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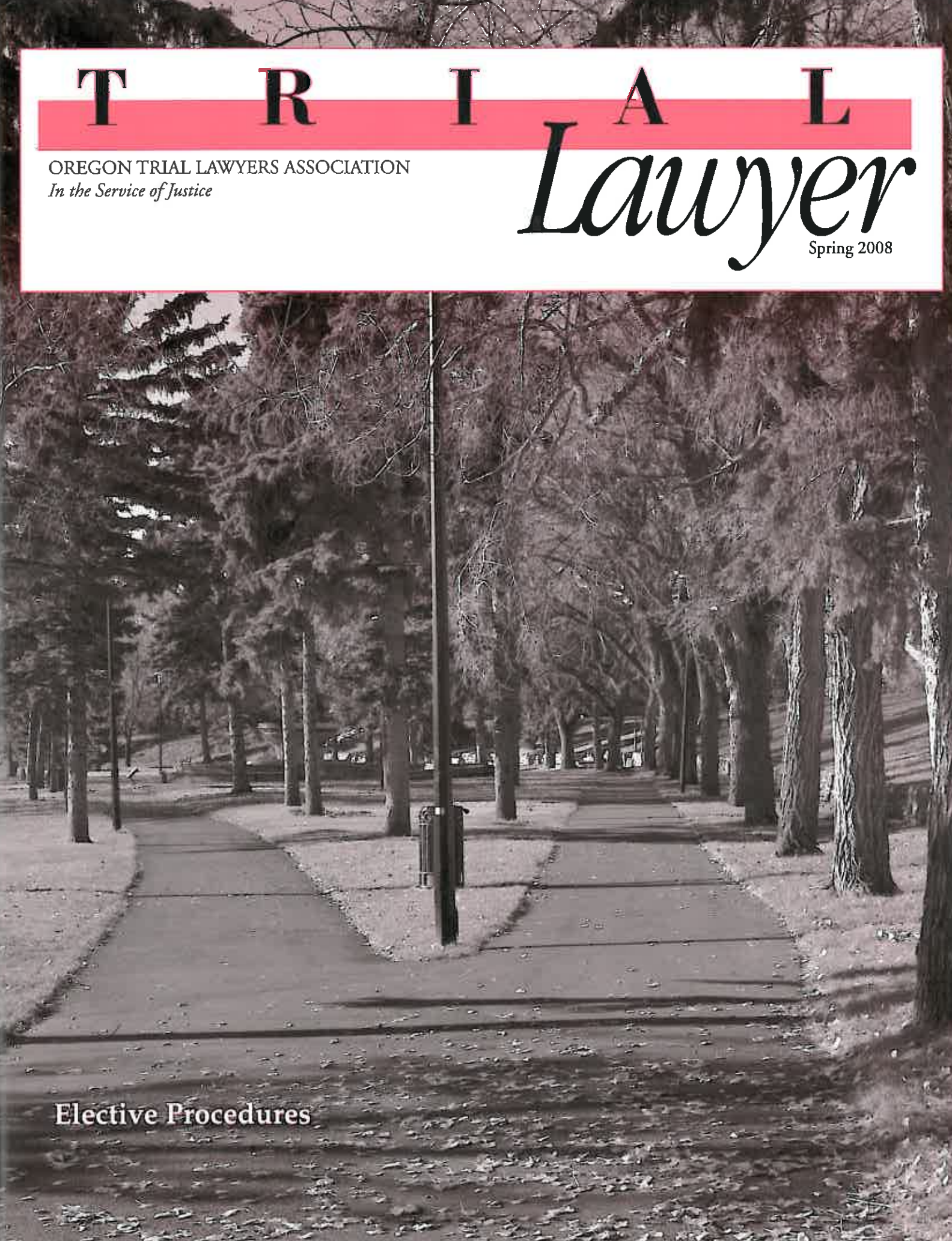
Spring 2008



## Elective Procedures

Taking a hard look at the benefits and risks of Lasik eye surgery

# 20/20 Foresight

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*By Greg Zeuthen*
*OTLA President's Club*

Eight years ago I met Brenda Ross, a young mother who was looking for a lawyer after a botched Lasik surgery severely damaged her right eye. Brenda sought out Lasik surgery so she wouldn't have to wear contacts any more. She enjoyed swimming and water sports. Contact lenses restricted her ability to be physically active with her family. Brenda sought a local Portland-area surgeon to perform her surgery. Unfortunately, the surgeon rushed through her operation and ignored critical signs that her surgery would likely end in failure. In discovery we learned the surgeon was motivated by profit to push through as many patients as possible. A medical device was not properly assembled and it cut deeply into Brenda's eye. She suffered permanent damage and distortion of vision. To make matters worse, she learned that she never was a good candidate for surgery in the first place and her physician failed to tell her.

