Laser Eye Surgery: Is It Worth Looking Into?

For Jeri Goldstein everything was a blur. Without her contact lenses she couldn't distinguish people, the scenes on television, the stars at night, and, generally, the world at large. Then, in March 1998, the 49-year-old California resident had eye surgery, and all that changed.

"After wearing contact lenses for 35 years, you can't imagine the freedom I felt," says Goldstein.

Goldstein underwent refractive eye surgery, an elective procedure intended to correct common eye disorders, known as refractive errors, such as myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (distorted vision). Although there are several types of surgical techniques being performed today to correct refractive errors, laser refractive correction is fast becoming the most technologically advanced method available, according to the American Academy of Ophthalmology in San Francisco. Doctors say it allows for an unparalleled degree of precision and predictability.

"Laser surgery is the most exciting advancement in ophthalmology," says James J. Salz, M.D., clinical professor of ophthalmology at the University of Southern California in Los Angeles and the doctor who performed Goldstein's surgery. But surprisingly, he says, despite its sudden popularity, "only 20 percent of ophthalmologists in the United States today are trained in its operation."

The Food and Drug Administration first approved the excimer laser in October 1995 for correcting mild to moderate nearsightedness. With that approval, the agency also restricted use of the laser to practitioners trained both in laser refractive surgery and in the calibration and operation of the laser. Currently, the excimer laser has been approved for use in a procedure called photorefractive keratectomy (PRK), and, as of November 1998, for a procedure called laser in situ Keratomileusis (LASIK).

Precision Surgery

PRK is an outpatient procedure generally performed with local anesthetic eye drops. This type of refractive surgery gently reshapes the cornea by removing microscopic amounts of tissue from the outer surface with a cool, computer-controlled ultraviolet beam of light. The beam is so precise it can cut notches in a strand of human hair without breaking it, and each pulse can remove 39 millionths of an inch of tissue in 12 billionths of a second. The procedure itself takes only a few minutes, and patients are typically back to daily routines in one to three days.

Before the procedure begins, the patient's eye is measured to determine the degree of visual problem, and a map of the eye's surface is constructed. The required corneal change is calculated based on this information, and then entered into the laser's computer.

Since 1995, a limited number of laser systems has been approved by FDA to treat various refractive errors, both with PRK and LASIK.

According to FDA's Center for Devices and Radiological Health, clinical studies showed that about 5 percent of patients continued to always need glasses following PRK for distance, and up to 15 percent needed glasses occasionally, such as when driving. In addition, many patients experienced mild corneal haze following surgery, which is part of the normal healing process. The haze appeared to have little or no effect on final vision, and could only be seen by a doctor with a microscope. Some patients experienced glare and halos around lights. These conditions, however, diminished or disappeared in most patients in six months. For about 5 percent of patients, however, best-corrected vision without corrective lenses was slightly worse after surgery than before. In view of these findings, FDA and the Federal Trade Commission (which oversees advertising) issued a letter to the eye-care community in May 1996 warning that unrealistic advertising claims, such as "throw away your eyeglasses," and unsubstantiated claims about success rates could be misleading to consumers.

LASIK

LASIK is a more complex procedure than PRK. It is performed for all degrees of nearsightedness. The surgeon uses a knife called a microkeratome to cut a flap of corneal tissue, removes the targeted tissue beneath it with the laser, and then replaces the flap.

"With LASIK, the skill of the surgeon is important because he'll be making an incision," says Stephen Crawford, O.D., an optometrist practicing in Virginia, "compared to the PRK method where the machine does more of the work." Crawford urges people to find qualified, experienced doctors to perform this surgery. "You'll want someone who's done a number of LASIK procedures since this is a surgeon-dependent operation," he said.

According to Ken Taylor, O.D., vice president of Arthur D. Little, Inc., a technology and management consultant firm in

Cambridge, Mass., "Last year, across the country, 40 to 45 percent of refractive surgeries performed by physicians were LASIK, which equates to approximately 80,000 procedures." Doctors not participating in clinical trials may choose to use the approved laser to perform LASIK procedures at their discretion, says Morris Waxler, Ph.D., chief of FDA's diagnostic and surgical devices section. But most uses are considered "off label" and are not regulated by FDA.

Ralph A. Rosenthal, M.D., director of FDA's division of ophthalmic devices, says, "The agency has ruled that individual physicians can perform LASIK under the general 'practice of medicine,' if it's in the patient's best interest."

