Cool Lasers and

How patients get hurt by LASIK surgery

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Make no mistake about it; Laser-Assisted *In Situ* Keratomileusis (LASIK) is big business. Many ophthalmologists, laser manufacturers, software engineers and medical device producers have a stake in this multibillion-dollar industry. More than 4 million people in the United States have undergone this "miracle" procedure in the past five years, with estimates that millions more will follow. LASIK is similar to cosmetic surgery in that it is elective, appeals to our vanity and involves the removal of normal, healthy tissue in an attempt to reshape our bodies. Touted as safe, this 10-minute procedure has swept the nation as baby boomers fend off the aging process. Also sweeping the nation is a new breed of refractive surgeons, the buccaneer ophthalmologists willing to take risks with patients' eyes in order to achieve quick and easy profits.

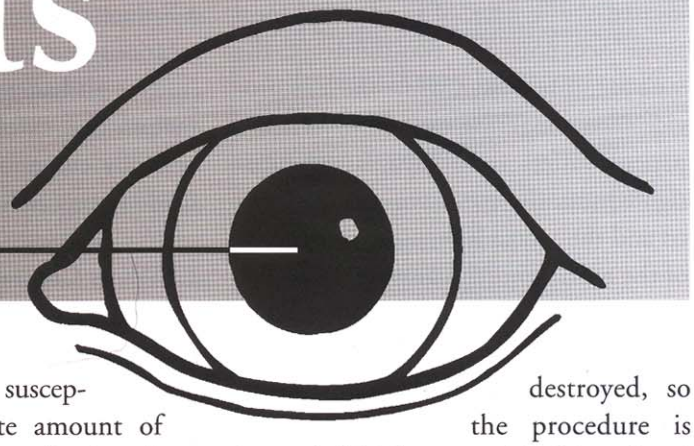
LASIK surgery was extensively marketed in the late 1990s as a guaranteed safe procedure with promises that one could "throw away contacts and glasses forever." The cost of LASIK surgery has dropped dramatically from $3,000 to as little $795 an eye. Radio, television and newsprint advertisements target audiences primarily espousing the cosmetic benefits and the improvement in visual acuity. In many ways the marketing of LASIK eye surgery is similar to the marketing of a product, not the practice of medicine.

LASIK surgical techniques were first pioneered in the late 1940s by Dr. Jose I. Barraquer, a South American surgeon who developed techniques to improve vision by surgically changing the shape of the eye. Using a small knife, known as a microkeratome, to slice layers of the cornea from the eye, Dr. Barraquer first froze, and then sculpted the pieces of corneal tissue. The newly shaped cornea was then sewn onto the patient's eyes, and, with amazing success, nearsightedness was essentially eliminated. Not surprisingly, Dr. Barraquer's technique had virtually no commercial success as his surgical procedure was not readily transferable to and mastered by other surgeons.

Beginning in the 1980s, Soviet ophthalmologists perfected radial keratotomy (RK) procedures in an effort to improve nearsighted vision. In RK, the ophthalmic surgeon uses a tiny scalpel to cut a series of spoke-like incisions around the center of the cornea to change the curvature and focusing power of the cornea. The problem with RK was that it was an imprecise art: The amount of correction varied by the skill of the surgeon, the depth and length of the cuts and the patient's unique corneal surface. Moreover, the refractive surgeons could not correct astigmatism, a common problem with nearsighted patients. The procedure, therefore, soon fell out of favor among refractive surgeons.

