# Medicolegal, Insurance and Regulatory Issues in Refractive Surgery

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## Introduction

This chapter will discuss the Medicolegal , professional liability, insurance and regulatory issues in refractive surgery.

An outline of the material covered follows:

I. Claims and Professional liability Insurance (Paul Weber, J.D.)

1. Jury verdicts and indemnity payments
2. Claims handling
3. National practitioner data bank
4. Insurance

II. Clinical Risk management (Richard L. Abbott, M.D.)

1. Physician training
2. Patient selection issues
3. Surgical technique and judgement
4. Informed consent

III. Overview of Negligence (C. Gregory Tiemeier, J.D.)

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1. Co-Management of refractive surgery patients
2. Marketing and advertising
3. Ambulatory refractive surgery centers

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# I. CLAIMS AND PROFESSIONAL LIABILITY INSURANCE

PAUL WEBER, J.D.

Refractive surgery presents a number of professional liability insurance issues that affect ophthalmologists. Although radial keratotomy is a relatively new procedure, the claims against ophthalmologists arising from radial keratotomy have caused a great deal of concern to medical professional liability insurance companies who provide insurance coverage to ophthalmologists. These following sections address some of these concerns.

## 1. REFRACTIVE SURGERY JURY VERDICTS AND INDEMNITY PAYMENTS

The following data is provided to give the reader a general idea of the wide variety of verdicts and settlements that have occurred over the past ten years with respect to refractive surgery. Two sources of data have been relied on. The first source of data is *Medical Malpractice-Verdicts, Settlement and Experts* (Verdict Reporter)[1]. The Verdict Reporter data in Table One is based on jury verdicts (nationwide) reported from January of 1986 through August of 1995. The second source of data is from the *Physicians Insurers Association of America Data Sharing Report* (PIAA)[2]. The PIAA information in Table Two is based on data submitted by over 20 PIAA member companies (representing over 110,000 physicians nationwide) that have submitted data from January 1, 1986 through December 31, 1994. There are over 3,731 claims against ophthalmologists in the PIAA database. At this time, claims arising from treatment of cataracts account for over 30% of the claims.

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[1] Medical Malpractice Verdicts, Settlements and Experts (1986 -1995) - Lewis L. Laska, Editor - Nashville, Tennessee

[2] Physician Insurers Association of America - Data Sharing Reports (1995) - Washington, D.C.

Prior to reviewing the two tables, it is important to understand the differences between the Jury Verdict data (Table One) and the PIAA Data (Table Two). There is no correlation or relation between the two tables. Table One lists only jury verdicts. Table Two lists indemnity payments (what the plaintiff actually was paid, if anything, by an insurance company). These tables are completely independent and the verdicts in Table One do not in any way correspond with the indemnity payments Table Two.

**A. JURY VERDICT DATA**

There are fourteen verdicts listed in Table One regarding medical malpractice trials arising from the performance of refractive surgery. The respective juries in these cases found for the plaintiff eight times and for the defendant six times. These verdicts are important to examine in order to appreciate what juries are capable of doing when deciding a refractive surgery case. A quick review of the verdicts in favor of the plaintiffs reveal that jurors have often been persuaded to award very large sums of money to plaintiffs in cases arising from refractive surgery. Although, the median jury verdict is approximately $300,000, juries have awarded substantially more, even into the millions of dollars in one case.

Keep in mind when reviewing the jury verdicts listed in Table One that the large awards in these cases are not *necessarily* the amount the plaintiff actually received when the case was finally closed. The attorneys and insurance companies for the respective defendants in these cases may appeal (or threaten to appeal) the verdict and the plaintiff may decide to accept a sum in settlement much less than what the jury awarded. The plaintiff may settle for less in

order to avoid the costs of litigating the appeal and the risk of the verdict being overturned by an appellate court. However, just as often the defendant does not appeal an adverse verdict and a payment is made to the plaintiff after the jury renders its decision.

**B. THE PIAA DATA**

The PIAA data (Table Two) gives a list of what was actually paid to the plaintiffs by the insurance company when the claim was closed. Table Two indicates that about 37% of the refractive surgery claims close with an indemnity payment to the plaintiff. This is slightly higher than the 30% average for all claims arising against ophthalmologists. The average indemnity payment was $156,596 which is also higher than the $122,699 for all claims against ophthalmologists. Finally, the average cost of defending these cases was $15,369 which is also slightly higher than the $13,843 average cost of defending an ophthalmology claim.

It is useful to compare and contrast the jury verdicts and the indemnity payments. The majority of lawsuits and claims do not go to trial. There is no exact estimate, but probably fewer than 3% of lawsuits ever go to jury verdict. However, the threat of trial is in the back of everyone's mind who is involved in the lawsuit (attorneys, the plaintiff and defendant, the insurance carrier). As can be seen by some of the large awards in Table One, the defendant and his or her representatives must understand that plaintiffs do often win.

The reality is that each refractive surgery claim or lawsuit must be reviewed by the attorneys,

insurance carriers and the parties (defendant or plaintiff) involved based upon the unique factors that arise in that particular case. How the claim is handled and the unique issues that arise in refractive surgery cases are discussed in detail in the remainder of this chapter.

## 2. CLAIMS HANDLING

Medical malpractice claims and lawsuits are expensive and time consuming and emotionally trying for the ophthalmologist involved. The claims often call into question not only the ophthalmologist's medical skill but his or her integrity as well. An ophthalmologist may find out about a claim or lawsuit in a number of ways. The first way be a request for records from the plaintiff's attorney. In some jurisdictions (e.g. Texas, Florida and California) the ophthalmologist may receive a Notice of Intention to Sue. Frequently, the patient or a relative of the patient will tell the ophthalmologist that he or she intends taking legal action. Quite often, the first notice of a claim by a patient is the service of Summons and Complaint (Petition).

Whenever a claim is suspected, the ophthalmologist should contact his or her malpractice insurance carrier immediately. Of course, any letter alleging wrongdoing from or on behalf of a patient should be forwarded to the carrier immediately. The ophthalmologist should never contact the patient/plaintiff's attorney prior to speaking to a professional in the claims department of the malpractice carrier. In most cases the ophthalmologist will be instructed by the malpractice carrier not to speak directly with the patient/plaintiff's attorney. This is for the ophthalmologist's protection since any conversation with the patient/plaintiff's attorney will

be used to their advantage in their claim or lawsuit against the ophthalmologist.

