

FDA TO EXPLORE POSSIBLE LINK BETWEEN FAILED *LASIK*, DEPRESSION PATIENTS WITH IMPAIRED SIGHT TURN SUICIDAL; SURGEONS REJECT ANY CONNECTION

Sunday, February 3, 2008

Section: NEWS

Edition: FINAL

Page: A1

Sabine Vollmer; Staff Writer

Illustration: Staff Photos by Ethan Hyman

Caption: Martha Walton of Raleigh fell into deep depression after lasik eye surgery in August left her with constant, severe pain from dry eyes. An elaborate treatment regimen has helped, but she still takes an anti-anxiety drug. Martha Walton feeds her hens outside her home in Raleigh. For months after surgery, she could not feed them because of the pain and the dust outside. 'It's been utter hell,' she says. Dorrian, 28, killed himself after surgery left visual distortions. Hybarger, 44, tried suicide after post-lasik problems.

Patients who undergo vision-correcting laser eye surgery sign a release form with an extensive list of risks, but some researchers and former patients say a potential complication is not mentioned: depression that can lead to suicide.

In response to patient complaints, the Food and Drug Administration plans to convene a large, national study to examine the relationship of *lasik* complications and quality of life, including psychological problems such as depression.

Malvina Eydelman, an ophthalmologist with the FDA's Center for Devices and Radiological Health, wrote in an e-mail message that the scant clinical data available "failed to suggest significant problems following *lasik* surgery," but she said the FDA wants a broad and systematic review. She wrote, "We also noted that quality of life issues related to *lasik* had not been evaluated consistently, and there were few reports of well-designed studies."

Frustration and even sorrow can follow any unsuccessful surgery, but when the procedure leaves a patient with unremitting eye pain or permanently impaired vision, the emotional toll can be particularly severe.

One who could not endure it was Colin Dorrian, 28, a patent lawyer and aspiring medical student from suburban Philadelphia. He committed suicide last summer, 6 1/2 years after *lasik* surgery left him with lasting visual distortions. The surgery was done at a *lasik* center in Canada that has since closed.

"If I cannot get my eyes fixed, I'm going to kill myself," he wrote in a note police found on his body. "I just cannot accept the fact that I'm supposed to live like this."

In the note, Dorrian wrote that there had been other instances when he felt down. "I have other problems like most people do. But this is something else," he wrote. "As soon as my eyes went bad, I fell into a deeper depression than I had ever experienced, and I never really came out of it."

Laser eye surgeons who treat patients with complications say they do come across cases of depression, but they don't think *lasik* complications are the root cause. They say patients who exhibit depression after the procedure were likely depressed or psychologically troubled beforehand.

"There's no cause and effect," said Dr. Steven C. Schallhorn, the former head of the Navy Refractive Surgery Center in San Diego and an expert on permanent visual distortions from *lasik*.

In September, The News & Observer reported on complications from *lasik*, a lightly regulated surgical procedure widely promoted as a quick and painless way to eliminate the need for eyeglasses. But patients across the country and in laser eye surgery hot spots such as the Triangle,

where 11 laser eye surgery centers operate, say the physical after-effects can cause or aggravate psychological problems.

Martha Walton of Raleigh postponed **lasik** twice. She had had bouts of depression and anxiety attacks and wasn't sure she was ready for the permanence of eye surgery. She still felt very anxious when she went ahead with it in August. Within a month, Walton, 41, a high school teacher, developed constant, severe pain from eye dryness. She couldn't cope with it and spent six days on suicide watch in a Triangle mental health facility.

"I was in so much pain," Walton said. "Twenty-four hours a day there was no escape. The only relief I could think of was to end my life. At least the pain would be over."

An elaborate regimen of taking supplements, wearing special goggles and switching to preservative-free eye drops has drastically reduced her pain. But her eyes still do not produce enough tears and she continues to take daily anti-anxiety medication.

Christine Sindt, an optometrist and associate professor of clinical ophthalmology at the University of Iowa in Iowa City, Iowa, has encountered the psychological effects that patients experience when they have trouble seeing.

"Depression is a problem for any patient with a chronic vision problem," she said. But in the case of post-**lasik** patients, she said, the depression is compounded by remorse.

"It's not just that they lose vision," she said. "They paid somebody [who] took their vision away."

