



Ophthalmology Update

Richmond Eye Associates, P.C.

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Ophthalmic Topics of Interest to the Medical Physician

Laser Vision Correction: Where it is now, and what is next.

Public awareness of LASIK (Laser In-situ keratomileusis) is rapidly increasing, not only through extensive marketing campaigns but also through national news publications and programs. Patients may turn to their physicians for advice as to whether or not they should have the procedure themselves. This issue of Ophthalmology Update explores the fact and fiction of Laser Vision Correction, and what developments are anticipated in the future of this rapidly changing field.

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The State-of-the-art in Laser Vision Correction: What Can it Do, and For Whom?

Laser Vision Correction is essentially the reshaping of the cornea using a laser in order to eliminate refractive error. Lasik is currently the most frequently performed refractive procedure with millions of cases performed annually. The interest in Lasik is well demonstrated by the unprecedented attendance at this year's Annual Symposium on Cataract, IOL, and Refractive Surgery, held in May in Boston. Over 10,000 physicians, staff, technicians, and corporate personnel were present, representing over 70 countries.

However, amid all of the media and marketing hype over Lasik is the fact that the procedure is designed to treat very

specific refractive conditions, and it is not for everyone. Currently, the lasers used are capable of correcting high degrees of nearsightedness with or without astigmatism, and fairly low degrees of farsightedness, without astigmatism. In no way can the procedure restore the ability to focus, which is generally lost by the time one turns 50 (presbyopia). Some individuals can opt for monovision (one eye set for reading, and one for distance) if desired, as is done with contact lenses.

As shown in the box on the left, Lasik can be very effective at reducing the need for glasses or contact lenses, in appropriate candi-

The Success of Lasik

The CRS Research Study is a physician lead study looking at the results of Lasik in nearly 2000 eyes using either the Summit or VISX excimer lasers:

- After treatment of low to very high levels of nearsightedness and astigmatism, 92% to 95% of eyes saw 20/40 or better by 6 months after surgery, without glasses.¹
- In treating low to moderate nearsightedness, 51% to 63% were 20/20 uncorrected after surgery.¹
- Less than 1% experienced an adverse event from Lasik.

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In the Next Issue of

Ophthalmology Update:

Neuro-Ophthalmology Update

- Optic Neuritis
- Myasthenia Gravis
- Pseudotumor Cerebri
- Retinal Emboli

New and Upcoming Laser Vision Correction Technology

Eye Tracking Lasers

The excimer lasers that treat refractive error are extremely precise, being able to alter corneal curvature at the level of microns. However, it is crucial for the laser to

be continuously centered and focused on the cornea during the ablation, or aberrant results can occur. Usually, this is accomplished successfully by simply having the patient

Continued on page 3 . . .

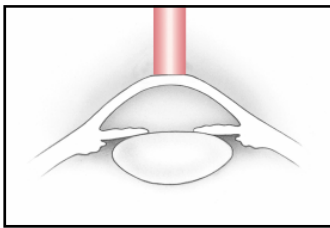
Laser Vision Correction: LASIK vs. PRK

Features Common to both Lasik and PRK

Both procedures use an excimer laser to reshape the corneal curvature to correct near-sightedness, astigmatism, and farsightedness (laser ablation).
Both procedures use only eyedrop anesthetics, and both take only minutes to perform.
Both procedures are FDA approved

Photorefractive Keratectomy (PRK)

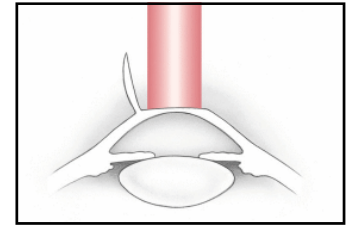
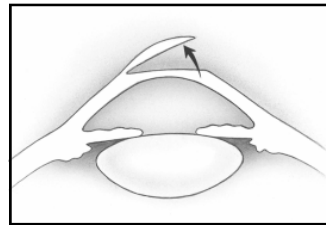
The ocular surface is prepared, and the excimer laser is used to treat the corneal surface.



Following PRK, a bandage contact lens is usually placed on the cornea for comfort, and the eye heals gradually over a period of weeks. For this reason, usually only one eye is treated at a time with PRK. One advantage of PRK is that there is no potential risk for corneal flap related problems.

Laser In-situ Keratomileusis (LASIK)

A microkeratome raises a thin corneal flap, creating an extremely smooth bed for laser treatment. The flap is reflected, and the excimer laser treats the corneal bed. The flap is then repositioned and smoothed into place.



Following LASIK, the eye has minimal discomfort, and vision usually returns rapidly over a period of days. For this reason, both eyes are routinely treated with LASIK at the same sitting. Patching and bandage contact lenses are rarely needed. Eyedrop medication is usually stopped after one to two weeks.