Advantages of LASIK

Some doctors believe that LASIK is a suitable procedure for correcting the most severe refractive errors. They also say that there is generally a faster recovery time after LASIK than after PRK. In addition, LASIK patients can see well enough to drive immediately and have good vision within a week.

After studying the options, Goldstein first decided on the LASIK procedure, but was surprised to learn that her doctor advised against it.

"Initially, I wanted the quick recovery that LASIK offers," Goldstein says, "but the bottom line was, which surgery will give me the best results, and after considering everything, eventually we agreed on PRK."

James Salz is currently involved in an FDA-sanctioned clinical trial at Cedars-Sinai Medical Center in Los Angeles, which is now studying the laser system specifically for farsightedness (hyperopia) with astigmatism. Although routinely performing laser eye surgery, he still encourages a small percentage of his low to moderately nearsighted patients to undergo radial keratotomy, or RK, an earlier refractive correction procedure that does not require the excimer laser.

With RK, incisions are made in a "radial" pattern along the outer portion of the cornea using a hand-held blade. These incisions are designed to help flatten the curvature of the cornea, thereby allowing light rays entering the eye to properly focus on the retina. The number and length of the incisions determines the degree of correction attained.

"Typically, this is still a practiced procedure for select people with very small corrections of myopia," Salz says.

Conversely, Crawford says that although he will mention RK as an option to his patients considering eye surgery, he is not in favor of this method. He says studies indicate that incisions made during this procedure, which penetrate approximately 90 percent of the cornea, appear to weaken the structure of the eye. Also, once you've had RK done you can't repeat it or have PRK done.

"I think that patients should understand and consider all available options for correcting refractive errors," Crawford says, "but I would never recommend RK to anyone."

Is Laser Surgery for You?

For some, like Goldstein, laser surgery has been the ultimate freedom from the everyday hassles of contact lenses, and a second chance at having normal eyesight. But can everyone expect such dramatic results?

"The answer is no," says Rosenthal. "It's not a foolproof procedure and people need to know that some can end up with worse eyesight than before they went in."

Mary Ann Duke, M.D., a general ophthalmologist practicing in Potomac, Md., adds that there are other reasons why the expectations for laser surgery vary from person to person.

"People who are slow healers or who have ongoing medical conditions [such as glaucoma or diabetes] are not good candidates for laser surgery," she says. "That's why it's so important for patients to undergo a thorough examination with their doctor."

Poor candidates for this surgery also include those with uncontrolled vascular disease, autoimmune disease, or people with certain eye diseases involving the cornea or retina. Pregnant women should not have refractive surgery of any kind because the refraction of the eye may change during pregnancy.

Looking Ahead

At present, a number of other lasers for eye surgery are currently being tested in FDA-sanctioned studies to determine their safety and effectiveness. Investigational Device Exemptions (IDEs) filed with FDA allow for clinical studies involving the excimer laser and the correction of farsightedness. The IDE process is designed to investigate the safety and effectiveness of a device, or a new procedure with an already approved device, either to obtain information for publication or to generate the data needed to obtain marketing approval from FDA.

"If the refractive surgery center says the laser is approved by FDA, it probably is," Waxler concludes. "Still, it is wise for consumers to check that the device being used for their surgery is FDA-approved," he says, or that they make sure they are being treated with a laser that is under study in an FDA-sanctioned clinical trial.

During the first few weeks immediately following laser surgery, Goldstein says, "Every week I kept thinking, 'this is as good as it gets'?" Then, she discovered by the sixth week, as predicted by her surgeon, that her eyesight was noticeably better and eventually stabilized.

"I would tell others to be patient about their expected outcome," she advises. "Even though with LASIK you can expect quicker results, I'm happy with the choice of PRK."

Carol Lewis is a staff writer for FDA Consumer.Are You a Candidate for Laser Eye Surgery? You may be a good candidate for laser eye surgery if you:

- are at least 21 years of age for a Summit laser or 18 years of age for a VISX laser, since the eyes are still growing to this point
- have healthy eyes that are free from retinal problems, corneal scars, and any eye disease (refractive errors are considered eye disorders, not diseases)
- have mild to moderate myopia (nearsightedness) within the range of treatment (see your doctor to determine your range)
- have a way to pay for the treatment since laser procedures are costly and probably not covered by health insurance policies
- are fully informed about the risks and benefits of laser surgery compared with other available treatments.