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NEWS

## LASIK lawsuits are preventable, experts say

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by Ellen Dean Wilson Correspondent

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**As LASIK has boomed, another industry has developed - the LASIK lawsuit business. But wise surgeons can take steps to avoid such problems.**

"There are claims out there," said Paul Weber, JD, an Ophthalmic Mutual Insurance Co. (OMIC) risk manager. "The last time I checked the data, in January, we had 19 laser in-situ keratomileusis cases." One or two others have already been settled.

Weber said he has spoken with physicians who are reviewing LASIK cases for attorneys and malpractice insurance companies. "Vision and problems related to vision can be very subjective. A case can be won by the plaintiff if a jury can be persuaded that even though the patient is 20/20 or 20/40, they must wear several pairs of glasses during the day because of fluctuating vision and/or never have the quality of vision they had prior to refractive surgery," he said. C. Gregory Tiemeier, JD, of Denver, represents physicians. He now has four LASIK cases and has settled several others out of court. He knows of at least one other LASIK case in his area. "The complaint that I've heard most about is reading in low light and driving at night," he said.

Ophthalmologists may not realize how annoying these problems are, he explained, and may not be discussing them sufficiently before surgery.

A patient from Washington had decided to sue his LASIK surgeon after experiencing complications. He faults his physician for not measuring his pupils in dim light, and for continuing the procedure despite a short flap. His claim will be filed in court soon, he said.

Robert M. Portman, JD, legal counsel to the American Society of Cataract and Refractive Surgery, said he does not know how many lawsuits have been filed regarding LASIK, but that the number is likely to rise with the procedure's increasing popularity. With media attention and "a lot of pretty aggressive claims" come higher expectations, he said.

The standard for a medical malpractice lawsuit is "whether the defendant physician has exercised reasonable care measured against what other similar doctors would do under similar conditions," Portman said. Plaintiffs could also sue for misrepresentation, if advertising claims were not met, he added. Because of the heavy marketing about LASIK, patients feel surprised even by small problems, Tiemeier said. Physicians should begin a consultation by asking patients what they've heard about LASIK, to clear up misconceptions. One physician he represents explains the possible complications, provides a thorough consent form, and then has patients check off from a list all the complications that have been explained to them. Although the lengthy procedure may not prevent a lawsuit, Tiemeier said, he would "rather defend at trial someone who did

everything he could."

Eileen Marie Wayne, MD, is in private practice in Moline, Ill. She is the founder of the InformedConsent.com Foundation Inc. The purpose of the foundation is to develop written procedure-specific informed consent documents for both diagnostic and therapeutic, medical and surgical procedures in all fields of medicine. The information is to be based on patient feedback and procedure-specific outcomes data.

"Generally, refractive surgeons have taken informed consent to a new level by providing patients with a very complete written list of specific risks, benefits, and alternatives. Young people come to us with eyes that are correctable to 20/20. They have an entire lifetime of potential ahead of them. LASIK offers an alternative to glasses, not necessarily improved vision. LASIK risks the loss of that precious vision and patients, who now see 20/20, need to be clear about that risk," Wayne said.

But the lack of information given to some patients is apparent by a check of the web site

[surgicaleyes.org](http://surgicaleyes.org). Patients complain that they were not informed of possible loss of good night vision or about poor results for large-pupiled eyes, for example.

"Ultimately, the buck stops at the surgeon's desk; so should the informed consent," said Pat Jacobson, JD, of Cleveland, a healthcare attorney who represents physicians. "Too often physicians refuse to take the informed consent process seriously, or leave it to staff - that's asking for trouble. Patients should not be assumed to be sophisticated," she said. For example, the physician should explain what halos are and how they can affect sight.

Wayne has been asked by plaintiff attorneys to testify against LASIK surgeons concerning informed consent. So far, she said, every LASIK surgeon has been legally protected because each patient's postoperative complication has been specifically addressed in the written enumerated list on the informed consent signed by the patient.

"There were many times I felt like jumping out of that chair and choking my physician. I was an emotional wreck," said a patient from California about her LASIK surgeon. Nonetheless, she praises his honest assessments after her bilateral LASIK operation led to complications.

This patient estimates that she has visited her physician about 100 times since her March 1999 surgery. Despite vision reduced to counting fingers for weeks after her surgery, she says, she never contemplated legal action. Her story shows how physicians can avoid lawsuits.

By the day after surgery, she said, both flaps had dislocated and wrinkled, one so badly that it was later replaced with a transplant. One year later, she has healed to the point of being able to wear contact lenses and drive again, although problems with acuity, ghosting, and pain remain.

The patient said her physician was "very honest" and "professional," even paying for her and her husband to fly to another city for a second opinion. She decided to have further treatment after confirming the extent of her complications, because she trusted her physician. "There's no attorney out there who can get my vision back, and that's my Number 1 thing I want," she said. "I don't think my doctor failed on me."

The patient has recommended her surgeon to friends who have gone on to have successful LASIK. "I said, 'If you're going to do it, go to him; at least if there's a problem he'll do his best,'" she said.

Daniel M. Shapiro, MD, JD, a former assistant clinical professor at Albert Einstein University/Montefiore, New York City, said lawsuits are more likely with elective procedures, which have been portrayed as risk-free. "That's the thing that medicine's done - it's shot itself in the foot," said Shapiro, who helped the American Academy of Ophthalmology organize OMIC, a San Francisco company that insures members of the Academy.

A registered nurse patient from Louisiana said the physician's video she watched and the seminar she attended before deciding on LASIK did not mention any negative side effects. "It pumps you up," she said.

She had bilateral LASIK in December 1998. She was one of 25 patients receiving the procedure from a single surgeon in one morning. The patients did not meet the surgeon until they were under a laser. "It was like cattle going in," she said. His procedure resulted in a free cap in the left eye, which was put back into place.

Five weeks postoperatively, the patient went in for a routine postop visit. At that time, her surgeon attempted to remove some epithelial ingrowth from around the flap of the left eye while she was seated at the slitlamp. The cap came off completely and an emergency surgery was performed to replace it. She has since undergone two other surgeries to remove epithelial ingrowth. This problem is now resolved, but her uncorrected acuity is 20/300 in both eyes.

This patient is suing her physician. She said the main reason is to let people know that LASIK can have serious complications, and that everyone considering the surgery should be able to have all the facts, both positive and negative.

Her attorney said he is likely to ask for economic damages as well as compensation for pain and suffering. The patient had to switch jobs because she could no longer be on call at night. She can tolerate her contact lenses for only 4 to 6 hours a day and her vision with spectacles is not adequate for night driving.

Weber, at OMIC, said LASIK cases are different from those the company has experienced with radial keratotomy. "The difference is the time between suing and the procedure. It was 2 years with RK, now it's 6 months. They want and expect immediate gratification," Weber said. About 35% to 45% of OMIC-insured physicians perform LASIK, he said.

James C. Hays, MD, in private practice in Atlanta, said he has patients look at their own eyes in the camera pre- and postoperatively and at their topography maps. "We say this is an engineering problem, but it is living tissue, so things can vary."

Glenn Hagele, executive director of the Council for Refractive Surgery Quality Assurance, said his group's web site gives informed consent information to potential patients, about 10% of whom decide not to have LASIK afterward.

Hagele said his consumer organization is certifying its first batch of LASIK surgeons, who can use the certification to show patients they have met certain standards.

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