April-May 2007 Number 519

JOURNAL

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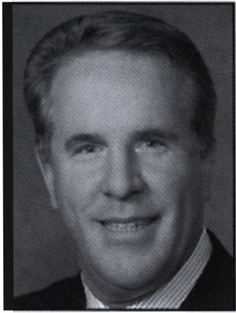

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Riding the Wavefront— An Update on Refractive Surgery Litigation©

The radio spots, newspaper ads and television commercials are pervasive and, in recent months, have increased in frequency: "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.[1] 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.[2,3]

This paper reviews the current trends in refractive surgery litigation, discussing the different types of refractive surgery and how newer technology can be used to help the trial lawyer in evaluating and preparing a case.

Refractive surgery is any type of surgery that 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) 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.[4] 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 (nearsightedness). However, in the late 1990's the FDA approved lasers capable of treating astigmatism and hyperopia (farsightedness).[5] 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, in which the inside of the cornea—the stroma—is ablated. 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 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 laser application, the surgeon replaces the epithelium over the corneal bed. After surgery, a bandage contact lens is placed over the eye 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 which 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

A form of refractive surgery which does not utilize an excimer laser is Conductive Keratoplasty, or CK for short. CK received FDA approval on March 16, 2002, to treat the effects of presbyopia.[6] 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 used primarily for distance vision, and the other eye is used for near vision. In a CK procedure, heat is generated by radio energy and applied to the cornea in a radial fashion around the periphery. The heat causes the cornea to contract, steepening the central cornea. What many patients do not fully appreciate is that CK provides only temporary correction. 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 to revert to reading glasses.

Monovision is also an option in Lasik procedures for middle-aged patients. The non-dominant eye is slightly undercorrected in a myopic treatment giving near vision in that eye. The dominant eye is fully corrected for distance vision.

Wavefront Aberrations

Corneal imperfections are referred to as Wavefront aberrations. These aberrations prevent light from focusing perfectly on the retina, resulting in a loss of visual quality. There are two kinds of Wavefront aberrations: lower order and higher order aberrations. Lower order aberrations consist of myopia, hyperopia and astigmatism. These types of aberrations are measured with a foreopter, a device used by all optometrists and ophthalmologists. The lower order aberrations are 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[7] which is used in the Visx laser system.[8] 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.[9]

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. See Figures 1 and 2 for a comparison between two Wavefront measurement technologies.

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.[10] 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. As a recent study suggests, angular misalignment can result in *significant* variance of Wavefront values and an accurate reading is dependent on the clinician's skills. The study concludes that 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."[11]

Types of Refractive Surgery Cases

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

1) Contraindications for surgery;
2) Surgeon error;
3) Equipment malfunction;
4) Failure to obtain informed consent; and
5) 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 Refractive 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 their patient's eyesight, performing surgery despite contraindications.

One of the most common cases seen in this field involves the patient with keratoconus. Keratoconus is a non-inflammatory corneal thinning that reduces vision as a result of irregular myopic astigmatism and corneal scarring. The cornea slowly bulges into a cone-like shape, hence the name keratoconus. 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.[12] Before Lasik surgery a topography machine is used to measure 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 sub-clinical disease process. In every refractive surgery case, it is incumbent on the lawyer to obtain all pre- and postoperative color topographies and scans. See Figure 3 which is a preoperative topography of a 42-year-old patient who had Lasik surgery. In the patient's chart the actual topography is in color but is reproduced in black and white for this publication. The cornial asymmetry between the superior and inferior segments are evident by comparing the different shates of gray between the upper and lower cornea. The surgery accelerated the sub-clinical keratoconus condition resulting in the patient receiving bilateral corneal transplants.

Keratoconus and related diseases, such as Pellucid Marginal Degeneration, are considered contraindications to refractive surgery. In the normal population, the prevalence of keratoconus is approximately 1 in 2000. Experts opine that the prevalence of keratoconus in patients seeking refractive surgery is actually significantly higher, perhaps 1 in 500. I have represented a number of clients who had pre-operative corneal diseases who underwent Lasik surgery, and the long term treatment involved corneal transplants for the majority of them. These cases are significant because of the long term impact a corneal transplant has on earning capacity and quality of life.

One of the largest verdicts in the country involved keratoconus. In it, a New York jury awarded the plaintiff over $7M in 2005. The plaintiff lost his career as an investment banker due to the deterioration of his vision because the Lasik surgeon failed to note the preoperative topographies were suspicious for keratoconus. AAJ member Todd Krouner of New York represented the plaintiff. In July 2005, the jury awarded $2.75M for pain and suffering, and $4.5M for lost income.

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.

