

# **The Promise of Refractive Surgery: A Promise Not Kept**

*An Insiders Journal on the Evolution and Misinformation of Refractive Surgery*

**Dedicated to:**

**And the thousands of others whose quality of life has suffered greatly as a result of believing the professionally communicated promise of refractive surgery**

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## INTRODUCTION

The practice of businesses selectively using information to market products is widespread. Selectivity is a critical tool in marketing. But is it ethical in the marketing of therapeutic products and/or services in healthcare? Isn't there more at stake when a manufacturer, a health system, and/or a health professional selectively uses information to move a medical or surgical therapy than when a business executive tries to move a product? Isn't the obligation to tell the truth heightened when something to treat and possibly alter a person's state of health is being proposed? Are not roles in healthcare clearly distinguished by their unique moral responsibility?

Unfortunately, the selective use of information in the marketing of healthcare products and services is rampant and growing. When I entered medicine years ago, the promise was to heal. Today, the promise of medicine has become money – to doctors, providers, and suppliers. This change in focus necessitates that we, as patients, more than ever, must take responsibility for our health.

But “Patient Power” in this changing landscape requires full knowledge, not a biased selection of facts. Knowledge that is unbiased, truthful, and complete. This puts the burden on the manufacturers, health systems, and healthcare professionals to provide patients with all unbiased, truthful information on expected costs, outcomes, and complications. Good, informed patient decisions cannot be made with selective information. Anything less than full disclosure is a disservice to the patient, the healthcare system, and society.

I have seen refractive surgery grow to 100,000 US procedures per year three years after 1978 introduction of RK (radial keratotomy). As long-term complications became known, it dropped to 30-40,000 procedures per year in the mid-1980's. RK was reinvented in the early 1990's emerging as “Mini-RK,” with shorter incisions and *enhancements*. It fell victim to laser based procedures in the mid-1990's with the FDA approval of PRK, and then, the off-label LASIK procedure. Laser based procedures, mainly on the strength of LASIK, topped out at 1½ million procedures per year in 2000.

My concern for the patient has also grown with the introduction of each new procedure and the increasing numbers of procedures. The accuracy, breadth, and depth of the information used to move patients to a decision have been deficient. Concerns and knowledge on both outcomes and complications by the medical community have not been fully disclosed to an unsuspecting public. This is unacceptable as these procedures are elective, cosmetic, and irreversible.

Defense lawyers and doctors will point to a signed “informed consent” as proof that the patient's are informed. But as you will learn, patients have been left out in the cold on key facts, and have been misled by clever copy. This began with the introduction of RK and has continued ever since. For instance, did RK patients, or even the more recent mini-RK patients, know that 40% of the corneas with RK after ten years were unstable and experienced progressive hyperopia? While evidence of these untoward outcomes were known in the late 1980's, they were not communicated to patients.

Refractive procedures, with one exception, are permanent and irreversible. While permanence, at first blush, appears to be a positive attribute, it has a dark side – permanent problems, permanent outcomes, and no upgrades. The so called permanent correction (outcome) will not be so pleasing as one ages since the optical system changes with age. The required visual correction at one point in life may not be the desired correction later. Upgrades to improved or newer ways to correct vision will be ruled out since most of the present procedures involve permanent changes to the corneal structure (permanent removal of tissue). Those opting for these procedures are locked-in. Imagine being locked into a clunky 1980 car phone with no chance to upgrade to a newer, smaller, portable, feature laden, cell phone.

I, like many who are interested, wear contact lenses and would like to be rid of them. But the question for me has always been *at what risk?* With what I know from surgeon's private hallway conversations, I prefer my contact lenses, and will have them for some time. I will get rid of contacts when something comes along with these proven attributes:

- minimal risk
- great vision
- no maintenance
- allows prescription changes as my visual system changes with age
- allows me to upgrade to newer procedures as they are introduced

- reasonably priced
- and allows me to undergo effective, proven therapies I may need as I age for glaucoma, cataracts(IOLs), and macular degeneration

Then I will put my contact lenses aside, and become an enthusiastic refractive surgery supporter and patient.

*"Letters to the Editor, Re: Corneal refractive power after myopic LASIK," Ophthalmology," September, 2003 (These letters refer to the difficulty of determining which IOL should be used in cataract surgery following LASIK. Since the cornea is now abnormal, there is some uncertainty on what should be done.)*

*Vahid Feiz, MD, Little Rock, Arkansas; Mark J. Mannis, MD, FACS, Sacramento, California*

"The recent article by Hamed et al<sup>1</sup> addresses an emerging problem that many ophthalmologists will be facing in the relatively near future. It has two main conclusions: (1) when manual keratometry and topography are used for intraocular lens (IOL) calculations after myopic LASIK, the power is underestimated, and (2) there is a direct, linear relationship between the degree of corneal refractive surgery and IOL power error as evidenced by regression analysis...What exactly is the source of error in determining true corneal power after keratorefractive surgery? The answer most commonly cited is the alteration in the relationship between the anterior and posterior corneal surface that results in a change in refractive index...In summary, the authors' conclusions and recommendations appear to verify the results of previously published studies.<sup>2,4</sup> The most accurate method of calculating IOL power *at this point* remains use of refractive change induced by LASIK and a *fudge factor* to compensate for the change in refractive index of the cornea. In doing so, the relationship between corneal power and refraction needs to be considered..."

*Douglas D. Koch, MD and Li Wang, MD, PhD, Houston, Texas*

"We enjoyed reading Drs. Feiz and Mannis' letter and welcome the study of new approaches for calculating intraocular lens (IOL) power in patients who have undergone LASIK and photorefractive keratectomy. However, we do not feel that their letter accurately characterizes their method or the current state of knowledge regarding this challenging problem..."

We are surprised by their comment that the clinical history method "still underestimated the IOL power." As they state in their article, *none of these methods has been tested in a clinical series...*Therefore, any comparative evaluation of these methods is purely speculation, pending further clinical study...the ultimate goal is the development of accurate methods of measuring true corneal power."

## REFRACTIVE SURGERY AND MISINFORMATION

Misinformation and hype in refractive surgery began with the introduction of RK and has followed a predictable pattern ever since. With the introduction of each new and/or improved procedure, the problems of older procedures, which were previously misrepresented or not even discussed, were made public. When "mini-RK," an "improved" RK procedure, emerged in the early 1990's, the real problems (and their probable incidence) of the "older RK" procedure were fully disclosed. The case for an improved procedure had to be made so that the new "mini-RK" would be adopted.

When the FDA approved PRK, the problems of the "mini-RK," heretofore denied, were now openly discussed in light of an even better procedure. When LASIK gained momentum in the late 1990's, PRK's problems, again accepted privately but previously denied publicly, were publicly discussed to move surgeons and patients to LASIK. And with the introduction of laser-based procedures, new stakeholders - optometrists, manufacturers and emerging commercial refractive chains - joined the refractive surgeons in misinformation and hype. The "refractive surgery industrial-medical complex" was born.

We are now moving into the era of Wavefront, IntraLASIK, LASEK, and various intraocular lenses. LASIK, which surgeons, optometrists, refractive surgery chains, and manufacturers just three short years ago said had "1 in 10,000 problems", "Throw your glasses away forever," and "100% of the outcomes are 20/20", etc., will now be beaten up with the unvarnished truth about its outcomes and complications. Unfortunately, the new and/or improved procedures will be marketed as LASIK was - with misinformation and hype. The truth on these newer procedures will emerge from the "refractive surgery industrial-medical complex" only when there is a need to obsolete them with "the next big thing". And pay close attention to the spokesperson

surgeons for the new procedures, they are the same people who hyped, with selective information, the procedures being abandoned.

Where have the Medical Societies been? Medical Societies need revenues to survive. They cease to exist without dues paying members and the financial support of industry. Industry provides financial support through medical journal advertising, medical meeting participation, and support to various causes vital to the member interests. Taking a stand, which can impact the revenues of an important member and industry group, can be difficult. One society did take a stand against RK in the early 1980's and suffered. A lawsuit was filed and was successfully litigated against this society for interfering with the commercialization of RK (free speech).

More recently in 2002, some surgeons, concerned with lawsuits, have discussed in their doctor-to-doctor web based chatrooms the blackballing of those doctors who serve as expert witnesses for plaintiffs. At the annual meeting of the American Academy of Ophthalmology in 2002, a Canadian surgeon, who testified in an Arizona malpractice case resulting in a \$4 million judgment, was accosted by fellow US surgeons. His mistake was testifying for the plaintiff. Remarkably, this doctor had changed his view saying that he mis-spoke under oath at the jury trial. The ruling has been set aside and the case is waiting to be retried.

Fear of retribution permeates the field of ophthalmology. Patient's, with legitimate malpractice issues, now have difficulty finding an "expert" surgeon who will testify on their behalf. Rather than taking responsibility, refractive surgeons are shifting guilt to the patient and to those trying to help the patient. Misplaced guilt is not restricted to business and politics!

And where has the FDA been? While the FDA can regulate manufacturers, they cannot regulate doctors. Physician advertising is the responsibility of the FTC. This complicates the communication of accurate, non-selective information as cross-jurisdictional responsibilities dilute the effort.

*"Vision Quest: Laser eye surgery has worked for millions but goes awry for 18,000 patients a year. A new approach aims to fix that." Mary Ellen Egan, Forbes, September 15, 2003, pg. 222.*

"...Two years ago Heinbockel had a new kind of eye surgery called wavefront, approved by the Food & Drug Administration in October 2002...Though some 3.7 million Americans have had successful surgery since 1995, problems such as night vision, cloudiness, glare and halos occur in about 3% of patients – upwards of 18,000 per year. The new wavefront approach reduces flaws to just 1% of cases and fixes vision problems LASIK cannot...The procedure costs about \$2,500 per eye, or 20% more than LASIK...But LASIK and wavefront are as different as ordering a suit off the rack and being fitted for a custom-tailored one... Thomas Wilson, 57, had two LASIK surgeries that left him with halos and night vision problems...His original LASIK doctors "thought I should be satisfied with my results," he fumes.

*"Lens-based refractive procedures offer advantages over LASIK," William F. Maloney, MD, Ocular Surgery News Europe/Asia Edition, September 2003*

"The limitations of LASIK and other keratorefractive procedures are increasingly difficult to ignore. The aberrations inherent in corneal reshaping methods simply do not always allow the accuracy and predictability most refractive surgery patients have come to expect.

Anatomical limitations (there is only so much cornea that can be ablated) combined with functional limitations (treatment zone vs. pupil size, etc.) have resulted in the realization that LASIK just cannot do it all, as many had hoped it would 5 years ago.

The steady reduction in the amount of ametropia that can be reliably corrected with corneal refractive techniques has left surgeons looking elsewhere...the IOL has clearly emerged to fill this void...

Lens-based refractive surgery also brings us back to basics, in the sense that surgical skill is a prerequisite to successful outcomes and satisfied patients. It seems to me that at least part of the appeal of LASIK and other corneal procedures was perhaps that they presented an opportunity to circumvent this basic issue, but this did not happen...

*"Ten-Year Results on Radial Keratotomy Released," National Eye Institute Information Office, NEI Press Release, October 13, 1994*

"...the study found that more than 40 percent of RK-operated eyes continued to have a gradual shift toward farsightedness. This finding suggests that some people who have RK may need glasses at an earlier age for poor close-up vision, a common problem after age 40, than if they had chosen not to have the surgery.

'Based on these findings, it may be that some people will be pleased with their vision shortly after having RK, but their opinion may change five, ten, or fifteen years down the road,' said Peter J. McDonnell, M.D., of the Doheny Eye Institute at the University of Southern California and the study's co-chairman.

Today's findings, published in *Archives of Ophthalmology*, were issued from the Prospective Evaluation of Radial Keratotomy (PERK). The PERK study is the first large, well-designed clinical study to evaluate the long-term effects of radial keratotomy on the eye and vision.

RK is performed to improve poor distance vision, called myopia, which affects millions of Americans. For some people with myopia, RK offers the prospect of good distance vision without the need for glasses or contact lenses.

The surgery changes the shape of the cornea, the clear, rounded tissue at the front of the eye. It is performed by making spoke-like, partial-thickness incisions into the healthy cornea. These wounds cause the cornea to flatten, producing clearer distance vision.

Today, about 250,000 RK surgeries are performed annually in the United States, up from 30,000 operations just five years ago. However, eye care professionals still have little scientific information about the procedure's long-term effects on the cornea and vision.

To provide these data, PERK clinicians periodically examined the eyes of the 435 participants since the study began in the early 1980s. Based on these examinations, researchers have published occasional reports in medical journals, including the results issued today.

At the PERK's 10-year mark, researchers reported that RK effectively reduced but did not completely eliminate myopia in all patients. They found that 53 percent of the RK-operated eyes registered 20/20 vision, while 85 percent of the eyes had 20/40 uncorrected vision or better (required for a driver's license in most states). Approximately 70 percent of study participants said they did not wear corrective lenses for distance vision at the 10-year mark.

RK also had "a reasonable margin of safety," resulting in few vision-threatening complications. However, the researchers noted that 3 percent of operated eyes had poorer distance vision with glasses one decade after surgery, although none had corrected vision worse than 20/30.

Interestingly, the PERK scientists reported that 43 percent of the RK-operated eyes continued to have a gradual change toward farsightedness, called hyperopic shift. In fact, 36 percent of the eyes had become farsighted at the 10-year point...According to the researchers, this shift was detected in some affected patients as soon as six months after surgery and continued to progress a decade later. They said they do not know when and if this change will cease in the future.

The scientists noted that the shift in vision was not related to the patient's age or post-surgical outcome. They added that they could not predict based on the PERK data which patients will develop the hyperopic shift. They did note, however, that the shift was more common in those who had RK surgery using longer incisions in the cornea, a common technique in younger and/or more myopic patients.

Participants (in this study) were examined before and after surgery at two weeks, three months, six months, annually for five years, and again at 10 years."

## **FUNDAMENTALS OF LASIK**

LASIK has inherent problems due to the nature of the procedure. These problems occur whether \$499 or \$5000 is paid for the procedure. It has been frustrating to observe the "refractive surgery industrial-medical complex" position the higher priced procedure as providing better outcomes and fewer complications. There are no unbiased scientific studies to support this.

### **LASIK's surgical landscape: the cornea**

Go to [www.surgicaleyes.org](http://www.surgicaleyes.org) for a complete description of LASIK and other refractive procedures.

The cornea, the part of the eye operated on during LASIK, is the front most tissue of the eye. It is normally transparent and does not contain blood vessels. The cornea is only 0.5 to 1 mm thick, and is generally

thinner centrally than peripherally. The cornea provides two-thirds of the eye's image focusing ("refracting") power. The other one-third is provided by the eye's internal lens, which is not involved in LASIK.

