



Thursday, June 28, 2001  
Arlington, VA

## Side effects can be worse than original problem

By Stephanie Armour and Julie Appleby  
USA TODAY

Laser eye surgery is being touted in advertisements as a quick, virtually risk-free procedure that can end patients' need for glasses.

But with more than 1 million patients expected to undergo the procedure this year, thousands are learning what the ads don't say: The surgery can cause life-altering complications that sometimes can't be fixed.

Problems include double or triple vision so severe patients can't watch TV or read, light distortions so blinding they can't drive at night and eyes so dry that goggles must be worn outside. Some

# Laser eye surgery has a downside Promise of clear vision brings misery to some

always return to wearing glasses.

"Now I can't drive at night because it's so bright it's like putting your head in a bag of Christmas lights," says Woodlock, 40, of Huntington Beach, Calif.

"I went to another doctor who said my corneas look like shattered windshields. I've had four more surgeries in my left eye, but it can't be fixed. It's important people know this can happen."

To be sure, the operation is generally a success and complications rare.

Millions have been helped. But some patients and doctors say advertisements touting laser eye surgery, also known as LASIK (short for Laser-Assisted In-Situ Keratomileusis), give the public dangerously unrealistic expectations.

"If you promote it as if it's a haircut, then you're not being genuine. That's one of the reasons there are more lawsuits, simply because people's expectations are that it's low-risk," says Dr. Roy Rubinfeld of Chevy Chase, Md., who has

California-based LaserVue Eye Center settled a lawsuit last year alleging it reused blades that could have potentially exposed patients to infectious diseases such as hepatitis and AIDS. LaserVue didn't return calls seeking comment.

"A lot of these places are becoming like mills, with patients literally getting in and out of chairs," says Bryan Lentz, a lawyer in Philadelphia who has represented a laser-surgery patient in another case.

**• Patients are at risk because doctors fail to do thorough screenings.**

With no standardization of screening procedures, some doctors aren't conducting enough tests on patients to determine risk of complications, critics say.

"They're doing the surgery on people who should not be patients," says Aaron Levine, a Washington lawyer. He estimates that there are about 100 malpractice lawsuits involving laser eye surgery.

**• Risks may not be known.** The Federal Trade Commission is now cautioning that LASIK surgery is "too new to

15, 2000, thinking it would be "neat to be able to see the clock when I woke up in the morning."

"I cannot read for any amount of time without experiencing substantial pain. I cannot go outside without wearing goggles because the wind is too much to tolerate," says Bishop, who spent \$3,000 on her procedure. "I have to close my eyes when people walk by me because I can feel the breeze they create in my eyes, and it is painful."

### Growing number of patients

As complaints mount, the American Trial Lawyers Association has started a laser eye committee, and dissatisfied patients are forming support groups in California, Florida and other states.

The number of people undergoing laser eye surgery has grown each year since its inception in 1996, when about 62,000 people had the procedure, according to Market Scope, a marketing firm that concentrates on the optical industry.

Last year, 835,000 people had the procedure. This year, a projected 1.1 million will. They're hoping it will correct their nearsightedness, farsightedness or astigmatism enough so they can do without glasses or contact lenses.

In an operation that takes about 10 or 15 minutes, surgeons use a device to cut a flap from the front of the eye and peel it back. A laser reshapes the cornea in an attempt to improve its focus. The flap is placed back over the cornea.

The surgery has become so routine that some patients undergo the operation in malls while curious bystanders look on. Ads promising "results you'll love" tout the operation as a "miracle," "safe and effective" and "revolutionary."

About 5% of patients -- which would equal 50,000 people this year if 1 million have the surgery -- face some kind of complication, according to data commonly touted by industry consultants. That may include temporary inflammation, a reduction in vision quality, dry eyes, halos and difficulty driving at night because of halos or severe glare. Some complications go away within months. Others may be permanent.

"A 5% (complication rate) might be correct early in a surgeon's experience, but later, it's more like half a percent," says Howard Gimbel, medical director of Gimbel Vision International, which runs surgery clinics in Calgary and Alberta, Canada.

As a comparison, cataract surgery has about a 3% complication rate, according to a study sponsored by the federal Agency for Health Care Research and Quality.

(over)

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patients have spent thousands of dollars trying to fix problems only to find the technology doesn't yet exist to provide a remedy. Industry analysts and reports from the Food and Drug Administration suggest that up to 5% of patients experience some sort of complication.

