

MEDICINE

WHY SETTLE FOR 20/20?

A new diagnostic tool and laser surgery promise eagle vision

Sometime in the 13th century, the first ungainly pair of spectacles were placed over squinting eyes. Since then the lenses have grown thinner, and the spectacles more elegant. But even amid radical innovations, including contact lenses and laser surgery, techniques for measuring visual acuity have failed to keep pace.

Now the science of vision measurement and correction is set to push beyond the familiar 20/20 line on eye charts to a benchmark described as "eagle vision." The basis for this shift is a powerful diagnostic technology known as wavefront analysis, which gives doctors a new window into the imperfections of the human eye. Paired with laser vision surgery—and, in time, with implantable, light-tunable lenses—the technology will enable physicians to customize laser treatments, yielding unparalleled results. "We're embarking on a monumental paradigm shift," says Dr. Steven C. Schallhorn, at the Navy's Refractive Surgery Center in San Diego.

Such shifts are always accompanied by risks. Fresh in the minds of many practitioners are the injuries, lawsuits, and bankruptcies caused by the unchecked explosion of laser surgery in the late 1990s.

Nevertheless, wavefront technology has already sparked a lot of excitement—in part because of purported improvements in quality. Armed with special software, doctors first generate a three-dimensional model, or wavefront map, of the changes they must make

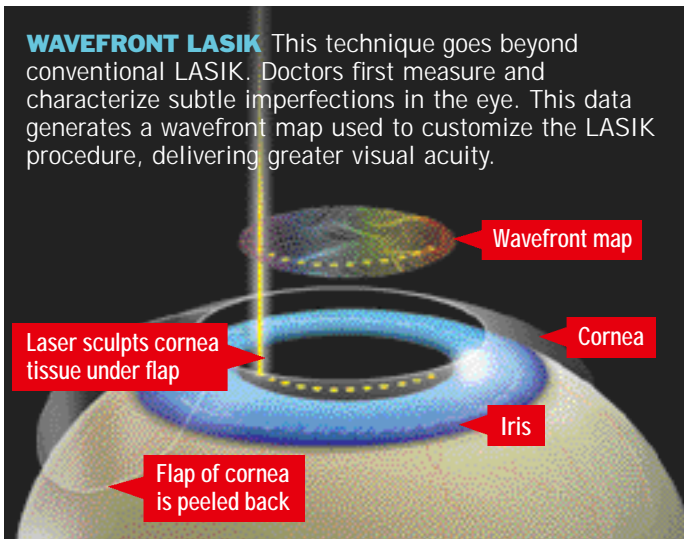
to a patient's cornea in order to correct a pattern of defects unique to his or her eye. Then, by positioning the map over the eye and tracing its contours with a laser, they can nullify each of the defects.

Alcon Laboratories Inc. of Fort Worth, Tex., was first to market with

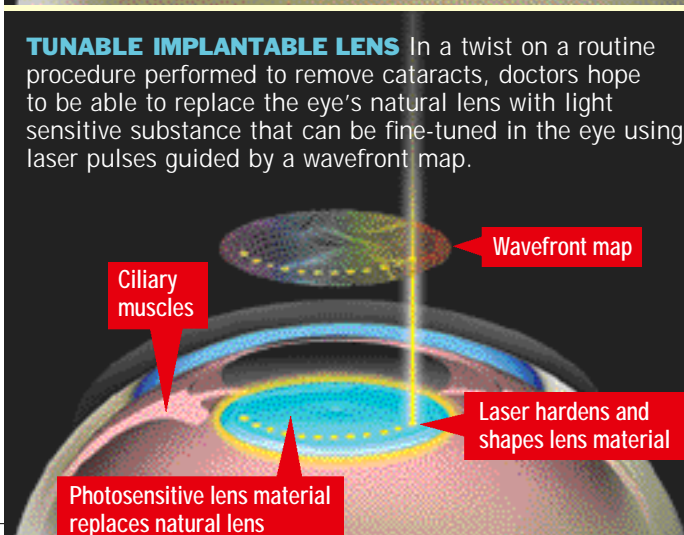
A GLIMPSE OF THE FUTURE

Whether patients are nearsighted or farsighted, new types of treatment could deliver crystal clarity:

WAVEFRONT LASIK This technique goes beyond conventional LASIK. Doctors first measure and characterize subtle imperfections in the eye. This data generates a wavefront map used to customize the LASIK procedure, delivering greater visual acuity.



TUNABLE IMPLANTABLE LENS In a twist on a routine procedure performed to remove cataracts, doctors hope to be able to replace the eye's natural lens with light sensitive substance that can be fine-tuned in the eye using laser pulses guided by a wavefront map.



such a customized treatment, for nearsightedness, winning Food & Drug Administration approval last fall. Alcon reports that many patients achieved greater than 20/20 vision, and other studies produced similar evidence. Last year, in clinical trials by visx Inc. of Santa Clara, Calif., 189 patients with mild nearsightedness were treated using a wavefront system. Six months later, 94% of the patients saw 20/20 without glasses, and 74% saw 20/16 or better. "That's what we call super-vision," says Dr. Robert K. Maloney, one of the study's investigators. Analysts say visx should receive FDA approval by midyear. And Rochester (N.Y.)-based Bausch & Lomb Inc.'s wavefront system could be approved by yearend.

