Twenty Years of Insuring Refractive Surgery

By Anne M. Menke, RN, PhD, OMIC Risk Manager

For over 20 years, since its founding in 1987, OMIC has insured ophthalmologists who perform refractive surgery procedures while monitoring a key measure of patient safety and satisfaction: professional liability claims (written notices or demands for money or services, including letters, lawsuits, and arbitration proceedings). This spring, we conducted a review of our refractive surgery claims experience to determine if additional measures are needed to ensure that our policyholders continue to reduce patient safety risks and minimize their—and the company’s—malpractice exposure. This article reports on the frequency and severity of refractive claims and analyzes the issues driving them. This issue’s Hotline article presents risk management recommendations.

Frequency of Refractive Surgery Claims

The first refractive claim—for negligent RK—was reported to OMIC in 1989. Claims were infrequent until 1999, four years after OMIC approved coverage for PRK and three after it added LASIK. As of May 2008, OMIC had a cumulative total of 289 refractive claims, of which 58 are still open and under evaluation. Refractive surgery is now the third most frequent area for claims against OMIC insureds, following cataract surgery and general ophthalmology. LASIK claims in particular, and refractive claims overall, represent a significant percent of total open claims (10.41% and 12.31% respectively), although the percentage is lower among total closed claims. LASIK makes up 85% of all open and closed refractive claims, and the number of LASIK claims reported to OMIC has recently increased. When evaluated by the year in which care occurred, however, LASIK incidents peaked in 2000 and have been dropping ever since.

Severity of Refractive Surgery Claims

While a frequency study shows how often a particular type of claim is filed, a severity analysis looks at how often an indemnity payment must be made in order to close the claim and the magnitude of the payment. Compared to OMIC’s overall claims data, refractive claims close more often with an indemnity payment and have higher average and median settlement amounts.

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**Lead OMIC**

9, Richard L. Abbott, MD, FACS, ICO’s Board of Directors. Hence, a corporation’s bylaws, asession for the nation’s specialists, or a person to lead OMIC, “is abbott’s entire career support and protection on.”

Boyd Endowed a clinical professor of surgery, chairman of the University of Southern California’s Department of Ophthalmology, Dr. Abbott has a long history with OMIC.

**Ethics.** The public demands ethical physicians and expects state medical boards to discipline those who are not. Ethics will continue to be stressed in medical school and more and more medical professional societies will develop codes of ethics, similar to the AAO’s. Sanctions against physicians by state medical boards may trend toward the punitive as has already occurred in some states, notably Florida.

**Professional Liability Insurance Industry.** The industry is cyclical with specific hard and soft markets that will recur over the next 20 years. In order to obtain market share, some companies will engage in predatory pricing. Such pricing tactics exist in the current soft market and can be expected in future ones. The end result is that these companies may decide to leave the market when their underfunded reserves catch up with them. Physicians may be abandoned and find it difficult or impossible to obtain affordable insurance from another company. Premiums will increase over time due to inflation, increasing claims severity, and rising defense costs.

These leads me to my final words about OMIC. As underfunded insurance companies leave the market, it becomes even more critical that ophthalmologists align themselves with OMIC. OMIC will be there for you in the future with premiums that are fairly priced and service that is...
Clinical issues predominate in refractive surgery claims, accounting for the majority of the 64 cases. This is supported by the table showing a large number of issues. The primary systems issues are documentation, consent process, and postoperative issues. The highest indemnities paid by the company were for systems issues. 

Two aspects of care accounted for the majority of the 101 intraoperative LASIK allegations, namely, flap creation (49) and identification of the patient, procedure, and laser settings (18). Corneal injury, decentration, equipment malfunction, anesthesia-related complications, double coring, ablation zone size, sterilization breakdowns, and power failure accounted for the rest, in decreasing order of frequency. The allegations in PRK intraoperative claims were decentralized ablation, wrong nomogram, and wrong procedure.

Not surprisingly, corneal complications led to 72 of 91, or 79%, of postoperative LASIK claims, with negligent diagnosis and treatment of post-LASIK ectasia and inflammation/infection the top allegations. Corneal issues included retinal complications, dissatisfaction with monovision, diplodia, glaucoma, depression, and pain. In PRK, postoperative problems accounted for 70% of the clinical issues; of these, cornea-related issues predominated (63%), including (in decreasing order) haze, ectasia, central island, abrasion, infiltrate, scarring, and SPK. Other allegations focused on glare, ghosting, night driving, diplodia, headache, and ptosis.

