LASIK and Beyond

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Laser-assisted *in situ* keratomileusis, better known as LASIK, is a surgical procedure for reducing refractive error in the eye. In this procedure, a device called a microkeratome is used to shave a thin, hinged flap in the cornea. The flap is folded back to expose the internal tissue of the cornea. Pulses from an excimer laser operating at a wavelength of 193 nm are then delivered to this tissue to modify its shape. This wavelength is used because it ablates tissue without extensive collateral damage and because it has low mutagenicity.

Upon repositioning the flap, the sculpted pattern is transferred to the front surface of the cornea. To correct for near-sightedness, or myopia, the radius of curvature of the anterior cornea is made longer, thus reducing the overall power of the eye. Conversely, to correct for far-sightedness, or hyperopia, the radius of the cornea is made shorter to increase the power of the cornea and eye. To correct for astigmatism, a toric pattern is ablated into the cornea.

LASIK was first made available to the general population in the United States in 1996, a year in which roughly 15,000 procedures were performed. Over the past 12 months, approximately 1.5 million LASIK procedures have been performed in the U.S. Since approximately 140 million adults in this country suffer from refractive error, the demand for refractive surgeries such as LASIK over the next twenty years will be staggering. Because of the increasing demand for this procedure, as well as competition among manufacturers of excimer laser systems for refractive surgery, the technology and techniques for the LASIK procedure have evolved quickly and may offer dramatic enhancements to the visual performance of those people undergoing the procedure. This article summarizes the optical technology involved in the original LASIK procedures, looks at the evolution to the current generation of refractive surgery, and speculates on some additional modalities that may replace or compliment LASIK in the future.

The two original excimer laser systems approved for refractive surgery by the Food and Drug Administration were based on "broad-beam" technology. They have a large beam diameter and a variable-sized aperture to modify the size and shape of the laser energy delivered to the cornea. By examining the preoperative corneal curvature and the patient's prescription, these lasers calculate, via the Munnerlyn formula, the amount of tissue to be removed. The postoperative radius of curvature of the cornea can be calculated by knowing the desired change in the optical power of the eye (the patient's prescription), the preoperative radius of curvature of the cornea, and the index of refraction of corneal tissue. Once the ablation pattern has been calculated, the surgeon cuts the LASIK flap, aligns the laser to the patient and delivers the sculpting pulses. A foot switch controls pulse delivery, and pulse rates are typically 6 to 10 Hz. Since patients are awake during the procedure, their eyes are in constant motion during laser delivery and must be tracked. Tracking is accomplished by a surgeon-controlled joystick that actively aligns the patient to the laser axis. If the eye drifts too far from the laser axis, the surgeon also has the option of interrupting pulse delivery by releasing the foot switch, realigning the patient, and resuming the procedure.

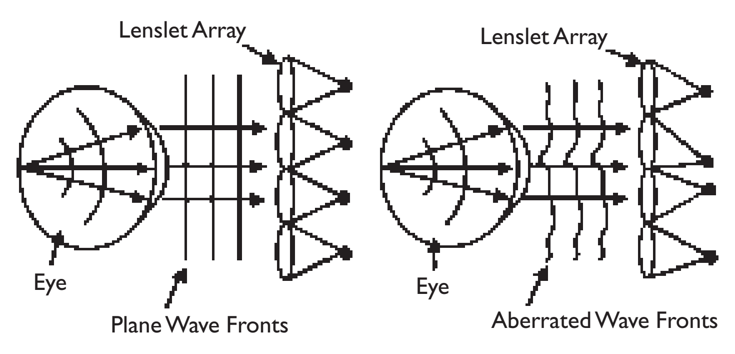

Figure 1. In the Shack-Hartmann wave-front sensor, the wave front emerging from the eye passes through an array of lenses. The left-hand image shows an aberration-free wave front that is focused by the lenslet to a regular grid of spots. The right-hand image shows an aberrated wave front and the resulting distortion in the grid spacing of the spots.