Sindt specializes in treating ectasia, a bulging of the eye that is considered the most severe and rarest **lasik** complication. She sees a few dozen patients with ectasia; all of them show signs of depression, she said.

Lasik usually safe

Since the mid-1990s, numerous studies have shown that the surgery known as laser-assisted in-situ keratomileusis, or **lasik**, is safe and successful in most cases and has become more so with the introduction of new technology. Most of the 1.3 million Americans who undergo the surgery every year are happy with the results. The American Society of Cataract and Refractive Surgery, which represents about 9,000 ophthalmologists specializing in laser eye surgery, suggests that 2 percent to 3 percent of **lasik** patients experience complications.

Dr. Alan Carlson, a laser eye surgeon at the Duke Eye Center in Durham, built his career on correcting the vision of patients at high risk of complications. He said people at risk of depression or anxiety are generally not good candidates for **lasik**. He compared them to patients who become depressed after undergoing cosmetic surgery, another elective and medically unnecessary procedure.

"Their motivation and expectations may reflect something they're missing in their life that they're not telling you about," he said.

But surgeons agree that **lasik** is unlike a face-lift or even most necessary surgery because it affects a process -- seeing -- that is essentially a mental function. The eyes focus light, but what a person actually sees depends on how the brain decodes an image. Neurological differences in decoding explain why dyslexics reverse letters and why alcohol consumption can produce double vision.

Although laser eye surgery has been around for years, little research has been done to explore how the ability to see affects how people feel and act. In 2006, the FDA began to look into **lasik** complications and quality-of-life issues and determined more research was needed. A task force that includes representatives of the National Eye Institute and the National Institutes of Health has since formed to design a large study that would be conducted by laser eye surgeons across the country.

Vision-mind connection

The FDA is also planning an open public meeting this spring to discuss experiences with **lasik** devices since their introduction to the U.S. market.

A few researchers have already looked at whether changes in vision can affect the mind. Scientists at the Emory Eye Center in Atlanta reviewed suicides among organ donors who had had laser eye surgery.

Preliminary results suggested the suicide rate might be four times as high among cornea donors who had had **lasik** as among cornea donors who had not. But the data were incomplete and the numbers

could be significantly skewed, said Dr. Henry Edelhauser, the professor of ophthalmology who oversaw the Emory study. One of the participating eye banks failed to provide vital statistical data. Research that Schallhorn did at the Navy Refractive Surgery Center suggests a relationship between satisfaction after **lasik** and certain personality traits among patients. Schallhorn declined to provide details. Like the results of the Emory suicide study, his research has not been published in peer-reviewed journals.

But some patients are unequivocal: **Lasik** complications drove them to contemplate suicide. In Cleveland, Tenn., Kim Hybarger, 44, a nurse, developed debilitating visual distortions after **lasik** surgery Dec. 21, 2006. She tried to walk into traffic, cut her throat and starve herself. "I was filled with anger," she said. "I felt so hopeless and helpless. I just wanted to die. The way I saw was so frightening."

Her vision was blurry. The moon had six to eight overlapping copies, a distortion called ghosting. Bright lights erupted into irregular star bursts in the shape of chicken feet. Hybarger compared her vision to looking through glass that is cracked and smeared with grease. She stopped driving, exercising, working and going to the grocery store. She couldn't read a book or watch television.

Hybarger said she had never had problems with depression before her **lasik** surgery. Afterward she felt so bad, she said, she told her husband to "load a gun with a bullet and give it to me. I'm not going to live the rest of my life like this."

Hybarger's mental state didn't improve until Ed Boshnick, a Miami optometrist, offered to fit her with special contact lenses. Sales of the special lenses have increased with the rising number of Americans who had lasik since 2000. The lenses can restore the cornea's shape and correct visual distortions.

New lenses help

Boshnick is one of a handful of specialists who have had considerable success fitting the lenses.

Hybarger is one of about 250 patients with complications from lasik who regularly see Boshnick.

About half of them suffer symptoms of depression, Boshnick said.

The new lenses can clear up more than vision.

Hybarger left Miami remembering the moment she first looked through them.

"It was indescribable," Hybarger said. "It was like the first time I smiled in a year."

Keywords: FDA; HEALTH; MEDICINE; SUICIDE; CENTER FOR DEVICES AND RADIOLOGICAL HEALTH; MALVINA EYDELMAN; MARTHA WALTON