have clinically acceptable 20/20 visual acuity in the daytime and still suffer from clinically dangerous visual aberration at night if that patient’s visual system must cope with an altered refractive error, increased glare, poorer contrast discrimination, and preferentially degraded peripheral vision. People die at night in motor vehicle accidents four times as frequently as they do during the day, and these figures are adjusted for miles driven. Night driving presents a hazardous visual experience to adults without aberrations. When we discuss aberration at night we are considering a possible morbid effect of refractive surgery.”

A Brief Chronology of Scientific Literature on Night Vision Impairment after Corneal Refractive Surgery

Factors responsible for visual impairment in low light following refractive surgery have been discussed in articles and reported in peer-reviewed studies for two decades:

- 1987 *“For a patient to have a zone of glare-free vision centered on the point of fixation, the optical zone of the cornea must be larger than the entrance pupil. The larger the optical zone, the larger the field of glare-free vision.”*¹¹

- 1993 *“Optical zone diameters must be at least as large as the entrance pupil diameter to preclude glare at the fovea, and larger than the entrance pupil to preclude parafoveal glare.”*¹²

- 1996 *“At nighttime, when the pupil dilates, rays from treated and untreated areas of the cornea reach the retina at different foci and produce haloes.”*¹³

- 1997 *“Corneal modulation transfer function calculations suggest that a significant loss of visual performance should be anticipated following photorefractive keratectomy, the effect being the greatest for large pupil diameters.”*¹⁴

- 1998 *“...after PRK, the diameter of the entrance pupil greatly affects the amount and character of the aberrations...”*¹⁵

- 1999 *“Changes in functional vision worsen as the target contrast diminishes and the pupil size increases.”*¹⁶

- 2000 *“The increase in ocular aberrations was significantly related with the virtual pupil size.”*¹⁷
- “Thus, an optical system may have no refractive error in the center of the pupil and an increasing error in the annular zones surrounding the pupil center. The resultant image may be sharp for small pupil diameters but degrade as the pupil expands.”*¹⁸
- 2002 *“The relation between pupil size and the optical clear zone are most important in minimizing these disturbances in RK. In PRK and LASIK, pupil size and the ablation diameter size and location are the major factors involved.”*¹⁹

The LASIK industry failed to take corrective action in response to scientific evidence regarding the importance of matching the effective optical zone to a patient’s pupil size. As a result, many LASIK patients are now permanently visually impaired in dim light.

IV. IATROGENIC KERATECTASIA

The cornea is under constant stress from normal intraocular pressure pushing outward. Collagen bands of the cornea provide its form and biomechanical strength. LASIK thins the cornea and severs collagen bands, permanently weakening the cornea. This results in forward bulging of the posterior cornea, which may progress to a condition known as keratectasia, characterized by loss of best corrected vision and possible corneal failure requiring corneal transplant.

The FDA, laser manufacturers, and refractive surgeons are aware of limits on flap thickness, ablation depth, and diameter of the optical zone imposed by corneal biomechanics. When the FDA initially approved lasers for LASIK, it established a minimum of 250 microns of corneal tissue under the flap after LASIK surgery to prevent corneal instability and progressive forward bulging. Subsequent reports in medical literature indicate that 250 microns is not sufficient to ensure corneal biomechanical stability.^{20,21} In response, some surgeons stopped performing LASIK or raised the residual stromal thickness limit in their practices. However, the majority of surgeons continue to observe the 250 micron rule initially established by the FDA, even though this limit has been shown to be insufficient.

The 250 micron rule is often violated inadvertently during surgery, as microkeratomes that cut the LASIK flap are unpredictable and produce flaps of varying thickness.²² For this reason, flap thickness should be measured intraoperatively. Most surgeons have not incorporated this important measurement into the surgical procedure prior to ablation, which places patients with thicker-than-expected flaps at greater risk.

Keratectasia may develop months or years following seemingly successful LASIK.²³ Since most cases are never reported, the true rate of this devastating complication may never be known. The only way to prevent surgically induced keratectasia is to abandon LASIK altogether. It is important to remember that LASIK is elective surgery. There is no sound medical reason to place patients at risk of vision loss from unnecessary surgery.

V. LIMITED HEALING OF THE CORNEA FOLLOWING LASIK

The human cornea is incapable of complete wound healing after LASIK surgery. In 2005, researchers at Emory University found permanent pathologic changes in all post-LASIK corneas examined, including undulation of Bowman's layer, spatial separation of the LASIK flap from the stromal bed, epithelial thickening over the wound margin, interface debris, and severed and severely disordered collagen fibrils.²⁴ The study reveals that the healing response never completely regenerates normal corneal stroma.

