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Ophthalmic Risk Management Digest

OMIC DIGEST

Premium IOLs Come of Age

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Patient satisfaction can be difficult to obtain and easy to lose. Despite the initial level of deference and trust a patient usually brings to the physician-patient relationship, that trust can be lost due to miscommunication about the diagnosis or treatment goals. Out-of-pocket expenses, especially if they are significant, can increase patient expectations and set the stage for dissatisfaction or malpractice lawsuits. A current case in point is intraocular lenses (IOLs), judging by the number of calls on this issue to OMIC's Risk Management Hotline.

Prior to World War II, ophthalmologists and their patients had few lens choices following cataract surgery. The only way to replace the focusing power of the lens once it was removed was with a thick cataract glass (remember the coke bottle glasses that elderly people wore years ago?). Today, cataract patients are fortunate because ophthalmologists can replace the natural lens with an artificial, clear, plastic lens implant.

The use of lens implants became common practice in cataract surgery in the 1970s, but the discovery of these lenses actually occurred years earlier in the late 1940s. Howard Ridley was an ophthalmologist in the Royal Air Force treating former fighter pilots who had sustained eye injuries during the war when bullets striking the plastic canopy of their aircraft caused small shards of plastic to fly into their eyes. Dr. Ridley realized that the polymethylmethacrylate (PMMA) acrylic from the aircraft canopy was made of an inert material that was compatible with eye tissue. In 1949, he replaced a cataractous natural lens with the first artificial plastic lens.

Fast forward sixty years to the wide selection of IOLs now available to ophthalmologists and patients. Ophthalmologists can recommend lenses based on a patient's individual postoperative vision goals, and patients willing to pay extra can upgrade to "premium" IOLs for even better visual results. But, as with any commodity, availability of a "premium" product has its downside. In the case of premium IOLs, patients may have unrealistic expectations and because patients are personally responsible for the added cost, they may insist upon guaranteed results. Management of expectations is thus critical to satisfaction when helping a patient choose the right IOL.

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MESSAGE FROM THE CHAIRMAN

As I step into the role of OMIC chairman amid the upheaval in the financial services industry, I am very pleased to be able to report that OMIC has never been in a stronger financial position than it is now. OMIC remains operationally sound and financially stable. Since 2005, OMIC policyholders have received significant dividends representing a return of premium above what was needed to prudently operate our company, a rare return on investment during turbulent times. This year, OMIC member-insureds will share in the company's profitability by receiving a 20% dividend totaling $8.1 million and an overall average rate decrease of 8.5% on paid premium in 2009.

This good news is particularly remarkable given the current economic crisis. As other malpractice carriers post their year-end 2008 results, OMIC member-insureds can rest assured that once again OMIC will be at or near the top of the list in all major financial performance benchmarks. OMIC's combined and operating ratios, two indications of a company's ability to meet future obligations, beat almost all other malpractice carriers. As the largest insurer of ophthalmologists in the United States with close to 40% of the market, OMIC's

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The choices are numerous. In addition to the standard monofocal lens, patients now have the option of a "multifocal" intraocular lens (the first one was approved by the FDA in 1997). "Multifocals" provide both near and far vision. Unfortunately, not all patients are eligible for "multifocals." Some patients who are fitted with "multifocals" may still need glasses or contact lenses for certain activities, such as those requiring near and extremely crisp, clear vision. In general, however, fewer need glasses and contacts when fitted with "multifocals" than they would with monofocals. Clinical studies have found that cataract patients who choose "multifocals" over monofocals express greater satisfaction and improved quality of life following surgery.

In addition to these benefits, each of today's available "multifocal" IOLs (ReStor, ReZoom, and Crystalens) have specific limitations that need to be communicated to the patient to reduce the potential for disappointment and dissatisfaction. To appreciate the need to move cautiously with premium IOLs, we'll examine OMIC's claims experience with cataract surgery.