Some patients' pupils are too large for refractive surgery. Current ablation zones range anywhere from 6.5 to 7.5 millimeters. 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 millimeters in dim light, and most of the earlier excimer lasers created an elliptical ablation zone of 6 mm by 4.5 mm. If a pupil is larger than 6 millimeters, the ablation zone could be smaller than the pupil, creating a disruption in vision. However, larger ablation zones come with a cost. As the size of the ablation zone is doubled, the ablation depth increases four-fold. This principle is described by the Munnerlyn formula which mathematically explains the correlation between the ablation depth and the ablation zone. A larger ablation zone increases the ablation depth. A smaller zone decreases depth.[13] Some surgeons are able to compensate for a thin cornea by reducing the ablation 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 currently heated disagreement among ophthalmologists as to whether a large pupil and a smaller ablation zone can cause visual aberrations.[14]

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)[15]

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.

In several cases, the wrong prescription was programmed into the excimer laser, or the wrong angle of astigmatism was entered. 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. Where a mis-programming error is suspected it is important to look at the preoperative refraction and compare it to what was actually programmed into the laser. In one case, a young nursing student received ten times the laser energy because the surgeon and laser operator misread the location of a decimal point on the operative plan. The client was mildly nearsighted before surgery. Because of the surgeon's error she is now extremely farsighted.

Equipment Malfunction

Sometimes the microkeratome fails. Instead of a flap of 180 microns, a deeper cut than intended is created, which 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. Rather than slow the surgery schedule to investigate, the surgeon pressed on and our client suffered a deep cut into her cornea. Later, the surgeon hid the mishap from the patient and tried to cover up his mistake by altering medical records. In that case, the court allowed the plaintiff to pursue a claim for punitive damages against the surgeon.

Informed Consent

Some patients who are poor or marginal candidates are nevertheless told they are ideal candidates when, in fact, they are not. 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)[16]

Following Lasik some patients will complain of starbursts, discomfort, difficulty with night driving, glare, haloes, loss of contrast sensitivity and other visual aberrations. Many surgeons' informed consent forms warn patients of these potentially debilitating conditions. 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 analogous to spiritual revivals where the "miracle" of refractive surgery is performed by the surgeon in front of an audience. In one case, the surgeon simultaneously held an informed consent discussion in front of a number of patients shortly before performing surgery on them.

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 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. Again, the AAO has a policy statement on this point. In part, the policy is:

> 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.[17]

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. Figure 4 depicts a client's visual quality following Lasik surgery. This exhibit was created from the InterWave scan (Figure 2) with the help of the treating doctor. Figure 5 is a trial exhibit created with the assistance of a vision scientist.

In a 2006 trial in Minnesota, the 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 $3M verdict, of which all but $2,950 was non-economic 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. While often the patients' expectations are high, the difference between what was promised and what was actually delivered may result in a promising malpractice case.

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[1] From Lasik Surgery News, available at: http://lasiksurgerynews.com/news/eye-vision-statistics.shtml.

[2] For a list of which lasers were approved for refractive surgery, see the FDA website at: http://www.fda.gov/cdrh/LASIK/lasers.htm.

[3] See Lasik Surgery News, *supra*.

[4] To understand how refractive surgery works, a basic understanding of how the visual system works is necessary. The human eye consists of six essential parts: cornea; aqueous; pupil; lens; vitreous; and the retina. Refractive surgery, as noted above, aims to change the shape of the

cornea, which is the outermost section of the eye. The shape of the cornea accounts for nearly seventy percent of the focusing power in the human eye while the remaining thirty percent is performed by the lens. When the cornea and lens work perfectly in unison, the image falls on the surface of the retinal plane, giving crisp vision. In myopic individuals the image falls in front of the retinal plane, while the image falls behind the retinal plane in hyperopic individuals. In refractive surgery, the surgeon attempts to adjust the focus of light image so that it focuses precisely on the retina.

[5] FDA website, *supra*.

[6] See FDA Approval Order at FDA Approval Order: http://www.fda.gov/cdrh/pdf/P010018s005a.pdf

[7] American Academy of Ophthalmology, *Clinical Optics*, pages 237—242, (2006)

[8] See FDA approval letter for Visx Wavefront www.fda.gov/cdrh/pdf/p930016s016b.pdf.

[9] See Wavefront Customized Visual Correction: The Quest for Super Vision II, Krueger RR, Applegate RA, MacRae SM, Slack Incorporated (2004), page 41.

[10] American Academy of Ophthalmology, *supra*, page 241

[11] Cervino A, Hosking SL, Dunne MCM, Operator-induced errors in Hartmann-Shack wavefront sensing: Model eye study. *J Cataract Refract Surg*. 2007;33:115-121.

[12] Rabinowitz YS and McDonnell PJ, Computer-Assisted Corneal Topography in Keratoconus, *Refractive & Corneal Surgery*, November/December 1989; 5:400-408.

[13] The Art of LASIK. JJ Machat, SG Slade, LE Probst, eds. 2d ed. Page 33 Thorofare, NJ: Slack Inc, 1998.