Preoperative assessment, informed consent process, and postoperative care. Misidentification of the patient, procedure, or laser settings occurred in 18 cases, accounting for 11% of systems issues. Claims of false advertising and fraud are becoming more common, as are complaints about component failures, such as refunds, procedure-related costs, and complications. As of 2008, patients were more likely to be involved in the outcome of LASIK than in PRK; 3 cases involved patient complaints. The Hotline article discusses preoperative assessment in more detail.

**Preoperative Issues**

The most frequent provider issue was consent, followed by equipment comanagement, and advertising. The primary systems issues were documentation, consent process, and postoperative issues. The highest indemnities paid by the company were for systems issues. Two aspects of care accounted for the majority of the 101 intraoperative LASIK allegations, namely, flap creation (49) and identification of the patient, procedure, and laser settings (18).

The table shows the average indemnity payment per case. The table also includes a breakdown of the types of claims, with a focus on preoperative and postoperative issues. The table includes categories such as preoperative issues, known issues, and postoperative issues. The figures are presented in a clear and organized manner, making it easy to understand the distribution of claims and indemnity payments.
Failure to

s first exam, the OMIC
him that he was a
r LASIK. Pachymetry
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was performed.
returned and repeat
neal thickness of 475
phy was also repeated.
was 20/400 OD and
signed a LASIK consent
the risks of operating
e date; however, after
he decided to proceed
sequential surgery.
that the patient was
LASIK, the insured
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me could not tolerate
corrected to 20/200 OU.
corneal thickness of 440 microns. There were also
preoperative clinical signs of keratoconus,
including an unstable prescription, a best
correctible visual acuity of less than 20/20, and
increasing irregular astigmatism. Plaintiff expert
stated that the patient suffered from forme
fruste keratoconus in the right eye as the
topographic data revealed inferior steepening
and a thin cornea should have been better
counseled on his condition and not allowed to
have bilateral PRK performed on the same day.
Plaintiff testified that he initially presented to the
OMIC insured, not for refractive surgery, but to
have his glasses prescription changed. He also
alleged that he was never told that the condition
of his corneas increased the risk that he might
suffer complications.

Unfortunately, there was no evidence in the
insured’s records that he had reviewed the
topographies that were taken on two separate
occasions. The insured clearly did not suspect that
the patient was suffering from either keratoconus
or forme fruste keratoconus and did not warn
the patient of the increased risk of ectasia.
Further complicating the defense was the fact
that the patient had not signed a consent form
specific to PRK.

Defense experts were unable to support the
insured’s care and focused instead on evaluating
the plaintiff’s claimed damages. Faced with the
probability of a plaintiff verdict exceeding his $1
million policy limits, the insured consented to a
settlement and the case was resolved.

Risk Management Principles
Diagnostic tools such as topographies are only
useful if they are accurately reviewed and
considered in tandem with the clinical picture. No
matter how similar the risks and complications,
specific informed consent must be obtained for
each procedure. This includes a discussion with
the patient of the procedure-specific risks,
potential complications, and benefits and
requires that the patient sign each consent form.
If a different procedure is substituted for the
original planned procedure, the consent process
should begin anew, including obtaining the
patient’s signature on a procedure-specific
consent form. To avoid an allegation of

Reduce Your Risk of a Refractive Surgery Claim
By Anne M. Menke, RN, PhD
OMIC Risk Manager

The refractive surgery claims study
featured in this Digest points to
actions ophthalmologists can take to
improve the safety of these
procedures and reduce the likelihood
of a malpractice claim. Document any
actions you take in the patient’s
medical record.

Q OMIC’s refractive surgery under-
writing requirements state that the
“surgeon must perform and document
an independent evaluation of the
patient’s eligibility for surgery, including
performing a slit lamp exam and
reviewing topography, pachymetry,
pupil size, and discuss monovision
option for presbyopic patients” and
“personally obtain informed consent.”
Is OMIC opposed to comanagement?

