

11 Ways to Avoid

● C. GREGORY TIEMEIER, JD *Denver*

Technical and clinical know-how, a knowledgeable staff, prudent co-management and the best patient communications will help head off legal trouble related to PRK.



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Because patient expectations of the excimer laser are sky-high and its actual performance is somewhat less than that, PRK is a fertile ground for medical malpractice. If you are doing or plan to do the procedure, it's imperative that you develop a strategy to avoid malpractice suits. The good news: with legal insights, good medicine, smart planning and common sense, I believe you can minimize your risks. Here's how.

1. Understand and respect 'agency.' This legal concept applies in several ways to PRK. When a staff member provides information or care to a patient, he or she is acting as

your agent. The same may hold true for a co-managing OD, depending upon your arrangement. As the surgeon, you can be legally responsible for your agents' actions, and the eventual outcomes of those actions.

How can you make sure your agents are trained to perform the tasks or duties assigned them, and perform them appropriately? There are several steps, and these must be applied equally to your staff, the staff of a laser center, or any co-managing doctor.

Train the staff and co-managing doctors yourself, or closely supervise the training. It isn't enough to recommend they take a course, or pay for the course. You must be extremely familiar

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with the training material, and take steps to make sure it is presented adequately.

Monitor your staff and co-managers when they begin to perform duties related to PRK. What exactly are they telling patients? Are they able to correctly identify normal healing and abnormal responses? Do they know when to refer back to you? Are the receptionists and technicians promising more than PRK can deliver?

Insist on thorough communication and documentation. Do your agents document their care and conversations with patients? Do they report these to you? Establish a formal system of information exchange between you, your staff, the laser center staff, and co-managing doctors.

Supervise periodically, on an ongoing basis, and require retraining or refresher courses. Prepare these courses yourself, or closely supervise their preparation and presentation.

This is hard work, but if you don't do it, the actions of a staff member or co-managing doctor may come back to haunt you in the courtroom. Think about how thorough your actions would seem if you had to explain them to a jury.

2. Behave ethically. While the law may not require compliance with the ethical code, ethical behavior is an important asset in defending a malpractice case. A good plaintiff's attorney will look for any way to attack the surgeon's credibility. A breach of ethics is made to order from his point of view.

Acquaint yourself with the Academy's Code of Ethics and endeavor to follow it. For example, many co-management relationships involve routine referrals from the OD to the MD for

surgery, then back to the OD for post-op care. In some situations, the MD may not independently determine the patient's suitability for follow-up by an optometrist. This may violate rules 7 and 8 of the AAO rules of ethics dealing with Delegation of Services and Postoperative Care. Advisory Opinion 85-1 of the AAO Ethics Committee states: "Provisions for postoperative care should be made on an individualized basis in light of what is best for each patient. A standing arrangement for post-op care for all patients violates this principle."

Each time you make decisions regarding PRK marketing, or how your office delivers PRK services, think about explaining your actions to a

THREE COMMON MISTAKES YOU DON'T WANT TO MAKE

Surgeons who are sued often make one or more of these three common mistakes:

Not talking enough to the patient. By making the time to talk with your patient you can make sure he or she clearly understands the risks of the procedure. An in-depth conversation also will reveal certain personalities or attitudes that are sure to spell trouble later.

Accepting a patient who has too many risk factors. Many surgeons are truly nice guys who try to help people. The bigger the patient's problems, the more the surgeon wants to help. With PRK, this is very dangerous because the FDA protocol is so limited, and our current knowledge of lasers is in its infancy. There are a lot of patients you just can't (or shouldn't) help with PRK.

Trying to achieve too much with the surgery. Yes, you want as positive an outcome as possible, but some goals are beyond our current capabilities. Keep your goals within reason and you'll avoid heartache later on.—C. G. T.

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jury. Are your actions ethical when compared to published professional standards like "The Ethical Ophthalmologist: A Primer?"

3. Understand the role of the laser center. Watch two key areas:

Your contract or agreement with a laser center. You can't protect yourself from liability for patient outcomes in this document. However, the center may try to minimize its responsibility by asking you to sign a release. Have your lawyer evaluate any agreement prior to signing, so that you don't inadvertently release the center from liability.