Since first meeting Brenda in January 2000, co-counsel Lawrence Baron and I have represented over 70 refractive surgery clients. We have discovered an industry that at times is driven by high patient volume, low discount prices and poorly trained staff who are economically motivated to clear patients for surgery. With the recent proliferation of Lasik advertisements, we sadly expect more injuries.

The radio spots, newspaper ads and television commercials are pervasive: "Get your vision corrected in as little as 10 minutes." "It's as easy as a haircut." "20/20 vision—guaranteed." "Read without reading glasses." This hype promises the allure of instant vision correction while minimizing the risks of these medical procedures.

An estimated 1.3 million Americans had Laser assisted in-situ keratomileusis (Lasik) surgery in 2005. Today's advertising targets not only the younger generation, but also those with "older" eyes who suffer from the effects of presbyopia (loss of near vision). Since 1995 when the Food and Drug Administration (FDA) approved the first laser for refractive surgery, millions of Americans have undergone this elective procedure.

Refractive surgery alters the refractive power of the eye. The most well known of these procedures is Lasik, but there are actually a wide array of other refractive procedures, including Lasik, PRK, Lasek, Epi-Lasik and IntraLase®. Each of these procedures relies on a laser. Another refractive procedure, which uses radio wave energy, is Conductive Keratoplasty (CK). It was first approved by the FDA in 2002. CK offers treatment for presbyopia, which is a condition that everyone eventually develops that limits the ability of the eye to focus for near vision.

**Forms of refractive surgery**

Laser guided refractive surgery relies on an excimer laser to remove corneal tissue and reshape the eye to correct refractive errors. With Lasik, the surgeon cuts a flap on the cornea, lifts it away exposing the stroma, or central part of the cornea. The excimer laser removes as little as one-quarter of a micron (.00025 millimeters) with every pulse. When guided by a computer, the excimer laser sculpts the cornea with a high degree of accuracy.

To correct myopia (nearsightedness) the central cornea is flattened. To correct hyperopia (farsightedness), the central cornea remains untouched by the laser and the peripheral cornea is steepened. The first generation lasers approved by the FDA could only correct myopia

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(nearsightedness). In the late 1990s the FDA approved lasers capable of treating astigmatism and hyperopia (farsightedness). In 2002 and 2003, the FDA approved the first custom Lasik systems utilizing Wavefront technology.

In PRK, the excimer laser ablates the surface of the cornea as contrasted to Lasik, which ablates the inner layers of the cornea. In PRK, the surgeon may remove the outer layer either mechanically or with a laser in a process called "transepithelial ablation." The risks of PRK include corneal haze and a prolonged healing time.

Lasek is a modified form of PRK. The surgeon loosens and temporarily sets aside the outer cell layer of the cornea, the epithelium. Unlike PRK, the epithelium is not ablated in Lasek. Rather, the surgeon scrapes back the loosened epithelium so that the laser can reshape the exposed cornea. After the laser application, the surgeon replaces the epithelium over the corneal bed, and a bandage contact lens is used to protect it. Typically, the recovery time after Lasek is generally faster than in PRK but slower than in Lasik.

An Epi-Lasik procedure requires the surgeon to use an oscillating blade, called an epithelial separator, to separate the epithelium sheet from the rest of the cornea. Once the epithelium is removed, the laser ablates the cornea like a PRK or Lasik procedure. Epi-Lasik causes some discomfort, which is reportedly less than with PRK or Lasek.

A variation of the original Lasik surgery is IntraLase® method. Instead of using a metal blade to create a flap, or a scalpel to remove the epithelium, a laser is used to form a corneal flap. The IntraLase® laser moves across the cornea producing a uniform layer of bubbles in the stromal bed that becomes the flap interface. The surgeon pulls back the flap and ablates the stromal tissue just like a regular Lasik surgery. IntraLase® creates a precise flap, leaving a smooth surface for the application of the laser energy that reshapes the cornea. The IntraLase® method eliminates the need for a mechanical microkeratome and reduces the incidence of severe flap complications.

