Ophthalmic Risk Management Digest

OMIC DIGEST

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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MESSAGE FROM THE CHAIRMAN

During the past 20 years as an OMIC Board and Committee member, I have had the opportunity to observe and learn a great deal about medical professional liability insurance and risk management. One thing that stands out is the dynamic and evolving nature of this business and how strongly it is affected by outside societal forces. This is particularly true of professional liability insurance for ophthalmic practices. I would like to use my final message as your chairman to mention several factors that I believe will impact the liability exposure of ophthalmologists over the next 20 years.

Aging Population. As boomers grow older, their higher expectations of medical care could result in more lawsuits from the elderly population, which in the past has tended not to question doctors' recommendations or the end result of care. Older individuals have more comorbidities and there will be many debates as to how to pay for their care. Medicare reimbursement is not likely to keep pace with inflation and may even decrease on an absolute basis. Decreasing reimbursement will lead ophthalmologists to perform more procedures that can be billed outside the Medicare system, such as multifocal and accommodative lenses for cataract

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Lead OMIC

9, Richard L. Abbott,
. McFarlane Jr., MD,
IC's Board of Directors.
ting off the OMIC
ıe company's bylaws,
ession for the nation's
nologists.
person to lead OMIC,"
bbott's entire career
support and protection
on."
Boyden Endowed
a clinical professor
Vision Center of the
ı Francisco, Dr. Abbott
almic research, clinical
re than two decades

and is widely regarded as one of America's foremost authorities on quality of care and risk management issues in ophthalmology.

Dr. Abbott joined OMIC's Board of Directors as chairman of the Underwriting Committee in 1999, after serving on the committee for six years. In 2006, he was elevated to the Executive Committee. In addition to his work at OMIC, Dr. Abbott has held several leadership positions within the American Academy of Ophthalmology, including serving on the Academy's Board of Trustees.

"OMIC is the leader in our industry because ophthalmologists trust and rely on our expertise," said Dr. McFarlane. "Dr. Abbott's commitment to improve the delivery of ophthalmic care and identify the trends that result in lower exposure to malpractice claims will benefit the entire ophthalmic community."

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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

Ensure Coverage for Your Refractive Surgery

By Kimberly Wittchow
OMIC Legal Counsel

Being specialists in the underwriting and management of risk for the practice of ophthalmology, OMIC makes sure that all insureds are individually reviewed and approved for their unique practices. Therefore, OMIC's policy excludes all refractive surgery until the company has had an opportunity to review the credentials and experience of ophthalmologists in the performance of each type of refractive surgery. Once approved, these services are covered at full policy limits by endorsement to the policy. No additional premium is charged for this coverage. However, coverage applies only to the specific procedure(s) added by endorsement. If an insured who has been approved for one type of procedure would like to perform other types of refractive surgery, he or she must apply and undergo underwriting review and approval for each additional type of procedure.

OMIC's refractive surgery endorsements all have a common condition for coverage to apply: the procedure must be "performed within OMIC's underwriting requirements or any exceptions to the requirements granted in writing by OMIC." Specific procedures have their own requirements, and there is also an overall set of refractive surgery requirements applicable to all. These requirements, which address patient selection criteria, informed consent processes, and postoperative care, among other issues, must be met in order for a claim to be covered. All applicants for refractive surgery receive these requirements, and, in their supplemental application, they warrant and represent that they

to the Refractive Surgery Informa
page of OMIC's web site (accessib
from the "Favorites" section of O
home page or by selecting "Produ
then "Professional Liability") and
select the procedure of your choi
within the supplemental refractiv
surgery questionnaires.