A No, but we have learned from
our claims experience that comanaged
care has risks that must be reduced.
Experts for the plaintiff regularly
scrutinize how much care is delegated
to non-ophthalmologists, whether
such delegated care is properly
supervised, and if the patient freely
consented to the arrangement. We
recommend that you develop and
implement written protocols for
comanagement (see “Comanagement
of Ophthalmic Patients” at www.omic.
com). Clarify in the protocol the role
of the surgeon in preoperative and
postoperative care and consent.
Release the patient to the care of the
non-surgeon only when deemed
stable, and especially continue to see
the patient if there have been compli-
cations. Request that comanagers send
OMIC’s position on the role of
surgeon reflects that of the Amer
Academy of Ophthalmology (AAO)
and the American Society of Cata
and Refractive Surgery (ASCRS). It
joint clinical statements, these
organizations have clarified that the
ultimate responsibility for obtain
accurate preoperative assessment
the patient’s informed consent to
refractive surgery rests with the
ophthalmologist who performs the
surgery.”1 Referencing case law,
Medicare regulations, actions by
Office of the Inspector General, an
ethical standards, their analysis
that the law imposes duties on sur-
geons who do not provide the postope-
rate care. Ophthalmologists who do
not meet this obligation could be accu-
medication abandonment and risk “liability
for patient injury, including injury
resulting from the acts or omission
others to whom the provision of
postoperative care is inappropri-
delegated, or for inadequate pat-
infomed consent, or both.”

Q What has OMIC learned that
help me improve the quality of my
preoperative care?

A Patients who present to
ophthalmologists have often alre-
decided that they want refractive
surgery, and know that they have
myopia, hyperopia, and astigmat-
ism. These conditions refractive
surgery is designed
to correct.

...
OMIC continues its popular risk management programs in 2009. Upon completion of an OMIC online course, CD recording, or live seminar, OMIC insureds receive one risk management premium discount per premium year to be applied upon renewal. For most programs, a 5% risk management discount is available; however, insureds who are members of a cooperative venture society (indicated by an asterisk) may earn an additional discount by participating in an approved OMIC risk management activity. Courses are listed below and at www.omic.com. CME credit is available for some courses. Please go to www.aoa.org to obtain a CME certificate.

**Online Courses (Reserved for OMIC insureds and members of cooperative venture societies/No charge)**
- Documentation of Ophthalmic Care
- EMTALA and ER-Call Liability
- Informed Consent for Ophthalmologists
- Ophthalmic Anesthesia Liability
- Responding to Unanticipated Outcomes

**CD Recordings (No charge for OMIC insureds)**
- After-Hours and Emergency Room Calls (2006)
- Lessons Learned from Settlements and Trials of 2004 (2005)
- Noncompliance and Follow-Up Issues (2005)
- Research and Clinical Trials (2004)
- Responding to Unanticipated Outcomes (2004)

Go to the OMIC web site to download order forms at www.omic.com/resources/risk_man/seminars.cfm.

**Upcoming Seminars**

**January**

**14** Difficult Patient-Physician Relationships
Washington DC Metropolitan Ophthalmological Society*
Location: TBA
Time: 6:00 pm
Register by calling (301) 787-6607 or e-mail info@wdcmos.org

**21** Now What Do I Do?
Hawaiian Eye 2009
Grand Wailea Resort, Maui
Time: 2:00 pm
Register by calling (888) 960-0256 or http://www.osnawahianeye.com

**February**

**21** Difficult Patient-Physician Relationships
Illinois Association of Ophthalmology*
Stevens Conference Center, Rosemont, IL
Time: 11 am–Noon
Register with the IAO at (847) 680-1666 or e-mail EyeOrg@aol.com

**21** Dissatisfied Patients
Ohio Ophthalmological Society*
Hilton at Easton Town Center, Columbus, OH
Time: 2:40–3:40 pm
Register with OOS at (614) 527-6799 or e-mail oos@ohioeye.org

**March**

**6** Handling Impaired & Incompetent Colleagues and Unanticipated Outcomes:
New England Ophthalmological Society*
John Hancock Hall, Boston
Time: Afternoon session
Register with NEOS at (617) 227-6484

**April**

**5** Preoperative Assessments
Issues Identified in LASIK Claims Study
American Society of Cataract & Refractive Surgery
Moscone Center, San Francisco
Time: TBA
Register with ASCRS at (703) 591-0614 or www.ascrs.org

**18** Dissatisfied Patients
American Association for Pediatric Ophthalmology & Strabismus*
Hyatt Regency, San Francisco,
Time: TBA
Register with AAPOS at aapos@aoa.org or call

The OMIC office will operate on a dramatically reduced schedule and will respond only to urgent matters between December 25 and January 2. If you have an urgent matter and must speak to a staff member during the holidays, please call (800) 562-6642, ext. 609, and leave a message. Staff will check this message line throughout the week and return urgent calls in a timely manner. Non-urgent calls will be returned on Monday, January 5. The OMIC staff wishes you and your family a safe and happy holiday season.

For further information about OMIC’s risk management programs, or to register for online courses, please contact Linda Nakamura at (800) 562-6642, ext. 652, or lnakamura@omic.com.

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