The malpractice carrier should also advise the ophthalmologist of the following should a claim be made:

1. Limit discussions with subsequent or current treating physicians of the patient to the medical facts surrounding the patient's care and treatment and refrain from discussing any medical-legal issues;

2. Maintain, absolutely, the integrity of patient's medical record. Do not alter, delete, make corrections or additions to the record. Make sure the original record is kept in a safe and secure location.

3. Do not keep correspondence from the insurance carrier or legal correspondence in the patient's medical record. Start a separate legal file which is maintained separately from the medical record.

4. Do not discuss any aspect of this case with anyone other than a representative of the insurance carrier or to the attorney if one has been assigned.

After an initial claims investigation, the malpractice carrier should have the patient's medical records reviewed by another ophthalmologist who is familiar with refractive surgery. This reviewer should attempt to provide an objective review of the strengths and weaknesses of the medical care rendered in the case. The investigation may take a number of weeks since it is sometimes difficult to collect all the relevant records of prior and subsequent treating ophthalmologists and health care providers (e.g. optometrists). Once the investigation is

completed, the malpractice carrier will confer with ophthalmologist and make a preliminary determination on how to proceed.

One of the non-medical issues that will be carefully reviewed in the claims investigation stage is the advertising and marketing material, if any, that the ophthalmologist used prior to seeing and treating the patient. Often the advertising will impact any claim of lack of informed consent made by the plaintiff. It is quite common for the plaintiff to show copies of television shows where the defendant appeared discussing refractive surgery and to enlarge (blowup) any print advertisments that may have made promises or gaurantees to the prospective patient.

Most medical malpractice carriers will vigorously defend cases in which the insured has rendered appropriate care. On the other hand, if it is in the best interest of the insured to settle, the malpractice carrier will attempt a prompt settlement. Many malpractice carriers have a clause in their insurance agreement with the physician that states a claim cannot be settled without the consent of the insured physician. Some states, such as California, give the physician a statutory (legal) right to grant or withhold consent. Other states, such as Florida, grant the insurance carrier to right to settle a claim without the consent of the physician. The malpractice carrier should address this matter if the ophthalmologist has any questions. Obviously, it is prudent for the ophthalmologist to understand this issue prior to becoming insured by any malpractice insurance carrier.

If a lawsuit has been filed and the ophthalmologist has been served with the Complaint

(Petition), the malpractice carrier will immediately assign counsel to the case. Defense counsel assigned should have a particular expertise in defending medical malpractice cases and preferably will have handled other cases against ophthalmologists. Although retained by the malpractice carrier, defense counsel have a "fiduciary duty" (a legal duty) to the insured ophthalmologist, not to the malpractice carrier. Defense counsel are expected to act responsibly and this includes keeping the ophthalmologist involved and/or apprised all aspects of the litigation, significant case developments and expert selection. The appointed attorney conducts all meaningful discovery, confers with the malpractice carrier and the ophthalmologist on defense strategy, and ultimately defends the case for those claims which proceed to litigation.

A question may arise in the course of litigation regarding whether the malpractice insurance covers the ophthalmologist for all the claims alleged in the lawsuit. Sometimes medical malpractice lawsuits also seek punitive damages or damages for fraud. Most medical malpractice insurance policies exclude indemnification (coverage) for damages resulting from allegations of willful, knowing, intentional, fraudulent, criminal or malicious acts or omissions and any obligation for punitive damages. If any of these allegations arise in the lawsuit or claim, the malpractice carrier will send the ophthalmologist what is called a "reservation of rights" letter and suggest that he or she retain their own counsel to review the non-covered claims. These coverage issues arise routinely whenever a punitive damages claim is made. It is very rare that punitive damages are ever awarded in a medical malpractice case and are usually dismissed prior to the trial itself. However, the malpractice carrier must still send the

reservations or rights letter.

### 3. NATIONAL PRACTITIONER DATA BANK

If a case is settled or an adverse verdict rendered against an individual physician, Title IV of the Public Law 99-660 mandates that certain payments be reported by the malpractice insurance carrier to the National Practitioner Data Bank. The Data Bank represents a depository of information relating to the "professional competence and conduct" of physicians, dentists, and other health care practitioners. This information is made available to state licensing boards, hospitals and other health care entities, and professional societies to provide data to those involved in credentialing or regulating physicians.

Another group allowed to request information from the Data Bank are medical malpractice attorneys and plaintiffs involved in a proceeding against a hospital and requesting information about a specific practitioner who is also named in the action or claim. Their access to the Data Bank is restricted, however, and they must first demonstrate that the hospital failed to request the information from the Data Bank as required. Any information they receive from the Data Bank may only be used in litigation resulting from the action or claim against the hospital.

Recently, the Data Bank changed and clarified some of its reporting requirements regarding fee waivers and refunds. Waiving a fee or choosing not to bill a patient should not be reported to the Data Bank. For example, if a patient has a documented history of an allergy

to a medication that is inadvertently prescribed post refractive surgery and the patient has a severe allergic reaction to the medication and is willing to accept a waiver of the fee as "settlement" that waiver is not reportable to the Data Bank. Likewise, if the practitioner waives a fee or chooses not to bill a patient for services relating to repair or treatment of a complication arising from refractive surgery that also is not reportable. However, a fee waiver may not actually "settle" a claim unless the patient signs a binding release of claims. Before drafting such a release, seek the advice of your malpractice carrier because releases can compromise liability insurance coverage. In many cases, an informal (non-binding) fee waiver can help defuse a litigious situation.

A fee refund is somewhat more complicated for reporting purposes. If an individual practitioner makes a refund out of personal funds, it is not reportable to the Data Bank. However, if a corporate entity (including solo incorporated practitioners) makes a refund, that payment is reportable to the Data Bank unless the refund is made solely on behalf of the entity, such as a hospital, clinic or group practice. An ophthalmologist should always consult with his or her attorney or insurance carrier to distinguish whether a refund is being made on behalf of an entity or an individual practitioner.