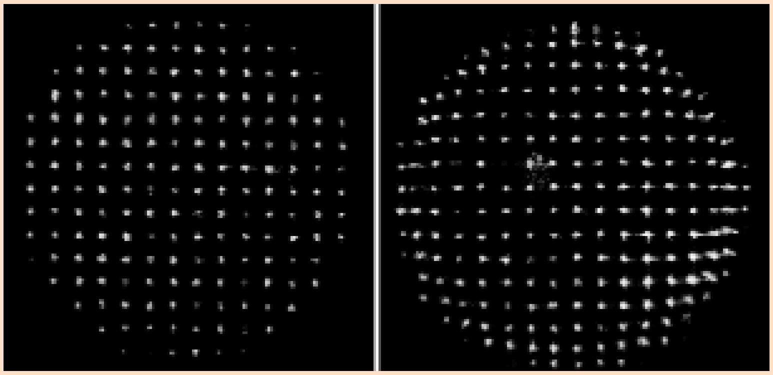

Figure 2. Examples of Shack-Hartmann images. The left image shows low aberrations and a uniform grid spacing. The right image shows spherical aberration following conventional refractive surgery.

Several drawbacks associated with broad-beam laser technology prompted the evolution of a new generation of refractive surgery lasers. First, broad-beam lasers are characterized by problems of beam uniformity across their area. This effect causes differential ablation of corneal tissue, or "hot spots," in the ablation pattern. Because of the use of mechanical apertures, broad-beam lasers also suffer from limitations on the shapes of ablation patterns that can be placed into the cornea. What's more, with the first-generation lasers plumes from the ablated tissue can interfere with subsequent pulses, causing nonuniformities in the ablation process. For these reasons, broad-beam lasers have been largely replaced in LASIK surgery with second-generation laser technology. Most of the new systems use small scanning spots between 0.8 mm and 2.0 mm in diameter. The spots are randomly placed on the cornea to avoid plume interference and the spots pattern is slowly built up to remove the desired amount of tissue. The ability to scan small spots provides dramatic flexibility in the shape of the ablation patterns that can be placed into the cornea. The small beam size also allows for good beam quality. Second-generation lasers operate at upwards of 200 Hz, allowing for total procedure time to be kept at roughly a minute although the smaller beam sizes remove less tissue per pulse.

A second drawback to the early laser systems was that with surgeon-guided eye-tracking, microfluctuations and rapid saccades limited the accuracy to which a desired ablation pattern could be imparted to the cornea. Second-generation lasers are incorporating active eye trackers that follow the patient's eye and adjust the positioning of laser pulse delivery to compensate for eye motion during the procedure. These active eye trackers are based either on laser radar technology that grew out of the Strategic Defense Initiative or on video-based pupil detection techniques. Eye trackers perform two tasks. First, they compensate for eye motion by adjusting fast x-y mirrors to realign the laser pulse with the eye; second, they sense gross movements in the eye and can automatically shut down laser delivery if eye motion is too great. With active eye trackers, each pulse is precisely placed on the cornea, resulting in smooth and accurate reproduction of the ablation pattern.

A final drawback to first-generation laser systems is the use of the Munnerlyn formula to calculate the required amount of tissue removal. This formula is based inherently in paraxial optics since the optical properties of the ablation are based solely on the preoperative and postoperative radii of curvature of the cornea. The paraxial assumption causes the aberrations inherent to the eye and the ablation pattern to be ignored. The cornea is typically a prolate ellipsoid and has positive spherical aberration. The positive spherical aberration is then partially compensated by the negative spherical aberration inherent to the crystalline lens of the eye. Following refractive surgery based on paraxial assumptions, the cornea typically takes on an oblate ellipsoidal shape. The resulting change in the asphericity of the cornea causes a dramatic increase—on the order of two to ten times natural levels—in the spherical aberration of the eye. Increased spherical aberration does not necessarily affect visual performance under room or daylight conditions because of the restricted size of the pupil. However, as the pupil dilates in a darkened environment, visual effects such as glare and haloes can be seen.

Customized LASIK similarly measures the subtle features of an individual's optical error and can deliver a tailored treatment to his or her eye.

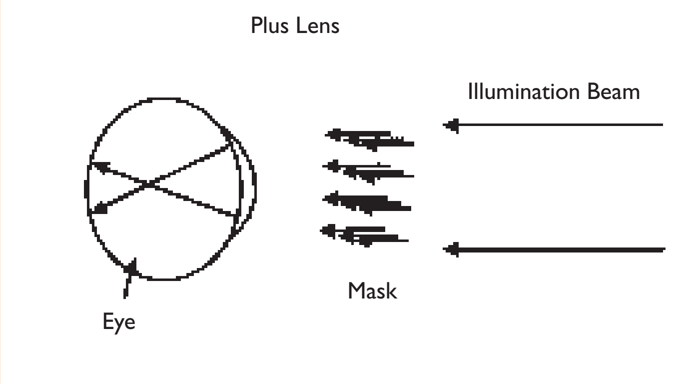

Figure 3. In the Tscherning aberrometer, a mask is used to separate a collimated beam into a uniform grid of light pencils. A plus lens is used to force these collimated pencils to focus in front of the retina. The out of focus pattern on the retina reproduces the grid pattern in the mask, but is distorted due to aberrations in the eye. A fundus camera (not shown) images the grid pattern to retrieve the aberration information.