The cornea has five layers, and two of these are very important in LASIK. The outermost layer, the epithelium, is a highly sensitive tissue about six cells thick. It acts as a barrier between the inner eye and the outside world, much as skin does for the rest of the body. It also provides a smooth surface allowing light rays to pass into the eye without being distorted. The epithelium has a basement membrane that helps it to adhere to the cornea's middle layer, the stroma. If the epithelium and/or its basement membrane are abnormal, the cornea may not heal properly, and an irregular surface and/or scarring may result.

The cornea's middle layer, the stroma, is the layer at which most of the LASIK procedure is performed. The stroma accounts for about 90% of the cornea, and is made up mostly of water and layered narrow bands of collagen/protein fibers. These bands crisscross the cornea and are under tension, much like the rubber bands in golf balls. The stroma consists of about 500 layers of these bands. Scarring in this layer can result in loss of corneal transparency.

LASIK makes the stromal layer thinner by removing tissue, and cuts through the collagen bands, severing them, to the depth of the flap. These bands *never reconnect* making the cornea *both weaker and non-homogeneous*. Enhancements make the cornea thinner and sever more collagen/protein bands. The severing of the bands allows a surgeon to lift the flap years after the procedure. The cornea is sealed around the periphery (minimal risk of infection) *but never heals* to its original anatomy. One of the biggest unknowns is what happens over time to the weakened cornea. It is under constant outward pressure from the intra-ocular pressure in the eye. Mechanics of materials would suggest that the cutting of the collagen bands would be a prime suspect in a serious complication called ectasia. Ectasia is the bulging of the cornea outward, and leads to progressive hyperopia and/or serious complications that may lead to a corneal transplant.

*How many LASIK's would have been done if patients were informed that the flap never healed, that the cornea was no longer anatomically homogenous, that the cornea had been weakened considerably, and that the cornea was under constant outward stress due to intra-ocular pressure? How many patients know that this could lead to ectasia, an unnatural and unforgiving bulging of the cornea?*

[\*"Epithelial in-growth after laser in situ keratomileusis: a histopathologic study in human corneas," Naoumidi I. Et al. Archives of Ophthalmology, Volume 121, \(7\): 950-5, July 2003\*](#)

Corneal epithelial cells lose their characteristic morphologic features and eventually degrade in the metabolically "unusual" environment of the flap interface. Concurrently, a capsule of connective tissue similar to scar tissue forms, *separating them from healthy cornea*.

[\*"Histological and immunohistochemical findings after laser in situ keratomileusis in human corneas," Philipp WE, Speicher L, Gottinger W., J Cataract Refract Surgery, 2003;29\(4\):808-20.\*](#)

This study, conducted in Austria, described histopathological and immunohistochemical findings in human corneas after myopic laser in situ keratomileusis (LASIK), followed by iatrogenic keratectasia and after hyperopic LASIK...Researchers concluded that the *wound-healing response is generally poor after LASIK*, which may result in *significant weakening of the tensile strength of the cornea after myopic LASIK, probably due to bio-mechanically ineffective superficial lamella*. After LASIK in patients with high hyperopia, compensatory epithelial thickening in the annular mid-peripheral ablation zone might be partly responsible for regression.

[\*"Late-onset traumatic laser in situ keratomileusis \(LASIK\) flap Dehiscence," American Journal of Ophthalmology, April 2001\*](#)

"A 37-year-old male had bilateral laser in situ keratomileusis (LASIK) surgery performed on November 5, 1999 in Canada...On May 16, 2000 a tree branch snapped into his left eye...He noted an immediate decrease in vision and went to a local emergency room. The on-call ophthalmologist diagnosed a corneal flap dehiscence...Visual acuity, LE, was count fingers (CF at 6 inches)...the patients clinical status did not change over the next three months.

This case has several interesting clinical lessons. Patients often ask when the LASIK flap will be finally healed. *Since there is minimal wound healing except at the edges of the flap*, given enough force directed against the cornea, the flap may become dislodged months and even years after uneventful surgery. 1,2 1,2 Patients should be educated about this possibility and wear eye protection when performing potentially

hazardous activities...This patient originally had bw myopia and a photorefractive keratectomy (PRK) procedure would have been equally effective and obviously would not have led to this complication."

*"The Cornea is Not a Piece of Plastic," Cynthia Roberts, PhD, [Journal of Refractive Surgery](#), Volume 16, July/August 2000*

Page 409+. A conceptual model is presented in Figure 4 that predicts biomechanical flattening as a direct consequence of severed corneal lamellae. Rather than a piece of plastic, the cornea can be conceived as a series of stacked rubber bands (lamellae) with sponges between each layer (interlamellar spaces filled with extracellular matrix). The rubber bands are in tension, since there is a force pushing on them underneath (intraocular pressure), and the ends are held tightly by the limbus (the peripheral edge of the cornea where the clear cornea merges with the white of the eye). The amount of water that each sponge can hold is determined by how tautly the rubber bands are pulled. The more they are pulled, the greater the tension each carries, the more water is squeezed out of the interleaving sponges, and the smaller the interlamellar spacing. This is analogous to the preoperative condition in Figure 4A. After laser refractive surgery for myopia, a series of lamellae are severed centrally and removed, as shown in Figure 4B. The remaining peripheral segments relax, just like the taut rubber bands would relax once cut...This allows the periphery of the cornea to thicken.

Postoperative corneal shape, and thus visual performance, is a function of at least three factors: the ablation profile, the healing process, and the *biomechanical response of the cornea to a change in structure*.

[Letters, American Journal of Ophthalmology, Volume 130 Issue 2 \(August 2000\) Pages 258-259](#)

"In the interesting article by R Lin and RK Maloney (*Am J Ophthalmology*) 127:129–136, January 1999), they confirm earlier reports that flap-related complications after laser in situ keratomileusis (LASIK) occur in 5.0% to 8.7% of cases...

Complications continue to be reported after LASIK, including unexplained delayed-onset keratectasia after treatment of moderate myopia...These reports indicate that LASIK weakens the structural integrity of the cornea and that the list of complications is as yet incomplete.

We feel that fast and painless recovery after LASIK and the marginally better UCVA of 20/20 or greater may not outweigh the risks of this procedure in myopia less than -6.0 diopters..."

[Letters, by Brauweiler, MD, Wehler, MD, and Busin, \*Ophthalmology\*, September 1999, pgs 1651-1655.](#)

"It is my opinion that PRK and LASIK should not have been approved beyond 8.00 diopters. Beyond this limit many corneas will have had *too much stroma removed to allow long-term stable vision*. ...Carmen Barraquer responded that 100% of eyes that had undergone similar thinning technique, known as myopic keratomileusis lost effective correction (in many cases up to 50%) *over a twenty year period*...Essentially what this means is that all eyes over 8 diopters that have their corneas thinned by laser surgery will result in significant return of their myopia...the main purpose of this communication is to alert patients to ask their patients physicians *how much of their cornea is being removed before it is irreversibly vaporized*.

["Iatrogenic Keratectasia Following Myopic LASIK of Between <4 and 7 Dioptres," S. Percy Amoils, et al, \*Poster, Annual meeting of the American Cataract and Refractive Surgery Society, Seattle, Washington, April 1999\*](#)

"Results: The cases show *progressive ectasia that developed from 1 week to 27 months after LASIK*...Conclusions: *LASIK surgery can cause permanent weakening and ectasia of the cornea even in low myopia*...LASIK has certain intrinsic problems and the combination of incisional surgery and laser ablation has the potential for serious short and long term problems. *Thinning and thus weakening of the stromal bed as well as the minimum strength inherent in the flap are the causative factors for the development of keratectasia.*"

### **Asphericity and imaging of light rays on the retina**

Think of the eye as a camera. Parallel light rays enter the eye through the transparent cornea. The cornea (and the eye's internal lens) then focus the light rays in much the same manner that the lens of a camera would, by bending the light rays so that they come to a single clear focus at a specific distance. This process of bending light is called refracting. In a normal eye, the cornea focuses light at a distance that

produces a single sharp image on the retina, the neurosensory tissue that is akin to the film in a camera. Light rays that are bent too little or too much do not focus at the correct distance, and a blurred image results from this refractive error. How much or little a cornea refracts light depends on the cornea's curvature. That is why refractive surgery seeks to change the refracting power of the eye by changing the cornea's curvature.

In nearsightedness (myopia), the cornea is too steeply curved, giving it too much focusing power and causing light rays to focus before they reach the retina. In myopia, the eyeball itself may also be elongated, contributing to the problem of light focusing in front of instead of on the retina. Conventional spectacle or contact lenses seek to optically decrease the focal power of the cornea, and thus correct the myopia, by placing a concave spherical lens (a "minus lens") in front of the eye. LASIK seeks to achieve the same result by removing tissue from the central cornea, flattening the cornea's overall curvature and thus reducing the cornea's focusing power. Exactly the reverse is true in farsightedness (hyperopia). Astigmatism is different from myopia and hyperopia, and it can occur concurrently with either condition.

But changing the curvature of the cornea is not simplistic, as some make it out to be. The natural shape of the cornea is what the medical community calls *aspheric which means that it is steeper in the center and flatter in the periphery*. If one were to focus light rays from any angle outside the cornea, the aspheric shape would bend them so that they would fall in a small area on the back of the eye on the retina, called the "the center of least confusion." This small area acts like a data collection plate for our human computer, the brain. The more data (light rays) that get to this collection plate, the more data the brain has to process for good vision. Since laser procedures get their effect by flattening the center of the optical zone, the cornea does not end up aspheric but oblate. After the procedure, the cornea is flatter in the center, and steeper in the periphery, causing light rays to fall outside the data collection plate. While this causes few problems in bright sunlight, since we do not need a lot of information to process a good image (much like a camera), it does cause problems as the Iris opens up seeking more data in low light or nighttime situations. Vision is not as sharp and is degraded. This can be demonstrated by testing for the loss of contrast sensitivity. *Most, if not all, laser procedures today work by flattening the central optical zone creating the oblate (reverse of aspheric) surface. For Wavefront Guided LASIK (discussed later), an aspheric surface can be created, but it requires deeper tissue removal (and weakening) in the periphery.*

The cornea has two surfaces that contribute to its refractive power, the front surface, which you see, and the back of the cornea, which you cannot see as it is inside the eye. It would be wonderful if these surfaces were uniform. If they were, then one could change the front curvature of the eye, in an aspheric shape, without concern for the back and its refractive power. Neither the front nor the back surfaces are uniform in their shape, which means that they are irregular. Therefore, cutting in the front, which is done at present, is not being done with the back surface taken in consideration. *This can lead to refractive differences and/or uneven corneal thickness across the front of the eye. The thinner areas will be weaker than the thicker areas.*

### **The loss of contrast sensitivity and quality of vision**

Visual problems come with the creation of an oblate surface, uneven thicknesses, and with the transition zone from the flap to the untouched cornea. The most important diagnostic test for the quality of vision is the test for *contrast sensitivity*. Arthur Ginsburg, PhD, developed this test for the U.S. Air Force. The AF wanted to learn why some pilots who tested for 20/20 (quantity of vision) were missing objects while others who were 20/20 were seeing them with ease. The Air Force learned that the Snellen Eye test (black letters on a white background) is not a good test for vision quality. While one may see 20/20 after LASIK, and be counted as a LASIK success, one may actually have degraded vision. There can be a significant difference between the quantity of vision and the quality of vision.

Years ago, hearing tests were crude and involved the movement of a single sound frequency towards the person being tested. When the person heard it, hearing ability was determined - 20/20, 20/100 hearing etc. Researchers then realized that we heard sounds across a range of frequencies and this test-measured sound only at one frequency. The audiometer was then developed to measure hearing losses/gains across the full range of frequencies required for high quality hearing. If you were to suffer from a hearing loss, it would be described as a low frequency, middle frequency, high frequency or multi-frequency loss. And fortunately, tunable hearing aids are now available to amplify sounds in regions where the loss(es) exist. The full range of frequencies has also been translated into improving the listening pleasure of car radios, stereo systems, etc. Today we have the use of equalizers for audio sound allowing us to amplify selected frequencies (high, lows, middle range) for our listening pleasure.

Vision is very similar to hearing in that the quality of vision is not a function of one frequency but rather a range of frequencies. In the case of vision, these frequencies are spatial frequencies. The Snellen Eye Chart is crude and tests vision at one spatial frequency, providing woefully incomplete data on the quality of vision. The test for Contrast Sensitivity test measures vision across the full range of frequencies needed for quality vision, like the audiometer does for hearing.

We know that any hearing frequency loss can interfere with the ability to discriminate what is heard. And we now know that any vision frequency loss can interfere with the ability to discriminate what is seen. This becomes particularly acute in low-light and/or nighttime situations, and explains why so many refractive patients like the vision they have in bright light but have significant difficulties in low light or nighttime situations. Bright light produces high contrast. Unfortunately, we do not have tunable eyewear to make up for these losses.

For a much more complete description of contrast sensitivity, go to either [www.surgicaleyes.org](http://www.surgicaleyes.org) or [www.vsrc.com](http://www.vsrc.com) (Dr. Ginsburg's site).

*"Post-LASIK changes in Corneal Asphericity," Optometric Physician May 2003, (SOURCE: Anera RG, Jimenez JR, Jimenez del Barco L, et al. Changes in corneal asphericity after laser in situ keratomileusis. J Cataract Refract Surg 2003;29(4):762-8)*

This Spanish study analyzed the origin of the changes in corneal asphericity (p-factor) after laser in situ keratomileusis (LASIK) and the effect of post-surgery asphericity on contrast-sensitivity function (CSF) under photopic conditions.

Clinicians measured the p-factor and CSF (best corrected before surgery and one, three and six months after surgery) in 24 eyes. They noted an increase in the p-factor after LASIK; there was an 87.2 percent change in the asphericity using the paraxial formula of Munnerlyn and coauthors. Other factors such as decentration, type of laser, optical role of the flap, wound healing, biomechanical effects, technical procedures and reflection losses of the laser on the cornea could account for the greater than expected increase (12.8 percent) in the p-factor. The CSF measurements deteriorated after LASIK; the change was significant in patients with myopia worse than -4.00D at frequencies of 9.2, 12, 15 and 20 cycles per degree. *The increase in corneal asphericity after surgery, greater with a higher degree of myopia, and the deterioration in CSF with high myopia justify new ablation algorithms and further study of the variables that could modify the ablation unpredictably.*

*"Capriati troubled by night matches," [www.SportingNews.com](http://www.SportingNews.com) , August 9, 2002*

MANHATTAN BEACH, Calif. -- Jennifer Capriati is wary of playing night matches because the court lights affect her ability to see the ball.