Clinical Pearl: Medical Concerns and Contraindications to Lasik

There are a number of medical situations which contraindicate the performance of Laser Vision Correction procedures which use the excimer laser, such as photorefractive keratectomy (PRK) and Lasik. Since patients may not be precisely aware of the name, status, or classification of medical disorders which they may have, it is useful for their medical physician to know that certain conditions should not be overlooked when considering Laser Vision Correction:

- Patients with collagen vascular and autoimmune disorders such as rheumatoid arthritis, lupus, Sjogren's syndrome, and Wegener's Granulomatosis should **never** have Lasik or PRK. There is a substantial risk of unpredictable corneal melting with possible corneal perforation with these disorders.
- Amiodarone becomes sequestered within the cornea, and can interfere with laser ablation.
- Accutane is associated with dry eye problems, which typically become worse after Lasik, for a period of time. This drug should be avoided.
- Laser Vision Correction should not be performed if there is any chance of pregnancy, or if pregnancy is planned within 6 months of the procedure. Breast feeding should be stopped for several months before Laser Vision Correction, due to hormonally induced changes in corneal shape, lubrication, and healing.
- Controlled medical disorders such as diabetes, hypertension, heart disease, etc. do not contraindicate Laser Vision Correction. However, any uncontrolled medical disorder does.
- Immunocompromised patients (whether medically induced, or due to infection), should seriously reconsider Laser Vision Correction, due to the risk of vision threatening corneal infection.
- Patients with pacemakers can have Laser Vision Correction, if the heart is not completely dependent on the pacemaker for functioning. Excimer lasers emit a large amount of electromagnetic energy, which could interfere with pacemaker function if the laser shielding mechanism was defective.
- A history of ocular herpes simplex infection, or of ocular zoster infection usually contraindicates Laser Vision Correction, due to risk of recurrence.
- Patients with a history of keloid formation should not have Laser Vision Correction.
- Patients considering Laser Vision Correction should be at least 18 years of age.
- Neurological problems, such as multiple sclerosis, do not contraindicate Laser Vision Correction.

Life Beyond Lasik: Alternative Procedures to Correct Refractive Error

While the excimer laser has been highly successful in treating high levels of nearsightedness with astigmatism, there are limits to how much reshaping the cornea can sustain without becoming unstable. Treatment of low to moderate levels of farsightedness has been less successful, with more risk of regression of the laser effect with time. Furthermore, in Lasik, there is always a risk of a microkeratome or flap related complication, even in the most experienced of hands. Some newer, non-excimer laser, non-Lasik procedures are alternative procedures which may be desirable in some cases.

Sunrise Technologies' Hyperion LTK

The FDA recently approved the Hyperion LTK (Laser Thermal Keratoplasty) system for treatment of low to moderate farsightedness. In order to steepen central corneal curvature, this Holmium:YAG laser treats the peripheral cornea with 2 concentric rings of eight simultaneous spots. The laser application takes only about 3 seconds to perform. The procedure was approved for individuals over 40 years of age, with a stable refraction. In a significant departure from excimer laser treatments using Lasik, the central cornea is untouched by LTK.

Keravision's Intacs

New Technology (from page 1)

fixate his gaze upon a blinking fixation target during the ablation, which usually lasts from 10 to 60 seconds. At the same time, the surgeon monitors the focusing of the beam and its position over the patient's pupil to maintain centration. It is rare to have decentered laser ablations when these techniques are used. Nevertheless, laser tracking devices have been developed, and are available with certain lasers to maintain the fixation of the laser automatically.

One such laser tracker is found with the Summit Autonomous laser (LADARVision). The ability of this laser to maintain its position on the cornea is quite remarkable. Using an infrared signal, eye position is captured 4000 times per second, with high speed servomotors maintaining laser beam position as needed. This is even effective in cases of nystagmus, where the eye rapidly oscillates involuntarily back and forth. In routine cases, patient fixation alone is adequately effective in maintaining laser centration.

The downfall of this particular laser tracker is that pupillary dilation is required for the tracker to operate. This reduces the ability of the patient and the surgeon to maintain fixation, thus placing laser fixation in the hands of the tracker. A study presented at the annual meeting of the Society of Cataract and Refractive Surgery by Keith Thompson, MD, found that the use of this laser tracker in cases of myopic astigmatism resulted in similar outcomes as the laser without the tracker. In 170 treated eyes with myopic astigmatism using Lasik with the Summit tracking laser, 95% were 20/40 or better uncorrected at 6 months, and 57% were 20/20 or better uncorrected¹.

Customized Laser Ablation Patterns

A feature available to some excimer lasers in countries other than the United States is the ability to customize the laser treatment to account for irregularities in the corneal contour other than the typical refractive errors of nearsightedness, farsightedness, and astigmatism.