A refund of a fee paid by any entity (not out of personal funds) is reportable only if the refund arises from a written complaint or claim demanding monetary payment for damages. The written complaint must be based on the ophthalmologist's provision of, or failure to provide, health care services. A written complaint or claim includes the filing of a lawsuit for

medical negligence or simply a letter from a patient or the patient's attorney demanding money for damages related to the practitioner's provision of health care services. However, if the patient orally demands and receives a refund, this does not have to be reported to the Data Bank. As with a fee waiver, a fee refund may not actually "settle" a claim, but it may help defuse a litigious situation.

**4. INSURANCE**

Insurance coverage for refractive surgery is in a constant state of flux and varies among the medical malpractice carriers. Some carriers will simply not provide malpractice insurance to ophthalmologists who perform refractive surgery. Other carriers "rate" ophthalmologists differently who perform refractive surgery and charge them a higher premium. Other carriers put conditions on the coverage provided (e.g. no bilateral simultaneous surgery; patients must be over the age of 21). It is important for the ophthalmologist to find a medical malpractice carrier that is appropriate (the "right fit") for the way that ophthalmologist practices. Prior to deciding to sign up with a particular insurance carrier, carefully examine each malpractice carrier to make sure they provide you the type of coverage, services and support that you need in your particular practice.

Given the complexities of today's health care services market, ophthalmologists need to understand the extent of liability they assume upon entering into any contracts they may enter into with manufacturers of the excimer laser and excimer laser centers. Physician contracts with these third parties may contain "hold harmless", exculpatory, or indemnification clauses.

These clauses may attempt to shift responsibility for economic harm or liability from one party to another. Sometimes such contract provisions are one-sided, where only one party indemnifies the other; in other cases, the contract provides "cross" or mutual indemnification where both parties indemnify each other.

Hold harmless clauses can drastically increase an ophthalmologist's potential professional liability by making it possible for either party to the contract to recover damages against the other in actions which otherwise could not be sustained. Significantly, the liability created by these clauses is not covered by a physician's standard liability policy and coverage can only be purchased at a much higher rate, if at all. An insurer must be able with some degree of certainty to compute the risks it may incur from a particular clause so it can control the cost of defending claims. Since it is often difficult to calculate the inherent risk in such clauses, insurers generally will not insure a physician's hold harmless liability. After carefully reviewing your contracts with excimer laser centers or excimer laser manufacturers, contact your personal (corporate) attorney and/or your professional liability insurer to discuss how this will affect your liability coverage.

## II. CLINICAL RISK MANAGEMENT

RICHARD L. ABBOTT, M.D.

### Introduction

Refractive surgery presents a distinctive risk management challenge to the ophthalmologist because of its elective nature and high patient expectations. As discussed previously, significantly larger financial payments have been awarded to plaintiffs in cases arising from refractive surgery as compared to other ophthalmic surgical procedures. This has occurred because refractive surgery primarily has been viewed by the jury as being cosmetic in nature. Although most cases have been decided on issues related to informed consent, there are other important areas of risk management that must be recognized so that the ophthalmologist will be in a better position to successfully defend the care provided to a patient if a malpractice claim is made. [3] The specific risk management issues that will be discussed include physician training, patient selection, surgical technique and judgment, and informed consent.

### 1. PHYSICIAN TRAINING

If a claim is brought to the courtroom, it is important that the operating surgeon be able to demonstrate that appropriate training and skill were obtained to perform the procedure. This can be accomplished by demonstrating either specific training in a residency or fellowship program, or participation in a formal, clinical, hands-on laboratory course. Surgical

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[3]Tiemeier CG, Abbott RL, and Ellis JH: Risk Management Issues in Radial Keratotomy Surgery. Survey of Ophthalmol: 39:52-56, 1994

training acquired in this manner should be consistent with the procedure performed on the patient. It is critical that techniques and specific surgical instruments recommended in a course be closely followed by the beginning refractive surgeon. Deviations from these recommendations and guidelines can be difficult to defend in cases where patient's had untoward outcomes.

Following formal surgical training in a specific procedure, it is recommended that the ophthalmologist observe or assist a more experienced refractive surgeon with several cases. Practicing on either animal or cadaver eyes prior to patient surgery is also helpful and shows a careful and methodical approach to learning a new surgical procedure. When practical, having an experienced refractive surgeon proctor early cases may help improve surgical results.

Patients requiring a more complicated surgical procedure should be referred to a refractive surgeon with greater experience. It is also recommended that patients be informed regarding the level of experience with a refractive surgical procedure at the time of the informed consent.

## 2. PATIENT SELECTION ISSUES

Careful attention to selection of potential refractive surgery candidates is a key component of risk management.

Failure to adequately screen surgical candidates can easily lead to litigation from unhappy patients. Unrealistic patient expectations regarding surgical outcome is often the primary issue in patient dissatisfaction. Preoperative evaluation of the patient from both a clinical and

psychological standpoint is essential prior to performing refractive surgery. It is strongly recommended that discussion of the patient's knowledge and perceptions of what the surgery can do for them be undertaken by the ophthalmologist. Often inaccurate information and misconceptions regarding the limits of the procedure are uncovered and need to be placed in a more realistic perspective.

Following this discussion, a clinical assessment of the patient's refractive error and its relative stability must be determined. Previous medical records or prior spectacles can assist the ophthalmologist in this determination. Never rely on the patient's assurances that their refractive error has remained "stable". A cycloplegic refraction should be performed to help confirm the most accurate refractive information. Once the refractive error and degree of stability have been established, then a decision can be made whether or not the patient is a reasonable candidate for surgery. The decision to operate must the match the patient's expectations with the reasonable ability of the surgical procedure to achieve these goals.

Various refractive outcomes, including both over and under correction, as well as vision at the 20/40 level, should be demonstrated to the patient in trial frames. This process allows the patient to better understand the possible levels of correction that may be achieved with surgery and to determine whether this meets their expectations. It is not uncommon for patients to comment that 20/40 vision is "not clear" and that they would be unhappy with this level of vision.

Patients often have a perception that undergoing refractive surgery will "cure" all of their vision problems and that their visual outcome will be stable for life. Part of the patient selection process is to avoid operating on patients with these unrealistic expectations. Many

patients considering refractive surgery, who are successful contact lens wearers, must be informed that their ability to wear lenses following surgery, to correct a remaining refractive error, may be impeded. In addition, the necessity to wear spectacles to correct presbyopia also should be emphasized. The goal of deliberate under correction as an early surgical refractive outcome must be discussed with each patient because of the risk of progressive hyperopia with the passage of time. Careful attention to these issues cannot be overemphasized.