Capriati, the No. 2 seed, struggled for more than two hours before beating No. 16 Tamarine Tanasugarn of Thailand 6-3, 6-7 (3), 6-2 in the third round of the JPMorgan Chase Open on Thursday night.

"Maybe I just started rushing a bit. I got thrown off a bit as soon as it was getting dark," she said. "I have problems playing at night. I was shanking some balls on my groundstrokes."

Capriati, who had Lasik eye surgery two years ago, also had trouble picking up the ball in a night match at last week's Acura Classic, where she lost in the quarterfinals.

"I feel like it's wearing off a little bit," she said of the surgery.

At Manhattan Country Club, the light poles are low on stadium court. "At night, lights can start to become very bright," Capriati said, describing the effect on her vision. "When they're really low like that, it just feels like there's a flashlight on me constantly."

She didn't react well to the glare, double-faulting numerous times in the second set. "In the second set, I just stopped hitting the ball and she started really dictating the points," said Capriati, who was cheered on by her friend, actor Matthew Perry.

At most tournaments, the top players are required to play at least one night match to draw crowds. Having survived that obligation, Capriati said officials here know not to schedule her under the lights again.

"I know there's going to be night matches, especially at the U.S. Open, so what am I going to do?" she said."

For more on this, go to [http://www.capriati.host.sk/a15\\_02.htm](http://www.capriati.host.sk/a15_02.htm)

[ASCERS, 2000 Presentation by William Jory, consultant eye surgeon at the London Centre for Refractive Surgery on Contrast Sensitivity.](#)

Dr. Jory, in his study, found that Contrast Sensitivity was impaired in *58% of the patients who had LASIK – to the point that these people were not fit to drive safely at night*. The Department of Health took this study seriously, in conjunction with a separate study at the University of Ottawa, and recommended that any patient who had refractive surgery should have a night driving test performed before a driving license is granted. Jory said that nighttime vision problems did not seem to be related to high corrections.

[“Determining Medical Fitness to Drive,” published by the Canadian Medical Association in 2000.](#)

In this booklet, *laser eye surgery was added to the list of risk factors for unsafe driving*. See *Canadian Press Newswire* for full press release, August 27, 2000. This recommendation was later overturned after pressure was brought to bear by the Canadian Ophthalmology Association.

[“Functional Vision and Corneal Changes After Laser In Situ Keratomileusis Determined by Contrast Sensitivity, Glare Testing, and Corneal Topography,” Jack T. Holliday, MD, MSEE, et al, \*Journal of Cataract and Refractive Surgery\*, Volume 25, May 1999.](#)

Conclusions: Functional vision changes do occur after LASIK. *The optical quality of the cornea is reduced and asphericity becomes oblate*. Changes in functional vision worsen as the target contrast diminishes and the pupil size increases. *These findings indicate that the oblate shape of the cornea following LASIK is the predominant factor in the functional vision decrease.*

[Guest Editorial, Michael Mrochen, PhD, Department of Ophthalmology, University of Zurich, \*EyeWorld Week\*, April 2001](#)

“Refractive corneal surgery currently focuses on the correction of spherocylindrical errors as the most apparent and disturbing optical aberrations of the human eye. Unfortunately, a significant increase in higher order aberrations accompanies these corrections; thus, higher-order optical errors such as coma and spherical aberration have become more common...*(this) correlates with a significant decrease in the quality of vision, especially under scotopic conditions.*

[“Inside LASIK – Screening the keratorefractive big picture show”, Maxine Lipner, \*EyeWorld\*, April 2001](#)

Quotes attributed to James T. Schweigerling, PhD, Assistant Professor, University of Arizona...

“Current refractive techniques, such as PRK and LASIK, dramatically increase aberrations in the eye.” After such procedures, a wave may look spherical in the center, but tends to deviate due to distortions in the corneal periphery. “What happens is light going through the edge of the pupil tends to focus in front of the retina, whereas light going through the center ..tends to focus on the retina. This gives you a multifocal effect...In areas with such spherical aberrations, patients can still see sharp points of light, but the contrast is reduced and *images appeared blurred and hazy.*” *In effect, during the day, the patient sees very well: however, as the pupil dilates, the error increases dramatically.*

Quotes attributed to Leo Maguire III, MD, Associate Professor, Mayo Clinic...

“It (refractive surgery) *threatens public health* to the extent that it *degrades optical performance and impairs the public’s ability to perform visually challenging tasks.*” Maguire also reminds practitioners of refractive surgery...*that changes will occur in the eye with aging*, independent of refractive surgery, and that patients in the keratorefractive market of today will grow old like everyone else. He is concerned about *how well these patients with seemingly insignificant higher-order aberrations today will perform when their visual systems are later taxed by conditions*, such as, early lenticular opacity, macular degeneration, and a decrease in psychophysical compensation. “By 2025, one in four drivers in the US will be over the age of 65...*Patients with degraded night vision and increased glare present a danger, not only, to themselves, but to others who share the roadway.*”

## **Dry eye**

Dry eye occurs naturally with age. Temporary relief from dry eye comes from the use of artificial tears. For some, it means eye drops every few hours; for others, it means infrequent use of eye drops. Drug companies and the NIH (The National Institute of Health, our tax dollars at work) have spent millions seeking a cure, and, at the very least, developing possible treatments.

It is now known that LASIK causes dry eye in a large number of patients. When the flap is cut, the microkeratome cuts the nerves in the front part of the cornea. Some believe that these nerves never heal completely interrupting the communication between the nerves and the tearing mechanism. Others believe that the unnatural post-LASIK oblate shape hinders proper tear flow across the cornea. Regardless of the cause, many feel that dry eye is the Achilles heel of LASIK.

Many surgeons implant “punctal-plugs” in the ducts that drain the tears to alleviate the symptoms of dry eye. These plugs prevent the tears from draining. Sales of punctal-plugs have skyrocketed with the introduction of LASIK. For those who still need relief, artificial tears are prescribed. The sales of tears have also skyrocketed.

LASIK has expanded the problem of dry eye from being a naturally occurring phenomenon to being a surgically induced problem.

## **DLK (diffuse lamellar keratitis)**

DLK is classified as a “real” complication in the FDA classification system. Little is known about its cause and its incidence may be much higher than what is being reported.

*“Bilateral diffuse lamellar keratitis following bilateral simultaneous versus sequential laser in situ keratomileusis,” McLeod SD, Tham VM, et al, British Journal of Ophthalmology, 2003;87:1086-1087*

“...A retrospective non-comparative case series of 1632 eyes that had undergone bilateral, simultaneous or sequential LASIK between April 1998 and February 2001 at a university based refractive centre by three surgeons...The main outcome measure was the incidence of unilateral and bilateral isolated, non-epidemic DLK...Of 1632 eyes, 126 eyes (7.7%) of 107 patients developed at least grade 1 DLK. In six operating sessions, DLK was observed in more than one patient per session...CONCLUSION: In isolated, non-epidemic bilateral DLK, a similar incidence (of DLK) was observed regardless of whether the surgery was simultaneous or sequential, *suggesting an underlying intrinsic cause for DLK.*”

## **Accuracy of the microkeratome**

Laser based refractive procedures were initially marketed to a wary public as space age technology with space age precision (laser accuracy is to the micron level). Since this was technology driven, not surgical skill driven, there was little to worry about. While surgeons today are trying to differentiate themselves by skill (to avoid price competition), the precision of the laser is still marketed as an attribute of the LASIK procedure.

What the “refractive surgery industrial-medical complex” does not talk about is the inaccuracy of the microkeratome that is used to cut the flap. If the desired depth of cut for a flap is 200 microns, the actual cut may be plus or minus 16-20% of this desired depth. The variation of the microkeratome has been a weakness of LASIK from the beginning. The creation of the flap, its depth, and its thickness are not only important to the visual outcome, but also to the potential for long-term complications such as progressive hyperopia and ectasia.

*“Some foresee limitations in wavefront technology.” Ocular Surgery News, August 1, 2002*

Noel Alpíns, MD, said, “No matter how finely tuned a microkeratome is, it’s still a gross change to the cornea as opposed to the changes required with wave-front guided treatments.” The flap presents a problem.

## **Enhancements and the use of misleading terms**

The term enhancement originated with the mini-RK in the early 1990's. The mini-RK involved making a small incision RK followed by a waiting period. For those who had good visual outcomes, nothing more was done. For those that did not, another procedure was done that involved slightly longer incisions. If this too failed, another procedure followed with even longer incisions. Rather than call these *re-operations*, ophthalmologists created a patient friendly but misleading term, *enhancements*. The term has continued with all subsequent refractive procedures.

One of the problems with the term is that it sounds like the procedure is benign. Does enhancing make it better? This is a matter of semantics. For LASIK and RK outcomes that are under-corrected, more tissue is removed or deeper, longer incisions are made respectively. While in some cases, vision can be improved; permanent damage to the cornea is increased. For LASIK and RK outcomes that are over-corrected, tissue cannot be added back to the cornea nor can permanent incisions be reduced or eliminated. In short they cannot be *enhanced*.

These procedures are not as flexible as some would have you believe nor are they upgradeable. While the cornea is further flattened, it is also made thinner, and weaker by the removal of more tissue. *Enhancements* are a one-way street and are irreversible.

Additional terms that are now finding their way into the vocabulary of refractive surgery include "Tear Savers" for the use of punctal-plugs (you still have symptomatic dry eye), "Advanced Surface Ablation" for PRK (once trashed, some are now trying to reintroduce it), "Blended Vision" for mono-vision (this is not like Varilux lenses where one lens is blended, but rather one eye is corrected to see far objects and the other eye is left untouched to see near objects), and most recently, "HD LASIK", high definition LASIK (is it really high definition for all? all the time? for many years?). Each of these terms provides a message to the patient that is selective, and misleads.

## **INFORMED CONSENT**

Patient informed consent while critical in all medical treatments takes on special importance in refractive surgery since patients are *electing* to undertake the risk of irreversibly altering an otherwise healthy eye. Information provided by advertising, promotional materials (brochures, etc), in-office staff, referring doctors, and the surgeon are all considered part of the legal informed consent. The truthful setting of expectations regarding potential outcomes and complications in all of these communication tools is crucial to making an informed decision.

Refractive patients seeking information on refractive procedures should know that doctors, their staffs, and referring professionals have been well schooled ("in-practice marketing skills sessions") on how to handle difficult questions and concerns in an effort to keep interested candidates "in play" for the procedure. "In-practice marketing" covers *every* contact the patient has with the practice. Training programs have been developed and offered by manufacturers to be given off-site or at the practice site. Many of these trainers/courses provide the doctor and his associates with tools to overcome patient objections. One of the pioneering laser manufacturers created their own teaching "University" to educate surgeons and their staffs. The "University" goal was to increase patient throughput and profitability for the physician and the manufacturer (the manufacturer received \$250 per procedure until 2000 when it was reduced to \$100-150). The course was offered to those who purchased the company's laser (a \$450,000 purchase).

### **The absence of incidence data**

The "Informed Consent" document was developed to provide a legal defense for doctors in the event of a lawsuit. It was also designed so patients would not be discouraged from the procedure. Many Informed Consents list possible adverse events, complications, and/or visual complications, including death (even though no one knows of anyone who has died from a procedure). And most do not list the incidence (how often something occurs) specifying only that a specific complication "may" occur. The inclusion of a significant life-changing event, death, that never happens, creates, by comparison, the perception that many of the other complications that "may" occur" are rare and "may" never happen as well.

For full disclosure, informed consents must list the incidence of complications to insure. There is a big difference between "may" occur and a 20% occurrence rate when one is making an irreversible decision. What would you do if you were told that a car you were considering "may" have a problem with the front brakes, and in the context of "may," you were led to believe that it was 1%? What if it were 20%? 40%? You

will see later in this document that the incidence of many refractive surgery problems warrant incidence percentages and not the word "may."

Today, when having a refractive procedure with a FDA approved (excepting the first LASIK approval) Class III technology, manufacturers are required by law to provide booklets noting the incidence of each untoward effect. The doctors, in-turn, are required to include these booklets as part of the informed consent to prospective patients. Read the booklet carefully, and do not let anyone lead you to believe that the outcomes and incidence of problems will be any different. Some doctors will try to tell you that "his/her" patients do not seem to have these problems. Don't believe it for a minute!

A hangover from the first FDA laser approvals is that many of the original laser machines are still being used. These approvals did not have great incident data when approved, nor were the manufacturers and doctors compelled to provide FDA reviewed booklets to the patients. As a result, the vast majority of LASIK patients did not receive full and accurate information on outcomes and complications.

Going forward, interested parties should stick to data generated from FDA studies (excepting the original LASIK study) to insure that apples are being compared to apples. All FDA studies must follow the same format. Be wary of non-FDA studies that create expectations of better outcomes and/or fewer problems. Pay very close attention to the inclusion criteria (who can be considered a candidate). Data can vary according to the type and size of correction required. The data generated for the FDA approval relate to a specific, well-defined population of people. For those who do not fit the study population, extrapolation of the results is problematic.

#### **A physician's internally developed data (personal studies)**

Some doctors may show you his/her own data, collected from his practice on a refractive procedure, and say that his/her data is much better than the FDA data. Be cautious! Have my colleague put this in writing.

The differences between a surgeon study and a FDA study are significant. FDA post-procedure exams take about three hours. And, a third party, who has no vested interest, must do post procedure follow-up exams. If a surgeon followed this rigor, he/she would lose control and money. They simply cannot afford the rigor required by the FDA in a commercial setting. A decision based on a physicians' data is speculative at best.

#### **Physicians' use of manufacturer sales aids**

When a doctor uses marketing materials, ask who developed the pieces, and ask if the FDA had approved the materials. The FDA has authority to insure that outcome and safety data from a manufacturer are provided accurately. Unfortunately, this is not true for physician developed marketing pieces. The FTC (Federal Trade Commission) has jurisdiction over physicians. Individual physicians are of little interest to the FTC so an interested patient must be on guard with non-manufacturer developed material.

