

Jim Schwiegerling

# Wavefront-Guided LASIK

VISX Inc.

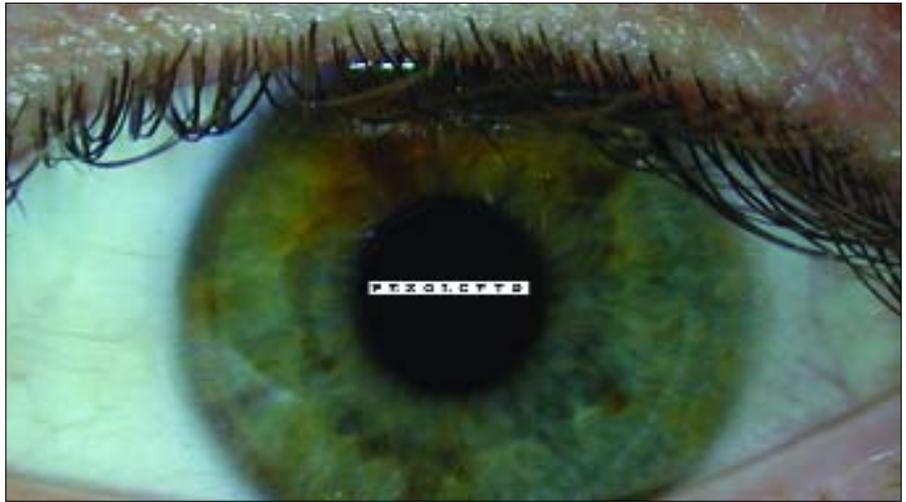
Laser-assisted in situ keratomileusis, or LASIK, entails reshaping the cornea to correct refractive error in the eye. In the United States, three companies have received approval from the federal Food and Drug Administration to market wavefront-guided LASIK systems, which measure individual aberration patterns pre-operatively so a customized ablation pattern can be generated for each patient. Studies show that wavefront-guided procedures are achieving excellent results, including in most cases improved visual acuity under all light conditions.

A seven-beam laser used for wavefront-guided LASIK was developed in response to problems associated with conventional LASIK, especially poor visual performance under large pupil sizes.

**L**aser-assisted in situ keratomileusis (LASIK) is a widely performed surgical technique for reshaping the cornea and correcting refractive error in the eye. The procedure involves mechanically shaving a thin flap into the front surface of the eye and using an excimer laser to ablate the underlying tissue. Proper removal of the appropriate amount of material results in the correction of refractive conditions such as myopia, hyperopia and astigmatism. In an earlier article,<sup>1</sup> I discussed much of the underlying optical technology associated with the procedure, including scanning laser spots, real-time eye tracking and ocular aberration measurement. All these technologies have been integrated into the current generation of refractive surgery systems and have undergone human testing in Food and Drug Administration (FDA) clinical trials. Several companies have received approval for their devices, and “custom” or “wavefront-guided” LASIK is rapidly becoming available to the general public. The purpose of this article is to describe the results of the clinical studies and to provide an overview of the potential of wavefront-guided refractive surgery.

The minimum goal of refractive surgery should be to provide patients with unaided vision performance following surgery that is equivalent to their pre-operative best-corrected vision. In other words, if a patient could see 20/20 with spectacles prior to surgery, he or she should be able to see 20/20 without spectacles following surgery. Furthermore, this equivalency goal should hold under all lighting conditions. With conventional excimer laser refractive surgery, only about two-thirds of patients achieve this level of vision. The balance of patients can typically be corrected to 20/20 with spectacles or contact lenses of mild prescription. With conventional laser refractive surgery, nearly all patients have an uncorrected visual acuity of 20/40 or better, the level required to operate a motor vehicle without corrective lenses. The percentage of patients who undergo conventional treatment and cannot be corrected to their pre-operative acuity with spectacles is less than 1 percent.

Visual acuity is a metric that does not fully describe visual performance. It is a



**The promise of wavefront-guided LASIK should be to provide uncorrected vision that is the equivalent of pre-operative corrected vision under all lighting conditions. Meeting the goal will be a true measure of the success of the technology.**

measure of the resolution limit of the eye under bright illumination and, consequently, under small pupil sizes. As illumination decreases, the diameter of the pupil dilates and a larger portion of the cornea becomes involved in the refraction of light into the eye. Estimates of the number of patients who undergo conventional refractive surgery and suffer visual disability under darkened conditions because of glare and halos are as high as 20 percent. The chances of achieving good daytime results and poor nighttime results with conventional treatment are therefore significant. The nighttime disability is primarily caused by aberrations introduced into the cornea by the laser procedure. High levels of spherical aberration and coma have been shown to exist in post-refractive surgery eyes. In optical engineering terms, the defocus of the eye is greatly reduced by the surgical procedure, but higher order aberrations are simultaneously introduced. The result is poor image quality, or poor visual performance, under large pupil sizes.

