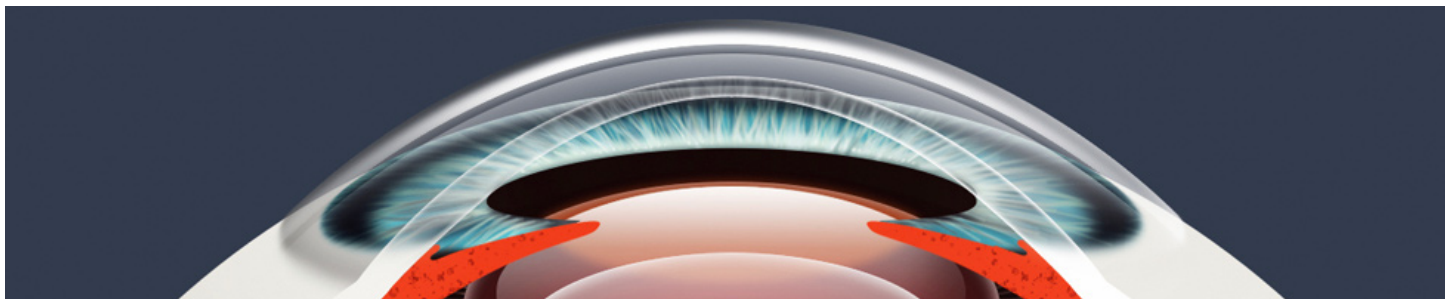


# Risk Management Issues in Radial Keratotomy Surgery



## Articles: Risk Management Issues in Radial Keratotomy Surgery

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The elective nature and high patient expectations of radial keratotomy (RK) surgery present distinctive risk management challenges to ophthalmologists who perform this procedure. With this in mind, OMIC has developed strong underwriting guidelines for keratorefractive procedures. To date, there have been few RK-related claims against OMIC insureds, partly because only 15% of policyholders currently perform RK surgery. As more insured ophthalmologists incorporate the procedure into their practice, the potential for claims increases.

By adhering to the risk management guidelines set forth in this article, an ophthalmologist will be in a better position to successfully defend the care provided to an RK patient if a malpractice claim is made. The examples cited are from non-OMIC cases.

### **Informed Consent**

Most patients elect RK to achieve less dependence on corrective eye-wear and contact lenses. Some patients, such as those in law enforcement or fire fighting, may choose RK so they can feel more secure and visually safe in their occupation. Because RK is generally an elective procedure, one of the greatest potential risk management challenges is the informed consent process.

With elective procedures like RK, it is important that the education surrounding the procedure begin with the patient's first visit. Educational videotapes sometimes are used to give patients a general overview of the procedure. Some ophthalmologists follow up with a written test to determine if the patient truly understood the information imparted on the video. This can be an

effective way to measure a patient's understanding of the procedure, but it is not a substitute for a personal dialogue between the surgeon and patient. As with all surgical procedures, the operating ophthalmologist must personally conduct an informed consent discussion with the RK patient. Other health care professionals may be involved in the informed consent process, but this duty may not be delegated exclusively to non-ophthalmologists.

Timing of the ophthalmologist's discussion with the patient is critical. If a videotape is shown, the informed consent discussion will be more meaningful if it follows the video since presumably the patient will know more about RK. When using the consent forms and written tests that accompany some videotapes, the patient should not sign the form until after talking with the ophthalmologist.

One patient successfully sued her ophthalmologist for lack of informed consent, based among other things on the fact that the consent form was signed after watching the videotape but before talking to the physician. The jury believed this was designed to encourage patients to commit to the procedure before learning of the risk from the physician.

Another pitfall in the informed consent process is showing videotapes *after* dilating drops have been administered. Patients can later claim the drops prevented them from clearly seeing the videotape. Ophthalmologists should communicate to ancillary personnel the importance of showing the videotape *prior* to dilation. If dilating drops are started before the patient views the video, the RK candidate should be brought back at a later time to view the video.

Some patients who sue their surgeon later allege they really had no personal incentive for having RK surgery, claiming their decision to have corrective surgery was based solely upon the recommendation of their ophthalmologist. An Arizona ophthalmologist, who was retained as an expert witness in a case where this claim was made, suggests that surgeons have prospective RK patients either complete and sign a prepared checklist of reasons for surgery or write in their own words why they want to have surgery. This type of documentation, signed by the patient, helps refute later claims that the patient had no personal reasons for choosing surgery.

Patients should be offered a signed and dated copy of the written informed consent form. The form must include details concerning the procedure's side effects. Potential risks should be specifically discussed by the ophthalmologist with the patient. The physician must document in the medical records that the informed consent discussion took place. If the ophthalmologist relies only on signed consent forms and does not document the consent discussion, the patient could later allege that he or she signed the forms without really understanding them.

A properly signed, witnessed and dated consent form, especially when accompanied by a handwritten entry in the medical record, can be a powerful ally in the courtroom. When faced with a contemporaneous chart entry documenting the physician's discussion of the risks specific to the patient, few plaintiffs have been able to recover for lack of informed consent by claiming they did not understand or take the time to read the consent form.