It even pays to scrutinize manufacturer materials, one well-known laser manufacturer created a physician sales support piece showing the comparison of several procedures. It was done in such a way that the competitive procedures were misrepresented. The FDA called them on it and asked them to desist. They, however, were not asked to recall the sales piece, so it was in use long after the FDA warned them. This type of marketing was done not for the benefit of the patient but for the benefit of the manufacturer,

#### **Physicians and conflicts of interest**

We have the problem of multiple conflicts of interest (payments, free use of lasers & equipment, travel) in the medical community. Surgeons are not immune. It is important for patient's to understand what a physician's and/or refractive surgery centers ties are. One doctor takes great pride in having no conflicts as he consults for all manufacturers, pulling in over \$1 million per year. It is not what he does for his clients, it is what he does not do...like talk about the complications that beset each category of procedures. The "Informed Consent" should include all conflicts so those seeking opinions and/or procedures can discern the ties of the physician or practice to outside forces.

Medical opinion Leaders, medical publication authors, optometrists, surgeons, and manufacturers all are suspect. Since many of these people are conflicted, the patient must be responsible for demanding full disclosure. One way to insure disclosure is to have my colleague state in writing that he/she has received no payments (cash, equipment, trips, discounts) in kind from any manufacturer.

## **Referrals to LASIK surgeons**

Many LASIK surgeons, LASIK centers, and National Chains have built their LASIK business on referrals. Most often these come from Optometrists (OD). Referrals generally involve payments to the referring doctor. Since kickbacks are illegal, a co-management arrangement is generally put in place. These payments, in the good days of 1998-2000, approached \$1000/eye. An OD could make much more from one referral than several contact lens or eyeglass fittings. Today, with the economic downturn and reduced LASIK pricing, referral payments have been reduced, and in some cases, eliminated. This change raises some serious questions - 'how much co-management was really being done?' and 'was co-management really a cover for a kickback' – which need to be answered.

If you are being referred, find out what the referral arrangement is, and find out how much the doctor has earned from referrals over the past three years. You may be dealing with someone who is seriously conflicted.

## **Looking through the patient's eyes**

The article that follows, which recently appeared in the New York Times (2003), addresses the issue of patient information and perception. It underscores the need for complete disclosure so patients can make an informed decision. These situations are fraught with misunderstanding, particularly when many sources are involved with providing information.

*"Seeing Risk and Reward Through a Patient's Eyes", Robert Klitzman, MD, [New York Times](#), May 27, 2003*

*"But more important, many doctors weigh the risks and potential benefits of treatments in ways different from their patients without realizing that wide contrasts exist. Risks, after all are relative: what one person considers too dangerous, another might not. The way risks are presented and framed shapes our perceptions of them...In research too, (medical) investigators are supposed to warn of possible dangers. Yet, at times, they minimize such hazards and promote only the benefits...According to research, humans do not always think rationally about risks...they see patterns where none exist...With a side effect, too, it is one thing to say that the odds of its occurring are 30 percent. But the importance or unimportance of that symptom may range widely between people in ways that doctors do not take into account. Doctors often have trouble dealing with the inadvertent, side effects of their own treatments."*

## **Websites**

Patient information websites are sponsored by doctors, refractive surgery centers, independent physician groups (many who have a vested interest in one procedure or another), former patients, manufacturers, and the FDA.

Surgical Eyes (SE) [www.surgicaleyes.org](http://www.surgicaleyes.org) is the best. Any person considering refractive surgery, as part of the informed consent, should be sent to SE during the consideration process. SE provides the other side of the story. It is a counterweight to the hype of the refractive surgery community (optometrists, surgeons, and manufacturers). Ron Link has done a real service for patients, and while some may disagree, he has done a service for the surgeons as well. The more the patient knows, even if it results in fewer procedures, the healthier the industry will be.

Misleading information characterizes most other websites and their chatrooms. Some website chatrooms have permanent contributors who post frequently as "independent experts". Be careful, some of these are not independent and are deeply vested. Discernment falls squarely on the shoulder of the reader. An appropriate caution for all is to *know whom the expert is*, and to *know what financial ties they have to refractive surgery*. If the person is a physician that does the procedure, find out how many procedures he/she had done and his/her annual income level from refractive surgery.

The procedure history is also important. For most, a high number would indicate experience and expertise. For some of us, a high number would indicate the physician's vulnerability as problems surface. One would expect the higher the number, the greater the emotional investment in believing he/she did the right thing, and the stronger the defense of his/her actions.

*"LASIK complications and the Internet: Is the Public Being Misled?" Fahey, Weinberg, [Journal of Medical Internet Research](#), Vol. 5, No. 1, March 2003.*

Conclusion: *the quality and quantity of the information on the Web on the complications of LASIK are poor.* More work is required to encourage clear, accurate, up-to-date, clearly authored, and well-referenced, balanced ophthalmic information. "The poor quality of the information represents a negligent omission, as the public are being misled into believing that LASIK is without risk," Fahey concluded. "This may lead to liability cases by patients with complications whose decision to have LASIK was based on the information they read on the Web site." Dr. Fahey said he believes that if a surgeon is responsible for the content of the site, he or she bears the burden to ensure that the information "is accurate, well-referenced and balanced."

["Surfer Beware: Don't Trust All Online LASIK Info: Online LASIK info incomplete, study finds," December 13, 2002](#)

NEW YORK (Reuters Health) - Consumers who turn to the Internet for information about LASIK eye surgery should know it's a surfer-beware environment, according to a team of eye specialists who evaluated online information and reported their results Friday at the American Optometric Association meeting in San Diego, California.

Dr. James O. LaMotte, a professor of optometry at the Southern California College of Optometry, Fullerton, and his colleagues used 10 search engines to find sites on LASIK...Next, using a 74-topic checklist derived from the Food and Drug Administration, the researchers then rated the sites for accuracy, awarding one point for accurate information on each of 74 topics related to the eye surgery.

Only 26% of the sites were rated as "markedly informative," with 28% moderately and 46% minimally informative, LaMotte said. A site had to contain at least 67% of the total possible points to win a label of markedly informative. The minimally informative sites contained less than 33% of the possible points.

"What the LASIK Web sites did was tend to talk about the benefits of LASIK and to ignore the risks and contraindications," he said. Misinformation on the Internet is nothing new, LaMotte told his colleagues. Previous studies have found misleading or even harmful information disseminated on the Internet about fever in children and vascular surgical procedures. Other sites contain misleading information on age-related macular degeneration, an eye condition that can lead to blindness, LaMotte stated.

["Medical Ethics and the Excimer Laser", Samuel Pecker, MD, Archives of Ophthalmology, May 1997](#)

"...the marketing required to achieve economic viability (of PRK laser surgery, and fits LASEK as well) is something that medical professionals are either uncomfortable with or would rather have someone else do." "This new technology and this new partnership (with laser companies) *have the potential to create notable ethical problems, in such areas such as (1) agency, (2) conflicts of interest, (3) informed consent, (4) marketing and advertising, and (5) social issues – the relationship of medicine to society.*

At the least, rule 15 of the American Academy of Ophthalmology's *Code of Ethics* would be observed. It reads, '*Disclosure of professionally related commercial interests is required in communications to patients, the public, and colleagues.*'

The marketing and advertising of PRK will put an increased burden on the ophthalmologist when it comes to informed consent because the customer will come to the physician's office with preconceived ideas obtained from the media and *because the physician is assumed to be a trusted agent for a patient.*"

### **Recent FTC actions**

The US Federal Trade Commission (FTC) recently took action against two companies that were considered to be advertising unsubstantiated claims for LASIK. The actions, taken against The Laser Vision Institute and Lasik Plus, are the first of their kind.

Despite welcoming its moves, Ron Link, Surgical Eyes, is concerned that the *FTC can only take action against national chains. "It's a pragmatic position to take, but how does the local violator (your local doctor) get addressed? I don't have an answer."*

## **FDA APPROVALS**

By law, anyone bringing medical technology (device, instrument, etc.) to the US market must seek FDA approval prior to commercialization. The three classes of devices and required approvals can be found at the FDA's website. Class III devices are generally the most innovative, having no precedent, and are the most regulated. A Class III device requires that safety and clinical data be provided to the FDA for analysis, prior to approval. The development of these data must adhere to guidelines issued by the FDA.

Most (99%) of the submissions to the FDA are made by manufacturers seeking commercial approval of a product that they have developed or want to distribute. These are called company sponsored IDEs/PMAs. Companies must follow strict guidelines in the selection of their clinical investigators, the patients that enter the study, how the procedure is provided, and how data is collected before and after the procedure. The first laser clinical studies which were for PRK (it does not involve the cutting of the corneal flap) were staged, with approvals for subsequent stages coming only after rigorous review of the previous stage, and took many years before completion of the third and last stage. In addition, the FDA required data from follow-up exams for up to two years before approval was even considered.

These studies, which were sponsored by companies, were required to have and did have high percentages of follow-up. These were over 95%, which means that 95% of their trial patients completed all of the required pre-operative and post-operative exams. These data were used to determine safety and efficacy. The higher the percentage, the higher is the confidence that the data truly reflects the outcomes and side effects.

Radial keratotomy (RK), which preceded PRK, did not require FDA approval. The device, a surgical scalpel, required for doing the procedure, was commercially available when the procedure was introduced in the US. Surgeons who wanted to provide this to the public were in business immediately. Unfortunately while the procedure was available, clinical data, and science-based information on outcomes/risks were not. Since this is what is considered an off-label use of a device/technology, the physician assumed full responsibility for liability.

### **Adverse events, complications, and visual symptoms**

The FDA's published refractive surgery clinical study guidelines establish three categories for the reporting of untoward consequences - adverse events, complications, and visual symptoms. The problem with this classification system is that patients with a serious "visual symptom" feel that they have a complication, a real problem. This classification methodology is not relevant to the consumer/patient and can lead to mischief. What will the patient be told when asking about complications?

When someone has significant visual symptoms - dry eye, loss of night vision, starbursts, etc. – their quality of life is truly impacted. Just go to [www.surgicaleyes.com](http://www.surgicaleyes.com) to their chatroom to see how much. A LASIK patient may be spending \$1000 per year for artificial tears, may have given up driving at night, may suffer with fluctuating vision, may have a whole host of other problems, and may still be counted as a LASIK success. He/she only suffers from a visual symptom!

### **LASIK - an unapproved, off-label use of medical technology**

Once the laser was approved for PRK in 1996, it became a candidate for any off-label use. Surgeons were free to use the laser as they saw fit. Prior to the PRK approval, surgeons outside the US (Italy, Greece, and Columbia) frustrated with some of the consumer unfriendly issues (pain, long term healing, and spontaneous corneal clouding) related to this procedure, began to apply both the laser and a device called the microkeratome. The resulting procedure became known as LASIK. LASIK *seemed* to be an improvement. It appeared to overcome many of the barriers (mentioned above) slowing the consumer adoption of PRK.

Since the microkeratome was approved for another use and was already available in the US market, US surgeons were free, after FDA approval of the laser for PRK, to combine the laser with the microkeratome for LASIK. As with RK, though, FDA clinical data and science-based information on outcomes and risks were not available. (Some will argue that data was available from outside the US, but this was not acceptable science-based clinical data). US Surgeons initially limited LASIK to patients who required more than 6 diopters of correction leaving PRK for those who required less. PRK had proven to be problematic with higher corrections. They were also concerned about the long term effects of cutting the flap and felt that

LASIK was warranted for those requiring significant corrections since they were handicapped when they were without corrective lenses.

### **LASIK- the initial FDA approval**

Refractive surgeons early-on were concerned about offering an “off-label” procedure which put them at risk if anything should go wrong. The FDA, at the same time, was concerned about the growth of what was becoming a very popular unapproved “cosmetic” surgical procedure.

Surgeons met with the FDA to find a path for gaining the FDA’s approval. If successful, an approval would get them off the liability hook, and they could offer it as “FDA Approved.” The FDA wanting to get a handle on this fast growing procedure agreed to letting the surgeons sponsor a clinical study. The FDA agreed to review the data. The FDA would grant approval if the procedure were “proven” safe and effective.

*In reviewing the FDA Panel discussion and approval, one can only wonder why the FDA approved LASIK after a clinical study that was incomplete, had minimal follow-up, and did not meet the same rigor manufacturers were required to follow.*

LASIK received its initial FDA approval in 1999, based on *two physician-sponsored, not manufacturer sponsored* studies – one for the VISX laser and one for the Summit laser. The manufacturers chose not to sponsor these studies - their products were on the market and expensive studies were not required to sell equipment. With an approval to sell, and with momentum building for LASIK, they needed to focus only on marketing, sales, and equipment service.

The FDA’s Ophthalmic Panel reviewed the two studies for approval in July 1999, three years after LASIK was introduced in the US and after several millions of LASIK patients. The transcripts of these proceedings are publicly available. They are PMA’s 990010 and P930034/S13 and are a most worthwhile read. The data used for the approval was deficient prompting key panel members to abstain from the final vote.

*Below are some key excerpts and the panel votes.*

#### **Day One**

PMA 990010 (VISX Star laser model C used with the Chiron ACS micro-keratome)

*Page 42 - Follow-up or “accountability as shown here with 90.3% at 3 months, dropping to 76.3% at 6 months....”*

*Page 67 – Dr. Pulido: “I would like some clarification from Jan Callaway about the patient accountability concerns and how she feels about the fact that there was 43 percent exclusion of the data”*

*Page 82 – Dr. Bullimore: “...The biggest is this issue of accountability...One characteristic of the PMA is the very variable accountability of these clinics. Overall the accountability is less than 75 per cent at 3 months and less than 63 percent at 6 months...So, the potential for patient bias or surgeon bias or investigator bias is considerable because of this at best mediocre accountability...The range of approval, also, has relevance to the question of corneal ectasia, and there are a number of reports and comments in the literature by very distinguished people in the field about the risk of corneal ectasia above minus 10...I would point out that the potential for long-term changes in refractive error still exist. Only going to six months would not, for example, demonstrate the long-term hyperopic shifts that we saw in the PERK Study (for RK).”*

*Page 89 – Dr. Pulido: “...but I have strong concerns regarding accepting the study as a whole because of the data set and if the FDA accepts this kind of study were accountability is only 57%, only because there was a large number of patients where will we stop?...the doctors should be chided for bad science..”*

*Page 92 – Dr. Yaross: “I think one of the messages that intended or not is sometimes perceived is that there are different standards for investigator-sponsored PMAs brought to this panel than for industry sponsored PMAs, and I think that is something the panel should be aware of.”*

*Page 96 – Dr. Ferris (National Eye Institute): “...and the fact that there is even the 15 or 20 percent missing information when we have bars that say you cannot have more than 5 percent of this or 1 percent of that...that tells me that as you added more patients you are reducing the mean and suggesting that the missing information might be in the direction of more harm or at least less efficacy and that is the concern...”*

Page 96 – Dr. McCulley (Panel Chairman): “In the guidance document there is a target, yes.”

Page 96 – Dr. Matoba: “Ninety percent, So, okay.”