In the early 1990s, refractive surgeons turned to the excimer laser and developed a process known as photorefractive keratectomy (PRK). The excimer laser uses a concentrated beam of light to remove as little as .25 microns (a micron is 1/1000th of a millimeter and the diameter of human hair is typically 200 microns) of tissue with each pulse. Ablative photodecomposition, or abla-

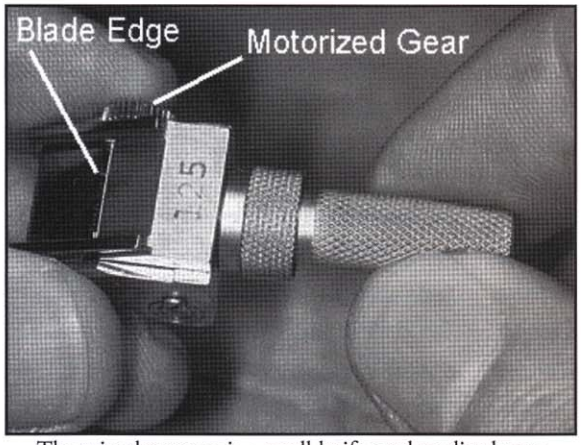
Hot Profits



tion, refers to the process of removing corneal tissue with an excimer laser. Ablation occurs when ultraviolet radiation reacts with organic molecules, resulting in a photochemical breakdown of the molecular bonds of the cornea. The excimer lasers rely on an argon-fluoride gas mixture to create an output wavelength of 193 nanometers.

Excimer lasers generate this cool, yet powerful beam of light and were first used in manufacturing and scientific applications. Because lasers offered more precision and could be controlled by a computer, refractive surgeons turned to the Excimer laser to obtain better surgical precision than what RK provided. However, PRK had its own problems, which were essentially twofold. First, in PRK, corneal tissue is removed from the top of the cornea, which is very painful for patients. Second, patients were susceptible to an inordinate amount of infections and other complications from the procedure.

As an alternative to PRK, the refractive surgery industry combined the techniques first pioneered by Dr. Barraquer in the 1940s with the excimer laser. Thus, LASIK surgery was born. In LASIK, the surgeon creates a small, shallow flap of tissue on the cornea. Unlike Dr. Barraquer's technique, either a nasal or superior flap is created on the top of the cornea. The flap is lifted and the excimer laser ablates the corneal tissue changing focus power of the eye. After the procedure the flap is put in place, and, in most cases, the patient's vision is improved. LASIK surgery can treat nearsightedness, farsightedness and astigmatism.



The microkeratome is a small knife used to slice layers of the cornea from the eye.

What Is LASIK?

In LASIK, a computer-controlled laser beam ablates corneal tissue following preprogrammed patient refractive information and algorithms developed by the surgeon and laser manufacturer. Unlike radial keratotomy the surgical outcome is no longer dependent on the surgeon's skill. Unlike PRK the top layer of cells—the epithelial cells—of the cornea are not being destroyed, so the procedure is less painful. The corneal bed is sculpted by the laser changing its contour and its refractive power. By limiting the amount of trauma to the surface of the cornea, surgeons avoid the incidents of infection and scarring and provide greater visual results. The creation of the flap can result in its own complications, such as a deep flap, short flap, debris, wrinkles and infections.

The microkeratome is used to create the flap is similar to a carpenter's plane. The cutting blade runs along a track and is connected to a suction ring. The suction ring is attached to the eyeball. After creating the cut, the flap is lifted, the underlying bed is exposed to the excimer laser and, if all goes well, the flap is replaced, smoothed out, aligned and heals without complications. It is common for some patients to undergo some enhancements that actually require the ablation of additional corneal tissue to fine tune the results.

How the Eye Works

In order to understand LASIK and evaluate potential malpractice claims, trial lawyers need a fundamental understanding of the anatomy of the eye. The cornea is located at the front where light first enters the eye. The cornea and the lens of the eye work together to focus