Claims Experience Involving IOLs

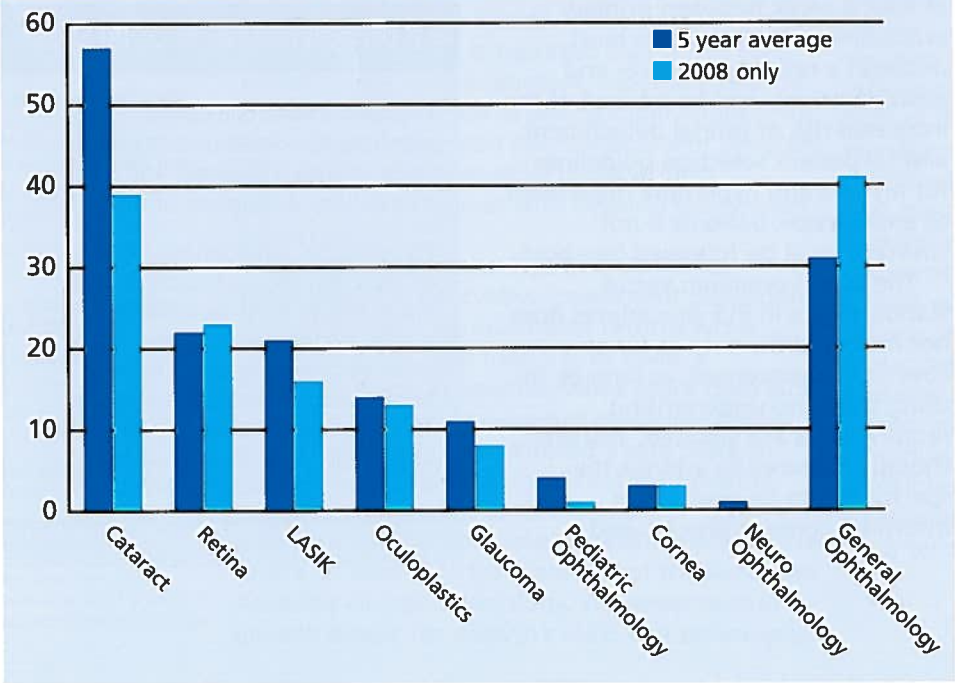
Issues that surface with patients who undergo cataract surgery with placement of IOLs include the typical complaints of incorrect lens power, size, type, and position. Another source of claims are complications of surgery that were not handled promptly by the surgeon or referred on to a specialist in a timely manner; these include vitreous loss, retained and dropped lens material, stripped descement's membrane and other corneal problems, and choroidal hemorrhage.

As indicated in **Graph 1**, cataract surgery claims continue to be the most frequent type of claim against OMIC insureds. The high rate of cataract-related claims reflects the large number of cataract procedures performed each year in the United States. (Claims involving the use of IOLs in cataract surgery are included in the overall cataract column, but claims involving the use of IOLs in refractive surgery are fairly new and few have been reported so far.) While the *average* indemnity for cataract claims over the past five years ($113,000) is less than the average indemnity for all types of ophthalmology claims ($145,000), the *aggregate* indemnity for cataract claims is significant given their high volume.

OMIC did experience a decrease in the number of cataract claims between 2005 and 2008 from 27% of all claims to 20% (see **Graph 2**). Whether this decline will continue during the current economic downturn remains to be seen. We are seeing an uptick in the number of small general ophthalmology claims, possibly the result of patients seeking financial compensation during hard economic times.

In order to decrease the risk of a claim and the amount of settlement or judgment if a claim is filed, the following risk management strategies are recommended for ophthalmologists who do IOL placement.

GRAPH 1
NUMBER OF CLAIMS REPORTED TO OMIC BY SUBSPECIALTY

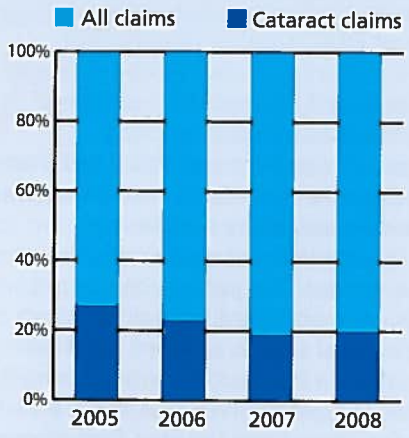


Manage Patient Expectations

Management of patient expectations with regard to cataract and refractive lens exchange surgeries begins with proper patient selection. Plaintiff attorneys and experts are quick to point out if the patient was a questionable candidate for surgery or if better alternatives existed for the patient's particular needs.