Page 101 – Dr. Rosenthal (FDA): “...the guidance is guidance, and as you know the office has I think quite publicly stated that is general for the office of Device Evaluation an 80 percent level is generally acceptable of accountability.”

Page 143 – Dr. McCulley: “..so just for the data as presented does the Panel feel like there is sufficient follow-up for the correction of myopia with or without astigmatism in the ranges indicated?”

Vote – 2 were yes, six were no.

Page 147 – Dr. Ferris: “And I take it this is an issue because the guidance suggests 1 year (follow-up). Is that right?”

Page 182 – Dr. Van Meter: “...why are you unhappy with less than 90 percent data now when you have not been happy in the past?”

Page 190 – Dr. McCulley: “...All right, we have a motion on the floor for approvable with the conditions that have been read into the record, and it has been seconded...All those in favor of the motion, please raise your right hand high?”

On the vote for approvable, there were 9 yeas, 0 noes, two abstentions.

Page 192 – Dr. Macsai: “I abstained because there is a body of information out there that is in the scientific literature that has undergone peer review regarding this subject which provides knowledge regarding this procedure. *However, I cannot assess that true safety and efficacy has been established due to the lack of accountability.*”

Page 193 – Dr. Ferris: “I abstained from the vote because it is my belief that *the data that were included in this PMA are not scientifically adequate for approval.*”

The Panel Session ended with this *recommendation to approve* this LASIK application, with labeling conditions, as sponsored by the physician group. *The uniqueness of this approval concerns itself with the low “accountability” and the short six months follow-up. No company would even be allowed to go to panel with data this inadequate. In the preceding fall, this panel recommended 3 year follow-up as a guideline for refractive IOLs.*

## **Day Two**

PMA P930034/S13 (Summit Apex Laser with unspecified microkeratome)

Page 100 – Dr. Kezirian: “ You will see that the PMA cohort has, at three months, an accountability rate of 89.6%, and at six months, 84 percent.”

Page 131 – Dr. Sugar: “We discussed this issue at very great length yesterday (VISX approval), and I don’t think it needs to be reviewed, but *I think that the exclusion of sites that did badly is not an appropriate way to present data, either badly in accountability or any other regard.*”

On the vote for approvable, there were 9 ayes, 0 noes, one abstention.

Page 172 – Dr. Ferris: I abstained from the vote of approvable with conditions, in part to be consistent, but also because *I think in an issue of a degree of public health importance such as this, and where the side effects, statisticians always say compared to what...I believe with a follow-up of missing information of this magnitude, that I can’t adequately assess what that is...I am not a corneal surgeon...so I don’t want to vote against it, but neither do I feel I can vote for it.*”

The panel session ended again with a recommendation to approve with conditions.

Unfortunately, the study as we shall see in future years was incomplete and flawed.

Many refractive surgeons downplayed the physician study saying that improvements in technology had been dramatic since the study, and in their hands, outcomes were significantly better. Of course, there was no scientifically based proof to support this. "They are out of date." "I get better results." "They did not consider the new (whatever they wanted to emphasize) in doing their studies." This refrain (since the days of RK) is repeated after each new study is released since most study results do not agree with what is being advertised to consumers.

Unfortunately, time has proven that claims like these are to be taken lightly and these boasts of better results are overstated. FDA study results (with the exception of this first, physician sponsored study) should be taken seriously. Because as you will see shortly, physician generated data (even this so called physician sponsored PMA) does not jive with what we now know about LASIK, its outcomes and its complications.

**"Company Sponsored" LASIK PMAs**

Note the data set - the complications and incidence of these complications - provided in this, the first company sponsored FDA study of LASIK. The data set differs significantly from the physician sponsored FDA study, and gives cause for concern about what was marketed to an unsuspecting public.

**Approval for the Bausch & Lomb Technolas™ 217A Excimer Laser for LASIK**

The following data were presented to the FDA for the Bausch & Lomb Technolas™ 217A Excimer Laser System for LASIK. The date of this document is 2/28/00 and is publicly available.

This is the first company sponsored PMA for a laser used in LASIK. Therefore these are the first data presented in the more rigorously controlled company sponsor clinical trial. These data come from a rigorously controlled study with the normally high accountability.

Note that while some people had improved symptoms, others had worsening symptoms Approval, I believe, was based on the fact that the "improved" vs. "worsened" averaged out. This was good news for those whose conditions improved, but bad news for those whose condition worsened.

These data suggest that symptoms LASIK patients were complaining about were real and more significant than what patients had been told since the introduction of LASIK to the US. And the incidence levels were more significant than what the informed consent's use of the word may suggested.

Data was presented for both 3 and 6 months for "eyes treated without astigmatism" and for "eyes treated for astigmatism." Only one set of data is shown since "without astigmatism" is considered to be "best case" for any refractive procedure, and since six months is the longest time presented after surgery. *To see all of the data, this document is available in the FDA archives. It is marked 217A-PINFO.*

*Eyes Treated Without Astigmatism at six months\**

<i>Visual Symptom</i>	<i>Better</i>	<i>No Change</i>	<i>Worse</i>
Dryness	21.6%	52.3%	26.1%
Halos	4.5%	76.1%	19.3%
Fluctuations of vision	6.8%	73.9%	19.3%
Variation of vision in dim light	14.8%	67.0%	18.2%
Light Sensitivity	14.8%	67.0%	15.9%
Blurred Vision	11.4%	73.9%	14.8%
Night Driving Vision	22.7%	63.6%	13.6%
Glare	10.2%	77.3%	12.5%
Variation of vision in bright light	6.8%	86.4%	6.8%
Redness	20.5%	73.9%	5.7%
Variation of vision in normal light	1.1%	93.2%	5.7%
Headaches	12.5%	83.0%	4.5%
Gritty feeling	18.2%	78.4%	3.4%
Tearing	9.1%	88.6%	2.3%
Burning	6.8%	90.9%	2.3%
Ghost images	1.1%	96.6%	2.3%
Double vision	3.4%	95.5%	1.1%

- While it is not stated, some of the symptoms may occur in conjunction with other of these symptoms.

### University of Rochester survey of FDA approved lasers

The University Of Rochester Medical Center *presently* has a Summary of Surgical Results Data for all FDA LASIK approved Laser Systems (The University of Rochester states all source data can be downloaded from [www.fda.gov/cdrh/lasik/lasers.html](http://www.fda.gov/cdrh/lasik/lasers.html) ) Note the percentage who achieved “20/20 or better” by amount of required correction. This is certainly not 90% or 100%. It falls way short. Those who miss the mark will either have re-operations (enhancements) or will have to live with much less than perfect eyesight (even in high contrast environments).

They promote this to highlight the data from the newer B&L systems, which they use, and are promoting.

For systems other than the newer B&L systems, it shows *uncorrected Snellen\** results\*\* as follows :

For -1.00 to -1.99 diopters of correction	46.4 to 88.2% achieved 20/20 or better**
For -2.00 to -2.99 diopters of correction	51.5 to 73.4% achieved 20/20 or better.
For -3.00 to -3.99 diopters of correction	41.7 to 67.9% achieved 20/20 or better.
For -4.00 to -4.99 diopters of correction	45.7 to 64.3% achieved 20/20 or better.
For -5.00 to -5.99 diopters of correction	40.5 to 50.0% achieved 20/20 or better.
For -6.00 to -6.99 diopters of correction	27.8 to 51.1% achieved 20/20 or better.
For -7.00 and above	32.0 to 49.1% achieved 20/20 or better.

*\* these data do not measure the quality of vision, eg. contrast sensitivity. The Snellen eye test was used and only measures vision in high contrast situations.*

*\*\* depending on system used.*

The Medical Center’s (which appears to be marketing LASIK as StrongVision) stat sheet goes on to show that patients done on the B&L system achieve 20/20 or better 84.8 to 87.3% of the time. These data do not, to my knowledge, include re-operations, which are called enhancements. With re-ops, some of these may achieve 20/20.

## REPORTED PATIENT PROBLEMS AND THEIR INCIDENCE

As you read the following publications, note the incidence of visual symptoms. These were not listed in the physician sponsored PMA data set (discussed previously), clearly supporting the abstentions by those who were concerned that the study was incomplete and insufficient. Unfortunately, for the millions of patients who underwent LASIK, either pre- or post- FDA approval, they made their decision on incomplete and insufficient data.

*“Patient Satisfaction and Visual Symptoms after Laser In Situ Keratomileusis (LASIK),” Bailey, OD, MS, et al, [Ophthalmology](#), Volume 110, Number 7, July 2003*

*“97% would recommend the procedure to a friend...Halos were reported by 30%, glare by 27%, and starbursts by 25% of all subjects...The 25-30% rates of night vision symptoms here are higher than another previous study with a higher survey response rate but similar to or lower than other studies of PRK and LASIK...Increased age is associated with decreased satisfaction...Prospective LASIK patients still should be informed that LASIK has been associated with decreased satisfaction, and we specifically found that there is a 50% increased odds of dissatisfaction for every 10-year period increase of age.”*

*“LASIK Has a 10% “failure” rate”, Michael Hatcher, [www.optics.org](http://www.optics.org), May 8, 2003*

*“That’s the conclusion of a study by researchers at the New Jersey Medical School. But because only most only need one eye retreated, it means that one in five patients actually undergo a second LASIK procedure.*

*...This is something we have been saying for a very long time – people are not being fully appraised of their degree of risk as it applies to their own set of eyes,” said Link (Ron Link, Executive Director of The Surgical Eyes Foundation).”*

["Night Vision Disturbances After Corneal Refractive Surgery", Fan-Paul, MD, MPH et al, Survey of Ophthalmology, November-December, 2002](#)

"A certain percentage of patients complain of 'glare' at night after undergoing a refractive surgical procedure. When patients speak of glare they are, technically, *describing a decrease in the quality of vision secondary to glare disability, decreased contrast sensitivity, and image degradations, or more succinctly, 'night vision disturbances.'* ...In most cases of corneal refractive surgery, there is a significant increase in vision disturbances immediately following the procedure. The majority of patients improve between 6 months to 1 year post-surgery...

*With the exponential increase of patients having refractive surgery, the increase of patients complaining of scotopic or mesopic vision disturbances may become a major public health issue in the near future...."*

In the conclusion, the authors note with regards to existing testing methods, "...lack of standardization, lack of scientific validity, hard to interpret by physician, time to administer test, hard to interpret by patient, cost, lack of correlation with symptoms, lack of familiarity with test, and superfluous..."

They go on to state, "an aging population with perplexing night vision impairments such as developing cataracts, dry eyes, or age-related macular degeneration may have worsening problems which may have a *significant impact on public safety and health (in conjunction with previous refractive surgery).*"

["Most Patients seem Happy after LASIK But They Still May be Having Vision Problems, German Study Suggests," John F. Henahan, www.esccs.org, October, 2002](#)

"Although most patients who undergo myopic LASIK appear to be quite happy with the vision they achieve after surgery, they may, in fact, have measurable and sometimes significant problems with glare, halos and contrast sensitivity...However, when they were examined with a variety of objective measuring instruments, their vision was not really as good as they thought...When the Regensburg investigators used objective measurements to determine contrast sensitivity, *they found that 24% had worse vision after surgery than they did before. That level of contrast sensitivity corresponds to dim-light conditions on a late autumn afternoon, and the difference was statistically significant. In addition, at 5% contrast, which simulates to night-time vision, 54% had problems...(for glare testing) 53.8% had significant problems with this test, which could be considered serious enough reduced their vision to the extent that it would interfere with their ability to drive a car...*In another test (for halos), 60% were found to have some level of halos, although only 32% of the patients had subjective complaints...Therefore, *even when our BCVA Snellen measurements tell us that the patient is seeing quite well, these (other) objective measurements tell us that they may be having problems especially at night...but if they come back and you question them carefully, you may find that they are no longer driving cars anymore or their vision is somewhat disturbed in the evenings.*"

["Consumers on LASIK: Down, but Not Out," Judith Lee, Senior Contributing Editor, Review of Ophthalmology, Vol. No. 139:101, Issue: Oct 15 2002](#)

"...VisionWatch Eyewear—a partnership of NOP/World Group, Jobson Publishing L.L.C. (publisher of Review of Optometry) and Greenfield Online—conducted a telephone survey of 72,000 U.S. consumers between June 2001 and June 2002. All respondents were age 18-65, and either wore some form of vision correction or had undergone refractive surgery.

Most patients surveyed who have had refractive surgery complained of nighttime glare, dry eyes, double vision and/or blurry vision. Still, most say they had recommended the procedure to others.

Also, many spectacle or contact lens wearers surveyed say they are aware of refractive surgery procedures, with LASIK the most recognized. About one-third of these patients say they will likely have refractive surgery. The patients who don't expect to have LASIK or other procedures are most worried about safety or complications. Additional concerns: cost, whether the outcome would be "worth it," and whether the surgery will be effective as one's vision changes.

#### You're Number 1 (The Importance of the Doctor)

The survey clearly shows that eye doctors have much influence on patients. Of those who had already scheduled refractive surgery or were very inclined to have it, 35% say "my eye doctor" was the most important source of advice regarding surgery. Older patients, those with annual incomes above \$60,000, and those living in the West are most likely to take their eye doctor's advice—although patients across the board list the eye doctor as their top adviser....

LASIK Rules

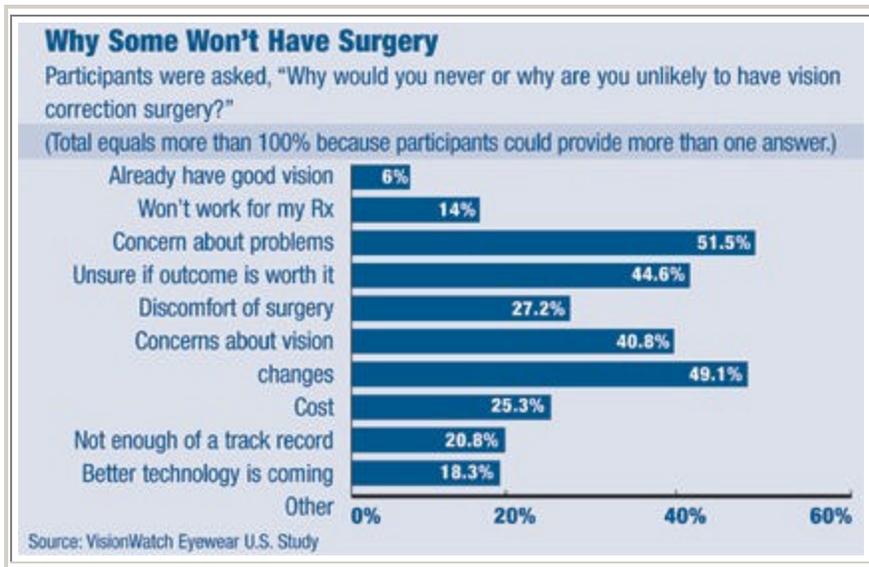
Only about 1.5% of the total sample had already had a refractive procedure. Of this group, 87% had LASIK, with the rest divided between PRK and LTK. A surprisingly high percentage of people who had already received surgery made less than \$40,000 a year. They tended to be young, live in the West or South, and had their surgery more than one year ago...