The reasons for these requirem
are threefold. Performance of ref
tive surgery procedures within th
parameters, based on sensible me
practice and sound risk managem
principles, should reduce the likel
hood of unanticipated outcomes,
consequently, claims. They also pr
the insured if a claim does arise, a
procedures performed within the
requirements are more defensible
requirements also protect the com
and its member-insureds, since m
defensible claims protect the fina
solvency of the company and the
fore enable OMIC to continue to
operate for the benefit of all insu

The requirements were implem
by OMIC's Board of Directors, und
the guidance of the Underwriting
Committee, composed entirely of
ophthalmologists, including refra
surgery specialists. They are conti
reviewed and updated as necessary
nearly all revisions to date expand
coverage. OMIC's requirements wi
respect to patient selection are ne
more restrictive than the FDA on-
requirements and are generally m
permissive. Information gleaned
past refractive surgery claims, inp
from defense attorneys, and stud
such as the one discussed in this is
lead article by Anne Menke, toge
with personal experience and
expertise, all help our Board devel
OMIC's refractive surgery requirem
On occasion, the Board also seeks
outside input from respected lead
the refractive surgery community
before implementing requiremen

ıical issues predominate in :tive surgery claims, accounting ılf of the identified problems in LASIK and PRK; systems, provider, atient issues follow (see graphs ge 5). The primary systems issues, :reasing order of frequency, are ment, informed consent, and nagement for LASIK claims; these three figure in PRK cases as well. der problems in LASIK claims r on documentation, failure to rm the preoperative assessment,

RACTIVE CLAIMS 1989-2008*

EDIAN	LOW	HIGH
),000	$4,600	$983,772
1,000	$5,000	$125,000
)0,000	$37,500	$850,000
/a	n/a	n/a
5,000	$25,000	$25,000
/a	n/a	n/a
5,000	**$4,600**	**$983,772**
)0,000	$80,000	$3,375,000
3,000	$500	$3,375,000

*As of 8/08

nowledge/skill deficits. ıalmologists were criticized for nent decisions and lack of ledge/skill in PRK. Patient issues not a significant factor in LASIK, ıey slightly outnumbered der allegations in PRK.

:al Issues

ꞁerative care was the focus in 83 5, or 42%, of LASIK claims. The ıry preoperative clinical issue was ꞅeop assessment (a factor in 71 of 86%, of claims). In particular, :iffs alleged contraindications to :tive surgery, especially clinical and topographical signs of forme fruste keratoconus, pellucid marginal degeneration, and other corneal problems (see **Table 3**). Other preop issues include candidacy for retreatment, monovision trials and candidacy, and the interval between retreatments. Only 8 of 39, or 20%, of the allegations focused on preop care in PRK claims; preoperative assessment and choice of procedure were the main issues. The **Hotline** article discusses preoperative assessment in more detail.

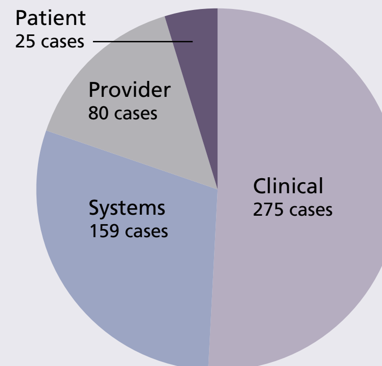
Two aspects of care accounted for the majority of the 101 intraoperative LASIK allegations, namely, flap creation (49) and identification of the patient, procedure, and laser settings (18). Corneal injury, decentration, equipment malfunction, anesthesia complications, double carding, ablation zone size, sterilization breakdowns, and power failure accounted for the rest, in decreasing order of frequency. The allegations in PRK intraoperative claims were decentered 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 (see **Table 3**). Non-corneal issues included retinal complications, dissatisfaction with monovision, diplopia, 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, diplopia, headache, and ptosis.

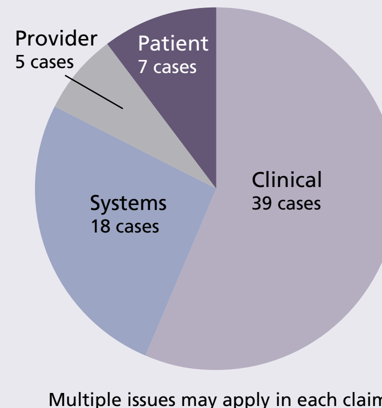
AVERAGE INDEMNITY PAYMENT

ISSUES IN LASIK AND PRK CASES REPORTED TO OMIC

196 LASIK CASES



16 PRK/LASEK CASES



Multiple issues may apply in each claim.