Even advocates of the procedure have lodged complaints. In February, the former president of Canada-based Lasik Vision, Michael Henderson, brought a lawsuit against the company. He said his eye surgery led to vision problems.

Despite warnings on detailed consent forms, few of the patients reporting problems from their laser eye surgery say they understood that such severe complications were possible.

Leslie Woodlock says she thought that if her surgery didn't work, she could

had the procedure himself and performed it on his wife. "This is surgery. As with all surgeries, the results are dependent on the skills, experience, judgment and ethics of the surgeon."

Problems with the surgery are getting more attention because of an increase in malpractice lawsuits. In addition, recent bankruptcies have prompted laser eye clinics to close, causing scores of patients to scramble for follow-up medical care.

What critics say:

\* Profit pressures are leading to sloppy care. With prices ranging from \$499 an eye to more than \$2,000, doctors who see dozens of patients a day can earn tens of thousands of dollars.

Profit pressures are prompting some clinics to recycle equipment or rush screenings, critics say. Lawyers say

know if there are any long-term ill effects beyond five years after surgery."

Others also are raising concerns.

Canada's Medical Association last year added LASIK to a list of 14 conditions considered risk factors when determining whether a person can legally drive.

In the USA, a researcher in Baltimore reported in a peer-reviewed journal in May that 41.5% of 176 LASIK patients surveyed said they had more difficulty driving after the surgery. "It's not that they can't drive, but just that some have glare that is worse than it was before," says researcher Oliver Schein, a professor of ophthalmology at Johns Hopkins.

Cathy Bishop-Clark, 37, a professor in computer science and systems analysis at Miami University's Middletown, Ohio, campus, underwent the surgery on Sept.

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## Laser eye surgery has a downside, continued

Attention to problems within the LASIK industry is welcomed by some who say consumers may have unrealistic expectations.

"The turbulence in the industry is needed. We need the reality check that this is a surgical procedure," says Elias Vamvakas, CEO of TLC Laser Eye Centers, whose U.S. headquarters is in Bethesda, Md. "The long-term focus on quality is needed."

### Exaggerated hopes

TLC, which performed laser surgery on golfer Tiger Woods, also has clinics in Canada. Vamvakas says equipment used there is more cutting edge than in the USA. And he says patients are referred to his clinic by their own doctors, which helps ensure fewer problems. He also says that exaggerated advertising has added to patients' exaggerated hopes.

"Ninety percent of ads are done by individual doctors. The vast majority bill it as easy and quick. People say things

is like someone threw acid in there. I keep thinking, 'Millard Stahle, you ruined your life.' Medicine should not be buyer beware. The ads, they're all hype."

Supporters say such bad outcomes were more likely when the procedure was new. They say tales of bad outcomes can too easily sway people from having a surgery that may substantially improve their lives.

And they say that, in many cases, problems can be fixed. For example, surgeons can redo procedures to make vision sharper for patients who have failed to come close enough to 20/20 vision. Wrinkles in the flaps that can cause vision problems can be fixed if caught early enough after surgery. Stray cells that get under the flaps can also be brushed out.

"Somewhere between 50% and 70% of those patients I can greatly improve," says eye surgeon Rubinfeld, who is part of a growing new subindustry: doctors who care for patients trying to correct laser eye surgery complications.

she says. "It's impacted everything in my daily life."

Officials at Kremer declined to comment.

Some of the lawsuits could potentially affect thousands of patients. Three sisters -- Marie Harris, Janet Janke and Sherry Stauffer -- are suing Canadian-based Lexington Eye Institute and Focus Eye Care, a company in Washington. Lexington handled their surgeries, and Focus Eye Care dealt with pre- and post-procedure care.

The lawsuit, filed in Seattle, seeks class-action status. The sisters claimed they experienced vision problems after their surgeries.

Steven O'Ban, a Seattle lawyer for Lexington Eye Institute, says the company "categorically" disputes the claims. He declined to comment, however, "because of a confidentiality order the judge has put in place."

Some say such lawsuits are to be expected. The increase in legal action against eye surgeons who use lasers sim-



British Columbia, laser eye surgery firm used by many in the USA, merged this year with another Canadian firm, Icon Laser Eye Centers. In April, Icon placed the subsidiary in bankruptcy and clinics closed throughout the USA and Canada.

Some doctors in the USA report that they've been treating patients who developed complications after having procedures done across the border.

"A large number of patients are coming in with serious complications," says Steven Wilson, chair of ophthalmology at the University of Washington in Seattle.

Some experts say complication rates are likely to decline as surgeons and the industry learn more about which patients make the best candidates for surgery.