**What problems have you had since refractive surgery?**  
(Responses broken out by age)

	Total	18-34	35-44	45-54	55-64
Night haloes, glare	31%	32.7%	29.1%	36.8%	16.3%
Dry eyes	38.1%	35.5%	44.8%	31.8%	41.5%
Double vision	6.6%	6.1%	8.9%	4.2%	6.5%
Blurry vision	17.4%	16.1%	24.3%	11.8%	12.4%
None of the above	38.9%	37.1%	35.0%	42.7%	48.6%

Source: VisionWatch Eyewear U.S. Study

Nearly 90 % of patients had bilateral surgery, and 83% were myopic. About half were astigmatic. Six of 10 say they have suffered from haloes and glare at night and/or dry eyes. Patients age 35- 44 and those 55 and older complained of dry eyes the most. Patients age 45-54 had the most problems with haloes and nighttime driving...



What Matters

Refractive-surgery candidates are most interested in improving their vision, but also would like to stop wearing glasses or contact lenses. These were the two top reasons given by patients who had already scheduled surgery or were very likely to have it.

<b>What's holding you back from having surgery now?</b>				
<i>(Patient responses broken out by annual income.)</i>				
	<b>Total</b>	<b>\$40K</b>	<b>\$40K-\$60K</b>	<b>Over \$60K</b>
Price/too expensive	47.2%	55.1%	51.2%	37.1%
Lack of long-term results	6.9%	5.1%	6.4%	8.9%
Fear of problems	15.8%	12.6%	14.6%	19.8%
Eye doctor against it	5.3%	5.1%	4.0%	6.1%
Waiting for new technology	6.0%	4.1%	6.2%	7.5%
Don't yet know enough	14.1%	14.0%	13.8%	14.4%
Haven't gotten around to it	4.7%	3.9%	3.8%	6.1%

Source: VisionWatch Eyewear U.S. Study

Better vision was most important to older patients, those who made less than \$40,000 and those living in the South. Eliminating hassle was most important to younger patients, those earning more than \$60,000 and those in the West.

When asked about other reasons they would have refractive surgery, patients mention eliminating discomfort of contact lenses or glasses, lower cost over the long term, never getting caught without glasses, and improving self image.

When deciding whether to have surgery, *these highly interested patients acknowledge the risk of complications* and the cost as concerns. Patients age 18-34, living in the Northeast and making more than \$60,000 are most worried about complications. The respondents most worried about cost? Southerners who are 35-44 and make less than \$40,000 a year..."

[\*"Laser In Situ Keratomileusis \(LASIK\) for Myopia and Astigmatism: Safety and Efficacy – A Report by the American Academy of Ophthalmology"\*, Alan Sugar, MD, MS, Christopher J. Rapuano, MD, et al, \*Ophthalmology\*, Volume 109, Number 1, January 2002.](#)

"Conclusions: Serious adverse complications leading to significant permanent visual loss such as infections and corneal ectasia probably occur rarely in LASIK procedures; however, *side effects such as dry eyes, nighttime starbursts, and reduced contrast sensitivity occur relatively frequently.*

Some of the most satisfied eye care patients are LASIK patients, and the goal is to continue to increase the percent of patients who are happy with this surgery."

[\*"LASIK Patients at Risk for Long-Term Eye Irritation, Study Says," American Academy of Ophthalmology, Press Release, July 2, 2001\*](#)

"Based on a July, 2003 study published in *Ophthalmology*. Authors say that LASIK patients with reduced ocular sensitivity due to long term wear may take *years to regain normal ocular surface sensitivity, if ever...*fluctuating vision reported by many in study improved after blinking or use of preservative-free artificial tears."

## **DISCERNING THE TRUTH ABOUT "THE NEXT BIG THING"**

The patient/consumer must be diligent with the introduction of "improved" and/or "new" refractive methodologies and technologies. The "refractive surgery medical-industrial complex" is looking for "The Next Big Thing." The refractive surgery market has contracted since its peak in 2000. Today, lasers are underused. Competition for the patient is fierce. Surgeons, national chains, and manufacturers are seeking a real or imagined competitive edge. With high fixed costs in laser based refractive surgery, financial problems lurk for those who fail to achieve adequate patient volume. The environment requires caution and discernment for those interested in "getting rid of their glasses and contact lenses."

History is a guide to how emerging procedure improvements and new approaches will be marketed to gain a competitive edge. Initially, PRK surgeons advertised that PRK was superior to RK since the procedure was not surgeon skill based but rather technology based. PRK brought to the procedure “Star Wars” technology, and micron accuracy. It was not too long after PRK was introduced that LASIK was introduced and LASIK competed against PRK on the basis of day one results - pain free and great vision. As competition grew, surgeons then competed on experience as LASIK was touted as skill based. Advertising moved to highlighting how many procedures a surgeon had done.

The low price National Chains entered the market in 2001 and price became the differentiator. These Chains believed they could create scale, leveraging the marketing/advertising expenses, and could provide LASIK, without compromising the quality of the procedure, at a much lower cost. The marketing costs per patient in those days were close to \$400 per eye.

Those surgeons who were not part of a chain were at a competitive disadvantage, including most of the Academics, and refractive elite. To retaliate, this group began to equate quality with price through advertising, and as spokespeople for local news stories focused on LASIK catastrophes. The overall strategy was to create fear in the mind of the consumer towards a lower priced procedure and national low priced chains.

The latter tactic is interesting. There is no data to support any claim that price is related to the quality of the outcome. In fact, the data presented thus far shows that the procedure has certain flaws, which are not surgeon or price dependent. *Patient’s should be concerned more with the procedure than its price.*

As price and quality became an issue, another group of surgeons, to differentiate themselves, advertised that they were the go-to surgeons for repairing LASIK complications. The message was “we are the best since we do the really tough cases.” Many of these were surgeons who promoted LASIK in its introduction as safe and complication free. Now, it has complications but if you come to me, I know how to deal with them. One reporter I know was confused as she talked to doctors She said that these doctors assured her only one year before that LASIK was problem free. Why were they now pushing their importance as the “go to docs” for LASIK problems. She wondered what problems were being fixed if none existed!

[\*“Off the Cuff: LASIK and Contact Lenses – Can’t We All Get Along?” Arthur B. Epstein, OD, FAAO, Chief Medical Editor, Optometric Physician, June 16, 2003\*](#)

*“Over the past month I’ve seen signs of a ramping up of anti-contact lens activity by some ophthalmologists involved in refractive surgery. It would seem that the success of silicone hydrogel contact lenses is making LASIK surgeons a bit nervous. After all, continuous wear contact lenses do make an attractive alternative to irreversible refractive surgery for many patients.*

Some in the contact lens community believe that the anti-extended wear onslaught of the past decade had politico-economic motivation. Whether this is true will always remain conjecture. However this time around, with *some optometric offices filled with LASIK disasters seeking rehabilitation and relief*, the shoe can easily be on the other foot...”

### **Wavefront Guided LASIK**

As you read about what is in development pipeline for commercialization, keep in mind the economics of refractive surgery, the economic investment and burden for a surgeon or a center, and the absolute need to increase throughput to remain solvent. Surgeons will adopt new procedures and/or modifications to old procedures, whether they are ready for prime time or not, due to competitive pressure.

Wavefront is a good example. Surgeons, even if they do not believe in it, will adopt it and push it so they will not be left behind. Despite wavefront’s adding little if any value, surgeons and national chains will try to use it to differentiate themselves from others (particularly those who cannot afford the change) and to raise prices. The hype and misinformation have already begun as some of those who have adopted it are already touting it as “safer” than the original LASIK. Since there is no FDA clinical data to support the claim of “safer”, this is a bogus and illegal claim. Like the original LASIK, it involves a flap, and the flap is still the major source of short term and long term “safety” problems.

["Challenges to Wavefront Correction, Introduction,"](#) George Waring, III, MD, FACS, FRCOphth, Editor-in-Chief, [Journal of Refractive Surgery](#), Volume 18, November/December 2002.

*"These, along with dozens of articles in other journals and presentations, can leave the impression that wavefront analysis will lead us to the holy grail of super vision for our patients, most seeing 20/10 without correction. Such a simplistic cartoonish view is, of course, unrealistic and inaccurate."*

["Wavefront technology: A New Advance That Fails to Answer Old Questions on Corneal vs. Refractive Astigmatism Correction,"](#) Noel A. Alpins, FRACO, FRCOphth, FACS, [Journal of Refractive Surgery](#), Volume 18, November/December 2002.

Page 738. "A second issue is that the correction of all ocular aberrations at the corneal surface pays no regard to the effects of corneal irregularities that will be produced by this uneven mode of treatment. Refractive surgeons have long known that corneal regularity (orthogonal and symmetrical astigmatism) is the foundation of a super visual outcome. Corneal irregularity can only increase if all corrections for internal optical errors are surgically sculpted onto the corneal surface without considering any pre-existing corneal topographical irregularities.

Technical challenges also impair our ability to accurately align the ablative patterns to make the focal changes to correct underlying optical aberrations. *It is difficult to permanently change regional corneal shape in this uneven manner, especially when the treatment can be neutralized by epithelial healing.* Any change in the crystalline lens will also complicate the long-term usefulness of wavefront driven changes."

["Thirty-four Challenges to Meet Before Excimer Laser Technology Can Achieve Super Vision,"](#) Isaac Lipshitz, MD, [Journal of Refractive Surgery](#), Volume 18 November/December 2002

"In correcting higher order aberrations, minor changes count. Corneal surface changes must reach an accuracy of one micron; only one or two laser shots delivered in a slightly wrong position or incorrect timing will interfere with the desired result... *These 34 challenges are divided into four main groups:*

- Ocular Challenges
  1. Changes in (the eyes) wavefront with age...*new aberrations will appear subsequently with age...*
  2. Changes of wavefront during accommodation (dynamic vision factor). (Accommodation is your eyes ability to focus far and refocus near) Even if we achieve super vision for distance vision, when looking at near, newly higher order aberrations may occur.
  3. Effect of pupil size on higher order aberrations. Change of pupil size – in light, dark, accommodation, convergence – dramatically affects vision...
  4. Biomechanical differences among corneas before surgery. *Corneas differ considerably in their biomechanical properties...*depends on age, corneal thickness, hydration, and collagen properties...
  5. LASIK flap biomechanics. Once a LASIK flap is created, the biomechanical properties of the cornea change dramatically depending on the depth of the incision, diameter of the flap, location of the hinge, and uniformity of the flap...even if the flap is returned to its place without ablation – there is a change in the wavefront measurement...
  6. Changes in tear film. Tear film properties in different eyes occur because of common pathologies such as dry eye and blepharitis...
  7. Changes in corneal thickness after laser surgery...affects tear film, the biomechanical properties of the cornea, the healing process, and mechanical strength of the cornea...
  8. Changes in wavefront during cycloplegia...
  9. Variation of ablation rate in different depths of the cornea...
  10. Variation in corneal thickness in different meridians. Usually the cornea is thinnest in the inferior or inferotemporal area, probably because these areas are dryer (they get less tears)...
- Uncontrolled Optical Changes During the Healing Process
  11. Corneal epithelium wound healing...
  12. Corneal collagen wound healing...
  13. *Effect of corneal biomechanics after surgery...*
- Technological Limitations of Surgical Equipment
  14. Eye positioning during preoperative measurement and laser treatment.

15. Accuracy of laser ablation...the exact amount of corneal tissue removed with each laser pulse changes continuously...
  16. *Microkeratome accuracy and profile*. At a specific setting, microkeratomes cut flaps of varying thickness – varying among manufacturers, among instruments, among eyes, and at different regions in a single flap...
  17. Tracking the location of the laser beam...
  18. Decentration...
  19. Accuracy of the wavefront sensors...
  20. Computer programs for the laser...the current capability of computer programs to integrate this enormous amount of data and to give to each piece of data the exact value required by the laser is questionable...
  21. Accuracy of the laser. Two instruments from the same company may work differently...
  22. Consistency of one laser. The laser pulse energy changes all the time, so the instrument calculates and uses an average energy...
  23. Chromatic aberrations are not detected by aberrometers...
  24. Location and shape of wavefront measurements...
  25. Objective aberrometers measure only the optics of the eye...This influence on surgical outcome is now known; perfect optics do not assure perfect vision...
- Uncontrollable Surgeon Variables
    26. Dryness of the ablation surface...
    27. Environmental issues during surgery...The temperature changes constantly due to the heat generated by photoablation...
    28. *Retinal problems of aberration-free optics. We still don't know if directing all the rays of light on the fovea (area of least confusion) – which is what we are going to do if we want to create super vision – will cause thermal or toxic damage to the retina. Maybe that's why there are optical aberrations in our eyes...*
    29. Possible worsening of visual performance with inaccurate surgery...
    30. *Effect of enhancement procedures on the wavefront. Currently, we have an enhancement rate of 5% to 25%, which is done only for lower order aberrations. If we expect to correct many higher order aberrations, a considerably higher number of re-operations may be needed. But, each enhancement procedure has its own effect on the total higher order aberrations because of lifting and repositioning of the flap.*
    31. Positioning the flap after ablation...
    32. Flap edema after ablation...
    33. Curvature of the flap and bed do not fit perfectly after ablation...
    34. *Irreversible procedure...the original condition of the eye cannot be restored.*

...Refractive surgery – especially LASIK – must overcome many challenges to reach this goal (super vision).”