Laser center staff. Even though these people do not work directly for you, when they provide information or care to your surgical patients, they may be acting as your agents. Evaluate their training and performance closely. Consider yourself responsible for all

aspects of your patient's care, no matter who delivers it.

4. Know the anti-self-referral and kickback laws. If you'll be co-managing PRK patients, or if you will be using a laser center in which you have invested, know state and federal statutes regarding self-referral and kickbacks. Although the provisions of Stark I and II only prohibit self-referral for certain services in the Medicare/Medicaid arena, some states and insurers use these statutes as models for private-paying patients. If you plan on investing in a PRK center which you will use, determine whether your state has or is considering a law to limit such practices. Careful planning can prevent expensive problems later on. Also, before setting up a co-management network, know your state's

laws regarding payment for referrals. Most states have anti-kickback and fee-splitting statutes; make sure you don't run afoul of them.

5. Stick to your training. You got to dance with the one that brung you. In general, do not vary from the techniques, nomograms and equipment with which you were trained. For instance, if you took all your training on one laser, but now would prefer to use another, do not use the new laser until you are retrained. Do the procedures in the way you were taught unless you have a clear, documented reason for changing. Time and again with RK cases, surgeons got in trouble by going outside the established protocols in order to accomplish more. Should you have a negative outcome, or one the patient perceives as

WHAT TO DO IF THE LASER MALFUNCTIONS

If you suspect the laser has malfunctioned, there are several steps to take that will minimize your liability and help you determine what went wrong.

First, contact your professional liability insurer.

Second, contact a qualified independent laboratory or consultant that can test an excimer laser and order immediate comprehensive testing with a full report to you, your attorney, and insurance company. If necessary, have the lab take possession of the laser.

Impound the excimer laser, your surgical supplies, and anything else related to the surgery. Do not allow anyone on your staff or the laser center staff to touch or check it.

Don't turn the laser off until it is checked by your independent lab or consultant. Important information may be stored in the laser microprocessor, which might be lost if the machine is turned off.

Determine if other lasers in the center should be taken out of service.

After the independent laboratory has checked and investigated the laser, turn it over to the manufacturer. Suggest that the independent lab assist in the 'autopsy' of the laser.

Ask your attorney and/or insurance carrier to determine if you should send a report to the maker in accordance with the FDA's medical device tracking regulations.

Report the laser malfunction to ECRI's Problem Reporting Program, which tracks medical device malfunctions and suggests ways to minimize recurrence. This service is free. Make reports to ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462; telephone 215-825-6000; fax 215-834-1275.

Thanks to Paul Webber, JD, the Risk Manager for Ophthalmic Mutual Insurance Company, for providing this information, which was adapted from ECRI's "Special Report on Medical Device Reporting Under the Safe Medical Devices Act: A Guide for Healthcare Facilities."

negative, your lack of formal training with a specific laser could be a problem in court and possibly with your insurer.

If a patient does not fall within the protocol, refer him or her to a Canadian surgeon. You'll lose that case, but the patient likely will come back to you for post-op and ongoing care, and you can save yourself from many expensive legal headaches down the line.

6. Train your staff. Teach them to answer questions accurately and to promote realistic patient expectations. The staff must thoroughly understand their clinical duties, and they must be closely supervised by you. Make sure they know when they're in over their heads, and need to get you involved.

Remember, too, that your staff isn't married to you. They can become disgruntled and they can leave or be fired. This can make for damaging witnesses. In one case I tried, a bitter ex-employee testified that her former boss considered any "myope with money" as an appropriate candidate for RK. Indoctrinate your staff with ethical, appropriate behavior, and set the best possible example for them. Do not joke or be cavalier about a patient; it can damage you later.

7. Keep a cool head. With so much interest in PRK, you may feel pressured to build this part of your practice quickly. Don't be overanxious. If a patient's refractive or physical findings are questionable, or if you have strong reservations about the patient's expectations or attitudes, turn him down. Let him become someone else's problem. It's not worth the risk.