Wavefront-guided LASIK is a response to the problems associated with conventional LASIK. In wavefront-guided LASIK, individual aberration patterns are

measured pre-operatively and a customized ablation pattern is generated for each patient. In theory, by correcting the monochromatic aberrations of the eye, diffraction-limited performance, resulting in a visual acuity better than 20/10, can be achieved. Early marketing efforts for wavefront-guided LASIK touted “*supervision*” and offered “20/10 by 2010.” But the true benefit of the customized procedure is to alleviate visual problems from the bottom up. It is far more beneficial to take a patient from 20/40 to 20/20 visual acuity than it is to take a patient from 20/20 to 20/10 acuity, even though both scenarios involve a doubling of the resolution limit. The promise of wavefront-guided LASIK should be to provide uncorrected vision that is the equivalent of pre-operative corrected vision under all lighting conditions. Meeting the goal will be a true measure of the success of the technology. If a percentage of patients achieve better than normal vision, then that is an added benefit.

To date, three companies have received FDA approval for their wavefront-guided refractive surgery systems. These include Alcon’s LADARWave<sup>2</sup> CustomCornea<sup>2</sup> wavefront system, VISX’s



VISX Inc.

Technician captures a patient's wave front.

CustomVue<sup>3</sup> system and Bausch & Lomb's Zyoptix<sup>4</sup> system. Alcon received FDA approval in October 2002. The VISX system was approved in May 2003 and the Bausch & Lomb system currently has preliminary approval from the FDA's advisory panel. All three systems use a Shack-Hartmann wavefront sensor to pre-operatively measure the aberrations of the eye. The resulting aberration map is used to create an ideal ablation pattern that will correct refractive anomalies in the eye. All three systems use active eye

tracking to properly register the ablation pattern on the moving eye during surgery. Below is a summary of the FDA clinical trial results for the products offered by these three companies.

#### Alcon

The Alcon FDA clinical trial, conducted in 1999–2001, was based on 426 eyes, 139 of which had only spherical refractive error and 287 of which had spherocylindrical error. After six months of follow-up, 98.6 percent of subjects had a

post-operative visual acuity of 20/40 or better and 79.9 percent had a visual acuity of 20/20 or better. In more recent studies at Tulane University, wavefront-guided treatment put 67 percent of the patients at 20/16 or better and 90 percent at 20/20 or better. The system is currently approved for up to -7.00 diopters of myopia with less than 0.5 diopters of astigmatism.

#### Bausch & Lomb

The clinical trial for the Zyoptix wavefront-guided system was based on 340 eyes. Of these, 117 had spherical error and 223 had both spherical and cylindrical error. After treatment, the subjects were followed for a period of six months. After six months, 99.4 percent of the eyes had a visual acuity of 20/40 or better and 91.5 percent had a visual acuity of 20/20 or better without any corrective lenses. Furthermore, 82 percent of subjects—compared to 76 percent with conventional LASIK—stated that, as a result of customized treatment, night driving capability was the same or better. Eighty-nine percent of patients—compared to 77 percent for conventional LASIK—stated that following the procedure their vision was the same or better under dim lighting conditions. The Bausch & Lomb system is currently approved for myopia up to -7.00 diopters and cylinder error up to -3.00 diopters.

#### VISX

The FDA trials of the VISX CustomVue system showed that, six months after treatment, 96 percent of subjects had an uncorrected visual acuity of 20/20 or better, with 71 percent achieving 20/16 or better and 22 percent achieving 20/12.5. As part of the trials, a questionnaire on night vision was distributed: 87 percent of patients who responded said they were satisfied with their night vision following surgery; prior to surgery, only 69 percent had reported they were satisfied with their night vision. Only 6 percent of subjects were somewhat or very dissatisfied with their night vision following surgery, as compared to 22 percent prior to surgery. After treatment, 88 percent of patients said they never or rarely had halos, compared to 76 percent prior to surgery. In a more recent study

conducted by the Kraff Eye Institute in Chicago, three months after the operation, 100 percent of subjects were seeing 20/20 or better uncorrected, 81 percent were seeing 20/16 or better and 31 percent were seeing 20/12.5 or better. While these patients were selected on the basis of having excellent pre-operative corrected visual acuity, the researchers were still able to demonstrate a marked improvement with wavefront-guided treatment. The VISX wavefront-guided refractive surgery system is currently approved for myopia up to -6.00 diopters and cylinder error up to -3.00 diopters.