**Conductive Keratoplasty**

Another form of refractive surgery is Conductive Keratoplasty, or CK for short. CK received FDA approval on March 16, 2002 to treat the effects of presbyopia. This procedure is indicated for the temporary reduction of farsightedness in patients older than 40 years of age.

Patients who undergo CK have monovision, which means one eye, usually the dominant eye, is primarily for distance vision, and the other eye is corrected for near vision. In a CK procedure, heat is generated by radio energy and applied to the non-dominant cornea in a radial fashion in the periphery of the cornea. The heat causes the cornea to contract, steepening the central cornea.

CK provides only temporary correction, a fact oftentimes lost on patients. It will not improve near reading vision on a permanent basis. The duration of treatment is dependent upon whether the patient's presbyopia continues to progress and how long it takes the cornea to revert to its original shape after CK. This means either a future re-treatment, or the patient will need reading glasses for near vision.

**Wavefront aberrations**

Corneal imperfections are referred to as Wavefront aberrations, which prevent light from focusing perfectly on the retina. There are two kinds of Wavefront aberrations: lower order and higher order aberrations. Lower order aberrations consist of myopia, hyperopia and astigmatism. These lower order aberrations are typically correctible with glasses and contact lenses.

It was not until this past decade that ophthalmologists have been able to objectively measure Wavefront aberrations in the human eye. One example of a Wavefront device is the Hartmann-Shack Wavefront sensor that is used in the Visx laser system. To measure imperfections, a laser beam is focused to a point on the retina. The emerging beam is measured and captured by a video camera. The pattern is compared to an aberration-free beam, and the Wavefront is computed from the difference between the sampling and the aberration-free beam.

The frequently used higher order aberrations are spherical aberrations, trefoil, defocus and coma. These aberrations describe various imperfections on the cornea and are described by mathematical formulas known as Zernike polynomials. A Wavefront analysis is displayed on a color printout that is usually placed into the patient's chart.

The ability to measure higher order aberrations has led to the development of Wavefront guided laser systems. These systems use the data from the Wavefront sensor to provide a computer-guided patient-specific ablation profile.

These lasers create smooth ablations, addressing the microscopic corneal deviations associated with aberration errors. Today, most Lasik surgery performed in the United States involves Wavefront technology for the treatment of both lower and higher order aberrations.

However, even this technology is only as good as the people who operate the machine. Angular misalignment of the patient at the time of the scan may result in significant variance of Wavefront values and an accurate reading is dependent on the clinician's skills. Notably, as one study revealed, the skills of the technician are particularly "important in the assessment of highly aberrated eyes, which are perhaps those most likely to benefit from customized ablation procedures."

**Types of refractive surgery cases**

Most injuries caused during refractive surgery can be divided into four major categories:

- Contraindications for surgery
- Surgeon error
- Equipment malfunction
- Failure to treat postoperative complications in a timely manner

As in every medical malpractice case, a bad result does not mean there was negligence. Each case must be carefully evaluated before a decision is made to proceed with litigation.

**Contraindications for surgery**

Many potential patients are poor candidates for Lasik surgery. For example, patients with eye diseases such as keratoconus, corneal dystrophies or retinal detachments are universally considered to be poor candidates for Lasik surgery.

Other disqualifying facts include large pupils, thin corneas, dry eye, amblyopia and strabismus. While many good ophthalmologists conduct a thorough eye exam prior to surgery, some refractive surgeons are willing to push the limits and take risks with a patient's eyesight, performing surgery despite contraindications.

**Keratoconus**

Keratoconus is a non-inflammatory corneal thinning that reduces vision as a result of irregular myopic astigmatism and corneal scarring. Keratoconus and related disorders such as keratoconus suspect and Pellucid Marginal degeneration are contraindications to refractive surgery.

With keratoconus, the cornea slowly bulges into a cone-like shape, hence the name. While advanced stages of keratoconus are easy to see, even with the untrained eye, early and mild forms of the disease are detectable only by examination of corneal topography. Before any refractive surgery the surgeon is supposed to map the eye with a topography machine, which measures the shape of a cornea.