One plaintiff, an attorney from a well-known Denver firm, when confronted on cross-examination with the consent form passage “I understand that my vision may be made worse as a result of the surgery,” tried to salvage his claim by saying he did not understand *how* his vision could be made worse. The jury was not impressed with his “loophole” and returned a verdict for the ophthalmologist on this and other allegations in the claim.

## **Effects of Advertising on Informed Consent**

The adverse impact of advertising on the informed consent process cannot be overemphasized. This is especially true when it concerns advertising and marketing of RK surgery. Nobody with vision problems can ignore advertising claims like the following taken from an actual ad for RK: “FREEDOM FROM GLASSES OR CONTACTS... IT TAKES LESS THAN 30 MINUTES AND THERE IS NO PAIN... YOU SEE IMMEDIATELY.” If a lawsuit is ever filed against the ophthalmologist who used this advertisement, the defense attorney will find it difficult to defend the ophthalmologist if the patient did not “see immediately” or had “pain” following surgery.

The largest jury verdict against an ophthalmologist in an RK case was awarded in California and exceeded \$5 million. The plaintiff contended that the ophthalmologist said on television that the procedure was “100% successful,” that the advertising and personal assurances regarding the safety and effectiveness of the surgery were misrepresented, and that the physician failed to obtain informed consent. Although the patient had in fact signed a multi-page informed consent form reviewing the procedure’s risks, the jury determined that the ophthalmologist’s representations on television and his advertising claims of 100% effectiveness outweighed the force and effect of the signed consent form.

Many people look askance at *any* advertising by physicians, and are likely to examine the message with a very critical eye. A jury may be less sympathetic to a physician who advertises, perceiving the physician to be more like a business or salesperson than a caring, qualified health professional. Furthermore, unless the surgery took place before the advertising started, all plaintiffs can and will claim they were influenced by the glowing promises of an ad campaign. Since it is virtually impossible to prove a claimant did not see the ads, most courts will find the advertising to be relevant and admissible at trial. The plaintiff’s attorney will subpoena, and ultimately obtain from the media consultant, all print, radio and television ads that could possibly have been seen or heard. The text will be scrutinized for anything that could be interpreted as an unreasonable promise or guarantee in the eyes of a layman.

Does the copy promise “freedom from contacts or spectacles,” or tell readers or listeners to “throw away your glasses”? Neither the attorney nor the jury will overlook the conflict between this seductive message and the more somber consent form telling the patient that the “results cannot be guaranteed” and “you may need glasses or contacts after surgery.” Before approving any ad

copy, the ophthalmologist should mentally place him or herself on the witness stand with a copy of the text in hand, explaining to a jury why the representations are accurate and consistent with the message the patient received in the examining room. If this mental picture makes the ophthalmologist uncomfortable, the ad should be rejected.

Even if the patient ultimately receives a thorough discussion of the risks, jurors will not look favorably on a professional's use of hucksterism to lure patients. One panel of jurors in Colorado, after awarding a substantial verdict to a plaintiff with a marginal claim, cited misleading advertising by the defendant-ophthalmologist as a decisive factor.

## **Physician Training and Technical Surgical Issues**

If a claim goes to trial, it is important that the surgeon be able to demonstrate that he or she obtained the proper training and necessary skill to perform RK surgery, either through a residency training program or a formal clinical hands-on laboratory course. Following this course, the surgeon should observe or assist an experienced RK surgeon with several cases. OMIC strongly recommends that its insureds also obtain experience on human cadaver eyes and be proctored for their first three to five cases.

In support of the value of proctorship, a study conducted at the University of California, Los Angeles Department of Ophthalmology showed that a beginning surgeon who operates under the supervision of an experienced refractive surgeon can obtain excellent results with radial and astigmatic keratotomy.<sup>1</sup>

Inadequate training is difficult to defend in a courtroom when a poor outcome is the result. While jurors understand that all physicians must have their first RK patient or their first 20 surgeries, they expect the patient to be told if the surgeon is inexperienced. They also expect the surgeon to be particularly conservative and cautious until a greater degree of proficiency is attained. For instance, inexperienced RK surgeons should consider referring out or deferring surgery on higher myopes or difficult astigmatic cases until they have more practice with the procedure and are more knowledgeable in how the patient's vision is likely to respond to their technique.

Jurors respect the skill and knowledge that come with experience in performing RK surgery. In one trial, several jurors commented that they regarded the defendant as being the true expert in the courtroom because he had far more surgical experience with RK than did any of the plaintiff's expert witnesses. In another lawsuit a Colorado jury believed the defendant acted properly in performing a difficult RK surgical plan, largely because of his extensive experience.

Many lawsuits, however, have resulted from surgeons "pushing the envelope" with innovative techniques to enhance the surgical result. While medical knowledge cannot advance without innovation, the physician must exercise caution before proceeding. The patient should be

informed of the innovative nature of such a technique, its scientific basis, its benefits, and any possible drawbacks or criticisms from other practitioners. Other options should be discussed and the patient should be encouraged to seek a second opinion before proceeding with an innovative technique. This discussion should be well documented.

