

# Medicolegal Aspects of Multifocal IOLs

How the informed consent process works and what cataract surgeons need to know.

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A number of new refractive IOLs have hit the US ophthalmic market recently, and some of them have technological features described as accommodating, apodized diffractive, or presbyopia correcting. All of these lenses correct for all ranges of vision—near, intermediate, and distance. The new IOL options for correcting both near and distance vision via cataract or refractive lens exchange surgery raise legal issues, according to Richard L. Abbott, MD. Dr. Abbott is the Thomas W. Boyden Health Sciences Clinical Professor of Ophthalmology at the Beckman Vision Center, University of California, San Francisco, and a member of the Executive Committee and Board of Directors as well as Chairman of the Underwriting Committee at the Ophthalmic Mutual Insurance Company (OMIC) in San Francisco.

With the advent of these new lenses, the distinction between refractive and cataract surgeons is blurred. Everyone needing cataract surgery is a potential refractive patient. Furthermore, cataract surgeons are ethically obligated to inform cataract patients about the pros and cons of the new lenses, what patients can and cannot expect from them in terms of postoperative vision, and other options that are available. Patients must be informed that they will not have clear uncorrected vision at all distances with these lenses. These requirements translate into more one-on-one patient counseling and potentially fewer patients seen on a daily basis, which may affect your revenue stream.

“I think the mindset of today’s cataract surgeons has to be one of ‘I am now a refractive surgeon,’” Dr. Abbott said in an interview with *Cataract & Refractive Surgery Today*. “If cataract surgeons are going to follow the basic principles of informed consent for patients seeking elective refractive surgery, the process requires more attention and time than that of conventional cataract surgery.” Dr. Abbott explained that

more questions need to be asked of and by the patient; the whole process does not simply consist of signing a consent form. Adequate information has to be provided to the patient (ideally, well in advance of surgery), and they must be able to ask questions of the surgeon face to face.

“The whole process of informed consent for refractive lens exchange surgery should be similar to that of a refractive surgeon performing LASIK,” Dr. Abbott commented. “I think what a lot of ophthalmologists do not realize is, if they are performing a refractive lens exchange in a young patient, or if offering an older cataractous patient a multifocal or accommodating IOL, the patient’s expectations are high for both excellent near and distant vision.” In addition, multifocal IOLs are not typically covered by health insurance if there is no cataract present, so patients are paying out of pocket for the benefits of the lenses and have come to expect near perfection in the surgical outcome.

Dr. Abbott offers several recommendations for risk management that are intended to promote the patient’s safety and reduce your liability exposure when performing cataract or refractive lens exchange surgery.

## PREOPERATIVE COUNSELING OF PATIENTS An IOL’s Approved Purpose

It is important to discuss with patients what it means for an IOL to be FDA approved and how it is intended to be used. If the lens was recently approved, you need to inform patients about the lack of long-term outcomes and experience with the lens and advise them that unanticipated problems may occur. For refractive lens exchange procedures, advise patients that the procedure is considered to be off label and offer patients a full explanation of what off label means. This discussion should be documented in the patient’s medical record.

### Alternatives

Dr. Abbott believes the informed consent should include a detailed description of alternatives to refractive lens exchange. A dialogue with patients about presbyopia and the options for near and/or distance vision correction should occur. Patients should not feel under any pressure to choose one option over another. Furthermore, patients appreciate additional explanation regarding the rationale for your recommendation.

Options patients should be made aware of include monofocal IOLs, reading glasses, monovision, and multifocal IOLs, according to Dr. Abbott.

Disclose and document the option of monovision and demonstrate what a patient's postoperative vision may be like using a contact lens or glasses. If the patient refuses a short-term trial of monovision, document this in his medical record. If the patient agrees to pursue monovision, explain the possible difficulties with depth perception. This is the value of having the patient wear a contact lens in one eye for a short period of time to simulate the monovision condition. Although popular with many patients, there are others who simply cannot tolerate monovision.

With multifocal IOLs, you should explain that the goal is to reduce the patient's dependency on glasses or contact lenses for both distance and near vision, but be sure to note that there is no guarantee that this goal can be fully achieved. The objective of a multifocal IOL is to restore some or all of the near (and intermediate, depending upon the IOL) focusing ability, but other factors may affect postoperative outcomes (eg, the IOL's power and position, wound healing, function of the ciliary muscle).

### Describe Risks

Side effects associated with multifocals may include less sharp vision, worse vision in dim light, halos around lights, decreased contrast sensitivity, and difficulty driving at night. Patients need to be informed of these possibilities. Furthermore, you need to explain that, if an intraoperative complication occurs, a monofocal IOL may have to be implanted instead of the scheduled multifocal lens.

Patients also need to know whether LASIK and/or PRK is available in your office if additional correction is required following refractive lens exchange. If your surgery center does not offer these procedures, Dr. Abbott advises that you be ready to provide the patient with a list of refractive surgeons in the area. Also, tell patients whether refractive surgery, spectacles, or other forms of correction, if required, are included in the global fee for the cataract surgery with a multifocal IOL.

Another clinical issue to discuss is the risks of retinal detachment in high myopes.

"There is a high risk for retinal detachment, especially in a younger patient with high myopia undergoing a refractive lens exchange," Dr. Abbott said. "The peripheral retina needs to be examined very carefully, and, if the surgeon is not comfortable in doing scleral depression of the peripheral retina, these patients should be referred to a retinal specialist preoperatively."