8. Watch for red flags. There's no easy way to pick out patients who will sue, but there are indicators that

should get your attention every time:

The patient has a history of depression. In many of the RK cases I handled, the patient was clinically depressed and under the care of a therapist at the time of surgery. These personalities tend to

look for an external scapegoat for their problems, and if they are at all unhappy with their post-op vision, they will obsess about it. It doesn't take long for this obsession to translate into a lawsuit.

The patient is a perfectionist. Pilots,

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¹"Assessment of Radial Aspheres by the Arc-Step Algorithm as implemented by the Keratron Keratoscope", AJO, November 1995

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lawyers and doctors fall into this category. Take the person's occupation, appearance and interests into account. If a fastidious engineer tells you he spends a great deal of time reading technical manuals, PRK probably isn't going to provide the perfection that he demands from everything around him.

The patient has unrealistic expectations. Reveal this by asking the patient to write down what she expects to get from the surgery. If she says she expects to throw away her glasses for life, or that she expects to realize her lifelong dream of becoming an airline pilot (be especially cautious with pilots and pilot wannabees), be skeptical.

9. Listen to your staff. When interviewing the staff of surgeons sued in RK cases, they often said, "I told the

doctor he shouldn't operate on that patient." Often, your staff can pick up clues about people that you can't, simply because they spend more time with them.

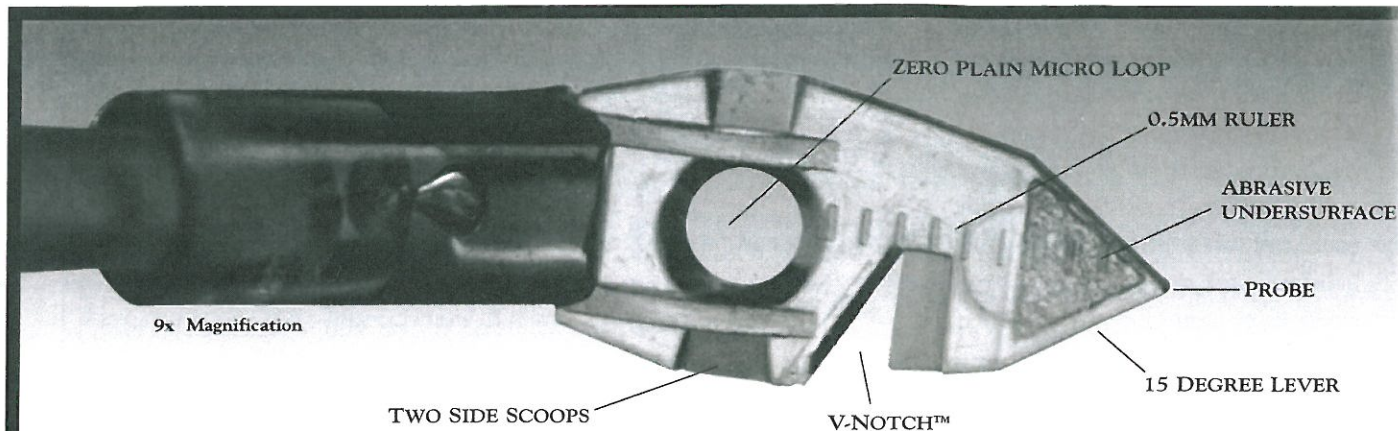
Encourage staffers to get to know each PRK candidate. This not only helps pick out troublesome patients; it can make them less likely to lash out later. One study revealed that the problems most often cited by patients of frequently sued physicians were feeling rushed during office visits and the perception that the physician would not offer information or listen.¹

10. Treat informed consent as a critical process. This is not just some paperwork formality. This process will have a major impact on whether you get sued, and how you'll do in court.

Develop an informed consent form just for PRK. In it, detail all the risks of and alternatives to the procedure.

State clearly that some patients will suffer a bad result. As one Canadian PRK surgeon likes to say, many patients tend to dismiss the risks as something that happens to someone else. "Everyone thinks that they will be in the 98 percent with no serious problems, not in the 2 percent who do have problems," he says. We know that someone will be in the 2 percent. We must remind patients that those who have problems are people who appear to be very good candidates.

