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Lasik worries? Some may see better with alternatives

By LAURAN NEERGAARD

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WASHINGTON -- Frightened by headlines about Lasik side effects? Lasik gets all the advertising, but there are half a dozen alternate eye surgeries _ from a simpler laser approach to implantable lenses _ that might solve your squint.

They all have their own risks. A key is finding a surgeon who doesn't have a favorite but is qualified to evaluate patients for all of the options, to find the best fit.

Topping the list is a pre-Lasik laser that's making a comeback thanks to precision-improving computer software. It goes by two names: Surface ablation, or wavefront-guided PRK, which stands for photorefractive keratectomy. What's most important is that it doesn't require cutting a flap into the cornea, the eye's clear covering, like Lasik does, a cut widely considered that procedure's riskiest step.

"There's a lot of us that are doing more and more surface ablation and much less Lasik," says cornea specialist Dr. Craig Fowler of the University of North Carolina.

PRK accounts for about 15 percent of the roughly 700,000 laser vision correction surgeries performed each year, up from 5 percent during Lasik's peak in popularity earlier this decade, says David Harmon of Market Scope, which tracks the industry.

Other Lasik alternatives have virtually no advertising and attract far fewer patients.

Tragic testimony before the Food and Drug Administration last week reinforced warnings that Lasik does come with risks: lost vision, painful dry eye, glare and other night-vision problems. Serious complications appear rare, affecting 1 percent or fewer cases, and the FDA estimates 5 percent of patients aren't satisfied with the outcome.

But aggressive marketing makes patients falsely believe clear sight is guaranteed, complained Dr. Jayne Weiss of Detroit's Kresge Eye Institute, who chaired the FDA advisory panel.

"Lasik is not a commodity. It's a surgical procedure, but it is being sold as a commodity," she told the meeting.

Here's the real rub: One in four patients who seeks Lasik and undergoes a battery of pre-surgery testing is deemed a poor candidate. Maybe the cornea is too thin, or the pupils too large, or nearsightedness too severe, or their expectations unrealistic. But it's not clear just how many patients get screened appropriately, and some forge ahead anyway.

"Some patients are just not a cornea laser eye surgery patient," stresses Dr. Kerry Solomon of the Medical University of South Carolina, a spokesman for the American Society for Cataract and Refractive Surgery. "There are still other options for them. ... And some are, quite frankly, better suited to staying with their glasses and contacts."

With Lasik, doctors peel back a flap in the cornea's surface and zap the underlying layer to reshape the cornea and ease either nearsightedness or farsightedness. The newest version, considered safer, makes

disqualify someone from LASIK, such as large pupils or severe nearsightedness, the AP reported.

"The FDA has called this a quality-of-life issue, because patients are complaining that their vision isn't sharp, they have poor night vision, some have glare or halos, some complain that their eyes are dry," said Dr. Robert Cykiert, associate professor of ophthalmology at New York University Langone Medical Center.

Some of those disgruntled patients were on hand for Friday's FDA hearing.

"Too many Americans have been harmed by this procedure, and it's about time this message was heard," said David Shell of Washington, D.C., who had the surgery in 1998 and said he has "not experienced a moment of crisp, good quality vision since," the AP reported.

Colin Dorrian was a law school student from suburban Philadelphia when he was told he wasn't a good candidate for LASIK, but got the surgery anyway. His father, Gerald, detailed on Friday the six years of eye pain and blurred vision experienced by his son, before reading his child's suicide note: "I can't and won't continue facing this horror," the news service reported.

Matt Kotsovolos worked for the Duke Eye Center when he had a more sophisticated LASIK procedure in 2006, and said his doctors classified him as a success because he now has 20-20 vision -- something Kotsovolos called a deceptive industry practice, according to the AP.

"For the last two years, I have suffered debilitating and unremitting eye pain," Kotsovolos said. "Patients do not want to continue to exist as helpless victims with no voice."

LASIK (laser-assisted in situ keratomileusis) surgery involves cutting a small flap in the eye's cornea using a laser. With the flap held out of the way, the surgeon can then reshape the corneal tissue with another laser. The procedure can be used for nearsightedness (as in Tiger Woods' case), farsightedness and, in some cases, astigmatism.

But, the much-touted procedure is not for everyone. Those who should rule it out include individuals who have a misshapen cornea or excessively thin cornea, who have early cataract formation or big pupils, who have dry eyes, or underlying conditions such as lupus or rheumatoid arthritis, said Dr. Norman Saffra, director of ophthalmology at Maimonides Medical Center in New York City.