### Make No Guarantees

During the informed consent process, verbally communicate to patients that they may not achieve a specific postoperative visual acuity with refractive lens exchange. The selection of a proper implant for a specific patient is based upon sophisticated equipment and computer formulae, but it is not an exact science. Let patients know that, if a postoperative refractive result is considerably different, eyeglasses, refractive surgery, or repositioning or replacement of the IOL may be required. The costs related to these procedures should also be clearly explained both verbally and in writing so that there is no misunderstanding if they are required.

### Decision Making During Surgery

Sometimes during surgery, the refractive lens chosen for insertion cannot be placed due to intraoperative issues. This risk needs to be discussed prior to surgery, especially with those patients at risk for such complications (eg, infection in a diabetic). Document in the patient's medical record that this topic was addressed during counseling.

### Pay Attention to Your Staff

Oftentimes, the staff will screen or spend more time with a patient. "I always put a lot of stock into what my staff tells me," Dr. Abbott said. "If the staff reports that the patient in room six is acting inappropriately, I pay attention to that." A patient's true colors often are displayed in front of the staff but are not obvious to the physician when they meet. If anything should go wrong in surgery, these personality traits come to the surface and you are left dealing with a very difficult and sometimes unreasonable patient. "I recommend paying close attention to your staff and their insights and avoiding operating on these patients if at all possible," Dr. Abbott said.

### Identify Inappropriate Patients for Multifocals

Communicate to patients that, although surgery may eliminate a cataract and/or refractive error and presbyopia, it will not correct any potentially sight-threatening

condition of the eye (ie, peripheral retinal degeneration) that may be found in a high myope. Furthermore, the surgery cannot be guaranteed to make a patient happy, more popular, or improve his life if he is inherently unhappy. It is true that satisfaction with a successful postoperative outcome can result in short-term happiness, but it will often not cure longstanding issues of depression or dissatisfaction with one's life situation.

Dr. Abbott recommends using a questionnaire to identify inappropriate patients. Talk to patients about their responses and ask them what they expect to obtain while assessing their emotional stability and reasonableness. Some patients to look out for are those on antidepressant medications. Others are engineers, pilots, doctors, and lawyers because of their high and often unrealistic expectations. Additional poor candidates for multifocal IOLs are those who drive long distances at night and/or perform detailed work that requires closer focus than just reading. According to Dr. Abbott, a monofocal IOL with reading glasses may be a better option for these patients.

## FINANCIAL IMPLICATIONS

### Patients

With refractive lens exchange, the beneficiary is responsible for the charge that exceeds that of a conventional IOL. You may want to give patients a Notice of Exclusion from Medicare Benefits.<sup>1</sup> Let your patients know that the Centers for Medicare & Medicaid Services will pay for one pair of glasses or contact lenses if needed after the implantation of a presbyopia-correcting IOL. If the lens needs to be removed due to medical complications, the Centers for Medicare & Medicaid Services will cover the insertion of a conventional IOL as a replacement. Also, make it known that private insurance may or may not pay for a multifocal IOL. Insurance generally does not cover the costs of a refractive lens exchange procedure.

### Surgeons

The AAO Code of Ethics advises surgeons against providing inducements that could encourage the use of services. An example would be offering incentives such as free rides to and from the surgery center.

Implanting refractive IOLs as an elective procedure for patients will demand more of your time due to the informed consent process and may impact the total number of patients seen in your practice. This may require more staff, the use of audio/visual aids, and possibly the need to conduct evening seminars where an exchange of information outside of patient hours can take place, Dr. Abbott said.

## ADVERTISING

Marketing and advertising include any promotional or informational activity used by an ophthalmic practice. With the addition of intraocular refractive surgery as a surgical alternative to vision correction with a laser, spectacles, or contact lenses, marketing efforts have increased as ophthalmic surgeons promote their new services. Although advertising by physicians remains an acceptable way to market one's practice, the Federal Trade Commission, many state laws, and the AAO Code of Ethics all state that material must not be false or deceptive in the way it is presented to the public. Even advertising that states true facts but conveys a misleading impression to reasonable consumers may be considered illegal. Ophthalmologists must be able to substantiate all claims made in their advertising. From a risk-management perspective, any deviation from appropriate marketing and advertising principles could weaken the defensibility of a claim or lawsuit, because this information is considered part of the initial informed consent process.

## CONCLUSION

The risk-management recommendations discussed in this article highlight the actions ophthalmologists can take to reduce the likelihood of a legal claim or suit. Cataract surgery is the most frequently performed ophthalmic procedure in the US and the source of the majority of medical malpractice claims reported to OMIC. The addition of multifocal IOLs and the refractive lens exchange procedure has raised the bar for potentially increased medicolegal risk for the surgeon and requires careful attention to the informed consent process. A strong informed consent process helps to protect you against unforeseeable risks.

A sample informed consent form containing the minimum information that you should personally disclose to the patient has been developed by OMIC and is available at the OMIC Web site for anyone to use.<sup>2</sup> At the upcoming ASCRS meeting in San Diego, OMIC will present a course on dealing with patient selection issues for all types of refractive surgery, including refractive lens surgery. ■

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1. Notice of Exclusion from Medicare Benefits. Available at: <http://www.cms.hhs.gov>. Accessed January 15, 2007.

2. Ophthalmic Mutual Insurance Company. Informed consent for refractive lens exchange (RLE) for the correction of hyperopia (farsightedness) or myopia (nearsightedness). Available at: <http://www.omic.com>. Accessed January 18, 2007.