If specific ocular or systemic conditions exist that are recognized contra-indications for refractive surgery, the patient should be so informed. In situations where it is either borderline or unclear whether or not surgery should be recommended, a detailed discussion should be undertaken with the patient as well as consideration for consultation with a more experienced refractive surgeon. In these circumstances, patient selection issues are not always "clear cut" and conservatism is certainly the safer choice.

Most patients assume they will be part of the majority of patients who are satisfied with refractive surgery. If, however, there is a complication of surgery or if the patients expectations are not met, the result can be a very unhappy patient. Unrealistic expectations can arise not only from overly optimistic marketing or inadequate informed consent, but also may be the result of a depressed or hostile personality. In addition, patients with alcohol and substance abuse problems are at a greater risk of a poor result, not only from their nutrition and health problems often seen in these situations, but also from poor compliance following surgery. The potential inability to follow postoperative instructions and keep followup appointments may lead to post surgical complications that could be avoided. Often, input

from the office staff regarding these issues can be a vital component of the patient selection process.

## 3. SURGICAL TECHNIQUE AND JUDGMENT

Although risk management guidelines do not attempt to dictate standard of care issues for performing refractive surgery, certain basic principals are recommended.[4] Certainly what is in the best interest for the patient is always a fundamental tenet that could be supported by all surgeons. However, it is the interpretation of this statement that might lead to controversy. The use of new and innovative techniques to enhance surgical results have been employed with presumably good intention, however have often resulted in mixed success. With a less than optimal outcome, the reaction of the patient often is one of upset and anger with the perception that the poor result could have been avoided. Therefore, when employing new and innovative surgical techniques, it is imperative for the surgeon to inform the patient of such a technique, including its scientific bases, its benefits, and any possible drawbacks or potential problems that may be known. Other options should be discussed and the patient encouraged to seek a second opinion before proceeding with the innovative technique.

The issue regarding bilateral simultaneous surgery vs sequential surgery for refractive procedures remains controversial. Once again, the concept of "what is in the best interest for the patient" should always be foremost. A detailed discussion regarding the potential risks, benefits, complications, and alternatives should be carried out with the patient with particular

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[4] Abbott RL: Risk Management Guidelines: A Patient Oriented Process, (Editorial): Ophthalmology World News: 1:9, 1995

emphasis on the bilateral issue. Demonstration of possible visual outcomes as well as the more common side effects is especially important in the informed consent process for bilateral simultaneous surgery.

In planning any refractive surgical procedure, it is imperative that the visual needs and demands of the patient be considered. In many instances, a patient's specific occupation or recreational activity may dictate the ideal refractive outcome. Once again, preoperative demonstration of possible postoperative refractive states will enable the patient and surgeon to reach the best decision. Following surgery and stabilization of the refractive error, if the patient's visual outcome is either under or over corrected, the decision to proceed with additional surgery vs other possible alternatives should be reviewed in detail with the patient. The recommendation for further surgical intervention should be based on the patient's needs and not simply on the remaining refractive error. It is imperative that the surgeon treat the patient and not the refractive error.

## 4. INFORMED CONSENT

Informed consent for refractive surgery is a significant risk management challenge because of the elective nature of the procedure and high patient expectation for an excellent result. Rather than being purely a legal function, consent is acknowledged as a process that begins during the patient-doctor encounter and continues through the operative and postoperative phases of patient care.[5] [6] The process allows an opportunity to establish a

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[5] Bettman JW and Demorest BH: Practice Without Malpractice in Ophthalmology. OMIC, San Francisco, 1995

"therapeutic alliance" between physician and patient. The law and standards of medical consent will be discussed later in this chapter. The role of the surgeon in the informed consent process will be presented with emphasis on practical considerations based on prior review of medical legal cases.

With elective procedures like refractive surgery, it is important that education about the procedure begin with the patient's first visit. Often the patient has prior knowledge of the procedure through advance marketing material or other marketing and information sources in the community. In some cases, the patient's perceptions and understanding of the potential risks, benefits, and complications of the surgical procedure are inaccurate or misunderstood. Part of the informed consent process is to listen to the patient and respond to their questions and statements regarding the procedure.[7]

Educational videotapes sometimes are employed to provide patients with an overview of the procedure. A followup written test may be given to help determine if the patient truly understood the information presented in the video. conduct an informed consent discussion with the patient. Although other health care professionals may be involved in the informed consent process, this duty may not be delegated exclusively to non-ophthalmologists. Documentation in 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 surgeon must personally the medical record in

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[6] Bettman JW: Ophthalmology - The Art, the Law, and a Bit of Science, Aesculapius Pub Co. Birmingham. 1977

[7] Levinson W: Physician-Patient Communication - A Key to Malpractice Prevention (Editorial). Jama: 272:1619-20, 1994.

the surgeon's own handwriting that the risks, benefits, alternatives, and complications were discussed in detail with the patient and that the patient understands and accepts these options, is strongly recommended.

Timing of the surgeon's discussion with the patient and signing of the consent form is extremely important. The patient should receive a copy of the informed consent document well in advance of the surgery, and be encouraged to take it home and read it at their leisure. [8] If the patient has viewed a videotape as part of the educational process, the informed consent discussion will be more meaningful if it follows the video, since presumably the patient will have a better understanding of the procedure. Similarly, all consent forms should not be signed until after completing the discussion with the operating surgeon. Finally, reading and signing of the consent form should be done prior to the patient having received dilating drops since they can claim the drops prevented them from clearly reading the document.

As discussed earlier, if new or innovative techniques are to be used, it is imperative that this be discussed in detail with the patient and is well documented in the medical record. The addition of handwritten notes on the chart by the surgeon documenting that certain discussions and explanations took place serves to enhance a properly signed, witnessed, and dated consent form.

