Fall 2008 Volume 18 Number 4 OPHTHALMIC MUTUAL INSURANCE COMPANY

Ophthalmic Risk Management Digest

OMIC DIGEST

# Twenty Years of Insuring Refractive Surgery

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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 comorbities 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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As expected, the majority of the 64 indemnities paid by OMIC for refractive claims were for LASIK and most were under $100,000 (see **Table 1**). PRK claims occur less frequently, but have a higher average and median payment and more often require an indemnity payment to close. In 2006 and 2007, there was a sharp increase in the average amount and number of refractive settlements, 50% of which involved ectasia; 2008 showed a marked decline (see **Table 2**).

Clinical issues predominate in refractive surgery claims, accounting for half of the identified problems in both LASIK and PRK; systems, provider, and patient issues follow (see graphs on page 5). The primary systems issues, in decreasing order of frequency, are equipment, informed consent, and comanagement for LASIK claims; these same three figure in PRK cases as well. Provider problems in LASIK claims center on documentation, failure to perform the preoperative assessment, and knowledge/skill deficits. Ophthalmologists were criticized for treatment decisions and lack of knowledge/skill in PRK. Patient issues were not a significant factor in LASIK, but they slightly outnumbered provider allegations in PRK.

TABLE 1: INDEMNITY PAYMENTS FOR REFRACTIVE CLAIMS 1989-2008*

| | NO. PAID | % PAID | AVERAGE | MEDIAN | LOW | HIGH |
|---|---|---|---|---|---|---|
| LASIK | 53/196 | 27% | $147,909 | $90,000 | $4,600 | $983,772 |
| RK | 7/21 | 33% | $35,000 | $21,000 | $5,000 | $125,000 |
| PRK | 4/13 | 31% | $321,875 | $200,000 | $37,500 | $850,000 |
| LASEK | 0/2 | 0% | n/a | n/a | n/a | n/a |
| RLE | 1/2 | 50% | $25,000 | $25,000 | $25,000 | $25,000 |
| CK | 0/2 | 0% | n/a | n/a | n/a | n/a |
| **TOTAL** | **65/231** | **28%** | **$144,564** | **$75,000** | **$4,600** | **$983,772** |
| ROP | 5/12 | 42% | $939,270 | $400,000 | $80,000 | $3,375,000 |
| OMIC | 530/2496 | 21% | $144,145 | $98,000 | $500 | $3,375,000 |

**As of 8/08*

## Causes of Refractive Claims

In our analysis, we divide the cause of claims into four groups: clinical, provider, patient, and systems. Two of these—provider and patient—are self-evident. Clinical issues are areas of controversy or of limits in knowledge or diagnostic/treatment modalities. Systems issues cannot be attributed to a single individual; instead these are processes in which many individuals and entities are involved. A much-studied example is medication: the process spans from research and product development, labeling, packaging, distribution, ordering, dispensing, and administering.

## Clinical Issues

Preoperative care was the focus in 83 of 196, or 42%, of LASIK claims. The primary preoperative clinical issue was the preop assessment (a factor in 71 of 83, or 86%, of claims). In particular, plaintiffs alleged contraindications to refractive 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.

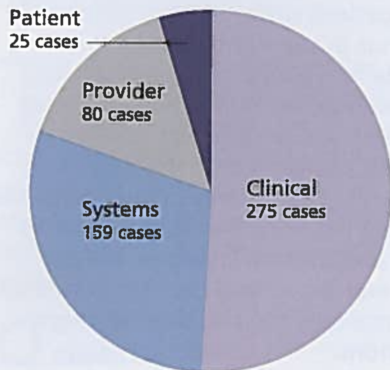
TABLE 2: REFRACTIVE SETTLEMENTS AND AVERAGE INDEMNITY PAYMENT

| 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008* |
|---|---|---|---|---|---|---|---|
| 3 | 6 | 12 | 5 | 5 | 9 | 10 | 3 |
| $31,667 | $58,333 | $156,217 | $35,400 | $56,250 | $242,954 | $335,550 | $81,667 |

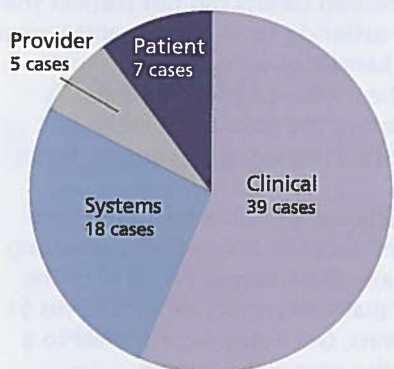
**As of 8/08*

## 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 complications, and monovision.

Comanagement allegations were found in 23% of claims, most often criticism of the surgeon's role in the 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 commonplace and occurred in 3% of claims. Financial issues, such as refunds, procedure-related costs, and collection efforts, as well as sterilization issues occurred in a few claims. Half of the 18 systems issues claims for PRK were due to consent, followed by equipment, comanagement, and advertising.

### Provider Issues

The most common provider issue in LASIK claims involved documentation; lack of documentation was the problem 85% of the time. Failure to perform needed tests and evaluations was alleged in 21% of claims. Missing elements in descending order included the preoperative assessment, refraction, topography, pachymetry, and monovision trials. Physicians were deemed to lack knowledge and skill in 16% of claims, specifically in topography interpretation, inadequate microkeratome suction, ablation profile, and poor centration. They showed poor judgment when deciding to retreat, performing bilateral procedures the same day, and choosing appropriate flap thickness (11%). Remaining issues, each accounting for 3% of allegations, included poor communication, practice issues (employee, on-call partner, nearing retirement), personality issues, treatment choices (for abrasion, dry eye, and the use of rigid gas permeable contact lenses with free flaps), and failure to diagnose the cause of decreased and fluctuating visual acuity. Provider issues were the least frequent allegation in PRK; 3 cases involved treatment choices and 2 the physician's knowledge/skill.

### Patient Issues

Defense expert witnesses did not feel patients played a significant role in the outcome of LASIK procedures, pointing to issues in only 25 claims. Noncompliance occurred in 9 and personality issues in 8. Unsubstantiated complaints and self-inflicted injury (head movement, rubbing, scratching) were found in 4 cases each. As with LASIK, noncompliance was the most frequent patient issue in PRK claims (4 out of 7), followed by individual healing patterns, and self-inflicted injury.

Go to the **Hotline** article for recommendations on how to reduce the risks associated with refractive surgery.

TABLE 3: PRE- AND POSTOPERATIVE ISSUES IN LASIK CLAIMS

| PREOPERATIVE ISSUES | | POSTOPERATIVE ISSUES | |
|---|---|---|---|
| **Alleged contraindications** | **71** | **Corneal complications** | **72** |
| Keratoconus/ectasia | 27 | Ectasia | 21 |
| Pupil size | 9 | Infection/inflammation | 16 |
| Prior ocular surgery | 7 | Flap problems | 9 |
| Refractive stability | 6 | Epithelial defects | 8 |
| Dry eyes | 5 | Epithelial ingrowth | 7 |
| Amblyopia | 3 | Central island | 3 |
| Glaucoma | 3 | Abrasion | 2 |
| Retinal conditions | 2 | Recurrent corneal erosion | 2 |
| Rheumatoid arthritis | 2 | Ulcer | 2 |
| Strabismus | 2 | Opacity | 1 |
| Blepharitis | 1 | Sands of the Sahara | 1 |