[\*“Biomechanics of the Cornea and Wavefront-guided Laser Refractive Surgery,”\* Cynthia Roberts, PhD, \*Journal of Refractive Surgery\*, Volume 18, September/October 2002](#)

Page S589+. Although it has been demonstrated that image quality after customized procedures is improved over that of standard procedures (based on higher order aberrations), *there are still significant aberrations induced after a wavefront-guided procedure that are neither expected or predicted...*

Figure 1...illustrates a preoperative cornea where the inter-lamellar spacing is defined by parameters including geometry of the system, the tension carried in the lamellae, the internal fluid pressure, the interlamellar cross-linking, and the load imposed by the intra-ocular pressure...Also illustrated is a postoperative cornea...The remaining peripheral lamellar segments are relaxed to the maximum depth of the cut, and cannot bear the same tension as in the preoperative state...(For LASIK) *there are only certain shapes the cornea will accept, and the “ideal” shape that produces the “ideal” correction is likely not among them.*

*Any procedure that circumferentially, or near circumferentially, severs corneal lamellae will produce a biomechanical response that will alter corneal shape in a manner that cannot be predicted with wavefront analysis alone.*

["Some foresee limitations in wavefront technology," \*Ocular Surgery News\*, August 1, 2002](#)

Michael Goggin, MD, of Adelaide University said, "Aberrations increase with age. What we do now may lose its effect in ten years. He "wondered whether there would be problems matching IOLs to customized corneas in patients who develop cataracts after wave-front ablations."

["Effects of Accommodation and Flap Biomechanics May Complicate Quest for Super-Vision," \*EuroTimes\*, March 2001,](#)

Ionnis Pallikaris, MD, pointed out in his presentation to the Winter Refractive Surgery Meeting in Cannes, that "vision in the human eye is not a static, but dynamic process, and the process of accommodation (adjusting for near and far vision) in a day-to-day basis and as an individual ages can influence the wave front aberration profile of the eye and consequently confound attempts to achieve "super-vision" with LASIK or other refractive procedures.

["Reflections on Refractive Surgery", Olivia Serdarevic, MD, \*EuroTimes\*, March 2001.](#)

Reporting on the Winter ESCRS meeting in Cannes...."There was also a consensus about the frustration with our current incomplete knowledge of and ability to modify many optical, biomechanical and biomolecular effects of refractive surgery... *The speakers agreed that the endpoints of 20/10 or better visual acuity and aberration-free vision, which have been promoted not only to ophthalmologists but also to patients, represent very simplistic, naïve and erroneous assessments of our visual function and needs...Wavefront aberrations of the optical system are dynamic..* How can successful integration of wavefront analysis and laser ablation occur before complete standardization of measurement in normal eyes during the performance of different visual tasks over time? ...How can we use wavefront information for computer programming of laser ablation in normal eyes before we adequately analyze wavefront aberrations induced by LASIK flaps and existing laser ablation methods and correlate these aberrations with corneal shape, biomechanics and wound healing?...*Many...attending the meeting were getting tired and worried about exaggerated and erroneous "super vision correction" claims."*

#### **IntraLASIK™ (Intralase™ LASIK)**

IntraLASIK is an all laser procedure that provides, most importantly, a laser alternative to making the flap. It claims to eliminate much of the variation caused by the mechanical microkeratome in flap creation. Some surgeons have purchased this to differentiate themselves from those that use a mechanical device. Some of the surgeons promoting IntraLASIK are promoting it as "safer" than LASIK. There have also been several recent stories in the mainstream news talking about it being safer than traditional LASIK with a mechanical microkeratome. Be aware that there is no FDA data to support this claim and it is illegal to for anyone to make this claim.

While there are trade-offs to using IntraLASIK over the microkeratome, some of which are positive, don't forget that a flap, regardless, of how it is made, is a flap. The creation of the flap is one of the fundamental flaws of LASIK as it destroys the homogeneity of the cornea, and weakens it. Only time will tell if LASIK and/or IntraLASIK leads to a loss of effect (as the cornea becomes steeper, or bulges out) or in worst case, leads to ectasia.

#### **LASEK (an emerging off-label procedure)**

["LASEK learning curve steep, despite experience, surgeons say," \*Ocular Surgery News\*, July, 2003](#)

"Mastering laser epithelial keratomileusis is challenging, and creating the epithelial flap is more difficult than the literature suggests...The study should alert surgeons that 'LASEK is not a reproducibly easy procedure at its start,' the authors said. 'Moreover, additional studies should be conducted with longer follow-up to guarantee that corneal haze (incidence of 65%) is not a long-term problem....'"

["Surface ablation gets high marks at LASEK meeting/ highlights of the international LASEK congress included discussion on corneal haze and night vision," Nicole Nader, \*Ocular Surgery News\*, July 1, 2003](#)

"Laser epithelial keratomileusis is a promising technique, but the pitfalls of older surface ablation techniques (PRK), such as corneal haze, are still an issue....Significant corneal haze 'may' occur after LASEK...At 6 months postop, grade 0.5 haze was present in 58% of the patients, grade 1 in 25% and grade 2 in 8% of patients. '(may' in this context means an incidence of 91%!)...ninety percent of my patients were testing

positive for starburst phenomenon,' he (Bruce Larson, MD) said....'Results showed that LASIK produced significantly more starbursts than LASEK'...

LASIK pitfalls discussed...LASIK has the potential for complications that are not seen in other refractive procedures, including increased coma, keratectasia (ectasia) and surgeon-induced irregular flaps, according to a number of presenters...several surgeons described complications seen in LASIK but not in surface ablation procedures such as LASEK."

### **Lens-based refractive surgery – Intraocular lenses (phakic IOLs)**

Refractive (phakic) IOLs are on the horizon. These include products like the ICL and the Artisan lens. As these products are introduced, their proponents will layout the problems of laser-based procedures (LASIK, wavefront, etc.) as never before. Pay close attention to FDA data on inclusion data (who can benefit), on adverse events, complications, and visual problems. These procedures are the most invasive of any known procedure. The surgeon must go into areas of the eye that are very small and/or dynamic presenting serious new risks. As an analogy, this is comparable invasive surgery for the eye as open-heart surgery is for the heart.

These procedures may be marketed as reversible. Understand completely what that really means. To extract and replace a lens is no simple procedure and can lead to other problems. If someone markets this as reversible, ask to see the FDA outcomes/complication (post removal) data that proves reversibility. Do not accept "personal study" results.

*"Some refractive procedures carry higher retinal risks, study finds," Ocular Surgery News, September 29, 2003, Re: Study published in The Journal of Refractive Surgery, September-October, 2003*

"Certain refractive procedures for myopia pose a greater risk of postoperative retinal problems than other refractive procedures, a large cohort study suggests. Phakic IOLs created the highest risk for retinal detachment in the study, followed by LASIK and then photorefractive keratectomy (PRK)...

...Retinal detachment occurred at a mean of 53.6 months after PRK in nine eyes (0.15%), 24.6 months after LASIK in 11 eyes (0.36%) and 20.5 months *after phakic IOL implantation in 12 eyes (4%)*. Choroidal neovascularization occurred in 10 eyes that had undergone LASIK (0.33%), in *seven with a phakic IOL (2.38%)* and in one that underwent PRK (0.01%)."

*"Multifocal phakic IOL an option for hyperopia," Ocular Surgery News Supersite, September 15, 2003*

MUNICH, Germany — A multifocal phakic IOL can be an efficient, potentially **reversible** refractive surgical option for patients with hyperopia, according to a presentation here.

Georges Baikoff, MD, spoke on the use of a bifocal anterior chamber phakic IOLs at the European Society of Cataract and Refractive Surgeons meeting. He shared the results of his personal study using the lens during a symposium on hyperopia...

...He said there was some incidence of glare and halos, but these were accepted by patients. There was also an acceptable loss of contrast sensitivity compared to preop, he said.

"It is mandatory to tell patients that this is a compromise between excellent vision with spectacles and good vision with the IOL," Dr. Baikoff said.

He noted that in using anterior chamber phakic IOLs, accurate biometry is necessary to ensure that patients have sufficient anterior chamber depths. Shallow anterior chambers are prone to angle closure, and there is risk of endothelial cell loss, he said.

*"Lens-based refractive surgery shifting focus from the cornea to the lens," Nicole Nader, Ocular Surgery News, July 1, 2003*

"...on the other hand, lens-based surgery also carries considerable risks: the increased risk of intraocular procedures..., the possibility of complications associated with IOLs, the heightened risk of retinal detachment, and with phakic IOLs, the possibility of inducing secondary glaucoma or cataract..."

## **The ICL™ (the Implantable Contact Lens)**

The ICL has been commercially available outside the United States for a number of years and is making its way through the FDA approval process in the US. The ICL is a very small micro lens that is placed in the eye (very invasive surgery) in a very narrow space between the iris and the crystalline lens. It has had a history of problems outside the US with complications that include cataracts and glaucoma. The company that manufactures the lens claims that these problems have been solved. One interesting historical note is that those surgeons promoting the ICL changed the terminology relating to pre-cataract conditions to a new term, "opacities". "Opacities" is a benign and misleading term compared to pre-cataract or cataract.

From an anatomical point of view, the ICL is being placed in one of the most dynamic and hostile environments of the eye. The iris and the crystalline lens (unless it has been replaced with an intraocular lens) are constantly moving. The iris opens and closes (like a camera lens) to let in the appropriate light rays, while the crystalline lens expands and contracts as it provides zooming power (accommodation) for reading and distant sight. If the ICL touches the iris, pigmentation of the iris, which provides your eye color, will be dispersed. This can lead to glaucoma, which, in turn, can lead to blindness. In addition, if the ICL touches the crystalline lens, the crystalline lens will develop an opacity, which historically has been considered a condition that could lead to a cataract. If it becomes a cataract, the natural lens must be removed and replaced by an intraocular lens. With the IOL, the eye loses its focusing capability. For those who do not need reading glasses, this may become a serious inconvenience. For those who have lost the ability to focus (usually over 50 years of age), this may not be a problem.

The ICL must be placed exactly right to avoid complications. When you understand the maneuver that must be made to insert this lens, you will understand that this procedure requires great skill. If a claim, or any semblance of a claim, of reversibility is made by a doctor, check the FDA approval. It is highly doubtful that the FDA will grant this marketing claim. Removing the ICL can result in touching either or both the iris (pigment dispersion/glaucoma) and the crystalline lens (opacity formation/cataracts). There is little if any margin for avoiding these problems in a removal.

The recent press releases and publications on this procedure need to be reviewed with great care. Hype and misleading statements have begun. For the publications, find out who the authors are and what relationship they have to the company.

One recent study argued that the complications like retinal detachments, glaucoma, and cataract were no different for the general population as they were for ICL patients. This was not a scientific head to head comparative study. The authors, some of whom are paid consultants for the manufacturer, implied that there is no need for concern when these problems occur after an ICL procedure. The study is bogus and the conclusion is not reasonable. For a study to reach this conclusion, it would require a scientific based longitudinal (five years or more) study including a control group that did not have the ICL.

Studies and conclusions like this will be developed and promoted by ICL enthusiasts to convince an unsuspecting public of the procedure's safety and efficacy.

The FDA panel has approved the ICL by a 8-3 vote for commercialization. Note the success rate in the Reuters news story on the approval, and information that the company provided preceding the approval. Note the differences.

### *[UPDATE - US panel urges approval for Staar implanted lens, Lisa Richwine, Reuters, October 3, 2003](#)*

"GAITHERSBURG, Md., Oct 3 (Reuters) - A U.S. advisory panel on Friday voted 8-3 to urge approval for Staar Surgical Co.'s (NasdaqNM:[STAA](#) - [News](#)) implantable lens to correct nearsightedness, a possible alternative to laser eye surgery.

If the Food and Drug Administration ([News](#) - [Websites](#)) agrees with the panel, which it usually does, the product would be the first implantable lens sold for people whose natural lenses are intact. Implanted lenses on the market now are used to replace lenses following cataract surgery.

Staar's product is a refractive lens that physicians inject through a small incision and place behind the iris. The company aims to market the procedure for people age 21 to 45 with moderate to severe nearsightedness, or myopia.

In a trial evaluating more than 500 eyes that had the lens implanted, *84 percent had vision of 20/40 or better one week after the procedure. Three years later, 81 percent had that level of vision, the company said.*

*Some patients experienced a gradual loss of cells in the cornea, an issue of concern to the panel. Some loss is normal, but panelists said they could not tell from the current research whether the loss would continue over time and damage the cornea.*

The company argued the cell loss stabilized in three to four years, but *the panel said the research did not prove that was the case.*

*"We don't know what's going to happen in 10, 20, 30 years," said Dr. Marian Macsai-Kaplan, a panel member and chief of ophthalmology at Evanston Northwestern Healthcare in Illinois.*

The panel, by a 6-5 vote, urged the FDA to require Staar to *monitor the cell loss annually* for five years in certain patients who took part in the clinical trial. *Some who dissented felt the long-term data should be collected before the device is allowed on the market.*

The Staar lens would offer an alternative to the popular Lasik surgery, in which physicians use a laser to reshape the cornea and correct vision.

Staar calls its device an implantable contact lens. *Panel member Timothy McMahon, professor of ophthalmology at the University of Illinois at Chicago College of Medicine, said that description was a "euphemism" that could mislead patients and should not be allowed..."*

["U.S. Food and Drug Administration clinical trial of the Implantable Contact Lens for moderate to high myopia," Staar Surgical, Ophthalmology, August, 2003](#)

*"Twelve months postoperatively, 60.1% of the patients had visual acuity of 20/20 or better, and 92.5% had an uncorrected visual acuity of 20/40 or better (ed note: 20/40 is required to drive a car without corrective lenses, therefore, 7.5% of ICL patients will not pass the driver's license exam)...presumably surgically induced anterior sub-capsular opacities (ed note: cataracts) were seen in 11 cases (2.1% of the group)...Patient satisfaction was reported by 92.4% of subjects on the subjective questionnaire."*

*In its investor related quarterly conference calls., the company has been projecting significant acceptance of the ICL procedure. Note that with an induced cataract incidence of 2.1%, 21,000 out of every million Americans having this procedure will develop cataracts. This will mean further irreversible surgery to remove what was once a healthy crystalline lens. It will be interesting to see how the company and surgeons market this procedure and what role the FDA will play in insuring that communications are not misleading.*

["99.4% ICL Patient Satisfaction Level Linked to Superior Image Quality," Press Release by Staar Surgical, July 24, 2003](#)

The above press release (available on the Staar website) is a company press release reporting on a study conducted by a group of doctors who compared their LASIK results to their ICL results. These doctors are not unrelated parties to Staar Surgical, the manufacturer. These doctors then took their results and created a mathematical model to simulate the visual image of what a patient saw after each surgery. *"The comparison clearly demonstrates a sharper and clearer image in ICL patients... the study concluded that the ICL was safer and more effective than LASIK...and why the ICL will become a prominent choice for vision correction."*

This press release is another example of the care patients must take to discern the facts. First, the referenced study group was very small. The study was not a FDA regulated study. And the claims of "safer and more effective" are not only misleading, but are also illegal. Secondly, patient satisfaction percentages are an exaggeration when compared to the FDA study (which precedes this section). Finally, the creation of a mathematical model requires numerous assumptions. Those who are in experts in mathematical modeling know that the models cannot provide specific, accurate information but only trends.