The issues of marketing and advertising will be discussed later in this chapter. However, the potential adverse impact of advertising on the informed consent process cannot

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[8] Duffey WS and Kennedy MP: Refractive Keratotomy, the Law of Informed Consent, and Medical Malpractice:IN
Waring, GO (Ed): Chapter 11. p.300-306. 1313 Mosby Pub Co., St. Louis, 1992.

be overemphasized. Most courts will find a surgeon's advertising to be relevant and admissible at trial. Representations on television or in advertisements by the ophthalmologist can often outweigh the effects of the signed consent. Advertisements will be viewed as anything that could be interpreted as an unreasonable promise or guarantee in the eyes of the layman. A jury may be less sympathetic to a physician who advertises, perceiving the physician to be more like a businessman or salesperson than a caring, qualified, health professional. Before approving ad copy, the surgeon should mentally place him or herself on the witness stand with a copy of the text in hand and be able to comfortably explain the content of the ad to the jury. Aggressive or misleading advertising will have a negative impact on the defense of any refractive surgery litigation and should be avoided.

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## III. OVERVIEW OF NEGLIGENCE

C. GREGORY TIEMEIER, J.D.

### 1. FOUR ELEMENTS OF NEGLIGENCE

When an ophthalmologist is sued for medical malpractice, the cause of action is usually *negligence.* Negligence is a tort, a private or civil wrong resulting from breach of a legal duty that exists because of society's expectations about interpersonal conduct, as opposed to a contract or private relationship. The plaintiff has the burden of proving four elements to prevail on a claim of negligence:

I. The existence of a legal duty to use due care owed by a defendant ophthalmologist to a patient;

II. Breach of that duty;

III. Causation;

IV. Damage or injury to the patient.

If the finder of fact (usually a jury) finds that any one of these elements is not established by the plaintiff, a cause of action for negligence fails.

#### I. Legal Duty

In medical negligence cases, the legal duty of due care is established by the physician-patient relationship. The ophthalmologist usually establishes this relationship by providing professional services to the patient. It is possible for a physician-patient relationship to be established without the patient being seen by the ophthalmologist, as when an ophthalmologist

gives advice or prescribes medication over the telephone.

A physician may be sued for malpractice even when direct patient care is not involved. For example, an ophthalmologist who shares call with other ophthalmologists may be sued for negligence in selection of the covering ophthalmologist if the covering ophthalmologist should commit malpractice. A physician may also be vicariously liable for acts of their employees or agents, regardless of the care taken in hiring or selection, if the wrongdoer was acting within the scope of their employment or agency.

**II. Breach of Duty**

Once the existence of a legal duty is determined by the court or the jury, the plaintiff must then prove a breach of that legal duty of due care, known as *the standard of care.* The standard of care in a medical negligence action requires that a physician exercise that degree of knowledge, and care ordinarily possessed and exercised by other members of the profession acting under similar conditions and circumstances. The breach may be a failure of or delay in diagnosis, improper treatment, failure to obtain informed consent, or substandard surgery. In performing professional services for treatment of the eye, an ophthalmologist will be held to the higher standard of care of a "medical specialist." And, the "medical specialist" standard may be even further extended to subspecialties within ophthalmology. The "locality" requirement - comparing the care of the defendant to that of other physicians in the same locale - has largely been ignored, particularly when the defendant is a member of a specialty that is subject to national board certification.

To prove breach of the standard of care in a medical negligence action, generally there must be expert testimony from a physician who is familiar through education, training or

experience with the medical specialty as the defendant. The testimony is necessary to establish the standard of care and whether that standard has been met. A general practitioner or other specialist who performs the same procedure as an ophthalmologist could be competent to testify as an expert with respect to that particular procedure (e.g., given a fluorescein stain to determine whether there are defects or abrasions on the cornea). In trial, however, each side will want the best qualified expert in a particular specialty. The jury will be instructed to evaluate the knowledge, skill, experience, training and education of each expert witness when considering the testimony. Jurors will follow this instruction not only because it is the law, but also as a matter of common sense. One particular "expert" who testified in several radial keratotomy malpractice suits had never actually performed the procedure. He was permitted by the judge to testify based on knowledge of RK through education and training, but in post-trial interviews the jurors consistently said they ignored his testimony because of his lack of experience.

**III. Causation**

The third element to be satisfied for medical negligence is *causation.* Causation is sometimes further broken down into *actual cause* and *proximate cause.* A question of actual cause may arise with the occurrence of a corneal infection following radial keratotomy surgery. If the infection occurred two days after surgery, the plaintiff would allege lack of proper precautions for ensuring a sterile operating theater as the actual cause. If the infection arose two weeks after the surgery, the sterilization procedures would not likely be questioned because they probably could not have actually caused an infection that late. The plaintiff may, however, allege other possible breaches of duty as the actual cause of infection, such as

improper medication or failure to instruct on proper post-operative eye care.

Likewise, an injury can be so remote from the breach that the ophthalmologist could not have "foreseen" it. The concept of proximate cause defies precise definition and has given courts and commentators much difficulty. An eminent legal scholar, Dean William Prosser, wrote:

> *"As a practical matter, legal responsibility must be limited to those causes which are so closely connected with the result and of such significance that the law is justified in imposing liability."*[9]

For example, a young woman who suffered from lupus erythematosus received RK surgery in her right eye and epikeratophakia in her left eye, for extreme myopia. (The parties to the lawsuit disputed whether the history of lupus was disclosed; it did not appear on the patient's intake history sheet.) Although her vision was objectively much better after the surgeries than before, the patient alleged that her disappointment with the surgical result caused her extreme depression and stress. She suffered from exacerbation of her lupus which led to strokes, and the strokes caused severe cognitive and functional impairment. Her psychiatrist/expert witness testified that it was the stress and depression from the subjectively "poor" surgical result that caused the exacerbation of lupus, and the exacerbation in turn led to the strokes, and the strokes in turn led to the cognitive and functional impairment. Thus, the plaintiff claimed that the brain injury was *proximately caused* by the refractive surgery.

Even if the plaintiff provides adequate proof of actual and proximate causation, the defendant may defeat the claim, in whole or in part, through proof of an intervening cause. In the example above of the lupus sufferer, the defense experts attacked the proposition that it

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9. Prosser, Keeton: Law of Torts (Fifth Edition). 1984; 7(41); 264

was the stress from a less-than-satisfactory visual result that caused the exacerbation of lupus. They argued that the plaintiff's divorce, death of a close relative, physical abuse from her husband and loss of her job were more likely causes of the stress.

