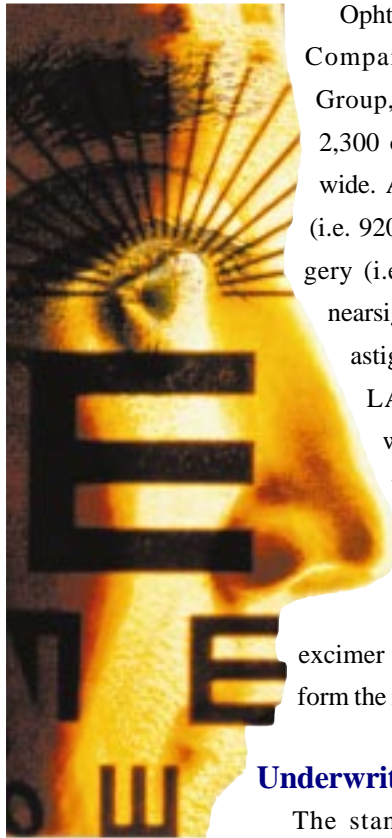


Insuring Refractive Surgery: Liability Risks

By Richard L. Abbott, MD and Paul Weber, JD

The following article explores the experience of the Ophthalmic Mutual Insurance Company (OMIC) in underwriting refractive surgery. As this surgery becomes more popular, issues such as truth-in-advertising as well as traditional underwriting issues become significant.



Ophthalmic Mutual Insurance Company, A Risk Retention Group, insures approximately 2,300 ophthalmologists nationwide. Approximately, 40 percent (i.e. 920) perform refractive surgery (i.e. surgical correction of nearsightedness, farsightedness, astigmatism and presbyopia), LASIK being the most widely performed refractive procedure. OMIC also insures ambulatory surgery centers and other entities where the excimer lasers are utilized to perform the refractive procedures.

Underwriting

The standard OMIC insurance policy actually *excludes* coverage for refractive surgery procedures. OMIC insureds must request coverage and be specifically endorsed for each refractive procedure. The insured must submit a *supplemental refractive surgery questionnaire*, which will be reviewed and approved prior to the insured being covered. A questionnaire is required for *each* type of procedure performed. The technology surrounding refractive surgery is developing at a dizzying rate, so OMIC has created questionnaires for not only laser procedures (ie:

LASIK, PRK, AND LASEK), but also clear lens extraction, LTK, Intacs, phakic implants, and RK/AK.

Each of the several questionnaires delves into the following areas: 1) training and experience; 2) patient selection; 3) informed consent; 4) operative procedures; 5) postoperative care (e.g. comanagement); and 6) advertising. Insureds who want to perform bilateral simultaneous procedures must undergo yet another level of underwriting review and approval due to the increased risk of a potential catastrophic bilateral complication.

As a condition of coverage, insureds must agree to comply with OMIC's standard refractive surgery guidelines and guidelines specific to a particular procedure. These guidelines, based on sensible medical practice and sound risk management principles, were developed by practicing refractive surgeons to reduce the likelihood of claims and to aid in the defensibility of any resulting claims. Furthermore, OMIC requires that insureds submit for review their consent forms, informational videos, patient education literature, and advertisements. At first, a small percentage of OMIC insureds perceived the guidelines as burdensome. Now, with the rapidly increasing frequency of LASIK lawsuits and claims, that perception is even more infrequent.

Risk Management

Our insureds' advertising and marketing is considered one of the risk exposures we are most concerned about and endeavor to minimize. Both the Federal Trade Commission and Food and Drug Administration have promulgated advisories setting forth guidelines for proper advertising. These federal advisories have also been addressed in American Academy of Ophthalmology publications. OMIC staff reviews the marketing material of our insureds and frequently advises them to delete misleading/untrue statements ("throw away your glasses," "fast, easy, painless procedure") and guarantees ("money back," "life-

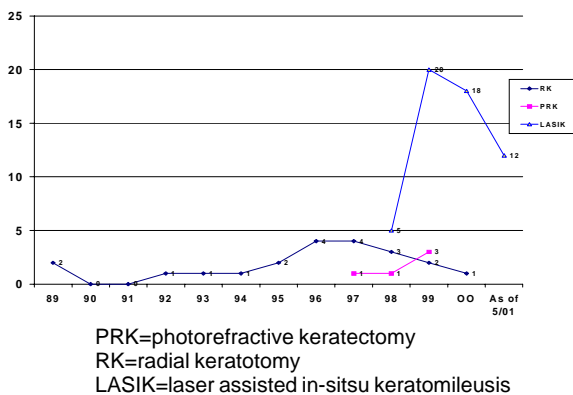
time”) found in the material. Staff also advises that they must be able to substantiate any claim (“millions satisfied,” “pioneers in corrective eye surgery”) made in the advertisement.

OMIC regularly provides seminars, articles, and audioconferences to remind our insureds (and the ophthalmic community) about the myriad liability risks associated with refractive surgery and to encourage their participation in minimizing those risks. This risk management information covers informed consent, patient selection, documentation issues, comanagement risks, advertising, and training. OMIC has drafted and distributed model informed consent documents for the various procedures, including bilateral simultaneous consents and consent to comanagement of care. The informed consent documents and articles can be found in the Underwriting and Risk Management sections of the OMIC web site at www.omic.com.