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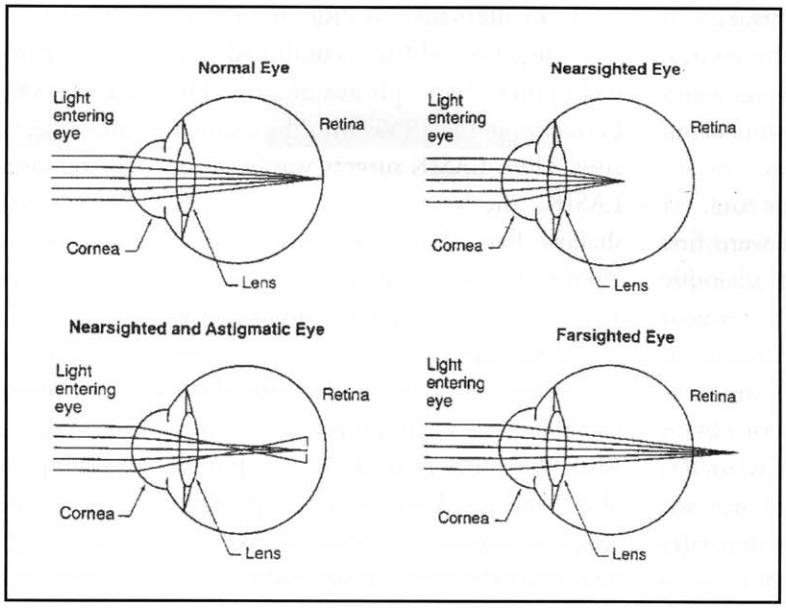
light like a camera lens onto the retina located at the back of the eye. Corneal tissue accounts for two-thirds of the eye's focusing power, while the lens provides the remaining one-third. When a patient suffers from myopia, or nearsightedness, the eye is typically elongated and the image is focused in the front of the retina. Individuals who suffer farsightedness, or hyperopia, have a flatter eyeball and the image is focused behind the retina. With astigmatism, the image is not focused to a single point on the retina, but the light rays are divided into two parts that focus along two lines.

Notice, in the diagram on this page, that the shape of a normal cornea is oblate like an egg. With astigmatism, the curvature of the eye is unequal, and the point source of light cannot be brought into a point focus on the retina, rather it spreads over a more diffuse area. In portraying astigmatism, many surgeons describe astigmatic cornea as more akin to the shape of a football rather than an egg. The eye is a rather complex organ and the fields of ophthalmology and optometry are likewise complex. Refraction involves mathematics; optometrists and ophthalmologists use their own language and LASIK entails familiarity with laser physics and anatomical variations of the cornea. No doubt this field can be intimidating.



With astigmatism, nearsightedness and farsightedness, the light entering the eye has a different focus point than a normal eye.

LASIK Malpractice Cases

Most injuries caused during LASIK surgery can be divided into five major categories:

- LASIK is contraindicated for the patient.
- Surgeon error.
- Equipment malfunction.
- Failure to obtain informed consent.
- Failure to treat postoperative complications in a timely manner.

Not all bad results are good LASIK malpractice cases. Each case must be carefully evaluated before a decision is made to proceed with litigation.

LASIK Is Contraindicated for the Patient

Improper candidacy involves any situation where the preexisting eye condition of the patient does not lend itself to LASIK surgery. For example, patients with eye diseases such as keratoconus or who have a history of retinal detachments are universally considered to be poor candidates for LASIK surgery. Other disqualifying facts include large pupils, corneas that are too thin or other eye diseases affecting the cornea. Many times a thorough eye examination prior to LASIK surgery will determine the absolute or relative contraindications, and surgery will not be performed. However, it has been our experience that there are a number of refractive surgeons that are willing to push the limits and take risks with their patient's eyesight and perform surgery despite the contraindications. Some patients' pupils are too large for LASIK. Current ablation zones range anywhere from 6.5 to 7.5 millimeters (mm). If a patient's pupils dilate in dim light to a size greater than the ablation zone, the patient is at risk of suffering from severe visual aberrations. A normal pupil is usually 6 mm in dim light, and early excimer lasers created an elliptical ablation zone of 6 mm by 4.5 mm. If a pupil is larger than 6 mm, the peripheral scar of the flap and ablation zone could be within the line of sight, creating a disruption in vision.