Videos are good because some patients can't or won't read. If the patient watches a video in your office, have a staffer sit in to answer questions. If you



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let the patient take the video home, have him sign it out for documentation.

Have a qualified staff member go through the informed consent form, word by word, with the patient. Alternatively, let the patient take the form home and review it. *Make sure* the patient has adequate time to review the form and is not rushed into signing. Make sure the patient signs the form in your office, though, and not at home, after your staff members have had an in-depth conversation with the patient.

Insert places where patients must initial, or write out phrases in their own handwriting. That Canadian surgeon I mentioned asks patients to write, "I understand that I am risking a loss of visual acuity and possible blindness."

Talk to the patient yourself before he or she signs the form. In one case I handled, the form was signed before the surgeon discussed risks. Later, the patient insisted that she didn't understand the risks, and the jury agreed.

11. Handle dissatisfied patients with exceptional care. If a patient has

a less-than-optimal outcome, requests repeated enhancement procedures, or continues to complain of visual flaws even though you are satisfied with the result, put on the kid gloves. These patients need special treatment.


First, alert your staff. Give them simple directives that must be followed at all times: Never keep this patient waiting, take the patient's calls and do not put him on hold, be kind and sympathetic at all times but do not comment on any clinical signs, symptoms or possible outcomes, always make eye contact with the patient and family members, and never make this patient feel rushed in any way. Also, do not admit fault; if you do, you may hear about it again.

Remember, not all patients openly show dissatisfaction. Some act pleasantly in your exam room and then march down to their lawyer to initiate a lawsuit. Just because someone appears calm doesn't mean they aren't going to sue.

If a patient is unhappy, consider referring to a colleague. Offer to pay for the referral. Choose a like-minded physi-

cian with whom you have good rapport. This doctor likely will tell the patient exactly what you told her, but it will have more credibility.

Sometimes a patient will display open hostility. Don't get flustered. Continue to display sympathy and interest.

Very often, malpractice suits stem from events that have little to do with the surgery: The patient's expectations were unrealistic, the doctor or staff appeared to be uncaring, or the patient's interpretation of the outcome was at odds with the facts. If these had been ameliorated, the surgeon could have avoided a painful experience. Take steps to prevent a PRK malpractice nightmare now, and avoid suffering later. 

Mr. Tiemeier, who is with the firm of Kaluk, Burg, and Tapfer, LLP, defended surgeons in 14 of the 17 RK malpractice cases brought in Colorado. This article is not meant as legal advice. If you have specific questions about your situation, consult an attorney.

1. Hickson, GB, Clayton, EW et al: Obstetrician's prior malpractice experience and patients' satisfaction with care. JAMA, Vol. 272 No. 20, p. 1583-7 Nov. 1994.

HOW PRK WILL DIFFER FROM RK MALPRACTICE

Two things will make PRK malpractice suits different than those related to RK:

- *Acceptance.* This is a two-edged sword. On the positive side, ophthalmologists will be less inclined to testify as expert witnesses against their colleagues because most are much more accepting of the procedure than they were of RK. Many RK cases were fueled in part by surgeons who condemned colleagues for 'operating on a healthy eye.'

On the negative side, patients may have extremely unrealistic expectations about PRK. Potential patients seem to think of laser surgery as a "magic bullet," less invasive than RK, less risky and less painful. They regard post-operative healing as intrinsically *easier* following a laser procedure, and believe the laser is so exact that they won't ever need corrective lenses again. Patients may have a rude

awakening that will translate for some into suing the surgeon. These dangerous expectations will only be exacerbated by aggressive marketing programs.

- *Technology.* This aspect of PRK muddies the legal waters in two ways. First, the FDA's protocol will become a legal weapon. The first time a surgeon deviates from FDA protocol and has a negative patient outcome (real or perceived), a lawsuit may be brought. Though the FDA cannot tell you how to practice medicine, failure to follow FDA protocol could be very damaging before a jury.

Second, there's the issue of product liability. Let's say you do everything right, but the machine malfunctions. The laser manufacturer may be the first one sued, but the plaintiff's attorney—and possibly the manufacturer's attorney—will also name the surgeon as co-defendant.