An expert's testimony is generally necessary to establish the causal link between the injury complained of and the practitioner's actions, particularly where the connection is as circuitous as in the example of the lupus sufferer above. There are exceptions to the requirement of expert testimony where causation may sometimes be inferred based on the common knowledge of the jury, as in the case of a surgical instrument which is inadvertently left in after surgery.

Another exception is the requirement of expert testimony to prove breach of the standard care and causation is the doctrine of *res ipsa loquitur*, Latin for *the thing speaks for itself*. This is a rule of evidence whereby a presumption of negligence of the alleged wrongdoer may be inferred from the mere fact that the injury occurred, provided thee conditions are met:

> It is the kind of thing that does not ordinarily happen without negligence;
>
> It must have been caused by an agency or instrumentality within the exclusive control of the defendant-ophthalmologist;
>
> It was not due to contribution or voluntary action by the plaintiff.

For example, the doctrine of res ipsa loquitur would apply to a situation in which a patient wakes up in the post-anesthesia recovery room following cataract surgery with a broken ankle. In such a scenario, all three elements of res ipsa loquitur theoretically would be met.

## IV. Damages

The fourth element the plaintiff must prove is *damages* - they were injured in some way by the breach of the standard of care. Compensatory damages - those which compensate the plaintiff for their injuries - are subdivided into economic and non-economic damages. Economic damages might include lost wages and medical expenses (past and future). Non-economic damages are subjective and include pain, physical impairment, mental suffering and inconvenience (past and future). In some jurisdictions, damages are limited by law in medical negligence cases.

Refractive surgery cases present their own special problems in proving or disproving damages. Although refractions may be obtained objectively, the quality of fine vision is entirely subjective, and only the plaintiff knows what their vision is really like. They can manipulate vision testing by stating that they cannot read or see something, whether they can or not. It is important for the defense to present objective evidence of what the plaintiff can actually do, so the jury can then infer the quality of vision the plaintiff enjoys. Driving records are a fertile field for objective evidence. In one RK trial, the jury was convinced that the plaintiff had suffered no injury whatsoever - despite the fact of an objectively proven and significant hyperopia - because he passed his drivers' license vision test with no correction. Speeding tickets in driving records can refute a claim of cautious driving due to poor vision. Surveillance videos are very helpful in demonstrating that an allegedly impaired plaintiff has no apparent impairment. A personal favorite is the plaintiff who was videotaped making a three-point shot to win a league basketball game - but was claiming an inability to work due to poor vision. The jury enjoyed the video and, not surprisingly, did not believe the

plaintiff's claim.

**AFFIRMATIVE DEFENSES**

Even though a plaintiff may prove all four elements of negligence, a defendant-physician can raise defenses which may bar or diminish the plaintiff's claims. One defense is the failure of the plaintiff to commence the action within the time limits set by statute in the jurisdiction where the case is being brought. This is referred to as the *statute of limitations defense.* Time limits for statutes of limitation or repose vary from state to state, as do the criteria which must be met to start the time period running.

Another defense is that of *contributory negligence or comparative negligence* by the plaintiff. Contributory or comparative negligence is conduct by the plaintiff that falls below the standard expected of a person for self-protection. A patient who refuses to return to the physician for post-operative examinations, or who does not take medications properly may be guilty of contributory negligence, if that conduct caused or contributed to their injuries.

**2. CLAIMS OTHER THAN NEGLIGENCE**

While negligence is by far the most common medical malpractice cause of action, other causes of action that may be asserted include battery (from no informed consent), abandonment, breach of contract, unfair trade practices, and misrepresentation (fraud). In some states, damage limitations may be available for one type of action, but not another, encouraging creativity in drafting complaints. Changes in the way medical procedures are performed and advertised have brought corresponding changes in the way actions are prosecuted. A few of these alternative claims which may have particular application to a refractive practice are discussed here.

## MISREPRESENTATION

Negligent misrepresentation occurs when someone negligently (as opposed to intentionally or recklessly) gives false information to anther person, and that other person suffers injury as a result of taking action in reliance on the false information. Such a claim can arise outside the context of a physician's duty to provide informed consent. For example, a well-trained physician may not have a duty under the doctrine of informed consent to tell a patient of their experience with a particular operation. But if a physician tells a patient that they have performed an operation before, when in fact they have not, this statement can give rise to a claim for negligent misrepresentation if the patient suffers injury from the operation.

Negligent misrepresentation and fraud are separate but related claims. A claim for fraud would arise if the physician knowingly gave a patient false information, with the intent that the patient would rely on the false information. Proof of such a claim is more difficult, because the plaintiff must show a subjective intent on the part of the defendant to deceive the plaintiff. But if fraud is proven, the defendant may be liable not only for compensatory damages but also punitive damages.

In the refractive surgery context a claim for negligent or intentional misrepresentation might arise in connection with advertising, brochures or pamphlets. In one case, the brochure in question listed a 100% success rate for RK in achieving at least 20/40 vision. Although the particular study on which this representation must have been based did in fact report such a result, the plaintiff alleged that, in light of all information known about RK, such a statement was false and misleading, and caused the plaintiff to undergo the procedure which led to her injury. In another case, a plaintiff was awarded a multi-million dollar verdict based

on a fraud claim which arose from representations of safety and efficacy in television advertisements for RK surgery.

Keep in mind that these are not medical negligence claims, and the plaintiff need not prove that the procedure which caused the injury was negligently performed. If a patient was negligently or intentionally misled into having an operation that they otherwise would not have had, and they suffer injury as a consequence of the operation, the physician will be liable for the injuries even if their surgical care was above reproach.

**BREACH OF WARRANTY**

Plaintiffs sometimes make a claim for breach of warranty. The gist of the claim is that the physician guaranteed a particular result, and the result was not achieved. Such a claim is distinct from a negligence claim because it arises from a contract, not a duty imposed by a physician/patient relationship. Ordinarily, a physician will be deemed to have warranted only that they have and will employ the degree of learning and skill had by physicians in similar circumstances, and will use their best judgment in utilizing this skill in the treatment of the patient. If the plaintiff alleges a guarantee or warranty above and beyond the duty to exercise due care, the court will require proof of special consideration (usually money) above and beyond the payment of normal medical or surgical fees.