Another study demonstrates that the LASIK flap produces a scar at the margin that is only 28.1% of the tensile strength of normal corneal stroma, and the flap itself heals to only 2.4% of normal tensile strength.²⁵ This publication reports that one author has lifted LASIK flaps out to 11 years after initial surgery, further attesting to long-term weakness of the LASIK interface wound. Reports of late flap dislocations suggest that LASIK patients are vulnerable to traumatic flap injury for life.²⁶

VI. OTHER COMPLICATIONS AND CONCERNS

Potential Complications of LASIK

Other vision-threatening complications are seen following LASIK surgery, such as infection, retinal breaks and detachment, macular holes and hemorrhage, optic nerve damage, diffuse lamellar keratitis, irregular flaps, flap folds and striae, slipped flaps, epithelial defects, and epithelial ingrowth. These and other complications may have severe, lasting adverse effects.

Bilateral Simultaneous LASIK

Performing LASIK on both eyes in the same day is convenient and financially beneficial for surgeons, but is not in patients' best interest. In a 2003 survey of American Society of Cataract and Refractive Surgery (ASCRS) members, 91% of surgeons who responded did not offer patients the choice of having one eye done at a time.²⁷ Bilateral simultaneous LASIK places patients at risk of vision loss in both eyes, and denies patients informed consent for the second eye.

Inaccurate IOP Measurement after LASIK

Changes in corneal thickness and biomechanical properties following LASIK affect intraocular pressure (IOP) measurements, resulting in falsely low readings. LASIK patients face lifetime risk of undiagnosed ocular hypertension, which may progress to glaucoma. Glaucoma is a leading cause of blindness.

Complicated Cataract Surgery after LASIK

Like the general population, LASIK patients will eventually develop cataracts. The altered corneal surface following LASIK prevents accurate measurement of intraocular lens power for cataract surgery. This may result in a "refractive surprise" following cataract surgery and exposes LASIK patients to increased risk of repeat surgeries.

LASIK Results in Loss of Near Vision

Patients are routinely misinformed that they will require reading glasses after the age of 40 whether they have LASIK or not. Nearsighted patients who do not have refractive surgery

actually retain the ability to see up close naturally after the age of 40 simply by removing their glasses. LASIK increases the need for reading glasses by changing the eye's focus from near to distance. The loss of near vision after myopic-LASIK affects many daily activities, not just reading. LASIK patients over the age of 40 may discover they have simply traded one pair of glasses for another.

Progressive Loss of Corneal Keratocytes after LASIK

A Mayo Clinic study demonstrates persistent decrease in corneal keratocyte density after LASIK.²⁸ Keratocytes are cells vital to the function of the cornea. This progressive loss of corneal keratocytes may have long-term implications in terms of corneal stability, refractive stability and cellular integrity of the cornea after LASIK. Ophthalmologists have speculated that progressive keratocyte loss may ultimately lead to post-LASIK ectasia.^{28,29}

Limited Rehabilitation Options after LASIK

LASIK is irreversible, and treatment options for visual rehabilitation after a poor LASIK outcome are extremely limited. Rigid gas permeable contact lenses may improve vision if the patient can tolerate lenses and obtain a good fit. The post-LASIK contact lens fitting process can be time consuming, expensive, and complicated by LASIK-induced dry eyes. Many patients eventually give up on hard contacts and struggle to function with impaired vision. In extreme cases, a corneal transplant may be required.

VII. PATIENT SATISFACTION

LASIK success is measured by the LASIK industry as uncorrected visual acuity under bright illumination. Patients seeking vision correction are most concerned with elimination of glasses or contact lenses, and are unaware of what it means to lose visual *quality*. Patient surveys typically show a high level of satisfaction with LASIK. However, an alarming number of satisfied patients also report complications such as visual disturbances in dim light and dry eye.

In the March, 1994 American Journal of Ophthalmology editorial mentioned previously in this article, Dr. Leo Maguire cautioned about misleading implications of quoting patient satisfaction rates:¹⁰

“A keratorefractive patient may simultaneously be happy with the result of surgery and have degraded vision – how can refractive surgery be a potential public health problem if patients are happy with the results? Inherent in this question is the assumption that a patient without complaint is a patient without optical degradation. That argument does not hold up to closer scrutiny. The keratorefractive literature contains disturbing examples of patients who have visual handicaps that place themselves and others at significant risk for nighttime driving accidents and yet they are happy with the results.”