In a simplistic sense, the surgeon looks for symmetry between the nasal and temporal, and inferior and superior portions of the cornea. Asymmetrical inferior steepening (depicted in reddish colors) is a sign that the patient may be suffering from a corneal disease which is contraindicated for refractive surgery. Topographies reveal subtle corneal changes which foreshadow the subclinical disease process. In every refractive surgery case, it is incumbent on the lawyer to obtain all pre- and postoperative color topographies and scans.

*Despite being broadly marketed, many people are not good candidates for Lasik.*

One of the largest verdicts in the country involved keratoconus. A New York jury awarded the plaintiff significant damages because he lost his career as an investment banker. His vision deteriorated because the Lasik surgeon failed to note the preoperative topographies were suspicious for keratoconus.

**The corneas are too thin**

Some patients should not have refractive surgery because their corneas are too thin. Most surgeons agree that it is imperative to leave at least 250 microns of corneal bed to preserve the structural integrity of the cornea. Before performing surgery, the ophthalmologist obtains an ultrasonic pachymetry reading of the corneal depth. By simple subtraction of the anticipated flap thickness and anticipated laser ablation from the corneal thickness measurement, the ophthalmologist can quickly determine whether the 250 micron rule will be violated. If the surgeon either cuts or ablates below 250 microns, the patient runs a dangerous risk of experiencing ectasia, a disabling eye condition that could result in a corneal transplant.

**Large pupils**

Some patients' pupils are too large for refractive surgery. In one case we prosecuted in King County Superior Court, we established our clients large 7 mm pupils were a contraindication to surgery because the corrective zoned of the laser was less than 6 mm. Current ablation zones range anywhere from 6.5 to 7.5 millimeters. However, if a patient's pupils dilate in dim light to a size greater than the ablation zone, there is a risk of suffering from severe visual aberrations. Thus the trend has been to manufacture lasers with larger ablation zones. However, larger ablation zones come with a cost. As the size of the ablation zone is doubled, the ablation depth increases four-fold. A smaller zone decreases depth.

Some surgeons are able to compensate for a thin cornea by reducing the ablation

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diameter so as not to violate the 250 micron rule. But the trade-off is smaller optical zone correction that may affect visual quality in a patient with larger pupils.

Whether a large pupil size and small ablation zone creates visual disturbances is by no means settled. There is heated disagreement among ophthalmologists as to whether a large pupil and a smaller ablation zone can cause visual aberrations.

**Evaluation by optometrists**

A surgeon is supposed to evaluate the patient prior to surgery. Unfortunately, that is not always the case. In one recent case, the task of preoperative evaluation was delegated to an optometrist with little experience. The optometrist, a recent graduate from optometry school, worked in a satellite clinic and did not have the benefit of the surgeon's advice before clearing the patient for surgery. In fact, the patient should have been rejected outright as a surgical candidate. On the day of surgery the surgeon failed to thoroughly review the chart and performed only a cursory ocular examination. The patient ultimately needed bilateral corneal transplants. In proving liability in that case, a policy statement from the American Academy of Ophthalmology (AAO) was helpful:

> The best interest of the preoperative patient is served by preoperative evaluation by the operating surgeon. Ethical and quality of care standards are met only if the individual patient's needs are addressed…*It is the ophthalmologist's responsibility to provide 'quality control,' prospectively, in the preoperative assessment.* (Emphasis added)

**Surgeon error**

In some cases the surgeon's inadequate technique results in a poorly aligned corneal flap, flap wrinkles or a decentered ablation. 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.

One of the most egregious cases we prosecuted involved a young nursing student who wanted to treat herself to Lasik surgery as a graduation present to herself. She did not realize the surgery center was owned by optometrists who performed all of the pre-surgical and surgical calculations, including the preoperative work-up, the preparation of the surgery plan and the data input into the laser. The surgeon's role was limited to a brief two or three minute interaction with the patient prior to surgery. The client's data was incorrectly added to the laser and she received 10 times too much laser energy to her corneas.

In a Eugene case tried in 2002, our client, Leo Morin, had the wrong angle of astigmatism was entered into the laser. Leo still struggles with his eyesight. He relies mostly on his right eye for vision as his left eye produces what he describes as "a dozen double images." In artificial light, Leo says he sees about 40 percent of what he could see prior to his surgery.