**BATTERY**

A claim for battery will arise if a physician performs a procedure on a patient without the patient's consent. It differs from a claim of lack of informed consent in that there is a complete absence of consent, as opposed to a failure to warn of a particular side effect or risk. A claim for battery could arise if the physician performed surgery on the wrong eye, or

made an intraoperative decision to change the surgical plan (e.g. adding an astigmatic incision) without discussing it first with the patient. Battery can usually be proven without expert witness testimony, unless causation is disputed.

Unfair Trade Practices, Consumer Protection Acts

Most states will have their own version of uniform statutes which are designed to protect either competitors or consumers from unfair practices. Standing to sue for a violation will depend on the language of the statute. For example, in Colorado a private individual can sue for a violation of the Consumer Protection Act because the language of the state statute permits private actions. In other states, private individuals may or may not have the same right to sue, depending on the language of the statute.

Claims based upon these types of statutes can be attractive to plaintiffs. A plaintiff may prevail on a claim and obtain injunctive relief (preventing the wrongdoer from engaging in the same conduct in the future), without having to prove actual losses. If a plaintiff proves money damages, the statute may require that the defendant pay three times the amount of damages.

Consumer protection statutes are intended to punish misleading advertising or other deceptive conduct which injures the public at large. A misrepresentation to a single person may give rise to an action for negligent misrepresentation, but will not constitute a violation of the consumer protection statute unless the misrepresentation was also directed to consumers generally. Conversely, a deceptive advertising campaign which is directed to the public generally may be subject to not only a private action for negligent misrepresentation to single plaintiff, but that same plaintiff might also be able to maintain an action under a consumer

protection statute and recover treble damages for misleading consumers generally. While this remedy has not been widely employed, even in cases involving advertising of refractive surgery services, it certainly is something the practitioner should keep in mind if they are engaged in advertising in a large market. What may be a clever choice of word to the advertising executive may be a deceptive or misleading ad to the unsophisticated consumer.

Unfair trade practices statutes are designed primarily to prevent monopolies and unfair competition, as opposed to deceptive statements to consumers. They may also permit a private individual to sue for violation of the statute, and may also provide for punitive damages. They will usually address such practices as selling goods or services at below cost, or variable pricing in different markets unrelated to the actual costs of the different markets, if the purpose of such activities is to drive out competitors.

Since these statutes may vary from state to state, or may not even exist in some states, it is important to consult legal counsel for the specific applicability of these laws in any given state.

**PRODUCT LIABILITY**

Strict liability in tort for damages resulting from sale of a defective product which is unreasonably dangerous to the consumer is commonly known as a "product liability" action. It applies to manufacturers of products and people who are in the business of selling the product. If the sale of the product is incidental to the business of the defendant, then liability will not exist. The definition of "incidental", however, varies from state to state, and may surprise the physician who does not think of themself as a "seller" of goods.

The significance of a product liability action to the physician will usually be other

than as a seller of a product. The impact will be felt when a patient is injured by a defective product - an IOL - and then sues the manufacturer of the product. The manufacturer, looking to deflect liability from itself, will look to the physician's conduct for an explanation of the product failure - they did not properly insert the IOL or it was damaged by improper handling prior to insertion.

The likely approval by the FDA of the excimer laser and its subsequent use will bring this issue to many refractive surgeons. In two federal circuit courts (there are eleven circuits in the United States) ruled that product liability lawsuits against medical device manufacturers are precluded if the devices had Class III pre-market approval.[10] The effect of these rulings is that injured plaintiffs in some states may not be able to look to manufacturers of medical devices for compensation, even if the injuries were caused by a defective product. The plaintiff will then look to the physician or hospital using the device in the course of treatment. Whether the plaintiff can recover from the physician or hospital will depend on the state where the claim is brought and the particular facts of the case. In a New Jersey decision[11] a patient was injured by a surgical needle. Not knowing the manufacturer, the plaintiff sued the dentist who was using the needle. The court denied recovery under the strict product liability doctrine because the product was only incidental to the professional services provided. In the case of an excimer laser, however, the outcome may well be different, if the device comprises a more substantial part of the professional services.

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10. Stamps v. Collagen Corp. (1993, 5th Circuit) and Slater v. Optical Radiation Corp. (1992, 7th Circuit).

11. Magrine v. Spector, 250 A.2d 129 (N.J. 1969)

Because state statutes which define terms and classify certain products vary (e.g. blood is commonly defined as a service, not a product, to protect hospitals from liability for tainted transfusions), and state court interpretations of the product liability laws vary, it is important to research the law of your state to find out what is viewed as a product or service, and who is a seller, manufacturer or consumer.

Refractive Surgery Case Studies

The following cases illustrate risk management principles in refractive surgery. The cases are from litigation in which the author was involved as counsel for the defendant physician.

INFORMED CONSENT

Informed consent is a process by which a patient learns of a procedure's risks, benefits and alternatives, so they can make an informed decision to have the procedure or not. The surgeon is ultimately personally responsible for ensuring the patient makes an informed decision, whether they undertake the education process themself or delegate it in part to assistants. In refractive surgery cases, the issues of informed consent seemed to center on problems with the mechanics of the education process, the time spent on the process, and failure to warn not only of risks, but the consequences of those risks.

**3. REFRACTIVE SURGERY CASE STUDIES**

**CASE #1** A 27 year old woman working as a computer systems operator wanted RK surgery to improve unaided vision. The informed consent procedure included a popular RK consent videotape and consent form package. The patient was instructed by the videotape to see the surgeon if they had any questions, but if they did not, to sign the consent form,

which she did, before seeing the surgeon. Above the signature line was an attestation to the effect that the patient understood the risks of the surgery and wished to proceed with the operation. Although the patient then met with the surgeon and admitted at trial that all of her questions and concerns were addressed by the surgeon, the jury nonetheless found in favor of the plaintiff on the issue of informed consent. Critical to the decision, according to post-trial interviews with jurors (permitted by the court), was the timing of the consent process. The patient had effectively "consented" to the procedure by her signature on the consent form, without ever having spoken to the physician. This case points up the importance of the timing of the consent process, and the physician's involvement in the consent process, regardless of delegation of some duties.