Refractive Surgery Litigation

Given the very high volume of refractive procedures, specifically LASIK) over the past 2 - 3 years, OMIC has seen a significant, but not surprising, increase in the frequency of refractive surgery claims and lawsuits. In 1999, LASIK complications represented 10 percent of all open OMIC claims. By 2000, the number had grown to 13 percent, and during the first six months of 2001, 19 percent of open claims involved LASIK. However, this increase does not appear to be disproportionate to the number of individual insureds adding refractive coverage to their policies since 1999 and the increase in the number of entities (ASCs and laser centers) that OMIC covers.

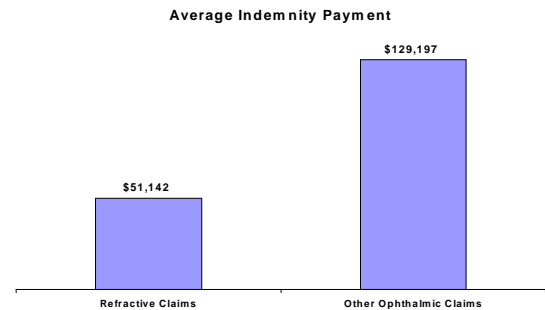
Chart I



The problems arising in the OMIC claims and lawsuits run the gamut from errors in programming the laser resulting in over-correction or astigmatism; improper patient selection resulting in intraoperative flap complications and generally poor outcomes; and postoperative failure/delay in diagnosing complications.

At OMIC, refractive procedures, including LASIK, continue to show only low to moderate claims severity when compared with other ophthalmic procedures or overall ophthalmic loss activity. OMIC has opened 55 LASIK cases over the past four years. Of the 18 cases that have closed, seven closed with an indemnity payment averaging \$51,142. OMIC’s average indemnity payment for all types of claims is \$129,197. On average, refractive surgery claims appear to be no more expensive to defend than other ophthalmic claims.

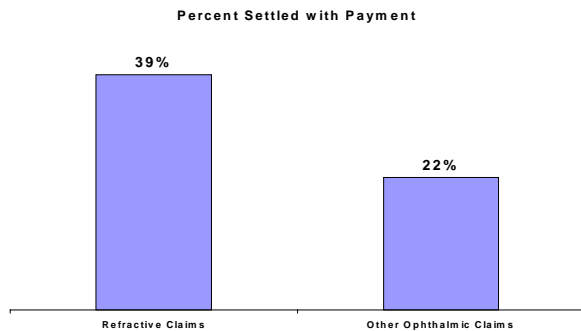
Chart II



LASIK settlements outside of OMIC are starting to be reported in the jury verdict reporters. One recently reported LASIK case settled for \$1.03 million. The LASIK surgery was performed in 1996 to correct the patient’s slight degree of farsightedness. In 1996, the excimer laser had only recently been approved for PRK correction of nearsightedness. The FDA had not approved the excimer laser for farsightedness. The ophthalmologist had to use a “black box”, a non-FDA approved laser, since the laser manufacturers did not calibrate their lasers for the correction of farsightedness. Further complicating this case, it appears the ophthalmologist tried to correct both eyes simultaneously. The patient ended up with irregular astigmatism in both eyes and a visual acuity of 20/400 left eye and 20/200 right eye. In 1996, it was rare indeed to find an ophthalmologist in the United States providing LASIK for the correction of farsightedness since LASIK for the correction of nearsightedness was still being investigated. It would

have been very difficult to find an expert witness to support the care that the ophthalmologist provided in 1996.

Chart III



It should be pointed out that “off-label” procedures using the excimer laser are not uncommon. The patient should be informed of the innovative nature of such a technique, its scientific basis, its benefits, and any possible drawbacks or criticisms from other practitioners. Other options should be discussed and the patient should be encouraged to seek a second opinion before proceeding with an innovative technique. This discussion should be well documented. Finally, professional liability insurance carriers need advice from consulting ophthalmologists to keep current with “off label” procedures that are standard in the community and should be covered if a claim arises. In addition it is also important for the insurance carriers to know which procedures are still “experimental” and should be specially endorsed or specifically excluded.

Class Actions

There are reports in the media that the plaintiff’s bar is fine-tuning its litigation machinery to sue ophthalmologists and others who perform or are involved in providing LASIK and other refractive procedures. So far, OMIC is aware of two class action lawsuits that have been filed, one in California and one in the state of Washington. Both class actions appear to be utilizing consumer protection statutes as a basis to certify the class. In the California case, the defendants reused the disposable microkeratome blade on several patients, allegedly without properly cleaning it between patients. The plaintiff’s attorney alleged that the ophthalmologists’ advertising, claiming the procedure was “safe,” was a misrepresentation due to the unsterile technique and this misrepresentation triggered the consumer legal remedies statute. The class actions are very expensive to defend and also raise complicated coverage issues since many professional liability insurance policies exclude coverage or only provide a conditional defense for fraudulent acts.

Conclusion

To date, it appears that LASIK and other refractive procedures are no more or less risky than any other type of surgery an ophthalmologist might perform. The lesson from the \$1.03 million settlement is that careful underwriting is essential in minimizing the risks of the catastrophic claim. Also, the aggressive marketing of the surgery and concomitant exposure to consumer protection class action lawsuits needs to be dealt with by careful monitoring and ongoing review of marketing material. ◆