One such technique involves the transfer of topographical cor-

neal data from a corneal topographer to a laser for treatment of corneal irregularities (CIPTA – Corneal Interactive Programmed Topographic Ablation). In the August 2000 issue of Ophthalmology, results of this technique in 42 eyes is reported. All eyes had preoperative corneal irregularities which would be untreatable by any other technique. 21 eyes had post-surgical astigmatism associated with either nearsightedness or farsightedness. Postoperatively, 92.8% of the farsighted astigmatism group, and 85.7% of the nearsighted astigmatism group were 20/40 or better uncorrected. Of even more significance, the best corrected visual acuity improved overall, due to smoothing of the corneal irregularity. Furthermore, halos and glare, present preoperatively in 97% of eyes, virtually disappeared postoperatively, in all but one eye².

Staar's Implantable Contact Lens

This device is undergoing scrutiny by the FDA, and is not yet approved. The "implantable contact lens" is an extremely thin, flexible, and biocompatible lens implant designed to rest in the eye, between the iris and the eye's natural crystalline lens. Being an intraocular procedure, this technique is somewhat more invasive than laser vision correction. However, nearly any level of refractive error, farsighted or nearsighted, is correctable. Furthermore, lens implant surgery is very familiar to most ophthalmic surgeons. The FDA is concerned with specific intraocular risks of the procedure, such as cataract formation, inflammation, and infection. Approval may come within the next few years.

Working Towards "Super Vision"

In the above example, a cornea of an irregular shape can be mapped and treated by laser to smooth the surface, and improve vision. What about corneas already having a "normal" curvature? A new technology referred to as "wave-front" analysis looks at the entire optical system of the eye in order to detect higher order refractive aberrations which can limit the visual acuity of even a normal eye. These aberrations are usually more noticeable at night, with the larger pupil size. When these small aberrations are then treated by an adjustment in the laser ablation profile, an eye may actually improve from its preoperative visual acuity of 20/20 to 20/10, or 20/8. (The best possible visual acuity of the eye, based on spacing of photoreceptors in the retina, is felt to be 20/5 to 20/8, up to 4 times as sharp as 20/20 vision). Wave-front guided lasers will hopefully be available within the next 3 to 5 years.

¹Thompson K, MD et al. Lasik for myopia and astigmatism with LADAR-Vision excimer laser system. ASCRS Abstracts 2000: 518.

²Alessio G, MD et al. Topography driven PRK. Ophthalmol 2000;107:1578.

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- Extensive patient information, including discussion of over 80 eye conditions and a section discussing risks and benefits of laser vision correction.
- Physician section with topics of interest, including a diabetes section.
- Office locations and information.

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Ophthalmology Update

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The Success of LASIK (page 1)

dates for the procedure. However, clinical success from the surgeon's viewpoint may not equate with patient satisfaction. This is why it is extremely important for the potential Lasik candidate to discuss their own personal situation, goals, and needs with the operating surgeon:

- **Unrealistic Patient Expectations – The Most Common Downfall of Laser Vision Correction** – While the success rate of achieving at least 20/40 vision is very high with Lasik, many patients may not be satisfied with this vision, especially while driving at night. The patient must accept the fact that optical correction (glasses or contact lenses) may be needed after Laser Vision Correction, especially for more challenging visual situations, and for reading if they over age 40. **The primary goal of Laser Vision Correction, and Lasik, is to reduce or eliminate the need for glasses and contact lenses to correct distance vision.** If the goal of the patient is to have the best possible visual acuity, then glasses or contact lenses may be a more realistic option.
- **Patients Should be Evaluated and Examined by the Operating Surgeon** – The surgical and technical expertise to perform Lasik and other Laser Vision Correction procedures requires a certain degree of training, experience, and attention to detail. However, the pre-operative evaluation may be more critical than the surgery itself in obtaining good outcomes and satisfied patients. Many key factors need to be evaluated during this examination, any of which could make a potential candidate not suitable for the procedure. The actual magnitude

and type of refractive error is only one aspect of the preoperative evaluation. Optometric co-management of refractive surgery is increasing in frequency, with some optometrists referring patients to distant locations to have the procedure. The optometrist, not the surgeon, performs the pre- and postoperative care. The optometrist collects a substantial fee for this "co-management", which is often higher than the surgeon's fee. This practice should be avoided, except in the situation where the procedure is otherwise not available in the patient's local area. Pre- and postoperative care should be provided by the operating surgeon whenever possible.

- **Patients with Potential Problem Situations Require a More Extensive Informed Consent as to the Risks and Benefits of the Procedure** – Some examples of these situations include:

Medical Contraindications and Concerns
 Potential Worsening of Dry Eye Symptoms
 Problems with Night Vision, Related to a Large Pupil Size
 Potential Corneal Instability with Very High Corrections
 Potential Procedural Difficulties (such as in patients with very deep set eyes, or in those who are very photo-sensitive)
 Unsuitable Irregular Corneal Curvatures that may be Better Managed with Future Technology
 Very High Corrections that may be better treated with Non-corneal, Non-laser Procedures awaiting FDA approval

Excellent results and patient satisfaction can be achieved using Laser Vision Correction when these details are properly addressed.

¹Data percentages are given respectively for the Summit and Visx lasers, from the Clinical Research and Statistics study group.