Negative results can include glare and halos around lights at night. Some patients have actually had to have corneal transplants when LASIK went wrong, Starr said.

Surgeons may also rule out patients with unrealistic expectations. "I had a patient who said, 'I want to be able to see a license plate on a dark country road from a mile away,' so I didn't do it," said Cykiert, who estimated that he declines about 20 percent of patients who come to him.

Cykiert recommends that the surgeon who is going to perform the LASIK surgery also be the one to pre-screen candidates. "One of the things [the FDA] is probably going to find is that some of the people who have complaints that are valid may possibly have not been evaluated pre-operatively as thoroughly as they could have been," he said.

"It's an elective surgery, you're operating on very healthy people, healthy eyes, you don't want to take any chances," said Starr, who turns away 50 percent to 60 percent of prospective patients who come to him.

Starr himself has declined to have the procedure, because he considers himself "borderline." (Refractive surgeons in general, however, are four times more likely than the general population to undergo LASIK, according to a survey from the American Society of Cataract and Refractive Surgery.)

But while screening is good, it can always be better.

"How can we identify that subset of patients whose lives are irreversibly changed from a relatively 'safe' procedure," said Saffra.

To that end, the new task force is undertaking a study to identify additional factors to help screen candidates for LASIK.

"This is a science in evolution, and it is unacceptable to any eye physician to do harm to a patient, to have people whose lives are changed negatively forever, when it should have been a slam dunk," Saffra said.

More information

The [FDA](#) has more on LASIK.

SOURCES: Christopher E. Starr, M.D., co-director Corneal Cataract and Refractory Surgery, New York-Presbyterian Hospital/Weill Cornell Medical College, New York City; Robert Cykiert, M.D., associate professor of ophthalmology, New York University Langone Medical Center, New York City; Norman Saffra, M.D., director of ophthalmology, Maimonides Medical Center, New York City

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FDA Panel Urges Stronger Warnings for LASIK Surgery

By Amanda Gardner

HealthDay Reporter

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FRIDAY, April 25 (HealthDay News) -- Golf great Tiger Woods lauds vision-correcting LASIK surgery as "life changing." NASA now allows astronauts to undergo the procedure, and the U.S. military says it has been performed on 112,500 military personnel, including pilots.

But are some of the risks and complications of this elective surgery being lost in this laudatory celebration?

The U.S. Food and Drug Administration's Ophthalmic Devices Panel convened Friday to discuss post-LASIK quality-of-life issues. Its recommendation at day's end: That the FDA warn more clearly about the risks of the increasingly popular surgery, the Associated Press reported.

"This is ground-breaking. It's the first time anything like this has happened around refractory, or LASIK, eye surgery," said Dr. Christopher Starr, co-director of Cornea, Cataract and Refractive Surgery at New York-Presbyterian Hospital/Weill Cornell Medical College in New York City. "I think it's a good thing, because I know that the surgery, when done on the right patients, is a great, great surgery with phenomenally good outcomes."

According to the LASIK Study Task Force, formed in 2007, studies indicate a 95.4 percent satisfaction rate among patients worldwide. The Task Force consists of the FDA, the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, and the U.S. National Eye Institute.

But of the 7.6 million people who have undergone the procedure in the United States since the mid-1990s, 140 have written letters of complaint to the FDA.

Now the FDA has followed up on those complaints. Friday's hearing was part of a larger review to see if new warnings about LASIK surgery are needed to alert consumers to the possibility of eye pain, dry eyes, blurred or double vision, and other problems.

The FDA panel will also advise the full agency about how to conduct a \$1.2 million study that the agency is planning with the National Eye Institute and the American Society of Cataract and Refractive Surgery to determine patients' quality of life after LASIK, the Washington Post reported.

On Friday, the FDA advisers recommended that the agency make clearer the warnings regarding LASIK surgery. The recommendations include: adding photographs to illustrate what people suffering certain side effects actually see, such as the glare that can make oncoming headlights a "starburst" of light; clarifying how often patients suffer certain side effects, such as dry eye; and making clearer the conditions that should disqualify someone from LASIK, such as large pupils or severe nearsightedness, the AP reported.

"The FDA has called this a quality-of-life issue, because patients are complaining that their vision isn't sharp, they have poor night vision, some have glare or halos, some complain that their eyes are dry," said Dr. Robert Cykiert, associate professor of ophthalmology at New York University Langone Medical Center.

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