OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
A Risk Retention Group

Risk Management Recommendations

Sponsored by the American Academy of Ophthalmology

Intraocular Refractive Surgery

Anne M. Menke, RN, PhD, OMIC Patient Safety Manager
Reviewed by Bradley Fouraker, MD; Christopher J. Rapuano, MD; and Steven Rosenfeld, MD

Purpose of risk management recommendations

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

Version 10/23/20

Intraocular refractive surgery poses a higher risk for patients than refractive procedures performed on the corneal surface. These patients tend to have high expectations and pay for these procedures out-of-pocket, which can heighten the likelihood of dissatisfaction and professional liability lawsuits. Implementing these risk management recommendations can benefit both you and your patient.

FDA status and off-label use

- Verify the Food and Drug Administration (FDA)-approved label on a regular basis, and carefully review any communications from the device manufacturer.
- Devices are approved for specific indications, conditions, and ages. Use outside of these criteria is considered off-label. Obtain and document consent for off-label use.
- Patient age
- Phakic implants were approved for a certain age range (e.g., 18 or 21 to 45 years). Use in patients who are younger or older than the approved ages is off-label.
- IOLs are approved for adult patients. Use in minor patients is off-label.
- Phakic implants
- Use only phakic implant lenses specifically designed and approved for that purpose.

- Clarify the approved range for myopia, hyperopia, and astigmatism, as well as other labeled indications, such as presbyopia or anterior chamber depth.
- Determine if the patient meets FDA-approved criteria. Document your decision-making process for off-label use, including why you feel this is the best option for the patient.
- IOLs used in refractive lens exchange
- Since IOLs are approved for cataract surgery, all use in RLE is off-label.

Preoperative evaluation and site of surgery

- Perform and document an independent evaluation prior to surgery to determine the patient's candidacy for surgery. Conduct a personal and independent examination of the patient's eyes and ocular history. Analyze and discuss the patient's expectations. Address monovision when appropriate.
- Ensure that all candidates have a complete retinal exam pre- and post-operatively. The retinal exam may be conducted by the surgeon, a retinal specialist, or other qualified ophthalmologist. In addition, advise patients of the increased risk of retinal detachment.
- Determine and document the amount of myopia, hyperopia, astigmatism, presence of presbyopia, and near and distance vision.
- Evaluate and document the patient's refractive stability. Depending upon the device, the minimum period of stability could range from 6 to 12 months.
- Ensure that the post-implant refraction is stable before performing repeat surgery.
- Perform the procedure in a hospital or outpatient surgery center approved for cataract surgery that meets the standards for sterile conditions as required for accreditation. Full sterile technique must be followed.

Immediately sequential bilateral surgery (ISBS)

- The risk of intraocular refractive surgery is increased if both procedures are performed on the same day. Complications can occur in either or both eyes.
- Determine if the patient is a suitable candidate for ISBS.
- Perform ISBS only on patients at low risk for surgical complications.
- Consider performing the procedure on the fellow eye on another day for "complex" surgical cases. Examples of "complex" cases include patients with amblyopia, pseudoexfoliation syndrome, previous ocular trauma, active macular SRNVM with leakage, significant diabetic retinopathy, high hyperopes with axial length < 20 mm (RLE), as well as those at higher risk of infection, such as patients who are immunocompromised or have poorly controlled diabetes.
- Consider ISBS only on patients for whom you can calculate the IOL power with a high degree of accuracy. Consider performing the procedure on the fellow eye on another day for patients for whom there is a greater than normal risk of having difficulties calculating or selecting the appropriate IOL power. These types of patients include those who have previously undergone refractive surgery (e.g., LASIK, PRK, SMILE, CK, and RK), have significant corneal scarring or keratoconus, have extremely long or short axial lengths, or have conditions that make it difficult to cooperate for the optical or ultrasonic biometry (e.g., nystagmus or dementia).

- Discuss and document the pros and cons of ISBS.
- Develop and follow appropriate protocols to reduce the risks for right-eye-left eye errors and errors in IOL insertion.
- Ensure complete aseptic separation of the first and second eye surgeries, including use of separate instrument trays that have undergone separate sterilization cycles; complete, repeat surgical scrub and draping; and separate intraocular irrigating fluids and drops with different lot numbers.
- Inform the patient of complications that occur in the first eye before proceeding to the second eye. The second surgery may need to be rescheduled. Have a low threshold for delaying surgery in the second eye if significant complications occur in the first eye.

Informed consent discussion and forms

- Conduct and document an informed consent discussion with each patient. Although other health care professionals may be involved in the informed consent process, this duty may not be delegated exclusively to non-physician staff.
- Inform patients of the risk of progressive myopia and under-correction, especially for patients younger than 25 years of age.
- Use a separate consent form for LASIK surgery performed in conjunction with or following phakic implant surgery ("bioptics" procedures).
- Obtain written informed consent for planned surgical comanagement. See OMIC's recommendations for surgical comanagement and sample consent form at https://www.omic.com/comanagement-of-surgical-patients/.
- Some states have passed legislation regarding comanagement and the surgeon's duties and responsibilities relating to the postoperative care of surgical patients. Follow all postoperative care requirements of your state.
- OMIC sample consent forms:
    - Phakic implants: www.omic.com/phakic-implants
    - Immediately sequential surgery: www.omic.com/bilateral-phakic-implant-consentaddendum
    - Refractive lens exchange: www.omic.com/refractive-lens-exchange.
    - Off-label use: https://www.omic.com/informed-consent-for-off-label-use-of-a-drug-or-device/.

Need confidential risk management assistance?
OMIC-insured ophthalmologists, optometrists, and practices are invited to contact OMIC's Risk Management Department at (800) 562-6642, option 4, or at riskmanagement@omic.com.