In May, 2001, results from a questionnaire completed by PRK and LASIK patients revealed that 19.5% reported a worsening in functioning, 27.1% a worsening in symptoms, 34.9% a worsening in optical problems, 33.7% a worsening in glare, and 41.5% a worsening in driving.³⁰

In one report, researchers suggest that factors such as the Hawthorne effect and cognitive dissonance may play a role in patient satisfaction following LASIK.³¹ The Hawthorne effect favorably influences patients' survey responses merely because patients are aware that they are

enrolled in a study. Cognitive dissonance is a change in one's attitude or beliefs to eliminate internal conflict with negative consequences of an irreversible action.

LASIK industry representatives have argued that no evidence links a poor LASIK outcome with depression or suicide. However, if it is credible that there may be a positive impact on quality of life after seemingly successful LASIK, then we must also accept that there can be a negative impact on quality of life after a poor LASIK outcome.

VIII. NEWER TECHNOLOGIES

Wavefront-guided and wavefront-optimized LASIK

Newer laser technologies were designed to reduce induction of aberrations and night vision disturbances. As complications from current technologies generate bad publicity, pressures to develop and market alternative technologies emerge. "Real" complication rates are openly discussed, not when a procedure is popular, but rather when providers push newer, "improved" technology. The LASIK industry and LASIK surgeons aggressively promote new technologies as "safer and more effective," blaming older technologies for past complications. Although the introduction of wavefront-LASIK was surrounded by hype, studies have shown that wavefront-guided and wavefront-optimized LASIK actually increase, not decrease, higher order aberrations, reducing visual quality in previously untreated eyes.^{32,33} A review of literature on wavefront-guided LASIK concludes that evidence does not support claims that wavefront outperforms conventional LASIK.³⁴ Wavefront, like previous forms of refractive surgery, fails to deliver on its promises.

Femtosecond laser flap creation (Intralase-LASIK)

Mechanical blade microkeratomes have been linked to flap complications and damage to the epithelium. The femtosecond laser keratome is currently promoted as a safer alternative. Studies have shown that the femtosecond laser produces flaps with smaller deviations from planned thickness than mechanical microkeratomes. However, it does not reduce most complications associated with the LASIK procedure and has been linked to extreme light sensitivity,³⁵ a complication of this technology. Femtosecond laser flaps are more difficult to lift than flaps created with a blade, which may result in a higher incidence of torn flaps.

The femtosecond laser keratome currently requires longer suction on the eye than blade microkeratomes to create the LASIK flap. The incidence of posterior vitreous detachment with blade microkeratomes is high at 13% overall, and 24% for patients with high myopia in one study.³⁶ Increased suction ring exposure associated with use of femtosecond lasers likely induces posterior vitreous detachment at even higher rates, as well as other serious complications such as retinal detachment, macular hemorrhage, retinal vein occlusion, and optic nerve damage following LASIK.

A search of peer-reviewed literature reveals problems associated with the femtosecond laser such as slipped flaps, interface inflammation, flap folds, infectious keratitis, corneal stromal inflammation, delayed wound healing, macular hemorrhage, and gas bubbles in the anterior chamber after surgery.³⁷⁻⁴³ The FDA medical device adverse events database (<http://www.fda.gov/cdrh/maude.html>) contains numerous reports involving femtosecond laser keratomes.

IX. CONCLUSION

Vision has always been considered the most important of the five senses. Vision loss, particularly as a result of an elective surgery, may bring about acute distress greater than that resulting from other sensorial impairment. LASIK surgery is performed on healthy eyes with good correctable vision; therefore, LASIK should be held to higher standards than other elective medical procedures.

Criteria used by the industry to measure LASIK outcomes fail to include induced visual disturbances, dry eyes, pathologic changes to the cornea and the psychological impact of a poor result.

Patients are denied the whole truth about the negative effects of LASIK; therefore, they are unable to give informed consent. The LASIK industry has been unresponsive to medical research findings, which should have resulted in a higher standard of care. Instead, LASIK surgeons have resisted raising the standard of care in order to maintain the potential pool of candidates and to protect themselves from liability.

The American Medical Association endorses certain principles of medical ethics. One principle states that: “A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.” (<http://www.ama-assn.org/ama/pub/category/2512.html>). The white wall of silence called for by Dr. Marguerite McDonald in 1999 violates this principle.

There has been and continues to be a pattern within the refractive surgery industry placing patients’ interests secondary to financial interests. Physicians are ethically bound to put the best interests of patients first. LASIK is an unnecessary surgical procedure that permanently damages the eyes of every patient; therefore it is a violation of a primary doctrine of medicine, “First, do no harm.” As such, the practice of LASIK should be discontinued.

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