In the case of all three systems, patients must be at least 21 years old. Contraindications for receiving LASIK treatment at any age include: diabetes, autoimmune or immunodeficiency diseases, signs of keratoconus, pregnancy and nursing.

Wavefront-guided treatments have achieved excellent results. In most cases, patients are almost guaranteed uncorrected vision that is the same or better than their pre-operative visual acuity. There is a marked reduction in night vision problems and a significant fraction of patients achieve better than "normal" 20/20 vision. The residual variances in visual outcomes are most likely caused by biomechanical changes in the cornea and healing effects. Since the cornea is not a stable isotropic material but a dynamic living tissue which is always under mechanical strain, its properties can change when tissue is removed. Furthermore, the cornea responds to LASIK surgery in the same manner that any body part responds to a wound: it heals itself. This healing response can change the shape of the post-operative cornea and modify the aberration structure of the cornea. Efforts are under way to reliably measure and predict the mechanical response of the individual cornea to surgery and to control the healing response of the cornea after surgery. The addition of these techniques to wavefront-guided treatments should lead to further improvements.

Several other modifications to help control the biomechanical response to cutting the cornea are under investigation. In LASIK, a microkeratome is used to cut a 150-180  $\mu\text{m}$  flap into the cornea.

## The added expense of wavefront-guided LASIK is well worth the money. Patients should not make decisions on the quality of their future vision based on price.

There is evidence that cutting the cornea to such a depth weakens the mechanical strength of its surface and causes bulging of the peripheral cornea. The bulging changes the refractive and aberration properties of the cornea and cannot be accounted for in wavefront-guided treatment, since there is currently no method of predicting this effect prior to surgery. Two alternative refractive surgical techniques are emerging to combat this effect. In the first, known as LASEK, a small ring filled with a mixture of alcohol and saline is placed on the cornea. The alcohol causes the corneal epithelium (a thin layer of cells that coat the front surface of the cornea) to separate from the underlying surface. This flap of epithelial cells is then folded back and laser treatment is performed in the usual manner. The theory behind this technique is that there will be fewer biomechanical changes to the cornea if the collagen fibers that make up the central portion of the cornea are not severed, as is the case in LASIK. More research is necessary to validate this theory. In a similar procedure, Epi-LASIK, a tool is used to delaminate the epithelial cells from the underlying cornea. The advantage of this technique is that no toxic alcohol is introduced into the eye, which reduces post-operative discomfort. Epi-LASIK is also in its early stages, and more research is necessary to demonstrate its value.

Finally, wavefront-guided refractive surgery cannot overcome the aging process. Prescriptions may change over time. Today's perfect correction may not be a perfect correction in ten years' time, or even next year. Wavefront-guided refractive surgery may however allow a visual reserve to be built up so that, with small changes in prescription, a subject will

have good vision despite the effects of the aging process. For example, a person who has 20/12.5 vision after surgery may be able to tolerate a 0.5 diopter change in prescription without needing corrective lenses since his or her visual acuity may only decrease to 20/20.

Presbyopia is another age-related change that may affect the outcome of refractive surgery. Our ability to accommodate—or to change focus from distance to near—is gradually reduced as we age. Presbyopia is usually not a problem until people reach their 40s. In this age range, however, the ability to comfortably focus on objects at reading distance becomes degraded. The typical cure is a pair of "readers," or spectacles that allow one to focus on near objects with minimal accommodative effort. Although wavefront-guided procedures can target perfect distance vision, corrective lenses may be necessary for near work in presbyopic patients.

Wavefront-guided LASIK can provide excellent results for people who have decided in favor of refractive surgery. As is the case with any surgery, the patient should be educated about the procedure, its possible complications and anticipated benefits. I recommend that individuals research the procedure and speak with several surgeons before deciding whether LASIK is right for them. The added expense of wavefront-guided LASIK is well worth the money, and patients should not make decisions on the quality of their future vision based on price. Surgeons should be more than willing to share their personal performance with regards to LASIK surgery outcomes. Finally, any surgical procedure carries risk: it's important for every potential patient to consider whether the risk is small enough and the potential benefit large enough to justify the undertaking.

#### References

1. J. Schwiegerling, Opt. Photon. News, 13(1) 30-3 (2002).
2. LADARWave and CustomCornea are registered trademarks of Alcon.
3. CustomVue is a registered trademark of VISX.
4. Zyoptix is a registered trademark of Bausch & Lomb.

Jim Schwiegerling is an assistant professor of ophthalmology and optical sciences at the University of Arizona. He can be reached by e-mail at [jschwieg@u.arizona.edu](mailto:jschwieg@u.arizona.edu).