In addition to proper training, the RK surgeon must invest in proper equipment. One legal claim arose from a case in which the patient suffered a substantial overcorrection, leaving her hyperopic. The ophthalmologist defended his operative plan, which seemed likely to result in overcorrection, by pointing out that it came from a widely used computer program for predicting RK outcome. Unfortunately, the program was outdated and its recommendations likely were based on less efficient equipment and techniques that produced less correction. The ophthalmologist apparently had attempted to economize by copying an older program from a colleague, rather than purchasing the updated program that was offered at the RK training session he attended. This false economy turned out to be quite costly for both surgeon and patient.

## **Patient Selection**

Failure to adequately screen surgical candidates can easily result in claims from unhappy patients. Patients have sued in cases with an objectively good result because of unrealistic expectations about what surgery could do for them. Preoperative evaluation of the patient from a clinical and psychological standpoint is essential prior to RK surgery.

Various refractive outcomes (both over- and under-correction) should be demonstrated to the patient during the informed consent process. This allows the patient to better understand the possible levels of correction that may be achieved with surgery and to determine whether this meets expectations. The need to wear spectacles to correct presbyopia must be emphasized to every patient undergoing RK. Patients also must understand that contact lens wear probably will be more difficult and may not be possible following RK to correct a remaining refractive error.

A history of the patient's refractive stability should be obtained. Never rely on patient's assurances that their refractive error has remained "stable." Make every effort to obtain and compare previous eye exam records. Keep in mind that an unstable refraction may indicate undiagnosed diabetes. RK is contraindicated in cases where the refraction has not shown reasonable stability over the 12 months prior to surgery.

Most patients assume they will be part of the majority of patients who are satisfied with RK surgery. One psychological study of patient satisfaction found 70.5% were extremely satisfied, 14.2% were somewhat satisfied, and 15.3% were somewhat or extremely dissatisfied.<sup>2</sup> In another study of RK patients, 48.5% indicated they were very satisfied, 42% indicated "average" satisfaction, and 9.5% indicated dissatisfaction.<sup>3</sup> A third survey of 593 patients found 73% percent were very satisfied, 22% were moderately satisfied, 1% were neutral, 3% were somewhat

dissatisfied, and 1% were very dissatisfied.<sup>4</sup>

However, when discussing the high percentage of satisfied patients, the ophthalmologist must temper the enthusiasm of the overoptimistic patient undergoing the procedure with the fact that some people are not satisfied. If the operation goes badly, the result can be a very unhappy patient. Ophthalmologists who subsequently treat patients suffering from poor uncorrectable vision or other side effects of RK surgery state that reports of the procedure's excellent success rates do not mollify these patients.

Unrealistic expectations can arise not only from overly optimistic advertising or poor informed consent discussions, but sometimes simply may be the result of a depressed or hostile personality. In one case, a patient with a history of clinical depression focused only on the usually minor side effects of RK surgery: starbursts, glare and fluctuations in vision. Despite the good result achieved from surgery (20/30 uncorrected), this patient was convinced his vision was ruined. With something as subjective as "good vision," the patient's perception of the result is as important as any objective test.

Patients with alcohol and substance abuse problems are at greater risk of a poor result, not only from the nutrition and health problems often seen in these situations, but also from poor compliance following surgery. Failure to take meticulous care of surgical incisions can result in far greater corneal scarring, fluctuations in vision and infection. Patients who appear unable to care for themselves are poor candidates for an operation that requires conscientious post-op use of antibiotic and steroid drops, careful hygiene and forbearance from the common habits of eye rubbing. Your office staff is likely to have spent a good deal of time with the patient. Listen to them if they express concerns about the patient's mental stability or personal habits that may lead to postoperative problems.

## **Litigation Issues**

Although RK surgery is considered by some to be controversial, in most lawsuits it is not the procedure itself that is on trial, but the use of unusual technique, improper execution or lack of informed consent. More than likely, if a plaintiff's experts are qualified to comment on RK care, they are probably performing RK surgery themselves and are not ideologically opposed to it.

RK surgery can be successfully defended in court, provided the surgeon approaches the procedure responsibly and with concern for the patient's ultimate well-being. To help ensure that claims against policyholders are defensible, OMIC's guidelines for keratorefractive procedures incorporate the risk management principles discussed in this article. Ophthalmologists who are considering performing RK surgery are encouraged to contact OMIC's underwriting department for further information on RK coverage. Underwriters are available to answer coverage questions from 7 a.m. to 4:30 p.m. (Pacific Time) at 1-800-562-6642, extension 639.

## Notes:

1. Friedburg, et al. Radial and Astigmatic Keratotomy. *Ophthalmology*. 1993;100(5):746-751.
2. Powers MK, et al. *Ophthalmology*. 1984;91:1193-1198.
3. Bourque LB, et al. *Arch Ophthalmology*. 1986;104:356-363.
4. *Chiron IntraOptics* 1992.