The innovation behind these systems goes back to the late 1970s, when German physicist Josef Bille devised a precursor to wavefront to correct for the atmospheric distortion of star light. A lens based on Bille's mathematical models was used to fix the Hubble Space Telescope's blurry vision in 1993.

Eye specialists began to adapt the method in the 1990s. By measuring how the cornea, lens, and transparent tissues of the tested eye process light differently from people with natural eagle vision, they were able to characterize visual disorders that went beyond near- and farsightedness and astigmatism. These visual flaws, called higher-order aberrations, are associated with subtle problems such as poor night vision and contrast sensitivity, or halo effects around light sources. "We're just beginning to understand how these aberrations affect vision," says Dr. Schallhorn.

Fortunately for wavefront pioneers, corrective laser surgery was already an established procedure, approved by the FDA in 1995. In LASIK, short for "laser-assisted in situ keratomileusis," a thin flap of transparent tissue covering the cornea is peeled back. Laser pulses then vaporize—or ablate—a pattern of cells below, and the flap is closed. By varying the shape of this ablation pattern, surgeons can resculpt the cornea to improve vision and correct

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most commonplace focusing errors.

What makes wavefront-guided LASIK so promising is its ability to customize the surgical procedure on the basis of the wavefront map, which is programmed into the LASIK device. In Alcon's clinical trials, some patients received traditional LASIK on one eye and wavefront-guided treatment on the other. Even with 20/20 vision in both eyes post-surgery, many patients reported superior clarity in the wavefront-treated eye. "It's not just about making out a letter on a chart," says Dr. Ronald Krueger, who has performed some 70 wavefront procedures using Alcon's device at the Cleveland Clinic. "Patients can see that letter in lower light. Contrast and night vision are improved."

The vision industry is depending on wavefront to halt a worrying slide. The number of LASIK procedures soared through the 1990s, fueled by the economic boom and a steady fall in the average price of the procedure from more than \$2,000 to under \$1,600. But after peaking at 1.4 million in 2000, the market has contracted by 8% over the past two years, says David Harmon, president of Market Scope, a St. Louis-based research firm.

The economic slowdown explains part of the decline in demand. But industry practices are also to blame. As LASIK started to catch on, a blitz of consumer marketing—complete with direct mail, billboard, TV, and radio ads—fired competition among local eye centers and nationwide chains. Advertised LASIK prices fell as low as \$299 per eye. "There were ads making unsupported claims and improper comparisons," says Matt Daynard, senior attorney at the Federal Trade Commission's Bureau of Consumer Protection. "People were going into this with their eyes wide shut."

Complaints rose as the number of procedures ballooned. Some doctors performed LASIK on candidates whose eye conditions were beyond the accepted range of LASIK treatment. A small percentage of patients suffering from maladies such as worsened night vision, painfully dry eyes, or infection sued their doctors. Mired in debt, a handful of national discount chains slid into bankruptcy.

The new procedures aren't risk-free. The most serious problems stem from sloppy surgical practices

With wavefront, the industry has a second chance. "It will attract a percentage of the population that was hesitant before," predicts Elizabeth H. Davila, president and CEO of VISX. SG Cowen Securities Corp. expects the total number of procedures to rebound by 4% this year. Within two years, half of all LASIK procedures will use wavefront, predicts Cowen analyst Peter J. Bye.

The Defense Dept. is spreading the word. After a 20-year ban, the military is funding corrective surgery, including wavefront techniques. It's giving priority to special forces and others likely to go into combat, figuring that freedom from glasses or contacts can improve combat readiness. One initiative, the Warfighter Refractive Surgery Program, has a \$15 million budget to correct the vision of soldiers, sailors, and aviators.

The new procedures aren't risk-free. To date, the most serious problems—detailed on Web sites such as surgicalcalesys.org—stem from sloppy surgical practices. If doctors disregard FDA guidelines, "it doesn't matter how good the technology is," says Ron Link, executive director of Surgical Eyes Foundation.

SG Cowen's Bye says the FDA is now tightening up approval standards. And that will benefit more advanced techniques on the horizon. For example, interest is growing in a new generation of lenses that are surgically implanted in the eye, then customized in the doctor's office using pulsed lasers. Called light-adjustable intraocular lenses (IOLs), these promise to deliver more consistent visual accuracy. And the surgical technique is well established: A version of IOLs has been used for many years to treat millions of cataract patients. With the development of an injectible, flexible form of IOLs, these techniques "could give 50-year-olds the adaptive vision of a 15-year-old," says Verne Sharma, CEO of Calhoun Vision Inc. Calhoun hopes to apply for FDA approval on its adjustable IOLs next year. Such cure-alls, though, are many years away. In the meantime, wavefront-guided LASIK offers the best chance for squinters to see like eagles.

By Adam Aston in New York