Wave-front sensing

The typical eye is limited in its performance by its aberrations. Wave-front sensing of the eye is an exciting technology that offers the potential to dramatically improve visual performance following LASIK surgery. Wave-front sensing not only replaces the Munnerlyn formula as a means of determining the required ablation pattern, but also measures the aberration content of the eye. Armed with this knowledge, patterns that correct the aberrations of the eye can be derived. Correction of the aberrations could drop the resolution level to the theoretical limit of about 20/8 and improve low-contrast vision as well. While extensive marketing has touted the possibility of super-vision with these new technologies, the true benefit of these techniques will be to reliably provide high quality, low aberration vision after LASIK surgery. Future treatments will avoid potentially introducing increased spherical aberration, as happens with the current surgery. This possibility should dramatically increase the number of patients achieving uncorrected vision of 20/20 following surgery and markedly reduce incidents of night vision problems.

Shack-Hartmann sensor

There are a variety of wave-front sensing technologies, two of which are linked to refractive surgery lasers. The first is the Shack-Hartmann wave-front sensor, which evolved out of the astronomy community and was first developed to measure aberrations caused by atmospheric turbulence. In the application of the Shack-Hartmann technique to the eye, a dim laser beam enters the eye and is focused to a point on the retina. Because of scattering, the point of light acts as a secondary source and emanates spherical wave fronts that will pass back out of the eye. As these wave fronts travel through the optical elements of the eye, they become aberrated. The wave front exiting the eye is passed through an array of small, regularly spaced lenslets that effectively sample the wave front at different points. At the back focal plane of each lenslet, the lateral position of the focal spot depends on the average slope of the wave front captured by the lenslet. A perfectly planar wave front causes the spacing between the focal spots of the various lenslets to be uniform. An aberrated wave front causes nonuniform spacing between the various focal spots. Knowledge of the distortion in the pattern of focal spots allows the aberrated wave front to be reconstructed. With the aberrations in hand, an ablation pattern to compensate for the aberrations of the eye can be developed.

Tscherning aberrometry

Another technique for measuring wave-front aberrations in the eye is called Tscherning aberrometry. While the Shack-Hartmann technique looks at the wave front emerging from the eye, Tscherning aberrometry measures the wave front converging towards the retina. In this technique, a collimated beam is passed through a mask to generate a regular grid of pencils of light that enter the eye. An additional lens is placed in front of the eye to effectively make the eye myopic. As the pencils of light pass through the eye/lens combination, they focus to a point in front of the retina. Further propagation of the pencils causes them to diverge and form a grid pattern on the retina. In an aberration-free eye, the grid pattern on the retina would be a minimized version of the grid pattern on the mask. In the presence of aberrations, the grid pattern becomes distorted. Measurement of the grid pattern is accomplished via a modified fundus camera that photographs the grid pattern on the retina. The distortions in the retina grid give the transverse ray errors for each pencil that entered the eye, and ultimately, the wave-front aberrations can be reconstructed from these ray errors. As with the Shack-Hartmann technique, a correction for these aberrations can be calculated.

By combining scanning laser technology, reliable eye tracking and wave-front sensing, customized LASIK treatments can be performed. Fitting shoes can be used as an analogy that illustrates current LASIK techniques and emerging customized LASIK. Shoes come in a set of standard sizes and widths and the wearer must find the size that best fits his or her foot. Similarly, current LASIK technology allows for fixed and discrete levels of correction of spherical and cylindrical errors and does not allow for the correction of any irregular errors. In the shoe analogy, by forming a mold of the foot, a shoe that is perfectly tailored to the foot in terms of length, width, and type of arch could be made. Customized LASIK similarly measures the subtle features of an individual's optical error and can deliver a tailored treatment to his or her eye. The goal of refractive surgery is to provide the patient with the best possible postoperative vision under all lighting conditions. Customized LASIK strives to reach this goal.