**CASE #2** A 41 year old man working as an undercover narcotics police officer sought to improve his unaided vision with RK surgery. He was highly myopic (-10.00 D) and extremely intolerant to contact lenses. Because of his high myopia, and likelihood of working at night or in low-light situations, the risks of glare, starburst and fluctuating vision were carefully explained and documented. After 16-incision RK in the left eye, the patient indeed suffered those complications, but they improved over the following year. The patient wanted RK for the right eye and again was warned of the problems with glare, starburst and fluctuating vision. The problems occurred again, but because the surgeon had moved to another state, and the patient was seen by other physicians who questioned the 16-incision technic, the patient becarne concerned. When one subsequent treating ophthalmologist performed PKP on the right eye only three months after surgery (and without ever refracting the eye for best corrected VA!) the patient's vision OD regressed and the now-dissatisfied

patient sued the RK surgeon.

The case was successfully defended on both the surgical negligence and informed consent claims. The handwritten notes documenting the discussion of this patient's likely problems with 16-incision RK were instrumental in convincing the jury that the patient had indeed received an informed consent. A pre-printed warning generally of the risk of glare would have been less effective, give the patient's special occupational concerns. Although general warnings in a printed consent form are helpful in defending against general claims of lack of informed consent, if a patient has special problems or needs make a handwritten entry documenting the discussion of those special problems or needs.

**CASE #2** Another issue which arose in the policeman's RK case was advertising. The RK surgeon had used several television advertisements to publicize the availability of RK in the community. Much was made by the plaintiff and his attorney of the impact of the advertising on the patient's understanding of risks, and decision to proceed with surgery. When advertising is introduced in an RK lawsuit, the complexion of the case can change. The physician may be seen less as a professional and more as promoter of a product. While in this case the jury was not negatively affected by the advertising, in at least two other RK trials (in which the author was not involved) they were affected. One case resulted in a low six-figure verdict, in which the jurors identified advertising as critical to their decision. They seemed to view television advertising as a warranty f safety and effectiveness. The other resulted in a multi-million dollar verdict, in substantial part due to what were thought by the jurors to be misleading promises as to the safety and efficacy of RK. In virtually every case where advertising was seen by the plaintiff, the issue was raised at trial by the plaintiff and

admitted for the jury's consideration.

**UNUSUAL TECHNICS**

Most of the lawsuits in which the author participated involved something other than a straightforward 8-incision RK. Several involved more than 16 incisions, multiple surgeries, or use of technics that were not well-established. While some of these claims were successfully defended, others were settled and in any event all resulted in a great deal of anxiety and expense to the defendant and his insurer.

**CASE #3** A 31 year old female flight attendant underwent RK in 1984 to improve her myopia and astigmatism. The surgery OS employed 16 radial incisions and four crossing T-cuts for astigmatism. Surgery OD employed 8 radials and one T-cut. A reoperation OD employed Ruiz-style (touching) transverse incisions for residual astigmatism. The patient suffered from wound dehiscence, particularly of the Ruiz incisions. At the time of surgery it was debated whether the crossing and touching incisions were troublesome, and the plaintiff claimed she had not been informed of the "experimental" nature of these procedures. The case was settled because of the significant complications and the foreseeable problems at trial supporting the surgical technics used. (This was the first and last case in which the surgeon used the touching Ruiz incisions.)

**CASE #4** A 27 year old railroad brakeman wanted RK surgery in early 1985 to improve unaided vision and hopefully eliminate the need for corrective lenses. (He had problems with contact lens maintenance and disliked glasses). Because of his high myopia (-8.50 D) 20 radial incisions were employed in the first procedure. This left the patient with -3.00 D, and the patient desired more correction. The second procedure employed an

additional 12 incisions, which remarkably left the patient with a +1.50 overcorrection. Over the next five years, the patient suffered from progressive hyperopia, his final refraction before trial being +5.25 +.50 X100. Allegations of negligence included too many incisions (32), too small an optic zone (2.8 mm in the second procedure) and inadequate informed consent give the unusual surgery utilized. Although the case was successfully defended, the aggressive surgical approach and lack of documentation of any special informed consent (reflecting increased or different risks from the extensive surgery) made the defense more difficult. The plaintiff's claim of a guaranteed perfect 20/20 vision" from surgery and overreaching in claimed damages harmed his case and helped the defense.

**PATIENT SELECTION**

In defending over a dozen RK lawsuits certain trends became apparent with respect to patient selection. Although the patients with a clearly bad result or an infection were understandably upset, there were many lawsuits brought by patients with an objectively good result, but subjective dissatisfaction. Many of these patients had histories of depression, alcohol abuse or tumultuous lives, and appeared to be looking to lay blame for their problems at the feet of the surgeon.

When screening patients for RK surgery, do not overlook the subjective reasons the patient is having surgery. Some may be expecting a life-changing event, rather than a change in their refraction. Others may be using vision problems as a scapegoat for their troubled lives, and expect the refractive surgery to eliminate not only the myopia, but their other problems as well. Explain to the hopeful candidate the limitations of the surgery, otherwise they will be disappointed, even if the result is objectively a success. Listen to your technical

staff if they raise questions about a particular patient. Many times the defendant surgeon recalled that his staff had warned him about a candidate who became a difficult patient and later a plaintiff.

**CASE #5** A young man working in construction sought RK surgery in 1987 due to problems with contact lenses. He was moderately myopic and astigmatic, and had trouble with both hard and soft contact lenses. He received 8 incision RK in both eyes, with non-touching transverse incisions for astigmatic correction. post-operatively, his refraction was plano -0.75 X25 OD and +1.25 sphere OS. Uncorrected VA was 20/20- OD and 20/30- OS, with a complaint of ghost images OS. The patient also complained of floaters, and believed they were caused by the surgery. The patient wore no correction until mid-afternoon, then wore contact lenses to drive home from work. Despite the result, a subsequent treating physician (who later appeared as an expert witness for the plaintiff) recommended PKP in the left eye to eliminate the ghosting problem. The patient claimed depression as a result of the surgery, and his therapist's deposition was taken by the attorneys. As it turned out the patient had been depressed for a long time before the surgery, had several stressors in his life, and appeared to be focusing on the vision problems disproportionately as the cause of his depression. It appeared that the patient, for purposes of secondary gain or otherwise, had become so involved with his rather minor vision problems that he was unable to get on with his life, and enjoy what was a good surgical result.