### Not good candidates

In the past few years, for example, many surgeons have begun advising patients who need a great deal of correction that they may not be good candidates, especially if their corneas are thin or their pupils wide, because those conditions increase the risk for problems, says Gimbel of Gimbel Vision International in Calgary.

"Many of us have seen patients with night-vision problems after LASIK," Gimbel says. "That's why we are selecting patients differently now than early on. With time and experience, we realize the limitations of a procedure. Then we have to back away from those situations. What's coming into the press now are those early results. Unfortunately, that's making some people afraid of the procedure."

Phyllis Knapp thinks a little fear may be a good thing. Ads make the procedure seem so easy, so safe. But more people considering the surgery also need to know how bad the problems can be when things go wrong, she says.

Knapp, of Kalamazoo, Mich., says she spent \$4,400 for her laser surgery in January 2000. A proper screening was never done, she says. Now she says she sees double in her left eye. Driving at night with her husband, she says the lights of oncoming cars appear to be spikes stretching up into the black sky. At work, she says she suffers from such painful dryness she spends breaks on a cot in the lounge putting ice on her burning eyes.

"I'm struggling to work every day because I can't see very well," says Knapp, 57, a secretary at Kalamazoo Valley Community College. "I often have to wake up every night to lubricate my eyes and put ointment in. It's made me a whole different person. I find no joy in anything. I had never envisioned it could be this bad. They're even doing the procedure in malls now. It's sickening. It's a circus. They're making a mockery of a serious medical procedure."

Contributing: Kate Morse

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that are out of line," he says. "It's a huge issue. Consumers have no idea. They trust doctors. Pressures in the industry have prompted some doctors to do surgery on patients who aren't the best candidate."

Others say there should be more regulation of the ads used to get patients in the door. The Food and Drug Administration is warning consumers to be wary of "slick advertising" and "deals that sound too good to be true."

Millard Stahle says that, based on the advertisements he saw, he believed the surgery would improve his vision.

Instead, he says, it has dismantled his life. Since undergoing laser eye surgery about a year ago, Stahle doesn't sleep much. The procedure left him with such dry eyes that he says he must awaken every few hours, peel his lids open and apply lubricating drops.

He doesn't drive much anymore, either. Night-vision problems mean the lights of an oncoming car can be almost blinding, he says. Because he's unable to meet clients in the evenings, the 54-year-old real-estate agent gave up his job.

"I didn't know this could happen or be this severe," says Stahle, of Fairfax, Va., who paid \$2,400 to have the surgery done. "For me, the night is the worst part. I wake up every hour, and the pain

"There are a number of problems that can be helped a great deal or eliminated," Rubinfeld says.

For some patients, nothing short of a corneal transplant will help. "A transplant will repair almost all LASIK problems, but it is not to be entered into lightly," Rubinfeld says. "It takes a long time for vision to heal, about a year. And it has its own set of risks, of rejection and infection."

### More lawsuits

Patients with problems are increasingly taking their stories to the courts -- alleging medical malpractice or consumer fraud.

Last year, Angel Bin Fang was awarded \$800,000 in her lawsuit against Kremer Laser Eye Center in King of Prussia, Pa. She says the first surgery left her farsighted in one eye. A second operation led to permanent double vision and other problems. The case is under appeal.

She can read for only 15 minutes at a time because of pain, she says. She can't play Ping-Pong, peruse a menu in a dimly lit restaurant, read road signs at night or spend any sustained period of time watching TV or movies, she says. "It's constant. It will always be like this,"

ply reflects an increased number of procedures being performed, says Paul Weber, risk manager for Ophthalmic Mutual Insurance, which insures about 2,200 doctors, about 850 of whom do laser surgery.

"There were more than a million procedures done last year," Weber says. "Anytime you have that volume of procedures done, there will be patients not happy with the result. I don't think this procedure is any riskier than any other ophthalmic procedure."

Last year, about 150 claims were filed against the insurer. Of those, 19, or about 12%, were related to laser surgery.

"It's something we're paying attention to, but it's not a number that's shocking," Weber says.

Treatment issues can take on a different twist for the scores of patients who go to Canada, which approved the procedure before the USA. Critics say problems arise because some Canadian centers have gone bankrupt, while others use equipment not approved by the FDA. And they say patients often return home right after surgery and are too far away to go back to their doctor in Canada if complications arise.

Other patients have been left without follow-up care because dozens of clinics have closed. Lasik Vision, a Vancouver,