[14] *Compare* Freedman KA, Brown SM, Mathew SM, et al, Pupil Size and The Ablation Zone in Laser Refractive Surgery: Considerations Based on Geometric Optics. *J Cataract Refract Surg*. 2003;29:1924—1931, and Schallhorn SC, Kaupp SE, Tanze DJ, et al. Pupil size and quality of vision after Lasik; *Ophthalmology*. 2003;110:1606—1614.

[15] American Academy of Ophthalmologists policy statement, "Pretreatment Assessment: Responsibilities of the Ophthalmologist" available at: http://www.aao.org/member/ethics/upload/PS Pretreatment Assessment 6.pdf.

[16] *Ibid*.

[17] American Academy of Ophthalmologists policy statement, "An Ophthalmologist's Duties Concerning Postoperative Care" available at: http://www.aao.org/member/policy/upload/An Ophthalmologists Duties 2006.pdf.

Note: You may find a color copy of these charts on our website at www.floridajusticeassociation.org

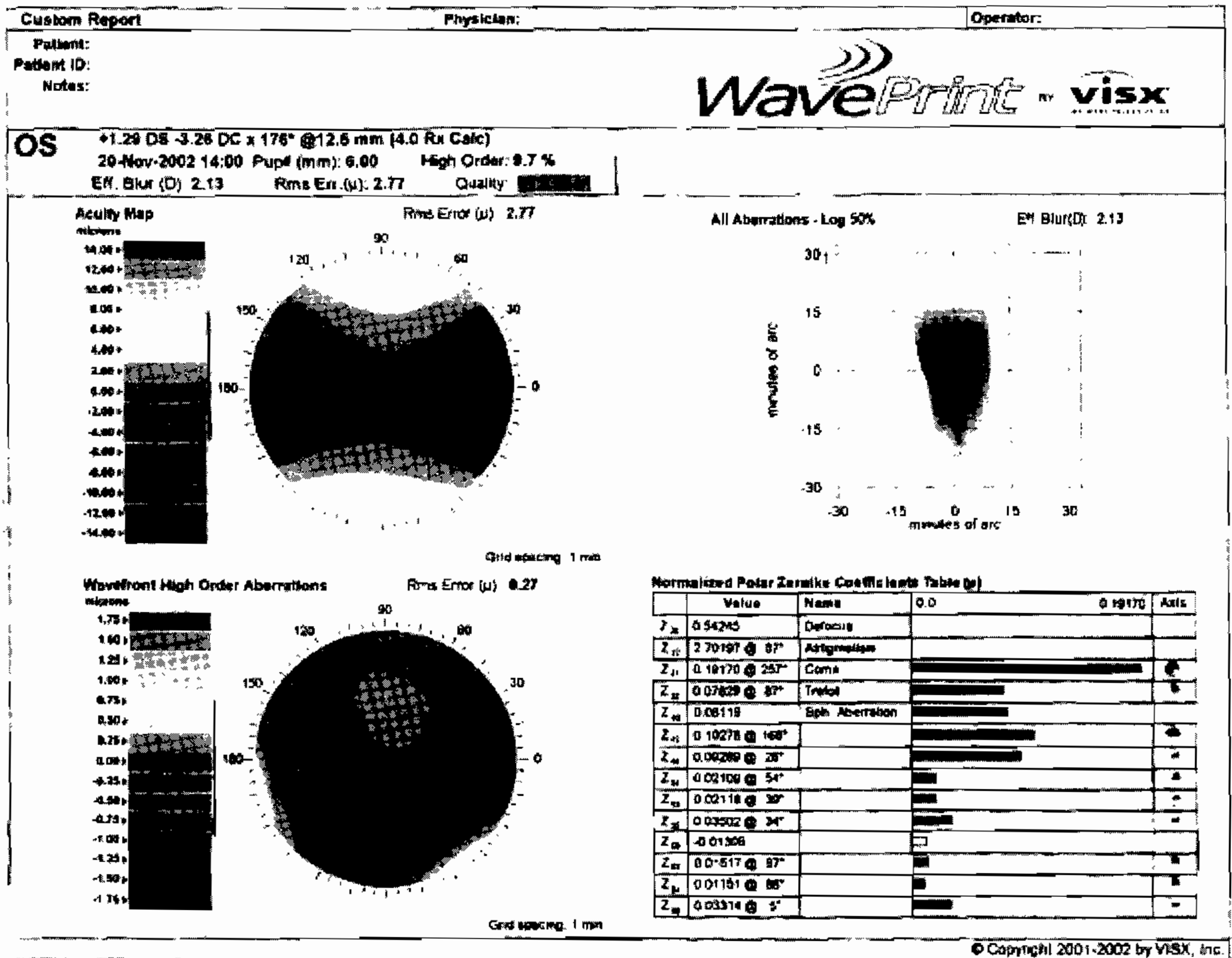

Figure 1. This printout is from a Visx Wavefront scan using Hartmann-Shack Wavefront sensor unit technology.