Systems Issues

Ophthalmology is heavily dependent upon medical devices, and equipment issues account for 30% (48 of 159) of LASIK claims involving systems issues. This was particularly true when there were problems with flap creation. Informed consent was a close second at 28%. Issues included failure to address ocular and medical comorbidities, the timing of the consent discussion, the surgeon's role in the consent process, the FDA status of the device, flap

preoperative assessment, informe consent process, and postoperati care. Misidentification of the pati procedure, or laser settings occur in 18 cases, accounting for 11% o systems issues.

Claims of false advertising and fraud are becoming more commo place and occurred in 3% of claim Financial issues, such as refunds, procedure-related costs, and colle efforts, as well as sterilization issu occurred in a few claims. Half of t systems issues claims for PRK were to consent, followed by equipmer comanagement, and advertising.

Provider Issues

The most common provider issue LASIK claims involved documentat lack of documentation was the prc 85% of the time. Failure to perfo needed tests and evaluations was alleged in 21% of claims. Missing elements in descending order inc the preoperative assessment, refra topography, pachymetry, and mo vision trials. Physicians were deem to lack knowledge and skill in 16% claims, specifically in topography interpretation, inadequate microk atome suction, ablation profile, a poor centration. They showed po judgment when deciding to retre performing bilateral procedures t

TABLE 3: PRE- AND POSTOPE

PREOPERATIVE ISSUES

Alleged contraindications
Keratoconus/ectasia
Pupil size
Prior ocular surgery
Refractive stability
Dry eyes
Amblyopia
Glaucoma

ailure to

ɜt

s first exam, the OMIC
ıim that he was a
r LASIK. Pachymetry
ıess of 545 OD and
 was performed.
t returned and repeat
neal thickness of 475
ɔhy was also repeated.
/ was 20/400 OD and
gned a LASIK consent
 the risks of operating
e date; however, after
he decided to proceed
ɛequential surgery.
ı that the patient was
LASIK, the insured
:o inform him that he
left eye and that he
(OS and LASIK OD.
ɛnt presented for
rmed him that PRK
 since he was not a
K surgery in either
ɛrformed.
uring the initial
:h uncorrected vision
)/100 OU. However,
rected vision declined
al haze greater OD
d not improve and,
owing the bilateral
d the patient's
ɛtter stating that the
lisabled due to
ɛnt was subsequently
ct lenses to help
esulting from the
ıe could not tolerate
ırrected 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 and 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 underwriting 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-

OMIC's position on the role of surgeon reflects that of the Amer Academy of Ophthalmology (AA(and the American Society of Cata and Refractive Surgery (ASCRS). I joint clinical statements, these organizations have clarified that tl "ultimate responsibility for obtair accurate preoperative assessment the patient's informed consent to refractive surgery rests with the ophthalmologist who performs tl surgery."[1] Referencing case law, Medicare regulations, actions by Office of the Inspector General, a ethical standards, their analysis n that the law imposes duties on sur who do not provide the postopera care. Ophthalmologists who do no meet this obligation could be accu patient abandonment and risk "lia for patient injury, including injur resulting from the acts or omissio others to whom the provision of postoperative care is inappropria delegated, or for inadequate pat informed consent, or both."[2]

Q What has OMIC learned tha help me improve the quality of n 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 astigmatisr conditions refractive surgery is desi to treat. Rather than focusing on indications for surgery, therefore, preoperative assessment aims to en that the patient is a good candidate to fully advise him or her of the exp risks, benefits, and alternatives. Firs avoid if possible meeting the patier the first time on the day of surgery you cannot avoid this, obtain and r the patient's medical record, especi

Calendar of Events

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.aao.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)*

- *Medication Safety and Liability* (2007)
- *After-Hours and Emergency Room Calls* (2006)
- *Lessons Learned from Settlements and Trials of 2006* (2007)
- *Lessons Learned from Settlements and Trials of 2005* (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.osnhawaiianeye.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

13–15 *Now What Do I Do?*
Florida Retinal Symposium
Ritz Carlton, Sarasota, FL
Time: TBA
Register at www.retinasymposium.com or call 863-683-3905

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@aao.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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