

# FDA Approves Eye Procedure Seen as Alternative to Lasers

By RHONDA L. RUNDLE

Aging baby boomers and certain others who rush out to buy reading glasses have a new option. And it isn't laser surgery.

Yesterday the U.S. Food and Drug Administration granted its approval to a procedure that uses radio frequency energy to treat an eye condition that causes farsightedness, which tends to creep up on people after they turn 40.

**Refractec** Inc., a closely held, eight-year-old company in Irvine, Calif., said its conductive keratoplasty procedure, known as CK, was approved for "the temporary reduction" of farsightedness in people over age 40. Eye doctors who tested the procedure-the effect of which lasts for at least two years-predict that it will spur more refractive surgery among farsighted people who have been reluctant to undergo laser surgery.

"CK is the safest way to correct farsightedness. It doesn't involve cutting or removing tissue from the eye and it's done on the peripheral part of the eye, so even- if something were to go wrong, it doesn't affect the central part of a patient's vision," said Robert K. Maloney, a professor of ophthalmology at the University of California at Los Angeles, who oversaw the CK tests. "We didn't have a single serious complication in 401 patients," he added.

Eye doctors are expected to charge patients between \$1,500 and \$2,000 per eye for CK, about the same as laser surgery.

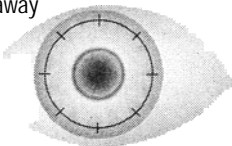
While laser surgery is popular as a treatment for poor distance vision, it has been slow to catch on with farsighted consumers, who tend to be older and more risk averse than nearsighted people. Only about 10% to 20% of refractive surgery patients are farsighted even though there are about 60 million people with this condition, nearly the same number who are nearsighted.

CK "will move that ratio to more of a 50-50 balance," predicted Richard L. Lindstrom, a Refractec consultant and professor of ophthalmology at the University of Minnesota. "The typical CK patient will be 40 to 70. Many of them will say they had fine vision when younger and saw like a hawk, but as they got to be 40, they started having trouble reading, and then trouble with distance as they get older," Dr. Lindstrom said.

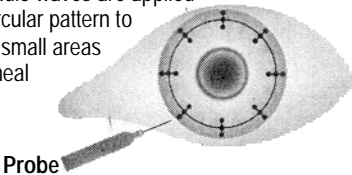
For farsighted people with severe conditions, laser surgery will still be the better option, says Penny Asbell, director

## Fixing Farsightedness

A circular treatment pattern is imprinted on the cornea using rinse-away ink to guide the doctor's treatment



Using a probe thinner than a strand of human hair, radio waves are applied in a circular pattern to shrink small areas of corneal tissue



Source: Refractec Inc.

of the refractive surgery center at Mount Sinai Hospital in New York. However, one of her laser patients decided to switch to CK after hearing that the new procedure had gotten a green light from the FDA.

Some older patients have been turned off by treatments for farsightedness that didn't work, Dr. Lindstrom noted. One procedure that he no longer performs, laser thermal keratoplasty, or LTK, gave only a temporary benefit, he says. Patients treated with CK two years ago are still stable, but no one knows how long the benefit will last. Patients "should appreciate that if they get a procedure that after four or five years they may need treatment, or enhancement," Dr. Lindstrom cautioned.

So far, however, at least one CK patients says he hasn't noticed regression since his surgery in April 2000. "I'm thrilled with the procedure," said James Drago, a materials manager at Mount Sinai Hospital who was a patient of Dr. Asbell. CK is also being tested for presbyopia, which occurs as a normal result of aging and is caused by a gradual hardening of the lens of the eye.

The company said it will sell its patented Refractec Viewpoint CK System to doctors for \$48,500 each, and disposable tips at \$150 per procedure.

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