Custom contact lenses

The LASIK procedure is not the only technology that offers the potential to provide superior human vision. Custom contact lenses may prove to be a viable alternative or compliment to custom LASIK. Advances in lathing technology, molding technology, and the use of laser ablation may allow for customized contact lenses to be manufactured in a cost-effective manner. As with customized LASIK, the wave-front aberrations of an individual's eye would be measured and used to determine an ideal correction. However, with custom contact lenses, instead of permanently imparting the correction into the cornea, the correction is designed into a contact lens. The advantage of this technique is that no permanent changes are made to the cornea, so the custom correction is reversible and can easily be modified in the future. Contact lenses have the disadvantage that they tend to move around on the cornea, causing less than perfect correction when they are not properly oriented. Contact lenses also require regular care, removal and insertion. Most likely, different segments of the population will choose between a permanent surgical change and a reversible, contact-lens-based approach. The choice will be made on the basis of the individual's lifestyle and comfort level.

In the future, it is conceivable that wave-front sensing and advanced manufacturing techniques will be used to design custom phakic IOLs that correct for aberration in the eye as well.

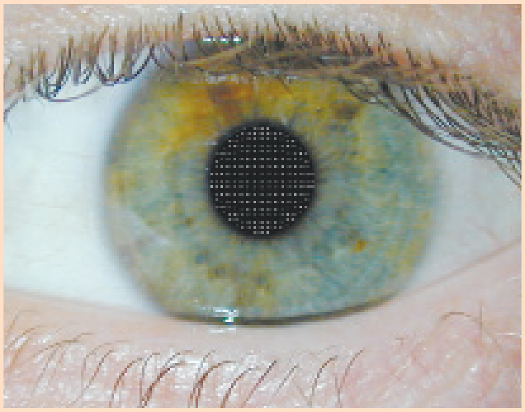

Figure 4. Customized techniques for correcting wave-front aberrations in the eye may lead to dramatic improvements in visual acuity and low-contrast vision. Emerging technologies will provide patients with the best possible vision following the procedure.

Phakic intraocular lense

Another emerging technology that may have dramatic effects on the correction of visual problems in the future is the phakic intraocular lense (IOL), typically used as a replacement for cataractous crystalline lenses. Cataract surgery is the most widely performed operation in the U.S. When opacities form in the natural human crystalline lens, the lens is removed and replaced with an artificial lens. Recently, implantation of artificial lenses in patients with clear crystalline lenses has been examined as a means of correcting refractive error. In this procedure, the crystalline lens is left intact, and a phakic IOL is implanted into the anterior chamber of the eye. Today, phakic IOLs that correct for spherical and cylindrical error are being examined in clinical trials; in the future, it is conceivable that wave-front sensing and advanced manufacturing techniques will be used to design custom phakic IOLs that correct for aberration in the eye as well. With proper implantation of these lenses, many of the benefits of the custom LASIK procedure are achieved in that there is a stable correction, without the requirements of regular lens maintenance associated with custom contact lenses. Furthermore, the procedure is reversible in that the phakic IOL can be explanted if there are changes in refraction or improper placement. Finally, custom phakic IOLs open the refractive correction market to a much broader range of practitioners since the procedure uses a skill set similar to that of cataract surgery but without requiring an initial investment in an expensive excimer laser.

Writable phakic IOLs are under development for the correction of refractive errors in the eye. These lenses are phakic implants as described above, but in this case, customization takes place after the lens is implanted in the eye. With the lens placed within the anterior chamber, wave-front sensing is used to measure the residual aberrations inherent to the patient's eye. An ultraviolet (UV) laser is then used to write to the surface of the phakic lens through the patient's cornea. The effect of the UV light is to locally change the material properties, and thus the refractive effects, of the phakic IOL. Once the phakic IOL has the desired characteristics, it can be fixed. The result is a customized implant that corrects for aberrations in the eye.

The preceding technologies illustrate the future of refractive surgery. The goal of these procedures is to provide superior optical correction of errors found in the eye. The common thread throughout each modality is the use of customization. Wave-front sensing is a critical technology that allows for the exact description of the optical properties of the eye to be described. Each technology takes advantage of this information to provide a customized correction tailored to the specific subtleties in refraction that characterize each patient. Patients will no longer need to be lumped into discrete levels of spherical and cylindrical correction and those patients with more complex optical irregularities will now be fully correctable. In other words, the old adage "if the shoe fits, wear it" will no longer apply.

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