### **The Artisan™ Lens**

The Artisan lens is a Dutch (Oftech, Groningen, Holland) developed lens that has been in use outside the US for more than 15 years. The lens is placed in the eye between the cornea and the iris contrasting with the ICL which is placed between the crystalline lens and iris. The company founder, Jan Worst, MD., is one of pioneers in intraocular surgery. Dr. Worst is principled and well-respected. He and his company have

historically not oversold any of their products. Unlike other procedures, excepting RK, the outcomes and complications of the Artisan Lens have been fully characterized over 15+ years. The Artisan is in US FDA clinical trials today.

Since the Artisan may prove to be a formidable competitor with its well-defined outcomes, those vested in other less characterized procedures have already started to put negative spin on the Artisan. One competitive company, in its press releases, calls the Artisan approach archaic and first generation surgery, claiming that surgeons will want something more modern. This company also claims to have the “third generation” product, which is much easier for a surgeon to use. This company has steered clear of the longitudinal (over time) outcome/complication comparison and is focusing investors, surgeons, and interested patients on ease of use. Discerning patients would be well advised to focus on the Artisan’s years proven outcomes, and not something that is “easier to use.” While “ease of use” may save money in the short term for the surgeon, it does little for the quality of life of the patient over a lifetime.

### **Radio-frequency Procedures for hyperopia**

An emerging group of procedures for hyperopia includes using heat to heat up the collagen in the cornea, causing it to shrink, and thereby causing the cornea to become steeper. Radio-frequency generated heat, and holmium laser heat are in this group of procedures.

Heating the collagen is a potential solution for hyperopia since the cornea is too flat and needs to be steepened. The good news about these procedures is that they are, to a great extent, reversible. The collagen in the cornea tries to return to its original thickness, and the cornea to its original shape. The bad news is that outcomes are variable, outcomes may be short-lived, and the variability of the outcome will persist as the cornea tries to reach equilibrium.

### **SUMMARY**

- Historically, the “refractive surgery medical-industrial” complex has used selective information to move patients to a refractive procedure. Patients must perform adequate diligence on their own to insure that they fully understand the risks and benefits of any procedure. Surgical Eyes, [www.surgicaleyes.org](http://www.surgicaleyes.org), is a very valuable resource for those seeking balance.
- An illusion of safety has been created around refractive surgery through selective marketing. Purveyors of the illusion have a vested interest in keeping it going. Interests can range from financial greed, fear of exposure for doing something that can cause harm (thou shall not do harm), to the fear of being sued. The enormous complexities of human behavior that are motivated by greed, a fear of exposure, and financial loss are at work here. Fear leads to oppression and tension. The natural inclination is to hide from failure and to give the impression of perfection. If exposed, public rejection and lawsuits will follow. LASIK surgeons have made their Faustian bargain, and at some level they know it.
- LASIK has basic flaws that are independent of a doctor’s skill level (and what you are being charged). These include quality of vision degradation due to loss of asphericity, dry eye due to several anatomical factors, a weakened cornea, due to the creation of a flap. The weakened cornea may lead to the loss of correction effect and ectasia. Ectasia may be the Achilles heel for LASIK as the cornea never regains its initial strength and homogeneity after the flap is cut. Cells may seal the flap preventing infection but the underlying structure never heals and remains in a weakened state. The cornea, with time, may bulge forward due to the internal pressure inside the eye causing a loss of effect and/or irregular bulging.
- Dry eye is a troublesome problem. A great deal of money is invested annually in the search for a cure and effective treatment by private industry and the US government (NIH). It is a paradox that while money (taxpayers dollars) is being allocated to solve this problem, refractive procedures now add to the prevalence of this problem.
- “Real” complication rates of a procedure are openly discussed, not when the procedure is popular, but rather when providers are pushing newer, “improved” procedures and want to obsolete the older procedure.
- The anatomy of the eye is dynamic, changing with age. Optical aberrations are dynamic as well. Irreversible correction of vision (particularly with tissue removal), whether with LASIK or wavefront guided LASIK, only corrects vision at one point in time. This becomes problematic with age when new aberrations are introduced and/or with the onset of certain eye diseases. Upgrades are not an option!
- Reaching 20/20 does not mean a high quality vision outcome. You may still be seeing 20/20 but you may have degraded vision, particularly in low light environments and at night. Nevertheless,

with a 20/20 outcome, the “refractive surgery medical-industrial” will consider and promote you as a refractive success.

- The use of adverse events, complications, and visual symptoms are medical terms unique to ophthalmology and are easily misunderstood by consumers when asking the incidence of problems. Patients should be informed of the definitions, should consider visual symptoms a complication, and should ask physician/providers for a full accounting, incidence, and severity of all visual symptoms.
- Due to the significant upfront investment and operating overhead required to operate a refractive surgery center/practice, throughput (volume of procedures) is critical to financial survival. Investments made include the equipment, a highly trained staff, marketing and advertising, and referral payments to other physicians. High investment and high fixed costs have been key drivers in the marketing of refractive procedures.
- There is no science-based study showing that paying a price of \$499 versus \$1500 will provide you with a better outcome or fewer complications. Those who charge more prefer that patients believe price makes a difference, but only so they can generate more patient traffic at a higher prices. But, the bottom line is a LASIK is a LASIK, cutting a flap is cutting a flap.
- Vision is critical to athletic performance. Professional athletes like Jennifer Capriati (tennis), Troy Aikman (football), Tommy Armour III (golf) and Scott Hoch (golf) have had LASIK, and have had their vision and their performance compromised. For example, Armour lost all depth perception after LASIK, nearly lost his PGA exemption, and now wears specialty hard contact lenses to compete. A quick search on [www.google.com](http://www.google.com) will yield information about the other athletes. One very special athlete to watch closely is Tiger Woods. Ophthalmology hallway conversation highlights that Tiger had an 11.0 diopter (nearsighted) correction with LASIK, and up to three enhancements. He had problems immediately after the procedure (as reported by him on HBO), appears to have some difficulty on overcast days (lowlight), and is now struggling two years after his procedure. Due to the size of correction (the depth of flap required), Woods is at “high risk” for an unstable cornea and ectasia long term.
- Do your homework before you proceed with any irreversible refractive surgery procedure. Investigate all potential conflicts of interests. Make sure that all of the healthcare providers you are dealing with have your well-being foremost in their hearts and minds. You only have one pair of eyes!!
- **Appendix A** contains a recent introspective editorial by William Maloney, MD. suggesting that the surgical profession must move forward cautiously in adopting new refractive techniques so as not to repeat the mistakes of the recent past. While it is much less detailed and shifts much of the blame to “sales people”, it is a good companion piece to “The Promise of Refractive Surgery: A Promise Not Kept.” The failure of keeping the promise is not a “salesman” problem but rather an industry problem. There has been and continues to be an unconscious conspiracy within the “refractive surgery industrial-medical complex” placing the patient’s interests secondary to vested interests.

## APPENDIX A

*“Apply lessons of the LASIK experience to refractive lens exchange : Surgeons should take it slow when it comes to this new lens-based refractive technique,” William F. Maloney, MD, OCULAR SURGERY NEWS September 15,2003*

This month we are going to take a short detour from our discussion of specific techniques used in refractive lens exchange. I would like to bring out an issue that needs to be addressed as this procedure takes center stage. Let us call it the bandwagon effect or “the next new thing” problem. After rereading each of my past columns on refractive lens exchange, I noted a clear sense of concern in comments such as these:

“I am one who feels strongly that the transition from cataract surgery to refractive lens exchange ought not be taken for granted.”

“The techniques are proven and ready. As surgeons are we ready?”

“Performing cataract surgery without the cataract suddenly shifts the outcome equation to results that consistently must be very near perfect. In order to cross the 20/20 threshold responsibly, each surgeon must ask, ‘Have I prepared enough to be sure that I can deliver results at this level on a consistent basis?’”

What concern lies beneath statements like these? Why am I suddenly the sober cautionary voice of restraint? After

all, my revolutionary credentials are intact. I was on the barricades teaching phaco and IOL-related innovations throughout the '80s and '90s. I have long been on record saying that refractive lens exchange is a procedure whose time has come, predicting that it will play a central role in the future of refractive surgery. Now that the tipping point has arrived and more and more surgeons are reaching the same realization, why am I suddenly feeling uneasy?

I think the answer is that I am concerned for what might happen to refractive lens exchange if it becomes the next new thing. I see increasing signs of hyperbole in such projections as the entire baby boom generation lining up to have their presbyopia corrected at \$3,000 per eye just as soon as one of the accommodating IOLs becomes available. If experience with LASIK has taught us anything, it should be that hype is not in the long-term interest of our profession.

#### Jumping on the bandwagon

Refractive lens exchange, increasingly seen as the fastest growing refractive surgery technique, is currently a white-hot topic. After steadily working with this approach in my cataract patients since 1986, the suddenness with which this procedure has become a front-page feature has begun to make me uneasy.

It reminds me of the first years of PRK and then LASIK, which was almost immediately proclaimed the treatment of choice for all refractive error from +8 D to -20 D. It never happened, of course. As the limitations of LASIK have become increasingly difficult to ignore, the recommended treatment range shrunk steadily to what is now a range somewhere around plano to -8 D. This is close to LASIK's starting point when it was introduced on the heels of radial keratotomy.

No one would argue that LASIK is not a major advance over RK. Significant progress was made, but in getting there, we got it backward. Instead of a measured, step-wise advance from -7 D (where RK had brought us), we joined in a collective leap of faith to -20 D and have spent a good part of the past decade backpedaling. How did we manage to get this one so wrong? I think it happened in part because LASIK was arguably our first bandwagon phenomenon — jump on now or risk being left behind. The seeds of the LASIK letdown were sewn from the start when LASIK was snagged by the next new thing phenomenon. The rest is history — a history that we must not repeat and with lessons that we must be sure to learn.

#### Too far, too fast

This bandwagon effect was enhanced by several factors. At least part of its origin can be found in the phaco and IOL revolution. We are all aware that this first technology-driven revolution led to a golden age of unprecedented progress in cataract and refractive surgery. Ophthalmology can be justifiably proud of the truly remarkable accomplishment that is cataract surgery today.

Revolution, however, is almost always a two-edged sword, and history repeatedly tells us that revolutions can end up devouring themselves if they are unchecked and allowed to carry too far. This phenomenon — call it overshoot — typically occurs because of the inevitable transfer of power at the center of every successful revolution. The principal players in the old power structure either capitulate and join the revolt, or they are marginalized. Either way, the old guard's conservative, usually self-interested voice of restraint and moderation is silenced. Like a coiled spring suddenly released, the momentum of unchecked forces for change can easily carry too far, jeopardizing the original gains of the revolution.

This historical template aligns perfectly with the phaco revolution. After a struggle (Ridley, Kelman and many early pioneers have all described this), the old guard of traditional ophthalmology finally capitulated and joined the ranks of phaco and IOL surgeons. They had seen their influence eclipsed. They had lost the spotlight to a ragtag army of private practitioners who took control of the podium, describing small-incision cataract surgery performed in unprecedented volumes with remarkable efficiency and vastly superior results.

The old guard learned all too well the futility of resisting the power of an idea whose time had come. It is hardly surprising that they were determined not to be on the wrong side of the next revolutionary concept when it first came into view. The stage was set with the bandwagon at the ready. Ophthalmology (surgeons and industry) scanned the technology-laden horizon for the next new thing. It was PRK and then LASIK, and the scramble to get on board erupted with a vengeance.

#### Progress with precautions

At the core of the next new thing problem is that it does not encourage the slow, steady and thoroughly verified progress that patients assume has already occurred by the time they encounter a new technique. The threshold for accepting and utilizing new technology tends to fall beneath the level required by the more sober long-term demands of our profession. In this overheated environment with a sense of urgency not to miss the boat, our collective point of persuasion can get reset too low, blurring the vital distinction between science and salesmanship.

We practitioners can too easily forget the one thing we must never forget: The industry representatives are the salesmen, and we are the scientists. Hype is often a completely appropriate tool for the sales force with specific short-term financial goals or a strategy for gaining market share. For us physicians, it can only be counterproductive. There is a line at which the interests of the industry and those of our profession, which are usually well aligned, can act at cross-purposes. One of our primary responsibilities as medical professionals is to carefully monitor that line.

#### Lessons from haiku

The oath we took separates us and defines us as the most esteemed of professions. We have much to lose when we fail to fully honor that oath.

This is a wonderful ideal that unfortunately may be at risk of becoming a cliché. Let me conclude with an appeal to sharpen our focus on that sentiment, for in my opinion it lies at the heart of this issue.

There are two Japanese art forms that I have particularly enjoyed since first visiting Japan to teach phaco with Dick Kratz and Dave Dillman in 1988. The first is a form of calligraphy that allows the artist only a single brush stroke. The other is a form of three-line poetry known as haiku in which the poet must follow this highly restrictive format: The first line has five syllables, the second line has seven syllables, and the third and final line has five syllables.

Artists who work in these media are set apart and defined by the restrictions to which they adhere. Their task is more difficult and the product of their efforts is therefore more highly esteemed. Should they fail to adhere to the restrictions then, de facto, they are no longer a member of that artistic group.

In like manner, we physicians have agreed to be restricted by the dictum of the Hippocratic oath, "First, Do No Harm." Just as with this group of artists, we physicians have accepted the challenge of greater restrictions on our efforts to advance progress with new technology and clinical innovation. By agreeing to do no harm, we accept that we must find ways to accomplish progress without a significant overshoot, without harm. Ophthalmology is not permitted the cyclical approach to progress: three steps forward followed by two steps back. Note that this core principle does not preclude progress. It does, however, require that our progress unfold in smaller, more measured and well-verified steps.

When we succeed, we fulfill our contract to the patient and continue to earn the trust and higher esteem in which physicians have long been held. However, if we sidestep the more measured approach to progress, if we overreach and create a significant innovation overshoot, then we too are de facto, no longer members of our more select professional group. We risk losing that trust and esteem and will eventually be seen as little different from a sales force, which as we know has a different dictum: caveat emptor.

I am not at all anti-industry. I just want to shine a bright light on this crucial fact: Physicians and sales people are defined by different roles and different rules. Only we have the responsibility that accompanies patients' trust because only we have taken the oath to protect them from harm, even as we advance progress.

So as we move now in earnest toward refractive lens exchange, I would like to appeal for a collective downshift to a lower gear. We may move slower, but as we have seen here, for us physicians that is exactly as it should be and as it must be if we are to continue to earn the trust and esteem that sets us apart.