The average cornea is 500 microns thick. The ordinary flap created by the microkeratome is between 160 and 180 microns thick (the approximate diameter of a human hair) and the laser ablation ranges between 30 to 100 microns below the flap. Most surgeons agree that it is imperative to leave at least 250 microns of corneal bed to preserve the structural integrity of the cornea. If the surgeon either cuts or ablates below 250 microns, the patient runs a dangerous risk of experiencing disabling eye conditions such as ectasia and may suffer damage to the endothelial cells on the cornea.

Surgeon Error

In some cases the surgeon's poor technique results in a poorly aligned corneal flap or flap wrinkles. On occasion, patients experience corneal infections caused by the surgeon cutting into the cornea with the microkeratome. In these cases, prompt action is required on the part of the surgeon to prevent permanent damage to the cornea and the patient's visual acuity.

In other cases, the surgeon misprogrammed the laser causing the permanent removal of tissue and permanent damage to the eye. Keep in mind that once the laser is started, it works automatically according to the information programmed into it by the surgeon. While the ophthalmologist has the exclusive responsibility over programming the laser, once the procedure begins the surgeon's involvement with the procedure is actually minimal and he is relegated to simply holding onto a joy stick and a foot pedal making sure that the eye remains properly aligned and the beam fires appropriately.

Equipment Malfunction

Sometimes the microkeratome fails. This can result in a deep flap, which could result in a catastrophic penetration into the anterior chamber of the eye. Other flap irregularities, such as short flaps, buttonhole flaps and free caps can result from improperly maintained equipment. The microkeratome is a delicate surgical instrument requiring careful cleaning and maintenance between procedures and surgery days. Oftentimes, the skill of the surgeon's medical staff is limited and proper care of the surgical instruments is not maintained.

Informed Consent

Following LASIK some patients will complain of star bursts, loss of vision, discomfort, difficulty with night driving, glare, halos, loss of contrast sensitivity and other visual aberrations. Our experience is that many surgeons' informed consent forms warn the LASIK candidates about many of these visual aberrations. Unlike other cases involving informed consent, LASIK cases are, arguably, much different. LASIK is big business and extensive marketing campaigns are being used by refractive surgeons. It is important to carefully uncover all of the various advertising and promotional materials used by the surgeon and relied on by the patient. In one case, our client was shown and relied upon a statistic that touted "100%" chance of achieving 20/40 vision. Our client now needs a corneal transplant.

The advertising campaign and marketing of a LASIK surgeon should be carefully examined if the surgeon's informed consent form is to be overcome. Most of the forms we have seen are multi-paged and quite extensive, listing all of the known complications, including blindness. As part of the informed consent process, and usually just before the patient is asked to sign the consent form, LASIK surgeons show a videotape that shows minimal risk and greatly highlights the procedure. Some refractive surgeons engage in seminars that are closely analogous to spiritual revivals where the "miracle" of LASIK is performed by the surgeon in front of an audience. While most of the focus is on the benefits of the procedure, very little explanation is given of the risks. When the risks are explained, it commonly occurs on the day of surgery and, in several cases, when the patient was under the influence of a sedative given to relieve the anxiety of the surgery. The failure to provide adequate informed consent in LASIK cases can be proven if the entire advertising and marketing program is put into context with the customary informed consent process.

Failure to Treat Post-operative Complications

By its very nature, LASIK surgery involves iatrogenic trauma to the cornea. This trauma can result in certain, and medically acceptable, complications such as flap folds, wrinkles, striae and infections. Prompt medical management of these problems is imperative to prevent further and permanent damage to the cornea. Oftentimes, the first day post-operative examinations are performed by a technician or a surgeon who may not take the time to conduct a complete examination.

With the emergence of intensive marketing of LASIK surgery, many patients look to this simple procedure as a cure-all from the hassles of glasses and contact lenses. In the hands of a skilled, careful and compassionate surgeon, a properly screened patient, knowledgeable of all the risks, should be satisfied with the results.

Unfortunately, not all surgeons are careful and not all patients are fully informed of the risks they face with their eyesight. While the patients' expectations are often high, the vexing difference between what was promised and what was delivered by LASIK may yield a good malpractice case.

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