While the ophthalmologist has the ultimate 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.

When a misprogramming error is suspected it is important to look at the preoperative refraction and compare it to what was actually programmed into the laser.

**Equipment malfunction**

Sometimes the microkeratome fails. Instead of a flap of 180 microns, a deeper cut than intended is created that could result in a catastrophic penetration into the anterior chamber of the eye. Other flap complications, 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.

In one case, we were able to prove the surgeon's inexperienced staff failed to properly care for the microkeratome and the surgeon ignored warnings that the microkeratome was not being properly assembled before each surgery.

**Failure to treat complications**

By its very nature, Lasik surgery involves trauma to the cornea. This trauma may result in certain, yet medically acceptable, complications such as flap folds, wrinkles, striae, epithelial ingrowth 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, not the surgeon, so some of these early and easily correctible complications are missed.

In some high volume clinics the surgeon does not see the patients post-operatively. Instead, that task is delegated to optometrists and ophthalmic assistants. In several cases the surgeon was unavailable for post-operative evaluation because he was too busy with other surgeries. Another AAO policy statement is on point. In part, the policy states:

> In all cases, of course, the law imposes special obligations on the operating ophthalmologist who does not provide postoperative medical care. If these obligations are not met, the ophthalmologist risks

liability for patient injury, including injury resulting from the acts or omissions of others to whom the provision of postoperative care is inappropriately delegated, or for inadequate patient informed consent, or both.

In general, a physician's failure to provide postoperative medical care may be considered 'abandonment' of the patient at the operating room door. This is the effect of the ophthalmologist's failure to provide, or make reasonable arrangements for the competent provision of, postoperative medical care throughout the patient's episode of illness.

**Informed consent**

In every malpractice case you should evaluate whether the patient gave the surgeon informed consent to the surgery. Our experience has been that nearly every patient is told they are a great candidate even when they are not. The patients who are most attracted to the procedure — that is those with the worst eyesight — are likely to be the worst candidates for refractive surgery. These patients are nevertheless told they are "ideal" or "perfect" candidates. Again the AAO policy provides helpful guidance:

> It is incumbent upon the physician *to assume the role of patient advocate* by assuring the appropriateness, effectiveness, and reliability of the proposed procedures, *and sharing this information with the patient*. (Emphasis added)

Unlike other medical malpractice cases involving informed consent, refractive surgery cases are, arguably, much different. The Lasik industry has engaged in extensive marketing campaigns to sell the product. It is vitally important to uncover all of the various advertising and promotional materials used by the surgeon and relied on by the patient. In one of my first Lasik cases, the client was shown, and relied upon, a statistic that touted "100 percent" chance of achieving 20/40 vision. That 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 refractive surgery consent forms 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, many Lasik surgeons show a video tape that greatly minimizes any risk, and greatly highlights the procedure.

Some surgeons hold "seminars" that are akin to spiritual revivals where the "miracle" of refractive surgery is performed by the surgeon in front of an audience. In one of our cases, the surgeon held a group informed consent discussion with five patients shortly before performing surgery on them.

*The patients who are most attracted to the procedure — that is those with the worst eyesight — are likely to be the worst candidates for refractive surgery.*

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.

Informed consent cases are generally difficult to prove. Howerver, refractive surgery cases are generally a little easier when the customary informed consent process is put into context with the positive spin of the advertising and marketing program.

**Proving visual losses**

With current technology, a client's visual losses can be explained and objectively illustrated with Wavefront scans and photographs depicting what the client actually sees. Wavefront scans and other topographical scans, including Humphrey topography and Orbscans, objectively measure the corneal surface. When asymmetry of the corneal surface is evident in the scans, the expert or treating doctor can easily explain the visual difficulties experienced by the client. Moreover, Wavefront scans can be used to create trial exhibits to demonstrate a patient's visual deficits following laser surgery.

In a 2006 trial in Minnesota, AAJ member Michael A. Zimmer used various digitally produced photographs to demonstrate how well his client could see at night. Plaintiff frequently drove on dark roads at night in the Duluth area, and oncoming headlights posed a particular problem to him. That case resulted in a plaintiff's verdict, most of which was noneconomic damages.

**Conclusion**

With the emergence of intensive marketing of refractive 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 to their eyesight.

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