Know and follow the indications for surgery in the American Academy of Ophthalmology's "Preferred Practice Pattern on Cataract in the Adult Eye." Determine the role of the cataract in the patient's vision loss. Ask about near and distant vision under varied lighting conditions for activities that the patient views as important. Document the functional impairment using the patient's own words. Consider using a vision-specific

GRAPH 2
CATARACT AS A PERCENTAGE OF ALL OMIC CLAIMS



questionnaire designed to help ascertain the impact of the cataract on activities of daily living, such as the Activities of Daily Vision Scale (ADVS)[1] or the Visual Function Index (VF-14).[2]

Identify whether there are other possible causes of the patient's visual problems besides cataracts. Evaluate the patient for medical comorbidities and medications that can influence the choice of anesthesia or affect the outcome of surgery (e.g., Flomax, anticoagulants).

Provide Thorough Informed Consent

In addition to a well documented medical record, a thorough and memorialized informed consent process will enable OMIC to mount a strong defense against a claim. Consent should be given in advance of surgery with time allowed for the patient to review this information and ask questions. Include a thorough discussion of the risks, benefits, alternatives, and complications of surgery and anesthesia. It is important to document the indications for surgery (e.g., for cataract surgery with premium IOLs, the need for near and distance VA and the impact of cataracts on the patient's daily life). Also disclose and document the impact of ocular and medical comorbidities on the outcome (e.g., removing a cataract will not cure other eye conditions such as glaucoma or AMD).

Your discussion with the patient should address the options for near vision and astigmatism reduction. If the IOL was recently approved, explain that there is a lack of information about long-term outcomes and the possibility of unforeseen complications. Patients should not feel pressured to choose a more expensive IOL option. Explain your rationale for recommending a particular IOL and provide information about it, including labeling information that a reasonable person would want to know.

More importantly, clarify that no guarantees can be made about postoperative visual acuity. Explain that the selection of the proper implant is based upon sophisticated equipment and computer formulas, but is not an *exact* science, and if the refractive result is considerably different than expected, there may be a need for glasses or contacts, additional refractive surgery, or lens repositioning or replacement. Also explain what will happen if the selected IOL cannot be placed due to problems that may arise during surgery. If the patient is at increased risk for a particular complication, disclose and document that (e.g., infection in a diabetic patient). More information on the informed consent process for cataract and refractive lens exchange surgeries can be found at http://www.omic.com/resources/risk_man/forms.cfm.

Handle Patient Complaints

Even patients with uncomplicated surgery may present with complaints after surgery. Unwanted visual images, residual refractive errors such as astigmatism, and overall poor quality vision may be cause for complaint. Manage these situations by being empathetic and reassuring to the patient. Emphasize that it may take time to adjust to visual changes and that you will be available to the patient throughout this process. If complaints persist, discuss the matter with OMIC's Risk Management Department.

Monitor Advertising

The ophthalmologist should personally review how IOL implants are being marketed to patients in the practice's advertising to ensure that patients are receiving "balanced" information on their risks and benefits. This will also help manage patient expectations before the patient presents in your office. OMIC's Risk Management Department will be happy to assist you in reviewing your advertising.

RISK MANAGEMENT RECOMMENDATIONS

- Assess impact of vision on patient's daily life.
- Recognize contraindications to surgery.
- Thoroughly explain risks and benefits of surgery, anesthesia, and chosen IOL.
- Make no guarantees as to outcome.
- Inform patient of intraoperative complications.
- Promptly manage complications and refer patient to a specialist if necessary.
- Ensure that your advertising is responsible and balanced.

1. Mangione CM, Phillips RS, Seddon JM, et al. "Development of the 'Activities of Daily Vision Scale.' A Measure of Visual Functional Status." *Med Care* 1992; 30: 1111-26.

2. Steinberg EP, Tielsch JM, Schein OD, et al. "The VF-14. An index of Functional Impairment in Patients with Cataract." *Arch Ophthalmol* 1994; 112: 630-8.